

NIHR: improving the health and wealth of the nation through research

Professor Tom Walley,
Director of NIHR Evaluation, Trials and Studies



The NHS

- Launched 1948
- Free at the point of use for UK residents (currently more than 63.2 million people)
- largest publicly funded health service in the world
- covers everything from antenatal screening and routine treatments for long-term conditions, to transplants, emergency treatment and end-of-life care
- The NHS deals with over 1 million patients every 36 hours



Why is the Government committed to Research in the NHS?



- improve health outcomes through advances in research
- improve quality of care by NHS participation in the research process
- strengthen International competitive position in science
- drive economic growth through investment by life science industries



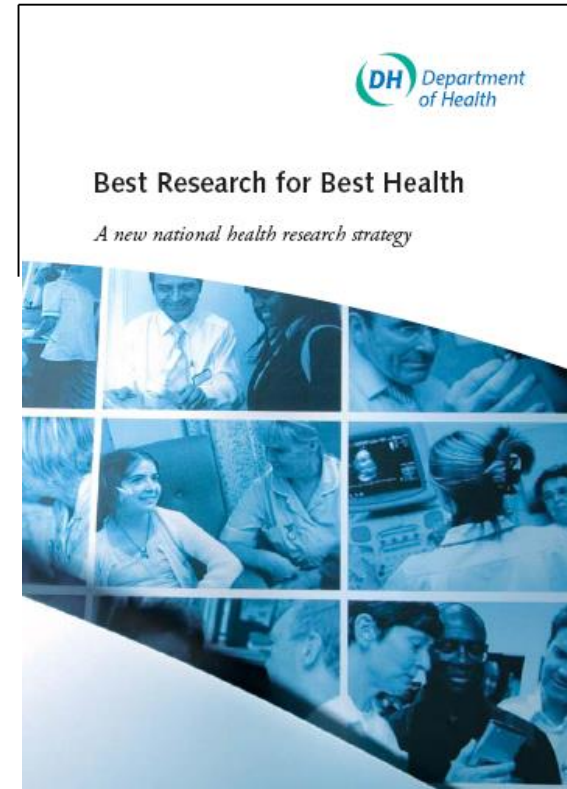
Why is the Government committed to Research in the NHS?



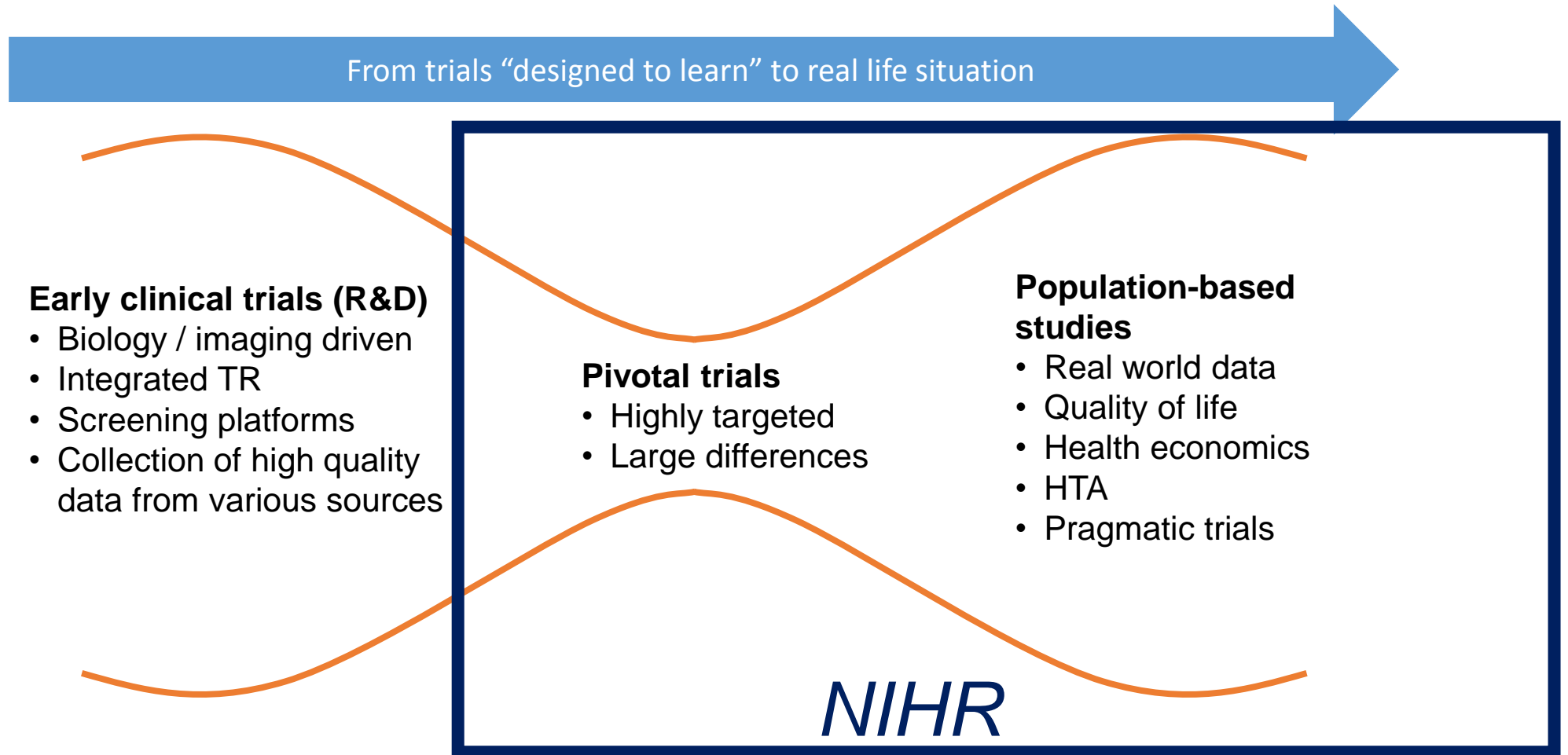
Health and Wealth



- NHS R&D Strategy 2006
 - To **transform** research in the NHS
 - To create a **health research system** in which the **NHS** supports **outstanding individuals**, working in **world-class facilities**, conducting **leading-edge research**, **focused on the needs of patients and the public**
 - Creation of the National Institute of Health Research – a government funded organisation for NHS research

