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West of England



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Disease detection by analysis of emissions

A novel method for rapid detection of bacterial and viral intestinal infections

Summary

- Diarrhoea due to infection is a major cause of morbidity and mortality worldwide.
- There is an unmet need for the rapid diagnosis of intestinal infections. Diagnostic delays of several days result in prolonged illness and the uncontrolled spread of disease.
- We have identified sample head-space gases (odours) that are diagnostic of a range of conditions and are developing non-invasive, near-patient devices able to rapidly diagnose multiple diseases by 'reading' the odour of biological samples. The technology platform has numerous applications, with the initial focus on infectious diarrhoeas for use by hospitals and other healthcare providers.
- Patents have been filed to protect both the methodology and device.

Market Need

Diarrhoea afflicts more than 4 billion people per annum worldwide, resulting in an estimated 2 million deaths. This is not just a third-world problem. The bacterium *Clostridium difficile* is now recognised as a major hospital acquired infection in the developed world with over 55,000 confirmed cases in the United Kingdom in 2006 with an associated cost to the NHS estimated at over £200 million. Major outbreaks of the viral infections Norovirus and Rotavirus are also commonplace with Rotavirus resulting in over 55,000 hospitalisations per annum in the United States alone.

Management practices within the UK NHS are moving towards the provision of flexible cohort wards for the rapid isolation of suspected cases of infectious diarrhoea, followed by confirmatory diagnosis, reporting and specialist treatment where required. However in the hospital setting diarrhoea is a symptom of a range of conditions in addition to infection, including treatment with steroids, statins and after radiotherapy. There is therefore a risk of non-infected individuals being put at risk of infection on a cohort wards and such practices also fail to identify asymptomatic individuals.

Diagnosis of the causal agents of diarrhoea currently relies upon standard culture assays, ELISAs and molecular techniques performed in hospital laboratories or centralised facilities. This represents a significant burden with several million assays required per annum. Reported delays of between 3-8 days are common as a consequence of transportation and laboratory batch processing. Such delays prevent effective management, treatment and can result in prolonged illness and the uncontrolled spread of disease.

Technology

Using standard laboratory techniques (GCMS) we have been able to demonstrate that the profiles of certain volatile compounds evolved from stool samples show little intra or inter individual variation regardless of diet or time. It's not what you eat but what you live with. This has led to the identification and validation of patterns of particular compounds that are diagnostic of the causal agent of disease. These findings offer the basis for a novel non-invasive means of detecting disease.

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Significant support from the Wellcome Trust has allowed the development and proof of principle for prototype point of care devices able to analyse for these diagnostic profiles in clinically relevant settings. Based on established and novel chemical sensor technologies, these devices offer inexpensive, rapid and unskilled means of detecting a range of disease and therefore meet both current and future unmet medical needs.

Intellectual Property

The University of Bristol and the University of the West of England manage a portfolio of patents to protect this technology. These include:

- The broad methodology of head space analysis from faeces (Granted US, examination in EU). See GB200216650 'Detection of disease by the analysis of emissions'.
- Novel, low power, high sensitivity gas sensor technology (PCT/EP2008/062391).
- Volatile markers for the detection of urinary tract cancers (In draft).

Future Opportunities

Using our established analytical techniques, early state proof of principle studies have shown that sample head space gases may be analysed for the diagnosis of a wide range of conditions in addition to infectious diarrhoeas. To date diagnostic profiles have been identified from faeces for ulcerative colitis and from urine for prostate cancers.

The Offering

The Universities are seeking a development partner / licensee with a proven track record in product development and regulatory approvals and able to build upon the success to date and take these devices into the market.

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