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# Risk Management of Health Information Technology Systems: Lessons Learned through the Lifecycle of Standards

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# Overview

- Risk Management of Health Information Technology Systems
- Evolution of Standards
  - IEC 80001-1
  - ISO TR 80001-2-7
  - Revision of IEC 80001-1
- Lessons Learned – Developing and Implementing Standards, Landscape and Foundations
- Conclusion

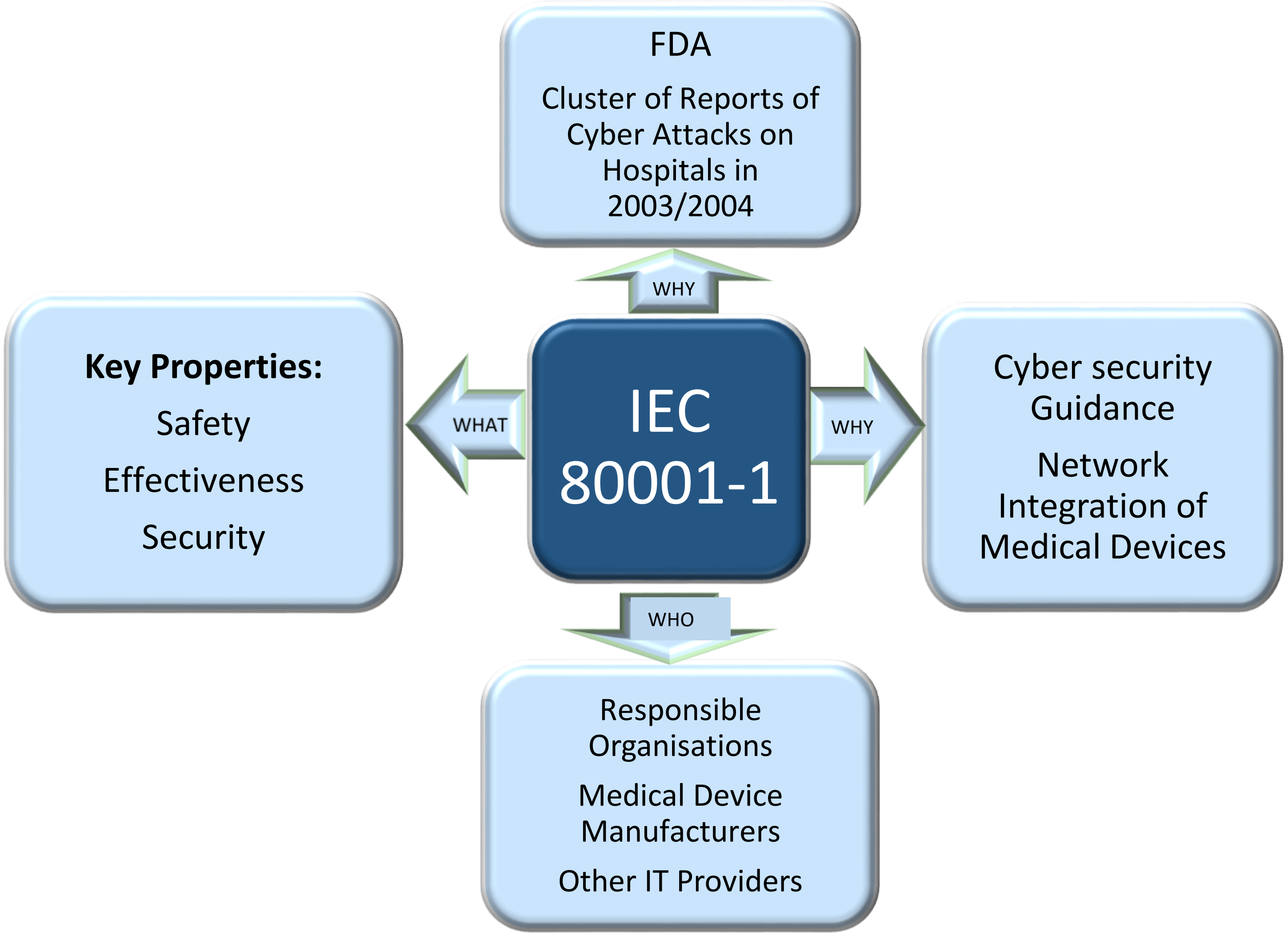
# Risk Management of Health Information Technology Systems - Background

