Medical Devices for Clinical Use

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Thanks to:

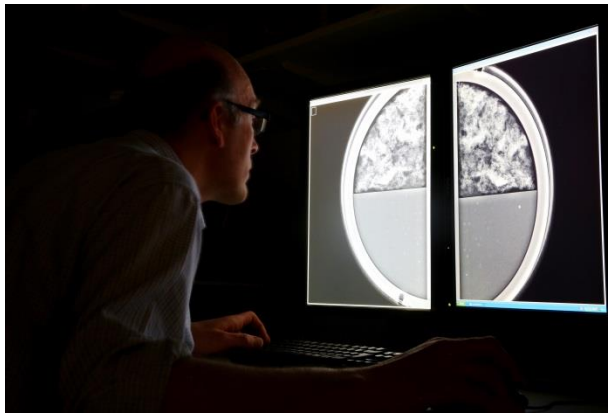
- James Blake
- Julie Burn
- Claire-Louise Chapple
- Helen Cole
- Michael Drinnan
- Ina Guri
- Susan Hillman
- Kim Keltie
- Alison Mackie
- Mike Whitaker
- Jim Wightman

Outline

- Background – who we are
- Medical devices – experience
- How are devices regulated?
- How are devices assessed?
- Evidence in practice
- Opportunities and challenges

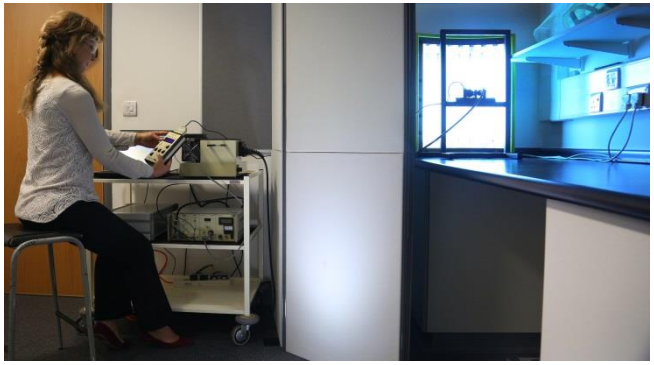
Northern Medical Physics & Clinical Engineering

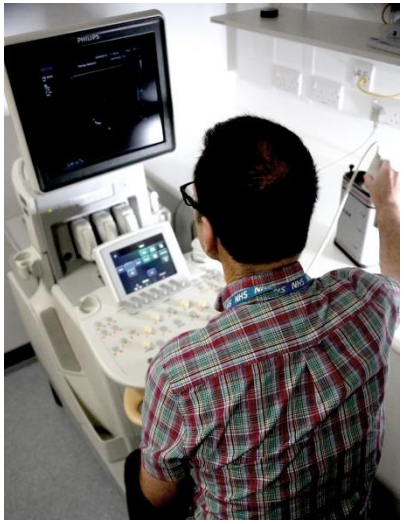
- ~130 staff
- 6 base sites
  - Freeman, RVI, CAV, UHND, DMH, UHH
  - and regional services
- 4 units
  - DDH, IPRS, REAL, CMEU
- ~20 customer organisations

