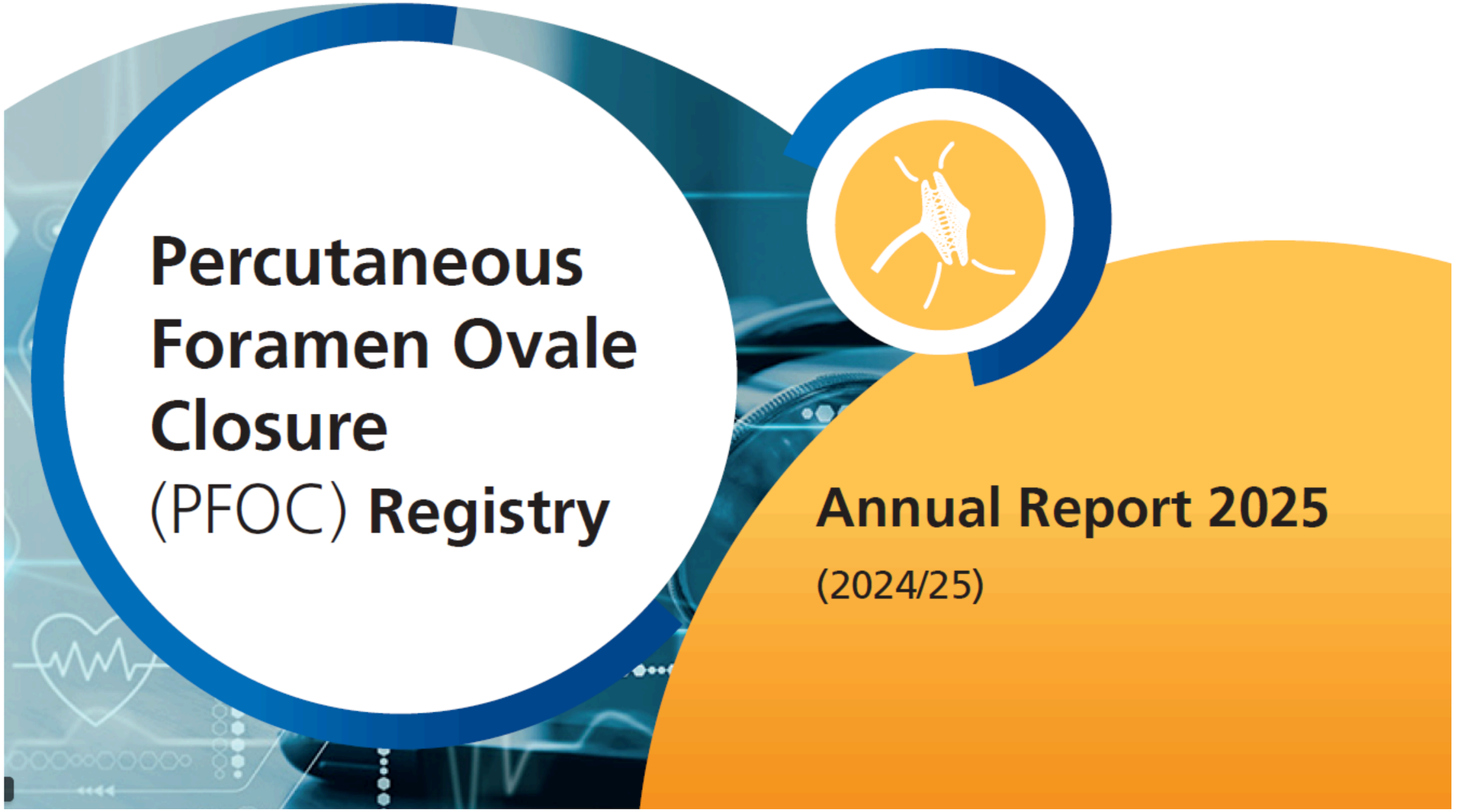
NCAP

NATIONAL CARDIAC AUDIT PROGRAMME

NICOR



Percutaneous Foramen Ovale Closure (PFOC) Registry

Annual Report 2025

(2024/25)

Report at a glance

All data are for 2024/25 unless otherwise stated

A total of 1,996 PFOC procedures were reported to NICOR

1,051 cases (53%) were submitted to the PFOC Registry and 945 (47%) to the National Congenital Heart Disease Audit (NCHDA)

Patient access to the PFOC procedure varies widely geographically, with people in the South East of England and Yorkshire being served best

80% of cases had the device type recorded (this should be 100%)

<60% of PFOC cases had the device serial number reported, which is very poor given legislation requires 100% recording of implanted devices

Completeness of demographic information for PFOC cases is good

77% of NHS patients underwent the PFOC procedure for the secondary prevention of stroke (the most common indication) with evidence of prior stroke on brain scans

PFO is most commonly diagnosed using bubble contrast transthoracic echocardiography, or bubble contrast transoesophageal echocardiography

PFOC procedures usually involve ultrasound-guided puncture of the femoral vein and procedural image guidance with transoesophageal or intra-cardiac echocardiography to confirm correct device placement

86% of procedures (where recorded) were performed with Amplatzer (Abbott), Occlutech and Gore devices

Most patients receive clopidogrel or anticoagulants prior to undergoing PFOC and dual anti-platelet therapy is the most common post-procedure treatment

Recommendations

1. All PFOC procedures in adults should be submitted to the PFOC dataset (unless they have congenital heart disease or undergone congenital surgery)

2. Device type and serial number should be completed in all cases to satisfy the requirements of the Medical Devices Outcome Registry

3. Data should be entered directly into the PFOC dataset, or can be submitted by third party software which is configured to submit all datapoints, as accurate conclusions about the practice of PFOC requires complete data

Introduction to PFOC and previous audits

The PFOC Registry is part of the National Cardiac Audit Programme, run by the National Institute for Cardiovascular Outcomes Research (NICOR).

Percutaneous closure of a Patent Foramen Ovale (PFOC) is a minimally-invasive catheter-based treatment to close a hole in the heart. This has been undertaken since the 1990s, initially as part of a congenital heart disease service. The predominant indication is to prevent stroke due to paradoxical embolus, where a clot from the leg veins moves up to the heart. In a normal heart the clot would go into the lungs and be 'filtered out' in the lung capillaries. However if a hole in the atrial septum is present, such as a PFO, the clot can miss out the filter, and pass into the systemic circulation, where it can be pumped into the brain, heart or peripheral circulation causing a blood vessel blockage and damage to the tissue that the blood vessel supplies. This mechanism is called a paradoxical embolus. Randomised controlled trials have shown that PFOC can prevent recurrent stroke in those who have suffered a stroke due to a paradoxical embolus.

Initial audits were undertaken through the NCHDA data collection, prior to a process of Commissioning through Evaluation from 2013-2016. Following a Preliminary Policy Proposal Process, routine commissioning started in 2019. A dedicated dataset was then designed and the PFOC database was opened in April 2024. NHS-funded centres are required to enter PFOC data into the audit, however as historically the audit was conducted through the NCHDA, it is taking some time to ensure that congenital centres switch to submitting to the new PFOC database, and new centres join the database and commence data entry.

The dataset has been designed to collect data that is specifically relevant to the indications for PFOC and assessing its safety and outcome. Furthermore it will accurately identify and record the serial number, manufacturer and model of the implanted device. It is planned to integrate the collected data with other nationally collected data, such as Hospital Episode Statistics and mortality reporting. More details on the PFOC registry and its methodology can be found here.

We are very grateful to all the hospital teams that provide the data to NICOR. This allows us to develop a quality improvement programme so that patients can receive optimal care. It is important that accurate and complete data are provided within the commissioned timelines for us to develop the most useful feedback information to those involved in the care of patients being considered for this treatment.

NICOR PFOC Registry team

20 NHS hospitals performed PFO closure procedures in 2024/25

NHS England has funded 20 hospitals to deliver PFO closure. This map shows the location of the centres that are registered or submitting data to NICOR. This does include private hospitals, one of which is performing NHS funded procedures.

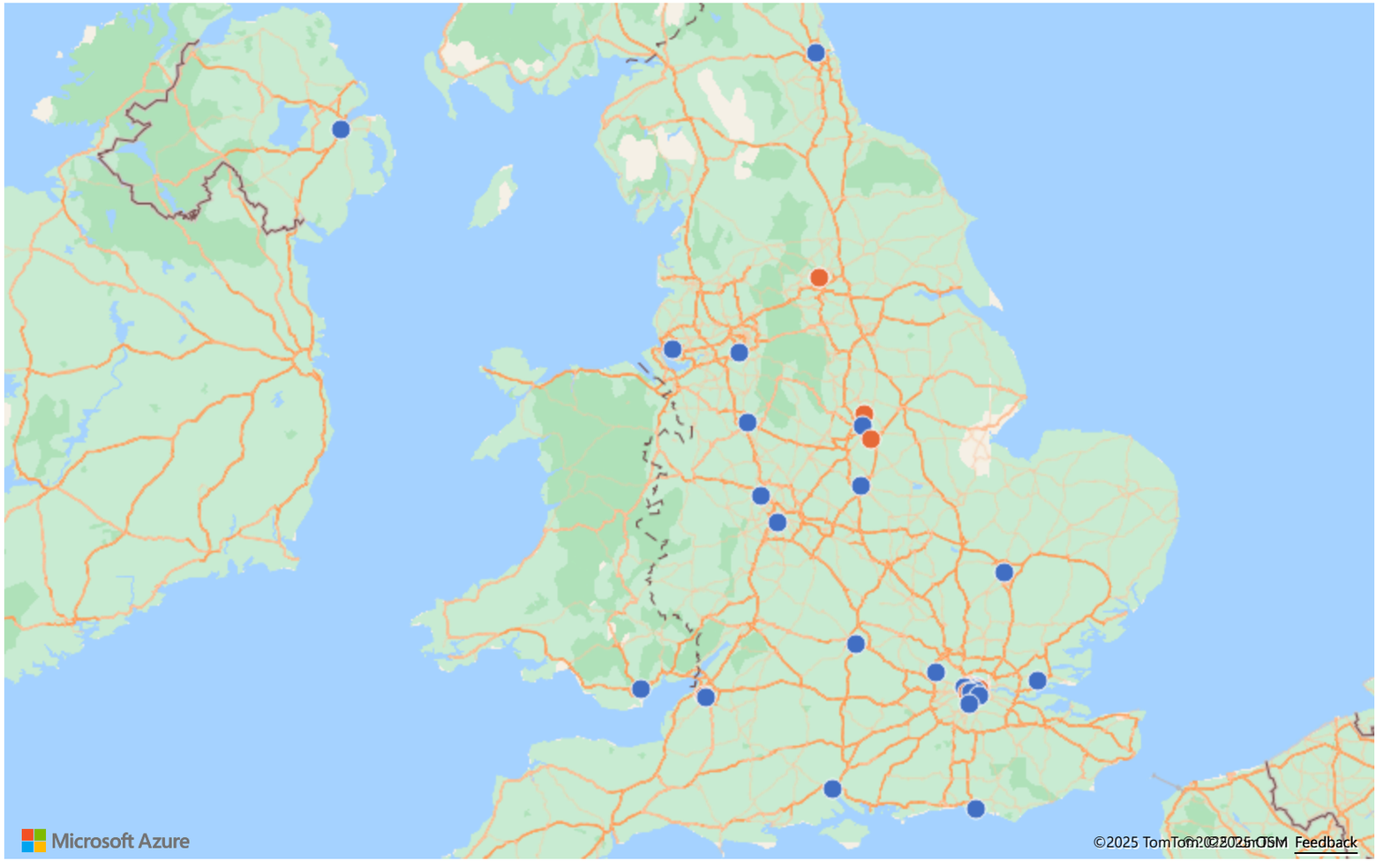
The following hospitals are commissioned to provide a service but have not submitted data to the PFOC Registry in 2024/25:
- Glenfield Hospital, Leicester (currently undertaking procedures at Spire Hospital, Nottingham and reporting from there)
- King's College Hospital, London
- Wythenshawe Hospital, Manchester
- University Hospital of Wales, Cardiff

Leeds General Infirmary and Queen Elizabeth Hospital ,Birmingham submitted data to the NCHDA but not to the PFOC Registry in 2024/25. New Cross Hospital has sent limited data.

The geographical distribution of hospitals shows some with very large catchment areas, with more hospitals in the South East of England, and the West Midlands.

An important focus of the audit is to confirm that there is equity of access to NHS-funded PFO closure procedures, and in order to do this a

Location of hospitals expected to submit data to the PFOC registry



Data completeness for procedural variables requires substantial improvement

Around a third of NHS funded hospitals did not submit PFO closure procedure data for 2024/25 to the audit. Furthermore, where data were provided, completeness of some data fields was below the expected level.

The new dataset captures important information about why and how PFOC procedures were performed. Data gaps may arise from using third party software that has not been configured to collect everything required as some hospitals appear to have 0% completeness for added data fields.

The most concerning issue relates to device serial numbers. Capturing this is a mandated requirement to be compliant with the directive for the Medical Devices Outcomes Registry.

