

PERSONAL INFORMATION

Deborah Ashby

WORK EXPERIENCE

October 2008–Present

Co-Director of Imperial Clinical Trials Unit and Professor of Medical Statistics

Imperial College London, (United Kingdom)

I have been appointed co-Director with Professor Neil Poulter of Imperial Clinical Trials Unit which we jointly set up. I am maintaining and developing a programme of clinical trials collaboratively with clinical colleagues; and lead a methodological programme of research on the role of formal statistical approaches to risk-benefit decision-making in drug regulation.

September 1997–October 2008

Professor of Medical Statistics

Barts and the London School of Medicine and Dentistry, Queen Mary, University of London, (United Kingdom)

September 1987–September 1997

Lecturer (1987-1992) / Senior Lecturer (1992 -1995) / Reader in Medical Statistics (1995-1997)

University of Liverpool, (United Kingdom)

September 1983–September 1986

Research Fellow / Honorary Lecturer in Medical Statistics

Royal Free Hospital School of Medicine, University of London, (United Kingdom)

EDUCATION AND TRAINING

September 1981–June 1983

PhD in Medical Statistics

Royal Free Hospital School of Medicine, University of London , (United Kingdom)

Completed thesis on 'A statistical investigation of the relationship of serum biochemistry and haematology to alcohol consumption' (supervisor Prof SJ Pocock).

September 1980–June 1981

MSc in Medical Statistics

London School of Hygiene and Tropical Medicine, University of London , (United Kingdom)

September 1977–June 1980

BSc (Hons) in Mathematics (First Class)

University of Exeter , (United Kingdom)

ADDITIONAL INFORMATION

Expertise

My research has encompassed clinical trials, systematic reviews, safety of medicines, and the utility of Bayesian statistical approaches in these areas, motivated by the desire to address substantive and important health problems, using the most appropriate methodologies. Clinical areas are wide-ranging but include longstanding interests in cardiovascular disease and diabetes, chronic pain, mental health and cystic fibrosis. I have extensive experience of clinical trials, as investigator, on steering groups and data monitoring committees, as well as a wider perspective from serving on an ethics committee and in drug regulation. My methodological interests in clinical trials have stemmed from these practical experiences, and include design of studies, especially cluster-randomised trials, data-monitoring, safety of medicines and statistical underpinnings of evidence-based medicine more generally.

I have been appointed to the Commission on Human Medicines, regularly advise the European Medicines Agency, have sat on many grants committees for NIHR and MRC and have served on editorial boards of many journals and as statistical editor for the Cochrane Cystic Fibrosis and Genetics Disorders Group and the BMJ. I am often asked by groups such as PSI (Statisticians in the Pharmaceutical Industry) and the Young Statisticians Meeting to give expository talks and courses on

recent methodological developments, and have been involved in a variety of courses for health professionals and, other professionals including journalists.

I have provided leadership both for those working directly with me and informally for statisticians working in other groups. Previous junior colleagues and PhD students now hold senior positions, including chairs of medical statistics and directorships of clinical trials units; others of my PhD/ MD students have gone on to careers involving clinical trials in both academic and pharmaceutical environments. Through my role on the CHM, I have also provided informal leadership through regular meetings, as the team of statisticians at the Medicines Healthcare and Regulatory Products Agency evolved from one statistician to a team that is now probably the strongest in the European Union. I have provided leadership to the statistical community through serving the Royal Statistical Society as Council Member and as Senior Honorary Secretary, in which role I oversaw major changes which modernised the structure and functioning of the Council. I have chaired the RSS Long-term Strategy group and am advisor to the NIHR on capacity building for statistics, clinical trials and economics.

Publications Selection of Peer Reviewed Articles

Lamb SE, Gates S, Williams MA, Williamson EM, Mt-Isa S, Withers EJ, Castelnovo E, Smith J, Ashby D, Cooke MW, Petrou S, Underwood MR; on behalf of the Managing Injuries of the Neck Trial (MINT) Study Team. (2012) Emergency department treatments and physiotherapy for acute whiplash: a pragmatic two-step randomized controlled trial. *Lancet*. 2012 Dec 18. doi:pii: S0140-6736(12)61304-X. 10.1016/S0140-6736(12)61304-X.