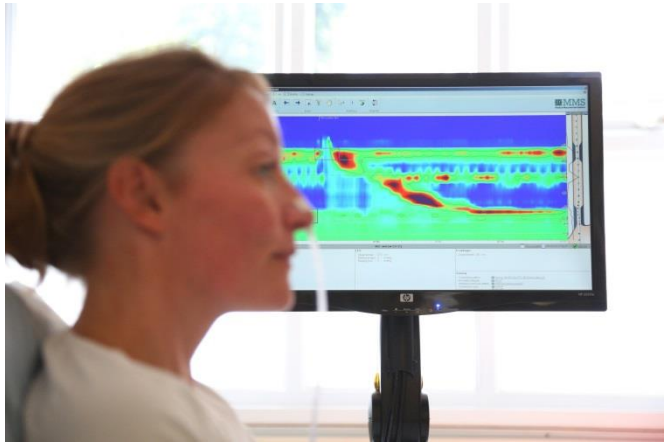


Imaging Physics & Radiation Safety Unit

- Diagnostic radiology QA
- Ultrasound QA
- Radiation Protection

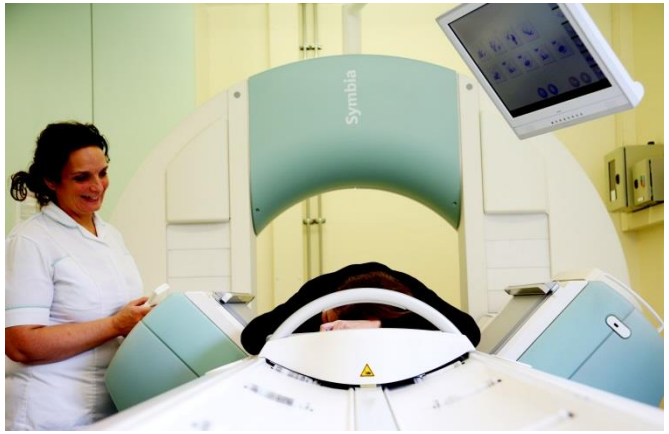


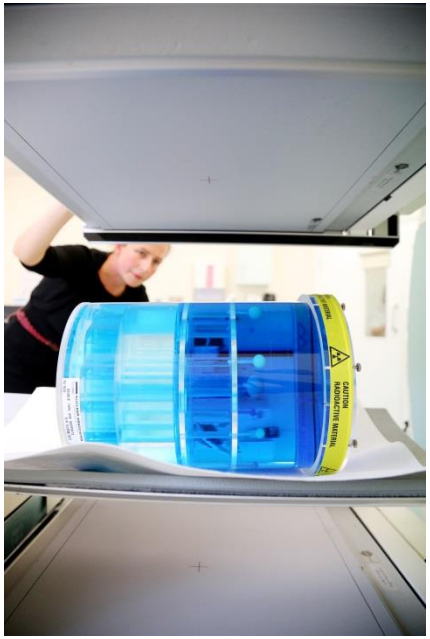


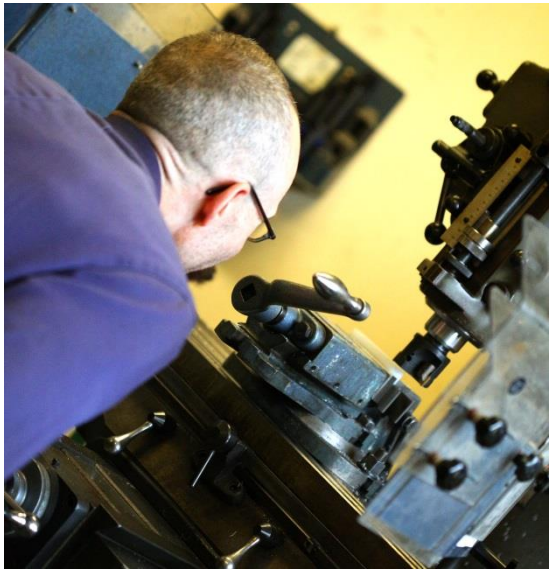


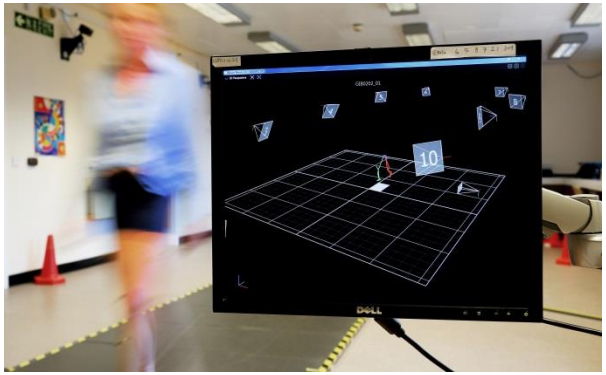
Durham, Darlington & Hartlepool Unit

- Nuclear Medicine
- Clinical Measurement (Urodynamics, GI)



