ACMS Stable Patient Extended INR Protocol as a model for reviewing, assessing, and implementing new clinical guidelines into patient care practices.

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Problem:

- The 2012 update to the American College of Chest Physicians (ACCP) Guidelines included a recommendation that patients with "consistently stable INR results" on warfarin may extend the INR monitoring interval from the every 4 week standard to "up to 12 weeks."[1]
- Anticoagulation Management Service (ACMS) patient care practices must continually evolve to incorporate updated evidence-based guidelines. A formalized process is necessary to review, evaluate, and implement new procedures to reflect current recommendations.

Objectives:

- Establish a model process for review of new clinical recommendations and patient care protocols as they pertain to BIDMC Anticoagulation Management Service (ACMS) patients.
- Create a protocol that incorporates updated INR testing frequency recommendations and standardizes anticoagulation clinic practices.
- Reduce patient INR testing burden while maintaining safe warfarin therapy.

Context and Intervention:

- The BIDMC ACMS is composed of nurses, pharmacist, and a medical director who manage warfarin care for about 800 patients with primary care doctors in a large academic care practice.
- ACMS established the below process for new evidence review to be utilized:

- The updated ACCP Guideline INR frequency recommendation and supporting clinical studies were critically evaluated by the ACMS team.
  - Review of primary data led to team assessment that the data for extending test interval to 12 week INR checks are not robust. The team decided on a conservative approach of maximum duration between INR tests of 6 weeks.
- A Stable Patient Extended INR Testing Protocol was created.
  - Inclusion, exclusion/discharge criteria were defined:
    - General inclusion criteria: patients enrolled in ACMS with therapeutic INR results and no maintenance warfarin dose changes for the previous three months.
    - General exclusion/discharge criteria: 80 years or older; home INR monitor use; recurrent thrombotic event or major bleeding history; recent INR values less than 1.5 or greater than 5.0; episodes of being overdue for an INR; requests for more frequent testing.
  - Eligible patients were offered the option of extending their INR testing frequency to every 6 weeks. The standard process followed by the ACMS includes:
    - Reminding the patient to contact ACMS if there are changes to medications, diet, scheduled procedures, and/or clinical status. This occurs at the time of protocol enrollment and with each subsequent INR assessment.
    - Informing the patient that more frequent INR tests will be required if subsequent results are outside of goal range; clinically significant to medications, diet, or clinical status occur; warfarin is held as part of a peri-procedural plan; or episodes of being 2 weeks or more overdue for an INR test arise.
  - Standardized documentation in the electronic medical record was defined.
  - The protocol was reviewed and a plan to pilot over a 6 to 12 month period was enacted:
    - Healthcare Associates QI Committee and ACMS Leadership approved the protocol.
    - ACMS staff were trained regarding the new protocol and completed a competency test before proceeding independently with patient assessment and enrollment.
    - The protocol was initiated into ACMS daily practice in February 2013.

Measurements of Improvement:

- Clinic adherence to the protocol.
- Decreased INR test burden and increased convenience for patients.
- Maintenance of INR results within range and overall safe warfarin care.

Findings to date:

- Patients were enrolled in the extended INR testing protocol and electronic medical records were reviewed to assess outcomes at 6 and 11 months following piloting of the protocol.
- Overall staff adherence to the extended INR testing protocol process was 95%.
- Analysis was performed on patients with at least 12 weeks of data over the last 11 months:

58 patients enrolled
41 males (71%), 17 females (29%)
Average age 67 years (range 41-79)
45 anticoagulated for cardiac condition (78%; 37 patients (82%) with atrial fibrillation/flutter), 13 for DVT/PE (22%)
Duration of anticoagulation: <1 year: 2 (3%) ; 1-5 years: 31 (53%) ; 6-10 years: 16 (28%); >10 years: 9 (16%)

46 patients with > 12 weeks data
Average length of time on protocol 40 weeks (range 14-48)

- 402 INR results were recorded:

Days between INR results [Average (range)]	Reasons for early INR tests	INR results within goal range	INR results outside goal range by >0.2	Reasons recorded for out of range INRs (% of occurrences)	Dose adjustments
29 (1-88)	MD appointment Hospital admission Pre/post procedure Antibiotics Last INR outside goal	315 (78%) 38 patients (83%) had >65% INRs within goal range	88 (22%)	Unknown (48%) Illness (18%) Dietary change (16%) Periprocedure (8%) Dosing error (7%) Interacting med (3%)	66 one time changes 32 weekly changes

- Clinical events that were noted during the pilot period included:
  - 2 patients stopped warfarin (failure to thrive and apixaban conversion, respectively).
  - 1 patient moved out of state and transitioned to a local anticoagulation service.
  - 13 hospitalization episodes involving 9 patients: influenza-like illness (#2), mechanical fall (#2), failure to thrive (#2), TIA/stroke (INR within goal) (#1), epistaxis (INR 3.39) (#1), atrial fibrillation (#1), atrial tachycardia s/p PVI (#1), leg injury (#1), non-warfarin allergic reaction (#1), ileus (#1).
    - 2 patients were discharged to rehabilitation facilities following hospitalization.
  - 9 patients had procedures performed: colonoscopy (#3); endoscopy (#1); epidural steroid injection (#1); eye surgery (#1); prostate biopsy and seed placement (#1); PVI (#1); rectal banding (#1)
  - 4 patients were 2 weeks or more overdue for an INR tests. One patient had four overdue episodes of 2-4 weeks. Six subsequent INR tests (86%) were within goal range.
- No patients met protocol discharge criteria.

Key Lessons Learned:

- A standardized multidisciplinary process for addressing new clinical guidelines is an effective method for evolving patient care in safe manner.
- Extending INR interval to 6 weeks in stable patients appears to provide safe care in pilot.
- Next steps include continuing to monitor and track patient success in the pilot program; refining protocol inclusion criteria based on additional data; and standardizing protocol resumption following temporary discontinuation (e.g. out of range INR, overdue episodes).

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[1] February 2012; 141(2_suppl) Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines