BMJ Open Quality Improving documentation of anticoagulation and antiplatelet recommendations after outpatient endoscopy

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ABSTRACT

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Clear documentation of instructions for resuming anticoagulant and antiplatelet (AC/AP) medications after gastrointestinal endoscopy is essential for high-quality postprocedure care. Yet, these recommendations are frequently absent, which may impact patient safety. We aimed to improve documentation of postprocedural AC/ AP instructions through targeted interventions during outpatient endoscopy at a Veterans Affairs Medical Center using validated Quality Improvement methodology. We identified patients on AC/AP agents presenting for outpatient oesophagogastroduodenoscopy or colonoscopy and found restart recommendations were documented in only 59.4% of procedures at baseline. After two intervention cycles, which included provider education, nursing prompts and alterations to endoscopic documentation software, postprocedure documentation increased by 26.7%-86.1% when compared with baseline (p<0.001). These interventions, which require low-resource utilisation, could be part of standardised processes readily implemented at other institutions to help potentially reduce postprocedure patient confusion, medication errors and complications.

PROBLEM

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br Brian Sullivan; brian.a.sullivan@duke.edu Following gastrointestinal (GI) endoscopy, resuming anticoagulant and antiplatelet (AC/AP) medications too early could increase the risk of bleeding, while restarting them too late may lead to thromboembolism.^{1–3} Professional societies, therefore, recommend clear documentation of instructions for the resumption of these medicines to ensure high-quality postprocedure care.^{4–6} However, several factors make this challenging, including poor communication between providers, conflicting guidelines, lack of prompts on documentation software and endoscopists' unfamiliarity with the management of these medications.

It is unclear how effectively endoscopists manage these challenges. We studied the communication of postprocedure AC/ AP recommendations at our institution's

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Clear documentation of instruction for resuming anticoagulant and antiplatelet (AC/AP) medications after gastrointestinal endoscopy is essential for high-quality postprocedure care. However, multiple barriers can interfere with the delivery of appropriate postprocedural AC/AP guidance, which may cause patient confusion or compromise safety after routine endoscopy.

WHAT THIS STUDY ADDS

⇒ We provide evidence that this often unaddressed problem can be successfully mitigated through simple interventions, including educational initiatives, updates to otherwise required nursing documentation, and a hard-stop reminder prompt encoded into the endoscopy note-writing software.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Given the importance of well-documented postprocedure AC/AP instruction on discharge from hospital settings, this Quality Improvement initiative should inform best practice quality guidelines for outpatient endoscopic procedures. These interventions, which require low-resource utilisation, could also be part of standardised processes readily implemented at other institutions to help ensure patient safety in the postprocedure period.

Veterans Affairs (VA) Medical Center and subsequently addressed deficiencies through stepwise changes over a 3-year time period (2018–2020).

BACKGROUND

Prescription of AC/AP medications is common with approximately 6 million people in the USA now taking these blood thinning medications.⁷ An estimated 10%–15% of these patients will require interruptions of therapy each year for invasive GI procedures.⁵ Given the increasing number of patients on AC/AP agents, standardised processes now

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exists at many institutions for managing these patients prior to GI endoscopy. At our institution, patients on any AC/AP medications are identified by an endoscopy nurse when processing GI endoscopy consultations at least 2 weeks prior to any procedure. Then, a referral is placed to the prescribing providers for preprocedural cessation guidance. However, no such standardised process exists for providing recommendations on resuming AC/AP agents after the GI procedure has taken place. Therefore, it is important to evaluate whether new protocols could inform updated, evidence-based practices for medication management after elective outpatient endoscopic procedures.

Variations in providing postprocedure guidance for these agents can lead to serious problems during routine clinical practice. Evidence suggests that up to 5% of hospitalisations for acute coronary syndrome may be due to prolonged discontinuation of AP therapy after noncardiovascular procedures.⁶ Conversely, clinically relevant bleeding events after high-risk endoscopic interventions may be as high as 20%, especially if AC/AP is resumed prematurely.⁸ ⁹ While professional societies have previously developed recommendations to help mitigate the risks surrounding postprocedure management of AC/AP agents, there is no literature evaluating how often these recommendations are provided to patients after routine outpatient endoscopy.

At our medical centre, frequent postprocedure queries from patients and non-GI Providers alerted the authors to this potential problem of deficient postprocedure AC/ AP instruction. This anecdotal experience suggested that these recommendations were either not provided to patients, or provided to patients who may still be under the effects of sedation and without concomitant postprocedure documentation for later review. Given the implications for providing safe and effective care, evaluating this problem was of significant interest to our quality leadership.

