Public Health and Intelligence

minutes

NHS National Services Scotland

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

04 February 2020 – Nine Bioquarter, Edinburgh.

Present: Dr Lorna Ramsay (Interim Chair)
              Dr Maria Rossi (MR)
              Penni Rocks (PR)
              Professor Danny McQueen (DM) until 1pm
              Professor Corri Black (CB)
              Dr Steve Pavis (SP)
              Kenneth McLean (KM) until 1pm
              Carole Morris (CM)
              Alan Ferrier (AlF)
              Professor Abbe Brown (AB) – T/C until 11am
              Angus Ferguson (AF) – T/C Until 1pm

              Dr Marian Aldhous (MA)
              Phil Dalgleish (PD)
              Susan Kerr (SK)

In attendance: Jackie Caldwell (eDRIS) for item 6

Apologies   Professor Alison McCallum
              Martin Bell
              Dr George Fernie
              Professor Helen Colhoun

1.   Chair welcome and apologies
The Chair welcomed all to the meeting and introductions took place. It was confirmed that the meeting was quorate.
AB requested that item 7 to be discussed before other items. This was agreed.

2.   Minutes and actions from previous meetings

2.1   Minutes of meeting held on 19th November 2019

The minutes from the previous meeting were approved with one minor clarification:
Page 6: item 3.5 should be clarified as "humans developing the models" can make mistakes.

ACTION   04-02-20/ 01 MA

2.2   Action Log from 19th November 2019

19-11-19/01 – Data Delivery Group
PR sent update on this: Roger Halliday has suggested that it would be appropriate to have Caldicott Guardian input on the Research Data Scotland Transition Board.
Alison McCallum has offered to take this on. In the meantime, there is nothing to feedback to Caldicott group.

19-11-19/02 Family Nurse Partnership (FNP) application to go to Tier 1 Panel
MA reported that responses from the applicant came back yesterday and have been passed to Tier 2 Out of Committee (Tier2 OOC). This application is going through the PBPP process although it was noted that there was quite a lot of information missing. This application did not come through eDRIS as they used it to pilot the Scottish Government toolkit.
It was agreed that this application is likely to be approved at the Tier2 OOC level.

SP said that the toolkit was used to try to obtain a live decision, but asked different questions.

MR spoke about once for Scotland approach for national programmes that are not research. PBPP would not be able to cope with these in its current capacity.

LR suggested a lessons learned to be done.

CM suggested that EB takes lead this on as she developed the process. What worked well with the toolkit and what didn't?

SP thought that CHIAG should also be involved as CHIAG approved the operational section.

LR suggested the Lessons Learned should be done jointly, with Elena Beratarbide from SG, the applicant, eDRIS and PBPP.

ACTION   04-02-20 /02 MA

19-11-10/06 SHARE
The implications for SHARE had been raised, with the change in recruitment process for the 1718-0233 Preiss ORION-4 application. SHARE was a different way/model of contacting data subjects. If it was not going to be the patient's clinician to look at records for e.g. recruitment to trials or for research, then SHARE has a research register of people that have given permission for their records to be searched, before being approached to take part in research. SHARE started because NHSS didn't allow others to search medical records. If NSS is used to search patient's records, does this infringe on SHARE's reason for being?
MA agreed to check the letter, PBPP need to review how it works to see if it could be used and if this has created precedence, and to be clear that a review of the process has been requested.

David Crossman was very supportive of both 1718-0233 Preiss and SHARE may not be aware of effect on another project he is involved in. Therefore, need to include CSO in discussion with SHARE and PBPP.

CB commented that an academic research view might be useful.

AB commented that SHARE is a research enabler.

LR to discuss with CSO, SHARE and Caldicott forum (to ensure no precedence has been made that may affect them).

ACTION   04-02-20/ 04 LR

3.   Matters arising

3.1   Proposed updated conflicts of interest policy

From the proposed document, it was agreed to revise wording of number 20 as proposed.
It was also agreed to delete clause 21 as this is not happening.
PR noted that there could be cases where she steps back on topics she is involved in at Scottish Government.

It was noted that for future meetings LR will ask at the beginning of each meeting if anyone has any conflicts of interest, with a reminder to be added to the agenda. If there is any agenda item with which any members may have a conflict, they should inform LR in advance if possible.

