John Amoore, Paul Blackett,
Fran Hegarty, Justin McCarthy, Richard Scott

Medical Device Governance for Effective and Safe Care

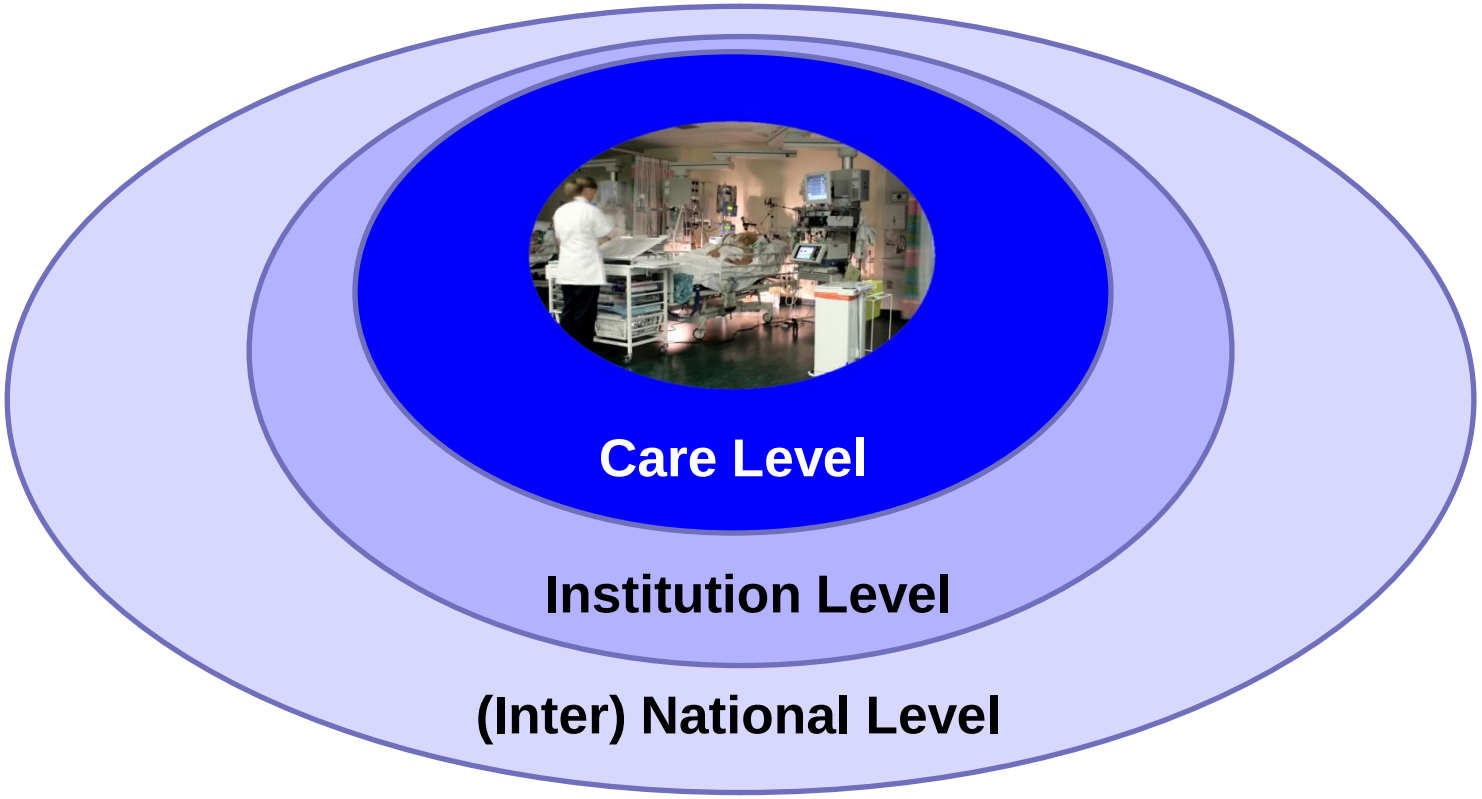
- What ensures effective and safe application of medical devices?
- How do Clinical Engineers contribute?

Definitions

- **Governance**
  - Organizational and operational policies, processes and actions
- **Effective and Safe**
  - The application of the Medical Devices must be effective and appropriate for the patient
  - The application must be safe
  - The application should **add value** to the patient's care.

How do we 'govern' medical devices?