MEASUREMENT

We created a multidisciplinary team comprised gastroenterology fellows, attendings and nurses to identify and improve any deficiencies in the documentation of postprocedure AC/AP management. The Institute for Healthcare Improvement's (IHI) Model for Improvement (http://www.ihi.org/) was employed for this Quality Improvement (QI) initiative. All patients on AC/ AP medications who underwent an outpatient endoscopy or colonoscopy at our VA Medical Center were prospectively evaluated from January to April of 2018, 2019 and 2020. These time frames were selected a priori, given local resource limitations precluding data collection in perpetuity throughout each calendar year. These specific time frames for measurement were chosen over the same calendar months to allow for the most consistency in provider/patient populations during successive intervention trials and over a sufficiently long time period.

Although new GI trainees onboard in July, attending physicians and support staff remained consistent during this periods. Staff were not made aware of the specific observation time frames to mitigate the impact of the Hawthorne effect. The time between measurement cycles was planned as 'run-in' phases to allow for the design and implementation of subsequent interventions as informed by the previous measurement cycle. Given the impact of COVID-19 on procedure volume and the presumed instability of subsequent measurement estimates, no further data were collected beyond April 2020. Patients on AC/ AP agents who underwent oesophagogastroduodenoscopy (EGD) and colonoscopy were identified from the central VA corporate data warehouse. Multiple exams in the same patient were counted as distinct procedures. All inpatient procedures as well as patients undergoing outpatient endoscopic ultrasound and/or endoscopic retrograde cholangiopancreatography were excluded. During each measurement cycle, patient-level data and outcomes from included patients were obtained by trained medical chart abstractors (the listed authors). Confidentiality was maintained by storing all patient-identifying information on a secure server designed for this purpose.

During the period of this QI study, there were no updates to national guidelines regarding the use of AC/ AP agents after endoscopy.^{4–6} Given that national guidelines have varying recommendations for differing AC/ AP agents after outpatient EGD or colonoscopy, we elected to define our outcome simply as the presence or absence of any instructions regarding AC/AP reinitiation on postprocedure documentation. At a minimum, providing recommendations would alleviate anxiety for patients regarding medication management and reduce postprocedure inquiries to providers with this question. Postprocedure complications, such as bleeding or thrombosis, were outside the scope of the original QI protocol and not included in this analysis due to the rarity of these outcomes and high likelihood for incomplete reporting.

DESIGN

The first measurement cycle from January to April 2018 was used to establish a baseline rate of postprocedure AC/AP documentation. Next, stakeholder interviews and process observation were employed to identify factors that may influence whether AC/AP restart recommendations are ultimately included in the endoscopy report. A process map was created which demonstrated that on the day of the procedure, both the nurse and the endoscopist ensure that the patient has stopped the medication as instructed by the referring providers. Once the procedure is performed, however, the endoscopist is then solely responsible for providing documentation of AC/AP restart recommendations based on any interventions performed, and also accurately communicating this information to the patient or their caregiver. Based on these findings, a fishbone diagram was created to summarise the potentially modifiable factors that may be most

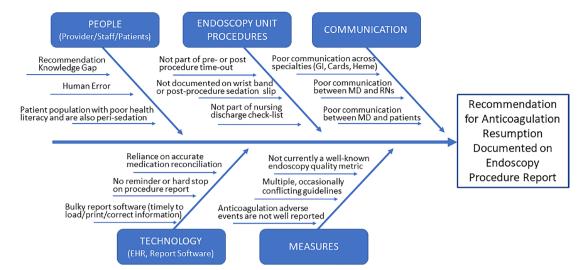


Figure 1 Fishbone diagram informing the root cause analysis for missing postprocedure AC/AP restart recommendations. AC/ AP, anticoagulant and antiplatelet. MD = Medical Doctor; RN = Registered Nurse.

amenable to QI intervention (figure 1). From this, we learnt that our process was overly dependent on a busy endoscopist to consider, document and communicate these important recommendations to each patient, in the few minutes available between high throughput GI procedures, and without any prompts. Therefore, we sought to support the endoscopist by empowering ancillary staff and implementing important process checks.

STRATEGY

The goal of this QI initiative was to increase documentation of postprocedure recommendations regarding AC/AP management. Our Plan–Do–Study–Act (PDSA) cycles sought to target key 'pain' points during endoscopy care processes that led to deficient instruction. Each PDSA intervention was informed by lessons learnt during the prior measurement cycle and based on updates to our initial root-cause analysis. To evaluate trends over time, a run chart was created to prospectively monitor the proportion of procedures with documented AC/AP restart recommendations (figure 2).

