










## ORIGINAL ARTICLE

# Reducing use of coagulation tests in a family medicine practice setting: An implementation study

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## Abstract

**Introduction:** Clinicians often order the international normalized ratio (INR) and activated partial thromboplastin time (APTT) to evaluate for the possibility of inherited bleeding disorders despite sensitivities and specificities of 1%–2%. The most accurate tool to evaluate for bleeding disorders is a validated bleeding assessment tool (BAT). Our aim was to reduce coagulation testing by >50% in a large family practice in Ontario, Canada.

**Methods:** We conducted an implementation study from May 2016 to February 2020. Iterative interventions included introduction of a validated BAT into the electronic medical record (EMR); removal of the APTT as a prepopulated selection from the laboratory requisition; and education targeting family medicine teams and laboratory personnel. The primary outcome was the rate of pre- and post-APTT testing. Creatinine testing was the control. Data were analyzed via an interrupted time series analysis using Stata 13.

**Results:** Immediately following education of the laboratory personnel on coagulation testing, the APTT rate level dropped by 1.26 tests per 100 patient visits per month ( $p < 0.001$ ) and was sustained until the end of the study. Meanwhile, the PT/INR and creatinine testing rate levels did not change (rate level =  $-0.02$  per 100 visits per month,  $p = 0.79$  and  $0.49$ ,  $p = 0.22$  respectively). There was good uptake of the BAT following integration and 18/88 (20%) obtained a referral to hematology after BAT completion.

**Conclusions:** Multidisciplinary, iterative interventions reduced APTT testing and enabled the use of BATs to guide hematology referrals in a large family practice.

Fatima Khadadah and Nadia Gabarin contributed equally to the development of the manuscript (Co-first authors).

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**KEYWORDS**

hemostasis, hemostatic disorders, implementation science, international normalized ratio, partial thromboplastin time

**Essentials**

- Coagulation tests are not 'rule out' tests for the most common inherited bleeding disorders.
- We evaluated iterative interventions on appropriate coagulation testing in outpatients.
- Interventions reduced aPTT use by 92% and incorporated use of a BAT in the primary care setting.
- Coagulation test utilization can be enhanced through implementation science.

## 1 | INTRODUCTION

The prothrombin time (PT) often reported as the international normalized ratio (INR) and activated partial thromboplastin time (APTT) are frequently considered "routine" laboratory tests in patients with a history of bleeding concerns.<sup>1,2</sup> The PT/INR has been validated for warfarin monitoring in steady-state, whereas the APTT has been validated for heparin monitoring and may be used for screening of inherited hemophilia preoperatively among family members of affected individuals. These tests were not designed nor validated as routine screening tests for bleeding disorders in unselected individuals<sup>3-5</sup>; however, they continue to be used in this regard.<sup>1</sup> In a prospective cohort study of patients referred to a hematologist for investigation of bleeding symptoms, the sensitivity of PT/INR and APTT for ruling out a bleeding disorder was only 1% and 2.1%, respectively.<sup>2</sup>

Given the low value of PT/INR and APTT as screening tests, it is safe to say that the vast majority of these tests performed for reasons other than anticoagulant monitoring are unnecessary. The unnecessary use of PT/INR and APTT testing can negatively affect patient care. When assessing a patient with a bleeding history, a physician may be falsely reassured by a normal PT/INR and/or APTT. Conversely, an abnormal PT/INR or APTT may lead the patient down a path of unnecessary investigations, referrals, procedure delays, anxiety, and even inappropriate plasma transfusion, causing potential harm to patient and contributing toward an increased financial burden on the health care system.<sup>1,6-8</sup>

The clinical history is an important screening tool for bleeding disorders.<sup>9</sup> To that end, bleeding assessment tools (BATs) such as the Condensed Molecular and Clinical Markers for the Diagnosis and Management of Type 1 von Willebrand Disease (MCMDM-1 VWD) Bleeding Questionnaire have been developed and validated in the clinical setting.<sup>9-15</sup> The Condensed MCMDM-1 VWD BAT provides a structured format to guide clinicians administering a bleeding history. It has also been shown to have a sensitivity of 100% and negative predictive value of 1 for detecting the most common bleeding disorder, von Willebrand disease (VWD) in adult women, as well as a sensitivity of >99% for other mild bleeding disorders.<sup>10,11</sup>