There were no declared conflicts of interest at this meeting.
Conflicts of Interest Policy document to be posted on the PBPP website

ACTION   04-02-20 /05 MA / PD

3.2   1718-0233 Preiss – Signatory for letters

It had been proposed that the Chief Scientist was the signatory for the letters for this proposal. The committee members had indicated by email that this should be a clinician within NHS Scotland. LR took the Chair's decision that it would be the principal investigator from each area that would sign the invitation letters and these would have the NHS Board logos on them.

All were happy for this to now be set as a precedent.

4.   Standing Items

4.1   Panel manager report

MA highlighted the PBPP management will be moving to Public Health Scotland, but hoped that the changes to PBPP would be minimal.

CM highlighted that the clock times at Tier 1 have reduced and that this is a good achievement.

Amendments were discussed:
LR pointed committee members to the table on top of page 4, which showed the numbers of applications and amendments to previously approved applications. She thought that applicants who regularly submit amendments have not done sufficient work and does not think the panel should be going back and looking at these. We are trying to prevent scope creep. It was noted that broad research projects can end up being very useful.

KM suggested that within the guidance for applicants it should advise that applicants need to look forward and look at what might need to change over time and what is then required. A lot of amendments may not necessarily mean a new application.

CB stated that long running projects will have changes in personnel, and that this is one change that happens a lot. It was agreed these changes are expected and will happen.

CM noted that with data minimisation principles, some applicants do find that they are missing variables that they actually do need.

MR if we are going to have 'Once for Scotland' would we need a steering group to be responsible for these types of projects, which include process management and automation? Will PBPP oversee national longer term rollout programmes? If not who should?

LR thinks we do need to get a handle on amendments, confirming that there is one application we are going to ask the application to send in a new application. This will be done on a case by case basis on each application.

LR thinks we should discuss further at another meeting. MA to add to a future agenda.
                                                            ACTION   04-02-20 / 06 MA
No other comments on report.

4.2   *Policy Decisions & Case Law Principles*
This had been updated in the light of recent applications.

MR thought this was a really useful document.

LR suggested that the mechanism for the use of HIC for recruitment for 1718-0233 Preiss should be added.
                                                            ACTION   04-02-20 /07 MA

4.3   *Scottish Government Update*

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PR gave a short update. Within SG the new Digital Directorate has a new director and depute director. These will bring changes and widening of functions, the team and resources.

The Information Governance stream has set out some work taking place under the oversight of the Strategic Portfolio Board, co-chaired by Scottish Government and local government. PR confirmed that the Digital Health and Care strategy working group does have public representation.

Safe Haven update

Previously SG were responsible for accrediting Safe Havens. The question was raised as to whether SG should be doing this, as they were not always very proactive for accreditation process. Things have moved on with the introduction of the General Data Protection Regulations (GDPR) and the Security of Network & Information Systems Regulations (NIS Regulations), both of which came into UK Law on 25th May 2018. SG have now set up an audit process with NIS Regulations as cybersecurity standards across NHS boards. Safe Havens as arms of NHS boards would be audited through this process.

Comments were invited from the committee members.

SP stated that he is not sure safe havens are responsible to NHS boards, as some safe havens are run by Universities rather than NHS boards. He thought this would be a very big ask of NHS boards.

CM ask that from a safe haven perspective, what does all this mean for us? Edinburgh University provides the infrastructure for the National Safe Haven, but NSS policies apply.

CB said that the Grampian Safe Haven (DaSH) is run as a partnership with NHS Board, University, patients, Health intelligence, (e.g. R&D responsibility) and with part funding from CSO. Who would do the audit? Would this count as an internal or external audit? The different partners involved may have different audit standards. This may raise investment risks if all the onus is put on NHS Boards.

LR asked what does this mean for PBPP as this will operationally affect the major safe havens that we ask people to use. The Safe Havens will have challenges to address which will affect their accreditation.

MR said that where do the Safe Havens each stand in accreditation? Are they all currently up to date with accreditation?

CM said that there were also multiple accreditation bodies. The National Safe Haven also needs accreditation under the Digital Economy Act, for hosting other public sector data, with the assessment on capacity and security. The three organisations providing one infrastructure (NHS, National Records of Scotland and University of Edinburgh) all have to be assessed. How would this fit under the new system?

