

# Session 4.07 - Accountability for Use or Disclosure of a Patient's Electronic Record

Requirements for a Security and Privacy Audit System

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## Session Objectives

- To review the regulatory requirement for a system of accountability
- To identify possible sources of standards for what such a system should be
- To define the key goals and objectives for a system of accountability
- To discuss how to determine key events of interest for logging accesses to a record
- To identify key information for logging to an access audit log
- To discuss key requirements for analyzing logged access events





## A System of Accountability

- Per the Privacy Rule the explicit requirement is
  - To provide for an accounting of disclosures of certain types (from any source – paper, electronic, oral)
- Per the Privacy Rule the implicit requirement is to support monitoring compliance with the Privacy Policy and Practices of the organization





## A System of Accountability

- Per the Security Rule the explicit requirement is to have in place audit control mechanisms to record and examine system activity
  - Entities have flexibility to implement the standard appropriate to the requirements of their own risk analysis
  - Should focus on assessing activities regarding protected electronic health information
- Clearly distinct from the accounting of disclosures requirement of the Privacy rule this does not satisfy that but does complement the objective to satisfy that but does complement the objective to uphold organizational accountability for use or transmitted wildisclosure of the electronic record per their MINA





- ASTM Guidelines (E2147-01)
  - A system of audit for electronic health records should
    - Be designed to provide a precise capability for organizations to see who has accessed patient information
    - Document and maintain a permanent record of all authorized and unauthorized access
    - Support audit of the use or disclosure in accordance with regulatory, legal, accrediting and consumer requirements for accountable privacy practices







- Per ASTM E2147-01, An audit system should be (Key items)
  - A record of actions performed on data by users
  - Identify and track user accesses in highly secure logs separate from the subject of the access events
  - Maintain before and after states of content linked to the patient record
  - Record and maintain information concerning breaches of access with notification capabilities
  - Allow for easy retrieval for analysis
  - Provide search capability by user and patient ID, type of data accessed, type of access event, etc
  - Support real time logging and retrieval
  - Help maintain chronology of the state of the access







- NIST 800-14 Principles and Practices for Securing IT Systems
  - Audit Trails
    - Should support individual accountability by tracing user actions
    - Should support reconstruction of user actions by after the fact investigation of how, when and why
    - Should support intrusion detection as the events occur or after the fact
    - Should support problem identification through auditing and monitoring







- HL7 Proposed Common Audit Message Guidelines
  - Key Objectives of Privacy and Security Policy Relevant Data Exchanged Between Systems
    - Provide data to support evidence of compliance with and violations of a healthcare enterprise's security and privacy policies
    - Depict the data that would reside in a common audit engine/database
    - Allow useful queries against audited events





## To Sum - Privacy v. Security Accountability

#### **Privacy Interests**

- -Confidentiality Upheld
- -Accountability to Patient
- -Proper Use and Disclosure
- -Focus on Personal Health Information

#### **Security Interests**

- -Need to Know Enforcement
- -Accountability of Authorized Users
- -Intrusion Detection and Forensic Audits
- -Recreate the State of the User Access



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## Where to Start - Scope of Auditing

What kinds of audit logging do you have today for patient record accesses?

- For what applications
- For what types of data
- How are the audits used

What policy objectives are supported by this auditing?

What other audit logging is performed?

– How is this information used?

How are changes to reference data audited?

– How is this information used?







## Priority and Scalability of Audit Logging

#### How much audit information should be logged?

- At what level of depth?
- How should the volume of audit logging be controlled?
- When is full audit logging needed?
- When is exception based audit logging needed?
- How are exceptions defined for logging?







#### Audit Log Data Requirements

Are there different kinds of audit log entries or events?

For security related audit logging, what data elements are important?





## Audit Log Viewing and Analysis - Security

For security related auditing, what routine reviews of audit data are used?

- Review of need to know policy?
- Fine tuning of access controls by organizational unit?
- Policing common kinds of heuristic analysis?
  - What kinds of predefined reports are used?
  - What ones are desired that are not available?
  - How would you want to manipulate the views of data?

When would you prefer an alert or notification to a report?

- How should the alert occur?

When is sampling appropriate? By what methods?





## Audit Log Viewing and Analysis - Security

How do you do pattern analysis of audit data?

– What information is useful for doing pattern analysis?

If you were to set up monitoring for particular kinds of accesses such as abuses or violations, how would you do this?

