NHS Scotland (NHSS) Public Benefit and Privacy Panel for Health and Social Care

Minutes of the Committee meeting held on 12th April 2022 by MS Teams

Present:	Dr Lorna Ramsay (Chair) (LR) Dr George Fernie (GF) Kenneth McLean (KMcL) Martin Walsh (MW) Professor Alison McCallum (AMcC) Carole Morris (CM) Alan Ferrier (Al F) Penni Rocks (PR) Dr Angus Ferguson (AF) Dr Richmond Davies (RD) Dr Mark McGregor (MMcG) Dr David Felix (DF) (arrived 10.15)
Apologies:	Martin Bell (MB) Professor Abbe Brown (AB) John Woods (JW) Professor Colin McCowan (CMcC) Dr Tara Shivaji (TS)
In Attendance:	Dr Marian Aldhous (MA) Phil Dalgleish (PD) Susan Kerr (Secretariat)

1. Chair's Welcome

The chair welcomed all to the meeting. LR welcomed Dr Mark McGregor, this is his first meeting as a Caldicott Guardian (CG) representative.

This is the last meeting for both Dr Angus Ferguson and Professor Abbe Brown, LR thanked them both for all their help over their years with the HSC-PBPP Committee.

The meeting was quorate.

2. Minutes and Actions from previous HSC-PBPP Committee Meetings

2.1. Minutes of meeting held on 26 January 2022

These were approved as a true record with one minor correction: on page 4 a slight typo on KMcL initials (C should be an L).

ACTION 12-04-22 / 01: MA to address minor correction

2.2. HSC-PBPP Committee Action Log

The Action log for 2020/2021 is now nearly complete. A new action log will now start for the year 2022/2023.

Outstanding actions:

- 26-01-22 / 05: is still showing yellow because it refers to the discussion for item 6 on the agenda and will be closed after today's meeting.
- 26-01-22 / 06: LR to introduce Roger Halliday to the chair of the National Caldicott Guardians group will be done as soon as possible.
- 26-01-22 / 08: Jackie Caldwell to send slides from the discussion of SMI at the last meeting. MA will chase again.
- 16-11-21 / 08: The discussion paper from AMcC and the Ops group was to be discussed at this meeting. However, with the application for review it was thought that there was not enough space on agenda today so will be carried forward to the next meeting in June 2022.

3. Matters Arising

3.1. Committee personnel update.

MMcG joined the committee today as a new CG representative. There is still a space for another CG. LR has agreed with Tracy Gillies (Chair of the CG Forum) that HSC-PBPP will not pursue this vacancy at this point in time to give time for the CG Forum, which has recently started meeting again, to feel established. At that point we will then look to see if someone else is able to join this committee.

It terms of Lay representation this is the last meeting for AF and AB. Unfortunately JW has now resigned from this committee. He has been with HSC-PBPP for approximately a year but was finding other commitments were taking more time than anticipated. A fourth lay rep was appointed, but unfortunately, had to stand down because of a conflict of interest due to a new post.

LR asked if anyone has any groups or contacts for potential lay members to please let us know. Healthcare Improvement Scotland (HIS) now holds a Citizen Panel, which will contacted to see if anyone on that panel may be interested.
PR suggested that some of the groups that the Digital Health and Care group go to for input may be able to help and Imme Jones is the person to contact for that.

ACTION 12-04-22 / 02: MA to contact Imme Jones and HIS Citizen Panel. Anyone with other suggestions to contact MA.

3.2. 2122-0054 McEwan

This application was discussed at the last meeting. This is now being checked whether the conditions have now been met before final full approval given.

4. Updates for committee

4.1. Panel Manager Report

Report for information only. Apologies for wrong dates: anything dated 31st December 2021 should be 31st March 2022. The numbers are for the end of year 2021/22. Two things to highlight:

i. There were 19 withdrawn applications. An application is usually withdrawn when there has been no response from applicants for 3 months after the review at a Tier 1 panel. This number of withdrawn applications is the equivalent of five Tier 1 panels, which is a lot of time taken by Tier 1 panel members.
ii. The number of amendment requests has increased this year, up to 294 from ~250. While slightly more than half of these have been approved by eDRIS, the rest were all initially processed and reviewed by PD, which has been a lot of work.

