

Joint Health Research Conference: **Committed to better research in the NHS**

Friday 27th November 2009

The Royal Berkshire Conference Centre, Madejski Stadium, Reading
Registration from 9.45am - Close at 4.30pm

The role of your local CLRN: Thames Valley CLRN

**Jeremy Fairbank MD FRCS
Clinical Director**

(and Professor of Spine Surgery, University of Oxford)

What we are presenting re CLRN's

- Summary of CLRN activities
- The speciality groups we have chosen
- Our policy with Trusts on
 - RM&G
 - Service support
- Policy on clinical support
- A few stats on what we're doing

What is CLRN?

We are 2 of 25 in England

I am Thames Valley

He is Hampshire and IOW

- Comprehensive Local Research Networks

As opposed to.....

- Topic Specific Local Research Networks
 - Primary Care
 - Mental Health
 - Cancer
 - Stroke
 - Diabetes
 - DENDRON
 - Medicines for Children

What is CLRN?

- Key Service Support
 - Pharmacy
 - Imaging
 - Laboratory
- Research Management and Governance
- Clinical support
 - 80+ Research Nurses
 - Clinical sessions

What is CLRN?

- 26 National Specialty Groups

- Anaesthetics
- Age & Ageing
- Cardiovascular
- Clinical Genetics
- Critical Care
- Dermatology
- Gastrointestinal
- ENT
- Hepatology
- Health Services Research
- Injuries and accidents
- Immunology & inflammation
- Infectious diseases & microbiology
- Metabolic & Endocrine
- Musculoskeletal
- Nervous system disorders
- Non – malignant haematology
- Ophthalmology
- Oral & Dental
- Paediatrics
- Public Health
- Renal
- Reproductive Health & Childbirth
- Respiratory
- Surgery
- Urogenital

What is CLRN?

- TVCLRN Local Specialty Groups

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- TVCLRN Local Specialty Leads

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- Clinical Genetics
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- ENT
- Injuries and accidents
- Immunology & inflammation
- Infectious diseases & microbiology

» **Dr Helen McShane**

Prof Henry McQuay

Prof Margot Gosney

Dr Adrian Banning

Prof Andrew Wilkie

Dr Duncan Young

Dr Graham Ogg

Dr Simon Travis

Dr Martin J Burton

Prof Keith Willett

Dr Raashid Luqmani

Prof Andrew Pollard

What is CLRN?

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- Metabolic & Endocrine
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- Nervous system disorders
- Ophthalmology
- Paediatrics
- Renal
- Reproductive Health & Childbirth
- Respiratory
- Urogenital **Mr John Reynard**

Prof John Wass

Prof Jeremy Fairbank

Dr Jacqui Palace

Mr Victor Chong

Dr Nicholas Wilkinson

Dr Chris O'Callaghan

Dr Stephen Kennedy

Prof Robert Davies

What is CLRN?