- Patient, Carer and medical device at centre
- Three Levels of 'governing' processes

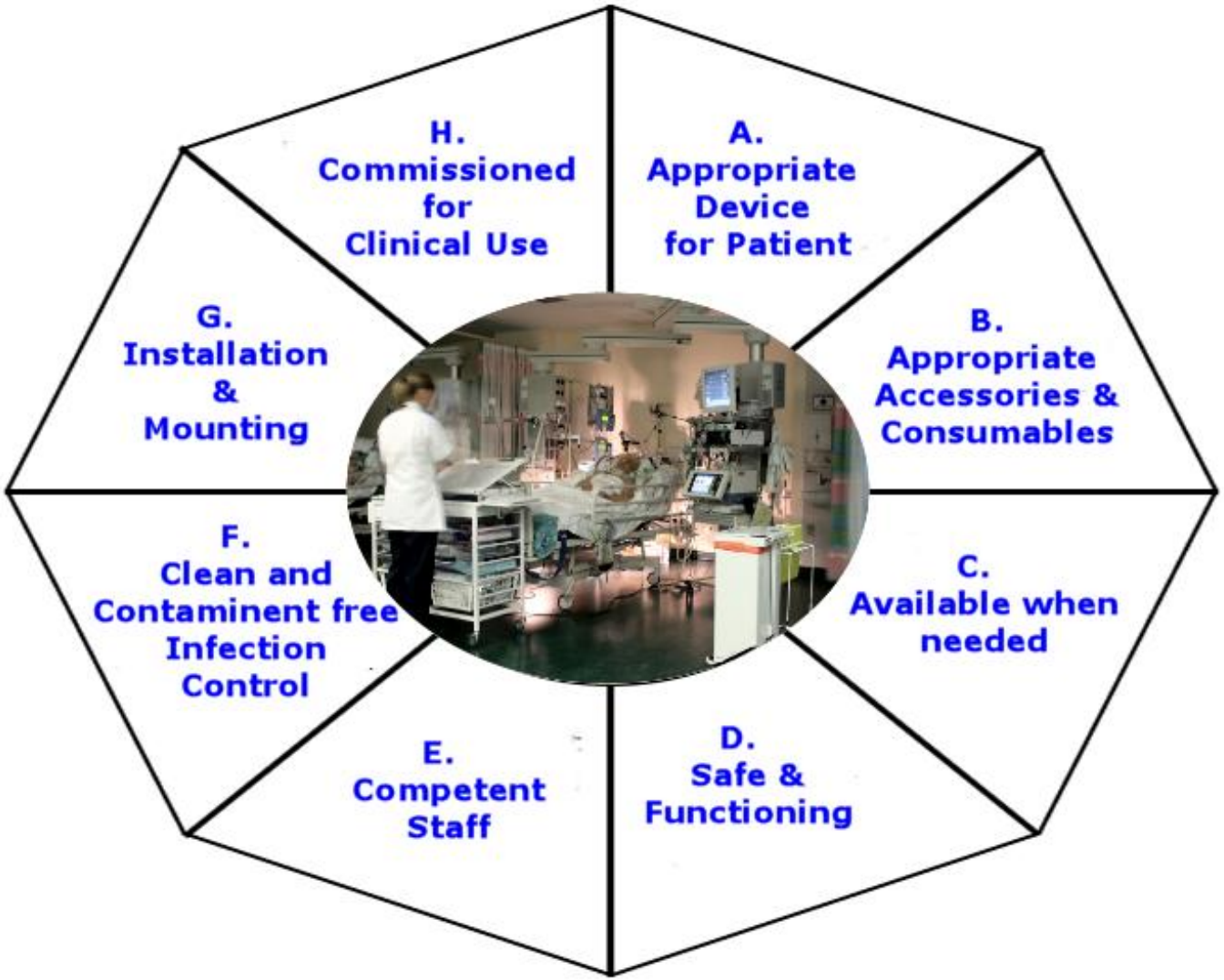


Medical Device Governance, Amoore et al. 2017.

How can Clinical Engineers support Governance?

- **At Care Level**:
  - Is the appropriate device available?
    Is it safe and effective, with staff competent in its use?
- **At Institution Level**:
  - Within your healthcare organization what processes support effective medical device management?
- **At (Inter) National Level**:
  - How can we support national groups such as UK'S MHRA and Standards bodies

1. At Care Level



Medical Device Governance, Amoore et al. 2017.

