Supporting the Latest Generation of Healthcare Technology

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Challenges in Supporting the Latest Generation of Healthcare Technology

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Speaker Biography

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Mr. Grimes has over 40 years' experience working with independent service organizations, academic medical centers, healthcare consulting and research firms.

He is a recognized authority and frequent speaker and author on topics ranging from future challenges facing the technology support industry to healthcare technology convergence, medical device security, risk management and quality management issues.

He recently co-edited/co-authored AAMI's *Medical Device Cybersecurity Guide for HTM Professionals* and teaches a graduate-level engineering course in medical device cybersecurity at the University of Connecticut. He has been involved in the development of many of the industry's key healthcare technology management (HTM) standards and has also served as a HTM consultant to the World Health Organization (WHO) and Pan American Health Organization (PAHO).

He is a fellow of *Healthcare Information and Management Systems Society* (FHIMSS), the *Association for the Advancement of Medical Instrumentation* (AAMIF), and the *American Institute of Medical and Biological Engineering* (FAIMBE) and the *American College of Clinical Engineering* (FACCE) where he is also a past president.

He is also a recipient of AAMI's annual *Healthcare Technology Management Leadership Award*, ACCE's *Lifetime Achievement Award*, and the ACCE-HIMSS annual *Excellence in CE-IT Synergies Award*. In 2019, he was inducted into the ACCE's *Clinical Engineering Hall of Fame*.

The Greatest Challenges We Face in Supporting of the Latest Generation of Healthcare Technology

For several decades, healthcare technologies have increasingly been incorporating information as well as medical technologies. While this has contributed to an evolution of healthcare technologies that are highly sophisticated and capable (e.g., robotics, 3D imaging & printing, systems-of-systems, cloud-based processing/storage, AI/AR technologies, telehealth), it has also greatly challenged those responsible for ensuring these same technologies are readily available and effectively supported. One of the principal challenges is that support has traditionally (and still largely) comes from two disparate groups: clinical engineering services and IT services … groups with decidedly different cultures and operating styles. While some larger and more progressive organizations may have established effective collaborations between CE and IT, those programs are in the minority and have not yet been translated into broad guidelines that can be effectively adopted on a wider industry basis. A second challenge comes from the fact that the changes in knowledge, skills and abilities (KSAs) required by support professionals is not keeping pace with the exponential evolution in healthcare technology. A third challenge is that the healthcare technology support services are often under resourced, having insufficient number and an inappropriate blend of healthcare technology managers, engineers and engineering technicians.

This session will further describe the nature of those challenges and the steps that our industry should now be taking if it hopes to address these issues in any timely manner.

Evolution of the industry

$$New\ \text{CE/HTM Roles} = f(New\ Technology)$$

CE/HTM Roles are *defined by the support requirements* of medical technology

New Technology ≠ Old Technology ∴ New CE/HTM Roles ≠ Old CE/HTM Roles

Evolution of the industry

Points to make

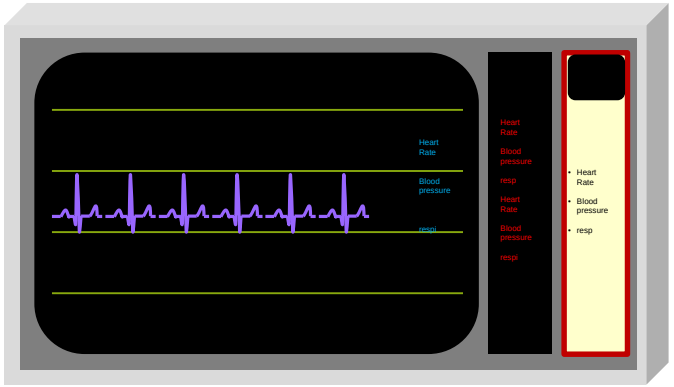
- **Trends in technology** …
  - increasing convergence (i.e., medical, information & communications technologies)
  - increasing complexity … growing number of Systems of Systems (SoS)
  - increasingly capable (smart & software-based)
- **Need for Evolution of HTM Roles …**
  i.e., What roles are necessary to support selection, deployment, and support
  - focus on changing roles
    (not necessarily the same as historical roles because the needs are changing)
  - continuous education required

Past and Future Trends in Healthcare Technology

Managing Convergence of Medical & Information Technologies

> 18 years ago

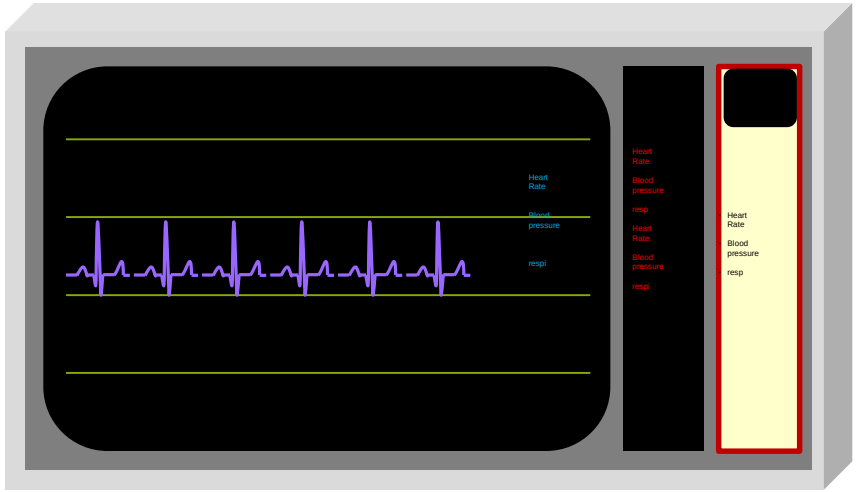
Medical devices were “discrete” (i.e., one device = one patient)



Managing Convergence of Medical & Information Technologies

≈ 18 years ago

Medical devices became special purpose computers capable with multiple features capable of collecting, storing and analyzing large amounts of data



