
THE ASTN AT *WORLDSLEEP07* (Cairns, September 2007)

At *worldsleep07*, the ASTN will host a section of the main scientific program focusing on issues in multicentre clinical trials in sleep health. This symposium session, programmed for the morning of Monday 3 September, will feature speakers with international reputations in large-scale trials and will include a panel discussion looking at the best ways to design and conduct such trials.

Researchers will also be able to visit the ASTN booth to discuss ideas for studies, and there will be opportunities to participate in discussion of proposals currently under development. To keep up to date, visit the ASTN website at www.sleeptrials.net and the *worldsleep07* site at www.worldsleep07.com.

ASTN-SUPPORTED RESEARCH PROPOSAL WORKSHOPS

While the ASTN continues to welcome study proposals from individuals or existing research groups, it has now also begun a series of proposal-writing workshops. At these one-day workshops, a small number of researchers in a particular field from around Australia and New Zealand meet to select perhaps two or three very promising research ideas and develop them into proposals to be brought to the ASTN Research Committee. ASTN biostatistics and health economics consultants can be on hand to contribute to a workshop if required.

The wider group of researchers in the relevant field is brought in through emails sent out via the Australasian Sleep Association. The wider group is encouraged to contribute suggestions and comments in the early stages of the process and later to nominate as investigators or collaborating sites. (*continued page 2*)

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ASTN-SUPPORTED RESEARCH PROPOSAL WORKSHOPS (Cont.)

The first of these workshops, convened in April by Amanda Piper, looked at multicentre studies in chronic respiratory failure. Amanda was joined by David Berlowitz, James Douglas, David Hillman, Mark Howard and Aeneas Yeo. In the workshop, multicentre study ideas were prioritised based on assessments of their feasibility and likely impact, and work was begun on the design of the highest priority studies. The group plans to have proposals ready for the August meeting of the ASTN Research Committee.

Workshops are now being planned to develop proposals in other areas including insomnia and shift work. If you would like to see a workshop for a particular field of sleep health, please contact a member of the ASTN Executive or the National Project Officer, Melanie Harris.

BIOSTATISTICS AND HEALTH ECONOMICS CONSULTANCIES

During 2006 the ASTN sought expressions of interest from consultant biostatistics and health economics groups with experience relating to sleep health and an interest in developing further expertise in sleep health studies. There was substantial interest in these consultancies and a panel conducted a thorough formal process to recommend one biostatistics group and one health economics group to the Executive.

The ASTN is very pleased to have formed relationships with the biostatistics consultancy led by Dr Wei Xuan, based at the Woolcock Institute of Medical Research, and the health economics consultancy led by Mr Duncan Mortimer, based at Monash University. These consultants assist in review and development of proposals as part of the ASTN Research Committee and provide additional consultancy services directly to investigators where needed.



Dr Wei Xuan and the Woolcock Biostatistical Consulting Team

With a background in mathematics and statistics, Senior Biostatistician Wei Xuan has been part of the Woolcock Institute for 10 years. In this role Wei has been involved in a number of clinical and epidemiology research studies at the Woolcock, and has gained substantial methodological experience relevant to study design and data analyses.

He has also provided statistical consulting for collaborating groups at Royal Prince Alfred Hospital and the University of Sydney. He is the author of 22 peer-reviewed journal articles, co-author of a book on quantitative research methods and a reviewer for leading international journals.

The Woolcock biostatistical consulting team also includes Keith Wong and Guy Marks, to bring a mix of skills and experience in biostatistics, epidemiology, clinical trials, and clinical sleep and respiratory medicine.



Mr Duncan Mortimer and consortium partners

Duncan Mortimer is a Senior Research Fellow at the Centre for Health Economics, Monash University. Duncan has academic qualifications in economics and psychology from the University of Adelaide and in health economics from Monash University. Duncan brings more than ten years experience conducting applied health economics research and economic evaluation. His past research work includes development of a micro-economic model of drug-resistant malaria for the World Health Organization, preparation of commentaries on new applications to the Pharmaceutical Benefits Advisory Committee, and econometric modelling of pricing in the market for GP services. His current research includes measurement of hospital efficiency in Australia and the UK, validation of Transfer to Utility technique, and economic evaluation alongside the IMPLEMENT trial.

Duncan is joined by Kim Dalziel, Elena Gospodarevskaya and Sandra Younie, also of the Centre for Health Economics, to provide extensive and wide-ranging experience in economic evaluation for health care interventions.

SECOND ASTN OPEN FORUM (Auckland)

The second ASTN Open Forum was held in Auckland on 25 March 2007 alongside the Annual Scientific Meeting of the Thoracic Society of Australia and New Zealand.

The Open Forum began with an introduction to the ASTN and a summary of recent developments by Principal Investigator Ron Grunstein. Sutapa Mukherjee, Chair of the ASTN Research Committee, then outlined the role of this recently formed committee and explained the processes which are followed when investigators bring study proposals to the committee.

