NCAP

NATIONAL CARDIAC AUDIT PROGRAMME

NICOR

Percutaneous Foramen Ovale Closure (PFOC) Registry

2025 Annual Report

2023/24 and 2021/24 data

Report at a glance

~ 750 PFOC cases per year reported in the National Congenital Heart Disease Audit (NCHDA) over the last three years

20 NHS hospitals commissioned to perform PFOC procedures for the prevention of recurrent stroke

19 hospitals (18 NHS 1 private) provided data to the audit

32-fold difference in the rate of PFOC procedures between patients living in different Integrated Care Boards (ICBs) (may in part be explained by incomplete data submissions)

18-60 the age of patients in the vast majority of PFOC cases

55% of PFOC patients under 50 years of age were female compared with only **42%** of patients aged 50 years or more

71% of patients treated as a day case

25% of patients had a 1-night stay in hospital

The Amplatzer range and GORE Cardioform devices are the most frequently used

1.4% Device embolization rate (other reported complications were very low)

Recommendations

1. All hospitals performing patent foramen ovale closure (PFOC) procedures should register with NICOR and submit their data to the PFOC Registry.

2. Complete and timely data submission is required, including the name and serial number of the PFOC device(s) used.

3. The vast majority of PFOC procedures should be submitted to the new database, which will collect data specifically pertinent to PFOC. Patients under 18 or with other forms of congenital heart disease (other than uncomplicated bicuspid aortic valve) or previous congenital or surgical intervention should be submitted to the National Congenital Heart Disease Audit (NCHDA).

4. Hospitals should collect data on all complications following a procedure and ensure these are submitted to the registry.

Introduction

The Patent Foramen Ovale Closure (PFOC) Registry is part of the National Cardiac Audit Programme (NCAP) which is run by the National Institute for Cardiovascular Outcomes Research (NICOR).

This report details activity for PFOC procedures for England & Wales and Northern Ireland (Scotland does not participate in the wider UK audit). It covers both NHS hospitals and also private centres that have agreed data sharing with NICOR.

The key focus of the audit is quality assurance and improvement. The report summarises the number of patients being treated, where this treatment is delivered, the quality of the care and the outcomes for patients.

This report is of value to a wide range of stakeholders but importantly it allows patients and their relatives to better understand PFOC practice and its outcomes in the UK. **The slides in the report are interactive so you can select and explore the data that interest you.**

The next slide provides some detail about the procedure and the data used for this early report. The new registry has only started in 2024 and currently we are asking all hospitals that perform these procedures to register and to submit their data. In this report, we have analysed data collected from the National Congenital Heart Disease Audit (NCHDA). We provide trends over three years where relevant. All summary statistics are based on data that are self-reported by hospitals and unadjudicated unless otherwise stated.

The NCHDA and PFOC Registry relies on the active contribution of all participating hospitals performing PFOC procedures. Detailed information has been entered by hospitals, queried and cleaned before analysis is undertaken by the NICOR team. We are very grateful to all the staff at the contributing centres for their time in developing this audit.

We will continue to work closely with the hospitals performing PFOC, as well as patients and other stakeholders to improve the quality of audit data and how these are used to ensure high quality care in the UK.

NICOR PFOC Registry and NCHDA teams

The collection of data on PFOC

The patent foramen ovale closure (PFOC) procedure aims to prevent recurrent stroke among individuals who have suffered a stroke due to a 'paradoxical embolus'. A paradoxical embolus is where a clot from the veins of the legs breaks off and moves up towards the heart. Instead of this clot passing into the lungs and being filtered out, it may cross through a patent foramen ovale (PFO), a small hole between the right and left upper chambers of the heart that remains open only in a minority of people after birth. If a clot passes across the PFO to the left side of the heart, arterial circulation may take it to the brain, potentially causing blood vessel blockage and subsequent damage of brain tissue (this is one mechanism for a stroke).

Transcatheter closure of a PFO has been undertaken in the UK since the late 1990s, usually by congenital heart disease interventional cardiology programmes. Data were therefore initially collected through the National Congenital Heart Disease Audit (NCHDA).

In 2013, NHS England ceased funding for PFOC and a Commissioning through Evaluation process was undertaken, with data collected from a restricted number of centres. Randomised controlled trials in 2017 proved the efficacy of PFOC in preventing stroke and two studies showed its cost-effectiveness. NHS England funded 20 centres to perform these procedures from October 2019.

Between 2019 and 2024, audit data on these procedures were collected as part of the NCHDA. From April 2024, a new audit database has been commissioned, to collect data specifically relevant to PFOC, and to ensure complete capture of all PFOC procedure undertaken in adults over 18 years of age who do not have any other form of congenital heart disease. The new database will seek to ensure that all PFOC procedures are collected whether undertaken as part of a congenital heart disease service or as part of an adult cardiology structural heart disease service.

In the early stage of the new registry, we are encouraging hospitals to register and to start submitting their data. This early report aims to gain insights into PFOC in the UK from the procedures reported to the NCHDA from 2021/22 to 2023/24, to inform development of the new database, confirm that appropriate patients are treated and provide a baseline with which to compare future results. Data for this report were submitted by 18 NHS hospital and 1 private hospital. Twenty NHS hospitals are funded to perform PFOC procedures.

