Development, Dissemination and Evaluation of a "Direct Oral Anticoagulant (DOAC) Monitoring Tool" in Family Health Team Pharmacy Practice

2018 – 2019 Pharmacy Residency Research Project Manuscript

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**Abstract**

**Background:**

The “Direct Oral Anticoagulant (DOAC) Monitoring Tool” was implemented at the Sunnybrook Academic Family Health Team (FHT) in an effort to improve the documentation and monitoring of DOACs. The utility and acceptability of the tool was assessed thereafter.

**Methods:**

The electronic tool was developed and implemented for use from February 11, 2019 to May 17, 2019. Quantitative data on the utilization of the tool and the drug therapy problems identified were collected. Additionally, individual semi-structured interviews were conducted with the FHT pharmacists involved to assess the utility and acceptability of the tool.

**Results:**

During the study period, 23 monitoring forms were completed. Three DTPs were documented when select high risk patients were targeted for assessments – a task which the pharmacists do not routinely engage in.

**Discussion:**

Benefits of the tool include its ease of use and electronic accessibility. Limitations of the tool include duplicate documentation in the patient electronic chart and its inability to facilitate selection of a DOAC. Overall, the tool was underutilized as it did not fit the current pharmacy practice of the family health team. However, the study did highlight the utility of conducting
proactive chart reviews in high risk patient groups. Standardized electronic forms can also allow for the monitoring of metrics and workflow.

**Conclusion:**
Pharmacists can play a key role in ensuring safe and effective use of DOACs within primary care. Although underutilized in this setting, piloting the form at other FHTs may provide additional information on the potential utility of the tool. Further research is required to explore the development and implementation of documentation tools specifically for pharmacists.

**Background**
Historically, patients requiring anticoagulation for the treatment and prevention of thromboembolic diseases were exclusively put on warfarin therapy as it was the only oral anticoagulant widely available at the time.\(^1\)\(^2\) However, this presented many challenges due to the numerous food and drug interactions associated with warfarin, along with the narrow therapeutic index of the drug.\(^1\) To help mitigate these risks, pharmacist adoption of INR monitoring and warfarin dosing have occurred in both the inpatient and outpatient setting. Both of which have been shown to have positive effects on clinical and cost-effectiveness outcomes.\(^3\)\(^-\)\(^6\)

Since then, the emergence of direct-acting oral anticoagulants (DOACs) has drastically changed the landscape of anticoagulation therapy.\(^1\)\(^7\) DOACs eliminate the need for frequent blood-level
monitoring (INR), have fewer drug and diet interactions, and no longer require patients to undergo heparin bridging for periprocedural management.\textsuperscript{1} Yet despite these benefits, DOACs continue to have a few important limitations including shorter half-lives, higher risk of gastrointestinal bleeding, and not having well validated assays available to monitor the degree of their anticoagulation effects.\textsuperscript{8} The short half-life is of particular concern in patients who are non-adherent with DOAC therapy. Studies have shown DOAC non-adherence rates as high as 50%, indicating a high proportion of patients potentially at subtherapeutic anticoagulation and at risk of experiencing a thrombotic event. \textsuperscript{9-11} Additionally, renal function is another concern as DOACs are eliminated by the kidneys and can accumulate in patients with impaired renal function. As there are no validated assays to monitor DOAC levels, regular assessment of renal function and drug dosing is prudent in preventing adverse bleeding events in this patient population.

Although DOACs eliminate the need for INR measurements, monitoring is still essential. Regular therapy assessments provide the opportunity for identifying risk factors and interactions which may put patients at an increased risk of experiencing a thrombotic or a bleeding complication. As with warfarin monitoring, ambulatory pharmacists can once again can play a key role in therapy management. A 2017 retrospective analysis by Ashjian et al found that a pharmacist-led outpatient DOAC service not only increased adherence to therapy but also ensured appropriate dosing of DOACs.\textsuperscript{12}
Recognizing this potential, Gladstone et al used the Thrombosis Canada physician-focused DOAC monitoring practice tool and adapted it in order to better facilitate cross-Canada community pharmacist adoption. To integrate DOAC monitoring within our own hospital, a study was conducted last year to develop and implement a pharmacy focused monitoring tool in the outpatient pharmacy setting at Sunnybrook Health Sciences Centre.

To expand on outpatient DOAC management, this current study aimed to disseminate and evaluate a pharmacist monitoring tool in a family health team (FHT) setting. To accomplish this, an electronic tool was developed with the input of the Sunnybrook Family Health Team pharmacists for use within their practice. The tool’s utility and acceptability were assessed thereafter.

