UK Perspective:

MHRA … NICE … and IDEAL

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IDEAL Conference

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REGULATION >>>> **EVALUATION**

or Assessment - HTA

MHRA **>>>>** **NICE**

Safety	>>>>	Efficacy
Performance		Cost effectiveness
Marketing	>>>>	Adoption
Vigilance		More evidence

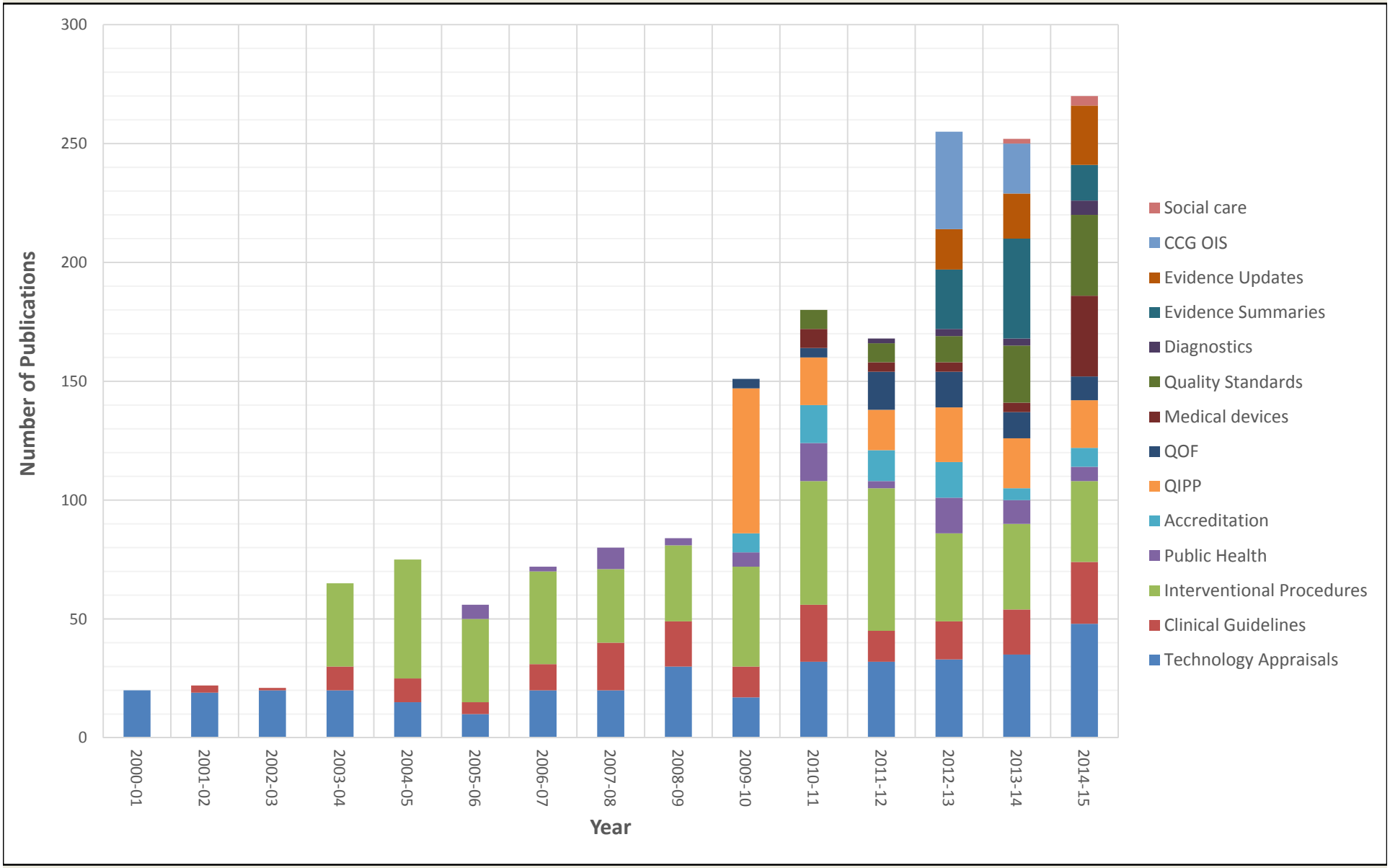
Why NICE was set up

in 1999

- To reduce variations in available treatments and care - '***postcode lottery***'