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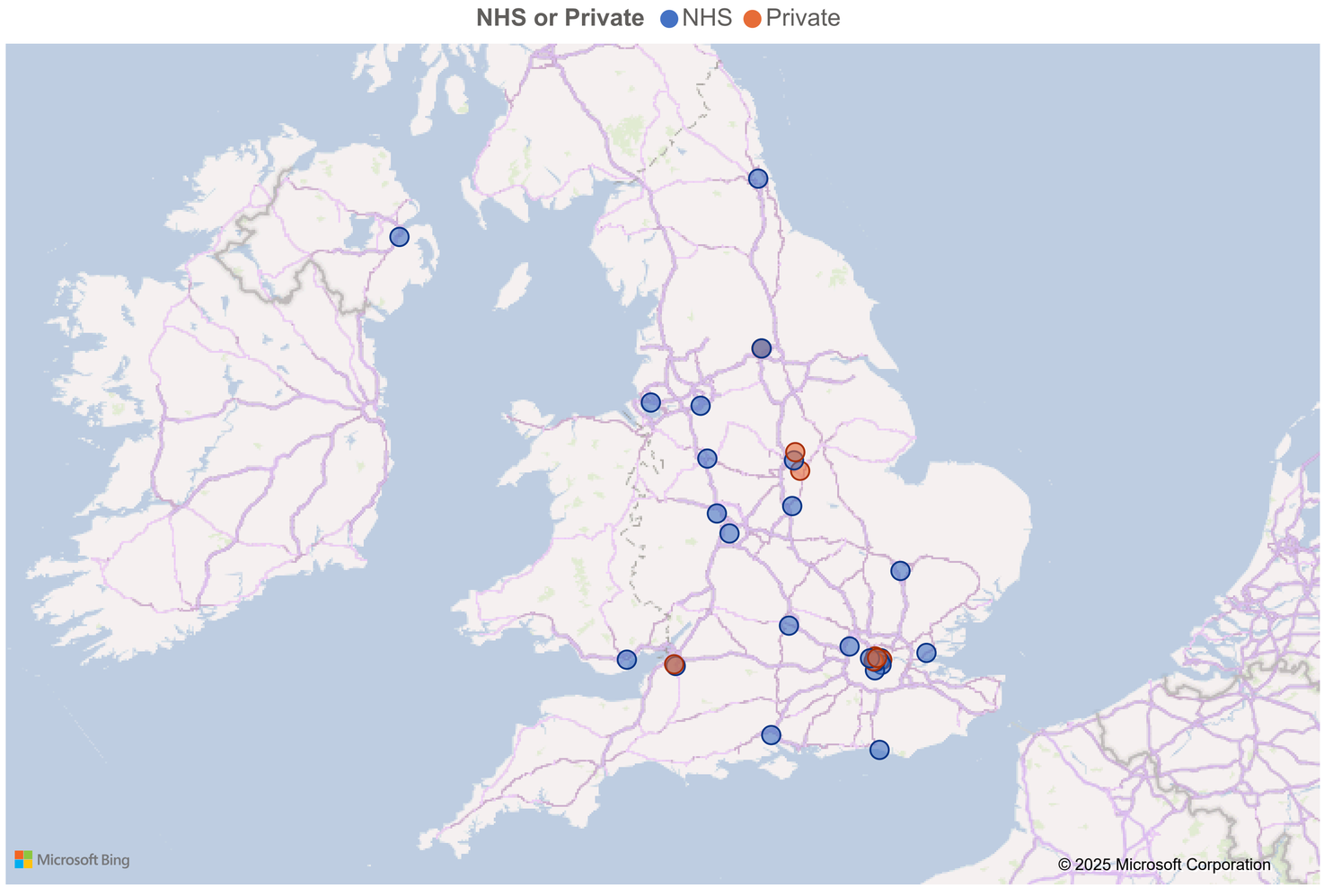
Hospitals performing PFO closure procedures

The PFOC Registry is expecting data to be submitted from 24 NHS and 8 private hospitals in 2024/25.

Of these, 18 NHS hospitals and 1 private centre have been providing data to the National Congenital Heart Disease Registry over the last few years. Of those NHS hospitals commissioned to perform PFOC procedures, not all have yet registered with NICOR to submit their data.

The NICOR PFOC Registry team is working with these hospitals to ensure that all register and start to submit data.

Location of hospitals expected to submitting data to the PFOC registry



Data completeness was below target levels, and not all commissioned centres submitted data from 2021/22 onwards

Data completeness by the 19 hospitals that have submitted data to the NCHDA so far is sub-optimal. Some fields have been completed well by all centres but some key fields, such as device type, have not been provided in more than 15% of cases.

Some fields are of particular importance, such as:

- device type and serial number (so that all implants are properly recorded and can be individually identified)
- variables that help better understand the nature of the patient's problem and the indication for PFOC treatment.

All hospitals performing PFOC procedures must provide complete and timely data to the PFOC Registry.

Select a hospital and year below to see specific data.

Key:
Data completeness by field or group of fields
Green > 90%
Orange 80-90%
Red <80%

