An Evaluation of EHR System Audit Functions in a Saudi Arabian Hospital

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Abstract. For both medical and legal reasons, hospitals adopting electronic health record (EHR) systems need to have comprehensive audit functions to ensure the integrity, security, and accuracy of data held in the records. Given the increasing use of EHR systems in Saudi hospitals, this paper aims to evaluate the key audit capabilities/functions and establish the level of compliance of the EHR system installed at King Abdul-Aziz Medical City (KAMC) hospital in Riyadh. A survey team conducted the evaluation of 17 different audit functions using an audit vignette in a test domain. The results of the evaluation showed that the category "event/transaction audit accessibility and display quality" (one function) had 100% compliance, "audit accuracy and comprehensiveness" (five functions) had 80% compliance, "system function and audit accuracy and comprehensiveness" (two functions) had 50% compliance, and "observation, comparison of narrative and audit" (nine functions) had 67% compliance. Overall, 12 out of the 17 functions (71%) fulfilled compliance and five functions received a score of zero (function not in evidence or not user accessible). The overall compliance level of 71% shows that the EHR audit functionalities are in general well established and fulfill the basic demands of the audit. The system's five non-complying items were found to be specific use requirements due to the delay in the implementation of phase II of the EHR system. The evaluation should be repeated when the EHR system is fully implemented in order to evaluate whether the level of compliance has increased. Similar evaluations of EHR system audit capabilities should be made in other hospitals in Saudi Arabia.

Keywords. Electronic health record system, audit functions, compliance, Saudi Arabia, hospitals

1. Introduction

Electronic health record (EHR) systems provide various benefits for healthcare, including having positive effects on outcomes such as the efficiency of care, the effectiveness of care, the reduction of error rates, and the reduction of healthcare costs [1,2,3]. Given the importance of EHR systems to the better management of healthcare, and the growing rates of EHR system adoption in both primary and hospital care settings, aspects of the integrity and accuracy of the data contained in EHRs have come to the forefront of interest in both the medical and legal domains. In the medical domain, documentation serves as a basis for high quality patient care by providing

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longitudinal records of symptoms, diagnoses, and treatments, and in the legal domain protects the legal interests of patients, physicians, and organizations [4].

With information increasingly being held in the electronic domain, and the different requirements for the protection of electronic information compared with previous paper-based systems, privacy issues have accordingly been highlighted. Both patients and physicians have concerns about the integrity and privacy of information held in EHRs, with concerns including information being accessed for mischievous purposes and security and privacy procedures not always being followed by those with access to EHRs [1]. In EHR systems, audit functions are essential to protect the accuracy, integrity, and security of health data, and the privacy of patients, by recording all instances of access to sensitive information including any actions taken on the data, when data were changed, and by whom. The American Health Information Management Association (AHIMA) defines data integrity as the "accuracy, consistency, and reliability of information content, processes, and systems" [5]. In these respects, audit functions in EHR systems are a vital component, given the particular characteristics of electronic information (compared with paper-based information) and the increasing electronic interconnectedness of healthcare organizations.

The integrity of health records is maintained through access, network security, audit trails, security, and disaster recovery processes [5]. However, EHR system auditing is currently in its infancy, and the needs of health information management regarding robust auditing and record verification functions are not necessarily matched by EHR product features [6,7]. Gelzer [7] made a candid assessment of auditing EHR systems by highlighting the unique challenges posed by such systems concerning accountability. However, Gelzer suggests that even a simple testing protocol will quickly reveal strengths and weaknesses. Such a protocol involves testing the usefulness of a system's audit functions, the accuracy of the author/signer of documentation, and how the system regards and reports alterations to records. Audit reports should be able to be generated either by individual patient or by individual user [8].

