University of BRISTOL

MRC Hubs for Trials Methodology Research
ConDuCT-II Hub

Conducting successful RCTs in surgery

Jane M Blazeby
Professor of Surgery & Honorary Consultant Surgeon,
Director MRC ConDuCT-II Hub for Trials Methodology Research
Director Royal College of Surgeon of England Trials Centre

COMMENTARY

Surgical research or comic opera: questions, but few answers

See pages 989, 995, 1000, 1004

How does surgical knowledge advance? In this week's issue, we focus on this question by publishing the results of four surgical investigations that adopt very different study designs. Majeed and colleagues report results from a randomised trial comparing laparoscopic with small-incision cholecystectomy. The design of this study, with appropriate sample-size calculation, in-theatre randomisation, and masked assessments of outco (identical wound dressings in both groups of patien sets a new standard for surgical trials. An evaluation how these new data, which suggest that laparosco surgery offers no clear advantage, might influence surg practice in a developing country is provided in accompanying commentary. But the way in which Maj et al set out to answer their question about effectiveness of these two techniques is very much exception rather than the rule in surgical research. Th study raises important issues about why surgeons research, how they do it, what criteria they use to ju the validity of their findings, and how their resea practice compares with that of the rest of the med community.

To obtain a clearer idea of what "surgical resear means, I read the first issue for 1996 of nine gen surgery journals.* Excluding letters and book revie these journals contained 215 articles, 175 of wh described the results of original research. Only 12/1 papers (7%) reported data derived from a randomi

situation that can only be damaging to surgical practice.

What mitigating arguments might explain this preoccupation with the case series? Perhaps many surgeons do not see randomised trials as a feasible strategy to resolve questions about surgical management. Cynics might even claim that the personal attributes that go to make a successful surgeon differ from those needed for collaborative multicentre research. Standardisation of surgical techniques, as Majeed et al point out, is one difficulty in designing randomised protocols. And problems about which endpoints to select or what study

A renaissance in surgery

A new and welcome vigour is evident in surgery, spurred by the enthusiasm of young surgeons and the collaboration of established researchers from other disciplines. In today's issue of *The Lancet*, the sixth annual surgery-themed issue published to coincide with the American College of Surgeons Clinical Congress (in San Francisco, CA, on Oct 26–30, 2014), we present recent developments in surgical research and consider how they might influence the conference theme: the surgeon of the future.

The Royal College of Surgeons of England has also examined the changing role and responsibilities of surgeons in *Good Surgical Practice*, published on Aug 29. A similar document, *Good Medical Practice*, was updated by the UK General Medical Council in 2013 to show the behaviour expected of any doctor registered with the Council. Whereas the General Medical Council took a philosophical approach to practice, *Good Surgical Practice* adopts a more practical attitude. Both documents can be commended for the promotion of compassionate, collaborative, and effective care. However, the emphasis on minimal standards, care pathways, and guidelines in *Good Surgical Practice* results in a document that might have been written by the government, rather than a Royal College promoting ambitions for the profession. Absent are the higher aspirations of providing a truly excellent service that might inspire the next generation, and the transition from experience-based surgery to evidence-based practice that could empower both surgeons and patients to achieve better outcomes more consistently.

The data for the aforementioned studies came from the National Joint Registry of England, Wales, and Northern Ireland—the largest such registry in the world with more than 1 million records. Many other registries for different devices exist in several countries. The potential to detect early signals of device performance from registry data is enormous, and was discussed at the annual meeting of the Medical Device Epidemiology Network initiative (MDEpiNet) during the past week in Washington, DC. Nurtured by the US Food and Drug Administration, MDEpiNet is evolving into a public–private partnership between regulators, universities, and other stakeholders to develop and apply new analytical techniques to assess devices throughout their life cycle.

Other aspects of surgical care also benefit from a cross-disciplinary approach, as in the surgical trauma Series, where common pathways in physiology and immunology contribute to understanding the derangements that follow acute trauma and how they can best be corrected. The opportunity equally exists for surgeons within the controlled trauma environment of an operation to contribute new insights into the underlying molecular biology of tissue damage and repair.

Research in Surgery crosses borders and cultures. The Comment on global child health competencies by Bhanu Williams and colleagues might well be expanded to discuss surgery within child survival initiatives. Indeed, surgery is a critical component not only for child survival, but for global health in general, as will be elaborated in *The Lancet* Commission on Global Surgery to be published in 2015.

See Comment pages 1405 and 1407

See Perspectives pages 1417, 1418, 1419, and 1421

See Articles pages 1429, 1437, and 1446

See Series pages 1455 and 1466

For ***Good Surgical Practice*** see http://www.rcseng.ac.uk/surgeons/surgical-standards/professionalism-surgery/gsp/documents/good-surgical-practice-pdf


Gryffindor

A new era

"to create a culture & provide an infrastructure for multidisciplinary research that contributes to significant changes in surgical services in the NHS and worldwide"

MRC | Hubs for Trials Methodology Research

www.methodologyhubs.mrc.ac.uk

http://www.rcseng.ac.uk/surgeons/research/surgical-research/surgical-clinical-trials

RCTs in surgery are possible

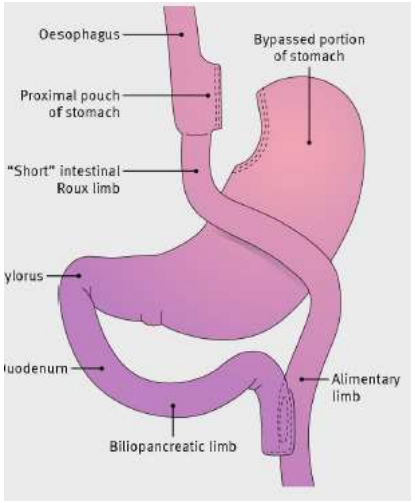
How to optimise recruitment

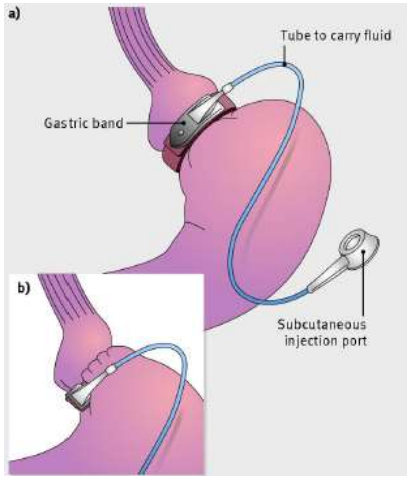
Keeping the research question relevant

How to collaborate....

