ACPGBI 2016 ANNUAL MEETING
EDINBURGH 4 – 6 JULY 2016

Sacral nerve stimulation versus FENIX™ magnetic sphincter augmentation for adult faecal incontinence

This project was funded by the National Institute for Health Research Health Technology Assessment (project number 12/35/07)

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Faecal Incontinence

- 3 – 8% adult population
- More common with advancing age
- 2nd commonest admission to nursing home
- Impacts on social, physical, and mental well-being
- Substantial burden on NHS resources

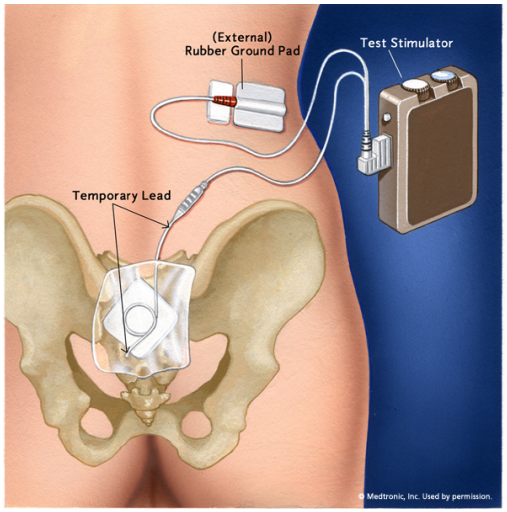
Sacral Nerve Stimulation

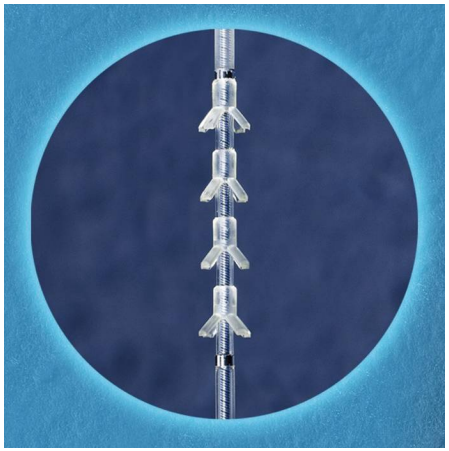
Sacral Nerve Stimulation

- NICE 2007 recommended

  "*trial of SNS be considered in patients in whom sphincter surgery is deemed inappropriate*"

- 2-stage procedure
  - i) PNE ii) Permanent InterStim





Sacral Nerve Modulation

Popular and well accepted

- Minimally invasive technique
- Well cited success rates ~70%
- Minimal morbidity 5 – 26%

Cost-effective

- Initial costs
  - Direct costs ~ £9,000
  - Indirect costs ~£12,959
- Cost of colostomy ~£27,000 over 5 years
- Cost-effective – ICER £25,070

Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence

N. N. Thin[1], E. J. Horrocks[1], A. Hotouras[1], S. Palit[1], M. A. Thaha[1], C. L. H. Chan[1], K. E. Matzel[2] and C. H. Knowles[1]