– When would you do this?





## So As To Electronic Systems Maintaining Patient Information

#### What are some key events that should be audited?

- Authentication Events and Session Events
  - · Log on failures
  - Abandoned sessions
- User Security Profile Modifications
- End User Access to Personal Health Information
  - Operations to Create, Modify, Verify/Complete, Error Correct, Query or Print PHI
- How Deep and How Broad?
  - Does the Requirement Differ By Type of System?
  - To What Depth? Persons? Visits? Clinical Data Objects Such As Orders, Results, Documents, etc?







### Inventorying What Is Available

- Critical to understand what audit event data sources are there
  - In current systems
    - How do systems represent end user operations?
    - Are they auditable?
    - What data is available?
    - How is it made available for logging?
      - Activity Data State Change Logs?
      - History Logs?
      - Transaction Logs?
    - Do you need a common mapping of an audit schema?
      - Interleafing to one repository?
      - Each patient record keeping solution have its own?
    - Where to reposit the data





#### Auditable Events As Accesses

Auditable Events Can Work to Be Primary Events or Access Paths

Person/Patient Searches

**Clinical Event Accesses** 

Visit Accesses

Auditable Events Can Work to Be Secondary Events Associated to a Primary Access

**Reviewing Order History** 

**Examining History for a Clinical Document** 

Auditable Events Can Be Query Actions Only or Represent End User Operations Upon Data

Auditable Events Can Be Print or Output Events

Auditable Events Can Be Ad Hoc Report Writer Accesses

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## Audit System Overview

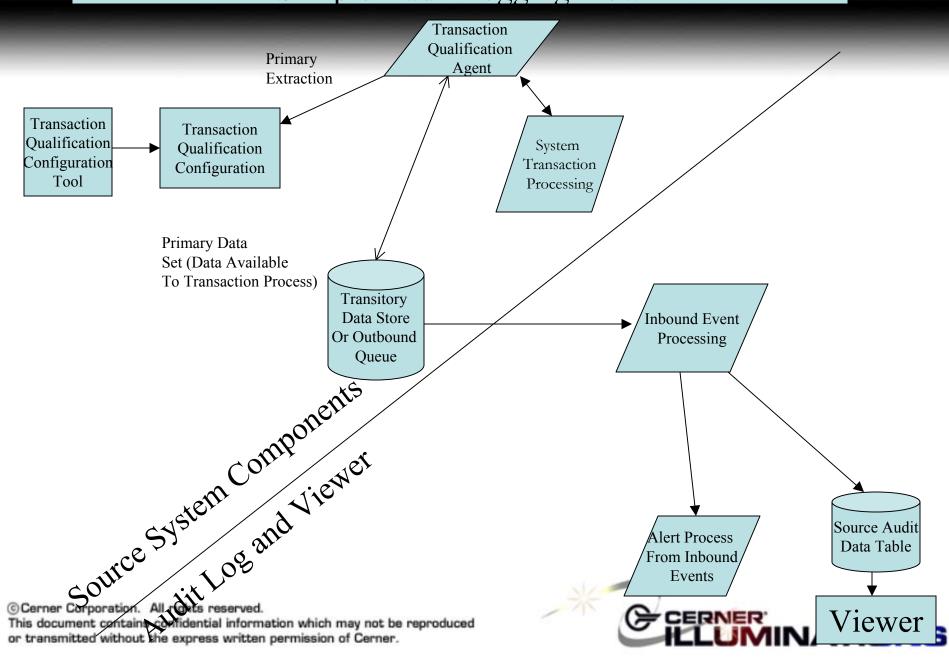
#### Basic Architectural Requirements to An Audit Solution

- Allow for specific events to be identified as those that view/add/modify targeted information
- The healthcare entity needs to be able to determine which of those events are to be audited
- When a user accesses a electronic patient record to commit a particular operation, the system captures information regarding the access through some process understanding of the operation execution for those events tagged as auditable
- The audit event information is passed to an audit repository
- Authorized users can view audit information