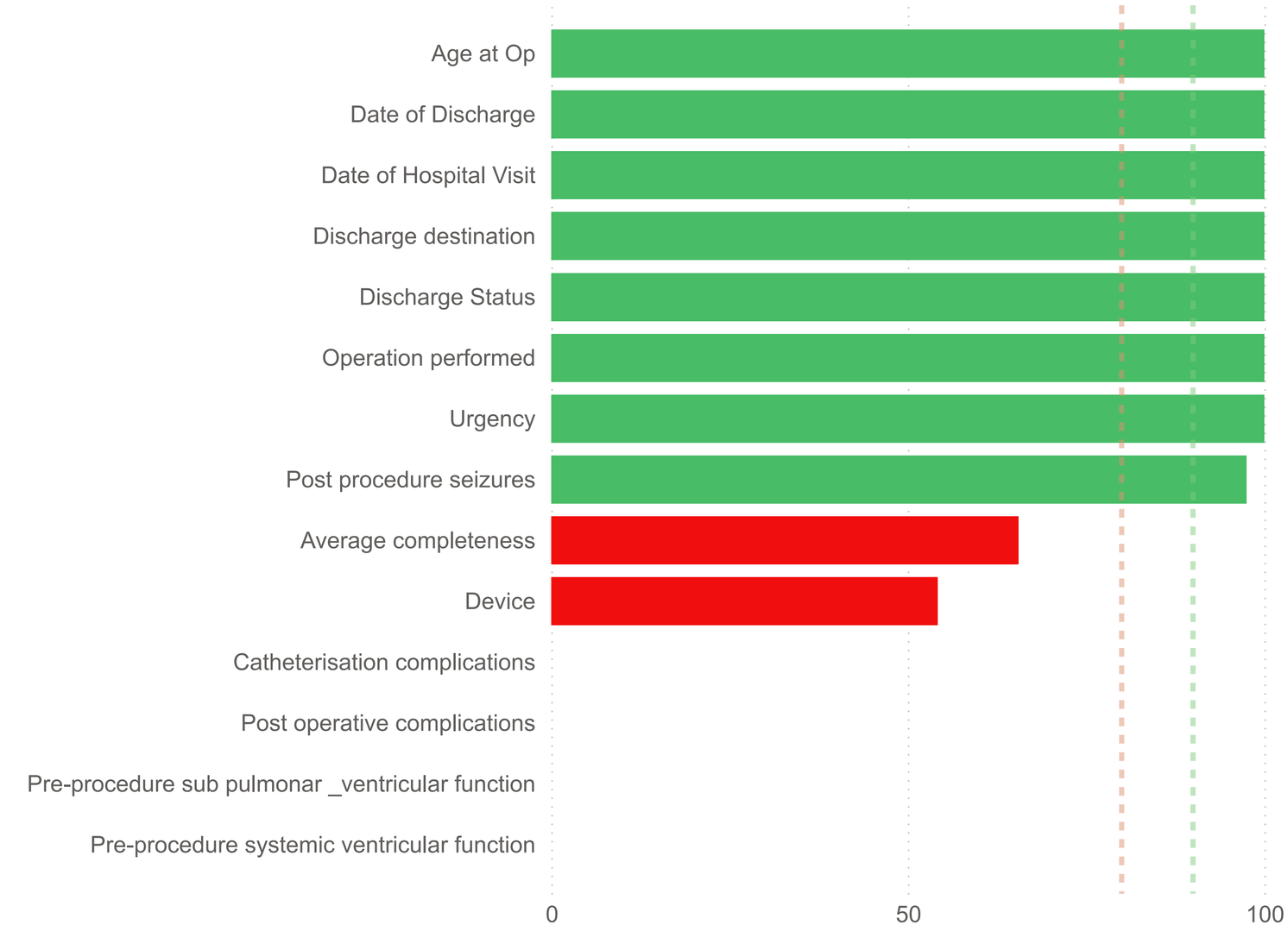
Select hospital

Brighton Royal Sussex County Hospital

Select year

All

Percent completeness of data variables in NCHDA



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PFOC procedure numbers varied widely across geographic areas

The maps show a wide variation in the rate of PFOC procedures per million (ppm) population across the:

- 42 Integrated Care Boards (ICBs) in England
- 7 Health Boards (HBs) in Wales and across the Cardiac Networks (CNs)

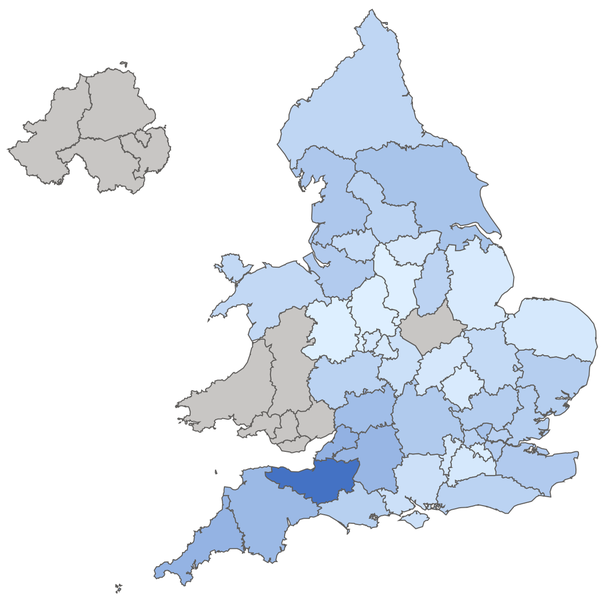
Rates varied from 3 pmp in South West London ICB to 55 ppm in Somerset ICB.

This is partly explained by the fact that only 13 of 20 NHS funded centres submitted data to the NCHDA. Even so, it is likely that many patients are not being offered PFOC procedures.

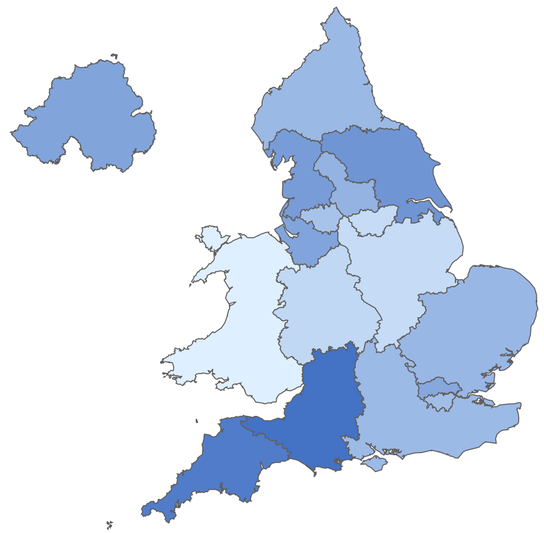
It is a priority for NHS and private hospitals that perform PFOC procedures to submit all of the eligible cases to the new PFOC Registry in order to establish whether there is inequity of access, and to determine how improvements can be made in geographical areas where access is poor.

Note: Patient home address data are not available for patients in Northern Ireland. Data for Northern Ireland in the CN map are incomplete. Grey areas also represent regions where no data are available.

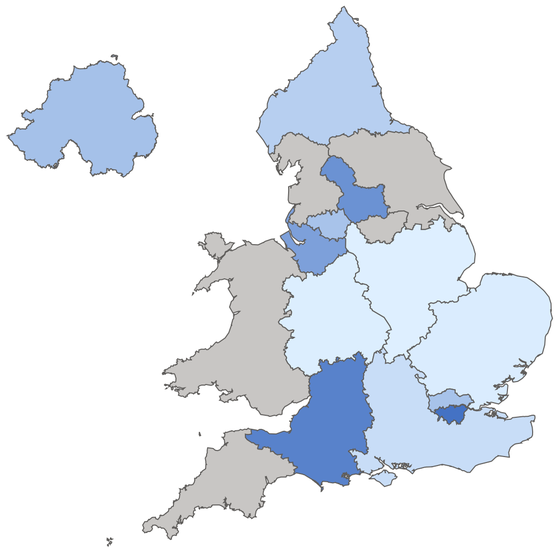
Rates of PFOC procedures pmp based on patient home address by ICB/HB (2023/24)



Rates of PFOC procedures pmp based on patient home address by Cardiac Network (2023/24)



Rates of PFOC procedures pmp based on hospital location by Cardiac Network (2023/24)



PFOC procedures were most frequently performed in the 40-60 years age group, with the vast majority in those aged 18-60 years

The majority of PFOC patients will have been treated because of a prior stroke due to a paradoxical embolus (while the new procedure-specific PFOC Registry will collect data on indication, the congenital database did not specifically record this).

