



# **NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)**

**Annual Report  
2023/24**

## Contents Page

|  |    |
|--|----|
| 1. Abbreviations and Glossary                                | 3  |
| 2. Executive summary   | 5  |
| 3. Chair’s Introduction                                      | 7  |
| 4. Purpose and Structure of the HSC-PBPP                     | 8  |
| 5. HSC-PBPP Tier 2 Committee members 2023/24                 | 11 |
| 6. Meetings of the HSC-PBPP                                  | 12 |
| 7. Performance metrics for HSC-PBPP applications for 2023/24 | 14 |
| 7.1. Summary tables of HSC-PBPP metrics for 2023/24          | 14 |
| 7.2. Comparisons with previous years                         | 16 |
| 7.3. Time to decisions                                       | 20 |
| 8. Adverse Event and Lessons Learned                         | 22 |
| 9. Quality Improvement and Development                       | 24 |
| 9.1. Ongoing Development Work                                | 24 |
| 9.2. Research Data Scotland                                  | 25 |
| 9.3. Access to data from GP practices                        | 25 |
| 10. Annual HSC-PBPP Workshop 2023/24                         | 26 |
| 11. Achievements and Priorities                              | 27 |
| 11.1. Achievements for 2023/24                               | 27 |
| 11.2. Priorities and Challenges for 2024/25                  | 27 |
| 12. Conclusion   | 28 |

## 1. Abbreviations and Glossary

|                      |  |
|----------------------|--|
| <b>AI</b>            | Artificial Intelligence is computer software that mimics the ways that humans think in order to perform complex tasks, such as analysing, reasoning, and learning.   |
| <b>CG</b>            | Caldicott Guardian: A senior person within an NHS board responsible for protecting the confidentiality of patients' health and care information.   |
| <b>CHI</b>           | Community Health Index number is the NHS number used as a patient identifier across NHSS.  |
| <b>CHIMB</b>         | CHI Management Board (previously the CHI Advisory Group [CHIAG]) manages the use of CHI for NHSS business and operational uses in the delivery of health and social care.  |
| <b>DPO</b>           | Data Protection Officer  |
| <b>eDRIS</b>         | electronic Data and Research Innovation Service within PHS. Applicants to HSC-PBPP are assigned an eDRIS coordinator to advise on data availability and provide support for the application processes.   |
| <b>IG</b>            | Information Governance.  |
| <b>IG Lead</b>       | Person in an NHS board responsible for Information Governance in that board, under the Caldicott Guardian.   |
| <b>HSC-PBPP</b>      | Public Benefit and Privacy Panel for Health and Social Care.   |
| <b>HSC-PBPP Only</b> | An application that does not require input from eDRIS prior to submission, as the application will not require data to be extracted from national datasets and the data will not be accessed via the National Safe Haven.  |
| <b>ML</b>            | Machine Learning is a subset of AI that uses algorithms trained on data to produce models that can perform such complex tasks.   |
| <b>NES</b>           | NHS Education for Scotland, a special (national) NHS board and a data asset holder.  |
| <b>NHSCR</b>         | NHS Central Register: contains basic demographic details of everyone born, registered with a GP or died in Scotland. NHSCR data can be requested for medical research to flag deaths or cancer diagnosis in the long-term follow-up of a research cohort.<br><a href="https://www.nrscotland.gov.uk/statistics-and-data/nhs-central-register">https://www.nrscotland.gov.uk/statistics-and-data/nhs-central-register</a> |
| <b>NHSS</b>          | NHSSScotland.  |
| <b>NRS</b>           | National Records of Scotland, a data asset holder.   |
| <b>NSS</b>           | NHS National Services Scotland (the common name for the Common Services Agency for the Scottish health service) and data asset holder.   |
| <b>NSH</b>           | National Safe Haven: a secure environment where access to NHSS data is controlled by eDRIS and the recommended space for researchers to access NHSS national datasets.   |
| <b>PHS</b>           | Public Health Scotland, a special (national) NHS Board and data asset holder, established in April 2020.<br>The HSC-PBPP management team sits within PHS, as part of the PHS Data Protection Team and feed into some of its governance processes.  |
| <b>RDS</b>           | Research Data Scotland, a Scottish Government initiative, formally established in 2021, and set up to bring together public sector data for use for research.  |

|                   |  |
|-------------------|--|
| <b>SG</b>         | Scottish Government.   |
| <b>Tier 1</b>     | Operational level at which all applications to HSC-PBPP undergo their first review.  |
| <b>Tier 2</b>     | Higher / strategic level of HSC-PBPP, which has oversight of HSC-PBPP, and at which higher risk applications are reviewed.   |
| <b>Tier 2 OOC</b> | The Caldicott Guardians and Public Representatives who sit on the full committee who review applications “out of Committee”. |

## **2. Executive Summary**

### **Background**

This Annual Report covers the operation of the NHSScotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) for the year April 2023 to March 2024.

Created in May 2015 by Scottish Government (SG), the HSC-PBPP is an information governance (IG) structure of NHSScotland (NHSS). It provides a central national IG scrutiny process focussed on requests for access to NHSS-originated data, which are held in the NHSS boards, for purposes other than direct care. Such purposes include research or service planning.

Support is provided to all applicants seeking access to data, via the electronic Data Research and Innovation Service (eDRIS). The HSC-PBPP works on a two-tier basis: the operational Tier 1 panel or the more strategic Tier 2 committee. Applications are scrutinised at fortnightly panels of NHS IG leads (Tier 1 panel), who attend on a rotational basis. The majority of applications are decided (usually approved) at this level. Where the applications are of greater privacy risk and require a higher level of consideration, applications will be referred to a convened-as-required subgroup of the Tier 2 Committee for scrutiny, known as Tier 2 Out of Committee (T2 OOC), and if deemed necessary, by the full Tier 2 committee.

### **Performance**

Through this year of operation, HSC-PBPP has continued to show good performance across a range of metrics. IG leads from the territorial and national NHS Boards within NHSS have been engaged in the process, thus embedding IG in the general operational approach of the NHS across Scotland.

The number of submitted applications in 2023/24 was the same as last year, but lower than that in previous years, possibly reflecting changes in data sharing across NHSS boards, reducing the requirement for HSC-PBPP approval for some activities. As in previous years, these applications came mainly from academia (~77%), with the proportion of NHS applications markedly reduced from over 30% in previous years to ~20% in the last 2 years; the remainder of the submissions came from SG and commercial companies. As seen in previous years, the majority of applications were from organisations within Scotland, with about a third of applications from the rest of the UK.

An Adverse Event occurred during 2023/24, arising from an HSC-PBPP-approved application. This was dealt with by the NHSS boards in which it occurred, the data providers and HSC-PBPP, with some immediate actions put in place but also a Lessons Learned process and Action plan, the implementation of which will continue into 2024/25.

### **Development work**

HSC-PBPP endeavours to keep abreast of current and future developments, particularly in this rapidly moving landscape. The requirement for regular updates from HSC-PBPP to the NHSS boards has continued during this year, through some of the different governance

forums that regularly meet within NHSS: the IG Forum, the DPO Forum and the Caldicott Guardian Forum.

An HSC-PBPP Development Day was held in March 2024, using a similar to the annual workshops that previously took place. This used the opportunity to bring together HSC-PBPP members from Tier 1 and Tier2, eDRIS and a few researchers, who were contributing to the day, but who joined with the other discussions. The day gave an opportunity to discuss some challenging scenarios that have recently arisen from different applications. It also included a session on Artificial Intelligence (AI) / Machine Learning (ML), with input from researchers working in this area. This provided opportunities for discussions about how applications for these are handled and processes for assessing the use of data for this methodology.

