

How to maximise involvement from a collaborative

Mr Thomas Pinkney

Senior Lecturer and Consultant Colorectal Surgeon

Academic Department of Surgery, University of Birmingham

Question to trainees:

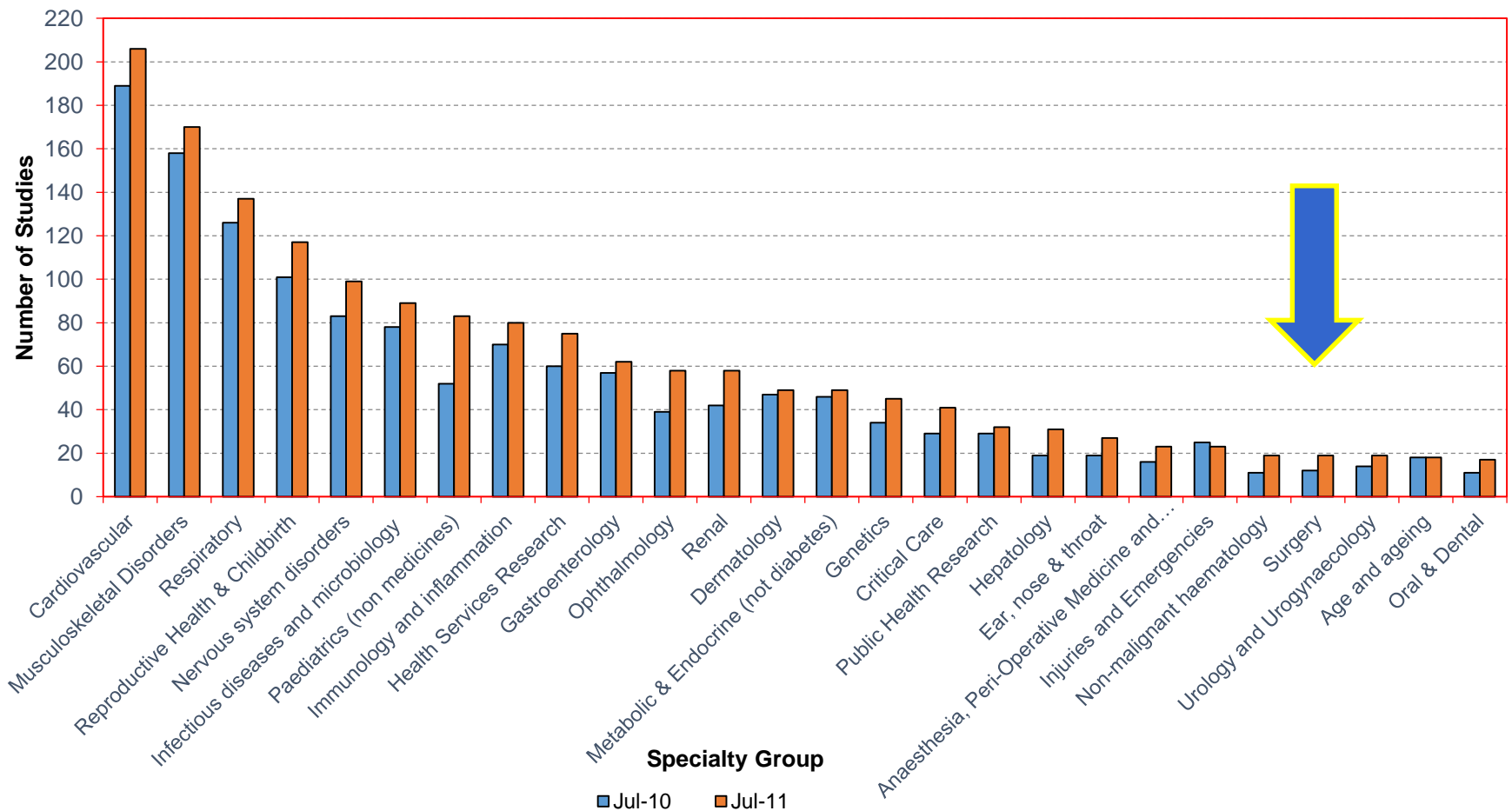
- Are you already actively involved in a trainee collaborative?
- Do you intend to become involved in one?
- If not, why not?

