NHS
National Institute for Health Research

NIHR HTA Programme: introducing the concepts

Dr Sarah Puddicombe

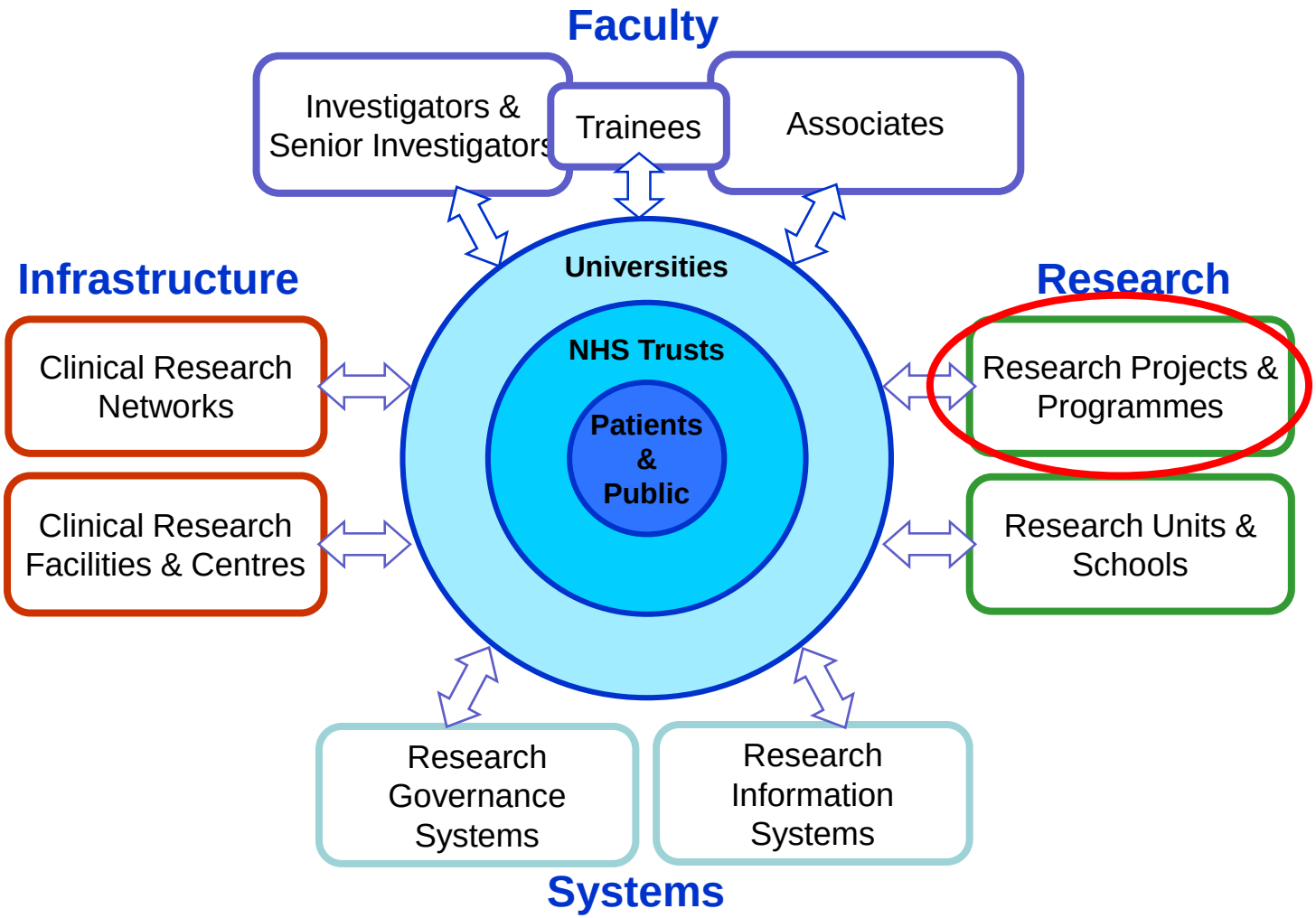
Assistant Director, NETSCC

Evaluation, Trials and Studies Coordinating Centre

KCE Brussels, 12 October 2016

NIHR Health Research System

NHS National Institute for Health Research

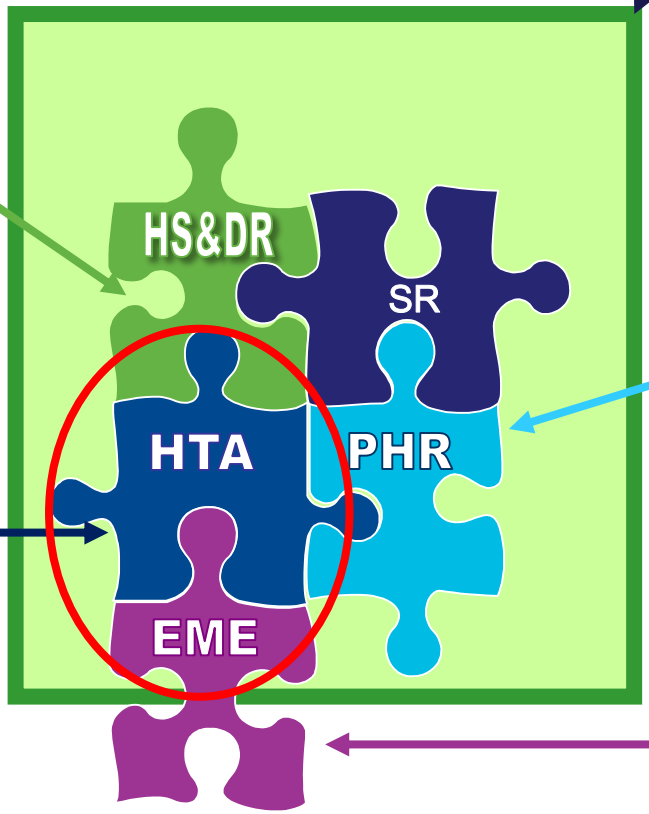


Some NIHR programmes

Commissioned and researcher-led calls
Full and appropriate funding, no upper limit (except SR)

Systematic Review (est 2012)
Production and updated SRs supported by core funding UK Cochrane Centre, Cochrane Review Groups and two funding streams (CPG and CIA)

Health Services and Delivery Research (est 2012)
Models of delivery, systems research, patient experience
Mainly qualitative or mixed methods



Public Health Research (est 2008)

Public health interventions outside the conventional health service.

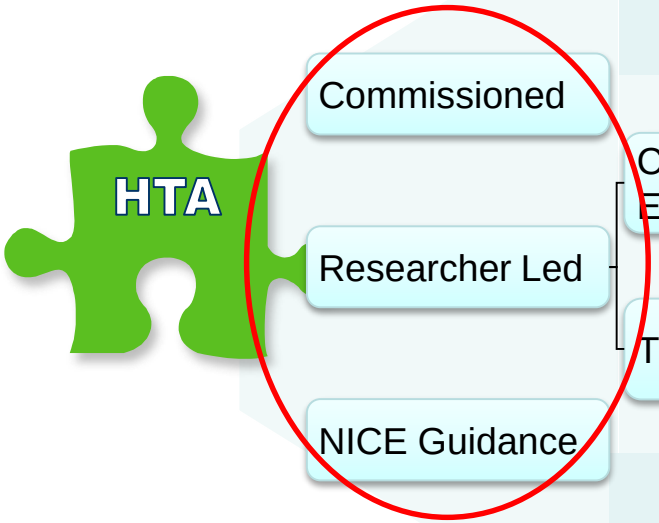
Health Technology Assessment (est 1993)
Pragmatic,
Clinical and cost effectiveness
Mainly quantitative.
Evidence synthesis and RCTs or any appropriate study design

Efficacy & Mechanism Evaluation (est 2008)

Funded jointly by the Medical Research Council & NIHR.
Translational research broker.
Efficacy (e.g phase 2b) and mechanistic studies. Mainly devices and pharmaceuticals

NIHR HTA programme

NHS National Institute for Health Research



Types of Research	Who defines the question?	Frequency Per year
Primary research Feasibility & pilot Evidence synthesis	HTA programme	3 calls
Primary research Feasibility & pilot Evidence synthesis	Researcher	Continuous with 3 closing dates
Primary research Evidence synthesis	NIHR theme & question from researcher	1 call
Specific technology assessment	NICE	Direct referral to On-contract teams

Funds independent research on the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS.

