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# BMJ Open Barriers and enablers to healthcare system uptake of direct oral anticoagulants for stroke prevention in atrial fibrillation: a qualitative interview study with healthcare professionals and policy makers in England

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## ABSTRACT

**Objective** To better understand the factors influencing the uptake of direct oral anticoagulants (DOACs) across different health economies in National Health Service England from the perspective of health professionals and other health economy stakeholders.

**Design** Qualitative interview study using a critical realism perspective and informed by the Diffusion of Innovations in Service Organisations model.

**Setting** Three health economies in the North of England, United Kingdom.

**Participants** Healthcare professionals involved in the management of patients requiring oral anticoagulants, stakeholders involved in the implementation of DOACs and representatives of pharmaceutical industry companies and patient support groups.

**Intervention** Semistructured interviews (face-to-face or telephone) were conducted with 46 participants. Interviews were analysed using the Framework method.

**Results** Identified factors having an impact on the uptake of DOACs were grouped into four themes: perceived value of the innovation, clinician practice environment, local health economy readiness for change, and the external health service context. Together, these factors influenced what therapy options were offered and prescribed to patients with atrial fibrillation. The interviews also highlighted strategies used to improve or restrict the uptake of DOACs and tensions between providing patient-centred care and managing financial implications for commissioners.

**Conclusions** The findings contribute to the wider literature by providing a new and in-depth understanding on the uptake of DOACs. The findings may be applicable to other new medicines used in chronic health conditions.

## BACKGROUND

Health innovations, including novel and cost-effective medicines, are regularly entering health systems, but their uptake is often slow.<sup>1</sup> This can result in delays for patients

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study is underpinned by implementation theory and explores multiple perspectives in multiple settings on the factors affecting the uptake of new medicines.
- ⇒ Moderate sample size of participants recruited with a varied range of roles from three health economies with different anticoagulation service provision models provided rich and in-depth insights into the uptake of direct oral anticoagulants.
- ⇒ The study was conducted in the North of England and relied on participants' accounts, which might have been affected by recall bias, thus limiting transferability of findings to other healthcare settings.

in receiving optimal treatment and for health systems in maximising benefits from innovations.

Atrial fibrillation (AF) carries a five-fold increased risk of stroke.<sup>2</sup> The risk of AF-related strokes can be reduced with long-term anticoagulation therapy.<sup>2,3</sup> Direct oral anticoagulants (DOACs) were developed to avoid some of the disadvantages of vitamin K antagonists such as warfarin, the commonly used oral anticoagulants. DOAC therapy offers advantages over existing oral anticoagulation therapy including reduced need for regular coagulation monitoring, having simpler dosing regimens, and fewer drug or food interactions.<sup>2,4</sup> In England, the uptake of DOACs was initially slow but increased substantially over the years. During the period 2011–2014, 95% of patients were prescribed warfarin and 5% DOACs, whereas during the period 2014–2017, DOACs prescribing had risen to 40% of all anticoagulants

prescribed.<sup>5 6</sup> There was also a high level of unexplained variation across health economies,<sup>5</sup> potentially leading to inequality of treatments offered to patients.<sup>7</sup>

Our earlier systematic review identified a broad range of factors affecting the uptake of new medicines within healthcare organisations.<sup>8</sup> These factors were grouped into patient, prescriber, medicine, organisation and external environment factors. However, studies reporting factors affecting new medicine use lacked exploration of the prescribers' orientation (eg, motivation, values and goals, or beliefs about new medicines) and organisational factors (eg, readiness for innovation, culture and climate, and implementation process) previously identified as potentially important in the health innovation implementation literature.<sup>9–11</sup> Deficiency in reporting these factors could be due to the data sources used by the reviewed studies (mostly secondary administrative data from various databases) and the lack of theoretical frameworks used to inform study designs of reviewed studies. This study, underpinned by implementation theory,<sup>12</sup> aimed to explore perspectives of healthcare professionals and other stakeholders to better understand the factors influencing uptake of DOACs for stroke prevention in AF in England.

