NCAP

NATIONAL CARDIAC AUDIT PROGRAMME

NICOR

Percutaneous Foramen Ovale Closure (PFOC) Registry

Interim Report 2026

Data from April to September 2025

Report at a glance

All data are for procedures performed between April and September 2025 unless otherwise stated

A total of 827 PFOC procedures were reported to NICOR.

746 cases (90%) were submitted to the PFOC Registry and 81 (10%) to the National Congenital Heart Disease Audit (NCHDA).

Patients have less distance to travel to a commissioned hospital in the South East and West Midlands.

Completeness of demographic information for PFOC cases is good, but improvements are needed for procedural variables. Complication rates are low.

75% of cases had the device type recorded and 67% had a serial number recorded (this should be 100%).

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

Self-reported complication rates are low.

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 commenced in 2017, 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, conduct and outcome. Furthermore it will accurately identify and record the serial number, manufacturer and model of the implanted device, as is now legally required for any medical device implant. 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

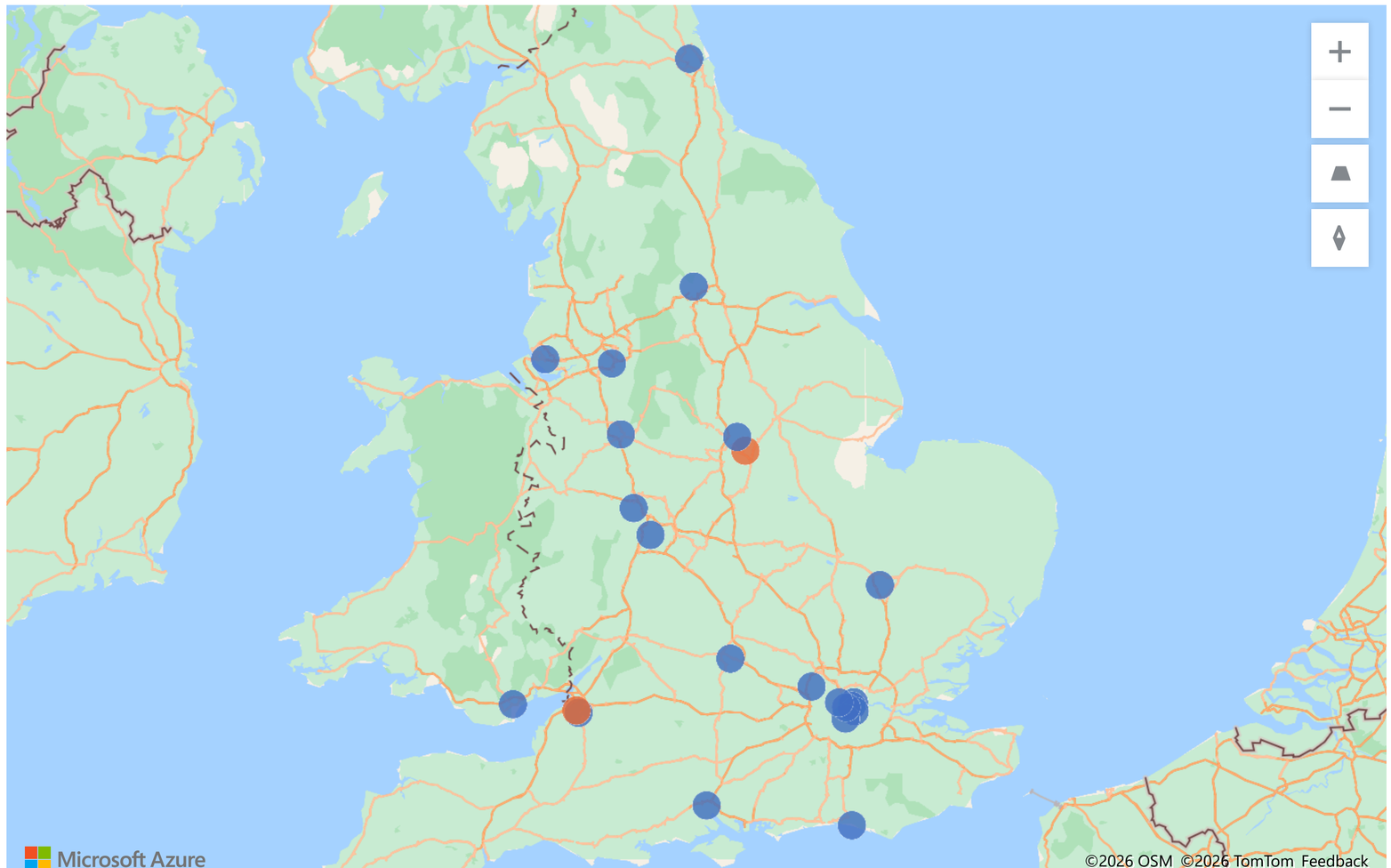
23 hospitals (NHS and private) submitted PFO closure procedures between April and September 2025

This map shows the location of the centres that have submitted data to NICOR for PFOC. This does include private hospitals, one of which is performing NHS funded procedures.

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 complete capture of NHS procedures is required.

Location of hospitals that have submitted data to the PFOC registry during April to September 2025



Standards for data completeness for demographic variables were met in most hospitals for Q1/Q2 2025/26 but date of discharge must be completed

Most hospitals submitted data on patient demographics to an acceptable standard in the period.

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 performing these procedures to NHS patients are required to provide complete and accurate data to the registry.