A quality improvement project carried out at St. Michael's Hospital (SMH), a large academic center in Toronto, Canada, targeting unnecessary coagulation testing in the emergency department resulted in a greater than two-fold reduction in test ordering rates (17.2 vs. 38.4 PT tests per 100 patients per week and 16.6 vs. 37.8 APTT tests per 100 patients per week), leading to an estimated \$6000 in savings per month.<sup>16</sup>

The Department of Family and Community Medicine (DFCM) at SMH is an academic family practice located in downtown Toronto. An interdisciplinary team provides comprehensive primary care through a family health team model. The department comprises five clinic sites located in the community as well as the hospital site. There are more than 48,000 patients across the sites comprising all age ranges; 55% are age 40 years or older and 16% are 65 years of age or older. Fifty-two percent of patients are female. More than 30% identify as being in the lowest income quintile. Rostered patients schedule their own appointments with their primary care provider (family physician or nurse practitioner) or another family health team member. In 2019, there were more than 90,000 physician/nurse practitioner visits across the different sites. Patients are treated for a range of acute and chronic health conditions. The family practice clinical teams are well organized, academically prolific, and highly engaged in quality improvement.<sup>17,18</sup> As such, the DFCM was an ideal target to evaluate the use of a BAT, with the goal of decreasing the rate of inappropriate coagulation testing in the outpatient setting.

We hypothesized that multimodal, sequential, iterative quality improvement interventions in the SMH family practice setting would decrease the rate of coagulation orders by more than 50% and successfully guide referrals for bleeding disorders.