- The increased prevalence of chronic disease combined with an ageing population has presented a major challenge for healthcare systems and has changes the way in which healthcare is provided
- The provision of care has moved away from acute episodic periods of care to a longer ongoing relationship between patients and care givers
- This relationship is increasingly being supported through the use of IT and in particular through the use of Health Information Technology Systems (HITS)
- Risk Management Standards are responding to changing use of technology in Healthcare

# Risk Management of Health Information Technology Systems - Standards

- Increasingly, medical devices are being designed to exchange electronic information with other devices, including medical devices.
- Traditionally, when a medical device was designed to be incorporated into a network, the provider of the device would also provide the network.
- To achieve full interoperability, medical devices are increasingly being incorporated into a healthcare provider’s general IT network which can introduce additional risks.
- IEC 80001-1: 2010 Application of risk management for IT-networks incorporating medical devices was developed to address these risks

# IEC 80001-1 Overview



IEC 80001-1

FDA

Cluster of Reports of Cyber Attacks on Hospitals in 2003/2004

**Key Properties:**

Safety

Effectiveness

Security

Cyber security Guidance

Network Integration of Medical Devices

Responsible Organisations

Medical Device Manufacturers

Other IT Providers

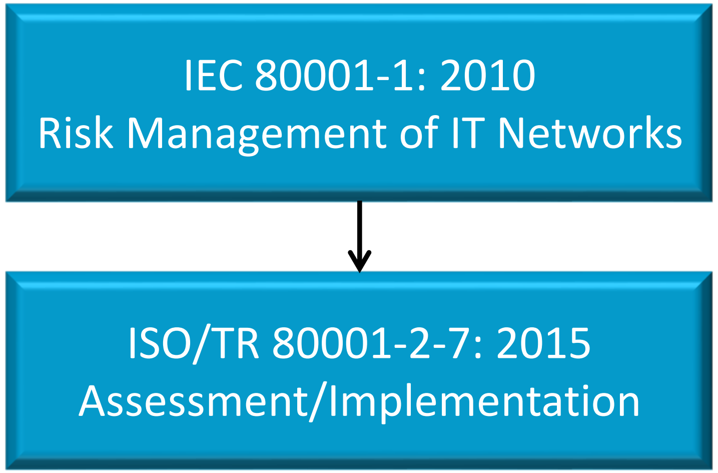
# Medical IT Network Risk Management

IEC 80001-1: 2010
Risk Management of IT Networks

# IEC 80001-1: Impact?

- Adoption of the standard was low
  - HDOs vary in size and in the capability of their risk management processes and provide care in different regulatory environments
  - Effective risk management activities require interaction between different stakeholder groups
  - HDOs may be unprepared for the organisational changes that are required to facilitate this level of interaction among stakeholders who typically operate in silos.
  - This highlighted the need for an assessment framework providing HDOs with a flexible approach to assessing the capability of their current risk management processes relating to medical IT networks
  - Maybe some guidance was needed?........