Children only very rarely suffer a paradoxical embolus, and the evidence available does not clarify benefits vs risks for certain groups such as very elderly frail patients. **The age range is therefore what might be expected.**

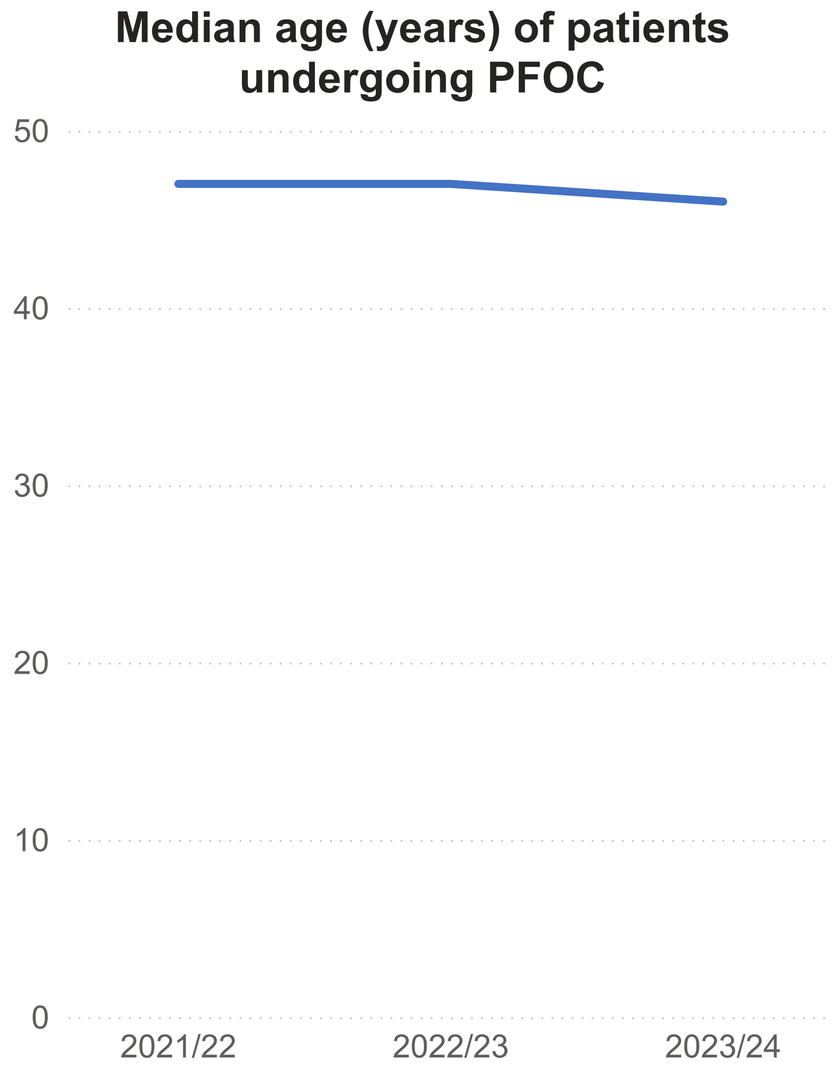
The main trials have been performed in patients aged 18-60 years, at the time of their stroke. NHS funding criteria suggest patients aged 18-60 years are the target age range.

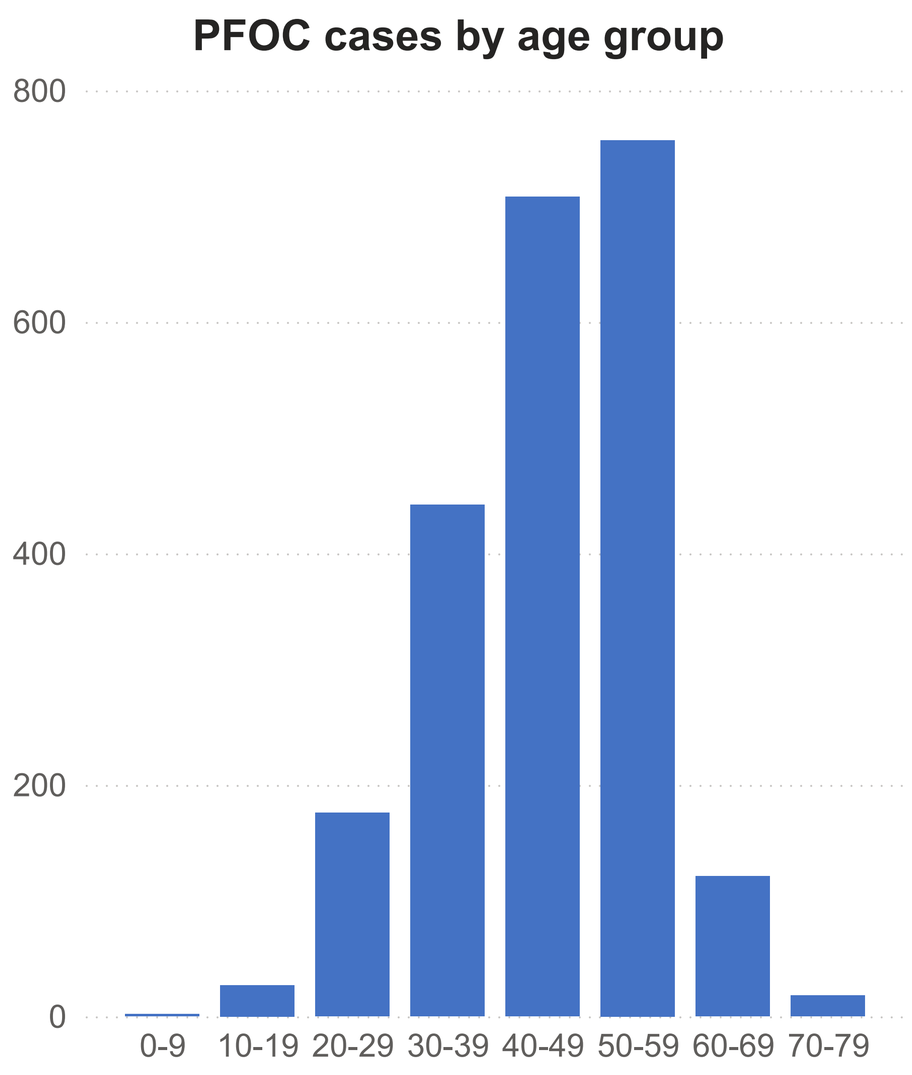
The new PFOC Registry will exclude patients under the age of 18 (as they will still be recorded as part of the congenital heart disease audit).

