



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

**Annual Report
2021/22**

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1. Abbreviations and Glossary

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| Caldicott Guardian | A senior person within an NHS board responsible for protecting the confidentiality of patients' health and care information |
| 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. Applications to HSC-PBPP are assigned an eDRIS coordinator to support applicants. |
| IG Lead | Person in an NHS board responsible for Information Governance in that board, under the Caldicott Guardian |
| IG | Information Governance |
| GDPR | General Data Protection Regulations, introduced into UK law with the Data Protection Act 2018 |
| HDR UK | 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 |
| 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 | NHS Scotland |
| 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 |
| NSH | National Safe Haven: a secure environment where access to NHS Scotland data is controlled by eDRIS and the recommended space for researchers to access NHS Scotland national datasets. |
| PHS | Public Health Scotland, a special (national) NHS Board and data asset holder, established in April 2020 |
| 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 NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) for the year April 2021 to March 2022.

Created in May 2015, HSC-PBPP is an information governance (IG) structure of NHS Scotland (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), although for the second half of 2021/22 this lessened through reduced capacity of eDRIS for non-COVID 'HSC-PBPP permissions only' applications. 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.

Response to COVID-19

The response to the COVID-19 pandemic required changes to the HSC-PBPP processes: this included prioritisation mechanism for applications, a shorter "COVID19" application form and the requirement for a Rapid Review Panel. This consisted of a pool of reviewers from Tier 2 and Tier 1 HSC-PBPP members, specifically convened for high priority applications for data to be used in the response to COVID19. These changes were implemented quickly in March 2020. The rapid review of applications contributing to the emergency response continued until the number of such applications reduced so that the panel was no longer needed. It had already been noted that the rapid review process was required and appropriate for a response to an emergency situation, but would not be sustainable in the long-term with current resources. However, other helpful changes made to HSC-PBPP processes due to the COVID19 response have been taken forward for 'business as usual'.

Performance

Through this year of operation, HSC-PBPP has continued to show good performance across a range of metrics. Approvals for both COVID19 and non-COVID19 applications continued, with the prioritisation of COVID19 applications reduced as the number submitted to HSC-PBPP decreased. There was still a lot of COVID19-related activity within the NHS 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 NHS Scotland 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 2021/22 was lower than that in previous years, possibly reflecting changes in data sharing across NHS boards and reducing the requirement

for HSC-PBPP approval for some activities. As in previous years, these applications came mainly from academia (~65%) and the NHS (30%) with the remainder from Scottish Government and commercial companies. As seen in previous years, the majority of applications were from organisations within Scotland, but in 2021/22 the gradual increase in the proportion of applications from the rest of the UK has continued.

Quality improvement is still important for HSC-PBPP. The annual audit of Tier 1-approved applications was not carried out for 2020/21 because of the number of applications approved by the Rapid review panel, the outcomes of which had already gone through an internal review.

However, there was a review of the application form and it was updated in the light of some of the changes that had been made for COVID19 applications. The updated form aims to be clearer as to what is required, with brief guidance notes added to the form.

A User Experience Survey was also carried out to ask previous applicants what they think would help new applicants in the application process. The outcomes have been considered and some have been taken forward for implementation either directly by HSC-PBPP or as part of the work to be done by Research Data Scotland.

Future developments in 2022/23

Looking forward to 2022/23, 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.

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 2021/22. The COVID19 pandemic has dominated much of our lives in the last 2 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.

NHS Scotland 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 COVID19 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 highly vulnerable people, thus raising new challenges for panel members and reflecting societal and technological changes.

The changes put in place in response to the COVID-19 pandemic showed how quickly and well HSC-PBPP and others in NHSS responded to an emergency situation and demonstrates the robustness of the processes and close working relationships that were already in place. Some of these changes have since become part of the business as usual frame-work for HSC-PBPP, whereas other changes were only viable for a short period of time.

The HSC-PBPP has continued to involve the IG Leads across the different NHS Scotland Health 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 2022, in total, the HSC-PBPP has approved over 700 applications, showing that the demand for using NHSS health data remains high.

Personnel changes to the HSC-PBPP Tier 2 committee were scheduled to take place in March 2021, but were not expected to take place during a pandemic, nor to be done remotely using virtual online processes. 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 Research Data Scotland (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 NHS Scotland that exercises delegated decision-making on behalf of NHS Scotland 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 data. It has successfully harnessed expertise across NHSS health 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. 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 Scottish Government 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 alongside 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, meeting 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 and takes place at a Tier 1 panel meeting. If the Tier 1 panel is 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 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). The panel members considered each application against a set of proportionate governance questions and criteria. Up to five applications and two amendments were considered at any one meeting.

