Direct oral anticoagulant (DOAC) monitoring within primary care: a quality improvement project

Isobel Joy McFadzean, Rhian Francis, Catrin Fischetti, Vanessa Morton, Susan Goodfellow

ABSTRACT

Background Poor monitoring of anticoagulants is a significant area of patient safety. It can lead to the dichotomous risk of haemorrhage/clotting without appropriate counselling and monitoring. While healthcare professionals may be familiar with the anticoagulant warfarin and the international normalised ratio, they might be unaware of the monitoring requirements of direct oral anticoagulants (DOACs), despite DOACs making up 62% of anticoagulants prescribed. The goal of this quality improvement (QI) project was to increase the compliance of monitoring of DOACs within general practice (GP) to improve patient safety and reduce the risk of an adverse outcome for patients.

Local problem In 2019, the GP surgery had 318 patients prescribed a DOAC and their medication reviews took place opportunistically. While initially, monitoring levels were nearly 100%, by December 2018 this had dropped significantly, and clinicians stated they were unfamiliar with this medication.

Methods and interventions This project aimed to resolve this by using QI methodology and Plan–Do–Study–Act (PDSA) cycles to create new sustainable processes with DOAC monitoring and aimed to increase DOAC monitoring by 20% within 6 months.

Results Within 6 months, the project improved the rate of monitoring, and 49% of all patients prescribed a DOAC were seen in a DOAC clinic (n=156) and 78% (n=230/294) had DOAC counselling; 97% (n=295/304) had appropriate blood tests and 72% (n=216/298) had a recent weight recorded within their medical records. Three years on, 600 patients within the practice are prescribed DOACs and 74% (n=445) have had an annual review adhering to the gold standards set within the project.

Conclusion This QI project confirms that by using QI methodologies, such as process mapping and driver diagrams, monitoring of DOACs can be better understood and consistent improvements in DOAC monitoring can be made.

WHAT THIS STUDY ADDS

⇒ Anticoagulants such as direct oral anticoagulants (DOACs) are used to treat a range of conditions, including atrial fibrillation, and for the treatment and prevention of arterial/venous thromboembolism. Inappropriate initiation, counselling and monitoring of these anticoagulants could lead to patient harm.

⇒ This quality improvement (QI) project reviewed monitoring processes of DOACs within primary care to improve patient safety.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These findings can help to support healthcare teams who monitor DOACs, to help them understand their current system and to consider improvements to also improve patient safety.
DOACs in the practice, to reduce patient harm. DOAC monitoring was also a ‘local enhanced service’ (LES) (see online supplemental appendix 1) and the practice would be financially compensated for the initiation, monitoring and education of these patients.

The aim of the project was to 'Increase the percentage of patients appropriately monitored, while being prescribed a DOAC, by 20%', while adhering to British National Formulary (BNF) guidance and LES protocol, between January and July 2019 at the Clydach GP Surgery, Swansea’.

**BACKGROUND**

Anticoagulants are prescribed for patients who have atrial fibrillation (AF) to prevent embolic events and for the treatment or prevention of arterial/venous thromboembolism. DOACs were incorporated into the National Health Service after National Institute of Clinical Excellence guidance in 2012, and in 2019, when this project started, they made up 62% of all anticoagulants prescribed in England. However, due to a lack of familiarity by healthcare professionals (HCPs), monitoring requirements may not be as closely adhered to as more longstanding anticoagulants such as warfarin and the international normalised ratio, with its use since the 1950s. Inappropriate monitoring and poor patient education can cause morbidity or mortality for this cohort of patients. Embolic events can occur with poor compliance, and meta-analyses (comparing dabigatran with warfarin) show that while DOACs have a reduced rate of bleeding in general, haemorrhage (specifically gastrointestinal) can occur with patients who inadvertently took/were prescribed aspirin or NSAIDs, or did not have appropriate dose reductions based on age or renal function — in essence, in patients with inappropriate monitoring.

There is extensive guidance available for HCPs and patients with regard to DOACs and the importance of monitoring and review; in toolkits, leaflets and training to prevent adverse events. It has been noted that a DOAC QI project detailing compliance with DOAC guidelines has recently been published in Qatar and a similar QI project was carried out in 2019 within a GP practice, with a PDSA cycle focused on patients prescribed apixaban, adding recall messages to medical records and engaging with pharmacists to increase adherence to monitoring. This QI project has considered other interventions and processes to improve DOAC monitoring and displays sustainability over 3 years.