Br J Surg 2013; 100; 1430-47

Success and cure rates

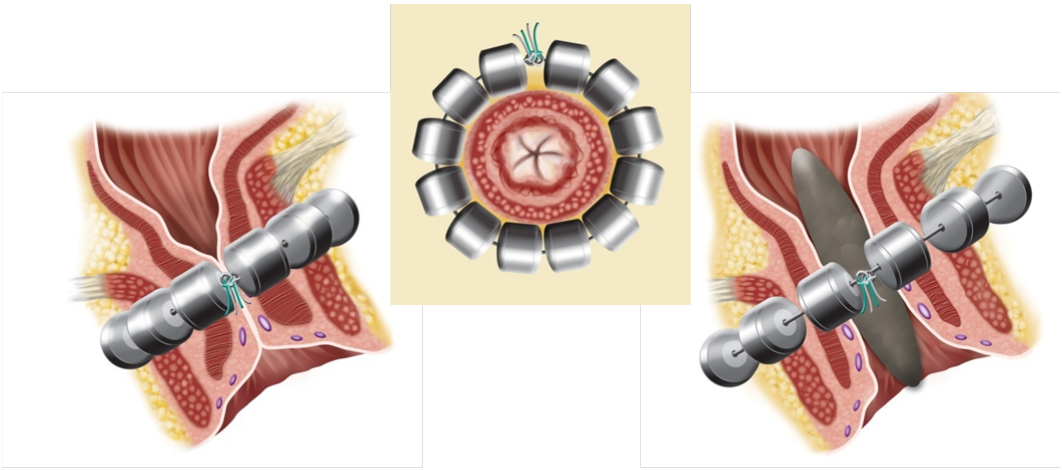
		Permanent implants					Intention-to-treat	
Reference	Median follow-up (months)	No. at baseline	No. at follow-up	% at follow-up	> 50% improvement in FI episodes per week (%)	100% continence (%)	> 50% improvement in FI epsiodes per week (%)	100% continence (%)
Summary*								
Short term	12 (6–12)		29 (12–106)	100 (56–100)	79 (69–83)	42 (21–68)	63 (33–66)	36 (8–68)
Medium term	25 (17–36)		37 (15–169)	100 (64–100)	80 (65–88)	40 (5–74)	58 (52–81)	32 (4–74)
Long term	56 (44–118)		21 (9–91)	79 (21–100)	84 (75–100)	35 (4–52)	54 (50–58)	20 (2–48)

Only 86 patients with long term FU data

Quality of Life

- Most report significant improvement in all domains of QoL
- Not ITT analysis

Fenix Continence Restoration System

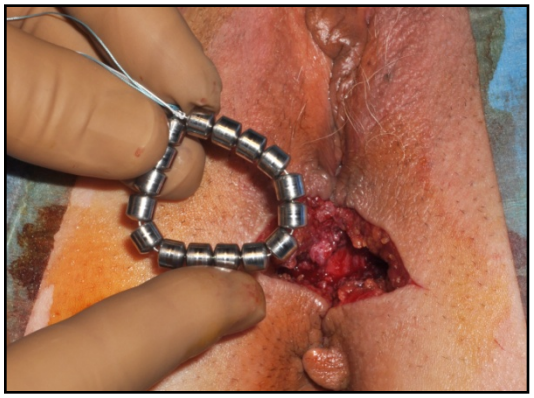


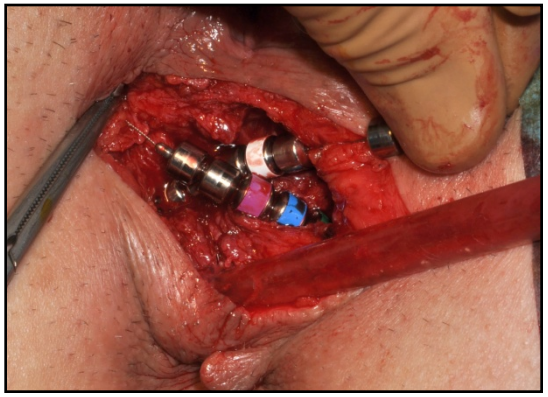
Implanted around anal canal to maintain closure

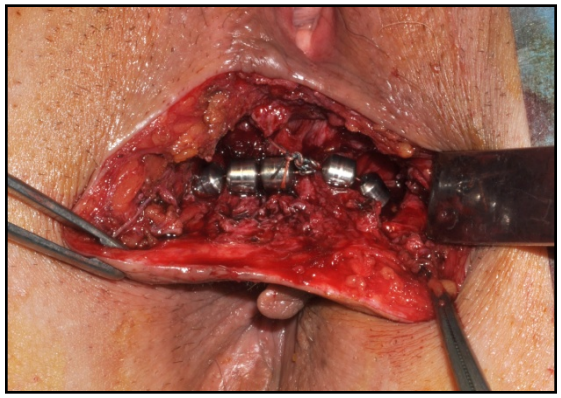
Expands during stool passage, then re-approximates

- CE marked 2011
- Minimally invasive
- Augments natural anal sphincter
- ~£4K per implant
- Limited clinical data – suggests safe & effective

