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TACKLING *C. DIFFICILE* IN HEALTH CARE FACILITIES

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"*C. difficile*" is one bacterium that has been getting a lot of attention recently – from infection control experts, the media, health care facilities, the Ontario government and others. Indeed, a class action lawsuit related to *C. difficile* was very recently launched against an Ontario hospital.

C. difficile (or *Colostridium difficile*) is a contagious infection that can cause diarrhea and more serious intestinal conditions, such as colitis. In some instances, *C. difficile* can be fatal. While *C. difficile* and other infectious agents may be acquired from anywhere, it a growing problem in hospitals and other health care facilities.

Infections such as *C. difficile* that arise in health care facilities are commonly referred to as "nosocomial", or "health care acquired" infections. Growing concern about nosocomial infections and their implications for patient safety have prompted a close look at infection prevention, control and reporting for health facilities across Ontario.

Hospital Reporting of C. difficile and Other Infections

In May 2008, the Ontario Ministry of Health and Long-Term Care (the "Ministry") announced that under its patient safety agenda, all Ontario hospitals will be required to report certain "patient safety indicator" rates in their facility through a public website. *C. difficile* has been identified as a patient safety indicator, and reporting requirements for *C. difficile* are expected to take effect on September 30, 2008. Hospitals will also be required to immediately report *C. difficile* outbreaks to their local public health units.

Reporting for the other identified patient safety indicators (MRSA and VRE infections; hospital-standardized mortality ratio rates; rates of ventilator-associated pneumonia, central line infections and surgical site infections; and hand hygiene compliance among health care workers) are intended to come into effect on identified dates over approximately the next year.

Key Points

- Nosocomial (health care acquired) infections with *C. difficile* and other contagious agents are of growing concern in Ontario, and are receiving increasing attention.
- Nosocomial infections are an issue for hospitals, long-term care facilities, and other types of health care facilities. Infection prevention, reporting and control are important for minimizing the risks associated with nosocomial infections.
- Even with preventive measures, infections and outbreaks in health care facilities are likely to occur.
- The Ministry of Health and Long-Term Care has announced the introduction of new reporting obligations for hospitals regarding infection rates with *C. difficile* and other "patient safety indicators". Amendments to Regulation 965 under the *Public Hospitals Act* came into force July 24, 2008, and the Ministry is in the process of finalizing reporting requirements. Reporting for *C. difficile* is expected to come into effect on September 30, 2008.
- A proactive approach is important for both patient safety and risk management.

Amendments to Regulation 965 under the *Public Hospitals Act* came into force on July 24, 2008 and require that a hospital disclose information on "indicators of quality health care", including disclosure of hospital-acquired infections, actions undertaken and mortality, when requested to do so by the Minister in writing. This includes disclosure through the hospital website.

The Ministry is currently finalizing the details on the collection and reporting of data; and certain key issues, such as the reporting processes and the definition of "outbreak", are not yet clearly defined. Our Health Industry Practice Group will continue to monitor developments on these reporting requirements.

Patient Safety and Risk Management

While prevention is a key component of infection control, it is important to recognize that even with preventative measures, there will be a certain baseline of incidence of infections and outbreak situations within health facilities. In other words, *C. difficile* and other infections will likely occur in health facilities despite all precautions.

Although the Ministry's new reporting requirements will only be applicable to hospitals, nosocomial infections are also an issue in long-term care and other types of facilities.

To minimize the risk of liability in the event of an infection or outbreak, it is important for a facility to be able to show that it met the standard of care appropriate in the circumstances. We recommend that <u>all</u> health facilities implement the following practices, to promote patient safety and to mitigate risks:

Key Points (continued)

- To minimize risk in the event of an infection or outbreak, it is also important for a facility to show it met the requisite standard of care. We recommend that all health facilities:
  - Establish appropriate policies and procedures for infection prevention, surveillance and control.
  - Identify and communicate risks of infection to patients and others.
  - Appropriately address infections and outbreaks, including ensuring proper documentation.
  - Conduct investigations and reviews of potentially nosocomial infections or outbreaks under appropriate quality assurance and risk management processes.
  - Where patient disclosure obligations exist, disclose to the patient.
  - Know their reporting obligations, and report accordingly.

