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## **Use of DOACs in Primary Care: An integration of patient and practitioner perspectives**

\*Dr Yeyenta Mina Osasu, Dr Caroline Mitchell, Dr Richard Cooper

### **Abstract**

#### **Background**

Elderly patients with atrial fibrillation (AF) are increasingly offered direct oral anticoagulants (DOACs) to reduce the risk of catastrophic stroke but still require clinical follow-up and compliance check to maintain patient safety. Although a recent qualitative meta-analysis has explored up to date research in this area (1), little is known qualitatively, in the United Kingdom, about clinicians' or patients' views and experiences of DOAC use in primary care.

#### **Aim**

To understand the experiences of healthcare practitioners and patients in relation to DOAC use in primary care.

#### **Design and setting**

Semi-structured interviews were undertaken. Sixteen elderly AF patients taking DOACs, ten pharmacists and six general practitioners (GPs) were interviewed in Sheffield in 2018.

#### **Methods**

Interview questions were developed from a systematic literature review. Interviews were audio-recorded, transcribed, and analysed using six stage thematic analysis.

#### **Results**

The integrated perspectives show that all three participant groups preferred DOACs over warfarin- driven mainly by the safety profile compared to warfarin. GPs valued pharmacists input in anticoagulant care and pharmacists discussed patient safety in the context of anticoagulant audits and highlighted the need for continuous patient education and counselling. Medication reviews by pharmacists was seen as a positive contribution to medicines optimisation.

#### **Conclusion**

Patients had an overriding trust in their doctors. GPs valued a collaborative approach with other clinicians and community pharmacists appeared to highlight operational challenges in primary care which may limit the effectiveness of interventions.

### **How this fits in**

Clinicians' experiences regarding oral anticoagulant prescribing for AF patients have been explored previously (1). Uncertainty and bleeding risks are still associated with DOACs despite their efficacy and safety profile (2). Reduced monitoring results in fewer encounters for opportunistic review and reinforcement of safety messages, especially in elderly patients with comorbidities (2). This research integrates the perspectives of clinicians, pharmacists and patients in anticoagulant optimisation in primary care.

### **Introduction**

Increasingly, elderly patients with atrial fibrillation are being prescribed DOACs to reduce the risk of catastrophic stroke (3). Although a recent qualitative meta-analysis has explored up to date research in this area (1), little is known qualitatively in the United Kingdom about clinicians' or patients' views and experiences of DOAC use in primary care.

The authors recently reviewed international literature on patient and professional perspectives on the safe and effectiveness of anticoagulants and identified a gap in the literature (4). The aim of this research is to understand the experiences of healthcare practitioners and patients in relation to DOAC use in primary care.

### **Methods**

A qualitative study, using semi-structured interviews. The researcher is a clinical pharmacist with previous experience in anticoagulation and working with the elderly. Semi-structured interviews were conducted with GPs, pharmacists, and patients.

### **Setting**

Interviews were conducted in patients' homes, GP surgeries and community pharmacies across Sheffield, UK. Sheffield's marked difference in socio-economic status and ethnic variation makes the city an ideal location for purposive and maximum variation sampling.

### **Sampling**

Twenty five GP practices were invited to participate via National Institute for Health and Care Research- Yorkshire and Humber Clinical Research Network. Participating GP practices were purposively sampled according to their size and indices of multiple

deprivation profiles (5). The Prescribing Lead GP and Community Pharmacist in closest proximity to participating surgeries were interviewed.

Elderly patients aged  $\geq 65$  years and diagnosed with AF with at least one co-morbidity and registered in the participating GP surgery in Sheffield were invited. Patients who wished to participate responded by post and were chosen randomly from each age bracket.

The sample size was not determined in advance, but all participants were interviewed, and analysis continued using a constant comparative approach until no new themes were identified (6). This was determined when additional data no longer provided new insights to the analysis. All through the process, the constituent of participants was regularly reviewed by checking variation by gender and age as stipulated in the recruitment protocol (7).

### **Data Collection and processing**

Semi-structured interviews were conducted based on the topic guide which was developed after reviewing the literature and after feedback from a public interest group (PPI). All interviews were conducted by YO and consent was sought before commencing each interview. Patient interviews lasted 45-60 minutes. GP and pharmacist interviews in lasted about 30-45 minutes.

Interviews were recorded using an encrypted digital audio recorder. Participants were anonymised and pseudonyms were used during transcription. All electronic information including audio recordings, and participant demographic details were stored electronically on a site file, which was stored on a password protected, and encrypted university computer (8). Recruitment and interviewing were conducted from May to December, 2018.

