



## NIHR HTA Clinical Evaluation and Trials Board

### Minutes of the 15<sup>th</sup> Meeting

<b>Date</b>	Wednesday 26 <sup>th</sup> and Thursday 27 <sup>th</sup> January 2011
<b>Venue</b>	Danubius Hotel, Regents Park, London, NW8 7JT
<b>Members Present</b>	Professor Tom Walley (HTA Programme Director) Professor Sallie Lamb (Chair) Professor Jenny Hewison (Deputy Chair) Professor Martin Bland Professor Jane Blazeby Professor Julia Brown Professor Alistair Burns (27 <sup>th</sup> January only) Dr Jennifer Burr Professor Linda Davies Professor Simon Gilbody Professor Steven Goodacre Professor Dyfrig Hughes Professor Paul Jones (27 <sup>th</sup> January only) Professor Khalid Khan Professor Richard McManus Professor Helen Rodgers Professor Jonathan Sterne (26 <sup>th</sup> January only) Mr Andy Vail Professor Clare Wilkinson Dr Ian Wilkinson (26 <sup>th</sup> January only)
<b>NETSCC, HTA Secretariat</b>	Dr Peter Davidson (Director of NETSCC, HTA) Mrs Stephanie Russell (Senior Programme Manager) (26 <sup>th</sup> January only) Mrs Emma Catlin (Programme Manager) Mrs Fay Habens (Programme Manager) Mrs Andrea Ingram (Assistant Programme Manager)
<b>Observers</b>	Dr Tom Foulkes, Programme Manager for Translational Research, MRC (27 <sup>th</sup> January only) Ms Kate Law, Director of Clinical Trials, CRUK (26 <sup>th</sup> January only) Ms Isabelle Read, NIHR Senior Leaders Programme (26 <sup>th</sup> January only) Dr Frank Wissing, Programme Director, The DFG (The German Research Foundation)
<b>Apologies</b>	Professor Keith Abrams Dr Vaughan Thomas (Consultant Advisor, NETSCC) Professor Ken Stein

Day One: Wednesday 26<sup>th</sup> January 2011

Discussion of full proposals

**09/144/47 - Corticosteroid Or Mesalazine FOR Treatment of moderately active Ulcerative Colitis (Comfort UC).**

*Professor Lamb chaired. Professors Blazeby and Sterne left the room.*

**The board discussed the proposal and rejected it.**

**09/144/09 A pragmatic randomised controlled trial comparing the effectiveness and cost effectiveness of levetiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs (SANAD-II).**

*Professor Lamb chaired. Professors Blazeby and Walley, and Mr Vail left the room.*

**The board discussed the proposal and recommended it for funding, subject to certain conditions.**

**09/144/34 Comparison of percutaneous coronary intervention versus coronary artery bypass grafting in diabetic patients: 5 year follow up of the CARDia (Coronary Artery Revascularisation in Diabetes) Trial. Randomised trial.**

*Professor Lamb chaired.*

**The board discussed the proposal and wishes to see a resubmission.**

Discussion of outline proposals

**10/57/67 REVascularisation of Ischaemic VEntricular Dysfunction (REVIVED): a randomised comparison of percutaneous coronary intervention (with optimal medical therapy) vs. optimal medical therapy alone for heart failure secondary to coronary disease.**

*Professor Lamb chaired.*

**The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.**

**10/57/27 Validation of a clinical decision rule to identify outpatients with chronic heart failure at high and low risk of hospitalisation: towards personalised care.**

*Professor Lamb chaired. Professors Brown and Hewison left the room.*

**The board discussed the proposal and rejected it.**

**10/57/43 Collaborative care for older people with established clinical depression.**

*Professor Lamb chaired. Professors Bland, Blazeby, Brown, Davies, Gilbody and Hewison, and Mr Vail left the room.*

**The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.**

**10/57/14 Randomised controlled trial of prophylactic enteral supplementation with bovine lactoferrin to prevent nosocomial infection in very low birth weight infants.**

*Professor Hewison chaired. Professors Bland, Gilbody, Lamb and Rodgers left the room.*

