UNIVERSITY OF BIRMINGHAM

# Applied Health Research Methodology Hub

# in the School of Health & Population Sciences

# Contents



# Applied Health Research Methodology Hub

## In the School of Health & Population Sciences

The Applied Health Research Methodology Hub comprises groups from the School of Health & Population Sciences (HaPS). HaPS is one of five schools in the College of Medical and Dental Sciences at the University of Birmingham. HaPS has £75m of current live funding, providing approximately 30% of the College research income. In the 2008 RAE, 60% of our Epidemiology outputs (UoA6) and 65% of both our Health Service Research (UoA7) and Primary Care research (UoA8) were rated world-leading (4*) or internationally-excellent (3*).

HaPS brings together the major clinical disciplines of the primary and secondary health care settings; that is Nursing, Occupational and Environmental Medicine, Primary Care, and Public Health. HaPS represents one of the largest and comprehensively inter-disciplinary population science centres in the UK principally focusing on chronic diseases (cardiovascular, cancer, respiratory), occupational/environmental medicine, maternal and child health, behavioural change, and health services research (horizon scanning, health technology assessment, public health and policy analysis. The School has a methodological focus, which has seen major expansion in the areas of health economics, patient reported outcomes and biostatistics as well as new investment in an interdisciplinary team comprising 'medical ethics, society and history'. Staff in HaPS conduct internationally recognised epidemiological and health services research in the hospital, community and population settings. The School's activities are focussed on translational research (bench-to-bedside-to-community population) as well as preventative medicine, disease aetiology, clinical management, and methodological research.

A strategic aim has been to add value by bringing together strong existing departments into a single School. This strategy will be further implemented for instance the Birmingham Clinical Trials Unit (BCTU) move to the School of Health and Population Sciences with effect from 1st August 2014.

The groups that are available for collaboration with the Institute of Translational Medicine through the Applied Health Research Hub are detailed in the table below. Information regarding how to access support from these groups along with details of their expertise is detailed throughout the brochure.

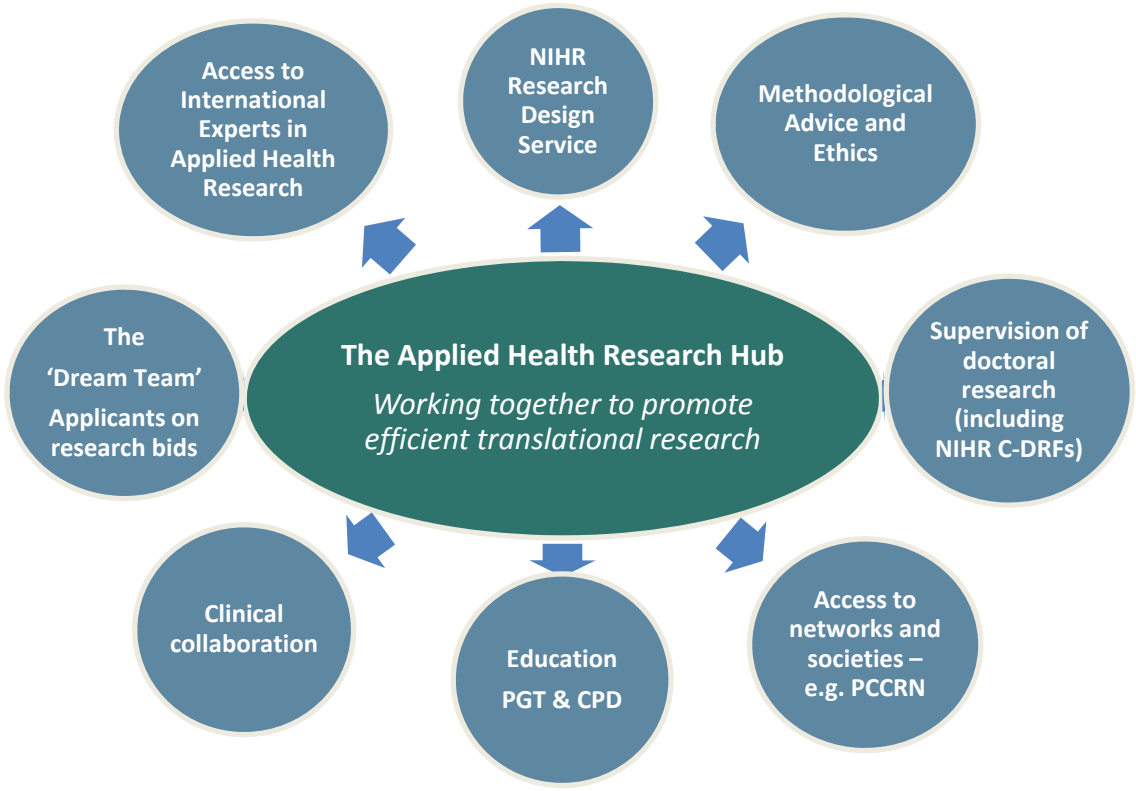
| | |
|---|---|
| **Biostatistics** | **Nursing** |
| **Birmingham Clinical Trials Unit (BCTU)** | **Patient Reported Outcomes** |
| **Clinical Research** | **Primary Care** |
| **Diagnosis & Biomarkers** | **Primary Care Trials Unit (PCCTU)** |
| **Epidemiology** | **Prognosis Research** |
| **Health Economics** | **Qualitative Research for Trials** |
| **Health Informatics Group ("phi")- Large Datasets** | **NIHR Research Design Service** |
| **Horizon Scanning** | **Ethics** |
| **Minority, Ethnic, and Socially Deprived Groups** | **Systematic Reviews & Meta-Analysis** |

# Accessing the Applied Health Research Methodology Hub

## When to access the AHR Hub

The earlier in the research development process that advice is given, the more helpful and useful it is likely to be. This can be at the idea stage or when a study design has been formulated and the first draft of the funding applications and/or protocol are being written. We ask that requests for help are made at least 12 weeks prior to any funding application deadline. Applicants requiring trials unit input must contact BCTU or PCCRTU at least 12 weeks in advance of submission. We offer range of advice and opportunities for collaboration.

## Members of the AHR Hub can work with you in a number of ways:




## Accessing the Hub

If you are interested in collaborating with members of the AHR Hub then please contact:

**Craig Maskell**
Deputy Head of R&KT Office
Senior Research Facilitator, School of Health & Population Sciences
Research & Knowledge Transfer Office, Medical School,
University of Birmingham, B15 2TT
**Email:** c.i.maskell@bham.ac.uk
**Tel:** 0121 414 6976

**Research Handbook:** www.intranet.birmingham.ac.uk/mds/research-handbook/
**Twitter:** @UoB_MDSRKTO
**Blog:** http://mdsresearchblog.wordpress.com
<http://mdsresearchblog.wordpress.com/

# NIHR Research Design Service

## Overview

The Research Design Service West Midlands (RDS WM) provides help on research design to researchers in the West Midlands who are developing proposals for open, national, peer-reviewed funding competitions for applied health or social care research.
We are funded by the National Institute for Health Research (NIHR) and our advice is provided free of charge. It is available through the use of online resources and consultations with experts.

## How can we help?

The Service is designed to help researchers at all stages of preparing grant applications:

1. Ensuring that the research topic is within the scope of the funding programme
2. Providing advice on the quality, practicality and feasibility of research questions and methods
3. Advising of the common pitfalls encountered in funding applications
4. Identifying enhancements to the proposal to improve chances of success
5. Dealing with feedback and failure from previous funding competitions

The RDS WM can also provide small bursaries to assist in the involvement of Patients and Public in the development of the research proposal.

### RDS WM Birmingham Hub

Team Leads:
Dr Neil Thomas, Regional Director
Dr Jonathan Mathers, Birmingham Hub Director

Expert Advisors
**Statistics & Epidemiology:**
Prof Jon Deeks (BCTU) - Biostatistics, evidence synthesis and test evaluation
Dr Jennifer Marsh - Applied statistics, missing data techniques
Ms Alice Sitch - Statistical analysis and design
Dr Hubert Lam (IOEM) – Environmental & chronic disease epidemiology, study design
Andrea Roalfe - Medical statistics, clinical trials
**Trials:**
Dr Jane Daniels (BCTU) - Methodology
Ms Natalie Ives (BCTU) - Phase 3 randomised trials
Mr Lee Middleton (BCTU) - Design and analysis of trials
Prof Keith Wheatley (CRCTU) - Methodology, trial design, systematic reviews
Prof Pam Kearns (CRCTU) - Methodology
**Health Economics:**
Prof Tracy Roberts - Model based economic evaluations
Dr Lazaros Andronis - Applied economic evaluations
Dr Emma Frew - Health economics, outcome measurement
Dr Phil Kinghorn - Assessment and valuation of health and broader outcomes
Dr Hugh McLeod - Health economics, policy analysis
Dr Andrew Sutton - Health economics, mathematical modelling
**PROs:**
Prof Melanie Calvert - Patient Reported Outcomes
**Evidence:**
Dr David Moore - Systematic reviewing
Ms Sue Bayliss - Information specialist, scoping
**Qualitative:**
Dr George Dowswell - Qualitative research, mixed methods studies

### Key contacts:

**Email:** rds@contacts.bham.ac.uk
**Twitter:** @NIHR_RDS

### RDS WM Birmingham Hub

Team Leads:
Dr Neil Thomas
Regional Director:
Chronic disease, epidemiology, study design

Dr Jonathan Mathers
Birmingham Hub Director
Qualitative research, mixed methods studies

## Advice

You will be allocated an RDS WM adviser who will take the lead on your enquiry and work with our other staff who have complementary skills. All RDS advisers and contacts are research active. We believe this engagement with local researchers and academics via the RDS WM provides the most effective model of research advice support. Although you can contact us at any stage of your proposal, early contact is preferable. Please bear in mind that developing successful funding applications takes a considerable amount of time. The lead-in time required for effective RDS support will depend on the amount and type of support required. Within 4 weeks of a submission deadline it is unlikely that substantive developmental support will be possible.

## Case Study

A feasibility study for a pragmatic RCT of pressure garment therapy (PGT) for burns patients

During the development of this proposal the RDS WM provided advice on several aspects of the design of the feasibility study and subsequent pilot trial. This has included the design of qualitative research which will include burns clinicians and patients to understand issues related to the acceptability of a trial of PGT, and also the definition of outcomes that would be valued by the clinical community, patients and carers. It has involved the development of proposals for the design and testing of economic measures that might feed into a large scale pragmatic RCT. The proposal is a collaboration with the Birmingham Clinical Trials Unit. Finally, RDS members have advised on the appropriate integration of patient and carer perspectives in this proposed research using the skills of local PPI experts. The development of this proposal has culminated with several local RDS advisers agreeing to take an active role as co-applicants on the submitted proposal, and also with a PPI co-applicant who has influenced the final proposal via work with the RDS advisers. The submitted proposal was successful at outline stage in May 2013, and a full proposal was then developed and successfully funded by the NIHR HTA.

# Health Economics

## Overview of Research

The vision of the Health Economics Unit (HEU) at the University of Birmingham is to be leading the development and application of health economics for the benefit of patients within the UK. The research strategy is directed towards achieving the Unit's vision of *providing an internationally competitive contribution to health economics research by retaining a coherent balance of methodological and applied research*, achieving research funding from the UK Research Councils, from the NIHR and from the EU, and publishing high quality outputs in both top medical journals and top disciplinary journals.