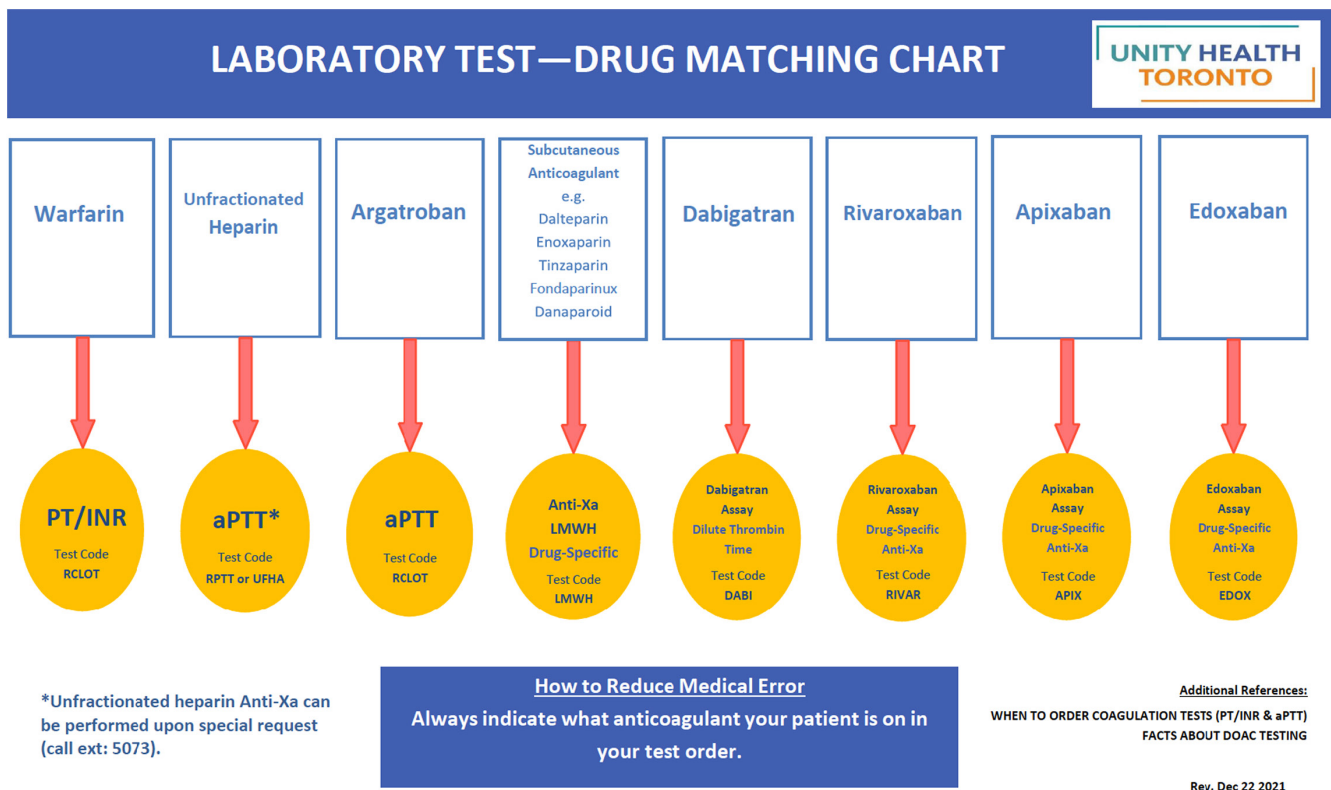
## 2 | METHODS

We conducted a prospective implementation study from May 2016 until February 2020 to assess the effects of multimodal, iterative plan-do-study-act cycles. We measured the baseline rates of APTT and PT/INR testing for 6 months before the first intervention and then we evaluated for change following each intervention. The interventions are summarized in [Table 1](#) and include:

**TABLE 1** Description of the four different periods in months

Period	Description	Evaluation period length (mo)
Baseline May 2016–Oct 2016	Baseline measurement	6
Intervention 1 Nov 2016–Oct 2017	BAT incorporated into the EMR	12
Intervention 2 Nov 2017–Oct 2018	APTT is uncoupled from the PT/INR and removed from the requisition	12
Intervention 3 Nov 2018–Feb 2020	Targeted education to laboratory personnel	16

Abbreviations: BAT, bleeding assessment tool; INR, international normalized ratio; PT, prothrombin time.

**FIGURE 1** Educational material (Supplement).

## 2.1 | Intervention 1

In November 2016, the Condensed MCMDM-1 VWD BAT was introduced to the DFCM for the first time, and integrated and launched on the DFCM electronic medical record (EMR). The Condensed MCMDM-1VWD BAT is an expert-administered and validated questionnaire composed of 12 questions that evaluate bleeding symptoms. Each bleeding symptom category is scored from -1/0 to +4 depending on its severity and required level of medical or surgical attention. A summative score of  $\geq 4$  is considered positive in adults.<sup>10</sup> Providers were taught how to use and interpret the BAT, the BAT was incorporated electronically into the EMR and directly linked to a referral form to hematology if appropriate. The rollout of the BAT into the EMR was supported by a teaching event on the appropriate use of coagulation testing at the DFCM grand rounds. Additionally, 15 posters on coagulation testing were hung up in one of the six clinic sites as well as numerous electronically disseminated educational materials (Figure 1).

## 2.2 | Coagulation testing appropriateness audit

Because we were unclear if family physicians were truly ordering anticoagulation tests inappropriately, we decided to perform an audit of all the patients on oral anticoagulants at one clinic site and had coagulation testing done over a 3-month period from August to October 2017. There were 116 individual patients. Of these, 31/116 (27%) were on warfarin, 34/116 (29%) were on rivaroxaban, 3/116 on dabigatran (3%), and 47/116 (41%) on apixaban. Of those who had an APTT done, we found that 40/45 (89%) did not have a clear indication for testing. The remaining few did have valid indications such as concern for antiphospholipid syndrome. In patients on oral anticoagulation being seen at a DFCM center, we found that 34/46 (74%) of those who had an INR test were on warfarin, whereas 7/46 (13%) had a PT/INR checked in the context of liver disease or in the perioperative setting, at the request of a surgeon. The remaining 5/46 (11%) had no clear indication for PT/INR testing.