Select the year below to see specific data.

Select year

All





PFOC procedures were performed more frequently in males than females

Though there is no known increased susceptibility of males to paradoxical embolus, the analysis shows that in every year of data, more males have been treated with PFOC than females.

Possible explanations are that female patients have:

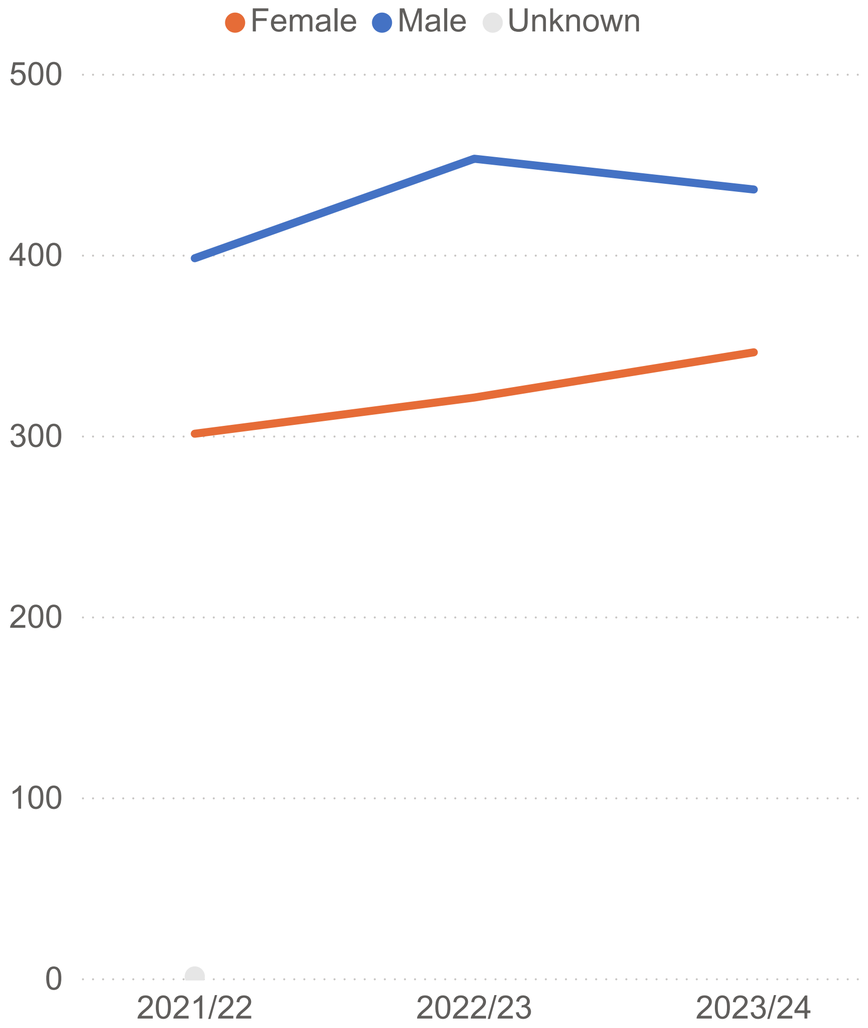
- a reduced chance of suffering a stroke due to a paradoxical embolus
- are less likely to present to stroke services
- are less likely to have a diagnosis of PFO made
- are less likely to be offered or to accept PFOC.

Select a year below to see specific data.

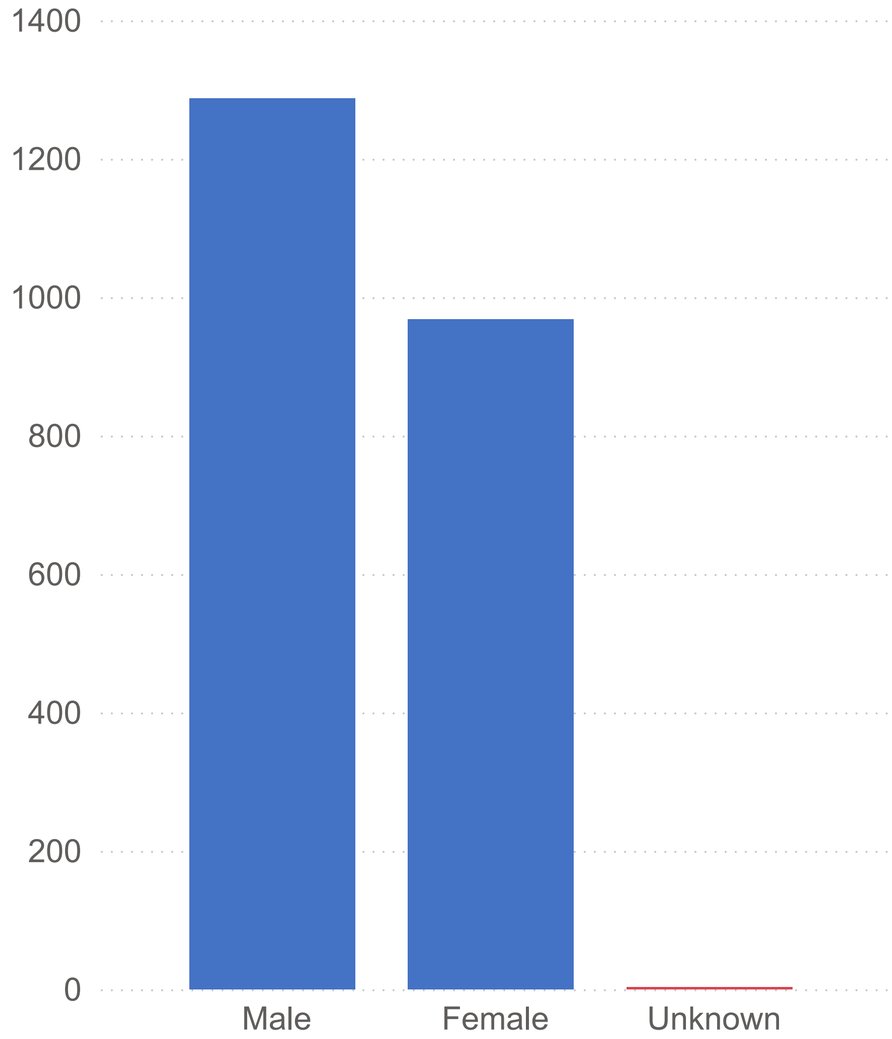
Select year

All

Number of PFOC procedures by gender



Number of PFOC procedures by gender



Females are treated more frequently below age 50 years, and males more frequently over 50 years of age

The median age of males receiving treatment is 48 years, that for females is 45 years. More females have been treated in the under 50 year age group while males are more frequently treated amongst those aged over 50.