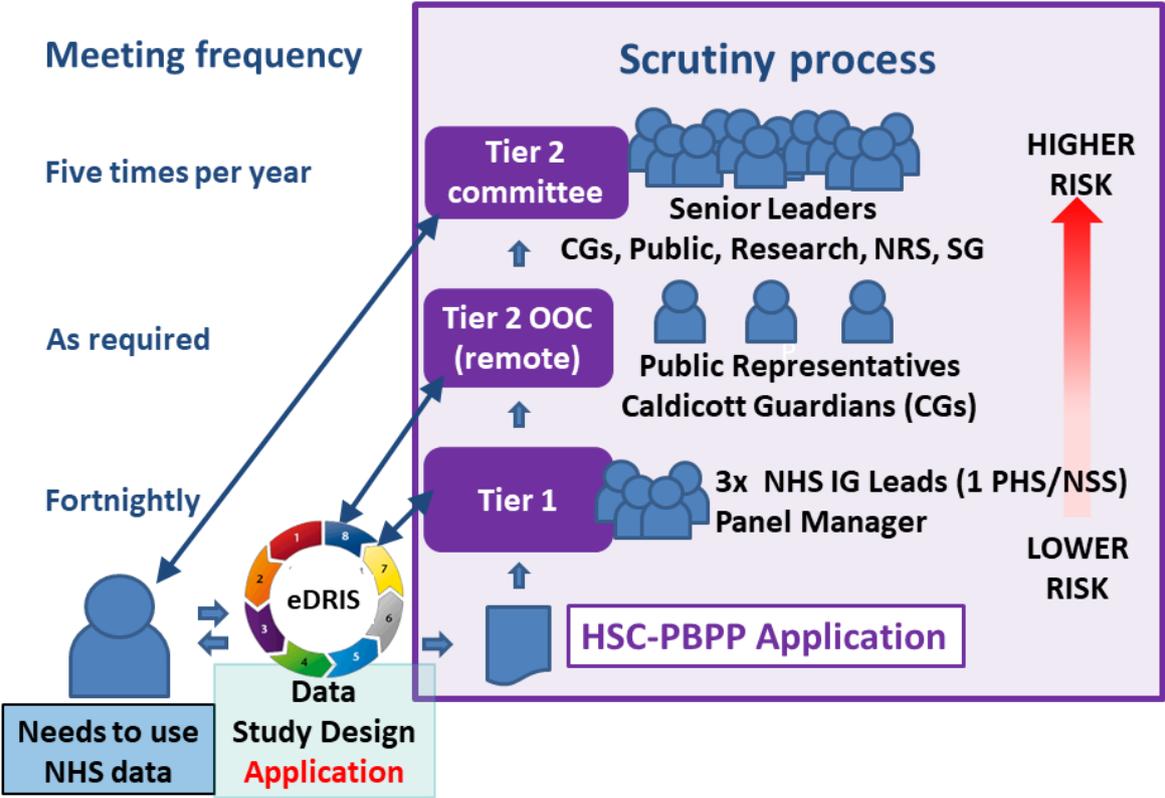


Figure 1 Flow-diagram of the HSC-PBPP scrutiny process

- 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 as ‘Out of Committee’. The latter comprises of the Caldicott Guardians and public representatives from the Full Committee. Applications referred from Tier 1 are reviewed 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 (NHS NSS), NHS Education for Scotland (NES, which also hosts the National Clinical Data Store) and National Records of Scotland (NRS)
- Representative Caldicott Guardians from NHSS boards
- 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 NHS Scotland 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 2021/22

Dr Lorna Ramsay (Interim Chair)

Dr Tara Shivaji (PHS Caldicott Guardian representative)

Dr George Fernie (NHSS Caldicott Guardian)

Dr Mark McGregor (NHSS Caldicott Guardian, from January 2022)

Professor Abbe Brown (Public Representative, extended to March 2022*)

Dr Angus Ferguson (Public Representative, extended to March 2022*)

Kenneth McLean (Public Representative)

John Wood (Public Representative, April 2021 – March 2022)

Martin Walsh (Public Representative, from July 2021)

Professor Helen Colhoun (Research Representative, extended to October 2021**)

Prof Alison McCallum (Research Representative from April 2021)

Prof Colin McCowan (Research Representative from April 2021)

Martin Bell (NSS Representative)

Dr Stephen Pavis (NES Representative, to April 2021)

Dr David Felix (NES Representative, from September 2021)

Alan Ferrier (NRS Representative)

Penni Rocks (Scottish Government representative)

* Two of the outgoing public representatives were extended at 6 monthly intervals for quorum purposes and to cover the transition for new public representatives joining the committee. When it was thought that the full requirement of public representatives were recruited, their term was deemed to have finished. Unfortunately, after this one public representative resigned and due to unforeseen circumstances, a potential new recruit was unable to join the committee.

** One of the outgoing research representatives was extended for 6 months to cover the transition to allow the new research representatives to be orientated to the ongoing work of the committee.

Committee membership vacancies

During the year 2021/22, the following changes occurred:

- For the two vacant Caldicott Guardian roles, one was filled from January 2022, but the other remained vacant
- One public /lay representative role remained unfilled throughout 2021/22
- The NES representative resigned in April 2021 and was replaced in September 2021.
- The Social Care representative role on the committee remained unfilled during 2021/22.