Old Laboratory Requisition		New Laboratory Requisition	
CODE	COAGULATION	CODE	COAGULATION
INR	INR	INR	
INRC	Coumadin given	Patient on Coumadin	
APTT	APTT	OTHER:	
APTTH	Heparin given		
THRCV	Thrombin time		
DDIM	D-Dimer		
OTHER:		INR & PTT are not indicated for monitoring of DOACs. <a href="#">More information here.</a> If concerned about a bleeding disorder, use the <a href="#">Bleeding Assessment Tool (BAT)</a> which is more sensitive than any lab test.	

**FIGURE 2** The changes implemented to the family practice laboratory requisition.

Therefore, this audit helped us understand that the primary issue was that of unnecessary APTT testing.

### 2.3 | Intervention 2

We predicted that our initial strategy alone was unlikely to induce sustainable change in coagulation testing and therefore implemented an additional process change. After obtaining access to the electronic outpatient laboratory requisition, we found that there was an entire field dedicated to coagulation testing of which four out of six prefilled tests were judged to be unnecessary in the outpatient setting. A new requisition was designed that removed all the tests except for PT/INR, which is certainly appropriate for those who had liver disease or were on vitamin K antagonists (Figure 2). Decision support was also added into the EMR, which included a hyperlink to the BAT and another to information on direct oral anticoagulants.

Although the APTT and PT/INR were not formally coupled at the laboratory end, they were placed adjacent to each other on the requisition, which we theorized may encourage simultaneous ordering. Because there was no clear indication for APTT testing in the outpatient family medicine setting, we removed this test from the requisition altogether (however, it could be written in free text by the provider if deemed appropriate). After approval by the institutional forms committee, the new electronic requisition was launched in March 2018.

### 2.4 | Intervention 3

In November 2018, in response to a lack of meaningful change in APTT testing rates, we went back to the laboratory with further educational interventions that included educational materials and

infographics targeted at laboratory technicians on the appropriate use of PT/INR and APTT testing. It was then discovered that the laboratory technicians were automatically coupling the APTT with the PT/INR because of entrenched coupling culture despite the institution of laboratory uncoupling of these tests years prior. This practice was out-of-scope without a clear medical directive to do so in standard operating procedures. The educational materials included an anticoagulant-laboratory test matching chart, with the relevant laboratory test codes. We also qualitatively assessed laboratory technician satisfaction with these materials.

### 2.5 | Data collection and analysis

Laboratory data were acquired from the family health team's EMR to determine baseline rates, testing patterns, and average costs of testing of the PT/INR, APTT, and creatinine. Rates were calculated per 100 patient visits per month. Data were analyzed on Stata 13 using an interrupted time series analysis. Results are expressed in terms of monthly rate level changes immediately after each intervention, slopes (representing the monthly rate trends) during each intervention period, and slope changes (sustained effect) from one period to the next.

### 2.6 | Outcome assessments

The primary outcome was the rate of APTT testing over time per 100 patients per month. Secondary outcomes included PT/INR testing rates, use of the BAT, and referrals to the hematology bleeding assessment clinic by family medicine practitioners. The control measure was creatinine testing per 100 patients per month and the balancing measure was the number of positive BAT scores where the patient was not referred to the Bleeding Disorders Program.

Creatinine was used as a control test because it is a commonly used test in the outpatient setting and is not typically linked to bleeding disorders by most practitioners. As such, creatinine testing rates were felt to represent an appropriate control measure for this study. Practitioner satisfaction with the educational materials was assessed with a qualitative survey.

## 2.7 | Ethics

This initiative was formally reviewed by institutional authorities at SMH and deemed to neither require Research Ethics Board approval nor written informed consent from participants.

