



The MDD and software

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Chair - Intellect Clinical Safety Forum

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BT Health

Should we manage clinical risks?

- Incidents/clinical risks are becoming better understood in the NHS
- Technology is perceived to be a solution in reducing incidents and mitigating clinical risks
- However it has been found that technology introduces new risks

What can go wrong?

- Nearly one-third of 153 US Veterans Association Medical Centers reported problems after the annual software upgrade was distributed
 - Stop orders, as for drugs like heparin, were not clearly displayed - led to drug errors
 - When doctors pulled up electronic records of different patients within 10 minutes of each other to offer treatment advice, the medical information of the first patient sometimes displayed under the second person's name
- Barts and The London and the MITOB virus - IT network affected by virus, protracted delays in restoring network

Other examples:

- 1st line of a Radiology report missing when viewed in another application – could have led to a misdiagnosis
- Saving an image in PACS moved the annotations – could have led to misdiagnosis

How are these problems managed?

Have in place a systematic process in place that looks at:

- Identifying clinical hazards in the design phase
- Identifying what controls are currently in place
- Designing in new controls
- Testing that the controls work
- Manage issues arising
- Residual Risk as low as reasonably practicable
- Present findings/evidence to a Customer / End Users
- Review Service Incidents and update the Hazard Register with the relevant information
- End to end view of safety

A Clinical Risk Management System – i.e. DSCN14/2009

DSCN 14/2009 born from the following standards:

- IEC 61508 – Functional safety of electrical, electronic, programmable electronic safety related systems
- ISO 14971:2007 – Medical Devices – Application of risk management to medical devices
- ISO/TR 27809:2007 – Health Informatics – Measures for ensuring patient safety of health software
- ISO/TS25238:2007(E) Health Informatics – Classification of safety risks from health software

Intellect Symposium – Poll of what It standards followed

Out of 68 delegates (32 individual companies) including speakers, we had the following response:

- ISO 9001:2008 – 10 replies
 - TickIT – 4 replies
- ISO 27001 – 6 replies
- ISO 20000 – 2 replies
- NHS Standard
 - DSCN 14/2009 – 5 replies
 - DSCN 18/2009 – 3 replies (NHS colleagues)

Intellect's position

Patient safety is paramount

Support the aims of the revised MDD

However

- suppliers need greater clarity on how to interpret regulations – difficult to apply to software
- The industry needs appropriate guidance to support change

An international standard is urgently needed for safety management of software not considered a medical device



Bringing it all together