Using consensus standards to promote a culture of safety in the health IT sociotechnical system

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"Using consensus standards…"

Consensus-"**agreement**…that is **shared** by people in a group" (Merriam Webster)

A *standard* is an **agreed** way of doing something" (British Standards Institute)
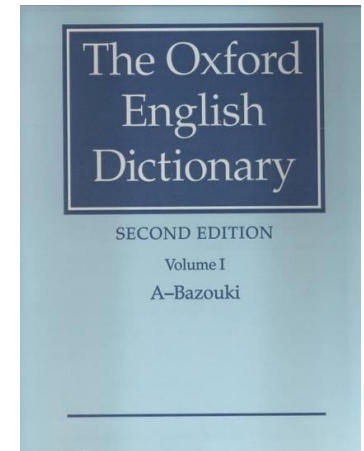
"…to promote a culture…"

"Culture is the deeper level of…assumptions and beliefs…**shared** by members of an organization….."* (Edgar Schein)

A consensus standard, therefore, is a way of establishing and documenting a shared culture.

…of safety..

Safety is "the condition of being protected from or unlikely to cause danger, **risk**, or injury."

High risk sectors (aviation, nuclear power, medical devices, etc.) address safety system-wide through quality systems, risk management and usability/human factors engineering.

"...in the HIT sociotechnical system"

"*Sociotechnical systems* (STS) in organizational development is an approach to complex organizational work design that recognizes the interaction between people and technology in workplaces".

The AAMI Health IT Standards Initiative

(ANSI) AAMI/HIT 1000 (series) Health IT software and systems

- Part 1: Fundamental concepts and principles

- Part 2: Application of quality systems principles and practices

- Part 3: Application of risk management

- Part 4: Application of for HIT

AAMI/HIT1000 series

- Not organization-centric—rather addresses the entire sociotechnical system

- Not developing "new processes"—uses existing approaches

- Applies principles and processes across the product life cycle

- Defines responsibilities and requirements by actors and "roles"—not by organization