CB stated that there needs to be clarity on accreditation process. If Safe Havens are operating as network, which boards should do this? The landscape is complicated.

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It was felt that there was a need to understand the new audit processes and review of what is happening.

LR said this links back to discussion of the equivalence of Safe Havens, discussed under item 7, for work being done outside the safe havens.

PR thanked all for comments and suggested holding mini workshop on the complexity of regional and national safe havens and how they should be accredited.

ACTION   04-02-20 /08   PR

4.4   Update from HDRUK
HDRUK making good process, number of people engagement in supporting this, CM is involved, e.g. eDRIS supporting metadata and multi-morbidity.
David Crossman taking forward a Scottish alliance for engagement with HDRUK, which includes Geoff Huggins from NDS and Marion Bain from NSS.

Innovation Gateway at the moment is not providing access to data.

In the current work at the moment there are no specific elements to our direct remit.

CB asked for insight as the Digital Innovation Hub (seems to have controller function for provision of data).

LR said there were three groups – the Alliance, the Hubs and the Gateway. The Hubs are not very visible but if they are requesting data then the projects would come through PBPP at project level.

CB should we engage with project leaders of hubs to understand their expectations of data and data use, both for updating and onward use of data.

SB suggested asking someone to come and give an update to the committee

LR thought that we need to have discussions earlier so PBPP could advise on the differences in Scotland, to prevent PBPP becoming a block. It would be good to have a half hour slot for people to come to PBPP to give oversight of their work.

LR asked MA to pick this up with CM and CB.

ACTION   04-02-20/ 09   MA, CM and CB

5.   PBPP Review

Chief executive led group now only has three members, as Brian Houston has resigned as Chair of NHS Lothian. Paul Hawkins has become Chief Executive for NHS Highland.

High level progression:

- Complex and challenging applications are now being worked through and addressed; FNP is the last of the current problematic applications.
- Caldicott Guardian resourcing for Tier 2: Alison McCallum gave feedback to the Directors of Public Health, where it was agreed that Gabe Docherty (NHS Lanarkshire) would take this forward. Further discussion with Caldicott Guardian forum required as we still need some Caldicott Guardians on the committee.
- Commercial model to get moving.
- Review of processes and alignment across PBPP and eDRIS with use of Service Now.

MR asked if there is a timescale for the Chief Executive review?
LR said there were a number of discussions with people regarding the scope of PBPP and how this balances with capacity. This will take time to review. PBPP could be pulled in a number of directions and need to be clear where each group requires PBPP to go and how this affects its function and sustainability. Wider group discussions are required at high-levels, as well as internally in NSS / PHS. In terms of scope, PBPP was largely supporting research activity, and this now includes some commercial applications. As there is now more of a pull from the HDRUK level, PBPP could be getting pulled in another direction and therefore stretched more. Obviously this will have implications for resourcing.

MR said that with her previous discussions with Caldicott Guardians that requests for NHS resourcing should come with monetary resourcing.
LR responded that people forget that it remains the responsibility of the NHS boards to do this as data controllers for the data. This will become part of the discussion with the Caldicott Guardian Forum. PBPP is helping with the boards to do their work.

6.   Applications

By this time in the meeting, all the lay people had left.
Jackie Caldwell from eDRIS joined the meeting for this item.

Two SBARs were sent in to the committee to ask for some advice as to the best way forward. These have come from eDRIS as problems had arisen, for which solutions need to be found, to advise the applicants on an amendment, so that the applicant can get the data that have been approved.

6.1   1516-0219 Whiteley: Whole Population Automated Reading of Brain Imaging Reports in Linked Electronic Health Records (WARBLER)
This research project 1516-0219 is to further develop and use a natural language processing (NLP) programme developed on radiologist opinions (structured reports) on a cohort of consented research images. It was thought originally that any identifiers within the reports could be removed by eDRIS, using their "usual" redaction tool.

Problem to be solved: Sample radiologist reports (~10-15 from each board) were sent to eDRIS with identifiable information. Whilst is was straightforward to manually redact the sample data eDRIS has now received 400,000 structured reports from NHS Greater Glasgow and Clyde. eDRIS have been trying to adapt a tool developed for de-identification of

information in the PIS (Prescribing Information system) but it has proved difficult and time consuming and is not considered a viable solution.

