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

Annual Report
2022/23

Contents Page

1. Abbreviations and Glossary

AI Artificial Intelligence is computer software that mimics the ways that humans think in order to perform complex tasks, such as analysing, reasoning, and learning.

CG Caldicott Guardian**:** A senior person within an NHS board responsible for protecting the confidentiality of patients' health and care information.

CHI Community Health Index number is the NHS number used as a patient identifier across NHSS.

CHIMB 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.

Disclosure control Statistical disclosure control is a technique used for outcomes from data analysis to ensure that no person is directly or indirectly identifiable.

eDRIS 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.

IEG Independent Expert Group: a Scottish Government initiative used to examine a subject from different viewpoints.

IG Lead Person in an NHS board responsible for Information Governance in that board, under the Caldicott Guardian.

IG Information Governance.

GDPR / UK-GDPR General Data Protection Regulations, introduced into UK law with the Data Protection Act 2018, and updated as UK-GDPR when the UK left the EU.

HDRUK Health Data Research UK: the national institute for health data science, whose mission is to unite the UK's health data to enable discoveries that improve people's lives.

HSC-PBPP Public Benefit and Privacy Panel for Health and Social Care.

HSC-PBPP Only 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.

ML Machine Learning is a subset of AI that uses algorithms trained on data to produce models that can perform such complex tasks.

NES NHS Education for Scotland, a special (national) NHS board and a data asset holder.

NHSCR 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.
https://www.nrscotland.gov.uk/statistics-and-data/nhs-central-register

NHSS NHSScotland.

NRS National Records of Scotland, a data asset holder.

NSS NHS National Services Scotland (the common name for the Common Services Agency for the Scottish health service) and data asset holder.

NSS DaS NSS Digital and Security who provide IT services for PHS.

NSH	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.
PHS	Public Health Scotland, a special (national) NHS Board and data asset holder, established in April 2020. The HSC-PBPP management team sits within PHS, as part of the PHS Data Protection Team and feed into some of its governance processes.
RDS	Research Data Scotland, a Scottish Government initiative, formally established in 2021, and set up to bring together public sector data for use for research.
SG	Scottish Government.
Tier 1	Operational level at which all applications to HSC-PBPP undergo their first review.
Tier 2	Higher / strategic level of HSC-PBPP, which has oversight of HSC-PBPP, and at which higher risk applications are reviewed.
Tier 2 OOC	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 2022 to March 2023.

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). 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. Applications for both COVID-19 and non-COVID-19 applications continued, although COVID-19 applications were no longer prioritised as the number submitted to HSC-PBPP decreased. COVID-19-related activity continued within the NHSS Boards, which had a direct effect on the availability of IG leads to be involved in HSC-PBPP reviews. 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 2022/23 was 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%) and the NHS (17%), but the proportion of NHS applications was remarkably lower; 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, but in 2022/23 the gradual increase in the proportion of applications from the rest of the UK reversed.

Quality improvement is still important for HSC-PBPP. The annual audit of Tier 1-approved applications was carried out for 2021/22 and showed that applications are still being appropriately approved by Tier 1. From the audit the proportionate governance criteria used by the Tier 1 panels were updated. A communications plan was put in place, which reflected and documented much of the information dissemination that was already in place.

Development work

HSC-PBPP endeavours to keep abreast of current and future developments. In light of this, the feasibility of moving to an online application system and form was investigated and discussed with members of the NHS National Services Scotland (NSS) Digital and Security (DaS) team , the IT providers to Public Health Scotland (PHS, where the HSC-PBPP management sits). Initially good progress was made in identifying the requirements and solution but unfortunately it could not be taken forward to implementation due to lack of resources.

A SG Independent Expert Group (IEG), called Unlocking the Value of Data, was set up to examine the use of public sector data by the private or commercial sector from different viewpoints. HSC-PBPP contributed some input to these discussions through the IEG Chair.

Artificial Intelligence (AI) / Machine Learning (ML) are particular topics that require the use of personal data. Discussions about how applications for these are handled and processes for assessing the use of data for this methodology are ongoing.

Future developments in 2023/24

Looking forward to 2023/24, 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.

Preliminary discussions regarding access to GP data are ongoing. It is hoped in 2023/24 a process aligned with HSC-PBPP will be developed, to make these data available to researchers, subject to resources and agreements with the GPs.

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

3. Chair's introduction

This report covers the work undertaken by HSC-PBPP during 2022/23. The COVID-19 pandemic has dominated much of our lives in the last 3 years, HSC-PBPP included. The outcomes achieved during this past year is a testament to the hard work of all those involved, sometimes in difficult circumstances.

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. This became even more apparent at the height of the COVID-19 pandemic and since, when further evaluation and recovery plans are being put in place. 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 challenges for panel members and reflecting societal and technological changes. Further down the line the use of artificial intelligence (AI) will bring new challenges for review of applications and governance for the use of data.

The use of Public Sector data, and in particular NHSS health data, by the commercial sector has been a subject of much discussion in different spheres. The Scottish Government Independent Expert Panel looking at 'Unlocking the Value of Data' (UVOD), has been looking at this issue, into which HSC-PBPP gave some input. This panel has started the wider conversation on a highly complex and controversial area.

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 2023, in total, the HSC-PBPP has made decisions for over 750 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, with the addition of two new Caldicott Guardians and a new public representative. The new committee members have brought new perspectives and ideas to the reviews of applications and policies. The recruitment of new lay members has been more challenging than anticipated and we continue to search for one or two further lay members.