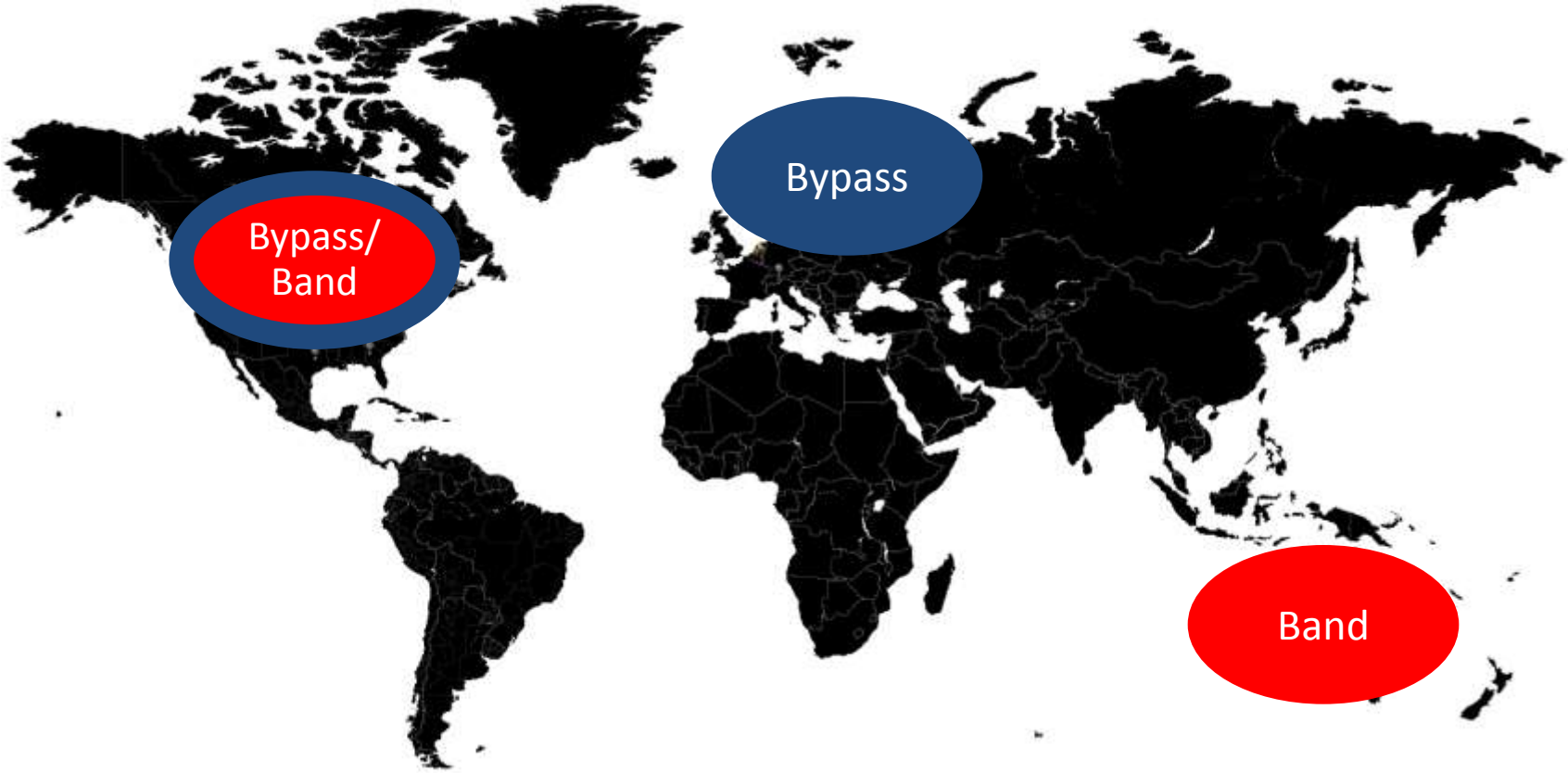
By-Band

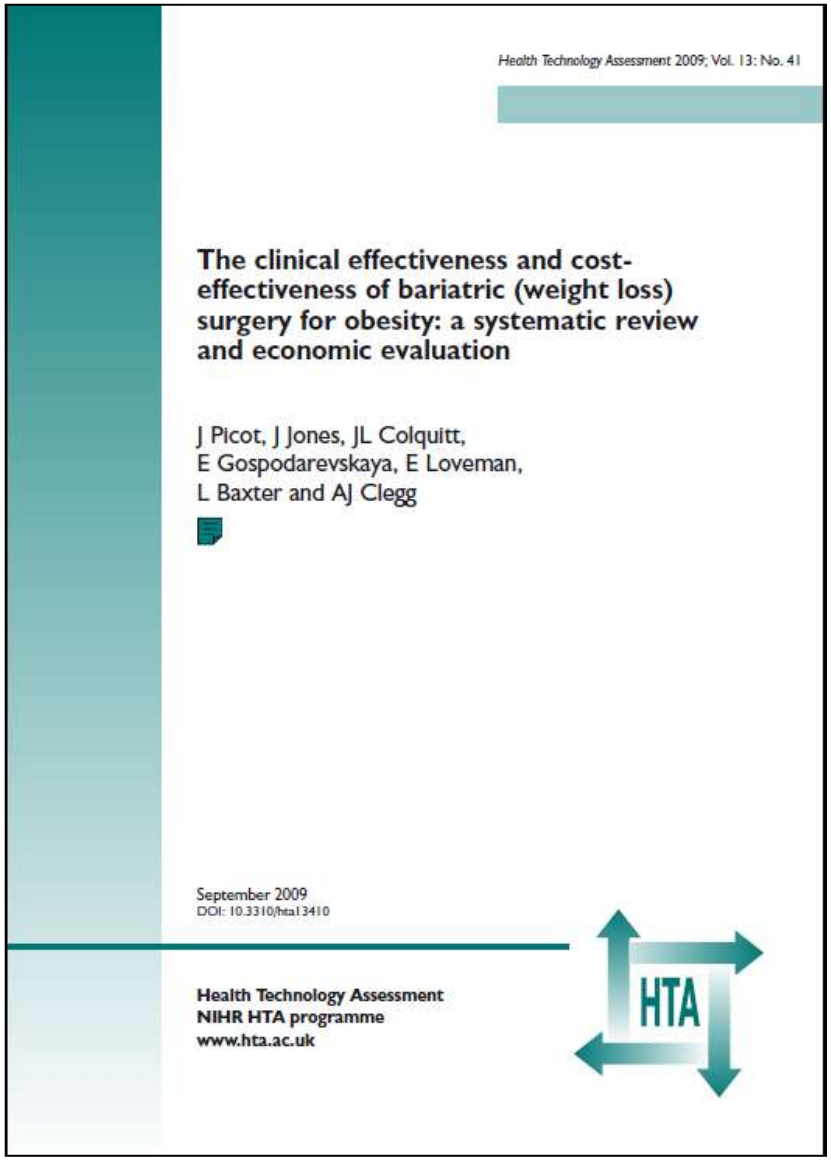
NHS
National Institute for
Health Research