PFOC centres have indicated that changing to enter data into the PFOC audit rather than the NCHDA registry was delayed because of Caldicott Guardian approval (e.g. data for the South West reflects only part of the 2024/25 period). NICOR is working with hospitals to ensure complete and accurate data collection to the PFOC registry

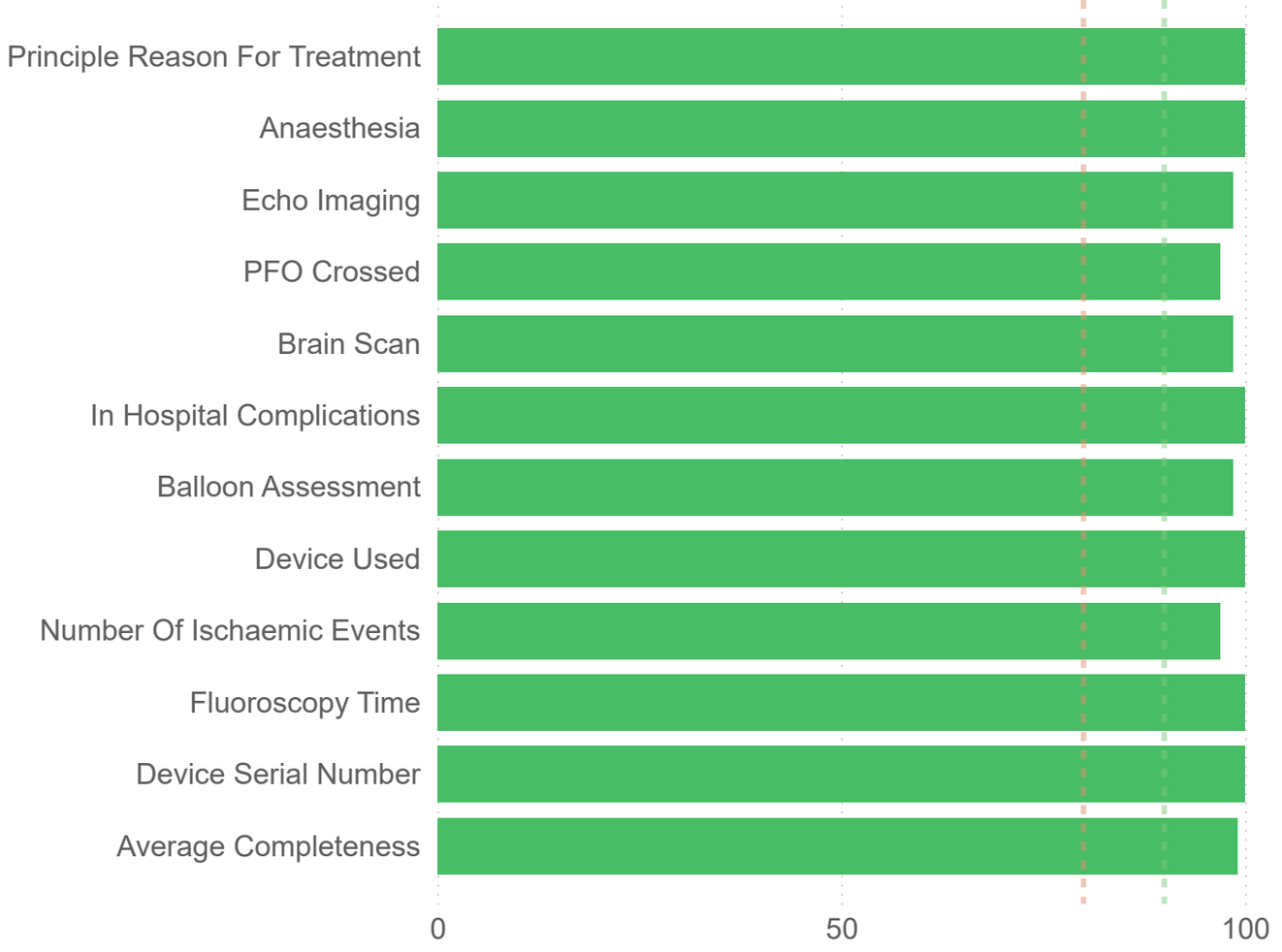
Select a hospital below to see its specific data.

Note: Vertical orange line = 80% data completeness, green = 90%

Select hospital

Freeman Hospital

Average percent completeness of selected procedural variables in PFOC audit (2024/25)



Contents page

Data completeness for demographic variables met standards in most hospitals in 2024/25

Most hospitals submitted data on patient demographics to an acceptable standard in 2024/25.

This is important to ensure that all patients can be cross-referenced with HES (Hospital Episode Statistics) and mortality data (Office of National Statistics) so that all complications, readmissions and death can be reliably recorded.

It also enables analyses to assess that the access to and quality of care is equitable across different population groups.

All hospitals should provide complete and accurate data to the registry.

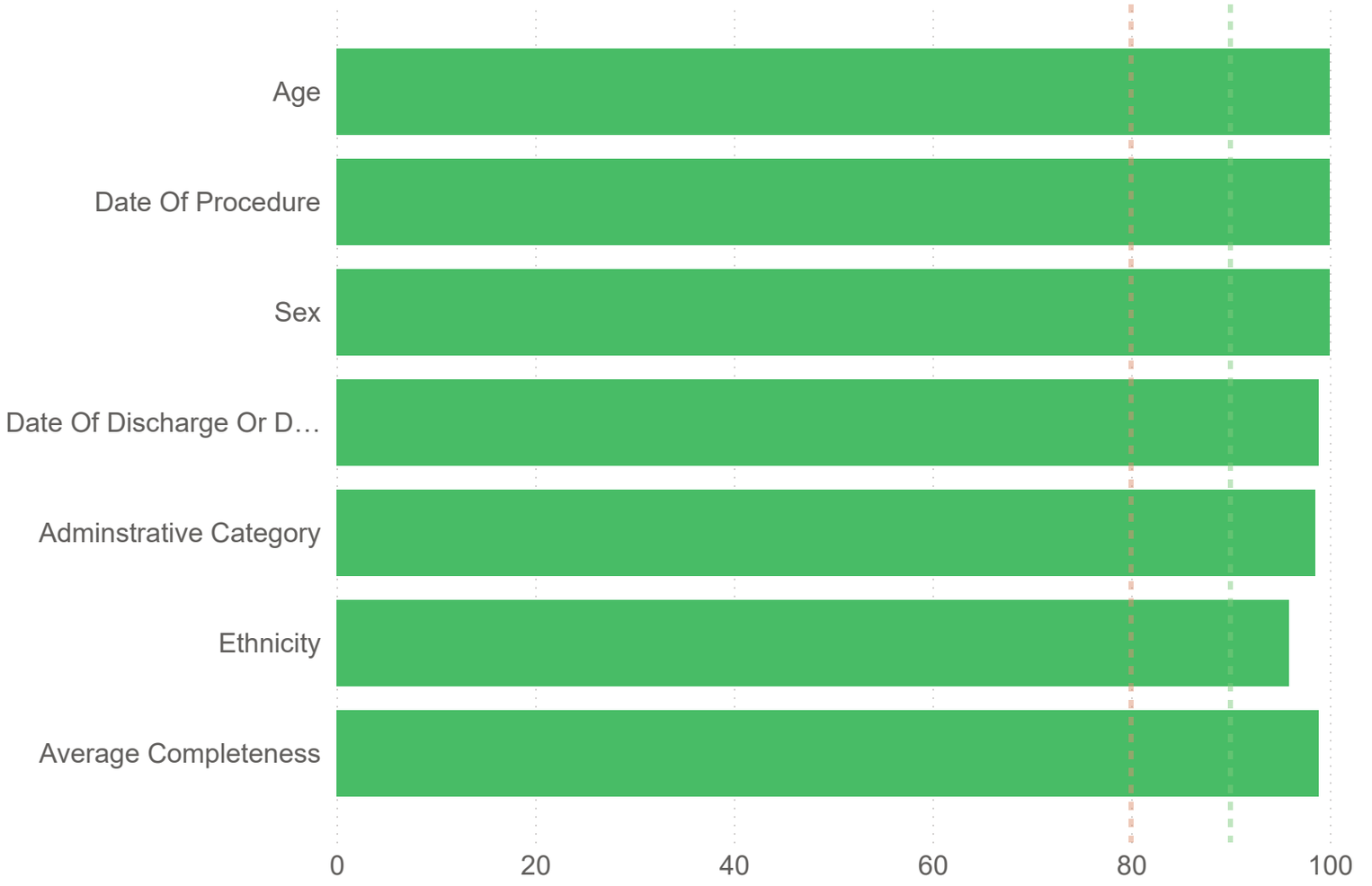
Select a hospital below to see its specific data.

Note: Vertical orange line = 80% data completeness, green = 90%

Select hospital

All hospitals

Average percent completeness of demographic variables in PFOC audit (2024/25)



Contents page

Contents

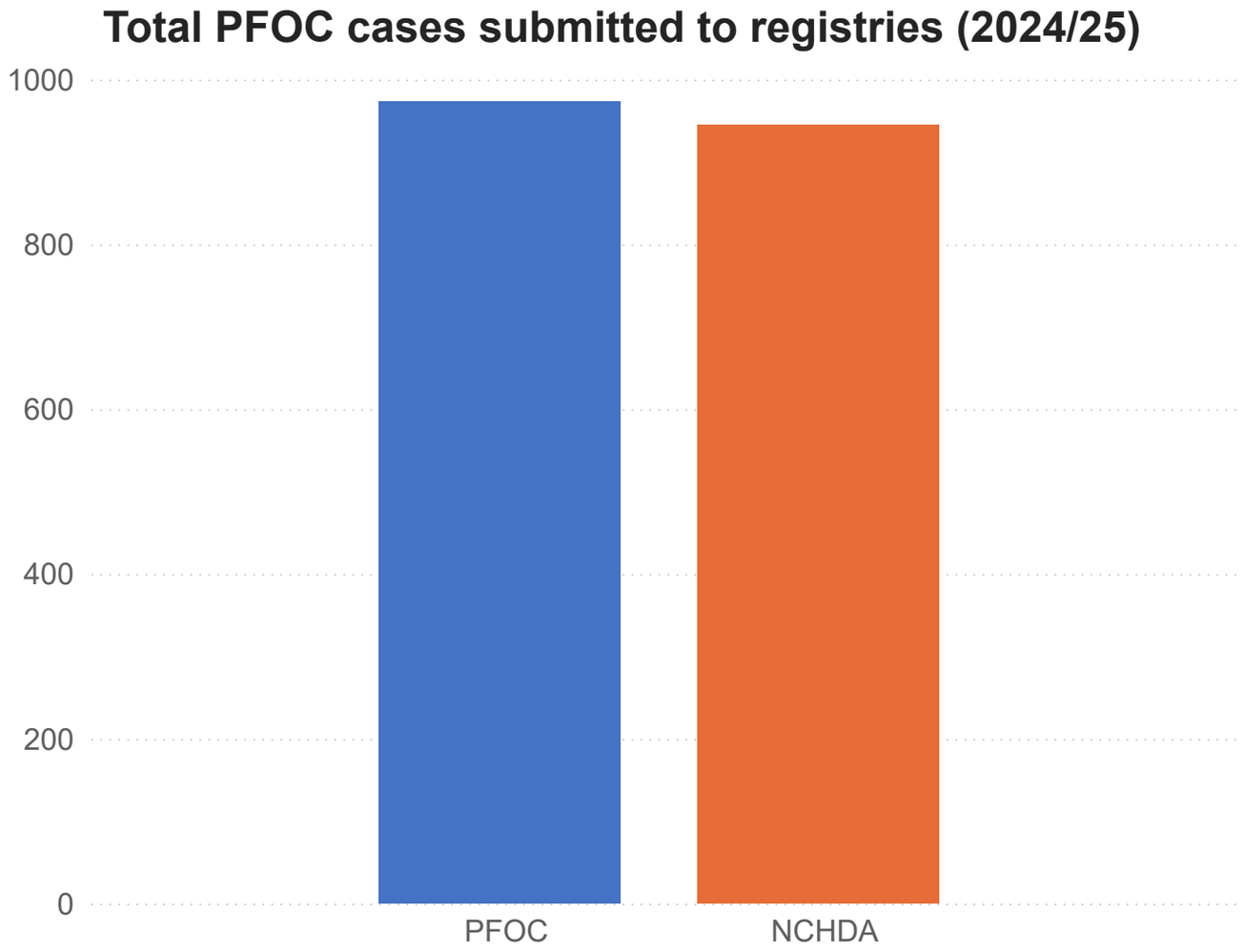
Clicking on the page title below will take you to the relevant slide

Only just over half of the cases are reported to the PFOC database

Around 2,000 PFOC procedures were reported to NICOR in 2024/5, but only 973 were reported to the PFOC database (>18 years old) and 945 were reported to the National Congenital Heart Disease Audit. It is likely that some cases are not reported to either database.

The dataset for each audit is different, so it is not possible to amalgamate the data. NICOR has written to the hospitals to request that future submissions will be to the PFOC database, in order to ensure the best possible data quality.

Data shown in subsequent slides are from the PFOC Registry but have relevance as they relate primarily to adult patients undergoing PFO closure to prevent stroke.



Contents page

PFOC procedure numbers varied widely across geographic areas

There is a wide variation in PFOC cases per million population for:

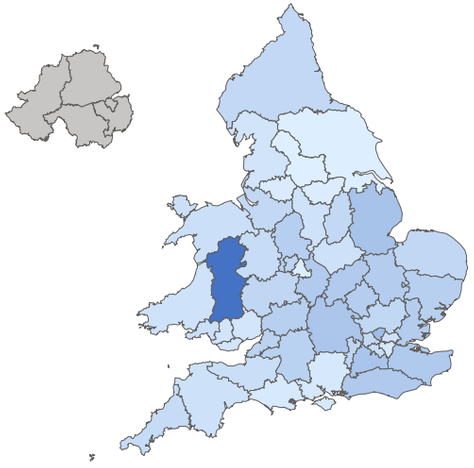
- The 42 Integrated Health Boards (ICBs) in England and 7 University Health Boards (HBs) in Wales (commissioning organisations)
- The 16 Cardiac Networks in England and Wales (service delivery networks).