Potential Solution: A redaction tool, developed in London, which will be extended for the National Imaging (SMI) project (1718-0316 Caldwell / SMI) anyway, could be tried instead. This tool was going to be tested using consented and non-consented radiologist reports, but work on it could be pulled forward to allow data to be safely provisioned to Warbler.

This solution was further discussed. The committee members thought that theoretically, this process is right way to go. Need to align with processes to validate the SMI tool. eDRIS would need to communicate clearly to the applicant that this might take quite a bit of time to do what he wants and therefore more time to get the actual data. A validation step would have to be thought about and how this would be done.

There should be clear communication to the other NHS boards, not to send any more reports or do anything further, until they hear later, when this process is done.

An amendment would need to be submitted accordingly.

6.2   1920-0066 Jackson: Validation of cases of peripartum cardiomyopathy (PPCM)
Application 1920-0066 Jackson, which is to validate the diagnosis and description of a rare condition, peripartum cardiomyopathy (PPCM), by looking at case notes across NHS Scotland boards. The applicant, Dr Jackson, has another approved application (1617-0359 Jackson) that has data within the National Safe Haven (NSH) to look at the long-term outcomes of this condition. When 1920-0066 Jackson was approved, both eDRIS and PBPP thought that Dr Jackson would request a flag back in the NSH to say which cases in 1617-0359 Jackson were validated, or not.

Problem to be solved: The applicant wishes to use the data in the NSH as a guide for her validation and therefore has requested that she can see both the CHI numbers and the ID numbers from the NSH, side by side, effectively breaking the pseudonymisation key. Dr Jackson requests that the data she collects for the validation, would then be added to the data within the NSH for the analysis of the long-term outcomes for the mothers.

Potential Solution: Release the National Safe Haven pseudonymised ID number, which like the CHI number would be kept separate from the data collection database and to access the National Safe Haven study area. Only Dr Jackson will have access to this information. On completion of the validation stage, the CHI number and ID number file to be deleted from NHS Great Glasgow & Clyde drive. The collected data to be added to the 1617-0359 study by eDRIS and at this point eDRIS would replace the pseudonymised ID number in the National Safe Haven.

This solution was further discussed. This would need to be submitted as an amendment and go through the normal scrutiny process. The applicant would need to make it really clear why this is really necessary and that this was a one-time process, that she can't go back and repeat.

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PBPP / eDRIS to develop best practice in setting up registries of rare conditions and make available on websites.

MA to feed back to the applicants for both studies.

ACTION   04-02-20/ 10   MA

7.   Principles for Requirement for "special" applications

LR explained that requirements need to be in place for applications to PBPP, that:
   a) involve a commercial organisation, and/or
   b) request considerable amounts of data for machine learning (ML) / artificial intelligence (AI) / extensive modelling.

The aim is to make the requirements clearer for applicants, eDRIS and both levels of panels so that the approval process is easier for all involved.

a) Commercial Applications

LR explained that having come back into this area she is not surprised that some commercial applications are coming through PBPP and that the panel have been working hard on how to review these, in the absence of any steer or guidelines. PBPP is trying to give balanced approach to applications, while applicants are unclear why applications taking so long.

LR thinks we need to be identifying early where we think there is a gap in discussions and decisions, and that policy steer is needed, explaining that this is not only for NHS Scotland. This has been discussed at the Data Delivery Group, as part of Research Data Scotland. For the Data delivery group, a commercial model will be agreed for health and pan-public sector and will be discussed under RDS banner. Need SG, NHS and broader input into these discussions.
For PBPP to get this model discussed and agreed would therefore be extremely helpful. It was also acknowledged that this will be discussed as a priority in other areas.

SP explained that when he is doing work with commercial companies it is the information/data sharing agreement they use, which has the details of the contractual relationships. He suggested making a decision that in future this should also come with a PBPP application.

CB stated that it is her understanding that R&D within NHS boards use template documents, including DPIAs, so PBPP may not have to re-invent the wheel, if it was at a local or regional level within the NHS. The gaps seem to be at national level – what is PBPP's role or the different hats of people involved? Not necessarily NHS and University people who are involved with the commercial partner.

LR explained that the issue is when it becomes a wider NHS Scotland application, e.g. Aberdeen Uni and Grampian Health board agree with a commercial organisation. But what happens when it is for national work?

