Public Health and Intelligence

minutes

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

28th June 2016

Waverley Gate, Edinburgh

Present:	Brian Houston (Chair) Prof Alison McCallum (AMcC) Dr Angus Ferguson (AF) Prof Helen Colhoun (HC) Prof Danny McQueen (DMcQ) Mr Gerry Donnelly (GD) Dr Stephen Pavis (SP) Dr Daniel Beaumont (DB) Dr Corri Black (CB) Dr Kirsty Licence (KL) Carole Morris, eDRIS representative (CM) Ashley Gray, Panel Manager (AG) Jenny Mann (JM)
Apologies:	Dr Hugo Van Woerden Dr Janet Murray Dr Harpreet Kholi Mr David Knowles Dr Abbe Brown

1. Chair's Welcome

BH welcomed all to the PBPP Committee meeting and noted apologies received.

2. Minutes of PBPP Committee meeting dated 19 April 2016

The minute was approved as a correct record.

Actions recorded in the previous minutes were noted as either complete or to be discussed as an item on the agenda.

3. Inpatient Census Update

A paper was circulated for information only.

No comments received.

4. PAC 46/14: Cohort Study of the Relative Incidence of Major Cardiovascular Events among Patients Initiating Prucalopride versus a Matched Comparator Cohort

A paper was circulated for information only.

No comments received.

5. Application 1516-0022 Kumari – Appeal for Review

AG advised the Panel that the applicant had been in contact to ask the Committee to reconsider the approval decision and conditions which had been applied at the meeting held in April 2016. AG advised that she had communicated to the applicant, via the eDRIS coordinator, that they should submit a paper to outline the specific areas for the Committees' reconsideration and provide any additional justification/evidence to support this.

AG requested that, with reference to the additional information, the Panel reconsider their position and that a member of the Committee lead in the communication of the response to the applicant.

The Committee agreed to revise the approval of the application to include the following condition:

- Linked health data can be stored and accessed via the UKDA subject to the following criteria being met:
    - Researchers, out with those listed in the application form, requesting to access Scottish Health data should submit an application to the PBPP for approval
    - This arrangement will be reviewed annually in order to assess the volume of applications received and to ensure that applications for secondary use continue to remain in line with the original purpose of the collection

It was agreed that this decision should be communicated to the applicant.

Action AG

6. PBPP Operational Group Update

A paper was circulated for information only.

No comments received.

7. eDRIS Commercial Sector Engagement

SP introduced the item and explained that the paper had arisen from an action assigned at the PBPP Committee in April 2016.

AMcC noted she had some minor suggested amendments on the paper but would communicate this out with the meeting.

SP advised that the PBPP are required to have clarity around the obligations which commercial sector organisations must meet in order to utilise NHSS data. This document outlines a proposed set of core principles which must be met to satisfy the 'public interest test' (over and above any legal requirements and public benefits test)

- ✓ Scientifically sound research

- ✓ Ethical approval
- ✓ Publication of results
- ✓ Acknowledgments

A template contract, created by CLO, is also appended for information. SP advised that this template should be viewed as a starting point and negotiations with the company can be entered into thereafter.

HC confirmed that she is supportive of the principles generally

CB noted that universities are increasingly being requested to work with industry and request clarity on the term 'partner'

HC queried the position if a commercial company wanted to place an analyst within the eDRIS team.
SP confirmed that under the current policy no direct access is granted to individual level data to commercial organisations and therefore no access would be permitted under secondment/honorary contracts. However as the landscape evolves we may need to consider types of contracts in the future. SP advised that eDRIS would report back to the PBPP as to the volume of enquires and projects involving commercial companies.
HC suggested to leave this as the default position at the moment (approval assumes that no-one is seconded) but to leave open for future consideration.

DB queried the demand for commercial companies to come in to access data.
CM advised that this is relatively small between 4/5 at present and SP confirmed that most commonly eDRIS conduct the analysis.
AMcC noted that this type of request may become more common in the future.

DB queried 'singling out' of private sector companies as partnership working is promoted.
AMcC noted that the quality of commercial research may not be of good quality and that the public benefit of this needs to be assured when undertaken.
SP confirmed that the Safe Haven Charter states that only public sector may access NHS Scotland data.

AMcC confirmed that she would feedback to SP directly regarding the inclusion of research confidentiality duty to the contract
HC raised the issue around Intellectual Property of data analysis and agreed to discuss with SP directly regarding the inclusion of clauses on Intellectual property within the contract.

The Chair confirmed that the Panel are happy with the proposal, subjects to amendments as noted.

Action SP

8. End Point Validation

SP introduced the item and explained the paper had arisen from the difficulties experienced in end point validation in the study 1516-0157 (Item 4).