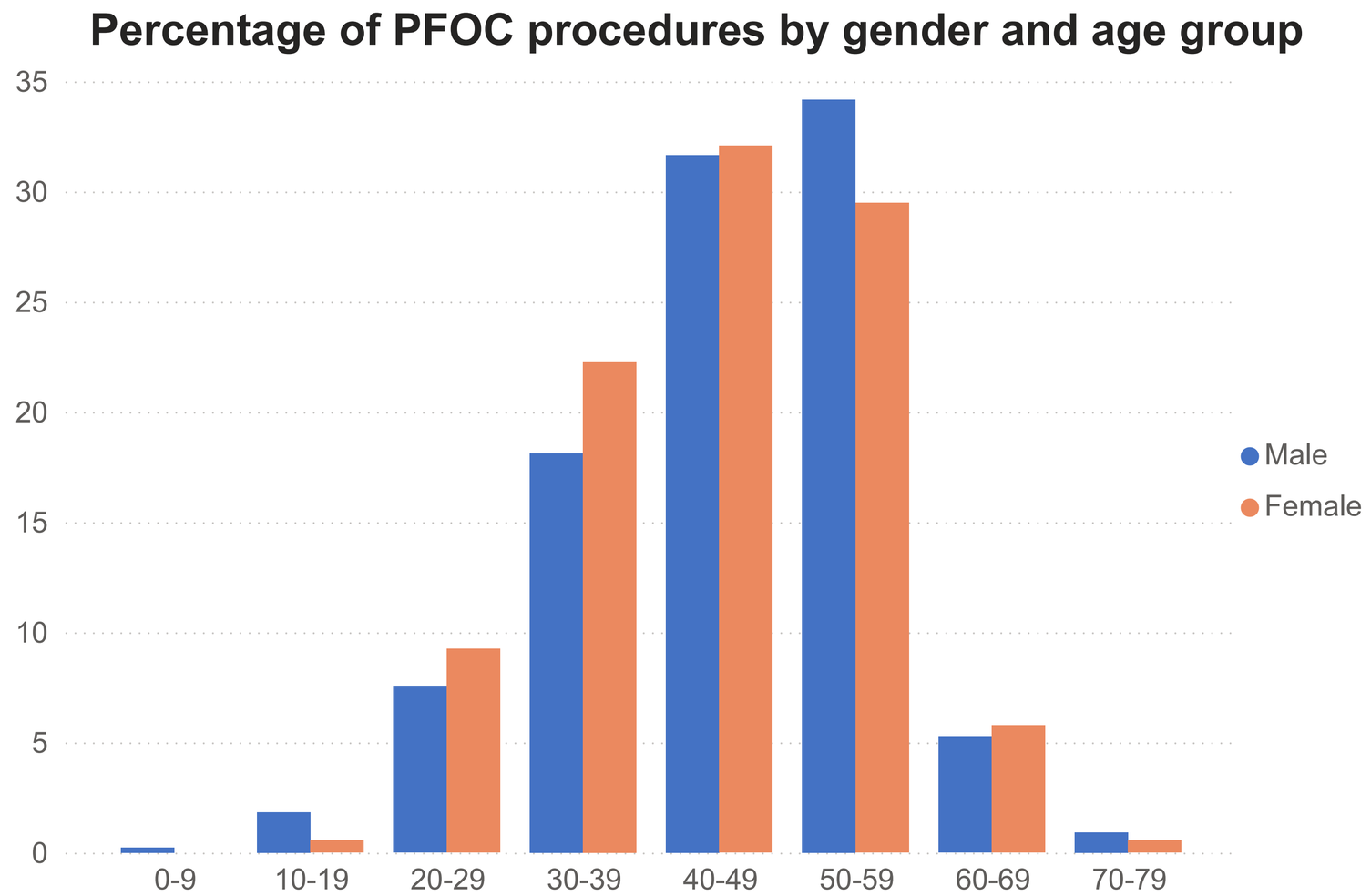
One possible explanation for this is that younger females may suffer more paradoxical emboli owing to:

- their higher levels of oestrogen that can promote clotting (those over 50 may have lower oestrogen levels due to the menopause)
- the use of the combined contraceptive pill that makes venous thrombosis more likely
- pregnancy that can promote clotting.

Another possibility is that younger females are either more likely to present with symptoms or be investigated more thoroughly.

It will be important to understand more about overall stroke rates and patterns of presentation before any conclusions can be made about inequity of access to care between males and females.

Select a year below to see specific data.