AB stated that she felt it was a helpful document but suggested, should we maybe have 2 documents, one for commercial and one for AI, although there will be some overlap. Some decisions / suggestions made were really helpful: e.g. in Section 4 (about public benefit), regarding what guidance is needed? Suggestions in context of commercial application –e.g. timescales to product, timescales, time for development and final product. Applicant may need to explain, licencing, generation of products, version support (their benefit). Are PBPP relinquishing responsibility, if we put the onus on the applicant to tell PBPP they have thought about this?

MR agreed with AB that it is good to look at reasons for commercial interest. Would like us to come to an understanding on commercial companies coming for marketing purposes. Could this be nipped in the bud at the start?

KM stated that one other issue needing to be covered is risk, looking at what the risk is as a panel. What is our risk appetite? Marketing vs. more obvious benefit? What about when benefits are less clear. Risk is not just DPIA but also other aspects of is. Not only incumbent on PBPP but also applicants. Rarely see any risk evaluation from applicants, as these are rarely articulated. Risk assessment would help.

CB asked why would this be any different for a commercial company, rather than an epidemiology study or a large dataset? We are highlighting benefits for public etc. and she is not sure anything she has read in this paper is any different for any other application. Therefore, the guidance should be consistent for everyone.

AB agrees but stated that there is sensitivity around the fact that money will be made from the information and therefore further indication of guidance is needed. There is a lot of wider engagements and that some members of the public feel it is wrong that an independent company is making money rather than the NHS.

CB said that the money-making should be independent from who the applicant is, as there are a number of NHS / University spin-out companies. The model is about making money regardless of the applicant.

SP suggested that the public benefit is not just about benefit to the NHS, but also to the wider economy.

AB said that some members of public are more uncomfortable about the commercial sector making money than the NHS making money.

LR gave the example of the PICTURES project, being developed and still to come through PBPP. The NHS is senior partner and the central legal office (CLO) has sorted the contracts with different partners. Those involved are beginning to tease out the different types of value to the project. They have clarified that there is value to NHSS with a good deal on outcomes of the project as well as the contributions to the development. However, universities may have different types of value, which for some will include money. PBPP needs to kook at value to NHSS and wider public value.

AB said it is important to ensure that the CLO has done due diligence. Also need to consider economic development, can we bring this back in at the start. PBPP's area of interest is to look at value for NHS?

PR agreed but asked what is the framework around how PBPP makes decisions? As we look at these further there may be a need to widen out how we look at these types of applications. We need to understand what the public benefit is and widen out how we look at applications and assess the benefit to the public in a way the public understands. Further work is required around this.

LR thought we need a way to assess value and risk.

MR stated that the public perception is that NHS does not sell people's data. But what about the use of data for development?

LR asked about public engagement?

PR spoke about Nesta. From their website: Nesta is an innovation foundation that aims to bring bold ideas to life that change the world for good. "We are particularly interested in the potential of digital and data-driven innovation to help tackle some of the big social challenges facing Scotland today."
One questions from them is What are people's thoughts and who do they trust in the use of their data. So the first phase of this is engaging with the public. Results from innovation projects will be researched end of summer, next set of studies in autumn for other pieces of work. These are all working through Roger Halliday and RDS and wider public sector and use of public sector data. Can give update at each PBPP committee.
However, we need a pragmatic way to assess applications right now. Therefore, public engagement / involvement would be useful and the suggestions in section 7 of the document were useful.

LR thought that public engagement at 3 levels was all useful and it was really good to have this steer from SG. Do we expect from applicants, including commercial companies to have done public engagement?

SP commented that project level public engagement can be poor, especially if it is done by the applicants, as they have little experience in this. There are people, like the Wellcome Trust, who do this well. We should encourage applicants to talk to them. There are cost implications to the applicants for doing public engagement. However, there is also published data from public engagement on different subjects and applicants could look at these for information.

CB asked why we should single out commercial companies? Everyone should be doing some. The applicant needs to know what the need is and what we are asking them to engage with. Need to have same level of engagement for all applications.

KM stated that the Scottish Health Council (SHC) have lots of guidance as they are experts in public engagement. He made the suggestion that applicants contact them re public engagement. PBPP needs to signpost to the SHC.