1.1. Research Objective

There is a need for health organizations to implement controls to safeguard data and information in EHRs from unauthorized intrusion, corruption/loss, accidental destruction, and intentional tampering/falsification. Audit systems are able to create a health information audit trail that allows establishment of accountabilities for the transactions and activities, and compliance to be measured with respect to organizational policies, procedures, and protocols regarding EHR access and maintenance [5]. In Saudi Arabia, EHR systems are in the process of being adopted in various hospitals, although with differential adoption rates according to region. Bah et al. [9] found that three of 19 MOH (public) hospitals in the Eastern Province of the country had implemented an EHRS. In Riyadh, 11 of 22 hospitals surveyed had implemented fully-functioning EHRSs, and eight had systems in progress [10]. However, whether the installed systems have comprehensive and robust audit capabilities is not yet known. Therefore, the objective of this paper is to evaluate the key audit capabilities and functions, and establish the level of compliance, of the EHR system installed at King Abdul-Aziz Medical City (KAMC) hospital in Riyadh, Saudi Arabia. KAMC hospital is one of the 11 hospitals in Riyadh with fully-functioning systems, and was chosen for the study as it is one of the most advanced healthcare

facilities in Saudi Arabia, including with respect to its integrated clinical information system.

1.2. KAMC Hospital and its EHR System

In Saudi Arabia, approximately 20% of healthcare provision is provided by non-profit government institutions such as National Guard Health Affairs (NGHA) hospitals and referral hospitals (combined total of 39 hospitals, 10,822 beds) [11]. The four NGHA hospital complexes ("medical cities") are located in Riyadh, Jeddah, Dammam, and Al Ahsa. King Fahad National Guard Hospital in Riyadh commenced its operations in May 1983. Since then, it has expanded and provides a wide range of services for a rapidly growing patient population. The hospital, along with other medical facilities, has evolved into an integral part of KAMC hospital. In the short period since its inauguration in February 2001, KAMC hospital has become recognized as a healthcare provider of distinction. The capacity of the hospital is currently 690 patient beds, in addition to 25 beds allocated for surgical operations, and 132 beds for emergency cases. KAMC hospital provides National Guard personnel, their eligible dependents, and Saudi Arabian citizens who suffer from Stage 3 medical and surgical illnesses with high quality primary, secondary, and tertiary healthcare services.

In September, 2004 KAMC hospital's Clinical Information Management Systems Department introduced QuadraMed's Computerized Patient Record System. The implementation was phased over two stages. Phase I included Patient Administration/Chart Management, Enterprise Scheduling, Medical Records, Abstracting, Order/Result Management, Pathology and Laboratory Medicine System, Care Coordination (Nursing Basic), Medication Management, Radiology, Longitudinal Clinical Data Repository/Chart Review and Pharmacy. Phase II implemented started in October 2007 and included Advanced Nursing. Assuring the integrity and accuracy of the integrated data is one of the principal objectives of the hospital, which relies on valid and up-to-date information to assess and improve the quality and quantity of healthcare.

2. Methodology

2.1. Site Visit Survey

A survey team visited KAMC hospital and performed an on-site audit during October and November 2010. The team conducted a testing and evaluation protocol for highlighting key EHR features and functions that pertain directly to, or support the auditing of, the documentation events in an EHR. These functions are a means to ensure and prove that documentation has not been modified or deleted without proper alerts. Two main tasks were conducted: A thorough review of the system audit functionality by observation, comparison of narrative, audit, and screen views; and interviews with back-end users of the Integrated Clinical Information System (ICIS).

A test vignette was used to evaluate the features, functions, performance, and output of the KAMC HOSPITAL EHR system. Test vignettes are scripts that portray "common documentation events, processes, and procedures that occur during an encounter" [12]. Generally, the information in the script is entered by system users while evaluators observe and measure. Documentation resulting from the test process is

assessed according to professional documentation principles. Here, an audit vignette [13] was performed on a test (scenario) domain so that patient confidentiality was preserved. The back-end users were not shown the script and were given instructions as needed. The script of the audit vignette is contained in Appendix 1.

2.2. Data Analysis

The Audit Function Rating Form used to evaluate the audit functions of ICIS was taken from Trites and Gelzer [13] and was organized into four main categories of tested function or event/transaction: 1. "Event/transaction audit accessibility and display quality" (tested using one item); 2. "Audit accuracy and comprehensiveness" (tested using five items); 3. "System function and audit accuracy and comprehensiveness" (tested using two items); and 4. "Observation, comparison of narrative and audit" (tested using nine items). The test methods used were: 1. Observation (for category 1); 2. Observation, comparison of narrative and audit (for categories 2 and 3); and 3. Observation, comparison of narrative, audit, and screen views or the printed output (for category 4).

Function scoring was performed using: (i) Weight: A. Overweight = 15; B. Standard weight = 10; and C. underweight = 5. In this study, weight for all items was set to a value of 10 so as to avoid bias across items and retain comparability [13]. (ii) Importance: A Critical = 4; B Required = 3; C Desirable = 2; D Useful = 1; DNA = 0. In this study, importance for all items was set to a value of 1 so as to avoid bias across items and retain comparability. (iii) Grade: A Superior = 5; B Acceptable = 4; C Acceptable with remediation = 3; D Not acceptable, remediation needs further evaluation = 2; E Not acceptable, no means of remediation = 1; F Not in evidence, not user accessible = 0.

The score for each item (function) was calculated by multiplying the weight by the importance by the grade. Because weight was set to a value 10, and importance to a value of 1, scores ranged between 0 and 50, reflecting the variation in grade assigned to each function. Thus, scores of 0-30 were deemed to indicate function non-compliance (needing remediation), and scores of 40-50 were deemed to indicate function compliance.

3. Results

The results were collated into four tables (Tables 1–4). When the event/transaction audit accessibility and quality display was tested through observation of the system (Table 1), the score was 50/50 (100%). Audit accuracy and comprehensiveness was tested over five items (Table 2), with four of the five items (80%) having compliant scores.

Table 1. Scores for tested category of event/transaction audit accessibility and display quality.

Item No.	Item Line in Vignette	Expected Result	Score
1	(General)	Audit is accessible on demand by appropriate administrative user and can be readily understood.	40

Table 2. Scores for tested category of audit accuracy and comprehensiveness.

Item No.	Item Line in Vignette	Expected Result	Score
1	1-26	Audit accurately represents each action executed by User 1.	40
2	20-21	Summary information functions, such as recorded and compiled family history, will record inputs, changes and their authors (and view-only events).	0
3	27	Audit accurately represents change in user authorship control.	40
4	29	Audit accurately represents change in authorship control.	40
5	31	Audit accurately represents information view actions that do not involve information input by user.	40

The testing of system function and audit accuracy and comprehensiveness was performed using two items and measured using observation, comparison of narrative and audit (Table 3). The overall rating result was 50%, with one function being compliant and the other not. The results of testing the function of observation, comparison of narrative and audit through observation, comparison of narrative, audit, and screen views or the printed output covered nine items (Table 4). A rating total of 67% was achieved, i.e., six out of the nine functions achieved compliance.

Table 3. Scores for tested category of system function and audit accuracy and comprehensiveness.

Item No.	Item Line in Vignette	Expected Result	Score
1	34-38	Systems vary in user tools. Where users utilize the same tools, in some systems have provider users overwrite information input by intake staff and deemed possibly inaccurate. Regardless of the system design, all authors' recorded information must be preserved and viewable on demand in the system.	40
2	36-38	Summary information functions, such as recorded and compiled family history, will record inputs, changes and their authors (and view-only events).	0

Table 4. Scores for tested category of observation, comparison of narrative and audit.

Item No.	Item Line in Vignette	Expected Result	Score
1	40	Vital signs and other recurrent data areas accessed by different skill-leveled staff will accurately represent input authors, dates, times, and changes.	40
2	41 and 42	The system represents abbreviations or other means of summarizing basic findings accurately and does not automatically expand to a lengthy narrative list of the components. The system accurately differentiates between summary examination and detailed examination.	0
3	42	The summary finding is accurately represented and does not automatically expand to a detailed component narrative.	0
4	45	Default functions, if available, can be readily distinguished from unique, new, author-originated information	40
5	51-58	Exiting clinical information recording screens ideally will trigger a save of an iteration of documentation in progress and will be evidenced in the audit.	40
6	60-61	Exiting and re-entering then modifying clinical information recording screens will be evidenced in the audit.	0
7	63-67	The audit accurately represents each action executed by User 2.	40
8	69	Signature/closure events will be readily distinguished.	40
9	71-72	Amendments and other changes to finalized documentation will be readily distinguished in the audit.	40