Applied work is geared towards providing both information for decision-making and a context and vehicle for methodological work, and methodological work will continue to lead and support the applied studies and the Unit has particular expertise in applied work related to economic evaluation alongside trials, model based economic evaluation alongside trials or systematic reviews and includes expertise in the evaluation of new technologies and diagnostic tests. More broadly the Unit has a particular strategic focus on *Economic analysis where a substantial proportion of costs and/or benefits are perceived to fall outside the health sector; and on interventions where context may have a particularly strong effect.* Much of the applied work within the Unit is already conducted in areas where economic evaluation is challenging, such as public health and complex interventions, and for which current evidence is largely poor or non-existent. It is anticipated that this trend will continue as policy decisions made by organisations such as NICE shift from focusing mainly on technology assessment to broader concern with areas such as public health, social care, mental health and end of life care.

## Case Study

**Evaluating PET-CT in Recurrent Cervical Cancer: A Cost-Effectiveness Analysis**

This study was a model based economic evaluation based on clinical data on accuracy and effectiveness of PET-CT collated through systematic reviews. The systematic reviews were separately conducted by a systematic review team. The reviews collated appropriate data for the health economic model based on advice provided by the health economic team. The study duration was 2.5 years and the health economic researcher was employed for 12 months full time (grade 7/ 8) to construct the model and conduct the analysis based on advice from two senior colleagues. The extent of advice required from senior colleagues (Grade 9 & 10) is dependent on the experience and grade of the researcher.

***Objective*** *To undertake a cost-effectiveness analysis that compares positron emission tomography – computed tomography (PET– CT) imaging with standard practice in the diagnosis of recurrent or persistent cervical cancer during routine surveillance and follow-up of women who have previously been diagnosed and treated.*

***Design*** *Model-based economic evaluation using data from a systematic review, supplemented with data from other sources, and taking a UK National Health Service (NHS) perspective.*

***Methods*** *A state transition (Markov) model was developed using TREEAGE PRO 2011. The structure of the model was informed by the reviews of the trials and clinical input. In the model, two diagnostic strategies were examined. A one-way sensitivity*

***Main outcome measures*** *Cost-effectiveness based on incremental cost per quality-adjusted life year (QALY).*

***Results*** *Adding PET–CT to the current treatment strategy of clinical examination and scanning [magnetic resonance imaging (MRI) and/or CT scan] during the routine surveillance and follow-up of women with recurrent or persistent cervical cancer is significantly more costly, with only a minimal increase in effectiveness. The incremental cost-effectiveness ratio (ICER) for the strategy of PET–CT as an adjunct to the standard treatment strategy that included clinical examination, MRI, and/or CT scan, compared with the usual treatment alone, was over £1 million per QALY.*

***Conclusion*** *The results of the current analysis suggest that use of PET–CT in the diagnosis of recurrent or persistent cervical cancer is not cost-effective.*

## Health Economic Unit

Team Leads:

Professor Tracy Roberts,
Head of Unit

Professor Jo Coast,
HAPS Research Lead

**Core Group includes:**

Dr Pelham Barton
Dr Emma Frew
Dr Sue Jowett
Dr Andrew Sutton
Dr Lazaros Andronis
Dr Hareth Al-Janabi

## Opportunities for Collaboration

**Advice:**

- To contribute to trial development/ management activities and arising publications
- To advise the ITM and associate trial team on the latest methodological developments relating to conducting economic evaluations and decision making under uncertainty

**Collaboration:**

- To facilitate collaboration between the ITM and the Health Economic Unit to ensure economic evaluations are appropriately resourced and conducted to the highest possible standard producing evidence that is robust and publishable
- Advise on the appropriate design of an economic evaluation and appropriate vehicle on which to base the evaluation: For example advice on which of the following is most appropriate :
    - within trial economic evaluation (i.e. alongside the trial and based on the outcome collected within the trial only)
    - model based economic evaluation based on the trial ( for example extending the outcome of interest beyond the outcome of the trial)
    - model based economic evaluation based on data collected from systematic reviews and / expert opinion
- *Provide advice on appropriate data collection relating to*
    - clinical data for example: accuracy of diagnostic tests and/or effectiveness of interventions
    - resource use data relating to new technologies whether devices, drugs or new model of delivery
    - outcome data for economic evaluation and whether the measure chosen is fit for purpose

**Education**: the Health Economics Unit runs two prestigious MSc programmes in Health Economics (page 33) the modules underpinning these programmes are available as short courses .

## Selected Recent Publications

### Trial Based Economic Evaluations


- Diwakar L, Morris RK, Barton P, Middleton LJ, Kilby MD, Roberts TE. (2013) Evaluation of the Cost Effectiveness of Vesico-Amniotic Shunting in the Management of Congenital Lower Urinary Tract Obstruction (Based on Data from the PLUTO Trial). PLoS ONE (12):e82564.doi:10.1371/journal.pone.0082564


### Model Based Economic Evaluations alongside Trials


- Sanghera S, Roberts TE, Barton P, Frew E, Daniels J, Middleton L, Gennard L, Kai J, Gupta JK. Levonorgestrel-Releasing Intrauterine System vs. Usual Medical Treatment for Menorrhagia: An Economic Evaluation Alongside a Randomised Controlled Trial. PLoS ONE. 2014. DOI:10.1371/journal.pone.0091891


### Model Based Economic Evaluations based on Systematic Reviews


- Auguste P, Barton P, Davenport C, Małysiak S, , Kowalska M, Zapalska A, Chomiak P, Guest P, Thangaratinam S, Martin-Hirsch P, Borowiack E, Meads C, Khan K Sundar S, Roberts TE. Evaluating PET-CT in Recurrent Cervical Cancer: A Cost-Effectiveness Analysis. British Journal Of Obstetrics and Gynaecology DOI: 10.1111/1471-0528.12460


### Diagnostic Tests


- Sutton A, Barton P, Sundar S, Meads C, Rosenthal AN, Baldwin P, Khan K, Roberts TE. Cost-effectiveness of sentinel lymph node biopsy versus inguinofemoral lymphadenectomy in women with vulval cancer. British Journal of Cancer. 2013. DOI: 10.1038/bjc.2013.631
- Hillman SC, Barton PM, Roberts TE, Maher ER,. McMullan DM, Kilby MD. BAC Chromosomal microarray for prenatal detection of chromosome anomalies in fetal ultrasound anomalies: an economic evaluation. *Fetal Diagnosis and Therapy* (in press)


### Outcomes Research


- Al-Janabi H, Peters T, Brazier J, Bryan S, Flynn T, Clemens S, Moody A, Coast J. An investigation of the construct validity of the ICECAP-A capability measure. Quality of Life Research 2013;22(7)
- Canaway A, Frew E. Measuring preference based quality of life in children aged 6-7 years: A comparison of the performance of CHU-9D and EQ-5D-Y. The WAVES pilot study. Quality of Life Research 2013;22(1)

# Patient Reported Outcomes (PROs)

## Overview of Research

PRO data, such as health-related quality of life or symptoms, may be used to inform clinical care and decision-making, predict long-term outcomes and inform health policy. Despite this, research suggests that the design, data collection, reporting and dissemination of PROs in trials are frequently suboptimal. These practices devalue important patient-centred data and limit the impact of PRO results in the clinical setting.

## University of Birmingham PRO Research Group

The PROs Research Group lead a programme of work, with international collaborators, aiming to enhance the design, implementation, analysis and reporting of PROs in trials and to improve the way that PRO results are used to inform clinical care. Recent success includes the development of the new CONSORT PRO extension which provides guidance for reporting PRO trial results and the publication of a JAMA viewpoint article addressing the management of PRO alerts in the clinical trial setting.

Specifically, the PRO research group focuses on the development of best practice in the following areas:

1. Trial Design and Protocol Development
2. Implementation of PROs in Clinical Trials
3. Reporting of trials where PROs are an outcome
4. Use of PRO trial data to inform clinical care

The cross cutting themes underpinning this work are ‘ethics, education, training and knowledge transfer’ for clinicians, researchers, policymakers, patients and carers.

### PRO Research Group

Team Lead:
Professor Melanie Calvert

Members:
Derek Kyte

Affiliated members
Dr Thomas Keeley
Dr Sabrina Grant

## Opportunities for Collaboration

- To advise the ITM and associate trial teams on the latest methodological developments relating to: PRO selection, trial design, conduct, analysis and knowledge transfer (KT) activities.
- Contribute to trial development/management activities and arising publications.
- Provide advice on PRO-related queries such as problems with compliance or management of PRO Alerts.
- To contribute to training initiatives to promote optimal PRO assessment within the ITM and its external collaborators.
- To facilitate collaboration between the ITM with international groups leading Best Practice for PRO assessment in clinical trials, specifically: CONSORT, the EQUATOR network, ISOQOL, NIH/NCI, PCORI, COSMIN).

## Selected Recent Publications


- Anker SD, Agewall S, Borggrefe M, Calvert M, Caro J, Cowie MR, Ford I, Paty JA, Riley JP, Swedberg K, Tavazzi L, Wiklund I, Kirchhof P. The Importance of Patient Reported Outcomes: A Call for Their Comprehensive Integration in Cardiovascular Clinical Trials. Eur Heart J (in press)
- Kyte D, Draper H, Calvert M. Patient Reported Outcome Alerts: Ethical & Logistical Considerations in Clinical Trials. JAMA. 2013 Sep 25;310(12):1229-30. doi: 10.1001/jama.2013.277222
- Kyte D, Ives J, Draper J, Keeley T, Calvert M. Inconsistencies in quality of life data collection in clinical trials: a potential source of bias? Interviews with research nurses and trialists. PLoS One. 2013 Oct 4;8(10):e76625. doi: 10.1371/journal.pone.0076625.
- Kyte D, Draper H, Ives J, Liles C, Gheorghe A, Calvert M Collection of Patient Reported Outcomes in Clinical Trials: Is 'In-Trial' Guidance Lacking? A Systematic Review Employing Qualitative Content Analysis. PLoS One. 2013;8(4):e60684. doi: 10.1371/journal.pone.0060684. Epub 2013 Apr 1.
- Pinkney TD, Calvert M. Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI Trial). BMJ. 2013 Jul 31;347:f4305.
- Calvert M, Blazeby J , Altman D , Revicki D , Moher D, Brundage M for the CONSORT PRO Group. Improving the Reporting of Patient Reported Outcomes in Randomised Trials: the CONSORT PRO Extension. *JAMA* 2013; 309 (8) 814-822
- Gheorghe A, Roberts T, Ives J, Fletcher B, Calvert M. Centre selection for clinical trials and the generalisability of results: a mixed methods study. *PLoS One.* 2013;8(2):e56560.
- Freemantle N, Calvert MJ. Interpreting composite outcomes in trials. *BMJ. 2010; 341:c3529.*


# Epidemiology

## Overview of Research

The establishment, development and exploitation of large-scale national and international cohorts is undertaken routinely.

### Epidemiological research into chronic diseases.

The team have a large international portfolio of research including cross-sectional, case-control and cohort studies in the UK, Europe and Asia. There is a particular focus on cancer, COPD, CVD, cognitive function metabolic syndrome, but include most chronic diseases.

### Epidemiological research using electronic primary care records.

The team has access to the THIN dataset which includes almost 6% of the UK population GP records (3.6M) that can be used to answer specific research hypotheses and generate supporting data for grant applications.

The team also utilises results from the data to inform treatment and preventative approaches. An example of which is a large scale randomised clinical trial into a Polypill for cardiovascular prevention with hard endpoints being conducted in Iran. Work from our studies has also been used to inform national and international guidelines.