**MEASUREMENT**

While considering the process measures for the practice, the QI team considered inclusion criteria to confirm that the patient had been appropriately monitored. They used the health board’s LES (online supplemental appendix 1) guidance with regard to DOAC initiation and monitoring, considering the fulfilment of these criteria to be the operational definition of a gold standard review: 1. Developing/maintaining a patient register. 2. Ensuring patient recall. 3. Educating patients. 4. At initiation and annually, reviewing patients (including weight and blood tests).

Similarly, the BNF guidance advises that HCPs must:

- Consider age, dose adjustments and weight adjustments.
- Review renal function (ie, annual creatinine clearance, urea and electrolyte blood tests).
- Monitor for bleeding and anaemia (ie, annual full blood count).
- Avoid use in severe liver disease (ie, annual liver function blood test).

The process measures for this project were the number of patients who had DOAC counselling and an updated weight and blood tests as part of the review to encompass this guidance. Medical records were reviewed at the end of the project to monitor compliance due to delays from invitations/blood forms sent out and the tests carried out. The outcome measure was the cumulative number of patients within DOAC clinics—the percentage of patients who were appropriately monitored while prescribed a DOAC, to meet the aim, between January and July 2019. Balancing measures were considered as a team, and feedback from staff highlighted concerns regarding increased administrative time (eg, distributing blood forms) and increased pharmacist workload. It was predicted that there would be an initial output of work but with a system shift, this should settle, and advantages should outweigh disadvantages, and this is further discussed within the limitation section of this study.

In January 2019, an administrative search was carried out for the read code ‘Anticoagulant monitoring’, focusing on the previous 8 weeks. After excluding patients taking warfarin, this indicated 0 results, and 0% of patients were monitored within the practice anticoagulant clinic. It transpired that anticoagulant reviews took place opportunistically usually within medication reviews of other medications that a patient was prescribed, and blood forms were distributed due to other comorbidities (eg, diabetes reviews) and after gaining stakeholder input, clinicians stated that they were unfamiliar with what was required.

A baseline audit retrospectively reviewing the previous 16 weeks (September–December 2018) (online supplemental appendix 2) revealed that 6% of patients prescribed a DOAC had a medication review (n=19) out of the 318 patients prescribed a DOAC. 1.9% (n=6) met all the standards set above, 3.8% (n=12) had counselling, 4% (n=13) had appropriate blood tests taken, and 3.1% (n=10) had a recent weight documented within their medical records often due to other comorbidities. This is in contrast with when the LES began in March 2018 with every DOAC review that took place being compliant with counselling and blood tests and 92% compliance with recording weight in each monitoring appointment.
between April and May 2018, usually initiated by the pharmacist.

When considering the validity and reliability of data, it was considered that while the team aimed to be rigorous with their methodology, there was variation in documentation and omission of coding due to human error.

**DESIGN**

Prior to starting the project, it was necessary to review the current process of DOAC monitoring and highlight waste in the process. This used Lean methodology\(^1\) to optimise the people involved, effort and organisation to create a safer and efficient system.

A process map (figure 1) showed that the current DOAC monitoring system was both multidisciplinary and multifactorial, and each step was a potential area for error, with holes lining up as per the Swiss cheese model.\(^1\)\(^6\) Each system is perfectly designed to get the results it gets,\(^1\)\(^7\) and this unwarranted variation was clear to see when visualised, showing how human factors played a role, leading to the inefficient monitoring of DOACs. It highlighted the important role that the pharmacist played in ensuring DOAC monitoring and sparked ideas for PDSA cycles.

During process mapping, it was evident that the coproduction of the project was vital for its success. The team considered the stakeholders involved, and their roles included the administrative team (coding/clinic organisation), prescribing clerks (sending prescriptions to the pharmacist), nurses and health care assistants (HCAs) (by running supporting clinics), doctors (DOAC education) and the practice manager/partners (to ensure the project was financially considerate and patient-centred).

With the stakeholders, the team created a driver diagram (figure 2).

Working with stakeholders aimed to give the project the best chance of success, creating a coalition using

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**Figure 1** Process map of initial DOAC monitoring. DOAC, direct oral anticoagulant.

**Figure 2** Driver diagram for DOAC monitoring. DOAC, direct oral anticoagulant.
coproduction, sharing the project and using their ideas to ensure the most efficient process.

The pharmacists were keen to support the project and to encourage sustainability, and the team wanted a changed culture and highlighted the tagline ‘Think DOAC, think Pharmacist’ to ensure that they always knew to refer to the pharmacist for help.

**STRATEGY**

This project initially involved three Plan, Do, Study, Act (PDSA) cycles, and at each stage of the cycles, there has been consideration to adapt or adopt changes.