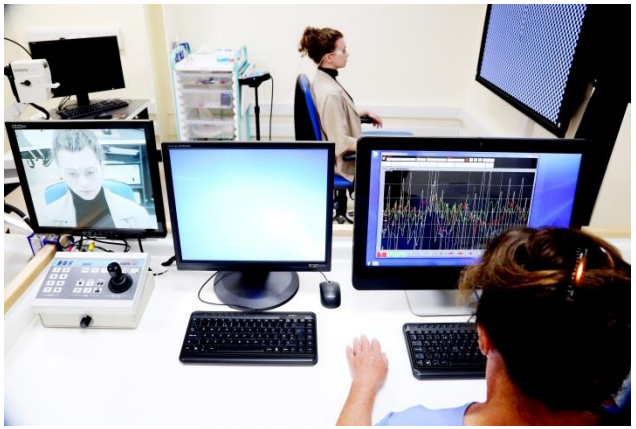


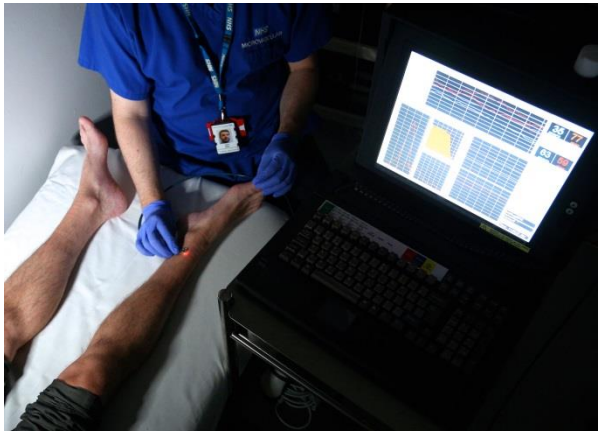


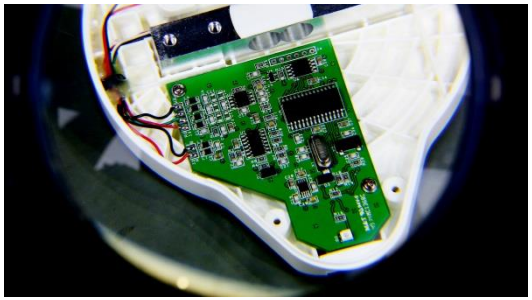


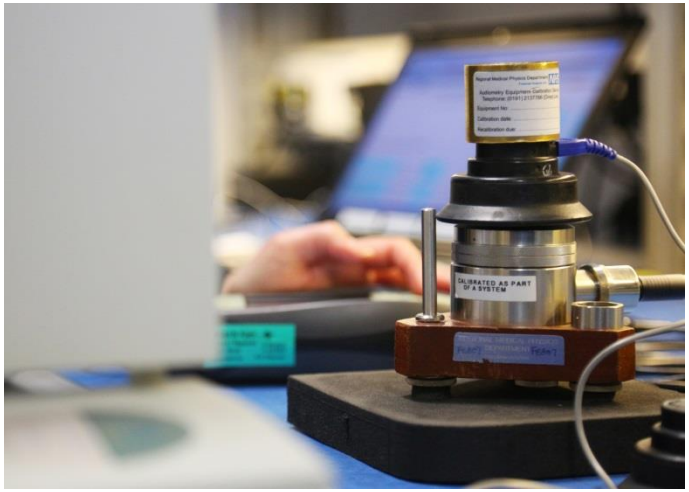
Rehabilitation and Aids for Living Unit

- Regional Rehab Engineering and Mobility Service
- Regional Technical Aids Service
- Gait assessment service
- Mechanical Engineering Service









Clinical Measurement & Engineering Unit

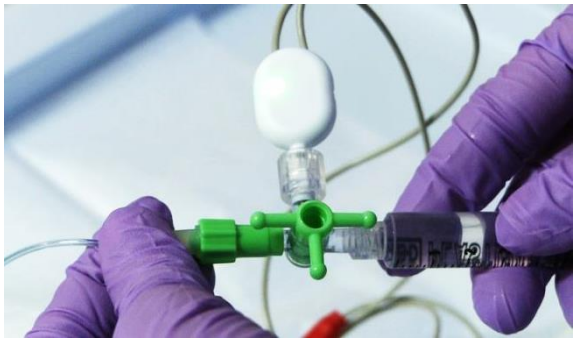
- Clinical measurement
- Clinical engineering
- NICE External Assessment Centre
- Clinical informatics