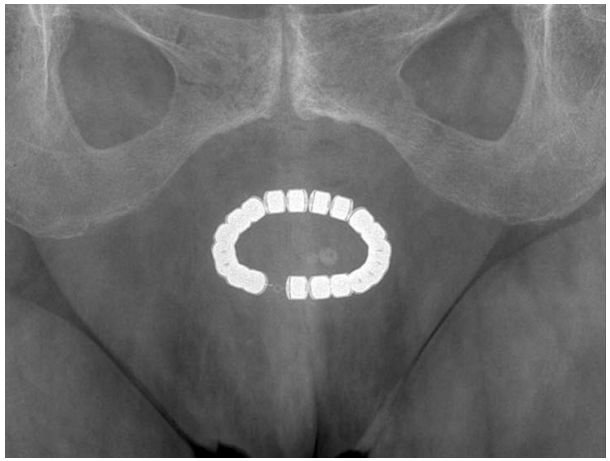
Surgical Technique





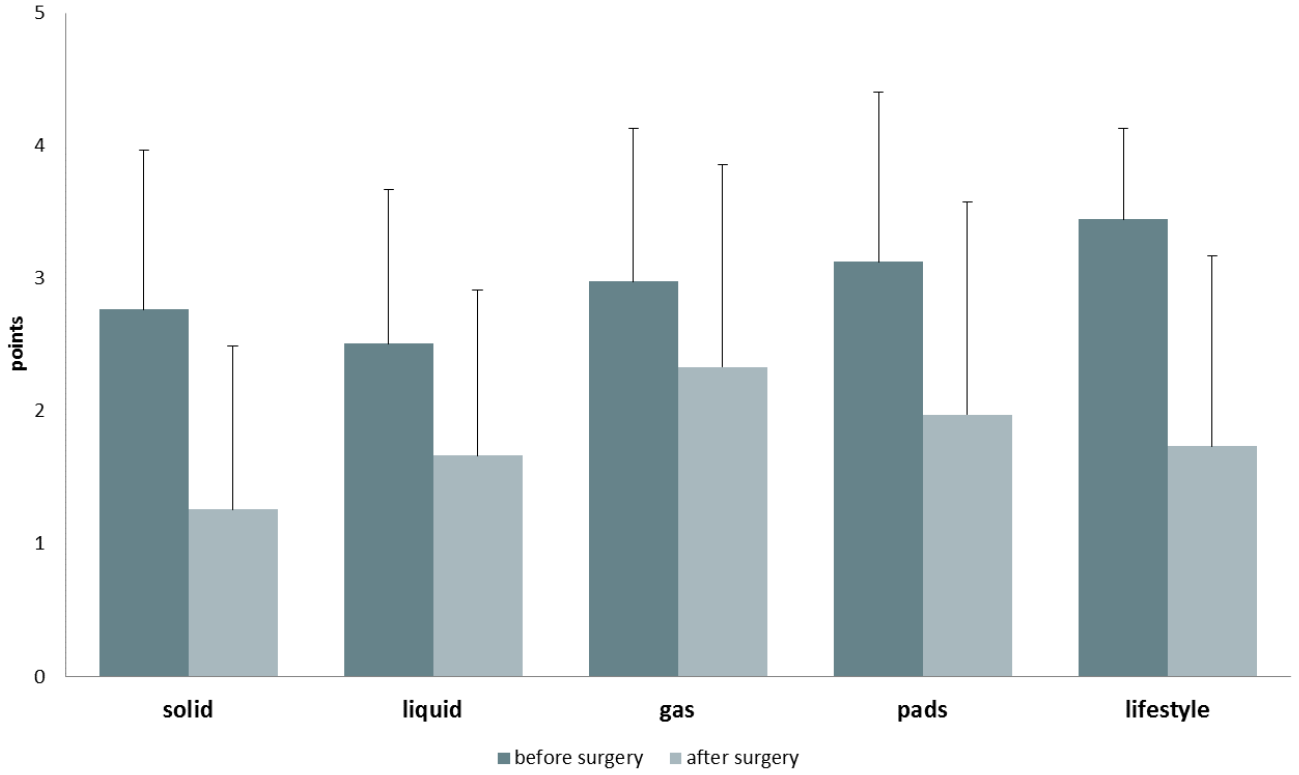


- Single perineal incision
- Tunnel in the ischioanal fossa just beneath the levator ani
- Sizing tool for model selection
- Implant and verify with fluoroscopy