## Case Studies

The British Childhood Cancer Survivor Study (BCCSS) cohort relating to 35,000 individuals who survived at least 5 years after diagnosis of childhood cancer in Britain has been electronically linked to the national death[1] and cancer[2] registries and has recently been linked to the national Hospital Episode Statistics database for England. Case-control studies addressing aetiological questions are undertaken nested within the cohort[3]. www.bccss.bham.ac.uk. Evidence produced has influenced national clinical follow-up guidelines and national cancer screening policy among survivors.

The recently established Teenage and Young Adult Cancer Survivor Study (TYACCS) cohort relating to 240,000 individuals who survived at least 5 years after diagnosis of cancer when aged 15 to 39 years in England or Wales has also been electronically linked to national death and cancer registries and to the national Hospital Episode Statistics database.

There are three FP-7 studies in progress PanCareSurFup, PROCARDIO and CEREBRAD addressing aetiological questions which require the establishment of Europe-wide cohorts. The Europe-wide data collection for PanCareSurFup is coordinated from Birmingham.

## Group

### Team Leads:

Dr Neil Thomas

Prof. KK Cheng

Prof. Mike Hawkins

### Members:

Prof.Tom Marshall
Prof. Peymane Adab
Dr Raoul Reulen

## Opportunities for Collaboration

The team are able to provide epidemiological advice and if appropriate to collaborate on projects that require cohort studies, case-control studies or the analysis of electronic records. The team are also experienced in a range of other methodologies.

In particular, the Cancer Survivorship team (Leads: Hawkins, Reulen) have a strong track-record of successfully delivering:

- efficient and robust epidemiological study designs, including sample size calculations
- national and international study protocol development
- national ethical and legal consents to undertake research using identified personal data
- efficient and effective national and international study co-ordination
- efficient and robust data management systems
- database designs for large-scale national and international studies
- appropriate and simple (as possible) statistical analysis/modelling solutions
- reliable and valid questionnaire design
- strategies to optimise response rates to surveys
- electronic individual patient record linkage to the national death registry (for causes of death), the national cancer registry (for incident cancers), the national Hospital Episode Statistics (HES) database (for illnesses resulting in secondary care within the NHS), the national registries held by the National Institute for Cardiovascular Outcomes Research (NICOR) including the Myocardial Ischaemia National Audit Project database (MINAP).

## Selected Recent Publications


- RC Reulen, DL Winter, C Frobisher, ER Lancashire, CA Stiller, ME Jenney, R Skinner, MC Stevens, MM Hawkins. Long-term Cause-Specific Mortality Among Survivors of Childhood Cancer. JAMA 304 (2): 172-179; 2010.
- RC Reulen, C Frobisher, DL Winter, JS Kelly, ER Lancashire, CA Stiller, K Pritchard-Jones, HC Jenkinson, MM Hawkins. Long-term Risks of Subsequent Primary Neoplasms Among Survivors of Childhood Cancer. JAMA 305 (22): 2311-2319; 2011.
- MM Hawkins, LM Kinnier Wilson, MA Stovall, HB Marsden, MHN Potok, JE Kingston, JM Chessells. Epipodophyllotoxins, alkylating agents, and radiation and risk of secondary leukaemia after childhood cancer. BMJ 304: 951-958; 1992.
- P Yin, CQ Jiang, KK Cheng, TH Lam, KL Lam, MR Miller, WS Zhang, GN Thomas, P Adab. Passive smoking exposure and risk of COPD among adults in China: The Guangzhou Biobank Cohort Study. Lancet. 370: 751-757; 2007.
- AH Jokhio, HR Winter, KK Cheng. An intervention involving traditional birth attendants and perinatal and maternal mortality in Pakistan. N Engl J Med 352: 2091-2099; 2005.


## Other Relevant Links

A selection of studies are described below:

- Guangzhou Biobank Cohort Study, China (KK Cheng, Neil Thomas) 30,000 older (≥50y) person chronic disease cohort, >1,800 deaths; Over 100 baseline data publications
- Guangzhou Biobank Cohort Study-Cardiovascular Subcohort, China (Neil Thomas, KK Cheng) 2,000 intensively phenotyped CVD-focused subcohort
- The LUdwigshafen RIsk and Cardiovascular Health (**LURIC**) study (Neil Thomas) 3,000 intensively phenotyped angiography patients, >1,000 deaths
- Cegedim Strategic Data through a sub licence for THIN dataset (Tom Marshall) >3.6 million patients with outcomes
- Golestan Cohort Study, Iran (KK Cheng, Tom Marshall, Neil Thomas), 50,000 population-based gastro-oesophageal cancer and chronic disease
- British Childhood Cancer Survivor Study (Mike Hawkins) 35,000 <15y at diagnosis surviving ≥5y
- Born in Guangzhou Cohort Study (KK Cheng) Currently >4,000 mothers and offspring recruited. Target 30,000
- The Birmingham COPD cohort: unique primary care COPD cohort in the West Midlands (Peymane Adab, David Fitzmaurice, Rachel Jordan). Currently recruited ~2300 patients to follow-up for 3 years in the first instance.

# Systematic Reviews and Meta-analysis

## Overview of Research

This cross school group has a strong track record in the techniques of evidence synthesis, systematic reviews and meta-analysis and their application to inform specific healthcare decision making problems, support development of primary studies and the education of others in these methodologies. The aim of this research group is to provide the best evidence to address a given question through the comprehensive assimilation of relevant information, using techniques to minimise bias and make explicit uncertainties.

The group has experience in undertaking research to inform national and international healthcare decision makers (e.g. for NICE and the NIHR), aid the development of new healthcare technologies, and improve methodologies to advance evidence synthesis. The group includes the information support unit for the School, which has a pivotal position in devising, undertaking and educating on advanced strategies to identify published, grey and unpublished research literature.

The group also have a strong methodological research track record in individual patient data meta-analysis. The group have also developed the technique of systematic reviews of medications across different interventions. This methodology helps inform clinical decision making in clinical areas where limited evidence of the effect of an intervention is available, but can draw on evidence of the same intervention in a related indication (for example are staples preferable to sutures in appendectomy, using evidence from intervention studies in emergency laparotomy).


## Case Studies

1) The effectiveness and cost-effectiveness of domiciliary non-invasive ventilation (NIV) in patients with end-stage COPD. A systematic review and economic evaluation.

This 18 month NIHR funded study aimed to review systematically and meta-analyse appropriately the evidence of effectiveness of the intervention from RCTs, non-randomised studies and uncontrolled studies to overcome deficits in existing less robust reviews and to inform the development and running of an economic evaluation. The systematic review and analysis components required an information specialist to develop and run the complex search strategies (1 month), a full time experienced systematic reviewer (1 year) and part time junior reviewer (6 months), input from an experienced statistician (2 months), oversight from a senior methodologist and a clinical specialist, as well as PPI engagement. NIHR Health Technology Assessment Programme (11/27/01), PROSPERO record: 2012:CRD42012003286.

2) The prognostic utility of tests of platelet function for the detection of “aspirin resistance” in patients with established cardiovascular or cerebrovascular disease. A systematic Review.

Similar to case study one, this 18 month NIHR funded project had a considerable systematic review component (although requiring more systematic reviewer and statistical input). It included approaching two hundred studies of mixed design and required extensive sub-group analyses. NIHR Health Technology Assessment Programme (10/36/02), PROSPERO record: 2012:CRD42012002151

## Evidence Synthesis Group

### Team Leads:

Dr David Moore

### Co-lead:

Dr Karla Hemming

### Members:

Janine Dretzke
Sue Bayliss
Malcolm Price
Amanda Farley
George Bramley
Zulian Liu
James Hodgkinson

## Opportunities for Collaboration

The team could provide a wide range of advice, support and active collaboration as required in systematic reviews and meta-analyses to the ITM.
Examples of such engagement are:

- Advice on identification of evidence through appropriate search strategies
- Developing and executing such strategies
- Advice on systematic review and meta-analytical methods
- Undertaking systematic reviews and meta-analyses
- Systematic review protocol development
- Systematic review grant development

The group has considerable experience of delivering training in systematic review and meta-analytic methods at post-graduate level and beyond; for example though the Systematic Reviews and Evidence Synthesis module run in HaPS. This, similar or tailored training could be offered to the ITM.

## Selected Recent Publications


- Dretzke J, Blissett D, Dave D, Mukherjee R, Price M, Bayliss S, Wu X, Jordan R, Jowett S, Turner A, Moore D. The cost-effectiveness of domiciliary non-invasive ventilation (NIV) in patients with end-stage COPD. A systematic review and economic evaluation. Health Technology Assessment 2015 *In press*
- Dretzke J, Riley R, Lordkipanidzé M, Jowett S, O'Donnell J, Ensor J, Moloney E, Price M, Raichand S, Hodgkinson J, Bayliss S, Fitzmaurice D, Moore D. The prognostic and diagnostic utility of tests of platelet function for the detection of "aspirin resistance" in patients with established cardiovascular or cerebrovascular disease: A systematic review and economic evaluation. Health Technology Assessment 2014 *In press*
- Meadows A, Kaambwa B, Novielli N, Huissoon A, Fry-Smith A, Meads C, Barton P, Dretzke J. A systematic review and economic evaluation of subcutaneous and sublingual allergen immunotherapy in adults and children with seasonal allergic rhinitis. Health Technology Assessment 2013;17(27).
- Orlando R, Pennant M, Rooney S, Khogali S, Bayliss S, Hassan A, Moore D, Barton P. Cost effectiveness of Transcatheter Aortic Valve Implantation (TAVI) for Aortic Stenosis in patients who are high risk or contraindicated for surgery. Health Technology Assessment 2013;17(33) doi: 10.3310/hta17330
- Moore D, Aveyard P, Connock M, Wang D, Fry-Smith A, Barton P. Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis. BMJ 2009;338:b1024
- Hemming K, Pinkney T, Futaba K, Pennant M, Morton DG, Lilford RJ. A systematic review of systematic reviews and panoramic meta-analysis: staples versus sutures for surgical procedures. PLoS One. 2013 Oct 7;8(10):e75132. doi: 10.1371/journal.pone.0075132. eCollection 2013. Review. PubMed PMID: 24116028; PubMed Central PMCID: PMC3792070.


# Test and Biomarker Evaluation

## Overview

This multidisciplinary research group was founded in 2006 by Jon Deeks. The research interests of the group focus on the development and investigation of methods for evaluating medical tests in healthcare, including both primary and secondary research. Major activities include undertaking methodological research aiming to identify and validate the best ways of designing, analysing and reporting studies evaluating medical tests used for diagnostic, prognostic, monitoring purposes. The scope of the group includes both methods for primary research, systematic reviews and meta-analyses, and also includes the evaluation of predictive tests used for stratified medicine. Many of the methodology activities are linked to supporting primary research studies evaluating the accuracy and effectiveness of tests in clinical practice, currently underway in collaborations with clinical research groups and the trials units both in the College and with other UK based groups. Projects have included looking at methods for evaluating accuracy in the absence of a reference standard, methods for meta-analysis, investigation of publication bias in test research, and the design and analysis of randomised trials of tests. They have recently started to investigate methodological issues arising in the application of tests for purposes of monitoring.

This group is also the international base of the Cochrane Collaboration's diagnostic test accuracy Reviews, which provides training and support in review methods for Cochrane Review Groups based in the UK. The Cochrane Library is recognised as the best resource for evidence on the effectiveness of health interventions, and has ambitions to publish similar reviews evaluating the accuracy of diagnostic tests.