## METHODS

### Study design

The local uptake of DOACs is an example of a complex open system of processes involving various stakeholders and influenced by both internal and external factors. Understanding the reasons for the different rates of uptake of DOACs in differing health economies requires exploration of underlining causes and the relationship between what we experience and what actually occurs. Thus, a qualitative study using a critical realism perspective was conducted.<sup>13 14</sup> The study was informed by the Diffusion of Innovations in Service Organisations model, which was developed from a comprehensive systematic review of published empirical studies from 13 different research areas exploring the diffusion of health service innovations.<sup>12</sup> The model proposes nine interacting elements influencing the diffusion of innovations: the innovation (eg, new medicine), adoption by individuals, assimilation by the system, communication and influence, system antecedents for innovation, system readiness for innovation, the outer context (interorganisational networks and collaboration), implementation process and linkage among components of the model.<sup>12</sup>

### Setting and participant recruitment

The National Health Service (NHS) in England is a publicly funded healthcare system. Some patients (eg,  $\geq 60$  years, certain medical condition, low income) qualify for free of charge prescriptions, others pay a set reduced fee for prescription (currently £9.65 per item), rather than the full cost of the prescribed medicine.<sup>15</sup> We recruited participants from three health economies in the North of

England using theoretical sampling;<sup>16</sup> see online supplemental file 1 for description of each health economy. In total, 46 participants were recruited for interview (14 in health economy A, 16 in health economy B, 13 in health economy C and 3 working across health economies; table 1).

Eligible participants were identified through the research team's clinical networks, review of relevant documents (eg, authors of clinical guidelines), observations of local formulary and commissioning meetings, and interviews with patients.<sup>7</sup> Eligible participants were healthcare professionals involved in the management of patients requiring oral anticoagulants (eg, prescribing, advising on treatment and monitoring); stakeholders involved in the implementation of DOACs (eg, Formulary Committee members) and producing or disseminating prescribing guidelines, including representatives of pharmaceutical industry companies who manufactured DOACs and an AF patient support group representative.

### Data collection

Semistructured interviews were conducted by KM between March and October 2019 using interview guides (online supplemental file 2) informed by the findings of a systematic review.<sup>8</sup> The guides consisted of nine (for healthcare professionals) and five (for other stakeholders) open questions with associated probes and prompts exploring their experiences of DOACs being introduced in their practice, organisation or health economy, how the anticoagulation practice and services changed with DOAC introduction, and the barriers and facilitators they experienced to their use. Interviews were face-to-face or by telephone and were audio-recorded and transcribed verbatim.

### Data analysis

Data analysis was undertaken using the Framework method, which is a form of inductive thematic analysis consisting of five inter-related stages (familiarisation with the dataset, developing analytical framework, indexing the data, charting, mapping and interpretation) that can be broadly divided into data management and data interpretation phases.<sup>17</sup> During data management process, an analytical framework was developed to organise the data, summarise and reduce it in a meaningful and manageable way. First, a selection of interview transcripts sampled for diversity and richness and providing the greatest opportunity for coding were read and coded line-by-line (open coding) by two authors and patient and public involvement (PPI) advisory group. The identified codes were refined after discussion with the research team. Those codes were used to develop preliminary categories and subcategories that best fitted the data related to the research questions (inductive process). Then, preliminary categories and subcategories were compared with the interview schedules and systematic literature review findings<sup>8</sup> and the Diffusion of Innovations in Service Organisations model<sup>12</sup> to refine the analytical framework

**Table 1** Characteristics of interviewed healthcare professionals and key stakeholders

Participant name*	Health economy	Patient-facing role	Place of work, role
P1-A-N	A	Yes	General practice, specialist nurse
P2-A-GP	A	Yes	General practice, GP
P3-A-GP	A	Yes	General practice, GP
P4-A-P	A	Yes	General practice, pharmacist
P5-A-P	A	Yes	General practice, pharmacist
P6-A-P	A	Yes	General practice, pharmacist
P7-A-GP	A	Yes	General practice, GP
P8-A-N	A	Yes	General practice, specialist nurse
P9-A-P	A	No	CCG, pharmacist (medicine optimisation)
P10-A-P	A	No	Hospital, pharmacist (medicines governance)
P11-A-P	A	No	Hospital, pharmacist (management)
P12-A-O	A	No	Public health
P13-A-GP	A	Yes	General practice and CCG, GP
P14-A-P	A	Yes	Hospital, pharmacist (clinical services)
P15-B-C	B	Yes	Hospital, consultant
P16-B-P	B	Yes	Hospital, pharmacy (clinical services)
P17-B-N	B	Yes	Hospital, specialist nurse
P18-B-C	B	Yes	Hospital, consultant
P19-B-O	B	Yes	Hospital, biomedical scientist
P20-B-P	B	Yes	Community pharmacy, pharmacist
P21-B-C	B	Yes	Hospital, consultant
P22-B-GP	B	Yes	General practice and CCG, GP
P23-B-P	B	No	CCG, pharmacist (medicine management)
P24-B-P	B	No	CCG, pharmacist (medicine management)
P25-B-P	B	No	AHSN, pharmacist (medicine optimisation)
P26-B-P	B	No	Hospital, pharmacist (medicine information)
P27-B-P	B	No	Hospital, pharmacist (management)
P28-B-P	B	No	Hospital, pharmacist (management)
P29-B-P	B	No	CCG, pharmacist (medicine management)
P30-B-P	B	Yes	Community pharmacy, pharmacist
P31-C-P	C	Yes	Hospital, pharmacist (clinical services)
P32-C-N	C	Yes	Hospital, specialist nurse
P33-C-C	C	Yes	Hospital, consultant
P34-C-N	C	Yes	Hospital, specialist nurse
P35-C-P	C	Yes	Community pharmacy, pharmacist
P36-C-P	C	Yes	Hospital, pharmacist (clinical services)
P37-C-GP	C	Yes	General practice and CCG, GP
P38-C-P	C	No	Hospital, pharmacist (medicine information)
P39-C-C	C	Yes	Hospital, consultant
P40-C-P	C	No	CCG, pharmacist (clinical services)
P41-C-P	C	No	CCG, pharmacist (medicine management)
P42-C-O	C	No	Public health
P43-C-P	C	No	CCG, pharmacist (medicines governance)
P44-PI	A, B and C	No	Pharmaceutical industry, representative
P45-O	A, B and C	No	Patient organisation, representative