This may reflect either the geographic distribution of PFOC centres or incomplete data entry by some. No data were received from Wales and data shown are for Welsh patients treated in England. Complete data are required to examine equity of access in the future.

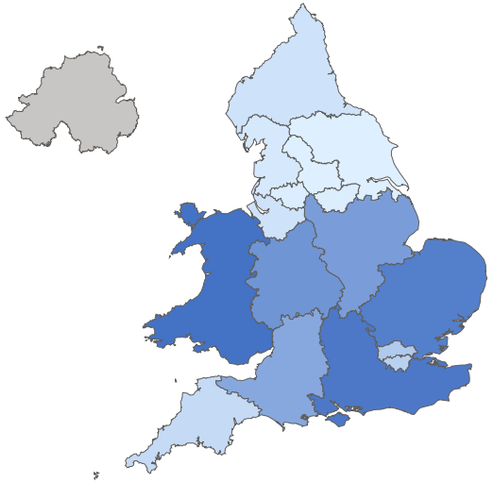
Despite these issues, there is likely to be high geographic variation in access to PFOC across. Access appears greatest in the South East, where the density of hospitals offering the procedure is highest.

Select the actual or age-adjusted rate below or hover over the maps to see specific data.

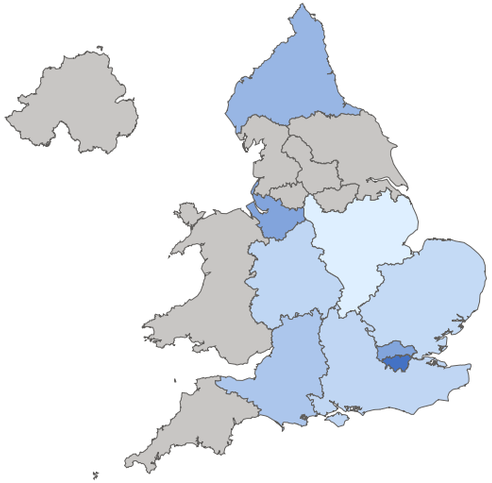
Rates of PFOC procedures pmp based on patient home address by ICB/HB (2024/25)



Rates of PFOC procedures pmp based on patient home address by Cardiac Network (2024/25)



Rates of PFOC procedures pmp based on hospital location by Cardiac Network (2024/25)



Select rate

Actual rate

There was a wide variation in the number of procedures by hospitals in 2024/25

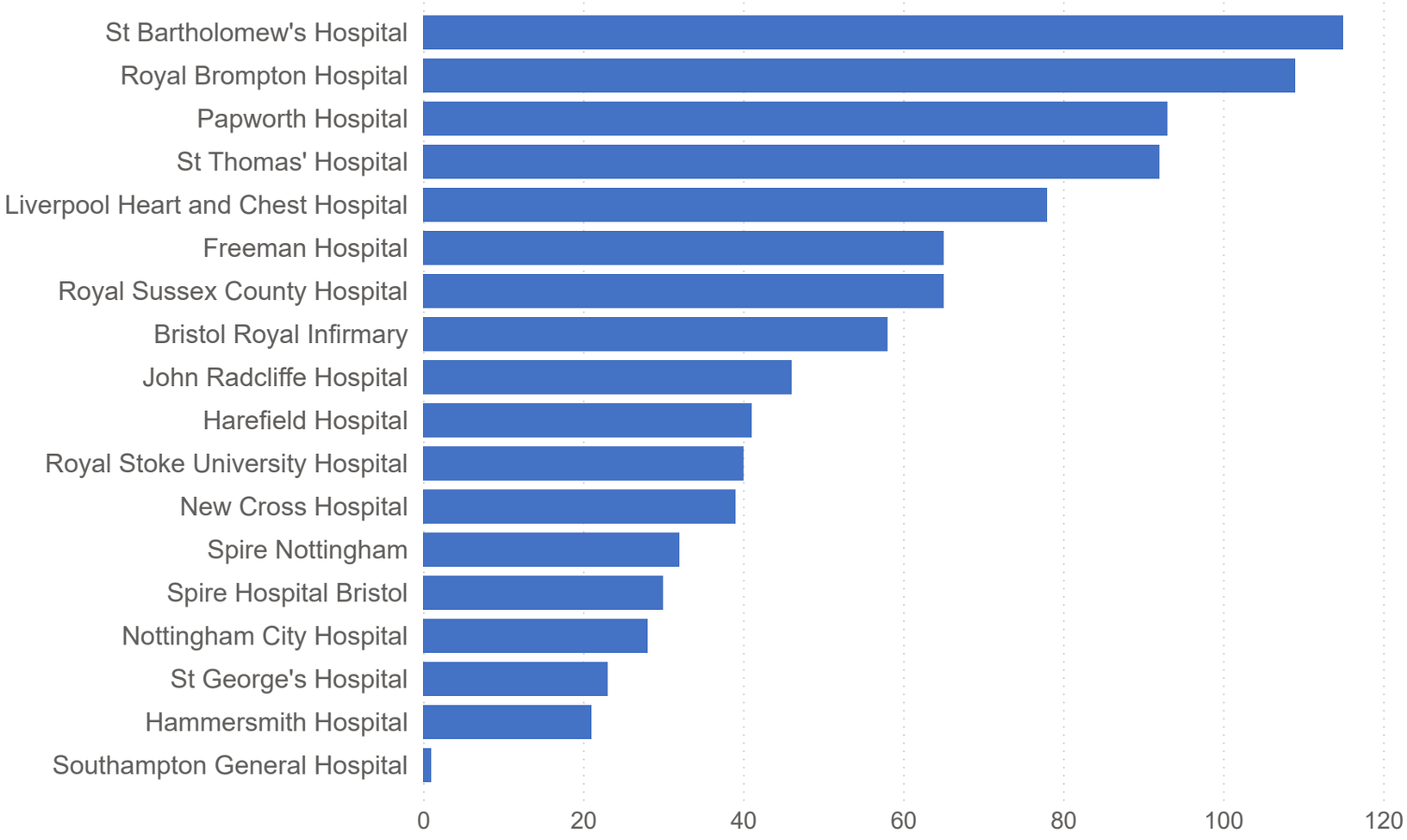
The number of PFOC cases reported by each hospital in 2024/25 varied from 117 in St Bartholomew's Hospital to 1 in Southampton General Hospital.

Knowledge of practice in the UK, including information from PFO device manufacturers and operators indicates that some hospitals are not submitting all cases undertaken. This may reflect delays in registration and difficulties transitioning from NCHDA data collection (often submitted via third party software), to the PFOC database.

If the data are taken at face value, only 9 hospitals undertook the recommended 50 or more PFOC procedures per year.

Some of these centres may have more than one operator, and some operators may work in more than one centre. Individual operator numbers have not been analysed.

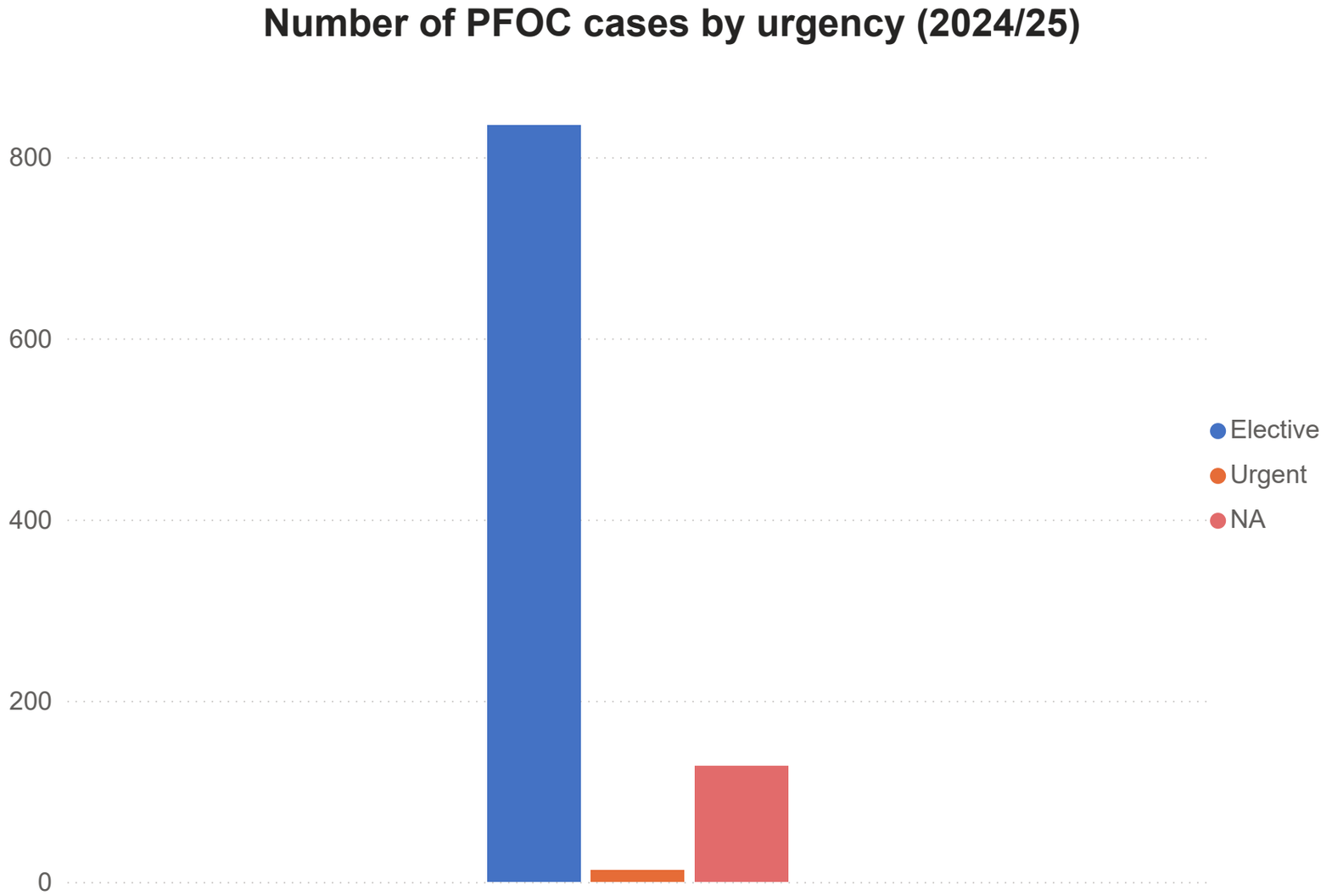
Number of PFOC procedures reported by hospital (2024/25)



98% of PFOC procedures in 2024/25 were elective cases

PFO closure for stroke prevention is almost always an elective procedure, as extensive investigation and multi-disciplinary team (MDT) discussion is required for these patients.

The most likely indication for PFO closure to justify it being urgent or an emergency would be desaturation such as in orthodeoxia platypnea, or other desaturation syndromes.



Female patients undergoing PFOC were on average 3 years younger than male patients in 2024/25

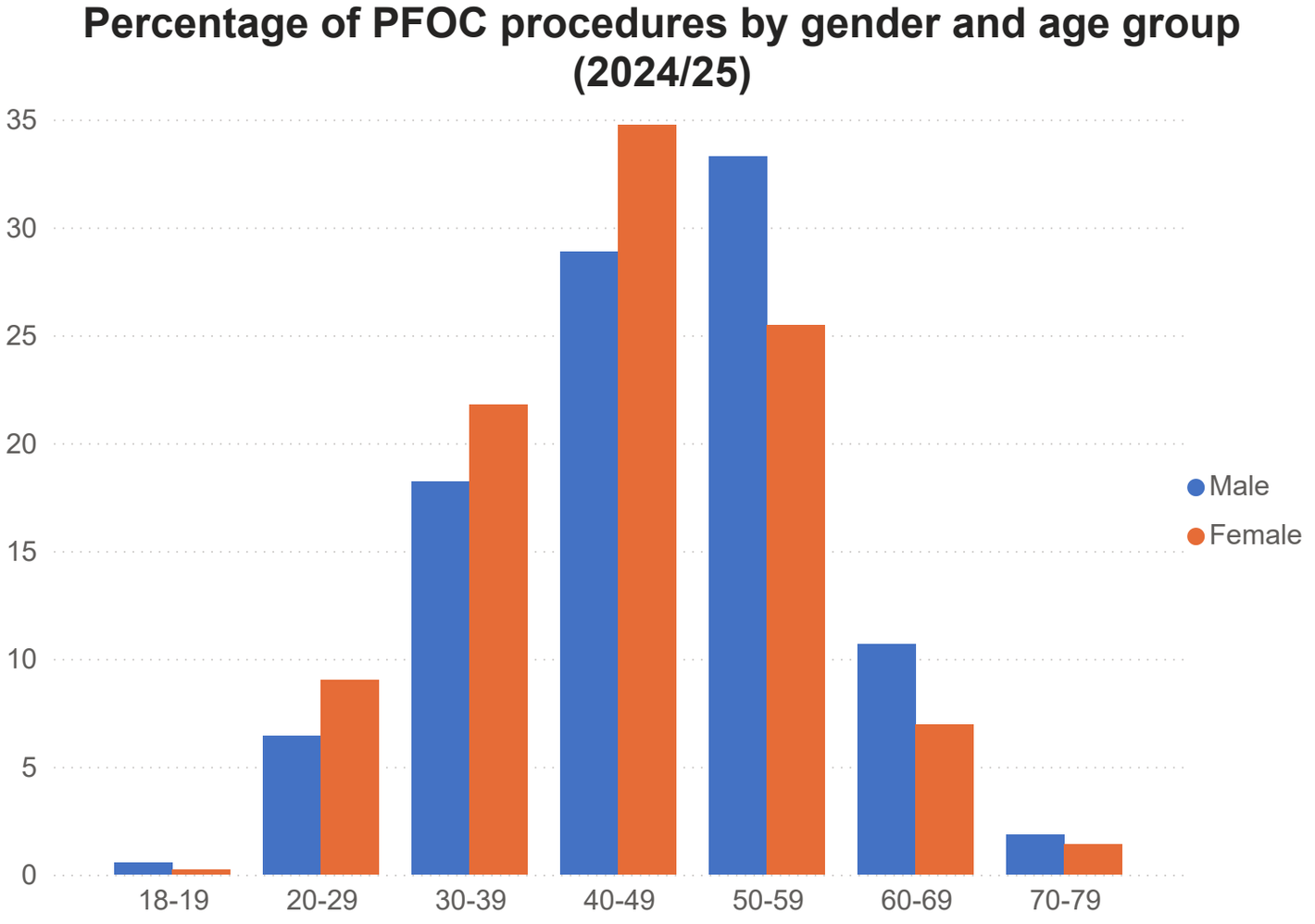
The median age of patients receiving PFOC treatment in 2024/25 was 48 years for males and 45 years for females. More females have been treated in the under 50s group, while males are more frequently treated amongst those aged over 50.