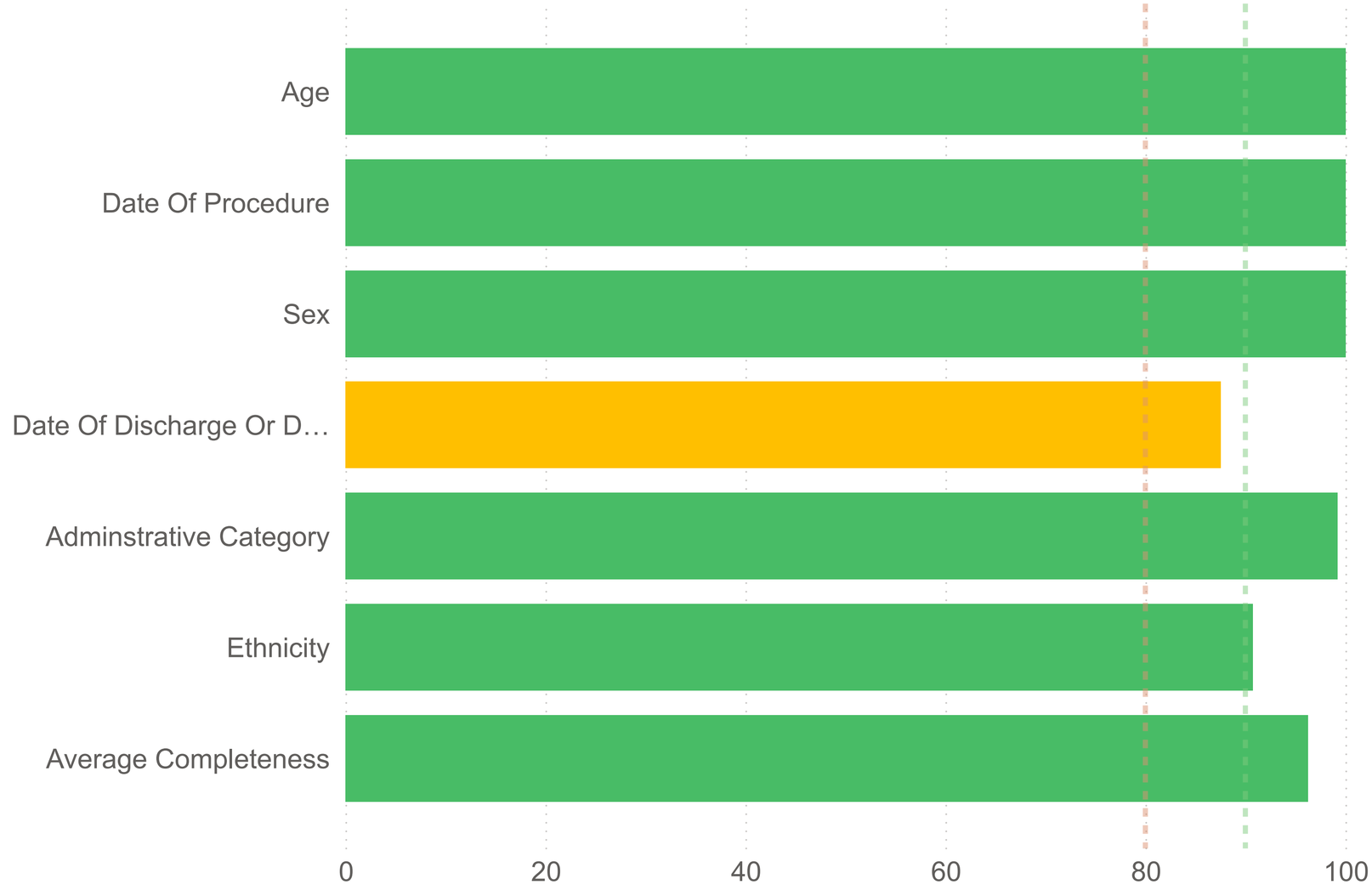
Select a hospital below to see its specific data.

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

Select hospital

All hospitals

Average percent completeness of demographic variables in the PFOC audit (April - September 2025)



Data completeness for procedural variables requires substantial improvement

Some hospitals are not submitting data at all, and some submitting to NCHDA, where the data collected does not record important and specific aspects of PFOC patients and the PFOC procedure.

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 data fields that do not appear in the NCHDA dataset.

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

NICOR is working with hospitals to ensure complete and accurate data collection to the PFOC registry.

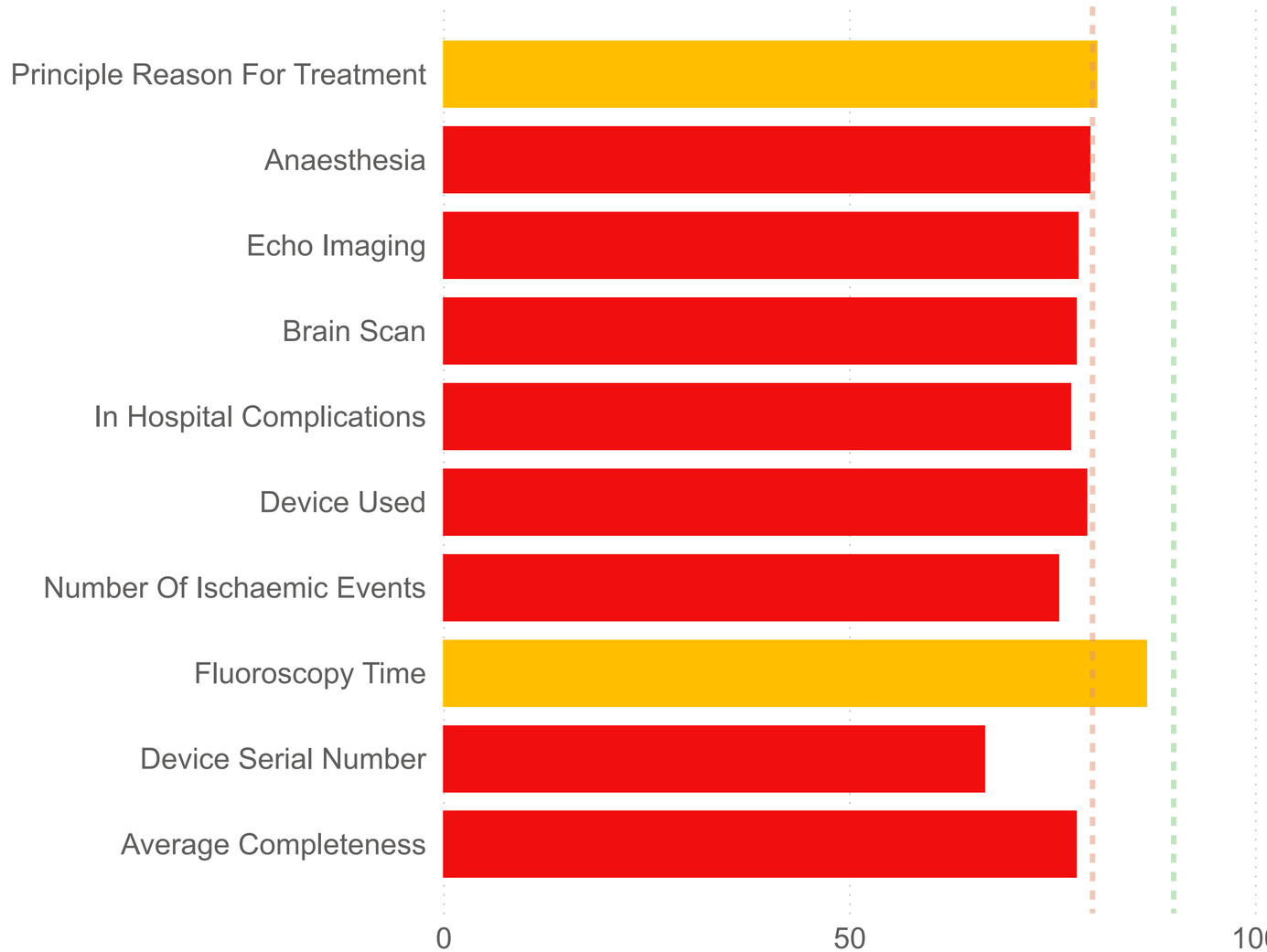
Select a hospital below to see its specific data.