The overall evaluation result for the audit functions of the KAMC hospital EHR system, comprising the four categories assessed (event/transaction audit accessibility and quality display; audit accuracy and comprehensiveness; system function and audit accuracy and comprehensiveness; and observation, comparison of narrative and audit) was that 12 out of 17 functions (71%) received compliant scores, and five functions received scores of zero (function not in evidence or not user accessible).

4. Discussion

Compliance involves ensuring that actions and events fall within the boundaries of best practices and legal regulatory and relevant certification requirements for the healthcare organization of interest. The overall process involves seven steps that an organization can use as a road map for due diligence for its specific EHR implementation [13]. Identifying compliance gaps is the fifth step in the due diligence process. In the testing reported here, compliance gaps (i.e., those items scoring zero in Tables 1-4) were identified. Compliance gaps should be mitigated in accordance with the American Health Information Management Association's (AHIMA) 2005 practice brief 'Maintaining a Legally Sound Health Record' [5], while also keeping the organization's internal policies and procedures in mind. Trites and Gelzer [13] provide an account of the requirements for a compliance-capable EHR system with respect to its audit functions, which are contained in Appendix 2 (it should be noted that several evaluation groupings besides audit functions are recommended to be assessed for full compliance capability including, amongst others: author, authentication, and timeliness; documentation principles; amendments; and documentation and coding [13]). The problems represented by the gaps found in this study were identified according to the requirements and options for mitigation which are assembled into five

broad categories for use in mitigation evaluations [13]: 1. Mitigation not required, not applicable = NA; 2. Specific use requirements needed = SUR; 3. Enable, Constrain or Disable function required = ECD; 4. Augmentation Required—Automatic = ARA; and 5. Augmentation Required—Manual = ARM. In this study, most functions were found to be compliant, and mitigation for these items was therefore not required. Table 5 contains the mitigation report for the five items that scored zero in the evaluation of the audit functions, i.e. requiring some form of mitigation. In the case of the KAMC hospital, the results for these items indicate that the functions were not in evidence due to specific use requirements (SUR). These functionalities will be added by the hospital when phase II of the implementation of the EHR system has been completed.

Table 5. Mitigation report for items that did not achieve compliance.

Tested Audit Function or Event / Transaction Category	Item No. In Category	Expected Result	Mitigation Plan
Audit accuracy and comprehensiveness	2 (Table 2)	Summary information functions, such as recorded and compiled family history, will record inputs, changes and their authors (and view-only events).	SUR*
System function and audit accuracy and comprehensiveness	2 (Table 3)	Summary information functions, such as recorded and compiled family history, will record inputs, changes and their authors (and view-only events).	SUR*
Observation, comparison of narrative and audit	2 (Table 4)	The system represents abbreviations or other means of summarizing basic findings accurately and does not automatically expand to a lengthy narrative list of the components. The system accurately differentiates summary examination and detailed examination.	SUR*
Observation, comparison of narrative and audit	3 (Table 4)	The summary finding is accurately represented and does not automatically expand to a detailed component narrative.	SUR*
Observation, comparison of narrative and audit	6 (Table 4)	Exiting and re-entering then modifying clinical information recording screens will be evidenced in the audit.	SUR*

*SUR = specific use requirements.

Audit functions of an EHR system represent part of a health care security management program, whereby users' knowledge that the process and content of clinical documentation can be utilized to detect unauthorized/fraudulent/inappropriate behavior provides a deterrent to such behavior [14]. However, although various technological solutions are available to help protect patients' information, privacy policies are also needed. EHR access and privacy policies provide essential support for audit tools [15], but such privacy policies need to be clear in their purpose and scope if they are to be effective [1]. Unless policies are clear and communicated to staff, and their adherence agreed to, then staff members cannot be disciplined [8]. Access permissions (create, read, update, and delete) for the data need to be set for users. The audit-policy tandem then allows a determination of whether the access was necessary to perform work duties (legitimate behavior), and if there is a problem (unauthorized/fraudulent/inappropriate behavior), what action should be taken. In this study, for reasons pertaining to confidentiality, EHR privacy and access policies for

KAMC hospital employees were not able to be obtained for examination. However, given the recommendations provided by the relevant literature, KAMC hospital should ensure that an effective audit-policy tandem is in place in the institution.

