Welcome!

Thank you for coming!

Programme

Aims:
- To clarify the current issues facing evidence-based healthcare in the field of implants and medical devices.
- To identify areas where organizations (including HealthWatch) might most productively concentrate their efforts.

Objectives: By the end of the symposium participants will:
- Have a clearer picture of the rules and regulations relating to medical devices.
- Be able to identify areas where evidence requirements coincide with the interests of healthcare organizations.
- Have developed a priority list of potential actions and activities.

Programme – Overview

12:00 Welcome, introduction and presentation of briefing paper
12:10 Plenary presentations
14:00 Breakout discussion groups Part 1
14:45 Coffee and return to discussion groups for Part 2
15:30 Plenary feedback and discussion session
16:15 Presentations round up session
16:25 Closing comments
16:30 – 17:00 Optional networking session with tea

Programme – Initial presentations

An overview of medical devices governance in the UK.

Til Boekner, Transform, MDD, Transform, Bristol and London, UK

Learners from surgical masks.

Cary Maggs, Director, Centre for Evidence-Based Medicine, Oxford University.

Current regulations fail to protect.

Deborah Cohen, investigative journalist, BBC and ABC, London.

The IDEAL Collaboration and necessary evidence.

Peter McCallon, Chair of the IDEAL Collaboration, Oxford University, Oxford.
Medical Device Governance
How can we make a positive difference?

KEY ISSUES
- Are evidence requirements appropriate and sufficient?
- Are processes for assessing evidence appropriate and sufficient?
- Is there enough transparency of evidence?

Remember: “evidence” means pre-market and post-market

OPPORTUNITIES
- Important details of MDR implementation still being developed
- New data publicly available from May 2020
- Possibility of setting stronger national standards (MHRA and/or NICE)

QUESTIONS
1. Should HealthWatch try to influence the MDR rules while they are still being written?
2. Once the MDR is in force, which aspects should HealthWatch focus on monitoring?
3. Can the UK impose more stringent evidence, safety and/or transparency requirements?
4. Are there important gaps in the current implant registry landscape in the UK?
5. Should HealthWatch worry about EUAMED potentially undermining clinical trial registries?

CONSTRAINTS
- Text of Medical Device Regulation has been finalised
- UK likely to remain within the framework for many years
- Currently no political will for measures that would imperil UK exports
- Limited ability of UK to keep CE-marked devices off the national market?
NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

1.1 The tension-free vaginal tape (TVT) procedure is recommended as one of a range of surgical options for women with uncomplicated stress urinary incontinence in whom conservative management has failed.

3.4 There are less data on long-term complications following TVT placement. Postmenopausal or severe fourralare symptoms following surgery and this may result in the tape to be set or removed. Erision of the tape material into the bladder, cuffing or erosion is a potential problem with synthetic sling devices.

5 Recommendations for further research

5.1 Further information on the long-term effectiveness and complication rate of the TVT procedure is required. It is recommended that observational data on effectiveness and safety of the procedure are collected over a period of 10 years or more. Implications on this should be nationally co-ordinated in the terms of the National Registry of audit data to include both the numbers of procedures carried out and measures of outcomes and adverse events.

NICE GUIDANCE

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Clinical data are sourced from:
- clinical investigation(s) of the device concerned, or
- other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated. or — published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.
IDEAL Framework
A 5-stage description of the journey of surgical innovation

- Stage 1: Idea
- Stage 2a: Development
- Stage 2b: Exploratory
- Stage 3: Assessment
- Stage 4: Long-term monitoring

IDEAL Recommendations

- **Stage 2a: Prospective Development Studies**
  - Delineate study design
  - Outcomes & endpoints
  - Methods & sub-analysis
  - Description of new endpoints
  - Profiling of patients

- **Stage 2b: Prospective Exploration Study**
  - **Objectives**
    - To examine & predict outcomes
    -混同 vs different populations
    - To develop & improve procedures
    - To examine new endpoints
    - To provide evidence for future studies

- Why do Development studies?
- Why do Exploration (2b) studies?

Key Questions at each IDEAL Stage

- **Stage 1:** What is the new treatment concept?
- **Stage 2a:** Have we perfected it?
- **Stage 2b:** Can we agree on what it is and who should get it (for the purposes of an RCT)?
- **Stage 3:** Is it better than current practice? (RCT if possible)
- **Stage 4:** Are there any surprises?
IDEAL Stage 4: Registries

- Prospective studies which record data on all patients in a group
- Allow long term study and analysis of rare adverse events
- Subject to bias from missing data
- Subject to bias if those involved in running them have bias

Recommendations
- Ease-based preferable to procedure-based
- Designed and curated by clinical community/governance
- Neutrally involved in governance
- Maximizes diagnosis
- Prior consent for involvement in approach about additional studies

Is IDEAL applicable to Devices: IDEAL (D)

- DELPHI: consensus process
- Conclusions
  - Needs a Stage 2 with minimum declared dataset
  - Needs a flexible approach to mindset of development (2a) and exploration (2b) steps
  - Needs registries from an early stage, developing and changing with needs

IDEAL-D modifications

How could it help?
Integrating IDEAL into regulation

- Minimize IDEAL Stage 2 studies for CE marking in high-risk devices
- Decide on basis of risk & Stage 2 study results whether to require an RCT (IDEAL Stage 3) — and whether to allow another cohort study alongside this
- Require high quality registry data and maintain this (IDEAL Stage 4)

IMPACT
- Effect on cost of evaluation likely to be moderate
- Overall effect on speed of evaluation likely to be positive
- Standardisation of process would yield major efficiency benefits
- Effect on safety and evidence quality likely to be substantial

SUMMARY

- Regulatory evidence requirements for therapeutic devices in the EU are nonuniform, vague and costly
- This is built on:
  - Lack of legislation to require clear consistent standards for evidence
  - Lack of a theoretical basis for such legislation
- A primary focus on economic, not clinical
- Missing is currently a prescriptive ISO 9001 decision, and attempts to ensure evaluation after approval are weak and unsatisfactory
- IDEAL-D provides a theoretical basis for more specific evidence requirements at each stage in a product lifecycle
- Requiring mandatory IDEAL format evidence could allow a change to a safer, graduated TPUC approach to licensing