**Methods**

The study took place at the Sunnybrook Academic Family Health Team and specifically involved the two pharmacists working at this location. At this FHT, there are a total of 9364 registered patients and of those patients, 311 with a DOAC listed on their electronic medical record. Prior to this study there was no standardized process for monitoring patients receiving DOAC therapy. The pharmacists at the FHT work primarily on a referral basis, seeing mostly patients for post-discharge medication reconciliations.

The study involved both the development and implementation of the monitoring tool.
Development:

The DOAC monitoring form which was being used in Sunnybrook’s ambulatory pharmacy was further adapted for use in our FHT. Revisions of this monitoring form were based on available literature such as Gladstone’s DOAC monitoring tool, and feedback from the FHT pharmacists themselves. After a few revisions the end result was the development of a DOAC monitoring tool specifically for family health team pharmacy practice.

The tool was developed as two separate forms to be used either for an initial therapy assessment or a follow up. The tool not only helps to guide the assessment of DOAC therapy, but it also standardizes the documentation of the therapeutic assessment. When using the tool it guides the user to consider not only the indication and dosing of the DOAC, but also lab parameters, weight, CHADS2 score, and a bleeding risk assessment. At the end of the forms is a recommendation section where the pharmacist can either recommend the patient to continue the DOAC as prescribed or can suggest either a dose adjustment or a new therapy altogether.

Implementation:

The implementation of the tool was another important aspect of this study. The first step in this process was to adapt the tool into an electronic format compatible with Practice Solutions Suite (PSS). PSS is the EMR used for communication, documentation, and management of patient information in the Sunnybrook FHT. For uptake of this tool to occur, it was essential that the form was accessible through this program. Because the form was integrated with PSS, an added benefit was that the form would auto-populate with information such as the patient’s most
recent laboratory readings and their most recent weight. In addition, the electronic form was intuitive as charts and checkboxes could easily be ticked off.

The pharmacists in the FHT used the form whenever a medication assessment involved a DOAC. In order to encourage pharmacy referrals, an email was sent out to the FHT physicians informing them of new American College of Cardiology recommendations now preferring the use of DOACs over warfarin for stroke prevention in atrial fibrillation. In addition to referrals, proactive chart reviews were also conducted which involved a pharmacist independently targeting patients and assessing their DOAC therapy. However, this was more so done for the purpose of the project and is not a regular task of the FHT pharmacists.

**Results**

Data for this project was collected from forms used between February 11, 2019 to May 17, 2019. Quantitative data was collected regarding utilization of the tool and the number of drug therapy problems identified. Semi structured interviews were also conducted with the FHT pharmacists in order to get qualitative data on their perspective of the utility and acceptability of the tool.

Within the three month time frame of the study, the tool was completed a total of 23 times for 23 different patients. The tool was used mostly for proactive chart reviews and post-discharge
medication reconciliations. There were three drug therapy problems identified from the forms – all of which were identified from the proactive chart reviews.

The proactive chart reviews were done by pharmacist selection of a select group of high-risk patients. These high-risk patients were identified by running a search through PSS to filter for patients whom had a DOAC listed on their profile and who were of 80 years of age or older. By selecting this group of patients, it helped the pharmacist identify those that may meet dose reduction criteria for apixaban. For stroke prevention in atrial fibrillation, apixaban requires a dose adjustment if a patient meets two of the following criteria: age ≥ 80 years, body weight ≤ 60 kg, or patients with serum creatinine ≥ 133 micromol/L (1.5 mg/dL).15

The three drug therapy problems identified all involved apixaban in patients who recently turned 80 years old. (Table 1) Based on either their most recently documented weight or serum creatinine they would qualify for a dose reduction based on guidelines. Recommendations were made to the family physician to reassess these parameters. By the end of the study period, the dose was decreased for one of the patients. For the other two, the physician made a reminder for themselves to reassess the serum creatinine or weight at the patient’s next appointment.

<table>
<thead>
<tr>
<th>DTP Category</th>
<th>DOAC</th>
<th>Age (yr)</th>
<th>Scr (umol/L)</th>
<th>Weight (kg)</th>
<th>Recommendation</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dose too high</td>
<td>Apixaban</td>
<td>80</td>
<td>67</td>
<td>55.7</td>
<td>Reassess weight</td>
</tr>
<tr>
<td>2</td>
<td>Dose too high</td>
<td>Apixaban</td>
<td>80</td>
<td>139</td>
<td>79.6</td>
<td>Reassess renal function</td>
</tr>
<tr>
<td>3</td>
<td>Dose too high</td>
<td>Apixaban</td>
<td>82</td>
<td>82</td>
<td>57.6</td>
<td>Reassess weight</td>
</tr>
</tbody>
</table>

Table 1: Description of DTPs
Qualitative data was collected through individual interviews with the family health team pharmacists. The information gathered was then organized into themes. Benefits of the tool included the fact that it could quickly be used in under five minutes. It was also found to be helpful as a quick reference and eliminated the need of looking through another drug information resource. When using the tool each section also served as prompts reminding the pharmacist of what to update and what to consider when assessing DOAC therapy.