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. 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 Lorna Ramsay
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

HSC-PBPP is an IG structure of NHSS that exercises delegated decision-making on behalf of NHSS Chief Executive Officers 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 in this area 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 NHS 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 2 weeks. Facilitated by the Panel Manager, each panel comprises of specialist IG practitioners from across the NHSS Boards. 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 any one meeting. If the Tier 1 panel were satisfied that the public benefit of the proposal is clear and that all privacy risks will be managed appropriately and securely, the application is approved. There may be an exchange of questions seeking clarification or reassurance before the approval or another outcome is 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).
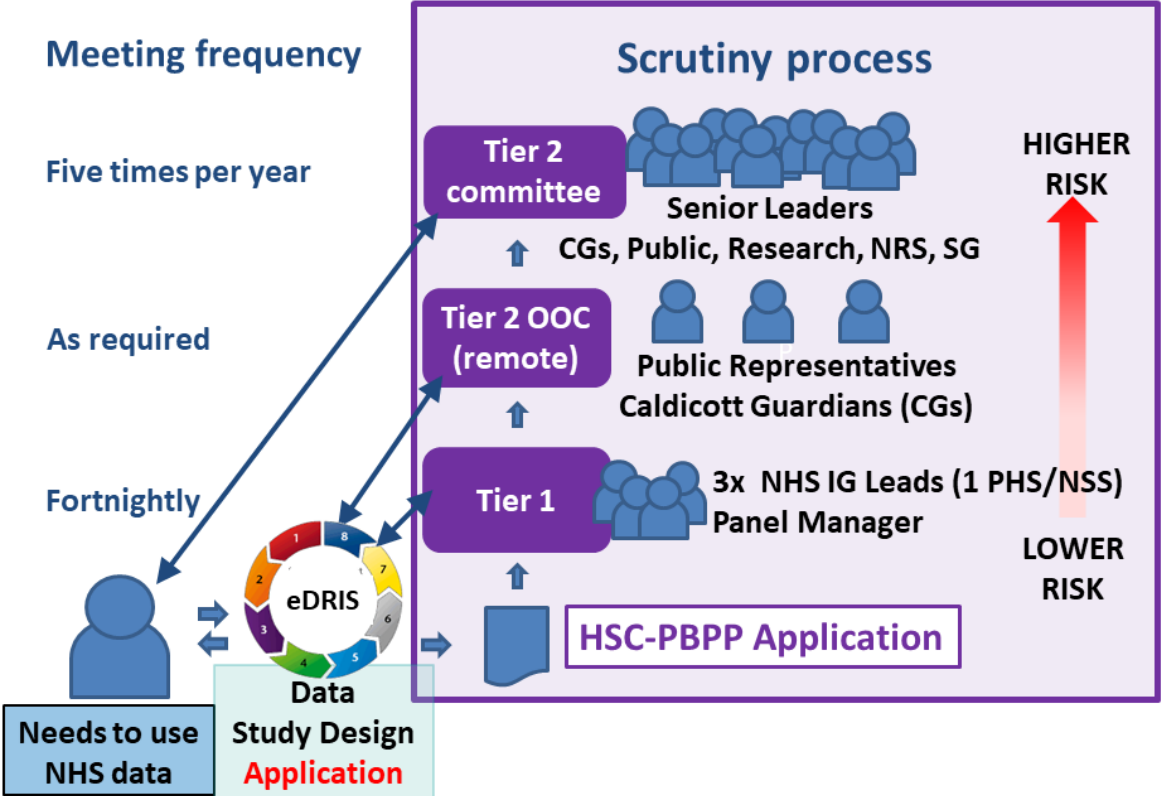
Figure 1   **Flow-diagram of the HSC-PBPP scrutiny process**

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

Tier 2

Tier 2 comprises a regularly convened strategic Full Committee, and a smaller subgroup of committee members working 'Out of Committee'. The latter comprises of the Caldicott

Guardians (CGs) and public representatives from the Full Committee. 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 2022/23

Dr Lorna Ramsay (Interim Chair)
Dr Tara Shivaji (PHS Caldicott Guardian representative)
Dr George Fernie (NHSS Caldicott Guardian)
Dr Mark McGregor (NHSS Caldicott Guardian)
Dr Arun Chopra (NHSS Caldicott Guardian, from January 2023)
Dr Pamela Johnston, (NHSS Caldicott Guardian, from January 2023)
Kenneth McLean (Public Representative)
Martin Walsh (Public Representative)
Chioma Dibia (Public Representative, from January 2023)
Prof Alison McCallum (Research Representative)
Prof Colin McCowan (Research Representative)
Martin Bell (CHIMB and NSS Representative)
Dr David Felix (NES Representative)
Alan Ferrier (NRS Representative)
Penni Rocks (Scottish Government representative)

Committee membership vacancies and changes

During the year 2022/23, the following changes occurred:

- The vacant Caldicott Guardian role was filled from January 2023, with two new Caldicott Guardians. This was because one of the current Caldicott Guardians would finish their term within 6 months and this would give an appropriate overlap.
- The full complement of public representatives was thought to be in place at the end of 2021/22. Unfortunately, one public representative resigned at the end of 2021/22 and another potential new recruit was unable to join the Committee, leaving two vacancies. One position was filled from January 2023, but the other remained unfilled throughout 2022/23.
- The Social Care representative role on the committee remained unfilled during 2022/23.

