

Lessons from NHS Connecting for Health

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Overview

- History / Background
 - NPSA Report, Report Findings & Conclusion
 - Action Taken & Second NPSA Report (2006)
- Clinical Safety Management System (CSMS)
 - Organisation, Operational Layout, Requirements & Content
- NHS & IEC Standards for Clinical Safety
- Lessons Learnt
- Conclusion & Key Metrics
- Q&A

NPSA Report

- Commissioned 2004 by Deputy Chief Medical Officer (DCMO)
- Conducted by NPSA Risk Advisor

Report Findings

- Not identifying safety as a benefit to drive the programme
- No formal risk assessment
- No formal clinical safety management system
- Reliance on clinicians to instinctively address patient safety problems

Report Conclusion

- NPfIT not addressing safety in structured, pro-active manner and other safety critical industries would

Action Taken

- Appointment of National Clinical Safety Officer (seconded from NPSA)
- Implementation of Clinical Safety Management System (CSMS)
- Adoption of principles of IEC 61508
 - Patient Safety Assessment
 - Safety Case
 - Safety Closure Report
- Accredited clinician training
- Governance Structure
 - Clinical Safety Group
 - Clinical Risk and Safety Board (quarterly)



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Second NPSA Report (2006)

Major findings: -

- Pro-active actions and progress made by NHS CFH to put in place systems and processes to address patient safety in the NPfIT in an explicit, proactive, structured and robust manner
- Gaps (opportunities for further improvement) where further development will enhance the effectiveness and efficiency of the NPfIT helping the NHS realise patient safety benefits
- Recommendations for NHS CFH's consideration, aimed at realising the opportunities for improvement identified
- On-going improvement opportunities



Connecting for Health

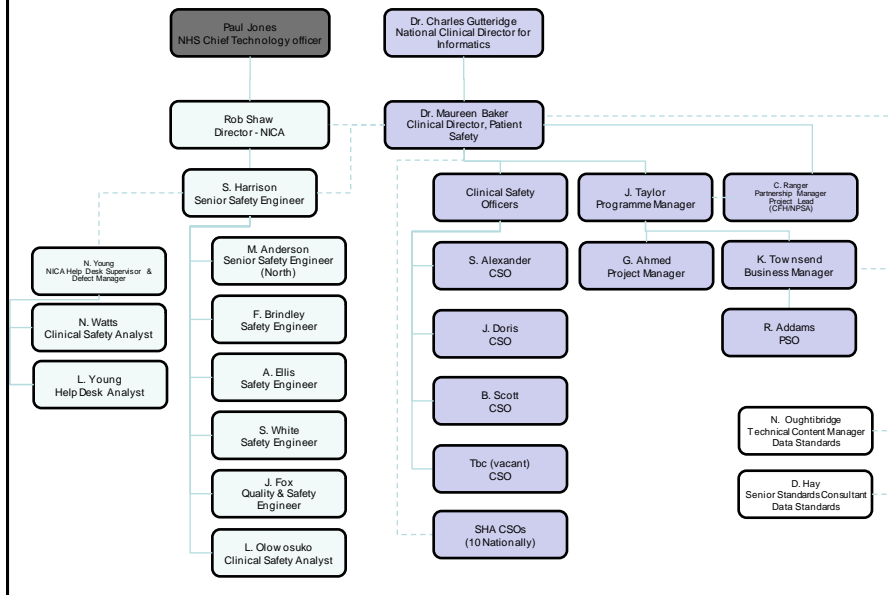
Standards for Clinical Safety in IT Systems

