

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

## **Annual Report 2018/19**

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## Abbreviations and Glossary

Caldicott Guardian	A senior person within an NHS board responsible for protecting the confidentiality of people’s health and care information and making sure it is used properly.
DHCS	Scottish Government Digital Health and Care Strategy review
eDRIS	electronic Data and Research Innovation Service
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
NHSCR	NHS Central Register
NHSS	NHS Scotland
NRS	National Records of Scotland
NSS	NHS National Services Scotland, a special (national) NHS board
PBPP	Public Benefits and Privacy Panel for Health and Social Care
SG	Scottish Government
Tier 1	Operational level at which all applications to PBPP undergo their first review
Tier 2 OOC	The Caldicott Guardians and Lay Representatives who sit on the full committee who review applications “out of Committee”
Tier 2	Higher /strategic level of PBPP, which has oversight of PBPP, and at which higher risk applications are reviewed

## **Executive Summary**

### **Background**

This Annual Report reviews the operation of the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (PBPP) for the period 2018/2019. Created in May 2015, PBPP is an information governance (IG) structure of NHS Scotland that provides a central national IG scrutiny process focussed on requests for access to NHS Scotland-originated data for purposes other than direct care. Such purposes include research or service planning.

### **Structure**

Support is provided to all applicants seeking access to data, via the electronic Data Research and Innovation Service (eDRIS). The 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 at this level. Where the applications are of greater risk and require a higher level of consideration, applications will be referred to a regularly-convened subgroup of the Tier 2 Committee for scrutiny, and if necessary, by the full Tier 2 committee.

### **Performance**

Through this year of operation, PBPP has continued to show good performance across a range of metrics. PBPP has built on and developed the processes established when it was set up in 2015, in the hope of giving an increasing and valuable consistency in the scrutiny procedures. Over 20 IG leads from the 14 territorial boards and 8 national boards within NHS Scotland, have been engaged in the process, thus embedding IG in the general operational approach of the NHS across Scotland.

During 2018/19, 128 applications were submitted to the PBPP, similar numbers to those submitted in previous years. These applications came mainly from academia (60%) and the NHS (36%) with the remainder from Scottish Government (1%) and commercial companies (3%). The majority of applications were from organisations within Scotland (70%), with the others from other parts of the UK.

The median times to approval decreased in 2018/19, (compared with 2017/18), by 1 day for clocked time and by 3 days for total time. The PBPP continues to work to improve the efficiency of the service in the interests of its stakeholders while maintaining its responsibility to preserve the privacy and security of the data it oversees.

### **Development**

During the year the PBPP increased its visibility with presentations, to the International Population Data Linkage Network Conference, in Banff, Canada and involvement in the Edinburgh International Science Festival's event of 'Diagnosing with Data'.

The PBPP devised a training course for potential PBPP applicants, 'The Why and How of PBPP applications', which was held at the Wellcome Trust Clinical Research Facility in March 2019. In a similar vein, an application from the "Tooth Fairy" was written as an example PBPP

application, for training purposes, giving some indication of the answers that would be required to each of the questions in the application form. This application was reviewed and approved at a Tier 1 panel.

### **Future developments in 2019 / 20**

Looking to 2019/20 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. A communications strategy is planned for 2019/20, to make information about the PBPP more accessible.

With an increasing public and professional awareness of IG and concern about the importance of the protection of personal data, PBPP has developed an ambitious set of aims and priorities for 2019/20. With the increasing complexity of uses of data, especially from increased computing power, PBPP aims to address some of the issues surrounding artificial intelligence and machine learning. Similarly, the increased involvement of commercial companies in research and the use of data provides challenges for the safeguarding of patients' privacy. The PBPP intends to begin to address these challenges in in the coming year, taking into account Scottish Government's policies in these areas.

## Chair's introduction

NHS Scotland has a wealth of excellent data on the health of its population, providing an exceptional opportunity for large scale research projects, quality improvement and patient-care audits to be undertaken. However, these data need to be used safely and in the interest of the public. Through the development of its proportionate governance criteria, the Public Benefit and Privacy Panel for Health and Social Care (PBPP) supports the information governance structures to enable NHS Scotland to conduct and contribute to the investigation and understanding of the health of its population, through the safe and trusted use of NHS-held data.

During the year 2018/19, the PBPP has continued to build and consolidate the processes that were previously established. This has led to consistency in the scrutiny procedures, which are the mainstay of the panel's work. PBPP has continued to involve the Information Governance Leads across the different NHS Scotland Health Boards, thus ensuring that the PBPP scrutiny is a truly national process and not limited to select individuals within specific Health Boards. Up to the end of March 2019, in total the PBPP has approved over 400 applications, showing that the demand remains high for using health data. The majority of applications continue to come from academia and NHS, showing that the use of health data is not only important for academic research, but also for audit and service-improvement purposes. This supports the ongoing commitment of the NHS in Scotland to develop and expand its services as required.

