Medical Devices for Clinical Use

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Healthcare at its very best - with a personal touch
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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

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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

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Clinical Measurement & Engineering Unit
- Clinical measurement
- Clinical engineering
- NICE External Assessment Centre
- Clinical informatics

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Developing devices...

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

- **NotePAD** – Commercialisation under negotiation

- **Safeplace** – Licensed to Vygon

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Research...

**Nairos** – Using Nasal airflow prediction of outcome from septoplasty

**OppAF** – Opportunistic AF detection using BP measurements

**Verdict** – Vector Doppler In Carotid Assessment

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Technology Assessment...

Assessment

New Guidance
(NICE MTEP – Newcastle EAC)

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Approval and assessment

Law

Safety

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

Efficacy (clinical effectiveness)

Systematic reviews
Experimental trials
Observational studies, registers

Guidance

Value for money (cost effectiveness)

Health economics

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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 (50-1000 Vac)
  - 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)

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Classification

• MDD Annex IX

• Simple Set of 18 rules, resulting in...
  – Class I
  – Class IIa
  – Class IIb
  – Class III

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

Kim Kellett,8,9, Soheir Elidaw,8, Ashwani Monger,9, Hannah Patrick,8, John Powell8, Bruce Campbell11 and Andrew J. Sims8,9,12

Complications of vaginal mesh procedures have led to legal cases against manufacturers worldwide and triggered national inquiries about their safety. The aim of this study was to investigate the rates of adverse events of these procedures for stress urinary incontinence in England over 8 years. This was a retrospective cohort study of two large national free-singled Mesh Tape (TVT) and trans-obturator tape (TOT) registry datasets, the Gynaecological Single Centre (GynASC) Project, and the NHS Foundation Trust (NHSFT) registry, which included data from 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 concurrent procedures, and frequency, nature and timing of complications. A.944 first cases vaginal mesh procedures (94,444 TVT: 3a, 100: 9, TOT: 8, 80: 5a and 40: 2) procedures were included, including 94,444 unconfounded procedures. Peri-procedural and 30-day complication rates in the unconfounded cohort were 24 % and 17 %, and 67 % and 68 % respectively. 5.9%. 6.4 % were restricted at least once with 8.5 % for further medical intervention or symptoms of complications, 2.4 % within the first 2 years. complication rates within 6 years of the mesh procedure was 11.8%. This database can inform future decision-making on this procedure.

Real-world evidence (RWE)
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