Study 1516-0157 was approved by PAC and outlined the approach which was to be taken by NSS to carry out end-point validation. However whilst this approach was sound in terms of Information Governance, it was not logistically practicable in real terms.

SP advised the document sets out several options for the Committee to consider in order to achieve clarity around acceptable and pragmatic ways to undertake end –point validation in non-consented safety of medicine research that use NHSS data.

SP summarised the proposal options for the Committee

1. Current process – no change
2. Single point of contact in Board and use of a research project funded research nurse (s) who are appropriately trained in governance
3. Use of ISD staff who work in the Boards
4. Use of NHS R&D teams within Health boards.

In line with the decision applied to study 1516-0157, to revise the procedure for end-point validation, SP requested that the Committee agree that Option 2 is considered acceptable, with appropriate permissions and safeguards in place, for the sole purpose of carrying out end-point validation.

The following conditions would be required to be satisfied before accessing patients' clinical data:

- The PBPP admin/eDRIS coordinator write to CG or Medical Directors of HB's containing patients whose records are required. CG will be asked to facilitate access
- Research nurses will be required to contact the CG's and make arrangements for how data will be accessed.
- Prior to accessing data the research nurses must
    - Hold professional registration
    - Hold a contract of employment that documents responsibility relating to patient confidentiality
    - Hold a research passport
    - Signed an amended version of the eDRIS T&C's
    - Completed an approved PBPP information governance training course

AMcC advised that this has been done in NHS Lothian for other studies as trial nurses look to assure the validity of the data. Issues have arisen because patient data is now primarily stored electronically and requires someone with local knowledge to show people how to use the system and/or supervise them during access. This is resource intensive for local staff and would attract a cost.

SP stated that researchers should have resource within grant funding to cover costs.

AMcC confirmed that studies such as EMA are run on the basis that they are financially low cost and may not have capacity within funding for this additional resource.

DM stated that Professor McDonald had intimated in the meeting held 4th May that not all HB's were accepting research passports and some are unwilling to allow access to the research nurses despite all the necessary pre-entry checks being documented. DM queried why this would be happening if national approval has been given.
Chair asked AMcC for local thoughts on this issue who advised this may be due to board resources and local staffing commitments.

DB asked the Panel to explain what a research passport is and its purpose.
CB advised that the passport provides a researcher with a mechanism to apply for access to multiple health boards using one nationally approved document which ensure a number of pre-entry checks have been completed e.g. PVG, occupational health.

DB stated that if there is access issues these should be brought to the attention of PBPP. He noted that all boards now have privacy detection systems and that the issues arising may be more of an IT issue in respect of logging onto the required systems.

CB stated that it also concerns the ability of the research nurses to navigate complex clinical records and systems and the need for a local team member to support.
DM asked if there was any scope to have recently retired or locum staff monitor those individuals and noted that the cost should not be borne by the NHS.
AMcC advised that this was possible but would still incur a cost.

KL noted that this may have an impact on the workload of Caldicott Guardians and may cause potential capacity problems.
DB requested if 'end-point validation' can be amended as this causes confusion with IT terminology
SP agreed to change to clinical event.

DM advised that from a lay perspective that he is keen that 'red tape' does not prevent researchers from carrying out work which can be beneficial

CB suggest that a letter is sent to R&D Directors which acknowledges that there is a cost associated with this type of work which may allow an opportunity for discussion to divert research funding

AG suggested that as meeting is running ahead of time that the Panel move to Item 10
The Chair agreed.

9. Statistics Public Benefit and Privacy Panel

This item was previously listed as Item 10 on the agenda.

GD provided an overview of the paper. The paper is to provide an update on the Scottish Governments plans to set up a similar panel for statistical and research projects using the SILC infrastructure but involving SG and Local Authorities data

SP questioned the point in the paper noting that the Panel was advising the SILC board.
AMcC noted it is important to acknowledge the gap in this area due to the different interfaces across Scotland e.g. housing, education and local authority.
DB advised that the original idea of the PBPP was to extend beyond health.
CB queried whether this was a parallel process but more of funding advisory body.

DB suggested that it would appropriate to get in touch with the data controllers to gain their support and revise the remit.
GD responded to say that the data controllers where wide and varied spanning across Scottish Government, Local Authorities, Education Departments and others.
AMcC also suggested inclusion of a representative from Solus. England has experienced issues regarding identifiable education data

GD asked the Panel if SPBBP was an appropriate name.
SP suggested that the remit is revised and then a name developed based on the function.

HC asked the Panel for clarification of SILC
SP provide a summary of the purpose and role of SILC as the operational arm that provides services to the infrastructure supporting research and data linkage. .

