

Hamilton researchers develop breakthrough for C. difficile

By Dr. Mark Crowther

Researchers at the Hamilton Regional Laboratory Medicine Program (HRLMP) have made an important contribution in the fight against C. difficile. Dr Padman Jayratne and his colleagues have developed a superior in-house PCR test that significantly improves turn-around-times, sensitivity, and specificity for C. difficile at dramatic cost savings. This development ensures that improved clinical outcomes and infection control efficiencies can now be made available to hospitals of all sizes across the province at a price more affordable than either existing toxin detection methodology or commercially available PCR assays.

C. difficile is one of the more common hospital acquired infections. In specific vulnerable patient groups C. difficile causes serious or life-threatening complications. Outbreaks in Ontario, Quebec, Alberta and across the globe have claimed many lives. In addition to the implications for patient care and safety, a C. difficile outbreak can wreak havoc on the daily operations of a hospital, increase length of hospital stay, and strain infection prevention and control resources.

Once a case of C. difficile is suspected, laboratory tests are ordered to confirm its presence. Traditionally, this involved detection of Clostridium difficile toxin A and/or B in a fresh or frozen stool sample. Current rapid testing using toxin detection methodology lacks both sensitivity and specificity and thus testing is required on three consecutive samples over a number of days to ensure cases are not missed. This delay in confirmation has a negative effect if infection prevention and control measures are ramped up prematurely or if control measures are delayed and a positive result confirmed. Delayed detection may result in an outbreak.

PCR testing can detect C. difficile. PCR is molecular testing which identifies the DNA of the C. difficile bacterium rather than its toxic by-product. PCR testing is a major step forward in the detection of C. difficile, offering unparalleled speed, sensitivity and specificity. With sensitivity over 90 per cent, PCR does not require repeat testing reducing time to diagnosis and treatment. Returning results within 24 hours improves clinical outcomes and may reduce length of hospital stay.

Although there are a variety of commercial PCR assays available, these have been available at only a limited number of centres in Ontario due to their cost and complexity. Dr. Padman Jayratne, Microbiologist at HRLMP has developed an in-house PCR kit which delivers speed, sensitivity and specificity in detection as good as, or better than commercially available kits at a fraction of the cost. "It is essential to accurately diagnose underlying infection, especially C. difficile infection (CDI) as delay in treatment for CDI can lead to significant complications, including deaths," says Dr. Padman. "It is estimated that there are approximately 30,000 deaths each year in the US due to CDI. PCR is replacing commonly used laboratory test, enzyme immunoassay (EIA) to diagnose CDI as PCR provides much more accurate results compared to EIA. One single PCR test can be used to determine whether or not a patient has CDI and can assist in managing patients appropriately."

Effective January 1st, 2011 all suspected cases of C. difficile at both St Joseph's Healthcare and the Hamilton Health Sciences are tested using the novel PCR assay. In its role as a regional and national reference laboratory, testing capacity has been expanded to accept C. difficile samples referred by other hospitals in Ontario.

"We are extremely pleased with the responsiveness of the laboratory – the ability of our laboratory scientists to move new testing methodologies forward into clinical utilization allows us to identify and treat earlier," Dr. David Higgins, President, St. Joseph's Healthcare. "This ability improves patient care and safety and also helps to ease the pressure on patient flow through. What is even more exciting is that we can offer this innovative test methodology to other centres."

Hospitals wishing to utilize HRLMP's PCR platform for C. difficile samples are asked to contact directly Hospitals In-Common Laboratory Inc. (HICL) at 416-391-1499 www.hicl.on.ca. HICL has partnered with HRLMP to make their PCR platform available through its Grid to all hospitals across the province and the country.

The Hamilton Regional Laboratory Medicine Program is owned and operated by St. Joseph's Healthcare Hamilton and Hamilton Health Sciences and is affiliated with the McMaster University Medical Centre.

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