2009/2010





20 RCTs

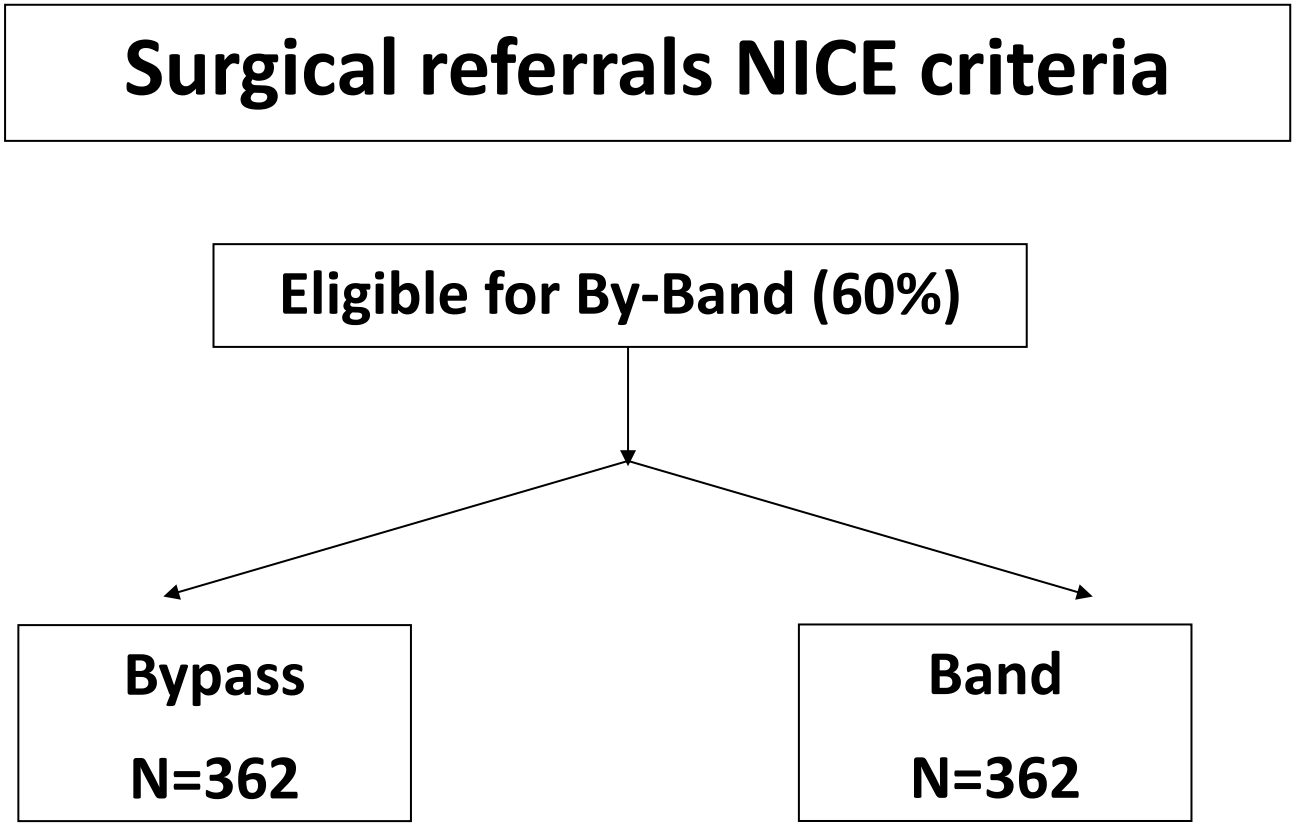
Just two: Band *vs.* Bypass

HTA report stated...

*"A comparison of procedures... such as **gastric bypass** with **adjustable gastric banding**, would be desirable....*