### **Data analysis**

Data analysis was carried out by YO using a thematic approach (9). This was done concurrently with data collection to enable recruitment of more participants until saturation was achieved (10–12).

The interview topic guide was refined based on responses from previous interviews. Recorded interviews were transcribed verbatim and re-read against the original audio recordings to check for transcript accuracy. All transcripts were imported into Nvivo 12 for Mac. There was independent verification of the emergent thematic framework including independent analysis of transcribed data by two members of the team (CM/RC). Following

analysis, the findings were also presented to members of the PPI group as feedback. The emergent themes were subjected to critical interpretative challenges during regular research meetings with CM and RC.

## **Results**

Thirty-two participants were recruited to the study, comprising 16 patients aged 67- 89 years old (Table 1), 10 pharmacists, and 6 GPs (Table 2). Six GP surgeries participated comprising teaching and non-teaching practices with varying DOAC prescribing rates. Four practices and one patient withdrew after initially expressing interest. The GPs and pharmacists were heterogeneous in gender, age and experience.

## **Integrated themes**

Integrated themes were: (i) Benefits of DOACs (ii) Patient safety (iii) Relationships and (iv) Operational challenges in primary care. Figure 1 is a diagrammatic representation of the integrated themes from all three participant groups.

## **Benefits of DOACS**

The integrated perspectives show that all three participant groups preferred DOACs over warfarin- driven mainly by the safety profile compared to warfarin. For patients, preference was driven by the tolerability of DOAC medication and the minimal impact on lifestyle, medication regime and management.

*“I’m quite happy with the treatment I’ve got and when you’re satisfied you don’t want to dig beneath it, it’s when you’re not satisfied that you want to dig beneath it.”* [Patient 9]

GPs and pharmacists reported having negligible patient complaints and the convenience of prescribing with less complexity in anticoagulation management appeared to influence GP preference for DOACs.

*Generally, I would much prefer [patients] to start on a DOAC than I would do on warfarin. Just because of the convenience.* [GP2]

## **Patient Safety**

Pharmacists discussed patient safety considerations in the context of anticoagulant audits which had been carried out by practice and CCG pharmacists in GP practices across the city:

*“...the first bit was done 2 years ago, and then we sort of did a mop up of it just to check, but when you compare the first year to the second year, a lot less patients were on doses that needed amending. You know, it was appropriate. So it sort of showed really that prescribing has improved.”* [Pharm 05, CCG Pharmacist]

While auditing was a good way of monitoring prescribing on GP systems, one pharmacist described a patient centred approach which involved speaking to the patient directly to improve health literacy, awareness and reinforce safety messaging:

*“I think there is a concern because obviously one advantage of seeing the patient regularly is that it’s a chance to reinforce all of the health education bit, and making sure that the patient is taking the medication. [Pharm07, Practice Pharmacist]*

### **Relationships**

The nature of relationships between patients, GPs and pharmacists was important in realising optimal anticoagulant therapy with DOACs. Patients’ trust in the doctor meant that they were willing to accept the GPs recommendations even when they were sceptical about the benefits of DOACs. For example, one patient put it this way:

*“...although I might say well I’m not too keen on it, if they say but you will benefit from it, then I’ll take their word for it”* [PT 12]

For other patients, this trust in the doctor appeared to result in a passive dependence on the doctor’s knowledge which emerged in patients’ claims that they did not read patient information leaflets because they believed *“the doctor knows best and isn’t trying to harm”* .

GPs also acknowledged the importance of maintaining good relationships and careful considerations when discussing medication choice with patients. Some GPs adopted a decision-making role for the patients because they presumed that the information being provided was too complex for patients to understand

*“And how are they supposed to make that decision? ...okay you can give them a leaflet but a lot of them haven't got the kind of academic background, that's really difficult stuff to ask people to do so of course they need us to guide them. So I don't feel bad about actually giving people a push in the direction that I think is right” [GP3]*

Meanwhile, some community pharmacists did not always feel they could access the GP to resolve queries. However, community pharmacists in close proximity to the GP (for example adjoined to the surgery) or those who had practice pharmacists with whom they could liaise with within the GP surgery reported better working relationships.