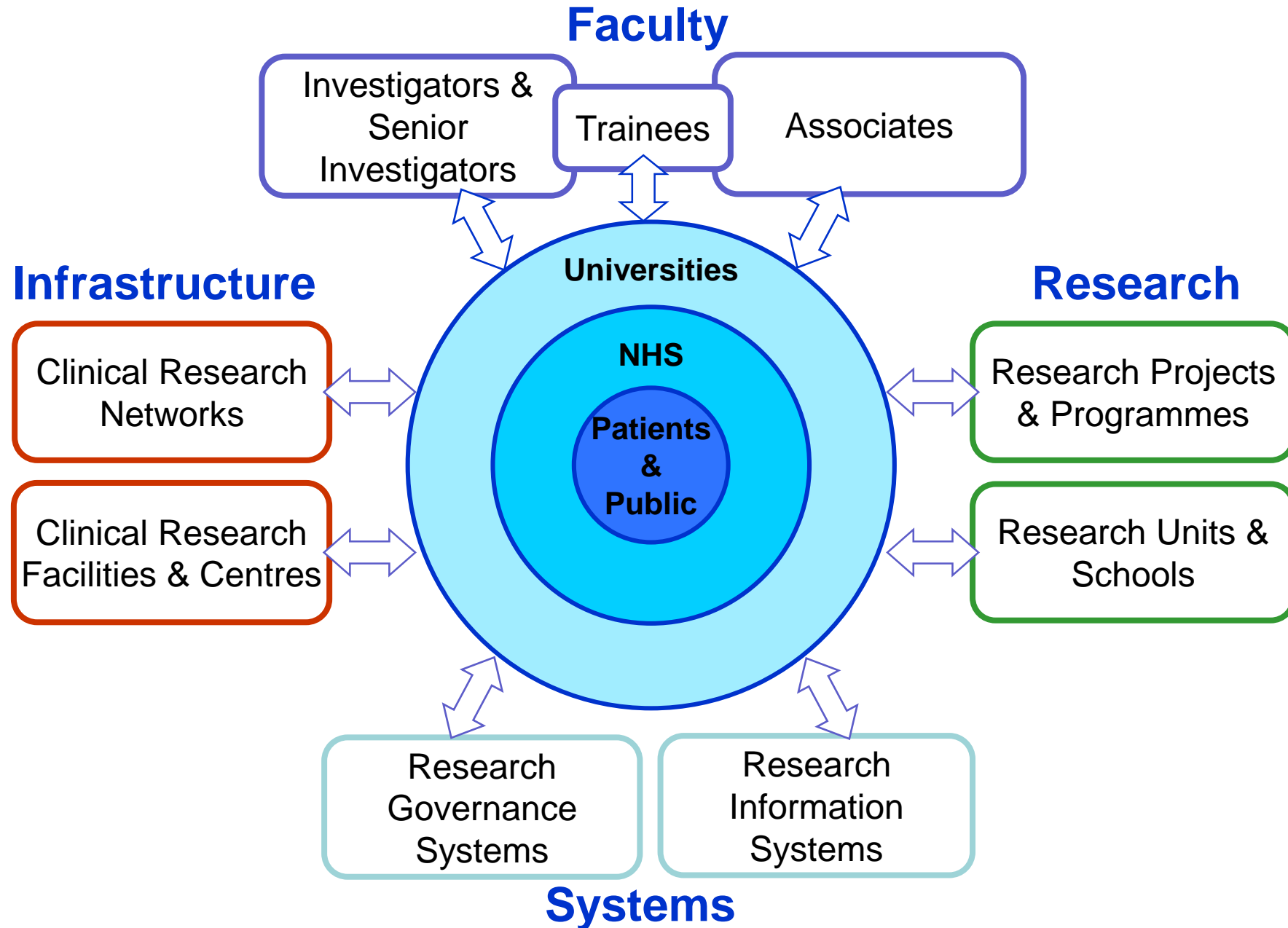


The changing clinical research pathway

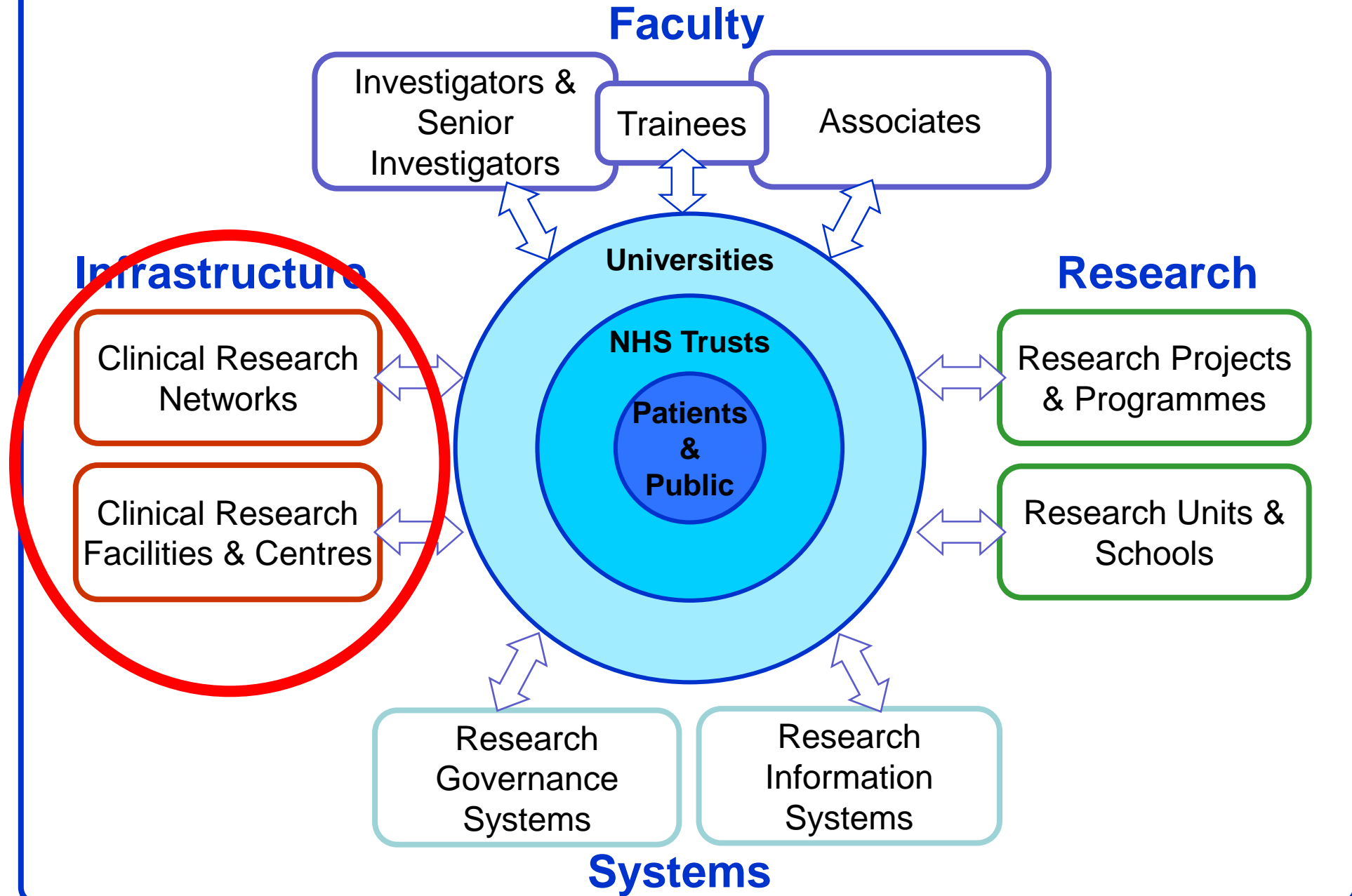


Burock et al. Eur.J.Cancer (2013), <http://dx.doi.org/10.1016/j.ejca,2013.05.016>

