AMIA
INFORMATICS PROFESSIONALS. LEADING THE WAY.

3E – Implementation and Operation of Clinical Information Systems

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Clinical Informatics Board Review Course

Clinical Informatics Subspecialty Delineation of Practice (CIS DoP)

Domain 1: Fundamental Knowledge and Skills (no Tasks are associated with this Domain which is focused on fundamental knowledge and skills)

Clinical Informatics

K001. The discipline of informatics (e.g., definitions, history, careers, professional organizations)
K002. Fundamental informatics concepts, models, and theories
K003. Core clinical informatics literature (e.g., foundational literature, principle journals, critical analysis of literature, use of evidence to inform practice)
K004. Descriptive and inferential statistics
K005. Health Information Technology (HIT) principles and science
K006. Computer programming fundamentals and computational thinking
K007. Basic systems and network architectures
K008. Basic database structure, data retrieval and analytics techniques and tools
K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])
K010. Development and use of transaction standards (e.g., American National Standards Institute X12)
K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)
K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System[LIS])
K013. Development and use of data model standards
K014. Vocabularies, terminologies, and nomenclatures (e.g., Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine --Clinical Terms [SNOMED-CT], RxNorm, International Classification Of Diseases[ICD], Current Procedural Terminology [CPT])
K015. Data taxonomies and ontologies
K016. Security, privacy, and confidentiality requirements and practices
K017. Legal and regulatory issues related to clinical data and information sharing
K018. Technical and non-technical approaches and barriers to interoperability
K019. Ethics and professionalism

The Health System

K020. Primary domains of health, organizational structures, cultures, and processes (e.g., health care delivery, public health, personal health, population health, education of health professionals, clinical research)
K021. Determinants of individual and population health
K022. Forces shaping health care delivery and considerations regarding health care access
K023. Health economics and financing
K024. Policy and regulatory frameworks related to the healthcare system
K025. The flow of data, information, and knowledge within the health system

Domain 2: Improving Care Delivery and Outcomes

K026. Decision science (e.g., Bayes theorem, decision analysis, probability theory, utility and preference assessment, test characteristics)
K027. Clinical decision support standards and processes for development, implementation, evaluation, and maintenance
K028. Five Rights of clinical decision support (i.e., information, person, intervention formats, channel, and point/time in workflow)
K029. Legal, regulatory, and ethical issues regarding clinical decision support
K030. Methods of workflow analysis
K031. Principles of workflow re-engineering
K032. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)
K033. User-centered design principles (e.g., iterative design process)
K034. Usability testing
K035. Definitions of measures (e.g., quality performance, regulatory, pay for performance, public health surveillance)
K036. Measure development and evaluation processes and criteria
K037. Key performance indicators (KPIs)
K038. Claims analytics and benchmarks
K039. Predictive analytic techniques, indications, and limitations
K040. Clinical and financial benchmarking sources (e.g., Gartner, Healthcare Information and Management Systems Society [HIMSS] Analytics, Centers for Medicare and Medicaid Services [CMS], Leapfrog)
K041. Quality standards and measures promulgated by quality organizations (e.g., National Quality Forum [NQF], Centers for Medicare and Medicaid Services [CMS], National Committee for Quality Assurance [NCQA])
K042. Facility accreditation quality and safety standards (e.g., The Joint Commission, Clinical Laboratory Improvement Amendments [CLIA])
K043. Clinical quality standards (e.g., Physician Quality Reporting System [PQRS], Agency for Healthcare Research and Quality [AHRQ], National Surgical Quality Improvement Program [NSQIP], Quality Reporting Document Architecture [QRDA], Health Quality Measure Format [HQMF], Council on Quality and Leadership [CQL], Fast Health Interoperability Resources [FHIR] Clinical Reasoning)
K044. Reporting requirements
K045. Methods to measure and report organizational performance
K046. Adoption metrics (e.g., Electronic Medical Records Adoption Model [EMRAM], Adoption Model for Analytics Maturity [AMAM])
K047. Social determinants of health
K048. Use of patient-generated data
K049. Prediction models
K050. Risk stratification and adjustment
K051. Concepts and tools for care coordination
K052. Care delivery and payment models

Domain 3: Enterprise Information Systems

K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
K054. Institutional governance of clinical information systems
K055. Information system maintenance requirements
K056. Information needs analysis and information system selection
K057. Information system implementation procedures
K058. Information system evaluation techniques and methods
K059. Information system and integration testing techniques and methodologies
K060. Enterprise architecture (databases, storage, application, interface engine)
K061. Methods of communication between various software components
K062. Network communications infrastructure and protocols between information systems (e.g., Transmission Control Protocol/Internet Protocol [TCP/IP], switches, routers)
K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
K064. Clinical system functional requirements
K065. Models and theories of human-computer (machine) interaction (HCI)
K066. HCI evaluation, usability engineering and testing, study design and methods
K067. HCI design standards and design principles
K068. Functionalities of clinical information systems (e.g., Electronic Health Records [EHR], Laboratory Information System [LIS], Picture Archiving and Communication System [PACS], Radiology Information System [RIS] vendor-neutral archive, pharmacy, revenue cycle)
K069. Consumer-facing health informatics applications (e.g., patient portals, mobile health apps and devices, disease management, patient education, behavior modification)
K070. User types and roles, institutional policy and access control
K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed loop communication)
K072. Security threat assessment methods and mitigation strategies
K073. Security standards and safeguards
K074. Clinical impact of scheduled and unscheduled system downtimes
K075. Information system failure modes and downtime mitigation strategies (e.g., replicated data centers, log shipping)
K076. Approaches to knowledge repositories and their implementation and maintenance
K077. Data storage options and their implications
K078. Clinical registries
K079. Health information exchanges
K080. Patient matching strategies
K081. Master patient index
K082. Data reconciliation
K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
K084. Non-regulated medical devices (e.g., consumer devices)
K085. Telehealth workflows and resources (e.g., software, hardware, staff)