5.1. Recruitment of new HSC-PBPP Committee members

A recruitment process was carried out during 2020/21 to replace some of the original members of the HSC-PBPP committee, as their tenure would end in March 2021. This was originally designed to allow changes of personnel and new members to be appointed, particularly for the roles of Caldicott Guardians, Public Representatives and Research Representatives. These roles are vital for stakeholder input into the work of HSC-PBPP.

As of April 2021, two new research representatives joined the committee. It was agreed to allow for continuity for the ongoing discussions and work of the HSC-PBPP committee, that there would be a 6-month overlap between the outgoing and incoming research representatives.

Similarly a recruitment process was carried out for public representatives, using various routes but was less successful: only two new public representatives were appointed. As with the research representatives, two of the public representatives remained on the committee, to ensure quorum for meetings and review of applications referred from Tier 1, as well as to provide continuity and overlap with new members. The search for a third new public representative continued throughout 2021/22.

The HSC-PBPP is grateful and thanks all 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 2021/22 the Tier 1 Panels met regularly but virtually, approximately every fortnight, using MS Teams. 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 usually 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 2021/22 IG Leads from 17 of the 22 NHS Scotland Boards were involved in the Tier 1 panels.

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, but who also undertake these reviews.

In 2020/21 the use of the rapid review panel for high priority COVID19 applications continued into 2021/22 and it reviewed and approved three applications. However, this rapid review process was discontinued as the number of requests for data for projects that would inform the immediate COVID-19 response decreased. The rapid review process was considered to be acceptable short-term during an emergency but it was very labour-intensive for those panel members and was not thought to be feasible to continue in the long-term, with the current resources. A further five non-COVID applications were reviewed by Tier 2 OOC, all of which were and referred to the full committee which were discussed and subsequently approved (with conditions).

The HSC-PBPP would like to acknowledge and thank all the Tier 1 and Tier 2 members for all their hard work in the scrutiny process and during 2021/22 often under busy and trying circumstances.

Tier 2 Full Committee

In 2021/22 the Full Committee met on the following occasions, with the meetings held remotely using MS Teams.

- Full Committee Meeting Tuesday 13th April 2021
- Full Committee Meeting Tuesday 15th June 2021
- Full Committee Meeting Wednesday 15th September 2021
- Full committee meeting Tuesday 16th November 2021
- Full Committee Meeting Wednesday 26th January 2022

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

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

7. Changes in HSC-PBPP processes

7.1. Previous changes in processes due to COVID19

Changes to the HSC-PBPP processes in response to COVID-19 were implemented in March 2020 and are explained more fully in the HSC-PBPP Annual Report for 2020/21 (available on the HSC-PBPP website).

The changes consisted of:

- A shortened 'COVID-19' HSC-PBPP application form, including brief guidance notes.
- Triage process by eDRIS, with discussion with the applicant, to determine the priority level of the applications.
- Review processes: Applications would be reviewed either by a rapid review panel for priority applications; other applications would go to Tier 1 as per normal processes but COVID-19 applications would be prioritised over non-COVID-19 ones.
- A separate review process was set up for review by GPs for the use of a specific GP dataset for COVID-19 applications.
Amendments to existing applications requesting COVID-19 data would follow normal processes but would be prioritised and processed as quickly as possible.

These processes were in place and followed for much of 2021/22, but as the applications that would feed into the immediate response to the pandemic decreased in number, the majority of the COVID19 applications were reviewed at Tier 1.

As COVID19 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.

7.1.1. 2021 Review of Timelines of HSC-PBPP approvals in 2020/2021 due to COVID19 applications

In June 2021 a review was carried out for a number of applications (n=21), submitted to HSC-PBPP during the year 2020/21, that had taken more than a total of 50 days to be approved. Of these, five were COVID19 applications and 16 were non-COVID19 applications. The total time to approval for these applications ranged from 52 to 142 days.

For applications that were related to COVID19 (for which the total time ranged between 52 and 95 days) the delays were due to further information being required from the applicant before they could be approved, and any delays in receiving that information. This was reflected in the clocked times for approval, which ranged from 12 to 33 days.

For non-COVID19 applications, three of these were approved at Tier 2 within the total expected time of 60-90 days. For the other 13 non-COVID19 applications, the delays were due to combinations of factors: they were all deferred from the first Tier 1 panel review because of other COVID19 applications that took priority; in addition, during the review process some delays arose at Tier 1, due to the availability of panel members who were involved in COVID19-work within their own NHS boards, which took priority over HSC-PBPP work.

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 NHS NSS. It is recommended that analysis of these datasets is 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 that are submitted to HSC-PBPP for approval, 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.

From February 2019 onwards, a member of the (then) NHS NSS IG team was seconded to eDRIS to support the HSC-PBPP Only applications, but in March 2020 returned to the IG team to help manage the IG requirements related to the COVID19 pandemic. From March 2020 to June 2021, eDRIS managed the HSC-PBPP Only applications with input and help from the Scottish Clinical Trials and Research Unit (SCTRU, also in PHS) but which was, in turn, reduced as the SCTRU team returned to their clinical trial work as COVID19 restrictions were lifted and sites opened up again. In June 2021, due to the increased demand on eDRIS due to ongoing COVID19 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 to support the applicants, with the assurance that a member of the PHS Data Protection team will be recruited and seconded to eDRIS to support these applications from April 2022 onwards.