- *Establish Appropriate Policies and Procedures*

  Ensure your facility has appropriate policies and procedures for infection prevention, surveillance and control that are reflective of best practices; and enforce compliance with those policies and procedures.

- *Identify and Communicate Risks*

  Facilities should know when a particular risk of infection exists. A general risk of *C. difficile* or other health care acquired infections will usually not need to be disclosed. However, in circumstances where there is a particular risk of nosocomial infection, patients and others should be notified as appropriate.

  If there is a treatment-related risk of an infection (e.g. related to a procedure generally, such as surgery; or related to a specific procedure the patient is undergoing) then disclosure of that risk may be consistent with obtaining informed consent. Given the recent attention on *C. difficile* and other infections, patients may also have specific questions about infection and risks. In these circumstances, notification may comprise part of the usual consent to treatment discussion.

In the event of an outbreak or other situation that presents a risk of infection for anyone in the facility (or a defined ward or area), you may wish to implement notification at the time of entry or admission.

Proactive patient communications, such as information sheets and handouts, can also be an effective way of informing patients and others of potential risks and the precautions they can take to prevent infection and minimize the risk of transmission.

- *Address Infections/Outbreaks*

  All reasonable steps should be taken to get early treatment for an infected patient and to prevent the spread of the infection. If it is suspected that one or more patients have *C. difficile* or another infection, it is important to ensure there is appropriate documentation of the incidence, including documentation of the signs and symptoms, testing and results, and the treatment provided. Infection control measures and internal notification in accordance with facility policy and procedures should also be documented.

- *Patient Safety Reviews and Investigations*

  Any investigation or review related to a potentially nosocomial infection should be conducted under appropriate quality assurance and risk management processes. Information and documentation generated through the review or investigation should also be adequately protected (e.g. through the *QCIPA* process or under solicitor-client privilege, as appropriate).

- *Fulfill Disclosure Obligations*

  Patient infection with *C. difficile* or other agents may trigger disclosure obligations. Aside from the new amendments to Regulation 965, the only current statutory obligation relates to mandatory disclosure of critical incidents for hospitals under the *Public Hospitals Act*. However, your facility likely has its own disclosure policy reflective of appropriate industry standards, and individual professional obligations may also come into play. Disclosure to a patient should be consistent with these obligations.

  It is important to remember that disclosure relates to facts, not speculations. An infection should not be identified as nosocomial without appropriate confirmation that it was, in fact, contracted in the facility. Similarly, injury or harm suffered by a patient should not be attributed to a *C. difficile* or other infection without appropriate verification.

- *Know Your Reporting Obligations*

  In addition to the new reporting/disclosure obligations discussed above, an infection or outbreak may trigger other statutory reporting obligations (e.g. under the *Health Protection and Promotion Act*). Where death occurs, there may also be an obligation to report to the coroner. Facility administrators should be aware of reporting obligations and when those obligations are triggered. Some reporting (e.g. for an “outbreak”) may depend upon a certain threshold being met, and appropriate assessments should be conducted to determine whether an obligation exists.

Being Proactive

Infections and outbreaks related to *C. difficile* and other nosocomial infections are receiving increased public attention, prompting greater awareness among patients and the public. It is important, from both a patient safety and a risk management perspective, for health care facilities to be proactive in addressing emerging issues and concerns.

Miller Thomson's Health Industry Practice Group would be pleased to provide you with assistance in ensuring your have appropriate policies and procedures in place for preventing and addressing infections and outbreaks. We can also provide assistance in managing legal risk in the event of an infection or outbreak.

For assistance or for more information, please contact us.

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