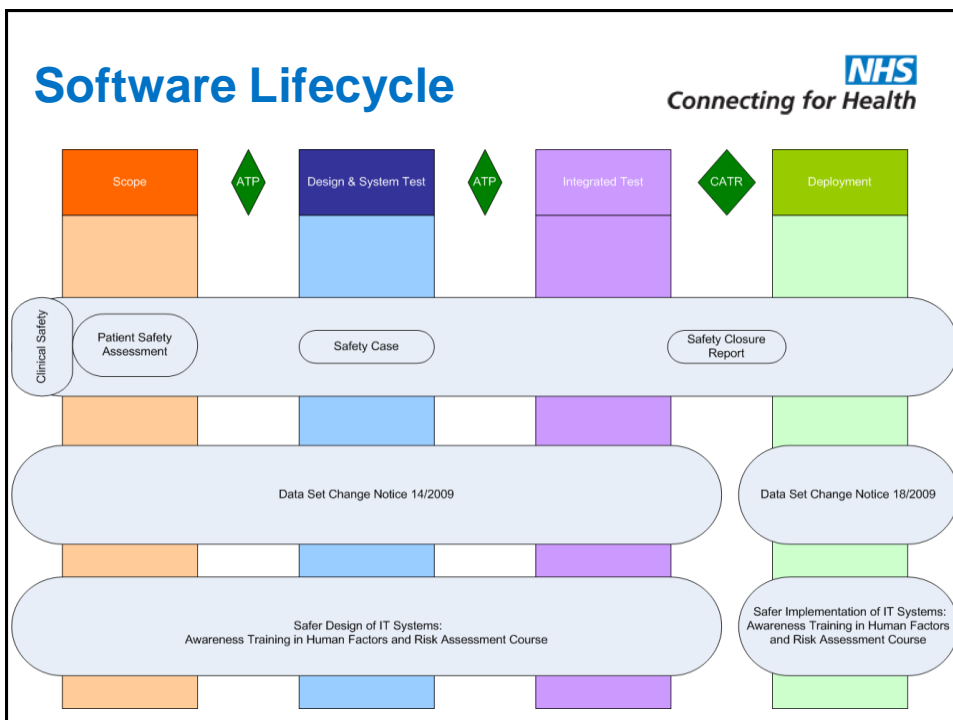
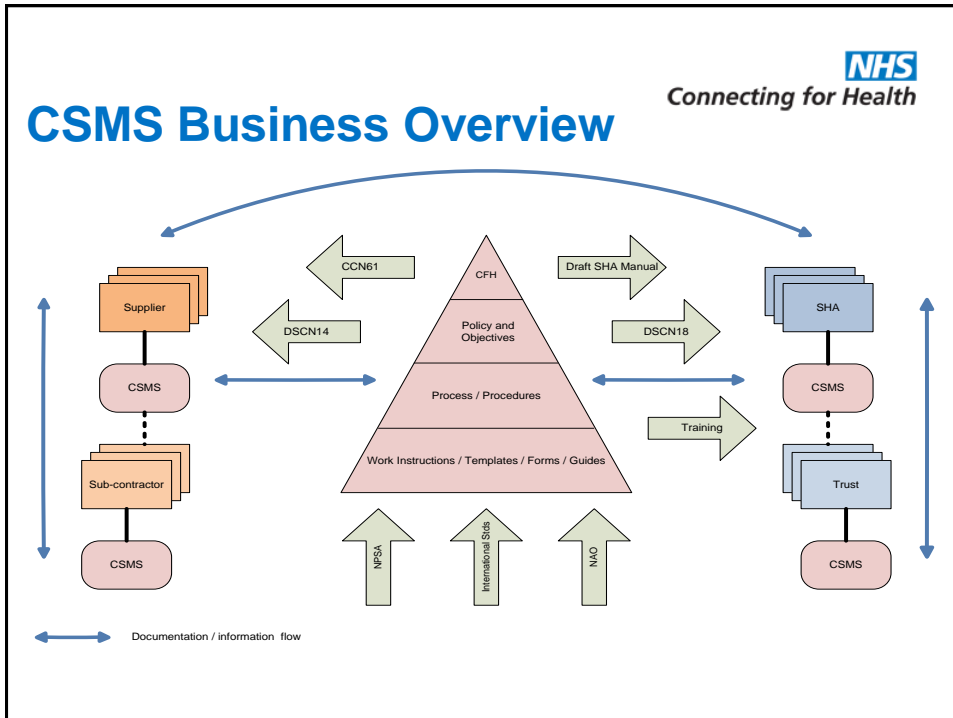
- DSCN14/2009
 - NHS ISB Health approved (hence link to the common assurance process)
 - Applies to the NHS in England and Wales (may be taken up by the other countries)
 - ISB 0160 Health Informatics — Application of clinical risk management to the manufacture of health software (formerly ISO/TR 29321:2008(E)) – DSCN14/2009
- DSCN18/2009
 - Guidance for health organisations 'how to' monitor the manufacturer's DSCN
 - Advises on how health organisations set up a Clinical Risk and Safety Management system
 - ISB 0129 Health informatics - Guidance on the management of clinical risk relating to the deployment and use of health software (formerly ISO/TR 29322:2008(E)) - DSCN18/2009

IEC 80001

- Joint IEC/ISO standard on integration, strongly supported by FDA
- Increasingly the case that medical devices not stand-alone
- Standard is on safety, security and effectiveness of integration of medical devices with health IT
- Standard published September 2010
- Sub-group writing guidance for Healthcare Delivery Organisations - chaired by Dr. Maureen Baker

Organisation Chart





Clinical Safety Management

- All assurance activities require 3 deliverables during the project lifecycle:
 - Patient Safety Assessment [end-to-end]
 - Safety Case
 - Safety Closure Report
- Guidance provided, but no set format
- All valid risk management methodologies accepted
- Documents are signed off by suitably trained and experienced clinicians
- Review of documents by NHS CFH Clinical Safety Group [Clinicians and Engineers]
- Certificate of Authority to Release [CATR] provided if documentation approved

Lessons Learnt

- The use of a safety case is appropriate
- Endorsed by no serious incidents to date
- Proactive approach using safety incident management process as a reactive element
- Not an onerous process
- Implementation and take up from Manufacturers has its problems

Metrics


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- Over 250 CATR's issued
- 755 Safety Incidents reported
- Choose & Book
 - To date 24 million patient referrals, approx 500,000 referrals a month from GP practices
 - 140,000 additional patient referrals being booked per month to other services, such as those run by Allied Health Professionals, Community Services and Diagnostic Services
- Electronic Prescription Service - EPS Release 2 will be implemented at different times over a considerable period in the 19,000 GP practices, community pharmacies and dispensing appliance contractors throughout England

Metrics


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- GP2GP - Latest deployment statistics
 - 5,046 GP practices have had technical upgrades to connect to the new system
 - 60% of these GP practices are now actively operating GP2GP
 - 428, 570 electronic health records have been transferred to date
 - 152 PCTs with eligible GP practices are currently involved in the roll-out
 - On average, 10,000 GP2GP transfers are being completed every week



Q&A

Any questions?