Domain 4: Data Governance and Data Analytics

K086. Stewardship of data
K087. Regulations, organizations, and best practice related to data access and sharing agreements, data use, privacy, security, and portability
K088. Metadata and data dictionaries
K089. Data life cycle
K090. Transactional and reporting/research databases
K091. Techniques for the storage of disparate data types
K092. Techniques to extract, transform, and load data
K093. Data associated with workflow processes and clinical context
K094. Data management and validation techniques
K095. Standards related to storage and retrieval from specialized and emerging data sources
K096. Types and uses of specialized and emerging data sources (e.g., imaging, bioinformatics, internet of things (IoT), patient-generated, social determinants)
K097. Issues related to integrating emerging data sources into business and clinical decision making
K098. Information architecture
K099. Query tools and techniques
K100. Flat files, relational and non-relational/NoSQL database structures, distributed file systems
K101. Definitions and appropriate use of descriptive, diagnostic, predictive, and prescriptive analytics
K102. Analytic tools and techniques (e.g., Boolean, Bayesian, statistical/mathematical modeling)
K103. Advanced modeling and algorithms
K104. Artificial intelligence
K105. Machine learning (e.g., neural networks, support vector machines, Bayesian network)
K106. Data visualization (e.g., graphical, geospatial, 3D modeling, dashboards, heat maps)
K107. Natural language processing
K108. Precision medicine (customized treatment plans based on patient-specific data)
K109. Knowledge management and archiving science
K110. Methods for knowledge persistence and sharing
K111. Methods and standards for data sharing across systems (e.g., health information exchanges, public health reporting)

Domain 5: Leadership and Professionalism

K112. Environmental scanning and assessment methods and techniques
K113. Consensus building, collaboration, and conflict management
K114. Business plan development for informatics projects and activities (e.g., return on investment, business case analysis, pro forma projections)
K115. Basic revenue cycle
K116. Basic managerial/cost accounting principles and concepts
K117. Capital and operating budgeting
K118. Strategy formulation and evaluation
K119. Approaches to establishing Health Information Technology (HIT) mission and objectives
K120. Communication strategies, including one-on-one, presentation to groups, and asynchronous communication
K121. Effective communication programs to support and sustain systems implementation
K122. Writing effectively for various audiences and goals
K123. Negotiation strategies, methods, and techniques
K124. Conflict management strategies, methods, and techniques
K125. Change management principles, models, and methods
K126. Assessment of organizational culture and behavior change theories
K127. Theory and methods for promoting the adoption and effective use of clinical information systems
K128. Motivational strategies, methods, and techniques
K129. Basic principles and practices of project management
K130. Project management tools and techniques
K131. Leadership principles, models, and methods
K132. Intergenerational communication techniques
K133. Coaching, mentoring, championing and cheerleading methods
K134. Adult learning theories, methods, and techniques
K135. Teaching modalities for individuals and groups
K136. Methods to assess the effectiveness of training and competency development
K137. Principles, models, and methods for building and managing effective interdisciplinary teams
K138. Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles, team management, identifying and addressing challenges)
K139. Group management processes (e.g., nominal group, consensus mapping, Delphi method)

Knowledge Statements from the DoP

K054 Institutional governance of clinical information systems

K056 Information needs analysis and information system selection

K058 Information system evaluation techniques and methods

K059 Information system and integration testing techniques and methodologies

K060 Enterprise architecture (databases, storage, application, interface engine)

K061 Methods of communication between various software components

K062 Network communications infrastructure and protocols between information systems (e.g., TCP/IP, switch, routers

K063 Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used

K064 Clinical system functional requirements

K068 Functionalities of clinical information systems (e.g., Electronic Health Records

K074. Clinical impact of scheduled and unscheduled system downtimes

K075 Information system failure modes and downtime mitigation strategies (e.g., replicated data centers, log shipping)

Key topics

Institutional governance models for clinical information systems

Implementation costs

Formal and informal methods to define and specify system requirements, and solicit vendor proposals

System conversion strategies and their relative merits

Elements of a system implementation plan

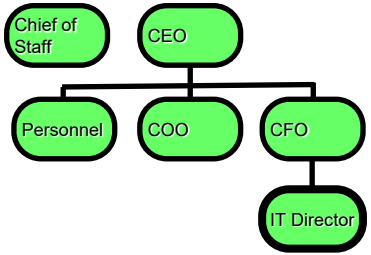
Key elements of clinical system operations and maintenance program