This annual report demonstrates some of the activities in which PBPP members have been engaged over the past year. It highlights some of the development work that has been done but also where PBPP has reviewed its own processes to try to improve the service. With the introduction of the GDPR and the Data Protection Act 2018 across the UK, the PBPP has tried to connect the many strands of relevant governance activity. In addition, the PBPP recognises the need to react quickly to the rapidly changing landscape of governance in an increasingly technological age, so that the use of data in the public interest and benefit is maintained. While the PBPP continues in its role, there is always room for improvement and the priorities for 2019/20 indicate that the PBPP will continue to develop its procedures to improve efficiency, while maintaining integrity.

The PBPP will continue to aim to work as effectively as possible to maximise the value of Scotland's health data, while managing emerging information risks and addressing public concern around privacy. The ongoing development of the Digital Health & Care Strategy by Scottish Government is part of this process. 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.

Brian Houston

Chair of Public Benefit and Privacy Panel for Health and Social Care 2015-2019

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

The Public Benefit and Privacy Panel for Health and Social Care (PBPP) is an information governance structure of NHS Scotland that exercises delegated decision-making on behalf of NHS Scotland Chief Executive Officers and the Registrar General for NHS Central Register (NHSCR) data.

The PBPP endeavours to operate as a centre of excellence for privacy, confidentiality and information governance (IG) in relation to Health and Social Care in Scotland, providing strategic leadership and direction in this area to NHS Scotland Boards, the research community, and wider stakeholder groups.

The panel aims to:

- Streamline the previous governance processes for the scrutiny of requests for access to NHS Scotland-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 information governance 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 NHS Scotland-originated data.

Since its inception in May 2015, the PBPP has provided a national Information Governance scrutiny process for the secondary use of patient data. It has successfully harnessed expertise across NHS Scotland health boards implementing a collaborative approach which contributes to consistency and continued capacity development across the sector.

### **Structure of the PBPP**

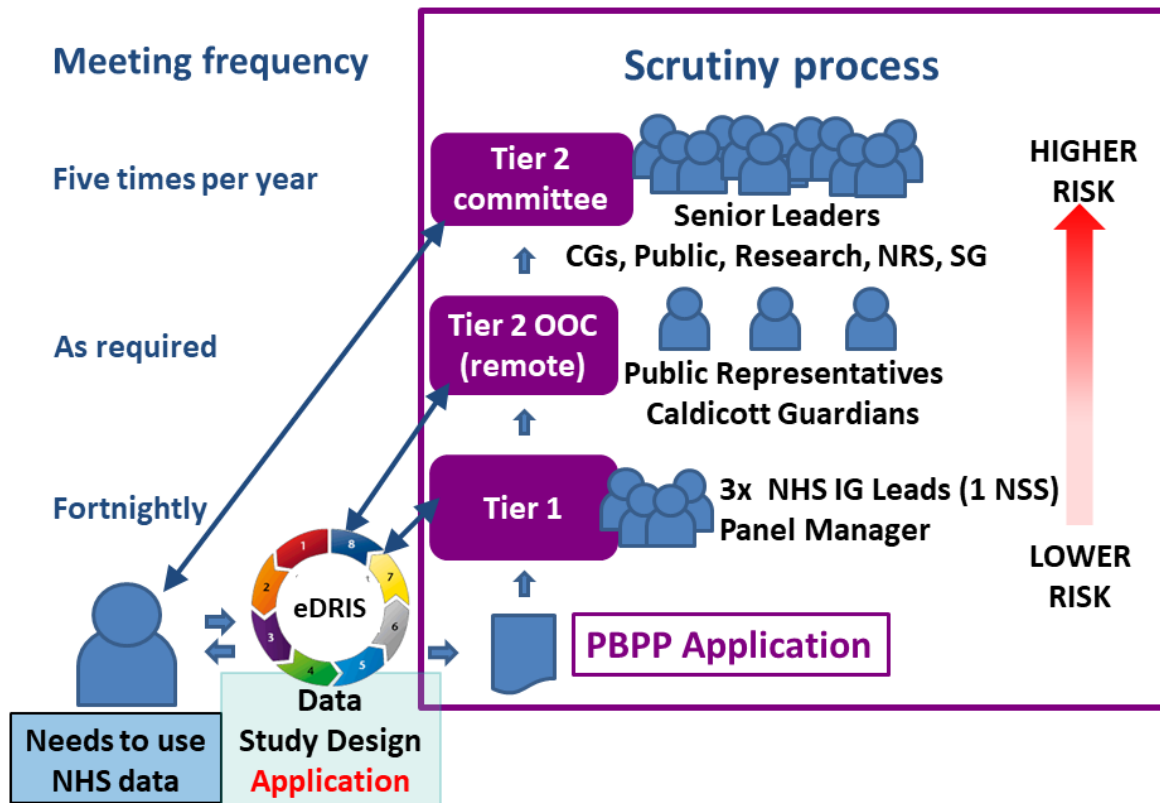
The PBPP structure and process is summarised in the flow diagram shown in Figure 1. There is a single entry point for all applications to PBPP, via the electronic Data Research and Innovation Service Team (eDRIS). This helps to maintain consistency of advice for all applicants, including those from NHS 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 PBPP. They do this by providing an eDRIS Coordinator to facilitate applicants to refine their data-linkage projects, as well as review and assist applicants to finalise their applications for submission. The eDRIS team works closely alongside the PBPP. Through shared learning between the two teams, this aims to ensure that applications are fit for submission, thus making the PBPP review process as efficient as possible for both applicant and reviewer.