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

Select hospital

All hospitals

Average percent completeness of selected procedural variables in the PFOC audit (April - September 2025)



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Some cases have been reported only to the NCHDA database, not the PFOC registry

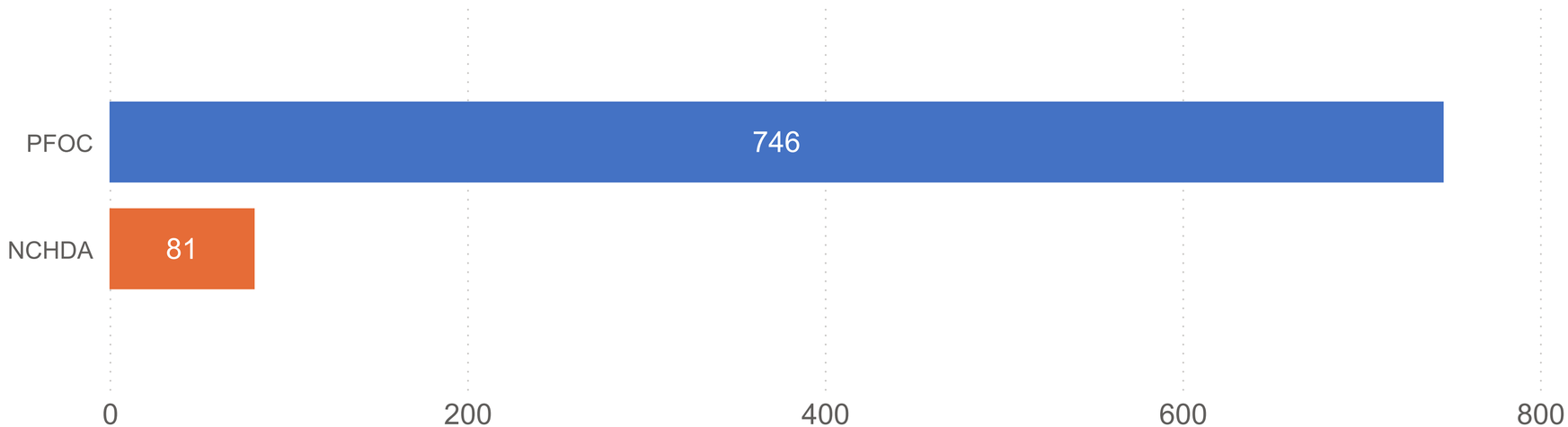
Around 850 PFOC procedures were reported to NICOR in Q1/Q2 2025/26, but only 746 were reported to the PFOC database (>18 years old). During the same period 273 records were submitted to the National Congenital Heart Disease Audit (NCHDA) for patients aged 18 or over, however analysis has shown 192 of these records were submitted to both databases, as a result of this only 81 of these records relate to additional PFOC. It is likely that some cases are not reported to either database.

The majority of cases submitted to either database are elective cases.

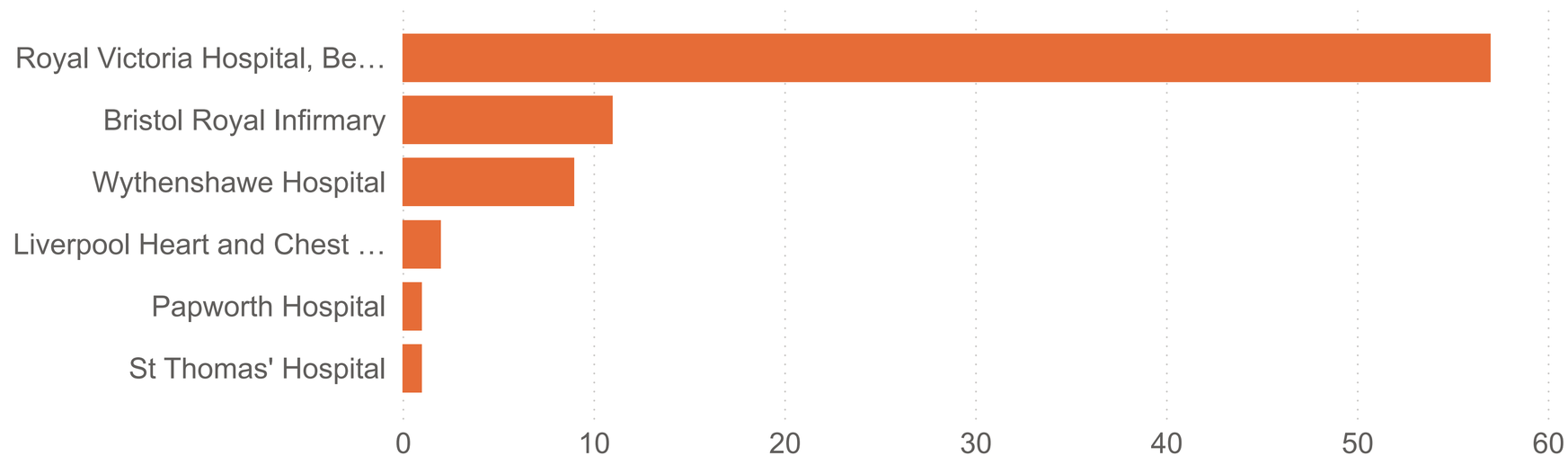
The dataset for each audit is different, so it is not possible to amalgamate the data. NICOR has written to the hospitals to request that future submissions will be to the PFOC database, in order to ensure the best possible data quality.

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.

Total PFOC cases submitted to NICOR registries (April - September 2025)



Total cases submitted to the NCHDA database by hospital (April - September 2025)