Lamb SE, Williams MA, Williamson EM, Gates S, Withers EJ, Mt-Isa S, Ashby D, Castelnovo E, Underwood M, Cooke MW; MINT Trial Group. (2012) Managing Injuries of the Neck Trial (MINT): a randomized controlled trial of treatments for whiplash injuries. *Health Technol Assess*. 2012;16(49):iii-iv, 1-141. doi: 10.3310/hta16490.

Gordon A C, Wang N, Walley K R, Ashby D, Russell J A (2012) The cardio-pulmonary effects of Vasopressin compared to Norepinephrine in septic shock. *Chest* Published online before print April 19, 2012, doi: 10.1378/chest.11-2604

Cheng K, Ashby D, Smyth R.L., (2011), Oral steroids for long-term use in cystic fibrosis. *Cochrane Database Syst Rev*, (10), CD000407. Doi:10.1002/14651858.CD000407.pub2

Selection of Invited Editorial, Review and Discussion

Mt-Isa S, Tzoulaki I, Callréus T, Micaleff A, Ashby D. Weighing benefit-risk of medicines: concepts and approaches (2011) *J. DDT Tech*.

Ashby D. Commentary. (2008) *Int Psychogeriatr* 6;1-2.

Ashby D. (2008) Establishing Causality in the Assessment of Safety of Medicines for Children (Review) *Acta Paediatrica* 97:1611-1616

Ashby D. (2008) Discussion of Kaduszkiewicz H., van den Bussche H., Zimmermann T.; Is the evidence for the efficacy of cholinesterase inhibitors in the symptomatic treatment of Alzheimer's disease convincing or not? *International Psychogeriatrics* 20: 286-88

Selection of Books and Edited Works

Papers from the International Society for Clinical Biostatistics, 2003.(2004) Ed. Ashby D. *Statistics in Medicine*, 23, 3725-3880

Bayesian methods with applications to science, policy and official statistics. Eds: George I.E. Ashby D., Bayarri M.J., Carlin P., Carriquiry L., Clyde A.M., Cohen M.L., Datta G.S., Defays D., Dellaportas P., Evans J., Fienberg S.E., Gelfand A.E., Geweke J., Pericchi L.R., Steel F.J.M. and Vlachos K.P.Eurostat (Statistical Office of the European Commission). Luxembourg. (2001).

Eldridge S. and Ashby D. (2000) *Statistical Concepts*. Eds: Carter Y., Shaw S. and Thomas C. Royal College of General Practitioners. London. Master Classes in Primary Care Research No 3.[highly commended in Primary Care category of BMA Book of the Year competition 2000].

Selection of Book Chapters

Ashby D. (2004) Bayesian Methods in Clinical Trials. In *Encyclopedia of Biostatistics*. Eds: Armitage P and Colton T. John Wiley and Sons Ltd.

Fayers P.M., Ashby D and Parmar M. (2004) Bayesian Data Monitoring in Clinical Trials. In *Tutorials in Biostatistics, Vol 1 Statistical Methods in Clinical Trials*, Ed D'Agostino R.B. John Wiley and Sons Ltd.

Ashby D. (2001) Bayesian Methods. In *Biostatistics in Clinical Trials*. Eds: Redmond C. and Colton T. John Wiley and Sons Ltd.