One community pharmacist described challenges in the way they were perceived by patients and suggested that patients were often reluctant to engage with community pharmacy services such as Medicines Use Review and New Medicine Service because these were seen as duplicated tasks which they received from the GP:

*“I think the limitation is that normally when someone has been started on a new medication, they're getting a lot of input from their doctor anyway, 'cause the doctor maybe says “Try that and come back in a few weeks and we'll review it” so there is a lot going on in terms of monitoring and they're often very reluctant to speak to me.” [Pharm 09, community pharmacist]*

In addition, patients preferred continued relationships with GPs due to the high regard and trust they had for GPs compared to pharmacists:

*“I know that pharmacists are now supposed to fulfil a more extensive role, on a consultative basis, but I don't really consult him about things at all and they're so damn busy that they don't talk to me about tablets. They hand over a prescription, and give me tablets, and that's it...” [Patient 10]*

### **Operational challenges in primary care**

GPs and pharmacists described how operational challenges in the workplace limited integration and communication between healthcare professionals with a potential impact on optimal management. This was mainly discussed in relation to workload, time pressures and interoperability between computer systems:

*“As a general pharmacist though, you get access to the summary care records. It doesn't always give you the information that you want, because if you have got an issue, you quite often want to actually look through to see why the doctors done it, and you can't get any of that from summary care.” [Pharm08, Community pharmacist]*

*“The hospital elected to go for Hospital SystemOne and Lorenzo and Hospital SystemOne and Lorenzo don't speak to each other and Hospital SystemOne doesn't speak to EMIS and Hospital SystemOne doesn't speak very nicely to the GP SystemOne.” [GP5]*

GPs also expressed challenges relating to time and work pressures:

*“The working day, it's so intense and you've got to be so efficient and so kind of lean with what you cover. So I wouldn't bring any complications into the conversation that weren't brought by the patient”. [GP3]*

## **Discussion**

### **Summary**

All three participant groups highlighted the perceived benefits of DOACs. Figure 2 is a diagram showing the relationship between the dominant emerging themes. Using the example of DOACs has illustrated enduring issues in primary care which appear to impinge on optimal medication management.

Table 1 shows that CHA2DS2VASc and HASBLED scores were not always recorded in the patient's clinical records with possible implications to treatment optimisation and patient safety. There was no clear correlation between place of initiation and the poor recording. Although arguably beyond the scope of this research, these findings suggest areas for improvement in primary care including interoperability, role boundaries and organisation of work within primary care.

Hard to reach sub-populations, such as those with historically poorer outcomes who may be digitally excluded, or unable to respond to letter, e-mails or text alerts to attend medication reviews due to poor literacy, complex health and social needs may be significantly disadvantaged. Medicines optimisation for patients on high-risk drugs such as DOACs should involve effective communication with patients to check adherence and potential side effects.

Community, PCN and practice pharmacists are best positioned to offer medication reviews to support appropriate anticoagulant dosing based on current weight and renal function.

Although patients relied on their GPs for decision making, patient's perspective of DOACs would likely vary depending on whether they had previously been on an oral anticoagulant or had a previous stroke. Prior to starting a DOAC, only three patients were previously on warfarin, eight on antiplatelets, four on neither, and one previously on aspirin and warfarin. Therefore, the implications for patient outcomes may be linked to poor understanding of the risks associated with anticoagulants such as bleeding and the stroke risk associated with poor adherence (13,14).

This research was conducted in 2018 and there is a risk that the covid-19 pandemic presented even fewer opportunities for medication reviews, routine monitoring, and reinforced messages post index consultations. Nevertheless, there are new models of working in primary care as services are restored, including the offer of structured medication reviews to patients. This also presents an opportunity for community pharmacists to extend their role in patient safety and medicines optimisation through more integration with GPs and practice pharmacists, facilitated by interoperability of computer systems.

### **Strengths and Limitations**

This is the first qualitative research in the UK that has explored the perspectives of all three participant groups- patients, GPs and pharmacists on the optimisation of direct oral anticoagulants. Patients and the public were involved from the research design stage and engagement continued throughout with findings presented to the PPI group. The sample sizes of 6 GPs, 16 patients and 10 pharmacists were small and resource limitations precluded a larger sample size. Nevertheless, the perspectives of patients and healthcare professionals were similar and confirmatory.

Of the four practices that withdrew, two did so because there was no funding allocation for interpreters this was potentially a barrier to recruiting from more ethnically diverse practices and a missed opportunity for insight and inclusive research from underserved patient populations. Notwithstanding, minority ethnic patients were invited by targeted invitations via telephone and a second wave of postal invitations, but no reply was received from this patient group.