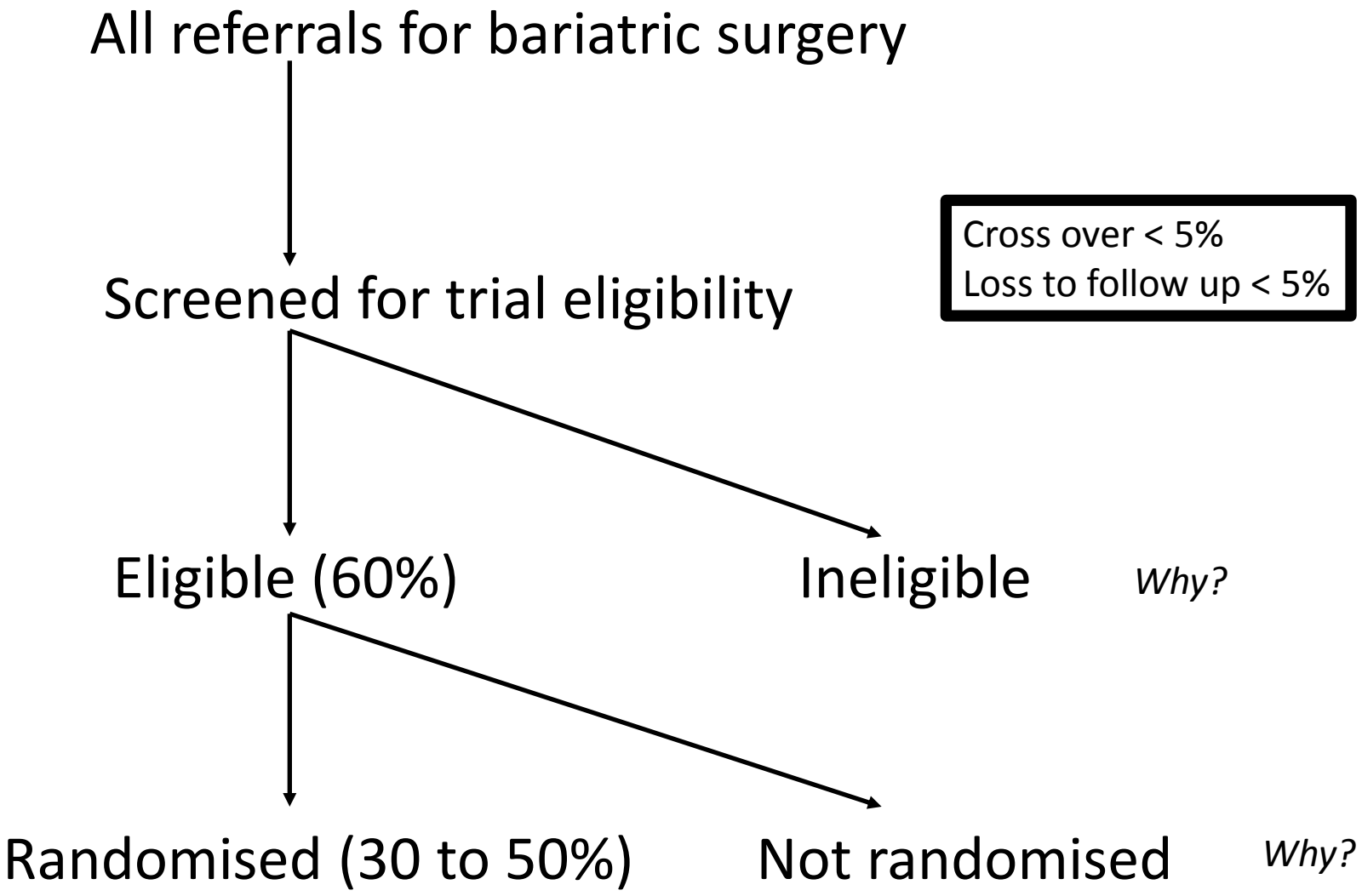
.....however, this may not be possible because of expert opinion"

The By-Band Study



Internal pilot phase with recruitment intervention

Rigorously use screening logs



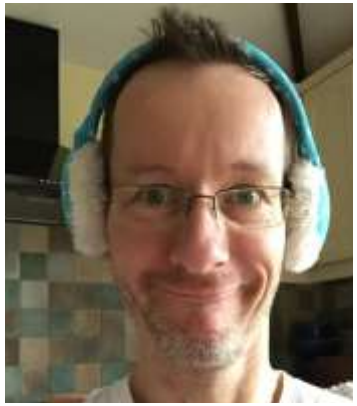
Hamish Noble

Jim Byrne

Richard Welbourn

David Mahon

Jez Hayden



Richard Byrom

Nick Davies

Abeezar Sarela

Jamie Kelly

Internal pilot results (24 centre months)

All referrals for bariatric surgery

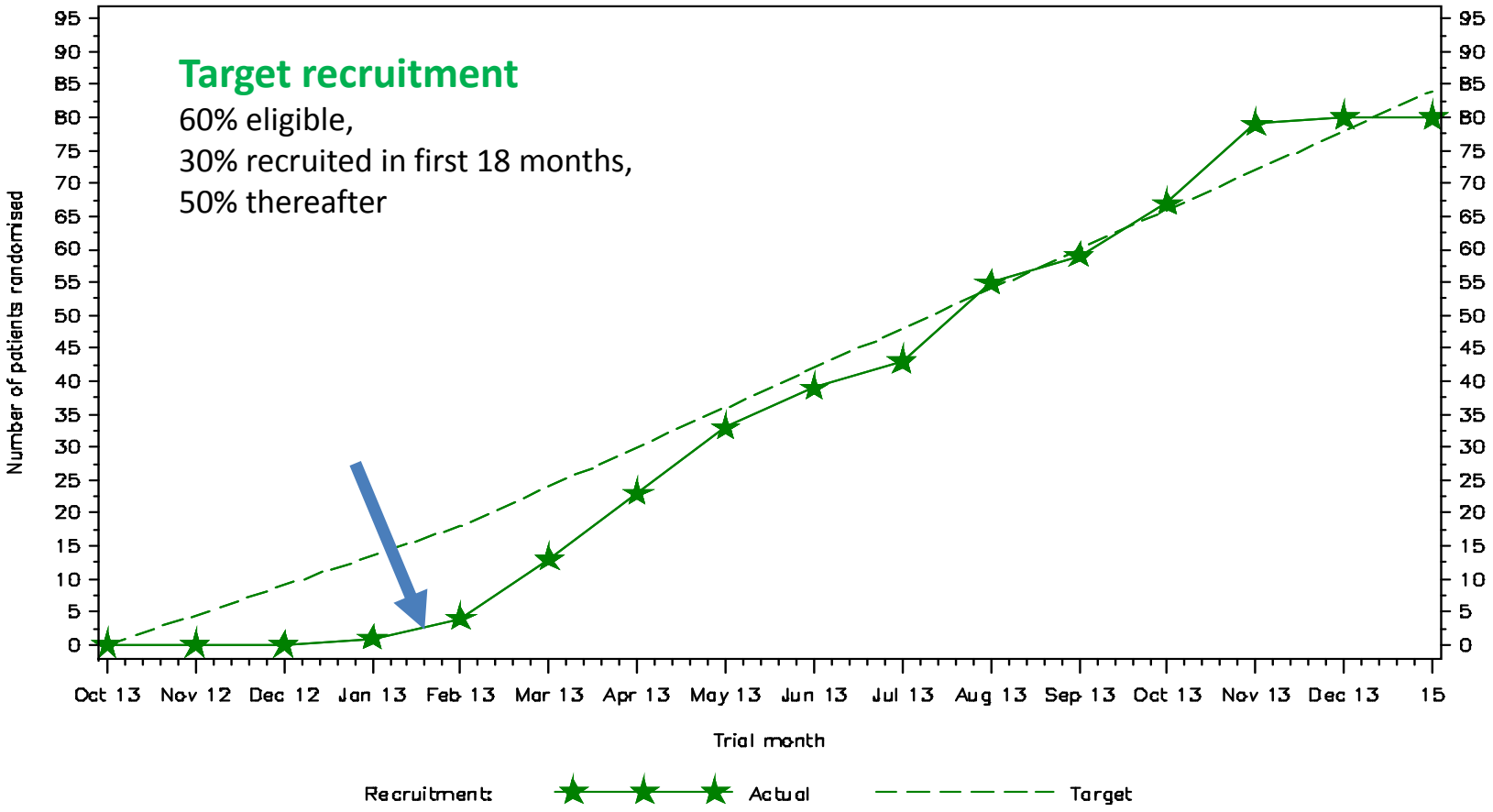
Screened for trial eligibility **333 pts (24% fewer)**

