Incident Reporting and Investigation Centre Conference

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Riaghaltas na h-Alba
gov.scot

Medical devices policy

- Commitment to have a strategy developed by 2020

- Policy on regulation of medical devices is set and continues – the Medicines and Healthcare products Regulatory Agency is the UK regulator

Rationale

- To transform care and improve outcomes
- Healthcare involves science / imagination / persistence / listening / collaboration / change
- EU Exit brought significance of medical devices requirements to the fore

Aim

- To understand risk
- To get necessary clinically wanted changes to products and their use to maximise health outcomes
- To ensure maximum efficiency
- Update current CEL 43 (2009)

Aspects of policy at conference

- Innovation
- Assessment
- Clinical care improvements – UDI
- Adverse event reporting
- Adverse event investigation

Specific new areas

- Medical devices significant incidents seen as public health issues – managed nationally as needed
- Medical device guidance and ongoing education
- EU Exit / Regs / Software

Linking topics

- UDI
- Health institution exemption
- Health board technology bridges
- Cost effectiveness / public discussion & risk
- Once for Scotland approach
- Adverse event reporting improvements
- Economic growth

SG Actions

- Supportive
- Inquisitive
- Forming
- 2020 onwards