The Funding Streams

NHS National Institute for Health Research

Commissioned work stream

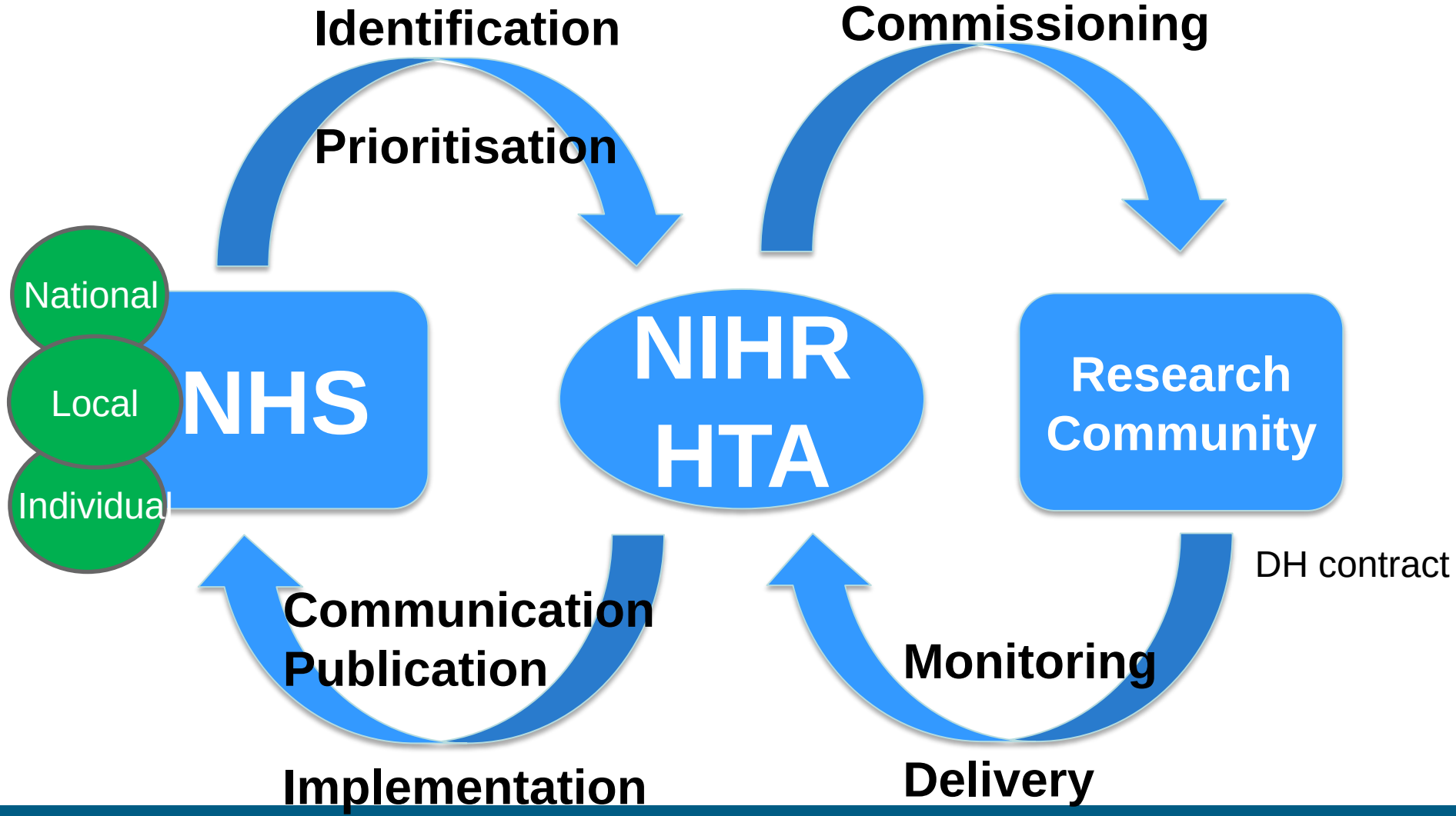
- Addresses ‘market failure’
- Designed to **meet the needs of decision makers** within NHS
- Topics prioritised by expert panels and **commissioning briefs advertised to address identified evidence need**
- Board assessment of compliance to brief, scientific quality, feasibility and value for money.