Eligible **231 pts (69%)**

Randomised **28% first three months to 49%**

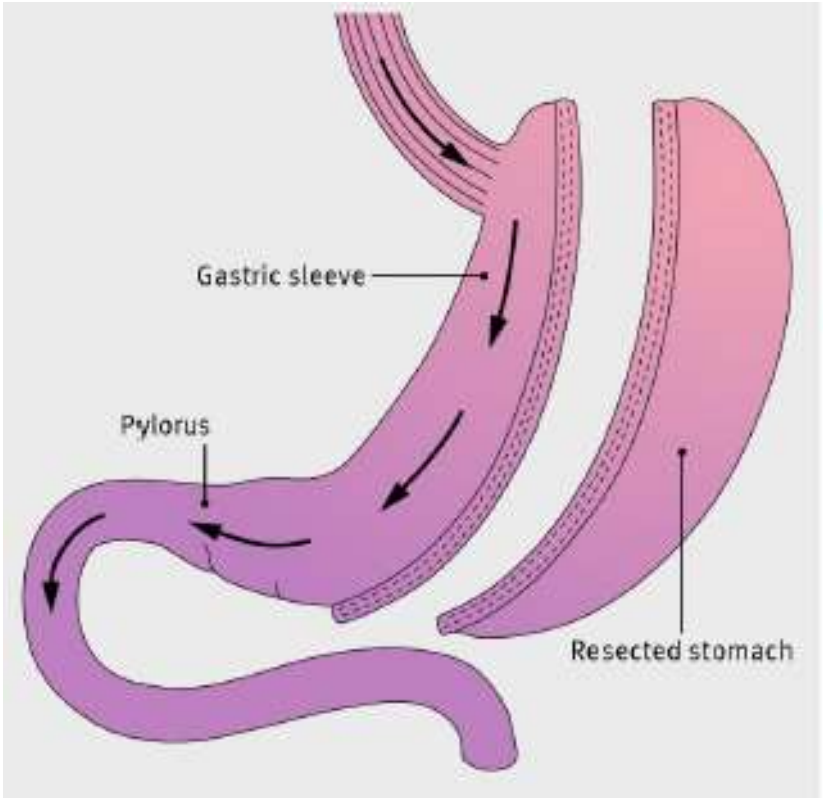
Cross over 3.5%
Loss to follow up 2%

Recruitment internal pilot



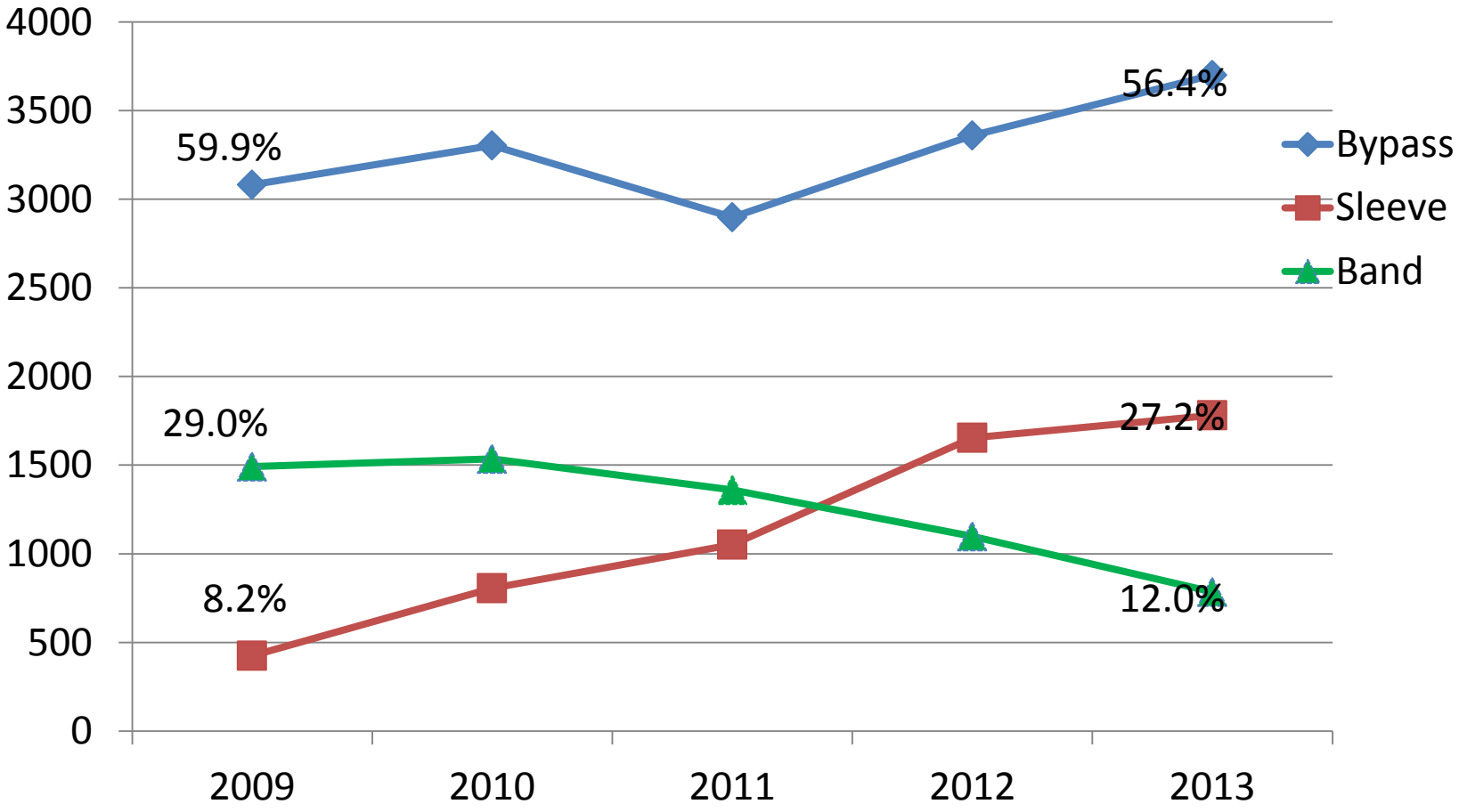