The PBPP operates on a two-tier structure (see figure 1).

## 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 Information Governance (IG) practitioners from across the NHS 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 (OOC). 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 (OOC).



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

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

## 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 Tier 2 Out of Committee. 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 to answer questions and inform the discussion.

The full committee provides the intellectual space for senior leaders, Caldicott Guardians, researchers and public representatives 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.

## **PBPP Committee Members 2018/19**

Brian Houston (*Chair*)

Dr George Fernie (*NHSS Caldicott Guardian*)

Professor Alison McCallum (*NHSS Caldicott Guardian*)

Dr Eleanor Anderson (*NHS NSS Caldicott Guardian\**)

Dr Maria Rossi (*NHS NSS Caldicott Guardian\**)

Professor Abbe Brown (*Public Representative*)

Dr Angus Ferguson (*Public Representative*)

Kenneth McLean (*Public Representative*)

Professor Daniel McQueen (*Public Representative*)

Professor Corri Black (*Research Community Representative*)

Professor Helen Colhoun (*Research Community Representative*)

Dr Steve Pavis (*NHS NSS Data Linkage Lead Specialist*)

Alan Ferrier (*NRS Representative*)

Penni Rocks (*Scottish Government representative*)

\* NSS Caldicott Guardian is a shared role and either member can attend the committee.

The following members retired or resigned from the committee during 2018/19:

Dr Emilia Crichton (*NHSS Caldicott Guardian*)      *Resigned July 2018*

Dr Janet Murray (*NHS NSS Caldicott Guardian*)      *Retired June 2018*

Dr Kirsty Licence (*NHS NSS Caldicott Guardian*)      *Resigned December 2018*

David Knowles (*NHSS CHI Advisory Group representative*)      *Retired March 2019*

During the year 2018/19, one Caldicott Guardian role became and remained vacant. This has led to capacity issues that are being addressed.

The Social Care representative role on the committee remained unfilled during 2018/19.

## **Application review processes and meetings of the PBPP**

### **Tier 1**

The introduction of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, in May 2018 meant that all the PBPP paperwork had to be reviewed, updated and ready in time for the change in legislation. This was achieved and the main challenges since have been how the changes under the new laws are to be interpreted and applied to application reviews.

The Tier 1 Panel met fortnightly at central locations in Edinburgh and Glasgow during 2018/19. Each panel comprised of three IG Leads/Practitioners from different NHS Boards, on rotation, and the PBPP Panel Manager. The IG leads were drawn from the territorial (regional) health boards around Scotland, as well from the national NHS Boards. During 2018/19 a few new IG leads joined the Tier 1 rota; each brings with them their experience and viewpoint from their NHS Board. 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. During 2018/19, 27 IG practitioners from across NHS Scotland participated in the Tier 1 PBPP scrutiny process, an increase from 24 IG practitioners in 2017/18. These IG leads represented 11 of the 14 territorial NHS boards and 7 of the 8 special (national) NHS boards, showing good representation from across NHS Scotland.

The PBPP would like to acknowledge and thank the Tier 1 panellists for all their hard work in making the scrutiny process possible.

### **Tier 2 Out of Committee**

The Tier 2 Out of Committee (OOC) group was convened as required to consider applications referred from Tier 1. This group consists of the NHS Caldicott Guardians and Public Representatives, who sit on the full committee, but who also undertake these reviews. During 2018/19, seven applications were scrutinised and approved by the Tier 2 OOC and a further two applications were referred to the Full Committee.

### **Tier 2 Full Committee**

In 2018/19 the Full Committee met on five occasions:

Full Committee Meeting	Thursday 26 <sup>th</sup> April 2018
Full Committee Meeting	Tuesday 26 <sup>th</sup> June 2018
Full Committee Meeting	Tuesday 25 <sup>th</sup> September 2018
Full Committee Meeting	Tuesday 27 <sup>th</sup> November 2018
Full Committee Meeting	Tuesday 15 <sup>th</sup> January 2019

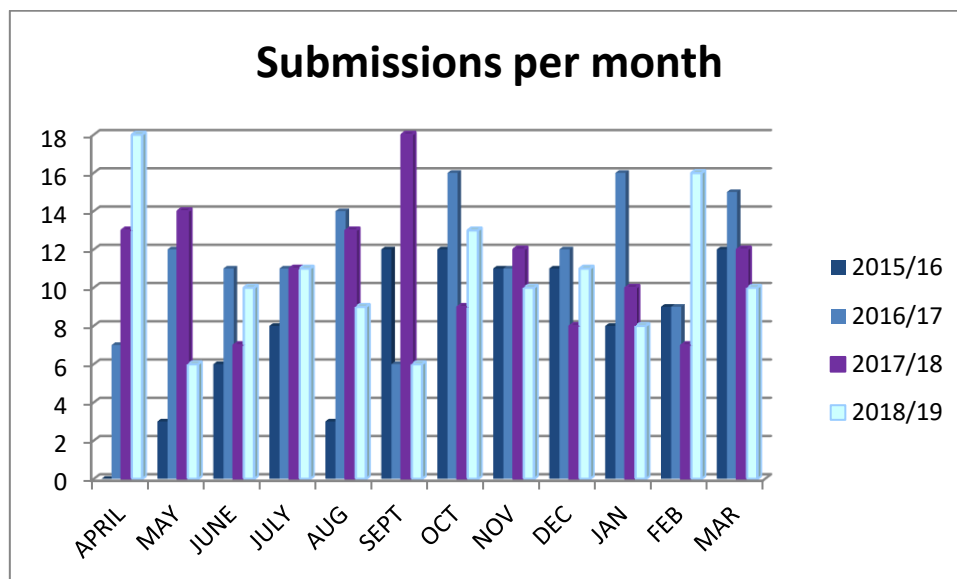
Minutes of these meetings are available on the PBPP website:

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

## Performance Metrics for PBPP applications for 2018/19

### Submissions

During 2018/19, a total of 128 applications were submitted to the PBPP. This is slightly lower than the numbers submitted in the previous two years (136 in 2017/18, 140 in 2016-17 and 95 in 2015/16). From Figure 2, it is clear the timing of submissions fluctuates throughout the year, but with no specific pattern. The PBPP monitors these peaks in submissions and tries to arrange Tier 1 panel meetings to accommodate these where possible.

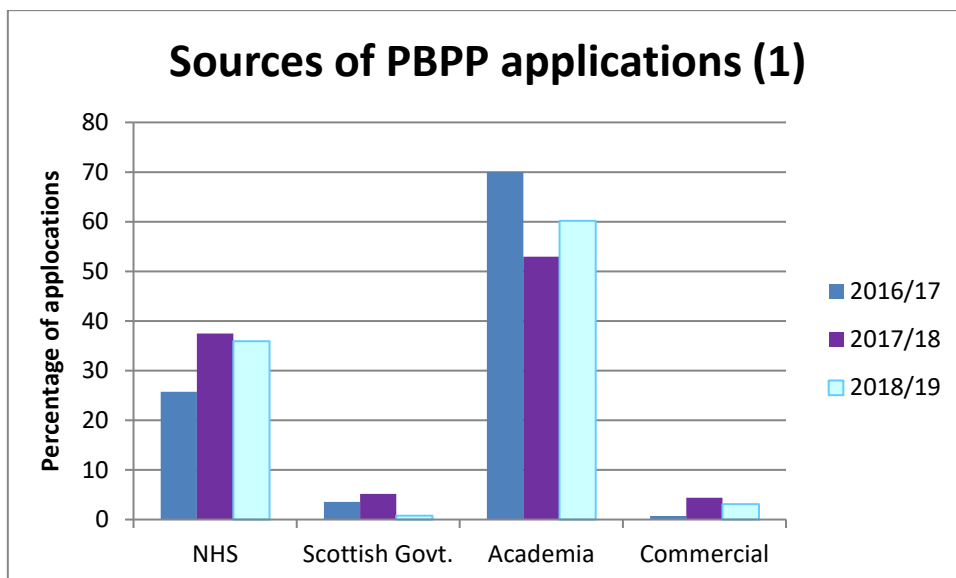


**Figure 2:** Numbers of applications submitted to the PBPP during 2018/19 (light blue) compared with 2017-18 (purple), 2016/17 (mid blue) and 2015/16 (dark blue)

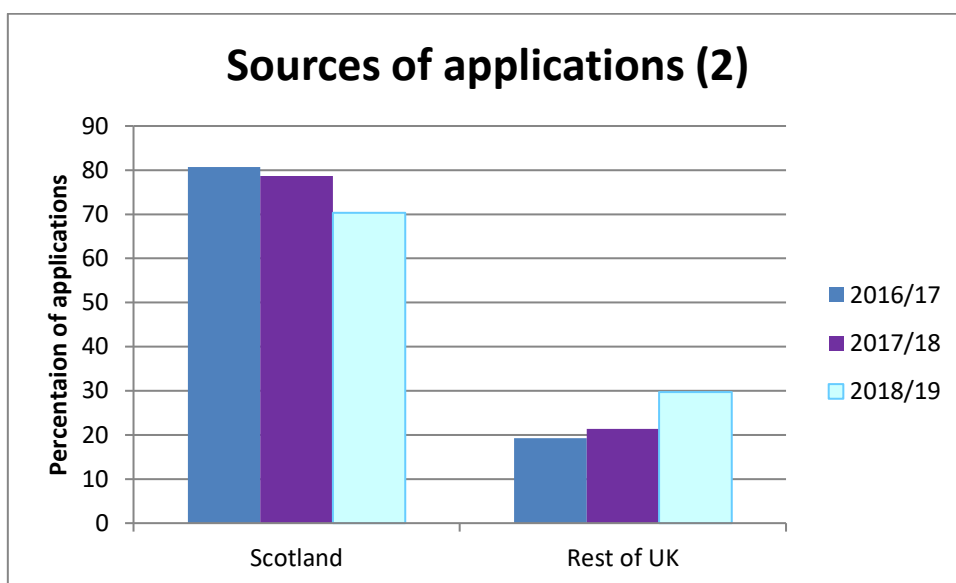
### Sources of applications

The organisations and countries from which applications were received are shown in figures 3a and 3b for 2018/19 (light blue) compared with 2017/18 (purple) and 2016/17 (blue). Figure 3a shows that the proportion of applications from academia remains high (60% in 2018/19 compared with 53% in 2017/18 and 70% in 2016/17); the proportion of applications from the NHS is similar to previous years (36% in 2018/19 compared with 38% in 2017/18 and 26% in 2016/17; only 1% of applications came from Scottish Government in 2018/19, compared with 5% in 2017/18 and 4% in 2016/17, while 3% of applications were from commercial companies in 2018/19 (compared with 4% in 2017/18 and 1% in 2016/17).