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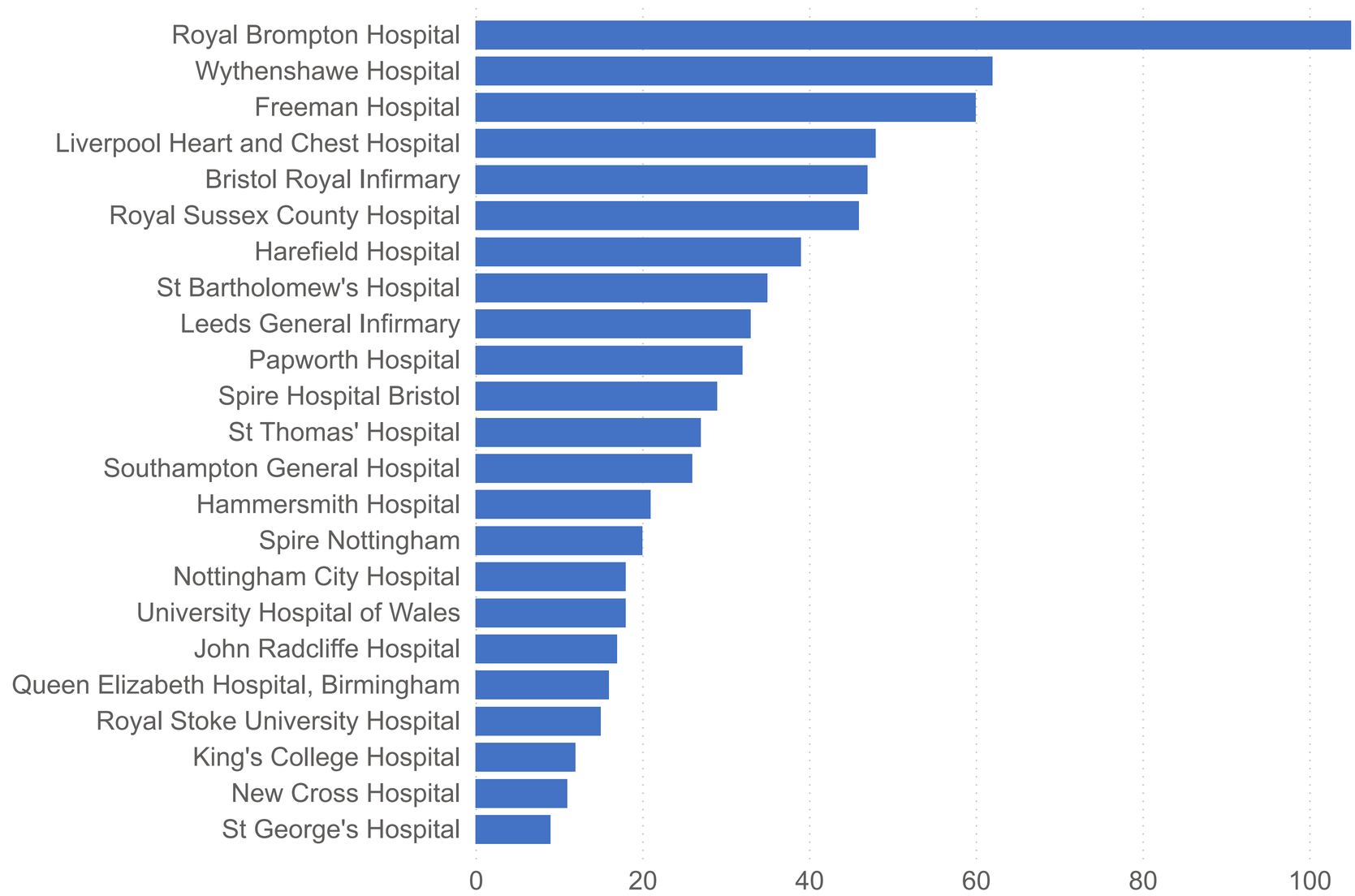
There was a wide variation in the number of procedures submitted by hospitals to the PFOC registry in the period April to September 2025

The number of PFOC cases reported by each hospital during the period varied from 105 in Royal Brompton Hospital to 9 in St Georges 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.

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 (April - September 2025)



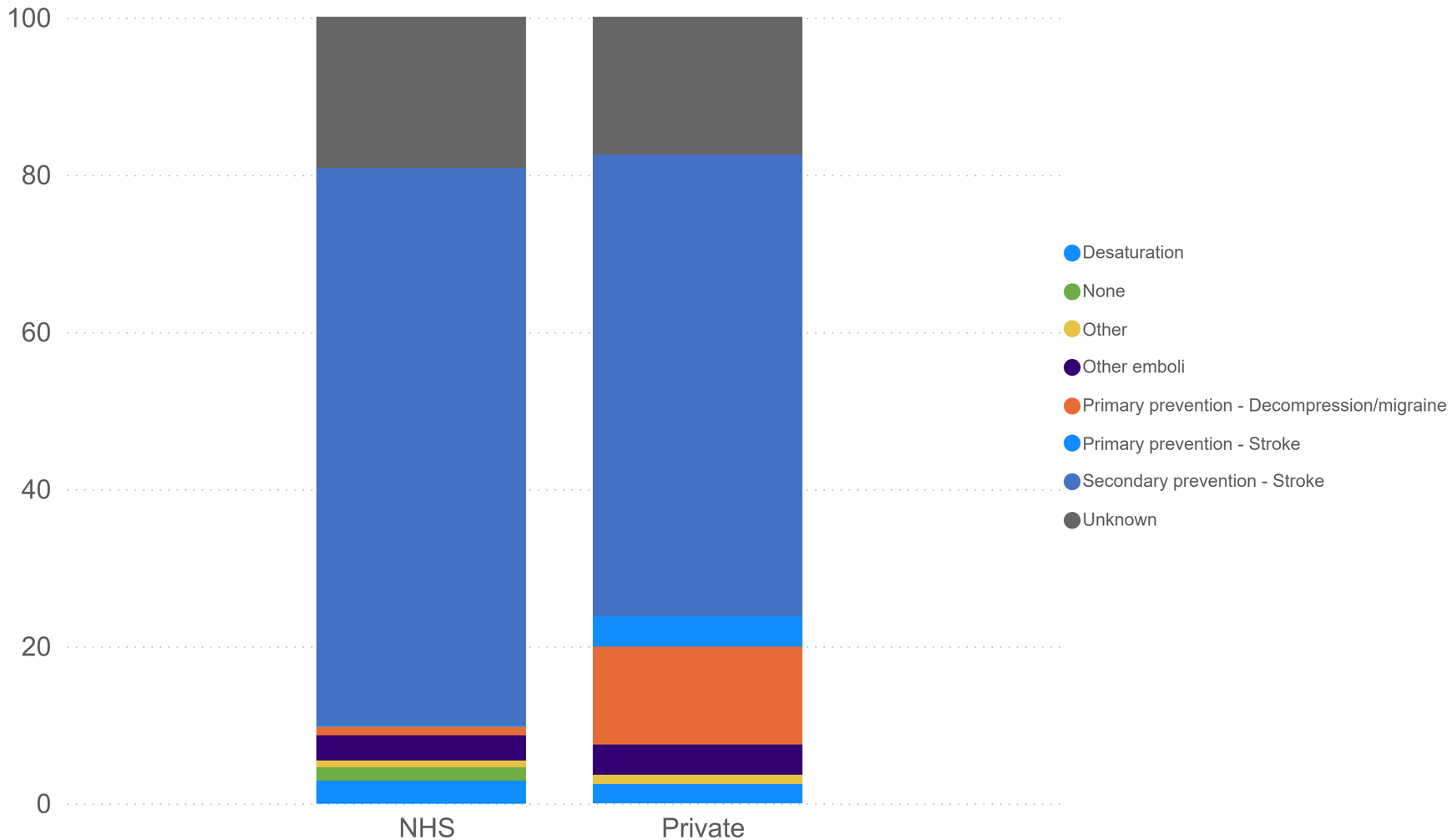
Indications for treatment with PFOC between April and September 2025

