

Patient Safety Alert: Periprocedural Management of Anticoagulation Therapy

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Over the past several years, there has been a dramatic increase in patients receiving long-term anticoagulation and antiplatelet therapy. Current estimates suggest that more than 4 million Americans are taking oral chronic anticoagulants for the prevention and treatment of venous and arterial thromboembolism. Anticoagulants are commonly indicated as a stroke prevention approach in patients with atrial fibrillation, and as a preventative measure for patients with mechanical heart valves or acute coronary syndrome.⁴ Anticoagulants are also routinely administered to hospitalized patients for the prevention of venous thromboembolism (VTE).

From a patient safety perspective, anticoagulants are not only considered high alert medications¹, but are among the most frequently listed medications associated with medication errors, comprising 7.2% of medication-related sentinel events reported to the Joint Commission's Sentinel Event Database.³

From a liability perspective, claims associated with anticoagulation therapy represent a significant percentage of medication-related claims. In the CRICO Strategies Comparative Benchmarking System (CBS) data repository there are 1,486 cases with a medication-related major allegation asserted in 2009–2013. Among these, 12% involved anticoagulants. The majority of these cases originated in the inpatient setting followed by the ED and Ambulatory clinical domains.

The AMC PSO recently convened to discuss this high-risk area and important patient safety issue, the contributing factors often associated with this medication event type, and the strategies to proactively mitigate this risk.

Risks

Fluctuating diagnostic evaluations and their impact on anticoagulation administration can add to the patient risk profile. When patients with complicated presentations and fluctuating anticoagulation levels require an invasive procedure, the risks are compounded.

This Patient Safety Alert highlights the need for guidelines to assist clinicians in the periprocedural management of patients at high risk in this area. Patients with thrombosis and hemorrhage related to anticoagulation/antithrombotic therapy have risks that are complicated by the use of multiple anticoagulants with different indications.

A Multidisciplinary Approach

Experts in anticoagulation management suggest that every patient on a blood thinner undergoing a procedure, have a plan for management of the blood thinner in the periprocedural period. This approach consists of four key elements in mitigating the risk of periprocedural hemorrhage or stroke/thrombosis in patients on anticoagulation therapy:

- Identifying if a patient is on a blood thinner.
- Shared decision-making, incorporating guideline-based care. For example, for some procedures, patients can stay on blood thinner.
- Clear communication of the treatment plan to all members of the care delivery team and the patient, as well as clear documentation of this plan in the medical record.

- Accountability for ensuring the plan is implemented, and goes well from start to finish. For GI Procedures, recommendations are attached as Exhibit A¹.

UTILIZING CASE-MANAGEMENT EXPERTISE

Engaging case management to facilitate multi-disciplinary, clinically based case review for patients with an in-house length of stay >5 days is another strategy aimed at providing active surveillance of patients at high risk for complications.

DEVELOPMENT OF AN ANTICOAGULATION TEAM

Other suggested strategies include using a Nursing/Pharmacy-led team to:

- Assist in risk assessment, monitoring and dose adjustment parameters for anticoagulants.
- In consultation with the responsible physician and care team, ensure that evidence-based guidelines and pathways are followed to optimize care for complex, high risk clinical conditions.
- Assist with identification of patients currently on blood thinners and scheduled for procedures.
- Promote use of clinical guidelines for management of antithrombotic therapy.
- Facilitate clear documentation and timely communication of critical test results.
- Leverage advanced practice clinicians to support existing staff and provide increased vigilance.

Conclusion

Paramount to the success of each of these strategies is clear documentation and communication by all providers to ensure that the patient's plan of care is articulated and understood by all members of the care delivery team.

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REFERENCES

1. Beth Israel Deaconess Medical Center (BIDMC) Primary Care and Gastroenterology: BIDMC Anticoagulation Grid; 2015. Further information on this grid can be requested from Diane Brockmeyer, MD (dbrockme@bidmc.harvard.edu), Daniel Leffler, MD (dleffler@bidmc.harvard.edu).
2. Institute for Safe Medication Practices (ISMP). ISMP List of High-Alert Medications in Acute Care Settings. 2014; <https://www.ismp.org/tools/highalertmedications.pdf>. Accessed October 8, 2014.
3. The Joint Commission: Preventing errors relating to commonly used anticoagulants. Sentinel Event Alert 41, September 24, 2008; http://www.jointcommission.org/sentinel_event_alert_issue_41_preventing_errors_relating_to_commonly_used_anticoagulants/. Accessed October 8, 2014.
4. National Institutes for Health

