Welcome to our third annual report (2010). We continue to expand with 25 staff, and 26 ongoing trials.

Our new director, Professor Lelia Duley took up her post in March 2011. Professor Duley was previously Professor of Obstetric Epidemiology, Centre for Epidemiology and Biostatistics, University of Leeds and Bradford Institute of Health Research. She was the chief investigator of two landmark studies, the Eclampsia and MAGPIE trials (Lancet 1995 and 2002), and has just been awarded an NHS HTA programme grant to study the immediate care of pre-term babies. It is a pleasure to welcome her to the Trials Unit.

One of her first tasks in 2011 will be to oversee the move to new premises on C floor of QMC between East and South block. By the time you read this we will probably be there.

I’m also delighted to welcome two new statisticians, Justin Fenty and Samir Mehta to join Professor Min Yang. This is now a really strong section of the unit, which will help us power forward.

Finally, I can’t resist reminding you of the five new trials awarded in the last year. Two drug trials, one of aspirin and fish oil to prevent bowel polyps, and one of a treatment for irritable bowel disease, a trial of rehabilitation to help people with arthritis get back to work, a trial of a heel cast to help heal diabetic foot ulcers and finally a trial of a treatment to improve the gait of patients with stroke.

What a varied life we lead! I’m already sad handing over to Prof Duley!

Jim Thornton
CLINICAL TRIALS UNIT

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CLINICAL TRIALS UNIT

Seminar Speakers 2010

SEMINARS 2010

Thursday 20th May 2010
Min Yang
Professor of Medical Statistics in School of Community Health Sciences

“Applying multilevel models in evaluation of bioequivalence in drug trials”

Professor Yang is currently working for both the NIHR NDL CLAHRC (a partnership between University of Nottingham and the NHS Trent Trusts) and the CTU of the university. Her research interest is multilevel models in analysing large and complex data. She has extensive experience in developing, applying and training to use multilevel models in the fields of social sciences, education, medical and public health study. Her publication covers multilevel multivariate models for both continuous and binary outcomes, multilevel multinomial models for ordinal and nominal data, multilevel survival models in health inequalities and multilevel models in meta-analysis.

Thursday 17th June 2010
Rowan Harwood
Consultant Geriatrician and special Professor in Geriatric medicine

“Tribulations of trials: evaluating complex interventions”

RCTs aim to give unbiased estimates of treatment effects, primarily when testing drugs. The pragmatics of performing trials can be difficult where the intervention is ‘complex’, such as services with multiple elements or contributors. The intervention can be difficult to describe or standardise, and the conditions for successful delivery or replication need to be elucidated. The measurable benefits of the intervention can be uncertain in advance of the research. Operational constraints in the health service can make conventional trial design difficult or impossible. This talk explored solutions to these issues using examples from trials (mainly done in Nottingham), and their application to the design of a trial on a medical and mental health unit for older people.
Thursday 7th October 2010
Casey Quinn
Health economist and econometrician

“Value of information analysis and pilot trials”

Dr Quinn is a health economist and econometrician working in the Division of Primary Care at the University of Nottingham. His research specialises in cost-effectiveness analysis alongside clinical trials, programme evaluation and the estimation of treatment effects. He also works on the microeconometrics of health and lifestyles using routine, administrative and survey databases. He is currently involved with several projects funded by the NIHR, MRC, Health Foundation and EPSRC.
CLINICAL TRIALS UNIT

Meetings and Training 2010

**Trial Manager’s Forums**

Thursday 3rd June 2010
Post Graduate Education Centre, QMC Campus

Thursday 4th November 2010
Post Graduate Education Centre, QMC Campus

**Nottingham CTU Away Day**

20th August 2010
Nottingham Activity Centre

**CTU Training Day**

24th May 2010
Clinical Trials ‘The Basics’
The key principles involved in the design, interpretation & clinical application of randomised controlled trials.
The Systematic Evaluation of Aspirin and Fish Oil Polyp Prevention Trial (seAFOod)
EME

A randomised controlled trial of eicosapentaenoic acid (EPA) and/or aspirin for colorectal adenoma (or polyp) prevention during colonoscopic surveillance in the NHS Bowel Cancer Screening Programme: The seafood (Systematic Evaluation of Aspirin and Fish Oil) Polyp Prevention Trial.

