

ABSTRACT: 2nd Progress Report on Medex Test™ 10th October 2007

GASTROINTESTINAL DISORDERS CLINICAL TRIAL - NEPEAN HOSPITAL NSW

The study has been conducted under the auspices of myself (Assoc. Prof. Martin Weltman - Snr Staff Specialist & Head of Dept of Gastroenterology & Hepatology, Nepean Hospital & Assoc Prof. of Medicine Sydney University). Collaborators are: Dr Nghi Phung, Staff Specialist Gastroenterologist;; Prof. Nicholas Talley (Appointment to Sydney University & currently Prof and Director Dept Medicine at Mayo Clinic, Jacksonville, USA); Dr A Simring; Dr L Shim - aided by Meryem Comertpay RA.

Aim of study: to evaluate the sensitivity & specificity of *Medex Test™* in the diagnosis of upper gastrointestinal luminal disorders. To facilitate a comprehensive study and permit accurate statistical analysis... 200 patients recruited through endoscopy unit... while fasted and awaiting upper gastrointestinal endoscopy... The *Medex Test™* is applied prior to patient endoscopy and the results are subsequently analysed... Dr Phung is blinded to the endoscopy result and none of her patients are enrolled - permitting independent analysis. Drs Shim & Simring collect endoscopy results & patient and any relevant laboratory data (from patient records).

INTERIM ANALYSIS of data –(Oesophagus, stomach & duodenum). 60 cases analysed (all having medical assessment, upper gastrointestinal tract endoscopy, and *Medex Test™*)

54 correct "*Medex Test™*" diagnosis
 3 over-diagnosis of "*Medex Test™*,"
 32 positive endoscopic findings
 28 normal (negative) endoscopic findings
Sensitivity – 32/35 = 91.4%
 False negative – 6/60 = 10.0%
Specificity – 28/34 = 82.4%
 False positive – 3/60 = 5.0%
 Positive predictive value – 32/32+6 = 84.2
Negative predictive value-28/28+3 = 90.3

CONCLUSIONS: preliminary results give good reason to believe that measuring skin-impedance is a reliable method of detecting upper gastrointestinal conditions in a referred population, thus providing a good *primary care screening tool* as to who to refer to a specialist gastroenterologist.

Further Plans:

- to submit abstract for **Digestive Diseases Week 2008** (by 1st Dec 2007) - **the premier international gastroenterological conference** where acceptance should allow for presentation of data in a critical peer reviewed forum – creating huge global interest from the c.17, 000 attendees.
- to submit abstract for the **Australian Gastroenterology Week, 2008**
- prepare for **submission of manuscript to peer reviewed international journal** end 2008 after input from Professor N Talley. His input & participation as collaborating author is invaluable considering he is regarded as the leading academic gastroenterologist (globally and in the USA). NB. Professor Talley is updated on the progress of the study via a fortnightly teleconference.
- to analyse presence of other internal organ disorders detected by *Medex Test™* on this patient cohort & compare these with medical records... important, as it will add potential further validity to using this broad screening test - not only to capture target information on the gastrointestinal tract, but to provide physicians with other information on their *internal* health, with important clinical implications – as gastrointestinal patients do not usually have an isolated single organ problem.

Although incomplete... it is my impression that *Medex Test™* is performing in a robust and accurate manner. The preliminary analysis is very encouraging and supportive of a role for *Medex Test™* as a non-invasive screening test for gastrointestinal complaints.

Yours sincerely



Associate Professor Martin Weltman MBBCh PhD FRACP FACHAM
 University of Sydney, Nepean Clinical School, Head of Dept of Gastroenterology & Hepatology, Nepean Hospital