LERO Software for a better world

DCU Dublin City University

A World Leading SFI Research Centre

Science Foundation Ireland SFI For what's next

Risk Management Standards and the Digital Transformation in Healthcare

Dr. Silvana Togneri MacMahon

HOST INSTITUTION

UNIVERSITY OF LIMERICK OLLSCOIL LUIMNIGH

PARTNER INSTITUTIONS

NUI Galway OÉ Gaillimh · Maynooth University · Trinity College Dublin · University College Dublin · UCC · MTU · DCU · SETU · Dundalk Institute of Technology · TUS · ATU

lero.ie

Overview

- Digital Transformation in Healthcare
- Risk Management of Health Information Technology Systems
- Development of Risk Management Standards and Technical Reports
- Revision of IEC 80001-1 – Impact on the Revised Standard
- Other useful standards
- Conclusion

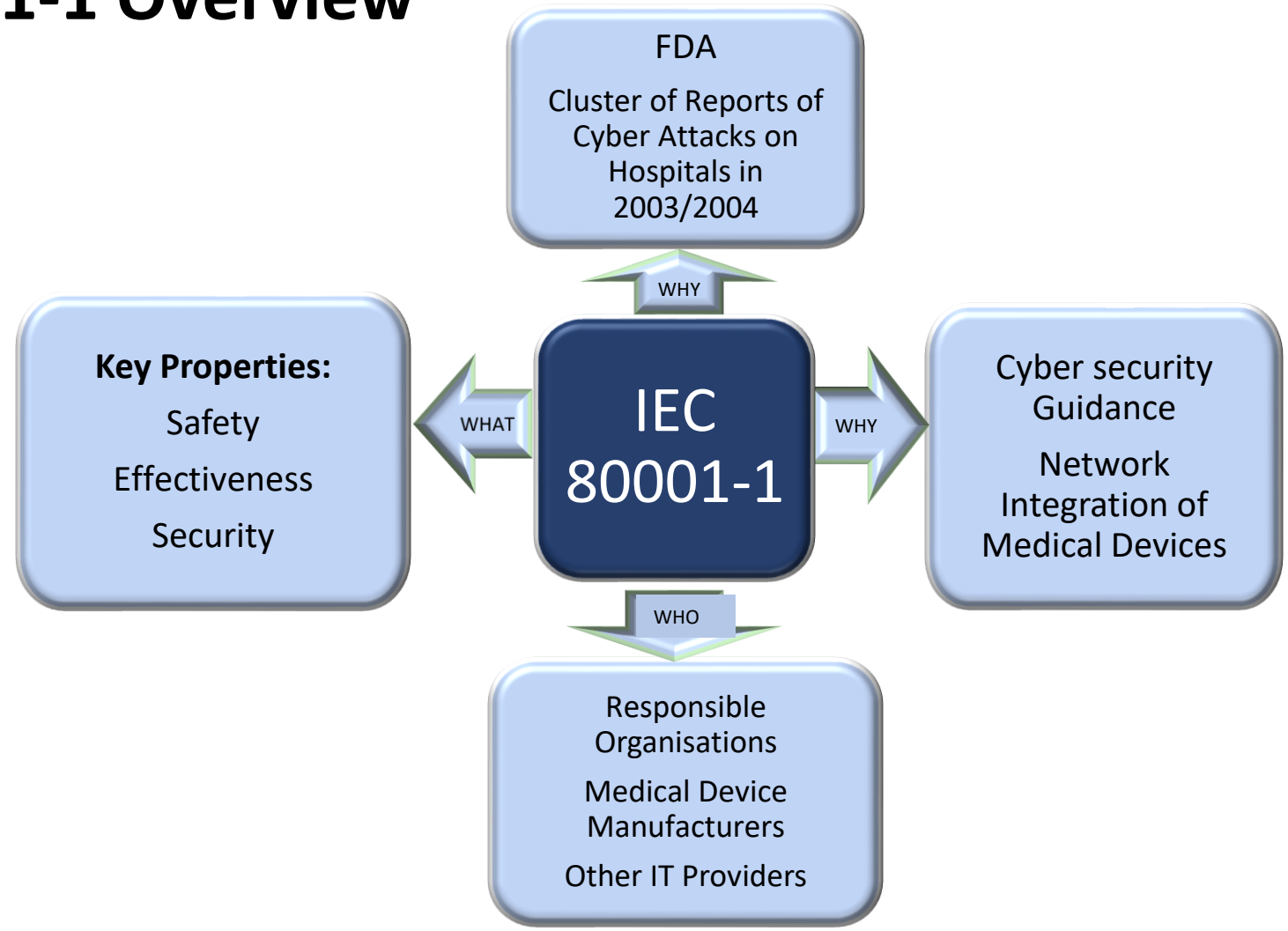
Digital Transformation in Healthcare

- 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 using IT and in particular using Health Information Technology Systems (HITS)
- Risk Management Standards are responding to changing use of technology in Healthcare

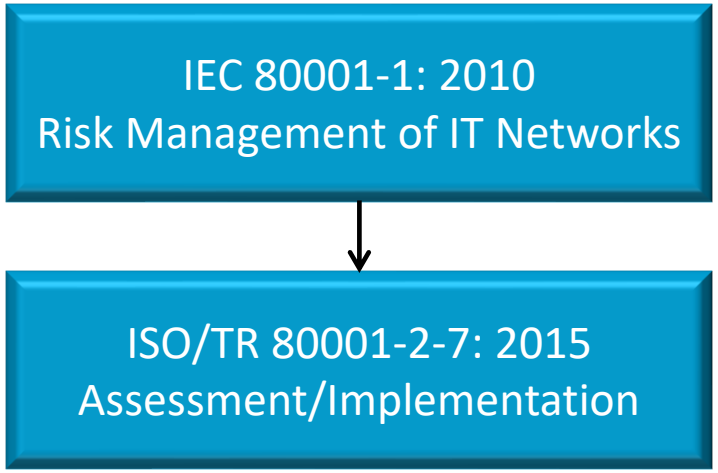
Risk Management of Health Information Technology Systems