**PDSA 1**

Distribution of letters to patients to invite them for a DOAC review.

The aim of this cycle was to initiate contact with patients: a database search identified the cohort, they were placed onto an anticoagulant register and all 318 patients were sent an invitation for review.

*Plan:* Invite patients for monitoring and encourage patient engagement.

*Do:* Letters were posted with blood forms and a weight requested.

*Study:* This cycle gleaned valuable data, helping to update the DOAC cohort, identified who could engage with the project, identified 30 patients subsequently excluded and helped inform the next PDSA cycle:

- 10 had died or left the practice.
- 10 lacked the capacity to discuss their medication (could not be counselled).
- Six were bedbound and could not be weighed.
- Four wanted to change their DOAC back to warfarin.

These letters led to:

- 34% (100/294) having a medication review and counselling.
- 64% (194/298) had an updated weight.
- 90% (273/304) had updated blood tests.

Abnormalities were flagged to the pharmacist/general practitioner to ensure dose reductions as needed or other interventions.

It was estimated by an administrative staff that this only took a morning’s session to arrange, running the administrative search, printing letters and filling envelopes with invitations and blood forms, although this should have been collected formally to understand the impact of these changes.

*Act:* This letter sparked the activity of DOAC monitoring to discuss blood results and counsel other patients, and pharmacist-led DOAC clinics (PDSA 2) were arranged.

One of the prescribing teams also ensured that patients prescribed a DOAC had prompts on their medical record for an annual review to ensure project sustainability and remove the reliance on memory. The team had planned to change only one thing at a time, but as highlighted by the Hawthorne effect, they had taken the initiative to support the project, and these results were assimilated within PDSA 1.

**PDSA 2: pharmacist-led DOAC clinics**

After discussing the results from PDSA cycle 1, it was felt by the team that the pharmacist would be best placed to carry out reviews within a set DOAC clinic. These sessions became embedded within the pharmacists available sessions.

*Plan:* Pharmacists to carry out DOAC clinics.

*Do:* This was an opportunity to counsel the patients, ensure appropriate monitoring and weigh them.

*Study:* This cycle took place over 6 months—therefore, the data were best displayed in a form of a Run chart (figure 3).

There were some difficulties with gaining the data from these clinics due to variability in the recording of notes by the pharmacists. The most frequent variation regarding documentation about blood tests or that blood forms had been issued. If it was not documented, it was felt not to have been carried out, something that could have been rectified with a DOAC clinic checklist.

Following these clinics, the patients monitored with counselling increased to 71% (n=209) with small numbers of patients reviewed each week for a continuous and steady change and to ensure that the pharmacists were not overwhelmed by the work taking into consideration the impact of these appointments.

*Act:* The team decided to take a different approach next to see if this could accelerate the rate of change, and the GP Registrar started carrying out their own DOAC clinics.

**PDSA 3**

Initiate doctor-led DOAC clinics, adapting the process of the current pharmacy led–clinics, to increase monitoring numbers and to ensure other HCPs could carry out reviews in the absence of the pharmacist.

Having learnt from PDSA 1, this cycle focused on small changes with a smaller pilot of patients. To ensure improved clinic access, telephone consultations were organised, with patients offered in-person appointments if preferred.
Plan: These sessions took place within the doctor’s self-directed learning sessions to allow sufficient consultation time.

Do. Twenty-four patients who had been recently prescribed a DOAC in 2019 were invited.

Study. 12.5% (n=3) were excluded from the QI project (one deceased, one switched to warfarin and one deemed not to have the capacity to be counselled), and out of the remaining:

► 100% were counselled (21/21).
► 100% had a recent weight recorded (22/22).
► 100% had updated bloods (22/22).

These clinics took an average of 8 min and were opportunities to counsel the patients about their medication and ensure that they were prescribed the correct dose for their weight/blood results, as well as answer their queries. Further additions included read codes (Anticoagulation monitoring) and annual recall on their records. A pop-up was also placed on their medical records, highlighting that they were on an anticoagulant which needs review/weight/blood tests.

This cycle showed the strength of focusing on a small cohort, before potentially considering the spread and scale of this intervention, and this was an opportunity to share learning and encouragement to other HCPs to carry out such reviews within the practice.

GP appointments cover a great deal in 10 min, and after engaging with other clinicians in the practice, it became clear that many of them ignore pop-ups on computer programs. This perhaps could lead itself to an expansion of this QI project in the future, aiming to review the medical record pop-ups for these patients and only leaving what is necessary (eg, advising the avoidance of NSAIDs/reminders that annual monitoring is required).