Selection of Reports

Best N, Ashby D, Dunstan F, Foreman D, McIntosh N (2013) A Bayesian approach to complex clinical diagnoses: a case-study in child abuse. *J. R. Statist. Soc. A* 176, Part 1, pp. 53–96

Report of the Academy of Medical Sciences (2011) “A new pathway for the regulation and governance of health research”

Report of the Committee on Safety of Medicines Expert Working Group (2004) Safety of Selective Serotonin Reuptake Inhibitor Antidepressants

Selection of Discussion and Correspondence

Ashby D, Bird SM, Hunt I, Grant R, King T, Atkinson AC, Riani M, Gandy A, Kvaloy JT, Caan W, Eames M, Arjas E, Boehning D, Campbell MJ, Jacques RM, Fotheringham J, Maheswaran R, Nicholl J, Chacon JE, Montanero J, Fienberg SE, Gelman A, Geskus RB, Jankowski HK, Longford NT, Louis TA, Mateu J, Mengersen K, Morton T, Playford G, Smith I, Militino AF, Ugarte MD, Porcu E, Alonso Malaver C, Zini A, Scott EM, Gemmell JC, Stein A, Woodall WH (2012) Discussion on the paper by Spiegelhalter, Sherlaw-Johnson, Bardsley, Blunt, Wood and Grigg. *Journal of The Royal Statistical Society Series A-Statistics in Society* 175:25-47

Watling RM, Poustie V, Ashby D, Smyth RL. (2008) Dietetic management of people with cystic fibrosis. *J Am Diet Assoc*; 108(12):1991-2.

Saperia J, Ashby D and Gunnell G. (2006) Suicidal behaviour and SSRIs updated meta-analysis (letter). *British Medical Journal*, 332, 1453.

Projects

Selection of Grants Awarded

£1,139,470, NIHR EME 2013-2016

A Gordon, R Orme, D McAuley, M Singer, G Perkins, D Ashby, A Morelli, K Liu, A Mason

LeoPARDS - Levosimendan for the Prevention of Acute Organ Dysfunction in Sepsis

£138,201.02 (£113,801), Arthritis Research UK 2012–2013

L Lightstone, T Cook, M Griffith, C Gordon, D Ashby, T Cairns,

D Jayne, D Isenberg, J Levy, M Pickering, S Marks

RITUXILUP – an open label randomised multicentre controlled trial of Rituximab and mycophenolate mofetil (MMF) without oral steroids for the treatment of lupus nephritis

£2,920,523, National Institute for Health Research 2012–2014

E Alton, D Ashby

A randomised double-blind placebo controlled Phase 2B clinical trial of repeated application of gene therapy in patients with cystic fibrosis

£1,396,886, Efficacy and Mechanism Evaluation Programme 2011–2013

S Johnston, C E Brightling, A Chauhan, C Corrigan, T W Harrison, B G Higgins, P W Ind, A H Mansur, D Singh, N C Thomson, E V Kulinskaya, R Chaudhuri, P Mallia, D Ashby

AZALEA: A Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy of Oral Azithromycin as a Supplement to Standard Care for Adult Patients with Acute Exacerbations of Asthma

£1,038,294 BHF, 2011–2016

M R Wilkins, L S G E Howard, J S R Gibbs, J Wharton, L Zhao, D Ashby

PAH (Pulmonary Artery Hypertension) Iron homeostasis in pulmonary arterial hypertension: study to establish the frequency and clinical significance of iron deficiency in different forms of pulmonary hypertension; investigate the mechanisms responsible and determine the impact of iron treatment in patients as well as animal models

£88,305 D Ashby NIHR Research Methods Fellowship 2011-2013

£2,747,145, MRC 2011–2013

S Bloom, T Tan, B Field, D Ashby

Peptide YY: Treatment of obesity by long acting analogues of peptide YY

£838,294 NIHR HTA, 2011–2014

N Poulter, C Bicknell, J Powell, M Watham, M Davies, M Thompson, S Dhanjil, D Ashby, N Cheshire

AARDVARK: Aortic Aneurysm Regression of Dilation: Value of ACE inhibitors on Risk, trial to evaluate the effect of ACE inhibitors on small aneurysm growth

£327,646 NIHR EME, 2010-2013

S Uthaya, N Modi, Bell, Dore, D Ashby, I Wong, M Rutherford, JB van Goudoever
NEON: Amino acid regimen and intravenous lipid composition in preterm
parenteral nutrition: a randomised double blind controlled trial