- 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

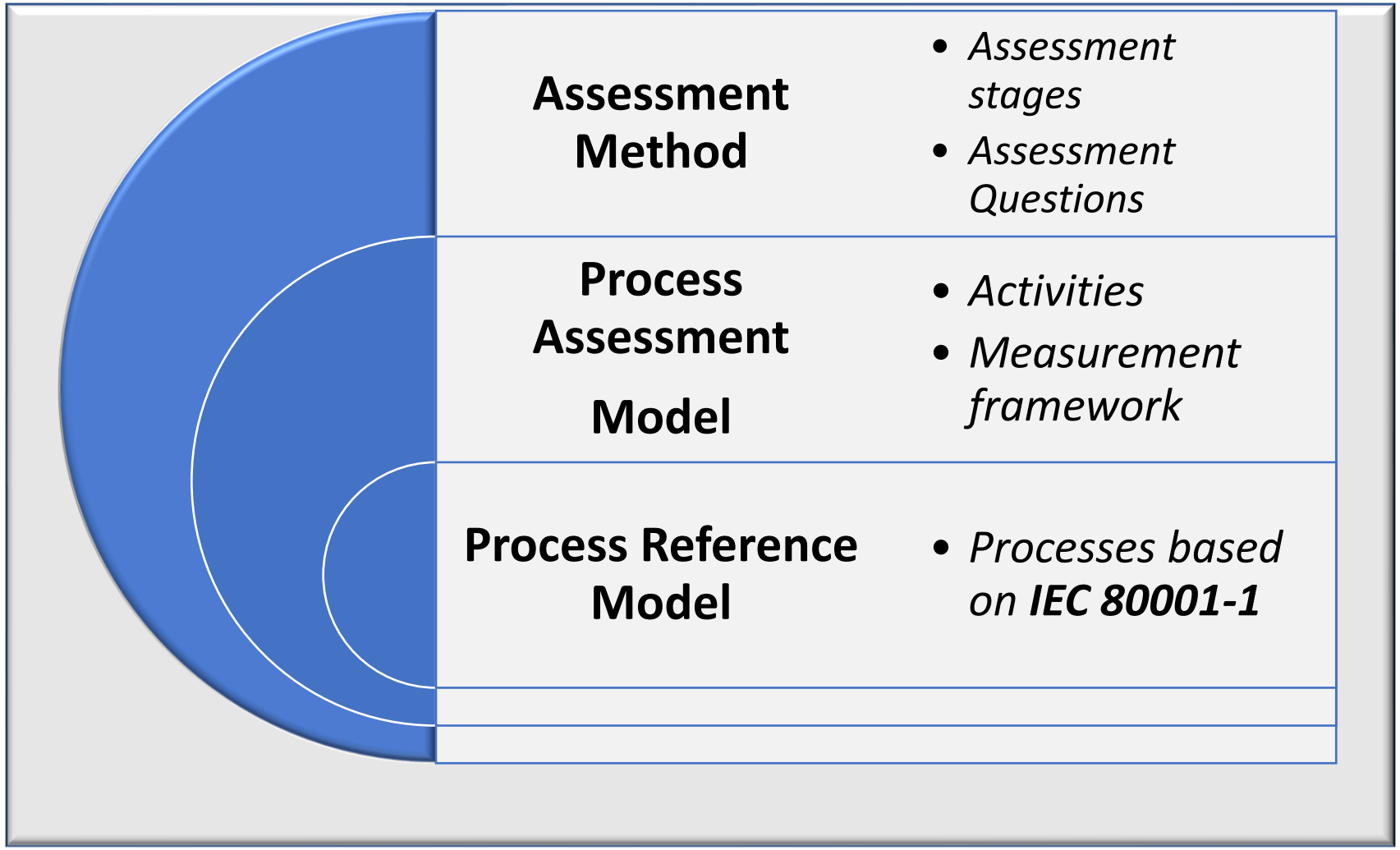
IEC 80001-1 Overview



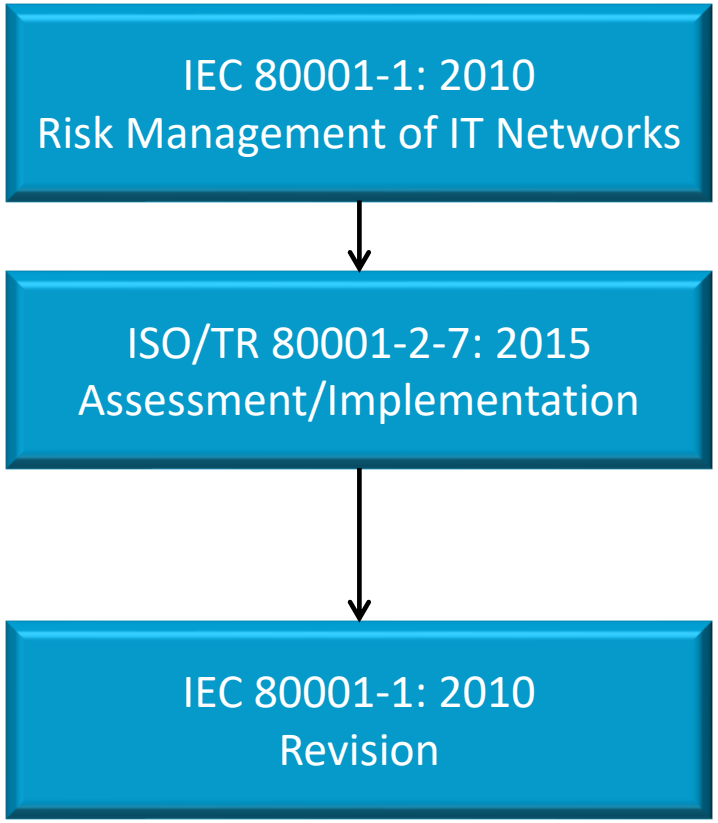
Medical IT Network Risk Management



ISO/TR 80001-2-7 Components



Medical IT Network Risk Management