The following steps were put in place:

- eDRIS enquiry form updated to indicate whether eDRIS input is required.
- Email with completion instructions for the HSC-PBPP application form, also pointing to support and guidance documents on the eDRIS and HSC-PBPP websites.
- On receipt of an HSC-PBPP Only submission, the application was sent to the panel managers for a Pre-Tier 1 check. This is a completeness check to decide whether the application was complete enough to send to a Tier 1 panel. If the checklist indicated that enough information was provided for review, the application was sent to the next available Tier 1 panel. While enough information may be provided, this check was not detailed enough to determine whether that information was correct, coherent, concise and consistent throughout the application. The Pre-Tier 1 checklist outcomes was sent to the Tier 1 panellists as a supporting document.
- If information was obviously missing or incorrect, the panel manager sent an email back to the applicant raising the questions noted during the pre-Tier 1 check, to ask that they are addressed before the application could go to Tier 1. There was no time-frame for the applicant to return the application. Once the application was returned

to HSC-PBPP it was sent to the next available Tier 1 panel without any further review as to whether the specific questions had been addressed.

- Due to the complexity of these applications and the time required to review them, the number of applications for review at a Tier 1 panel was reduced from five to four.

From June 2021 to March 2022, 77 applications were received and 30 of these were classed as HSC-PBPP Only and requiring a pre-Tier 1 check. Of these 20 were deemed to have sufficient information for review at Tier 1 and 10 required further information before review at Tier 1, of which eight were returned and subsequently reviewed at Tier 1. The effect of this change in procedure on performance outcomes are shown as part of the performance metrics below.

8. Performance Metrics for HSC-PBPP applications for 2021/22

8.1. Summary Tables of HSC-PBPP metrics for 2021/22

The applications and amendments submitted to HSC-PBPP for the year 2021/22 to 31st March 2022 for all applications and for COVID19-applications, are summarised in tables 1 and 2, respectively, below.

| | Number submitted | Number with decisions * | Level of decision | (n) | % | |
|--|------------------|-------------------------|-------------------|--------------------------------|-----------|------|
| Applications received for 2021/22 at 31/03/2022 | 104 | Approved: | 68 | T1 panel meeting | 30 | 37% |
| | | Not approved: | 3 | T1 review | 43 | 53% |
| | | Withdrawn | 10 | T2 OOC | 0 | 0% |
| | | In progress | 23 | T2 full committee | 5 | 6% |
| | | Total | 104 | COVID19 rapid review | 3 | 4% |
| Applications carried over from 2020/21 | 19 | Approved | 10 | | | |
| | | Withdrawn: | 9 | | | |
| | | | | Total with decisions | 81 | |
| | | | | Total withdrawn | 19 | |
| | | | | Carried over to 2022/23 | 23 | |
| Total | 123 | | | | | |
| Amendment requests for 2021/22 at 31/03/2022 | 294 | Approved: | 275 | eDRIS | 152 | 55% |
| | | Not approved: | 1 | Panel Manager | 116 | 42% |
| | | Withdrawn: | 3 | Tier 1 | 7 | 2.5% |
| | | Still to be | | Tier 2 | 1 | 0.5% |
| | | Approved | 15 | | | |
| | | Total | 294 | | | |

Table 1: Summary of the applications and amendments processed by HSC-PBPP in 2021/22.

| | Number submitted | Number with decisions* | Level of decision* | (n) | % |
|---|------------------|------------------------|-----------------------|-----|-----|
| COVID-19 applications at 31/03/2022 | 18 | Approved: 13 | T1 panel | 3 | 23% |
| | | Not approved: 0 | T1 review | 6 | 46% |
| | | Withdrawn: 3 | COVID-19 rapid review | 3 | 23% |
| | | Ongoing 2 | Full committee | 1 | 8% |
| COVID-19 Amendments requests at 31/03/2022 | 62 | Approved: 62 | eDRIS | 29 | 47% |
| | | Not approved: 0 | Panel Manager | 29 | 47% |
| | | Withdrawn: 0 | Tier 1 | 3 | 5% |
| | | | COVID-19 rapid review | 1 | 1% |

Table 2: Summary of the applications and amendments processed by HSC-PBPP in 2021/22 for COVID-19.

Types of Applications

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

- Local and national (Scotland and UK-wide) audits assessed the outcomes and needs of different conditions or procedures.
- NHS Scotland 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 NHS Scotland data to look for patterns in disease onset, processes and responses to interventions.
- Use of NHS Scotland data for NHS service planning and improvement, for assessing the cost-effectiveness of specific interventions, or the interactions of social and environmental factors on health outcomes.
- Use of NHS Scotland 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/pbphsc/application-outcomes/>

8.2. Comparisons with previous years

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

Submissions

During 2021/22, a total of 104 applications were submitted to the HSC-PBPP, which included COVID-19 and non-COVID-19 applications. As can be seen from figure 2, the number of applications has fluctuated, but the number of submissions for 2021/22 is lower than the mean number of 121 per year over the past 6 full years of HSC-PBPP.