AMcC asked about amendments and withdrawn applications and wondered for future meeting if there was anything we could look at as a panel to help Tier 1. Also, for withdrawals, when communicating with the applicant, perhaps it should be highlighted that the principal investigator has a duty to respond as they are legally responsible for the research.

4.2. Policy Decisions & Case Law Principles

Updated report for information only.

4.3. Update from Health Data Research UK (HDRUK)

CM provided a paper and a brief update:
National Core Study Programme continues. Main updates continuing around ISARIC data platform which will become Outbreak Data Analysis Platform (ODAP). This will bring together a lot of COVID studies and data from NHS Digital and NHS Scotland, to analyse data from current outbreak so that it is ready for the future. Universities of Edinburgh and Oxford (for ISARIC) will be data controllers. HDRUK is looking at a data access panel for data on ODAP. PHS will act as a trusted third party to hold the linkage keys. Others are contributing data.

AMcC asked about access for research purposes and business and usual (BAU) purposes for data that originally went to private companies was not fully tied down at the start of the pandemic. Therefore it is important to ensure that the statutory basis for collecting data and bringing data together for research is properly tied down legally and all data is there for public benefit. AMcC agreed to email CM and PR about specific examples.

ACTION 12-04-22 / 03: AMcC to email and clarify with CM and PR

The remit of the Data access panel is still being worked out as to how it will take place operationally. HDRUK and RDS are doing similar work and need to talk to each other.

It was agreed that it is helpful to know that this work is going on and developing but needs further understanding of how this will be done. How many of the different studies have come to HSC-PBPP for approval that are now being combined? Will the access panel divert things away that should come to HSC-PBPP?

The Co-CONNECT study is going well. The virtual machine for querying from HDRUK Gateway is now ready for sign off. This will be replicated for the National Safe Haven (NSH) with IT security on board for penetration testing. Disclosure control mechanisms (no numbers <10 to be released) are being tested and checked across UK Trusted Research Environments (TREs). HDRUK researchers to query high level NHSScotland information as to whether they have COVID vaccination, serology, SMR01. Data will be extended to see what is useful and non-sensitive for research community.

4.4. Scottish Government (SG) update

Sophie Ilson (SI) from SG joined the meeting and gave a short presentation with slides on her work with Albert King on private sector use of public sector data: Unlocking the Value of Data. This is a Citizen-centred approach to explore unlocking the value of data.
The use of public sector data by commercial stakeholders, needs SG policy or framework. This will ask a number of questions: How to value data? How to define public benefit for data access? This requires citizen engagement. In addition, contractual and Intellectual Property (IP) issues need to be addressed and legal advice will be required.

Ministerial approval has been given and they are working with an Independent Expert Group (IEG) and practitioner forum, aiming to produce a high level policy statement and framework.

Outputs would be meaningful public engagement and international engagement.

Unfortunately due to timing, the presentation was brief but the slides will be circulated after the meeting.

The Chair of the IEG is Professor Angela Daly, Professor of Law & Technology in the Leverhulme Research Centre for Forensic Science and Dundee Law School.

There is a recognised gap and need for steer from SG in this area and this work ties in with RDS. It might require someone from HSC-PBPP to join the group, to help educate the expert group regarding the health and care world. This is important work and any input would be welcome. In addition, proper engagement with public is required so that SG can take a policy decision. HSC-PBPP to be kept updated in how this work is evolving.

ACTION 12-04-22 / 04: SI and MA to circulate slides after the meeting

5. Application for Review 2122-0023 Dennison

GF as lead reviewer outlined the issues raised for discussion and questions for the applicant. The Early Life Cohort Feasibility Study (ELC-FS) aims to provide evidence on the potential for successful recruitment into a new UK-wide birth cohort study, and the best approach to design and measurement. After an initial contact by letter from a Field Agency contracted to do the work, the families will be visited in their homes for interview, assessment and collection of biological samples. The ELC-FS will also collect rich data on babies and their families capturing their economic and social environments and their health and well-being and development in the babies' first 6-9 months. In Scotland this would involve several hundred babies. While the reviewers had thought there was public benefit to this application, there were also concerns that had been raised:

i. Calling at someone's address, including if they have not responded to the initial invitation letter agreeing to an interview. Could this be done with a two-stage approach, with the initial contact coming from the local NHS Board and only those who had not opted out to be contacted by the field agent
ii. Contacting one parent for the other parent's contact details if they are not at the same address.
iii. Use of data from those who have not responded and whether people can opt out.
iv. Use of biological samples by commercial sector.