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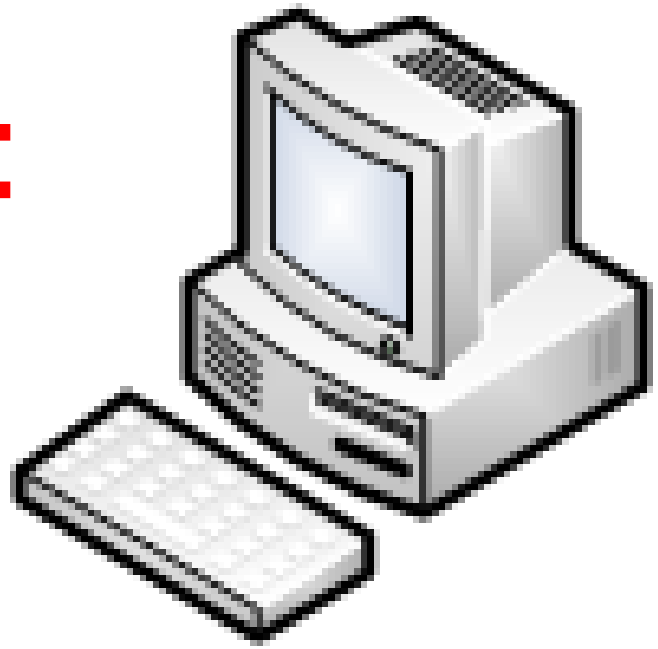
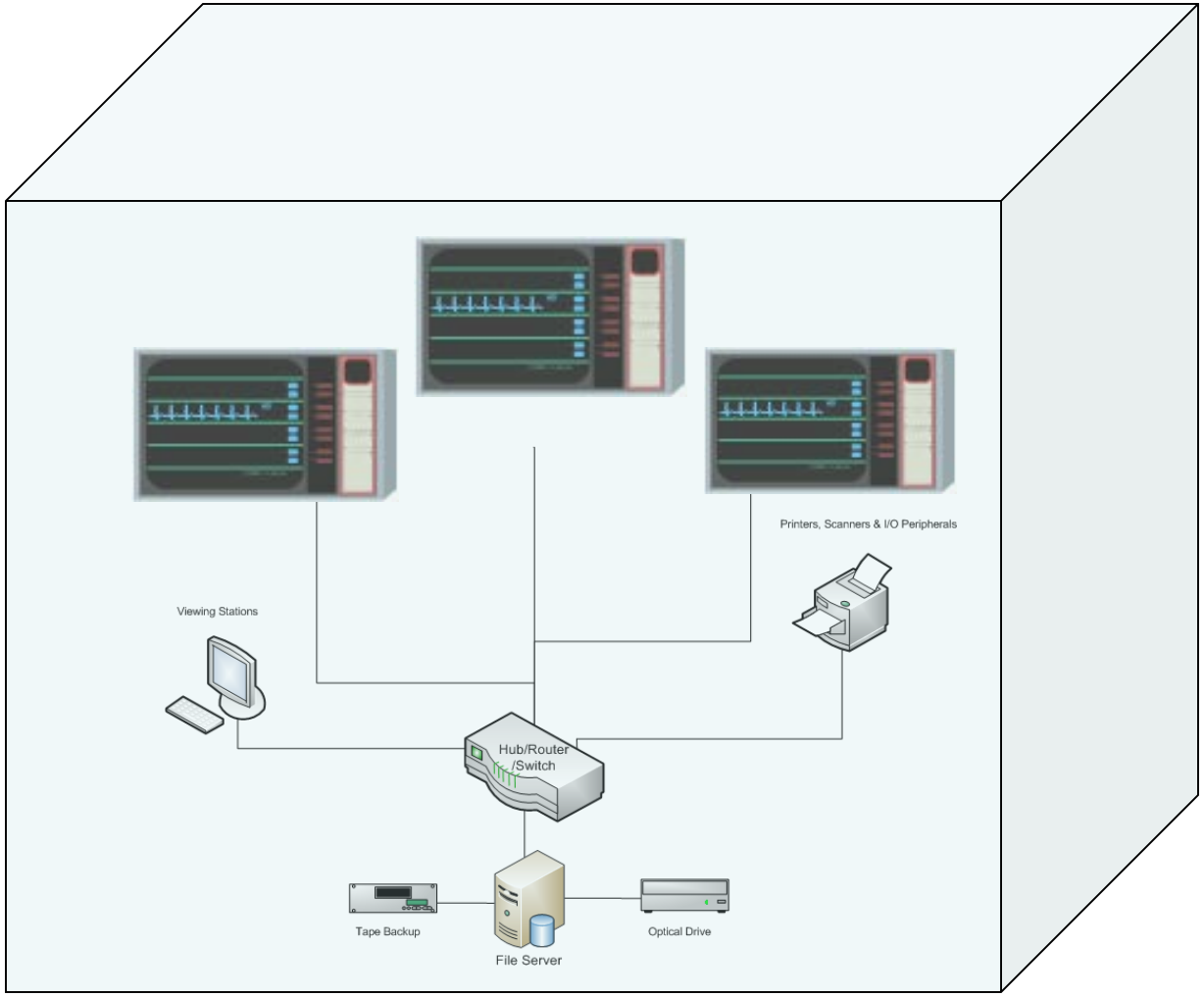
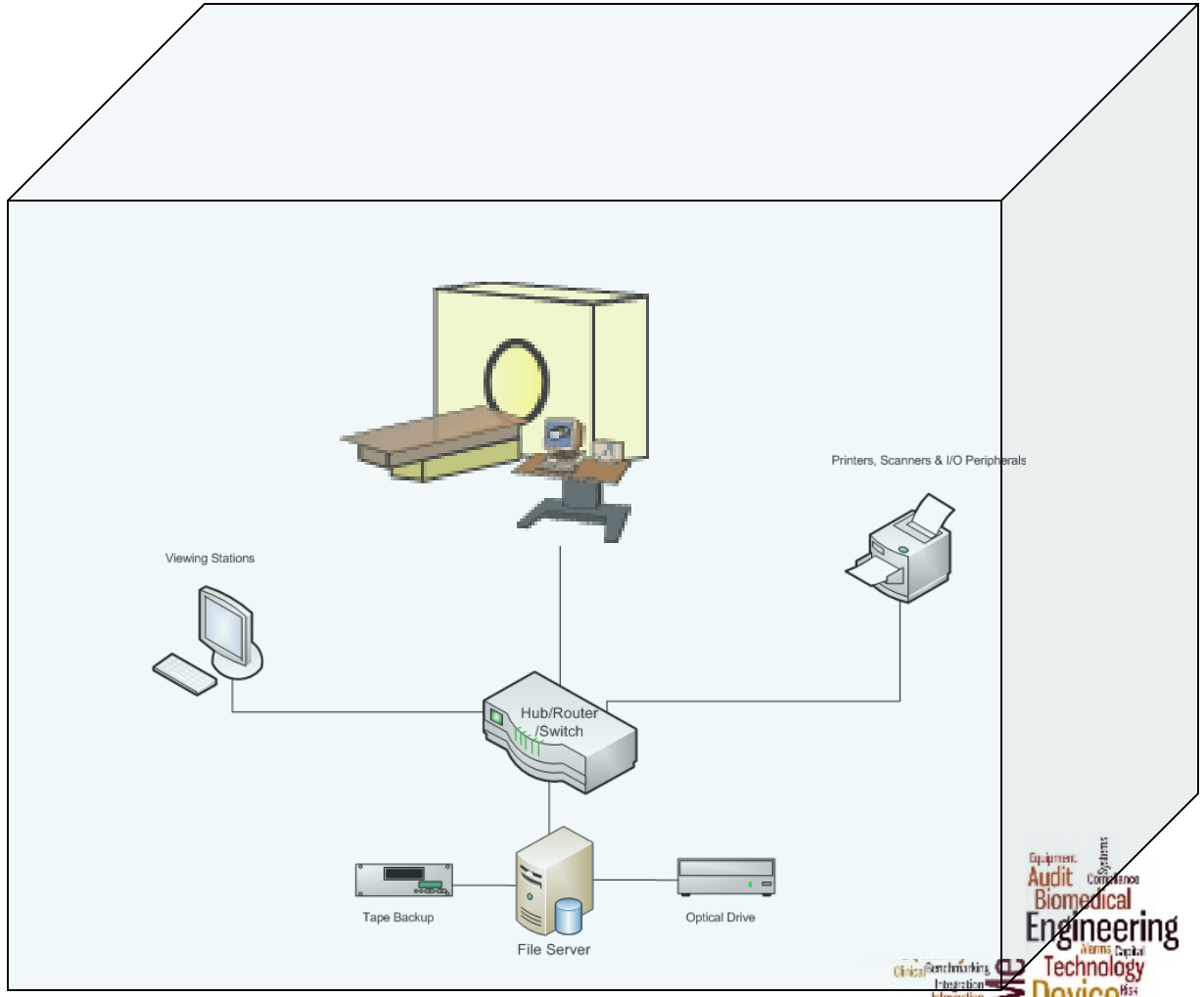


Managing Convergence of Medical & Information Technologies

≈12 years ago

More medical devices became systems running on their own proprietary networks (box bound)