....my job in the next 14 minutes:

- Extol the virtues of collaborative research...
- Personal gains for a trainee
- Demonstrate what can be achieved
- Successful project types
- Successful collaborative behaviours
- Authorship models
- (Carrots and sticks; the future of training in clinical research)

Clinical surgical research

(1) Number of Open Studies



UK implements national programme for surgical trials

A clinical research programme is being developed by the UK's Royal College of Surgeons that puts new surgical devices and techniques through randomised clinical trials. Becky McCall reports.

Together with the UK's National Institute of Health Research (NIHR) and charitable partners, the Royal College of Surgeons (RCS) has initiated a nationwide Surgical Trials Programme with professor Dion Morton, consultant colorectal surgeon at University Hospitals Birmingham NHS Foundation Trust, and director of clinical research at the College. Morton notes that before the new initiative, the situation was incompatible with current surgical needs. "Patients were being let down, because new techniques and devices were not being robustly evaluated."

In fact, surgical research funding comprises less than 5% of the UK Government's medical research

First, if the choice lies between a non-invasive medical intervention versus a higher risk surgical procedure, the randomisation decision is more challenging. Second, anyone undertaking an RCT instinctively considers the principle of clinical equipoise, but surgery harbours the additional potential to directly harm a patient. "Not only do we have to inform the patient about a novel option but at the same time remain aware of the alternative", says Morton. "That's a tough choice for the surgeon as well as the patient."

"Patients were being let down, because new techniques and devices were not being robustly

of clinical research networks. In the UK, surgical trainee networks were initiated by the West Midlands Research Collaborative, and now there are more than ten diverse networks nationwide.

These networks have greatly expedited recruitment of patients into the trials. For example, the ROSSINI trial recruited 800 patients from 25 UK hospitals, and likewise the DREAMS trial investigating anti-emetics in pre-operative care have both recruited well ahead of schedule. "Trainees have the advantage of rotating around hospitals in the region, as well as being at the coalface enabling the engagement of all surgical units", says Morton.

The colorectal unit in Birmingham is

See [Series](#) pages 1121 and 1130

Clinical Research Initiative Steering Committee

Royal College of Surgeons and partners

**Manchester &
Liverpool
NWSTC**

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BiSTC**

**Oxford
SITU**

**Bristol
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Surgical Specialty Leads

Orthopaedics, Trauma, Neurosurgery, ENT, Head and neck,
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Upper GI, Urology

Consultant
+ Trainee
network 1

Consultant
+ Trainee
network 2

Consultant
+ Trainee
network 3

Consultant
+ Trainee
network 4

Consultant
+ Trainee
network 5

Consultant
+ Trainee
network 6

Trainee Research Collaboratives



Welsh Barbers Research Group



West Midlands Urology Regional Audit Collaborative



Wessex Research Collaborative

lsrg London Surgical Research Group

NoSTRA - Northern Surgical Trainee Research Association

Northern Urology Research Collaborative

Yorkshire Surgical Research Collaborative



EMSAN

WSRG WARWICKSHIRE SURGICAL RESEARCH GROUP



KMRC - Kent and Medway Research Collaborative



ENT Trainee Research Collaborative

Collaborative Orthopaedic Research NETWORK



ee Research Collaborative

RSTN

Reconstructive Surgery Trials Network

PSTRN

paediatric surgery trainees research network



BNTRC

Vascular & Endovascular Research Network
www.vascular-research.net



Forming the WMRC

- Difficult to conduct research alone
- Natural network
 - Registrars rotating
 - Potential for multicentre studies
- A multitude of benefits



Types of prospective studies that research collaboratives can do well

1. Very common events – broad-based snapshot audit
2. Rarely occurring events – collate simultaneously across multiple centres
3. Simple interventional RCTs

Trainee-led RCTs

- Formulating a good clinical question
- Writing the protocol
- Basic stats
- Obtaining ethical approvals
- Writing the grant application
- Interacting with clinicians
- Managing a team, chairing meetings
- Writing and publishing the paper



