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# Clinical and Healthcare Audit: Assuring Software Quality in Hospitals

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## Structure of Presentation

- Research Background
- Medical Device Software
- Quality and Compliance
- Research Project – Development of H-QAP
- H-QAP Layers and Protocols
- Conclusion

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## My Research Background

- Software Quality and Software Process
  - Regulated industry
    - Medical Device & Financial Services
  - **Hospital Software Quality**
  - Global software development
  - Services
- Research Method
  - Study practice to inform research
  - Develop theories about software process
  - Develop models for software process
  - Implement research to inform practice
- Supervise Research
- Lecture to Undergraduate and Postgraduate Software Engineering students

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## Software Engineering Regulation

- Do the Regulatory/Certification bodies need to review/approve your product?
  - Medical Devices (including Health Information Systems)
  - Automotive Systems
  - Financial Information Systems

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## Medical Device software

Software within Medical Devices  
Up to 70% of budget on software related activities

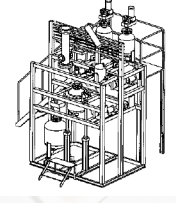
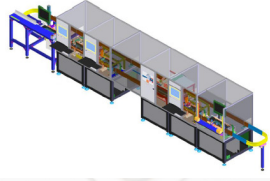




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## Medical Device software

Software in Medical Device production lines

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- For Software Engineers – *System quality* is important
- Additionally, we need to think about
  - Information quality, Service quality, Intention to use, User satisfaction
- DeLone and McLean
- Health Information Systems
  - Confidentiality, privacy, accuracy, integrity.....
  - Proactively identify and manage risk

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- Development of Hospital Quality Assurance program (H-QAP)
  - Analysis of published research and standards
  - Review of relevant hospital inquiries
  - Research in hospital (first cycle of action research)

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- Health Standards
  - HSE (Ireland) Quality and Risk Management Standard, Health Insurance Portability and Accountability Act, FDA requirements
- Software standards
  - Capability Maturity Model Integrated (CMMI), IEEE Standard for Software Quality Assurance Plans, IEEE Std. 730-2002

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- Focus on patient privacy and security with very little focus on integrity and accuracy
- Definitions of risk factors remains ambiguous
- Smartphone healthcare applications increased
  - Regulatory or quality guidelines not implemented
- Software Quality Plan for Hospitals as basis for H-QAP

– Shroff et al

*H-QAP: Software systems should be managed within a broad hospital quality program*

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**lero** THE IRISH SOFTWARE ENGINEERING RESEARCH CENTRE **Previous Relevant Inquiries**

- Therac-25: Fatal overdoses of radiation
- Bristol: above average death rates for children undergoing heart surgery
- Lourdes: outcome removal
- Shipman: patients of a General Practitioner
- Tallaght: unopened General Practitioner referrals and unread X-rays

*"Bristol was awash with data but was at the same time singularly uninformed."*

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**lero** THE IRISH SOFTWARE ENGINEERING RESEARCH CENTRE **Previous Relevant Inquiries - Findings**

- Outcomes not software related
  - Quality assurance requires more than dedication and commitment
- Outcomes were software system related
  - Use of existing information systems must be optimised
  - Existing software systems significantly improve outcomes and minimise the effects when things go wrong

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**Previous Relevant Inquiries - Findings**

- Outcomes had relevance to software implementation
  - Proactive and reactive risk management must be continually in place
  - Continually reviewed standards must be set

*H-QAP: Includes formal structures such as communication strategy, audit committee and stakeholder analysis; measures HIS quality*

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**Research in Hospital**

- Information systems used hospital wide
- Information systems used specifically by single departments
- Information systems are used personally by clinicians
- No integrated electronic patient record (EPR)
- Primary medical record is paper based

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**Research in Hospital**

- Software System Review
  - Emergency Department software system, two Clinical Nurse Specialist databases and the Hospital In-Patient Enquiry (HIPE) database.
- Key stakeholders: clinicians, software engineers, data entry personnel

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**Hospital Research – Key Findings**

- Low understanding of IS quality by clinicians
- Requirements engineering processes are often not used during systems development
- Healthcare staff, not qualified in software engineering and without an understanding of compliance, develop and implement systems
- Little emphasis is placed on data reporting even when data is available

*H-QAP: Understand and use strengths and weaknesses of existing quality processes*

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**H-QAP Layers and Protocols**