National Institute for Health Research NIHR



National Institute for Health Research

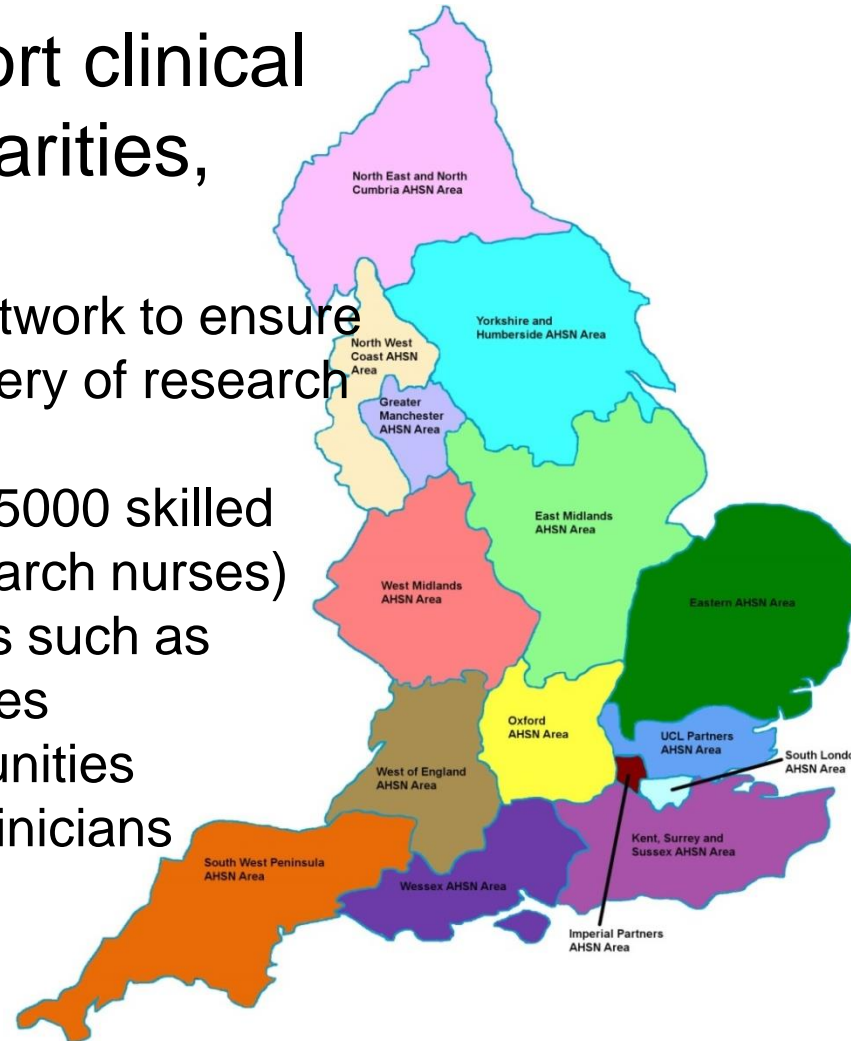


NIHR Networks - 15 Local Clinical Research Networks (LCRNs)

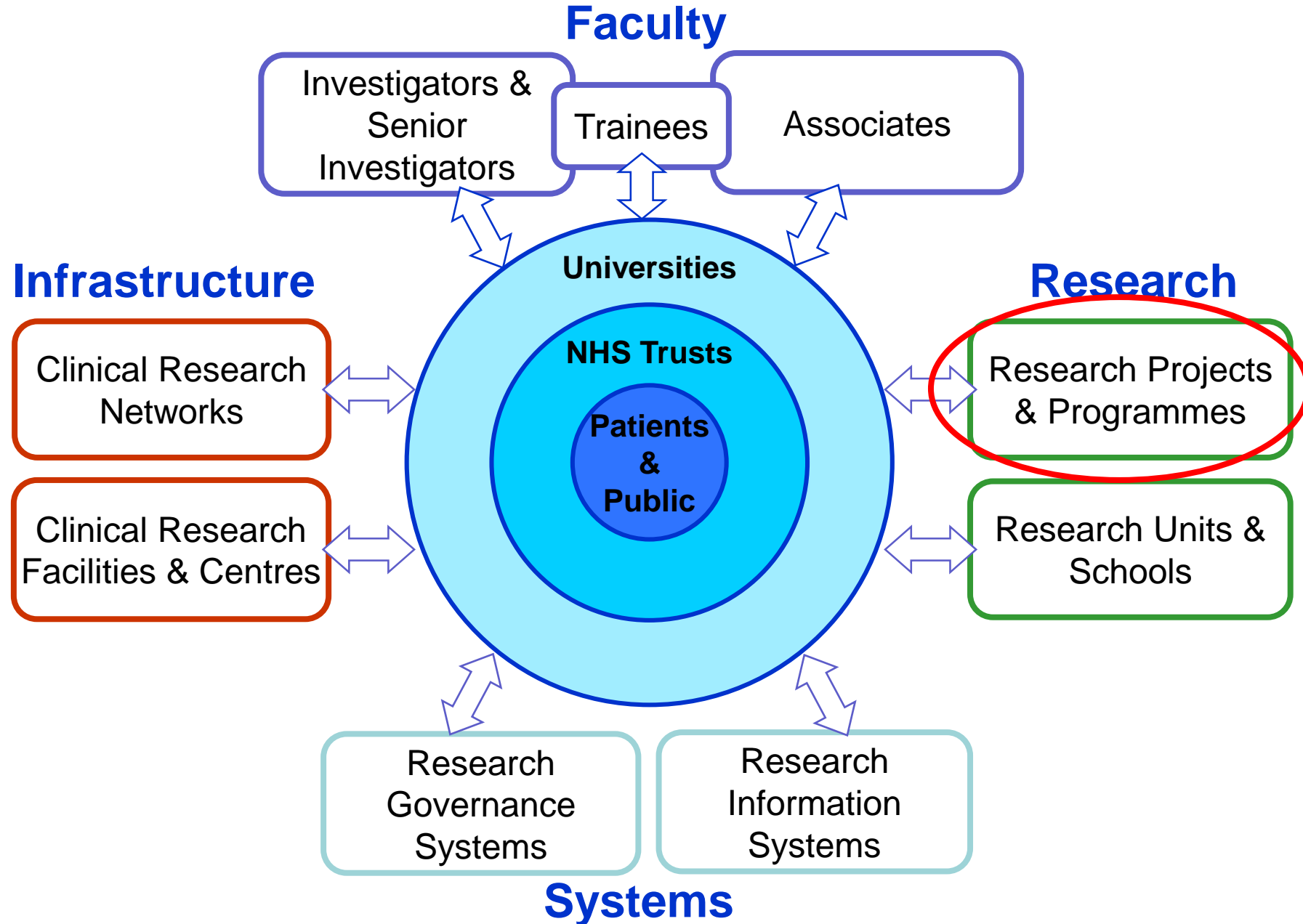
Infrastructure to support clinical research for NIHR, charities, industry

A local and national support network to ensure the successful set up and delivery of research projects

- Access to a local network of 15000 skilled research support staff (eg research nurses)
- Access to service departments such as pharmacy, radiology, laboratories
- Access to free training opportunities
- Dedicated research time for clinicians