Continued

**Table 1** Continued

Participant name*	Health economy	Patient-facing role	Place of work, role
P46-PI	A, B and C	No	Pharmaceutical industry, representative

\*Participant name included participant number (eg, P1), health economy the participant was from (A, B or C) and role of the participant. AHSN, Academic Health Science Network; C, consultant; CCG, clinical commissioning group; GP, general practitioner; N, nurse; O, other; P, pharmacist; PI, pharmaceutical industry representative.

(deductive process). Once the analytical framework was agreed between the research team, it was applied to all interview transcripts (full dataset). KM read all transcripts in depth and organised the data into categories of the developed analytical framework. The last stage of data management was charting during which KM systematically summarised and hence reduced the data from each transcript. The summaries were displayed on a matrix by both category and case (individual interviewee) with links to the original data. The matrix was re-read afterwards to ensure clarity, the balance of information and emphasis. The organisation of the data resulted of six matrices, recorded using NVivo (V.11).

During data interpretation stage, KM started with descriptive analysis by identifying similarities and differences between and across cases. Then, the researcher moved towards explanatory analysis by looking for emerging patterns and connections across cases. In line with the critical realism ontology, the researcher focussed on casual mechanisms or conditions to develop explanations for the identified barriers and enablers to the uptake of DOACs within the studied health economies. During the process, potential themes and subthemes were identified. The credibility and clarity of the interpretation were checked by discussing the interim and final analysis results with the research team and PPI advisory group.

### Patient and public involvement

Three people with AF taking oral anticoagulants were involved in the design and conduct of the study. Their detailed involvement has been described elsewhere.<sup>18</sup> Their experience of services informed strategies for recruitment of participants, and they were involved in co-design of participant information documents and interview guides. Also, they were involved in data analysis by providing interpretation of some transcript excerpts, which prompted new lines of analysis.

### Researcher characteristics and reflexivity

The multidisciplinary team had expertise in pharmacy (KM, KS and DP) and care of patients requiring anticoagulation (KS and DP), patient safety research (BF) and social research (SR), which enhanced reflexivity during the study design, data collection, analysis and challenged assumptions. Three authors (KM, KS and DP) were pharmacists with assumptions that patient-centred care was influenced by limited financial and staff resources in the NHS. The patient safety researcher (BF) held an assumption that patients are at risk from healthcare system and

how it is calibrated. The social researcher (SR) held the view that at different levels, systems will influence each other, and it is difficult to isolate levels because they are complex; thus, the Diffusion of Innovations in Service Organisations model was selected. Qualitative methodology was employed which aligned with the study aim. The first author (KM), who conducted interviews, completed training in undertaking qualitative interviews and data analysis. BF and SR have extensive experience in conducting qualitative research.

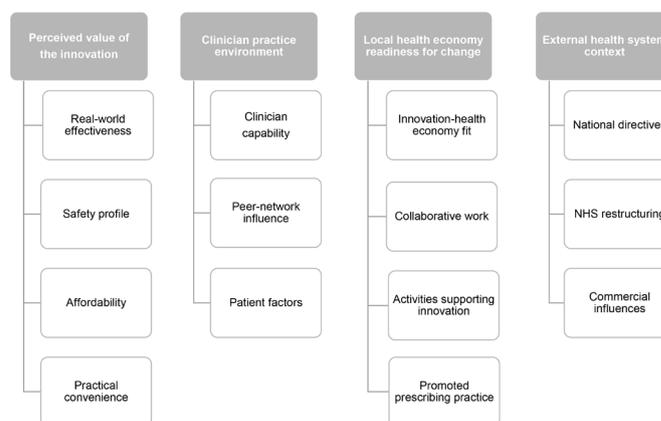
## RESULTS

Four themes with 14 subthemes influencing local uptake of DOACs were identified (figure 1). Distribution of identified subthemes in each participant's transcript is presented in online supplemental file 3.