5. Conclusion

This investigation set out to evaluate the audit functions of the EHR system installed at KAMC hospital in Riyadh, Saudi Arabia. The results of the evaluation showed that EHR system audit functionalities, in general, are well established and fulfill the basic demands of the audit functionality. Among the tested functionalities, "event/transaction audit accessibility and display quality" achieved 100% compliance, "audit accuracy and comprehensiveness" achieved 80% compliance, "system function and audit accuracy and comprehensiveness" achieved 50% compliance, and "observation, comparison of narrative and audit" achieved 65% compliance. The overall compliance level was 71% (12 out of 17 tested functions were compliant). The system's five non-complying items (function not in evidence or not user accessible) were found to be specific use requirements due to the delay in the implementation of phase II of the EHR system. Therefore, it is recommended that another evaluation take place after the second phase of the project is implemented, which will indicate the extent of the organization's commitment to gap mitigation. Also, given the general lack of information regarding EHR system audit capabilities in Saudi Arabian hospitals, similar evaluations to the one reported here should be made in other hospitals.

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Appendix 1: Audit Vignette Used for the Study

Notes: (1) Vignette taken from Trites and Gelzer [13] pp. 24-25 (original used with permission from Advocates for Documentation Integrity and Compliance, LLC); (2) Line numbers relate to items specified in Tables 1-4.

1   **Purpose:** To demonstrate key attributes of an EHR's audit capabilities and functions.
2
3   **Set Up Introduction and Instructions**: An established patient presents with a scheduled
4   appointment for a follow-up visit. The patient has previous medical history, social history,
5   medications, laboratory results, and radiology information in the system but no family history.
6   The setting is an office where one staff member (Intake, User 1) gathers initial information from
7   the patient and records it in the system. Then, that Intake staff member, using system tools,
8   conveys the information to the provider (Clinician, User 2) who will be performing an evaluation,
9   making a diagnosis, and determining treatment.
10
11   User 1 logs into the system, selects the appropriate patient, and creates or identifies the proper
12   encounter event for this patient.
13
14   User 1 then documents the following information:
15   1.   Chief complaint of headache
16   a.   Mild, right frontal only
17   b.   Lasting 3 days
18   c.   Relieved by over-the-counter medications
19   d.   No other symptoms noted
20   e.   No family history of migraine-type headaches
21   f.   No family history of stroke
22   2.   Follow-up visit from visit 2 weeks ago for blood pressure medication review, blood
23   pressure medication dose had been increased at last visit. No problems with the new medication,
24   no dizziness, lightheadedness, or cough.
25   3.   Vital signs recorded (T 98.6 Oral BP 110/70, P 72, R 16)
26
27   User 1 then executes the actions that transfer the encounter to User 2.
28
29   User 2 logs into the system and identifies the appropriate patient and encounter.
30
31   User 2 reviews prior information, using those tools available for reviewing the prior encounter
32   where blood pressure medication changed.
33
34   Patient advises that headache actually severe, had not wanted to discuss with User 1. The pain
35   was relieved only by using spouse's acetaminophen with codeine, last dose taken yesterday
36   evening. No medications today. Patient recalls father did have a stroke in his 40s but recovered
37   all function sufficiently to return to work. Patient also notes concerns that he/she seems to be
38   tripping over things past 3 days.
39
40   Physical examination: Constitutional normal BP repeated 110/72 P 72
41   HEENT No facial asymmetry, PERRL, EOMI
42   Lateral gaze to both right and left challenged
43   Funduscopic examination normal