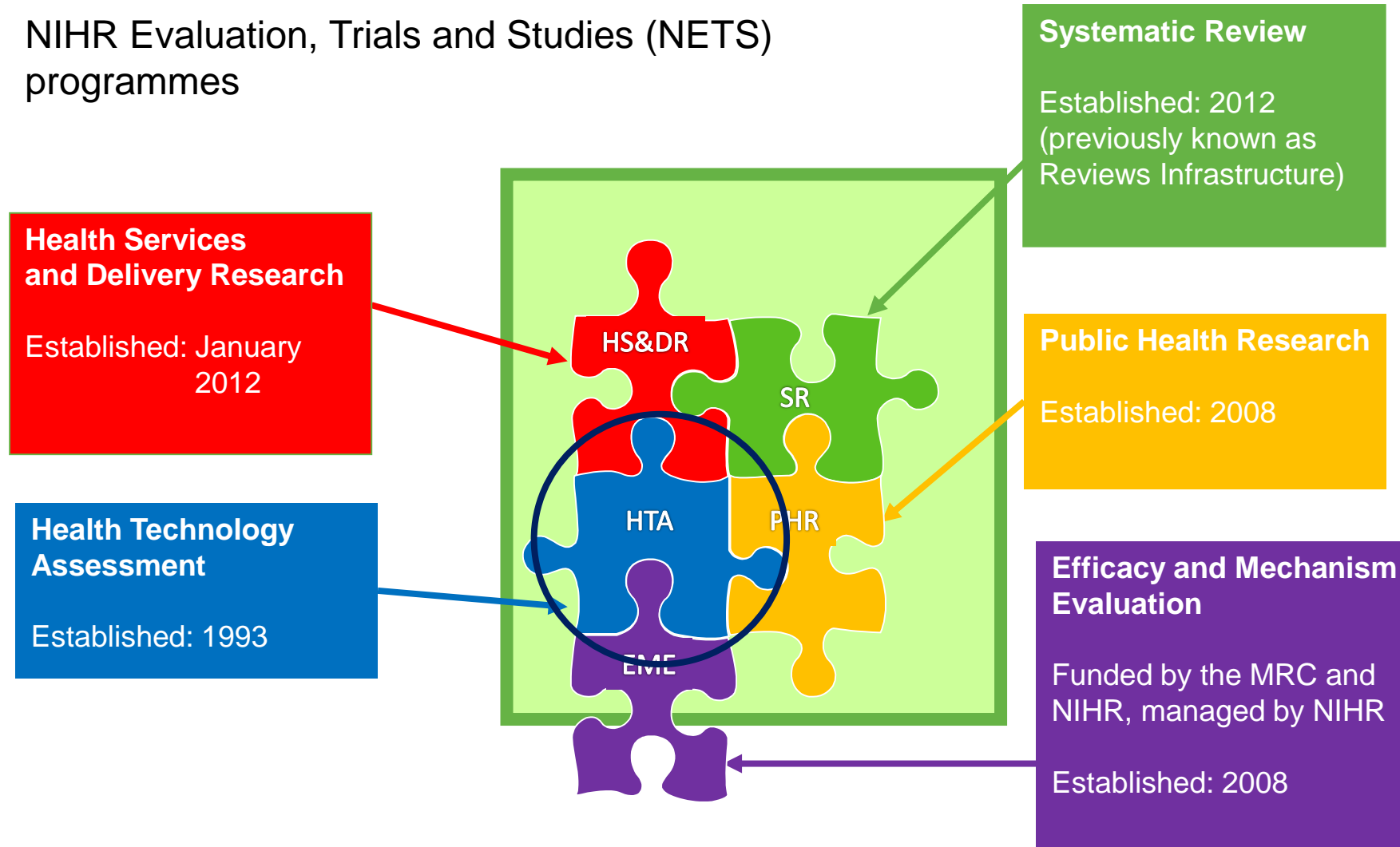


National Institute for Health Research



Some NIHR programmes

NIHR Evaluation, Trials and Studies (NETS)
programmes



Effects of cognitive behaviour therapy for worry on persecutory delusions in patients with psychosis (WIT): a parallel, single-blind, randomised controlled trial with mediation analysis

Graham Dunn, Helen Startup, Katherine Pugh, Jacinta Cordwell, Helen Mander, Emma C. Kingdon

Calculating when elective abdominal aortic aneurysm repair improves survival for individual patients: development of the Aneurysm Repair Decision Aid and economic evaluation

Stuart W Grant, Matthew Sperrin, Eric Carlson, Dionysios Ntais, Matthew Hamilton, Linda Davies and Charles N McColl

March 10, 2015, Vol 313, No. 10 >

JAMA The Journal of the American Medical Association

Surgical vs Nonsurgical Treatment of Adults With Displaced Fractures of the Proximal Humerus The PROFHER Randomized Clinical Trial

Amar Rangan, FRCS(Tr&Orth)¹; Helen Handoll, DPhil²; Stephen Brealey, PhD³; Laura Jefferson, PhD³; Ada Keding, MSc³; Belen Corbacho Martin, MSc³; Lorna Goodchild, MSc¹; Ling-Hsiang Chuang, PhD⁴; Catherine Hewitt, PhD³; David Torgerson, PhD³; for the PROFHER Trial Collaborators

Trial of Early, Goal-Directed Resuscitation for Septic Shock

Paul R. Mouncey, M.Sc., Tiffany M. Osborn, M.D., G. Sarah Powell, David A. Harrison, Ph.D., M. Zia Sadique, Ph.D., Richard D. Rahi Jahan, B.A., Sheila E. Harvey, Ph.D., Derek Bell, M.D., Timothy J. Coats, M.D., Mervyn Singer, M.D., and Kathryn M. Rowan, Ph.D., for the

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

MARCH 12, 2015

VOL. 372 NO. 11

Liberal or Restrictive Transfusion after Cardiac Surgery

Katie Pike, M.Sc., Chris A. Rogers, Ph.D., Sarah Wood, M.Sc., Angelini, F.R.C.S., and Barnaby C. Cotton

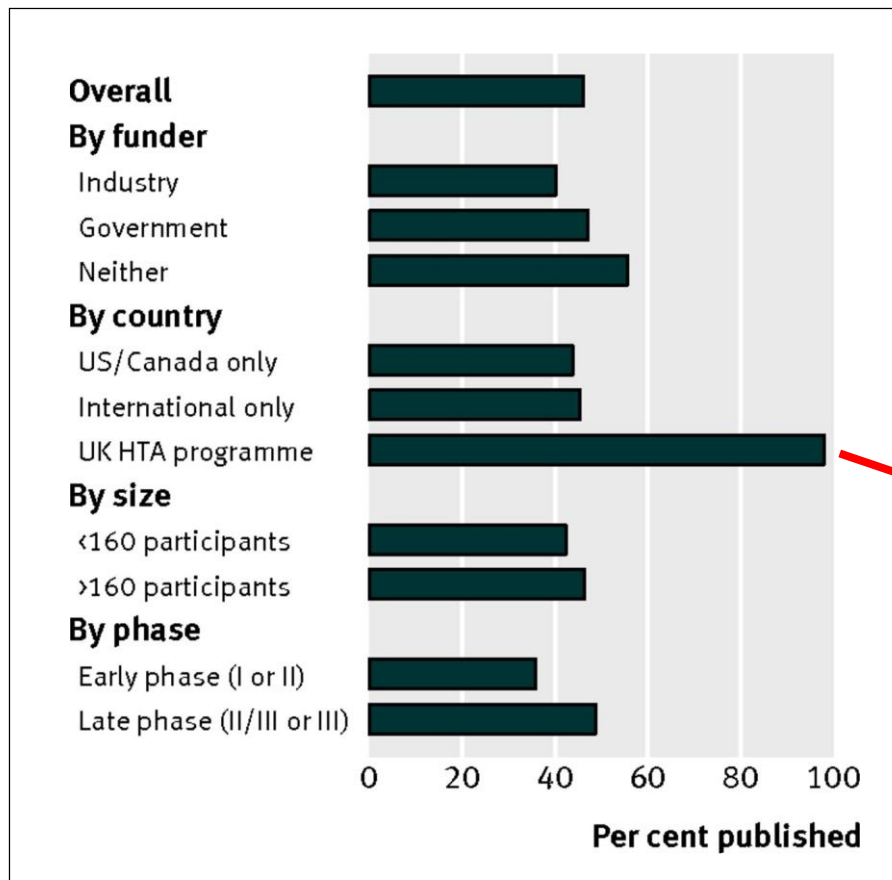
HEALTH TECHNOLOGY ASSESSMENT

VOLUME 19 ISSUE 27 APRIL 2015
ISSN 1366-5278

Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the Comparison of LAser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial

Julie Brittenden, Seonaidh C Cotton, Andrew Elders, Emma Tassie, Craig R Ramsay, John Norrie, Jennifer Burr, Jill Francis, Paul Bachoo, Ian Chetter, Julian Scott, Sara A Baker, and Kathryn M. Rowan, Ph.D., for the

Proportion of clinical trials registered by 1999 and published by 2007



How do we do it?