Revision of IEC 80001-1: Revised Scope

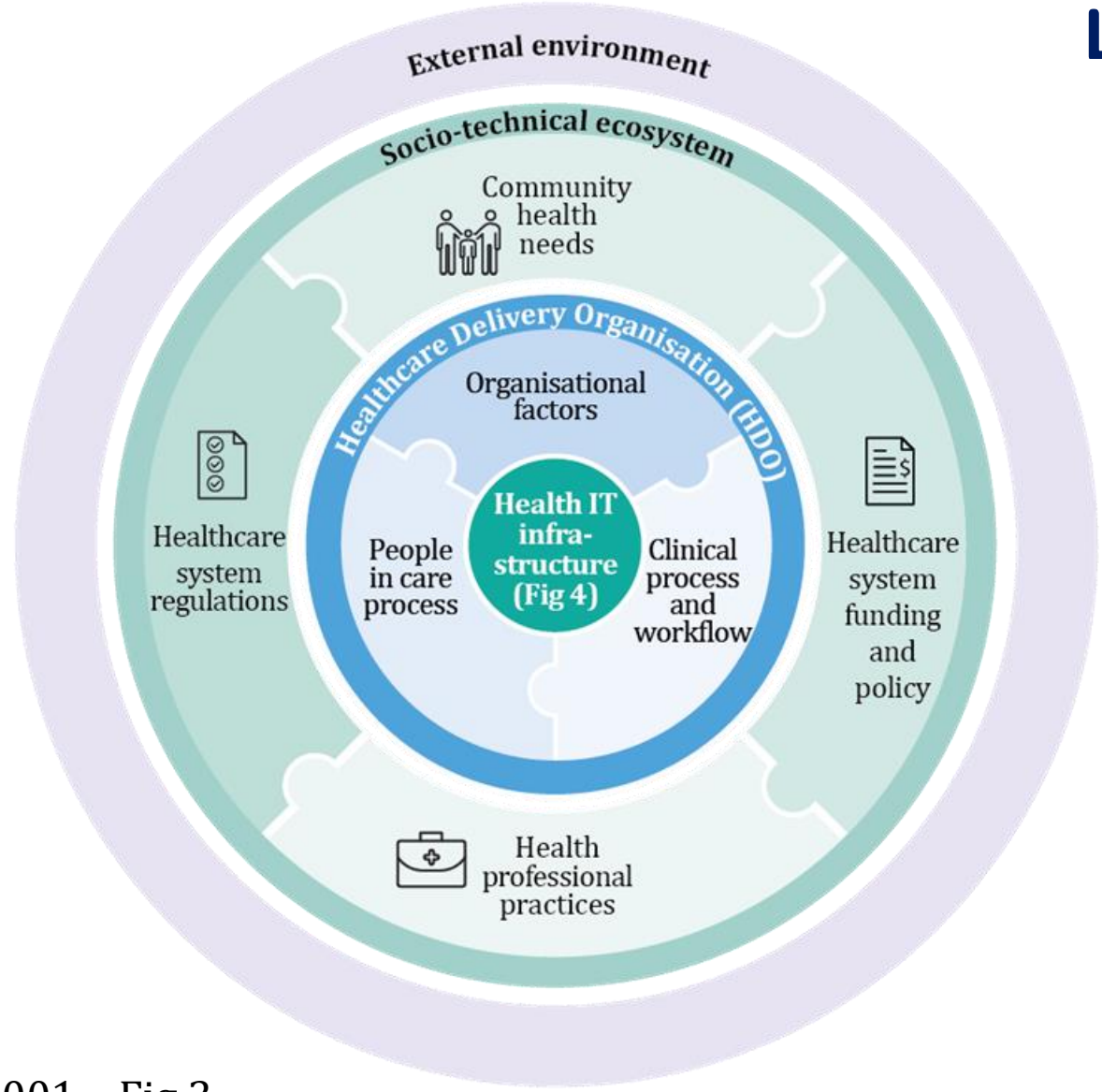
IEC 80001-1 (2nd Ed), safety, effectiveness and security in the implementation and use of connected medical devices or connected health software.

“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.”