<p>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</p>
<p><b>10/57/20 A randomised controlled trial of standard-of-care wound management versus negative pressure wound therapy in the treatment of adult patients with an open fracture of the lower limb.</b></p>
<p><i>Professor Hewison chaired. Professor Lamb left the room.</i></p> <p>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</p>
<p><b>10/57/41 Enhanced recovery after hip fracture with rapid repletion of vitamin D: double blind randomized clinical trial of efficacy and safety [RED- HIP: Rapid rEpletion of vitamin D after HIP fracture].</b></p>
<p><i>Professor Hewison chaired. Professor Lamb left the room.</i></p> <p>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</p>
<p><b>10/57/29 NAVIGATOR Trial: a feasibility study to investigate the case management (CM) model as an intervention to maximise return to work (RTW) of the seriously injured patient in the NHS.</b></p>
<p><i>Professor Hewison chaired. Professor Lamb left the room.</i></p> <p>The board discussed the proposal and rejected it.</p>
<p><b>10/57/57 A factorial RCT of supervised vs unsupervised and daily vs twice weekly dispensing of opiate maintenance therapy in opiate dependent patients.</b></p>
<p><i>Professor Lamb chaired. Dr Burr left the room. Professor Walley absent.</i></p> <p>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</p>
<p><b>10/57/23 Clarifying the management of men with recurrent urethral stricture disease: A randomised trial of open urethroplasty versus endoscopic urethrotomy (OPEN).</b></p>
<p><i>Professor Lamb chaired. Professor Rodgers and Dr Burr left the room. Professor Walley absent.</i></p> <p>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</p>
<p><b>10/57/24 Rehabilitation of Memory following Brain Injury - a Phase III Randomised Controlled Trial.</b></p>
<p><i>Professor Lamb chaired. Professor Walley absent. Professor Hughes arrived at the meeting.</i></p> <p>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</p>
<p><b>10/57/28 Effectiveness and cost-effectiveness of Nurse-led Hypertension CarE versus general practitioner led care in Primary Care (ENHANCE) in newly diagnosed patients: a cluster-randomised controlled trial.</b></p>
<p><i>Professor Lamb chaired. Professor Walley absent.</i></p> <p>The board discussed the proposal and shortlisted it. The applicants will be invited to</p>

submit a full proposal.
<b>10/57/08 Predicting foot ulceration in people with diabetes: An analysis of Individual Patient Data (IPD).</b>
<i>Professor Lamb chaired. Professor Walley absent.</i>
<b>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</b>
<b>10/57/50 Pharmacy- based interventions for initiating effective contraception following emergency contraception: a feasibility study.</b>
<i>Professor Lamb chaired. Professor Walley absent. Dr Wilkinson left the meeting.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/57/60 Evaluation of the feasibility of a future RCT (randomised controlled trial) to study the use of bone biopsy in the management of osteomyelitis of the foot in diabetes: the BBAB feasibility study.</b>
<i>Professor Lamb chaired. Professor Wilkinson and Mr Vail left the room. Professor Walley absent.</i>
<b>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</b>
<b>10/57/22 Systematic review and economic modelling of optical coherence tomography (OCT) for the diagnosis, monitoring and guiding of treatment for neovascular age-related macular degeneration.</b>
<i>Professor Lamb chaired. Dr Burr left the room. Professor Walley absent.</i>
<b>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</b>
<b>10/57/52 A systematic review of the clinical and cost-effectiveness of non-pharmacological treatments for stammering in adults and children.</b>
<i>Professor Lamb chaired. Dr Burr left the room. Professor Walley absent.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/57/15 Improving return to work after mild traumatic brain injury: systematic review of intervention studies and feasibility study for a randomised controlled trial.</b>
<i>Professor Lamb chaired. Professor Walley absent.</i>
<b>The board discussed the proposal and rejected it.</b>

Day Two: Thursday 27<sup>th</sup> January 2011

Discussion of full proposals

**09/104/16 CONtrol of Faecal Incontinence using Distal Neuromodulation (CONFIDeNT).**

*Professor Lamb chaired. Professors Bland, Davies and Khan, and Mr Vail left the room.*

The board discussed the proposal and recommended it for funding, subject to certain conditions.