£550,840 BBSRC (Diet and Health Research Industry Club) 2010–2013

G Frost, D Ashby, S R Bloom, J E Blundell, W S Dhillon, K G Murphy

The effect of propionate on appetite regulation, body weight and insulin sensitivity

Selection of Higher Degree Supervisions

In Progress

Shalini Santhakumaran, 'Quantifying variation in clinical outcomes across neonatal units in England'

2011-date (jointly with Prof N Modi) staff registration current PhD supervision

Nelson Kinnarsley, 'Evaluation of methods for the conversion of prior opinion'

2010–date (jointly with Professor M Wilkins and Dr S Day) Part-time – current PhD supervision

Kimberley Hockley, 'What role should formal risk-benefit decision-making play in the regulation of
medicines?'

2009-date (jointly with Dr S Meredith) current PhD supervision

Juan Gonzalez-maffe, 'Application of Bayesian Methods to Biomarker Evaluation

2008-2013 (lead supervisor Prof S Richardson) current PhD supervision

Completed

Shahrul Mt-Isa, 'Improving evidence-based risk-benefit decision-making of medicines for children'

2007-date (staff registration, jointly with Dr N Croft) PhD minor corrections submitted, August 2011

Elizabeth de Souza 'Does paternal age affect the couple's risk of having a pregnancy with a
chromosomal anomaly?'

2005-2008 (lead supervisor Prof J Morris) PhD awarded October 2008

Annette L Boaz 'Evidence based policy and practices'

2002-2006 (staff registration, jointly with Prof K Young) PhD awarded November 2006

Dawn Carnes 'Picturing Persistent Pain'

2002-2006 (jointly with Prof M Underwood), PhD awarded July 2006

Examining

PhD examiner, Liverpool 1992; Kent 1997; ICSTM 1998; Cambridge 1998; Lancaster 1999; UCL
1999; Kent 2000; Bath 2000, Lancaster 2000, Reading, 2000, Leicester 2001, ICSTM 2001,
Cambridge 2002; ICSTM 2004; CRUK/UCL 2005; UCL 2006; Lancaster 2006; LSHTM 2007; Institute
of Education 2007, Nanyang Technological University, Singapore 2007; Leicester 2008; Imperial
2009; Liverpool 2009

MPhil examiner, Liverpool, 1987; LSHTM, 1995

Docut Privat, Geneva, Switzerland 2003

MSc in Biometry University of Reading 2006-9

BSc/ MSc module in Medical Statistics, University of Liverpool 2006-9

MBBS 'The Principles of Biometry and Medical Statistics' Royal Free Hospital School of Medicine
1991-3; QMW 1996-1997

Examination Board of the First Examination for the Fellowship (Clinical Oncology) of the Royal
College of Radiologists 1991-1997

Teaching

One of my key objectives has been the development of good teaching in statistics and public health. I
have written on aspects of teaching and didactic material at post-graduate level as well as reviewing
textbooks and teaching videos for journals. In Liverpool I monitored colleagues' teaching in
mathematics and statistics as part of the preparation for Teaching Quality Assessment.

Teaching innovation has included development of an Honours course in Medical Statistics, leading
curriculum development of biostatistics for medical and dental undergraduates and Masters in Public
Health in Liverpool and Imperial College London. At Queen Mary I led the changes in year 1 and 2
Public Health teaching and also supported more junior staff in curriculum development.