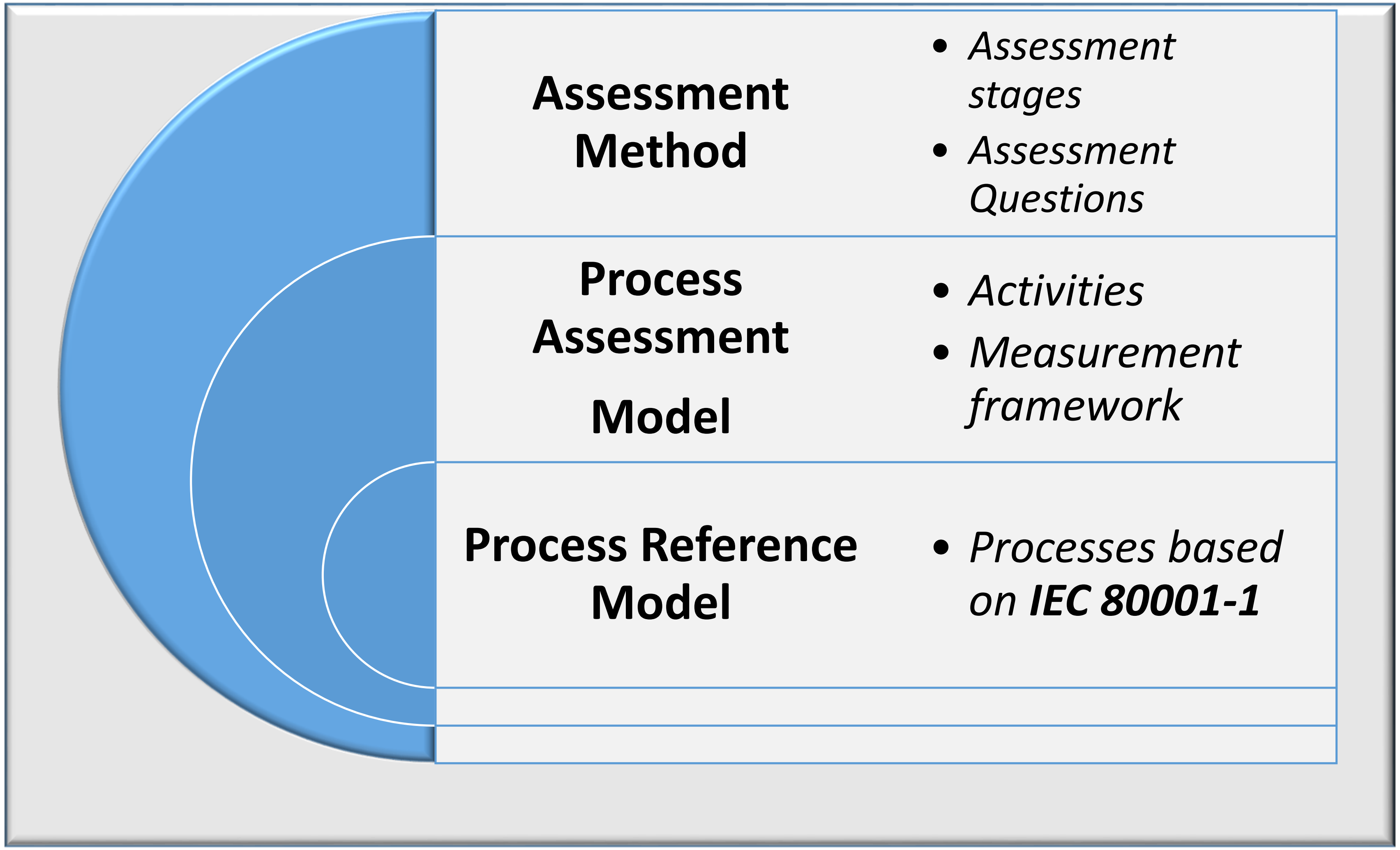
# Medical IT Network Risk Management



IEC 80001-1: 2010
Risk Management of IT Networks

ISO/TR 80001-2-7: 2015
Assessment/Implementation

# ISO/TR 80001-2-7 Components



**Assessment Method**

- *Assessment stages*
- *Assessment Questions*

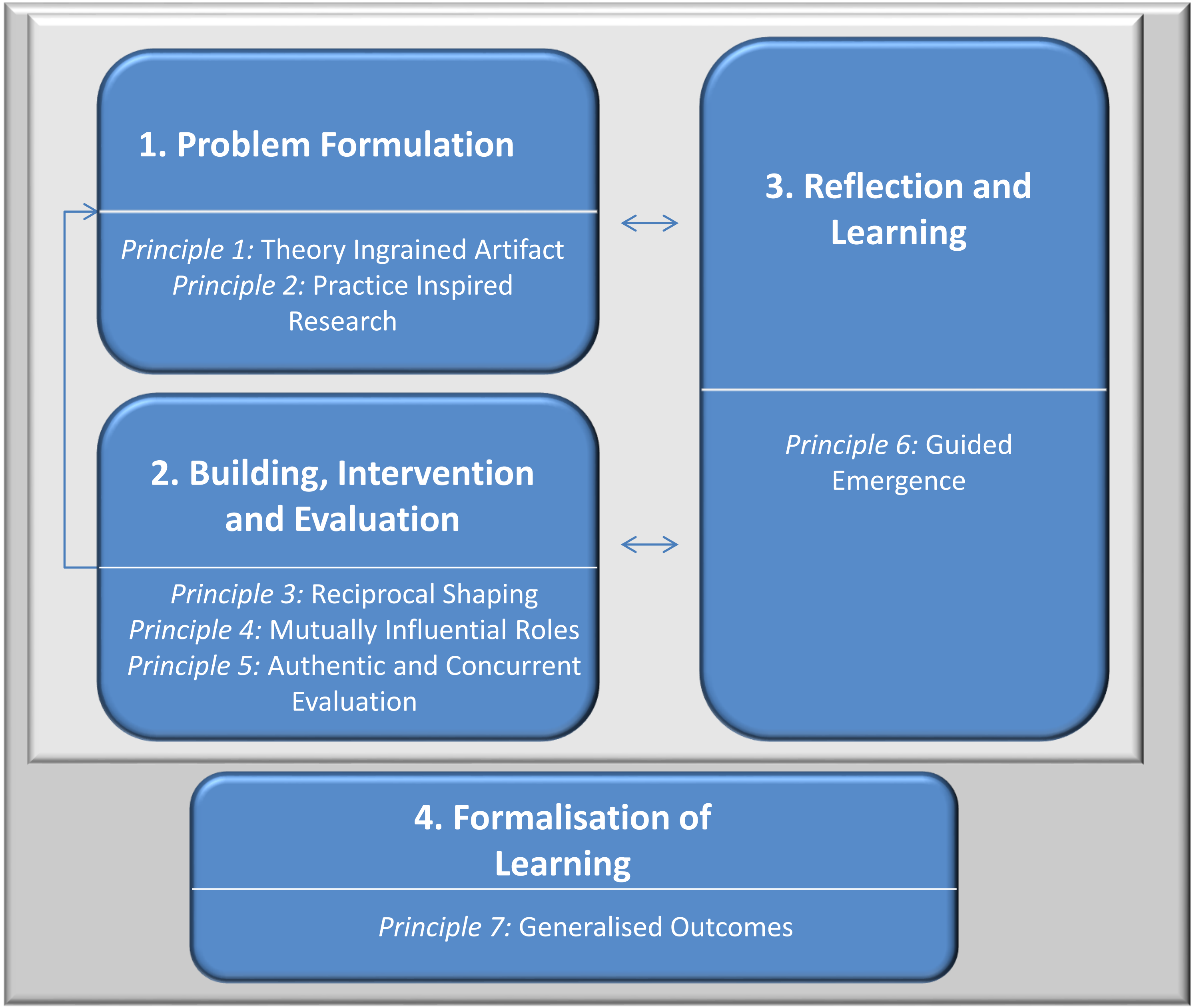
**Process Assessment Model**

- *Activities*
- *Measurement framework*

**Process Reference Model**

- *Processes based on **IEC 80001-1***

# Addressing the Barriers to Adoption? – Action Design Research



1. Problem Formulation

*Principle 1:* Theory Ingrained Artifact
*Principle 2:* Practice Inspired Research