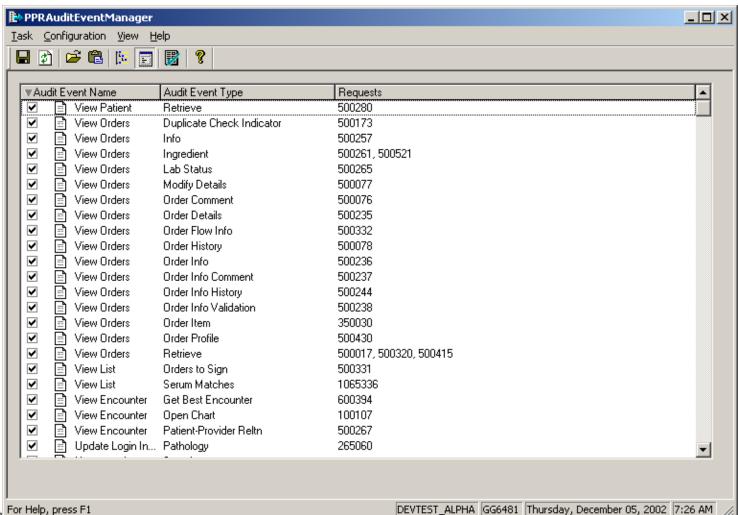
#### Sample Audit Logging Flow







#### Qualifying Auditable Events - One View



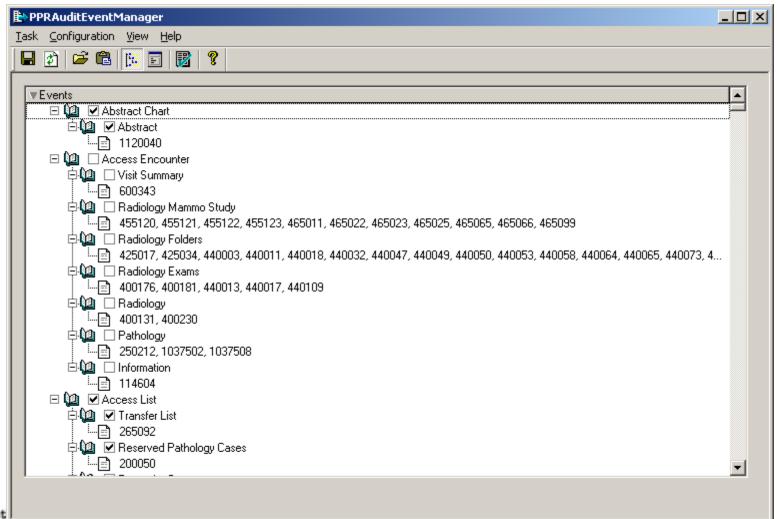
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#### Qualifying Auditable Events - One View



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## Some Typical Basic Analysis of Audit

#### **Events**

**Access by Patient** 

Access by Encounter

Access by User

**Access by VIP Patient** 

**Access by Confidential Patient** 

**Access by PC Location** 

Access by Relationship Type to Patient

Access by Audit Event Type





## Some Key Types of Audit Log Data Columns

Event Date & Time

Outcome Indicator

User ID

User's full name

User's position/role

Application Task/Function

Person ID

Person name

VIP code

**Encounter ID** 

Organization of Encounter

Medical Service

Location

**Encounter Confidentiality** 

Encounter Type

Encounter Status

Admit date & time

Discharge date & time

Encounter MRN

**Encounter FIN** 

Reason for relationship creation

Relationship creation date/time

Relationship created by

Relationship creation type

Relationship type

Participant Object Data Set

Type

ID

Alias

Operation





Accesses by Visit

Accesses by User

Accesses by Device

Accesses to VIPs

Accesses by Event Type

Accesses by Relationship Type

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## Possible Examples of Relating Events to Views and

Analysis Uses			
View Type	Significant Events	Key Uses	
	_		

Person Searches, Person Inquiries through Registration or Common Monitor Possible Surfing

Searches

Relationship Access, Visit Inquiries

through Registration or Common

Person Searches, Visit and Person

Inquiries, Clinical Data Accesses

Person Searches, Relationship use,

Self Declared Accesses, Proxies,

Administrative Relationships,

Person and Visit Accesses, Sensitive

**Person and Visit Accesses** 

Clinical Event Accesses

Person Inquiries through

Visits when Visit Inquiries through Registration

Registration

**Overrides** 

Searches

Monitor Access Patterns to Visits,

Monitor Access Patterns by a User, Examine Possible Suspect Cases.