Mesalazine for the treatment of IBS-D (MIBS)
EME

This is a multi-centre randomised, double-blind, placebo-controlled trial using a parallel group design to assess the effect of mesalazine on stool frequency.

Work Rehabilitation in Inflammatory Arthritis (WORK IA)
ARUK

Effectiveness and cost effectiveness of an occupational therapy (OT) job retention intervention: a pilot randomised controlled trial.

Fibreglass casts for heel ulcers in diabetes (HEELS)
HTA

To evaluate the use of fibreglass heel casts in the management of ulcers of the heel in diabetes.

Visual cues for gait training post-stroke
RfPB

2-arm parallel group, multicentre randomised controlled pilot trial comparing Visual Cue Training (VCT) to same amount of conventional over-ground walking training.
Bullous pemphigoid steroids & tetracyclines study (BLISTER)  
NIHR HTA  
A randomised controlled trial to determine whether doxycycline (a member of the tetracycline family of antibiotics) would be a good alternative to prednisolone (a corticosteroid) for treating bullous pemphigoid.

A clinical trial to investigate the best treatment for pyoderma gangrenosum (STOP GAP)  
NIHR via Skin Disease Programme Grant  
A randomised controlled trial to determine whether ciclosporin (an immunosuppressant) is better at treating Pyoderma Gangrenosum (PG) than prednisolone.

Psychological treatments for depression in aphasic stroke patients (CALM)  
Stroke Association  
A randomised controlled trial to evaluate behaviour therapy to treat low mood in people with aphasia after a stroke.

Getting out of the house (TOMAS)  
NIHR HTA  
Comparing the effectiveness of treating people who have had a stroke with a new outdoor mobility rehabilitation intervention or standard care

Pre-treatment interview reduce dropouts for patients with personality disorders (PCI)  
NIHR RfPB  
A pilot study to test the feasibility of delivering a motivational intervention in a community personality disorder treatment service.
CLINICAL TRIALS UNIT
Projects—Ongoing

Pilot study for Obstetric Cholestasis Trial (PITCH)
NIHR RfPB
A pilot trial to test the feasibility of a factorial trial to evaluate two interventions, ursodeoxycholic acid and timed early delivery, for the treatment of obstetric cholestasis.

Psychoeducation & problem solving - effects on social functioning (PEPS)
NIHR HTA
A randomised controlled trial to evaluate the effectiveness of PEPS therapy (Psycho-education with problem solving) compared with standardised treatment as usual in improving social functioning in community adults with personality disorder.

Smoking, Nicotine and pregnancy (SNAP)
NIHR HTA
A randomised controlled trial to investigate whether nicotine replacement therapy (NRT) is effective and safe when used for smoking cessation in pregnant women.

Prophylactic Antibiotics for the treatment of cellulitis at home (PATCH)
Action Research
A double-blind, parallel group, randomised controlled trial comparing 12 months of penicillin with placebo, in patients with at least 2 previous episodes of cellulitis of the leg.

Efficacy of Nitric Oxide in Strokes (ENOS).
MRC
A collaborative, international, multicentre, parallel-group, single-blind randomised controlled trial designed to test the safety and efficacy of: transdermal glyceryl trinitrate (a nitric oxide donor) or control; and continuing or temporarily stopping prior anti-hypertensive medication.
Autologous Stem Cell Transplantation for Crohn’s Disease (ASTIC)
European Bone Transplant Group. The Broad Foundation
An open label, randomised, international multicentre study comparing early transplantation procedure with transplantation carried out to the same protocol but delayed by one year. Evaluating the potential clinical benefit of hematopoietic stem cell mobilisation followed by high dose immuno-ablation and autologous stem cell transplantation versus hematopoietic stem cell mobilisation in patients with Crohn’s disease.

Bacterial QSSMs, Innate and Adaptive Immunity in Healthy Subjects
A randomised controlled trial to determine the effects of antibiotics, probiotics and prebiotics on quorum sensing signal molecules (QSSMs).

Reducing Falls in elderly patients (REFINE)
NIHR RfPB
Pragmatic parallel arm randomised controlled trial to evaluate the effect of pressure sensors upon in-patient falls in hospitalised older people.