2. Building, Intervention and Evaluation

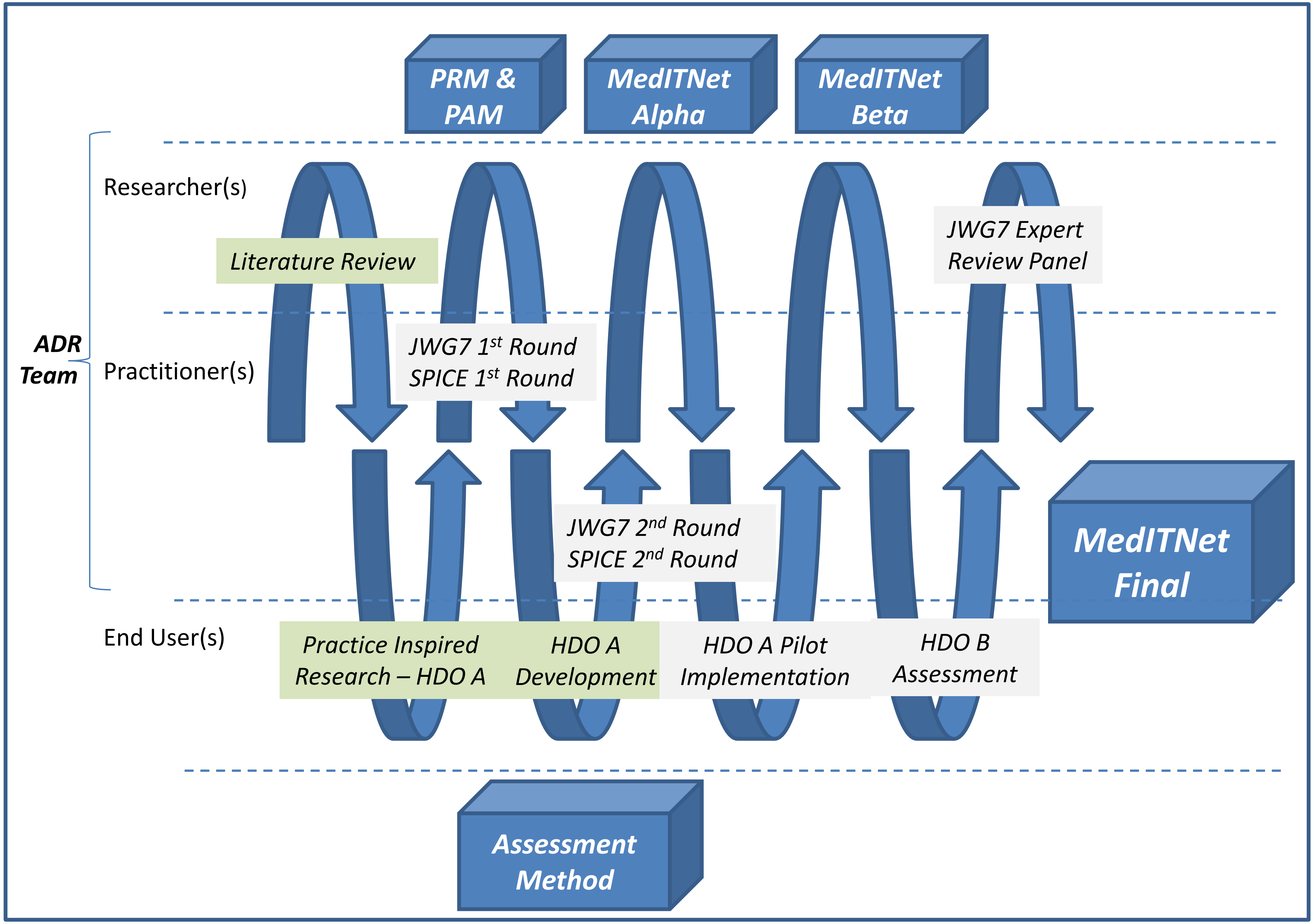
*Principle 3:* Reciprocal Shaping
*Principle 4:* Mutually Influential Roles
*Principle 5:* Authentic and Concurrent Evaluation