## 3 | RESULTS

The APTT, PT/INR, and creatinine monthly testing rates time series for the four study periods are displayed in [Figure 3](#).

### 3.1 | Baseline

In 2016, there was a mean of 18,030 patient visits per month or a total of 216,356 patients that year. In the 6 months preceding the first intervention, the mean APTT rate was 1.54 (95% CI 1.40–1.68) per 100 visits per month, the mean PT/INR rate was 1.59 (95% CI 1.45–1.74) per 100 visits per month, and the mean creatinine rate was 8.12 (95% CI 7.72–8.53) per 100 visits per month ([Table 2](#)).

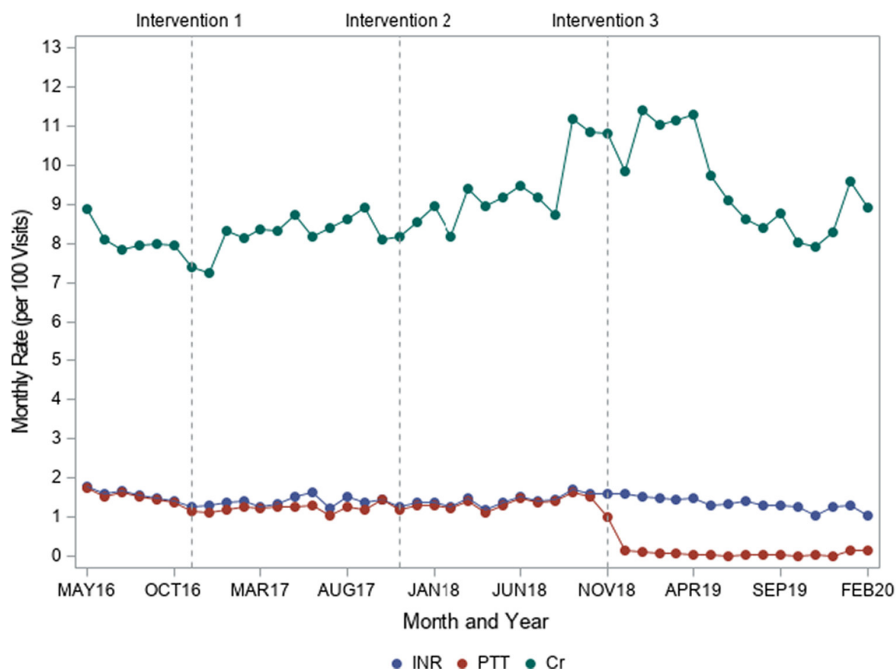
### 3.2 | Intervention 1: BAT incorporation into EMR

We assessed the uptake of the EMR-integrated BAT. From November 2016 to February 2020, EMR BAT use and referrals to the bleeding disorder clinic were tracked. Over that period, 88 BATs were completed and a total of 18 referrals (20%) were made to hematology. Of the 80/88 (91%) who had a negative BAT (score <4), 11/80 (14%) were referred to hematology, whereas of the eight patients who had a positive BAT (score  $\geq$ 4), seven (88%) were referred to hematology. Of the BATs completed, 11 were completed in children younger than age 18 years.

Immediately following the implementation of the BAT into the EMR, the APTT rate level decreased by 0.14 per 100 visits per month ( $p = 0.001$ ), which was not sustained throughout the period (slope change = 0.08,  $p < 0.001$ ). PT/INR rates remained virtually unchanged with a decrease of only 0.04 per 100 visits per month ( $p = 0.25$ ). However, there was a slight increasing trend during the period (slope change = 0.08,  $p < 0.001$ ). Likewise, the creatinine rate level did not change (0.10 per 100 visits per month,  $p = 0.71$ ), but there was an increasing trend during the period (slope change = 0.23 per 100 visits per month,  $p < 0.001$ ).