PD mentioned that there are resources on current PBPP website, pointing to public involvement.
https://www.informationgovernance.scot.nhs.uk/pbpphsc/the-public-benefit-and-privacy-panel-for-health-public-involvement/

LR suggested that this is something we need to engage with, with a broad group of people.

MR asked what makes commercial applications different from others and should we consider these applications in a 2-phase process? The first phase would be a review of the commercial idea and proposal, when we could say no; if the idea is good, then the second phase would be an approval once all the contracts in place, with signposts to the CLO.

LR suggested putting something on website that says we are looking at commercial applications with some pointers of where applicants can go for further information. It was agreed that it is better to be upfront about these applications. She asked if this something the PBPP Ops group could look into to see what this would look like.
MR thinks maybe a small group to look at this. This was agreed.
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ACTION   04-02-20/ 11 MR

and Ops Group
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LR asked PR to keep this group up to date with the work of Nesta. PR Agreed.
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ACTION   04-02-20/ 12 PR
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LR asked, are we saying these applications need to have a NHS partner?
The Cunningham one – we asked for a clear NHS partner. Do people have a view on this?
Up to now PBPP has said that a public sector partner, which also includes universities, and they can review the legal documentation.

PR suggest we don't change this just now, as felt just now is not the right time. Has anything changed that removes the need for a public partner?

CM suggested that that might depends on the purpose of what they are doing, if they are creating something for the NHS would they still need a NHS partner? Would we expect NHS partner, to be involved in the contractual discussions re discounted costs for the future?

CB asked what does a partner mean? Would we expect some Data Processing agreement with NHS? Is that the partnership that we're looking for? Also would it include liabilities and benefits. What about certainty – do we have an appetite for certainty as well as risk? If a group is doing research into pathogenesis, then forms a spin-off company to develop a drug. Long-term is not that long. With SMEs there is the likelihood that it may fall at different hurdles.

MR this could be used as justification for a project – if they cannot find a public partner, is it then too high risk to consider? If has NHS or University partner, this would give some reassurance that might be useful and has possibility of success.

KM thought that if a commercial applicant comes with some involvement in NHS or University, this is only a comfort blanket. We may not need to be bothered with who the partner is, but does it have some chance of success? Need to look at track record, as there are many commercial companies that have a good track record.

SP stated that, on balance, he thinks NHS or Social Care should be involved.

CM said that if data provisioning is being done by eDRIS, the eDRIS coordinator will give advice.

LR need to add information to the website about commercial applications for people looking for guidance and points raised earlier. As a minimum MoU, DPIA, ISA, Accountability. It is clear that we have good thoughts and additional questions. Need to get his moving as quickly as possible. The public engagement on the commercial model will start in April. These applications will need to be reviewed on a case by case basis until Scot Gov (NESTA) work completed.

ACTION   04-02-20/ 013 MA/PD

MR suggest having someone from CLO on the committee possibly only for advice.
LR did not think this was really appropriate for just now.

KM thinks we need to look at track records, whether they have a partnership from NHS or not.

LR thanked everyone for a very good discussion on what are we trying to do and what is pragmatic for now. She thought that 5 areas need to be clear:
- Who is a public sector partner? (Does it have to be from NHS Scotland?)
- The need for formal agreement to be in place.
- Has there been any Public involvement or engagement?
- What is the value to the public?
- Assessment of value and risk.

b) Large volume data
This has the same issues as we have discussed above although a specific question would be when people want to use their own environments rather than a safe haven.
What is a suitable alternative to a safe haven environment? Who decides on the standards and what if the applicant can't do it on what we can offer? Some saying that capability is not available in Safe haven (SH) environment.

CB stated that all the safe havens are investing money and time to improve capability of the safe havens. Could do it for one project today but longer term these safe havens will have capacity. Still in early stages. For the alternative location, the applicant would need to

demonstrate SH equivalency and justify why not using SH, unless we decide the risks are too great.

CM said that things are continually evolving with requirements in technology.

SP noted that eventually things are likely to go to the cloud, due to the sheer volume of data.

KM thought that while we're building capacity, the applicant will need to demonstrate equivalency. Suggests that pilot study would help them to think about what they really want and do they really need the data? Have they formulated their question properly? He asked if we can have assurances that other entities can supply the security then yes we can look at this while we are trying to build our capacity with our safe havens.