Institutional governance of clinical information systems

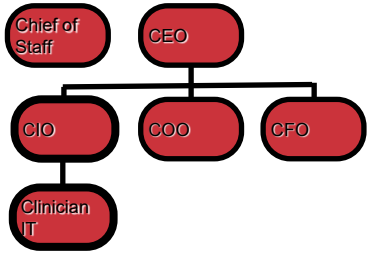
- Integrate into existing governance (or build new)
- Information system projects are best viewed as clinical rather than IT
- Leadership best derived from opinion leaders versus technophilic users

The relationship between clinical computing and operational leadership

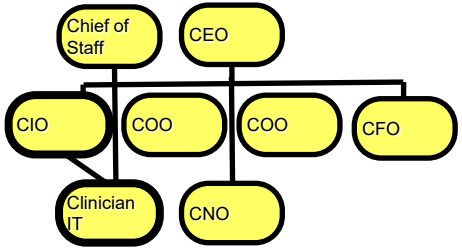
Model 1



Model 2

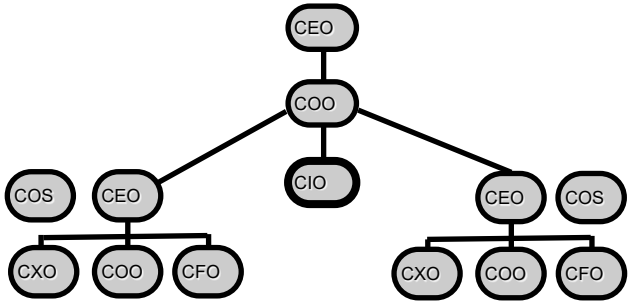


Model 3



In general, health IT leadership has migrated up the org chart

Model 4



Medical Center bylaws and medical records

Bylaws typically cover:

- Content of medical record
- Who is permitted to add to and view it
- Responsibility of physicians for entering into the medical record for their patients
- Standards for timely completion

Oversight of medical records often vested in Medical Record or Health Information Management Committee

- Who can enter into medical record, use of alerts, retention of records, medical record completion, co-signature requirements

Consider also: State, federal law

Accreditation

The Joint Commission (TJC)

- United States-based nonprofit tax-exempt 501(c) organization that accredits more than 21,000 US health care organizations.
- The Joint Commission is one of several organizations approved by CMS to certify hospitals.

DNV (Det Norske Veritas)

- Granted CMS Deeming Authority in 2008
- Accredited nearly 500 hospitals of all sizes and in every regior of the United States.
- Survey teams visit annually

Regarding legal agreements in health IT:

A. BAAs, DUAs, and SLAs are all required by HIPAA.

B. BAAs are used when a business associate has access to PHI.

C. BAAs, DUAs, and SLAs are usually formal legal agreements rather than contractual.

D. DUAs are required before sharing of data between healthcare organizations.

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D. DUAs are required before sharing of data between healthcare organizations.

ANSWER: B. BAAs are used when a business associate has access to PHI.
Not A. SLA is Service Level Agreement which are not required by HIPAA.
Not C: BAAs, DUAs and SLAs are usual contractual agreements.
Not D: DUAs are not required to share data, for example transferring discharge summaries or images.

EHR Functionality

☐	Results reporting (lab, radiology, other)	☐	Lecture external e-mail for patients
☐	Order entry (lab, radiology, other)	☐	Patient web portal
☐	Multiple note creation options (templates, macros, dictation, voice recognition, handwriting recognition)	☐	Patient education
☐	Automated E/M coding advisor	☐	Scanning
☐	Software interfaces with internal outside labs	☐	Automated chart documentation (problem lists, medication lists, vital signs, health maintenance)
☐	Prescription writer and database (with online formularies and drug-interaction checking)	☐	Automated charge entry
☐	Flow charting (labs, vital signs, growth parameters)	☐	Inpatient reports (downloadable)
☐	Remote access	☐	Electronic fax reports (dictation, lab, radiology) to outside specialists
☐	Referral ordering and tracking	☐	Patient follow-up/health-maintenance deficiency alerts
☐	Patient registration information (master patient index)	☐	Practice population analysis tools
☐	Telephone message documentation and tasking	☐	Decision support tools
☐	Internal e-mail	☐	Security (audit trail, user access hierarchy, passwords)