A recruitment process was carried out for two public representatives during 2022/23, using various routes. One new public representative was appointed during 2022/23 and another was recruited in time to start in 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 2022/23 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. Since the emergency measures for COVID-19 had been eased, the IG teams within each of NHS boards underwent audits with the Information Commissioner's Office (ICO) which meant some IG leads had reduced availability at particular times during the year. In 2022/23 IG Leads from 16 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 2022/23 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 particularly to thank 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

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 2022/23 four (non-COVID-19) applications were reviewed by Tier 2 OOC, two of which were referred to the full committee. These were discussed and subsequently approved with conditions.

Tier 2 Full Committee

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

Full Committee Meeting Tuesday 12th April 2022
Full Committee Meeting Wednesday 29th June 2022
Full Committee Meeting Wednesday 28th September 2022
Full committee meeting Tuesday 29th November 2022
Full Committee Meeting Thursday 26th January 2023

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 2022/23, who contributed their time and considerable expertise to the scrutiny process and wider strategic work, 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 generosity of these highly qualified people.

7. Changes in HSC-PBPP processes

7.1.   Previous changes in processes due to COVID-19

Changes to the HSC-PBPP processes in response to COVID-19 were implemented in March 2020, including a reduced application form, and are explained more fully in the HSC-PBPP Annual Report for 2020/21 (available on the HSC-PBPP website). By 2022/23 these processes had been stopped and all applications were reviewed through the normal pathways.

As COVID-19 applications have reached their expiry dates, those that wish to be extended have been asked to give a full justification of the need for the continued use of the data and also have been asked to be transferred to the full application form.

7.2.   Change in pre-submission support for "HSC-PBPP Only" applications

HSC-PBPP has the delegated authority to review applications for the use of NHSS data across the NHSS Boards. For many of these applications, this includes the national datasets held within PHS and NSS and with analysis carried out in the National Safe Haven (NSH). The NSH is a secure environment where data for different projects is uploaded by eDRIS for access by researchers. It offers a high-powered secure computing service, secure analytic environment and secure file transfer. Outcomes from the analysis undergo statistical disclosure control by eDRIS before being released.

Some applications request data that will be obtained directly from NHS Boards and will not require eDRIS to extract and provide data nor will they use the NSH for analysis. These are known as 'HSC-PBPP Only' applications, (and includes those applications which only request NHSCR data). Many of the HSC-PBPP Only applications are more complicated in nature than those that are supported by eDRIS, due to the different uses and data flows of NHSS data; these often require more IG input than applications that would use the national datasets within the NSH.

In June 2021, due to the increased demand on eDRIS due to ongoing COVID-19 work, eDRIS recognised that they did not have capacity to support HSC-PBPP Only applications. A temporary measure was put in place by HSC-PBPP, whereby the panel manager and depute panel manager reviewed the application for 'completeness' before sending to the Tier 1. If there was sufficient information, the application was sent to Tier 1 for review. If further information was required, this was requested from the applicant and once received, the application was sent to the next available Tier 1 panel. From April 2022, a member of the PHS Data Protection team was seconded to eDRIS to support these applications.

During 2022/23, 64 applications received of which 21 (33%) were classed as HSC-PBPP Only. The effect of these changes in procedure on performance outcomes compared with the previous processes used are shown as part of the performance metrics below.

8. Performance Metrics for HSC-PBPP applications for 2022/23

8.1. Summary Tables of HSC-PBPP metrics for 2022/23

The applications and amendments submitted to HSC-PBPP for the year 2022/23 to 31st March 2023 for all applications and amendment requests are summarised in table 1 below.

	Number submitted	Number with decisions *		Level of decision	n	%
Applications received for 2022/23 at 31/03/2023	64	Approved	42	T1 panel meeting	20	31
		Not approved	3	T1 review	41	63
		Withdrawn	3	T2 OOC	2	3
		In progress	16	T2 full committee	2	3
Carried forward from 2021/22	23	Approved	20	**Total with decisions**		**65**
		Withdrawn	3	**Total withdrawn**		**6**
		In progress	0	**Carried forward to 2023/24**		**16**
Total	87	Total	87			87

	Number submitted	Number with decisions		Level of decision	n	%
Amendment requests for 2022/23 at 31/03/2023	258	Approved:	244	eDRIS	138	56
		Not approved:	2	Panel Manager	98	40
		Withdrawn:	9	Tier 1	10	4
		In progress	18	Tier 2	0	0
Carried forward from 2021/22	15			**Total decisions**	246	
Total	273	Total	273			

Table 1: *Summary of the applications and amendments processed by HSC-PBPP in 2022/23.*

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
ALL applications	**64**	22	12	15	15
Analysis in NSH	30	10	6	7	7
HSC-PBPP Onlys	21	6	3	5	7
Others (eDRIS provides data)	13	6	3	3	1
Carried over from 2021/22	**23**	-	-	-	-
Total applications in progress	**87**	45	35	32	31

Application Decisions	Annual	Q1	Q2	Q3	Q4
Approved	**62**	20	18	13	11
Not approved	3	0	0	2	1
Tier 1 decisions	61	19	17	13	12
Tier 2 decisions	4	1	1	2	0
Withdrawals	6	2	0	1	3
Ongoing	16*	23	17	16	16*
Total applications progressed	**87**	45	35	32	31

Table 2: *Numbers of application submissions and decisions for each quarter of 2022/23*
*These applications will be carried forward to 2023/24

Amendment Submissions	Annual	Q1	Q2	Q3	Q4
New amendment requests	**258**	65	76	59	58
Carried over from 2021/22	**15**	-	-	-	-
Total amendments in progress	**273**	80	87	77	74