HIT software and HIT systems in a sociotechnical system
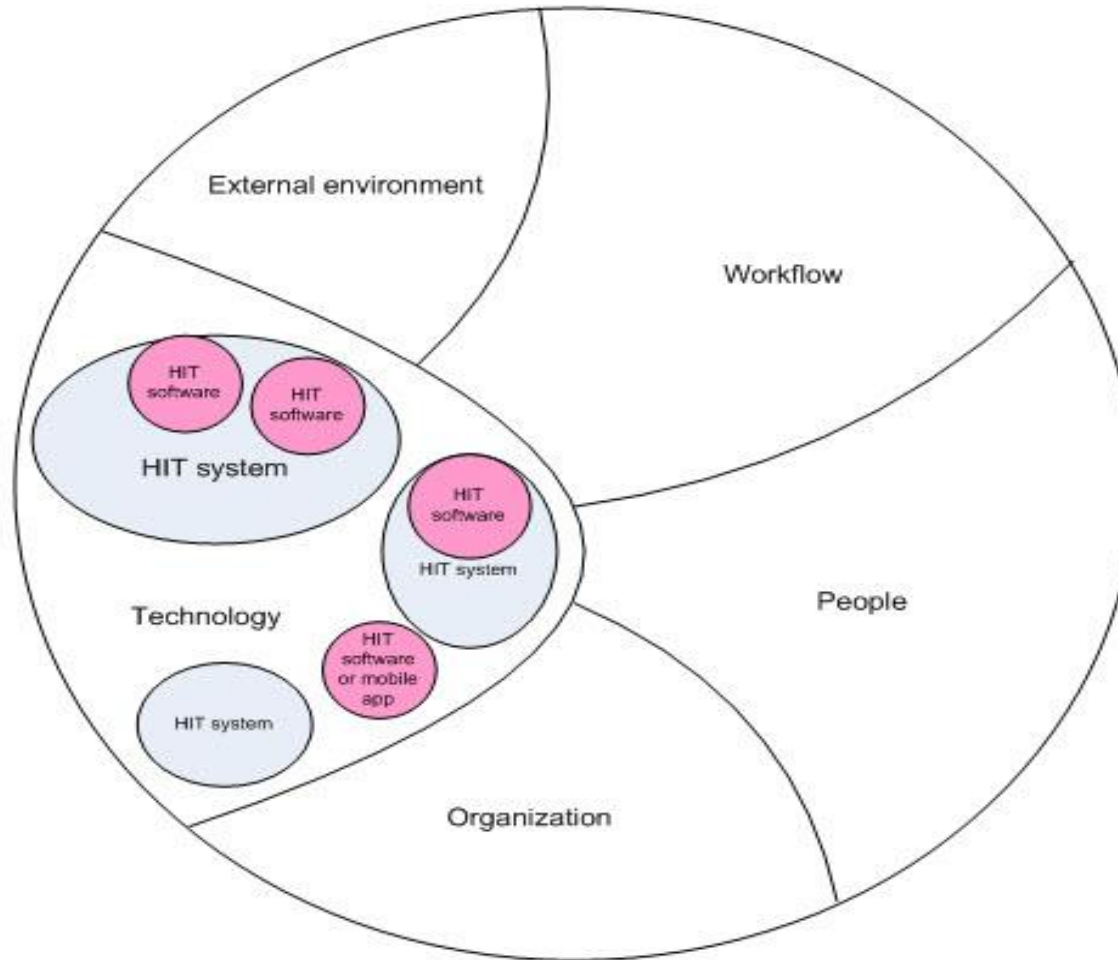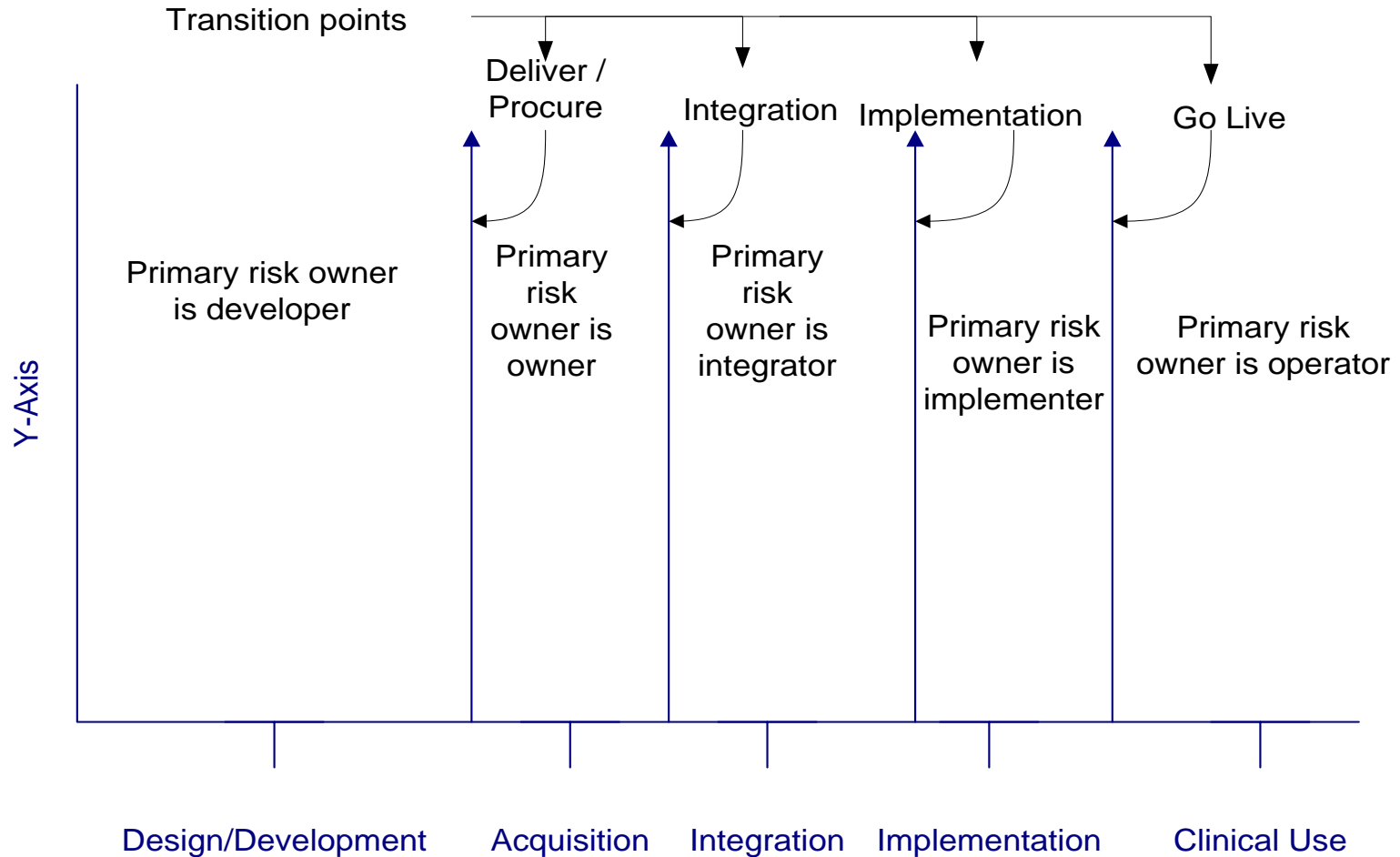
Roles and responsibilities