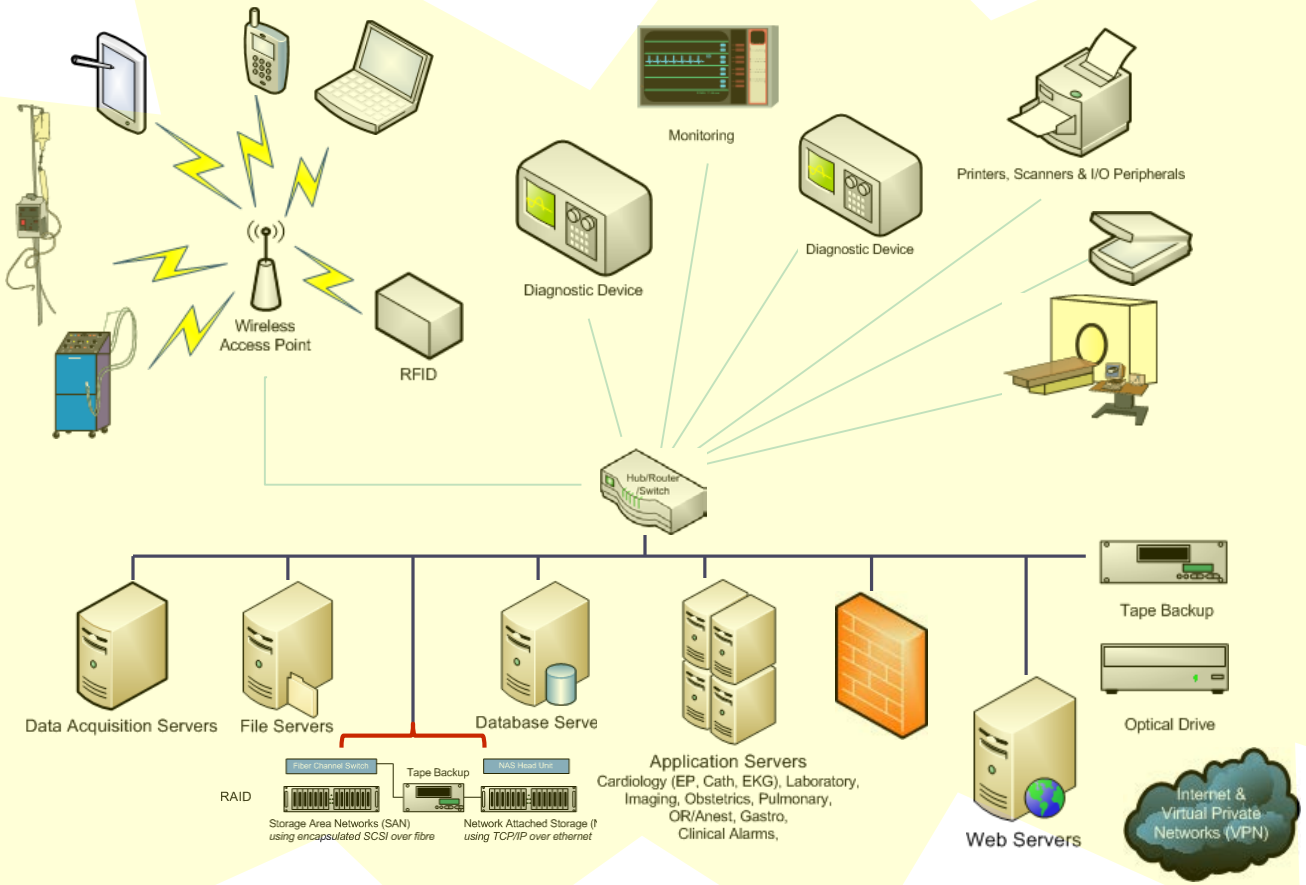




Managing Convergence of Medical & Information Technologies

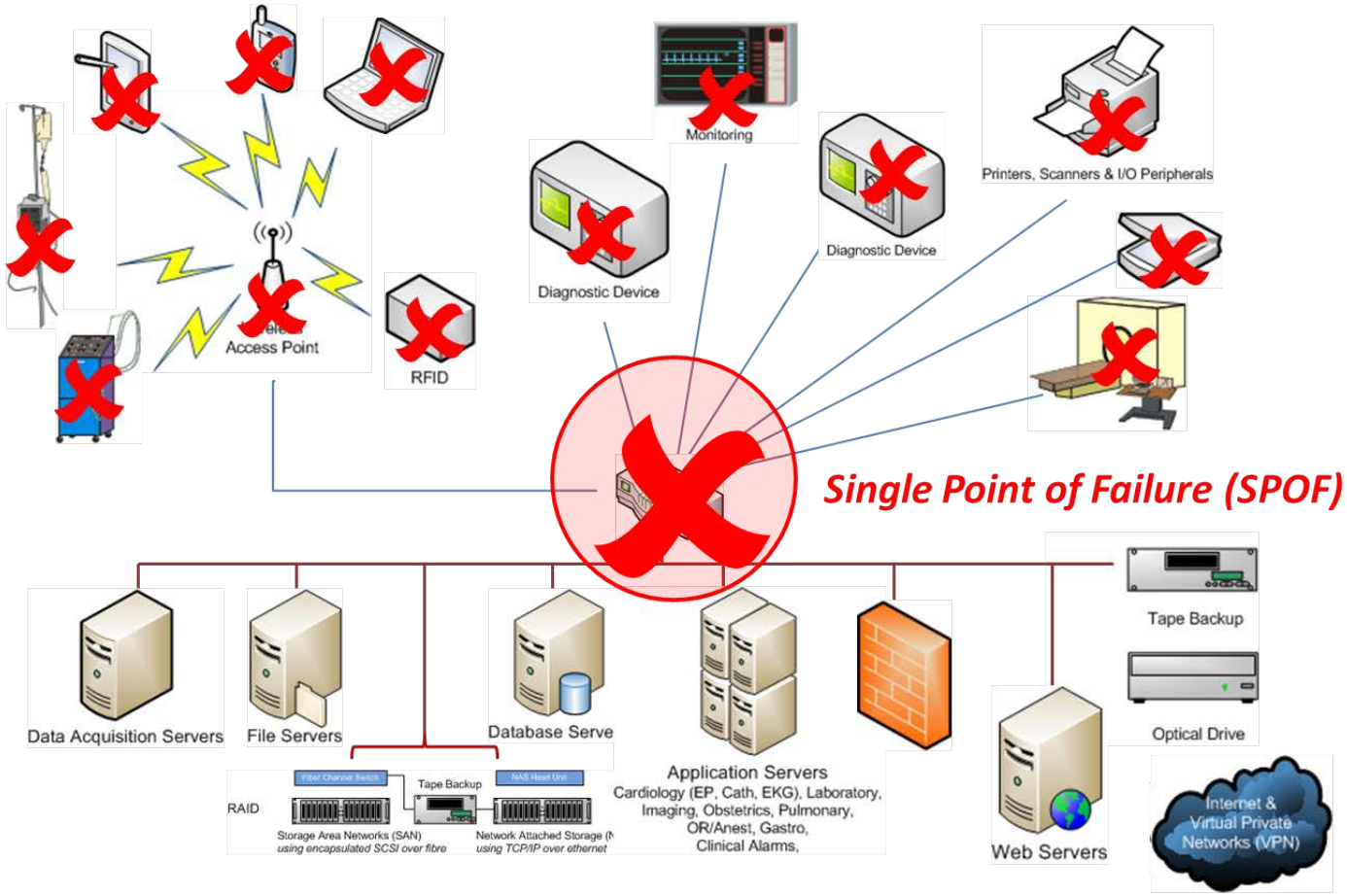
between 7-12 years ago

More medical devices & systems began migrating to enterprise networks (unbound)

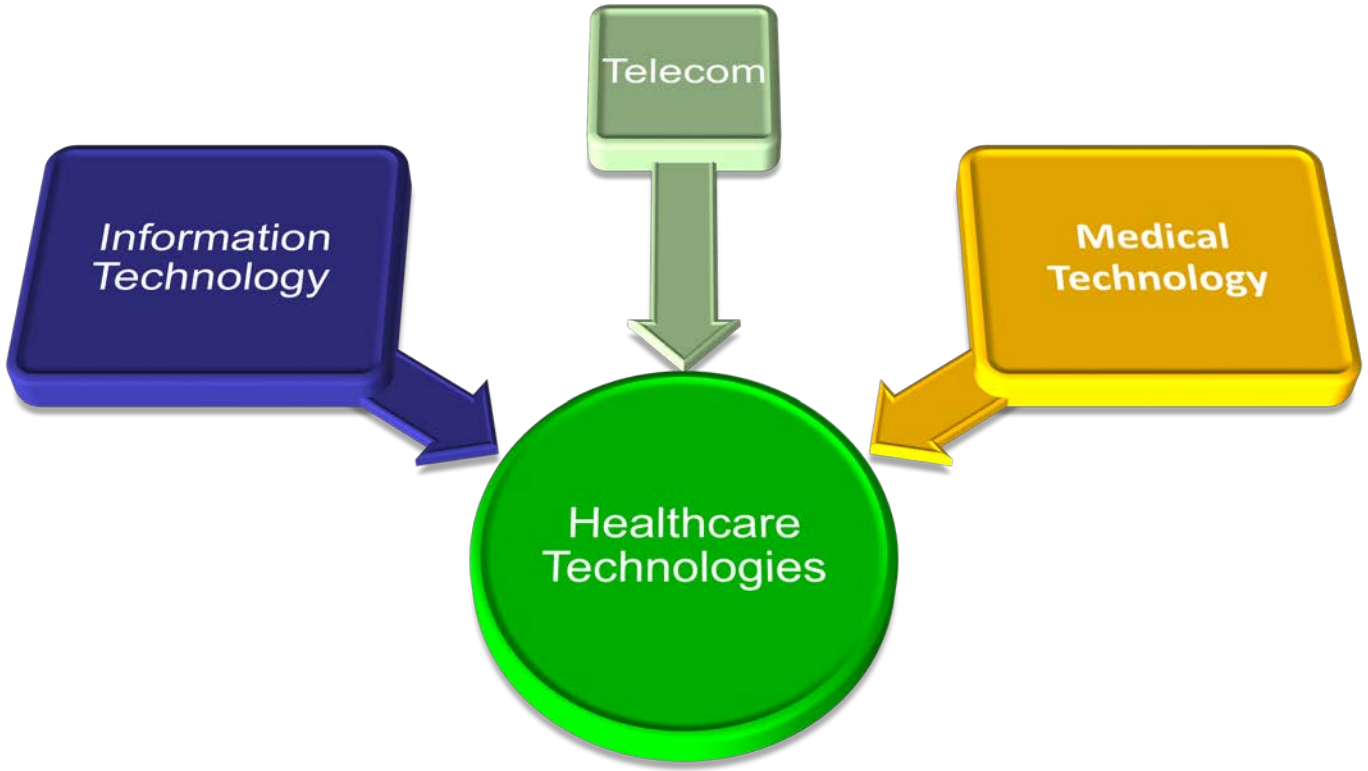


7-12 years ago

Among the unintended consequences of medical devices on enterprise networks is the introduction of single points of failure (SPoF)