## Biostatistics

Team Lead:
Professor Jon Deeks

Members:
Lavinia Ferrante di Ruffano
Jac Dinnes
Yemisi Takwoingi
Clare Davenport

## Case Study

In addition to methodological research, Prof Deeks has also provided statistical and methodological expertise for a portfolio of primary studies of research, from evaluation of blood tests for tuberculosis, to the use of PET imaging for the diagnosis and staging of cancer.

## Opportunities for Collaboration

- To advise the ITM on the latest methodological developments relating to diagnostic test accuracy, biomarker evaluation and stratified medicine.
- Contribute to study development/management activities and arising publications.
- To contribute to training initiatives relating to test and biomarker evaluation.
- To facilitate collaboration between the ITM with international groups working in this area e.g. Cochrane.

## Selected Recent Publications


- Malottki K, Biswas M, Deeks JJ, Riley RD, Craddock C, Johnson P, Billingham L.Stratified medicine in European Medicines Agency licensing: a systematic review of predictive biomarkers.BMJ Open. 2014 Jan 27;4(1):e004188. doi: 10.1136/bmjopen-2013-004188.
- Leeflang MM, Deeks JJ, Takwoingi Y, Macaskill P.Cochrane diagnostic test accuracy reviews. Syst Rev. 2013 Oct 7;2:82. doi: 10.1186/2046-4053-2-82.
- Takwoingi Y, Leeflang MM, Deeks JJ. Empirical evidence of the importance of comparative studies of diagnostic test accuracy. Ann Intern Med. 2013 Apr 2;158(7):544-54. doi: 10.7326/0003-4819-158-7-201304020-00006.


# Qualitative Research for Trials


## Overview of Research

Our research focuses on integrating qualitative research components with clinical trial research in order to inform the design and implementation of clinical trials, particularly those in complex situations where trial research may be difficult to design and conduct. The group are currently leading the qualitative research components for a number of clinical trial feasibility studies funded by the NIHR Health Technology Assessment and Research for Patient Benefit programmes. These studies will focus on a core set of themes which are key to the successful design and delivery of pragmatic clinical trials. These include

- understanding the acceptability of trial questions to key stakeholders, including patients and clinical staff
- understanding the factors that are likely to influence trial recruitment and participation
- selecting outcome measures that are important to the range of key stakeholders, including patients and clinicians, and that are transferable across trials (e.g. via the construction of core outcome sets)
- understanding patient experience of trial treatment regimes, and patient and clinical experience of trial processes in order to optimise design and delivery

- Another focus of our research is the development of novel methodologies in health care research in order to involve groups whose voices can be 'seldom heard' in research studies. This research lays important groundwork for trials as it can identify the perspectives and priorities of ethnic minorities who are underrepresented in clinical trials.

### Qualitative Research Team

Prof Sheila Greenfield

Dr Jonathan Mathers

Dr Laura Jones

Dr George Dowswell

Dr Antje Lindenmeyer

## Case Studies

1) The Pegasus study is a feasibility study for a trial of pressure garment therapy (PGT) in burns scar management, funded by the NIHR HTA programme. A trial in this area is thought to be difficult as this established treatment is currently in routine use with a broad range of adult and paediatric patients across burns centres in the UK. It's therefore unclear whether patients or clinical staff will participate in a trial of PGT; what range of outcomes will be valued by patients and clinical staff; whether patients will comply with treatment options; and how outcomes can be assessed in a valid and rigorous manner.

Pegasus is an external pilot trial with preliminary qualitative (e.g. interviews and focus groups) and survey research with patients and clinical staff. This research will help assess the likelihood that a national pragmatic RCT will succeed, and how that study should be designed and implemented. Dr Mathers and Dr Jones are leading the qualitative research in collaboration with clinical leads, Birmingham Clinical Trials Unit and other methodological specialists from HaPS who have expertise in outcome methodology, health economics and trial statistics. The team also work closely with patient partners to ensure that patient perspectives can inform the design and delivery of this research.

2) A highly accessed paper in BMC Cancer illustrated the value of qualitative research within randomised controlled trials (RCTs). In developing an intervention to help people with colorectal adenomas reduce their intake of red and processed meat and increase their levels of physical activity, we followed the Medical Research Council guidance for the development, evaluation and implementation of complex interventions. Before running our RCT, we organised focus groups for people who had been diagnosed and treated through the National Bowel Screening Programme to discuss their experience, motivations and preferences. We also interviewed service providers and reviewed the literature on lifestyle interventions. On the basis of these findings, we designed the intervention and ran the trial.

## Opportunities for Collaboration

The team are interested to explore potential areas of collaboration around feasibility studies, clinical trials and other clinical research where applied qualitative research approaches are relevant.

## Selected Recent Publications


- Dowswell G, Ryan A, Taylor A, Daley A, Freemantle N, Brookes M, Jones J, Haslop R, Grimmett C, Cheng KK, and Wilson S. Designing an intervention to help people with colorectal adenomas reduce their intake of red and processed meat and increase their levels of physical activity: a qualitative study *BMC Cancer* 2012, **12**:255 doi:10.1186/1471-2407-12-255
- Jones LL, Atkinson O, Longman J, Coleman T, McNeill A and Lewis S. The motivators and barriers to a smoke-free home: identifying the positive levers for change. Nicotine and Tobacco Research (2011), Jun;13(6):479-86.
- Jones LL, Hashim A, McKeever T, Cook D, Britton J and Leonardi-Bee J. Parental and household smoking and the increased risk of bronchitis, bronchiolitis and other lower respiratory infections in infancy: systematic review and meta-analysis. Respiratory Research (2011), 12:5.
- Lindenmeyer A, Sturt JA, Hipwell A, Stratton IM, al-Athamneh N, Gadsby R, O'Hare JP and Scanlon PH. Influence of primary care practices on patients' uptake of diabetic retinopathy screening: a qualitative case study. Br J Gen Pract (2014) 64:e484-e492;
- Redwood S, Gale NK, Greenfield S. 'You give us rangoli, we give you talk': using an art-based activity to elicit data from a seldom heard group. BMC Med Res Methodol (2012), 12:7. doi: 10.1186/1471-2288-12-7.

# Recruitment of Diverse Population Groups from Primary Care

## Overview of Research

The aim of health research is to determine the best strategies for preventing and treating disease and to inform health policy. To ensure health policies serve a diverse population, it is important that all patients from all ethnic groups participate in health research. This ensures the generalizability of research results and addresses inequalities in health. Birmingham and the Black Country, with a population of over 2million, is a diverse area in terms of ethnicity and socio-economic status. We have extensive knowledge and skills in facilitating patients from diverse ethnic and socio-economic backgrounds into research.

### Team Lead

Dr Paramjit Gill

Dr Gill has extensive links with local communities and is a Trustee of the South Asian Health Foundation (www.sahf.org.uk )

## Case Study

Dr Gill is the chief investigator of a landmark study examining the community prevalence of heart failure amongst minority ethnic groups in the UK (E-ECHOES) funded by the BHF and the Heart of Birmingham Teaching PCT. This is a large heart failure screening study that has phenotyped 5,408 South Asian and African-Caribbean subjects – so-called 'hard-to-reach' population groups. We recruited above target and completed the study early. This study now provides a platform for further work (including establishment of minority ethnic cohort study) and has already generated further funding, as well as 3 higher degrees (1 MD; 2 PhDs); and *22* publications to date.

## Opportunities for Collaboration

Able to provide epidemiological advice and if appropriate to collaborate on projects that require cohort studies, case-control studies or the analysis of electronic primary care records.

## Selected Recent Publications


- Gill PS, Calvert M, Davis R, Davies M, Freemantle N, Lip GYH. (2011) Prevalence of heart failure and atrial fibrillation in minority ethnic subjects: The Ethnic-Echocardiographic Heart of England Screening study (E-ECHOES). PLoS ONE. 6(11): e26710. doi:10.1371/journal.pone.0026710.
- Bennett PC, Lip GYH, Silverman S, Blann AD, Gill PS. (2011) Validation of the Edinburgh Claudication Questionnaire in 1st generation Black African-Caribbean and South Asian UK migrants: A sub-study to the Ethnic-Echocardiographic Heart of England Screening (E-ECHOES) Study. BMC Medical Research Methodology, **11:**85.
- Plumridge G, Redwood S, Greenfield S, Akhter N, Chodhury R, Khalade A, Gill P. (2012) Involving interpreters in research studies. Journal of Health Services Research & Policy 2012 ; 17 (3): 190–192.
- Gill P; Plumridge G; Khunti K; Greenfield S. (2013) Under-representation of minority ethnic groups in cardiovascular research: a semi-structured interview study. Family Practice 30: 233-241.
- Gill P, Wright N, Brew I (eds). (2014) Working with Vulnerable Groups: A Clinical Handbook for GPs. London: Royal College of General Practitioners.

# Health Informatics

## Overview of Research

There is nationally an emphasis on the role of informatics and digital technology in transforming healthcare. The college of medical and dental sciences at the University of Birmingham has a strong track record in research and education in the health informatics domain. The research group will bring together research and educational initiatives in different disciplines (primarily focussing on hospital medicine, primary care, clinical pharmacy and public health) pertaining to health informatics to catalyse inter-disciplinary and cross disciplinary work streams that have impact and recognition nationally and internationally. To strengthen the initiative the research group will accommodate outstanding individuals from leading local and national organisations to promote research in real settings and enhance knowledge transfer in real time.

## Health Informatics Group

**Team Leads from School of Health and Population Sciences:**

Professor Tom Marshall (Joint Theme Lead for Primary care Informatics)

Dr Krish Nirantharakumar (Joint Theme Lead for Public Health Informatics)


**www.phi.birmingham.ac.uk**

**Twitter: @phi_Bham**

**Members**

Dr. Karla Hemming –Senior Lecturer in Biostatistics (Cross Theme Lead for Biostatistics)
Dr. Brian Willis, NIHR Clinical Lecturer
Ronan Ryan- Research Fellow (Joint Theme Lead for Primary care Informatics)
Gavin Rudge - Research Fellow (Joint Theme Lead for Public Health Informatics)
Dr. Shamil Haroon - NIHR Clinical Research Fellow
Paul Fisher - Research Fellow

**Lead collaborators within MDS:**

Dr. Jamie Coleman -Senior Clinical Lecturer (Theme Lead for Hospital Informatics)
Prof. John Marriot - Professor of Pharmacy (Theme Lead for Pharmacy Informatics)

**Lead collaborating departments across the University:**

Computer Science Department (Data mining and analytics)
Economics (Econometrics in healthcare data)
Geography (Climate data)

**Lead external service sector collaborators:**

University Hospital Birmingham
Public Health England
Birmingham Cross City CCG
Birmingham City Council

**Societies and networks:**

Health Informatics Unit, Royal College of Physicians
Royal College of General Practices
Faculty of Public Health
UK Council for Health Informatics Professionals
West Midlands Health Informatics Network
Academic Health Science Network

## Key Areas of Research:

1. **Routinely available electronic medical record data from primary care (THIN) and secondary care (HES / PICS)**

Under this area we carry out numerous epidemiological studies to:

- Understand causation of disease / adverse outcome
- Measure performance of general practices and hospitals against good practice and study factors that influence the quality of care provided
- Develop prediction models to stratify patient groups to facilitate prioritisation and improve efficiency and patient outcomes

2. **Clinical Decision Support Systems**

Under this area we aim to develop, implement and evaluate clinical decision support systems in primary and secondary care settings. Current work involves:

- Trials using the primary care EMR for active case finding of high risk patients in a variety of chronic disease patient groups
- Developmental work around translating NICE guidelines into computer executable format that can provide patient specific recommendations
- Decision support tools to improve inpatient care and patient safety at the University Hospital Birmingham NHS Foundation Trust

3. **Future initiatives include:**

- Climate and Health Impact (Joint collaboration with School of Earth, Geography and Environmental Sciences and Public health England)
- Econometrics in Healthcare (Joint collaboration with colleagues in Economics Department)
- Data mining techniques to analyse and understand big data and social media data in healthcare (Joint collaboration with Computer Science Department)
- Data linkage between housing and health data for investigation of the relationships between housing improvement and health outcomes.