Fenix Registry

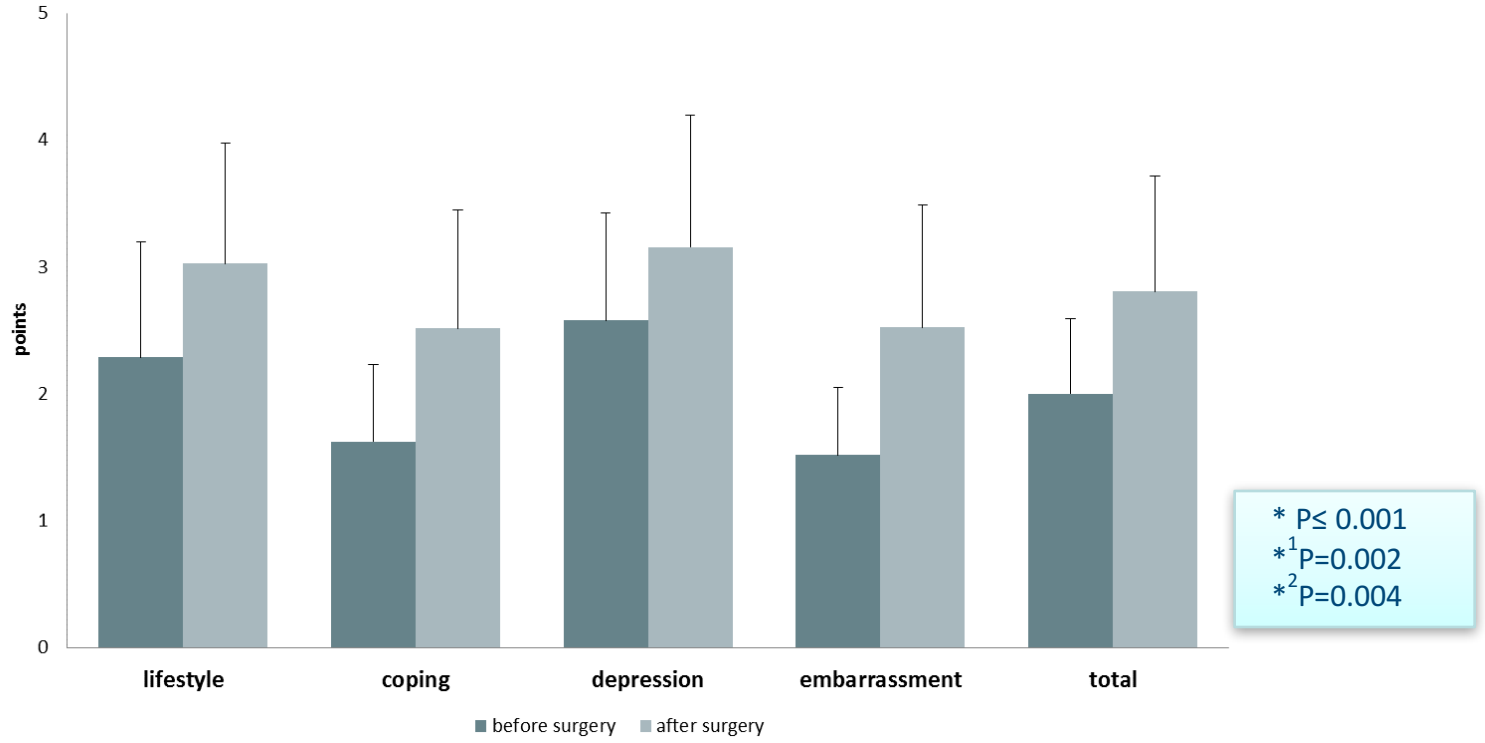
Cleveland Clinic Incontinence Score



* P≤ 0.001
*[1]P=0.002
n.s.=0.068

Fenix Registry

FI Quality of Life



Insertion of a magnetic bead band for faecal incontinence

Issued: March 2014

NICE interventional procedure guidance 483

guidance.nice.org.uk/ipg483

- Current evidence on safety and efficacy of a magnetic bead band for faecal incontinence is **limited**….. If further evidence supports the efficacy of this procedure, it has the potential to significantly improve quality of life for appropriately selected patients