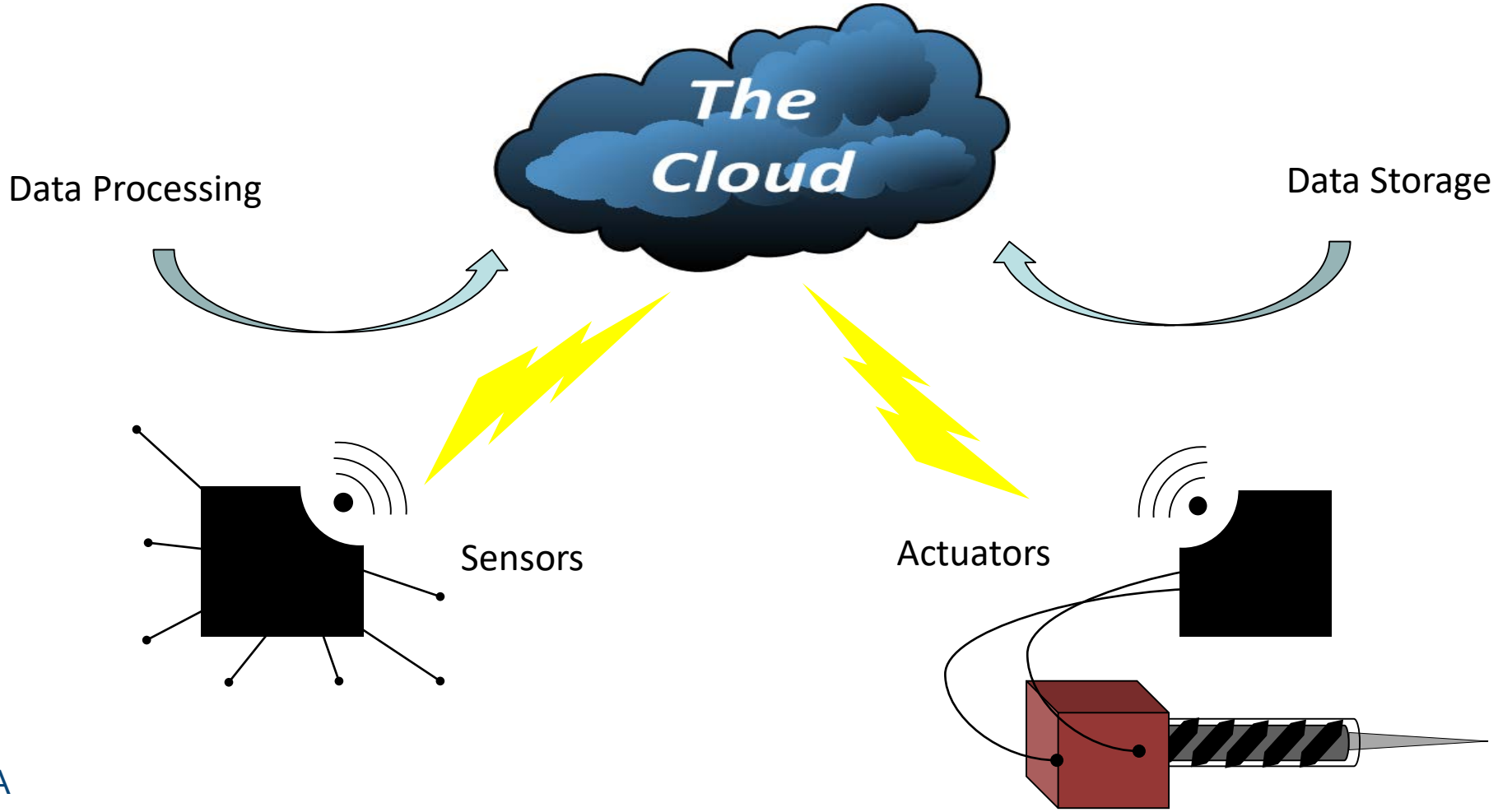


Since 2010
Convergence of Technologies has continued
Growing Number of Hybrid (i.e., Medical-Information-Telecom)
Healthcare Technology Systems



Future of Smart, Software Based Medical Technologies

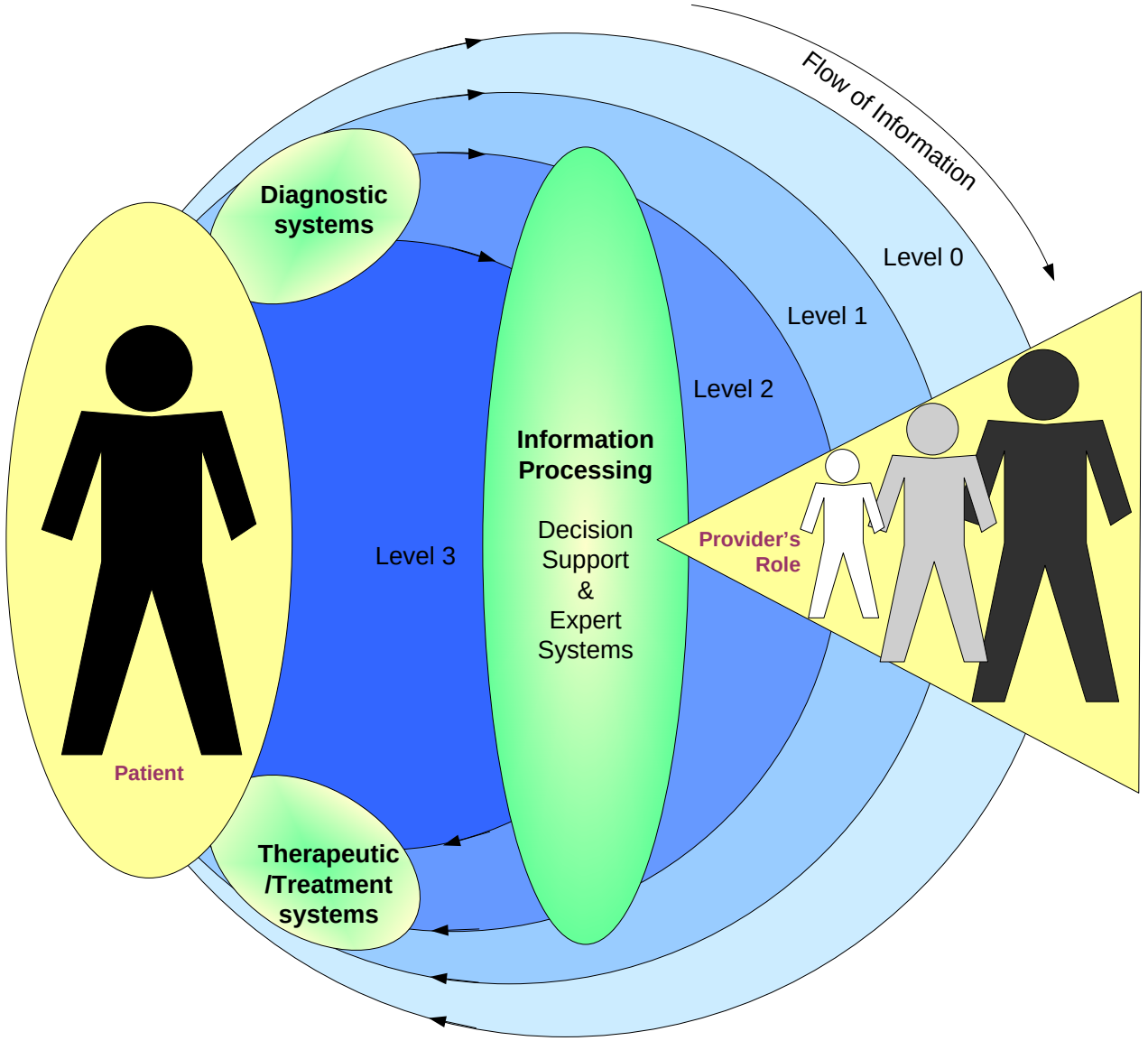
Many traditional medical devices will be replaced by
Software-based “Smart” Medical Devices
Manufacturers are increasingly focused on software development



Examples of some technological advancements healthcare

- robotics
- 3D imaging & printing
- telemedicine & remote monitoring
- micro- and nano- technologies
- individualized medicine (including use of genomics)
- connected, systems-of-systems, and cloud-based solutions (including IoMT, 5G)
- clinical decision support (CDS) & expert systems
- artificial intelligence (AI)
- augmented reality (AR)