### Case Study

An analysis of hospital data was undertaken to determine the predictors of excess length of stay and mortality in diabetic in-patients. The aim was to use data that were readily available at the time of admission or within 24 hours of admission, to identify those patients most at risk of an adverse outcome. Using reliable data (demographic data, blood test results and treatments) our model successfully discriminated between those patients who had an adverse outcome (excess length of stay or death) and those that did not. Discussions are under way to validate the model in other hospital settings and to implement use of the model to identify on admission, those diabetic patients at risk of an adverse outcome so that they can be targeted for more intensive intervention. Reference: Nirantharakumar K, Hemming K, Narendran P, Marshall T, Coleman JJ. A prediction model for adverse outcome in hospitalized patients with diabetes. Diabetes Care. 2013 Nov;36(11):3566-72.

## Opportunities for Collaboration

We have strong links with the Health Informatics Directorate at University Hospital Birmingham and will expand on this through the Institute of Translational Medicine to excel in research and education.

**Research (Advice and Collaboration)**
We have four main research themes. Use of routine data for epidemiological research, use of routine data for health services research, methodological developments in the analysis of routine data and development of novel clinical decision support systems. Strong collaborations between University of Birmingham and UHB will lead to both collaborative research projects and capacity development through joint appointments and supervision of doctoral research students.

**Education**
University of Birmingham's prestigious Masters in Public Health programme runs a successful Health Informatics module in collaboration with colleagues from the UHB. This paves the way to create further postgraduate taught courses focusing on the analysis of routine secondary care and primary care data for service improvement and research.

**Links to clinical themes in the ITM**
A key clinical focus is in the management of chronic diseases in primary and secondary care. For example we enjoy strong links with UHB Diabetes Department.

## Selected Recent Publications


- Holt TA, Fitzmaurice DA, Marshall T, Fay M, Qureshi N, Dalton AR, Hobbs FD, Lasserson DS, Kearley K, Hislop J, Jin J. AUtomated Risk Assessment for Stroke in Atrial Fibrillation (AURAS-AF) - an automated software system to promote anticoagulation and reduce stroke risk: study protocol for a cluster randomised controlled trial. *Trials* 2013 Nov 13;14(1):385
- Nirantharakumar K, Hemming K, Narendran P, Marshall T, Coleman JJ. A prediction model for adverse outcome in hospitalized patients with diabetes. *Diabetes Care* 2013 Sep 11. doi: 10.2337/dc13-0452
- Wu J, Yao GL, Zhu S, Mohammed MA. Marshall T. Patient factors influencing the prescribing of lipid lowering drugs for primary prevention of cardiovascular disease in UK general practice: a national retrospective cohort study. *PLoS One* 2013 8(7): e67611.
- Mohammed MA, Marshall T, Nirantharakumar K, Stevens A, Fitzmaurice D. Patterns of warfarin use in subgroups of patients with atrial fibrillation: a cross-sectional analysis of 430 general practices in the United Kingdom. *PLoS One*. 2013 May 2;8(5):e61979.
- Nirantharakumar K, Marshall T, Hemming K, Narendran P, Coleman J.J. Electronic prescription data can identify 'lost' discharge codes for diabetes. *Diabetic Medicine*. 2012 Dec;29(12):e430-5.


# NIHR Horizon Scanning Centre (HSC)

## Overview of Research

The HSC is a NIHR funded research programme which aims to provide advance notice to the Department of Health (England) and key health service policy-making bodies of significant new and emerging technologies, up to three years prior to launch on the NHS that need:

- further evaluation,
- consideration of clinical and cost effectiveness,
- consideration of cost impact,
- consideration of implementation requirements, or
- modification of clinical guidelines

The remit of the HSC includes: pharmaceuticals, devices, diagnostic tests and procedures, surgical and other interventions, rehabilitation, public health and health promotion activities. We undertake this by scanning the development horizon for potentially significant technologies. Our scanning includes discussions with major pharmaceutical and medtech companies to discuss their research pipelines, and reading of commercial news. Technologies identified are then filtered according to possible time to licence/launch/availability, innovation and potential for impact on patients, services and costs. We provide brief information directly to NICE, NHS England (specialised services), the NIHR research programmes (HTA, EME, i4i) and the UK National Screening Programmes, as well as via our website and tweets to the wider NHS and the public.

### NIHR HSC

Team Lead:
Dr Claire Packer

Members
Dr Derek Ward
Professor Andrew Stevens

Twitter: @OfficialNHSC
Weblink : www.hsc.nihr.ac.uk

### Advisory Role

The NIHR HSC offers advice to teams who are contemplating undertaking horizon scanning of the development pathway.

The HSC has increasing links to new NIHR Health Technology Co-operatives (HTCs), one of which (Trauma) is situated in Birmingham. Dr Packer is Head of Secretariat to EuroScan International Network www.euroscan.org.uk and a member of the ethics and translational medicine group.

## Selected Recent Publications


- Packer C, Boddice B, Simpson S. Regenerative medicine techniques in cardiovascular disease: where is the horizon? Regenerative Medicine 2013:8(3):351-360.
- Ward DJ, Martino OI, Packer C, Simpson S, Stevens A. Burden of disease, research funding and innovation in the UK: do new health technologies reflected by research inputs and need? Journal of Health Services Research & Policy 2013:18(Suppl. 1):7-13. DOI: 10.1177/1355819613476015
- Ward DJ, Martino OI, Simpson S, Stevens A. Decline in new drug launches: myth or reality? Retrospective observational study using 30 years of data from the UK. BMJ Open 2013;3:e002088. doi:10.1136/bmjopen-2012-002088.
- Linden Phillips L, Bitner-Glindzicz M, Lench N, Steel KP, Langford C, Dawson SJ, Davis A, Simpson S, Packer C. The future role of genetic screening to detect newborns at risk of childhood-onset hearing loss. International Journal of Audiology 2012; Early Online: 1–10. DOI: 10.3109/14992027.2012.733424
- Packer C, Fung M, Stevens A. Analyzing 10 years of early awareness and alert activity in the United Kingdom. International Journal of Technology Assessment in Health Care 2012;28(3):308–314. doi:10.1017/S026646231200030X

# Ethics and Translational Medicine

## Overview of Research

Translational medicine (TM) aims to improve the health of individuals and populations by ensuring that the best possible evidence and results of clinical research relating to diagnostics, medicines, surgery, therapies, preventive techniques and policies are implemented into practice. Our team is already involved in a range of relevant research across primary and secondary care, as well as public health. Further information on our latest research can be found at:
http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PCCS/MESH/index.aspx

### Ethics and Translational Medicine Team

Team Leads:

Prof Angus Dawson

Prof Heather Draper

Dr Jonathan Ives

Examples of our research include the following:

**(a) Research to improve the patient experience within research**.

We have been conducting empirically grounded research exploring how to improve the way in which information about research is provided to potential research participants. For instance: we have developed an 'unfolding' electronic participant information sheet; we are looking into ways in which non-text based information can be provided to potential research participants; and we have a project underway that is looking at how research participants interpret information provided about patient reported outcomes (PROs) in participant information sheets with a view to improving participant understanding about PRO research.

**(b) Research into understanding practice and policy options.**

Empirical work to understand the issues relating to an area of medicine and possible options for and impediments to change. This work has been carried out with patients and professionals across a range of areas such as transplantation, reproduction, antenatal care and pandemic response. Understanding the context of care, and exploring different policy options, can provide the basis for improvements in implementation and delivery and so further the aims of TM.

**(c) Research exploring underlying principles and justifications.**

Philosophical methods such as analysis and argumentation can be used to explore the normative basis of any area of healthcare and thereby improve ethical conduct. For example, we have a track record in exploring the interaction between research methodology and ethics, developing ethical arguments about health promotion and vaccination, and the ethics of remote monitoring.

**(d) Research into aiding ethical decision-making.**

It is useful to articulate key values that inform actions in practice and policy. One common way to do this is to seek to outline a framework for ethical decision-making. Doing this can help non-ethicists to make ethical decisions. How any framework is to be structured is related to the purpose behind it, and so requires bespoke development.

### Case Study: Improving information for research participants

We have developed an 'unfolding' electronic information sheet that offers potential research participants initial basic information about the research they have been invited to participate in. Potential participants can then select specific areas (e.g. risks, benefits, payment) about which they would like more information, and within those areas can select increasing levels of detail until their information needs have been satisfied. During the development of this unfolding information sheet, we were able to collect information on those areas that most interested potential participants, average reading times for those areas and information as a whole. We are using this research to develop an electronic research information template that will be made freely available in the near future. This template will help researchers to provide information – including paper-based information – in a format that is more accessible to patients. This template has the potential to be further developed for use in providing information for patients about treatment options in the clinical environment.

## Opportunities for Collaboration

Our team can provide a range of services and advice including the following:

- Advice on the ethical aspects of research methods e.g. on how to resolve the tensions between ethical requirements and robust research design in a sensible, practical way, with a robust justification for the research ethics committee (REC).
- Where necessary we would also be willing to attend REC meetings to help to defend methods chosen from an ethical point of view.
- Advice on design/improvement of participant information sheets and consent methods and forms.
- Advice on designing and running patient and public involvement.
- Giving practical and grounded ethics 'fire fighting' advice to projects that are underway, with an on-call service.

Collaboration

Our research is marked by engagement with health care practice and collaboration. As suggested above, TM is characterised by many different ethical issues, and we would be keen to be involved in projects at an early stage to identify opportunities for in-grant or additional ethics research opportunities. The identification and elaboration of ethical issues in research projects would add value and distinctiveness to any project as a whole, and to the Birmingham ITM as an institution through the identification and writing up of interesting ethical aspects of activities across the Institute – adding further value to the reporting of results. We already work with other research teams across UoB and UHB and beyond, including: PRO Research Group, Health Economics, Maternal and Infant Health, End of Life etc.

Such collaboration might, for example, focus on substantive research in research ethics, or be based around understanding patients' and professionals' beliefs, or exploring impediments to the implementation of research at the clinical, practice or policy level.

Education

Our team has considerable and varied experience in clinical, public health and research ethics at local, national and international levels. We can provide lively and informative training in research ethics that identifies and explores the application of the basic principles of research ethics in practice (to complement GCP training, which is largely about processes and regulation). This provision runs all the way from a one hour session to an existing 20 M-level module on research ethics housed within the MPH programme and a 20 M-level module on 'Introduction to Bioethics' housed within the Masters of Primary Care. Such training can provide a valuable insider perspective on how to navigate the process of ethical review of research.