- Clinicians should offer all eligible patients entry into the HTA trial – 12/35/07

- The procedure should only be performed in units specializing in the assessment and treatment of faecal incontinence

SaFaRI

Objectives

- Short-term safety and efficacy of FENIX and SNS
- Impact of FENIX and SNS on QoL and cost effectiveness

SaFaRI

Primary outcome

- Proportion of patients with FENIX or SNS in situ at 18-months follow-up with device working and with ≥50% improvement in CCIS

Secondary outcomes

- Length of stay
- Complications
- Re-interventions
- Constipation
- QoL
- Cost effectiveness

SaFaRI

Design

- UK, multi-centre, prospective, parallel-group, randomised controlled, unblinded study

Eligibility

- Failed medical management
- Moderate to severe FI
  - Incontinence > 6 months, suffering ≥2 incontinent episodes per week

SaFaRI

Sample size

- 350 participants to detect at least 20% in percentage of success at 18-months post-randomisation between FENIX and SNS at 5% significance, 90% power
- Success – device in situ and working with ≥50% CCIS improvement
- Allows 20% loss to follow-up

Recruitment

- 2-years
- 24 surgeons recruiting 15 patients

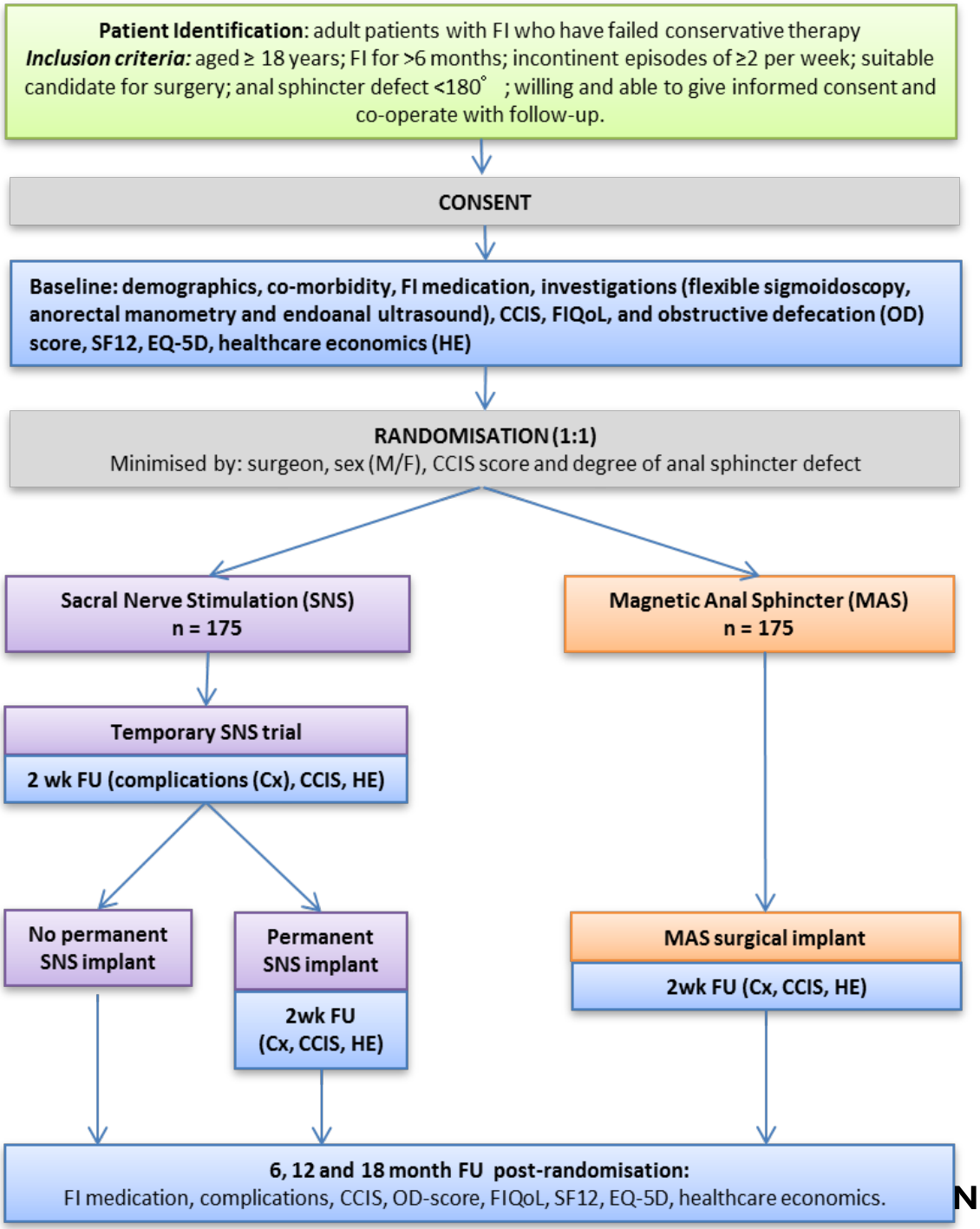
SaFaRI

Site eligibility

- NHS hospital providing specialist treatment for FI with membership of ACPGBI