**09/144/50 Randomised controlled trial of the clinical and cost-effectiveness of a contingency management intervention for reduction of cannabis use and of relapse in early psychosis.**

*Professor Hewison chaired. Professor Lamb left the room.*

The board discussed the proposal and recommended it for funding, subject to certain conditions.

**09/01/48 Glucose Lowering In Non-diabetic hyperglycaemia Trial (GLINT).**

*Professor Hewison chaired. Professors Khan, Lamb and Walley, and Dr Wilkinson left the room.*

The board discussed the proposal and recommended it for funding, subject to certain conditions.

Discussion of outline proposals

**10/57/21 A Randomised Controlled Trial of the Effectiveness of PDSAFE to prevent Falls among People with Parkinson's Disease.**

*Professor Hewison chaired. Professors Lamb and Rodgers left the room.*

The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.

**10/57/51 A randomised controlled trial to determine the effectiveness of body weight supported treadmill gait retraining as an adjunct to rehabilitation of military personnel who have sustained life changing injury.**

*Professor Hewison chaired. Professor Lamb left the room.*

The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.

**10/57/53 Echocardiography with (C)ontrast-enhanced (A)denosine (S)tress to evaluate (C)oronary (A)rtery disease versus (D)obutamine (E)chocardiography. (Echo-CASCADE Study)**

*Professor Hewison chaired. Professor Lamb left the room.*

The board discussed the proposal and rejected it.

**10/57/32 A randomised controlled trial of intra-operative cell salvage during caesarean**

<b>section in women at risk of haemorrhage.</b>
<i>Professor Lamb chaired. Professors Khan, McManus and Rodgers left the room. Dr Burr left the meeting.</i>
<b>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</b>
<b>10/57/02 Better Outcomes for people with Borderline personality disorder: an evaluation of the clinical and cost-effectiveness of Cognitive Analytic Therapy (The BOBCAT trial).</b>
<i>Professor Lamb chaired. Professor Goodacre left the room.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/57/26 The PEER-PAL study: a PEER Programme for Active Lungs.</b>
<i>Professor Lamb chaired. Professor Blazeby left the room.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/57/35 Randomised controlled trial of Skills Training for Affective and Interpersonal Regulation with Prolonged Exposure versus waiting list in the treatment of chronic post traumatic stress disorder with emotional dysregulation.</b>
<i>Professor Lamb chaired. Professor Wilkinson left the room.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/104/06 Preoperative intravenous iron to PREVENT blood Transfusion in major surgery (PREVENTT).</b>
<i>Professor Hewison chaired.</i>
<b>The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.</b>
<b>10/57/61 A feasibility trial of cluster vs. individual randomisation strategies for the design of a large RCT of thromboprophylaxis in hip fracture patients to be conducted via the National Hip Fracture Database.</b>
<i>Professor Hewison chaired. Professor Lamb left the room.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/57/63 Feasibility Study of a Cluster Randomised Trial of an Early Group-based Psychosocial Intervention to Develop Resilience in Military Personnel following Complex Trauma.</b>
<i>Professor Hewison chaired. Professor Lamb left the room.</i>
<b>The Board discussed the proposal and wishes to see a resubmission.</b>
<b>10/57/48 Is the levonorgestrel intrauterine system (LNG-IUS) more effective than oral progestogens in treating endometrial hyperplasia without atypia?</b>
<i>Professor Lamb chaired. Professor Khan left the room. Professor Burns left the meeting.</i>
<b>The board discussed the proposal and rejected it.</b>
<b>10/57/46 A multi-centre randomized controlled trial comparing rubber band ligation with haemorrhoidal artery ligation in the management of symptomatic second and third degree</b>

**haemorrhoids.**

*Professor Lamb chaired. Professor Goodacre left the room.*

**The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.**

**10/57/55 Long-term follow up of a trial of annual mammographic screening from age 40.**

*Professor Lamb chaired. Professor Hewison left the room.*

**The board discussed the proposal and shortlisted it. The applicants will be invited to submit a full proposal.**

**10/57/25 Network meta-analysis of efficacy and cost-effectiveness of botulinum toxin A (BoNT-A) compared with anticholinergic medications for detrusor overactivity in women.**

*Professor Lamb chaired.*

**The board discussed the proposal and rejected it.**