Evolution of Smart Healthcare Technology and the Impact on Provider Roles



0) *Clinician's direct observation and action in diagnosis and treatment*

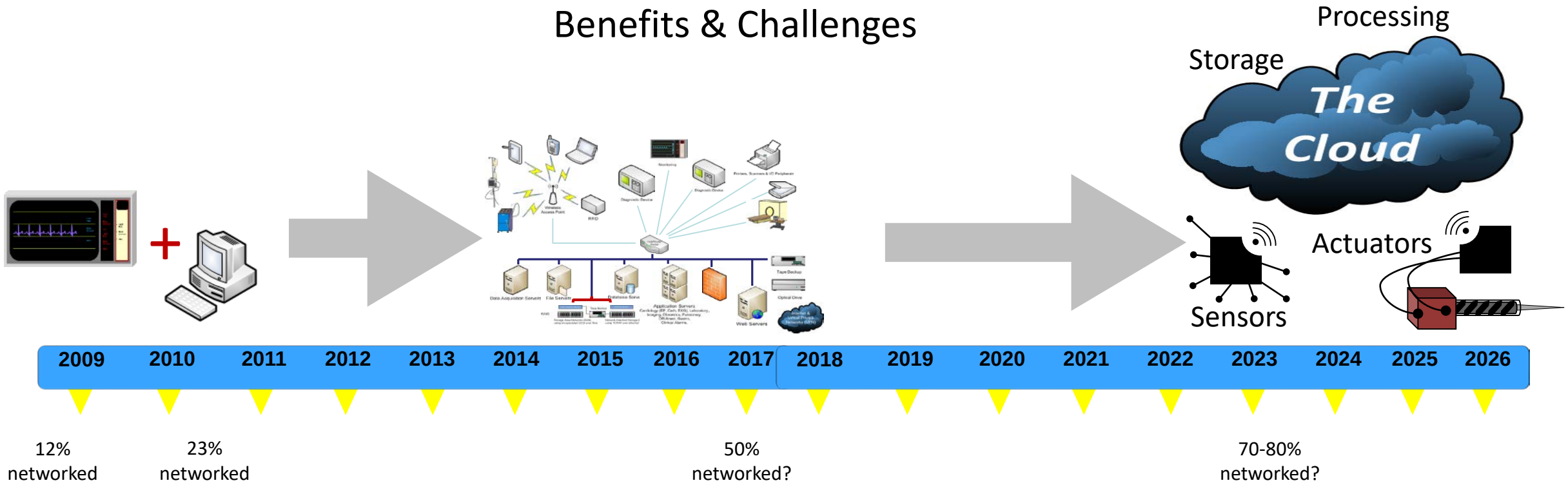
1) *Diagnosis and treatment by clinician augmented by medical devices*

2) *Diagnosis and treatment by clinician further augmented by clinical decision support systems and medical devices*

3) *Diagnosis and treatment directly done by expert & clinical decision support systems and medical devices*

Managing Convergence of Medical & Information Technologies

Benefits & Challenges



BENEFITS

- centrally managed
- increased capabilities *(faster, more reliable diagnosis & treatment)*
- self-diagnostic
- self configuring
- self repairing

CHALLENGES

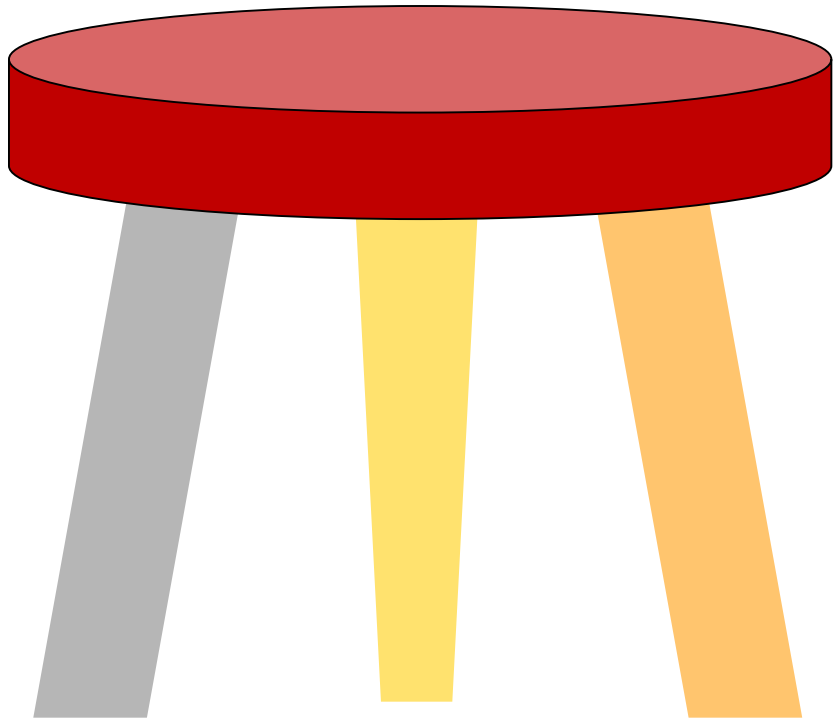
- increased complexity *(requires systems support)*
- multiple SPOF
- multiple vulnerabilities

Trends in CE/HTM Roles and Career Paths

Required Technology Support Roles and their Evolution

The Healthcare Technology Support Professional Paradigm

Healthcare Technology Support Services



Three Roles that are the three legs of the **Healthcare** Technology Support Services Stool

Clinical Engineer

Healthcare Technology Manager

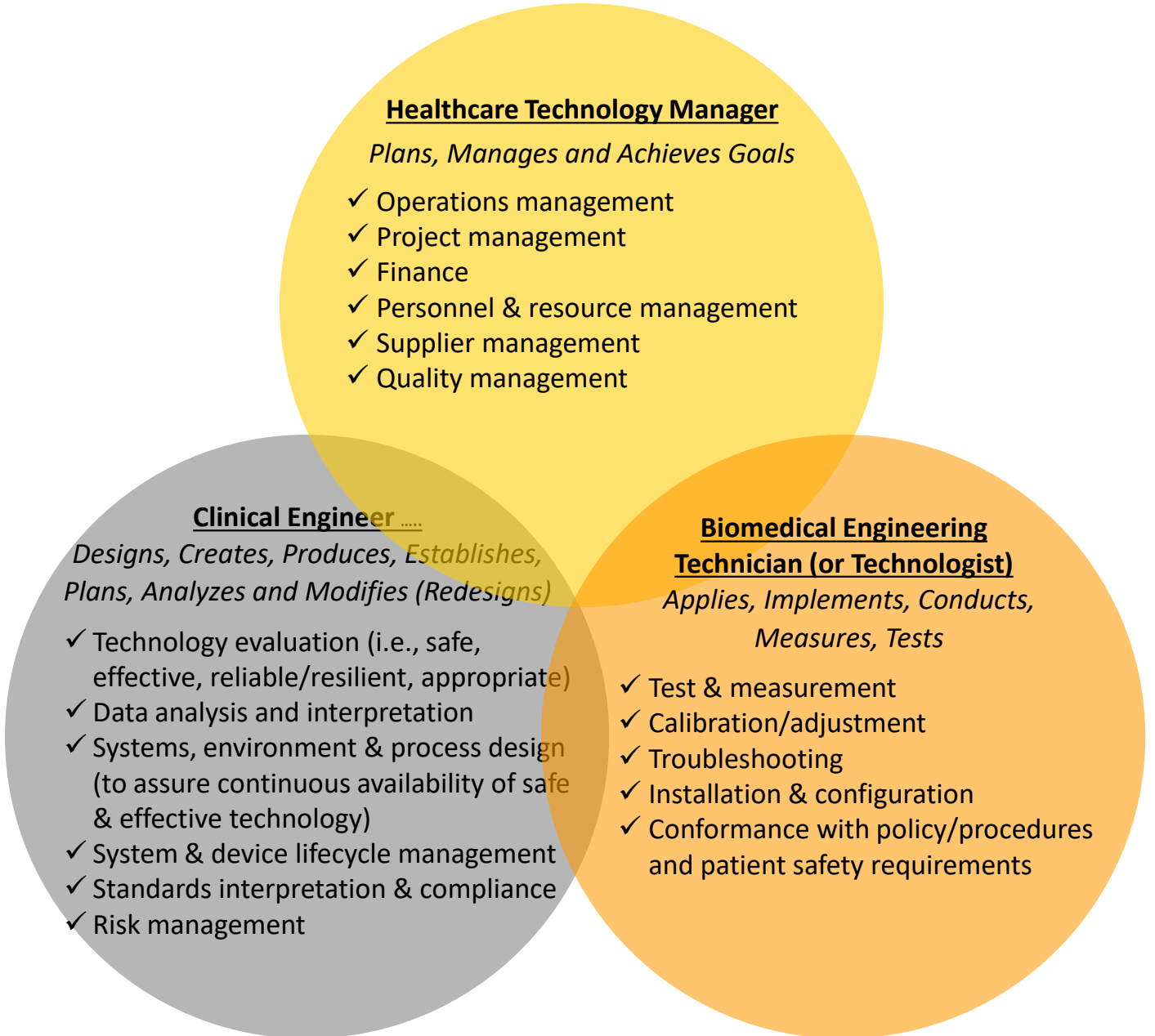
Biomedical Engineering Technician or Technologist