LR These are good things to put out pro-actively. A pilot study shows commitment to obtaining an outcome, and to give an indication of whether this idea is going to be achievable? Research funders often want some indication that.

SP said that applicants could use synthetic data for pilot studies and testing.

DM said that it's not the health data but the privacy that concerns people. People need some payback and reassurance that their privacy is not infringed. Should not be giving out any personal data and should not be identifiable. Pilot would also show that the project might work. No personal/private data for commercial, operational benefits. Anonymisation is irrelevant as they should apply to small and large data.

MR asked whether we trust alternative 'safe haven' environments? Even if they technically satisfy requirements, the company may have different ethical approach to data and their risk appetite may be different. Where does the trust for big organisations come in? Some can get it horribly wrong but we have no indication of their attitude to people's data. Public organisations have more of a reputation to uphold.

CB replied that that's the hurdle that we have to overcome. The trustworthiness of Safe Havens is through working partnerships and accreditation.

LR noted that it is the five safes which build the trust around the project. These are the basis of the PBPP form and the different sections of it.

KM – this comes back to PBPP's appetite for risk.

PR thought that all this was fine for just now but a bit constrained and inflexible for future. Could we consider baseline standards for security for everything? If an application met this standard on these aspects, then could be comfortable that all will be well. Going forward we need to think about things and recognise that we need to work with other environments.

LR said that Safe havens are very useful and will be still useful going forward but will need other environments that are just as robust.

CB noted that Disclosure Control had not been included in the paper. What are these complex models doing when they are requested to go out of safe environment?

Need to pull together some of the points from this discussion.

ACTION   04-02-20/ 14   MA

8.   Tier 1 Audit Report

The committee accepted the audit report and its recommendations.

9.   Any other business

There was no other business

10.   Date of the next meeting

Then next meeting will take place on Tuesday 05 May 2020 at Edinburgh Bio quarter, Edinburgh.

ACTION TABLE

Action ref	Action	Responsible
04-02-20/ 01	Update minutes from 19th November 2019 with agreed minor change.	**MA**
04-02-20/ 02	**Related to 19-11-19/ 02** Organise a Lessons Learned for FNP with SG, applicant, eDRIS, CHIAG? and PBPP	**MA**
04-02-20/ 03	**Related to 19-11-19/ 06 SHARE** Check approval letter for 1718-0233 Preiss (ORION-4) and check that there was a request for PBPP to evaluate the recruitment process.	**MA**
04-02-20/ 04	Discussions to be had with SHARE to see whether this has created a precedent that impacts their reason for being. Similarly, discussions with Caldicott Forum and CSO, regarding the implications of this process for recruiting patients for Randomised Clinical Trials.	**LR**
04-02-20/ 05	Documentation related to Conflicts of interest policy to be updated and placed on PBPP website and reminder to be added to the agenda.	**MA / PD**
04-02-20/ 06	Add item to future agenda regarding amendments and their use in PBPP. How would this affect the governance of 'Once for Scotland' projects, if it is expected that these would come through PBPP?	**MA**
04-02-20/ 07	Update of the Policy Decisions and Case Law Principles to include the use of Health Information Centre (HIC) for recruitment of patients for the 1718-0233 Preiss ORION-4 study.	**MA**
04-02-20/ 08	Workshop or further discussion with Safe Havens and relevant NHS Boards regarding the process for accreditation of regional and national Safe Havens.	**PR**
04-02-20/ 09	Develop processes or discussions whereby PBPP can advise HDRUK applicants.	**MA, CM & CB**
04-02-20/ 10	Advise the applicants for 1516-0219 Whiteley and 1920-0066 Jackson regarding the discussion and feedback from the SBARS for the application. Both would require amendments to be submitted and would go through the normal amendment process.	**MA**
04-02-20/ 11	Information to be drafted for PBPP website that says we are looking at commercial applications with some pointers of where applicants can go for further information. It was agreed that it is better to be upfront about these applications.	**MR and Operations Group**
04-02-20/ 12	Updates on the work of Nesta and the public engagement exercise regarding use of public sector data.	**PR**
04-02-20/ 13	Update of information on the PBPP website about commercial applications for people looking for guidance. As a minimum MoU, DPIA, DSA/ISA, Accountability.	**PD / MA**
04-02-20/ 014	Pull together the salient points from the discussion about large data requests, for further guidance to applicants.	**MA**