### **Comparison with existing literature**

This study found that great importance was placed on patient- GP relationships and trust. The subject of trust in healthcare has been well documented in previous research (15). In this study, many patients felt doctors were the experts and would make the right choice or decisions concerning their treatment. Patient narratives in another UK qualitative study also suggested that patients preferred to be led by the doctor when making anticoagulant treatment decisions for atrial fibrillation (16). This may have been due to a lack of suitable educational resources and decision aids to help patients understand AF and anticoagulation at the time. However, although DOACs have been used widely since, there may still be an unmet barrier in clinical practice today with consequences for patient centred care (17).

When discussing patient centred care and shared decision making, some GPs in this study assumed that their practice was patient centred but GP narratives described a directive and paternalistic approach to consultations and decision making. GPs presumed patient involvement in shared decision making but their assumed decision maker role may risk undermining patients' values, opinions, preferences and potentially confidence to question the clinician's decisions (18).

Pharmacists in this study had concerns about patient safety and some highlighted barriers to providing the necessary patient support. The benefits of integrating pharmacists into the primary care team has been demonstrated in previous studies (19–21). However, blurred roles in decision-making and therapy management posed a barrier for optimised anticoagulant therapy in previous qualitative studies and this was linked to patient safety and potential harm (22,23).

### **Implications for practice**

This research demonstrates that patients place a high level of trust in their GP and despite the increasing integration of pharmacists within primary care, patients prefer continuity with their GP over other healthcare professionals, such as community pharmacists. Nevertheless, GP workload continue to rise. As we emerge from the covid-19 pandemic, community pharmacists can assume more clinical roles and long-term medication management, for example, by supporting patients who have recently started medications for long term conditions through the new medicines service. GPs could play a role in supporting integration by encouraging patients to foster positive relationships with the community pharmacy teams who can work collaboratively with primary care colleagues to improve the quality of patient care.

In this research, patients expressed dissatisfaction with the quality and quantity of information they received from healthcare professionals. Capacity and health literacy should be taken into consideration when communicating information about high-risk medication such as DOACs. Patients highlighted a need to improve the quality of patient information through making information succinct and involving patients in the development of patient tailored medication information.

Interoperability between computer systems between healthcare settings such as community pharmacy and GP surgery will facilitate integration and communication between healthcare professionals to enhance patient care and medicines optimisation.

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### **Ethical approval**

The study was approved by the North West- Greater Manchester West Research Ethics Committee- REC reference 17/NW/0697

### **Competing interests**

The authors declare they have no competing interests

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Table 1 Demographic information of patient participants

Patients	Gender	Age	No. of Co-morbidities	Hospital or community initiation	Anticoagulant	Previous anticoagulant/ antiplatelet	*CHA <sub>2</sub> DS <sub>2</sub> VASC	*HASBLED	*IMD Quintile Group	IMD Classification	*ONS Occupation coding
PT1	F	79	10	Hospital	Apixaban	Clopidogrel	6	not recorded	3	Average deprivation	4
PT2	M	72	3	GP	Rivaroxaban	Aspirin	1	2	5	Most deprived	4
PT3	M	81	3	GP	Apixaban	Aspirin	4	2	3	Average deprivation	3
PT4	M	89	2	Hospital	Dabigatran	Warfarin	3	2	3	Average deprivation	5
PT5	M	81	3	GP	Apixaban	Aspirin	5	1	3	Average deprivation	1
PT6	F	77	3	GP	Apixaban	None	3	not recorded	3	Average deprivation	4
PT7	F	71	9	Hospital	Rivaroxaban	warfarin	not recorded	not recorded	1	Least deprived	7
PT8	F	76	7	Hospital	Apixaban	Aspirin	4	not recorded	2	Below average deprivation	6
PT9	M	78	3	Hospital	Apixaban	None	3	not recorded	4	Above average deprivation	2
PT10	M	85	7	Hospital	Apixaban	Warfarin	4	3	2	Below average deprivation	1
PT11	F	80	3	GP	Apixaban	Aspirin, Warfarin	not recorded	not recorded	5	Most deprived	9
PT12	M	67	6	GP	Apixaban	Aspirin	not recorded	not recorded	5	Most deprived	3
PT13	F		7	GP	Apixaban	Aspirin	2	1	1	Least deprived	9/7
PT14	M	76	4	Hospital	Apixaban	Aspirin	not recorded	not recorded	1	Least deprived	4
PT15	F	73	4	GP	Apixaban	None	3	1	1	Least deprived	4
PT16	F	77	6	Hospital	Apixaban	None	not recorded	not recorded	5	Most deprived	2

\*CHA<sub>2</sub>DS<sub>2</sub>VASC score- Congestive heart failure (1), Hypertension (1), Age ≥ 75yrs (2), Diabetes (1), Stroke or transient ischaemic attack (2), Vascular disease (1), Age ≤ 65yrs (1), Sex category (1)