Biostatistics experts Wei Xuan and Guy Marks spoke about study design issues relevant to multicentre clinical trials, including stratification, minimisation and concealment, and data analysis for multicentre trials. They also discussed the advantages of using modern statistical techniques in analysing clinical data collected longitudinally.

Health economist Duncan Mortimer demonstrated the usefulness of carrying out economic analysis to add clarity to clinical and health system decision-making and then considered when it might and might not be appropriate to collect economic endpoints in a clinical trial. Duncan concluded his presentation by listing a number of pitfalls to be wary of when conducting economic analysis alongside multinational, multicentre trials.

The SAVE trial is an ASTN-endorsed large-scale international clinical trial to determine the effectiveness of CPAP in preventing cardiovascular disease in patients with high cardiovascular risk and obstructive sleep apnea. SAVE Principal Investigator Doug McEvoy spoke about the launch of lead-up studies and plans for conducting and funding the main trial. Another ongoing study is the ASTN-sponsored trial of methods for improving PSG concordance between laboratories. Rob Pierce, who leads this study with Andrew Thornton and Peter Rochford, reported on the design of the study and levels of variation between the 15 collaborating laboratories at baseline.

Two researchers then gave presentations on proposed multicentre studies and invited audience comment and input. Maree Barnes spoke about a trial of a specific diet and exercise program for OSA patients. In this study, obese subjects with mild to moderate OSA are randomised to treatment with either CPAP or the program. The hypothesis is that the program will be as good as CPAP in improving sleep disordered breathing, but will have greater benefits in the reduction of cardiovascular risk. Long-term follow-up and a health economic analysis are important aspects of this trial. David Berlowitz then outlined a multicentre study looking at a CPAP intervention in acute tetraplegia and showed pilot data obtained to date.

ASTN Chief Investigators look forward to hosting further thought provoking and informative sessions relating to multicentre studies at *worldsleep07* in September.



Guy Marks, Rob Pierce, Sutapa Mukherjee, Maree Barnes and David Berlowitz give presentations at the Open Forum in Auckland.

ASTN CONSUMER REPRESENTATIVE



To ensure that the consumer viewpoint was included in the review and development of sleep health studies, the ASTN Executive allocated a consumer representative position on the Research Committee, and approached the Consumers' Health Forum of Australia to recommend a person for this position.

We are pleased to announce that Mr Jeff Kirby has now been appointed to the Research Committee as consumer representative. Jeff is the current President of the NSW Branch of Sleep Disorders Australia. He developed and manages the SDA website and is in regular contact with SDA state branches. Now retired from a career in science education and information technology teaching at secondary and university level, including some work for UNESCO, Jeff maintains an engagement in science, and has a particular interest in CPAP treatment. If you would like to contact Jeff about consumer issues and sleep research, his email address is consumer.rep@sleepoz.org.au.

BRINGING A STUDY TO THE ASTN

The ASTN Research Committee is now meeting regularly to assess whether proposed studies meet the ASTN mission and can be recommended to the Executive for ASTN assistance, and to offer advice to researchers to improve their prospects of attracting external funding.

Current members of the Research Committee are researchers Dr Sutapa Mukherjee (Chair), Dr Alister Neill, Professor Leon Lack, Dr Maree Barnes, CI representatives Professor Rob Pierce and Professor Doug McEvoy, consumer representative Mr Jeff Kirby, biostatistician Dr Wei Xuan and health economist Mr Duncan Mortimer. The Committee can co-opt additional members when particular outside expertise is needed.

The Committee welcomes study proposals for multicentre studies in any field of sleep health. Researchers are asked to complete the ASTN Study Proposal Form (available on the website) and to send it to the National Project Officer with a lead time of at least 3 weeks before a Committee meeting. The Committee might ask for additional details in the lead-up to the meeting and might invite the researcher to phone in to join part of the discussion of the proposal. A decision is made, immediately or after further development of the proposal, about the suitability of the study to fulfil the mission of the ASTN. The Committee is looking for high quality, adequately powered, intervention studies involving at least 2 sites, with good justification from the literature and perhaps preliminary data, and can help researchers to develop proposals and collect preliminary data where needed. For studies meeting the mission, a recommendation is made to the ASTN Executive that the study be adopted as an ASTN-Endorsed Study. A degree of ASTN resourcing, appropriate to the study, can be committed for these studies, and can be put forward in grant applications.

Network resources include facilities for recruitment of subjects, biostatistician and health economist advice, advice on outcomes measurement, central data management, inter-lab quality control and bioinformatics.

For a small number of particularly high impact studies, very extensive support and input will be available. These will be ASTN-Supported Studies.

Further details including Research Committee terms of reference and ASTN policy documents are available on the website at www.sleeptrials.net.