44   Neck: Carotid bruit on left side of neck
45   Chest: (Default Normal if function available in system) Clear to auscultation
46   Cardiac: Normal S1, S2, no S3 or S4
47   Abdomen: No organomegaly, no tenderness, normal bowel sounds, midline bruit above
48   umbilicus but no pulsatile mass
49   Extremities: Upper and lower extremity strength normal and symmetrical but R. patellar reflex
50   greater than left, also Achilles but biceps symmetrical
51   **Impression:**
52   Neural deficits right lower extremity, stroke vs. mass
53   Vascular disease
54
55   **Plan:**
56   CT scan with contrast ASAP.
57   Discuss with family members regarding emergency intervention if symptoms change.
58   Complete blood count, chemistry profile ordered.
59
60   User 2 decides to listen again to patient's neck. Neck auscultation repeated, bruit now heard on
61   both left and right, left is louder.
62
63   User 2 signs encounter back to User 1.
64
65   Follow up instructions given by User 1:
66   CT scan scheduled for today 4 p.m., Ibuprofen only for pain.
67   Call or go to emergency department if symptoms worsen.
68
69   Completed encounter documentation is signed by the provider.
70
71   Provider creates an addendum/amendment to refer to neurology department and return to office
72   in two days to review CT scan.

Appendix 2: Guidelines and Recommendations for Support of a Compliance-Capable EHR: Audit Functions

Minimum Requirements	Highly Recommended
1. The system will have an audit function that meets organization requirements for capturing specific information as identified in medical records policies and procedures.	1a. System demonstrates capture of all information per a specific checklist inventory of requirements mapped to the practice/organization medical records policies/procedures, for example date, time, user identification, data entered, device/source, etc.
2. System will have a user-friendly capability for displaying and exporting an encounter-specific documentation event audit report that includes all information captured for item 1. above.	2a. Display and output will be a normal system function and not require unique programming, special skills, or significant costs.
3. The audit captures all required data at all times and cannot be disabled (or cannot be disabled without extraordinary, secure, restricted administrative actions.)	3a. System will not support an ability to disable HIPAA-required access reporting so that, if documentation event audits are nonfunctional, access audits will at least provide reliable, auditable evidence of encounter access.
4. If the audit functions are not operating normally and correctly, users are notified by an alert that requires the user indicate acknowledgement before continuing use.	4a. If documentation audit functions are not operating correctly, data entry cannot occur.
	4b. If continued data is permitted, an additional administrative authorization is required.
5. If the audit is not operating normally and correctly, viewing patient information continues unimpaired.	5a. The system supports a method for recording encounter information created in the course of executing the practice/organization's contingency plan for documentation when the system is not operating correctly and normally.
6. Event recording in the event audit will include any attempts to access audit functions and any episode of malfunction of the audit.	
7. The audit records data entry of all types and from all sources into the EHR, including keyboard, scanned, voice recognition, copy/paste, etc., whether structured or free-text.	7a. System provides a source legend or similar function to indicate information source systems (scanning program, voice recognition software, device interface, etc.
8. The audit records will preserve and offer for display on demand the "before" and the "after" versions of changes to the record in successive iterations.	
9. Specific events will trigger the preservation of iterations or versions of documentation in progress. These will include changes in user, user log off, any cue of a Save function by the user, any viewing of documentation in progress by a user other than the author(s), plus events X,	9a. System will retain as a version the state of documentation when the user indicates that the encounter is available for business functions (billing).

Y, Z. (Trigger events must be clearly defined in the supporting software documentation.)	
10. Documentation that has been indicated complete will be saved in the audit function. Any addenda, corrections, clarifications, or modifications of any type to the encounter documentation will be preserved and will offer for display on demand the "before" and "after" versions, with each clearly indicated by date, time, and user. The system will also require means to describe the reason for the change.	
11. Audit functions will also record the status of clinical business rules, such as care guidelines, prompts, alerts, changes to those rules, plus present on demand the "before" and "after" state along with the user who changed the rule.	11a. The system will require description for the reason for the rule change. The system will record the user's response to a prompt or alert.

Note: Table taken from Trites and Gelzer [13] pp.28-29 (original used with permission from Advocates for Documentation Integrity and Compliance, LLC).