Legal agreements

BAA – Business Associates Agreement

- Required by HIPAA
- Associate has access to PHI

DUA – Data Use Agreement

- Conditions for use and sharing of data between organizations

DSA – Data Storage Agreement

- Similar to above, but parties store data for another

SLA – Service Level Agreement

- Typically contractual rather than legal agreements for performance

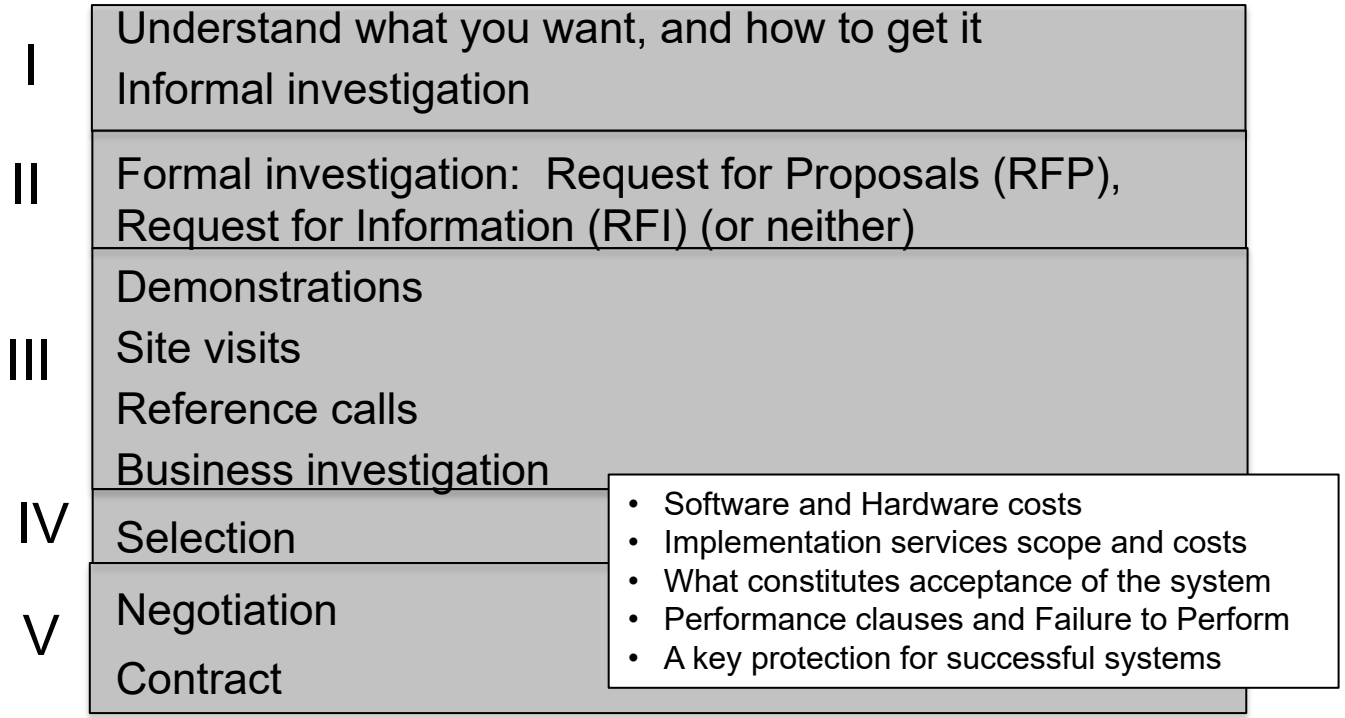
Slide courtesy of Dave Chou

Methods for identifying clinical information system needs

- Create project team
- Define requirements
- Identify viable candidates
- System selection…

- Observation
- Mapping
- Interviews
- Focus groups
- Expert interviews

Clinical information system selection



Clinical information needs analysis and system selection

RFP Request for proposal. A document that an organization posts to elicit bids from potential vendors for a product or service. A weighted point assignment method of evaluation may be used if considered appropriate.

RFI Request for information. Request made typically during the project planning phase where a buyer cannot clearly identify product requirements, specifications, and purchase options. RFIs clearly indicate that award of a contract will not automatically follow.

RFQ Request for quotation. Used when requirements are clear-cut

"You are buying what they are selling."

Clinical system functional requirements
Example

1. General System Functionality
2. Patient Flow and Records Retention
3. Health Information Management Requirements
4. Account Management and Billing
5. Clinical Features
   - a. Order Management
   - b. Medication Administration Record
   - c. Workflow Management
   - d. Documentation
   - f. Clinical Summary
   - g. Medication Reconciliation Documentation
   - h. Informed Consent Documentation
   - i. Evidence-based resources and CDS
6. Data Management, Data Mining
7. Population Health Management Reporting
8. Pharmacy
9. Dietary
10. Capabilities
11. Service and Support
12. System Training

Contents of the RFP
[Kelly 1999]

Describe your organization

Describe your needs—functional, technical, business requirements

Timing and implementation requirements

Financial issues

Lay out the vendor selection process, timeline, and selection criteria

Conform to organizational requirements

HealthIT.gov RFP Template

Vendor investigations—due diligence

Demonstrations for small or large groups

- Useful for group investigation, ↑ buy-in
- Require vendor to specify what is future functionality

Site visits

- Critically important part of vendor selection
- Visit sites like your own

Conference calls

- Cheaper and faster than site visits
- Expand your reach

Business investigation

Will the vendor remain in business or not?

How long have they been in business?

Are they privately or publicly held?

Are they likely to be acquired?

What does their balance sheet tell you about their likely future?

Involve your business office/CFOs.

Contract negotiations

Basis for long-term financial and professional relationship

For large contracts, strongly consider hiring legal counsel. Vendor will have it.

Vendor proposal should be submitted in form to be included in contract.

Contract controls project, functionality, payments

Allow sufficient time to do this properly

Remember that over long term, most money is in support payments, which are governed by the contract—strongly consider legal counsel in contract negotiations.

EHR implementation costs

healthit.gov "How much is this going to cost me?"

Several studies estimate the cost of purchasing and installing an electronic health record (EHR) ranges from $15,000 to $70,000 per provider.