Select year

2023/24

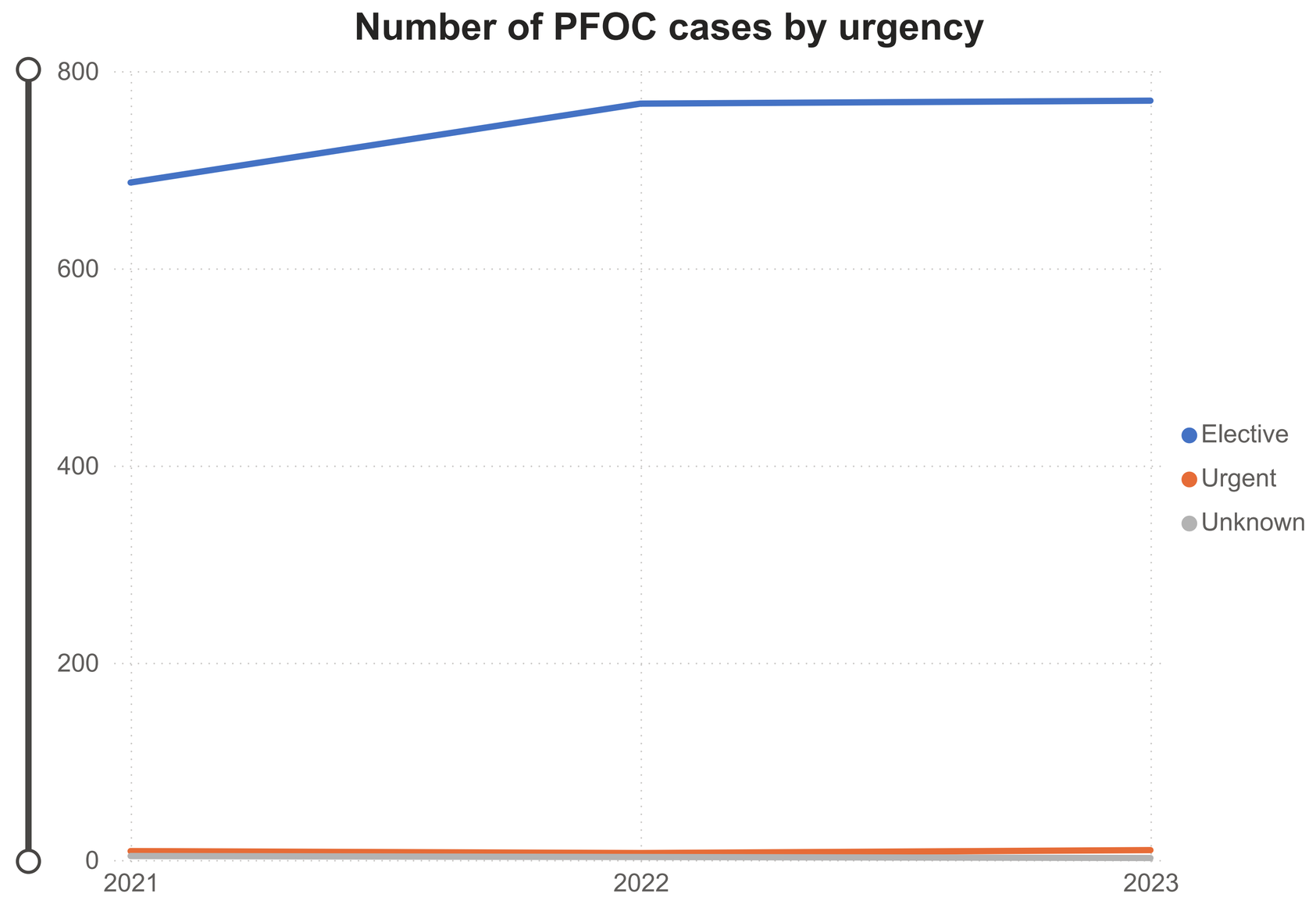
The overwhelming majority of PFOC procedures are elective, with very few urgent procedures

The vast majority of PFOC procedures have been elective, as would be expected. As the NCHDA dataset does not collect indication, we do not know if the urgent patients were treated for stroke prevention, or whether they may have had a different reason for treatment.

It may be that the urgent patients were suffering from desaturation of the blood due to continuous right to left shunting of blood, or because of a condition called orthodeoxia platypnea.

In this situation a patient may present with low oxygen levels, which is due to the blue blood from the right side of the heart passing through the PFO to the left side of the circulation.

The new PFOC procedure-specific dataset will include the reason for treatment, so will be able to confirm if any urgent procedures are undertaken for the more common indication of prevention of recurrent stroke.



The most frequent devices used for PFOC are Double Disc Nitinol wire devices, followed by the Goretex devices

The commonest device was the Amplatzer PFO occluder, used in the RESPECT study, and the CLOSE study of PFO closure to prevent recurrent stroke.

The next most frequent device was the Gore Cardioform device used in the REDUCE study, which is of a different design with a Nitinol wire frame encapsulated in ePTFE (Goretex).

The other devices were predominantly other Nitinol wire double disc devices that have similarities with the Amplatzer PFO occluder. These included other designs of Amplatzer devices including those designed for Atrial Septal Defect (ASD), Coccoon PFO, Occlutech devices of various designs, and Ceraflex devices. 60 patients were treated where no device type was recorded.

No patients were recorded as having been treated with suture only devices (such as NobleStitch), flat stents or biodegradeable devices.

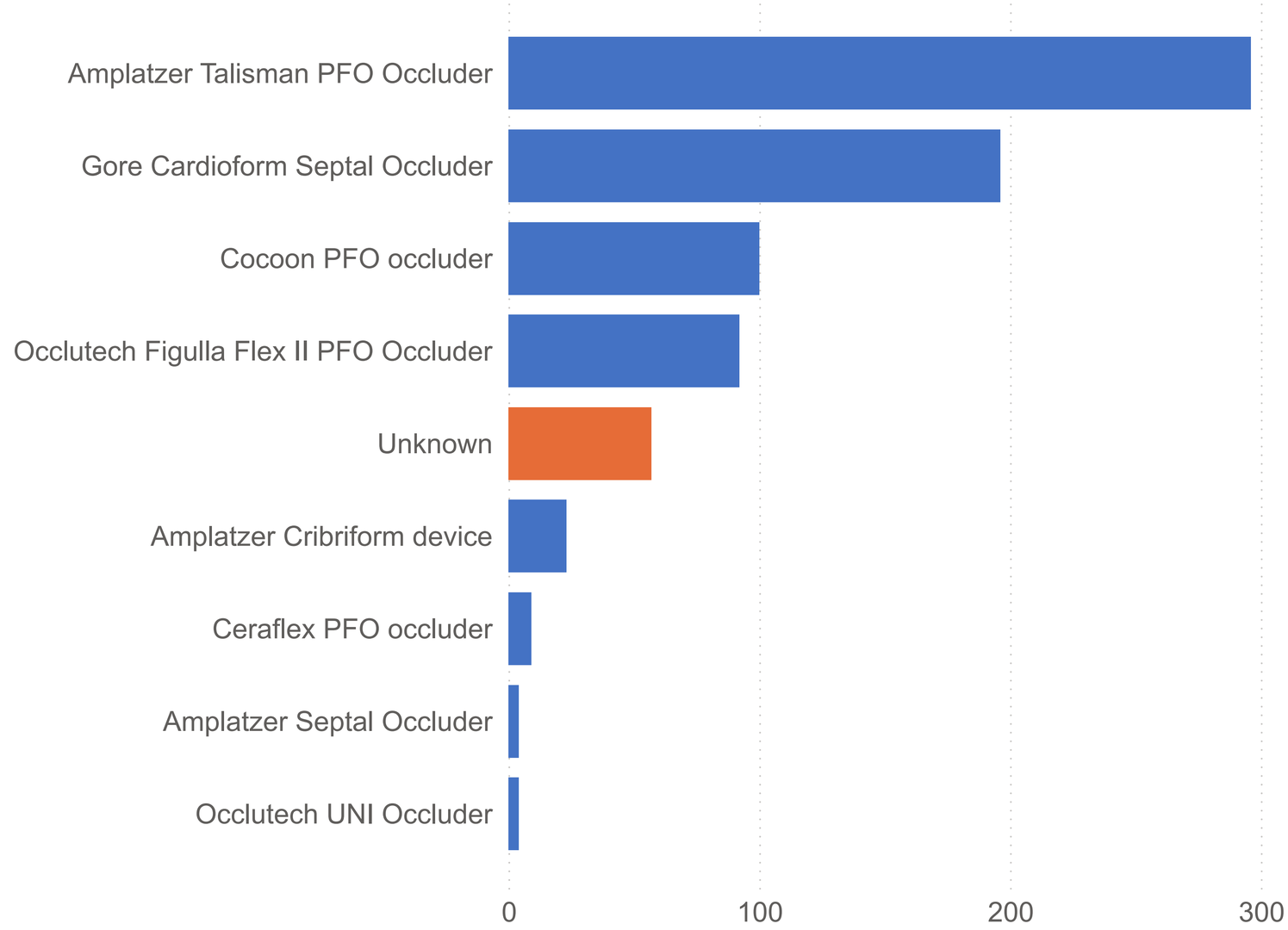
More specific detail will be collected in the new database, and complete capture of device type and serial number will be required.