- Experience in SNS
- Facilities to perform endoscopy, manometry, EAUS

Surgeon eligibility

- Performed minimum of 10 SNS
- Minimum 1 observed FENIX + 2 performed FENIX
- Moderate to severe FI
  - Incontinence > 6 months, suffering ≥2 incontinent episodes per week


Patient Identification: adult patients with FI who have failed conservative therapy
Inclusion criteria: aged ≥ 18 years; FI for >6 months; incontinent episodes of ≥2 per week; suitable candidate for surgery; anal sphincter defect <180° ; willing and able to give informed consent and co-operate with follow-up.
CONSENT
Baseline: demographics, co-morbidity, FI medication, investigations (flexible sigmoidoscopy, anorectal manometry and endoanal ultrasound), CCIS, FIQoL, and obstructive defecation (OD) score, SF12, EQ-5D, healthcare economics (HE)
RANDOMISATION (1:1)
Minimised by: surgeon, sex (M/F), CCIS score and degree of anal sphincter defect
Sacral Nerve Stimulation (SNS)
n = 175
Magnetic Anal Sphincter (MAS)
n = 175
Temporary SNS trial
2 wk FU (complications (Cx), CCIS, HE)
No permanent SNS implant
Permanent SNS implant
2wk FU (Cx, CCIS, HE)
MAS surgical implant
2wk FU (Cx, CCIS, HE)
6, 12 and 18 month FU post-randomisation:
FI medication, complications, CCIS, OD-score, FIQoL, SF12, EQ-5D, healthcare economics.