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 5 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 (April - September 2025)



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The PFO was most commonly diagnosed by bubble contrast transthoracic echocardiography

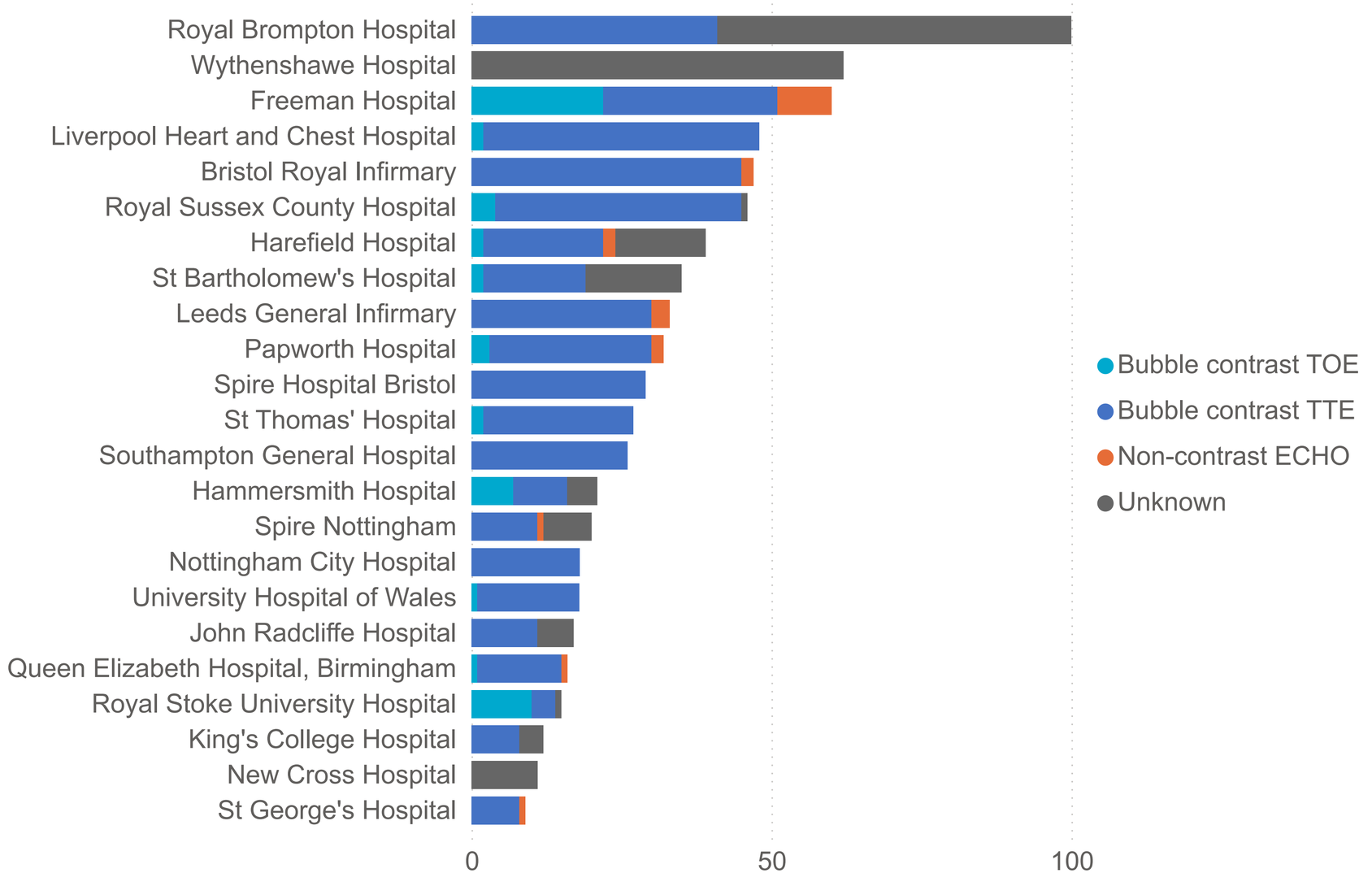
The majority of PFOC patients have a diagnosis made based on bubble contrast echocardiography, either using transthoracic echocardiography (TTE) or transoesophageal echocardiography (TOE). Intracardiac echocardiography (ICE) is rarely used in the diagnostic work-up.

When compared to transoesophageal echocardiography, bubble contrast TTE is the less 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.

Percentage of PFOC cases by diagnosis method (April - September 2025)



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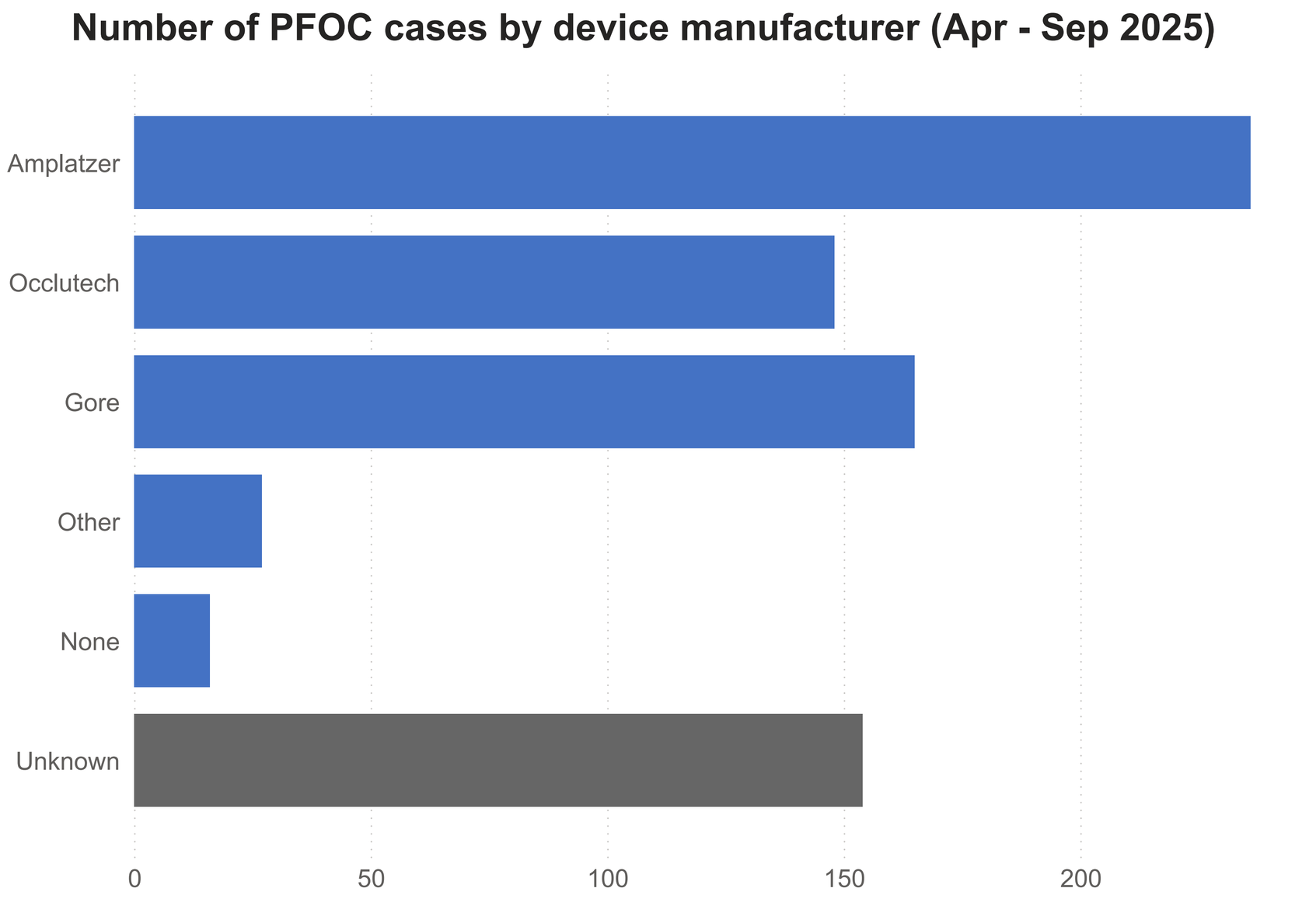
Amplatzer, Occlutech and Gore were the most frequently used devices in PFOC procedures between April and September 2025