Memberships

Professional Societies

Honorary Member of the Royal College of Radiologists 1998 - present

Royal Statistical Society, Fellow 1980, Chartered Statistician 1994 - present

Honorary Member of the Faculty of Public Health Medicine 1992 - present

Current and Previous External Membership of Trial Steering Groups

CF-WISE inhaled steroid withdrawal in cystic fibrosis (CF Trust, Imperial College)

OSCAR High frequency oscillatory ventilation in patients with acute respiratory distress syndrome (NIHR HTA, University of Oxford) (Chair)

UK Lung Cancer Screening Trial (NIHR HTA, University of Liverpool)

Current and Previous External Membership of Data Monitoring Committees

OE02 pre-operative chemotherapy in oesophageal cancer (MRC Clinical Trials Unit)

Botulinum toxin for leg spasticity in cerebral palsy (Action for Medical Research, University of Liverpool) (Chair)

TOPIC once versus thrice daily tobramycin in cystic fibrosis (CF Trust, University of Nottingham) (Chair)

SIOP chemotherapy regimes in childhood liver cancers (CRUK, multinational trial)

INIS neonatal immunotherapy (MRC, National Perinatal Epidemiology Unit)

CALM-AD donepezil and risperidone in agitation in Alzheimer's disease (MRC, Institute of Psychiatry)

DOMINO-AD donepezil and memantine in moderate to severe Alzheimer's disease (MRC, Institute of Psychiatry)

INFANT trial of decision-making in management of labour (NIHR HTA, University of Oxford) (Chair)

CEQUEL trial of QUetiapine-Lamotrigine combination versus quetiapine monotherapy, and folic acid versus placebo, in people with bipolar depression (MRC, University of Oxford)

Current and Previous Steering Groups Memberships

ADRCIC Adverse Drug Reaction in Children Research Programme (NIHR Programme grant, Prof RL Smyth, University of Liverpool)

Drug Intervention Programme Children and Young People (Matrix Research and Consultancy Ltd)

Internal Appointments

Imperial College, including Academic Health Science Centre

Head of Department, Clinical Trials, School of Public Health 2011- date

School of Public Health Executive Committee 2009-date

AHSC Interventional Public Health Clinical Programme Group Board 2008 - 2011

Statistical Advisory Service Steering Committee 2008-date

Queen Mary, University of London

Wolfson Institute Graduate Tutor 2003-2008

Elected to the Barts and the London School Board, 2005-2008

Centre for Statistics Deputy Director, 2005-2008

ESRC Centre for Evidence Based Policy & Practice Associate Director (Methods) 2000-4

Faculty of Medicine, University of Liverpool

Academic Sub-Dean 1995-1997

Other Relevant Information

Honours and Awards

OBE for services to medicine- New Year's Honours List 2009

NIHR Senior Investigator 2010 – 2015

Fellowship to the Academy of Medical Sciences; FMedSci – June 2012

Evidence of Esteem, External Visibility and Professional Activities

European Medicines Evaluation Agency

Cardiovascular Scientific Advisory Group 2010 – present
CHMP representative on Highly Active Anti-Retroviral Therapy Oversight Committee 2010 - present
European Expert 2004 - 2010
European Network of Centres of Pharmacovigilance and Pharmacoepidemiology Implementation Advisory Group 2008 - 2010
Department of Health
Commission on Human Medicine, member 2005 - 2012
Committee on Safety of Medicine, member 1999 - 2005
Subcommittees including CHM Nicotine Containing Products Working Party 2011 - present
CHM Patient Information Expert Advisory Group 2006 - 2007
CHM Bioequivalence Ad Hoc Group 2007- 2010
CSM Safety of Vaccines Working Group 2000 - 2005
CSM HRT Working Group 2002
CSM SSRI Working Group 2003 - 2005
Committee on Safety of Medicine's Safety and Efficacy Sub-Committee, 1993 - 1995
Panel of Expert Assessors for Artificial Implants and Medical Devices, 1992 - 2006
National Institute of Health Research
NIHR Senior Investigators Appointment Panel 2011-date
NIHR Fellowship Advisory Board 2011 – present
External Chair of the Trial Managers Network Oversight Group, 2011 - present
Advisor NIHR Capacity Building, Statistics, Clinical Trials and Economics 2008 - present (20% secondment)
Clinical Trials Unit Advisory and Steering Group 2007 - present
Programme Grants for Applied Research Programme, College of Panellists 2008 - 2010
Core Methodological Expert 2010 - 2012
Health Technology Assessment Commissioning Panel 2005-11 including Commissioning Strategy Group 2008 - 2011
Department of Innovation, Universities and Skills (Government Office for Science)
Steering Group for Science Review of the Department of Health 2007- 2008
Medical Research Council
Member of PhD Studentship Skills Portfolio Advisory Group 2011
Biostatistics/ Methodology/ Population Health Scientist Fellowships panel 2009 – 2011; Chair Biostatistics sub-panel 2010 - 2011
Biostatistics Fellowships Panel 2007 and 2008
Hubs in Trials Methodology Research Panel 2008
Patient Research Cohort Initiative Oversight Group 2008 - present
Patient Research Cohorts Initiative Panel 2008
College of Experts 2004 - 2008
Academy of Medical Sciences
Member of Academy working group to review the regulation and governance of medical research. 2010
Member of Sectional Committee. 2013 –
Royal Statistical Society
Member of Academic Affairs Advisory Group, 2011 – present
Member of Honours Committee, 2011 - present
Chair of Long-Term Strategy group 2008 - 2009
Co-ordinator of 175th Anniversary Celebrations in 2009, 2008 - 2009
Vice-President, 1993-1995; Honorary Secretary, 1998 - 2004