3. Reflection and Learning

*Principle 6:* Guided Emergence

4. Formalisation of Learning

*Principle 7:* Generalised Outcomes



PRM & PAM

MedITNet Alpha

MedITNet Beta

ADR Team

Researcher(s)

Practitioner(s)

End User(s)

Literature Review

JWG7 1st Round
SPICE 1st Round

JWG7 2nd Round
SPICE 2nd Round

JWG7 Expert Review Panel

Practice Inspired Research – HDO A

HDO A Development

HDO A Pilot Implementation

HDO B Assessment

MedITNet Final

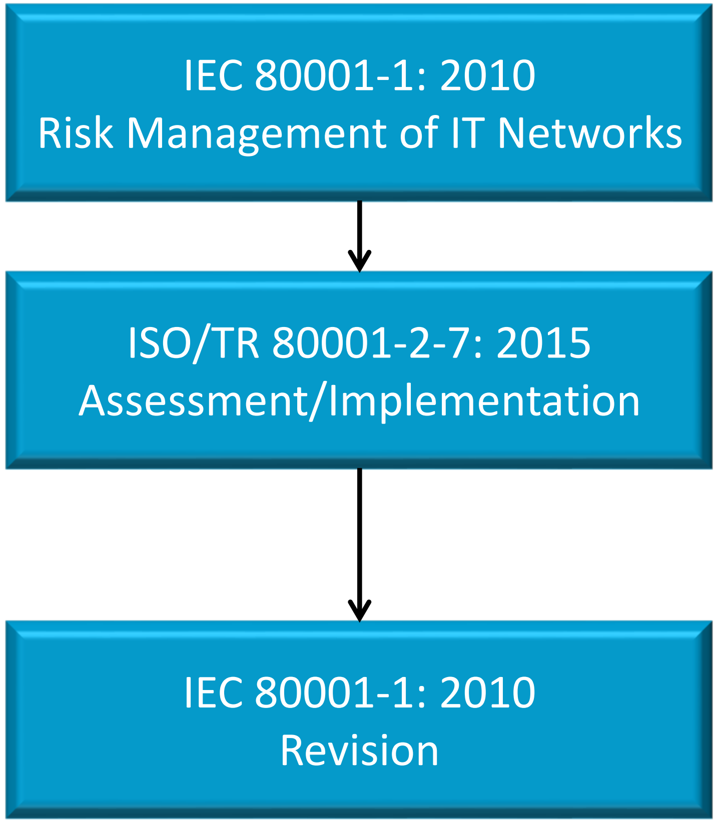
Assessment Method

# Impact of Implementation*:

- Promoted understanding of the role of risk management stakeholders
- Common terminology and understanding of risk
- Improved documentation of risk management policy and process
- Raised awareness of the need for groups within the hospital to come together and address risk-related issues specific to network technology management

*Hegarty, F.J., MacMahon, S.T., Byrne, P. and McCaffery, F., 2014. Assessing a hospital's medical IT network risk management practice with 80001-1. *Biomedical instrumentation & technology*, *48*(1), pp.64-71.

# Medical IT Network Risk Management



IEC 80001-1: 2010
Risk Management of IT Networks

ISO/TR 80001-2-7: 2015
Assessment/Implementation

IEC 80001-1: 2010
Revision

# Revision of IEC 80001-1: Revised Scope

**IEC 80001-1 (2nd Ed), safety, effectiveness and security in the implementation and use of connected medical devices or connected health software.**

- “This international standard provides general requirements for applying risk management  to Health Information Technology (HIT) systems by addressing the key properties of safety, effectiveness and both data and system security (including privacy) while engaging appropriate stakeholders.”