Progression criteria

Keep the research question relevant

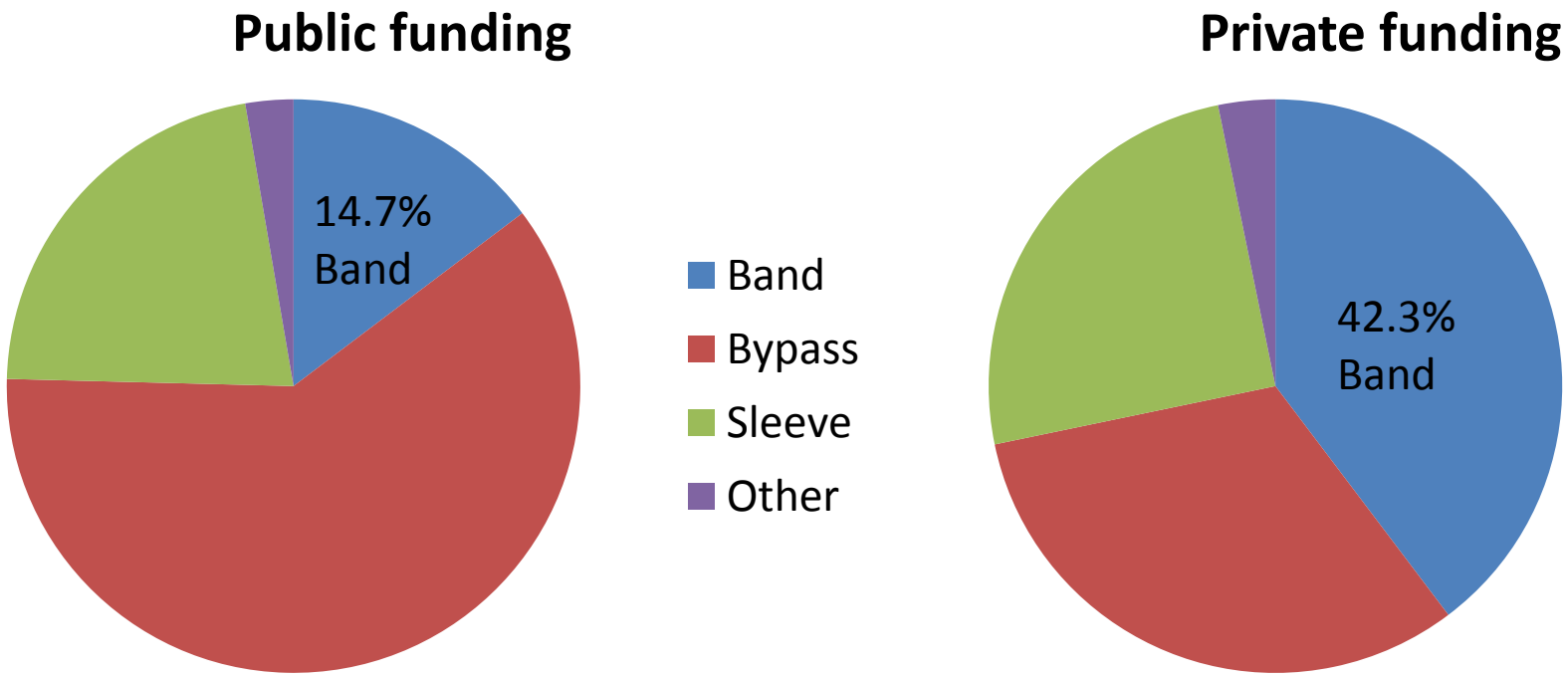


Sleeve gastrectomy

Changes in UK bariatric surgery



Private & public surgery 2011- 2013



Surgery for weight loss in adults (Review)