Some other useful standards and TR from JWG7…

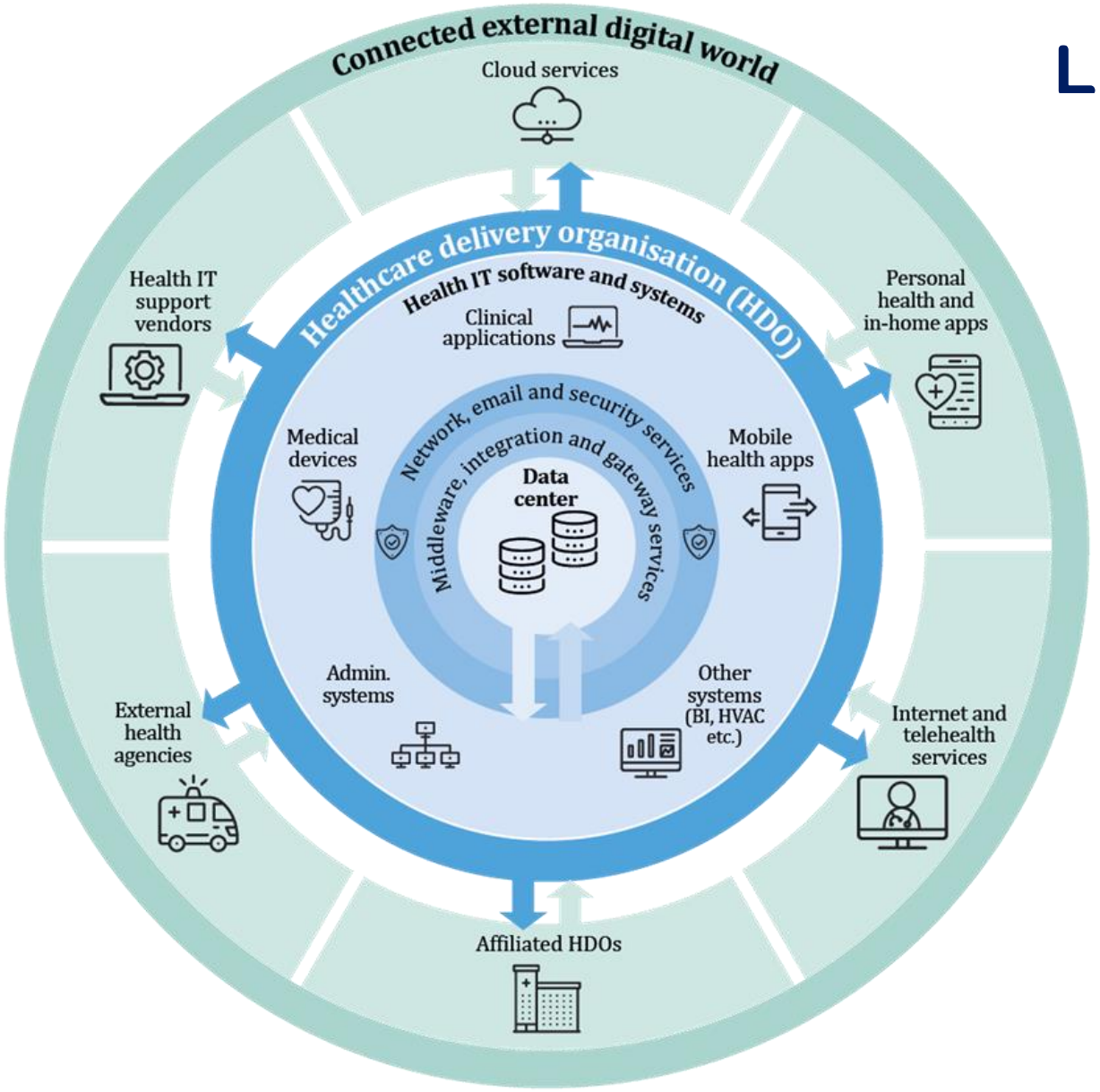
- ISO 81001:2021 - Health software and health IT systems safety, effectiveness and security — Part 1: Principles and concepts
- ISO TS 81001-2-1 - Health software and health IT systems safety, effectiveness and security — Part 2-1: Coordination — Guidance for the use of assurance cases for safety and security
- IEC/CD TS 81001-2-2 - Health software and health IT systems safety, effectiveness and security — Part 2-2: Guidance for the implementation, disclosure and communication of security needs, risks and controls
- IEC 81001-5-1:2021 - Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle

ISO 81001



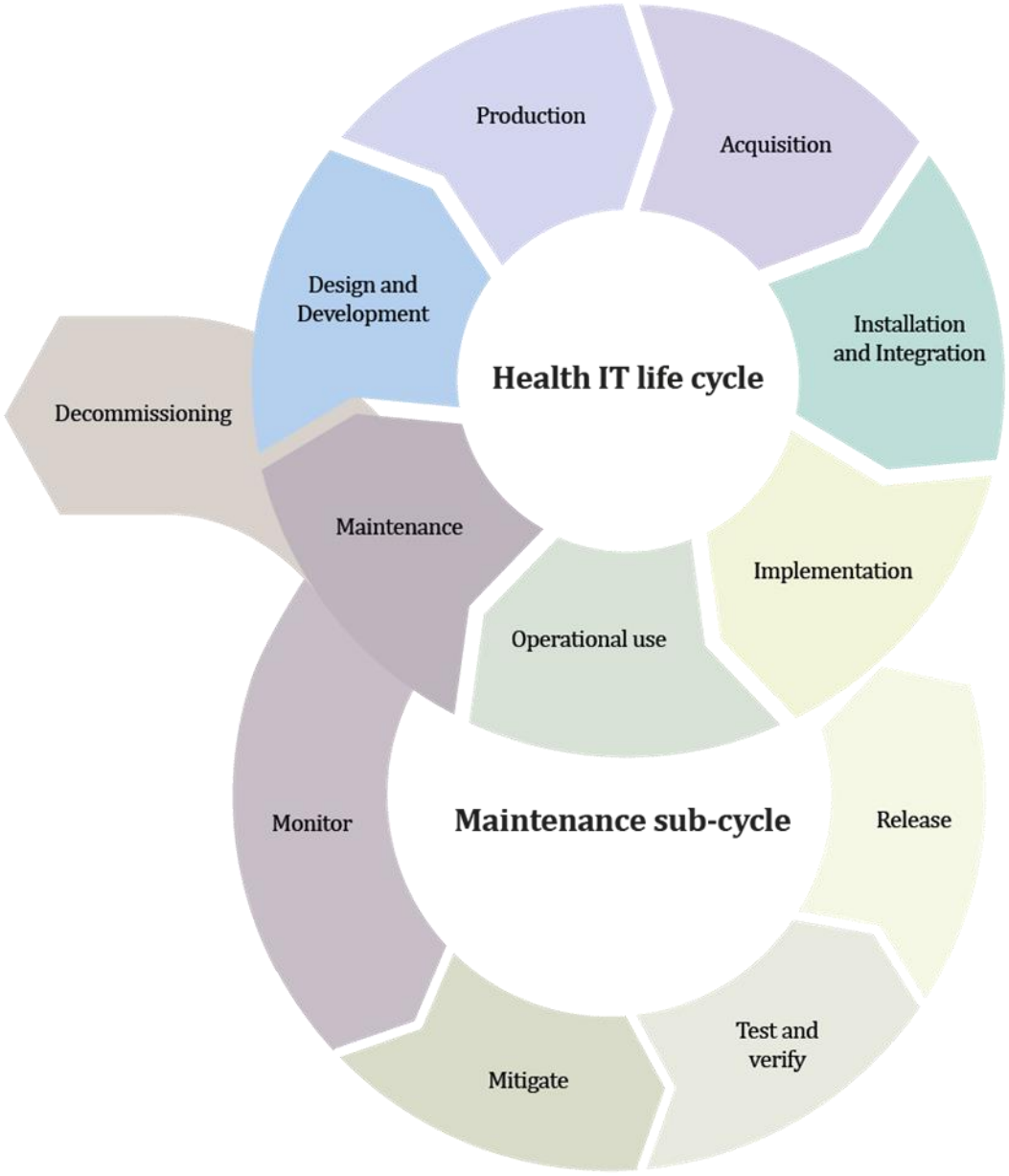
ISO 81001 – Fig 3:
Health software and health IT systems within their socio-technical ecosystem