### Perceived value of the innovation

Perception of DOACs' value, low or high, influenced prescribers' willingness to use DOACs in their practice and commissioners' decisions on local policies. Many participants discussed whether DOAC efficacy demonstrated in clinical trials translated into routine clinical practice.

People in trials generally do better than people who aren't in trials, in terms of compliance etcetera...I think people who are able to take warfarin, who have got good compliance, will probably get better outcomes in a real-world situation than people on these newer agents. (P39-C-C)



**Figure 1** Summary of developed themes and subthemes from the interview data with healthcare professionals and other key stakeholders.

Participants who preferred DOACs viewed them as being as effective as warfarin or better than inadequately controlled warfarin; more stable and reliable due to less drug/food interactions, being less affected by patients' health changes and offering immediate stroke risk reduction.

The DOACs are far more reliable. You know, you are not getting the swings that some of the patients get with warfarin. (P20-B-P)

Some participants described a cautious approach to the use of DOACs due to general anxiety about the use of new medicines, lack of real-world evidence and historical view of anticoagulants being 'high-risk' medicines requiring specialist input. When discussing safety of DOACs, most commented on the unknown risk of bleeding and long-term effects, lack of reversal agents and insufficient understanding of how to use bleeding risk scoring tools. Others reflected that the concerns diminished over the years with clinicians becoming more comfortable with DOACs and availability of real-world data indicating their safety.

The lack of reversal agent was a significant concern to general practice; it was a significant concern to patients with the initial discussions while we became more comfortable. It was certainly a reason that we were cautious about the introduction. (P15-B-C)

Some commented that both clinicians and patients were used to warfarin monitoring and that monitoring was also needed for safe use of DOACs. However, there was uncertainty about what to monitor and how frequently, as advice differed among experts. Others argued that many medicines, including other anticoagulants and antiplatelets, were not regularly monitored like warfarin to confirm their ongoing safety or patient adherence.

They (doctors) are very fixated on the idea of an INR (international normalised ratio) check to make them safe. And yet, in other drugs, we don't (check) beta-blocker levels, we don't do aspirin levels or something to see whether or not other drugs are working. (P33-C-C)

Many participants highlighted how the costs associated with DOACs influenced prescribing and local commissioning decisions. Some commented that health economies initially chose a controlled introduction of DOACs to manage budgets and preferred warfarin, which was perceived as a cheaper option. Others critiqued this approach due to a lack of consideration of cost-benefits associated with DOAC therapy, lack of a patient-centred approach and prioritising managing costs over patient safety.

If it (DOACs) had been the same price as warfarin, people would have just let it happen...I'm still of the belief that actually the main driver for looking at the reasons for managing the entry of these drugs was

around cost. Only once cost was considered was then a process put in place in order to manage patient safety. (P25-B-P)

Others noted the warfarin monitoring service cost varied between different health economies as there was no national tariff. Also, some commissioners revealed payments for medicines, and their monitoring was made from separate local health economy budgets (eg, prescribing budget and commissioned service budget); thus, the true cost of therapy at the time of decision making was unavailable.

The costs of that (warfarin monitoring service) varied wildly between PCT to PCT to PCT (local health areas), and some of it was secondary care (hospital) led models, some of it was primary care (general practice) led models, some of it was a mix of models, some of it no-one bloody knew what the cost was. (P12-A-O)

Others commented that stroke was more expensive than DOAC therapy due to associated health and social care costs; thus, DOAC use was justified. However, some noted the savings from using DOACs (eg, stroke prevention) were difficult to demonstrate to local decision makers, could take a couple of years to be realised and went into budgets other than the local health economy prescribing budget that funded DOACs. Others commented that additional money spent on DOACs would lead to less funding available for other health and social care services.

When you look at the cost of a stroke for the NHS and social care, you know you've got your hospital admission, you've got rehab, you've got social care, you've got people needing nursing homes, etc. So, I think, I seem to remember circulating that data made people realise that it was worth it. You know you've got to look wider than just our drug budget. (P36-C-P)

They (medicine and monitoring costs) don't come out of the same budget. They come out of the same overall budget, but nobody looks at how much warfarin costs in my drug budget, that is not linked together...the (commissioner) will pay for them both, but they're never looked at together. (P9-A-P)

The consensus across participants was that DOAC therapy was more convenient than warfarin for both clinicians and patients. DOAC initiation and management was perceived as less complex, aiding safer and quicker discharges from hospital, saving clinician's time in consultations, and general practice could manage patients themselves. Patients benefited from simpler dosing with no or limited dose changes and a less onerous impact on daily life.