Top Management	Group of people who direct and control an organization and have overall accountability for a Health IT System.
HIT Safety Officer	Person in an organization responsible for ensuring the safety of a Health IT System in that organization.
Primary Quality Owner	The role that has primary responsibility for quality management during a life cycle stage
Primary Risk Owner	The role that has primary responsibility for risk management during a life cycle stage
Primary Usability Owner	The role that has primary responsibility for usability during a life cycle stage
Developer	Role responsible for the design, development, manufacture and maintenance of the health software (also referred to as "manufacturer" or "supplier" in some standards)
Integrator	Role responsible for the technical installation, configuration and integration of HIT software with the other technology being used by the healthcare organization.
Implementer	Role responsible for the clinical installation and integration of the HIT software in the clinical setting (an implementer may be the developer or the owner),
Owner	The healthcare organization procuring the software,
Operator	Role responsible for keeping the HIT system operational (and/or may be the implementers for a managed service),
User	Persons using the health software in the clinical setting, which may include, for example, consumers in the case of personal health records.

HIT software and HIT system life cycle
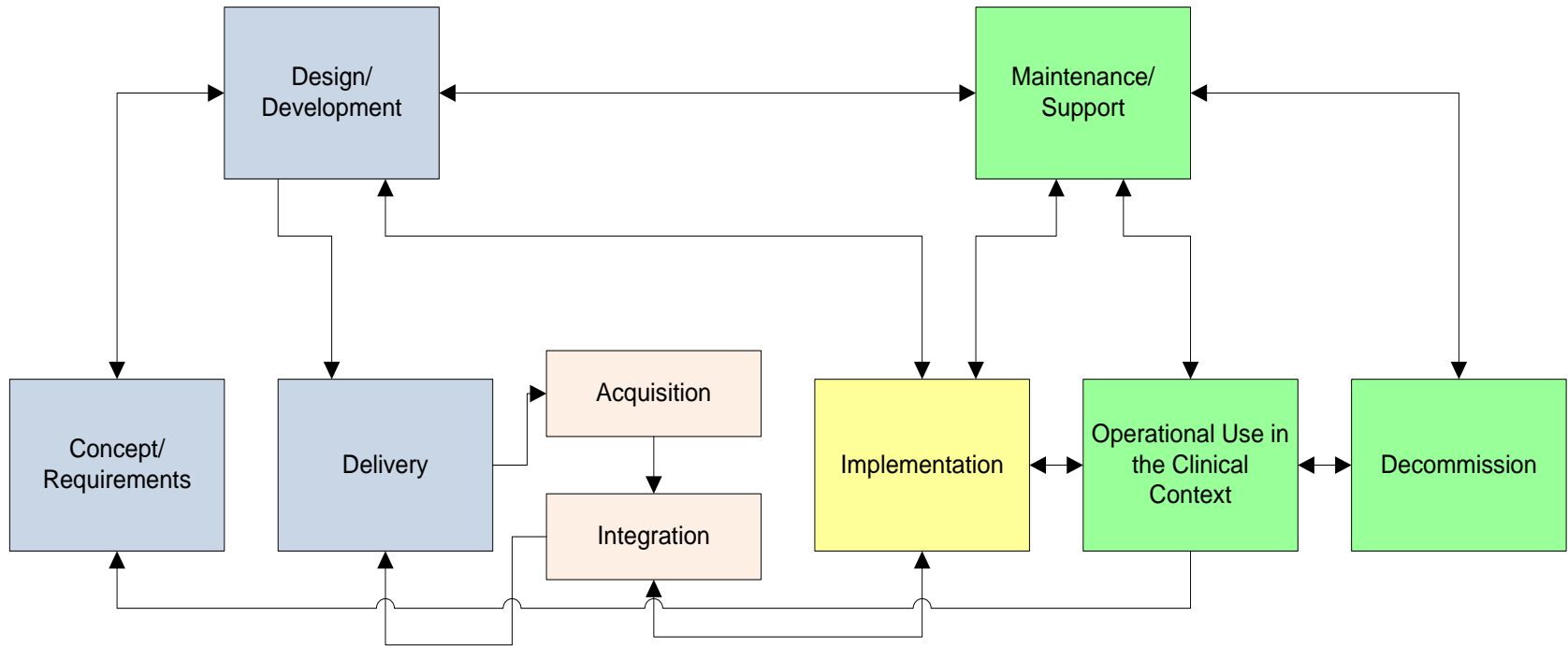
Health software life cycle—Iteration and recursion possible on all paths