- Expectation
- Contract
- Own journal
- Pay for publication in other journals (threats...)

1. Chalmers I, Glasziou P, Godlee F. All trials must be registered and the results published. BMJ 2013; 346:f105

Does it change practice?

Effects of tranexamic acid on death, vascular events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised placebo-controlled trial

Mechanical versus manual chest compression for out-of-hospital cardiac arrest (PARAMEDIC): a pragmatic, cluster randomised controlled trial

Gavin D Perkins, Ranjit Lall, Tom Quinn, Charles D Deakin, Matthew W Cooke, Jessica Horton, Sarah E Lamb, Anne-Marie Slowther, Malcolm Woollard, Andy Carson, Mike Smyth, Richard Whitfield, Amanda Williams, Helen Pocock, John JM Black, John Wright, Kyee Han, Simon Gates, PARAMEDIC trial collaborators*

Summary

Background Tranexamic acid can reduce bleeding in patients undergoing early administration of a short course of tranexamic acid on death, vascular events, and blood transfusion in trauma patients.

Methods This randomised controlled trial was undertaken in 274 patients with, or at risk of, significant bleeding were randomly assigned (loading dose 1 g over 10 min then infusion of 1 g over 8 h) or randomised to manual chest compressions according to the first trial vehicle to arrive on scene. The primary outcome was survival at 30 days following cardiac arrest and was analysed by intention to treat. Ambulance dispatch staff and those collecting the primary outcome were masked to treatment allocation. Masking of the ambulance staff who delivered the interventions and reported initial response to treatment was not possible. The study is registered with Current Controlled Trials, number ISRCTN08233942.

Findings 10 096 patients were allocated to tranexamic acid or placebo. All-cause mortality was significantly reduced in the LUCAS-2 group (1613 [16.0%] placebo group; relative risk 0.91, 95% CI 0.86–0.96; $p < 0.001$). Relative risk of death or need for blood transfusion was significantly reduced (489 [4.9%] vs 574 [5.7%]; relative risk 0.86, 95% CI 0.74–1.00; $p = 0.04$).

Interpretation Tranexamic acid safely reduced the risk of death or need for blood transfusion in trauma patients. These results, tranexamic acid should be considered for use in trauma patients.

Funding UK NIHR Health Technology Assessment Programme.

Methods The pre-hospital randomised assessment of a mechanical compression device in cardiac arrest (PARAMEDIC) trial was a pragmatic, cluster-randomised open-label trial including adults with non-traumatic, out-of-hospital cardiac arrest from four UK Ambulance Services (West Midlands, North East England, Wales, South Central). 91 urban and semi-urban ambulance stations were selected for participation. Clusters were ambulance service vehicles, which were randomly assigned (1:2) to LUCAS-2 or manual CPR. Patients received LUCAS-2 mechanical chest compression or manual chest compressions according to the first trial vehicle to arrive on scene. The primary outcome was survival at 30 days following cardiac arrest and was analysed by intention to treat. Ambulance dispatch staff and those collecting the primary outcome were masked to treatment allocation. Masking of the ambulance staff who delivered the interventions and reported initial response to treatment was not possible. The study is registered with Current Controlled Trials, number ISRCTN08233942.

Findings We enrolled 4471 eligible patients (1652 assigned to the LUCAS-2 group, 2819 assigned to the control group) between April 15, 2010 and June 10, 2013. 985 (60%) patients in the LUCAS-2 group received mechanical chest compression, and 11 (<1%) patients in the control group received LUCAS-2. In the intention-to-treat analysis, 30 day survival was similar in the LUCAS-2 group (104 [6%] of 1652 patients) and in the manual CPR group (193 [7%] of 2819 patients; adjusted odds ratio [OR] 0.86, 95% CI 0.64–1.15). No serious adverse events were noted. Seven clinical adverse events were reported in the LUCAS-2 group (three patients with chest bruising, two with chest lacerations, and two with blood in mouth).

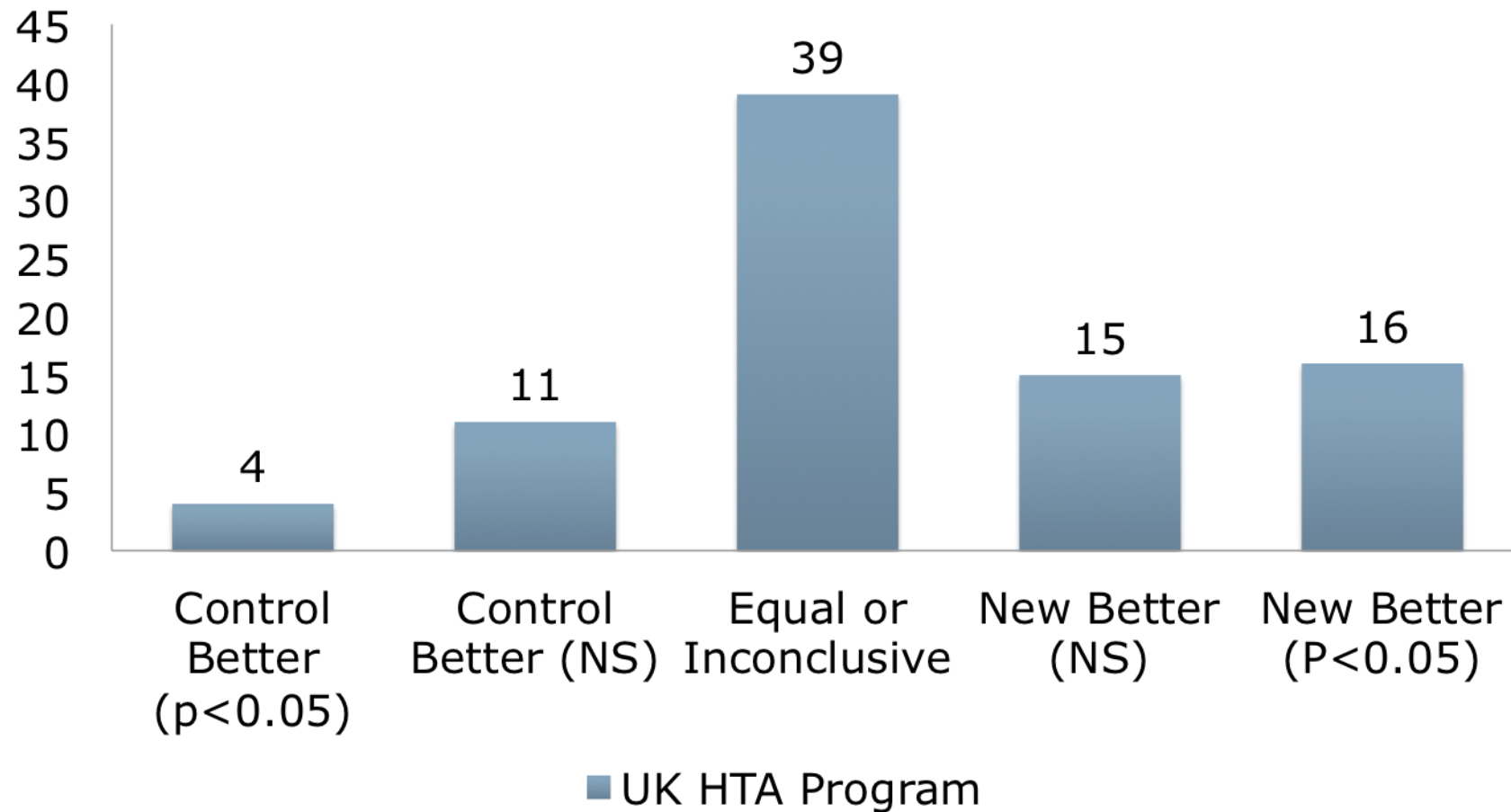
Lancet 2015; 385: 947–55
Published Online
November 16, 2014
[http://dx.doi.org/10.1016/S0140-6736\(14\)61886-9](http://dx.doi.org/10.1016/S0140-6736(14)61886-9)