From figure 2, in recent years there has been a fall in HSC-PBPP submissions, particularly in 2019/20 and 2021/22. Some of the reasons for this might be 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. With the creation of PHS as a national NHS board with well-defined core functions, some projects that would have previously required scrutiny and approval from HSC-PBPP will now be 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.

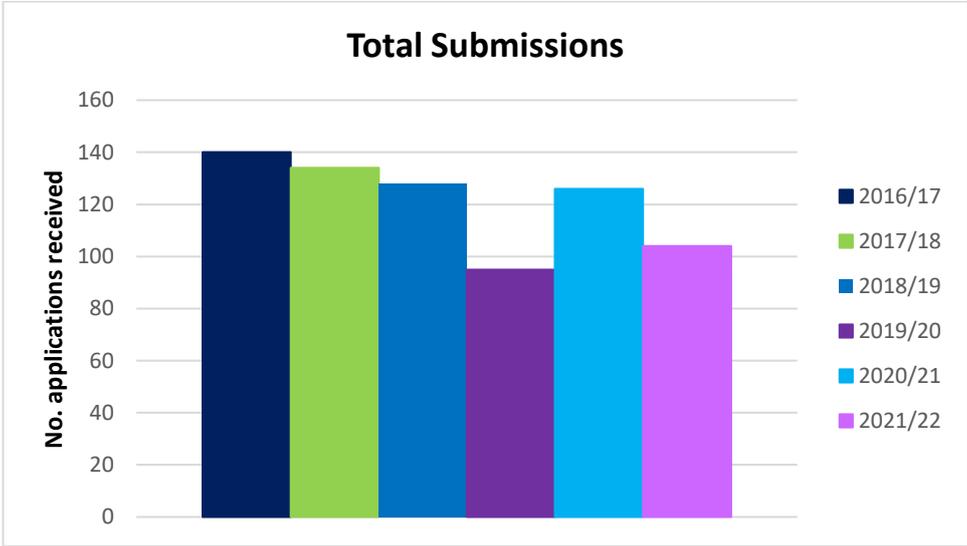


Figure 2: Numbers of applications submitted to the HSC-PBPP in the six years from 2016/17 to 2021/22.

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 2021/22.

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 across the past 5 years from NHS and academia has remained fairly constant, indicating that the smaller number of submissions overall was not due to a specific reduction in the request for data from any particular sector.

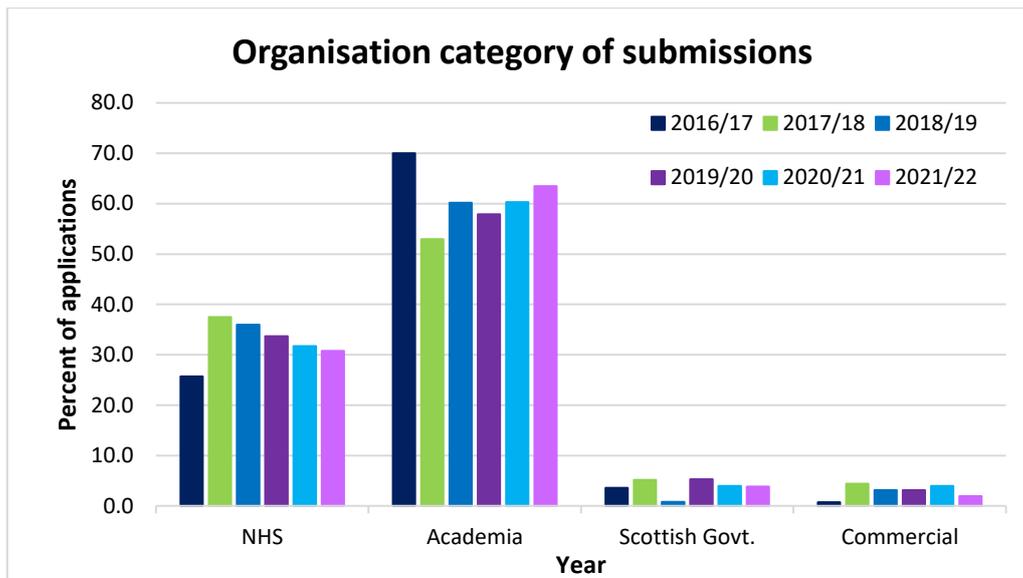


Figure 3a: Sources of applications to the HSC-PBPP in 2016/17 to 2021/22

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 2022/22 this had dropped to 51% of applications. There has been no noticeable impact arising from this change.