Figure 3b shows that the majority of the applications were initiated from within Scotland but this has decreased slightly (70% in 2018/19 compared with 79% in 2017/18 and 81% in 2016/17), with the others applications from the rest of the UK.



**Figure 3a:** Sources of applications to the PBPP in 2018/19 compared with 2017/18 and 2016/17.



**Figure 3b:** Sources of applications to the PBPP in 2018/19 compared with 2017/18 and 2016/17.

### Types of Applications

Applications for different types of studies were submitted and reviewed in 2018/19, reflecting the variety of research and service assessment that used NHS Scotland data for the benefit of the public. The different types of study are:

- Local and national 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.
- Various epidemiological studies investigated the risk or environmental 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; in particular, there were a few studies that were following up radiation workers exposed to radiation and their long-term health outcomes.
- 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.

A list of the approved application titles is available on the PBPP website:

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

## **Application outcomes**

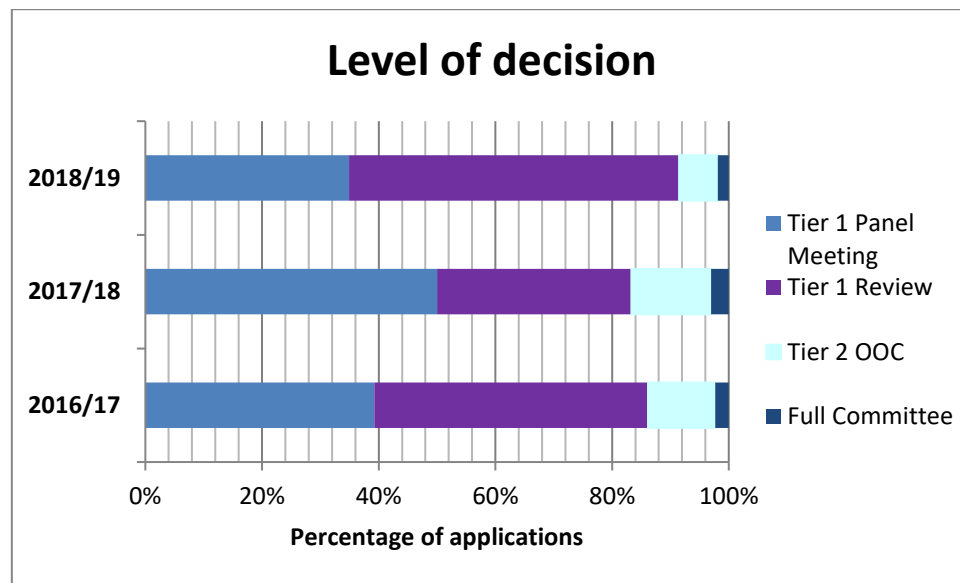
During 2018/19, following the scrutiny process, 106 applications had decisions made by the PBPP. Of these, 14 decisions were for applications that had been submitted during 2017/18 but had not completed the scrutiny process before the end of March 2018; 92 decisions were for applications submitted during 2018/19. The number of decisions is lower than that in 2017/18 (n=132) and in 2016-17 (n=130).

Of the 128 applications submitted during 2018/19, 86 were approved, seven were not approved, eight were withdrawn and 27 were carried over into 2019/20 to finish the scrutiny process.

The levels at which these applications were approved (tier 1 or tier 2) are shown in figure 4. Of the approved applications, 35 (33%) were “Approved with conditions”, whereby the application was approved subject to specific conditions which the applicant had to fulfil, usually before the project could start.

From figure 4 it can be seen that the majority of applications were approved either at a Tier 1 Panel meeting, or shortly afterwards following clarification sought from the applicant (Tier 1 Review). During 2018/19, 83 (91%) applications were decided at Tier 1 a slightly higher proportion than that in 2017/18 (n=110, 83%) and 2016/17 (n=112, 86% applications) were approved at Tier 1.

In 2018/19, only 9 applications (9%) were approved at Tier 2, which is lower than that for 2017/18 (n=22 applications, 17%) and 2016/17 (n=18 application, 14%). This may be a matter of timing, as by the end of March 2019, there were another 6 applications that had been referred to Tier 2 but had not yet reached decisions. All the referred applications had been assessed by Tier 1, and referred to the Tier 2 for further scrutiny as they were deemed to be of higher risk under the proportionate governance criteria.



**Figure 4:** Level of decisions for applications during 2018/19 compared with that in 2017/18 and 2016/17.

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

The NHS Central Register contains demographic details of everyone who was born or have died in Scotland, and anyone who has been registered with a General Medical Practitioner 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.

During 2018/19 there were 14 (11%) applications that requested flagging by NHSCR, either as part of a study requiring other NHS data, or as the only data requested. This is a similar proportion of applications to that requested NHSCR data in 2017/18 (22 applications, 16%) and 2016/17 (15 applications, 11%).