Required Technology Support Roles and their Evolution

The Technology Support Professional Paradigm

Required Technology Support Roles and their Evolution

The Healthcare Technology Support Professional Paradigm



Required Technology Support Roles and their Evolution

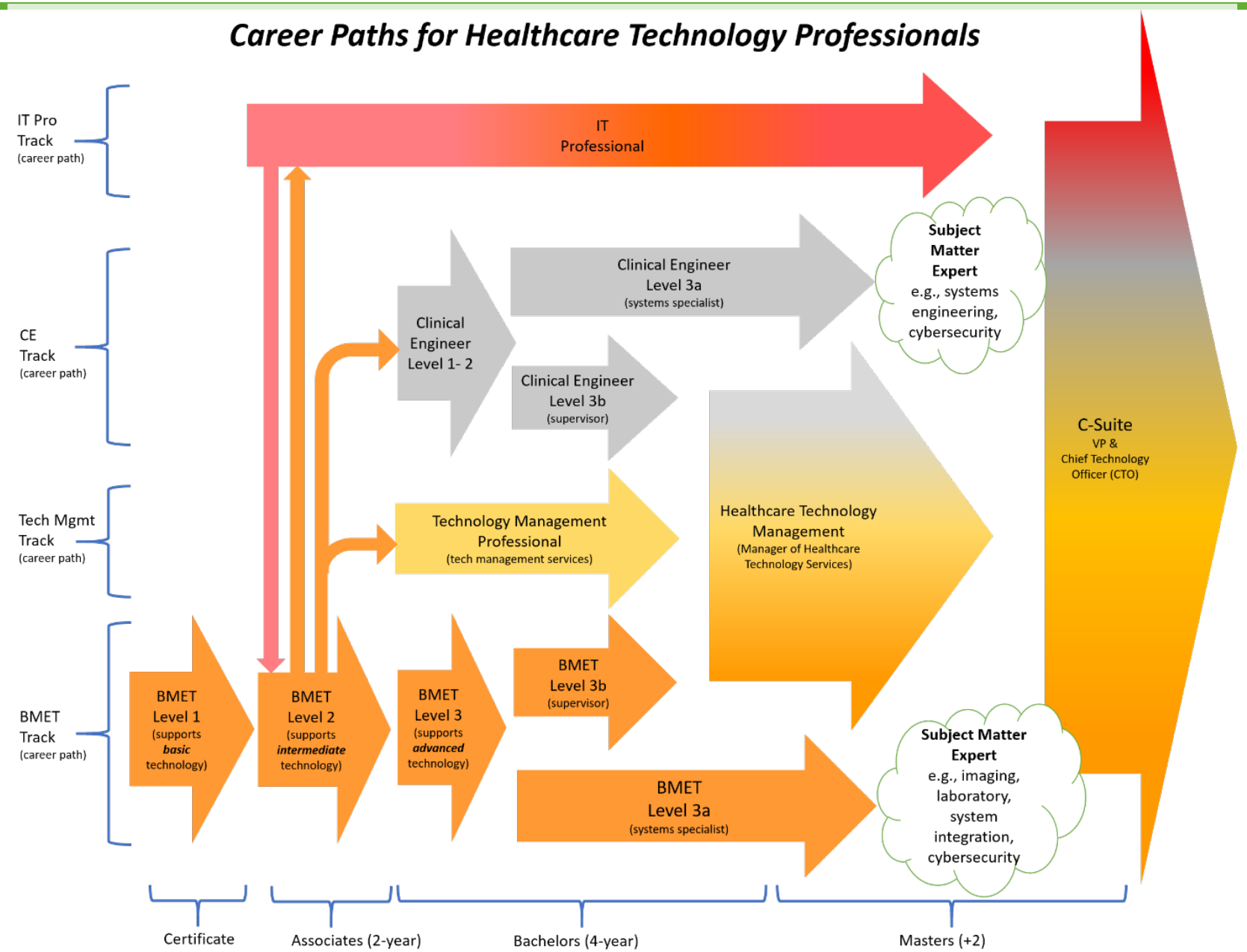
Career Paths for Healthcare Technology Professionals

CE
Track
(career path)

Clinical
Engineer
Level 1- 2

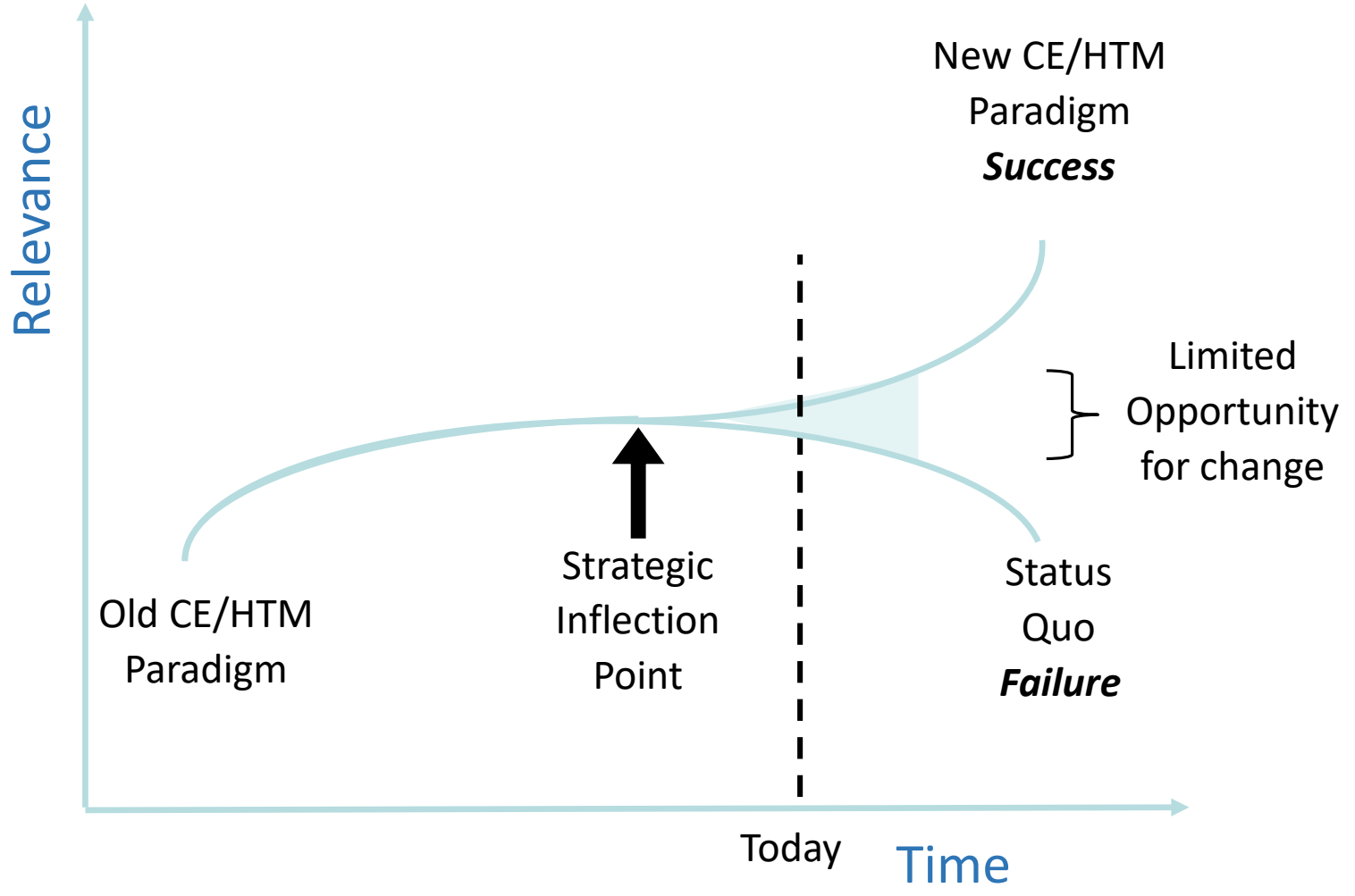
Bachelors (4-year)

