

# “Medical devices, healthcare innovation”

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# Aims

- Health technologies as ‘medical devices’
- Factors influencing innovation into healthcare systems
  - regulation, policy, ethics, evidence, stakeholders....
- UK – EU
- 1990 →

# Innovative thermoplastic technology



The largest collection of vintage plastics in Britain.

**The Bakelite Museum**

# Thermoplastic technology innovation in orthopaedics, 2006

“next generation joint prostheses..... PEEK polymer has been employed as an acetabular liner for articulation against a ceramic femoral head. Hip-joint simulator testing up to 10 million cycles showed that the wear of the CF-reinforced PEEK polymer cups was approx 1% that of ultra-high molecular weight polyethylene (UHMWPE) cups. Further work....shows that the combination...approaches the bearing performance of metal-metal or ceramic only surfaces – without the brittleness or metal ion release..’

*(Jarman-Smith, 2006, Medical Device Technology Sept 2006, p51-52).*

# Medical devices into healthcare

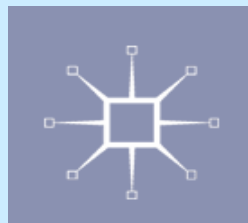
- questions of risk and benefit both to health and to the healthcare system and its stakeholders
- issues of safety, efficacy/effectiveness, useability and societal acceptability
- dynamics between medical device industries, healthcare systems, and policy networks, health professions and patient-public groupings

social processes of governance and evidence differ between device technologies

→ detailed comparative case studies

# “Medical devices and healthcare innovation” – the book

- Evidence and governance (& regulation)
- The world of medical devices
- 5 case study device technologies
- ‘Devising health’: societal dynamics of healthcare technology innovation



# Artificial hips: surveillance of success



# PSA test for prostate cancer: scientific uncertainty as participative governance?

## EFFECTIVENESS *Matters*

### SCREENING FOR PROSTATE CANCER

- There is increasing pressure on doctors to test men for the early detection of prostate cancer.
- Unlike breast cancer screening, which has been shown to reduce mortality, prostate cancer screening has not yet been evaluated and there are several reasons why it may be less effective.
- Many men with prostate cancer never experience any ill effects because some tumours are slow growing and not aggressive.
- The most sensitive screening tests for prostate cancer are based on levels of prostate specific antigen (PSA). However, the PSA test and follow up biopsies cannot predict reliably whether a man has a cancer that will progress to cause ill health or death.
- There have been no reliable evaluations of the effect of treatments for early prostate cancer on mortality. Active treatments can result in major complications such as incontinence and impotence.
- There is no evidence on the number of deaths (if any) which could be averted by screening asymptomatic men. Screening may lead to physical and psychological harm resulting from testing, biopsy and treatment. It is not known whether screening for prostate cancer does more good than harm.

*Effectiveness Matters* is an update on the effectiveness of health interventions for practitioners and decision makers in the NHS. It is produced by researchers at the NHS Centre for Reviews and Dissemination at the University of York, based on high quality systematic reviews of the research evidence. *Effectiveness Matters* is extensively peer reviewed by subject area experts and practitioners.

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# Infusion pumps : governing life-support technology



# Coagulometer: healthcare governance at home and away



*Acknowledgements; Roche Diagnostics;  
Anticoagulation Europe*



**'All at sea? Not me!'  
says Marianne Gill**

**Marianne's labour  
of love**

# Tissue-engineering: 'governance' of a new technological zone



<b>Device technology</b>	<b>‘User’</b>	<b>Advocates</b>	<b>Primary policy issue/ ‘frame’</b>	<b>Salient evidence</b>	<b>Healthcare governance</b>
<i>Hips</i> Implant - surgical	surgeons  elderly- OA	Industry; surgeons	Proliferation; cost	Preclinical; HTA; inquiries; Risk re- assessment	NICE; registry; E-b P; EU Directive
<i>PSA</i> blood test—  detection/ monitor	physician or nurse;  men - cancer	Clinical special- ists; citizens; insurers	Use: uncertain- clinical interpretat ion; demand;  ‘screen?’	HTA – incl. innovative participat ive trial	DoH Risk Management; professional guidelines; HTA (NHSCRD)

<b>Device technology</b>	<b>‘User’</b>	<b>Advocates</b>	<b>Primary policy issue/ ‘frame’</b>	<b>Salient evidence</b>	<b>Healthcare governance</b>
<p><i>Tissue Engineered</i></p> <p>Surgical; cell culturing</p> <p>‘regeneration’/self-repair</p>	<p>specialist health professional</p> <p>various – burns victims; athletes</p> <p>?coronary +</p>	<p>EU Parliament &amp; Commission</p> <p>Industry; DTI - biotech; some clinicians</p>	<p>safety/ industry-friendly</p> <p>experimental status</p>	<p>Clinical – trials; surveillance;</p> <p>innovative science</p> <p>ethical values</p>	<p>MHRA – voluntary guidance for industry; NICE;</p> <p>delayed EU Regulation to define the EU zone and make it regulatable</p> <p>dual role ↑↓</p>

# **‘Devising health’: societal dynamics of healthcare technology innovation**

- ‘regulatory state’; technological zones; policy ‘frames’; collective clinical practice; regulatory and evidential regime; users; device technology (= artefacts +practices +beliefs)
- stakeholder/user powers – patterns and routes vary
- disruptiveness of technology trajectories to prevailing order of innovation/regulation/practice – outcome of ‘negotiations’
- policy trends conflict - e.g. evidentiality vs. patient empowerment
- device/practice innovation may re-shape the methodologies of healthcare science and evidence

..... *Trustworthy medical futures?*



Thank you!

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# EFFECTIVENESS Matters

SCREENING  
FOR  
PROSTATE  
CANCER

- There is increasing test men for the ear cancer.
- Unlike breast cancer been shown to reduce cancer screening has and there are several less effective.
- Many men with 1 experience any ill tumours are slow gro
- The most sensitive prostate cancer or prostate specific ant PSA test and follo predict reliably when that will progress to
- There have been no effect of treatments on mortality. Active major complications and impotence.
- There is no evidence (if any) which could asymptomatic men, physical and psych from testing, biopsy know whether wate does more good than

Effectiveness Matters is an online intervention for practitioners and published by members of the Department at the University. Evidence review of the research community peer reviewed by subject

The NHS Centre for Reviews and Evidence and the Health Care Research Unit, a contribution to University of York. The views expressed are those of the authors and not necessarily Health Departments of Scotland, UK

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## Closes more wounds faster

