A quick, cheap, accurate test for gluten intolerance

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Coeliac disease causes gluten intolerance, triggering inflammation of the small intestine after the sufferer consumes food containing gluten - everything from bread and pasta to some drinks and processed meat products. Bloating, abdominal pain, nausea, constipation, diarrhoea, anaemia, headaches, mouth ulcers, skin problems, depression, joint or bone pain, nerve problems and recurrent miscarriages are among the symptoms. The only effective treatment is a gluten-free diet.

The condition is thought to affect one in a hundred genetically predisposed individuals, but many sufferers may be unaware of the causes of their health problems: the average delay from onset of

symptoms to diagnosis is almost 12 years. And, if they seek medical attention, there is a high risk of misdiagnosis: for every case of coeliac disease that is correctly identified it is thought that there are seven more that are undiagnosed or misdiagnosed.

'Part of the problem is a lack of awareness about the disease among medical professionals and the general public. In some countries awareness is high, whereas in others many doctors have never heard of it,' explains Ciara O'Sullivan, a research professor in the Nanobiotechnology & Bioanalysis Group at Universitat Rovira i Virgili in Spain. 'On the other hand, current testing procedures are costly, invasive and complicated, and in some European countries, particularly in Eastern Europe, and in developing countries there simply aren't the facilities to test for it.'

That is all set to change thanks to a groundbreaking new diagnostic and monitoring system that is soon to undergo clinical trials in Slovenia and should be available in hospitals and clinics across Europe and elsewhere within a few years.

Developed in the CD-Medics* project by a consortium of 20 partners with the support of EUR 9.5 million in funding from the European Commission, the system is the result of a convergence of innovative technologies from several scientific disciplines including microfluidics, nanotechnology and genetic testing.

'Our goal was to develop a quick, low-cost and highly accurate test for coeliac disease that can be carried out at point-of-care, in the doctor's clinic or even perhaps in the patient's home,' Prof O'Sullivan, who coordinated the project, explains. 'Before CD-Medics there was nothing like this available and while our focus was on coeliac disease, the technology we developed can also be used to diagnose and monitor a wide variety of other diseases - essentially any disorder that can be detected by looking for DNA or protein markers.'

Current procedures for testing for coeliac disease rely on a doctor performing a biopsy to extract patient tissue that is then sent for analysis, usually to an external specialised lab. The procedure is invasive, usually takes several days to get results and each test costs several hundred euro.

A bleed-to-read solution

The CD-Medics approach addresses all these issues. It requires only one drop of blood placed into a so-called lab-on-a-chip device, which looks like a credit card but incorporates several innovative components: a micro-structured fluidic network allowing for a precisely controlled flow of reagents, a specially adapted surface for capturing the biological components being looked for, and an electrically driven sensor system to enable integrated and extremely fast detection.

The disposable lab-on-a-chip is placed into a biomedical interface instrument and analysis of the blood sample is carried out in a matter of minutes. Results can then be immediately output to the hospital information system and added to the patient's electronic health record (EHR).

'For the first time, we have two microsystems of completely different functionalities - one for DNA typing and the other for the detection of antibodies - and we have designed these microsystems to have a common interface with the instrument so that only one instrument with one slot is required for both microsystems,' Prof O'Sullivan says. 'For diagnosing coeliac patients two tests are necessary as DNA testing - specifically for variants of the HLA gene associated with the disease - or testing for gluten antibodies alone can return false positives. Testing for both means the results are much more accurate.'

Follow up tests to monitor the patient's response to treatment can be carried out in the same way using only the microsystem to detect gluten antibodies.

The project partners have patented the technology along with several other important microsystems innovations that went into the CD-Medics devices with a view to developing a commercial product in the near future.

Over the summer, the team will conduct trials with two to three hundred patients at University Medical Centre Maribor in Slovenia, comparing the results of coeliac tests using their system with analysed tissue samples from biopsies.

'Slovenia has a very advanced electronic health record system and one of our goals was to ensure our tool interfaces with EHRs,' the CD-Medics coordinator says. 'Evidently, we also want to make sure it is as accurate and robust as possible.'

The team then plan to present a prototype integrated coeliac disease testing solution at MEDICA 2012, the world’s biggest medical trade fair in Düsseldorf, Germany, in November. They are also carrying out workshops for doctors and are involved in efforts to raise awareness about coeliac disease across Europe.

'We hope to have a product on the market within two years,' Prof O'Sullivan says. 'We are also looking to launch a follow-up project, probably with public funding, to adapt and extend the system to test for and monitor many other types of diseases.'

Prof O'Sullivan says that the same lab-on-a-chip technology could be used to create cheap, quick and accurate tests for a range of other autoimmune disorders, such as rheumatoid arthritis, spondylitis, thyroiditis, and even cancer: 'It's just a question of changing the DNA and the antibodies you are trying to detect.'

The versatility of the technology is further enhanced by its low cost. Compared to a normal biopsy and analysis for coeliac disease, which usually costs in the range of EUR 150-200, each CD-Medics test is estimated to cost less than EUR 20 with the biomedical interface device a one-off expense of around EUR 6,000.

'The system is a complete bleed-to-read solution: cheap, quick, effective, easy for doctors to use and with big benefits for patients compared to current procedures,' Prof O'Sullivan says.

CD-Medics received research funding under the European Union's Seventh Framework Programme (FP7).

* 'Coeliac Disease Management Monitoring and Diagnosis using Biosensors and an Integrated Chip System'.

- Project website for 'Coeliac Disease Management Monitoring and Diagnosis using Biosensors and an Integrated Chip System' [2]
  - CD-MEDICS project factsheet on CORDIS [3]
- CD-MEDICS project videos [4]
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- Projects news and results [5]

Around Europe & the World:

- Slovakia [6]
- Spain [7]
- Germany [8]

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