A main limitation of the tool was that the pharmacists felt it was not helpful when they were approached by physicians with specific questions related to DOAC therapy. Specifically, questions asking about which particular DOAC to initiate in a patient. It was felt that the tool did not guide the choice of DOAC therapy and did not differentiate between the options. Additionally, the tool also resulted in duplicate documentation in certain cases. When the pharmacists were conducting a medication reconciliation they had to complete a separate documentation note in addition to documenting in the tool.

When it came to barriers to using the tool, there was concerns about the acceptability of the tool by physicians in the FHT and whether this new template would confuse them from the regular free form notes they were used to seeing in the charts. Another barrier to the use of the tool was the fact that it did not really fit the pharmacist workflow as it wasn’t helpful in guiding the decision-making process when having to recommend a specific DOAC. Lastly, standardized forms such as this tool are not regularly used for patient care in the FHT.
Discussion

From the information gathered, it seems that there was a discordance between the utility of the tool and pharmacy practice in the FHT. The tool was created to facilitate the “monitoring” of DOAC therapy whereas it seems the FHT pharmacists described their role as being involved more so with the “prescribing” of DOACs and providing recommendations to the physicians of which drug to use for a particular patient. (Figure 1) It is likely that the misalignment of the tool with the practices of the pharmacists is why the form did not entirely fit the workflow of the FHT pharmacists.

Figure 1: Medication Use Process

Out of the 311 patients with a DOAC listed on their profile, only 23 of them had a monitoring form completed to assess their anticoagulation therapy. There are a few reasons as to why the form was underutilized. First, the pharmacists work primarily on a referral basis where the FHT physicians will request a consult when they require drug therapy guidance. However, it seems that over time and with the increasing use of DOACs, family physicians have gained comfort with this class of medications and do not routinely require a pharmacist’s expertise. When they do refer to the pharmacy team, the consults were limited to peri-procedural questions and complex patient cases as opposed to concerns regarding routine monitoring. Lastly, routine
monitoring and proactive chart reviews – which although were done for the purpose of this project and did result in the identification of DTPs – are not a part of the pharmacist’s regular workflow at the Sunnybrook FHT. Together these factors contributed to the overall underutilization of the tool.

Although the tool may not have fit the current workflow of the FHT pharmacy team, our research was able to highlight a potential opportunity for proactive chart reviews. From the 12 proactive chart reviews which were conducted throughout the study, 25% were able to identify a drug therapy problem. All three drug therapy problems identified are classified as “dosage too high” and would likely require a dose decrease of the DOAC. By targeting patients based on dose reductions criteria (age, renal function, weight) pharmacists can increase the likelihood of identifying drug therapy problems. Working in a family health team allows the pharmacists to directly communicate these findings to the physicians for re-evaluation either immediately or at an upcoming appointment. Pharmacists can ensure safe and appropriate use of DOACS in high risk patients – helping to minimize the risk of these patients experiencing a bleeding event.

Creating the tool into an electronic format compatible with Practice Solutions Suite was very important to help in the integration of the tool into the family health team workflow. Not only did it help with integration, but creating a standard form embedded in the EMR allowed for easy searching and data retrieval. Through PSS, a user can do a search for every competed DOAC monitoring tool in the patient roster and within seconds can create a list of every patient
chart with the form in it. Forms of this nature potentially could be helpful for measurement of metrics and pharmacist workload.

**Conclusion**

The "Direct Oral Anticoagulant (DOAC) Monitoring Tool” was the first electronic, drug specific tool developed specifically for pharmacy practice within a family health team setting. Although the form did not meet the needs of the current model of pharmacy practice within the Sunnybrook Academic Family Health Team the study did highlight potential opportunities. The adoption of routine DOAC monitoring for selective patient groups (high risk patients with elevated serum creatinine levels, advanced age, low body weights) can be an effective method to identify drug therapy problems related to DOAC therapy. As well, using a standardized form embedded into the family health team’s EMR can be useful for the measurement of metrics or workflow. The form could also be enhanced into a decision support tool to help pharmacists working in an environment where their role is to help make recommendations on which specific DOAC to prescribe for a patient.

As family health team practice is variable between locations, this tool may be better utilized at a different FHT or alternatively an anticoagulation clinic. Piloting the form at other family health teams will provide additional information on the potential utility of the tool. As the indications for DOACs continue to broaden, ensuring safe and appropriate use of these drugs will become
an even greater priority and future research will be needed to explore the pharmacist’s role in DOAC monitoring.
References