This confirms a previous finding from data collected between 2021 and 2024, collected by the NCHDA audit and described in our 2023/24 PFOC report, where we reported a similar age and sex relationship.

One possible explanation for this is that younger females may suffer more paradoxical emboli owing to:

- Their higher levels of oestrogen, which can promote clotting (those over 50 may have lower oestrogen levels due to the menopause)
- The use of the combined contraceptive pill, which makes venous thrombosis more likely
- Pregnancy, which can promote clotting.

Other possibilities may relate to patterns of presentation or equity of access.



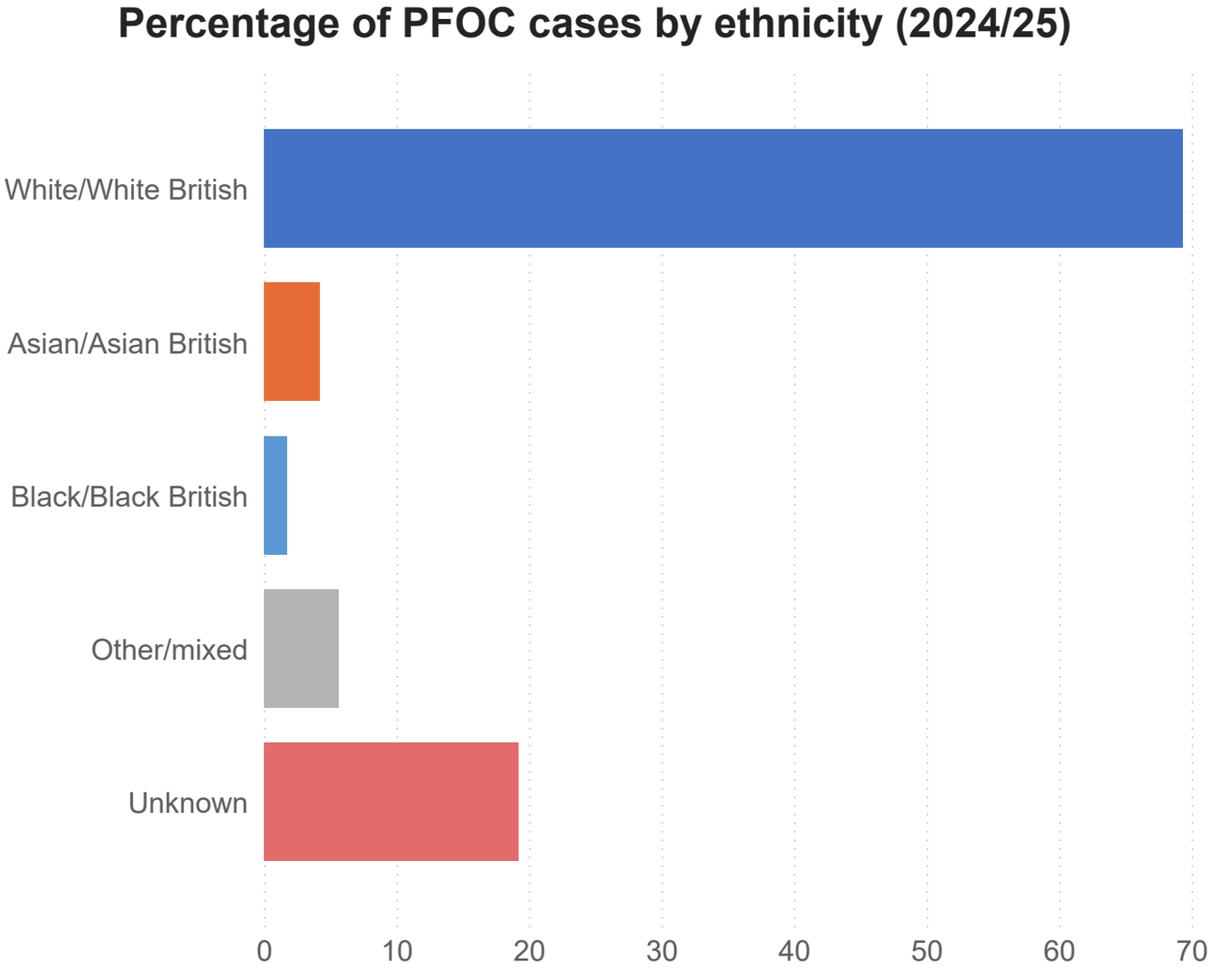
In 2024/25, reported PFOC closure procedures were performed predominantly on patients of white ethnicity, but data completeness is poor

The most frequent ethnicity of PFOC patients is White/White British.

Unfortunately, the second most frequently recorded outcome is 'unknown', limiting the usefulness of the derived information.

There is no scientific evidence of a difference in PFO frequency across ethnic groups and we would therefore expect the proportion of procedures to match the national distribution of ethnic groups.

Hospitals should ensure submission of complete ethnicity data, as without this it is not possible to ensure equity of access across all ethnic groups. Changes to the list of options for ethnic origin may be needed, or cross-reference with HES data, to more precisely describe the cohort of PFOC patients.



PFOC patients come from all socio-economic groups, though the procedure may be more accessible to those in higher economic groups

This graph suggests that access to NHS-funded PFOC is slightly better in the top two socioeconomic quintiles as measured by the index of multiple deprivation (IMD) (group 1 is the most deprived, group 5 the least deprived).

For private care there is a markedly higher prevelance of the top two quintiles, which is less marked, but still present for NHS care.

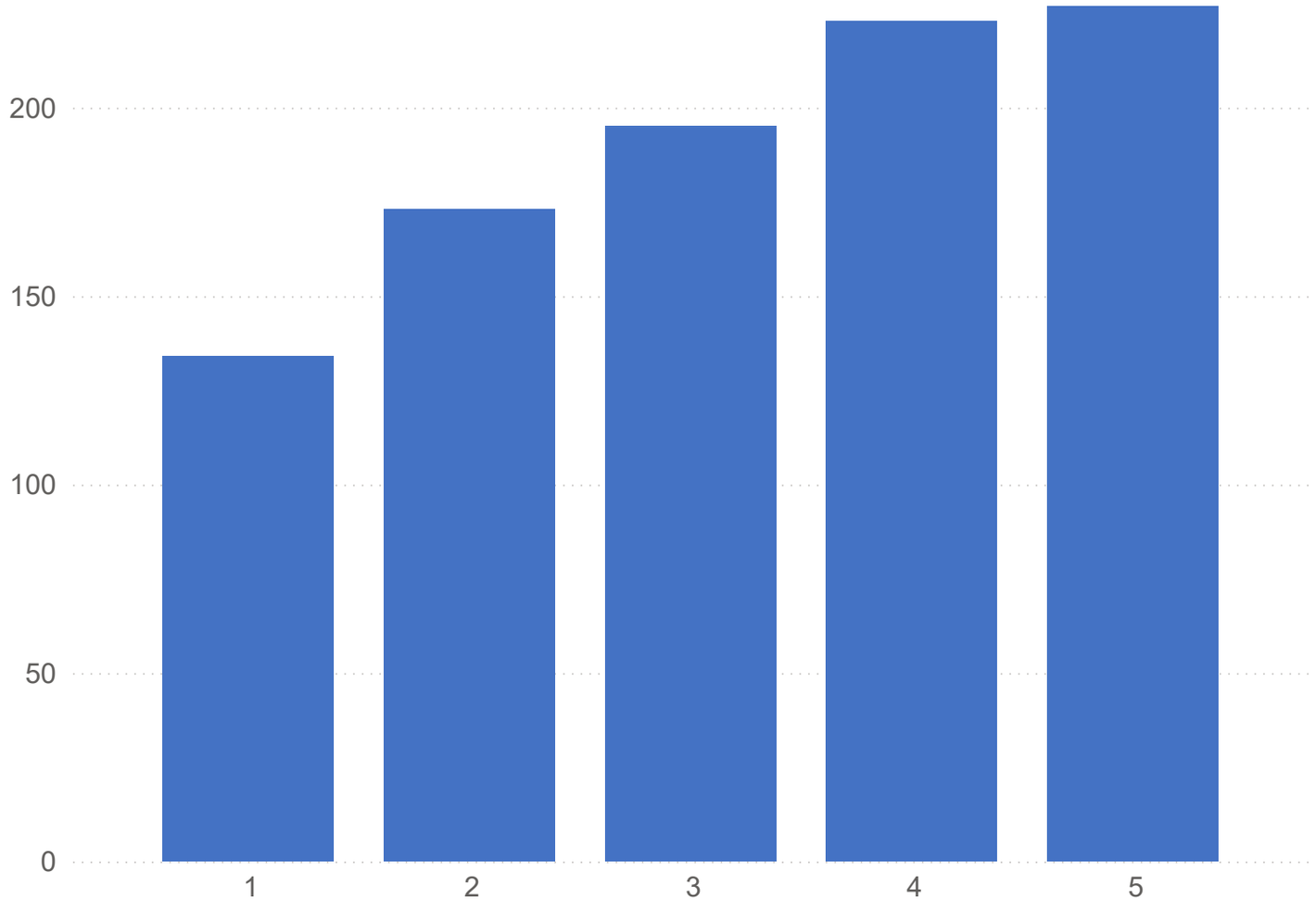
Self-funded care is expensive and the cost of private medical insurance is also high.

Select NHS-funded and/or Self-funded below to see specific data, showing the higher numbers in the top two quintiles receiving private care.

Select NHS-funded and/or Self-funded

All

PFOC cases by IMD quintile (2024/25)



NICOR

Contents page

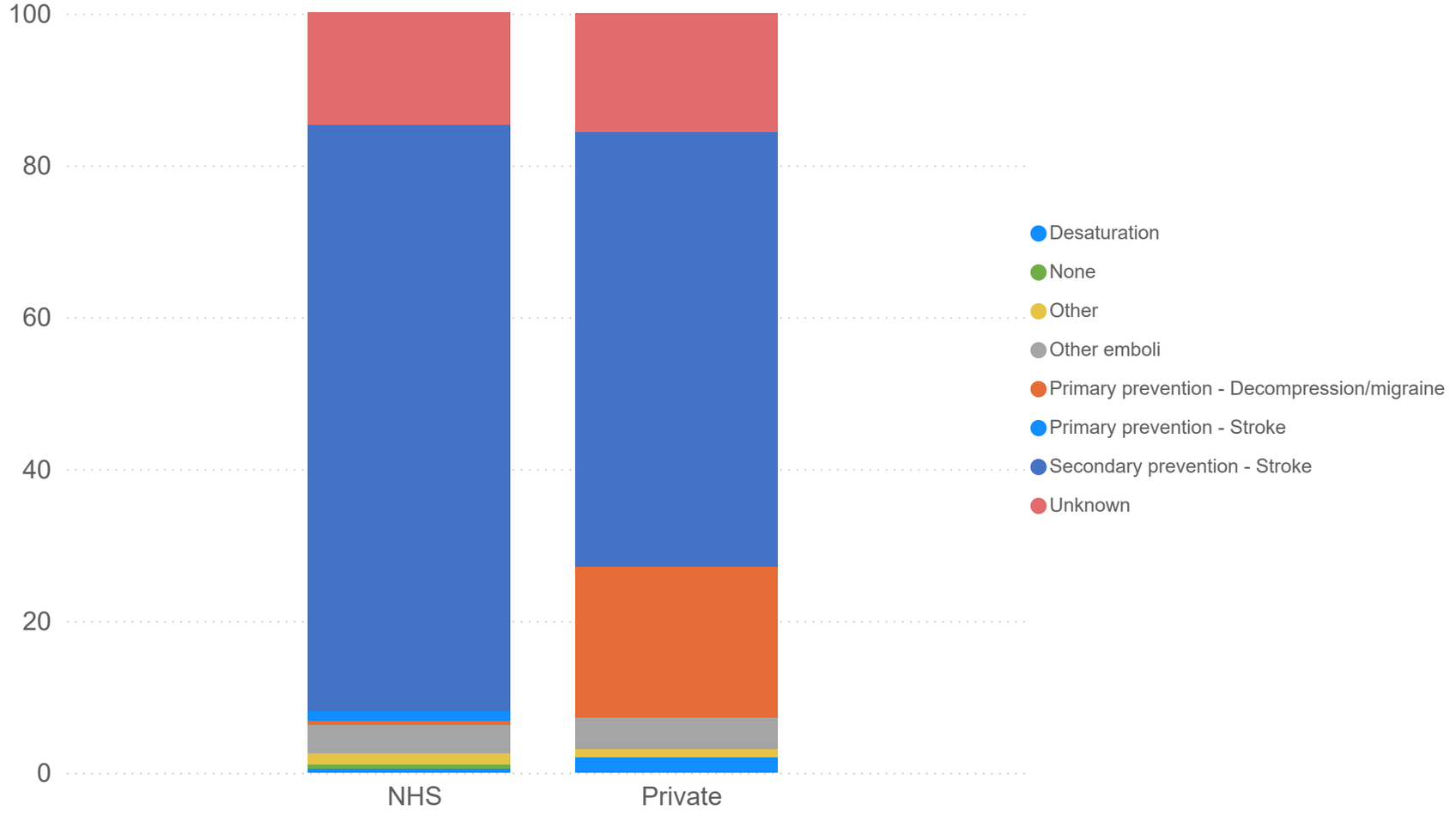
Indications for treatment with PFOC in 2024/25

Most PFOC patients in the NHS are treated for the secondary prevention of stroke, in accordance with commissioning criteria. This means that the patient has already suffered a stroke and the treatment is provided in an attempt to prevent recurrent stroke. This indication is supported by three large randomised controlled trials.

