Public Health and Intelligence

minutes

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

NHS Lothian, Edinburgh

15 January 2019

Present:	**Prof Alison McCallum (AM) Acting Chair** Prof Danny McQueen (DM) Dr Stephen Pavis (SP) Penni Rocks (PR) Alan Ferrier (Al F) Dr Maria Rossi (MR) Dr Angus Ferguson (AF) – T/C Prof Abbe Brown (AB) – T/C (until 1pm) Dr Helen Colhoun (HC) – T/C Carole Morris (CM) Dr Marian Aldhous (MA) Phil Dalgleish (PD) Susan Kerr, Secretariat
Apologies:	Brian Houston (BH) Kenneth McLean (KM) David Knowles (DK) Dr George Fernie (GF) Prof Corri Black (CB) Dr Eleanor Anderson (EA)

1. Chair's Welcome and Introductions

Prof Alison McCallum will chair this meeting in the absence of Brian Houston.

Noted that due to a number of apologies today's meeting is not quorate. It was therefore agreed that this committee can make recommendations but not final decisions. Any decisions to be made will be circulated electronically to all members with an active response required.

There are no PBPP Applications for review at this meeting.

AM: An application on National Laboratories Information and Intelligence Platform (NLIIP) Proof of Concept was withdrawn before being reviewed by PBPP. AM and SP will to look at this application in more detail and, at a later date this application will be submitted to PBPP. This was agreed.

Action AM / SP

2. Minutes from Previous PBPP Committee Meeting

Minutes of the meeting from the 27th November 2018

It is not possible to approve minutes at this meeting as meeting is not quorate.

A couple of corrections were raised:

Section 3.2 Report from ACONF Data Issue

SP raised point regarding section 3.2. Action SP/MR is not correct.

The separation of function for data linkage, with the indexing being done by NRS and linkage done by NSS is part of the guidance principles of NRS. These can be reviewed to enhance the Quality Assurance process and have better transparency but these cannot be changed.

SP suggested Al F from NRS should also be involved to review and make any recommendations. This was agreed.

Action SP / Al F

DM expressed concerns that there was no reassurance on correct linkage and PBPP Committee could be exposed to risk if errors happen.

HC commented that no linkage is 100% accurate and any research project should contain variables to verify the linkage.

The need to be clear about reproducibility and validation of the linkage needs to be incorporated into the system.

MA agreed to amend minute to make more explicit.

Action MA

Section 8.2 Brexit

Noted incorrect – the term 'Brexit Czar' to be removed and the phrase changed to reflect the range of preparatory work being undertaken across Scottish Government, including Health.

It was noted that the risk lies in flow of data from EU to UK rather than from UK to EU. This may also affect researchers from the EU accessing the National Safe Haven.

MA agreed to amend and the corrected minutes to be circulated to all for agreement.

Action MA

3. Matters Arising

3.1 Resourcing for PBPP T2/Committee

MA stated that the committee still has a Caldicott Guardian (CG) vacancy that needs to be filled.
DK (representing CHIAG) is retiring in March 2019.
SP is moving to NES Digital Service in March 2019.

AM will follow this up with BH, as he has previously written to the NHS NSS Chief Executives regarding CG representation on PBPP. The person replacing DK will have operational director responsibility for the CHI database as part of his role as Director for Practitioner Services and Counter Fraud and should be a CHIAG representative on PBPP.

It was noted that Caldicott Guardian representation on this panel is crucial. MA stated that there should be four CGs in total, one being from NSS. Ideally, the PBPP committee needs another CG from a territorial NHS board.

PR suggested this should also be raised at the Board Chief Executives' meeting, together with providing them with the PBPP Annual Report and stress that it would be good for regional boards to provide representation.

CM proposed drafting a letter to take to the Chief Executive group. This was agreed.

Actions AM / BH / MA

3.2 Report from the ACONF Data issue

CM stated that the report has gone to the ACONF Steering Committee, but no response has been received as yet.

CM is writing an action plan from the lessons learned. It is intended for more general use and describes issues in relation to assuring the quality of the data and the data linkage. This should guide researchers in future.

Discussion took place on this report, CM is happy to circulate this but it was agreed that the detailed report does not need to published on the webpage. CM to produce a summary of recommendations to go on the web page.

HC suggested that there should be an updated statement regarding quality control guidelines and that it is the responsibility of the researchers to check the linkage within their datasets.

The question was raised regarding wider circulation of the recommendations as some data linkage is undertaken primarily for NHS purposes rather than research. The question was posed as to whether the report should be circulated to NHS information governance leads as well as Caldicott Guardians.