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.



PFOC median procedure time varied very widely between centres between April and September 2025

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.

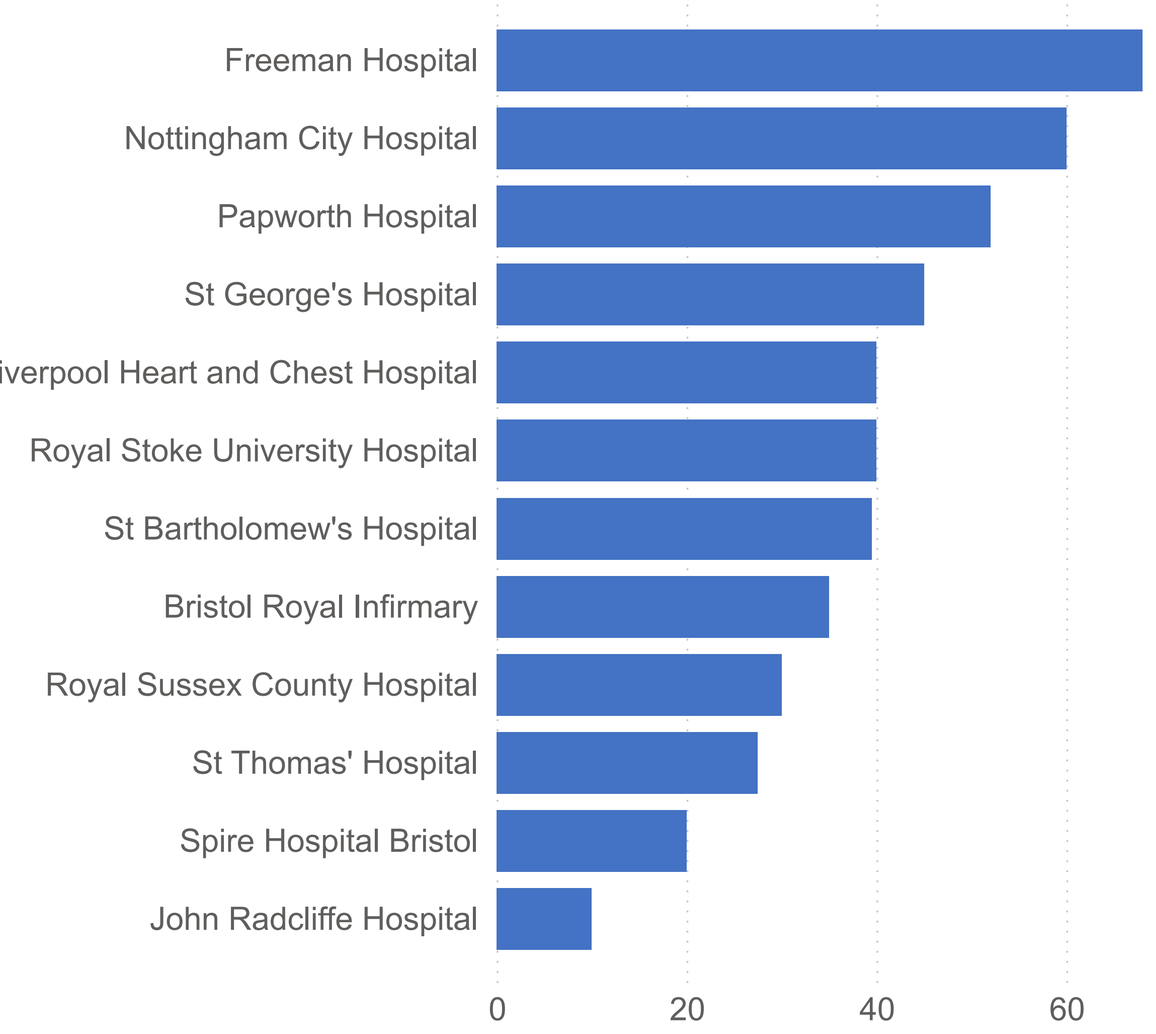
The NCHDA definition of procedure time is 'time of puncture to time of sheath removal'. If the time of onset is the 'time entering the catheter laboratory' and completion as 'leaving the catheter laboratory', much longer times would be expected.

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:

- *Hammersmith Hospital*
- *Harefield Hospital*
- *Kings College Hospital*
- *Leeds General Infirmary*
- *New Cross Hospital*
- *Queen Elizabeth Hospital*
- *Royal Brompton Hospital*
- *Southampton General Hospital*
- *Spire Hospital Nottingham*
- *University Hospital of Wales*
- *Wythenshawe Hospital*

Median procedure time (minutes) by hospital (April - September 2025)



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Median fluoroscopy times and X-ray/contrast dosage were low, but with significant variation between hospitals between April and September 2025

The median time to undertake fluoroscopy ranged from 2 to 10 minutes and with median X-ray dosage ranging from 2 - 2,000 cGy·cm^2 .

Median contrast was zero for most hospitals, with only 3 having a median contrast dose greater than zero. This is not surprising as most centres rely on ultrasound guidance for this procedure.