- Additional Local TV Specialty

- Spinal Cord Injuries

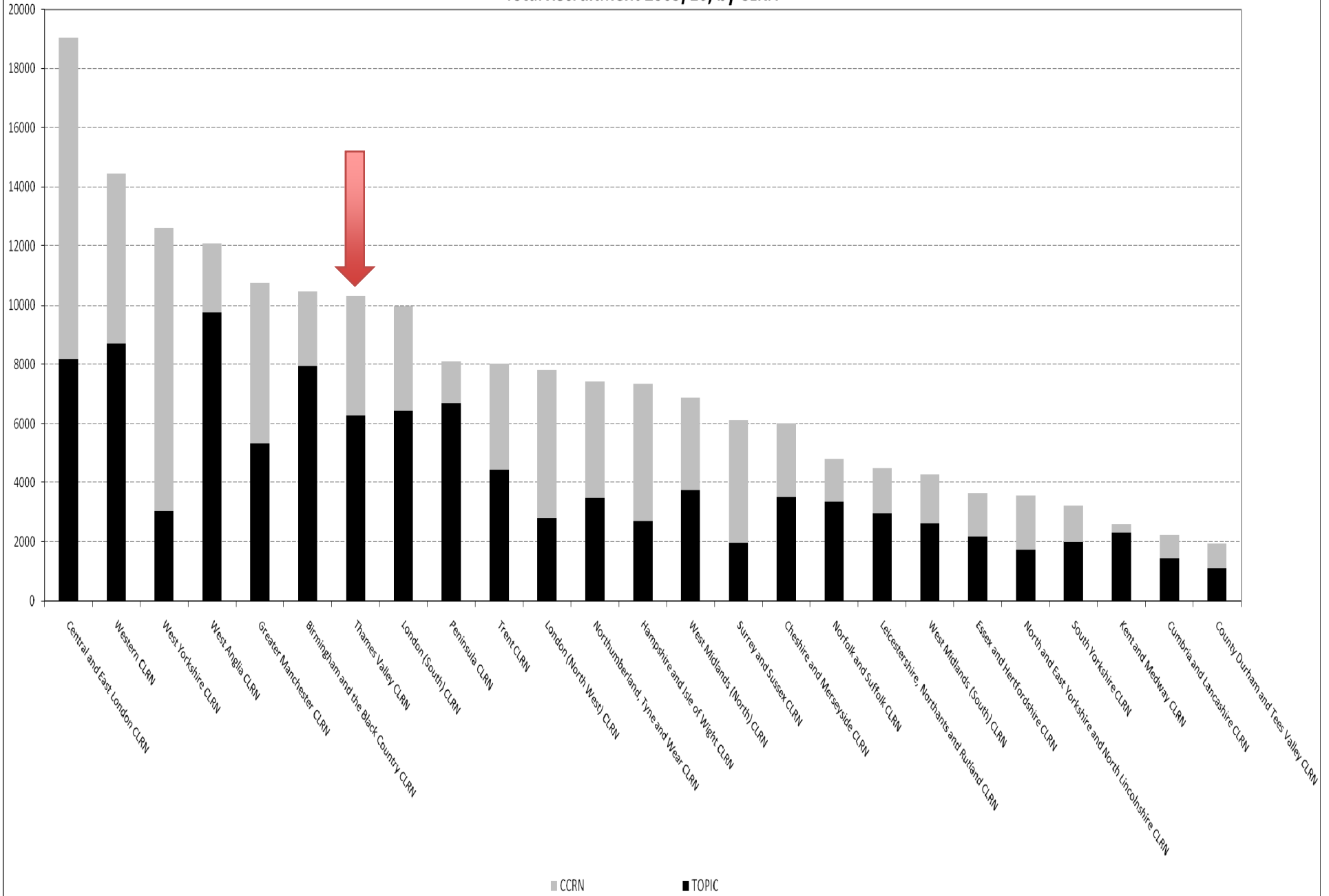
Dr Paul Kennedy

Budget 2009/10

Forecast Expenditure 2009/10

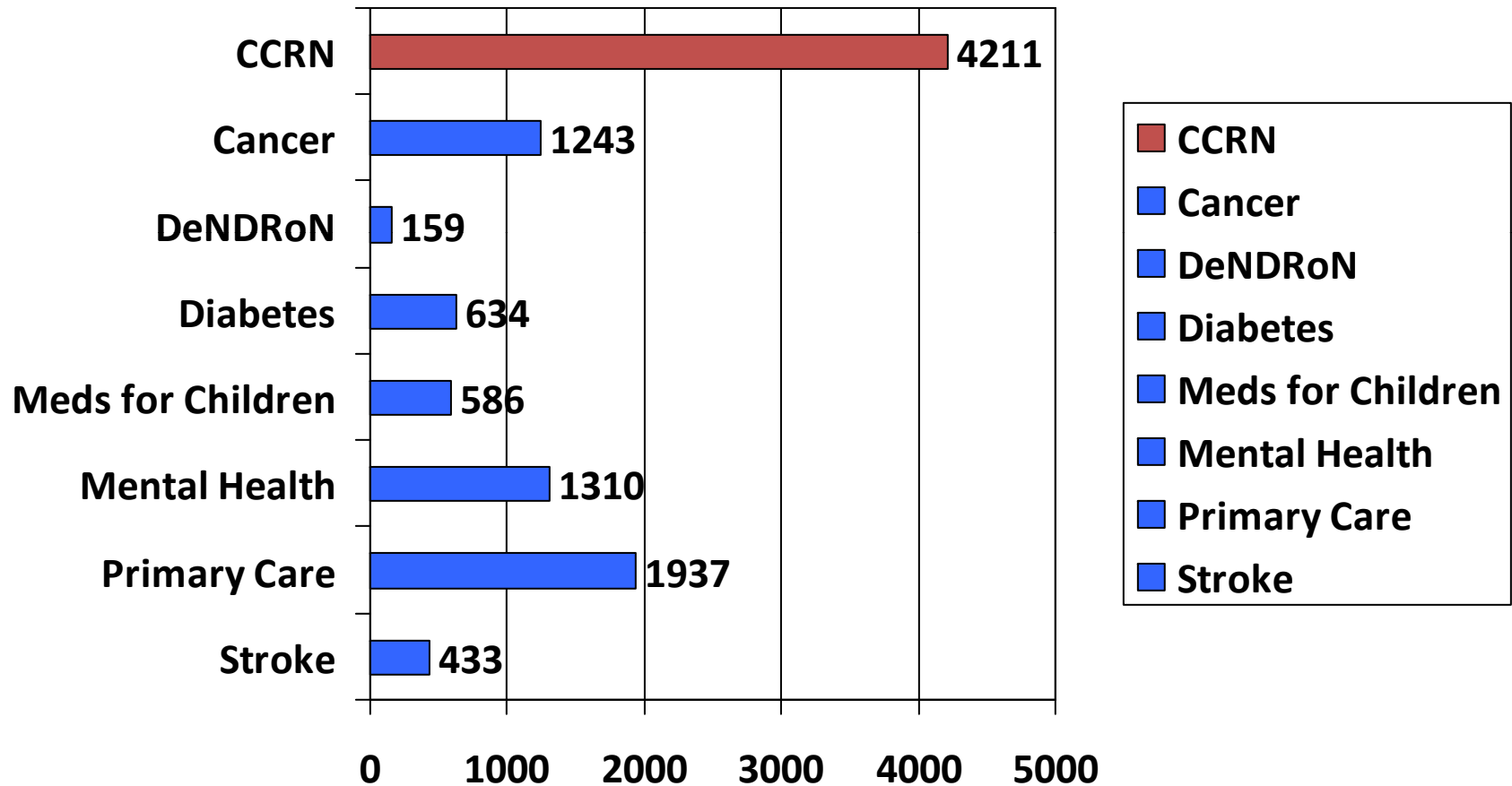
	£
CLRN Management	455,000
Clinical Sessions	5,165,000
Key Service Support	2,100,000
Other Service Support	0
Research Management	590,000
Other	400,000
TOTAL	8,710,000

Total Recruitment 2009/10, by CLRN



Overall TVCLRN Accrual Rates

(up to 23rd November 2009)



No. of TVCLRN Portfolio Studies by Trust Actively Recruiting

(not including studies currently in CSP)

Berkshire East PCT	10
Berkshire Healthcare NHS FT	8
Berkshire West PCT	11
Buckinghamshire Hospitals NHS Trust	10
Buckinghamshire PCT	7
Heatherwood & Wexham Park NHS FT	32
Milton Keynes Hospital NHS FT	23
Milton Keynes PCT	10
Nuffield Orthopaedic Centre NHS Trust	13
Oxford Radcliffe Hospitals NHS Trust	267
Oxfordshire & Buckinghamshire Mental Health NHS FT	23
Oxfordshire PCT	24
Royal Berkshire NHS FT	39

TVCLRN Recruitment by Trust

Berkshire East PCT	110
Berkshire Healthcare NHS FT	109
Berkshire West PCT	218
Buckinghamshire Hospitals NHS Trust	436
Buckinghamshire PCT	243
Heatherwood & Wexham Park NHS FT	202
Milton Keynes Hospital NHS FT	182
Milton Keynes PCT	276
Nuffield Orthopaedic Centre NHS Trust	971
Oxford Radcliffe Hospitals NHS Trust	4,208
Oxfordshire & Buckinghamshire Mental Health NHS FT	1,176
Oxfordshire PCT	1,712
Royal Berkshire NHS FT	503

Unsolicited testimonials

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Letters

Future of flu vaccines

Expediting clinical trials in a pandemic

In response to the urgent need for paediatric data comparing the two new variant A/H1N1 vaccines in the UK before the onset of a second wave of flu,¹ and a call for proposals related to new variant A/H1N1 by the National Institute for Health Research (NIHR),² we designed a clinical trial of immunogenicity and tolerability in children aged 6 months-12 years. We submitted a collaborative funding application to NIHR on 24 July 2009, receiving an award letter on 1 September. We redeployed trials staff, funded variously by the agencies given in this letter, to prepare submissions for ethical, regulatory, and NHS research and development approval.