AM asked if the report and papers have to come back from the ACONF steering group before it can be sent to NHS Boards Caldicott Guardians and Information Governance leads?

CM is happy for the report to be shared with those who require to take action.

CM said it was human (copy and paste) error. The error was hard to detect because privacy guidelines mean that no single party sees all of the linked data together with its identifiers, through separation of function. CM explained the occurrence and the solutions used.

CM to produce a summary document of the issues.

*A*M suggested that it be taken to the NHS Boards by 31/3/19 to build into 2019/2020 plans

AM, CM, SP and MR to discuss communication with NHS Boards.

Action AM / CM / SP / MR

3.3 Actions from Lessons learned for PFS Genomics

AM asked if anyone had any comments or issues on the paper circulated.

SP expressed concern with the fact that some NHS territorial boards are engaging with commercial organisations differently from the national boards.

There is guidance for engaging with commercial organisations in the Safe Haven Charter, and this broadly reflects the findings of research undertaken with patients and public in Scotland. The implications for commercial partnerships, however, are considered to be unclear. The guidance, therefore, is therefore being interpreted differently in different Boards. There was a request for a clear statement from Scottish Government that could be applied to research and innovation across NHS Scotland.

PR noted that partnerships with the commercial sector would be addressed in the implementation of the Digital Health and Care strategy and an update from SG will be circulated.

4. Standing Items

4.1 Panel Manager Report (November 2018)

MA informed the committee that no applications have been referred to T2 in the last 2 months.

SP asked about T1 involvement and how many applications are approved directly at Tier 1 panel. This is shown in the report: 28/85 applications (33%) were approved at the T1 panel meetings with no requirement for further tier 1 review.

MR asked if there was a way of including a record who were first time applicants, but this information is not gathered from participants so would require manual review.

MR asked if a T1 panel had ever been unable to meet due to lack of availability of Information Governance leads. MA reported that this has not yet happened as some IG leads are happy to fill in when someone else is no longer available to attend a meeting.

4.2 Policy Decisions and Case Law

There had been no changes from the previous meeting, Any changes to policy arising from the recommendations from the ACONF report will need to be agreed and added.

Action MA / CM

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

PR gave an update on the progress around Digital Health and Care Strategy and wider work within 'Domain B'.

She described the scope of this work package which extends beyond the current role and scope of PBPP but will have an impact on various aspects of its work. It includes a broader view of IT security and information governance across NHS and Local Government functions. It is also considering research and innovation, including that which is funded by industry.

This area is being looked at collectively by a working group led by Roger Halliday, Scottish Government Chief Statistician. It includes expertise from Scottish Government, Chief Scientist Office, Chief Medical Officer, NHS Common Services Agency, NHS Education for Scotland Digital Services. In recognising the range of information governance issues, the group has identified that many apply beyond the health service.

PR highlighted the three current areas of focus:

- Research and Statistics – many issues to be resolved
- Service delivery– the operational difficulties in health, including 3rd sector involvement, with IG challenges in these areas.
- Citizens/public section – how should digital services be provided to people and how should this work across different technologies?

She noted the importance of a national perspective with a level of consistency across the public sector (health and non-health) that could be applied locally and nationally. The aim was to produce a high level set of core principles that could be applied in different settings.

Issues that required further attention included:

- How do we make use of information and ensure trust from citizen's prospective?
    - Which areas should be monitored?
    - How should we bench-mark success?
- Clear policy, structure, reporting lines and approval processes to simplify and improve Information Governance assurance across the public sector.
- Review of approval processes, including PBPP and the equivalent statistics panel that considered non-health approvals.
  Development of a national centre of expertise to provide help and guidance on the conduct of projects as well as keeping information safe.

Specifically, conversations with Ministers regarding the development of advice to help them make decisions e.g. regarding working with industry within the framework established by GDPR and the particular rules regarding the use of health and other sensitive data. At the same time, NHS Education for Scotland Digital Services has been commissioned to undertake work on aspects of a digital platform for health and social care data. This is intended to help improve routine use of technology.

A Standards working group is considering the current and potential future standards across health and care. In addition, the group is reviewing the appropriate standards regarding access to data of different types, data quality and use of the digital platform. The aim is to address apparent inconsistencies in standards and to provide data of agreed quality for linkage. At the moment there are different levels of standards involved. This work is still in its initial stages and will be steered by Ministers.