The fuff about having to normalise or getting the INR within target and the interactions that warfarin has with other drugs and food and everything else, overseas travel, convenience for the patient, just

convenience really. It frees the patient up to do other things. (P7-A-GP)

### Clinician practice environment

Participants talked about differences in experience and willingness among general practice clinicians to use DOACs, especially among those not involved in warfarin monitoring service.

There is a little bit of deskilling...within primary care (general practice), where GPs historically haven't managed anticoagulation very much at all, they've handed anticoagulation to the secondary care (hospital)...(some GPs) don't have the confidence to sometimes get on and treat these patients...and they just hand it off. (P17-B-N)

Some discussed that commencing DOACs in time-constrained general practice was challenging because of the need for relatively long appointments to assess patients and facilitate informed discussions. Hence, some GPs preferred anticoagulation managed by specialists. Others commented that hospital specialists experienced different pressures and could not see all patients requiring anticoagulation. Thus, in their view, these patients should be managed in general practice, but commissioners must resource the additional workload.

As soon as you ask primary care (general practice) to do anything, very rightly they will say to you, where is the resource for this coming from? I am stretched way beyond my means, how am I going to do this? And some CCGs (commissioner) don't really get that... (P13-A-P)

Participants talked about peer influence within or outside their organisation influencing their prescribing decisions. Some commented on how they started using DOACs when they saw them being prescribed by their peers in general practice or hospitals.

Probably the growing numbers of patients initiated on DOACs in secondary care (hospital). And most of us would realise this is crazy; you can't have a patient receiving treatment at the hospital, which is completely different from the treatment they would receive at general practice. (P3-A-GP)

Presence of local champions for or against DOACs was perceived to have a huge influence on local uptake. Some described general practice clinicians driving DOAC use, others noted that opinions differed between hospital specialists, with some pushing for greater DAOC use and others opposed to their widespread use.

I would say primary care (general practice) was the main driver. The haematology team (hospital) were on board, so they were interested, but there were reservations...it was being driven very heavily by the prescribing lead GP, (who) was very heavily involved in pushing this particular project. (P10-A-P)

Many clinicians described patient clinical characteristics (renal and liver functions, other prescribed medicines, comorbidities and frailty) influencing their prescribing decisions. Clinicians also talked about patient involvement in decision making, which varied from shared decision making to limited involvement.

Depending on the patients' characteristics I will normally select one for them, give them my preferred agent for their particular situation and then if they say "Oh have I got to take this drug twice a day have I? Not once, like warfarin? Oh I can't cope." Then I might say "Well you can take rivaroxaban but that might interact with some of your other drugs more than apixaban might or your renal function is not so good. So that's the way I would do it and talk about the risks and benefits. (P33-C-C)

Most clinicians also revealed that patients with well-controlled warfarin therapy were not usually informed about DOACs unless they struggled to attend monitoring appointments or had poor warfarin control.

I would only talk about DOACs if I looked at a patients' time in therapeutic range and I thought it was below 60% or like you know it was very low, and I could not see any change happening in bringing it up. (P5-A-P)

Some clinicians stated that patient demand for DOACs encouraged them to use more in their practice. Patients were learning about DOACs from their social network, internet searches and media.

They (patients) would read, they would Google, they would hear neighbours saying: 'Oh I used to be on warfarin, but I'm no longer, I'm on this.' Yes, they do come and ask. And then when they ask if they are all right, we fast forward that request to the doctor. (P4-A-P)

### Local health economy readiness for change

Many participants described how the innovation aligned with the existing goals, priorities and ways of working locally. Increasing and achieving optimal anticoagulation of patients with AF, and consequently reducing the incidence of AF-related strokes, was a high clinical priority in all three health economies. Thus, some noted that DOACs were seen as a tool to improve their anticoagulation service or hospital arrhythmia clinic service (eg, reduce waiting times).

Everybody's anticoagulation service was on its knees. We didn't have a single anticoagulation service in (the region) that wasn't at...full capacity. The work that we'd done in (health economy B) had shown that actually, their anticoagulation service...was massively under-resourced and under-funded and really struggling to maintain its patient load. (P25-B-P)

Some discussed that structure of existing clinical services supported the use of DOACs. For instance, an existing clinical pathway for DOAC use in deep-vein thrombosis meant that initiating DOACs for patients with AF did not require a demanding change to existing ways of working among general practice clinicians. They were seen to have gained experience and confidence in using DOACs, which potentially lead to higher uptake of DOACs in health economy A by primary care clinicians.