A randomised, parallel group design, placebo-controlled trial of Necator americanus-mediated immunomodulation for relapsing multiple sclerosis (WIRMS)
MS Society
A randomised controlled trial of hookworm versus placebo in multiple sclerosis patients.

The effect of n-3 PUFA supplementation in patients with steatosis due to non-alcoholic fatty liver disease
The purpose is an objective assessment to determine any true effects on the hepatic steatosis content and biochemistry of n-3 PUFA supplementation in Non-Alcoholic Fatty Liver Disease patients.
Ondansetron for the treatment of IBS with diarrhoea (IBS-D): Identifying the “responder”
NIHR RfPB
A crossover randomised trial comparing Ondansetron dose titration up or down according to response, with matching Placebo.

Physical activity as an aid to smoking cessation during pregnancy (LEAP)
NIHR HTA
A trial to test the hypothesis that among pregnant smokers, an exercise programme increases smoking abstinence rates. Randomisation and database support

PPAR-gamma: a novel therapeutic target for asthma (PANTS)
NIHR EME
A double blind, parallel group, randomised placebo controlled trial to determine whether the effects of peroxisome proliferator-activated receptor seen in the laboratory can be a potential drug target in asthma

Effect of Topical Imiquimod on Lentigo Maligna (LIMIT 1)
NIHR RfPB
A pilot study to determine whether imiquimod is a sufficiently effective treatment for lentigo maligna to progress to a randomised controlled trial (RCT) which would compare imiquimod with the current standard treatment (surgery).

Doxycycline in lymphangioleiomyomatosis (LAM)
British Lung Foundation Grant
A randomised, double blind, placebo controlled trial of doxycycline to determine if doxycycline will prevent tissue destruction in lymphangioleiomyomatosis (LAM) thus preserving lung function, exercise capacity and quality of life.
Pilot trial; Diet & Endometrial Cancer Risk in Polycystic Ovary Syndrome (PCOS)
Cancer Research UK

A pilot study to test the feasibility of a trial to test the hypothesis that dietary interventions in PCOS can reduce risk markers for later cancer development.

Potential of the family history in risk assessment and primary prevention of coronary heart disease (ADDFAM)
DoH

A trial to estimate the extra proportion of patients at higher risk of CHD, who would benefit from intensive lifestyle advice and medications, when systematically collected with family history risk assessment, in comparison with current practice.

Water Softeners for the treatment of atopic eczema in children (SWET)
NIHR HTA

A randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children.

Comparing two fixed daily doses of FSH for ovarian stimulation during in-vitro fertilisation
NUH Trust

A prospective, randomised study among women without 3 D ultrasound evidence of polycystic ovaries (PCO) who are undergoing IVF/ICSI treatment. To examine the hypothesis that increasing the dose of gonadotrophins from 225 IU to 300 IU during IVF does not change the number of mature oocytes retrieved or the pregnancy rates in women with predicted low or intermediate ovarian reserve based on antral follicle count.
Helicobacter Eradication v Aspirin Toxicity Trial (HEAT) Pilot study
MRC
Double blind randomized multi-centre study of early versus delayed Helicobacter Pylori eradication in infected patients taking aspirin ≤ 150mg daily, recruited from primary care.

Proactive Or Reactive Telephone Smoking Cessation Support (PORTSSS)
DoH
A parallel group, factorial design RCT, conducted through the English national NHS Smoking Helpline, comparing proactive versus reactive support and the offer of NRT versus no offer.

Hookworm infestation as therapy in Crohn’s disease
Broad Foundation
A randomised controlled trial to compare a single dose of hookworm larvae and placebo in reducing disease activity in Crohn’s disease

Water Softeners for the treatment of atopic eczema in children (SWET)
NIHR HTA
A randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children.

Efficacy of Nitric Oxide in Strokes (ENOS).
MRC
A collaborative, international, multicentre, parallel-group, single-blind randomised controlled trial designed to test the safety and efficacy of: transdermal glyceryl trinitrate (a nitric oxide donor) or control; and continuing or temporarily stopping prior anti-hypertensive medication.
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Thomas KS, Sach TH on behalf of the SWET Trial Investigators

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