PDSA cycle 1

Our first PDSA measurement cycle (January–April 2019) occurred after a period of educational outreach to stakeholders through team meetings and departmental grand rounds during the 'run-in' period of July–December 2018. This outreach stressed patient identification and medication reconciliation before and after the procedure, as well as the importance for documented AC/

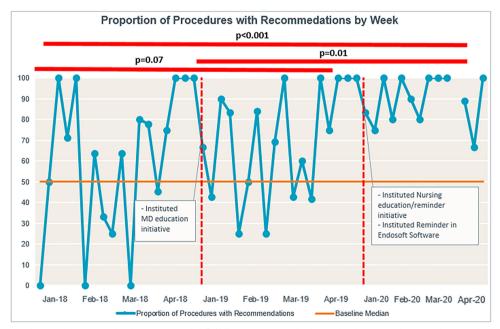


Figure 2 Run chart of procedures with documented AC/AP recommendations during the observation periods across PDSA cycles. AC/AP, anticoagulant and antiplatelet; PDSA, Plan–Do–Study–Act. MD = Medical Doctor.

AP restart recommendations on postprocedure reports. During these sessions, we reviewed current guidelines for postprocedure AC/AP management, and the potential for accurate recommendations to mitigate the rare, but potentially serious, postprocedure complications such as bleeding and thrombosis. However, it became clear during ongoing data monitoring using a run-chart (figure 2) that stronger interventions were needed.

PDSA cycle 2

For our second PDSA measurement cycle (January-April 2020), we added multiple interventions to support both our nurses and endoscopists. These processes were created and refined based on ongoing feedback from select stakeholders, and ultimately approved by VA endoscopy leadership during the period of August-December 2019. Specifically, if AC/AP agents were identified, a hard copy paper prompt was provided to the endoscopist from the nurse about the presence of this medication and need for postprocedure recommendations. This paperwork augmented an existing nursing documentation requirement. This paperwork also included a summary of procedure sedation and findings, which was already traditionally used by our endoscopists when completing their postprocedure documentation. Simultaneously, we also implemented a 'hard-stop' notification within EndoSoft documentation software around patient AC/AP use, in an effort to remind endoscopists to provide postprocedure guidance. During the completion of procedure documentation, the endoscopist would be unable to finalise the recommendations until a response was provided for a simple 'yes or no' query regarding whether the patient was on AC/AP regimen.

Statistical analysis

At the end of the QI project, descriptive statistics were calculated using means and proportions. We compared differences in the proportion of endoscopy postprocedure reports with AC/AP restart documentation between the preintervention period (January–April 2018) and after the first PDSA cycle (January–4/April 2019), between the first PDSA cycle and the second PDSA cycle (January–April 2020), and between all three time periods using a χ^2 tests (missing data excluded).

RESULTS

Demographic comparison

A total of 308 procedures (95 EGDs, 212 colonoscopies and 1 flexible sigmoidoscopy) performed at our VA Medical Center met the criteria and were included in our analysis. Our cohort was primarily male (97%) and Caucasian (70%). The most common AC/AP agents were clopidogrel (32.15%), rivaroxaban (20.90%), apixaban (20.25%) and warfarin (12.86%). There were no significant differences in participant age, sex, race, procedure type or AC/AP agent across PDSA cycle periods (table 1).

Baseline data

At baseline, postprocedure AC/AP restart recommendations were documented on average in only 59.4% of procedures (January–April 2018). As shown in figure 2, there was significant variability in providing AC/AP recommendations throughout the entire baseline observation period, with multiple periods of 0% and 100% adherence at various weeks. This finding highlights the inconsistency and unpredictability AC/AP guidance on postprocedure documentation during routine practice. These results were presented to the gastroenterology division at grand rounds and QI didactic conferences to help motivate subsequent improvement through our intervention cycles. By highlighting this problem in a transparent, non-punitive environment, our providers responded positively and expressed interest in practice modification.

PDSA cycles

After our educational 'run-in' period, documentation quantitatively improved to 70.7% (p=0.07) on average during the first PDSA cycle (January-April 2019), including 1 month with 96.3% of procedures with documented recommendations. During this period, observation of process improvement was ongoing and led to significant buy-in from additional stakeholders, such as nursing staff who volunteered as 'champions' to redesign nursing documentation and address the goal of ensuring postprocedure AC/AP documentation. Yet, given that the overall magnitude of improvement was highly variable and not sustained at a sufficient level (figure 2), a stronger intervention of a 'hard-stop' in the endoscopic documentation software was also envisioned. Ultimately, both nursing and endoscopic software interventions were created during the 'run-in' period of late 2019 and combined as the next PDSA cycle based on experiences from the first time period.