In the private sector, secondary prevention of stroke is also the most common indication. However other indications that are clinically appropriate but not commissioned by the NHS are more prevalent, as would be expected. These include prevention of decompression illness in divers, primary prevention of stroke, migraine prevention and emboli to other locations such as coronary emboli causing heart attack.

However, around 1 in 7 patient records do not specify the reason for treatment. All hospitals should be able to complete the indication for treatment in the registry, and will be encouraged to do so in future.

Percentage of PFOC cases by reason for treatment (2024/25)



Contents page

A single focal abnormality was the ischaemic event shown most frequently on brain imaging

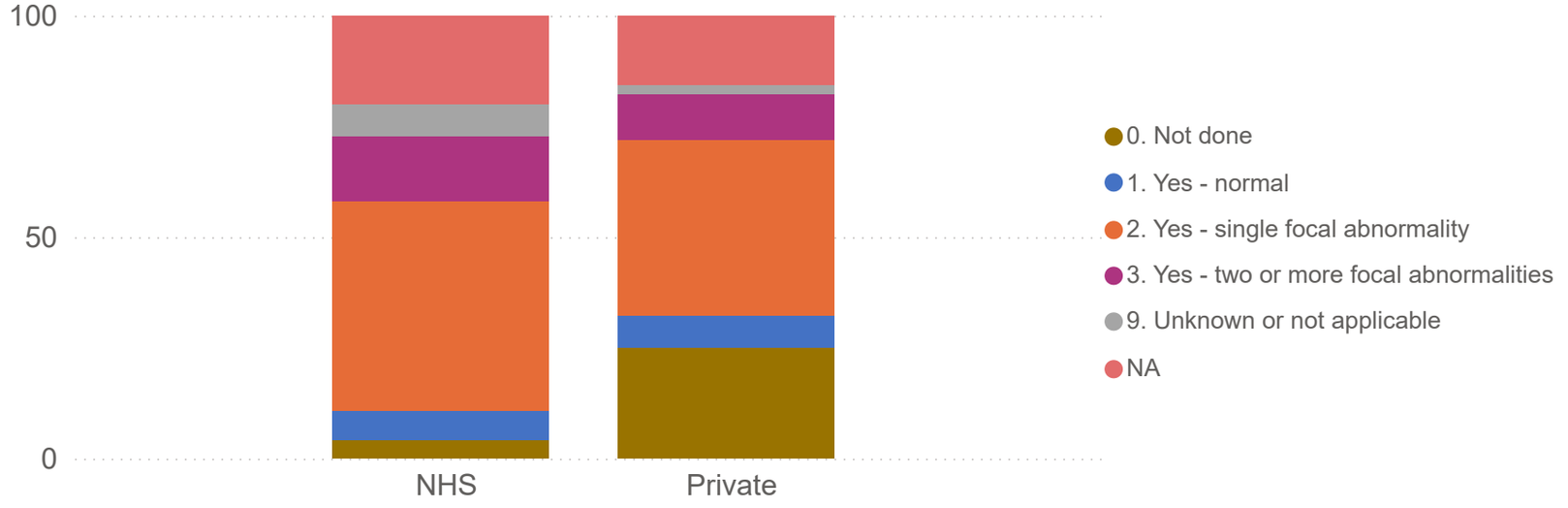
The majority of patients in 2024/25 had a single abnormality documented on brain imaging (in line with NHS England commissioning criteria that require there to have been an imaging-proven stroke).

For patients treated outside the NHS, some may have no ischaemic events if the indication is a desaturation syndrome, decompression illness, migraine or primary prevention.

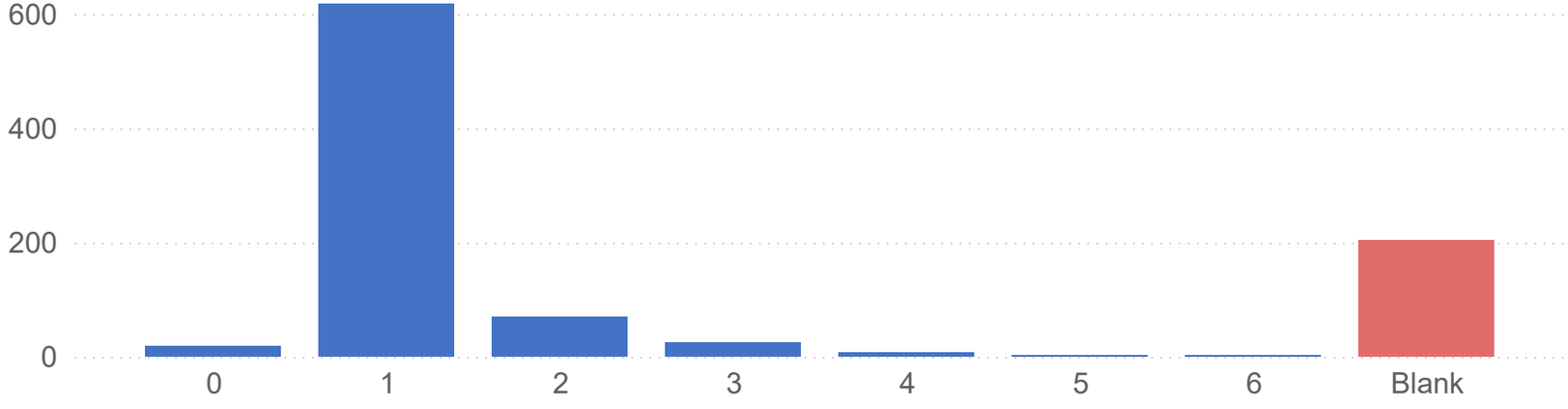
In total, around 80% of patients had abnormalities on brain imaging, with a normal scan being documented in 7%. Some patients with indications such as desaturation or decompression illness do not require brain imaging.

The brain scan findings of around 200 patients were not recorded in 2024/25, possibly because these were undertaken in a referring hospital. Nonetheless, data completeness for this should be improved.

Percentage of PFOC cases by brain scan result (2024/25)



Number of prior ischaemic events in PFOC cases (2024/25)



The PFO was most commonly diagnosed by bubble contrast transthoracic echocardiography

The majority of PFOC patients have a diagnosis made based on bubble contrast echocardiography, either using transthoracic echocardiography (TTE) or transoesophageal echocardiography (TOE). Intracardiac echocardiography (ICE) is rarely used in the diagnostic work-up.

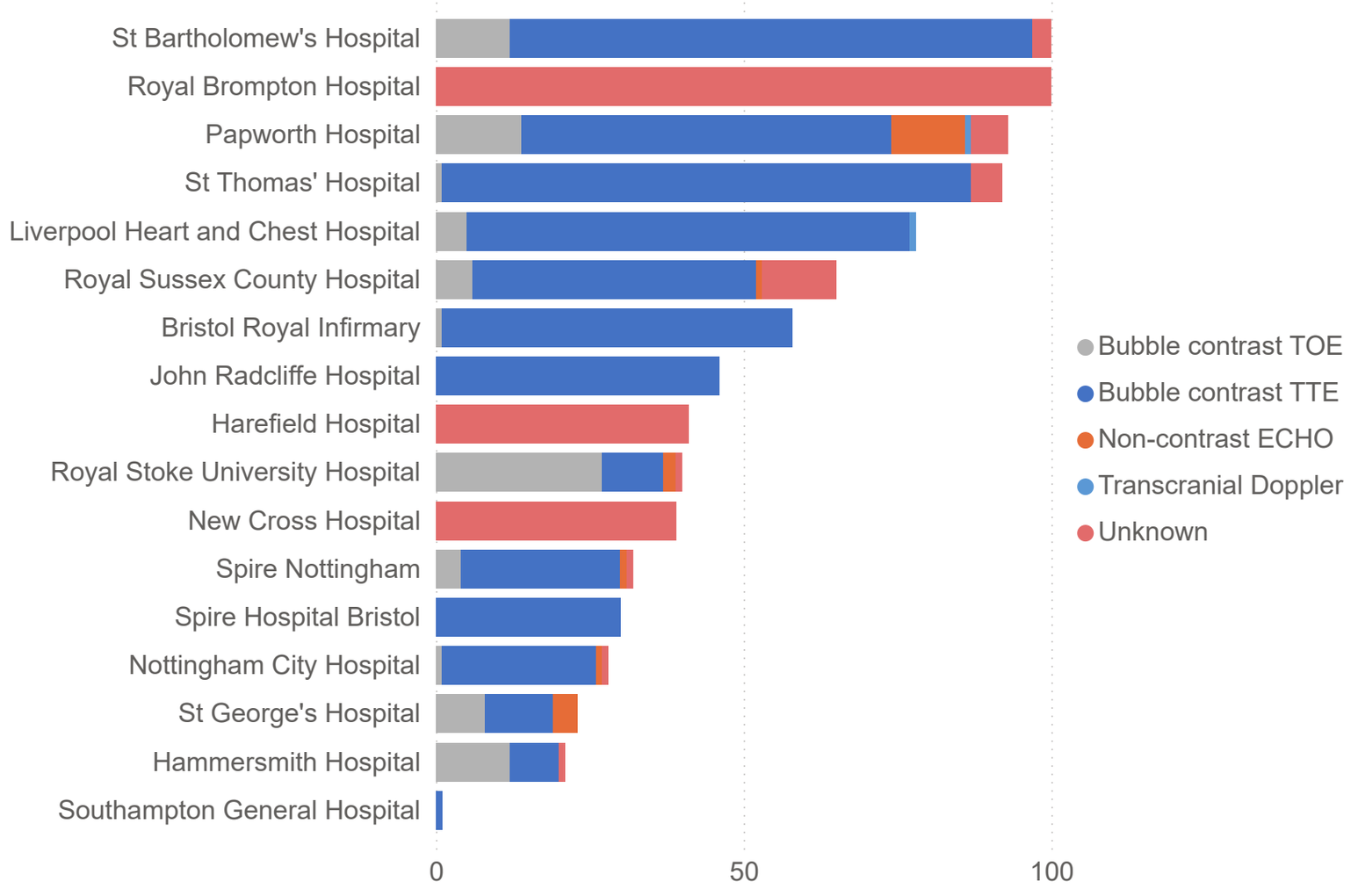
Bubble contrast TTE is the least invasive, less expensive and allows provocative manoeuvres to be undertaken to encourage right-to-left shunting.

Transoesophageal echo (TOE) allows higher quality imaging of the atrial septum itself and can identify other potential causes of stroke. However, TOE is insensitive to identifying right-to-left shunting only present on provocative manoeuvres, unless general anaesthesia is undertaken and a cuffed endotracheal tube is placed, and a Valsalva manoeuvre undertaken by the anaesthetic team.

A very small number of patients have a diagnosis made with transcranial Doppler.

Note: Insufficient data were provided for this analysis by the Freeman Hospital.