## Time to decisions

The PBPP measures two time-periods for decisions to review its efficiency and processing times, between an application being submitted to the 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 PBPP, from submission to decision. The time taken by the applicant to respond to any queries from the 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 PBPP, nor the time taken between PBPP approval and provision of the data requested.

The mean and median days to decision for both clocked days and total days are shown in Table 1 for 2018/19 (left) compared with 2017/18 (middle) and 2016/17 (right).

	2018/19		2017/18		2016/17	
Days to decision	Total	Clocked	Total	Clocked	Total	Clocked
Mean	37.38	26.16	40.82	30.28	42.10	30.98
Median	31	21	26.5	22	33	25

**Table 1:** Numbers of days to decision for 2018/19 compared with 2017/18 and 2016/17. The total and clocked mean and median times for all applications (i.e. with decisions at Tier 1 or Tier 2 are presented.

From table 1 it can be seen that the mean and median clocked times to a decision decreased by 4 days and 1 day, respectively, in 2018/19 compared with those in 2017/18. However, the changes are not big, perhaps suggesting that the processes are becoming as efficient as possible. Both the means and medians are shown for both clocked and total times, as the mean may be disproportionately affected by any outliers in the length of time for a decision. The median provides an idea of the middle point in the entire time-range for all applications reviewed by the PBPP. The PBPP continues to endeavour to improve the efficiency of the service.

## Performance Monitoring

The PBPP has a duty to be accountable to the public and stakeholders and strives to improve its processes continuously, 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 PBPP also takes on board lessons learned from novel, complex or commonly sighted applications often recording Policy Decisions and Case Law Principles to enable consistent decision making at both Tiers.

## Audit of Tier 1 review processes

In 2016/17 an auditing process was introduced with the purpose of reviewing the decisions made regarding applications to the PBPP. For this process, a set of applications that had been approved at Tier 1, were chosen at random to be reviewed by the Tier 2 committee.

The Tier 2 review was to consider whether these applications had been approved appropriately, using the proportionate governance criteria by Tier 1, or whether they should have been referred to Tier 2 for further scrutiny. Due to the success of this audit process in 2016/17, it was repeated for 2017/18. The results and feedback was considered as part of the Annual PBPP training day in September 2018. The audit report summary is published on the PBPP website at the link below.

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

## **Lessons Learned**

In 2018/19 a “Lessons learned” exercise took place, after one specific application had taken a long time to proceed through the PBPP process. The application was a follow-up to a cancer trial and was using cutting-edge technology to try to define specific genetic biomarkers that would predict the responses to a specific treatment regimen. The application was further complicated by the involvement of a US-based biotechnology company. The biotech company requested tissue and patient information to be sent to the USA for use by their researchers, which, potentially, might contravene UK data protection law. The application was reviewed by the full committee on more than one occasion. Eventually, and after much discussion and changes, it was approved after 189 clocked days. The lessons learned exercise consisted of a meeting between the applicants, the eDRIS coordinator, the then PBPP Panel Manager and a member of the Tier 2 committee. The issues that arose were discussed and some suggestions made for improvement of the PBPP process. A report was written with recommendations for PBPP, most of which, where practicable, are in the process of being implemented.

Not long after this Lessons Learned process, another application was received that was not dissimilar to this first application and the research team contained some of the same applicants. Due to the Lessons Learned process, the second application was more clearly written and the many of the difficulties encountered in the first application had been avoided through changes in methodology and process. This application was referred to Tier 2 Out of Committee from the Tier 1 panel. After some clarifications the application was approved, after 52 clocked days.

This exercise has indicated that Lessons Learned processes can be useful for applicants and all involved in the PBPP process, to try to increase understanding for both applicants and panel members and to implement adaption of processes to reduce privacy risk while still achieving the required outcome.

## **Annual PBPP Workshop 2018**

The third PBPP Annual Training Day was held on 4<sup>th</sup> September 2018, at the Technology Innovation Centre, Strathclyde University, in Glasgow. The programme consisted of a mixture of presentations and workshop-style discussions.



Brian Houston opened the proceedings as Chair of the Public Benefits and Privacy Panel and set out the day and its interesting and informative agenda. Professor Chris Dibben, from the University of Edinburgh, presented on the Scottish Longitudinal Study (SLS) cohort. His presentation included information on how the SLS was created, the sorts of information that it includes and its governance processes. The presentation was well received and people appreciated the background to a cohort for which there have been a number of applications to PBPP. Carol Porteous, from the University of Edinburgh, gave a timely presentation on Public Engagement. This included some definitions of what it is and what it is not, as well as some examples of things to look at on a PBPP form. The discussion afterwards was lively and wide-ranging, and many people were interested and stimulated. The information from this session has informed the reviews of applications at Tier 1 panels.

The morning workshop discussions looked at Data Controller Scenarios, in the light of changes from the introduction of GDPR, which had been written by the PBPP Panel Manager. There were five scenarios and each breakout group addressed one of them. The feedback was that these were quite tricky, as they were designed to be, but they were helpful to highlight many of the 'greyer' areas which are encountered in the Information Governance world.