Healthcare at its very best - with a personal touch

Developing devices…

Allmed Medical – **NIDUS®**
CE under submission

NotePAD – Commercialisation under negotiation

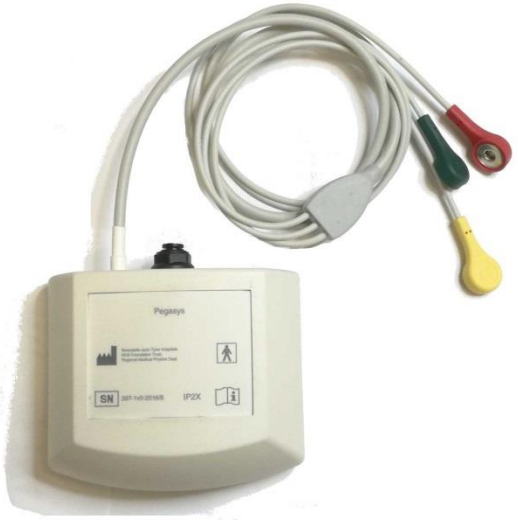


Safeplace – Licensed to Vygon

Research…

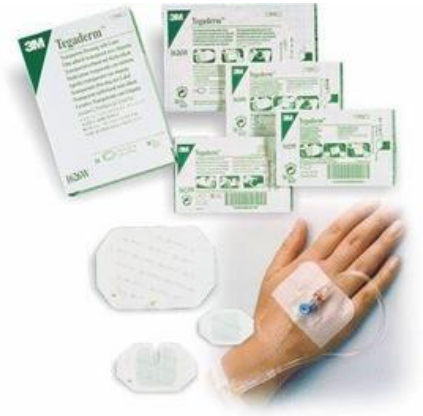
Nairos – Using Nasal airflow prediction of outcome from septoplasty

OppAF – Opportunistic AF detection using BP measurements



Verdict – Vector Doppler In Carotid Assessment

Technology Assessment…

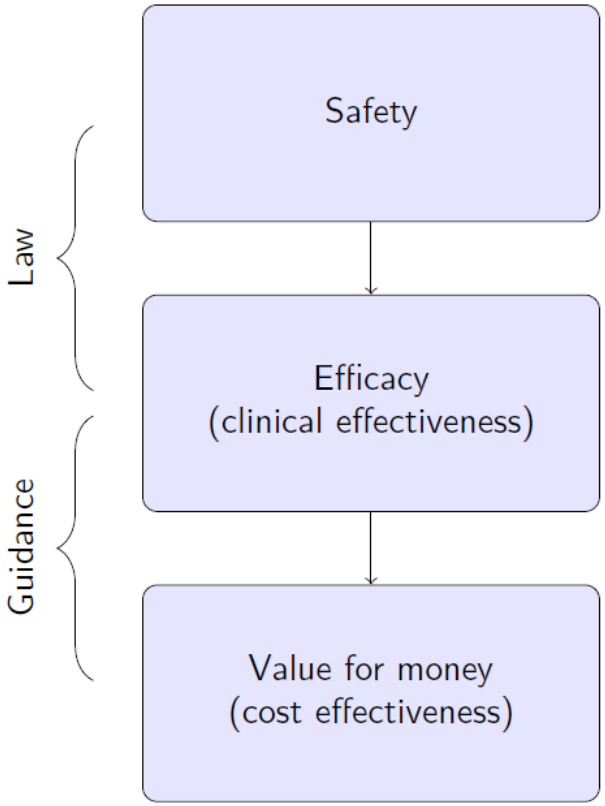


Assessment

New Guidance

(NICE MTEP – Newcastle EAC)

Approval and assessment



Regulatory affairs (MDR, drug licensing)
Post market surveillance (adverse incidents)
Experimental trials, Clinical Investigations

Systematic reviews
Experimental trials
Observational studies, registers

Health economics

What is CE marking?