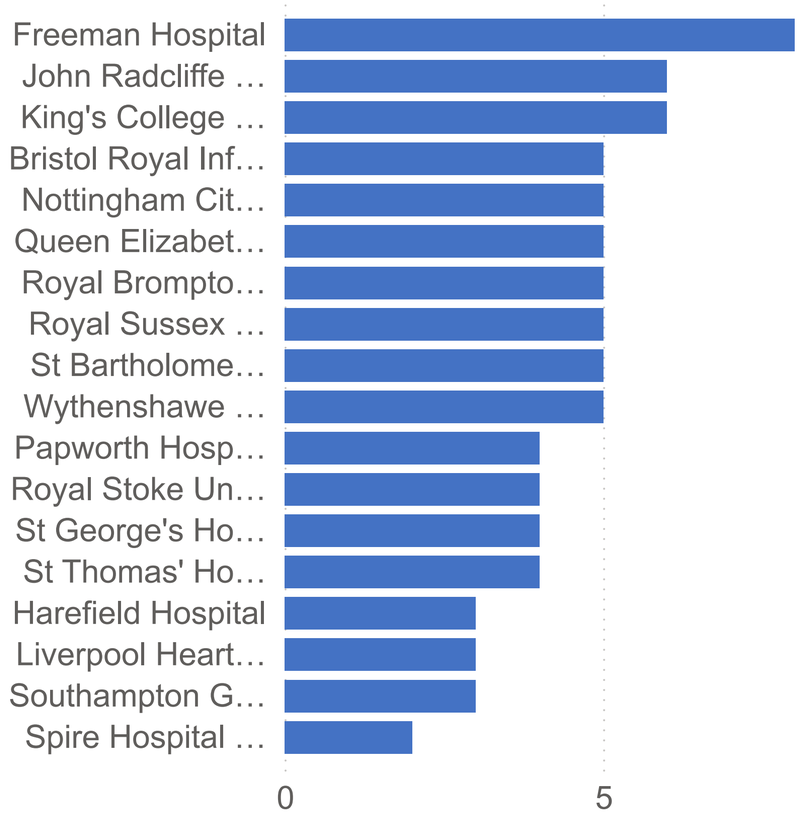
It may be preferrable in future for the registry to collect screening time in seconds (rather than rounded to the nearest minute currently), as some procedures can be undertaken in less than a minute of screening (especially when also guided with echo).

Select a procedure guidance method below to see specific data.

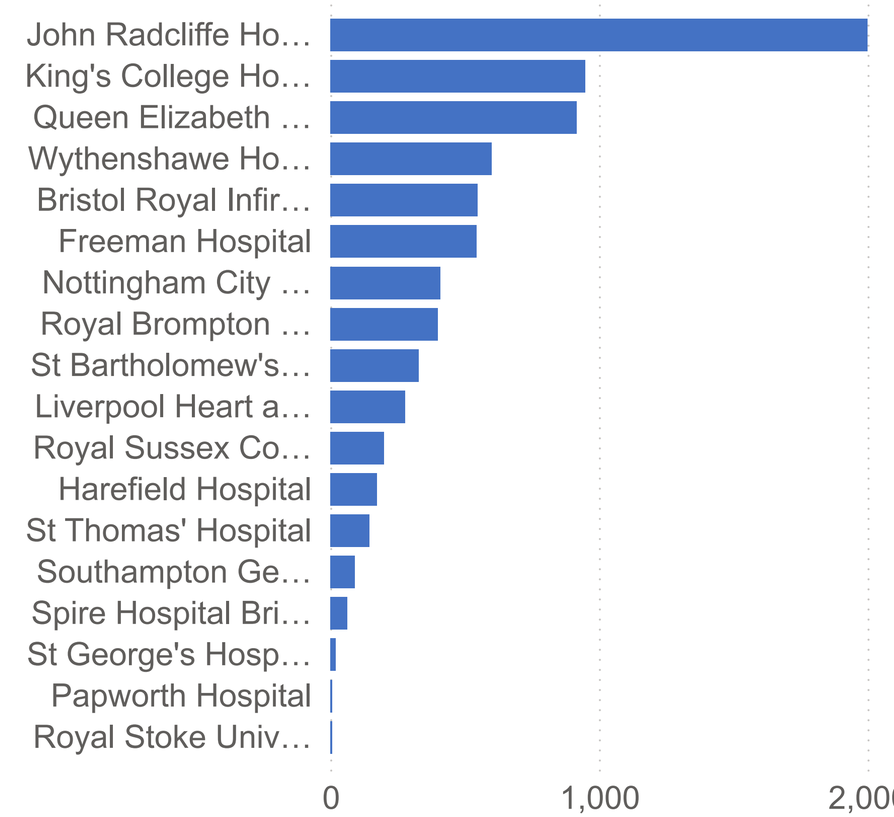
Select procedure guidance method

All

Median fluoroscopy time (minutes) by hospital (April - September 2025)



Median Xray dose by hospital (April - September 2025)



Median contrast dose by hospital (April - September 2025)

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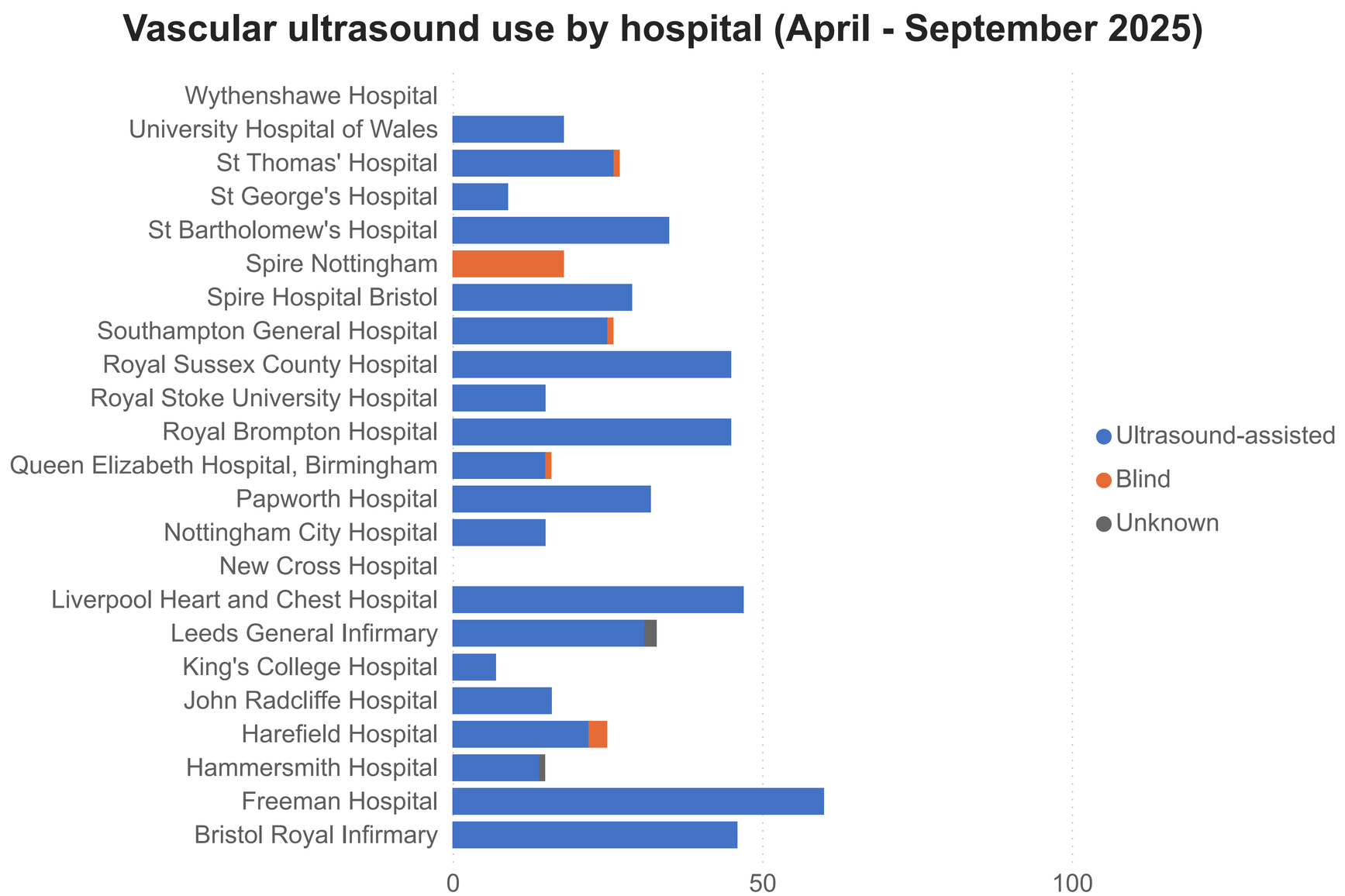
Most centres followed the recommendations to use ultrasound-guided puncture of the femoral vein between April and September 2025