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Exhibit A

| | COLONOSCOPY | | | EMR | EGD | | | | | ERCP | | EUS or RFA | | OTHER | | |
|---|--|--|--|---|--|---|--|--|--|--|--|--|--|--|--|---|
| | COLONOSCOPY & Flex Sig (SCREENING) | COLONOSCOPY (High Risk Surveillance) ** | COLONOSCOPY for IBD Surveillance | EMR (Large Polyp) with COLONOSCOPY or EGD | EGD or SBE with or without biopsy | EGD EMERGENT Varices ligation | EGD ELECTIVE Varices ligation | EGD with Stent | EGD with Dilation | ERCP - Diagnostic | ERCP with Sphincterotomy | EUS without FNA | EUS with FNA -or- RFA | PEG | Paracentesis (elective therapeutic) | Percutaneous Liver Biopsy |
| ASPIRIN = Ecotrin, Bufferin, etc. | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Discuss for each patient | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Discuss for each patient | Continue, no pt letter needed, no email needed | Stop 7-10 days pre biopsy & restart 48 hours after § |
| COUMADIN = Warfarin | Continue Goal INR 2.5 or less | Discuss for each patient | Discuss for each patient | Med must be stopped § | Continue Goal INR 2.5 or less | Continue Goal INR 2.5 or less (w emergent reversal if clinically indicated) | Discuss for each patient | Med must be stopped § | Med must be stopped § | Discuss for each patient | Med must be stopped § | Continue Goal INR 2.5 or less | Med must be stopped § | Med must be stopped § | Discuss for each patient | Stop 5 days pre biopsy & restart 48 hours after § |
| CLOPIDOGREL = Plavix and other anti-platelets‡ | Continue | Discuss for each patient * | Discuss for each patient * | Med must be stopped § * | Continue | Continue | Discuss for each patient * | Med must be stopped § * | Med must be stopped § * | Discuss for each patient * | Med must be stopped § * | Continue | Med must be stopped § * | Med must be stopped § * | Discuss for each patient * | Stop 7-10 days pre biopsy & restart 48 hours after § |
| DABIGATRAN = Pradaxa, APIXABAN = Eliquis, RIVAROXABAN = Xarelto, EDOXABAN = Lixiana | Continue | Discuss for each patient | Discuss for each patient | Med must be stopped § | Continue | Continue (with emergent reversal if clinically indicated) | Discuss for each patient | Med must be stopped § | Med must be stopped § | Discuss for each patient | Med must be stopped § | Continue | Med must be stopped § | Med must be stopped § | Discuss for each patient | Stop 2-5 days pre biopsy & restart 48-72 hours after § |
| Enoxaparin = LOVENOX and blood thinner shots‡ | Continue | Discuss for each patient | Discuss for each patient | Med must be stopped § | Continue | Continue (with emergent reversal if clinically indicated) | Discuss for each patient | Med must be stopped § | Med must be stopped § | Discuss for each patient | Med must be stopped § | Continue | Med must be stopped § | Med must be stopped § | Discuss for each patient | Stop 24-36 hrs pre biopsy & restart 48-72 hours after § |
| NSAIDS = ibuprofen, naproxen, ALEVE , MOTRIN , ADVIL , etc.‡ | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Med must be stopped § | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Continue, no pt letter needed, no email needed | Stop 5 days pre biopsy & restart 48 hours after § |

**High Risk Colonoscopy = history of large or mult polyps - OR - 1st degree relative with colon ca at age<60 -OR- personal history of colon cancer



* For PLAVIX etc., Procedure MD must have explicit clearance from CARDIOLOGIST in order to stop this med -OR- DEFER procedure - OR - do procedure on med

‡ See Med List On back of this sheet for full list of med names

§ MD: Please use BIDMC Guidelines re: when to stop and restart blood thinners for procedures. These Guidelines are on the back of this page, and are available on the BIDMC Portal in PPGD Section under "Manual of Anticoagulant and Antiplatelet Therapy"

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BIDMC PROTOCOL FOR GI PROCEDURES & BLOOD THINNERS



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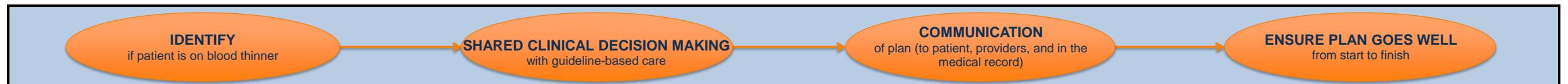
GREEN = OK to stay on med. SCHEDULER Informs patient at time of scheduling. GI COORDINATOR 1. Sends providers an FYI email (GI, PCP, Anticoag Team). 2. Sends patient a letter w plan to stay on med, which also serves to document in Medical Record.