Percentage of PFOC cases by diagnosis method (2024/25)

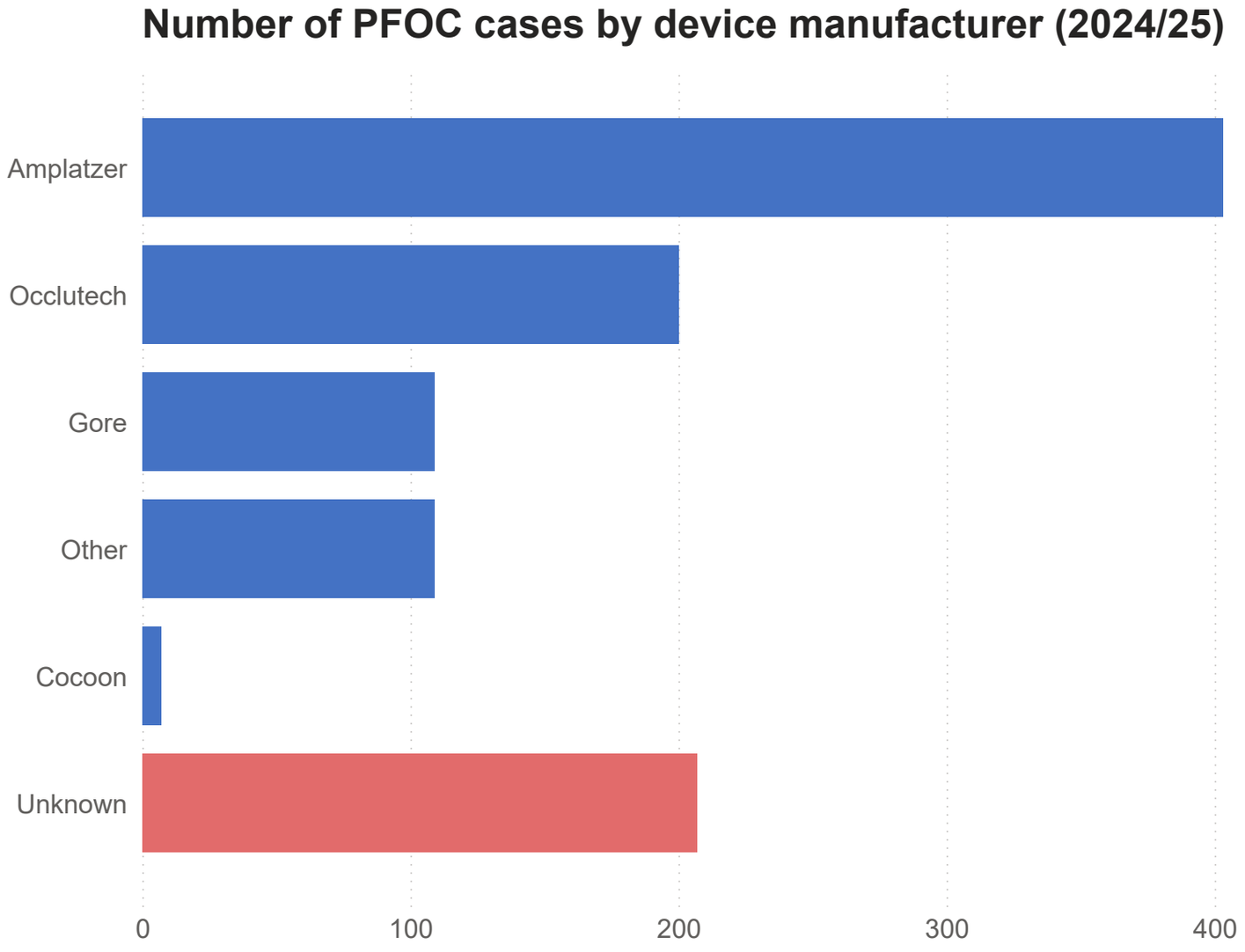


Amplatzer, Occlutech and Gore were the most frequently used devices in PFOC procedures during 2024/25

Amplatzer devices remain the most commonly used in PFOC procedures, with Occlutech (a similar double disc nitinol device) the next most common. Gore Cardioform devices, with a different design, were the third most common.

Changes are planned to the dataset to ensure accurate recording of device type, as the double disc nitinol devices have a range of sizes and shapes.

Validation of the device type will be undertaken by cross-referencing serial number with device type, in collaboration with medical device companies. This further emphasises the importance of correct collection of the device serial numbers.



The majority of PFOC patients were treated as a day case or had only a 1-night stay in hospital

Most PFOC procedures are undertaken as a day case. A 1-night stay is occasionally required.

As PFOC is funded in only 20 NHS hospitals in England, patients may have to travel a long distance from home. Longer stays may also be due to complications or due to an indication other than a previous stroke.

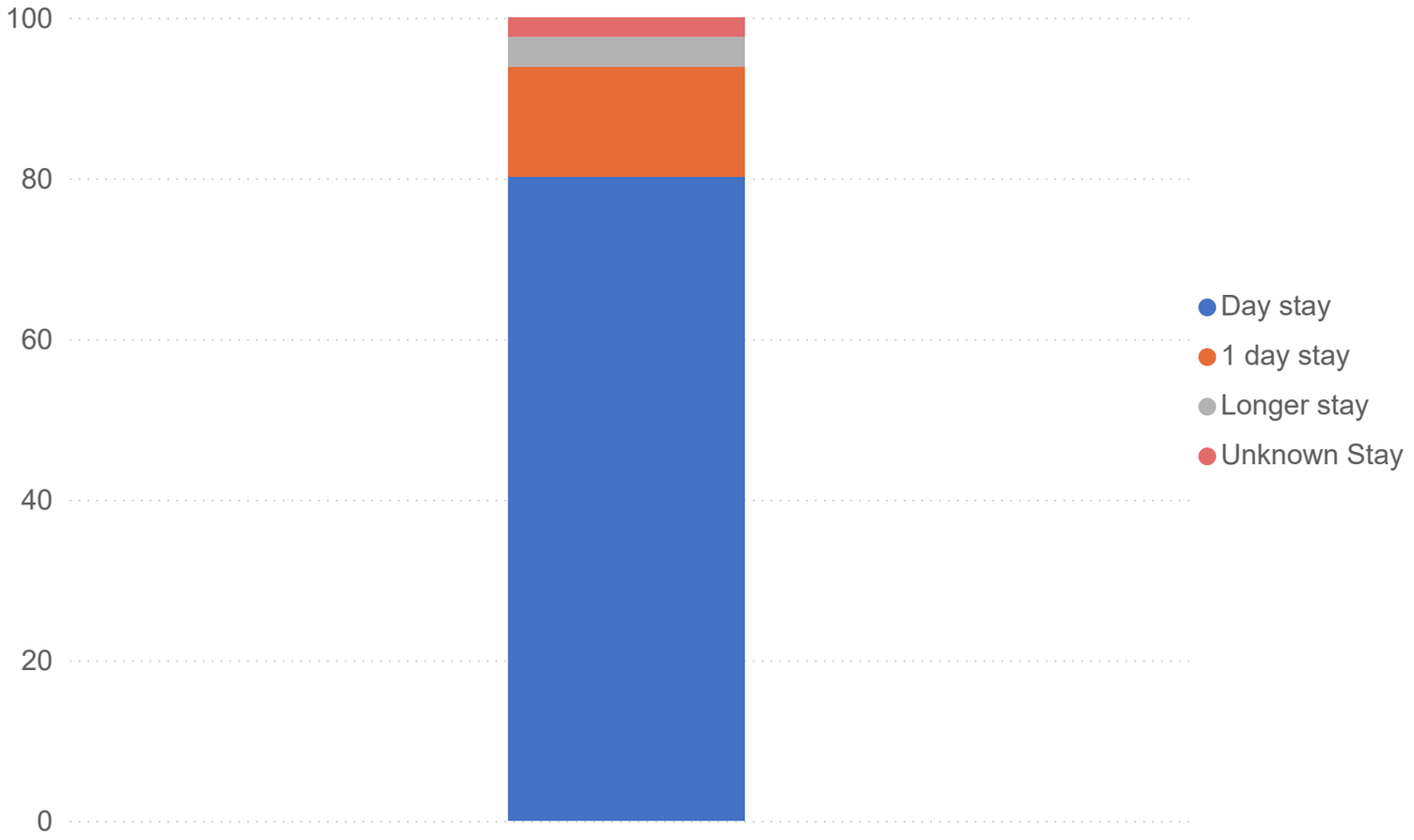
Length of stay (LOS) reflects the number of nights spent in hospital (e.g. a patient admitted 1 day prior to the procedure and discharged the day after the procedure would have a length of stay of 2 days). Longer-stay patients represent patients with greater than 2 nights spent in hospital.

Select a hospital below to see specific data.

Select hospital

All

Percentage of PFOC cases by length of stay (days) (2024/25)



NICOR

Contents page

PFOC median procedure time varied very widely between centres in 2024/25

There is a very wide variation in the average time taken to perform PFOC procedures across different hospitals.

It is not clear whether this represents different approaches to recording 'time of onset' and 'time of completion', or whether there is truly a wide range of procedural duration.

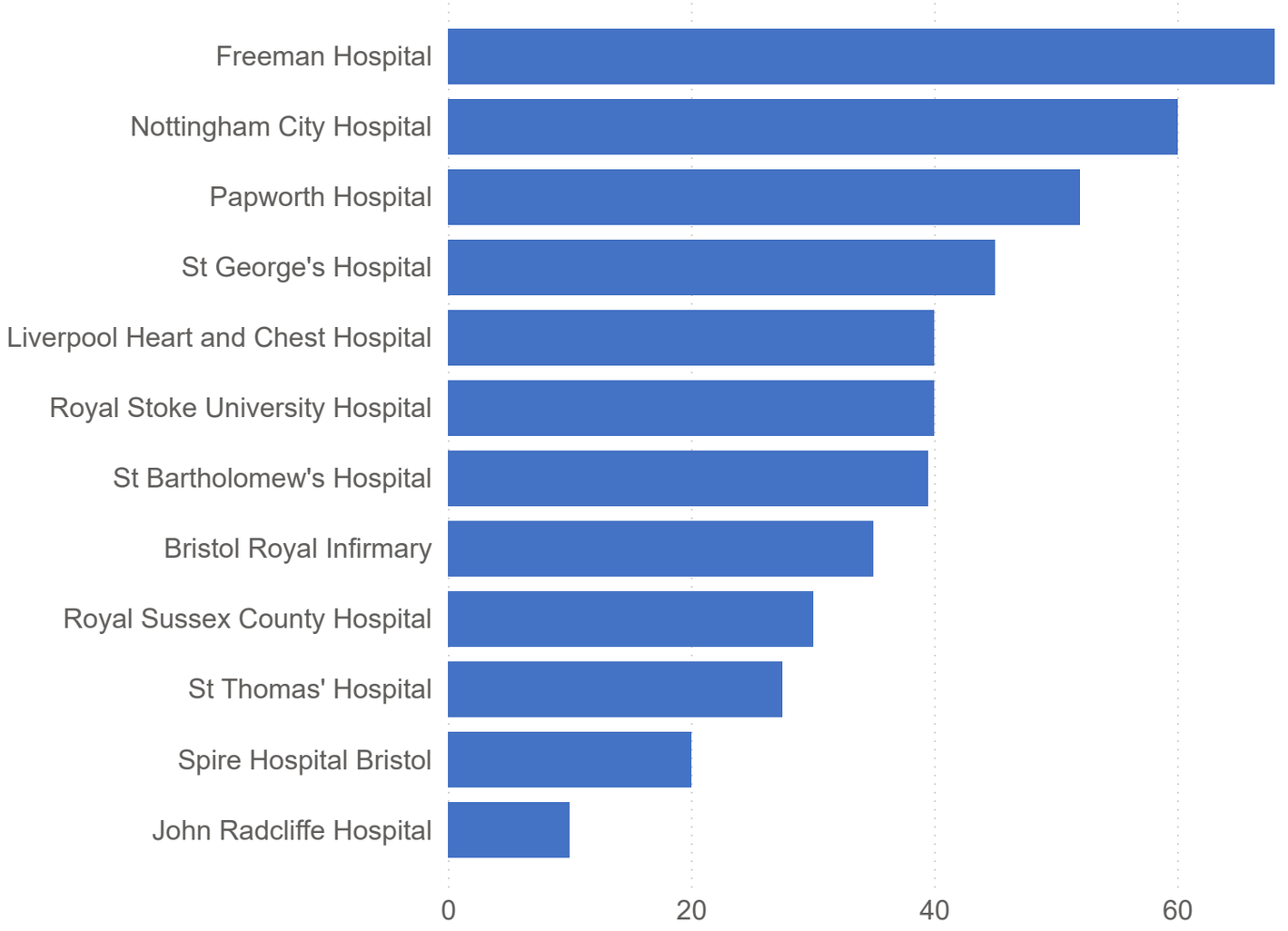
The NCHDA definition of procedure time is 'time of puncture to time of sheath removal'. If the time of onset is the 'time entering the catheter laboratory' and completion as 'leaving the catheter laboratory', much longer times would be expected.

The PFOC audit will adopt the NCHDA definition of procedure time and this will be clearly explained in the data entry portal. All hospitals should record these times for the start and end of the procedure.

Note: Insufficient data were provided for this analysis by the following hospitals:

- *New Cross*
- *Southampton*
- *Harefield*
- *Hammersmith*
- *Royal Brompton*
- *Spire Hospital Nottingham*

Median procedure time (minutes) by hospital (2024/25)



Median fluoroscopy times were low, but with significant variation between hospitals in 2024/25

The median time to undertake fluoroscopy ranged from 3 to 8 minutes. This is the duration of screening time with an X-ray system.