### 3.3 | Intervention 2: APTT test removed from requisition

Immediately following the removal of the APTT from the laboratory requisition, the APTT and PT/INR rates decreased by 0.12 ( $p = 0.20$ ) and 0.23 ( $p < 0.001$ ) per 100 visits per month, respectively. However, during this period, there was an increasing trend in APTT and PT/



**FIGURE 3** Interrupted time series analysis showing monthly rates of APTT, PT/INR, and creatinine testing rates per 100 patient visits.

**TABLE 2** Descriptive changes in APTT, PT/INR, and creatinine testing rates per 100 visits per month

Study period	APTT		PT/INR		Creatinine	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
Baseline	1.54 (0.13)	1.40–1.68	1.59 (0.14)	1.45–1.74	8.12 (0.38)	7.72–8.53
Intervention 1	1.23 (0.10)	1.17–1.29	1.39 (0.12)	1.31–1.47	8.23 (0.49)	7.93–8.54
Intervention 2	1.35 (0.15)	1.26–1.45	1.42 (0.15)	1.32–1.52	9.25 (0.93)	8.65–9.84
Intervention 3	0.13 (0.24)	0.00–0.25	1.36 (0.17)	1.27–1.45	9.56 (1.23)	8.91–10.22
Relative change: Intervention 3 vs. Baseline	91.6% reduction		14.5% reduction		17.7% increase	

Abbreviations: APTT, activated partial thromboplastin time; CI, confidence interval; INR, international normalized ratio; PT, prothrombin time; SD, standard deviation.

INR rates (slope = 0.03,  $p < 0.00$ ; 0.03,  $p < 0.001$ , respectively). Creatinine rate level was reduced by 0.67 per 100 visits per month ( $p = 0.03$ ), but increased during the period (slope = 0.20 per 100 visits per month,  $p < 0.001$ ).

### 3.4 | Intervention 3: Targeted education to laboratory personnel

Immediately following the implementation of the final laboratory-targeted educational intervention, the APTT rate level dropped by 1.26 ( $p < 0.001$ ) per 100 visits per month. This reduction was sustained during the study period (slope change =  $-0.05$ ,  $p = 0.01$ ). The PT/INR rate level went down by 0.02 per 100 visits per month ( $p = 0.79$ ), and there was a continuous decrease over the period (slope =  $-0.03$ ,  $p < 0.001$ ). Creatinine rate levels did not change (0.49,  $p = 0.22$ ) but, surprisingly, rates decreased during the period (slope =  $-0.20$ ,  $p < 0.001$ ).

Eleven laboratory technicians completed a survey in November 2018 and 91% reported increased confidence in their coagulation testing knowledge posteducational intervention (“Strongly Agree” or “Agree” on a 5-point Likert scale). Laboratory staff also indicated that the educational interventions led to process improvement in the laboratory.

These results are consistent with the descriptive statistics (Table 2). Therefore, we conservatively estimate that with the 92% reduction in APTT testing (from a mean of 282 APTT tests per month to 20 tests per month), the potential savings at our institutions are about \$124,380 Canadian per year. This amounted to a cost of \$94,290 Canadian and \$30,090 per year for APTT and PT/INR respectively (Figure 1).

## 4 | DISCUSSION

In this study, through multimodal, multidisciplinary, iterative interventions, we were able to reduce APTT testing in a large, urban family practice in Ontario, Canada, by 92%. In addition, we were able to successfully implement a BAT into the family medicine EMR to help effectively guide referrals to hematology for patients with concerns about hemostatic disorders. Although we note that there were

sustained decreases in both PT/INR and creatinine testing rates during the Intervention 3 or educational period, the drop was much more pronounced for APTT compared with PT/INR and creatinine (Table 2; Figure 3).