Act. Having this prompt on the system created a new process for the pharmacist. Once patients have appropriate read codes/recalls and the aim is to review this cohort each month to identify who needs a DOAC review, prompting a letter requesting up-to-date bloods/weight and the invitation for DOAC clinic review to ensure ongoing sustainability. This helps to remove human factors by ensuring that there has been a system change for sustainability, making it easier for everyone to do the right thing, every time.

RESULTS

The Run chart (figure 3) displays PDSA 2 and how many patients were appropriately monitored with a DOAC review, displaying baseline data too. Week 1 began following the distribution of patient invitation letters and the data were gained by manually reviewing the pharmacist’s appointments (because unfortunately there was no appointment code for anticoagulant monitoring).

► Between 7 January and 15 April 2019 clinics were carried out by pharmacist A, who had previous cardiology experience and was an experienced anticoagulant pharmacist.

► April 22 onwards was carried out by pharmacist B. This pharmacist was also experienced but was new to the practice and the patients, having not worked in the community before. While acclimatising to the practice, they started with a smaller task load of DOAC clinics and took time to become familiar with the process.

Patient feedback showed that they were pleased they were being monitored and could ask questions about their DOAC medication which they were often unsure about. The Run chart shows that at its most successful, up to 15 patients were being reviewed within these clinics each week, and in total 42% of patients (n=135) were reviewed within these clinics. The worst-performing weeks revealed that zero patients had a DOAC review. On review it was felt that common/special cause variation could explain this. It was predicted that there would always be a variable number of patients attending the clinics, due to non-attendance of patients and other pharmacist commitments/meetings, also known as common-cause variation.

With regard to special cause variation:

► Pharmacist A: annual leave in February meant that no DOAC clinics took place because cover had not been arranged.

► Pharmacist B: began in April and during their first weeks in the practice DOAC clinics did not take place. Annual leave in July also meant that DOAC clinics did not take place and cover had not been arranged.

While these reviews are important, they were not deemed clinically urgent and were planned electively; therefore, the practice did not want to arrange DOAC clinic cover when the pharmacists were not available; however, if the absence was ongoing, this would have been considered.

Taking into consideration all three PDSA cycles, within 6 months, the project improved the rate of monitoring of patients prescribed a DOAC (considering the process measures): 78% (n=230/294) having had documented DOAC counselling; 97% (n=295/304) had appropriate blood tests for monitoring and 72% (n=216/298) had a recent weight recorded within their medical records.

When reviewing the outcome measure, 49% (n=156) of patients had a review in a set DOAC clinic. The project successfully met the project aim, noted above the target line of 20% in figure 3.

Three years of anticoagulant reviews and monitoring are established—identifying the scale and spread of the project, gathering data longitudinally and considering a patient-centred approach. Recognising the important role of pharmacists and allied HCPs within the other PDSA cycles, the practice has currently adapted DOAC clinics (PDSA 4 on the chart) with the addition of two practice pharmacists, the international normalised ratio nurse and pharmacy technician who now carry out the majority of DOAC reviews over three GP sites, usually by telephone. There is now a computer template used during the consultation and documentation of the stroke risk assessment tool CHADVASC19 score when appropriate (a point scoring system to risk stratify strokes in patients...
with AF). DOAC clinics have become more flexible, and reviews are added to pharmacist slots as appropriate (instead of set afternoon clinics), medication recalls are created for annual review and consultations are coded as ‘Anticoagulant Medication Review (8BT3)’ to ensure appropriate recall.

By October 2022, there were over 600 patients at the practice taking a DOAC and 54% (n=324) of these patients had a review within the last 12 months and 43% (n=258) of over the age of 75 had a review—considering this cohort to be at risk of the sequelae of poor monitoring (see online supplemental appendix 3 for monthly DOAC reviews).

The practice has now focused on upskilling the prescribing clerks and there is an emphasis on patients taking responsibility for their monitoring, being empowered to organise their own blood tests, submit weights and arrange their DOAC review with support from the practice that have all been seen to impact DOAC monitoring levels. Patients who do not avail of this are contacted by the practice and supported to make an appointment, and housebound patients are assisted by district nurses.

This further adaptation of the project has corresponded with the introduction of a nationwide Quality Assurance and Improvement Framework of anticoagulation registers, which has helped encourage the sustainability of the project with up to 10% of DOAC patients (n=60) per month receiving a DOAC review—which also highlights the impact that patient autonomy can have on sustaining monitoring numbers, with patients reporting their preference to arrange monitoring based on their schedules, which patients have reported has supported them with their DOAC monitoring, with patients stating that they recognise the importance of regular review for their own safety.