ISO 81001



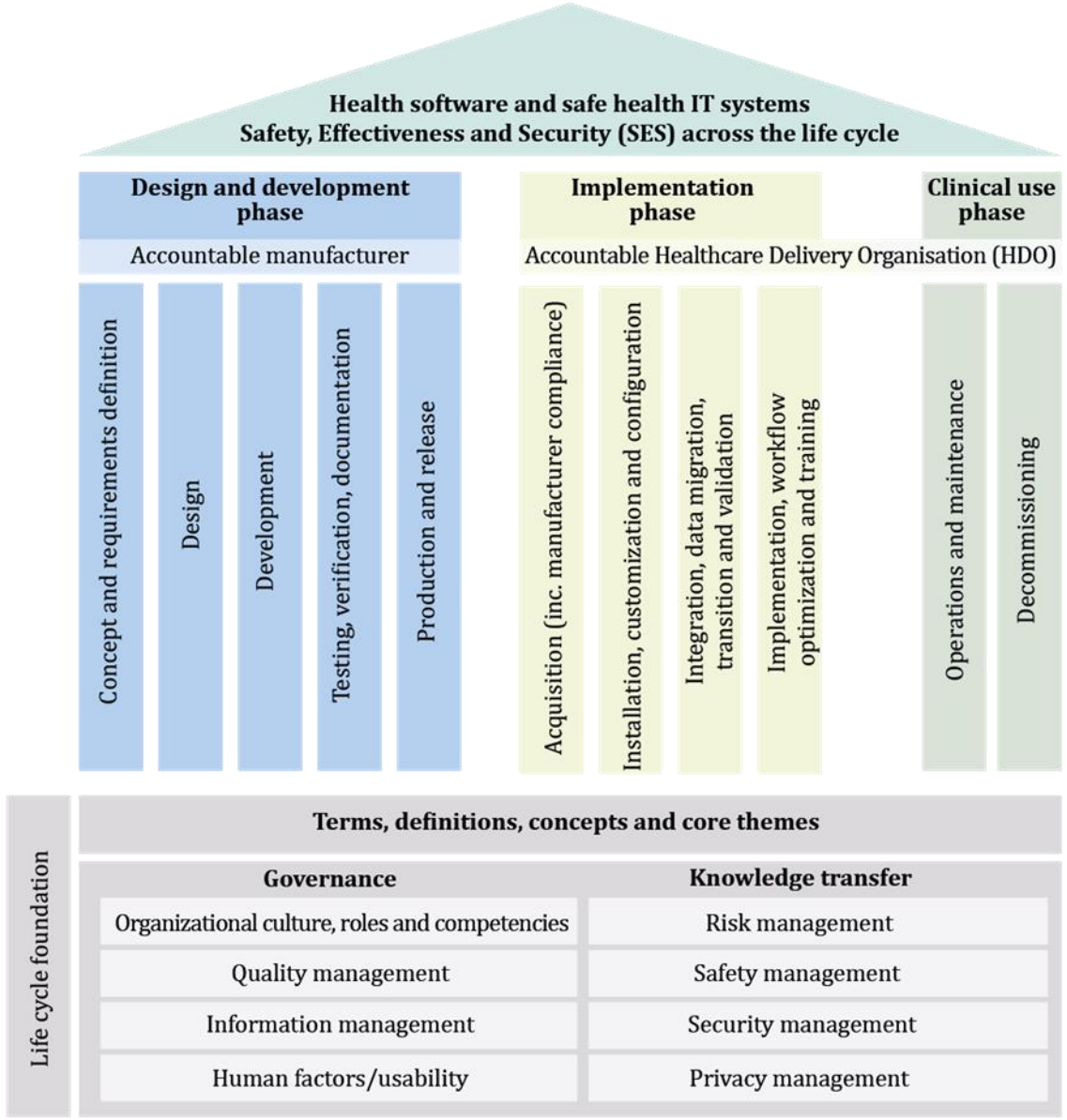
ISO 81001 – Fig 4: System of Systems

ISO 81001



ISO 81001 – Fig 5: Life cycle stages

ISO 81001



ISO 81001 – Fig 1: Life cycle framework addressing safety, security and effectiveness of health software and health IT systems

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 will be revised as a process standard
- The revised standard is closely aligned with other Risk Management and Management System Standards
- Risk Management Standards are responding to the Digital Transformation in Healthcare