YELLOW = *Might* need to stop med. SCHEDULER Informs patient that clinical team will decide and that patient will hear back from GI Team. GI COORDINATOR 1. Sends providers email (GI, PCP, Anticoag Team, Specialists). 2. Ensures clinical team makes a decision and 3. Calls patient, then sends patient a letter w plan, which also serves to document in Medical Record.

RED = Med will probably need to stop. SCHEDULER Informs patient that clinical team will decide & that patient will hear back from GI Team. GI COORDINATOR 1. Sends providers email (GI, PCP, Anticoag Team, Specialists). 2. Ensures clinical team makes a decision & 3. Calls patient, then sends patient a letter w plan, which also serves to document in Medical Record.

This Guideline was authored by the GI/Anticoagulation Working Group: Diane Brockmeyer MD, Daniel Leffler, MD, Jennifer Mackey, Pharm D, Jacqueline Wolf, MD, Avi Ketwaroo, MD MSc. Approved by Faculty and Fellows of the Division of Gastroenterology, 4/2/14 Beth Israel Deaconess Medical Center.

References: 1. ASGE Guidelines, Gastrointest Endosc. 2009 Dec;70(6):1060-70. 2. N Engl J Med. 2013 May 30;368(22):2113-24. 3. ACCP Guidelines, Chest. 2012 Feb;141(2 Suppl):e326S-50S. 4. BIDMC Guidelines, available on BIDMC Portal.



LIST OF MED NAMES

| BRAND NAME | GENERIC NAME | HOW IT IS TAKEN |
|---|-------------------------|---|
| ASPIRIN = Ecotrin, Bufferin, etc. | Ecotrin, Bufferin, etc. | Aspirin = AS-pir-in Pill |
| COUMADIN = Warfarin | Coumadin | Warfarin = WAR-far-in Pill |
| BRAND NAME | GENERIC NAME | HOW IT IS TAKEN |
| Clopidogrel = PLAVIX and other anti-platelet meds | Plavix | Clopidogrel = kloe-PID-oh-grel Pill |
| | Effient | Prasugrel = PRA-soo-grel Pill |
| | Brilinta | Ticagrelor = tye-KA-grel-or Pill |
| | Ticlid | Ticlopidine = tye-KLOE-pi-deen Pill |
| | Pletal | Cilostazol = sye-LOE-sta-zol Pill |
| | Persantine | Dipyridamole = dye-pir-ID-a-mole Pill |
| | Aggrenox | Dipyridamole/aspirin Pill |
| BRAND NAME | GENERIC NAME | HOW IT IS TAKEN |
| Dabigatrin = PRADAXA Apixaban = ELIQUIS Rivaroxaban = XARELTO Edoxaban = LIXIANA | Pradaxa | Dabigatran = da-buh-GAT-ran Pill |
| | Eliquis | Apixaban = a-PIX-a-ban Pill |
| | Xarelto | Rivaroxaban = riv-a-ROX-a-ban Pill |
| | Lixiana | Edoxaban = ee-docks-uh-ban Pill |
| | Zontivity | Vorapaxar Pill |
| BRAND NAME | GENERIC NAME | HOW IT IS TAKEN |
| Enoxaparin = LOVENOX and other blood thinner shots | Lovenox | Enoxaparin = ee-nox-a-PAR-in Shot |
| | Fragmin | Dalteparin = dal-te-PAR-in Shot |
| | Heparin | Heparin = HEP-a-rin Shot |
| | Arixtra | Fondaparinux = fon-da-PAR-in-ux Shot |
| BRAND NAME | GENERIC NAME | HOW IT IS TAKEN |
| NSAIDS = ibuprofen, naproxen, ALEVE , MOTRIN , ADVIL , etc. | Advil, Motrin | Ibuprofen = eye-bue-PROE-fen Pill |
| | Aleve, Naprosyn | Naproxen = na-PROX-en Pill |
| | Voltaren | Diclofenac = dye-KLOE-fen-ak Pill |
| | Orudis | Ketoprofen = kee-toe-PROE-fen Pill |
| | Toradol | Ketorolac = kee-toe-ROLE-ak Pill |
| | Lodeine | Etodolac = e-TOE-doe-lak Pill |
| | Clinoril | Sulindac = SUL-in-dak Pill |
| | Celebrex | Celecoxib = sel-e-KOX-ib Pill |
| | Indocin | Indomethacin = in-doe-METH-a-sin Pill |
| | Feldene | Piroxicam = pir-OX-i-kam Pill |
| | Mobic | Meloxicam = mel-OX-i-kam Pill |
| | Tolectin | Tolmetin = TOLE-met-in Pill |
| | Daypro | Oxaprozin = ox-a-PROE-zin Pill |
| | Ansaid | Flurbiprofen = flur-bi-PROE-fen Pill |