Amendment Decisions	Annual	Q1	Q2	Q3	Q4
Approved	**244**	65	69	60	50
Not approved	2	1	1	0	0
Level of decision					
eDRIS	138	41	39	31	27
Panel Manager	98	23	26	26	23
Tier 1 decisions	10	2	5	3	0
Tier 2 decisions	0	0	0	0	0
Withdrawals	9	2	0	1	6
Ongoing	18*	12	18	16	18*
Total no. amendments progressed	**273**	**80**	**88**	**77**	**74**

Table 3: *Numbers of amendment request submissions and decisions in each quarter of 2022/23*

* These amendment requests will be carried forward to 2023/24

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 and the development of mobile phone apps to monitor patient care.
- Applications relating to the COVID-19 pandemic and the effects of the response to it.
- 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/pbpphsc/application-outcomes/

8.2. Comparisons with previous years

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

Submissions
During 2022/23, a total of 64 applications were submitted to the HSC-PBPP, which were mostly non-COVID-19 applications.
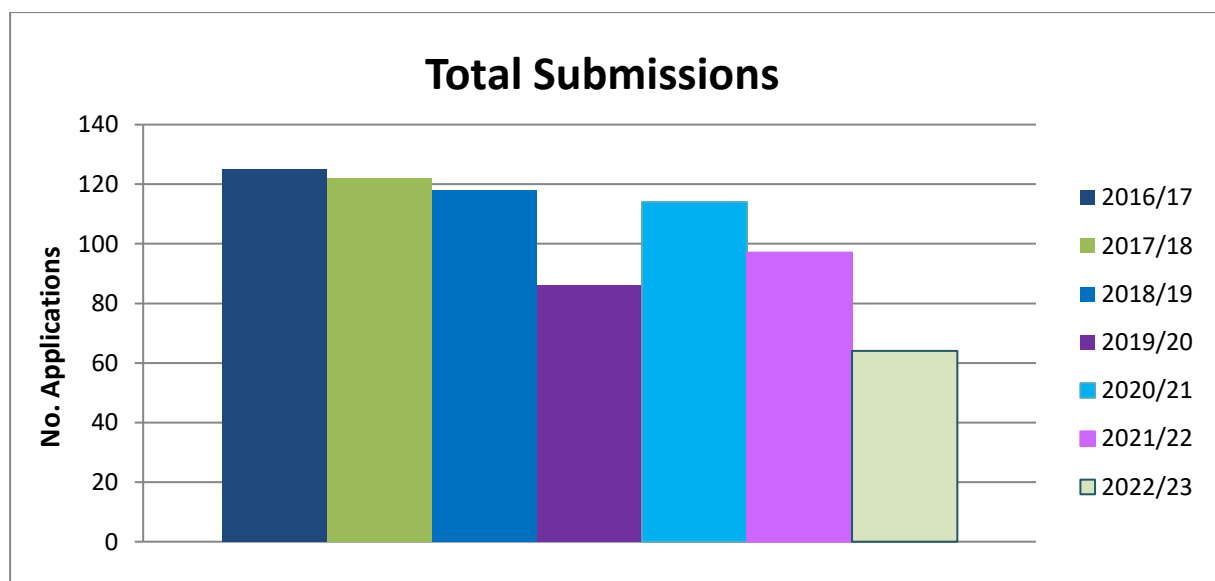

Figure 2: *Numbers of applications submitted to the HSC-PBPP in the seven years from 2016/17 to 2022/23.*

As can be seen from figure 2, the number of submitted applications has fluctuated but is decreasing particularly in 2019/20, 2021/22 and now a further decrease in 2022/23. 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 required 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), but the decrease in requests from the NHS in 2022/23 and increased proportion of academic requests suggest that the reasons given above may indeed be pertinent.
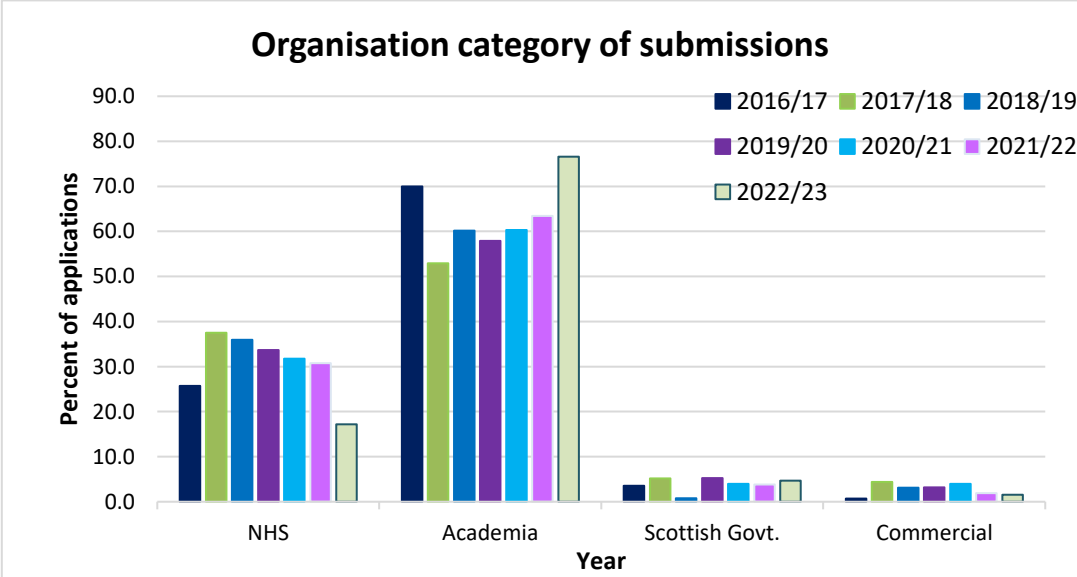