ROSSINI

Reduction Of Surgical Site Infection using a Novel Intervention

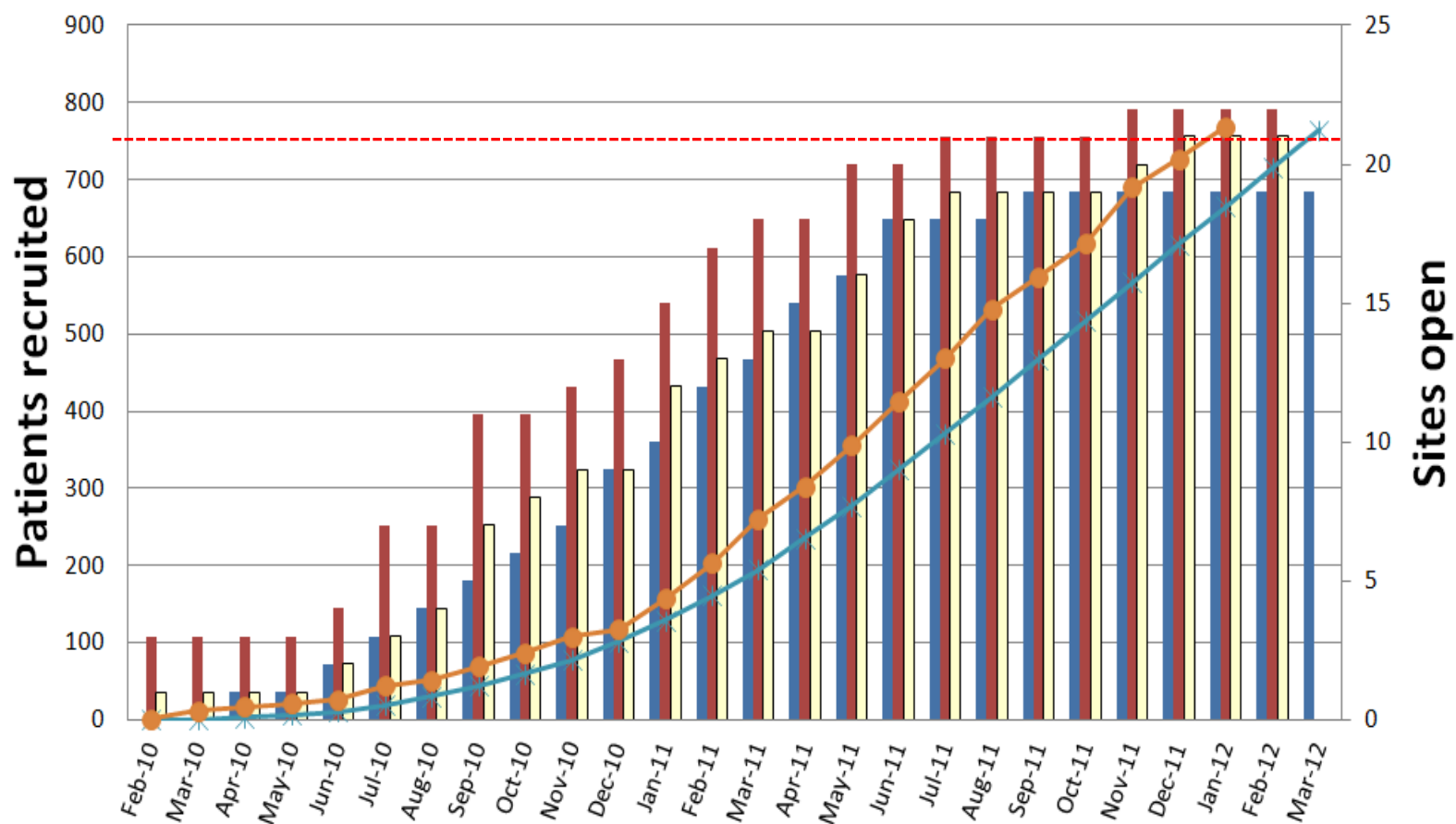
A randomised controlled trial of a wound-edge protection device to reduce surgical site infection



