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CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

International Normalized Point of Care Testing for Patients on Anticoagulant Therapies: Clinical Utility, Cost-Effectiveness and Guidelines

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Research Questions

1. What is the clinical utility of international normalized ratio point of care testing for patients on anticoagulation therapies?
2. What is the cost-effectiveness of international normalized ratio point of care testing for patients on anticoagulation therapies?

Key Findings

Nine non-randomized studies were identified regarding the clinical utility of international normalized ratio point of care testing for patients on anticoagulation therapies. No relevant economic evaluations were identified regarding the cost-effectiveness of international normalized ratio point of care testing for patients on anticoagulation therapies.

Methods

A limited literature search was conducted by an information specialist on key resources including Medline, Embase, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were International Normalized Ratio (INR) or Prothrombin time and point-of-care (PoC) testing. No search filters were applied to limit retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2015 and April 6, 2020. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients on anticoagulant therapies
Intervention	International Normalized Ratio (INR) point of care (PoC) testing
Comparator	Central laboratory testing or no testing

Outcomes	Q1: Clinical utility (e.g., length of hospital stay, timely treatment, hospital admission, morbidity, mortality) Q2: Cost-effectiveness
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports and systematic reviews are presented first. These are followed by randomized controlled trials, non-randomized studies, and economic evaluations.

Nine non-randomized studies[1-9] were identified regarding the clinical utility of international normalized ratio (INR) point of care testing for patients on anticoagulation therapies. No relevant health technology assessments, systematic reviews, or randomized controlled trials were identified. In addition, no relevant economic evaluations were identified regarding the cost-effectiveness of INR point of care testing for patients on anticoagulation therapies.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

Nine non-randomized studies[1-9] were identified regarding the clinical utility of international normalized ratio (INR) point of care (PoC) testing for patients on anticoagulation therapies. The authors of the first identified non-randomized study[1] evaluated the feasibility, reliability and usefulness of PoC testing for prothrombin time INR for stroke patients. The authors found that PoC testing reduced door-to-INR time compared to laboratory testing and concluded that PoC testing for prothrombin time INR was feasible for stroke patients.[1] The second non-randomized study[2] evaluated PoC testing compared to laboratory testing for prothrombin INR test results to determine INR measurement agreement relative to dosing decision. The authors found that measuring INR through PoC testing and laboratory testing lead to different dosing decisions and concluded that PoC INR testing may require laboratory INR confirmation to provide a decision on dosing.[2] The third non-randomized study[3] assessed the use of PoC testing compared to laboratory testing for INR measurements inpatients presenting with symptoms of stroke at the emergency department. The authors found that PoC testing produced faster results for INR measurements than laboratory testing and concluded that PoC testing is a safe and rapid method to determine patients INR values in acute care situations.[3] The authors of the fourth identified non-randomized study examined patient INR values measured by PoC testing versus laboratory testing and found that laboratory verification of PoC testing prevented adverse treatment events for patients undergoing warfarin therapy compared to PoC testing.[4] The fifth non-randomized study[5] evaluated the clinical decision making variability of two PoC testing devices compared to laboratory testing methods for INR measurements for patients undergoing warfarin therapy. The authors of this study concluded that PoC INR measurements with a correction factor reduced variability in dosing decisions.[5] The authors of the sixth non-randomized study aimed to evaluate the clinical utility of PoC testing for INR values for patients undergoing warfarin therapy and patients with mechanical health

valve replacement compared to laboratory testing INR values, however, patient outcomes were not specified in the identified abstract.[6] The seventh non-randomized study[7] evaluated the safety, efficacy and quality of anticoagulant control using PoC INR monitoring compared to laboratory INR monitoring. The authors found that PoC monitoring was associated with lower time in therapeutic range (TTR) and is a safe alternative to laboratory INR monitoring.[7] The authors of the eighth non-randomized study[8] evaluated whether the use of PoC testing produced more rapid INR results compared to laboratory testing in trauma patients and found that PoC INR testing produced more rapid results than laboratory INR testing.[8] Finally, the last identified non-randomized study[9] evaluated the outcomes of monitoring anticoagulation patients using i-STAT PoC machines and found that the use of the i-STAT PoC machines improved safety and cost for anticoagulation patients.[9]

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

1. Han JH, Jang S, Choi MO, et al. Point-of-care coagulation testing for reducing in-hospital delay in thrombolysis. *Hong Kong Journal of Emergency Medicine*. 2019 01 Jul;26(4):218-224.

2. Moiz B, Rashid A, Hasan M, Jafri L, Raheem A. Prospective Comparison of Point-of-Care Device and Standard Analyzer for Monitoring of International Normalized Ratio in Outpatient Oral Anticoagulant Clinic. *Clin Appl Thromb Hemost*. 2018 Oct;24(7):1153-1158.
PubMed: PM29374969

3. Zenlander R, von Euler M, Antovic J, Berglund A. Point-of-care versus central laboratory testing of INR in acute stroke. *Acta Neurol Scand*. 2018 Feb;137(2):252-255.
PubMed: PM29068041

4. Baker WS, Albright KJ, Berman M, et al. POCT PT INR - Is it adequate for patient care? A comparison of the Roche Coaguchek XS vs. Stago Star vs. Siemens BCS in patients routinely seen in an anticoagulation clinic. *Clin Chim Acta*. 2017 Sep;472:139-145.
PubMed: PM28774502