# Revision of IEC 80001-1: Impact of Lessons Learned from Implementation

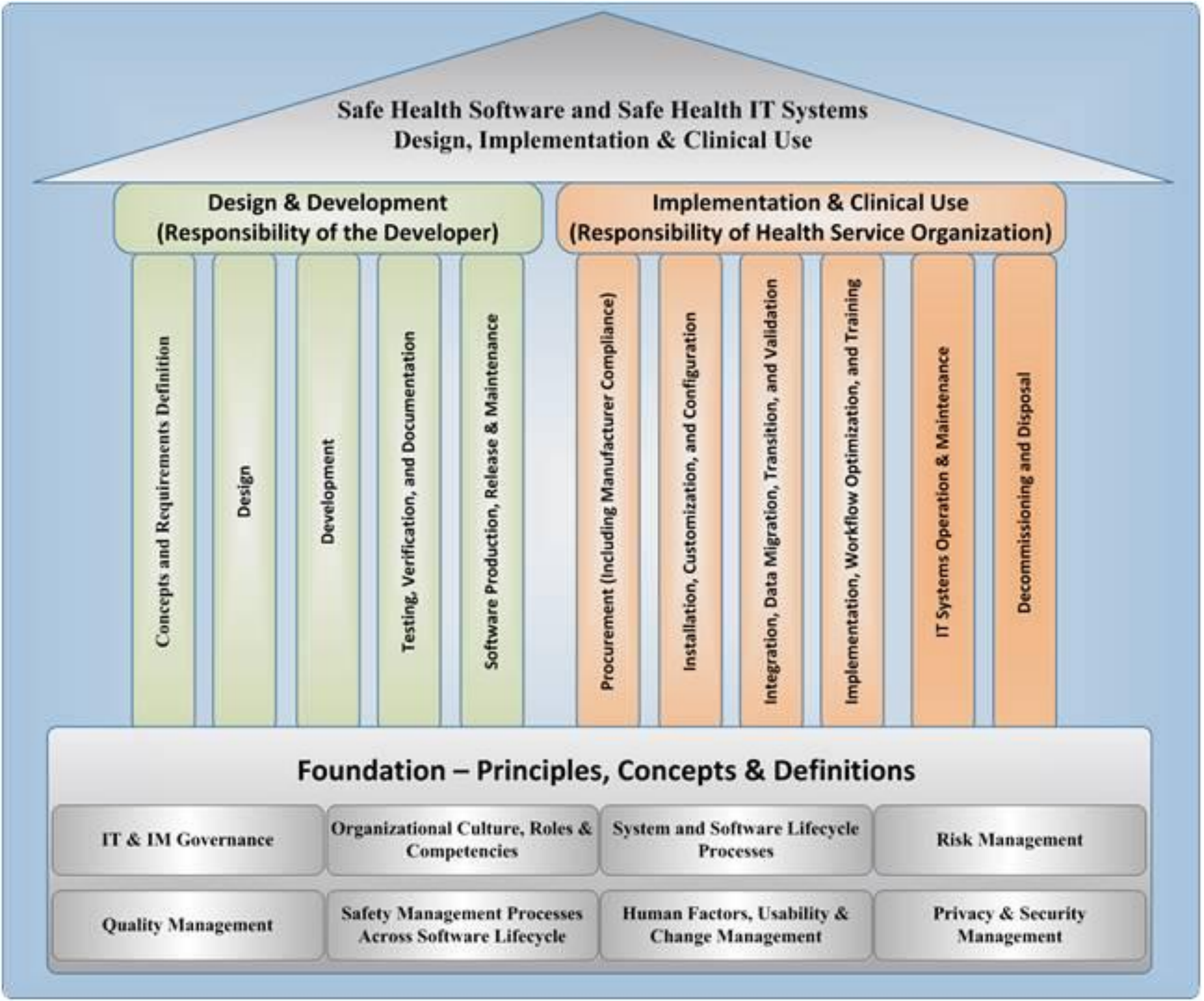
- Lack of Drivers to Motivate Top Management
- HDO Organisational Challenges: IT and BME not aligned
- 80001-1 standard is too complicated and complex to implement