UNIVERSITY OF
BIRMINGHAM



ROSSINI recruitment at 31st January 2012



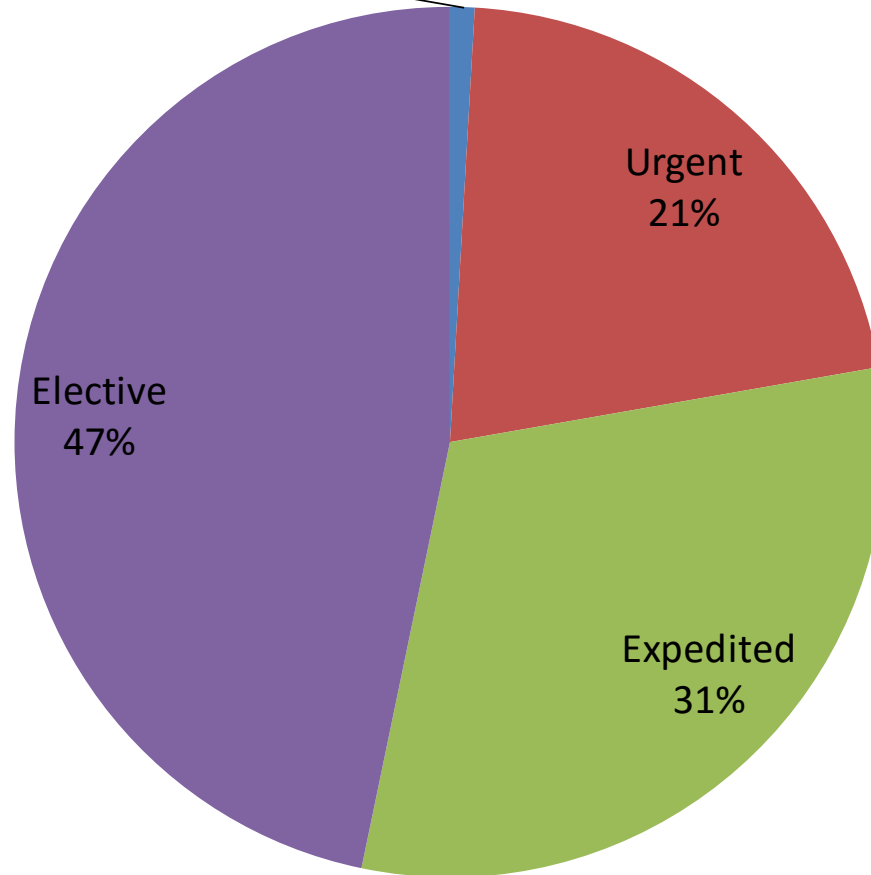
	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12	Mar-12
Predicted Sites	0	0	1	1	2	3	4	5	6	7	9	10	12	13	15	16	18	18	18	19	19	19	19	19	19	19
Sites Open	3	3	3	3	4	7	7	11	11	12	13	15	17	18	18	20	20	21	21	21	21	22	22	22	22	
Sites Active	1	1	1	1	2	3	4	7	8	9	9	12	13	14	14	16	18	19	19	19	19	20	21	21	21	
Minimum Cumulative	0	0	3	6	11	19	30	44	60	78	102	129	161	195	235	277	324	371	418	468	517	567	616	665	715	764
Actual Cumulative	1	12	17	21	26	44	51	69	87	108	117	157	203	260	302	356	412	469	532	574	617	690	727	769		

The ideal ROSSINI site

- Pre-op assessment clinic
 - Discussion of study, PIS**FY1**
- Morning of surgery
 - Recruitment + Consent**SpR**
- Randomisation
 - Whilst pt in anaesthetic room**SpR/Consultant**
- Inpatient wound review
 - Before discharge**SHO/CNS/Research Nurse**
- Outpatient (30 day) wound review
 - Arranged by
 - Undertaken by**FY1/research nurse/clerk**
FY1/SHO/SpR/research nurse

Recruitment by Urgency of Operation

Immediate
1%



Why ROSSINI recruited well

- Simple
- Very broad inclusion criteria
- High levels of interest in SSI at present
- Participant buy-in: design + running of trial
- Portfolio trial

RESEARCH

Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI Trial)

OPEN ACCESS

Thomas D Pinkney *senior lecturer and consultant colorectal surgeon*^{1,2}, Melanie Calvert *reader in epidemiology*^{1,3}, David C Bartlett *specialist registrar*¹, Adrian Gheorghe *doctoral researcher*³, Val Redman *trial manager*³, George Dowswell *research fellow*^{1,3}, William Hawkins *consultant upper gastrointestinal surgeon*¹, Tony Mak *assistant professor colorectal surgery*¹, Haney Youssef *consultant colorectal surgeon*¹, Caroline Richardson *specialist registrar*¹, Steven Hornby *specialist registrar*¹, Laura Magill *colorectal trial team leader*^{1,4}, Richard Haslop *trial manager*³, Sue Wilson *professor of clinical epidemiology*^{1,3}, Dion Morton *professor of surgery*^{1,2,4}, on behalf of the West Midlands Research Collaborative and the ROSSINI Trial Investigators



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BMJ. 2013 Jul 31;347:f4305. doi: 10.1136/bmj.f4305.

Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI Trial).

Pinkney TD, Calvert M, Bartlett DC, Gheorghe A, Redman V, Dowswell G, Hawkins W, Mak T, Youssef H, Richardson C, Hornby S, Magill L, Haslop R, Wilson S, Morton D; West Midlands Research Collaborative; ROSSINI Trial Investigators.

Collaborators (459)

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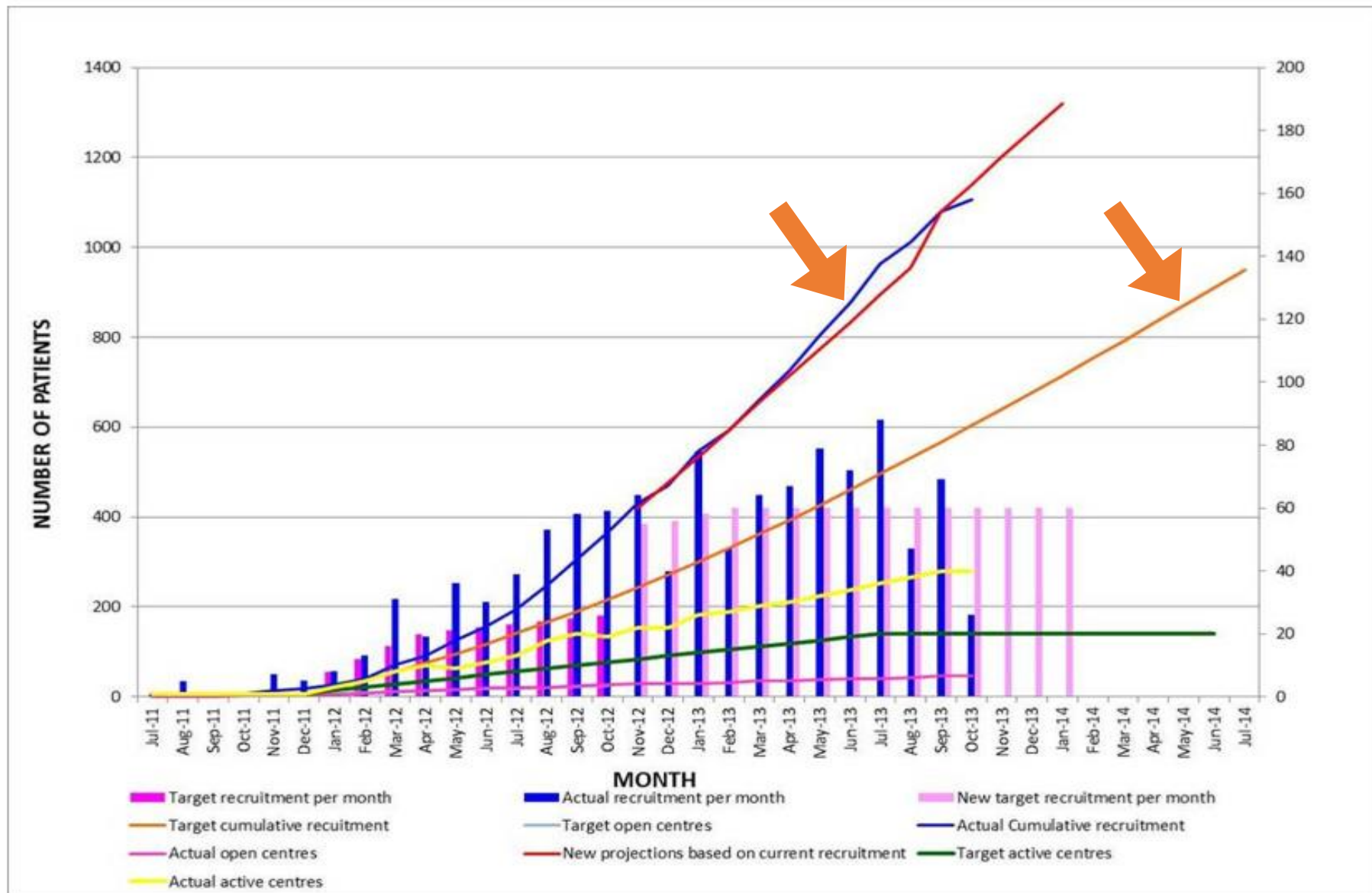
Impact of wound edge protection surgical site infection after laparo