## Selected Recent Publications


- Kirkby H.M., Calvert M., McManus R.J., Draper H. (2013) Informing Potential Participants about Research: Observational Study with an Embedded Randomized Controlled Trial. *PLoS ONE* 8(10): e76435. doi:10.1371/journal.pone.0076435
- Kyte D., Draper H. and Calvert, M. Patient report outcome alerts: ethical and logistical considerations in clinical Trials. *Journal of the American Medical Association* 2013;310(12):1229-1230. doi:10.1001/jama.2013.277222.
- Sim, J. & Dawson, A. (2012) 'Informed consent and cluster randomized trials'. *American Journal of Public Health*, 102, 3: 480-5.
- Ives, J. Redwood, S. Damery S. (2012) PPI, Paradoxes and Plato: Who's sailing the ship? *Journal of Medical Ethics* 39(3):181-185
- Antoniou, E., Draper, H., Reed, K., Burls, A., Southwood, T. R., Zeegers, M. (2011) An empirical study on the preferred size of the participant information sheet in research. *Journal of Medical Ethics* 37(9); 557-562

# Primary Care Clinical Research Trials Unit (PC-CRTU)

## Overview

The Primary Care Clinical Research & Trials Unit (PC-CRTU) is one of 46 Registered Trials Units in the UK Clinical Research Collaboration (UKCRC). Eligibility to be part of this network requires units to demonstrate that they are capable of the following:

- Centrally co-ordinating multi-centre clinical trials and other well designed studies
- Taking overall responsibility for the design, conduct, data management, publicity and analysis of a trial in line with appropriate standards and regulations.

Professor Tom Walley , Director of the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Programmes announcing the 2012 registration results said *"The NIHR continues to recognise the important and crucial role played by Clinical Trials Units (CTUs) in helping to deliver quality research projects. This registration process confirms the international standard of quality of units in the UK and that units are capable of delivering the high -standard required"*.

PC-CRTU coordinates both large and small community-based clinical research and trials (selection, recruitment, training, randomisation, data management and data validation). The PC-CRTU has links across the region and throughout the UK, the PC-CRTU has access to more than 3000 GPs, in almost 700 practices across England and Wales, covering an estimated patient population of over four million. PC-CRTU works closely with the Primary Care Research Network – Central England (PCRN-CE)

The aims of the PC-CRTU are to:

- deliver high quality primary care-based research
- enable primary care research teams to participate in high quality research
- facilitate quality assurance in the execution of research in general practice

The PC-CRTU has been successfully conducting clinical trials since its inception as 'MidReC' in 1985 and has an excellent track record in designing, implementing, coordinating, monitoring, analysing studies and publishing the results from this research. It has strong links to Secondary Care Trusts and with local networks of Primary Care, Cancer, Mental Health, Medicine for Children, Stroke and the CLRN. PC-CRTU has been proactively building relationships with these new key organisations: CCGs, Academic Health Science Networks, Clinical Senates and Strategic Clinical Networks. The PC-CRTU has close links to several academic departments working on primary care-related studies on a local and national level. The PC-CRTU is collaborating with Birmingham Clinical Trials Unit (BCTU) and the Cancer Research UK Clinical Trials Unit (CRCTU) within the University to establish a Birmingham Centre for Clinical Trials (BCCT), to streamline clinical trials activity and share best practice.

Professor David Fitzmaurice took over as Head of Primary Care Clinical Sciences and as the Clinical Director of the Trials Unit, and our portfolio of research has continued to expand. At the close of 2012 the unit was actively involved with over 30 recruiting studies and various initiatives developed in preceding years came to fruition. These included the research nurses programme; where nurses are embedded in research active General Practices, and the GP Champions scheme. The Host Nurse scheme employs six nurses who are based in specific GP practices in Birmingham & Black Country and is overseen by a Nurse Lead. They work as research nurses, identifying and recruiting patients from their practices into studies. They also collaborate with the research teams at the University, assisting in design of electronic searches, study feasibility and notes reviews. The GP Champions initiative employs two part-time GPs to encourage the participation of GPs in research.

Looking ahead, our New Business Team is being kept very busy as many new trials come on board and we are always keen to expand our portfolio. The unit welcomes enquiries from local, national and international colleagues who may be interested in collaborative working.

## Clinical Trials Unit

The PC-CRTU offers a range of bespoke services including:

- Clinical Advice
- Statistics
- Diverse Methodologies
- Funding and Grant Proposals
- Randomisation ( Online and telephone)
- Trial Management
- Data Management
- Protocol Development
- Regulatory Requirements

Ethics submissions

- Pharmacovigilance
- Governance and Quality Assurance
- Training (GCP)
- Database and web design

Researchers are advised to consider all these bespoke services for their studies. We offer bespoke packages of support, tailored to the requirements of the Trial. The Clinical Trials Unit offers a full trial management service, for the design, implementation and coordination of trials. The CTU's expertise in working on CTIMP and Non CTIMP studies is apparent in the studies which are currently being managed by the Clinical Trials Unit. The ASPIRE and PRIMIT trials offer examples of the wide-ranging resources available and the ability the unit has to adapt to the differing requirements of individual studies.

## Primary Care Research Network for Central England (PCRN-CE)

The PCRN provides researchers and practitioners with practical support to deliver on clinical studies in an NHS primary care setting. This ensures that more research takes place across England, and more patients can participate. The network was established in Central England in late 2007 following a competitive award from the UKCRN. The PCRN-CE is one of eight research networks across England and has a hub and spoke model. The hub and one of the spokes is based at the University of Birmingham, with the other two spokes at the Universities of Keele and Warwick. Since the establishment of the PCRN-CE, the network has recruited over 127,000 participants into UKCRN-adopted Primary Care studies. For financial year 2012/13 the network recruited over 27,300 patients. In order to achieve these numbers the PCRN-CE works closely with the regional Comprehensive Local Research Network and their Topic Specific Specialities such as Stroke, Cancer, Medicines for Children, Mental Health and Diabetes Research Networks, and works closely with the regional Comprehensive Local Research Networks.

## PCRN-CE Birmingham & Black Country

The Clinical Lead, Network Manager, GP Champions, Host Nurses, Research Facilitators and Administrators work together to provide expert advice on recruitment within Primary Care. The PCRN-CE Birmingham & Black Country supports researchers to deliver study recruitment to time and target; to engage primary care sites; to identify, calculate and access NHS support costs; and to provide governance advice and signposting for NHS permissions. Furthermore, the network supports local primary care sites to access relevant training and relevant accreditation. In 2012/13 the PCRN-CE Birmingham & Black Country team supported 53 studies and this resulted in over 6,800 patients being recruited into these studies.

# Birmingham Clinical Trials Unit (BCTU)

## Overview of Research

The Birmingham Clinical Trials Unit (BCTU) is one of the three clinical trial units within the Birmingham Centre for Clinical Trials (BCCT) based at the University. BCTU specialises in late phase trials, evaluating the value of tests and treatments in hospital settings, and is a UK Clinical Research Collaboration (UKCRC) registered trials unit.

Established in 1997, BCTU has evolved into one of the largest clinical trials units in the UK. The Unit undertakes high quality clinical trials, diagnostic and test evaluation studies, systematic reviews and methodological research across a wide range of diseases in hospital settings. The Unit hosts the Birmingham Surgical Trials Consortium (BSTC), an initiative funded by the Royal College of Surgeons that brings together the activity and expertise in surgical trials across the three clinical trials units.

## BCTU's mission statement:

**BCTU-designing and delivering definitive trials of tests and treatments for patients and the health service**

BCTU has the scientific, administrative, computing and statistical expertise needed to support clinical research from conception through to completion, following all the necessary regulatory requirements. The unit is currently co-ordinating over 30 randomised trials, diagnostic and test evaluation studies in obstetrics and gynaecology, neurodegenerative diseases, coloproctology, surgery, renal disease, burns, trauma and critical care. These studies are mainly funded through the National Institute for Health Research funding streams – Health Technology Assessment (HTA), Efficacy and Mechanism Evaluation (EME) and Research for Patient Benefit (RfPB) programmes.

The Unit has strong collaborative links with the other two clinical trials units at the University (Cancer Research UK CTU and Primary Care Clinical Research Trials Unit). We also frequently collaborate with other groups within the School of Health and Population Sciences, for example with the Health Economics Unit for economic evaluations alongside trials or with the Evidence Synthesis Group for reviews to inform and support BCTU studies. More recently, we have worked with the Qualitative Research Team in bringing acceptability questions into all stages of our clinical trials, and are developing core outcome sets with the PRO Research Group.

The unit is directed by Professor Jon Deeks, and has over 50 staff including trial managers, statisticians, IT programmers, systematic reviewers and administrative staff.

## BCTU Team Leads:

Professor Jon Deeks
Director

Dr Jane Daniels
Deputy Director

Miss Natalie Ives
Assistant Director &
Statistics Lead

Dr Margaret Grant
Operations Director

### Core Group includes:

Elizabeth Brettell
Laura Magill
Nicholas Hilken
Lee Middleton
Amanda Knight
Caroline Rick

## Opportunities for Collaboration

BCTU's remit is to support non-cancer research in the secondary care setting. BCTU has the expertise and computing facilities required to co-ordinate multi-centre and multi-national clinical studies, with particular expertise in:

- Late phase (III/IV) randomised trials, diagnostic and test evaluation studies
- Study design, including sample size calculations
- Protocol development and case report form design
- Research costs and funding applications
- Gaining ethical and regulatory approval
- Randomisation procedures
- Strategies for patient recruitment
- Study co-ordination and data management
- Database design and computerised data management systems
- Statistical analysis and reporting

The unit provides an open access collaboration and advice service covering all aspects of study design, management and analysis. We can work with investigators to develop their ideas into clinical studies by providing advice on the appropriate study methodology, and then work together to deliver the study. More information on the Collaboration and Advice service and how to access this is available at the BCTU website (www.birmingham.ac.uk/bctu)

## Research Training

BCTU runs a 3 day CPD approved course in research methods for clinical trials designed to help researchers apply the most effective practical methods to answer key problems in clinical and other health care. The course is designed to appeal to a broad audience ranging from those who have little experience in clinical trials to those who wish to widen their knowledge of the conduct of such trials. The course is currently running three times a year.

## Case Study

Pulse Oximetry screening for congenital heart defects in newborn infants – the PulseOx study

Critical congenital heart defects (CCHDs) are a significant cause of morbidity and mortality in newborn babies. Screening for CCHDs relies on antenatal ultrasound and postnatal examination; both have a relatively low detection rate and up to 30% of babies are discharged with undiagnosed CCHDs . Some will die or present with collapse, which compromises outcome. Pulse oximetry is a rapid, safe, non-invasive, painless method of measuring blood oxygen levels, which are low in the majority of CCHD.

A meta-analysis of existing pulse oximetry screening studies showed the test was highly specific for detection of CCHDs, but a large prospective study was required to assess its sensitivity with greater precision. The PulseOx study (funded by the NIHR HTA), led by Dr Andy Ewer and working with the BCTU, screened 20,000 newborns from seven hospitals in the West Midlands and collected all diagnoses. The study showed that the addition of pulse oximetry screening resulted in 92% of CCHD being detected, and also demonstrated that screening was cost-effective, acceptable to parents and staff.

The results of PulseOx were published in the Lancet, and have directly contributed to a shift in international opinion on the benefits of screening. The US Health Secretary recommended the addition of pulse oximetry to the newborn screen, with our study being fundamental to that decision. The UK National Screening Committee updated its policy in May 2014 to recommend piloting pulse oximetry screening within the newborn screening programme countrywide, whilst the hospitals that participated in the study continue to screen their babies.

*References*


- Thangaratinam S, Daniels J, Ewer AK, Zamora J, Khan KS. Accuracy of pulse oximetry in screening for congenital heart disease in asymptomatic newborns: a systematic review. Arch Dis Child Fetal Neonatal Ed. 2007;92(3):F176-80.
- Ewer AE, Middleton LJ, Furmston AT, Bhoyer A, Daniels JP, Thangaratinam S, Deeks JJ, Khan KS, on behalf of the PulseOx Study Group. Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study. Lancet 2011;378(9793):785-794.