5. Vazquez SR, Fleming RP, Johnson SA. Comparison of two point-of-care international normalized ratio devices and laboratory method. *Blood Coagul Fibrinolysis*. 2017 Oct;28(7):534-539.
PubMed: PM28379875:

6. Benade EL, Jacobson BF, Louw S, Schapkaitz E. Validation of the CoaguChek XS international normalised ratio point-of-care analyser in patients at Charlotte Maxeke Johannesburg Academic Hospital, South Africa. *Samj, S*. 2016 Feb 03;106(3):280-283.
PubMed: PM26915943

7. Biedermann JS, van Rein N, van den Besselaar AM, et al. Impact of point-of-care international normalized ratio monitoring on quality of treatment with vitamin K antagonists in non-self-monitoring patients: a cohort study. *J Thromb Haemost*. 2016 Apr;14(4):695-703.
PubMed: PM26806724

8. Weyrauch E, Walliser G, Hartwell J. Point-of-care international normalized ratio testing is rapid and reliable: A prospective observational cohort study. International Journal of Academic Medicine; 2016;2(1):27-31.

9. Challen L, Agbahiwe S, Cantieri T, et al. Impact of Point-of-Care Implementation in Pharmacist-Run Anticoagulation Clinics Within a Community-Owned Health System: A Two-Year Retrospective Analysis. *Hosp Pharm*. 2015 Oct;50(9):783-788.
PubMed: PM26912919

Economic Evaluations

No literature identified.

Appendix — Further Information

Previous CADTH Report

10. Point-of-Care testing. *(CADTH Evidence bundles);* Ottawa (ON): CADTH; 2019: https://www.cadth.ca/evidence-bundles/point-care-testing
Accessed 2020 Apr 20.

11. Frequency of Prothrombin Time and International Normalized Ratio Testing: Guidelines. *(CADTH Rapid Response Report).* Ottawa (ON): CADTH; 2018: https://www.cadth.ca/frequency-prothrombin-time-and-international-normalized-ratio-testing-guidelines
Accessed 2020 Apr 20.

12. Point-of-Care Testing: Summary of Evidence. *(CADTH Tools).* Ottawa (ON): CADTH; 2017:
https://www.cadth.ca/tools/point-care-testing-summary-evidence
Accessed 2020 Apr 20.

13. Point-of-Care INR Testing Compared with Lab INR Testing: What Does the Evidence Say? *(CADTH Optimum Use Report).* Ottawa (ON): CADTH; 2015.
https://www.cadth.ca/tools/point-care-inr-testing-compared-lab-inr-testing-what-does-evidence-say
Accessed 2020 Apr 20.

Systematic Reviews

Outcomes Not Specified

14. Buss VH, Deeks LS, Shield A, Kosari S, Naunton M. Analytical quality and effectiveness of point-of-care testing in community pharmacies: A systematic literature review. *Res Social Adm Pharm*. 2019 05;15(5):483-495.
PubMed: PM30057328

Non-Randomized Studies

Alternative Outcome

15. Guisado-Alonso D, Fayos-Vidal F, Marti-Fabregas J, et al. Reliability of point-of-care coagulometer measurements in patients with acute ischaemic stroke receiving intravenous fibrinolysis. *Neurologia*. 2017 Sep 25;25:25.
PubMed: PM28958393

16. Dillinger JG, Si Moussi T, Berge N, Bal Dit Sollier C, Henry P, Drouet L. Accuracy of point of care coagulometers compared to reference laboratory measurements in patients on oral anticoagulation therapy. *Thromb Res*. 2016 Apr;140:66-72.
PubMed: PM26901852

17. Niederdockl J, Dempfle CE, Schonherr HR, et al. Point-of-care PT and aPTT in patients with suspected deficiencies of coagulation factors. *Int J Lab Hematol*. 2016 Aug;38(4):426-434.
PubMed: PM27384253

18. Sen I, Stephen E, Agarwal S, Rebekah G, Nair SC. Analytical performance of a point-of-care device in monitoring patients on oral anticoagulation with vitamin K antagonists. *Phlebology*. 2016 Oct;31(9):660-667.
PubMed: PM26415605

19. Al-Meman A. I-stat, Coaguchek XS plus, And hemochron versus reference laboratory INRs: Pharmacist-managed clinics. *International Journal of Pharmacy and Pharmaceutical Sciences*. 2015;7(1):284-288.

Alternative Population

20. Singer AJ, Taylor M, LeBlanc D, et al. Early Point-of-Care Testing at Triage Reduces Care Time in Stable Adult Emergency Department Patients. *J Emerg Med*. 2018 08;55(2):172-178.
PubMed: PM29887410

Review Articles

21. Barcellona D, Fenu L, Marongiu F. Point-of-care testing INR: an overview. *Clin Chem Lab Med*. 2017 May 01;55(6):800-805.
PubMed: PM27754958

22. Moffat KA, Lewis CW. Laboratory Monitoring of Oral Vitamin K Anticoagulation. *Semin Thromb Hemost*. 2017 Apr;43(3):245-252.
PubMed: PM27677177

23. Bolliger D, Zenklusen U, Tanaka KA. Point-of-care coagulation management algorithms during ECMO support: are we there yet? *Minerva Anestesiol*. 2016 09;82(9):1000-1009.
PubMed: PM27028451