During the second PDSA cycle (January-April 2020), consistent and durable improvement was then demonstrated with 86.1% of procedures on average having postprocedure AC/AP recommendations (p=0.01, compared with the prior PDSA cycle). Overall, our interventions significantly improved documentation of postprocedure AC/AP management by 26.7% (p<0.001). As shown in figure 2, a shift towards improved outcomes began by the end of PDSA cycle 1, as defined by the proportion of documented AC/AP instruction above the baseline median (50%) for more than 6weeks.¹⁰ This shift was sustained throughout PDSA cycle 2. Overall, this shift towards improved postprocedural AC/AP documentation seems to be correlated with our simple updates to otherwise required nursing documentation and a hardstop reminder prompt encoded into the endoscopy notewriting software.

No unexpected consequences of these interventions were identified based on informal feedback from relevant stakeholders. Our simple interventions required almost no interruption to the usual workflow during elective outpatient endoscopy. While slightly increased documentation

	Overall* (n=311)	Intervention cycle		
		Baseline (n=106)	PDSA cycle 1 (n=133)	PDSA cycle 2 (n=72)
Age in years, mean	68.0	66.5	68.9	68.7
Male sex, n (%)	303 (97.4)	102 (96.2)	130 (97.7)	71 (98.6)
Race				
White, n (%)	212 (68.2)	71 (67.0)	90 (67.7)	51 (70.8)
African American, n (%)	85 (27.3)	28 (26.4)	38 (28.6)	19 (26.4)
Other, n (%)	7 (2.3)	4 (3.8)	2 (1.5)	1 (1.4)
Procedure				
Colonoscopy, n (%)	215 (69.1)	74 (69.8)	95 (71.4)	46 (63.9)
EGD (%)	95 (30.5)	32 (30.2	38 (28.6)	25 (34.7)
Flexible sigmoidoscopy, n (%)	1 (0.3)	0 (0)	0 (0)	1 (1.4)
AC/AP agent				
Plavix, n (%)	100 (32.2)	33 (31.1)	48 (36.1)	19 (26.4)
Ticagrelor, n (%)	7 (2.3)	2 (1.9)	1 (0.8)	4 (5.6)
Warfarin, n (%)	40 (12.9)	20 (18.9)	11 (8.3)	9 (12.5)
Dabigatran, n (%)	33 (10.6)	11 (10.4)	16 (12.0)	6 (8.3)
Apixaban, n (%)	63 (20.3)	15 (4.8)	30 (22.6)	18 (25.0)
Rivaroxaban, n (%)	65 (20.9)	24 (22.6)	25 (18.8)	16 (22.2)
Edoxaban, n (%)	1 (0.3)	0 (0)	1 (0.8)	0 (0)
Prasugrel, n (%)	2 (0.6)	1 (0.9)	1 (0.8)	0 (0)

*Missing data excluded.

AC/AP, anticoagulant and antiplatelet; EGD, esophagogastroduodenoscopy; PDSA, Plan-Do-Study-Act.

requirements may have required somewhat more time for team members, this inconvenience was ultimately felt to be outweighed by the potential benefits from everyone in our division. Integration of these interventions soon became an efficient routine, and all remain in use today.

LESSONS AND LIMITATIONS

In this QI initiative, we demonstrated significant improvement in documentation of postprocedure AC/ AP management instructions in the outpatient setting by employing a well-known model for improvement. Postendoscopic management of AC/AP medications represents a frequent challenge to the practising endoscopist. On investigating this problem further, we found that periprocedural AC/AP management is actually quite complex with the involvement of multiple providers across various subspecialties. In 2016, the American College of Cardiology Anticoagulation Initiative Work Group looked to evaluate current periprocedural anticoagulation practice patterns in hopes of improving the management of anticoagulation care. They found cardiologists to be the most involved, with 88% responding that they considered themselves to be the sole or major decision-maker for patients on an anticoagulant, whereas gastroenterologists only considered themselves to be the sole decision maker 67% of the time.¹¹ Furthermore, only

a minority of respondents noted that their institution had a standardised postprocedural protocols with respect to anticoagulation management. Given the lack of standardised approaches to postprocedural AC/AP management, it was not surprising that these recommendations were initially lacking on >40% of procedure reports performed at our institution.