## Selected Recent Publications


- PD MED Collaborative Group (Writing committee: Gray R, Ives N, Rick C, Patel S, Gray A, Jenkinson C, McIntosh E, Wheatley K, Williams A, Clarke C). Long-term effectiveness of dopamine agonists and monoamine oxidase B inhibitors compared with levodopa as initial treatment for Parkinson's disease (PD MED): a large, open-label, pragmatic randomised trial. The Lancet 2014 [epub ahead of print]
- Gupta J, Kai J, Middleton L, Pattison H, Gray R, Daniels JP for the ECLIPSE Trial Collaborative Group. Levonorgestrel intrauterine system versus medical therapy for menorrhagia. New England Journal of Medicine 2013;368:128-137.
- Kenyon S, Armstrong N, Johnston T, Walkinshaw S, Petrou S, Howman A, Cheed V, Markham C, McNicol S, Willars J, Waugh J, on behalf of the HOLDS Collaborative Group. Standard- or high-dose oxytocin for nulliparous women with confirmed delay in labour: quantitative and qualitative results from a pilot randomised controlled trial. British Journal of Obstetrics & Gynecology 2013;120(11):1403-12.
- Senapati A, Gray RG, Middleton LJ, Harding J, Hills RK, Armitage NC, Buckley L, Northover JM; The PROSPER Collaborative Group. PROSPER: a randomised comparison of surgical treatments for rectal prolapse. Colorectal Disease 2013;15(7):858-868.
- Morris RK, Malin GL, Quinlan-Jones E, Middleton LJ, Hemming K, Burke D, Daniels JP, Khan KS, Deeks J, Kilby MD. Percutaneous vesicoamniotic shunting versus conservative management for fetal lower urinary tract obstruction (PLUTO): A randomised trial. The Lancet 2013;382(9903):1496-1506.
- Foxtrot Collaborative Group. Feasibility of preoperative chemotherapy for locally advanced, operable colon cancer: the pilot phase of a randomised controlled trial. Lancet Oncology 2012;13(11):1152-60.
- Ewer AE, Middleton LJ, Furmston AT, Bhoyer A, Daniels JP, Thangaratinam S, Deeks JJ, Khan KS, on behalf of the PulseOx Study Group. Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study. Lancet 2011;378(9793):785-794.

# Clinical Research

There is research into a number of clinical areas within the School of Health and Population Sciences:

- **Cardiovascular Disease**
  There are research interests in prevention of cardiovascular disease in primary care led by Professor Tom Marshall. There is active research into heart failure, with Dr Clare Taylor investigating the diagnosis and prognosis of heart failure and Dr Paramjit Gill investigating heart failure in minority ethnic groups. Professor Kate Jolly has an interest in behavioural change in relation to cardiovascular prevention and also in cardiac rehabilitation for patients with heart disease and in particular with heart failure.
- **Palliative Care**
  Through the ICECAP programme of research the Department of Health Economics has an interest in the assessment of quality of life at the end of life. This is led by Professor Joanne Coast.
- **Anticoagulation**
  Professor David Fitzmaurice has a longstanding interest in thrombosis and haemostasis. He has particular interests in the prevention of venous thromboembolic disease, the use of anticoagulants in atrial fibrillation and the management of anticoagulants in primary care.
- **Obesity**
  Professor Peymane Adab leads a programme of research into the prevention of childhood obesity in the UK and in China, and is running a cluster randomised controlled trial to assess the clinical and cost-effectiveness of an intervention to prevent childhood obesity in a multi-ethnic population. Dr Amanda Daley and Professor Kate Jolly are undertaking projects on obesity and weight management in adults.
- **Chronic Obstructive Pulmonary Disease (COPD)**
  Professor Peymane Adab, Professor David Fitzmaurice, Professor Jon Ayres and Dr Rachel Jordan lead a programme of research into COPD: Birmingham Lung Improvement Studies (BLISS). This includes a trial to compare the clinical and cost-effectiveness of two approaches to case-finding for undiagnosed COPD in Primary care, and the development of a unique primary care COPD cohort (~2300 individuals) to examine the prognosis of COPD.
- **Guanzhou Biobank Cohort Study**
  Professor KK Cheng leads a large programme of research into the genetic, environmental and behavioural determinants of a range of chronic diseases in South China, through the Guanzhou Biobank Cohort Study.
- **Centre for Childhood Cancer Survivors Studies**
  Professor Mike Hawkins is the director of the Centre for Childhood Cancer Survivors Studies and leads a programme of research into the long term outcomes in survivors of childhood cancer.
- **Maternal and Child Health**
  Professor Christine MacArthur has led a number of research projects evaluating maternity care services and investigating various maternal health topics such as the effects of epidural analgesia and postnatal incontinence. She continues to work on maternal health through CLAHRC-WM.
- **Mental Health**
  Dr Liz England's work is focussed around the development and implementation of primary care mental health and mental health policy. Dr England leads a programme of work entitled "PARTNERS2: development and pilot trial of primary care based collaborative care for people with serious mental illness".
- **West Midlands Collaboration for Leadership in Applied Health Research and Care (CLAHRC-WM)**
  CLAHRC-WM is a five-year programme of applied health research led from University of Birmingham in collaboration with University of Warwick and University of Keele. It links academic centres to the regional NHS and public health departments of local authorities and is primarily concerned with evaluation of service change. There are four main clinical themes in CLAHRC-WM: Maternal and Child Health, Youth Mental Health, Prevention and Detection and Chronic Disease. Within the Maternal and Child Health theme led by Professor Christine MacArthur there is a specific focus on maternal health services, led by Dr Sara Kenyon who enjoys close links with Birmingham Women's Hospital and children's health services led by Dr Carole Cummins in collaboration with Birmingham Children's Hospital. Linked to this, Dr Lavanya Diwakar is researching the economics of paediatric allergy services. Within the Prevention and Detection theme Professor Tom Marshall focuses on case-finding of chronic diseases and Professor Kate Jolly on behavioural change.

# Institute of Occupational and Environmental Medicine (IOEM)

## Overview

Our research programmes cover two broad areas of work:

- Work and Health
  - the effects of work on health (e.g. occupational causes of asthma).
  - the effect of health on work (e.g. the effect of COPD on work effectiveness –the BLISS programme).
- Environment and Health
  - e.g. the effects of biomass burning on respiratory disease in developing countries.

Occupational and environmental health research is truly multi-disciplinary and, while we attract stand-alone major grants, we frequently contribute specific skills to multi-institutional/multi-disciplinary projects. Studying interventions in the workplace and in environmental settings where many factors are uncontrollable provide specific challenges which are not present in conventional clinical trials. Approaches to these problems are developing and we are working on methodological developments in both the occupational and environmental settings.

**Examples of our research include the following:**

1] Understanding and measuring (rather than guessing) exposures to environmental or occupational hazards is critical in defining dose response relationships and thus appropriate targets for control of exposures. Technology is advancing at such a pace (for example the development of small, cheap monitors, use of new sensor technology and mobile phone technology, new approaches to time series analysis) that in the near future there will be a real likelihood of large epidemiological studies being able to incorporate accurate measures of exposure for the first time.

2] In conventional clinical trials the intervention/treatment and the patient are the two main variables but when considering interventions in the workplace, other agencies are critical especially the employer and employee representation (e.g. trade union). In addition, the role of the GP is not always in good linkage with that of the Occupational Physician so work related health impacts often pass unrecognised in primary care (e.g. our work in occupational asthma). In many cases this means that where a workplace intervention an RCT approach is not feasible and so different approaches need to be considered.

3] Globally, environmental exposures are a major cause of ill health, for example, the effect of indoor air pollution from biomass burning in the developing world. Defining the burden from these exposures is difficult as are interventions studies as populations are often remote and widespread so we are developing a novel descriptive, toxicological/epidemiological approach to intervention studies.

4] The importance of quantifying the contribution of occupational or environmental exposures to ill health is to help define policy at a national or institutional basis to define interventions that will reduce the impact of these exposures on health. We have contributed to the development of national guidance and policy development in both these areas for many years.

## IOEM

### Team Leads:

Professor Jon Ayres

Dr Steve Sadhra

Dr Hubert Lam

## Case Study:

Cigarette smoking is the major cause of chronic obstructive pulmonary disease (COPD). However, it has been estimated that around 15% of the health burden from COPD, the only chronic disease whose prevalence is rising worldwide, is due to occupation. Defining the contribution from different occupations (notably those where exposure to dusts, gases and fumes is significant) is difficult as exposure assessment is retrospective, as at the time of diagnosis the important exposures are likely to be historical. The best approach to quantifying this impact is to create a job exposure matrix (JEM) whereby all historical jobs are defined, relevant exposures identified and quantified and a summary risk assessment made. Once a JEM has been characterised using a (usually single country based) database, this can be used in other workforces to define and quantify the degree of exposure and hence its impact on health. There are no completely adequate JEMs for COPD. We are taking the lead, in conjunction with Imperial College and the Health and Safety Laboratories, to develop a universal JEM for COPD which can be modified for use in other countries. Initially we are using the UK Biobank dataset to quantify for the first time in a general population the effect of occupation on COPD but plan to use this in a cohort from China and in two other UK based populations.

## Opportunities for Collaboration

We have strong links with the Life and Environmental Sciences in the University and also with the department of respiratory medicine at University Hospital, Birmingham.

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**Research (Advice and Collaboration)**

We have two main research themes, work and health and environment and health. We can provide advice on assessing both environmental and occupational exposures and also how best to deal with work or environmental factors either as direct or confounding influences in epidemiological studies and in clinical trials where these important factors are usually ignored. We have expertise in time series analysis and in study design for workplace interventions.

Our collaborations with UHB will lead to both collaborative research projects and potentially capacity development through joint appointments and supervision of doctoral research students.

**Education**

Our postgraduate teaching in occupational health is amongst the best in the UK and we have the capacity to link with our clinical colleagues at UHB in small Master's projects in any clinical area where work is or may be an issue.

**Links to clinical themes in the ITM**

We are keen on identifying and quantifying the work component of chronic conditions in primary and secondary care (e.g. COPD/asthma, orthopaedic problems, mental health). For example, our work in under-recognition of occupational asthma in primary care has identified the need for a nationwide intervention study. We are also developing a triangular approach to inhaled environmental hazards by quantifying exposure and assessing exposure toxicity in epidemiological studies. We are linking with respiratory medicine in this area already but have the potential to develop this in other areas.

# Nursing

## Overview

The aim of the Institute for Translational Medicine (ITM) is to improve the health of individuals and populations by serving as a collaborative vehicle to ensure the best possible evidence and results of clinical research and policies are implemented in practice. If this is to occur and discoveries from research are to be applied rapidly to benefit patients, staff engagement and involvement with the process of translation is vital. Given that nurses constitute the single largest group of staff in the National Health Service understanding and harnessing their contribution to the conduct and implementation of research is crucial. Our team is involved in a range of activities in health care and nursing which is centred on conducting patient focussed research and making changes based on the findings in partnership with clinical colleagues. This newly formed research group has the potential to foster implementation of research findings to improve patient care. Examples of our research include the following:

### End of Life Care

Decision making in end of life care. The process of decision making at a number of levels provides a research focus for our work in this area. Investigation of the factors that shape decisions about end of life care in a range of settings is vital if care for patients is to improve. For example political decisions determine the context of end of life care and require critique and investigation; clinical decision making governing the patient and family experience needs to be understood and informed with evidence; and identifying the organisational approaches that are most effective in managing the complex process of decision making in end of life care is essential. Members of the team are engaged in research in acute and hospice settings. Recent projects include evaluations of the implementation of the Gold Standards Framework for End of Life Care in Care Homes; An investigation of the experiences of patients with lung cancer and chronic pulmonary obstructive disease during emergency admission to hospital; and a study of service redesign of end of life care in acute hospitals.