### **Future developments in 2024/25**

Looking forward to 2024/25, HSC-PBPP must continue to ensure that the right balance is struck between safeguarding the privacy of people in Scotland and the benefit to all from improved treatment and care informed by high quality research. Ongoing development to improve processes will continue, particularly with guidance arising from the lessons from the Adverse Event and the Development Day.

The establishment of Research Data Scotland (RDS) will change the provision of data from across the public sector for research. The role of HSC-PBPP will continue and adapt to changes in the landscape, while ensuring consistency and maintenance of the public confidence in the scrutiny process.

Preliminary discussions regarding access to GP data are ongoing. It is hoped in 2024/25 a process aligned with HSC-PBPP will be developed, to make these data available to researchers, subject to resources and agreements with the GPs.

### **3. Chair's introduction**

This report covers the work undertaken by HSC-PBPP during 2023/24. The outcomes achieved during this past year is a testament to the hard work of all those involved, sometimes in difficult circumstances. It is opportune to be able to express gratitude to everyone who has contributed to these processes in such a conscientious and professional manner. I should especially like to thank the Panel Manager for all she has done in helping us negotiate this period of very significant change which has not been any easy task.

NHSS has a wealth of health data for its population, providing an exceptional opportunity for large scale research projects, quality improvement and patient-care audits to be undertaken. Applications have become more complex since the time when HSC-PBPP was originally set up, and often includes the use of highly sensitive data from extremely vulnerable people, thus raising new questions for panel members and reflecting societal and technological changes. The use of artificial intelligence (AI) has brought fresh challenges for review of applications and governance for the use of data. We have started to address these issues in 2023/24 and these will continue into 2024/25.

The HSC-PBPP has continued to involve the IG Leads across the different NHSS Boards, thus ensuring that the HSC-PBPP scrutiny is a truly national process and not limited to select individuals within specific Health Boards. From its inception in 2015 up to the end of March 2024, in total, the HSC-PBPP has made decisions for 850 applications, showing that the demand for using NHSS health data remains high.

Some personnel changes to the HSC-PBPP Tier 2 committee have taken place, the main one being the change in interim Chair of the Committee: the outgoing Chair, Dr Lorna Ramsay, was extremely competent and well- respected and will be hard to follow. However, as a previous Caldicott Guardian representative on the Committee, and Depute Chair of the UK Caldicott Guardian Council, I will maintain continuity in this governance space and bring new perspectives from my own experience. The addition of a new public representative in 2023/24 and a new Caldicott Guardian starting in 2024/25 will bring new skills, approaches and ideas to the reviews of applications and policies, which is always welcome.

HSC-PBPP recognises the need to react quickly to the rapidly changing landscape of governance in an increasingly technological age. The establishment of RDS is part of this, so that the use of data in the public interest and benefit is expedited but the scrutiny processes are not compromised and public confidence is maintained. There are obvious difficulties with a smaller number of potentially more complicated cases coming to the panel, especially when there is a change of membership meaning less experience of the workings of the group. As RDS develops, HSC-PBPP will continue to develop its procedures to improve efficiency, while maintaining integrity. Ultimately the aim is that this will all work together so that the people of Scotland will gain the benefits of better health and social care.

Dr George Fernie  
Interim Chair of Public Benefit and Privacy Panel for Health and Social Care

## **4. Purpose and Structure of the Public Benefit and Privacy Panel for Health and Social Care**

NHSScotland (NHSS) is the healthcare service in Scotland, with 14 territorial NHS Boards, which are responsible for the protection and the improvement of their population's health and for the delivery of frontline healthcare services. There are also 8 national bodies, which provide a range of support, specialist and national level services. The responsibilities of NHSS also include population health, health protection, education and training.

HSC-PBPP is an IG structure of NHSS that exercises delegated decision-making on behalf of NHSS Chief Executive Officers acting on behalf of their boards and the Registrar General of the National Records of Scotland (NRS) for NHS Central Register (NHSCR) data.

The HSC-PBPP endeavours to operate as a centre of excellence for privacy, confidentiality and IG in relation to Health and Social Care in Scotland, providing strategic leadership and direction to NHSS Boards, the research community, and wider stakeholder groups.

The panel aims to:

- Streamline the governance processes for the scrutiny of requests for access to NHSS-originated data for purposes other than direct care, e.g. audit, service-improvement, research, or health and social care planning;
- Provide robust, transparent, consistent, appropriate and proportionate IG scrutiny of such requests;
- Strengthen the direct involvement of members of the NHS and public in the scrutiny process and decision-making regarding access to NHSS-originated data.

Since its inception in May 2015, the HSC-PBPP has provided a national IG scrutiny process for the secondary use of patient health data held within NHSS Boards. It has successfully harnessed expertise across the NHSS Boards implementing a collaborative approach which contributes to consistency and continued capacity development across the sector.

### **Structure of the HSC-PBPP**

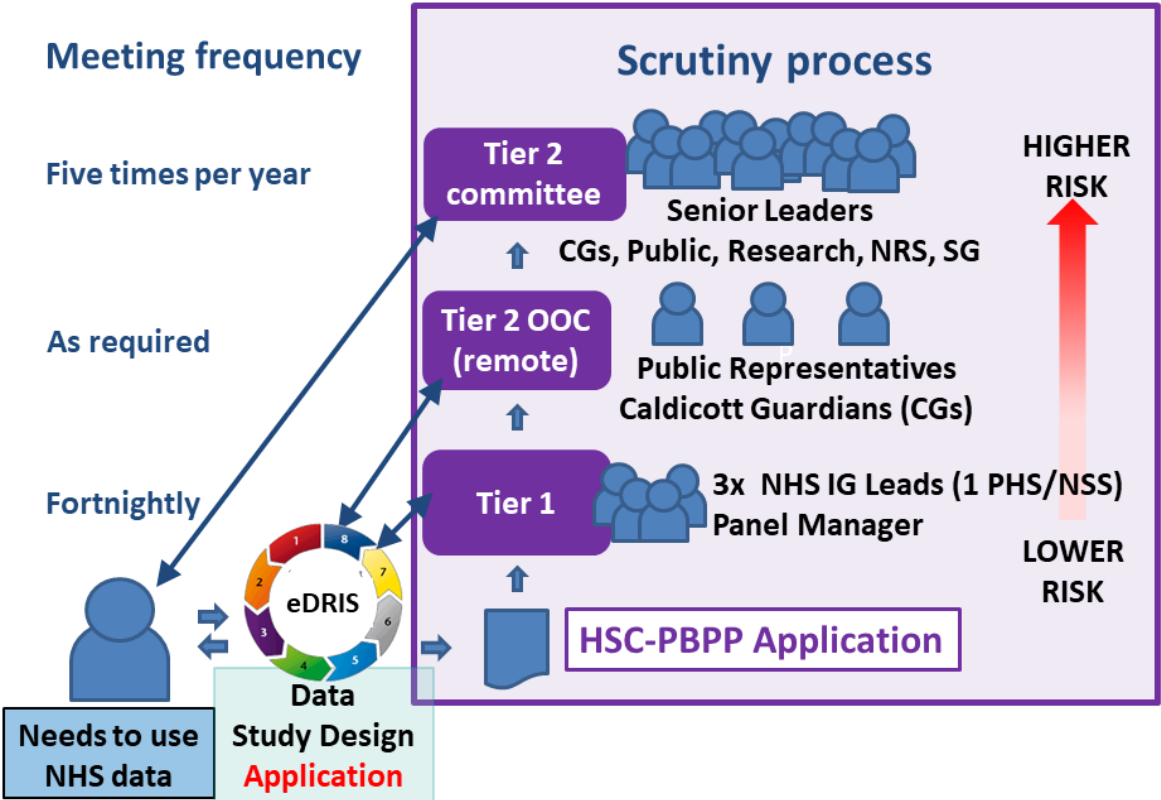
The HSC-PBPP structure and process is summarised in the flow diagram shown in Figure 1. Currently, eDRIS provides a single entry point for all applications to HSC-PBPP. This helps to maintain consistency of advice for all applicants, including those from NHS services or SG for core business, as well as those wishing to use NHSS data for research.