Colquitt JL, Pickett K, Loveman E, Frampton GK

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2014, Issue 8

http://www.thecochranelibrary.com

WILEY

15 RCTs of surgical interventions

Internal pilot to main trial

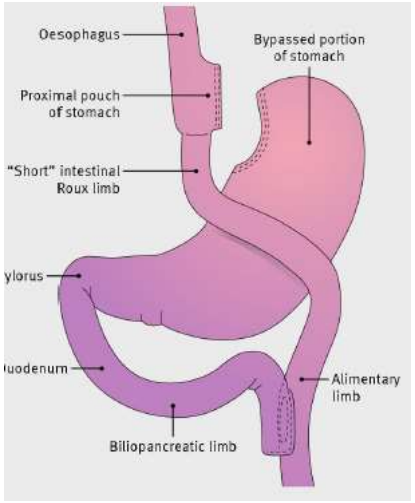
By-Band-Sleeve

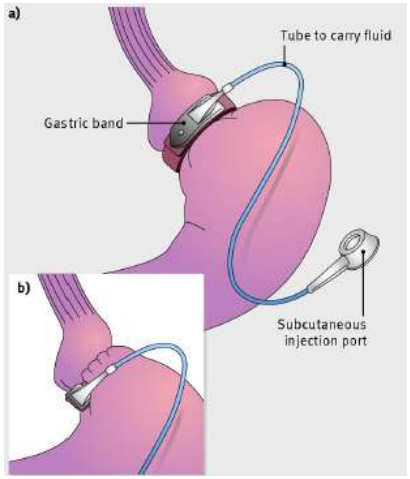
By-Band-Sleeve

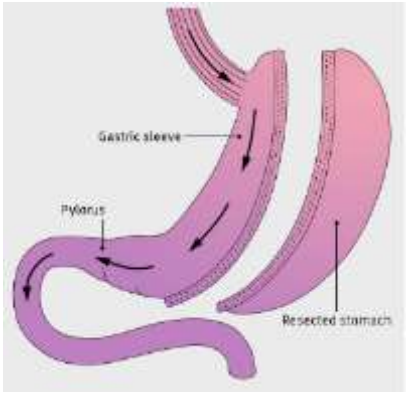
BUILDING EVIDENCE TOGETHER

NHS

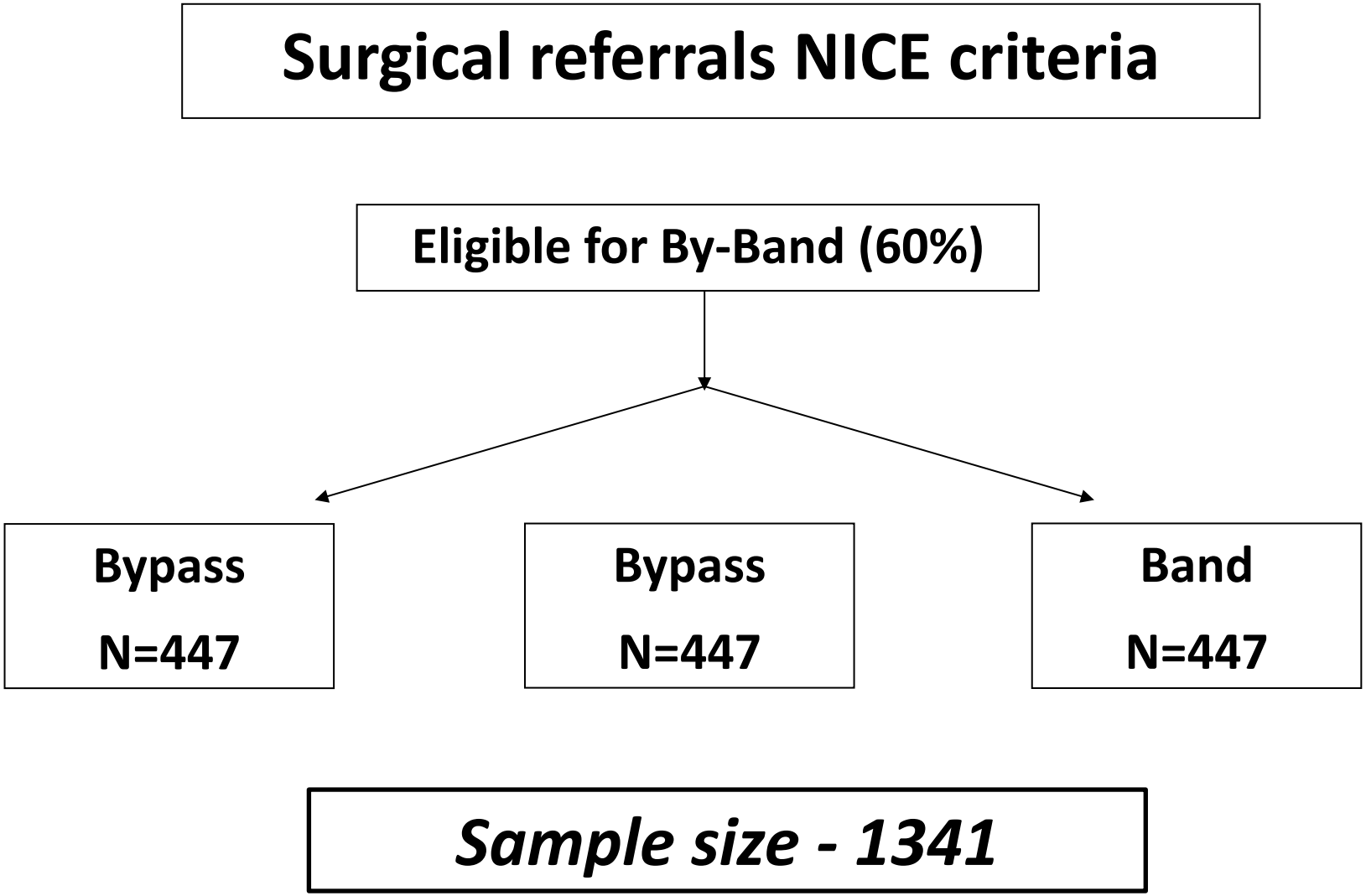
National Institute for Health Research







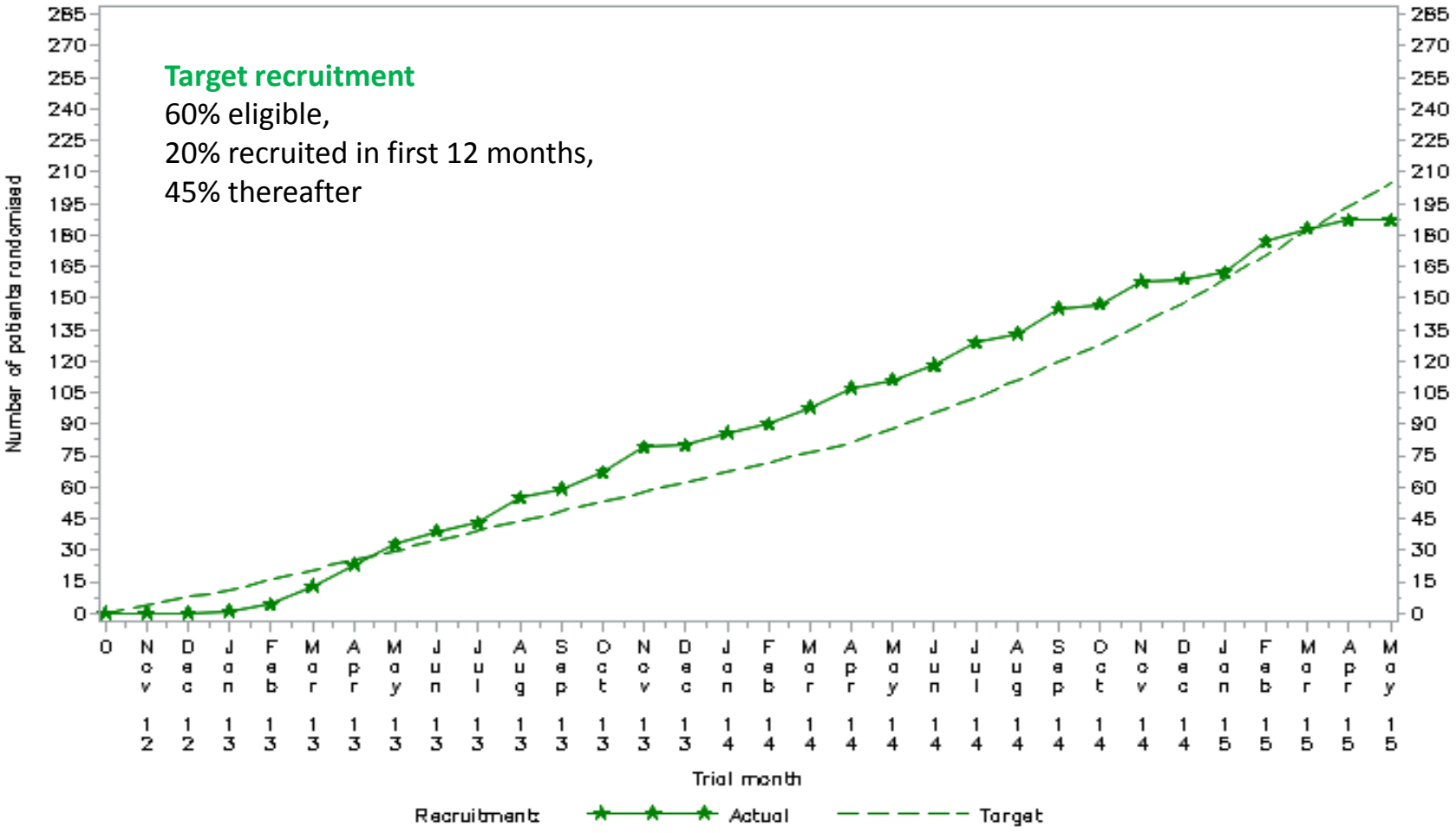
The By-Band-Sleeve Study



Target recruitment in By-Band-Sleeve

- Calculated as 60% eligible,
- 20% recruited in first 18 months,
- 45% thereafter with training

By-Band-Sleeve recruitment



Recruitment

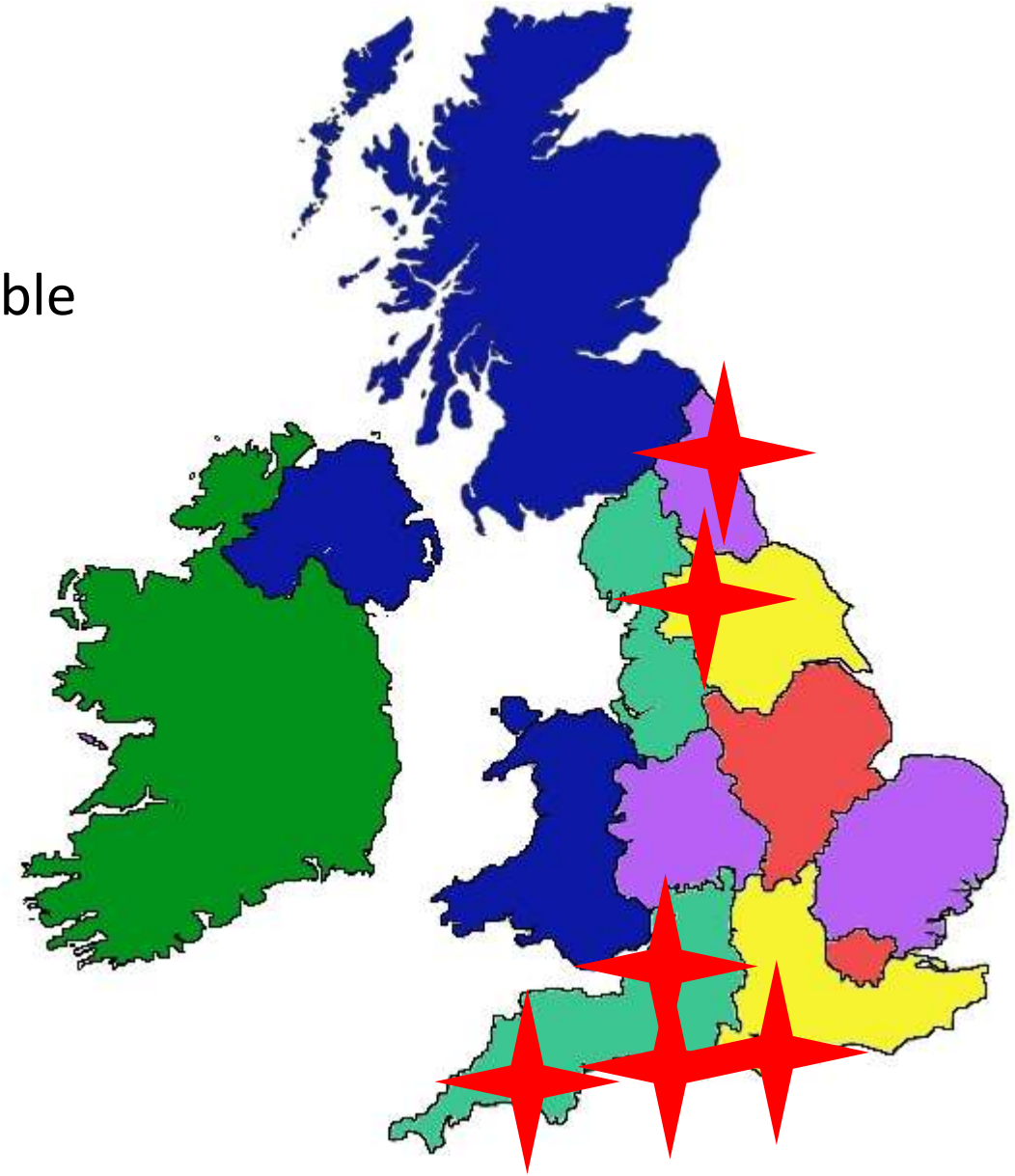
Centre	Mnths open	New pts	Audio (%)	Eligible (%)	Recruited (%)
Centre 1	30	499	260 (52%)	354 (71%)	112 (33%)
Centre 2	27	160	115 (72%)	130 (81%)	57 (47%)
Centre 3	8	86	31 (36%)	57 (66%)	10 (18%)
Centre 4	6	18	12 (67%)	17 (94%)	9 (53%)
Centre 5	4	75	3 (4%)	66 (88%)	1 (…)
Centre 6	**Just opened**				
Overall	**75**	**838**		**624 (75%)**	**189 (30%)**

Collaboration is the new competition

By-Band-Sleeve Centres (n=12)

6 open

7. Homerton
8. Luton & Dunstable
9. Portsmouth
10. Derby
11. Birmingham
12. Imperial
13. Whittington



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CTEU Bristol

UNIVERSITY OF OXFORD

NHS

Musgrove Park Hospital

Southampton NHS

University Hospitals NHS Trust

- Ask important questions
- Team important (linguists)
- Pilot phase (for sheep)
- Keep abreast of practice

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Thank you for listening

j.m.blazeby@Bris.ac.uk