# High Level Initial Mapping – Annex SL to ISO TR 80001-2-7

| Clause : | Title: | Notes: |
|---|---|---|
| Clause 4 | Context of the Organisation | *Advice on understanding the context and tailoring*<br>*Organisational Maturity Model – Stepwise Approach* |
| Clause 5 | Leadership | **Organizational Risk Management Process** |
| Clause 6 | Planning | **Medical IT-Network Risk Management Process**<br>**Medical IT-Network Planning Process** |
| Clause 7 | Support | **Medical IT-Network Risk Management Process**<br>**Risk Management Policy Process**<br>**Medical IT-Network Documentation Process**<br>**Responsibility Agreements Process** |
| Clause 8 | Operation | **Risk Analysis and Evaluation**<br>**Risk Control Process**<br>**Residual Risk Process**<br>**Change Release and Configuration Management Process**<br>**Decision on how to apply Risk Management**<br>**Go-Live** |
| Clause 9 | Performance Evaluation | **Monitoring Process**<br>**Event Management Process** |
| Clause 10 | Improvement | The organisation shall continuously improve ….<br>Refer back to OMM and stepwise approach |

# Lessons Learned - Revisited

- Lack of Drivers to Motivate Top Management
  - Certification, Knowledge of ISO 9001,Integration with existing processes
- HDO Organisational Challenges: IT and BME not aligned
  - Common Language , Adoption of ISO 9001, Reference to TRs
- 80001-1 standard is too complicated and complex to implement
  - Context, Organisational Maturity, Simplified Structure



Safe Health Software and Safe Health IT Systems
Design, Implementation & Clinical Use

Design & Development
(Responsibility of the Developer)

- Concepts and Requirements Definition
- Design
- Development
- Testing, Verification, and Documentation
- Software Production, Release & Maintenance

Implementation & Clinical Use
(Responsibility of Health Service Organization)

- Procurement (Including Manufacturer Compliance)
- Installation, Customization, and Configuration
- Integration, Data Migration, Transition, and Validation
- Implementation, Workflow Optimization, and Training
- IT Systems Operation & Maintenance
- Decommissioning and Disposal

Foundation – Principles, Concepts & Definitions

| | | | |
|---|---|---|---|
| IT & IM Governance | Organizational Culture, Roles & Competencies | System and Software Lifecycle Processes | Risk Management |
| Quality Management | Safety Management Processes Across Software Lifecycle | Human Factors, Usability & Change Management | Privacy & Security Management |

# Revision of IEC 80001-1: Summary

- IEC 80001-1* has been revised:
  - With an extended scope
  - As a process standards to allow for capability of processes to be assesses and facilitate a stepwise approach to implementation
  - To facilitate greater integration with existing risk management standards
  - In closer alignment with management system standards – Annex SL

*IEC 80001-1:2021 APPLICATION OF RISK MANAGEMENT FOR IT-NETWORKS INCORPORATING MEDICAL DEVICES — PART 1: SAFETY, EFFECTIVENESS AND SECURITY IN THE IMPLEMENTATION AND USE OF CONNECTED MEDICAL DEVICES OR CONNECTED HEALTH SOFTWARE

# Conclusion

- While IEC 80001-1:2010 assisted HDOs in managing the risk associated with placing a device onto an IT network, the standard was complex and difficult to implement
- To address this ISO/TR 80001-2-7 was developed and based on the experience of implementing the TR, IEC 80001-1 has been revised as a process standard within the “Temple”
- Using ADR or similar methodologies allows for authentic evaluation of standards during the development process aids implementation and fosters adoption – have your say!

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# Thank You!

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