Inappropriate hematology laboratory testing is common.<sup>1,3,19</sup> In one systematic review and meta-analysis of 42 studies over 15 years, the overall mean rate of laboratory test overuse was 20.6% for all laboratory tests and 33.3% for hematology tests including hemostatic panels, and 19.1% for chemistry tests.<sup>3,20</sup>

In addition to the direct financial implications of inappropriate laboratory testing, an abnormal APTT and PT/INR can lead to mislabeling of a patient's condition as most abnormal results are false positives or clinically irrelevant, and may lead the patient down a path of unnecessary and costly investigations resulting in anxiety and the so-called Ulysses syndrome.<sup>19</sup>

The APTT and PT/INR are in vitro assays that measure the time for a fibrin-rich clot to form in a test tube on platelet poor plasma. They therefore test one component of hemostasis and are affected by many preanalytical variables.<sup>2,21</sup> This is important as disorders of primary hemostasis such as VWD and platelet function disorders are more common and are typically not detected by the APTT and PT/INR.<sup>2,4</sup> In one study, extending a hemostatic panel to also test for a VWD and platelet function was able to increase the sensitivity of testing to 30% but this still left 70% of patients with an undiagnosed hemostatic disorder.<sup>2</sup>

In this study, we were able to identify high and inappropriate use of the APTT and to a lesser extent the PT/INR. Removing the APTT from outpatient laboratory requisitions is an easily adopted quality improvement intervention. What was remarkable in this study was the depth of the cultural link between the APTT and PT/INR, both by bedside clinicians and laboratory technicians. Over decades, the APTT and PT/INR have together assumed the position of tests for bleeding disorders in the minds of many health care workers despite evidence to the contrary. This cultural coupling of the APTT and PT/INR was also found in the emergency department study by Fralick et al., with these tests being coupled on multiple ordering panels and at different levels of the ordering chain.<sup>16</sup> The education of the laboratory personnel on the appropriate use of PT/INR and APTT had the biggest impact on effectively reducing inappropriate coagulation testing in this project.

The implementation of the BAT into the EMR combined with education on the value of the bleeding history enhanced referrals from the family practice to hematology, resulting in the appropriate referral of 86% (7/8) of patients for assessment where there was a high BAT score. Additionally, 69/80 patients with a negative BAT were reassured in real time that their risk of a bleeding disorder was low and were not referred on to the bleeding disorders clinic. To our knowledge, this is the first implementation science study enhancing the use of the BAT in the nonhematologist setting and using it successfully to guide referrals to centers of bleeding and hemostasis.

One limitation of this study is that we did not have a baseline hematology referral rate for bleeding disorders. In addition, we do not know the denominator of patients that presented with concerns about bleeding or hemostasis, and thus cannot determine which patients had coagulation testing versus a BAT performed versus both. Additionally, the DFCM does serve children younger than age 18 years. Although the MCMDM1 questionnaire has not been validated in patients younger than age 18 years, the Pediatric Bleeding Questionnaire (PBQ) has been and it has an identical scoring system to the MCMDM1.<sup>22</sup> There were 11 patients in total younger than age 18 years, and most were appropriately adjudicated as per the PBQ cutoffs. We are missing some data for about 3 children and are unsure whether they were adjudicated appropriately. This is a possible limitation of our work.

Another major limitation in this study is its single-center nature. The SMH DFCM is a large, urban family practice spread over six sites encompassing more than 48,000 patients, but it still represents a single academic center. We therefore cannot make assurances of the external generalizability of our interventions; however, we believe that our use of different modalities and insight provided on the culture of coagulation testing may be helpful for those considering similar quality improvement initiatives.

In conclusion, by going through an iterative plan-do-study-act cycle process, we were able to determine that (1) following appropriate education and implementation of the BAT into the EMR, physicians used the BAT to help determine the need for referral to hematology, and (2) coupling of PT/INR and APTT tests was occurring mostly at the laboratory outside of the control of the physicians, making the laboratory an important target for implementation strategies.

#### AUTHOR CONTRIBUTIONS

F.K. and N.G. drafted the manuscript, R.N. performed the interrupted time series analysis, and A.J. and H.C. helped obtain information on BAT and INR/APTT use and performed the cost analysis. P.J., J.H., C.H., and R.G. contributed and reviewed the manuscript. M.S. conceived of the project, and contributed and reviewed the manuscript.

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