A paper will be circulated to the committee for comment. This will include the development of a pack, including IG for national non-research projects. A draft has been presented to the PBPP Operations group for initial discussion.

Action PR / MA

AM asked for clarification, whether there was wider local government engagement beyond health and social care, including, for example wider local authority functions including education and children's services, from a research and service delivery perspective, given the extensive links with the NHS?

PR said that IG representation from local government and NHS National Services Scotland Caldicott Guardians are aware of work with children, environmental health and other public sector areas, e.g. Police Scotland, and Justice directorate. The aim is to produce the models and draft documents and see what fits the different functions; it is possible that membership of the group will have to be widened.

HC asked what is the immediate business of PBPP and NHS data? What is the range of the authority? Is PBPP the authority for commercial access to data? If not who is? Does PBPP authority extend to Board level?

PR said that each NHS Board is responsible for what happens in their Board, as they are data controllers of their data. If they give out data to industry they must comply with the law and SG guidelines. The Caldicott Guardians should be involved with the Chief Executives in processes and decisions should be made by NHS Boards.

PBPP has delegated authority to make decisions regarding data sharing on behalf of the Chief Executives for research and non-research projects. In practical terms, where policy decisions reflected the remit of more than one Minister, PBPP could only speak for health and social care. Ultimately, SG Ministers are responsible for taking policy decisions regarding industry's use of data within the confines of current legislation. PR advised that Ministers would make decisions on advice from senior PBPP members. AM noted the various responsibilities of Directors of Public Health, for example, in relation to CHI, for which they are accountable to CMO in line with the existing Scottish legal framework. She also highlighted the findings of SG-commissioned research on the public's view of the use of health data by industry.

SP commented that the English Department of Health and Social Care had commissioned a paper from the Reform group on its website. SP agreed to circulate this around the committee; he thought it would be helpful for this group to see this paper as it breaks down the difference concepts of industry and value of industry. This was written for a wider report to be launched in February.

Action SP / MA

DM asked how the citizen can be reassured that all of the various aspects of the strategy will work together for the citizen's benefit?

PR stated that Scottish Government have commissioned NHS Education for Scotland Digital Services; their remit includes developing this functionality.

SP explained that NHS Education for Scotland is a national health board; it currently delivers across NHS Scotland. NHS Education for Scotland Digital is recruiting people with IT and technical skills to deliver a national set of processes. NHS Education for Scotland Digital strategy is trying to integrate data from different formats into one common standard or open platform. They will then develop new systems to comply with these standards so that consistency is maintained across the whole health and social care system.

5. Proportionate Governance paper

SP presented the paper on Proportionate governance for projects for which the Information Governance and privacy risks are consider to be lower. The aim is to maintain the level of assurance to the public for use of personal data, but to do so more efficiently using what was described as 'IG scrutiny by design'. The example was given of the governance requirements that had been established for the Health Information Centre (HIC, Dundee) (at the time of the Scottish Health Informatics Programme). HIC has an agreement with Tayside Health Board

that means that applications that fall within specified guidelines, and which use agreed, linked datasets do not require individual Caldicott review; similar processes are used in, for example, SAIL Databank (the National Safe Haven in Wales), and in similar set ups in certain Canadian Provinces and in Western Australia.

If adopted, this approach would move away from every individual application being scrutinised. Researchers working to pre-specified, agreed guidelines would be covered by a generic approval by programme or programme type. The reduction in variation would produce 'safer' projects.

The requirements of Information Governance review would be addressed in advance, with Data Controllers being clear about how they wished data to be used and clear guidelines that set out the parameters for use

MR said the concept was welcome but felt there was scope for improving the overall process. What information has been used to determine that there is a bottle-neck at Tier 1? It was not clear that this was the biggest issue to be addressed.

SP said that Tier 1 was not necessarily a bottle-neck, but the current process was resource intensive for territorial Boards. The proposed model would support consistency of scrutiny where multiple bodies were involved and where use of multiple public sector datasets was proposed.

HC asked how much of Tier 1 does is algorithmic. How does this work with the data controller depositing data within the Safe Haven? Would the same issues be addressed by the new form as under the current PBPP form?

SP noted that the proposal he had described was about explicit criteria regarding use of data and the process of scrutiny. By following specific guidelines, projects could be made more low-risk, with rigorous and systematic enforcement of privacy protection and quality assurance.

AM noted that NHS Lothian has a suite of governance documentation for delegated Caldicott Guardian authority within NHS Lothian. These could be shared with the panel.

AB noted that if the proposal were approved, it would be essential to undertake random audit, to ensure that this process was working as intended. This would be an additional task, undertaken as part of the PBPP audit function.