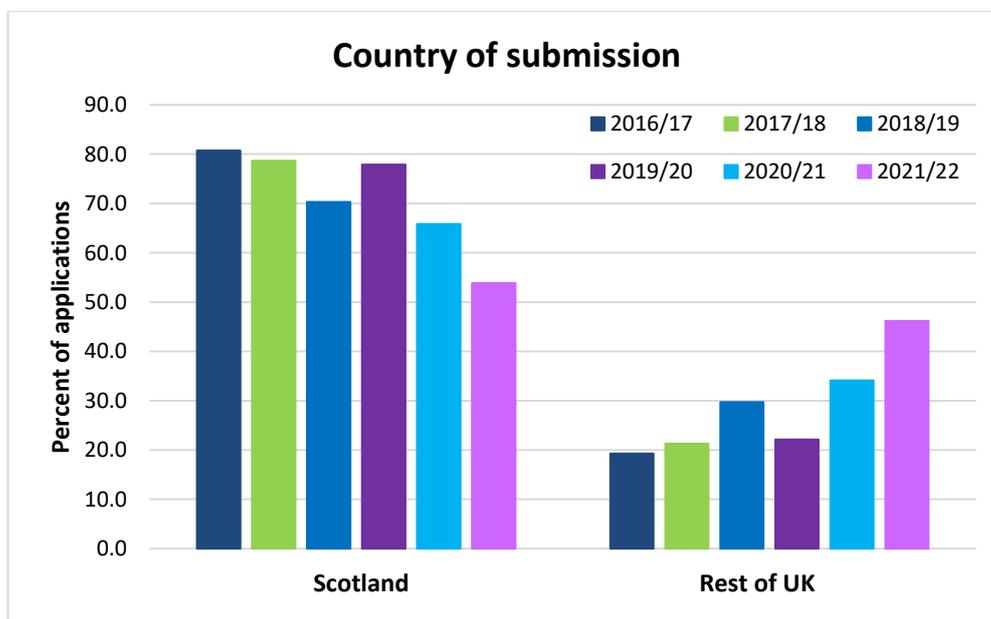


Figure 3b: Sources of applications to the HSC-PBPP from 2016/17 to 2021/22

Application Outcomes

The number of application decisions per year are shown in figure 4, with 81 decisions made in 2021/22. This is lower than previous years, and lower than the mean number of 109 decisions per year from 2016/17 to 2021/22.

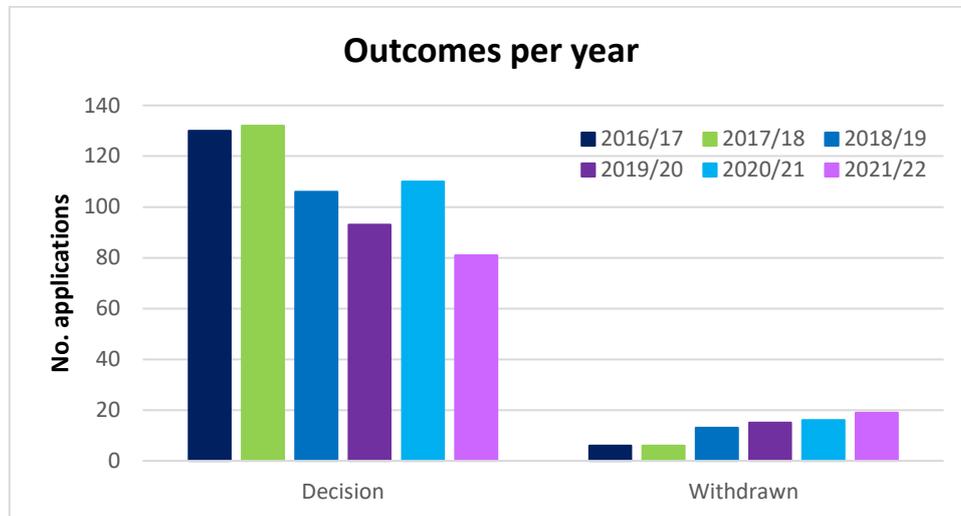


Figure 4: *Number of applications with decisions and withdrawn applications from 2016/17 to 2021/22*

The number of applications that have been withdrawn has gradually increased over the past six 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. For the 19 applications withdrawn in 2021/22, three were actively withdrawn by the applicants. For the others, some of these delays may be due to applicants being moved onto other projects due to the response to COVID19. The proportion of withdrawn applications, as a percentage of all the outcomes has increased from 4% in 2016/17 to 19% in 2021/22. It will be interesting to see whether this level of withdrawal is maintained in 2022/23.

The level of HSC-PBPP at which these 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 have been reviewed by Tier 1 panel members. The number of applications approved by the COVID19 rapid response panel (COVID RRP) decreased in 2021/22, reflecting the different stage of the pandemic response.

