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HEALTHCARE ASSOCIATED INFECTIONS

Healthcare-associated infections (HAIs) are a major cause of morbidity and mortality around the world.
An estimated 200,000 HAIs occur each year across Australia [(1)], while New Zealand has published Guidelines for the Control of Multidrug-resistant organisms (MDROs) in response to concerns about their emergence [(2)].

Three of the most troublesome forms of organisms that cause HAIs include:

o Methicillin-Resistant *Staphylococcus aureus* (MRSA)

o Vancomycin-Resistant *Enterococci* (VRE)

o *Clostridium difficile* (C. diff)

Bloodstream (BSI) and surgical site infections (SSI) are significant areas of concern. Studies in Australia document that 17-29% of patients with HAI BSI die while still in hospital [(4)].
Beyond the human toll, there is an enormous financial burden to the healthcare system, with the greatest cost being bed days lost to infection [(5)].
Prevention of HAI is the responsibility of all who care for patients, and can cost less than treating such infections.

1. Cruikshank, M. Ferguson, J. (Ed), *Reducing harm to patients from health care associated infection: the role of surveillance*, July 2008 Australian Commission on Quality and Safety in Healthcare, Commonwealth of Australia pp3
2. Ministry of Health. *Guidelines for the control of multidrug-resistant organisms in New Zealand*. 2007. www.moh.govt.nz pp. iii
3. Cruikshank, M. Ferguson, J. (Ed), *Reducing harm to patients from health care associated infection: the role of surveillance*, July 2008 Australian Commission on Quality and Safety in Healthcare, Commonwealth of Australia pp. 6
4. ibid pp.15
5. ibid pp. 3

Executive Summary

The technological innovation of rapid molecular testing is enabling new ways to approach the prevention of Hospital Acquired Infections (HAIs).

BD GeneOhm™ Rapid Diagnostic MRSA PCR System is a qualitative in-vitro molecular ***diagnostic*** test cleared by the U.S Food & Drug Administration for the direct detection of nasal colonisation by MRSA. **BD GeneOhm™ Rapid MRSA assay** provides definitive results within two hours of the laboratory time in a single assay, compared to the 24-72 hours necessary for analysing a conventional microbiology-based culture. This rapid technology leads to faster detection of MRSA colonisation in patients, enabling hospitals to swiftly implement appropriate interventions which can ***prevent*** the transmission of infection, limit the costs associated with complications and treatment, and improve patient outcomes.

With the rate at which MRSA infections can be transmitted, especially in healthcare settings where carriers of microbes are common, the capability of providing rapid molecular results for MRSA nasal colonisation on the day of admission represents an advantage for infection control ***management*** programs by:

- identifying carriers so that appropriate interventions and ***treatment*** can be swiftly implemented;
- avoiding costs associated with unnecessary pre-emptive isolation;
- avoiding administration of unnecessary or inappropriate antibiotics which would not only be ineffective in treating the patient's condition but also have been attributed to the emergence of antibiotic resistant organisms.

BD GeneOhm™ Rapid Diagnostic PCR System also offers rapid (<2hours) detection of the following other Multi-Resistant Organisms (MROs):

- Vancomycin-Resistant *Enterococci* (VRE)
- *Clostridium difficile* (C. diff)

These organisms can take up to a week to detect via traditional culture methods. Detecting these organisms in under 2 hours can allow the health care facility to isolate patients carrying or infected with these organism and prevent the onset of an outbreak.

BD is committed to applying its expertise, resources, and technologies toward the prevention of HAIs in Australia and worldwide.

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BD GeneOhm™ has made significant contribution to improving patient outcomes by enhancing quality of life

Healthcare Associated Infections (HAI's) and Multi-Resistant Organisms (MRO's) are a major cause of morbidity and mortality in Australia.

MRO's including Methicillin-Resistant *Staphylococcus aureus* (MRSA) are an entrenched problem in Australia.

It is estimated that in Australia there may be as many as 150,000 healthcare associated infections, contributing to 7,000 deaths each year, many of which could be prevented through implementing appropriate infection control practices [(1)].

BD GeneOhm™ Rapid Diagnostic PCR System can detect MRSA in less than 2 hours compared with the current 2-3 days wait for results with culture methods.

Early identification is the basis of good public health management. Patients identified with MRSA can be managed rapidly with recommended precautions and treatment to prevent subsequent MRSA infections to themselves or others.

Studies have illustrated that rapid screening for MRSA on admission to Critical Care Units is associated with a significant reduction in MRSA transmission, 4.90 transmissions per 1000 patient days using **GeneOhm™ Rapid Diagnostic PCR System** versus 13.89 transmissions when using traditional 2-3 day culture methods. Quality of life deteriorates when an infection is acquired. Pain, disability and sometimes death are intensified by the costs of increased length of stay (an average of 12 days [(2)]), consumables, pathology and pharmaceutical costs. All of which results in a lack of confidence in the health system.

Prevention is best and achievable through the use of rapid PCR technology in conjunction with other infection control measures within the hospital such as handwashing. Treating an infection is difficult, takes time and is costly.

Delay in the management of MROs is contributing to the escalating problem for everyone with many people now carrying resistant organisms.

Through delivering patient results significantly faster than current laboratory methods the **BD GeneOhm™ Rapid Diagnostic PCR System** can make a significant contribution to improving patient outcomes and enhancing quality of life.

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Evidence of a positive contribution to health economic benefits

Infection Prevention through use of the **BD GeneOhm™ Rapid Diagnostic PCR System** makes good economic sense.

Beyond the human toll, HAI's add an enormous financial burden to the healthcare system. Most HAI's are caused by antibiotic resistant organisms and are costly to treat.

In Australia, it is estimated that surgical site infections could be costing as much as $268 million per year and that the total annual health care costs associated with blood stream infections may be as high as $686 million [(3)].

Patients are carrying the personal burden and health facilities are carrying huge costs associated with not reversing the trend of this escalating problem.

A recent Australian study found that 18% of MRSA colonised patients remain undetected at 48 hours. Not identifying these patients may cost the institution more in the long term and prevent effective eradication of MRSA from our hospitals [(4)].

The NSW Expert Group on MROs stated in July 2006, that while not all MRO infections are preventable, MRSA is endemic in NSW healthcare facilities and contributes a significant proportion of preventable healthcare associated morbidity [(5)].

Despite vigorous attempts at eradication over the last 3 decades, MRSA remains a major health care cost.

The cost of infection is not reimbursable, and erodes the operating income of healthcare facilities.

Intervention strategies are needed or Australia will continue to pay a high price in financial and human terms.

BD GeneOhm™ Rapid Diagnostic PCR System gives a good return on investment.

<u>References:</u>

1. Australian Infection Control Association Expert Working Group, 2001
2. Abramson MA, Infection Control Hospital Epid,1999
3. Nimmo et al, 2001
4. van Hal, S. et al, Journal Clinical Microbiology, 2007
5. Gilbert, L NSW Expert Group on Multiple Resistant Organisms, 2006

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About BD

BD is a leading global medical technology company that manufactures and sells medical devises, instrument systems and reagents, is dedicated to improving people's health throughout the world. BD is focused on improving drug therapy, enhancing the quality and speed of diagnosing infectious diseases, and advancing research and discovery of new drugs and vaccines. The Company's capabilities are instrumental in combating many of the world's most pressing diseases. Founded in 1897 and headquartered in Franklin Lakes, New Jersey, BD employs more that 25,000 people in approximately 50 countries throughout the world. The company serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public. For more information please visit www.bd.com.

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