Professor Lisa Calderwood, Professor Pasco Fearon and Karen Dennison joined the meeting. GF introduced himself and summarised the concerns raised. These were discussed with the applicants and the committee member's questions answered. GF thanked them for attending.

Further committee discussions took place and it was agreed their responses had been reassuring. What about the concerns raised?

i. A one stage or a two-stage approach?

While some preferred the two-stage approach, it was agreed that NHS branding should be included in the initial letter, as people respond to the NHS more easily than a possibly unknown field agency. As all babies are visited by a local health visitor (and/or community midwives), it was suggested that these could be trusted third parties who could be available to engage with the invitees and explain and support them? This might help with the response in a one-stage process.

ii. Wording for contacting absent parent?

It was agreed that AMcC should work on proposed wording for this.

iii. Use of pseudonymised / anonymised data

The core team should manage the data for those who opt out, so data going to field agency for interviews is only those who have not opted out. Anonymised data would be provided for those who opt-out or do not respond.

iv. Use of DNA by a commercial organisations without public sector partner

It was agreed that we should push back on this point at this stage as it would not affect the recruitment stage and suggest further discussion is required.

It was agreed that this application could be approved with conditions taking in the above points.

ACTION 12-04-22 / 05: MA, LR, GF. KMcL and AMcC to compose a response for this application.

6. HSC-PBPP Development Slot: RDS SECURE pathway

Roger Halliday (RH) and Alistair Rennie (AR) from Research Data Scotland (RDS) joined the meeting.

RDS aims to be a simpler and quicker route to access public sector data, to give a better 'journey' for researchers. This is being done in collaboration with partners throughout UK not just Scotland. There will also be engagement with the public for their support and transparency.

The SECURE (Safe, Enhanced, CURated E-dataholding) pathway is designed to be a simple rapid access route for access to data for low-risk projects that meet agreed criteria: non-commercial use; fully described public benefit and which have undergone scientific peer and ethical review. The numbers of applications going through this route will be relatively low. Data controllers will agree the datasets to be included and the conditions of use. Data protection impact assessments (DPIAs) and Data sharing agreements (DSAs) with the data controllers will be put in place.

The process aims to streamline access approval, create and manage a digital process for access control and remove duplication in application forms. The "five safes" principles are embedded in the process: access by trained researchers from known organisations. The public benefit of research outcomes would be clear, using secure datasets for purpose of research and no additional data to be linked. The linked data would only be accessed in safe locations (national or regional safe havens).

Oversight and governance would be done by a SECURE governance body, which includes public partners and data controllers, and this would meet twice a year. A specialist SECURE team would review and approve data requests. Data would be provided with formal user agreement which would include penalties for misuse.

Q: What about access to data that would previously been available locally for research and BAU purposes but now could be done nationally?

A: RDS is talking to local data holders and Administrative Data Research (ADR) to review available datasets and how these could be provisioned safely. Data linkage process through National Records of Scotland (NRS) Indexing so pseudonymised prior to provision. Linkage to Local authority (LA) or third sector data can be done in RDS with NRS to create linkages. If deemed more high risk then would have to go to the PBPPs rather than through SECURE pathway. Some data controllers do not think their data is fit for purpose for wider use. Further dialogue is required so that use and quality of data can be addressed. RDS may ensure that there is a feedback loop for researchers, regarding the quality of data provided. RDS is about use of data for research purposes, not for BAU or operational purposes but some space for those discussions to take place.

LR: BAU can help public sector bodies to fulfil their functions as well as research and both need to be addressed.

Q: Regarding guidance for researchers for applications that go through RDS and then need to be redirected to the PBPPs: will there be a pathway in place for such redirection, or would it require a new application? If something doesn't work through SECURE pathway, would they need to go away and start again?
A: RDS wants to consolidate access across both PBPPs with guidance to provide simpler and more logical access to information, to provide a uniform set of guidance across Scotland, and with HDRUK, across UK. Any application through RDS needs to be complete enough so that it can be passed directly to the PBPPs, if necessary. If there is not enough information, RDS would ask researcher to provide it for the PBPPs. Much of this would be done through the pre-application process.