The eDRIS team provides support to all applicants applying to HSC-PBPP. They do this by providing an eDRIS Coordinator to facilitate applicants to refine their projects and the data requested, as well as review and assist applicants to finalise their applications for submission. The eDRIS team works closely with the HSC-PBPP. Through shared learning between the two teams, this aims to ensure that applications are fit for submission, thus making the HSC-PBPP review process as efficient as possible for both applicant and reviewer.

The HSC-PBPP operates on a two-tier structure (see figure 1). Tier 2 is the level of strategic oversight and consideration of policy, whereas Tier 1 is the more operational level at which most applications are approved.

**Tier 1**

Tier 1 is the first level of scrutiny of applications, acting at an operational level, with panels meeting approximately every two weeks. Facilitated by the Panel Manager, each panel comprises of IG practitioners from across the NHSS Boards, who attend on a voluntary basis as representatives of the NHSS boards as data controllers. Applications are reviewed according to agreed proportionate governance criteria. The Tier 1 scrutiny examines the technical and IG aspects of an application at a Tier 1 panel meeting. Each application is scrutinised against a set of proportionate governance questions and criteria. Up to four applications and two amendments were considered at each meeting. If the Tier 1 panel were satisfied that the public benefit of the proposal was clear and that all privacy risks will be managed appropriately and securely, the application was approved. There may have been questions to the applicant seeking clarification or reassurance before the approval or another outcome was agreed. For more complex, novel or potentially contentious applications, the Tier 1 panel may refer the application on to Tier 2. This would be assessed by a subgroup of the full committee, the Tier 2 Out of committee (T2OOC).



**Figure 1** Flow-diagram of the HSC-PBPP scrutiny process

- CG: Caldicott Guardian
- SG: Scottish Government
- IG: Information Governance
- NRS: National Records of Scotland
- OOC: Out of Committee

## **Tier 2**

Tier 2 comprises a regularly convened strategic Full Committee, and a smaller subgroup of committee members working 'Out of Committee' (T2OOC). The latter comprises of the Caldicott Guardians (CGs) and public representatives of the Full Committee. All Committee members attend on a voluntary basis because they have an interest in the governance and use of data. Applications referred from Tier 1 are reviewed first by the T2OOC. Most applications referred to Tier 2 are approved at this level, with only a minority referred on to the full committee. When applications are referred to the full committee, the applicant is invited to attend the meeting to answer questions and inform the discussion.

The full committee consists of senior leaders from the different stakeholders involved in HSC-PBPP. This includes:

- Representatives of the major data asset holders relevant to HSC-PBPP: Public Health Scotland (PHS), NHS National Services Scotland (NSS), NHS Education for Scotland (NES, which hosts the National Clinical Data Store) and National Records of Scotland (NRS)
- Representative Caldicott Guardians from NHSS boards
- Representative from the CHI Management Board (CHIMB)
- Representatives from the research community
- Representatives from the public (public or lay representatives)
- Representative from Scottish Government.

The full committee provides the intellectual space to consider the wider privacy issues in regard to:

- Particularly contentious, sensitive or novel applications;
- Applications that would set precedence;
- Proposed policies in the Scottish Government and/or NHSS relating to the use of health and social care data.

The use of the two tiers also ensures that scrutiny is proportionate, and that available resources are effectively used. Each of the two tiers focuses on the assessment of privacy risks as well as the balancing of privacy risk with likely public benefit.

## 5. HSC-PBPP Tier 2 Committee Members 2023/24

Dr Lorna Ramsay (Interim Chair) until October 2023  
Dr George Fernie (Interim Chair) from November 2023  
Dr Tara Shivaji (PHS Caldicott Guardian representative)  
Dr George Fernie (NHSS Caldicott Guardian) until June 2023  
Dr Mark McGregor (NHSS Caldicott Guardian)  
Dr Arun Chopra (NHSS Caldicott Guardian)  
Dr Pamela Johnston, (NHSS Caldicott Guardian) until March 2024  
Kenneth McLean (Public Representative)  
Martin Walsh (Public Representative)  
Chioma Dibia (Public Representative)  
Dr Stacey Noble (Public Representative) from April 2023  
Prof Alison McCallum (Research Representative)  
Prof Colin McCowan (Research Representative)  
Martin Bell (CHIMB and NSS Representative) until March 2024  
Dr David Felix (NES Representative)  
Alan Ferrier (NRS Representative) until August 2023  
Julie Ramsay (NRS Representative) from September 2023  
Penni Rocks (Scottish Government representative) until June 2023  
Lisa Hill (Scottish Government representative) from July 2023.

### Committee membership vacancies and changes

During the year 2023/24, the following changes occurred:

- The Chair of HSC-PBPP changed as Dr Lorna Ramsay resigned. Dr George Fernie was appointed as interim Chair of HSC-PBPP.
- One Caldicott Guardian completed their 6-year term. Another Caldicott Guardian retired at the end of March 2024 and replaced in 2024/25.
- A new public representative was recruited during 2022/23 in time to start on the Committee from April 2023. This gave the full complement of public representatives.
- The CHIMB and NSS representative was present for the year but retired in March 2024 and will need to be replaced in 2024/25.
- The NRS Representative changed in August 2023, due to the promotion of the representative and was replaced by their successor.
- Similarly the SG representative changed in June 2023, due to the retiral of the representative and was replaced by their successor.
- The Social Care representative role on the committee remained unfilled during 2023/24.

The HSC-PBPP is grateful and thanks all current members as well as those who have left the Tier 2 committee for their contribution over the years and in particular in the early years as HSC-PBPP has grown and developed.

## 6. Meetings of the HSC-PBPP

### Tier 1

During 2023/24 the Tier 1 Panels continued to meet regularly on MS Teams, approximately every fortnight. Each panel comprised of three IG Leads/Practitioners from NHSS Boards, on rotation, and the HSC-PBPP Panel Manager. The IG leads were drawn from the territorial (regional) and national NHS Health boards around Scotland. Each IG Lead brings their experience and viewpoint from their NHS Board. At the Tier 1 panels, questions and clarifications are often requested from the applicant regarding specific points within the applications. In previous years, these were reviewed by the Tier 1 panel members by email. With the use of MS Teams, an *ad hoc* meeting can be convened to review these clarifications, which has improved the Tier 1 review process. In 2023/24 IG Leads from 17 of the 22 NHSS Boards were involved in the Tier 1 panels.

The HSC-PBPP wishes to acknowledge and express thanks to those who sat on Tier 1 panels during 2023/24 and who contributed their time and considerable IG expertise to the scrutiny process, in addition to their day jobs, often under busy and trying circumstances. The HSC-PBPP wishes to thank particularly the NHS Boards for releasing their IG leads for HSC-PBPP work, to help the HSC-PBPP function well, due to the work of these highly qualified people.

### Tier 2 OOC and Full Committee

The Tier 2 OOC was convened as required to consider applications referred from Tier 1, with reviews being done by email. This group consists of the NHS Caldicott Guardians and Public Representatives, who sit on the full committee, and who also undertake these reviews. In 2023/24, seven applications were reviewed by Tier 2 OOC, five of which were referred to the full committee. These were discussed and subsequently approved with conditions.