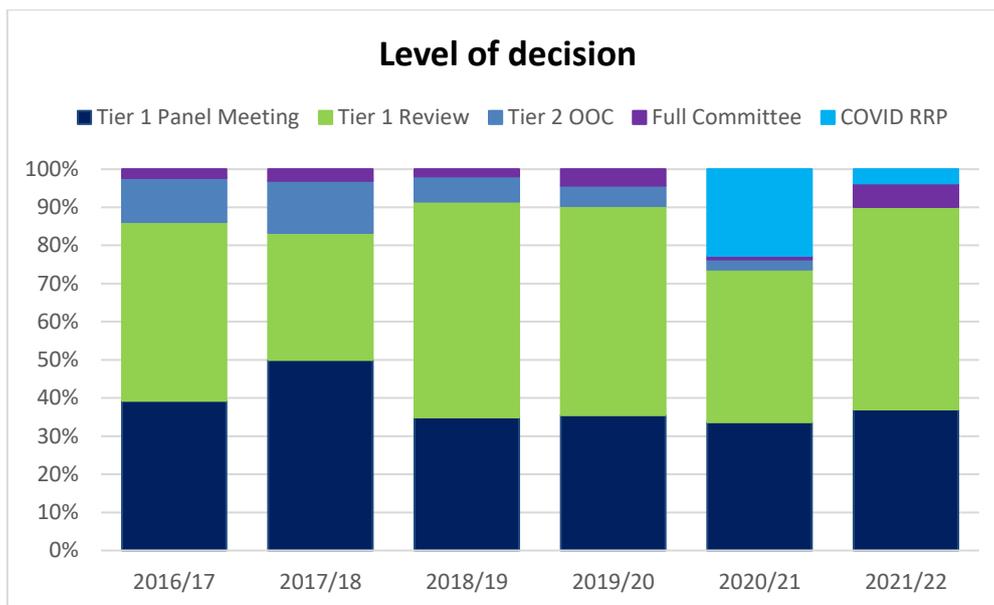


Figure 5: *Level of decisions for applications from 2016/17 to 2021/22*

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 2021/22, 14 applications (13.5 %) 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. The mean over the past 5 years is ~11% of applications requesting NHSCR data.

8.3. Time 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.

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 2021/22

The time taken for decisions to be made by HSC-PBPP are summarised in table 3. These data are presented for all applications and divided into COVID-19 and non-COVID-19 applications. The times are given for all decisions (ALL) and separately for those decided at Tier 1 and those applications decided at Tier 2/COVID-19 rapid review panel to 31st March 2022. 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 2021/22 to 31/03/2022 | N | 81 | 81 | 73 | 73 | 8 | 8 |
| | Mean | 40.8 | 20.4 | 39.8 | 19.0 | 49.8 | 32.9 |
| | Median | 34 | 17 | 34 | 17 | 35 | 35 |
| | IQR | 23–50 | 13–24 | 23–50 | 13–22 | 20–70 | 14–46 |
| | | ALL | | Tier 1 | | Tier 2 | |
| | | Total | Clocked | Total | Clocked | Total** | Clocked** |
| COVID-19 applications to 31/03/2022 | N | 13 | 13 | 9 | 9 | 4 | 4 |
| | Mean | 37.7 | 18.6 | 34.6 | 15.8 | 43.3 | 25.0 |
| | Median | 29 | 14 | 29 | 14 | 16.5 | 12.5 |
| | IQR | 24–37 | 9–18 | 28–37 | 13–18 | 8–51.5 | 8–29 |
| | | ALL | | Tier 1 | | Tier 2 | |
| | | Total | Clocked | Total | Clocked | Total | Clocked |
| Non-COVID-19 applications to 31/03/2022 | N | 68 | 68 | 64 | 64 | 4 | 4 |
| | Mean | 41.4 | 20.7 | 40.5 | 19.5 | 56.3 | 40.8 |
| | Median | 36 | 17.5 | 35 | 17 | 50 | 42 |
| | IQR | 23–52 | 13–24 | 23–51 | 13–22 | 36.5–70 | 36.5–46 |

Table 3: Time to approval for applications for applications with decisions in 2021/22

** For 2021/22 applications, this is the time to approval for 3 applications approved by the rapid review panel for COVID-19 applications and five applications that were approved at the full committee, one of which was also for a COVID19 study.

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

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 4), 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.

| | 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 |

Table 4: Time to approval for HSC-PBPP Only applications compared with eDRIS-supported applications after the change in June 2021

Comparison of Times to decisions across years

The median times to decisions at the different levels of HSC-PBPP from 2016/17 to 2021/22 are shown in figure 6. The figures for 2020/21 and 2021/22 are just for non-COVID-19 applications. The times for all applications shows that these have remained fairly constant over the years, with a slight decrease for Tier 1 clocked times. By the nature of their referral to Tier 2, the few applications that are referred to Tier 2 will take longer. The Tier 2 times were at their highest in 2019/20 compared with previous years, but decreased in 2020/21 and this decrease was maintained in 2021/22.