- Hardware
- EHR software
- Implementation assistance
- Training
- Ongoing network fees and maintenance

Cost	In-Office			SaaS		
	Upfront Cost	Yearly Cost	5 Year TCO	Upfront Cost	Yearly Cost	5 Year TCO
Estimated Average Cost	$33,000	$4,000	$48,000	$26,000	$8,000	$58,000

EHR cost considerations

89% (estimated) monetary benefits accrue to payers

10% drop in physician productivity may occur

Implementing and maintaining EHRs est. $40-50k

Federal incentives do not cover all of this, nor cost to operate EHRs.

Sittig and Singh, Pediatrics 2011;127(4).

EHR implementation factors

Table 1 Electronic health record implementation factors common to all user groups

Factor	User groups (number of studies)				Number of studies (%)
	Physicians	Health care professionals	Managers	Patients	
Design or technical concerns	9	9	3	1	22 (42.3)
Privacy and security concerns	4	5	4	8	21 (40.4)
Cost issues	8	3	7	1	19 (36.5)
Lack of time and workload	7	6	3	1	17 (32.7)
Motivation to use EHR	3	7	2	4	16 (30.8)
Productivity	4	5	3	2	14 (26.9)
Perceived ease of use	3	6	2	2	13 (25.0)
Patient and health professional interaction	3	4	1	4	12 (23.1)
Interoperability	2	2	3	3	10 (19.2)
Familiarity, ability with EHR	2	2	2	3	9 (17.3)

McGinn et al. BMC Medicine 2011, 9:46

Implementation overview

1. Assess current state
2. Process Design--future state
3. Software design
4. Configuration—building the system
5. Test, Test, Test…
6. Train
7. Convert/Go-Live
8. Post Conversion Assessment
9. Move into Ongoing Support Model

Elements of a system implementation plan. 1

- Project management (PMP=Project Management Professional)
- Budgeting
- External audit
- Testing
- Training
- Support

Elements of a system implementation plan. 2

Transition planning (“go-live,” “activation”, “conversion”)

- Big bang (or modified), versus pilot, or phased (staggered, sequential)
- By medical service or location
- Consider risks, budget for support, costs of transition

When choosing transition approach, consider:

- Functionality
- Geography

[Grisim, Longhurst 2011]

Testing. 1

Unit. Directed at menus, templates, and other modules and subunits of the system, without regard to other system components internal or external to a given application.

Application. All modules and subunits of the application work in connection with each other.

Integration. Conformation that information flow between the EHR and external systems occurs as expected.

Performance. With production loads and users, system functions within expected boundaries.

Post-production. After conversion, all aspects of system operate as required.

Regarding testing, which statement is the most accurate?

A. Contingency testing is usually not needed if other testing has occurred prior to go-live.

B. Integration testing assures all functional modules within an EHR system work together.

C. Unit testing is usually the final step in testing the entire EHR before go-live.

D. Regression testing determines if other components of a system operate after a change is introduced.

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ANSWER: D. Regression testing determines if other components of a system operate after a change is introduced

Testing. 2
Other testing terms you may hear

System. Tests all aspects of a given system or application, e.g. - how well the software satisfies the stakeholders' functionality, security, performance, load, reliability, compatibility, availability, etc. requirements

Regression. Tests to make certain that, with the exception of the change currently being requested, all components of the software's functionality / behavior are unchanged.

Backout or contingency. Tests the ability to back out the changes being made to a system or, if changes cannot be backed out, tests the contingency plan if modifications cause problems once implemented.

Testing. 3

Test environment. Domain (or instance) of system with configuration and data similar to production in which testing occurs.

Scripts. Structured simulations of workflow and system use that can reproducibly be used for testing versions of proposed production version.

Testing is tiring, monotonous, critically important, and shortened at great risk.

Clinical information system testing
Before, during and after implementation

- Before implementation—as above
- Real-world active surveillance
- Upgrade testing
- Capturing user feedback
- Safety reporting systems
- Simulation of production use
- Robot monitoring of user experience

Conversion. 1
(aka activation, go-live)

Command Center

- On-site presence
- All teams: technical, application, interface, user liaisons
- Planning duration and logistics should begin early

User support team

- Goal is overwhelming support, “at the elbow”
- Project and non-project team
- Roamers

Communication methods and plan

- Pagers, cell phones, scheduled status calls, shift reports

[Ash 2003]

Conversion. 2

Issue management

- Capture and triage
- Documentation
- Communication and closing the loop

Review downtime procedures

Have back-out or remediation plan

Models of user training and support processes that can meet clinician needs

- Classroom, web-based or blended
- Concierge
- In-person—tailor to specialty
- Strengths and weaknesses of SuperUser
- Be on wards/clinics—”at elbow”
- Onsite vs remote
- Escalation procedures
- Remote viewing of user experience vs. in-person Super User or IT team member

Barriers to EHR use in ambulatory settings

EHR products are expensive and require a major investment

EHR applications are not standardized

EHRs are more difficult to use than paper-based records

EHR implementation reduces practice productivity and disturbs workflow (at least initially)

EHR benefits accrue to others (such as society and payers) not to providers.