CB noted that the diagram was incorrect in terms of the relationships between Farr/ADRC and PBPP

DB commented on the feasibility of the Local authorities grouping together to organise a similar Panel.
GD noted that this would be extremely difficult due to the number of local authorities involved as well as the complexities
CB suggested that the process start small and then look to expand.
GD to revise remit and provide an updated paper to PBPP

Action GD

10. SHARE

Brian McKinstry (BMcK) and Shobna Vasishta (SV) attended the meeting to provide the Panel with information on the work of the SHARE.

SHARE (Scottish Health Research Register) is a new initiative created to establish a register of people interested in participating in health research and who agree to allow SHARE to use the coded data in their various NHS computer records to check whether they might be suitable for health research studies. This access can be incredibly useful when it comes to developing new treatments and cures for a wide variety of health conditions
SHARE also asks for permission to store any spare blood left over from routine clinical tests to be used for research purposes in conjunction with the general SHARE register. This will allow investigations find new ways to improve the safety and the effectiveness of drugs to combat disease.

SP asked how the SHARE access Committee assesses the public benefit of projects, particularly commercial studies.
BMcK confirmed that commercial studies have been directed to SHARE through the CSO review process and that clinical trials are subject to other regulatory approvals processes.
SP advised that for commercial applicants the PBPP insist on evidence of peer review.
BMcK confirmed that SHARE has not yet experienced this issue but it is something which they will note to consider for the future. BMcK added that most projects should have R&D and/or ethics before approaching SHARE and must include SHARE in their proposals. He confirmed that the SHARE access committee includes experienced clinicians and researchers.

DM asked the presenters who are the data controllers for SHARE
BMcK confirmed that SHARE the ownership lies with NHS Scotland and funded in collaboration with Scottish Government, CSO and NHS.

GD enquired as to the process for if a researcher should contact a person who has died since the eligible list has been populated.
SV confirmed that there are daily death updates and an overnight clean for her system view but would check if this is the same for the researchers view.
CB asked what national data will be requested.
BMcK confirmed that this is only SMR's and Prescribing data so far. Currently each regional safe haven is providing data and they respond at different speeds. They are currently investigating a national approach as not all participants are covered e.g. Highland and Lanarkshire.

HC enquired how accessing the data works
BMcK advised that each regional safe haven holds a list of patients registered with SHARE in their area and that they use this list to search through their records to see if anyone in their area meets specific criteria for a potential research proposal.

DB noted that even though individuals have consented each project should still come to PBPP if seeking access in multiple boards.

HC confirmed that SHARE is an initiation point for recruitment only.

AF asked the presenters if they gather information as to why people have consented to be a part of SHARE.
BMcK stated that the people are keen to help and that the motivation is very altruistic. Individuals are looking to give something back.

AF asked if those who participate are given feedback.
BMcK explained this would be the responsibility of the researchers at the moment.

The Chair thanked the Brian McKinstry and Shobna Vasishta for presenting to the Panel.

11. Performance Update

A paper was circulated for information only.

HC requested information on application 1516-0377 as she considered that the issues may be similar around secondary use as those in 1516-0022. HC queried whether the decision would demonstrate a consistency in PBPP approvals.

AG advised that this application was approved by the Tier 2 Out of Committee, a subset of the Full Committee and that she would send HC the application information and Master Record.

Action AG

12. Any other business

Accreditation of Safe haven

DB provided an update on the Accreditation of Safe Havens. DB confirmed that that Scottish Government had made a commitment to accredit safe havens. The National Safe Haven has been accredited and will be reviewed annually. The Chief Operating Officer at the Scottish Government accredited and will sign letter.

HC queried paper submitted to previous meeting and enquired what the role of PBPP was in this process.

DB clarified that Scottish Government will be the accreditor and will advise PBPP of what is happening in terms of the accreditation process to enable the Panel to comment or challenge as appropriate.
HC requested documentation regarding the criteria which are required to apply for accreditation assessment.
DB advised he is happy to provide this to PBPP.

Chair requested that DB provide a revised paper for PBPP regarding the assessment criteria and PBPP role the process.

Action DB

PBPP Committee Membership

The Chair noted that Ms Margaret Dakers Thomson has been notified in writing that her services to the Committee are now concluded and thanked Ms Dakers Thomson for her contribution to the Panel.
The Chair confirmed that as per the terms of reference the PBPP Committee is required to recruit a lay representative and enquired if a process for doing so had been agreed.

CM confirmed that the recruitment process is being developed and will be presented to the Committee for comment and agreement. The Chair enquired if it would be appropriate for the draft document to be viewed by him prior to tabling for discussion by the Committee.

CM and AG agreed to action this

13. Date of next meeting

The next meeting is scheduled to take place on Tuesday 4th October 2016 at 10am in Meeting Room 7, 2nd Floor, Waverley Gate
Proposed agenda items to be emailed to PBPP mailbox by 31st August 2016.

Note: PBPP Training and Review Day will take place on 1st September 2016 at Technology and Innovation Centre, Strathclyde University