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## Busseton Health Study Turns to Proteomics to Discover 'Diabetes' Biomarkers

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*This story originally ran on Aug. 10 and has been updated with additional comments.*

By [Tony Fong](#)

**A landmark study begun** in Australia more than 40 years ago has entered the proteomics age, as work has begun to discover protein biomarkers predictive of the early onset of diabetes in people with obesity.

The project, which was announced last week but actually began in January, will use volunteers from the Busseton Health Study. It marks the first use of proteomics for the longitudinal study, which has been tracking thousands of patients for decades in order to gain in-depth knowledge about health trends in the Australian population.

The research is being conducted as part of the Centre for Food and Genomic Medicine, an initiative of the Western Australian Institute for Medical Research, which is investigating the genetic and environmental causes of various diseases. For the BHS diabetes biomarker effort, the work is directed by Proteomics International and the Fremantle Hospital Diabetes Research Group, which began collecting blood samples from BHS volunteers and other patients in January.

That effort is about halfway complete. At the end of this first round of the study, about 500 patient samples will be collected, Richard Lipscombe, managing director of Proteomics International, told *ProteoMonitor*. Based on the findings from the initial analysis, a larger study could be conducted.

Nevertheless, "based on the field in general, we feel that a population study of that size will give us good evidence for what's going on and ... we'll make some preliminary findings," Lipscombe said.

The goal is to identify protein biomarkers from plasma and serum for diabetes generally, and for diabetes caused by obesity, or "diabetes," specifically. Obesity is a well-known cause of diabetes, and the recent rise in type 2 diabetes worldwide is being directly attributed to the increase in obesity.

In Australia about 7 percent of the population over the age of 25 is affected by diabetes, Tim Davis, a professor of medicine at the University of Western Australia School of Medicine and Pharmacology, Fremantle Hospital Unit, said in an e-mail. He is directing work done at the hospital connected to the "diabetes" project.

Over the past 12 years, he said, the number of Australians between the ages of 10 and 25 has more than doubled, and high-risk groups such as migrants from southern Europe and indigenous Australians are adding to the growing diabetic population.

He called proteomics a "fledgling field" in diabetes though interest is growing in using proteomics technology, "perhaps in part because genetic association studies have not always delivered clinically useful results."

Still, there is a poverty of blood-based candidate markers, and further, it is not known whether "diabetes" markers are different from diabetes markers. One of the goals of the Australian research will be to determine that.

To Lipscombe, differences between diabetic and "diabetes" markers should exist "on the basis that the metabolisms of these groups are different and ... once you start to affect metabolism, then there are a number of biological pathways and proteomic pathways that could be potentially switched on or off," he said.

In biomarker discovery work, the presence of one disease has often complicated the search for biomarkers of a co-existing disease. According to Lipscombe, this is where the value of the BHS group comes into play. Because the health histories of the BHS volunteers have been documented sometimes going back decades, there is a wealth of information about this cohort.

"It's a matter of making sure the way the individual disease manifests in an individual is well documented so that you can hone in on the exact difference between" two patients

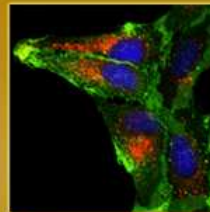
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with the same disease but different underlying causes, he said.

Davis added that the challenges are to get "very detailed data from the participants so that we can get rid of the potentially confounding variables when looking at associations."

The BHS volunteers are "the cleanest type of cohort that we can get," Lipscombe said. "The beauty of this work is the access to the pristine set of samples, which are very well annotated. There's a lot of history behind these people and that really lends a lot more weight to the work we can do. The Busselton group allows us to design [the study] from the start and we've got all that information behind us to really tease out these finer differences."

Started in 1966, BHS is one of the longest running epidemiological research programs in the world. Initiated by a doctor who practiced in the seaside town of Busselton in southwest Australia, the goal was to conduct research and collect data from a community setting "that would not only provide important information into the prevalence and causes of common disease, but also to empower participants to take an active role in their health and well-being," according to BHS's website.

The BHS had five original goals that continue today: to study the prevalence of common diseases in the Australian population; "to assess the range and variation of a large number of clinical and laboratory variables in a natural population"; to provide a service to the community and educate it by detecting, treating, and possibly preventing disease; to perform a longitudinal study of the risk factors related to health and disease; and to study mortality within the Australian population from certain diseases "and to define the usefulness of risk factors in predicting such mortality."

To date, more than 16,000 people have participated in BHS surveys.

The deal with the Centre for Food and Genomic Medicine is also the second instance in the past year in which a major longitudinal study has turned to proteomics as a method to gain more information about a disease state. In March, the Framingham Heart Study announced an agreement with molecular diagnostics company BG Medicine, headquartered in Waltham, Mass., for the discovery of biomarkers, including protein markers, associated with heart disease with the goal of developing diagnostic tools to screen for people at risk for certain kinds of heart disease. The cooperative research and development agreement was the first between FHS and a commercial partner [see [PM 12/07/06](#) and [03/19/09](#)].

While Proteomics International has no history in the arena of diabetes biomarkers, it has performed biomarker-based studies for other firms, primarily drug manufacturers, as part of its contract research organization business. The company, founded in 2001, also offers MRM analysis, differential expression analysis, N-terminal sequencing, and proteome mapping of poorly characterized organisms.

Recently the Perth-based firm developed a mass spec-based approach to determine peptide identity to map out the proteomes of venoms for the purpose of new-drug development [see [PM 05/07/09](#)]. That technology will not be part of the BHS-related work, however.

Financial terms of the BHS project were not disclosed.

For Proteomics International, being included in such a study carries value beyond any immediate influx of cash, Lipscombe said.

"The ability to be involved in a study like Busselton is fantastic for us because that's an example of one of the world's best epidemiological studies, and to be recognized as being capable of working in that space is great recognition for us and something that we believe ... that a lot of other companies in different parts of the world would like to get access to, samples of that type," he said.

"The potential ... that could come out of this type of work, obviously [reflects] the potential for us as a company — if we can find a diagnostic for early-onset diabetes that has real market potential in the current western world," Lipscombe added.

The intellectual property for any discovery stemming from the research will be split equally between Proteomics International and the University of Western Australia.

For the "diabetes" project, Proteomics International will be using the MALDI-TOF/TOF and LC-MS/MS platforms. The company will handle the technical aspects of the research — "sort of the cracking of the code," Lipscombe said — and researchers at Fremantle Hospital will handle the clinical aspects from deciding on the cohorts to performing the clinical interpretation of the data.

Though Fremantle's Davis has no experience using proteomics in his research, he said that he and his group have been thinking of using novel approaches to diagnostic and prediction of outcomes and "proteomics seemed an interesting way ahead. The advantages for us are that the samples required are not difficult to obtain and there is the opportunity to see whether such an analysis could replace prediction using a lot of clinical and laboratory (including genetic) variables.

"We have a particular interest in cost-effectiveness in our studies of diabetes and we hope to incorporate this in our proteomic data analysis," he said.

If the researchers are successful in finding "diabetes" markers, the road map would be to develop diagnostic tests using them — first lab-based tests, and then tests for the clinical setting. The ultimate goal is the development of therapeutics against the disease.

Despite the barren results in protein biomarker research in general, and the grueling nature of the work, Lipscombe said that finding a diagnostic "diabetes" marker a year from now would be a "reasonable target." After a year of sample collection, analysis of the samples would take about six months, he said.


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