Lorenzi, BMC Medical Informatics and Dec Mak 2009, 9:15

Operating Clinical Computing Systems

Operations entails the day-to-day

- running,
- maintenance,
- enhancement, and
- safeguarding

of the system to meet the

- availability and
- reliability requirements

Slide courtesy of Soumitra Sengupta.

Operations – Trends

- The primary mission of most healthcare organizations care rather than information technology
- Outsourcing specific applications such as EHR
- Managed services with internal systems
- Cloud computing
  - the provision of dynamically *scalable* and often *virtualized* resources as a service over the Internet on a utility basis (Wikipedia)
  - Infrastructure/Platform/Software as a Service (IaaS/PaaS/SaaS)
  - Makes good economic sense due to scales of operations
  - Privacy issues must be addressed
- Models of operational consolidation

Cloud computing

A model for enabling convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction, characterized by:

- **On-demand self-service.** Customers can utilize or release more or less computing resources as needed, and automatically, without the need for human intervention at the cloud provider.
- **Broad network access.** Services are provided over the network in formats that promote access by a wide variety of desktop and mobile client devices.
- **Resource pooling.** The cloud provider pools its computing resources, dynamically allocating and releasing resources like storage, processing, memory, network bandwidth, and virtual machines, to multiple consumers.
- **Rapid elasticity.** The provider's resources can be elastically scaled out or quickly released to scale in, depending on customer demand, giving the customer the appearance that resources are unlimited.
- **Measured service.** The provider monitors and reports consumer usage of services.

CIS transitions and decommissioning of systems

Data transfer risk/benefit

Keep old system for review?

Drivers

- External—E.g. certification, Y2K, ICD10
- Internal
  - Best of breed vs integration
  - Better system now available
  - What is cycle time between systems?

The best phrase to describe change control:

A. A process for pacing functionality change experienced by users when implementing and EHR.

B. Permits assessment of testing of technical features before introduced into production systems.

C. Most consider it a useful but optional step.

D. Is a formal process used to ensure that changes to a system are introduced in a controlled manner.

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ANSWER: D. Is a formal process used to ensure that changes to a system are introduced in a controlled manner.

Change control

Change control requires that updates or changes to software, hardware, or other parts of the infrastructure or application go through testing and analysis of its expected and potential impacts. Those making the change are expected to test changes, understand impacts, notify users, and minimize unexpected side effects. (Chou, Sengupta).

Change control is a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. (Wikipedia)

Example of Change Control Checklist

UW Medicine IT Systems Change Request Criteria Checklist

CRITERIA	RESPONSIBLE PARTY***	COMPLETE? YES	NO	N/A, WHY?
General Info				
1. USD Number for this Change Request				
2. Affected stakeholders have been identified and sign-off on the implementation date has been obtained by the appropriate authorizing party (e.g. – Application Owner, Manager, etc.). See definitions at the following network path: \\file path				
3. List potential impact(s) on real-time patient/business critical systems due to this change (e.g. – Security, Operations, Ongoing system management & support)				
4. List the name of the person or group that has reviewed and approved the technical soundness of the change.				
Documentation				
5. End User documentation has been created (or modified) and distributed to the appropriate parties.				
6. Production support documentation has been created (or modified) and distributed to the appropriate parties.				
7. System/application configuration documentation has been created (or modified) and distributed to the appropriate parties.				
8. Implementation instructions (including implementation monitoring steps) for the group that will implement the changes have been developed, documented, communicated, and accepted.				
9. Back out or other contingency plan has been developed, documented, communicated, and accepted.				
10. Post-implementation validation plan that will involve operations, application support, and customers has been developed, documented, communicated, and accepted.				
11. If the change will affect batch job schedules, database maintenance schedules, remote support capabilities, monitoring, alarming, security, data retention requirements, etc., detailed operational support instructions have been developed, documented, communicated, and accepted.				
Testing				
A. If changes CAN be tested before implementation				
12. Test results summary has been provided at the end of this document. ***				
B. If changes CANNOT be fully tested before implementation				
13. Code review or implementation procedure walkthrough has been completed with successful results.				
14. Post implementation validation and signoff plan has been provided as an attachment to the change request. ***				
15. Back out or other contingency planning has been reviewed with successful results.				

CRITERIA	RESPONSIBLE PARTY***	COMPLETE? YES	NO	N/A, WHY?
Communication				
16. All affected customers, interface groups, and downstream systems required to make corresponding changes have been notified.		List here.		
17. If the change requires downtime, downtime notification procedures are followed.				
18. If the change requires downtime, it is scheduled during approved maintenance window. If no, then why?				
Operations / Maintenance				
19. Software version control standard has been followed.				
20. Security review has been completed (if applicable).				