Required Technology Support Roles and their Evolution

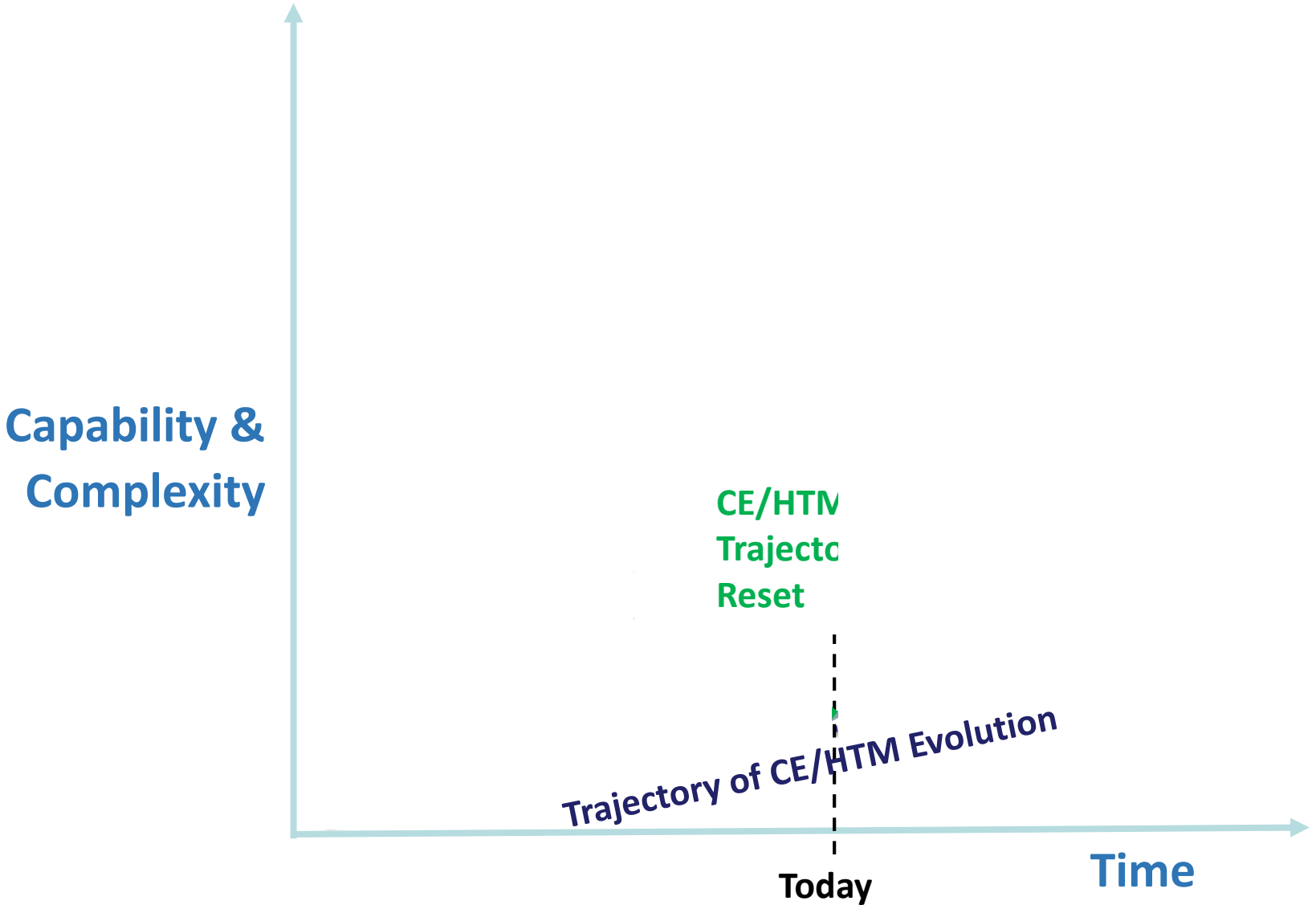


Major Challenges

At a Critical ("Strategic Inflection") Point related to Survival of CE/HTM



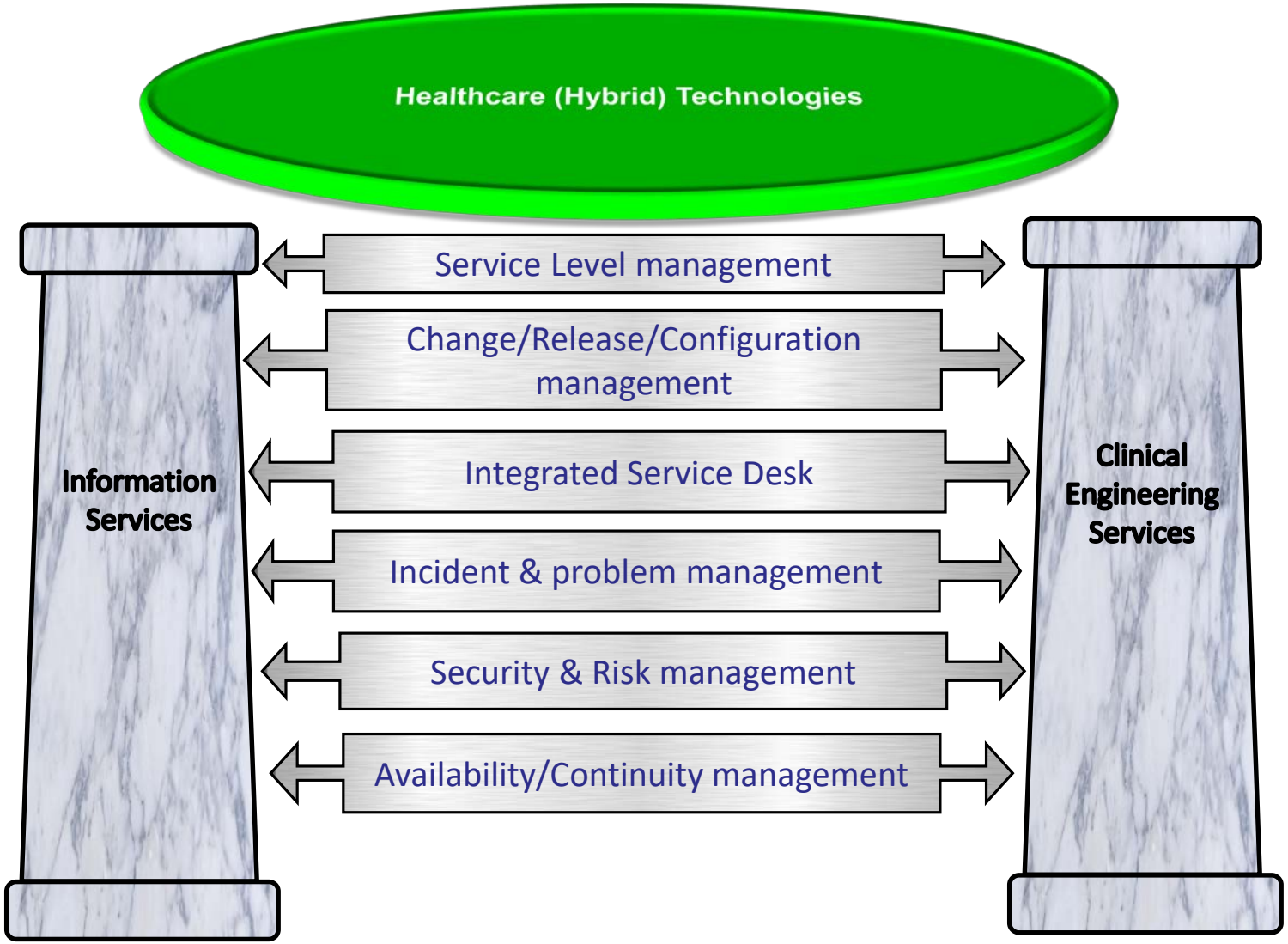
Trends in Evolution of Healthcare Technology and Impact on CE/HTM Roles



New CE/HTM Approaches to Explore

Changes in Reporting, Organization & Infrastructure necessary to manage converged technologies

Traditional IS and CE infrastructures (pillars) need to collaborate (using common practices as braces strengthening pillars) in support of new converged technologies



Consider adopting & adapting Information Technology Service Management standards (i.e., ISO/IEC 20000 or ITIL) into a set of Information & Medical Technology Service Management guidelines

Changing CE/HTM Roles

CE/HTM & IT need to take steps necessary to modify their trajectory in a manner that better aligns and supports converging & evolving technologies

- redefine CE/HTM roles (originally defined decades ago) in a manner that reflects how best to apply CE/HTM (i.e., engineering, engineering technology and technology management) education, skills and experience to meet both today's support needs and future support needs
- better define education, skill, experience and certification requirements for the CE/HTM professionals so the in position to fill new roles
- develop guides and standards that define CE/HTM & IT roles & responsibilities in a manner that ensures seamless collaboration and support of increasingly integrated, hybrid systems
- identify key organizations that have best potential to facilitate necessary changes to technology support including developing underlying stakeholder roles & relationships

CE/HTM Education

Technology will evolve at a pace that will require CE/HTM professionals to commit to continuous education if they are to remain relevant ….