Prioritisation of the review process and dialogue between investigators and senior staff in the reviewing agencies allowed rapid review and resolution of queries. Oxfordshire research ethics committee reviewed the application three days after submission, providing written approval 18 days later. Clinical trials authorisation was submitted to the Medicines and Healthcare Regulatory Agency (MHRA), including dossiers provided by the manufacturers, on 11 September, with written approval received after seven days; NHS research governance approval was received after 19 days. Two separate substantial amendments to the protocol were also reviewed and approved by both the ethics committee and MHRA within 48 hours.

The first vaccine was given on 26 September, and by the end of the first week almost 500 children had been enrolled, just over 4 weeks after the study's initial submission for ethical and regulatory review. We expect to enrol almost 1000 children four weeks after giving the first dose of vaccine.

These efforts to start important H1N1 trials are unprecedented and show a welcome responsiveness. Despite the expedited process, the bureaucratic burden was undiminished. The capacity of trials staff funded by NIHR proved essential, supporting the need for NIHR to invest in the clinical trials infrastructure. Evaluation of these exceptional processes should help to improve timelines for setting up clinical trials beyond a pandemic threat.

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Andrew J Pollard, *professor of paediatric infection and immunity*¹, **Amanda Reiner**¹, **Tessa John**¹, **Elizabeth Sheasby**², **Matthew Snape**¹, **Saul Faust**³, **Andrew Collinson**⁴, **Adam Finn**⁵, **Paul T Heath**⁶, **Elizabeth Miller**²

¹ Oxford Vaccine Group, Department of Paediatrics, University of Oxford, Oxford OX3 9DU, ² Immunisation Department, Centre for Infection, Health Protection Agency, Colindale, ³ University of Southampton Wellcome Trust Clinical Research Facility, Southampton, ⁴ Royal Devon and Exeter NHS Foundation Trust, Exeter, ⁵ Bristol Children's Vaccine Centre, University of Bristol, Bristol, ⁶ St George's Vaccine Institute, University of London, London

Unsolicited testimonials

Shoulder & Elbow. ISSN 1758-5732

MISCELLANEOUS

The UKUFF trial and the NIHR comprehensive local research networks

Andrew Carr & Cushla Cooper

The Nuffield Department of Orthopaedic, Rheumatology & Musculoskeletal Sciences, University of Oxford, Oxford, UK

ABSTRACT

Research opportunities in the NHS have changed greatly over the last year or so. The UKUFF study demonstrates the advantages of these changes to orthopaedic research. Analysing the recruitment rates of each surgeon involved in the study found inconsistencies in recruitment patterns. As a result projected recruitment targets were suffering. The UKUFF team took advantage of the new research initiative and at the end of 2008 obtained the support offered by the new infrastructure at many participating sites. The recruitment total at the end of June 2009 showed that supported sites recruited almost double the number of patients compared to the unsupported sites. Surgeons involved in research need to access available resources to help them improve their participation in research. Being actively involved in specialist research like UKUFF can lead to further support for new studies instigated by shoulder surgeons.

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Conflicts of Interest

None declared

Correspondence

Cushla Cooper, The Nuffield Department of
Orthopaedic, Rheumatology &
Musculoskeletal Sciences, Oxford, UK.

Tel: +44 1865 737643

fax: +44 1865 737640

E-mail: cushla.cooper@ndorms.ox.ac.uk

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Discussion points

- Policy on Trust support
- Selection of specialty groups
- Do you go for PA's or Research Nurses (physios, other PAM's)
- How do you ensure flexibility?
- Variable policies of funding agencies
- Portfolio development