Recommendations from the *Clostridium difficile* Infection (CDI) Laboratory Best Practices Working Group

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Recommendations from the *Clostridium difficile* Infection (CDI) Laboratory Best Practices Working Group

The purpose of this working group was to address issues related to access, testing and laboratory processes in Ontario. Through the knowledge exchange of CDI experts, recommendations were generated to provide actionable suggestions for increasing access to best CDI laboratory practices.
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Introduction

In spring of 2012, a *Clostridium difficile* infection (CDI) multi-stakeholder workshop was convened by the Ministry of Health and Long-Term Care (the ministry) to identify the issues, challenges and successes in prevention, control and outbreak management for hospitals, public health units and supporting organizations relating to the diagnosis and management of CDI. The knowledge gained from this workshop identified a need for a comprehensive strategic framework to strengthen Ontario’s CDI prevention and management practices and processes, including reviewing practices for laboratory testing.

A CDI Best Practices Laboratory Working Group (CDILWG) was convened to review current laboratory practices and provide recommendations on best practices aimed to strengthen them. Membership was comprised of CDI experts in Ontario, including the Public Health Policy and Programs and the Diagnostic Services and Planning Branches within the ministry, Public Health Ontario, the Ontario Medical Association’s Quality Management Program – Laboratory Services (QMP-LS) and laboratory and infection control professionals from hospitals serving a variety of diverse communities across the province. By capitalizing on the knowledge exchanged from our expert members, the CDILWG gained a better understanding of the challenges, limitations and opportunities for CDI testing in Ontario.

Improvements were suggested in four key areas of CDI laboratory testing in Ontario. These recommendations were made with consideration to the information gathered by the expert members and existing recommendations and best practices provided by such bodies including the Provincial Infectious Disease Advisory Committee (PIDAC) and QMP-LS.
Recommendations on the Laboratory Processes for CDI

Laboratory diagnosis of CDI
Challenges with current laboratory processes were identified with regards to the local availability of diagnostic methods and transportation of specimens to referral laboratories. Consequently, limited availability of testing methods, and compromised integrity of specimens were identified as concerns. As a result, a series of recommendations were generated to address best testing methods, turnaround times (TATs) and specimen collection and repeat testing.

**Recommendations:**

i) The use of a polymerase chain reaction/nucleic acid amplification technique (PCR/NAAT) testing as a best practice standard for the laboratory diagnosis of CDI with or without a GDH screening test.

ii) Alternatively, CDI laboratory testing can be performed using an algorithm: a *C. difficile* antigen screen (GDH) followed by enzyme immunoassay (EIA) testing for toxins A/B. TATs and accuracy should be considered when choosing the best test and/or process for the facility.

iii) The CDILWG does not support the use of EIA for toxins A/B as a standalone test for CDI laboratory diagnosis.

iv) Laboratories using a combination of GDH screen followed by EIA for toxins A/B should refer specimens with discordant results to another laboratory for confirmatory testing by PCR/NAAT, if testing is not available on-site.

v) Testing, including PCR/NAAT testing, should be available 7 days a week.

vi) TATs for CDI laboratory testing should be within 24 hours from sample collection to the communication of confirmatory positive or negative test results, unless geographical limitations (i.e. remote area) make this unfeasible.

vii) Repeat testing following negative confirmatory CDI test results on the same patient should be restricted to a minimum of 7 days after a negative test, unless the patient’s clinical status deteriorates or it’s required to diagnose relapse of CDI following an absence of symptoms.

viii) Repeat testing following positive confirmatory CDI test (‘test for cure’) is not recommended.

In addition to the above recommendations, the CDILWG supports the recommendations in the PIDAC’s best practices document Annex C: Testing, Surveillance and Management of *Clostridium difficile* and acknowledges their importance for the laboratory diagnosis of CDI, notably:

a) Testing for CDI should not be conducted on formed stools.
b) Test results for CDI must be correlated with the clinical condition of the patient.

For additional recommendations, please refer to PIDAC Annex C - pg. 14: CDI Testing and Surveillance.

Regional Laboratory Networks
Various regional laboratory networks were identified in Ontario where a laboratory performing on-site PCR/NAAT testing provided access to the test to nearby hospital laboratories that did not perform this diagnostic method. The existence of these networks increase the accessibility of tests aligned with best practice standards and minimizes the TAT. As a result, recommendations to establish, utilize and expand these networks were generated.

Recommendations:

i) The formation of regional laboratory networks for the purpose of CDI testing where these are not already established. This is where laboratories without recommended CDI laboratory testing methods send their specimens to laboratories with recommended testing methods.

ii) Hospitals without recommended CDI laboratory testing methods may join existing regional laboratory networks.

iii) Hospitals/facilities may seek advice within their Local Health Integration Network (LHIN) to initiate and discuss the possibilities to establish or expand these networks.

Remote, Rural and Northern (RRN) areas
Unique challenges relating to funding, availability of instruments and expertise and specimen transportation in RRN areas were identified and geographical disparities noted. Recommendations to further engage hospitals, public health and community laboratories in RRN areas to discuss and strengthen the CDI testing were provided to ensure access to the best testing methods while reducing TAT and ensuring specimen integrity.

Recommendations:

i) Increasing overall accessibility and availability of testing in these areas; to this end, future engagement of hospital, public health and community laboratories may be required.

ii) Efforts should be made to ensure that the laboratory testing for CDI is conducted geographically close to the patient to reduce TAT and maintain specimen integrity.
Educational Opportunities

Targeted education was identified as an opportunity for improvement to further address the interpretation of CDI test results. In addition, reporting processes were identified for improvement to ensure tests are reported to the most appropriate personnel.

Recommendations:

i) Laboratories should consider the value of including information on the laboratory report of CDI test results, such as the importance of correlating test results with the clinical picture (PIDAC’s Annex C: Testing, Surveillance and Management of Clostridium difficile).

ii) Processes must be in place for laboratories to report positive CDI test results to the infection control team.

iii) Laboratories should discuss with their antimicrobial stewardship team (AST) and/or pharmacy whether reporting positive CDI test results to the AST or pharmacy would be of benefit and establish a reporting process, if warranted.

Next Steps and Future Directions

The recommendations generated from the CDILWG are intended to provide actionable suggestions for ensuring best CDI laboratory practices. The release of these recommendations is in line with and strengthens the existing recommendations produced by PIDAC and QMP-LS. They emphasize the important role of adopting laboratory best practices to decrease the burden of illness of CDI in Ontario.

This report will be disseminated to all members of the May 2012 CDI workshop “CDI Prevention and Control: The Collaborative Road Towards Clear Roles and Responsibilities”. In addition, this report will be sent to all Medical Officers of Health, Laboratory Directors, the Ontario Hospital Association and LHIN representatives.

The ministry is committed to continue working with stakeholders on other components of the CDI strategic framework, all aiming to decrease the burden of CDI in Ontario. This includes defining the roles and responsibilities of hospitals and public health units for CDI reporting and outbreak management, in addition to increasing CDI education and knowledge exchange mechanisms.