suggett n (7)

[Laparoscopic versus open resec

Lessons learned

- Pre-op assessment clinic
- Involve very junior trainees
- No follow-up beyond 30 days if possible
- RCTs:
 - Very simple interventions
 - Consultant equipoise
- Obtain letters of intent from interested parties



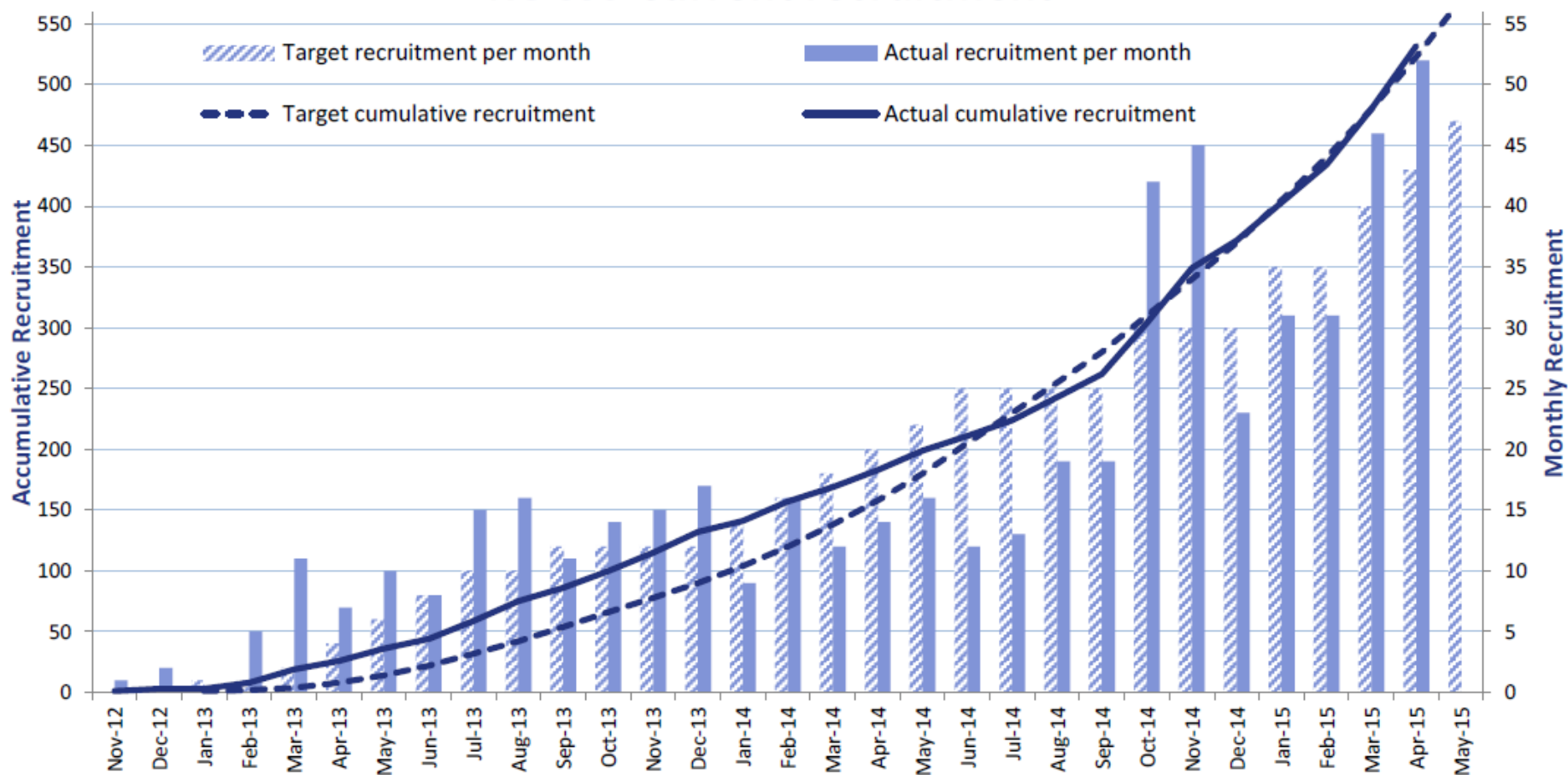


Reinforcement Of Closure of Stoma Site Trial



Recruitment Graph:

ROCSS Current recruitment



Non-Randomised Research

Multicentre prospective cohort studies:

- Why? - 'State-of-the-nation'
- Hypothesis-generating
 - Sample size calculations
 - Background of grant/protocol

Appendicectomy multicentre prospective snapshot audit

- To bring together all of the general surgical research collaboratives
- 2 months of standardised data collection
- **95 centres**
- **3327 patients**



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Br J Surg. 2013 Aug;100(9):1240-52. doi: 10.1002/bjs.9201.

Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy.

National Surgical Research Collaborative.

Collaborators (241)

Abstract

BACKGROUND: Identification of variation in practice is a key step towards standardization of service and determination of reliable quality markers. This study aimed to investigate variation in provision and outcome of emergency appendicectomy.

METHODS: A multicentre, trainee-led, protocol-driven, prospective observational cohort study was performed during May and June 2012. The main outcome of interest was the normal histopathology rate; secondary outcomes were laparoscopy and 30-day adverse event rates. Analysis included funnel plots and binary logistic regression models to identify patient- and hospital-related predictors of outcome.

RESULTS: A total of 3326 patients from 95 centres were included. An initial laparoscopic approach was performed in 66.3 per cent of patients (range in centres performing more than 25 appendicectomies over the study period: 8.7-100 per cent). A histologically normal appendix was removed in 20.6 per cent of patients (range in centres performing more than 25 procedures: 3.3-36.8 per cent). Funnel plot analysis revealed that 22 centres fell below three standard deviations of the mean for laparoscopy rates. Higher centre volume, consultant presence in theatre