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

Hospitals that use third party software to record 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 (where NHS procedures from Leicester are undertaken) appears to routinely use "blind puncture" (an approach used only rarely elsewhere).



The majority of centres used transoesophageal or intracardiac echocardiographic guidance during PFOC procedures between April and September 2025

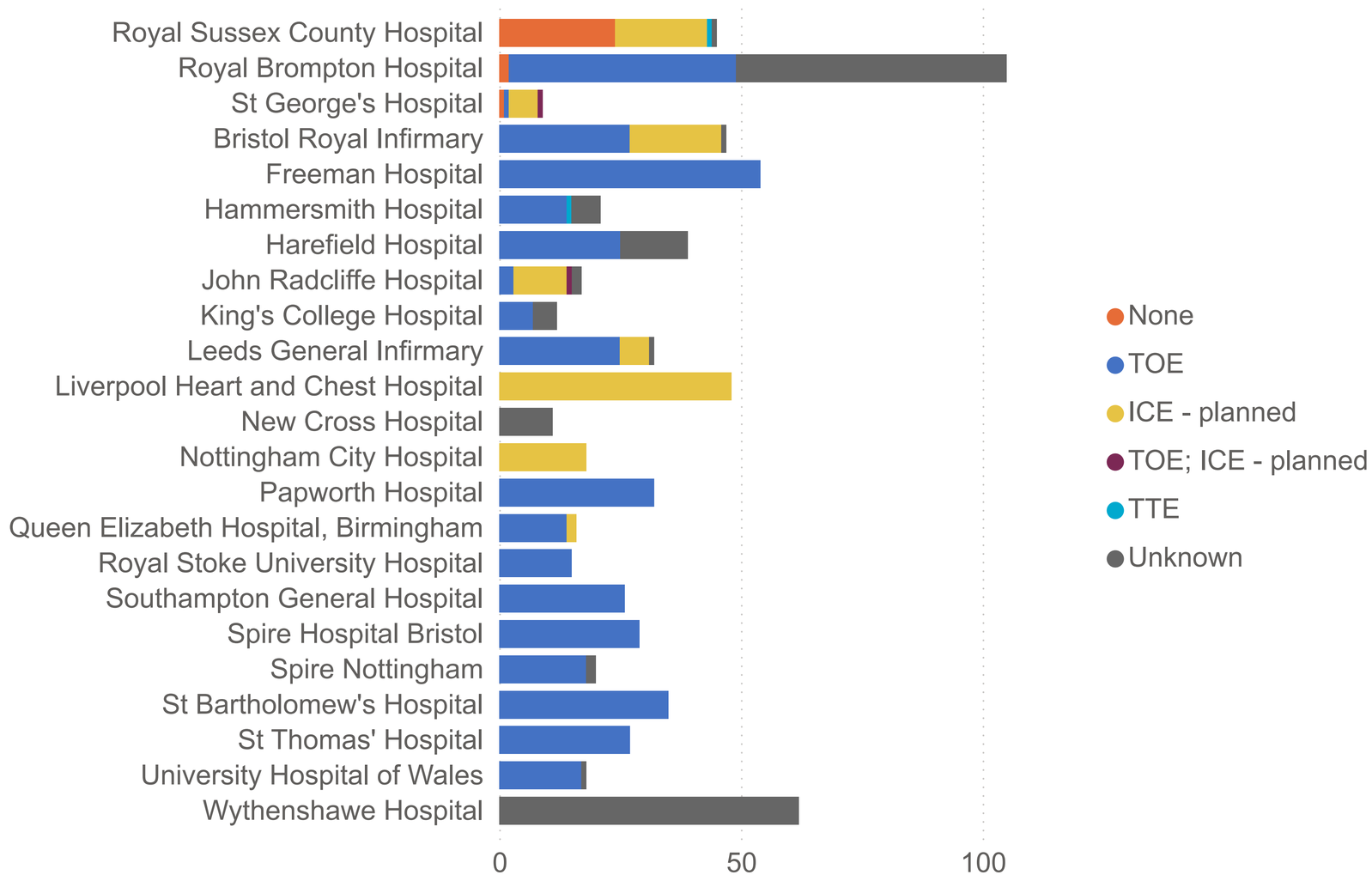
The majority of hospitals use transoesophageal echocardiography (TOE) or intracardiac echocardiography (ICE) for imaging guidance in PFOC procedures during the period. These modalities provide much better images than transthoracic echocardiography (TTE).

Several centres used exclusively transoesophageal echocardiography, one of which was a private hospital, where general anaesthesia is usually more easily available. Some centres (seemingly higher volume 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.

BCIS recommend that new operators start PFOC with TOE 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 (April - September 2025)



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 procedural 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 serious complications are very rare.

Atrial fibrillation is reported in the Randomised Control Trials and we are awaiting HES data to determine if this is having any impact on UK / NHS patients.

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. Hospitals however should record all complications that occur prior to discharge.

PFOC complications counts (April - September 2025)