See Comment page 920
*Collaborators listed at end of paper

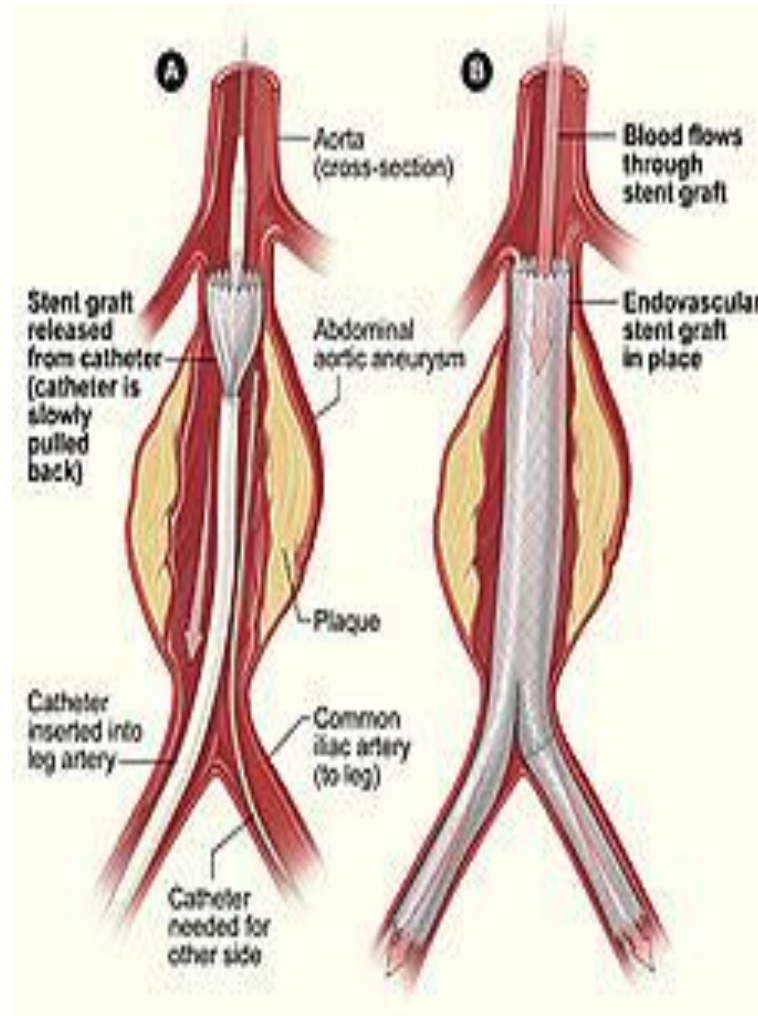
Warwick Clinical Trials Unit,
University of Warwick,
Coventry, UK
(Prof G D Perkins MD, R Lall PhD,
J Horton MSc,
Prof S E Lamb DPhil,
A-M Slowther DPhil,
M Smyth MSc, Prof S Gates PhD);
Heart of England NHS
Foundation Trust,
Birmingham, UK,
(Prof G D Perkins); Surrey
Peri-operative Anaesthesia
Critical care collaborative
Research Group

Finding the effective innovations

Results of 85 trials in UK HTA



The UK EndoVascular Aneurysm Repair (EVAR) trials: EVAR versus surgical



CL

Endovascular

Roger M. Greenhalgh

This journal feature begins with a of the clinical problem and the main the clinical use of the therapy, if (if they exist, are present).

A 72-year-old man who was that were successfully managed 10% of patients with cerebral aneurysms, abdominal aortic aneurysms, abdominal aortic aneurysm formed the diagnosis.

The patient was assessed general anesthesia. Electrocardiogram (ECG) and forced expiratory volume in second, and the serum creatinine and angiotensin-converting enzyme (ACE) levels were measured.

The patient was considered for review of his CT scan also. This raised the question of an endovascular method or the

The incidence of abdominal aortic aneurysm (AAA) is approximately 1.7% of men and 1.7% of women. The prevalence of AAA increases with age, with a peak prevalence of 10% in men aged 65 years and older. The risk of developing an AAA is increased in patients with a family history of AAA, a history of smoking, and a history of hypertension. The risk of rupture is increased in patients with a maximum diameter of 5.5 cm or greater, a rapid increase in diameter, and a history of rupture. The risk of rupture is also increased in patients with a history of AAA who are treated with open repair.

Abdominal aortic aneurysm (AAA) is a condition in which the abdominal aorta becomes enlarged. It is a condition that can be life-threatening if it ruptures. The risk of rupture is increased in patients with a maximum diameter of 5.5 cm or greater, a rapid increase in diameter, and a history of rupture. The risk of rupture is also increased in patients with a history of AAA who are treated with open repair.

The New England Journal of Medicine

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THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Endovascular Repair of Aortic Aneurysm in Patients Physically Ineligible for Open Repair

The United Kingdom EVAR Trial Investigators*

ABSTRACT

BACKGROUND: Endovascular repair of abdominal aortic aneurysm was originally developed for patients who were considered to be physically ineligible for open surgical repair. Data are lacking on the question of whether endovascular repair reduces the rate of death among these patients.

METHODS: From 1999 through 2004 at 33 hospitals in the United Kingdom, we randomly assigned 404 patients with large abdominal aortic aneurysms (≥5.5 cm in diameter) who were considered to be physically ineligible for open repair to undergo either endovascular repair or no repair; 197 patients were assigned to undergo endovascular repair, and 207 were assigned to have no intervention. Patients were followed for rates of death, graft-related complications and reinterventions, and costs until the end of 2009. Cox regression was used to compare outcomes in the two groups.

RESULTS: The 30-day operative mortality was 7.3% in the endovascular-repair group. The overall rate of aneurysm rupture in the no-intervention group was 12.4 (95% confidence interval [CI], 9.6 to 16.2) per 100 person-years. Aneurysm-related mortality was lower in the endovascular-repair group (adjusted hazard ratio, 0.53; 95% CI, 0.32 to 0.89; $P=0.02$). This advantage did not result in any benefit in terms of total mortality (adjusted hazard ratio, 0.99; 95% CI, 0.78 to 1.27; $P=0.97$). A total of 48% of patients who survived endovascular repair had graft-related complications, and 27% required reintervention within the first 6 years. During 8 years of follow-up, endovascular repair was considerably more expensive than no repair (cost difference, £9,826 [U.S. \$14,667]; 95% CI, 7,638 to 12,013 [11,556 to 18,376]).