Researcher-led work stream

- **Calls for applications on research topics/questions directly proposed by researchers**.
- *Highlight notices/ themed calls used to promote areas of need.*
- Applications prioritised on NHS or other information need by advisory panels
- Board assessment of scientific quality, feasibility and value for money.

Addressing NHS and policy customers needs

NHS
National Institute for Health Research



NIHR HTA programme

NHS National Institute for Health Research

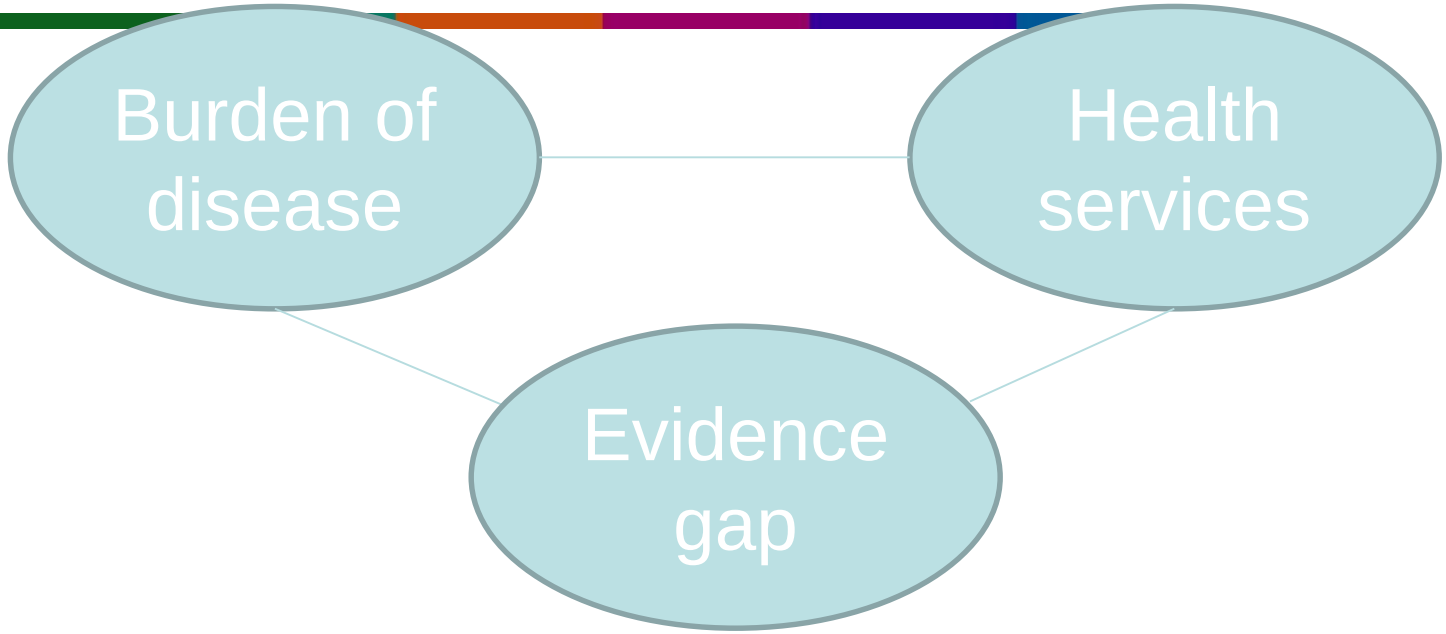
- Multidisciplinary and multi-centre
- Effectiveness and cost-effectiveness (usually estimate £/QALY)
- Pragmatic and externally valid
- Median number of patients = 700 (Range of 15 to 75,000 across current projects)
- Average duration ~4 years and £~1.5 m
- Protocols available on web site with costs