- Manufacturer's declaration
  - Compliance with EU safety, health, environmental legislation
  - Often Involves Notified Body assessment/testing/certification
- Indicates Essential Requirements of relevant Directives/Standards
- Allows product to be legally placed on market (anywhere in EU)
  - Making device available, in return for payment, or free of charge

Product categories…

- There are 20+ product categories requiring CE marking
- Here are a few:
  - Low Voltage Electrical Equipment (50-1000Vac)
  - Machinery
  - Medical Devices
  - In Vitro Diagnostic Medical Devices
  - Radio and telecommunications terminal equipment
  - Household refrigerators and freezers
  - Toys
  - Pressure Vessels

Legal framework

- UK Medical Device Regulation
  - Invokes '93/42/EEC as amended by 2007/47/EC'
  - EU Medical Devices Directive – MDD

- Now being replaced by…
  - EU Medical Device Regulation (MDR)
  - Regulation (EU) 2017/745
  - Also replaces AIMDD (90/385/EEC)

Article 1.2 of MDD defines a medical device as:

'any instrument, apparatus, software, or other article, …used specifically for diagnostic or therapeutic purposes, …of:

- diagnosis, treatment of disease,
- diagnosis, or compensation for injury or handicap,
- investigation, modification of anatomy or physiological process,
- control of conception,

…and… not a medicine.