*** The change request may not be approved without this.

Test Results Summary *(Fill out this section if your changes can be tested before implementation)*

Test Performed By: Test Results Validated By ***:

Test Start Date: Test Completion Date:

The following are some common types of testing and the objective of each testing type. It is not an exhaustive list. The required testing types will depend on the nature and complexity of the change. Please check the boxes (double click) to indicate which testing has been completed with successful results:

- ☐ **Unit Testing** – Tests the basic functionality of the smallest piece of software, without regard to other system components internal or external to a given application.
- ☐ **Integration Testing** – Tests how all system components (e.g. – modules, programs, subsystems, interfaced systems, etc.) interact with each other and with data.
- ☐ **System Testing**- Tests all aspects of a given system or application, e.g. – how well the software satisfies the stakeholders' functionality, security, performance, load, reliability, compatibility, availability, etc. requirements
- ☐ **Back out or Contingency** – Tests the ability to back out the changes being made to a system or, if changes cannot be backed out, tests the contingency plan if modifications cause problems once implemented.
- ☐ **Regression Testing** – Tests to make certain that, with the exception of the change currently being requested, all components of the software's functionality / behavior are unchanged.
- ☐ **Workflow** – Generally conducted by functional (non-IT) representatives, workflow tesing tests whether or not system modifications work well within functional workflow.
- ☐ **Other (Specify)** –

Please itemize functions that worked as expected and functions that did not work below:

Functions tested that worked:
•

Functions tested that did not work:
•

Functions not tested and why:
•

How did differences between test and production environments, if any, affect testing?

Downtime

Definition

- Systems not available to significant group
- Significant functions not available
- Performance has degraded below usable threshold

Planning is essential

Divided between planned and unplanned

Downtime mitigation strategies, policies and procedures should be in place and rehearsed (see SAFER Guides)

Scheduled downtime

Develop and train downtime procedures including patient registration, patient matching, workflow, data access, preparation and backloading from paper

Select optimal time based on

- Schedule of clinical activity and key business
- Availability of internal and external technical resources

Stratify plans by length of planned downtime

Notify user community in advance

True or false?

The most common causes of downtime include human error insufficient system testing of changes.

True or false?

The most common causes of downtime include human error insufficient system testing of changes.

ANSWER: True. Although there are many causes of downtime, human error is a common cause.

Unscheduled downtime

Causes:

- Human error
- Changes in system insufficiently tested
- Software fault
- Hardware or connectivity failure
- Reaching capacity
- Disaster
- Malicious activity

Have and follow plan that includes structured incident command, triage, communication, post-mortem review

Disaster recovery

- Unanticipated large-scale loss of clinical computing functionality and/or data
- Recovery of business operations requires ability to rapidly restore both data and functionality.
- Off-site storage, remote hosting, HVAC and local power generation and communications may be part of this plan.
- Planning, rehearsal, and updating plans will increase risk of success

Operations – Actions when down

Communicate

- Conference calls, emails, personal calls to Sr. Mgmt.
- Right frequency, right timing, with right, relevant details
- If big problem, then have separate technical solution group and User communication group
  - Shield solution group from communication group (no lynching rule – it wastes time)
  - Comm. group triggers business continuity plans, unless it is triggered automatically
- Each affected work area manager and each affected service follows their business continuity plan

Issues when the system is back up

- Are data on paper back-loaded? When, and by whom?
- Are results generated by departmental systems loaded retrospectively?
- Plan transition of orders and medication administration from paper to EHR.
- Pay attention to staff fatigue.

How can we reduce risk?

- Code Updates
  - Avoid the “bleeding edge”, let others go first
  - Limit changes to those that are absolutely necessary
- Downtime Windows
  - Allow resources to adjust their body clock
  - Ensure backup plans for key resources, check-in in advance and keep in contact throughout the downtime
- Vendor Availability
  - Get on the vendor’s activity calendar – Make sure they know what you’re doing ahead of time and that they can support it
- Planning, testing, and post-implementation validation
  - Sufficient test environments, testing tools, and standardized / reusable test scripts
  - Post-Implementation validation should be done by people on the front-lines

Disaster recovery and downtime

Off-site storage needed

Test restore processes

Corruption risks—stagger versions

Rehearse downtime, day and night

To/from Daylight Savings Time

Operations – ITIL

- Information Technology Infrastructure Library is a framework for “IT service management.”
- Developed in the UK by the CCTA (Central Computer and Telecoms Agency) in the 1980’s, initially to cut costs
- Gained recognition in the 1990’s when Microsoft used ITIL as the basis for its Microsoft Operations Framework (MOF)
- Defines the organizational structure and skill requirements of an IT area and documents a set of operational management procedures to foster more effective management of an IT operation and infrastructure
- Portfolio → services → processes → procedures

Operations – Service View

Information Technology Service Portfolio

- A collection of high level, grounded, objectives
- *Manage performance, Secure assets, Manage identities, Plan strategically*

Each folio is a set of Services

- Offered to a user, peer, institution with Service Level Agreements
- *Minimize expected downtime, Manage a reported performance problem, Protect perimeter*

Each service is a collection of processes

- Processes are collection of procedures using a set of tools by a collection of custodians
- Who does what using what?

Each procedure is measured for resource and efficiency, and these collections generate operational metrics

Operations – Actions when down

Solution group

- Needs a General: solution group must be led
- The solution group must have time to propose, vet and try alternatives
- The General and the group focus on alternatives to minimize downtime, *not necessarily* solve the problem
- Pay attention to when to let members of solution group to be fed and relieved
- Involve vendor early, show urgency, demand speed, call their bosses
- Conduct detailed post-mortem for root cause analysis later, if not found as yet

Processes and mechanism that obtain and respond to clinician feedback

- Embedded in clinical world—Rounding, using systems give insights
- Monitoring remotely
- “Feedback button,” “Pizza budget,” meals coupled with feedback sessions are valuable
- Regular communication at meetings, via pages, using ad hoc hallway and clinical setting conversations

[Ozdas and Miller, 2007]

SAFER Guides – AHRQ and ONC

Nine guides organized into three broad groups. These guides enable healthcare organizations to address EHR safety in a variety of areas.