- Completion of traditional education will no longer be sufficient for new HTM roles
  - AAS for engineering technicians
  - BSET for engineering technologist
  - BSE, MSE for engineers
- Continuous education will be required
  - additional college and university-based education
  - certificate programs
  - specialty (industry-based) programs
- Education in new role elements will be required as traditional roles change and some previously required skills and expertise become obsolete

HTM Skills

Technology will evolve at a pace that will require HTM professionals to commit to acquisition of new relevant skills ….

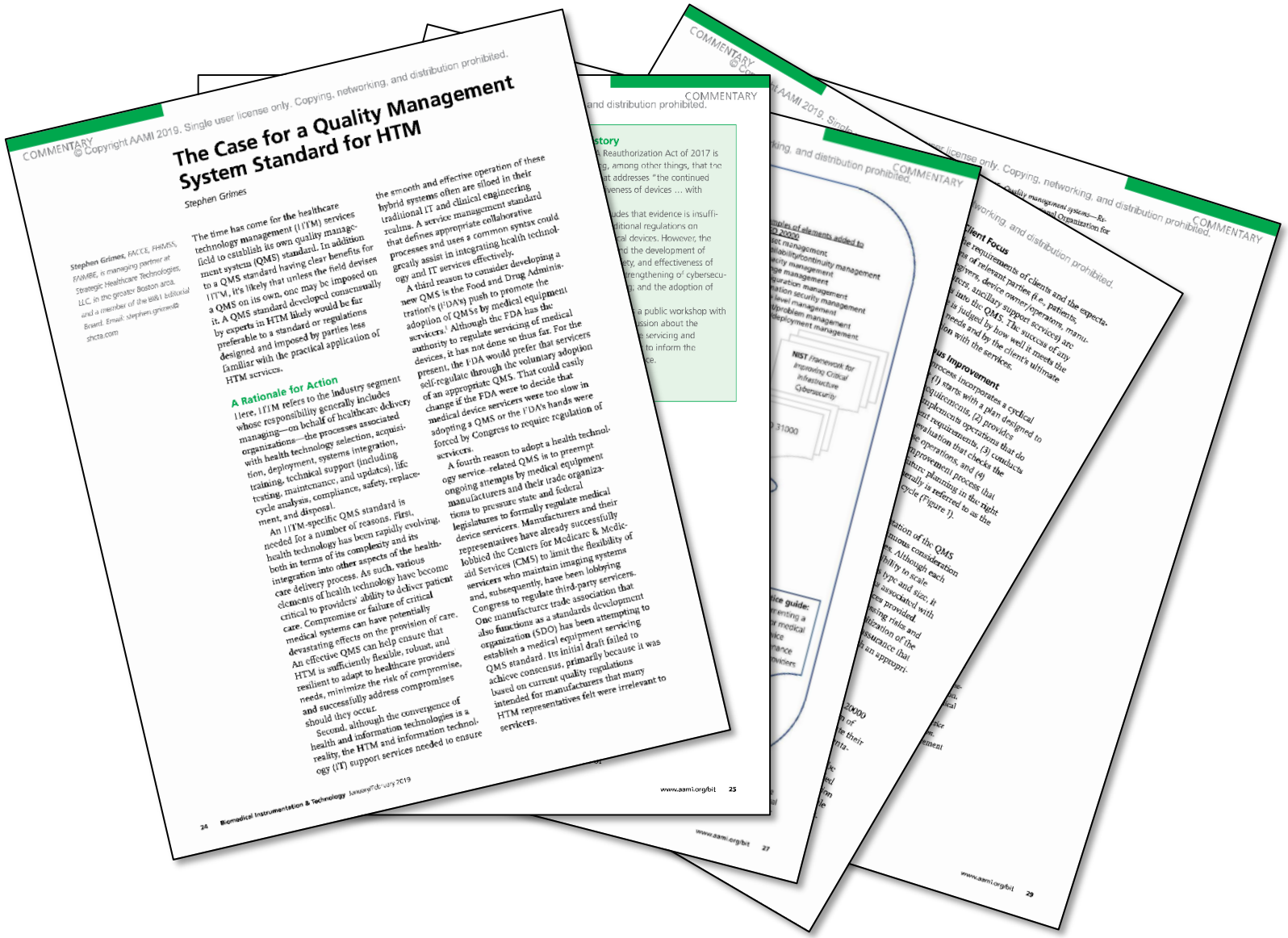
- Strategic planning
- Evaluation of newly evolved technologies (safe, effective, resilient/redundant)
- Systems of Systems (SoS) … integration
- Technology service management (e.g. ISO 9001, ISO 20000, ISO 13485, ITIL)
- Risk and Security Management
- Incident / problem management
- Continuity management (redundant and resilient systems)

Summing up – Radical Changes in next 5-10 yrs

- Medical and Information Technology will continue to evolve in ways that blur lines between our old ideas
  - ✓ when is a computer (or when is software) a medical device?
  - ✓ medical equipment manufacturers will primarily focus on software that will be hardware platform agnostic
  - ✓ future of clinical data analysis and storage is in cloud
- Rapid technology innovations will place increasing burdens on
  - ✓ regulators who are challenged to regulate effectively without stifling innovation
  - ✓ healthcare organizations who are financially constrained but want new technology in order to effectively compete for patients
  - ✓ existing CE & IT infrastructures that must collaborate, acquire new tools and learn to prioritize in order to address greatest risks if they hope to support new technologies (e.g., ITIL, vulnerability assessments, risk & security management)

Publications

http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/BIT/JanFeb19_BIT_HTMQualSyst.pdf



The Case for a Quality Management System Standard for HTM

Stephen Grimes

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COMMENTARY

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The time has come for the healthcare technology management (HTM) services field to establish its own quality management system (QMS) standard. In addition to a QMS standard having clear benefits for HTM, it's likely that unless the field devises a QMS on its own, one may be imposed on it. A QMS standard developed consensually by experts in HTM likely would be far preferable to a standard or regulations designed and imposed by parties less familiar with the practical application of HTM services.

A Rationale for Action

Here, HTM refers to the industry segment whose responsibility generally includes managing—on behalf of healthcare delivery organizations—the processes associated with health technology selection, acquisition, deployment, systems integration, training, technical support (including testing, maintenance, and updates), life cycle analysis, compliance, safety, replacement, and disposal.

An HTM-specific QMS standard is needed for a number of reasons. First, health technology has been rapidly evolving, both in terms of its complexity and its integration into other aspects of the healthcare delivery process. As such, various elements of health technology have become critical to providers' ability to deliver patient care. Compromise or failure of critical medical systems can have potentially devastating effects on the provision of care. An effective QMS can help ensure that HTM is sufficiently flexible, robust, and resilient to adapt to healthcare providers' needs, minimize the risk of compromise, and successfully address compromises should they occur.

Second, although the convergence of health and information technologies is a reality, the HTM and information technology (IT) support services needed to ensure the smooth and effective operation of these hybrid systems often are siloed in their traditional IT and clinical engineering realms. A service management standard that defines appropriate collaborative processes and uses a common syntax could greatly assist in integrating health technology and IT services effectively.

A third reason to consider developing a new QMS is the Food and Drug Administration's (FDA's) push to promote the adoption of QMSs by medical equipment servicers.[1] Although the FDA has the authority to regulate servicing of medical devices, it has not done so thus far. For the present, the FDA would prefer that servicers self-regulate through the voluntary adoption of an appropriate QMS. That could easily change if the FDA were to decide that medical device servicers were too slow in adopting a QMS or the FDA's hands were forced by Congress to require regulation of servicers.

A fourth reason to adopt a health technology service–related QMS is to preempt ongoing attempts by medical equipment manufacturers and their trade organizations to pressure state and federal legislatures to formally regulate medical device servicers. Manufacturers and their representatives have already successfully lobbied the Centers for Medicare & Medicaid Services (CMS) to limit the flexibility of servicers who maintain imaging systems and, subsequently, have been lobbying Congress to regulate third-party servicers. One manufacturer trade association that also functions as a standards development organization (SDO) has been attempting to establish a medical equipment servicing QMS standard. Its initial draft failed to achieve consensus, primarily because it was based on current quality regulations intended for manufacturers that many HTM representatives felt were irrelevant to servicers.

Publications

https://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/BIT/2019_BIT_MJ_CE-HTM_Roles.pdf

Publications

http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/BIT/JulAug19bit_FracturedSupportIndustry.pdf

How Can a Fractured Healthcare Technology Support Industry Hope to Be Effective?

Stephen Grimes

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Discussion & Questions

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