Select year below to see specific data.

Select year

2023/24

Number of PFOC cases by device used



The majority of patients are treated as a day case or have only 1 night stay in hospital

Most PFOC procedures are undertaken as a day case.

A 1-night stay was also relatively common.

As PFOC is funded in only 20 hospitals, patients may have to travel a long distance from home.

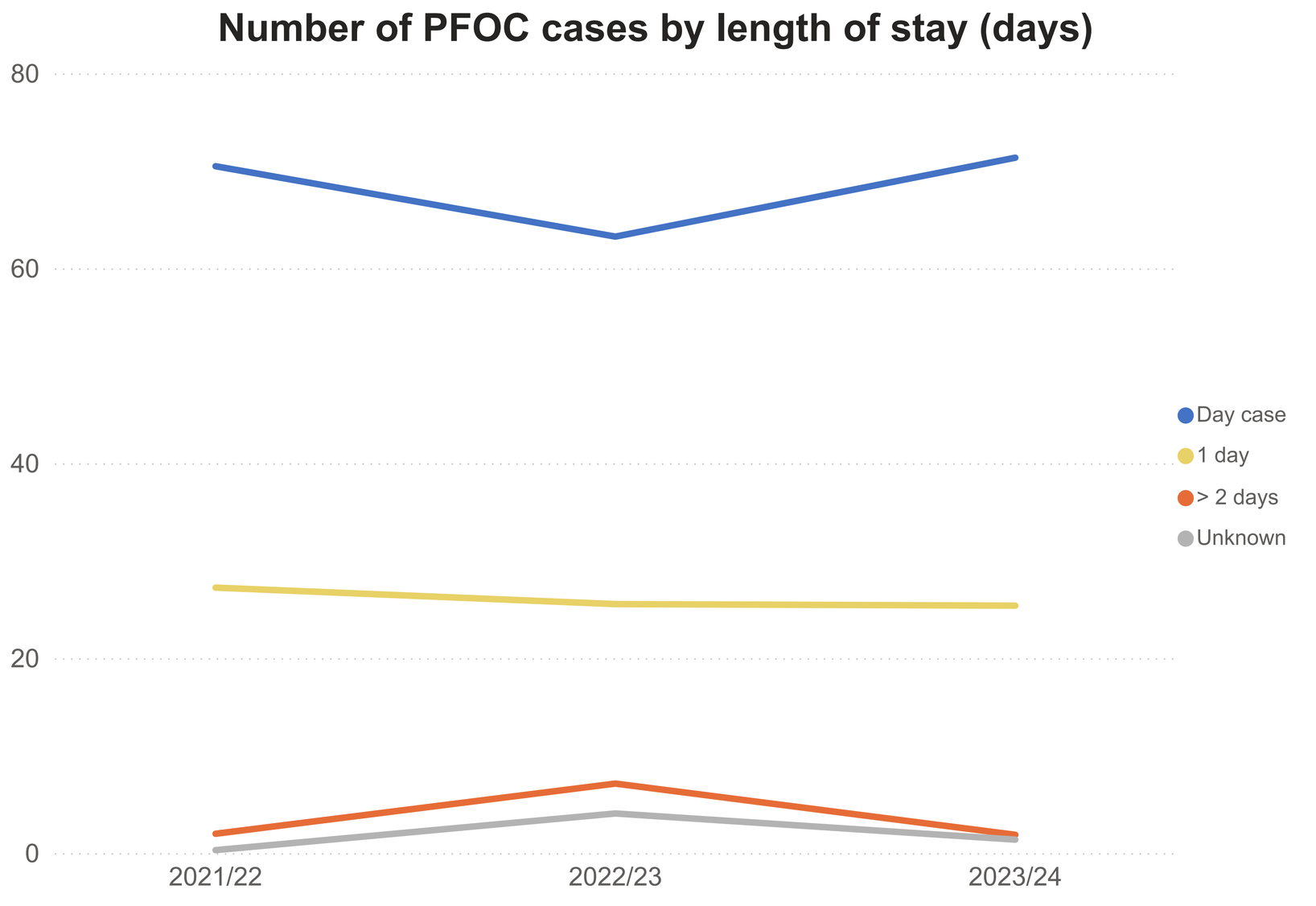
Longer stays may be due to complications or due to an indication other than stroke prevention.

The future PFOC dataset will include the indication for treatment, so we can better evaluate the patients who have longer stays.

Select a hospital below to see specific data.

Select hospital

All



Reported complication rates are low, with device embolisation being the most frequently reported

There is a very low level of recorded complications following PFOC procedures.

This is consistent with the results from the randomised trials.

The 1.4% reported device embolisation rate is higher than in the randomised controlled trials, but with the small numbers of procedures, it is unclear if this is significant.

Future audit data will be linked to hospital admission data to ensure the best possible capture of complications.

Select year

All

Percentage complication rates after PFOC procedures