and daytime surgery were independently associated with an increased use of laparoscopy, which in turn was associated with a reduction in 30-day morbidity (adjusted for disease severity). Daytime surgery further reduced normal appendicectomy rates. Increasing volume came at the cost of higher negative rates, and low negative rates came at the cost of higher perforation rates.

CONCLUSION: This study reveals the extremely wide variation in practice patterns and outcomes among hospitals. Organizational factors leading to this variation have been identified and should be addressed to improve performance.

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PMID: 23842836 [PubMed - in process]

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More progressive authorship models



Feasibility of preoperative chemotherapy for locally advanced, operable colon cancer: the pilot phase of a randomised controlled trial

*FOxTROT Collaborative Group**

Diagnostic accuracy of preoperative magnetic resonance imaging in predicting curative resection of rectal cancer: prospective observational study

MERCURY Study Group

Publication of results and Authorship – other collaborative studies

- ROCSS – 5 patients per trainee
- HART – 10 patients and undertake training
- Bluebelle phase A – 20 patients

Advice to another research collaborative

- Authorship
- Direction and 'clout' - *godfather* figures
- Committee / management
- Communication
- Types of research you might want to do
 1. Consider a snapshot audit - easy, quick and forms the group
 2. Simple RCTs are definitely possible

Henry Ford 1863 – 1947



“Nothing is hard if you divide it into small jobs”

The future of training in **clinical** surgical research

- RCS: *“All surgical specialists in the future should be active in clinical research”*
- Formalised
- Part of consultant job plans
- Revalidation
- Training is therefore needed

The future of training in **clinical** surgical research



The future of training in **clinical** surgical research

- Yr 1 Complete GCP, develop awareness of trials in their dept
- Yr 2 Recruit patients to at least 1 RCT
- Yr 3 Mentorship with a local PI and gain experience of processes
- Yr 4 One day course in clinical trials methodology and practise