In 2022/23 the Full Committee met on the following occasions, with the meetings held remotely using MS Teams.

Full Committee Meeting Wednesday 26<sup>th</sup> April 2023  
Full Committee Meeting Tuesday 13<sup>th</sup> June 2023  
Full Committee Meeting Wednesday 13<sup>th</sup> September 2023  
Full committee meeting Wednesday 15<sup>th</sup> November 2023  
Full Committee Meeting Thursday 25<sup>th</sup> January 2024

Minutes of these meetings are available on the HSC-PBPP website:

<http://www.informationgovernance.scot.nhs.uk/pbpphsc/application-outcomes/>

The HSC-PBPP wishes to acknowledge and express thanks to those who sat on the Tier 2 Committee during 2023/24, who contributed their time and considerable expertise to the scrutiny process and wider strategic work, again in addition to their day jobs. The HSC-PBPP wishes particularly to thank the NHS Boards and other organisations for releasing their senior staff for HSC-PBPP work, as the HSC-PBPP only functions well due to the contribution and generosity of these experienced people.

With both tiers, there is a considerable amount of documentation to consider, analyse and upon which to reach a conclusion where it remarkable that this can be done in such a timely manner given the complexity of the subject matter.

## 7. Performance Metrics for HSC-PBPP applications for 2023/24

### 7.1. Summary Tables of HSC-PBPP metrics for 2023/24

The applications and amendments submitted to HSC-PBPP for the year 2023/24 to 31<sup>st</sup> March 2024 for all applications and amendment requests are summarised in table 1 below.

|  | Number submitted | Number with decisions * | Level of decision | n                           | %         |      |
|--|------------------|-------------------------|-------------------|-----------------------------|-----------|------|
| <b>Applications received for 2023/24 at 31/03/2024</b> | <b>64</b>        | Approved                | 44                | T1 panel meeting            | 27        | 45.0 |
|  |                  | Not approved            | 5                 | T1 review                   | 26        | 43.3 |
|  |                  | Withdrawn               | 3                 | T2 OOC                      | 2         | 2.3  |
|  |                  | In progress             | 12                | T2 full committee           | 5         | 8.3  |
| <b>Carried forward from 2022/23</b>                    | <b>16</b>        | Approved                | 9                 | <b>Total with decisions</b> | <b>60</b> |      |
|  |                  | Not approved            | 2                 | <b>Total withdrawn</b>      | <b>8</b>  |      |
|  |                  | Withdrawn               | 5                 | <b>Carried forward</b>      | <b>12</b> |      |
| <b>Total</b>   | <b>80</b>        | In progress             | 0                 | <b>Total</b>                | <b>80</b> |      |

|   | Number submitted | Number with decisions | Level of decision | n                      | %          |      |
|---|------------------|-----------------------|-------------------|------------------------|------------|------|
| <b>Amendment requests for 2023/24 at 31/03/2024</b> | <b>214</b>       | Approved:             | 214               | eDRIS                  | 99         | 45.8 |
|   |                  | Not approved:         | 2                 | Panel Manager          | 108        | 50.0 |
|   |                  | Withdrawn:            | 7                 | Tier 1                 | 9          | 4.2  |
|   |                  | In progress           | 9                 | Tier 2                 | 0          | 0    |
|   |                  |                       |                   | <b>Total decisions</b> | <b>216</b> |      |
| <b>Carried forward from 2021/22</b>                 | <b>18</b>        |                       |                   |                        |            |      |
| <b>Total</b>  | <b>232</b>       | <b>Total</b>          | <b>232</b>        |                        |            |      |

**Table 1:** Summary of the applications and amendments processed by HSC-PBPP in 2023/24.

The same information from Table 1 is broken down into by application type and for each quarter of the year for applications in Table 2 and for amendment requests in Table 3. The numbers of applications or amendments progressed in each quarter do not add up to the total number of applications as an application may have been progressed over more than one quarter.

| Application Submissions               | Annual    | Q1 | Q2 | Q3 | Q4 |
|---------------------------------------|-----------|----|----|----|----|
| <b>ALL applications</b>               | <b>64</b> | 15 | 24 | 16 | 9  |
| Analysis in NSH                       | 25        | 4  | 11 | 9  | 1  |
| HSC-PBPP Only                         | 20        | 6  | 6  | 4  | 4  |
| Others (eDRIS provides data)          | 19        | 5  | 7  | 3  | 4  |
| <b>Carried over from 2022/23</b>      | <b>16</b> | -  | -  | -  | -  |
| <b>Total applications in progress</b> | <b>80</b> | 31 | 36 | 36 | 25 |

| Application Decisions                | Annual     | Q1 | Q2 | Q3 | Q4  |
|--------------------------------------|------------|----|----|----|-----|
| <b>Approved</b>                      | <b>53</b>  | 12 | 11 | 18 | 12  |
| <b>Not approved</b>                  | <b>7</b>   | 3  | 2  | 2  | 0   |
| Tier 1 decisions                     | 53         | 12 | 12 | 18 | 11  |
| Tier 2 decisions                     | 7          | 3  | 1  | 2  | 1   |
| <b>Withdrawals</b>                   | <b>8</b>   | 4  | 3  | 0  | 1   |
| <b>Ongoing</b>                       | <b>12*</b> | 12 | 20 | 16 | 12* |
| <b>Total applications progressed</b> | <b>80</b>  | 31 | 36 | 36 | 25  |

**Table 2:** Numbers of application submissions and decisions for each quarter of 2023/24

\*These applications will be carried forward to 2024/25

| Amendment Submissions               | Annual     | Q1 | Q2 | Q3 | Q4 |
|-------------------------------------|------------|----|----|----|----|
| <b>New amendment requests</b>       | <b>214</b> | 46 | 66 | 65 | 37 |
| <b>Carried over from 2021/22</b>    | <b>18</b>  | -  | -  | -  | -  |
| <b>Total amendments in progress</b> | <b>232</b> | 64 | 79 | 77 | 55 |

| Amendment Decisions                    | Annual     | Q1 | Q2 | Q3 | Q4 |
|--|------------|----|----|----|----|
| <b>Approved</b>                        | <b>214</b> | 50 | 61 | 58 | 45 |
| <b>Not approved</b>                    | <b>2</b>   | 1  | 0  | 1  | 0  |
| <b>Level of decision</b>               |            |    |    |    |    |
| eDRIS                                  | 99         | 23 | 32 | 28 | 16 |
| Panel Manager                          | 108        | 26 | 27 | 28 | 27 |
| Tier 1 decisions                       | 9          | 2  | 2  | 3  | 2  |
| Tier 2 decisions                       | 0          | 0  | 0  | 0  | 0  |
| <b>Withdrawals</b>                     | <b>7</b>   | 0  | 6  | 0  | 1  |
| <b>Ongoing</b>                         | <b>9*</b>  | 13 | 12 | 18 | 9* |
| <b>Total no. amendments progressed</b> | <b>232</b> | 64 | 79 | 77 | 55 |

**Table 3:** Numbers of amendment request submissions and decisions in each quarter of 2023/24

\* These amendment requests will be carried forward to 2024/25

From the above tables it can be seen that while there is generally an even distribution of submissions of both applications and amendment requests, these do reduce slightly in quarter 4 (January to March).

### Subjects of Applications

Applications for different types of studies were submitted and reviewed, reflecting the variety of research, audit and service assessment that used NHSS data for the benefit of the public. Some of the different types of study are:

- UK-wide audits assessed the outcomes and needs of different conditions or procedures.