Figure 3a: *Sources of applications to the HSC-PBPP in 2016/17 to 2022/23*

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 by ~20% back up to ~70% while the number of requests from the elsewhere in UK were noticeably lower in 2022/23.
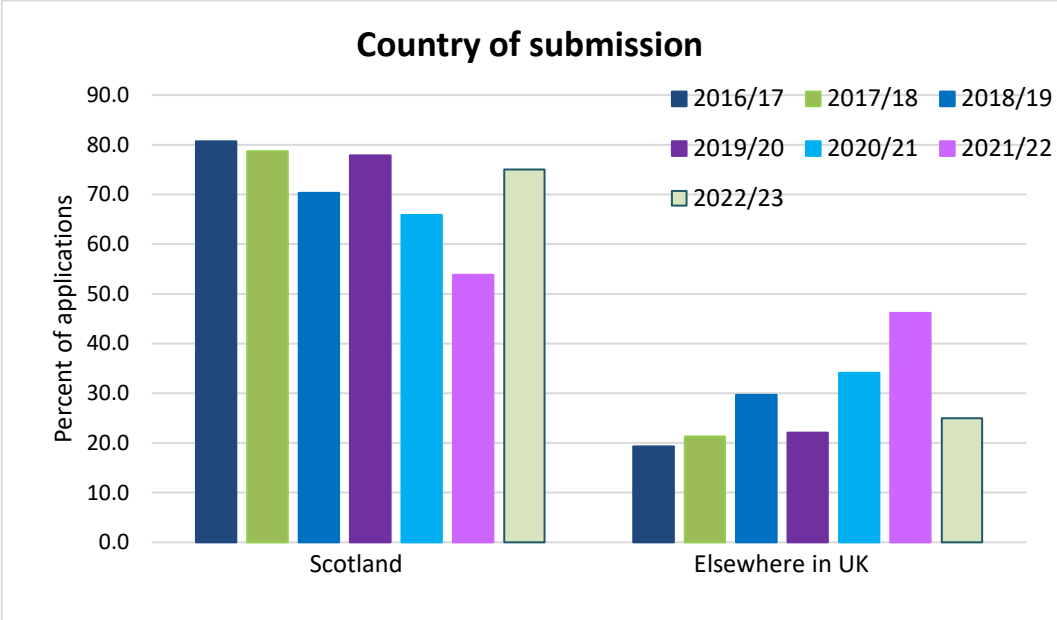

Figure 3b: *Sources of applications to the HSC-PBPP from 2016/17 to 2022/23*

Application Outcomes

The number of application decisions per year are shown in figure 4, with 65 decisions made in 2022/23. This is lower than previous years, and lowers the mean number of decisions to 102 per year from 2016/17 to 2022/23.
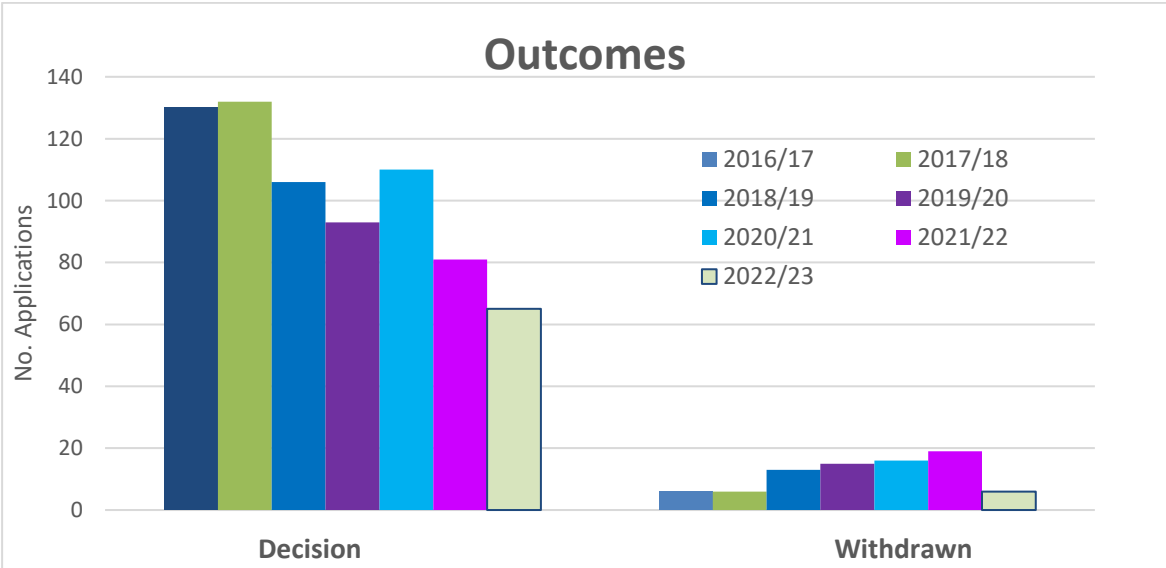

Figure 4:   *Number of applications with decisions and withdrawn applications from 2016/17 to 2022/23*

The number of applications that have been withdrawn has 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 2021/22 the number of withdrawn applications peaked at 19 applications, as this fell again to 6 withdrawn applications in 2022/23.