Types of studies funded:

- randomised controlled trials and non-randomised trials
- cohort studies (retrospective or prospective)
- adaptive and efficient study designs, methodological studies
- evidence synthesis and modelling studies (plus support for NICE/ policy customers)

Prioritising research need

NHS
National Institute for Health Research



Need = frequency x severity x impact of technology x evidence deficit

(Discounted for time to produce evidence)

Important question on an important subject

Commissioned workstream

NHS National Institute for Health Research

Topic suggestions

PICO question developed → Portfolio checks

Topic Identification meeting

Panel Topics developed

Panel Meeting

Vignettes developed ← Expert review

Methods Group

Final Vignettes

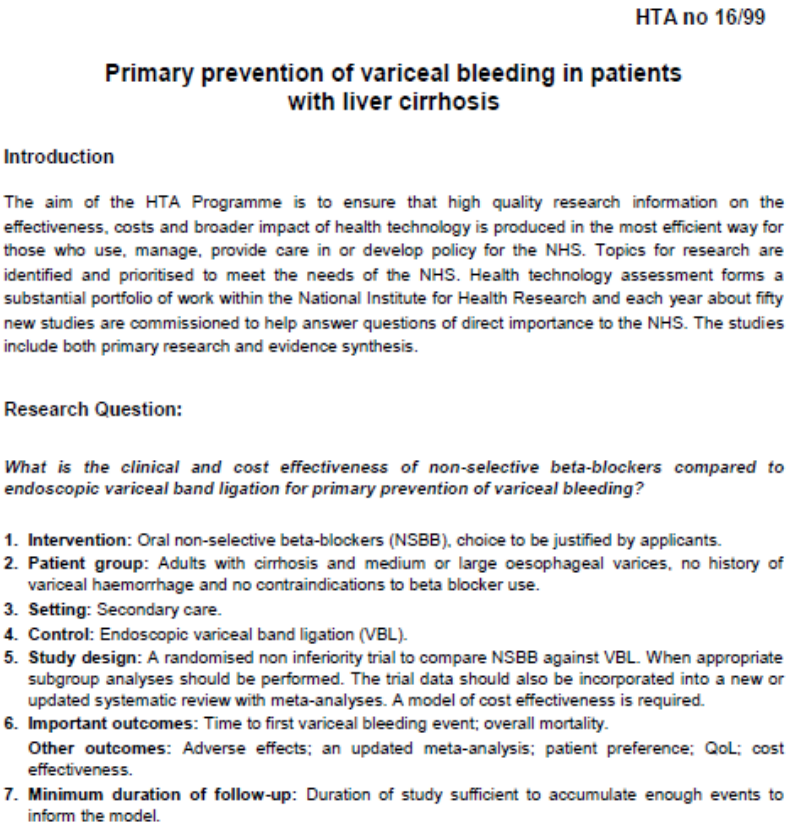
Prioritisation Group → **Advertised Commissioning Briefs** → **EOI applications** → **1st Commissioning Board**

NHS

5 Panels

- **Primary Care, Community and Preventive Interventions**
- **Maternal, Neonatal and Child Health**
- **Interventional Procedures**
- **Mental, Psychological and Occupational Health**
- **Elective and Emergency Specialist Care**

Priority Research Advisory Methodology Group – for direct policy customer priorities