\*HASBLED Score- Hypertension (1), Abnormal renal/ liver function (1), Stroke (1), Bleeding history or predisposition (1), Labile INR (1), Elderly (1), Drugs/alcohol concomitantly (1)

\*IMD- Indices of multiple deprivation, \*ONS- Office of National statistics classification, LVSD- Left ventricular systolic dysfunction, COPD- Chronic obstructive pulmonary disease, CKD- Chronic kidney disease

NVAF- Non valvular atrial fibrillation, BPH- Benign prostatic hyperplasia, CVA- Cardiovascular accident, TIA- Transient ischaemic attack, CABG- Coronary artery bypass graft

Table 2 Demographics of healthcare professionals

Professional	Gender	Age band	Year Qualified	Status
<b>General Practitioners</b>				
GP1	F	40-44	2006	Partner
GP2	M	35-39	2011	Partner
GP3	F	35-39	2011	Salaried
GP4	M	35-39	2009	Partner
GP5	M	55-59	1986	Partner
GP6	F	40-44	2006	Partner
<b>Pharmacists</b>				
Pharm1	F	30-34	2009	CCG Practice pharmacist
Pharm2	F	40-44	1996	Practice employed
Pharm3	F	25-29	2012	Community
Pharm4	F	40-44	1998	Practice employed
Pharm5	M	30-34	2010	CCG Practice pharmacist
Pharm6	M	35-39	2009	Community
Pharm7	M	45-49	1994	Community
Pharm8	M	40-44	1998	Community/ practice
Pharm9	M	25-29	2016	Community
Pharm10	F	40-44	2006	Practice employed

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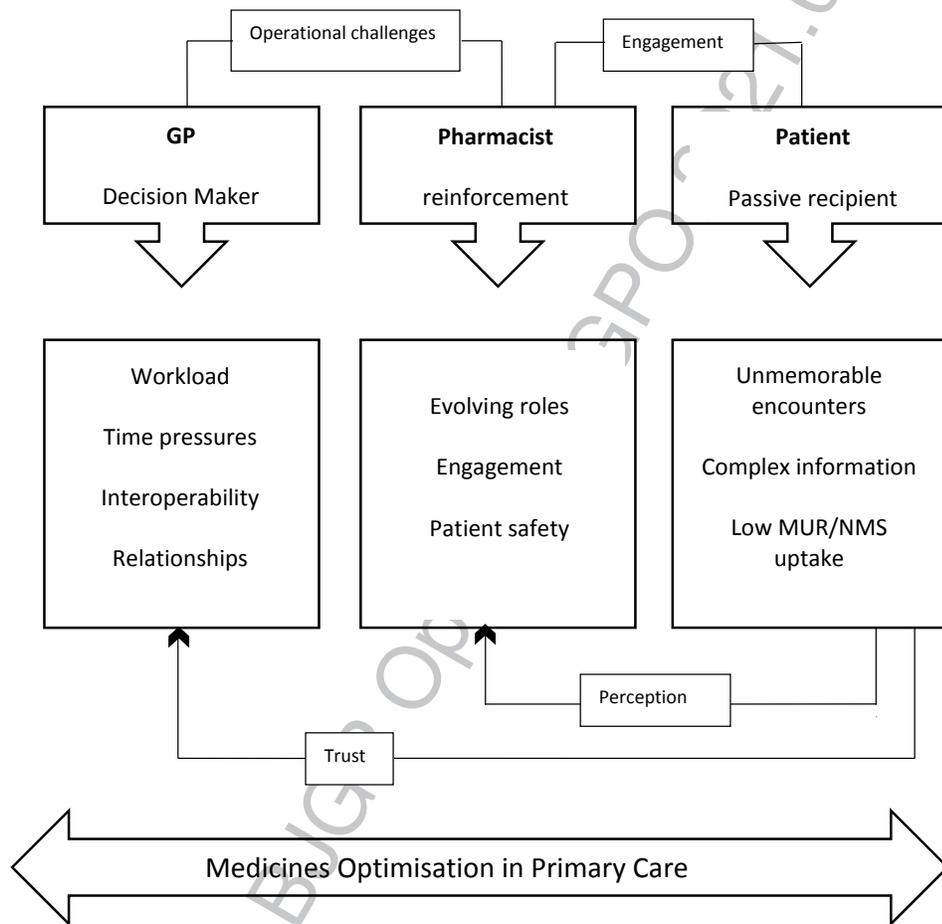


Figure 2 Emergent framework and the interplay between themes