Macro

- 6 GOVERNANCE LAYER: Define governance, Apply governance
- 5 STRUCTURE LAYER: Audit Committee, Stakeholder analysis, Standards, PPPC's Communication Strategy
- 4 TOPIC SELECTION LAYER: Information (computer) systems, Departmental KPI's, Clinical outcomes planned/unplanned, Incident forms, Risk register, PPPC's Satisfaction surveys, Complaints, Timeliness, Reports and Reviews Internal and External, Equity of care, National and Regional priority audits, Suggestions from patient forums
- 3 QUALITY LAYER: Define Structure, Define processes, Define desired outcomes
- 2 AUDIT LAYER: Engage correct stakeholders, Engaged governance relevant to topic, Define objectives, Set standards, Collect data, Change practice
- 1 RAPID ESCALATION LAYER: 3 Tier audit process

Micro

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**H-QAP Layers and Protocols**

Macro

**6 Governance Layer**  
Define governance  
Apply governance

Establishes relevant person or persons in authority  
Places them in control of the program  
Ensure that other layers are set-up & reviewed

Micro

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**Implementation in Hospital**  
**6 Governance Layer**

- Clinical Audit given priority within Hospital
- Governance Committees set up for particular departments

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**H-QAP Layers and Protocols**

**5 Structure Layer**  
Audit Committee  
Stakeholder analysis  
Standards, Policies  
Communications

Develop & maintain a suite of quality protocols  
QA program high profile  
Awareness of risks of non-compliance  
Escalation to management

The diagram shows six concentric layers from Macro (outer) to Micro (inner): 6 GOVERNANCE LAYER, 5 STRUCTURE LAYER, 4 TOPIC SELECTION LAYER, 3 QUALITY LAYER, 2 AUDIT LAYER, and 1 RAPID ESCALATION LAYER. The 5th layer is circled in red.

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**Implementation in Hospital**  
**5 Structure Layer**

- Focus on Radiology Department
  - Correct diagnosis within acceptable timeframe
  - Radiation ALARA principle
    - As Little As Reasonably Achievable
- Quality Requirement
  - Software engineers ensures MD software correct
  - Physicist calibrates MD
  - Radiographer uses MD correctly
  - Radiologist reviews and reports diagnosis

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**H-QAP Layers and Protocols**

**4 Topic Selection Layer**  
Define KPIs  
Incident forms  
Satisfaction surveys

QA program holistic  
Audit committee choose relevant topics  
Every topic reviewed regularly

The diagram shows six concentric layers from Macro (outer) to Micro (inner): 6 GOVERNANCE LAYER, 5 STRUCTURE LAYER, 4 TOPIC SELECTION LAYER, 3 QUALITY LAYER, 2 AUDIT LAYER, and 1 RAPID ESCALATION LAYER. The 4th layer is circled in red.

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**Implementation in Hospital**  
**4 Topic Selection Layer**

- Understanding problem exists in department
  - Measurement of results from X-Ray
- Focus on Shoulder X-Ray

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**H-QAP Layers and Protocols**

**3 Quality Layer**  
Define structures, processes, desired outcomes

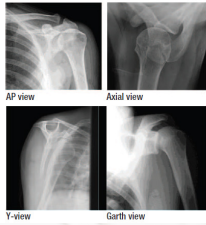
Ensure compliance through equipment, software, education  
Efficient software processes  
Reliable systems  
Access to policies

The diagram shows six concentric layers from Macro (outer) to Micro (inner): 6 GOVERNANCE LAYER, 5 STRUCTURE LAYER, 4 TOPIC SELECTION LAYER, 3 QUALITY LAYER, 2 AUDIT LAYER, and 1 RAPID ESCALATION LAYER. The 3rd layer is circled in red.

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### Implementation in Hospital 3 Quality Layer

- Focus on Shoulder X-Ray
  - Develop policies: angle, contrast, view
  - Standard technique for shoulder imaging
  - Standardisation of images



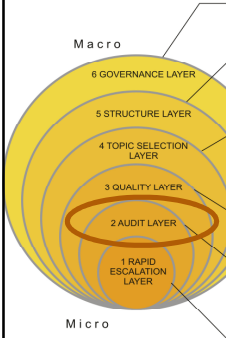
Departmental shoulder protocol

AP view      Axial view

Y-view      Garth view

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### H-QAP Layers and Protocols



**2 Audit Layer**

- Engage stakeholders
- Define objectives
- Set standards

Define data  
Define measurements  
Define standards

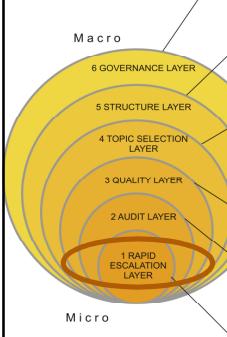
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### Implementation in Hospital 2 Audit Layer

- Defining data collection
  - Percentage of incorrectly taken x-rays
  - Number of times patients were x-rayed
- How data was to be reported

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### H-QAP Layers and Protocols



**1 Rapid Escalation Layer**

3-tier audit process

- Collect data
- Measure against standards
- Implement change
- Re-audit

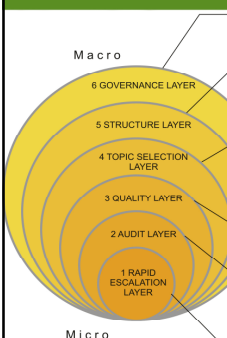
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### Implementation in Hospital 1 Rapid Escalation Layer

- Percentage of incorrectly taken x-rays
- Reporting data
  - Information posters
  - Department meetings
- Educating radiographers
- Improved to 95% compliance

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### H-QAP Layers and Protocols



- 6 GOVERNANCE LAYER**  
Define governance  
Apply governance
- 5 STRUCTURE LAYER**  
Audit Committee  
Stakeholder analysis  
Standards  
PPPG's Communication Strategy
- 4 TOPIC SELECTION LAYER**  
Information (computer) systems  
Departmental KPI's  
Clinical outcomes planned/unplanned  
Incident forms / Risk register  
PPPG's Satisfaction surveys  
Complaints  
Timeliness  
Reports and Reviews Internal and External  
Equity of care  
National and Regional priority audits  
Suggestions from patient forums
- 3 QUALITY LAYER**  
Define Structures  
Define processes  
Define desired outcomes
- 2 AUDIT LAYER**  
Engage correct stakeholders  
Engaged governance relevant to topic  
Define objectives  
Set standards  
Collect data  
Change practice
- 1 RAPID ESCALATION LAYER**  
3 Tier audit process

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## In summary

With H-QAP

- Staff know about process prior to audit
- Staff correct process prior to governance
- System use has improved
- Data is more accurate
- Teams made up of all stakeholders
- Clinical & Healthcare Audit more holistic with compliance of software systems included

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## In summary

- For Software systems within the hospital
  - Information quality
  - System quality
  - Service quality
  - Intention to use
  - User satisfaction
 Are seen as important
- And, all stakeholders are becoming involved in ensuring this can happen

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## References

- EU directive 2007/47/EC, European Union Council, 2007
- EU directive 93/42/EEC, European Union Council, 1993
- HSE (2007), The National Standard for Quality and Risk [http://www.hse.ie/eng/About/Who/OQR009\\_20080221\\_v3\\_Quality\\_and\\_Risk\\_Management\\_Standard.pdf](http://www.hse.ie/eng/About/Who/OQR009_20080221_v3_Quality_and_Risk_Management_Standard.pdf)
- DeLone H. William, McLean R. Ephraim, 2003 "The DeLone and McLean Model of Information Systems Success: A Ten-Year Update" Journal of Management of Information Systems, Vol. 19, No. 4, pp.9-30.
- Harding Clark Nancy, M, 2001. The Lourdes Hospital Inquiry, An Inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda.
- Kennedy, I, 2001, The Report of the Public Inquiry into childrens' heart surgery at the Bristol Royal Infirmary 1984-1995, Learning from Bristol
- Smith, J, 2004, The Shipman Inquiry, Fifth Report – Safeguarding Patients: Lessons from the Past, Proposals for the Future. Downloaded 04/03/2011 <http://www.the-shipman-inquiry.org.uk/fifthreport.asp>

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## References

- Hayes, M, 2010, Tallaght Hospital Review, Report of the Review of Radiology Reporting and the Management of GP Referral Letters at the Adelaide and Meath Hospital (Dublin), Incorporating the National Children's Hospital, (AMNCH) [Tallaght Hospital]
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, downloaded 30th September 2011 <http://www.hhs.gov/ocr/privacy/>
- US Food & Drug Administration, "Code of Federal Regulations Title 21 Part 820 Quality System Regulation," Apr-2010.
- Shroff Vispi, Reid Louise, Richardson Ita, "A Theoretical Framework for Software Quality in the Healthcare and Medical Industry" Proceedings of the Eurospi Conference on System & Software Process Improvement and Innovation, June 2011
- IEEE Standards Association. "730-2002 - IEEE Standard for Software Quality Assurance Plans", 2002.
- SEI "CMMI for Development : Version 1.2," August, 2006.

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