- NHSS data were used to investigate the long-term outcomes of a number of Clinical Trials.
- Epidemiological studies investigated the risk of different factors on the patterns of disease incidence or health outcomes.
- Longitudinal studies of specific cohorts used NHSS data to look for patterns in disease onset, processes and responses to interventions.
- Use of NHSS data for NHS service planning and improvement, for assessing the cost-effectiveness of specific interventions, or the interactions of social and environmental factors on specific health outcomes.
- Use of NHSS data for technological advances such as machine learning / artificial intelligence to help develop algorithms for detection of specific conditions.
- Applications for flagging of patients from the NHS Central Register.

Lists of the approved applications for each year with their lay summaries, where available, is available on the HSC-PBPP website:

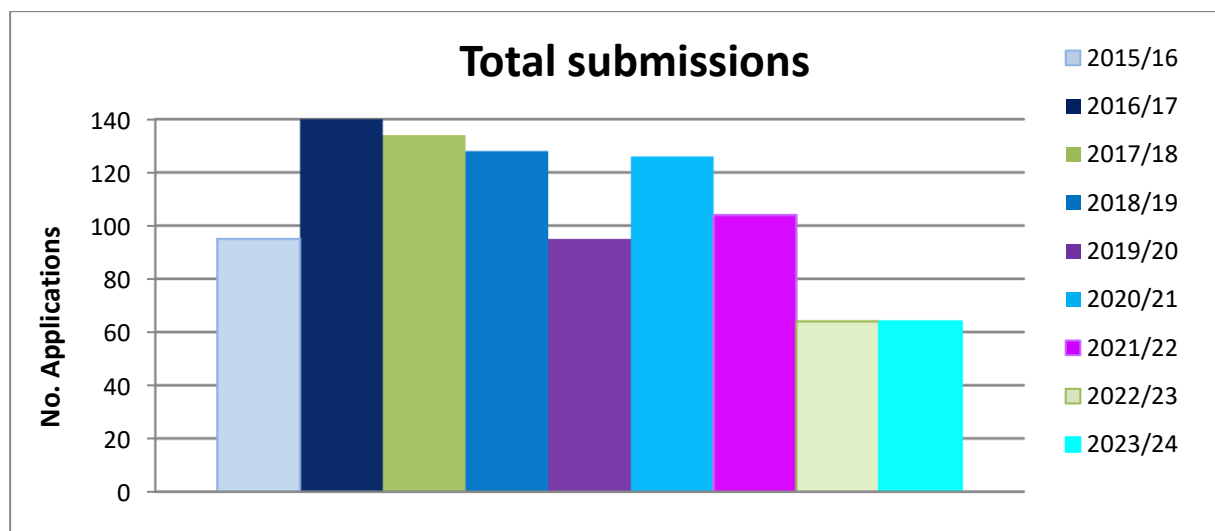
<https://www.informationgovernance.scot.nhs.uk/pbphsc/application-outcomes/>

## 7.2. Comparisons with previous years

Comparisons with previous years indicates the demand for NHSS data and HSC-PBPP scrutiny over time.

### Submissions

During 2023/24, a total of 64 applications were submitted to the HSC-PBPP.



**Figure 2:** Numbers of applications submitted to the HSC-PBPP from 2015/16 to 2023/24.

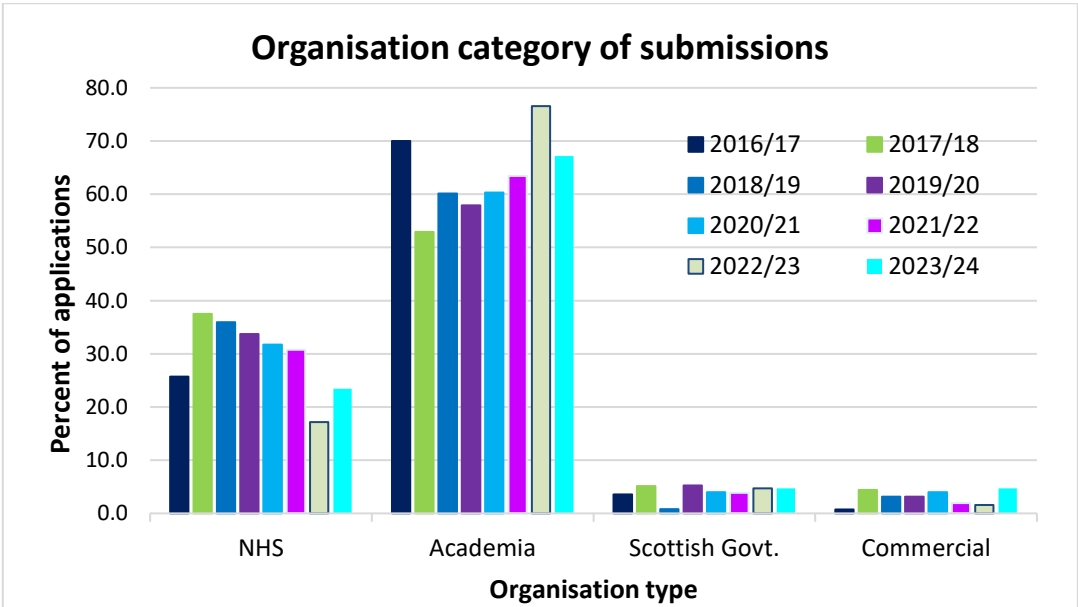
As can be seen from figure 2, the number of submitted applications has fluctuated but has decreased, particularly in 2019/20 and with a further decrease post-pandemic in 2022/23 and 2023/24.

The reasons for this are unclear, but might include the fact that previous new applications for ‘pilot’ studies for new processes that were reviewed and approved by HSC-PBPP, then became ‘business as usual’ and so were not renewed. Another factor may be the more recent emphasis on using the Intra-NHS Scotland Information Sharing Accord across NHSS and therefore applications to HSC-PBPP are no longer necessary for some NHSS projects. With the creation of PHS as a national NHS board with well-defined core functions, some projects that would have previously requested approval from HSC-PBPP are now covered by PHS governance processes. The higher number of submissions in 2020/21 reflects the increased demand for the use of NHSS data as part of the response to COVID-19.

**Sources of applications**

The organisation category and countries from which applications were received are shown in figures 3a and 3b, respectively, for the years 2016/17 to 2022/23.

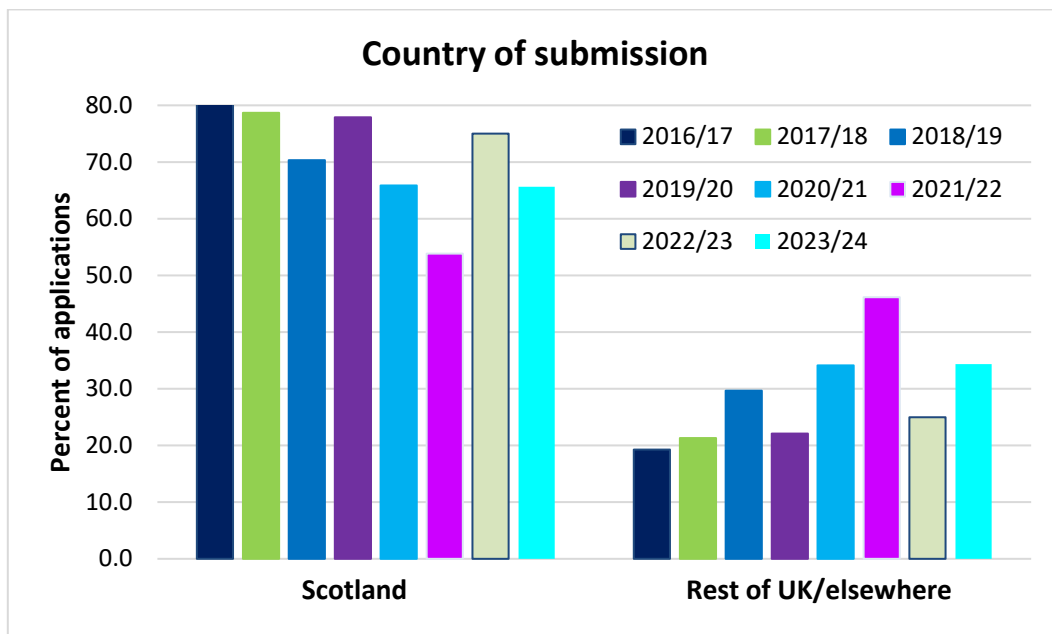
Figure 3a shows that the majority of applications were received from academia and NHS with only a small percentage from commercial companies or Scottish Government. The proportions of submissions between 2016/17 and 2021/22 from NHS and academia has remained fairly constant (~30-40% and 50-60% respectively); the requests from the NHS in 2023/24 were higher than in 2022/23 but the trend is still decreasing, suggesting that the reasons given above may indeed be pertinent. The requests from Scottish Government or commercial companies has remained constant over the years.