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§ Table below contains the BIDMC Guidelines re: when to stop and restart blood thinners for procedures. These Guidelines are available on the BIDMC Portal under PPGD Section under "Manual of Anticoagulant and Antiplatelet Therapy"

Table 16. Recommended Timing for Periprocedural Interruption and Initiation of Antithrombotic Therapy

| ANTITHROMBOTIC MEDICATION | STOP PRIOR TO PROCEDURE | RESTART AFTER PROCEDURE | |
|---|---|-------------------------|--------------------|
| | | Low bleeding risk | High bleeding risk |
| Antiplatelet Medications [†] | | | |
| Aspirin (81-325 mg daily +/- dipyridamole) | 7-10 days | 24 h | 48 h |
| Ticlopidine (250 mg twice daily) | 10-14 days | 24 h | 48 h |
| Clopidogrel (75 mg once daily) | 7-10 days [*] | 24 h | 48 h |
| Prasugrel (10 mg once daily) | 7-10 days [‡] | 24 h | 48 h |
| Ticagrelor (90 mg twice daily; t ½ = 8 h) | 5 days [‡] | 24 h | 48 h |
| Cilostazol (100 mg twice daily; t ½ = 11 h) | 3 days | 24 h | 48 h |
| Anticoagulant Medications [‡] | | | |
| Warfarin (t ½ = 36-42 h, but highly variable) | 5 days [§] | 12 h | 24 h |
| Intravenous UFH (t ½ = 60 min) ³ | 4-6 h (and PTT normal) | 24 h | 48-72 h |
| LMWH (t ½ = 3-7h) ^{3,4} | | | |
| Prophylactic dosing | 12 h (24 h for CrCl < 30 mL/min) | 12 h | 24-36 h |
| Therapeutic dosing | | | |
| • Once daily (give 50% of last dose) | 24 h (36 h for CrCl < 30 mL/min) | 24 h | 48-72 h |
| • Twice daily | 24 h (36 h for CrCl < 30 mL/min) | 24 h | 48-72 h |
| Fondaparinux (t ½ = 17) ⁴ | 2-3 day (3-5 days for CrCl < 50 mL/min) | 24 h | 48-72 h |
| Dabigatran (150 mg twice daily) ^{5,5} | | | |
| CrCl > 50 mL/min (t ½ = 14-17 h) | 3 days | 24 h | 48-72 h |
| CrCl 30-50 mL/min (t ½ = 16-18 h) | 4-5 days | 24 h | 48-72 h |
| CrCl 15-30 mL/min (t ½ = 16-18 h) | 4-5 days [£] | 24 h | 48-72 h |
| Rivaroxaban (20 mg once daily) ^{5,6} | | | |
| CrCl > 50 mL/min (t ½ = 8-9 h) | 2-3 days | 24 h | 48-72 h |
| CrCl 30-50 mL/min (t ½ = 9 h) | 3-4 days | 24 h | 48-72 h |
| CrCl 15-29.9 mL/min (t ½ = 9-10 h) | 3-4 days [‡] | 24 h | 48-72 h |
| Apixiban (5 mg twice daily) ^{5,7} | | | |
| CrCl > 50 mL/min (t ½ = 7-8 h) | 2-3 days | 24 h | 48-72 h |
| CrCl 30-50 mL/min (t ½ = 17-18 h) | 3-4 days | 24 h | 48-72 h |

This guideline has been designed to assist the clinician in decision making. It is not intended to replace clinical judgment where individual patient characteristics may require modification of these recommendations.

[†] Assuming minimal platelet effect by 7-days and no effect by 10-days for (irreversible) agents: aspirin, ticlopidine, clopidogrel, and prasugrel; ticlopidine drug clearance is prolonged by an additional 4-days after repeated dosing. [‡] Ticagrelor and cilostazol half-life depends on rate of drug clearance.

^{*} 5-days is sufficient for cardiac surgery. [‡] 7-days per manufacturer, 10 drug effect may persist up to 10 days.

[£] 5-days per manufacturer, 11 shorter interval expected based on half-life.

[§] Intervals based on 4-5 drug half-lives to achieve minimal residual anticoagulant effect; shorter intervals may be appropriate for procedures with low-risk or consequence of bleeding, but there are limited data to guide recommendations. 1, 5, 20-22

[§] > 90% of patients will achieve an INR < 1.5 after skipping 5 doses. 1

[£] Patients receiving dabigatran 75 mg twice daily.

[‡] Patients receiving rivaroxaban 15 mg daily.