### The Context of Care

A strand of work of the nursing team is examining the context of care and the factors that influence the provision of compassionate care for patients. This area of work can be developed into a broader programme of study investigating the culture of health care organisations, particularly with regard to the process of change arising from the emergence of new evidence. Current projects include: a collaboration with Birmingham Community Healthcare NHS Trust and Heart of England NHS Foundation Trust to investigate the organisational support nurses need to provide high quality care; an investigation of whether nurse expertise in epilepsy and intellectual difficulties, working to a defined competency-based clinical role can improve clinical outcomes; and a number of educational projects examining how best to prepare students for practice in end of life care.

### Nursing Research

Team Leads:

Dr Alistair Hewison

Prof Fiona Irvine

Members

Dr Cara Bailey

Dr Nikos Efstathiou

Dr Amelia Swift

## Case Study

Emergency Admission to Hospital at the End of Life

A study was conducted to investigate the admission of patients with lung cancer and chronic obstructive pulmonary disease when admitted to the emergency department (ED). The accounts of the patients' families and the professionals who cared for them were also examined. It was found that Patients attending the ED were initially on a 'spectacular trajectory', and then shifted to a 'subtacular' one once in the 'recovery phase'. On the subtacular trajectory there was a lack of attention to the continuing complex needs of the patients. This is not to suggest a simplistic interpretation of the spectacular as good and the subtacular as bad. Rather to highlight that those patients on the subtacular trajectory had care needs that were complex and long-term, requiring co-ordinated care during their hospital stay and subsequent discharge home. In contrast the spectacular has a more linear, algorithmic approach with goals of care that are immediate, and focused predominantly on treatment and cure, which was more familiar to the staff in the ED.

The 'two phase' nature of the admission has implications for practice. The framework developed in the research, contrasting the spectacular and subtacular trajectories of care, provides a useful schema for reviewing and evaluating care. Considering the differing care needs evident in the two trajectories highlights the competing care demands of these patients and how they change over time. This is beneficial in conveying the complex nature of care required by patients with advanced lung cancer and COPD. Discussion of care needs in the context of the trajectories of care will assist policymakers, educationalists and healthcare professionals in providing a fresh perspective on a familiar challenge.

Bailey C Hewison A Karasouli E Staniszewska S Griffiths F Munday D (2014) From the spectacular to the subtacular; experience of hospital care for patients with advanced respiratory illness following emergency admission. 8th World Congress of the European Congress for Palliative Care, Lleida, Spain, 5th-7th June 2014.

## Opportunities for Collaboration

Advice

Our team can provide a range of services and advice including the following:

- Advice on research methods, particularly qualitative methods.
- Advice and guidance concerning researching vulnerable groups, including those at the end of life, and useful strategies and methods that can be used.
- Good practice in service user involvement in research design
- Accessing key nursing staff in a range of organisations

Education

All members of the nursing team are skilled and experienced educators. We deliver an NIHR funded MRes programme which equips nurses and allied health professionals to develop research knowledge and skills. It consists of a range of research focussed modules that can be accessed on a 'standalone' basis to provide students with specific methodological and project management education. In addition we provide a number of PG Taught modules in health related areas including pain assessment, emergency medicine and health care management. The undergraduate nursing programme is informed by our research, and students are prepared to base their practice on evidence.

The nursing team is engaged in active collaboration with colleagues from a range of academic departments and clinical practice settings. For example a member of the team is working with the Health Economics Department on an EU funded project investigating the economics of end of life care; another is working in partnership with the Health Services Management Centre to investigate the quality of nursing care. A number of external collaborations are also in progress including with the University of Warwick, Cambridge University and King's College London. In terms of clinical partners we have active research links with the Marie Curie Hospice Solihull, St Mary's Hospice Birmingham and with the Queen Elizabeth Hospital NHS Foundation Trust and Heart of England NHS Foundation Trust.

## Selected Recent Publications


- Badger F, Plumridge G, Hewison A, Shaw K L, Thomas K. and Clifford C. (2012) An evaluation of the impact of the Gold Standards Framework on collaboration in end-of-life care in nursing homes. A qualitative and quantitative evaluation. International Journal of Nursing Studies 49 (5), 586-595.
- Badger FJ, Shaw KL, Hewison A, Clifford C, Thomas K. (2010). Gold Standards Framework in Care Homes and advance care planning, Palliative Medicine, 24, 4, 447-448.
- Bailey, C., Murphy, R., Porock, D. (2011) Dying cases in emergency places: caring for the dying in emergency departments. Social science & medicine, 73: 1371-1377.
- Hewison A, Lord L and Bailey C (2014) 'It's been quite a challenge'-Redesigning End of Life Care in Acute hospitals. Palliative and Supportive Care-doi:10.1017/S1478951514000170.
- Munday D, Karasouli E, Staniszewska S, Griffiths F, Clerici J, Hewison A, Bailey C, Badger F and Clifford C (2013) Exploring Understanding and Reducing Emergency Cancer Admissions (EURECA). University of Warwick, University of Birmingham, Macmillan Cancer Support, Warwick/Birmingham.


# Postgraduate Programmes

## Higher Degrees by Research

In the School of Health & Population Sciences we offer our postgraduate researchers a unique opportunity to learn and develop in a dynamic and diverse environment, working alongside leading academics at the forefront of clinical and non-clinical research.

Our main research programmes are in the fields of primary care, public health and epidemiology, clinical trials, health technology assessment, health economics, outcomes research, occupational and environmental medicine, biostatistics, health services research and nursing. At present we have a total of 120 postgraduate researchers in the School. All students who register with us have access to a range of training opportunities, including IT, presentation skills, training in statistics and other relevant research methods. Students are encouraged to attend School seminars and College events.

The School high success rates in securing NIHR and MRC funded doctoral studentships and welcomes collaboration in applying for industrial case studentships and clinical training fellowships.

Potential students can contact the School of Health and Population Sciences Director of Graduate Studies, Dr Raoul Reulen (r.c.reulen@bham.ac.uk), for further information.

**Dr Raoul Reulen**
School of Health and Population Sciences

# Teaching and Learning
# Postgraduate Teaching (PGT)

## Overview of Postgraduate Programmes

The school takes pride in having the two most popular Masters course in the college namely the Masters in Public Health (MPH) and Masters in Health Economics (MSc Health Economics).
MPH has as many as 23 modules to offer most of which are also accessible as standalone courses. For more details on the courses please visit our website and click on the relevant programme.

We are keen to support development of new educational programmes that can address the gaps in skills and staff competency of those working in the NHS and affiliated organisations.

### Case Studies

The MSc in Health Economics and Econometrics is an entirely new programme hosted by the Health Economics Unit in collaboration with the Department of Economics. This new programme incorporates two core modules provided by the Department of Economics (Microeconomics, Econometrics) and three core modules from the MSc Health Economics and Health Policy Programme (Economic Evaluation, Statistics II, Modelling for Health Economics) and one relevant policy based optional module.

The purpose is to enable you to be fully equipped to utilise, analyse and interpret the big data sets that are increasingly available across health systems in addition to understanding these in the context of health and economic related issues and policy. This programme is designed to build on the strength and experience of both the Department of Economics and the Health Economics Unit in providing high quality Masters programmes.

This programme provides a contrast to the current MSc Health Economics and Health Policy programme by providing a greater focus on the underpinning advanced economic theory and econometrics for those students with excellent undergraduate degrees in economics. However it retains the provision of the key skills associated with the conduct of economic evaluation, modelling as well as an exposure to economic policy (expected in many health economic posts).

PGT Lead

Dr Krish Nirantharakumar, Senior Clinical Lecturer

URL:
http://www.birmingham.ac.uk/schools/haps/postgraduate/index.aspx

Members

**Masters in Clinical Primary and Community Care**

- Dr Ellen Murray

**Masters in Public Health (MPH)**

- Dr Krish Nirantharakumar

**Masters in Health Economics and Health Policy**
**Masters in Health Economics and Econometrics**

- Dr Pelham Barton

**Masters in Occupational Health**

- Dr Steven Sadhra

**MRes**

- Nikolaos Efstathiou (for Nurses and Midwives)
- Dr David Punt (for Allied Health Professionals)

**Physician Associate Studies PGDip**

- Prof. Jim Parle

# Continuing Professional Development (CPD)

**CPD Lead:**
Dr Ellen Murray
0121 414 2677 / e.t.murray@bham.ac.uk

## Primary Care MSc accredited courses

- Anticoagulation Management in Primary Care Management of Heart Failure in primary care
- Management of Hypertension in primary care
- Atrial Fibrillation Management and Stroke Prevention
- Management of Gynaecology in the Community
- Mental Health Care in the Community

## Continuing Professional Development Courses (not currently part of the MSc)

- Anticoagulation management for health care assistants
- Understanding Haematology tests – when to refer
- An Introduction to Anticoagulation Management
- Liver disease in primary care
- Management of DVT and Pulmonary Embolism within primary care
- Management and Diagnosis of Headache disorders in primary care
- Anticoagulation Management Update Day

**Programme Administrators:**

Tamara Ball t.c.ball@bham.ac.uk
Amy Partleton a.partleton@bham.ac.uk

More details about these modules can be found at
http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PCCS/anticoagulation/courses/index.aspx

## MSc in Health Economics and Health Policy

- Introduction to Health Economics
- Economic Evaluation in Healthcare
- Policy and Economics of Healthcare Delivery
  Modelling for Health Economics

**Programme Administrator:**

healtheconomics@contacts.bham.ac.uk

More details about these modules can be found at
http://www.birmingham.ac.uk/postgraduate/courses/taught/med/health-economics-policy.aspx

## Public Health MPH

- Epidemiology, Statistics and Research Methods
- Practical Epidemiology & Statistics
- Health Information and Informatics
- Principles of HTA
- Introduction to Leadership and Management in Health
- Public Health in low/middle income countries
- Sociology and Social Policy
- Health Protection 1
- Healthcare Evaluation and Commissioning
- Health Promotion
- Health Economics
- Research Ethics
- Public Health Ethics
- Systematic Reviews and Evidence Synthesis
- Clinical Trials
- Oral Health and Dental Services
- Further Public Health in low/middle income countries
- Advanced Statistical Methods
- Qualitative Research Methods
- International Health Protection
- Health Protection 2

**Programme Administrator:**
mph@contacts.bham.ac.uk

More details about these modules can be found on the MPH website
http://www.birmingham.ac.uk/university/colleges/mds/postgraduate/public-health-mph.aspx

## IOEM

**MSc/Diploma**

In addition to our MSc in occupational health we also co-deliver a Master's course in occupational health, safety and the environment. This joint programme recognises the increasing demand from both industry and enforcement bodies to integrate occupational health, safety and environmental management issues. On completion of this course you will be in a position to identify, evaluate and provide solutions to a wide range of hazards and risks to be found in industry, commerce, marine and agricultural situations. It is accredited by the Institute of Occupational Safety and Health and the Institute of Acoustics (Environmental Noise module).
We also offer short (3 day) courses as follows:

- Introduction to CBT for Occupational Health Professionals
- Occupational Mental Health
- Practical Workplace Ergonomics

## Additional Courses

- Mini Medical School
- Birmingham Medical School Christmas & Easter lectures

UNIVERSITY OF BIRMINGHAM

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