When it comes to medical implants, HealthWatch says:

➢ Implant approval should be graduated and supported by step-by-step evidence. This should replace the 'equivalence' system of approval using Notified Bodies which has failed.

➢ Those who implant a device must know (and be able to explain to their patient):
   o *What it is and what its constituents are*
   o *How it is identified and tracked*
   o *How the evidence shows that it works*
   o *What risks are involved*
   o *What to do if things go wrong*

➢ Regulators, academics and professional bodies should work together to achieve these aims

A. Conclusions from Symposium
- Approval has been a technical rather than a medical process.
- The 'equivalence' system using Notified Bodies has failed.
- Using and recording device serial numbers would be a simple first step.
- The IDEAL-D framework provides for evidence-based implant development.
- Adequately funded registries are needed with compliance monitoring.
- Political action will be required to influence the developing rules and to draw agencies together.
- There are academic responsibilities: early reporting; development of evidential standards; guidelines for data reporting and appropriate data amalgamation procedures.
- Putting the issues into simple statements will be a powerful aid to progress.

B. Aims
HealthWatch will concentrate on implantable devices, seeking to develop an evidence base by pressing for:
- identifying numbers,
- evidence of efficacy,
- evidence of safety,
- registry and feedback

HealthWatch will press the NHS to purchase only devices that meet these requirements.

HealthWatch will seek to encourage surgeons and those who implant devices to develop appropriate evidence and ensure it is available to support the use of any implant they use.

Since manufacturers are unlikely to report adverse effects, HealthWatch will press for an independent regulator / holder of registries.

C. Routes to achieving our aims:

- Political / Regulatory
  - Let parliamentarians (House of Commons Health and Social Care Committee) know of our strategy and how this addresses the public questions
  - Discuss with MHRA what is required to develop this area, then campaign to provide this enhancement – based on IDEAL-D Framework
  - Discuss with the NHS (and NICE) how our strategy can be implemented within the NHS
- Academic
  - Press Cochrane etc to develop better evaluation tools
  - Press academic institutions (especially RCS) to promote *an approach such as* IDEAL-D
  - Work with academia / MHRA / NHS to design a basic form of registry for medical devices
- Commercial
  - No-fault compensation for devices developed through IDEAL-D / MHRA collaboration and NHS approved
  - Consult about practical ways of managing post-marketing surveillance
- NHS
  - Encourage the wider use of registries
  - Help develop evidence requirements to justify purchase of implants
  - Monitor use of and expenditure on implants
- Public
  - Promote our summary of conclusions as the basis for patients' right to know:
    - *What's implanted inside me?*
      - What is the purpose of the implant and the materials?
    - *How is it identified and tracked?*
      - Every device should bear a serial number and bar code and be traceable to the patient in whom it is inserted
    - *What's the evidence that it works?*
      - Risk of not having device and risks of having device, with information presented as absolute numbers, common denominator, framed both ways (NICE CG138) as fact boxes/ icon arrays
      - Follow the IDEAL-D framework
    - *What is known about the risks?*
      - HW to lobby for standard package inserts for patients (like pills)?
    - *What do I do if things go wrong?*
      - All patients given information/ how to report electronically.
      - Everyone in whom a device is implanted should be issued with an equivalent to Yellow Cards for drugs and be told how to use it.
      - Information on, and improved routes to, compensation for harms caused by devices
  - Work with patient groups
    - Discuss the findings
    - Seek approval/ endorsement of the 'asks'
    - Publicise the issues and the solutions discussed above
    - Encourage relevant groups to take on the political action?