In the afternoon, Penni Rocks and Elena Beratarbide, from Scottish Government, gave a presentation on the Scottish Government Digital Health Care Strategy. Participants were invited to give feedback and to contribute to with the review.

The afternoon discussion was asking "What does every applicant need to know?" from a Tier 2, Tier 1 or eDRIS Research Coordinator perspective. The responses were put onto post-it notes and these have been collected and collated for further use in developing course materials, including an application from the "Tooth Fairy" (see below).

At the end of the afternoon, Professor Abbe Brown, from the Tier 2 committee summarised and closed the day, with comments on the day and what we had learned.

## **Resourcing the PBPP**

The Panel is managed centrally from NHS NSS by the Panel Manager (funded by Scottish Government) and a Panel Administrator (part-funded by NHS NSS). During 2018/19, the team was augmented by the addition of a part-time Depute Panel Manager (Scottish Government-funded).

The Tier 1 Panels are resourced by NHS IG Practitioner staff, whose time is provided by the NHS Health Boards at the request of the Scottish Government.

The Tier 2 Panel members contribute their time voluntarily, and is not formally committed by any organisation. During 2018/19 a vacancy arose for a Caldicott Guardian to sit on the Tier 2 committee, but despite a number of queries, this was not filled.

All members are entitled to reimbursement of expenses for travel to and from meetings or PBPP events, reimbursed by the Scottish Government.

## **Operational Group**

The Operational Group was established in 2016 by the PBPP committee, and has continued its work during 2018/19. The Operational Group focuses on the development of PBPP processes, public engagement and support for the PBPP management team. Members of this group comprise the NSS Caldicott Guardian (Chair), Panel Manager, an eDRIS representative, a Data Protection Officer, two Information Governance leads, and a representative from NHSCR. Some key areas that the group worked on throughout the year were:

- Training and communications: these included the development of a PBPP training course to be held at the Wellcome Trust Clinical Research Facility and plans for ongoing updates to the PBPP website.
- Resourcing of PBPP: Plans and processes for recruiting panel members.
- Performance Monitoring: Implementation of the recommendations from the Lessons Learned process; analysis of audit results.

## **Achievements for 2018/2019**

### **Training and Communications**

The PBPP acknowledges that transparency in decisions made to access NHS Scotland data is vital in order to protect the rights of participants and patients. The PBPP must ensure that the right balance is struck between safeguarding the privacy of all people in Scotland and the benefit to patients from improved outcomes and care informed by high quality research.

To help achieve this aim, a communications strategy was further developed in 2018/19, to make information about the PBPP more accessible to the public.

### **Conference Presentations**

Carole Morris (Information Consultant from eDRIS) gave two presentations at the International Population Data Network Conference in Banff, Canada from 12<sup>th</sup>–14<sup>th</sup> September 2018.

- The first presentation was entitled “NHS Scotland Public Benefit and Privacy Panel for Health and Social Care: 3 Years and counting...” Carole outlined the work and development of PBPP over the past three years. It was interesting to look back and see what has been achieved in that time.
- The second presentation was entitled “NHS Scotland Public Benefit and Privacy Panel for Health and Social Care: Audit of Tier 1 Decisions.” In this presentation, Carole summarised the process and outcomes of the first audit of Tier 1 approvals by the Tier 2

committee. The results and recommendations that have since been put into practice were also presented.

This was good publicity for PBPP and an illustration of how its processes and can be used as examples of good Information Governance practice on an international stage. PBPP congratulated Carole on the acceptance of her presentations.

### **Review of the PBPP website**

There is a lot of information on the PBPP website, but some of it could be made clearer. Through a plan of ongoing updates over time, the website has been updated and these will continue into 2019/20.

### **Development of an external PBPP training workshop, for potential applicants.**

On 7<sup>th</sup> March 2019, the first training course for applying to PBPP was held at the Wellcome Trust Clinical Research Facility, Western General Hospital. The aim was to educate applicants about when and why PBPP applications are needed for access to data, and the Data protection principles and processes to consider when filling in the application form. There were 18 attendees, 11 of whom filled in feedback forms. The feedback is summarised below.

The course was rated using grades **1** (bad) to **10** (good) under the following headings:

Course content:	<b>7</b> (n=1), <b>8</b> (n=4), <b>9</b> (n=4), <b>10</b> (n=2)
Course trainer:	<b>7</b> (n=1), <b>8</b> (n=1), <b>9</b> (n=4), <b>10</b> (n=5)
Course organisation:	<b>8</b> (n=2), <b>9</b> (n=5), <b>10</b> (n=4)

There were some very constructive comments regarding the course content and organisation, with some suggestions for improvement. These have been noted and incorporated into the course that, we plan to repeat.

### **Public Engagement**

On 8<sup>th</sup> April 2019 the Edinburgh International Science Festival held an event: Diagnosing with Data. The publicity material stated: 'Every time you visit the doctor or a hospital you generate medical data about you, your health, your treatment and the outcome. What happens to this data, who can access it and who does it benefit? At Edinburgh BioQuarter, a leading health and science campus which focuses on translational medical research, 'big data' is essential in exploring modern health care'. The event consisted of a panel discussion, chaired by Professor Polly Arnold (University of Edinburgh) and aimed to discuss digital healthcare data and its future. The panellists were Professor Nicholas Mills (University of Edinburgh Chair of Cardiology and Consultant Cardiologist), Dr. Sarah Chan, (University of Edinburgh, expert in the ethics of medical research) and Dr. Angus Ferguson (University of Glasgow, Public Benefit and Privacy Panel for Health and Social Care representative). The discussion was wide-ranging but tried to address the benefits of use of 'big data', and not necessarily just health data, while acknowledging the safeguards that need to be in place for this process.