**Figure 3a:** Sources of applications to the HSC-PBPP in 2016/17 to 2023/24

Figure 3b shows that the majority of the applications were initiated from within Scotland with the other applications from the rest of the UK. However, the proportion of applications from the rest of the UK is gradually increasing: in 2016/17 80% of applications were from Scotland whereas in 2021/22 this had dropped to 54% of applications. In 2022/23 the proportion of requests from Scotland has increased again up to ~70% while the number of

requests from the elsewhere in UK were lower in 2022/23. In 2023/24, the proportion of requests from Scotland vs. rest of the UK was similar to that in 2020/21.



**Figure 3b:** Sources of applications to the HSC-PBPP from 2016/17 to 2023/24

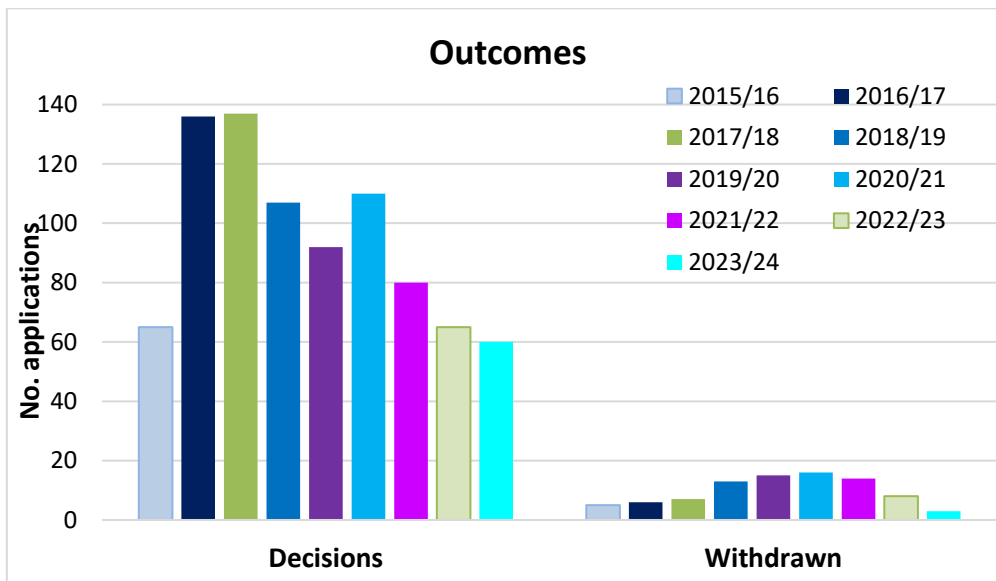
### Requests for data and/or flagging from the NHS Central Register (NHSCR)

The NHS Central Register contains demographic details of everyone born, registered with a GP or died in Scotland. The register exists to allow the smooth transfer of patients who move between health board areas, across borders within the UK or in and out of the Armed Forces. The NHSCR can ‘flag’ patients (for cancer or death) as part of a medical research project, so that researchers can keep track of their progress and be notified if their patients develop cancer or die. In 2023/24, 12 applications (18.8 %) requested information from NHSCR, either as part of a study requiring other NHSS data or as the only data requested. This is a slightly higher percentage than that requested in previous years (range 8.4-16.2).

### Application Outcomes

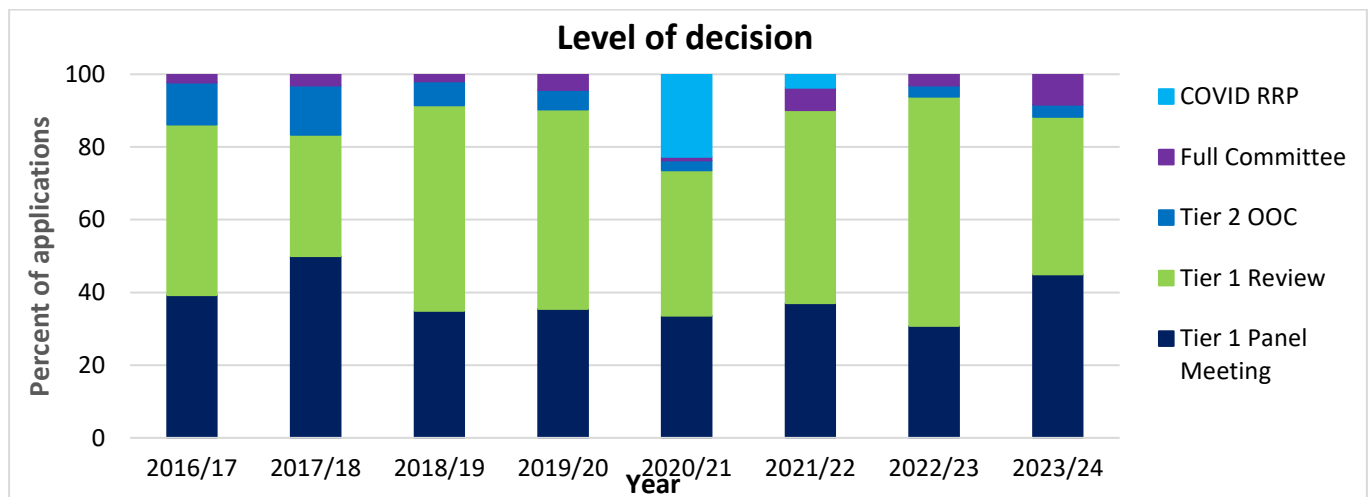
The number of application decisions per year are shown in figure 4, with 60 decisions made in 2023/24. This is lower than previous years, and lowers the mean number of decisions to 98 per year from 2016/17 to 2023/24.

The number of applications that have been withdrawn had gradually increased over the past years. Sometimes withdrawal of an application has been requested by the applicant for various reasons; in addition, applications are withdrawn by HSC-PBPP if there has been no response from the applicant to the clarifications requested by Tier 1 within three months of the date of the Tier 1 panel review. The reasons for the applicants’ failure to respond are unclear. In 2020/21 the number of withdrawn applications peaked at 16 applications, but has fallen again to 3 withdrawn applications in 2023/24. There were 12 still ongoing from 2023/24 so it is still possible that some of these may yet be withdrawn.