1. At Care Level: some examples

E. Competent staff fully trained:

- Are there opportunities to support, formally & informally, clinician training in the use of medical devices?
- Do repair reports suggest training needs?

F. Clean Medical Devices:

- Who is responsible for keeping medical devices clean?
- Does your department have links with Infection Control?

H. Commissioning Medical Devices:

- Is Commissioning discussed with clinicians?
- Is there a planned process for Configuration?
- What about alarm configurations?

2. At Institution Level

Medical Device Governance, Amoore et al. 2017.

2. At Institution Level: examples

I. Medical Device Policy:

- Why have a Medical Device Policy?
- If you have one is it endorsed by the Chief Executive?

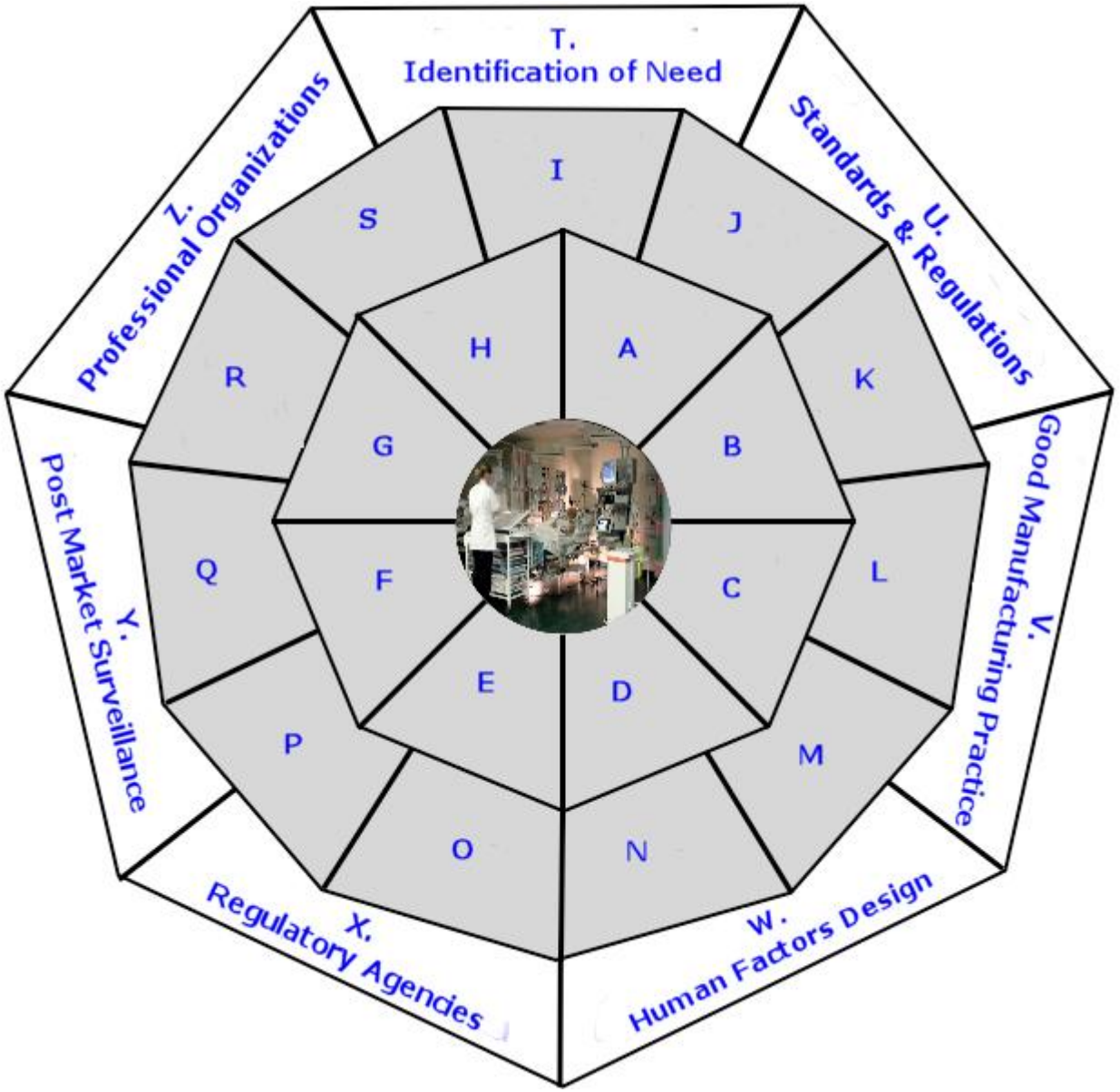
L. Selection of Medical Devices for purchase:

- Is there a multi-disciplinary process?
- What does the specification dictate?
- What are the selection criteria?