Member of Council, 1992-1997, Member of Executive, 1993 - 1996
Mersey Local Group Committee, 1994 - 1997, Deputy Chair 1995 - 1997
Medical Section Committee, member 1987 - 1989, Honorary Secretary 1989 – 1992
International Society for Bayesian Analysis
Mitchell Prize Committee (for best applied Bayesian paper) member 2008; chair 2009
Executive Secretary 2004 - 2006
Board of Directors 2000 - 2002
International Society for Clinical Biostatistics
ISCB/Society for Clinical Trials joint meeting Programme Co-Chair, London 2003
Cystic Fibrosis Trust
Statistical Advisor to Gene Therapy Consortium 2006 - 2009
Clinical Trials Advisory Group 1998 - 2005
National Perinatal Epidemiology Unit
Advisory Group 1997 - 2001
Editorial work
Statistics in Medicine Editorial Board 1991-2005, Associate Editor 2007 - date
Bayesian Analysis Associate Editor 2004 - 2012
British Medical Journal Hanging Committee 2003-2006, Statistical Editor 2006 - 2009
Biometrics Editorial Panel 1997 - 2000
Statistics in Society Editorial Panel 1997 - 1999
Statistical Methods in Medical Research Editorial Board 1995 - 2009
Applied Statistics Editorial Panel 1991 - 1994
Cochrane Collaboration
Adverse Effects Methods Group member of Specialist Advisory Group 2007 - date
Cochrane Cystic Fibrosis and Genetic Disorders Group Editor 1997 – 2009, Editor Emeritus 2010 - date
North West Regional Health Authority
Liverpool Adult Ethics Committee, 1996 - 1997
Small Grants and Research Training Committee, 1993 - 1995
Merseyside and Cheshire Cancer Registry Deputy Director and Statistician (Honorary Contract), 1990-1994, Statistician (Honorary Contract) 1994 - 1996
Committee of Professors of Statistics
Executive 2005 - 2007
HRB Clinical Research Facility, Galway
Member of Scientific Advisory Board 2010 -
University of Lancaster
Senior Visiting Research Fellow 1994 - 1995; Adjunct Senior Lecturer in Statistics 1995 - 1998
External Interview panels
External member of interview panels for chairs and other appointments in UK universities and Eire, and for appointments at the Medicines and Healthcare Regulatory Products Agency
BMA Book of the Year competition 2000
Highly commended in Primary Care category for Eldridge S. and Ashby D. (2000) Statistical Concepts. Eds: Carter Y., Shaw S. and Thomas C. Royal College of General Practitioners. London.
Master Classes in Primary Care Research No 3