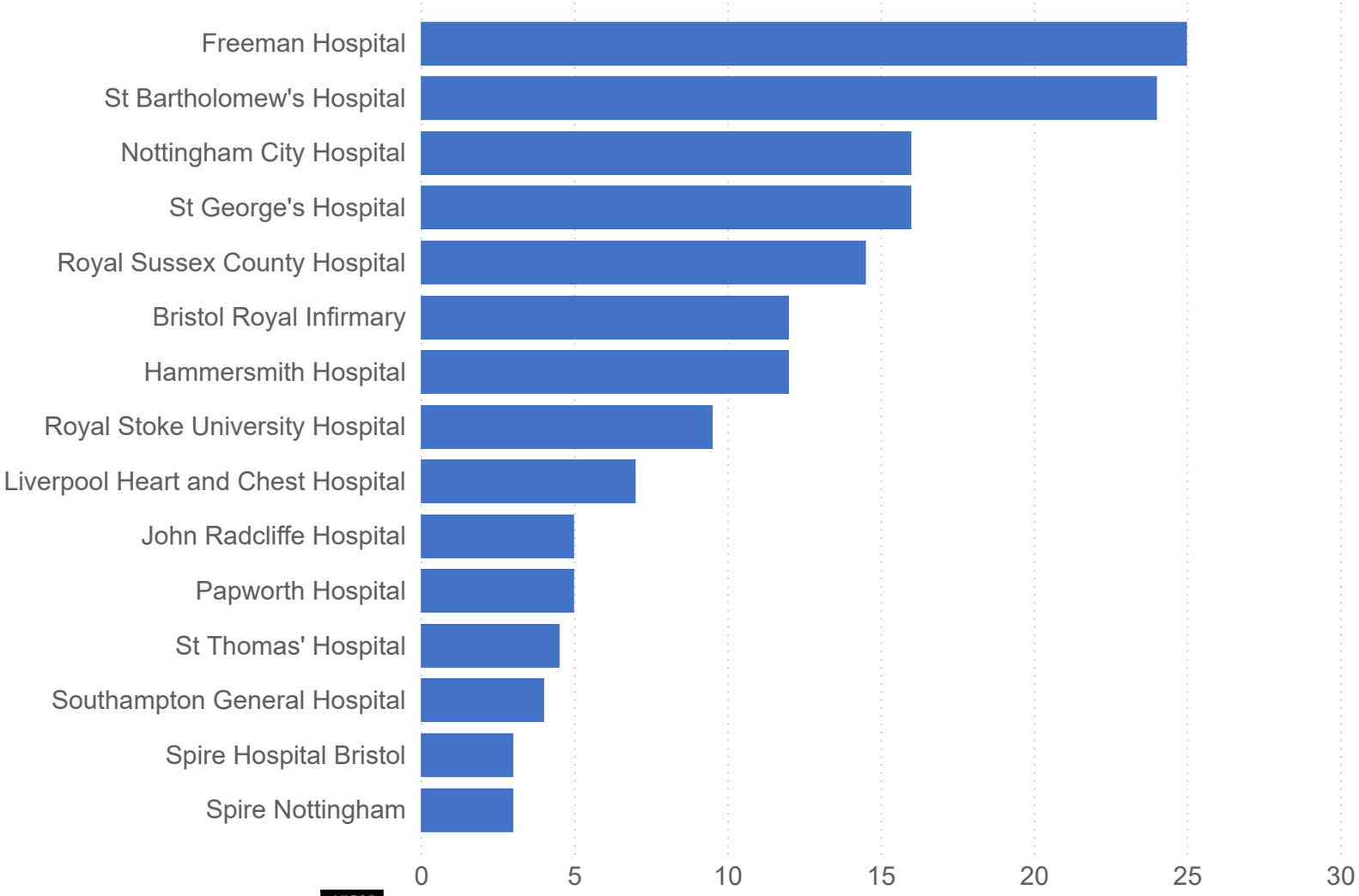
It may be preferrable in future for the registry to collect screening time in seconds (rather than rounded to the nearest minute currently), as some procedures can be undertaken in less than a minute of screening (especially when also guided with echo).

Select a procedure guidance method below to see specific data.

Select procedure guidance method

All

Median fluoroscopy time (minutes) by hospital (2024/25)



Contents page

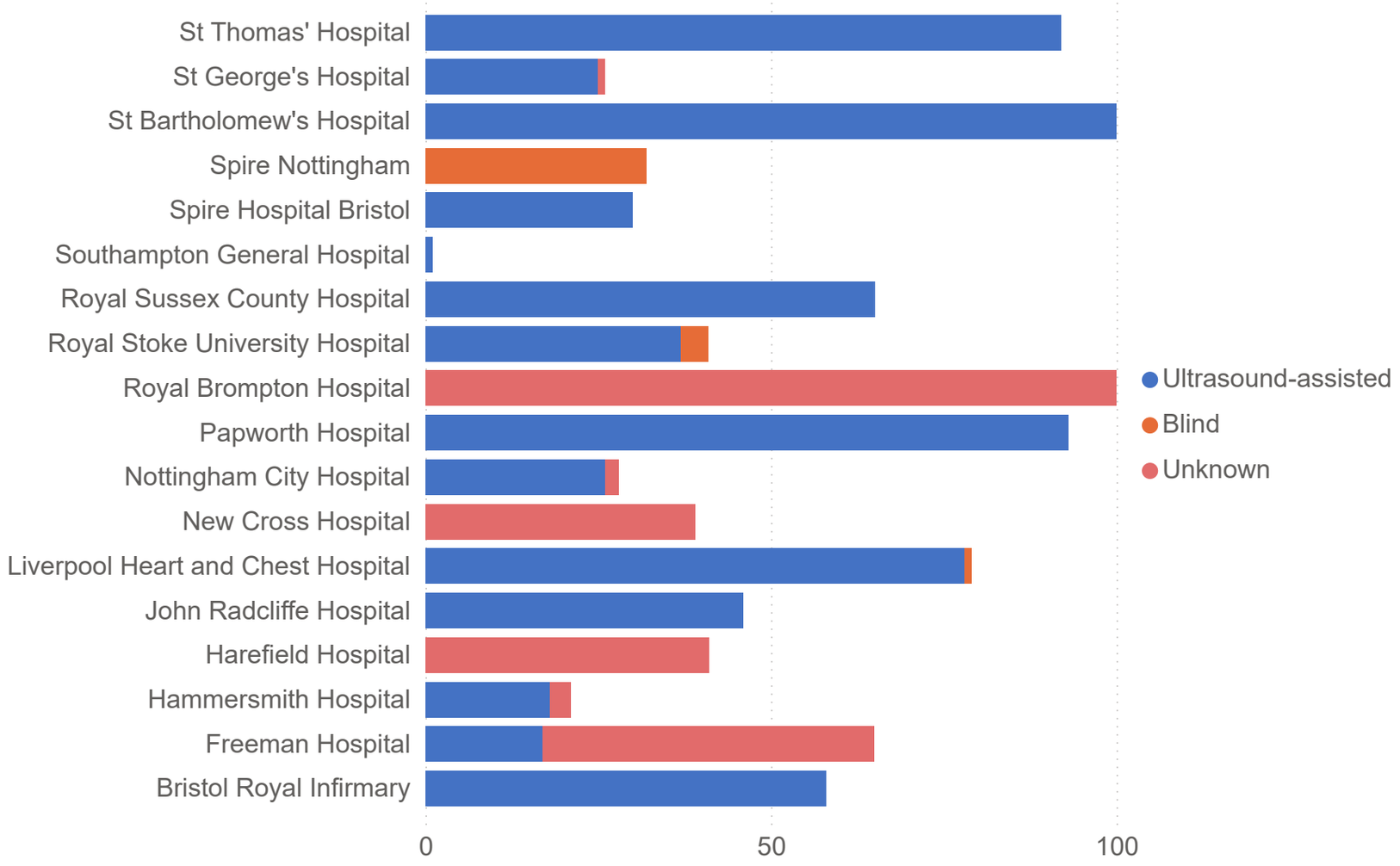
Most centres followed the recommendations to use ultrasound-guided puncture of the femoral vein in 2024/25

The majority of hospitals are using ultrasound guidance for venous puncture, as is recommended in PFOC Guidelines.

Data completeness for this metric is low. Hospitals that use third party software recording data for the NCHDA dataset, do not record whether venous puncture is ultrasound guided. Whilst the use of vascular ultrasound is recorded as 'unknown' for these hospitals, a majority of cardiologists report that they routinely use ultrasound to guide femoral vein puncture, in accordance with guidelines.

For those hospitals providing data, only Spire Hospital, Nottingham appears to routinely use "blind puncture" (an approach used only occasionally elsewhere).

Vascular ultrasound use by hospital (2024/25)



→ Contents page

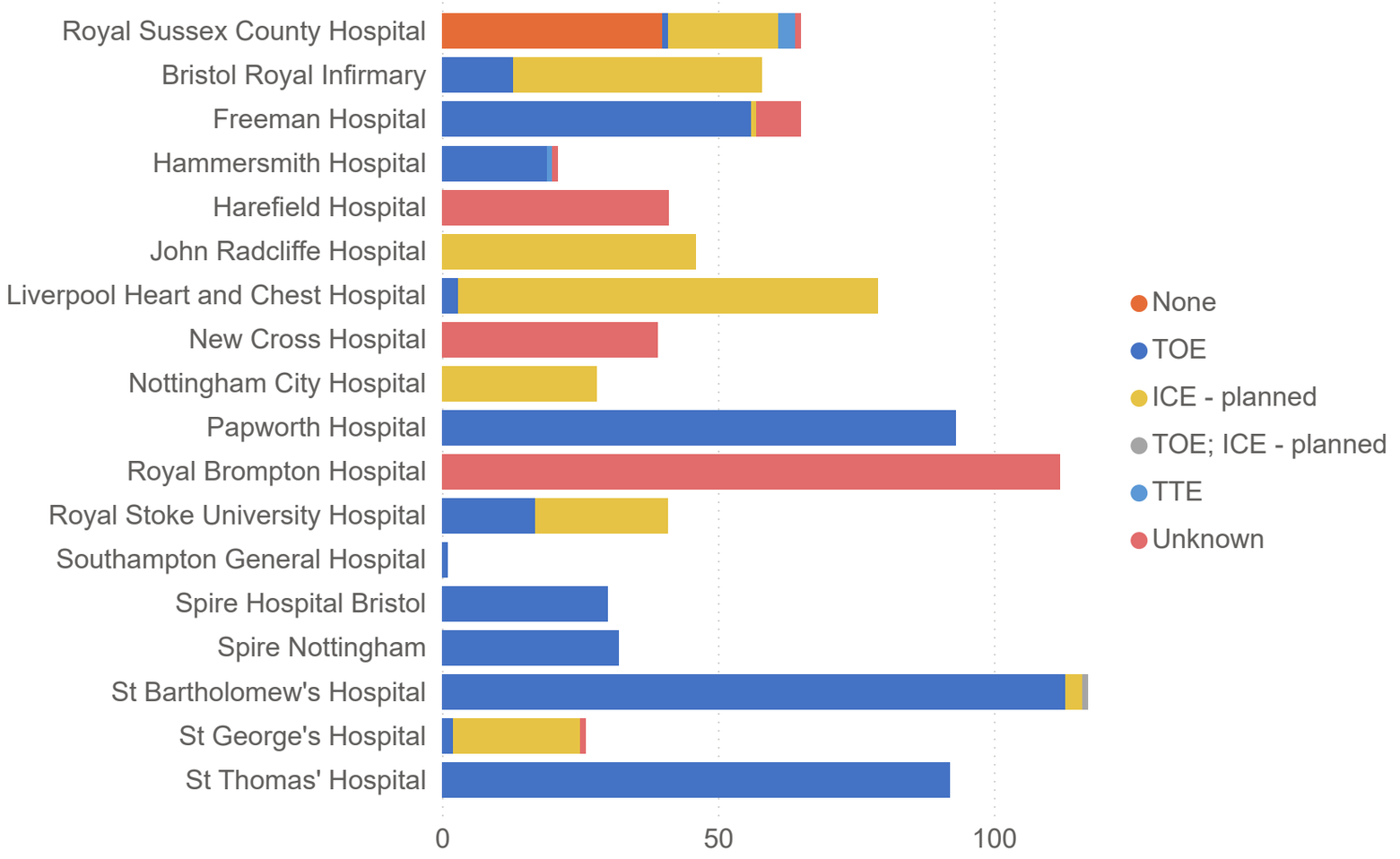
The majority of centres used transoesophageal or intracardiac echocardiographic guidance during PFOC procedures in 2024/25

The majority of hospitals use transoesophageal echocardiography (TOE) or intracardiac echocardiography (ICE) for imaging guidance in PFOC procedures during 2024/25. These modalities provide much better images than transthoracic echocardiography (TTE).

Two centres used exclusively transoesophageal echocardiography, one of which was a private hospital, where general anaesthesia is usually more easily available. Some centres treated the majority of patients using intracardiac echocardiography guidance, while the Royal Sussex County Hospital undertook a large number of procedures without echo guidance.

Guidance documents recommend the use of some form of ultrasound, either transoesophageal or intracardiac echocardiography, but there is a body of opinion that believes that x-ray and angiographic guidance can be sufficient.