I'm still convinced to this day that the big thing was to mandate it (DOAC) into another part of GP practice. (P2-A-GP)

Some also viewed that the limited capacity of warfarin monitoring services to see increasing numbers of patients with AF triggered the use of DOACs. However, some commented that warfarin monitoring services in secondary care were not commissioned to switch patients to DOACs, and some primary care monitoring services had non-prescribing clinicians. Thus, patients were referred to their GPs with advice to switch warfarin to DOAC therapy. Others noted that there was also not enough resource within the warfarin clinic to identify all patients taking warfarin that could be switched to DOAC therapy.

There are still a lot of people on warfarin who we would like to switch, but we have not got the resource to do that. We can't do that with our current staffing levels and the number of prescribers we have...there is an unmet demand. (P21-B-C)

Some decision makers stated that it was unclear when and how DOACs should be used within existing local anticoagulation pathway designed for warfarin use. Also a reluctance, from general practice, to use DOACs led to the creation of a hospital clinic for DOAC initiation. Although some perceived it to be a good approach to get things moving, others argued that it slowed down DOAC uptake as the new pathway was complex and had a limited capacity.

If you set up a clinic like that, every patient has to go through a DOAC clinic; you are automatically creating barriers because you're saying, well, the only way to start a DOAC is to refer to this clinic, so how are GPs going to start a DOAC then? So, if you keep it in that way, you won't spread it out. (P18-B-C)

Some participants described collaborative working between general practice, hospital clinicians and commissioners to develop a joint anticoagulation guideline with accompanying education. The approach resulted in high acceptance of the guideline and opened access to resources, which contributed to successful guideline uptake and increased use of DOACs.

I think getting the involvement of the CCG...getting the buy-in involving all the main players is much

more important. So, you know with DOACs it's been a success story in (health economy C). (P33-C-C)

Many viewed educational activities to be pivotal in increasing the use of DOACs through removing perceived barriers to use, improving clinicians' understanding and confidence and reducing aspirin use. Others commented it was difficult to educate everyone concurrently, and delivery of educational activities varied between different health economies. Thus, some stated activities could have been continuous, better timed, coordinated and integrated across the health economy.

The training needs to be more coordinated and integrated, so you know, that it was working within pharmacist GPs you know, community pharmacy and nurses and all that was working had the training at the same time; we knew what everybody was being told. (P29-B-P)

Some participants described using local stroke data to provide feedback to general practitioners on their anticoagulation prescribing rates to encourage anticoagulation use.

We used GRASP (The Guidance on Risk Assessment in Stroke Prevention for Atrial) data to give (general) practices feedback...so they know what their anticoagulation rates are against their peers, talked about that in a lot of meetings. (P40-C-P)

Also, participants described the varying influence of local policies, guidelines and commissioning statements communicated via medicine formularies on the use of DOACs. Some decision makers described a local clinical pathway promoting warfarin as the first-line therapy, but many clinicians explained they had no local restrictions when deciding between warfarin and DOACs for new patients.

There (health economy B) were lots of barriers to using it (DOACs); you really had to spell it out why the patient couldn't have warfarin. It had to be manipulated sometimes to get them onto a DOAC and to keep them on it. (P1-A-N)

### External health system context

Many participants highlighted that local priorities and prescribing decisions were informed by national health campaigns and changes in national health directives and policies. Some commented that most restrictions to DOAC use stipulated in local policies and formularies were removed after publication of the NICE (National Institute for Health and Care Excellence) AF management guideline. However, some noted that local advice was slow to change, interpretation of the guideline varied and information to support local uptake of DOACs came late and was impractical due to requiring 'huge amount of capacity' to use it.

Once NICE has issued that guidance then no local area restrictions are going to trump and supersede that guidance because it's within NICE. (P17-B-N)

A few participants discussed the impact of changes in the Quality and Outcomes Framework (QOF; national payment contract for general practices), which included a change in stroke risk calculation and removing aspirin from recommendations. Hence, they viewed that general practitioners had the incentive to ensure their patients were on appropriate anticoagulation to receive the allocated contract payments.

What the real cruncher was, was the change to QOF, so QOF changed and said: use 'CHA<sub>2</sub>DS<sub>2</sub>-VASc, not CHADS<sub>2</sub> (stroke risk score calculator), no aspirin. Anticoagulate.'...So there were a lot of points riding on AF in QOF and if you look at where QOF changes you see the line suddenly flick and we started to anticoagulate properly. (P2-A-GP)

Some participants discussed changes in the funding and provision of NHS services, for example, restructuring, added complexities to the uptake of DOACs.