HTA no 16/99

Primary prevention of variceal bleeding in patients with liver cirrhosis

Introduction

The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

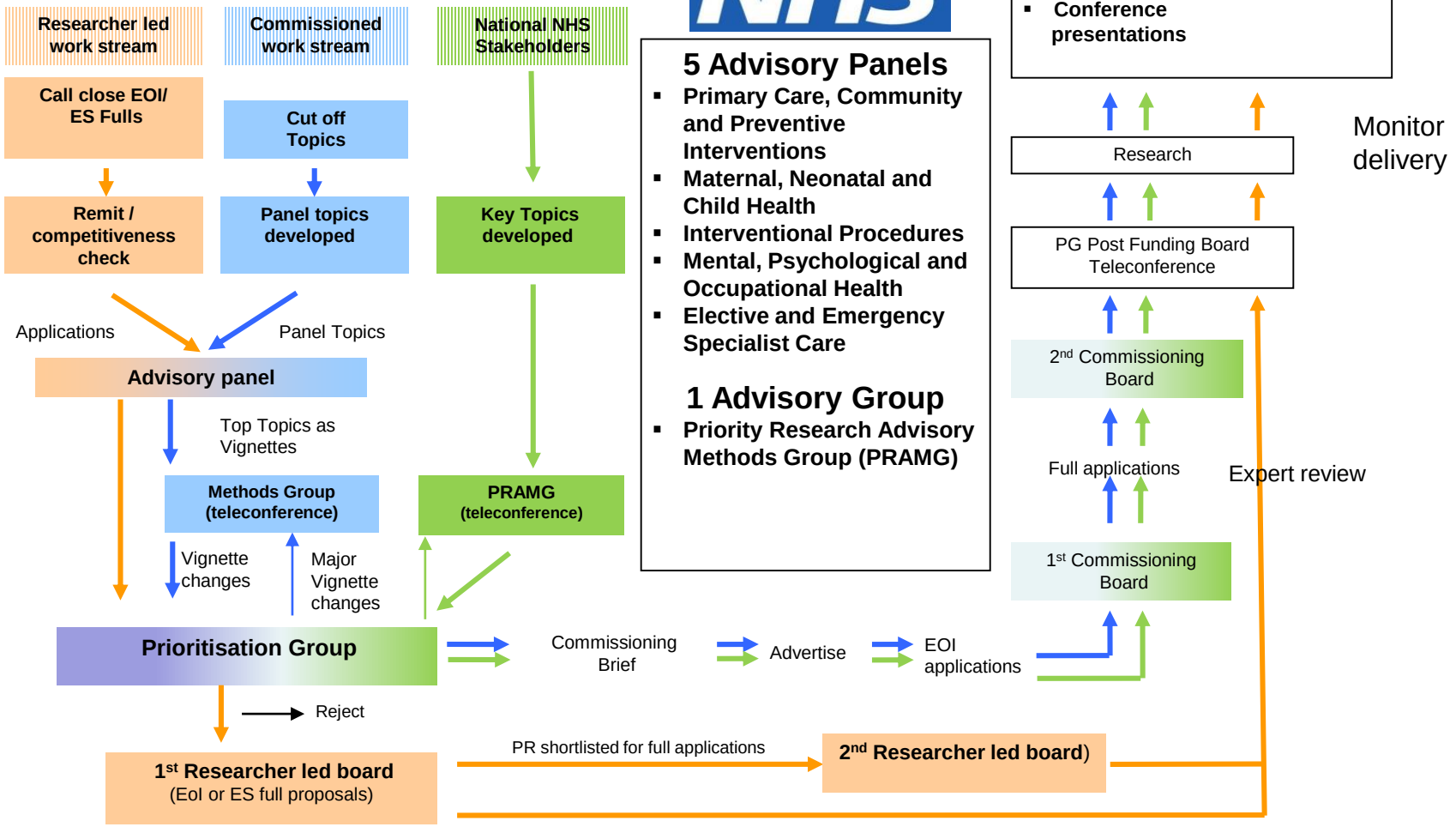
Research Question:

What is the clinical and cost effectiveness of non-selective beta-blockers compared to endoscopic variceal band ligation for primary prevention of variceal bleeding?