Monitor Time of Day Access Issues

Monitor Differences in User and

Monitor Sensitive Clinical Event

Monitor Accesses to Sensitive

Accesses, Monitor Suspect Access

Monitor Use of Self Declaration and

Overrides, Monitor Use of Proxies

Monitor Mecesses to Sensitive Visits

Monitor Differences in User and

**Patient Location** 

**Patient Location** 

Events by Type

**Persons** 

**Accesses by Person** Monitor Access Patterns to Persons,



	Possible Examples of Relating Rey Filtering or		
Searches to Views			
View Type	Filtering or Search Criteria		

View Type Filtering or Search Criteria

To a specific person, To a specific person by a user, To a specific Accesses by Person person by time period, etc

Accesses by Visit To a specific visit, To a specific visit within a time period, To a specific visit other than by certain relationships

By a specific user, By a specific user of a particular event type, By a Accesses by User specific user to a person or visit, By a specific user within a time

period **Accesses by Device** By a specific user, By a specific user to locations not expected, At

certain time periods

Accesses by Event Type For specific event types, For specific event types to particular sensitive data, For specific event types to particular sensitive data

by users within or not within certain positions

Accesses to VIPs By a specific user, For a time range, By users not within certain positions

Accesses by Relationship Type For overrides, for self declared relationships, By specific users to specific patients

Accesses to Confidential Visits By a specific user, For a time range, By users not within certain positions

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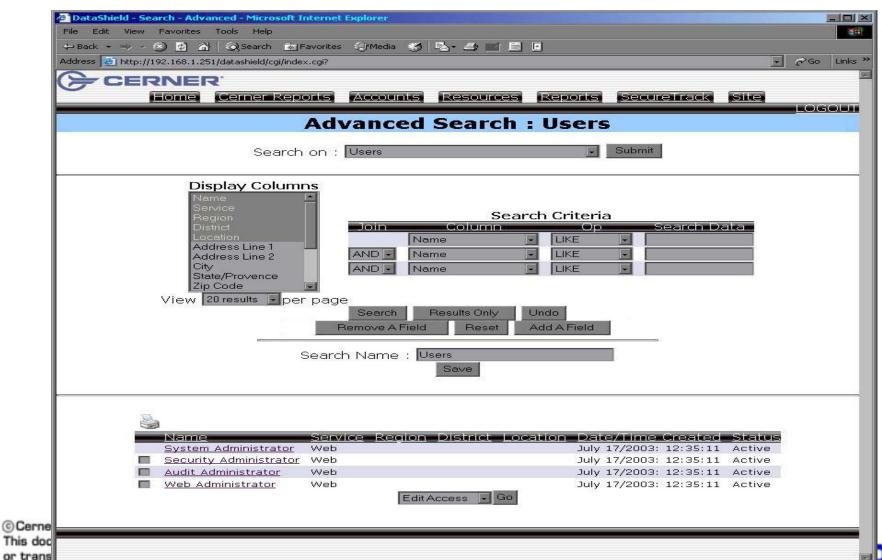
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## The Importance of a Search Engine







#### Sample Report View







#### Case Tools

What do you do with audit data when you suspect an abuse?

- How do your auditors document investigative steps?
  - How are findings documented? Recommendations?
- When you have a suspected violation, how does this get reported?
  - To whom? In what format?
- How does the recipient of the notification respond?
  - Does this get documented?

If you have to respond to an internal or external auditor, how do you show them you have an occurrence of fective system for identifying suspected





#### **Sample Case Tools**







#### Summary

- -Important to have policy objectives in mind for use of audit system
- -Critical to understand what audit event data sources are there
  - -In current systems
    - -How do systems represent end user operations?
    - -Are they auditable?
    - -What data is available?
    - -How is it made available for logging?
    - -Do you need a common mapping of an audit schema?
    - -Where to reposit the data?
  - -Analytical Requirements?
    - -What kinds of views do you need?
    - -Do you need to be able to define case studies?
    - -Do you need alerting?







#### Sources

- -ASTM Citation E2147-01 Audit and Disclosure Logs for Use in Health Information Systems (http://www.astm.org)
- -HL7 Citation Common Audit Message HL7 Security and Accountability Working Group (www.hl7.org)
- -NIST 800-14 Generally Accepted Principles and Practices for Securing Information Technology (http://www.itl.nist.gov/lab/specpubs/sp800.htm)
- -Common Criteria v 2.1 Functional Requirements Section 3 Security Audit (http://csrc.nist.gov/cc/Documents/CC%20v2.1/p2-v21.pdf)







#### Questions?

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