Throughout the project, the wider practice team has been regularly updated on progress and asked for comments and feedback to ensure continuous improvement. There is now discussion within the practice to focus on other medications that require monitoring to replicate some of the processes from this project.

LESSONS AND LIMITATIONS

The strength of this QI project is that it has helped to improve patient safety with this cohort of patients by aligning their monitoring with appropriate standards. This was achieved with the introduction of QI methodology, creating a robust system, co-production and collaboration of the wider multidisciplinary team and empowering patients to understand and be involved within their own care. Similarly, the project has ensured sustainability with system changes that incorporated prudent healthcare by using experienced pharmacist-led teams for reviews, which has also freed up GP appointments.

There were some limitations within the project; in hindsight, it would have been useful to review the medical records of all (300+) patients prescribed a DOAC to accurately describe the baseline of anticoagulant reviews. However, a pragmatic baseline of 16 weeks was decided on by the project team, and although many of the reviews met the set criteria, for example, counselling, it was felt that they were often substandard. Reviewing current medical records has shown a significant improvement in the quality of DOAC reviews and accurate coding practices which has ensured that this cohort can be monitored more closely.

Similarly, the scale PDSA 1 was too large, inviting too many patients at the same time, causing both practical difficulties and missing the chance to initiate and learn from the first reviews. In retrospect, if PDSA 1 had involved a smaller patient sample, PDSA 2 could have tested spread and scale on larger patient numbers in the same cohort.

The QI project also took longer than expected because while all teams wanted to be supportive, often other tasks and other clinical work took precedence over the project, occasionally delaying patient reviews highlighting the conflict between scheduled and unscheduled care.

It is possible that there are some patients who have not been included in the results within PDSA cycle 2 due to unclear documentation about the consultation. The pharmacists and clinicians had different approaches to documenting findings and consultations, and a formal computer template now helps mitigate this.

This project highlights the importance of carrying out one change at a time, and in keeping with QI ideology, small changes. Perhaps in the future, to avoid reliance on memory, medication reviews should coincide with the patient’s birthday month. Or there will be a DOAC month—in which all such reviews should occur, with sufficient time given for this by all teams.

Similarly, balancing measures were considered from the start of this study; however in retrospect, these could have been formally collected, for example, counting how many of the pharmacist appointments were taken over by DOAC appointments, timing how long it took the administrative team to send out invitations and so on. If this study was repeated, these should be taken into consideration, something that was lost within this study during the realities of working within primary care, but are vital within QI work to fully understand whether all changes are improvements.

This project took place prior to the COVID-19 pandemic, and it continued using telephone reviews for monitoring. Most patients have a weighing scale at home and would still be able to attend phlebotomy appointments within specified health board clinics, removing unnecessary appointments and simultaneously preventing potential harm, and ongoing results proved this.

CONCLUSIONS

This QI project met its aim by carrying out of 74% (n=445) of DOAC reviews across four PDSA cycles, even as the number of DOAC prescriptions doubled. Process
and outcome measures evolved from the planning stage to the implementation of the project, considering that this was a large project, and the team was initially unsure about the ultimate outcome measure until the healthcare system was understood further. The different measures helped the team to focus on how changes were having an impact, with the important consideration of balancing measures and the unintentional consequences of change at the forefront of many changes were positive: improved teamwork, empowerment of pharmacists and patients, data gained for improvement and others were less desirable: increased workload and administrative tasks.

The project used several QI tools: process mapping and driver diagrams to help to understand the problem, PDSA cycles to test improvements and Run charts to visualise data.

As per the process map, patient-centred processes are an important factor. Regardless of simplifying the system and creating DOAC clinics, the patient must engage with the process, attending appointments, travelling for blood tests, and so on, and the practice has attempted to encourage this as much as possible. Perhaps initiating peer patient sessions could help support DOAC patient education in the future, although patient confidentiality would remain at the forefront of such a session.

This QI project has shown that DOAC monitoring within primary care can take place efficiently and safely, and 3 years since its initiation it has shown consistent and sustained improvement in rates of DOAC reviews. The project is ever-evolving, highlighting continuous change within a recently challenging environment during the COVID-19 pandemic. Focusing ahead the team could aim for 100% of all patients prescribed a DOAC to have annual monitoring within the practice.

Twitter Isobel Joy McFadzean @JoyMcfadzean

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ORCID ID Isobel Joy McFadzean http://orcid.org/0000-0001-9766-2681

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