Foundational Guides	• High Priority Practices • Organizational Responsibilities
Infrastructure Guides	• Contingency Planning • System Configuration • System Interfaces
Clinical Process guides	• Patient Identification* • Computerized Provider Order Entry with Decision Support • Test Results Reporting and Follow-Up • Clinician Communication

https://www.healthit.gov/topic/safety/safer-guides

SAFER Guides. Example Worksheet

Domain 1 – Safe Health IT	Domain 2 – Using Health IT Safely	Domain 3 – Monitoring Safety
Hardware that runs applications critical to the organization's operation is duplicated.	Staff are trained and tested on downtime and recovery procedures.	There is a comprehensive testing and monitoring strategy in place to prevent and manage EHR downtime events.
An electric generator and sufficient fuel are available to support the EHR during an extended power outage.	A communication strategy that does not rely on the computing infrastructure exists for downtime and recovery periods.	Functional system downtimes (i.e., unacceptably slow response time) are identified and addressed proactively.
Paper forms are available to replace key EHR functions during downtimes.	Written policies and procedures on EHR downtimes and recovery processes ensure continuity of operations with regard to safe patient care and critical business operations.	Review unexpected extended system downtimes greater than 24 hours using root-cause analysis or similar approaches.
Patient data and software application configurations critical to the organization's operations are backed up.	The user interface of the locally maintained backup, read-only EHR system is clearly differentiated from the live/production EHR system.	
Policies and procedures are in place to ensure accurate patient identification when preparing for, during, and after downtimes.	Users are trained on ransomware prevention strategies including how to identify malicious emails.	

https://www.healthit.gov/topic/safety/safer-guides

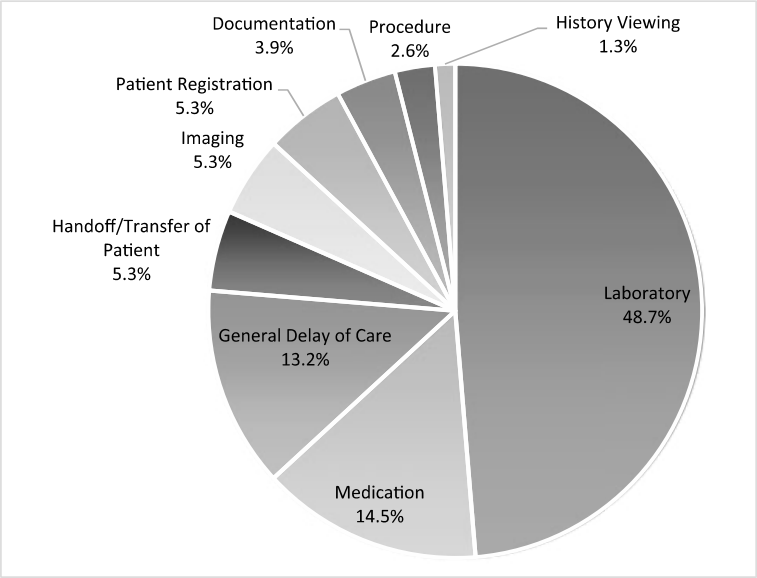
Clinical impact of scheduled and unscheduled system downtimes

Downtime procedure adherence

Table 2. Downtime procedure adherence

Code	Definition	Frequency of Occurrence
Yes	Report indicates downtime procedures were properly and successfully executed.	21
Insufficient Information	Report content does not mention downtime procedures, so no conclusion could be drawn.	20
Failure	Downtime procedures described and improperly executed, or it is explicitly mentioned that no downtime procedure exists.	35

Laboratory and medication incidents most common



Larsen JAMIA 2017; 25(2), 2018, 187–191

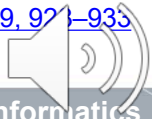
Clinical impact of intraoperative EHR downtime

Surgical patients at Mayo Clinic

2047 downtime incidents were identified over the 6-year study period involving the 7 EHR applications

- EHR downtime had no impact on 30-day mortality
- Possible association with increased postoperative LOS and OR time

Harrison 2019; 26(10), 2019, 92[illegible]–933



Organizational Strategies Necessary to EHR safety

- Care-process transformation
- Patient safety
- Human-factors engineering
- Software safety
- Project management
- Continuous improvement

Walker 2008

EHR Optimization

Post-implementation focus on features and functionality that have been incompletely or sub-optimally adopted.

Review of workflow and tailored education.

Use of EHR to assist in meeting organizational quality, safety and financial goals.

Clinical computing systems and compliance

Documentation, orders, results review and other tasks and audit trails scrutinized by compliance are increasingly accomplished using computing systems

- Compliance officers charged with protecting the organization may not have full understanding of clinical computing system functionality and workflow

Compliance and DOJ focus on cloning, upcoding, copy/paste

Clinical computing systems and the law

The importance of authentication and authorization

Concept of non-repudiation

Audit trails, document version history

Close cooperation with compliance and general counsel

Key Readings

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