HIGHLY SENSITIVE DIAGNOSIS OF IRRITABLE BOWEL SYNDROME VIA NON-INVASIVE METHODS**Stomach and Small Bowel Disorders***Irritable Bowel Syndrome: Clinical*

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Background: Irritable bowel syndrome (IBS) is a common and difficult to diagnose condition. Experts advise use of the Rome IV criteria, which can provide a positive diagnosis, but have poor sensitivity. More commonly, IBS is a diagnosis of exclusion after patients undergo colonoscopy to exclude organic disease. There is a need for a new approach that provides certainty to the vast majority of IBS patients. We previously achieved proof-of concept for use of bowel sound features to allow differentiation between IBS and healthy individuals and between sufferers of IBS and inflammatory bowel disease. Previous research employed basic piezo based sensors to collect the sounds. Here we describe a larger study with clinic-appropriate hardware based on Micro-Electro-Mechanical systems (MEMS) microphones for noise cancellation and bowel sound collection.

Methods and Results: Our study had a case-control design. We recruited 205 study participants with an existing clinical diagnosis of IBS or healthy (asymptomatic) digestive systems. We recorded bowel sounds for two hours post-fasting, and then for 40 minutes after a standard meal, and asked patients about the frequency of symptoms. Using the first 140 participants we built and optimised a logistic regression based model to characterise the two groups. The optimised model was based on 13 sound features related to motility and the migrating motor complex and two symptom features. Internal testing of the model via leave one out cross-validation gave 93% accuracy for IBS diagnosis. Independent testing (data analyst blind to participant condition) using the next 33 IBS and 32 healthy participants revealed 94% sensitivity, 88% specificity and 91% accuracy for IBS diagnosis.

Conclusions: These results provide great promise that combined use of symptoms and sound analysis may provide a more sensitive, cost-effective and less-invasive approach to IBS diagnosis. It offers a positive diagnosis with much greater sensitivity than symptom based diagnostic criteria. The test could be combined with limited laboratory tests to screen for organic disease. However, our next step is to gather more sound data with the new hardware that allows us to broaden the approach to differentiation between IBS and organic gastrointestinal diseases. We will then conduct a multi-centre prospective study to confirm our findings. Our belief is that the test will be especially valuable when used in primary care where it would offer greater confidence to the patient and clinician, whilst reducing the burden of unnecessary colonoscopies.

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Figure 1. Sensors and recording unit used to gather the bowel sound recordings. One sensor head was placed on each of the four quadrants of the abdomen and held in place with a stretchy fabric belt.

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BLIND TESTING RESULTS		Actual status	
		IBS	Healthy
Model prediction	IBS	31	4
	Healthy	2	28
Accuracy		91%	

Figure 2. The results of the independent testing.

Disclosure: X. Du: No Conflicts; K. Webberley: Noisy Guts Pty Ltd: Board Membership, Stock Shareholder; The University of Western Australia: Patent Held/Filed; B. J. Marshall: Hongmed-Infagen HK: Management Position; Noisy Guts Pty Ltd: Advisory Committees or Review Panels; Shenzhen University: Employment; University of Western Australia: Employment;

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