**Figure 4:** Number of applications with decisions and withdrawn applications from 2016/17 to 2022/23

The level of HSC-PBPP at which decisions were made are shown in figure 5. As can be seen the majority of applications were approved by Tier 1, either at a panel meeting or after the questions and clarifications from the initial review have been reviewed by Tier 1 panel members. In 2023/24 seven (11.7%) applications were decided at Tier 2, which were the most complex with the highest privacy risks. This is indicative of the amount of work done by Tier 1 as ~90% of applications are approved at that level. The COVID-19 rapid response panel (COVID-19 RRP) was stopped in 2021/22.



**Figure 5:** Level of decisions for applications from 2016/17 to 2023/24

### 7.3. Times to decisions

The HSC-PBPP measures two time-periods for decisions to review its processing times between an application being submitted to the HSC-PBPP and the decision by the panel:

- ‘Clocked’ time: this is the number of working days for which the application is being processed by the HSC-PBPP, from submission to decision. The time taken by the applicant to respond to any queries from the HSC-PBPP regarding the application is not included.
- Total time: this is the total number of working days from submission until the final decision is made, which includes any time the application spent back with the applicant. The difference between the clocked and total times indicates the number of days an application spent with the applicant during the approvals process.

Neither of these measures includes the time that any application spends with an eDRIS coordinator before submission to HSC-PBPP, nor the time taken between HSC-PBPP approval and provision of the data requested.

#### Time to decisions (days) for applications 2023/24

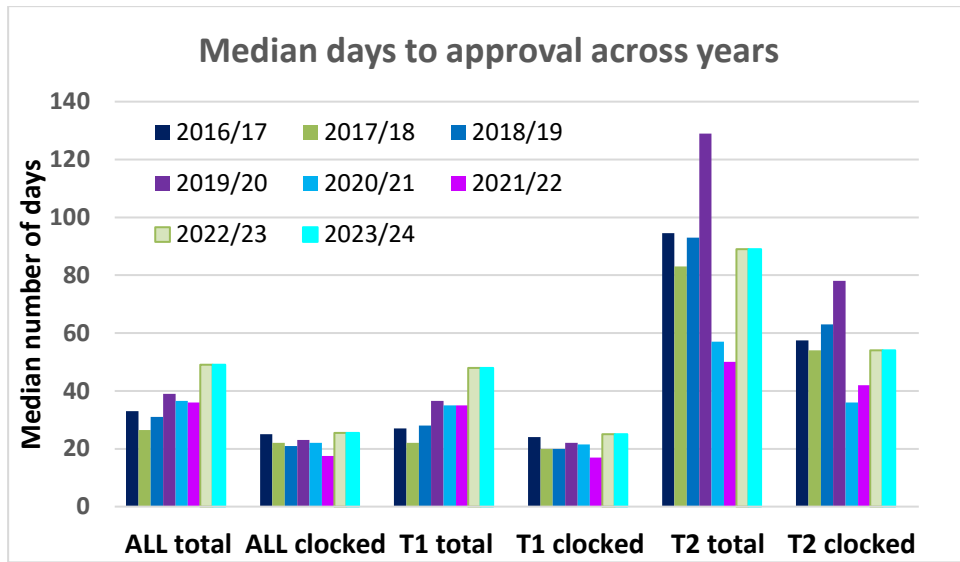
The time taken for decisions to be made by HSC-PBPP to 31<sup>st</sup> March 2024 are summarised in table 4. The times are given for all decisions (ALL) and separately for those decided at Tier 1 and those applications decided at Tier 2. The mean, median and interquartile range (IQR) are given below.

| No. of days                                       |        | ALL   |         | Tier 1 |         | Tier 2 |         |
|---|--------|-------|---------|--------|---------|--------|---------|
|   |        | Total | Clocked | Total  | Clocked | Total  | Clocked |
| <b>ALL applications for 2022/23 to 31/03/2023</b> | N      | 60    | 60      | 53     | 53      | 7      | 7       |
|   | Mean   | 54.6  | 25.1    | 50.3   | 19.9    | 87.4   | 64.6    |
|   | Median | 51.5  | 20      | 46     | 19      | 113    | 75      |
|   | IQR    | 31–75 | 16–26   | 37–72  | 14–23   | 62–113 | 43–86   |

**Table 4:** Time to decision for applications 2022/23

#### Comparison of times to decisions across years

The median times to decisions at the different levels of HSC-PBPP from 2016/17 to 2023/24 are shown in figure 6. The figures for 2020/21 and 2021/22 are for non-COVID-19 applications. The times for all applications shows that these have remained fairly constant over the years. By the nature of their referral to Tier 2, the few applications that are referred to Tier 2 will take longer for a decision. The Tier 2 decision times were at their highest in 2019/20 compared with previous years, but decreased in 2020/21 and 2021/22. The times to decision have increased slightly in 2022/23 and 2023/24: for the clocked times these are similar to the times to approval pre-2020. The most notable increases were seen in the total times, which suggests that applicants are taking longer to respond to clarification requests, but perhaps not so long that the applications are withdrawn.



**Figure 6:** *Median times (days) to decisions at different levels of HSC-PBPP*

## **8. Adverse Event and Lessons Learned**

In July 2023, HSC-PBPP was notified of an adverse event that had taken place in an NHS Board, which was related to an application that had been approved by HSC-PBPP at the full committee.

### **Adverse Event and Immediate Actions**

The event was that an inappropriate contact had caused harm to those contacted. In this scenario, NHS patients were selected at random, based on a particular health event, and contacted by letter to invite them to take part in a research study. The invitation letter was opened by another family member and revealed the health event, that was not known to the wider family. Those involved were extremely upset that this information had been disclosed and potentially raised the possibility that another ongoing process for a further family member may not be able to take place. The description provided is understandably vague in order to avoid a further breach of confidence should the specifics make the family unit identifiable.

The study was stopped immediately and an investigation took place, by those in the NHSS boards where the patients were affected, and who consulted the researchers, the data providers and HSC-PBPP. At the end of the investigation, a letter of apology was sent to the family involved, via the local NHSS boards.

The investigation found that while the processes of sending invitation letters closely followed the approved procedures in the HSC-PBPP application, one scenario had not been envisaged by HSC-PBPP and this was the one that had arisen in this event. This scenario was confounded by some assumptions that were made about the data provided to them by the researchers' team. As with many adverse events, this was multifactorial in nature and without hindsight was not something that could have been readily anticipated.

Processes were put in place immediately for extra data checks to be put in place to ensure that the main reason and assumptions that led to this scenario would not arise again. These were implemented for another two applications that had similar approaches, in that they were directly approaching people based on this health event. Understandably, there has been a degree of caution exhibited although the expectation is that there will be a gradual recalibration as part of the learning process.

### **Lessons Learned**

A Lessons Learned exercise was carried out and a separate report and recommendations were provided to the HSC-PBPP Committee. The committee agreed the report and the recommendations. The recommendations were put into an Action Plan by the Operations Group for implementation during 2024/25. While some of these related to the event itself, some of them also related to the wider landscape of HSC-PBPP, particularly relating to risk appetites within NHS Scotland Boards and communication between HSC-PBPP and the NHS boards and especially as applications for NHSS data are becoming more complex. These discussions will be taken forward by the HSC-PBPP Operations Group.

As this event could have taken place at any NHSS board, the NHSS Data Protection Officer Forum and the Caldicott Guardian Forum were informed by the HSC-PBPP manager about the event and immediate actions, which gave the opportunity for wider discussion and thoughts about ways to prevent it from recurring. Careful consideration has been given on how best to publicise this event so that learning is disseminated as widely as possible without compounding any breach of confidentiality.