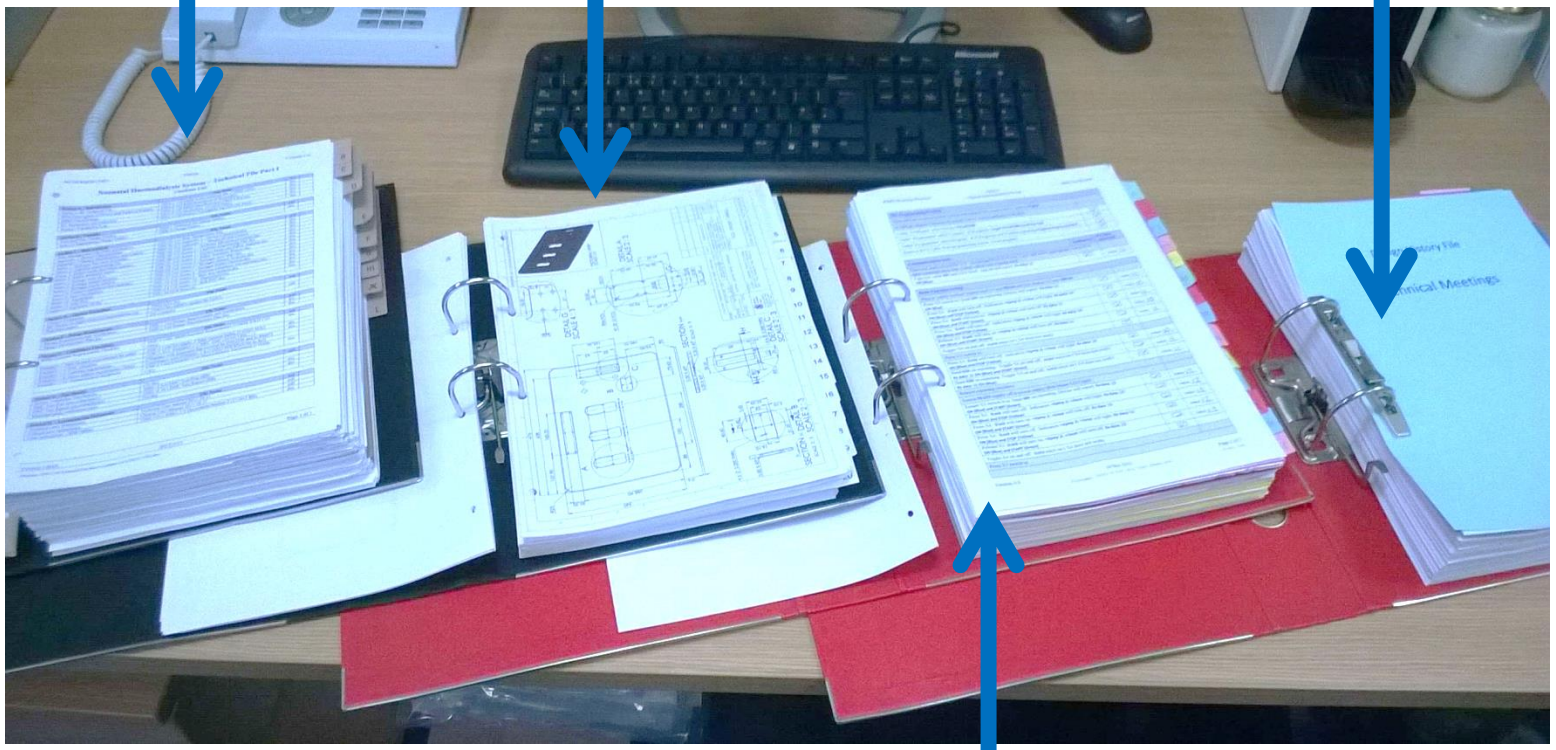
MDD allows no CE mark if…

- Made in-house in a Healthcare Institution
  - Providing target groups' needs not met by a CE device
  - Device not transferred to another legal entity
  - Still meets Essential Requirements (evidence in Technical documentation)
- For Clinical Investigation
  - CA (MHRA) must assess device and Technical Documentation
- Custom device for named patient
  - Manufacturer must hold Technical Documentation for CA audit
- Everything else does require CE marking…
  - Route depends on Classification (all require Technical Documentation)

Technical File

Construction File (DMR)

Design History (DHF)

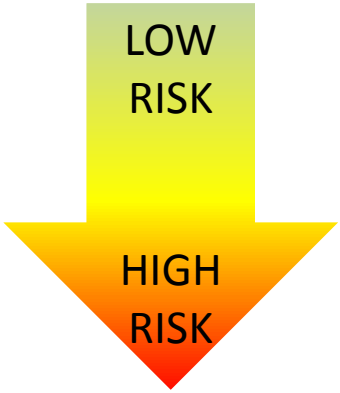


Device Records (DHR)

Classification

- MDD **Annex IX**

- Simple Set of 18 rules, resulting in…
  - Class I
  - Class IIa
  - Class IIb
  - Class III



Standards

Following standards makes it a lot easier to show conformity.

- Design/Engineering…
  - **EN 60601-1** Electrical/Mechanical Safety & Essential Performance
  - **EN 60601-1-2** Electro-magnetic Compatibility
  - **EN ISO 10993-1** Biocompatibility

- Process/Activity…
  - **ISO 13485** Quality management systems
  - **ISO 14155** Clinical investigation of medical devices for human subjects
  - **ISO 14971** Risk Management
  - **EN 62304** Software Development Life-Cycle

National Institute for Health and Care Excellence (NICE)

- NICE
  - Not a regulator
  - Not a “watchdog”
  - A guidance factory
- Established 1999
- Assesses
  - Health technologies and procedures
  - Clinical practice
  - Health promotion and ill health avoidance
  - Social care interventions

Hierarchy of evidence

1. Systematic reviews and meta-analysis
2. RCTs with definitive results
3. RCTs with non-definitive results
4. Cohort studies
5. Case-controlled studies
6. Cross-sectional surveys
7. Case series
8. Case reports

Real-world evidence (RWE)

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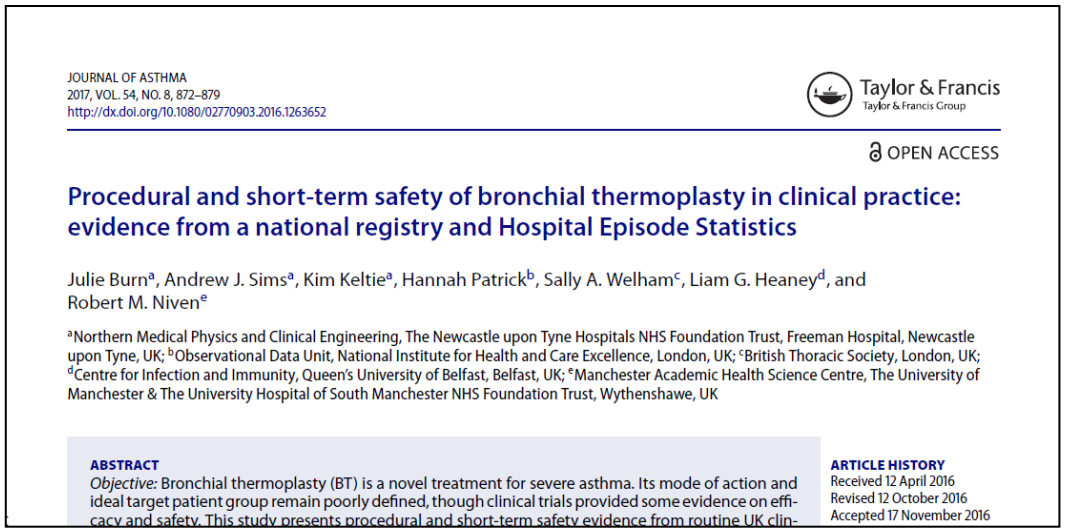
Received: 2 June 2017
Accepted: 30 August 2017
Published online: 20 September 2017

Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women

Kim Keltie[1,2], Sohier Elneil[3], Ashwani Monga[4], Hannah Patrick[5], John Powell[5,6], Bruce Campbell[7] & Andrew J. Sims[1,2]

Complications of surgical mesh procedures have led to legal cases against manufacturers worldwide and to national inquiries about their safety. The aim of this study was to investigate the rate of adverse events of these procedures for stress urinary incontinence in England over 8 years. This was a retrospective cohort study of first-time tension-free vaginal tape (TVT), trans-obturator tape (TOT) or suprapubic sling (SS) surgical mesh procedures between April 2007 and March 2015. Cases were identified from the Hospital Episode Statistics database. Outcomes included number and type of procedures, including those potentially confounded by concomitant procedures, and frequency, nature and timing of complications. 92,246 first-time surgical mesh procedures (56,648 TVT, 34,704 TOT, 834 SS and 60 combinations) were identified, including 68,002 unconfounded procedures. Peri-procedural and 30-day complication rates in the unconfounded cohort were 2.4 [2.3–2.5]% and 1.7 [1.6–1.0]% respectively; 5.9 [5.7–6.1]% were readmitted at least once within 5 years for further mesh intervention or symptoms of complications, the highest risk being within the first 2 years. Complication rates were higher in the potentially confounded cohort. The complication rate within 5 years of the mesh procedure was 9.8 [9.6:10.0]% This evidence can inform future decision-making on this procedure.

Mesh insertion is the most common surgical procedure used to treat stress urinary incontinence (SUI) in women[1], with 3.7 million meshes sold worldwide between 2005 and 2013[2]. However the safety of these procedures is the subject of international debate and scrutiny[3] with court actions against mesh manufacturers underway in various countries, including Australia, Belgium, Canada, England, Israel, Italy, the Netherlands, Scotland, USA, and Venezuela[4]. In the USA, the FDA has proposed to raise the risk classification of urogynaecological meshes, requiring premarket notification and special controls[5]. In the UK, safety concerns have led to parlia-



JOURNAL OF ASTHMA
2017, VOL. 54, NO. 8, 872–879
http://dx.doi.org/10.1080/02770903.2016.1263652

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Procedural and short-term safety of bronchial thermoplasty in clinical practice: evidence from a national registry and Hospital Episode Statistics

Julie Burn[a], Andrew J. Sims[a], Kim Keltie[a], Hannah Patrick[b], Sally A. Welham[c], Liam G. Heaney[d], and Robert M. Niven[e]

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ABSTRACT

Objective: Bronchial thermoplasty (BT) is a novel treatment for severe asthma. Its mode of action and ideal target patient group remain poorly defined, though clinical trials provided some evidence on efficacy and safety. This study presents procedural and short-term safety evidence from routine UK clin-

ARTICLE HISTORY
Received 12 April 2016
Revised 12 October 2016
Accepted 17 November 2016

Opportunities and challenges

- Newcastle connectedness (academic, clinical, research, regional)
- Track record in clinical device research
- Influence national agenda in device R&D ("regulatory science")
- Calls to strengthen regulation for devices (metal-on-metal hips, PIP breast implants, mesh)
- Timescales and lack of capacity/ infrastructure for regulatory advice and support
- Role (and timing) of RWE in approvals and assessment

Questions?