The level of HSC-PBPP at which these decisions were made are shown in figure 5. The COVID-19 rapid response panel (COVID-19 RRP) was stopped in 2021/22.

As can be seen the majority of applications were approved by Tier 1, either at a panel meeting or after the questions from the initial review and clarifications have been reviewed by Tier 1 panel members. Only 4 (6%) applications were decided at Tier 2 in 2022/23 and which were the most complex and highest privacy risk. This is indicative of the amount of work done by Tier 1 as 94% of the applications are approved at that level.
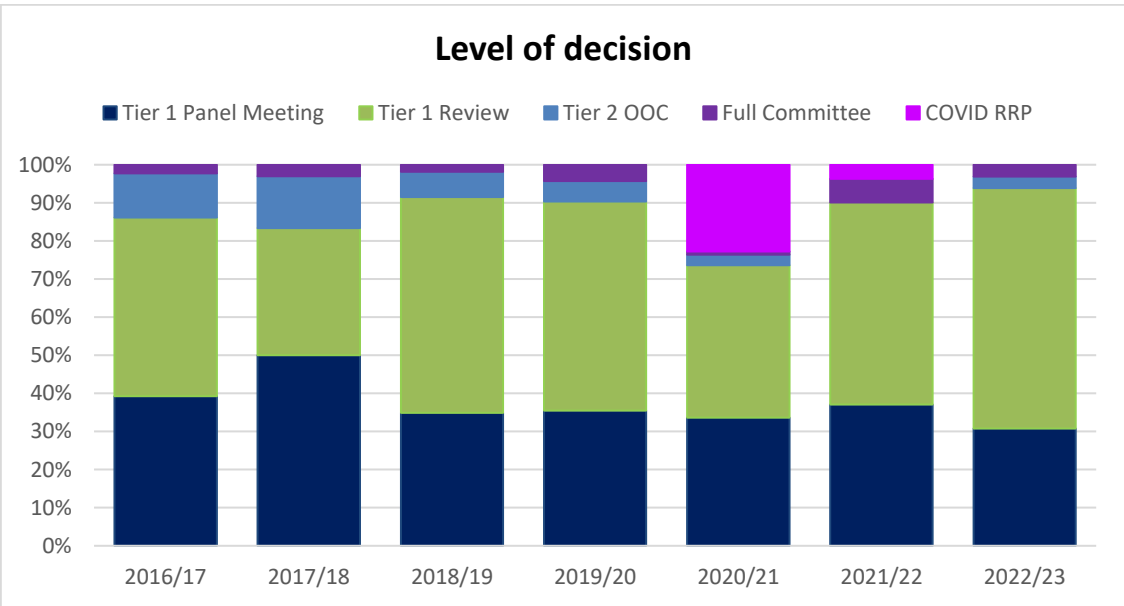

Figure 5:   *Level of decisions for applications from 2016/17 to 2022/23*

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 2022/23, 8 applications (12.5 %) requested flagging by NHSCR,

either as part of a study requiring other NHS data or as the only data requested. This is similar to that requested in previous years.

8.3. 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 <u>not</u> 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 2022/23

The time taken for decisions to be made by HSC-PBPP to 31st March 2023 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
ALL applications for 2022/23 to 31/03/2023	N	65	65	61	61	4	4
	Mean	62.1	27.9	60.3	26.5	90.3	49.0
	Median	54	26	53	26	89	54
	IQR	37–81	19–35	37–81	17–33	52–127	35–68

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

Effect of changes in HSC-PBPP Only process on approval times.

In June 2021 The time to approval for applications approved after June 2021 was analysed according to whether they were HSC-PBPP Only applications or those supported by eDRIS. HSC-PBPP Only applications took slightly longer to be approved, compared with those that were supported by eDRIS (table 5), with an increase in 4-6 days in total time and clocked time. However, as noted, this difference could also be due to the fact that these applications tend to be more complex and require more clarification and discussion, rather than the loss of support from eDRIS. From the applications received and approved in

2022/23, the provision of a designated support for the HSC-PBPP only applications has reduced the time to approval, as compared with eDRIS-supported applications.

(a) June 2021 - March 2022	ALL		HSC-PBPP Only*		eDRIS supported	
	Total	**Clocked**	**Total**	**Clocked**	**Total**	**Clocked**
N	67	67	26	26	41	41
Mean	50.7	24.1	53.7	26.1	48.8	22.9
Median	40	20	44	24.5	38	18

(b) 2022/23	ALL		HSC-PBPP Only*		eDRIS supported	
	Total	**Clocked**	**Total**	**Clocked**	**Total**	**Clocked**
N	45	45	15	15	30	30
Mean	50.6	24.0	44.1	23.1	53.9	24.4
Median	43	24	36	23	46	25