## 9. Quality Improvement and Development

The HSC-PBPP has a duty to be accountable to the public and stakeholders and strives to continually improve its processes, so that applications are processed as efficiently and quickly as possible, whilst maintaining standards of governance. In addition to regular monitoring of processing times for applications, the HSC-PBPP also takes on board feedback and lessons learned from novel and complex applications; these are usually those that were reviewed by the Tier 2 full committee, especially if a precedent was set. Such information is recorded in a Policy Decisions and Case Law Principles document to enable consistent decision making.

### Tier 1 audit

An audit of the applications approved in 2022/23 did not take place in 2023/24. This is partly because of the timing and assessment of the adverse event that took place. The adverse event has highlighted other aspects of HSC-PBPP, such as communication and risk-appetite between HSC-PBPP and the NHSS boards, which began to be addressed in 2023/24, continuing into 2024/25.

### 9.1. Ongoing development work

#### Development Slots

A Tier 2 'Development Slot' was inserted into the HSC-PBPP Committee meetings as a regular item to give an opportunity to discuss e.g. potential new developments in technology, which may affect different types of applications and how these may be reviewed. This was initially because the Development workshops had stopped during COVID and its recovery, but this has been found to be useful in its own right. In 2023/24 particular subjects for this item were researcher access to GP data and updates from Research Data Scotland.

To inform the IG leads that sit on Tier 1 panels of new developments, the HSC-PBPP manager has given regular updates at the monthly IG Forum or quarterly Data Protection Officer (DPO) Forum. These have been based on applications that had been reviewed by the panel and the challenges, implications and new ideas, or changes in procedure that had arisen from the review of these applications, or presentations relating to the Development Slots discussed by the HSC-PBPP Committee. Not all IG leads that attend the IG Forum sit on HSC-PBPP panels and this has helped to widen the discussions with the NHSS boards.

#### Guidance Papers

From a previous application that was reviewed at the Tier 2 Committee and a subsequent development session in 2022/23, a Guidance paper has been written about the Scope, Definitions and Approval routes for different types of applications that are regularly seen by HSC-PBPP. These include: Audit; Research and Research Databases; Surveillance; Service Evaluation; Registries. This is available on the HSC-PBPP website:

<https://www.informationgovernance.scot.nhs.uk/pbpphsc/application-outcomes/>

## **9.2. Research Data Scotland (RDS)**

RDS is a Scottish Government initiative, which aims to bring public sector data together, including health data as well as data from other parts of the public sector, specifically for use in research and for the benefit of the public. Further details can be found on their website: <https://www.researchdata.scot/>.

During 2023/24, various members of HSC-PBPP had many discussions with RDS about the proposed mechanisms of their new processes. RDS will provide data to researchers, which it states will be effectively anonymised, through the use of the National Safe Haven (NSH), and therefore no longer be considered to be personal data. This makes the approval and governance process much simpler, but adds restrictions on how the data can be used. During 2023/24, PHS agreed to share the nine most commonly used health datasets with RDS for their Researcher Access Service (RAS), within specific parameters and for the most straight-forward data linkage projects. Using the RAS pathway, researchers will obtain access to data from these nine datasets within the NSH. This access will be approved by the RAS panel, which is separate from HSC-PBPP. The launch of the RAS pathway took place in April 2024.

## **9.3. Access to data from GP practices**

A number of preliminary discussions about access to data from GP practices for researchers have been ongoing, particularly about the required governance process relating to access to these data. A separate GP Editorial Board has been proposed, that will consist of GP representatives to review the use of patient health data from GP practices for all types of uses, including research. As some of these applications will also request data from the NHSS boards and will require HSC-PBPP scrutiny and approval, discussions are ongoing and will continue into 2024/25 as to how any new process will align with the HSC-PBPP approval processes. The appointment of a GP Editorial Board Manager will aid in these discussions. There is also a plan to have HSC-PBPP representation on this board to promote reciprocal learning.

## 10. Annual HSC-PBPP Development Workshop 2023/24

In March 2024, a joint development day was held for Tier 1 and Tier 2 HSC-PBPP members and eDRIS at COSLA, in Edinburgh. This was the first HSC-PBPP development day since 2019 and the first that took place as a hybrid meeting. Around 50 participants attended in person and approximately 30 attended online. The aim was to strengthen working relationships and to improve review strategies that are applicable through all stages of an HSC-PBPP application as it goes through the scrutiny and approval process. It was also an opportunity to discuss issues that arise during the application reviews and try to find appropriate and pragmatic ways to address some of these challenges.

There were four sessions during the day:

- **Session 1** outlined the 'journey of an application' showing the different people involved in each stage from the first enquiry at eDRIS to approval by HSC-PBPP at either Tier 1 or Tier 2. It was interesting and helpful to all present to hear how the people involved evaluate an application at its different stages.
- **Session 2** was a round-table discussion of challenging scenarios from several different HSC-PBPP applications over the past year or two. Such scenarios which break the Common Law Duty of Confidentiality, have been requested by researchers. These were discussed in terms of what privacy risks do they represent and how do we help applicants to assess these risks and mitigate them? The scenarios were: (i) Deferred consent for research; (ii) Direct and unsolicited contact with patients for research; (iii) Opting-out (assumed consent) in research and (iv) Unsolicited home visits of patients for research. The feedback from these discussions will be added to some of the discussions and recommendations from the Lessons Learned for the Adverse event and become guidance papers for researchers.
- **Session 3** was a panel discussion of artificial intelligence / machine learning (AI / ML) and how these types of applications should be completed and reviewed. As these studies are highly complex with large amounts of data requested, three researchers from the University of Edinburgh (Professor William Whiteley, Professor Bill Nailon, Professor Miguel Bernabeu) and Alister Pearson (Principal Policy Technology Advisor at the ICO) were invited to present different aspects of AI/ML and the review of these studies. A discussion took place of what is the best ways to present and review the issues raised by these applications. It was agreed that over the next year, HSC-PBPP would try to continue these discussions, with the aim to increase mutual understanding and produce some specific guidance for both applicants and reviewers.
- **Session 4** was a plenary by Professor William Stewart, from University of Glasgow, who spoke about the FIELD-LONG study: a study of footballers and head injury and how data linkage was used to identify and address the phenomenon of head injury in football and long-term risk of dementia.

It was wonderful to see so many people attending and HSC-PBPP is grateful that so many gave up their time to attend and contribute to some very helpful discussions. The HSC-PBPP were extremely grateful for the contribution of the NSS Events Team, who helped particularly with the hybrid element. It is hoped that these workshops will now resume on an approximately annual basis.

## **11. Achievements and Priorities**

### **11.1. Achievements for 2023/24**

The previous training offered through the Wellcome Trust Clinical Research Facility was trialled online using Zoom, through the University of Edinburgh. One of the strengths of this course was the in-person interactions and discussion with participants. This was successfully repeated on Zoom in 2023/24 with more scheduled time for discussion and interactive exercises. The feedback from the participants who attended this course has given high scores for content and delivery.

### **11.2. Priorities and Challenges for 2024/25**

In a constantly changing data landscape with new demands and new technologies, there is always more things to develop. It is hoped that a number of tasks will be addressed in 2024/25:

- i. Continued discussions with RDS.
- ii. Continued discussions with GP Editorial Board management about processes to allow researchers access to data from GP practices.
- iii. Guidance papers from the Lessons Learned for the Adverse Event, particularly for applications that break the Common Law Duty of Confidentiality.
- iv. Conversations try to help develop guidance for applications that use or wish to develop models for AI / ML.

## **12. Conclusion**

From this report it can be seen that 2023/24 has built on and further developed some of the practices that were started in 2022/23. These processes will continue to be refined as the HSC-PBPP continues to operate to ensure the safe use of NHSS data for the benefit of the public in Scotland. This report reflects the volume and excellent quality of service and advice that was provided during what was a challenging period for the NHS.