Transition points

Transition points

Deliver / Procure   Integration   Implementation   Go Live

Y-Axis

Primary risk owner is developer

Primary risk owner is owner

Primary risk owner is integrator

Primary risk owner is implementer

Primary risk owner is operator

Design/Development   Acquisition   Integration   Implementation   Clinical Use

Health IT Life Cycle stages and activities

Lifecycle Stage	Lifecycle steps	Step Definition and risk management activities during the step	Role(s) with responsibility
Design/ Develop		Design and development is a process (or a set of processes) using resources to transform requirements (inputs) into characteristics or specifications (outputs) for products, processes and systems.	The developer has primary responsibility during the design and development stage.
	Concept/ requirements	Conceiving, imagining and specifying the initial design of the aesthetics and primary functions of the software.	Developer , User
		A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties.	Developer
	Design/ Development	A design is concerned with how the problem is to be resolved.	Developer
		The design is transformed into a product, process or system.	Developer

Defining responsibilities and the transition points

Lifecycle Stage	Lifecycle steps	Step Definition and risk management activities during the step	Role(s) with responsibility
	Delivery	A release is a specific version of a product, service or system that is released for a particular purpose and made available by distribution to owners or implementers.	Developer, owner, implementer
Transition point from developer to Owner. After procurement responsibility transitions to the Integrator.			
Acquisition	Procurement	Defining requirements and acquiring a solution to meet the organization's needs through an available product, or engaging an organization for the production of "bespoke or in-house developed" products.	Owner. The owner has primary responsibility during the acquisition; responsibility then transitions to the integrator.
	Installation	Software conformance testing and certification	Integrator.

Next steps and goals…

- Working groups are meeting to begin fleshing out the four draft documents

- Goal is to issue these drafts as provisional American National Standards for trial implementation beginning next year

- Transition to full American National Standards beginning in 2018/2019

International standards for health software and HIT systems

- Under development by a Joint ISO/EC Working Group (ISO/TC 215-IEC/SC 62A JWG 7)

- Work is jointly managed by AHIMA (ISO/TC 215) and AAMI (IEC/SC 62A)

- Broad common membership between JWG and AAMI HIT standards initiative

- AAMI adopts these International standards and technical reports in the U.S.

Three areas of focus

- Health software life cycle processes (IEC 62304) and general requirements for product safety (IEC 82304)

- Health software and health IT systems safety, effectiveness and security (81001 series [proposed])

- Connected medical devices/connected health software (ISO/IEC 80001 series)

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