O. Cyber protection:

- Do you work with your IT department to ensure this?
- Mutual understanding of perspectives of IT and Clinical Engineering?

3. At National Level



Medical Device Governance, Amoore et al. 2017.

3. At National Level: examples

W. Human Factors Design:

- Can you as a Clinical Engineer influence the approaches to human factors design taken by manufacturers?

  Consider: feedback you give when talking with suppliers

X. Regulatory Agencies:

- How can you support the work of the MHRA?
- Medical Device Liaison Officers – what is their role?

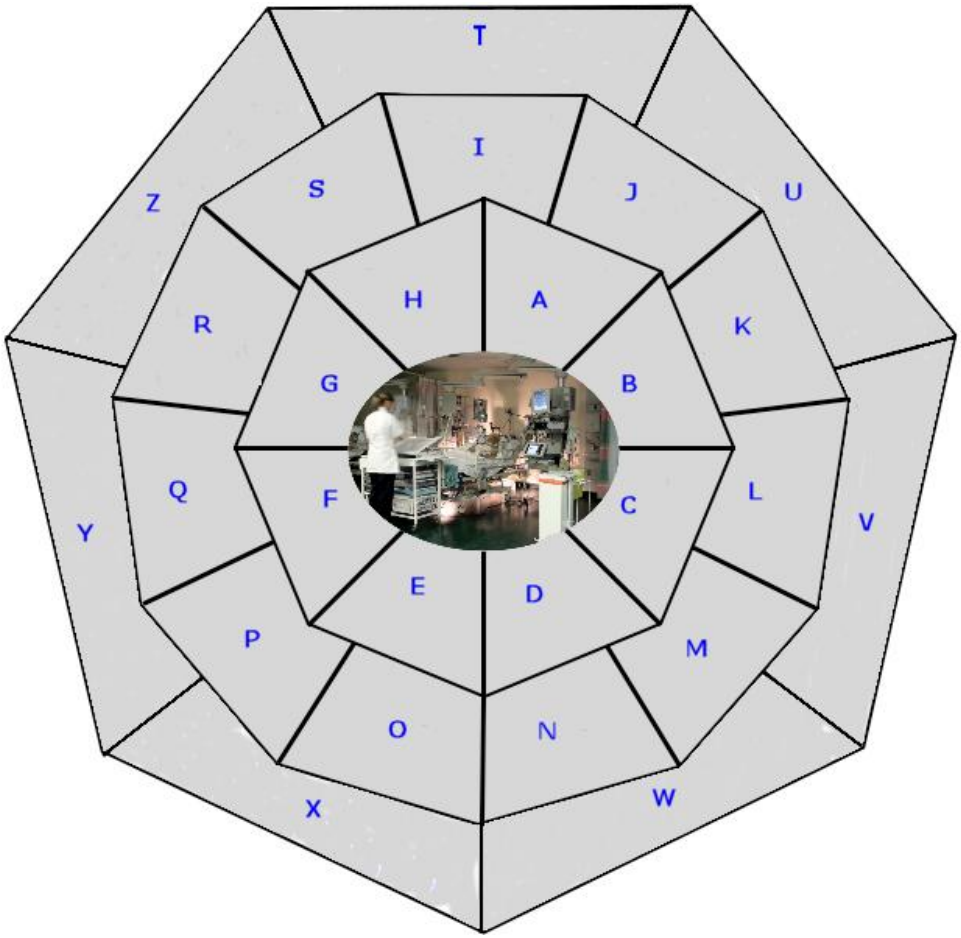
Y. Post Market Surveillance:

- Reporting problems to supplier and to MHRA?

Conclusion

- **Summarised the processes that, <u>combined</u>, ensure effective and safe application**
- **Clinical Engineers have roles in all the processes**
- **Not just Clinical Engineers – Team work essential**

A to Z of Device Governance



Reference

Healthcare Technology Management:
A systematic approach.

Fran Hegarty, John Amoore, Paul Blackett,
Justin McCarthy & Richard Scott
www.htmbook.com

Any Questions