Echocardiography guidance during PFOC procedures by hospital (2024/25)



Contents page

The result of the diagnostic bubble contrast echo was very poorly recorded in the audit, with over 500 records stating 'unknown' or 'not applicable'

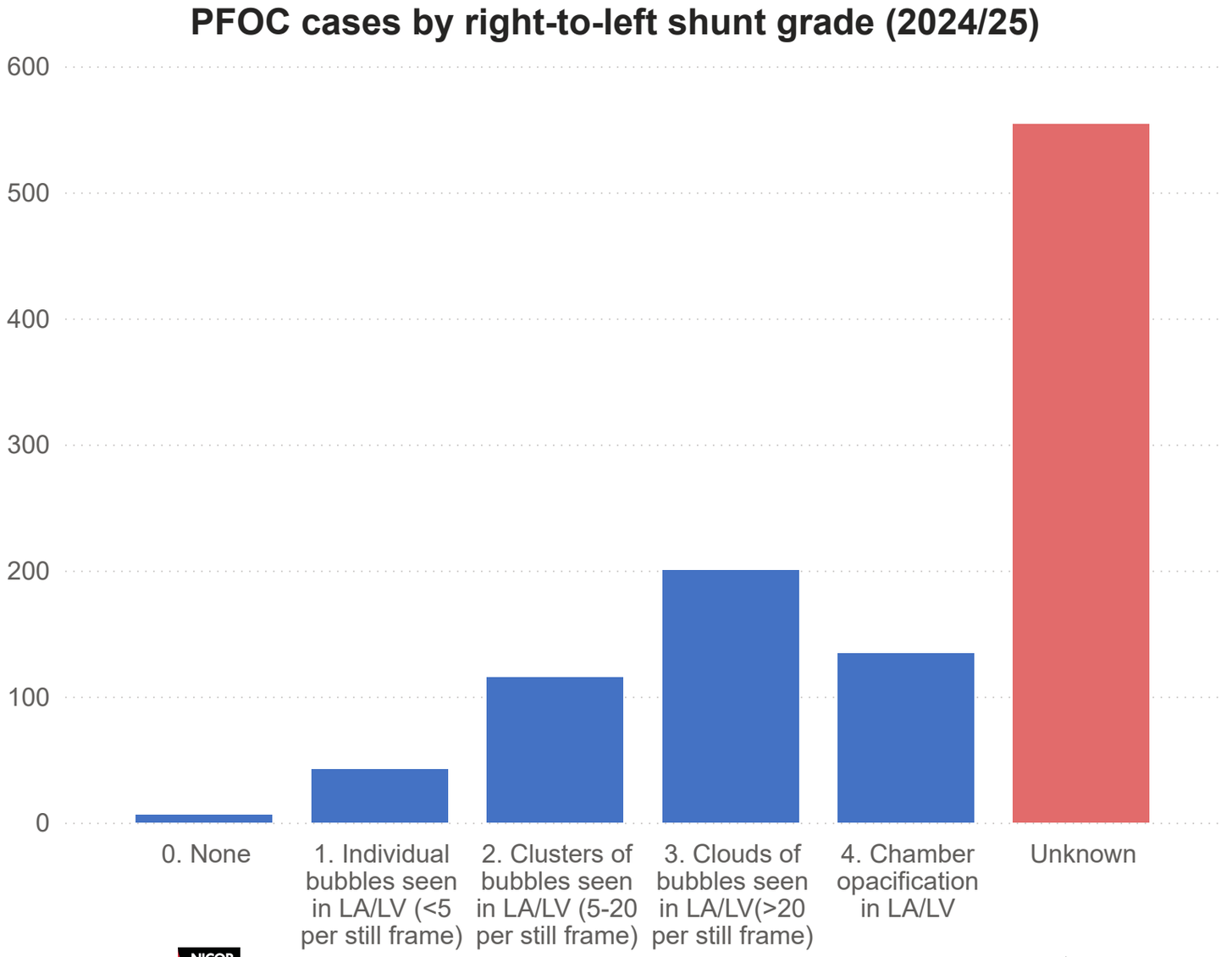
Hospitals provided very poor data on the results of diagnostic bubble contrast echocardiography for PFOC cases in 2024/25. This is used to detect abnormal blood flow between the right and left sides of the heart.

Given that the vast majority of patients underwent either bubble contrast transthoracic or transoesophageal echocardiography, there will be data for many of these patients that has not been entered in the registry.

It is not uncommon for this echocardiography to be performed in a referring hospital, and given the fact that different hospital trusts do not have access to other hospital trusts results, this may account for some of the missing data.

Given that the evidence of a significant shunt is an important part of the indication for the procedure, great improvement in data reporting is needed.

Once the not applicable/unknown response is removed, the majority of patients have evidence of a significant right-to-left shunt. A small number have either no evidence of bubbles crossing into the left heart, or only very small numbers.



→ Contents page

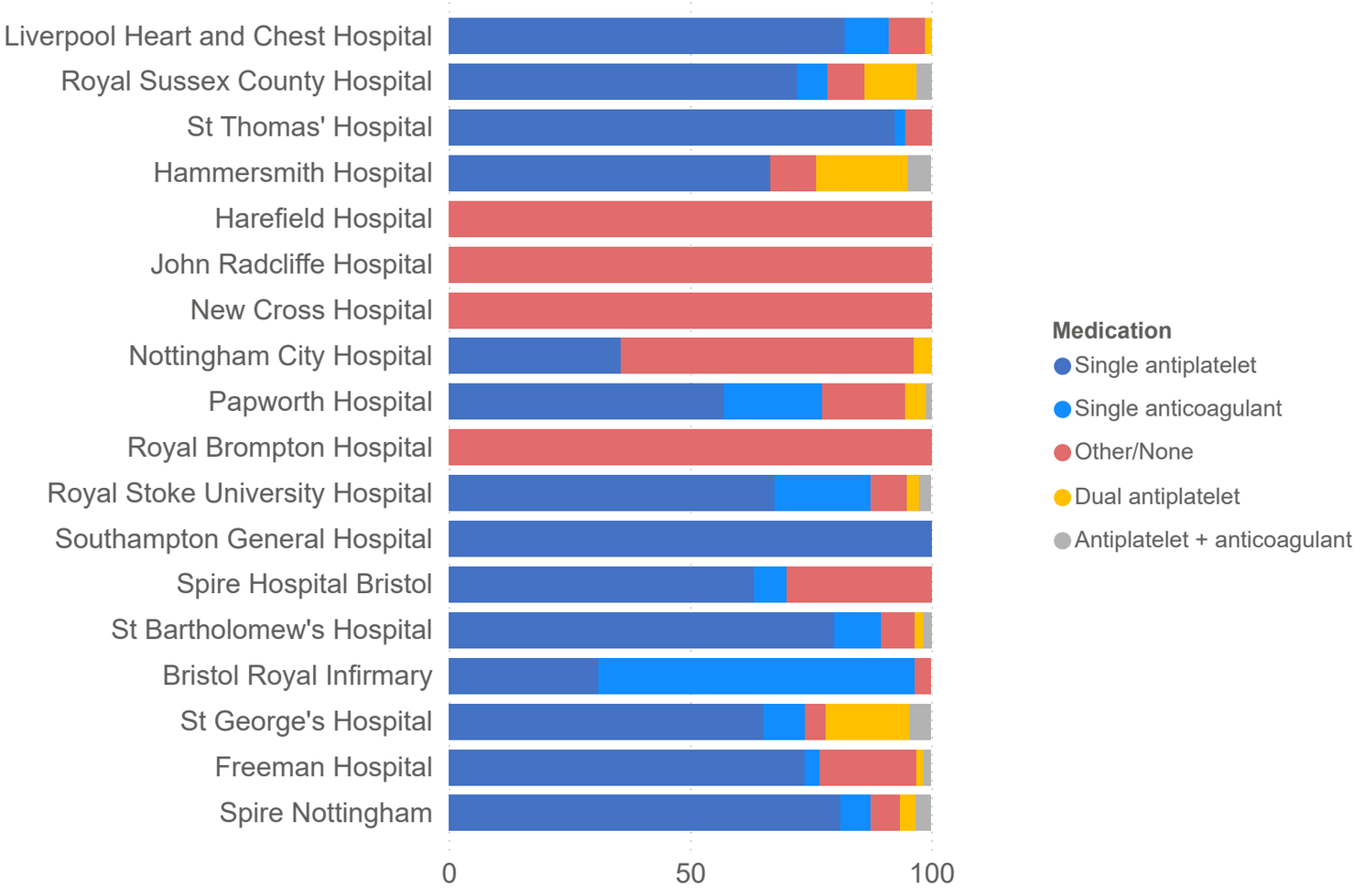
PFOC patients were usually on single antiplatelet treatment at admission to hospital, in accordance with current stroke guidelines in 2024/25

The most common pre-admission medication regimen is single antiplatelet therapy, consistent with the UK and Ireland stroke guidelines for patients who have had proven stroke (clopidogrel is the preferred agent).

Some hospitals have not submitted data for this, possibly again because of using third-party software configured to the previous NCHDA dataset which does not require this to be reported. This explains a large proportion of the 'Other/None' category in the chart.

Where the indication for PFOC is not a stroke, some patients may only be started on drug treatment after a closure procedure. The majority of patients who meet NHS England funding criteria are likely to be either on single antiplatelet therapy or an oral anti-coagulant.

Proportion of patients (%) receiving different medication regimens prior to PFOC, by hospital (2024/25)



Contents page

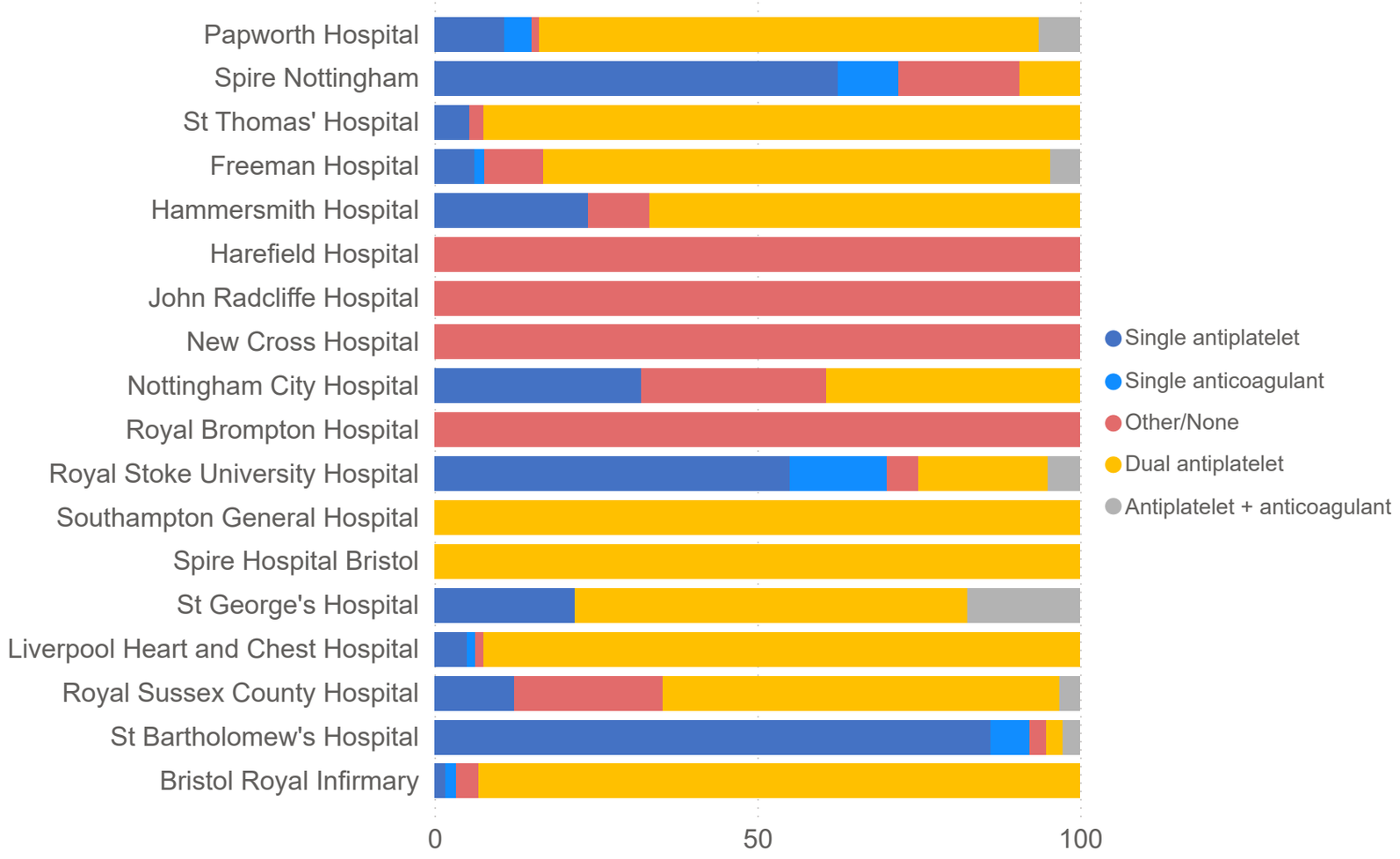
PFOC patients are most commonly discharged on dual antiplatelet medication

Dual antiplatelet therapy is the most common medication for PFOC patients on discharge, followed by single anti-platelet therapy.

Oral anticoagulants are relatively rarely prescribed. Given that the NHS England funding criteria excludes alternative indications for anticoagulation, a low rate of oral anticoagulation following the procedure is expected, which may reduce even further during follow-up.

Unfortunately, some centres have not provided data on this and it would be very surprising if patients were discharged after a PFOC procedure on no medication. Reporting of this needs to improve.

Percentage of PFOC patients on different medication regimens on discharge, by hospital (2024/25)



Contents page

Complications after PFOC procedures are infrequent

Randomised trials of PFOC show the majority of procedures are uncomplicated and report low complication rates.

Bleeding is the commonest reported complication. Minor bleeding is most common from the femoral vein puncture and is exacerbated by the use of intraprocedural anticoagulants, usually heparin, along with the antiplatelet agents that most patients are pre-treated with.

Other complications are very rare.

In future audits, HES data will be used to identify complications to compare with complications recording in the PFOC database, and to assess complications after discharge.