Table 5: *Time to approval for HSC-PBPP Only applications compared with eDRIS-supported applications (a) after the changes in June 2021–March 2022 and (b) after the seconded support provided in 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 2022/23 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 in 2022/23: for the clocked times these are similar to the times to approval pre-COVID-19. 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.
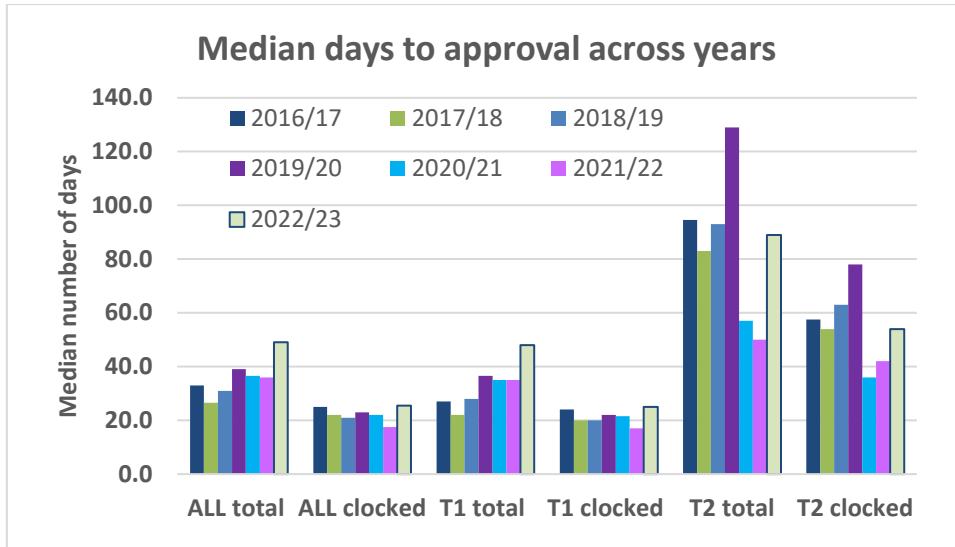
Figure 6: *Median times (days) to decisions at different levels of HSC-PBPP*

9.   Continuing Quality Improvement

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 of 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.

9.1.   Tier 1 audit

During 2022/23 the audit of Tier 1 approved applications for 2021/22 took place. This was the first since the measures for COVID-19 applications had stopped, and was the first audit for many of the Committee members. The HSC-PBPP Committee members reviewed a total of 10 applications approved at Tier 1 between April 2021 and March 2022, selected at random by the HSC-PBPP Manager, so that each application was reviewed by three committee members. After the reviews were returned from Committee members, the HSC-PBPP Manager identified applications where an application raised a point of discussion or discrepancy between the Tier 1 decision and the auditors' reviews.

From the 10 selected applications, six were considered to be appropriately approved by Tier 1. For three applications, only one of the three auditors thought it should have been referred to Tier 2; while another application raised a point for discussion. From this audit, the proportionate governance questions, used by Tier 1 to review applications, were updated with the recommendations from the Tier 2 Committee members. The recommended changes were for questions related to: public benefit; use of data to achieve the purpose of the application; requirement for lay input; the use of mobile IT devices and the use of fax or postal services for transferring personal data. These changes aim to strengthen the application review processes.

The Tier 2 audit of Tier 1 approved applications has shown that approval of HSC-PBPP applications at Tier 1 are generally correct and no application was thought to have been erroneously approved by the Tier 1 panels. The proportionate governance questions used by Tier 1 have been updated as recommended.

9.2.   Communications Plan

A Communications Plan was developed by the Operations Group and accepted by the HSC-PBPP Committee to outline the processes in place to communicate the work of HSC-PBPP to its stakeholders and the general public. In addition, the communications aimed to highlight any gaps in the communications processes and to try to identify any procedures or developments that need to be put in place to address any issues that arise. The Operations Group will continue to contribute to the development and delivery of the Communications Plan, under the overall oversight of the HSC-PBPP committee.

9.3. Move to SharePoint

As part of the move to Microsoft SharePoint in PHS, the HSC-PBPP files moved to SharePoint in October 2022, which has changed some of the ways in which the team work.

The versatility of SharePoint has not yet to be fully explored by the HSC-PBPP team. It is hoped that SharePoint may help with files being able to be shared more easily, particularly for reviews of applications and reduce the need to send emails with many attachments.

10.   Development work

10.1.   Assessment of the feasibility of an online application form

During the 2022/23, there was an aim for the requirements and possible solutions for an online application form and application tracking process to be assessed, evaluated and implemented, subject to available resources within PHS and their IT provider, NSS DaS.

A short life working group (SLWG) discussed the practicalities of creating an online application form for HSC-PBPP. The group consists of the HSC-PBPP Panel managers, two eDRIS coordinators, a PHS business analyst from Strategic Development, a NSS DaS Digital Business partner, with input by a PHS Service manager and project support from PHS Strategic Development.

It soon became clear in early discussions that the requirements for this online application form were more than just the conversion of a word document into an electronic version and would also require a case management system for applications. The requirements of the process were assessed as:

- Must be available to applicants and the eDRIS team prior to submission to HSC-PBPP, and to the HSC-PBPP team, Tier 1 members and Tier 2 members after submission.
- Must cover all types of applications that are submitted to HSC-PBPP: those that will require support and data to be provided by eDRIS and the "HSC-PBPP Only" applications. Once the form has been created for HSC-PBPP's purposes, it should then be widened to be able to 'talk to' other online approvals or data access processes.
- Must be able to allow different questions to be shown, depending on the prior responses of the applicant and to be able to check the responses to some questions for consistency across different sections of the application.
- Must be secure but public facing for applicants.
- Must include an effective applicant and application management system so that applicants can login and access their applications and be able to return to their form in whatever stage it was left while completing it before submission to HSC-PBPP. Some applications will also require other applicants to access them to complete specific sections.
- Must be able to be updated in light of comments from eDRIS and HSC-PBPP as it goes through the review process before first approval.
- Must be able to have a link to supporting documents, and be able to add, remove or update them.
- Must be able to support the HSC-PBPP Amendment request process as project circumstances change with time. An approved form must be able to be updated and resubmitted as an amendment so that the system can be used throughout the length of each project, which is likely to be over several years. Previous approved versions need to be available for audit trails.
- Applicant management and progress notifications should be included. The status of the application will change depending on where it is in the whole HSC-PBPP process.
- Further engagement with applying organisations may be required with regard to the use of an online solution and how this may affect completion of the form.