- To resolve uncertainties about which treatments work best and give best ***value for money***

NICE guidance by year 2000-2015



NICE guidance on health technologies

Technology Appraisals - Clinical and cost effectiveness

Interventional Procedures - Safety and efficacy
- Not cost

Medical Technologies - device/diagnostic adoption

Diagnostics – complex, costly, competing options

Clinical Guidelines - Managing specific conditions
- Link to **Quality Standards**

How does NICE assess technologies?

- **Wide range of "evidence":**
  - ***Published studies*** (± abstracts, registers, audits)
  - Expert advice
  - Views of patients and carers
  - Manufacturers and other stakeholders

- Independent advisory committees
- Explicit and transparent processes
- Public consultation
- Opportunity for appeal/resolution

NICE National Institute for Health and Care Excellence

Technology Appraisal Guidance

Since 1999

- Clinical and cost effectiveness ("cost per QALY")

- Topic Selection: agreed with Department of Health

- High cost/high impact technologies
  - ➢ Dominated by expensive medicines
  - ➢ Some devices/procedures: hips, hernias, EVAR

<u>The only guidance with a funding mandate</u>

Interventional Procedures guidance

Always generic *procedure* name ….

… not name of device

- Evaluates evidence on all devices
- Guidance applies to all devices
  - Different manufacturers
  - Different versions of same device

Interventional Procedures Recommendations
specify circumstances for use of procedures

1. **Evidence adequate**: "normal arrangements"

2. **Evidence limited**: "special arrangements"*** for:
   – Governance – tell your hospital
   – Consent - tell your patients
   – Audit/research – review your outcomes

3. **Evidence so limited** research ethics oversight: "Research only"****

4. **Evidence of harm** or does not work: "Do not use"

Interventional Procedures guidance

578 published since 2002 (67 procedures)

- In practice the “regulator” for procedures
- Often referred to as “NICE approval”
- “Special arrangements” or “Research only” is not “suspect” - <u>means need more evidence</u>

  Potential for IDEAL

Medical Technologies Evaluation Programme

Medical devices and diagnostics

Since 2009

AIM:

identify >>> evaluate >>> adoption

Specific products notified by manufacturers

NICE Medical Technologies Evaluation Programme

1. Topic selection by committee

<u>Advantages</u> over "current management" in:

- Patient outcome or experience
- System benefit (cost): facilities, staff, tests, disposables
- Sustainability (energy saving)

2. Evaluation to produce NICE guidance

"*The evidence supports the case for adoption …*"

What companies need to produce ……

Claims + Value proposition

List advantages (patients, service, energy)

- "Current management" as comparator

Clinical evidence

IDEAL culture would be wonderful!!!

- Relevant patients, setting, outcomes
- Clinical utility important
- Consider care pathway

Cost model with plausible assumptions

Topic	Patient benefits	System benefits	Annual saving £/patient
MTG12 (2013) EXOGEN ultrasound system for non-union or delayed healing	For non-union fractures gives high rates of fracture healing	For non-union fractures, avoidance of further surgery	£1164

Evidence generation

- **Plan ahead for** regulators, HTA, payers, clinicians, patients
- **Maximise relevance** and value of evidence for these successive audiences
- **IDEAL** describes the framework for this …

NICE Scientific Advice

- Detailed advice packages (£££)
- Brief advice/ META Tool (£)
- Symposia (with MHRA input)
- Link with FDA initiative

Potential to introduce IDEAL concept