MR asked how many of the projects previously approved at Tier 1 would have been approved using this approach.

SP said that there would be 'red flags' that would take projects out of the process and those applications would go through the same route as at present and go to a Tier 1 panel.

MR felt that although the IG parts were covered, the IG scrutiny often needed to be complemented by a better understanding of the overall project and proposed methodology to ensure that the IG and confidentiality issues were covered.

SP noted that this process of pre-approval would only apply to Approved Researchers, that is those working in the public sector who had undertaken an approved IG course, signed eDRIS agreements and who were using data held in the Safe Haven.

PR asked if this process could be automated? What was the risk of a 3 –month trial which would possibly develop into a simpler process for access to data for those undertaking low-risk projects?

AM considered that it was good for low-risk projects to go through the system smoothly and in a timely manner, but expressed a concern that higher-risk projects might be incorrectly classified as low risk.

Al F asked if there was information available from countries that have already implemented this sort of approach and their experiences?

HC asked if we could road-test the approach with the initial applications that came to tier 2 to demonstrate that they would not have got through this process.

SP noted that the proposed approach did not fundamentally change the rules that guided PBPP decision making.

The committee felt that the proposal should be agreed in principle but that the details may need to be refined so that it worked as intended.

It was agreed that the paper should go to the PBPP Operations Group and that SP / CM / MR should have further discussions to develop the proposal further.

Action SP / CM / MR

6. PBPP Annual Report

The updated report was approved by those present, subject to ratification by those not present. The published report will be put onto the PBPP website.

A copy should be sent, with a covering letter from BH to the Board Chief Executives' group.

Action MA /BH

7. Ongoing Sharing of Research Data

This item considered the ongoing issue of making research data available for reanalysis/verification, as part of "open science". It was noted that this was now becoming a requirement for publication and grants. The question was asked regarding how this should apply to potentially identifiable patient/personal data, and whether the increasing requirement for validation/scrutiny/reproducibility would this require additions or changes to existing governance processes?

HC noted that this issue had been raised and discussed approximately two years ago. In practice, most journals now have data declaration statements. Researchers can make a statement that data governance does not allow direct data sharing but have a form of words that outlines the process for bona fide requests to review data for verification. These statements will be circulated.

HC stated that further requests would be referred back to PBPP. In her experience, there had not been as much push-back from the journals as expected.

It was considered that PBPP needs to have an agreed statement of approach and agreed wording for researchers so that it is clear that any proposed data sharing is subject to PBPP approval and may require an amendment to the existing approval.

Action HC / MA

AB noted that MRC and other research councils administer the public money which pays for research and that data should be available for public benefit; the issue was to make sufficient data available for scrutiny etc without breaching the privacy and confidentiality requirements for research with data belonging to individuals.

CM noted that the UK Secure Data Access Group is seeking a dialogue with funding bodies regarding this issue.

AM noted that it may be necessary to established an authorised data repository from which data could be requested for scrutiny or further studies. Dataset strategy would need to agree a set of principles that applicants need to apply to, for these to be considered

SP: HDRUK has initiatives to create national linked datasets to give a repository of data.

AM suggested following steps and that we would need to revisit this over the next few meetings.

i) Verification – wording to be agreed for advice note
ii) Sharing datasets – agree principles to advise applicants that apply for access to approved datasets; these principles will be the framework under which each dataset will be considered under a case-by-case basis.
iii) Agreement that the composition of large national datasets may change, with some further aggregation and collation over the next few years.
iv) Discussions with funding bodies.

SP commented that HDRUK (https://www.hdruk.ac.uk/about/partners/) and collectives of academics are reviewing the ICD09 and ICD10 coding of data, looking at the consistency across datasets to determine the ability for these data to be linked. If eDRIS, [as a function of the proper statistical authority] can hold linked data centrally, then it could give access after normal governance processes. [DN formal review of ICD09 and ICD10 is a function of the National Statistical Authority]

AF noted that the Wellcome Trust and UK Research Councils have set up a website "Understanding patient data", which is from an English context but includes animations to explain to the public how health data is used in the UK.

AM how do we keep abreast of developments in this area? Suggest that eDRIS Committee member need to contribute to this by providing regular, more formal updates to the committee.

Action CM

It was suggested that HDRUK could do a presentation on this. To be considered further outside the committee.

8. AOB

No other business was raised.

9. Date of next meeting

The next meeting will take place on 16 April 2019 at Nine, BioQuarter.