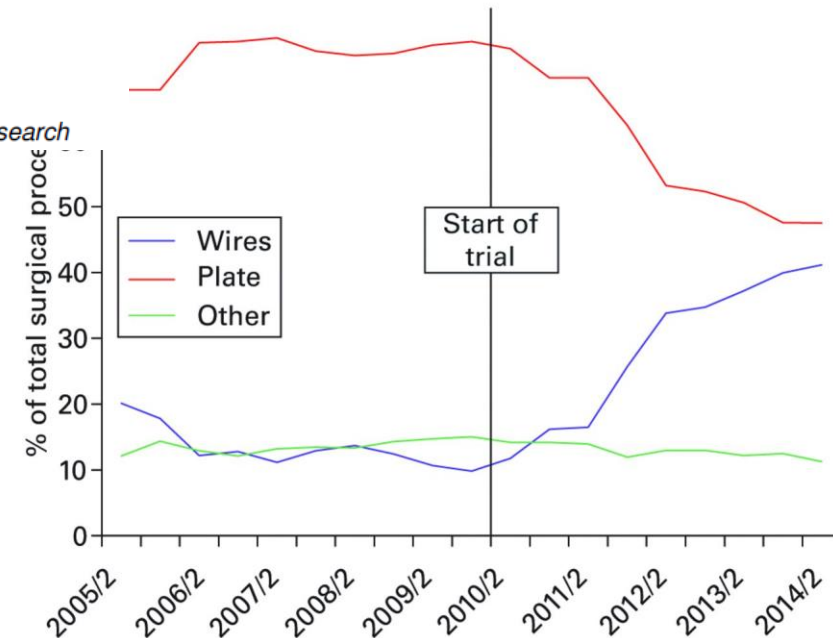
CONCLUSIONS: In this randomized trial involving patients who were physically ineligible for open repair, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower rate of aneurysm-related mortality than no repair. However, endovascular repair was not associated with a reduction in the rate of death from any cause. The rates of graft-related complications and reinterventions were higher with endovascular repair, and it was more costly. (Current Controlled Trials number, ISRCTN55703451.)

1872

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RESEARCH

Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: randomised controlled trial OPEN ACCESSMatthew L Costa *professor of trauma and orthopaedic surgery*^{1,2}, Juul Achten *senior research*



RESEARCH

Open Access



Impact of NIHR HTA Programme funded research on NICE clinical guidelines: a retrospective cohort

Sheila Turner^{1*}, Sheetal Bhurke¹ and Andrew Cook²

Abstract

Background: It is vitally important that there is a connection between health research and clinical practice. Indications as to the impact of the research on evidence-based practice and policy can be obtained by tracking the use of outputs of health research, especially its use in clinical guidelines (CGs). This study aims to assess the proportion of National Institute for Health and Care Excellence (NICE) CGs citing National Institute for Health Research Health Technology Assessment (NIHR HTA) studies and the impact of evidence from those studies on the included NICE CGs.

Methods: This is a retrospective cohort study assessing the proportion of NICE CGs from all NICE CGs issued between April 2001 and April 2012, which cited evidence from studies funded by the NIHR HTA Programme and the impact of those studies on the CGs as the primary and secondary outcome measures.

Results: Of the cohort of NICE CGs ($n = 122$), 3 (2%) CGs were based on previous NIHR HTA reports and would not have been issued in that form without those NIHR HTA studies, 90 (74%) included evidence from NIHR HTA studies, and 29 (24%) did not include evidence from NIHR HTA studies. The impact of NIHR HTA evidence on NICE CGs varied in the type and quantity of data used.

Conclusions: Findings suggest that NIHR HTA funded research impacts on clinical guidance from NICE and hence is well connected to both clinical practice and policy.

Keywords: Impact, Health Technology Assessment, NICE, Clinical guidelines

The impact of the NIHR Health Technology Assessment Programme, 2003–13: a multi-method evaluation

The Health Technology Assessment (HTA) programme, established in 1993, is the largest and longest-running research programme of the National Institute for Health Research (NIHR). Its purpose is to ensure that those who use, manage and provide care in the NHS have good quality information to make evidence-based decisions about health technologies. The HTA programme funds research on the effectiveness, costs and broader impact of health technologies.

Objective

RAND Europe assessed the impact of HTA-funded research and the HTA programme on patient health, clinical practice, health policy, economic activity and academic research. The study primarily assessed the impact arising from research between 2003–13, and also considered how the HTA programme could maintain and increase its impact in the future.

Results

Using data gathered through interviews, bibliometric analysis, a survey and 12 case studies involving HTA-funded research, we identified impacts in three areas:

- (i) the NHS
- (ii) the UK research system
- (iii) industry and the economy.

Impact on the NHS

We conclude that the HTA programme has a significant impact on patient care in the NHS through its funding of the clinical trials and evidence syntheses that underpin clinical guidelines produced by the National Institute for Health and Care Excellence (NICE). While we did not look at the uptake of this guidance by clinicians nationally

Summary

- RAND Europe assessed the impact of the Health Technology Assessment (HTA) programme on patient health, clinical practice, health policy, economic activity and academic research between 2003–13 using interviews, bibliometric analysis, a survey and case studies.

- Overall, the evaluation found that the HTA programme is having a positive impact on patient health, clinical practice, health policy, economic activity and academic research.

- The programme has funded a large number of clinical trials and evidence syntheses that underpin clinical guidelines.

- Case studies identified a range of impacts on patient health, clinical practice, health policy, economic activity and academic research, including the development of new markets.

- As a major source of evidence, HTA research has helped build and maintain the NHS's reputation as a world leader in health care.

- Papers on HTA research have been cited in the expected literature.

- To increase the impact of HTA research, the programme should:

- Providing targeted support for research on the short-term costs of implementing new technologies
- Monitoring and evaluating the impact of patient and public involvement
- Improving the transparency of its priority-setting process.

POLICY BRIEF

HEALTH TECHNOLOGY ASSESSMENT

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The impact of the National Institute for Health Research Health Technology Assessment programme, 2003–13: a multimethod evaluation

Susan Guthrie, Teresa Bienkowska-Gibbs, Catriona Manville, Alexandra Pollitt, Anne Kirtley and Steven Wooding

DOI 10.3310/hta19670


National Institute for Health Research

BMJ Open Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review

Annette Boaz,¹ Stephen Hanney,² Teresa Jones,² Bryony Soper²

To cite: Boaz A, Hanney S, Jones T, *et al*. Does the engagement of clinicians and organisations in research

ABSTRACT

Objective: There is a widely held assumption that engagement by clinicians and healthcare organisations in research improves healthcare performance at various

Strengths and limitations of this study

- This review brings together for the first time a diverse body of literature addressing whether

The NIHR as an engine for growth

Thursday 5 March 2015, Westminster

Minister for Life Sciences, George Freeman said:

“The Government’s investment in the NIHR has led to a transformation in the environment for health research, including research funded by the life sciences industry. The NIHR’s integrated health research system is a key element of our international competitiveness, improving both the health and wealth of the nation.”