Q: Does this mean that RDS would become a single 'front door' for researchers and will decide which applications go to the PBPPs and which to RDS? E.g. New linkage to health data would this go through RDS or come directly to HSC-PBPP? Many applications approved at Tier 1 would still need to go through HSC-PBPP and the higher risk ones would still come to HSC-PBPP committee.
A: RDS would like to be the route to all research data in Scotland. RDS would do the screening and engagement, as an enhanced role for what eDRIS already does. RDS is really keen to work with committee to try to make process smoother for researcher.

Q: If wish for access to CHI that would need to come through HSC-PBPP?
A: RDS will also be a signpost. So for access to CHI they will likely direct to eDRIS, who will provide direct services to users as well.

Q: Clarification on thought processes: wholly behind idea of streamlining process but always gets more complicated as this is applied. What about structures vs. individual applications? Public benefit is nebulous concept and hard to define. How does this work in short- or long-term?
A: Public benefit is very emotive and lots of guidance and discussion around this. RDS would not approve a project without public benefit even if the risk is low, similar to that in the panels. RDS will employ people whose day jobs are to review public benefit and will balance risk and public exposure. ADR also aware that public benefit is subjective. There is a need to encourage wider public engagement with an engagement strategy for different panels and public at large.

Q: The potential to researchers to have career-ending outcome if data are misused, would this include the research organisation too?
A: Yes, research organisations will also have penalties and institutions will have to sign up to those agreements. Mitigation of risk will include disclosure control for use of data. If researcher has gone outside their remit then this would be breach of conditions and they would be penalised accordingly.

Q: In terms of governance, the HSC-PBPP committee also considers confidentiality and has a number of CGs as members. The importance of maintaining confidentiality of the dead is important and something Scotland does well, especially with regard to genetic material. How will RDS address this?
A: Any identifiable information will be built in to ensure full confidentiality of identifiable information. The ADR public panel is engaged with this and RDS will engage further with others. The processes and issues around pseudonymisation /anonymisation are part of this as what is anonymised today may not be in future due to increased technology. Need to ensure that privacy is maintained in the future given technological advancement. GDPR and Duty of Confidentiality needs to be kept under consideration and will be built into the agreements.

Q: Regarding discussions with data controllers, would these be with each of the DCs directly, i.e. each NHS Board, and not just HSC-PBPP as proxy for them?
A: Some things may be passed to HSC-PBPP for review, to indicate what concerns are raised, but this would not have critical dependency as don't want to increase burden on panels. It would be useful to get feedback but active engagement would be with the data controllers.

Q: Can you confirm whether there are two pathways or only the SECURE secure pathway?
A: SECURE pathway is a defined 'new' pathway (previously pathway 2). Pathway 1 is the normal process and not a specific pathway, but part of the streamline of existing processes.

Q: What will be the first health datasets to start this process?
A: Testing out using real data sets, around children's related health data sets: education, social care and related health datasets of SMR02 maternity datasets and Child Health Surveillance Programme (27-30 month checks). These will show the unknown and unpredictable elements. Around 30-40 datasets are already in NSH through COVID database. Start with them to get necessary agreements in place.

Q: What about Primary care data?
A: There is a new post to look at datasets that not currently available through NSH. Public engagement has broad strategy for alignment and collaboration at UK-level through HDRUK and ONS and NHS England that can act at scale, in which RDS needs to be involved. Need Scottish public engagement network to provide range of processes that might be appropriate for this. Aim to have something by the summer.

LR Thanked both RH and AR for coming to HSC-PBPP and highlighted the need to continue the conversation.

ACTION 12-04-22 / 06: AR/MA presentation and additional documents to be circulated to committee members.

7. Any other business

Question on remit of HSC-PBPP for further use of data provided from NHSS and approved by HSC-PBPP – no time to discuss. This will be carried forward to the next committee meeting.

8. Date of next meeting

The next meeting will take place on Tuesday 29th June 2022.

ACTIONS

Action Reference	Action	Responsible person
12-04-22 / 01	Correct minor typographical error in minutes	**MA**
12-04-22 / 02	MA to contact Imme Jones and HIS Citizen Panel. Anyone with other suggestions to contact MA.	**MA / ALL**
12-04-22 / 03	AMcC to email and clarify with CM and PR	**AMcC / CM / PR**
12-04-22 / 04	SI and MA to circulate slides after the meeting	**SI / MA**
12-04-22 / 05	Relevant Committee members to compose a response for this application.	**MA, LR, GF, KMcL, AMcC**
12-04-22 / 06	Slide presentation and additional documents to be circulated to committee members.	**AR/MA**