When you have continuous reconfiguration and people at risk...people are consumed by what jobs they may or may not have...but sometimes that slows pieces of work down because people are then distracted by other continuous reorganisation, reapplication for jobs. (P26-B-P)

Policies and prescribing guidelines regarding DOACs required rewriting and updating for new incoming organisations, which took several years to complete. Others noted that decision makers were given more freedom on how to implement DOACs. Some highlighted that with the NHS reforms in 2011–2012, clinical networks were dissolved, making it more difficult to work with other health economies in the same region.

...we have a good cardiovascular clinical network... we developed a set of guidelines and a flow chart to help practitioners and prescribers to come to a decision on appropriate anticoagulation...all that disappeared with the new regime...So, we then had to spend several years rewriting all the policies and prescribing guidelines for CCGs (new NHS structure organisation). (P42-C-O)

Some noted the pharmaceutical industry used resource gaps created by NHS resource limitations to sponsor work that would increase awareness of DOACs or the need for anticoagulation. For instance, the industry sponsored scientific and educational meetings and independent providers to help healthcare organisations to restructure their anticoagulation service or obtain additional workforce to review eligible not anticoagulated.

I think in this particular area the fact that the drug companies want to increase the number of people taking their product I think nicely aligns with the fact

that I want everyone who is appropriate and who has a thrombotic risk and they have to be on an appropriate anticoagulant. I think you can align those aims and use the resources in the pharmaceutical companies to improve the communication, to have patient information leaflets, to have educational events for GPs. (P33-C-C)

Many participants acknowledged that the pharmaceutical industry tried to influence local prescribing and commissioning decisions indirectly by increasing attention to DOACs and thus pressure to use their agents. Other participants avoided meeting pharmaceutical representatives or attending their sponsored events.

There has been pressure in the background all the time; they're very present, things like discounts, that's obviously pressure to use their agent. They are always there at educational meetings if pharma is allowed. Then there's the tedious story about which one's best. And I'm pretty sure that they'd be behind some of the key markers and drivers for the story about Warfarin/DOAC balance, not using innovative medicines. (P23-B-P)

## DISCUSSION

The uptake of DOACs is influenced by intersecting factors acting as barriers and/or enablers and influencing what therapy options were offered and prescribed to patients with AF. Our findings may be applicable to other new medicines recommended nationally for use in chronic health conditions.

Our study adds to the body of knowledge on cost impact by indicating that not only the selling price but also wider economic costs (eg, direct health outcome, opportunity and societal costs) were considered, although to a varying extent, by clinicians and commissioners during decision making. The understanding or consideration of total costs of new medicines was hindered by the compartmentalisation of local and national commissioning and lack of information on cost impact within a health economy for clinicians and commissioners. Furthermore, information about cost savings across the system was not available to clinicians and local commissioners. Although assessment of the total costs of new medicines is a complex process, consideration of wider costs applicable to local populations should be part of decision-making discussions and could promote the use of cost-effective medicine.<sup>19</sup> If possible, local health economic models to assess the cost benefits of the new medicine should be used. Also, decision makers should consider collecting and providing local data to clinicians and key stakeholders on its effectiveness and safety in clinical practice to address any safety or effectiveness concerns more promptly.

Participants in our study did not mention affordability of prescribed medicines by patients to have impact on the uptake of DOACs. In our previous study, interviewed

patients shared their views on the cost of DOACs and warfarin and its impact on the NHS services but not their ability to obtain the prescribed medicine.<sup>6</sup> This could be because many patients with AF in England would qualify for free prescriptions; in 2005–2015, 90% of all prescription items were dispensed free of charge.<sup>20</sup> However, affordability by patients of prescribed medicines has been shown to be a barrier in healthcare settings where patients pay for the prescriptions.<sup>8</sup>

Similarly to previous studies,<sup>8</sup> our results suggest that lack of knowledge and experience of prescribing DOACs or anticoagulation was a barrier to their uptake. Training and educational support provided to clinicians (online and/or offline) should be delivered as soon as the new medicine is made available, be continuous and integrated across the health economy. Also, our findings are in agreement with previous research,<sup>21–23</sup> suggesting that hospital clinicians influence other peers prescribing decisions. However, narratives from our interviews indicated that the presence of a local champion within general practice had a greater impact on the uptake of DOACs than hospital peers, which agrees with several implementation frameworks.<sup>10 12</sup> Furthermore, the choice of DOAC was also influenced more by peers within their organisation or professional network than peers outside their organisation. Our study also indicated that patient influenced the uptake of DOACs, which was enacted through patient demand for new medicines and participation in therapy decision making. Barriers to patient involvement and strategies to overcome them have been discussed in our previous study.<sup>7</sup>