This finding highlights an important concern that medication reconciliation of high-risk medications during a transition of care is often incomplete. It is well established that a thorough medication reconciliation is associated with a reduction in adverse drug events on discharge from the hospital setting, and that nearly 60% of all reported medication errors occur as a consequence of communication errors during transitions of care.³ Similarly, the postprocedure period is a transition period vulnerable to these types of adverse drug events, yet remains understudied. On quantification of the magnitude of this problem, addressing this issue quickly became a priority of our pre-existing, multidisciplinary QI team. Using validated IHI methodology, we have now shown that multifaceted interventions significantly improved discharge AC/AP documentation, including educational initiatives (70.7% vs 59.4%, p=0.07) and the addition of nursing interventions together with 'hard-stop' Endo-Soft software changes (86.1% vs 59.4%, p<0.001), when

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compared with baseline. These interventions targeting critical periprocedural processes, such as nursing/physician communication and endoscopic documentation software, demonstrated sustained practice change in post-procedure documentation, often at levels of 100% adherence. Importantly, these interventions not only have the potential to reduce adverse drug events but could also reduce possible medical professional liability.^{1–3}

Our study's strengths include a long period of follow-up, across multiple different improvement cycles, which allowed us to more precisely evaluate the impact of each intervention across a spectrum of different AC/AP agents. We also benefited from the centralised data repository at the VA Medical Center, which includes complete capture of all GI procedures with linked VA Pharmacy data. As such, we were able to readily identify all eligible patients on AC/AP agents who had endoscopic procedures during the study period independent of any recognition by GI providers. Lastly, we benefited from strong and enthusiastic support from a number of interested stakeholders, including providers, nursing and ancillary staff, administrators, and the software engineers at EndoSoft.

There are limitations to our study. Our data were collected over relatively limited time frames at a single centre in a homogeneous population. Nevertheless, processes of care at our institution are consistent throughout the year and likely representative of other endoscopic centres. Furthermore, although our PDSA cycles were initially meant to be small and rapidly scale the more successful components of our interventions, most of our interventions were not amenable to limited introduction (eg, education outreach and changes to endoscopic software). During each year's 'run-in' between measurement periods, our team meticulously designed and disseminated preliminary ideas for interventions to various stakeholders and then optimised these ideas based the feedback. These processes often required weeks to months to complete, given the delays in various feedback and time to make the respective changes (eg, the endoscopic software changes) or receive approvals from QI leadership. Our team also realised that optimising interventions prior to widespread implementation was critical to the success of our project at our busy endoscopic practice. In addition, we did not track a robust set process or balancing measures, such as who received our educational or nursing feedback or if our 'hard-stop' documentation software intervention added significant time to the completion of procedure reports. However, informal polling of our Providers demonstrated favourable responses to our interventions, reporting that our interventions were efficient, relatively simple to complete, and that improved documentation was helpful to patients during postprocedure counselling. Finally, we also do not report postprocedure complications such as bleeding or

thrombosis, nor did we assess for provider compliance to national guidelines. These complications and compliance assessments were outside the scope of the original QI protocol. In regard to these potential postprocedure complications, these data are likely unreliable with unclear relation to specific postprocedure AC/AP recommendations.¹² In terms of adherence to national guidelines, these recommendations are not standardised and often conflict, which makes it challenging to perform or interpret such analyses. Larger studies are needed to evaluate the most effective AC/ AP recommendations from specific guidelines in terms of reducing the incidence of postprocedural complications.

CONCLUSIONS

In conclusion, documented postprocedure AC/AP management recommendations were frequently lacking at our institution, but this documentation improved significantly with standardised communication and endoscopic software initiatives. Given the importance of well-documented postprocedure AC/AP instruction on discharge from hospital settings,^{2 3} these interventions should inform best practice quality guidelines for outpatient endoscopic procedures.¹³ These interventions, which require low-resource utilisation, could also be part of standardised processes readily implemented at other institutions to help potentially reduce postprocedure patient confusion, medication errors and possible complications.^{6 8 9 13}

Contributors B0'C: Study concept and design, data extraction, interpretation of data, and drafting and critical revision of the manuscript. AB: Study concept and design, data extraction, interpretation of data, and drafting and critical revision of the manuscript. DK: Study concept and design, interpretation of data, and critical revision of the manuscript. NM: Study concept and design. JC: Study concept and design, data extraction, interpretation of data and critical revision of the manuscript. NM: Study concept and design. JC: Study concept and design. BS: Study concept and design, data extraction, interpretation of data and drafting and critical revision of the manuscript. All authors approved the final version of this manuscript. BS is the overall guarantor, and accepts full responsibility for the finished work and the conduct of the study, had access to the data, and controlled the decision to publish.

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