Some preliminary work had been done previously using Service Now for application tracking, but was deferred because of other priorities due to COVID-19. That earlier work would be useful for this process.

The Project Team discussed initial requirements with NSS DaS colleagues, and a suitable tool within which to develop a solution (ServiceNow) was identified. Subject to resources becoming available by the start of October 2022, the aim was to develop a solution to meet the needs of HSC-PBPP users by the end of March 2023. Unfortunately in January 2023, after making good progress, this development process was stopped due to the lack of Business Analyst capacity within NSS DaS.

This was hugely disappointing. The requirement for an online form will not disappear and, if possible, this work will be picked up and progressed at the earliest opportunity.

10.2. Unlocking the Value of Data

During 2022/23 Scottish Government set up a new Independent Expert Group (IEG) for "Unlocking the Value of Data", especially to examine the use of Public Sector data by the commercial sector.

HSC-PBPP was invited to give a presentation to the initial meeting to explain some of the issues raised by requests for commercial access to personal health data and the check-list that HSC-PBPP developed for such commercial applications. During 2022/23 the HSC-PBPP Committee has given input to this IEG, through discussions with and feedback to its Chair, Professor Angela Daly.

The final report from this IEG was published in August 2023. https://www.gov.scot/publications/final-report-independent-expert-group-scottish-government-unlocking-value-data/pages/1/

10.3. Applications using Artificial Intelligence / Machine Learning

In January 2023 the Information Commissioner's Office held a seminar on Artificial Intelligence (AI) and Data Protection, including looking at their tools in place to assess the privacy risks to individuals about the use of personal data for AI. Currently the number of applications to HSC-PBPP which will use AI or machine learning (ML) are quite small, but are likely to increase in the near future. eDRIS is particularly involved in developing processes to assess the use of data for AI, particularly for removing models and outputs from the National Safe Haven. As a consequence of these discussions, for such applications, HSC-PBPP has started to request that the ICO AI Tool Kit be completed to show that the applicants have thought about and assessed the privacy risks involved before the work has started.

11.   Annual HSC-PBPP Workshops

2022/23 Annual Workshop

In 2022/23, the HSC-PBPP Annual Workshop was cancelled for a third consecutive year.

A Tier 2 'Development Slot' has been inserted as a regular item at the HSC-PBPP Committee meetings, to give an opportunity to discuss potential new developments in technology or changes in the ways different types of applications may be reviewed in the future. Subjects for this item have included: Research Data Scotland; the use of Scottish Medical Imaging data; preliminary discussions about access to GP data; preliminary discussions on the requirements for provision of data for long-term audits and research databases; Unlocking the Value of data; review of applications referred to the Committee which have set new precedents. In the case of new challenges, the Caldicott Guardian Forum may also be consulted.

To inform the IG leads that sit on Tier 1 panels of new developments, the HSC-PBPPP manager has given regular updates at the quarterly IG Forum, based on applications that had been approved 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 discussion.

12. Achievements and Priorities

12.1. Achievements for 2022/23

The HSC-PBPP website has continued to be updated regularly with outcomes and meeting reports. The approved application lists for each year of HSC-PBPP now include the lay summaries for each application.

A plan of ongoing website updates is in place and these will continue.

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 2022/23 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.

12.2. Priorities and Challenges for 2023/24

A number of tasks will be addressed in 2023/24:

i.   There have been preliminary discussions about access to data from GP practices for researchers. The required governance process relating to access to these data and how it will align with the HSC-PBPP process will be investigated and developed.

ii. From the preliminary discussions about long-term provision of data for audits and research databases, a framework and set of definitions will be developed.

iii. There is an intention to hold a joint development day for Tier 1 and Tier 2 HSC-PBPP members and eDRIS. This is to enable good working relationships and to develop joined up thinking that can be applied consistently through all stages of an HSC-PBPP application as it goes through the scrutiny and approval process. This would also be an opportunity to discuss challenges that arise during the application reviews and find appropriate and pragmatic ways to address these challenges.

iv. Continued discussion with RDS and HDR UK (see below)

Research Data Scotland (RDS)

RDS is a Scottish Government initiative which aims to bring public sector data together specifically for use in research for the public benefit. The aim is to improve and expedite the processes from initial discussion and application to provision of data for research. If NHSS health data is included in these applications then HSC-PBPP will continue to be part of the scrutiny process and discussions with RDS as to the mechanisms of how this will take place are ongoing. In the meantime HSC-PBPP will continue to function as normal. HSC-PBPP scrutinises applications for NHSS data that will not go through RDS and these will benefit from any improvements that are made.

Health Data Research UK (HDRUK)

A number of applications that are submitted to HSC-PBPP are funded by HDRUK. HDRUK describe themselves as the national institute for health data science. Their mission is to unite the UK's health data to enable discoveries that improve people's lives. As the work commissioned by HDRUK includes the use of health data from NHSS, HSC-PBPP will have input to the work via the approvals processes.

13. Conclusion

From this report it can be seen that 2022/23 has built on and further developed some of the practices that were started in 2021/22. 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.