Consistent with implementation work,<sup>9 10 12 24</sup> our study indicated that the willingness of the organisation to assimilate the innovation was shaped by its priorities, implications for existing services, power balances, resources and capacity, and external health system context. Importantly, these findings address the gap identified in the systematic review<sup>8</sup> by providing considerable insight into impact of wider organisational and personal attributes identified in this study on the uptake of new medicines. Our study findings highlight that collaboration between different stakeholders increased chances of a successful outcome. Also, shared vision or collective agreement on goals, value and purpose of innovation acted as enablers, whereas disagreements about the value and place of DOACs caused fragmentation in the uptake of DOACs. Local clinician communities and decision makers should employ a multidisciplinary approach and aim for a balanced view with supporters and opponents to the use of new medicine. A shared vision on how the new medicine should be used within the health economy should be achieved to facilitate the uptake. Although the extent to which health innovations aligned with organisations' existing services, workflow and skill mix has previously been suggested to affect their uptake,<sup>10 12 25</sup> their impact on new medicine uptake has been under explored.<sup>8</sup> Our findings suggest that the greater the disruption to existing services or more complex newly created services,

the higher the number of resources with increasing intensity were needed to increase the uptake of DOACs. Decision makers and clinicians should consider positive and negative effects of the new medicines' impact on existing services, and clinical pathways incorporating the new medicine should be made as simple as possible with the least numbers of steps to encourage their uptake and appropriate resources being allocated (eg, staffing levels and consultation times). Another important finding is that the shared positive impact of DOACs on services and patient clinical outcomes obtained through local monitoring promoted the uptake of DOACs. Decision makers should monitor and provide feedback on service changes during the uptake of new medicine to clinicians and key stakeholders.

External health system context was important too. Our study identified that factors outside the local health economy were said to have influence on the uptake of DOACs. This included national policies (eg, NICE), directives (eg, national payment by results scheme) and groups (eg, patient support) had an impact on the uptake of DOACs to a varied extent by changing local recommendations or individual clinician practice. The continuous restructuring of the NHS was also highlighted as a barrier by creating difficulties in delivering collaborative working or prolonging decision making. Furthermore, our study findings add to the body of knowledge on the indirect marketing influence of pharmaceutical industry on the uptake of new medicines. The interview narratives suggested that pharmaceutical industry used the 'resource gaps' created by the limitations of NHS resources to sponsor work that would increase awareness of DOACs or the need of anticoagulation in AF. Nevertheless, the benefits and harms of pharmaceutical sponsorship where resources are limited are yet to be determined.

This study was completed before the COVID-19 pandemic; thus, its impact on the uptake was not explored. During the pandemic, there was a national guidance on switching patient from warfarin to DOACs to minimise the risk of potential virus transmission during warfarin clinic appointments,<sup>26</sup> which drove an increase in DOAC prescribing.<sup>27</sup>

### Strengths and limitations

The main strength of this study is that it is underpinned by implementation theory exploring multiple perspectives in multiple settings. Another strength of the study was the moderate sample size and recruitment of participants with a varied range of roles from three health economies with different anticoagulation service provision models. Thus, the findings provide novel insights and understanding of factors influencing the uptake of new medicines within local health economies. There are number of limitations to this study. First, the study involved a single data collection method and semistructured interviews. Second, the study relied on participants' accounts, which could be affected by recall bias. Participants were asked to describe implementation of DOACs which, in most cases,



were not recent events. Thus, the interviews may not be an accurate representation of the events that occurred. However, semistructured interviews allowed exploration of factors that could not be captured by quantitative studies (eg, innovation-health economy fit). Third, the study was conducted in the North of England (UK), thus limiting transferability of findings to other healthcare settings. Nevertheless, identified barriers and enablers could offer explanation for national variability in uptake.

## CONCLUSIONS

Our study shows that the uptake of DOACs was influenced by multiple intersecting factors acting as barriers or enablers with prominence of some factors differing between the studied health economies. The study indicates that the uptake of new medicines could be eased by incorporating considerations of wider costs applicable to local population in decision making, providing local data to clinicians and key stakeholders on its effectiveness and safety in clinical practice, considering impact (positive or negative) of new medicines on existing services, completing timely update of local policies and guidelines, providing adequate resources to support initial use of new medicines and educational support to healthcare professionals, and simplifying clinical pathways that incorporate the implemented new medicines. As there is a growing focus on a sustainable healthcare, future research should evaluate if the uptake of new medicines is influenced by their carbon footprint as participants in our study did not refer to it.

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