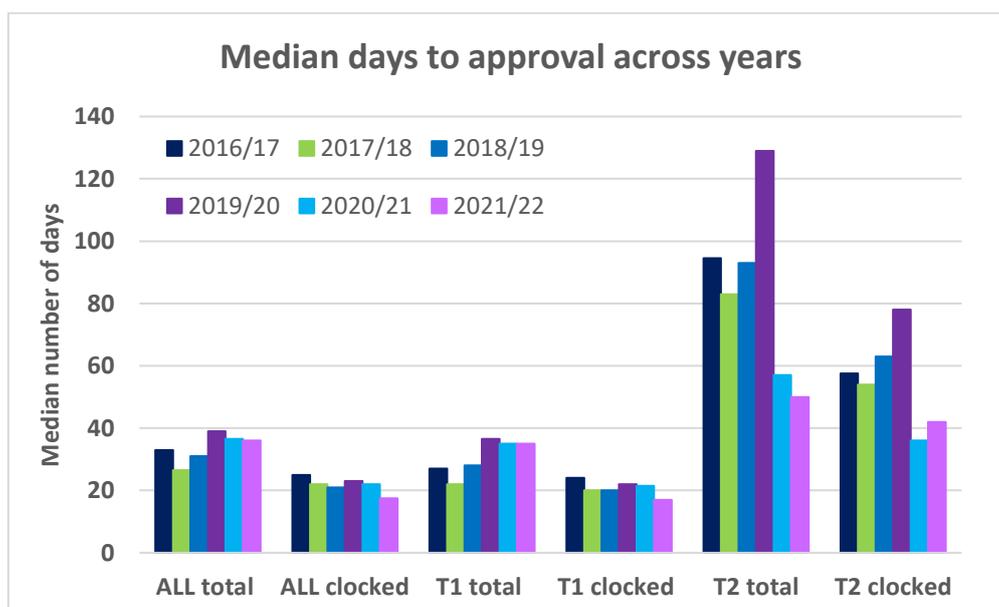


Figure 6: Median times (days) to decisions at different levels of HSC-PBPP

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.

During 2021/22 the audit of Tier 1 approved applications for 2020/21 did not take place as many of the applications approved during that year had been done under the COVID Rapid Review panel, which itself had undergone an internal review (noted in the HSC-PBPP Annual Report for 2020/21). In addition, due to new committee members establishing themselves, it was felt to be impractical.

2021 update to the application form

During 2021 the application form and guidance documents were updated. The updated form contains brief and clear guidance alongside the questions to help applicants. Initial informal feedback indicated that this helped applicants in completion of the form as well as the Tier 1 reviewers. The 'Tooth Fairy' application was also updated using the new form. The 'Tooth Fairy' application was written by the HSC-PBPP team and reviewed and approved at Tier 1, as an example of a completed and approved application to help applicants.

2021 User Experience Survey

A User Experience Survey was carried out by PHS to aim to find specific ways to improve the applicant experience. A short questionnaire was devised and sent to 42 people (chosen at random), who had all applied to HSC-PBPP within the last three years. From these responses were obtained from 10 previous applicants.

Generally the feedback was positive and constructive. There were mixed responses: some thought the process had been acceptable, especially once their application had been submitted, but there were others who thought the HSC-PBPP process could be greatly improved.

A number of suggestions were made relating to:

- Application form (online, shorter)
- Advice, further guidance and completed application forms
- Online tracker for progress of application
- Faster approval processes
- Feedback for users or a network of champions /mentors to assist applicants

In response to the suggestions, the HSC-PBPP Operations group have considered possibilities for implementation of some of these suggestions, within the resources available to HSC-PBPP.

Some of the suggestions that were made are likely to be implemented through Research Data Scotland (see section 11).

10. Annual HSC-PBPP Workshops

2021/22 Workshop

In 2021/22, the HSC-PBPP Annual Workshop was cancelled for a second year due to ongoing COVID-19 restrictions.

Due to changes in work practices with increased remote working, it is unlikely that HSC-PBPP annual workshop will be resumed in the future using the same format as previously. A number of interim measures put in previously to cover the “horizon scanning” have continued at Tier 2 and Tier 1.

For Tier 2, a ‘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; Commercial applications; discussion of processes or innovations from the introduction of new policies; review of applications referred to the Committee which have set new precedents.

To inform the IG leads that sit on Tier 1 panels of new developments, the HSC-PBPP 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.

In the case of new challenges, the Caldicott Guardian Forum may also be consulted.

11. Achievements and Priorities

11.1. Achievements for 2021/22

The HSC-PBPP website was used for posting weekly outcomes of COVID-19 applications and is 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. While this was attempted, it was harder to keep the same level of interaction online. If this can be done successfully, a further advantage is that it could then be offered more widely throughout the UK. A further online course will be attempted in 2022/23 with more scheduled time for discussion and specific interactive exercises.

11.2. Priorities and Challenges for 2022/23

A number of tasks will be addressed in 2022/23:

- i. The requirements and possible solutions for an online application form and application tracking process will be assessed, evaluated and implemented, subject to available resources. This was one of the requests from the User Survey.
- ii. A Communications plan for HSC-PBPP will be developed
- iii. Continued discussion with RDS and HDR UK (see below)

Research Data Scotland (RDS)

Research Data Scotland (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 NHS Scotland 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 NHS Scotland 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 Health Data Research UK (HDRUK). HDR UK 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 NHS Scotland, HSC-PBPP will have input to the work via the approvals processes.

12. Conclusion

From this report it can be seen that 2021/22 has built on and further developed some of the practices that were started in 2020/21. These processes will continue to be refined as the HSC-PBPP continues to operate to ensure the safe use of NHS Scotland 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.