1. **Intervention:** Oral non-selective beta-blockers (NSBB), choice to be justified by applicants.
2. **Patient group:** Adults with cirrhosis and medium or large oesophageal varices, no history of variceal haemorrhage and no contraindications to beta blocker use.
3. **Setting:** Secondary care.
4. **Control:** Endoscopic variceal band ligation (VBL).
5. **Study design:** A randomised non inferiority trial to compare NSBB against VBL. When appropriate subgroup analyses should be performed. The trial data should also be incorporated into a new or updated systematic review with meta-analyses. A model of cost effectiveness is required.
6. **Important outcomes:** Time to first variceal bleeding event; overall mortality.
   Other outcomes: Adverse effects; an updated meta-analysis; patient preference; QoL; cost effectiveness.
7. **Minimum duration of follow-up:** Duration of study sufficient to accumulate enough events to inform the model.

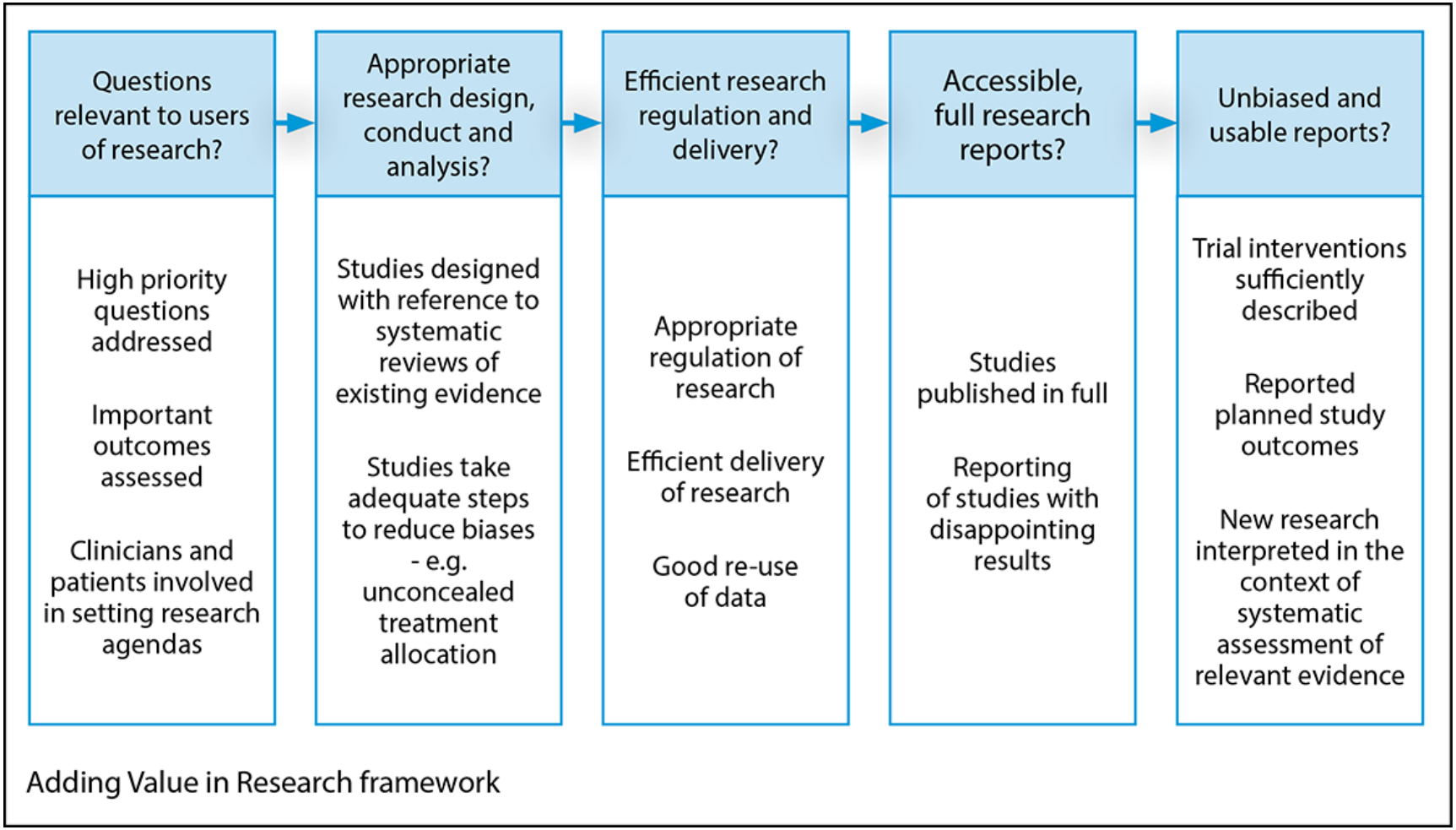
Overview of HTA Programme

National Institute for Health Research



Maximising the potential impact of health research funding

NHS
National Institute for Health Research



Adding Value in Research framework

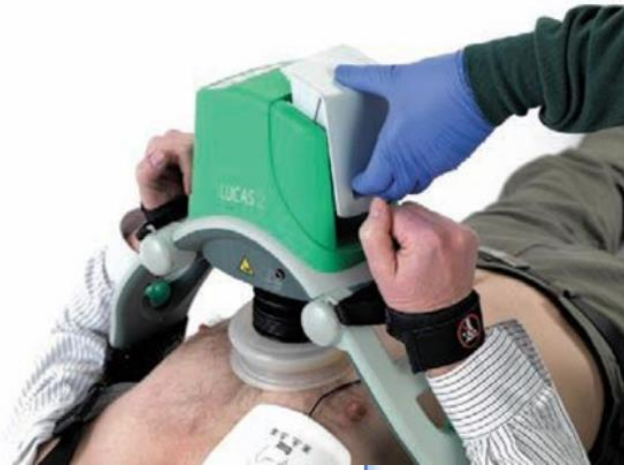
HTA - Trial of the year 2014

NHS
National Institute for Health Research

THE LANCET

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 J M Black, John Wright, Kyee Ha Simon Gates, PARAMEDIC trial collaborators*



Summary

Background Mechanical chest compression devices have the potential to help maintain high-quality cardiopulmonary resuscitation (CPR), but despite their increasing use, little evidence exists for their effectiveness. We aimed to study whether the introduction of LUCAS-2 mechanical CPR into front-line emergency response vehicles would improve survival from out-of-hospital cardiac arrest.