Study delivery and management: Managing performance with quality

- A research-ready workforce

10,000+ GCP-trained research staff embedded in the NHS to support investigators with patient identification, recruitment, clinical delivery

- ICH GCP training

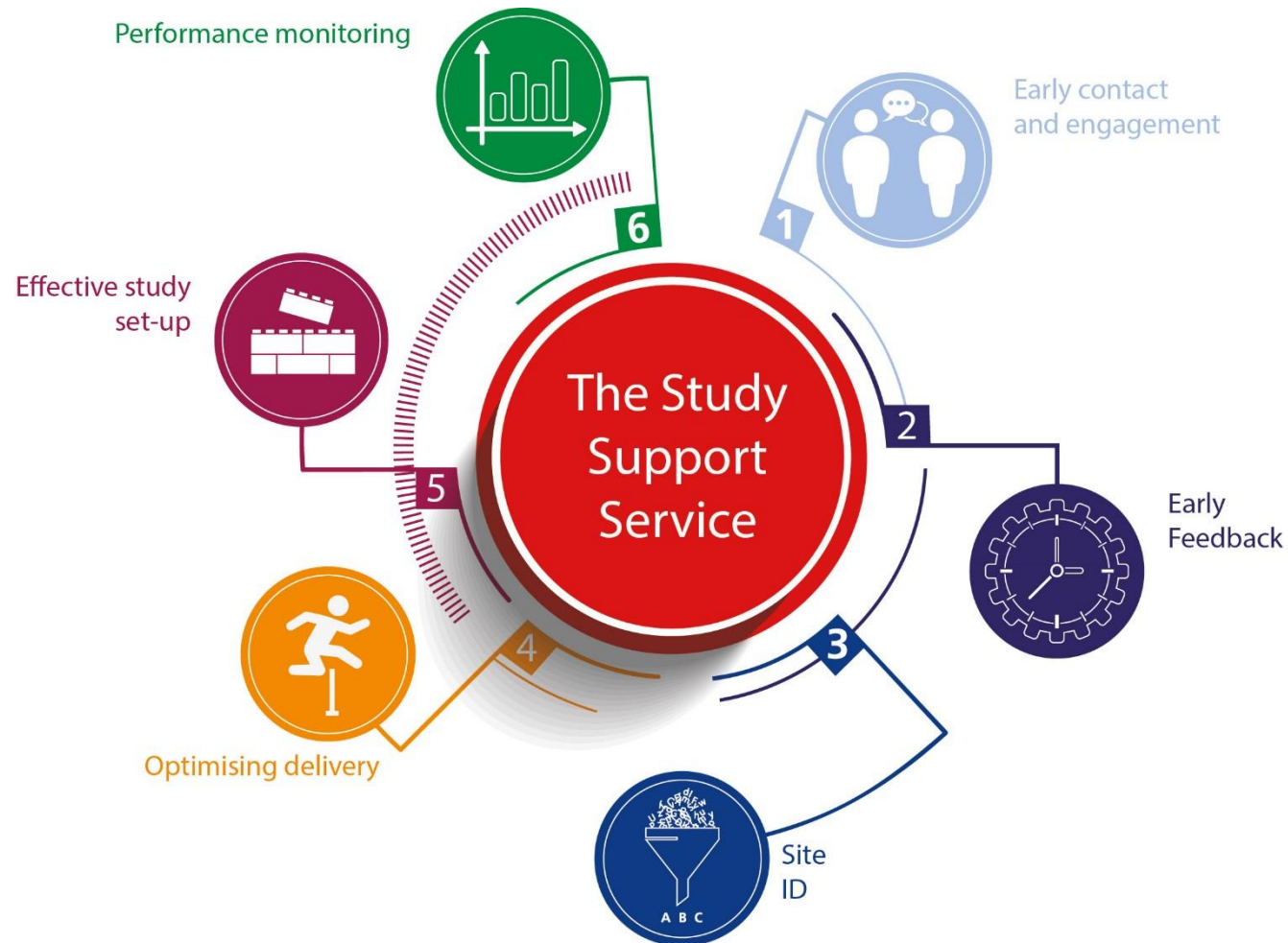
Free to any staff working on NIHR CRN clinical trials

Supported by MHRA

Added to the list of GCP programs mutually recognised by TransCelerate

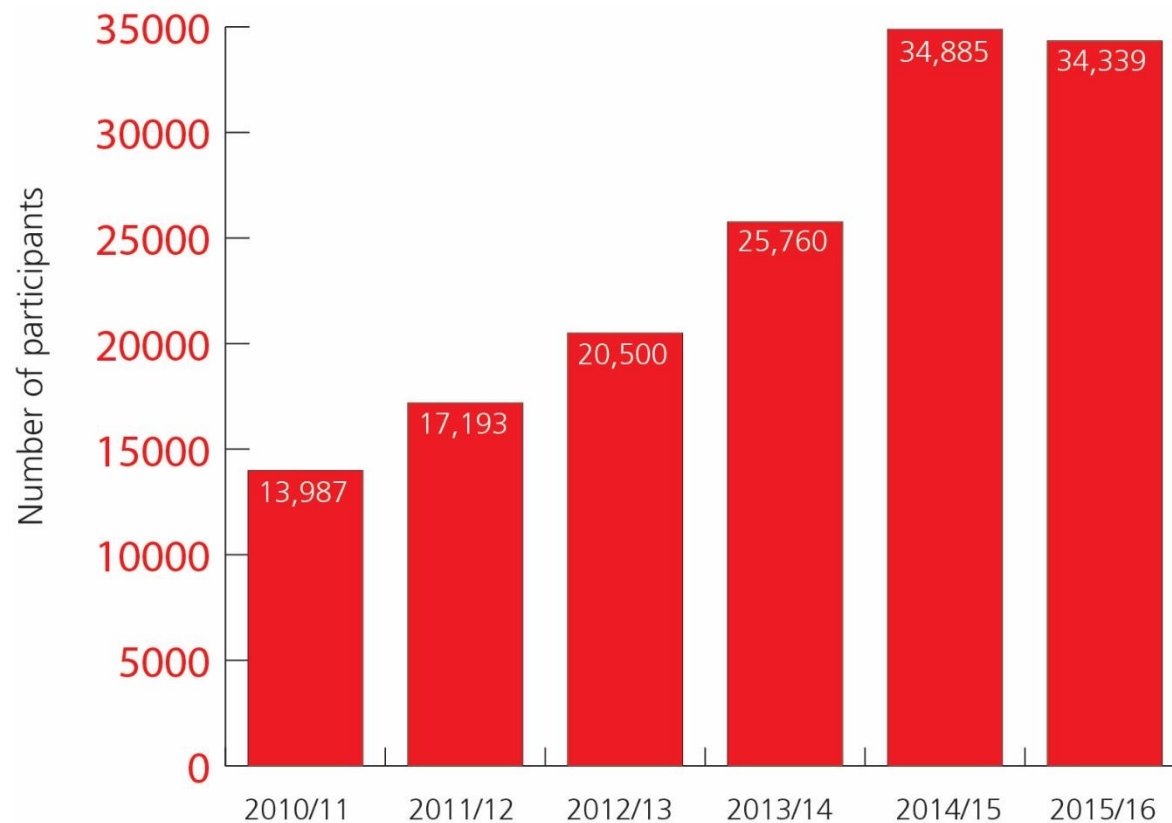


Service summary



The evidence: recruitment

Number of participants into commercial NIHR CRN Portfolio studies



- **146,664** patients recruited to industry studies over the last 6 years
- **34,339** patients recruited to commercial contract studies in 15/16
- **16 first global patients** in 2015/16
- **13 first European patients** in 2015/16

Success of NIHR

- Solid foundations in basic and clinical science
- Government support - research health economic growth
- Focus on NHS/patient needs
- Collaboration patients/clinicians/NHS/industry
- Challenges ahead for NHS
 - Changing demographics
 - New technologies
 - Economic austerity
 - Research and NIHR part of the answers to these challenges

If you think research is expensive, try
disease.

Mary Lasker (1901-94)