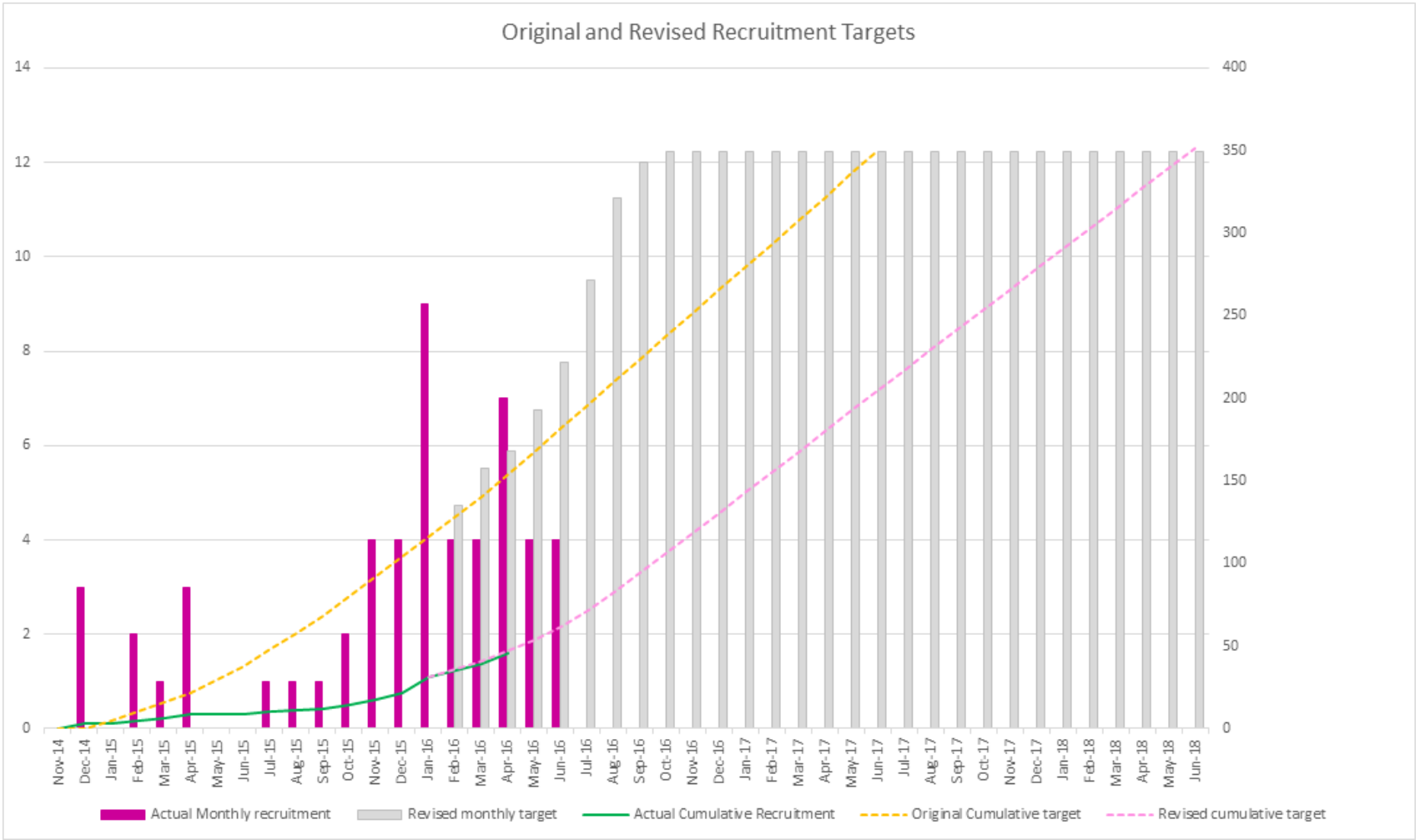
FENIX™ MSA Device Funding

- The FENIX™ MSA device was classed as an NHS treatment cost in line with the DoH's AcoRD guidance.
- No process in place for funding of NHS treatment costs through NHS England
- QIPP proposal developed and submitted to NHSE in Q1 2015
- Signed off by NHSE centrally- then filtered out to NHSE regional teams – Q2 2015
- Knock on effect on site set-up
  - Sites unable to submit local applications until funding resolved

SaFaRI Sites

SaFaRI Sites	
St James's University Hospital	Ninewells Hospital
University Hospital of North Durham	UCHL
Southampton General Hospital	Royal Liverpool
Northern General Hospital, Sheffield	Leicester Royal Infirmary
St Peter's Hospital	St. Thomas' Hospital, London
Poole Hospital	Queen Elizabeth Hospital, Birmingham
Royal Devon & Exeter Hospital	Derriford Hospital, Plymouth
Churchill Hospital (Oxford)	St Mark's Hospital
Wythenshawe Hospital	Dewsbury District Hospital
Good Hope Hospital	Royal Victoria Infirmary
University College London Hospital	Bristol Royal Infirmary
Manchester Royal Infirmary	

SaFaRI Recruitment



Summary

- SaFaRI addresses an important research question
- Provides a rigorous and safe evaluation of a new technology that could save the NHS money
- 12 months behind schedule due to national FENIX™ MSA device funding issues
- Recruitment picking up with resolution of funding issues and timely opening of sites

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