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.

Lancet 2015; 385: 947–55
Published Online November 16, 2014 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, Prof M W Cooke PhD, J Horton MSc, Prof S E Lamb DPhil, A-M Slowther DPhil, M Smyth MSc, Prof S Gates PhD); Heart of England NHS

NIHR Infrastructure to support the design and delivery of research

NHS National Institute for Health Research

- Our **Research Design Service (RDS)** provides design and methodological support to health and social care researchers **across England**
- **INVOLVE** is our national advisory group supporting active **public involvement** in *NHS*, public health and social care research
- Our **Clinical Trials Units (CTUs)** provide specialist expert statistical, epidemiological and other advice and coordination to undertake successful clinical trials
- **Clinical Research Networks** (**CRN**) across the UK to support development and delivery of clinical studies

Summary HTA

NHS National Institute for Health Research

- Funds pragmatic, clinical and cost effectiveness research to inform decision makers, clinicians and patients.
- Identify and prioritise NHS research needs using expert advisory panels (clinicians, patient/public, commissioners)
- Boards assess scientific rigour and value for money of research proposals to ensure high quality research
- All studies are informed by review of existing evidence
- Require active public and patient involvement at every stage
- Monitor delivery of research to time and target
- Publication and dissemination to NHS evidence users

Thank you

NHS
National Institute for Health Research

Any Questions?

Contact:
S.M.Puddicombe@nihr.ac.uk