### **Tooth Fairy application**

From the discussions at the Annual PBPP workshop, it was proposed that an application be written as an example application for applicants. The request was for an application that could not just be copied and pasted, but would give an indication of the how to fill in an

application form. Ideas floated were for applications from Father Christmas, the Easter Bunny but eventually the Tooth Fairy was decided upon, as it could request health (dental) data for an audit. With some input from Tier 1 panellists, the Tooth Fairy application was written by the Panel Manager and reviewed and approved at a Tier 1 panel, similar to the process for any other application. The proposal is to be used for training purposes and placed on the website as one example of an accepted application, although it does not cover all the different types of applications received by PBPP.

## **Ongoing Priorities and Challenges for 2019/20**

### **Partnership with other UK Governance bodies**

The PBPP is committed to working with governance partners across the UK in order to streamline the approvals process for those seeking access to health and social care data and to make the whole process across the UK as smooth as possible.

To achieve this aim, the PBPP will seek to strengthen collaborative relationships across the UK to sustain and develop information-sharing and to promote the UK as a centre of excellence for research. This will include strengthening our contacts with other approval bodies:

- Acting in an advisory capacity to the Human Fertility and Embryology Authority (HFEA) to scrutinise applications from Scottish applicants using HFEA and/or NHS Scotland data;
- Exploring the possibility, and practicalities, of incorporating the PBPP application process into the Integrated Research Application System (IRAS), provided by the Health Research Authority (HRA). This system is used for the approval processes for all research projects involving patients and seeking both NHS Ethics and NHS R&D permissions. The Confidentiality Advisory Group (CAG), which approves use of confidential patient information without consent in England and Wales, also uses the IRAS system. In theory, addition of the PBPP process for research applications would reduce a layer of complexity currently seen for the approvals processes required for research, requiring data from across the UK. This is on hold but there have been ongoing conversations with CAG/HRA and NHS Digital regarding cross-border applications;
- Establishing further contact and conversations with MRC Regulatory Support and other approval bodies (e.g. ethics) to increase understanding of the complementary roles of different regulatory bodies.

### **Increasing Capacity of PBPP at committee level**

The PBPP committee is aware that there are ongoing capacity issues at Tier 2 that need to be addressed. An audit of Tier 2 will be carried out in 2019/20 and the results used to inform an internal review of PBPP and how it can improve its processes.

## Scottish Government Digital Health and Care Strategy

In 2017, the Scottish Government launched its Digital Health and Care Strategy for Scotland. This will focus on person-centred health and social care and is at the heart of the strategic agenda in Scotland. A new, integrated Digital Health and Social Care Strategy is being developed that will build on achievements to date and set out future development and priorities.

A number of “domains” are under review:

- A National direction and leadership
- B Information Governance, Assurance cyber security
- C Service transformation
- D Workforce capability
- E Digital Platform
- F Transition process

Under Domain B, the Information Governance processes across NHS Scotland and use of data will be reviewed, including those of the Public Benefits and Privacy Panel for Health and Social Care. The aim of this review is to ensure that health and social care information is available to patients and their health and social carers when it is required. At the same time, it is imperative that such personal information is handled appropriately, safely, secure and in an approved and controlled way.

The Domain B review strategy aims to:

- Partner with other groups across health and social care to improve access using ‘privacy by design’
- Use data for research and innovation, within the wider NHS and public sector
- Prepare research-ready data for research and statistics
- Streamline the information governance and assurance landscape reducing unnecessary complexity and develop a national approach for assurance and cybersecurity – as a “Once for Scotland.”

The aim is that by 2020, clear arrangements will be in place to deliver a simplified and consistent national approach for information governance, that will take into account the different needs of users and citizens and provide clarity around information sharing across health and social care,

Further details are available on the Scottish Government website:

<https://www.digihealthcare.scot/home/news-and-events/scotlands-new-digital-health-and-care-strategy-published/>

## Conclusion

From this report it can be seen that 2018/19 has been a year where the PBPP has developed and built on the processes previously established. These processes will continue to be refined as the PBPP continues to operate to ensure the safe use of NHS Scotland data for the benefit of the public in Scotland.

## Quotes

**Applicant:** *My personal experience with eDRIS, PBPP and the national data safe haven, is that I have found them extremely helpful and approachable, facilitating various complex data linkages for our study in a timely fashion and with little difficulty. I have also been guided thorough the PBPP application and amendment processes regularly by them and again, our various approvals have come through with little difficulty -I think in a large part thanks to eDRIS support.*

**Tier 1 member:** *I would add that the Tier 1 panels have been really fun; they are a different aspect of daily life in the NHS which is fascinating.*

**Tier 2 member:** *From the PBPP training day: the scenarios were really tricky and highlighted the grey areas that exist in Information Governance.*