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Design, Implementation and Evaluation of an Architecture based on the CDA R2 Document Repository to Provide Support to the Contingency Plan

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Abstract

The pervasive use of electronic records in healthcare increases the dependency on technology due to the lack of physical backup for the records. Downtime in the Electronic Health Record system is unavoidable, due to software, infrastructure and power failures as well as natural disasters, so there is a need to develop a contingency plan ensuring patient care continuity and minimizing risks for health care delivery. To mitigate these risks, two applications were developed allowing healthcare delivery providers to retrieve clinical information using the Clinical Document Architecture Release 2 (CDA R2) document repository as the information source. In this paper we describe the strategy, implementation and results; and provide an evaluation of effectiveness.

Keywords:
Electronic Health Record; CDA repository; Contingency plan.

Introduction

There is an increasing use of electronic health record, specifically the replacement of paper-based health record with Electronic Health Records (EHR) [1]. Therefore, every healthcare delivery process relies on information systems to ensure patient care. This brings up the threat of a lack of information for decision making in case of system downtime. One of the biggest risks in this scenario is inaccessibility of information needed to administer medication [2, 3].

Unexpected information technology (IT) downtime occurs more and more often with widespread adoption of electronic systems in healthcare [4]. Although the reliability of computing hardware has improved significantly, the complexity of software has escalated, especially in healthcare [4]. Risk identification and risk assessments are essential steps for developing preventive measures. Equally important is institutionalization of contingency plans as our data show that not all failures of health IT can be predicted and thus effectively prevented [5].

Most institutions had only partially implemented comprehensive contingency plans to maintain safe and effective healthcare during unexpected EHR downtimes [6]. Preparing for these unexpected downtimes should be a part of every EHR-enabled healthcare organization's overall patient safety strategy.

As most experts state, an effective contingency plan should address the causes and consequences of EHR unavailability, triggering processes and preparations that can minimize the frequency and impact of such events, ensuring continuity of care [7-9].

The objective of this paper is to describe the design, implementation, and evaluation of the IT component of a contingency plan that uses the Clinical Document Architecture (CDA) Release 2 (R2) document repository to support continuity of care during system downtime.

Methods

Settings

The Hospital Italiano of Buenos Aires (HIBA) is a nonprofit academic medical center founded in 1853. HIBA has a network of two hospitals with 750 beds (250 for intensive care), 800 home care patients under care, 25 outpatient care centers, and 41 operating rooms. There are more than 2,800 physicians, an equal number of medical team members and 1,900 administrative and support staff. During 2013-2014 there were 45,000 admissions, 3 million outpatient visits and 45,000 surgeries (half of them ambulatory).

In 1998 HIBA began the gradual implementation of a Healthcare Information System (HIS) developed in-house, from data capture to analysis. It includes a web based, modular, problem-oriented and patient-centered EHR. This EHR is known as Italica and allows inpatient, outpatient, home care, and emergency care records. Italica also allows users to order ancillary tests, prescribe medications and view results including imaging through an integrated picture archiving and communications system (PACS).

The EHR has a relational database record and also a CDA R2 document-based repository, which is digitally signed by professionals participating in healthcare delivery. This repository is used to interoperate with payers and other EHRs, and to make information portable for patients or other external healthcare providers. The system architecture for sharing medical information is based on HL7 CDA and a repository/registry XDS (Cross Enterprise Document Sharing) model defined by IHE (Integrating the Healthcare Enterprise). The document repository currently contains 36.4 million CDAs [10].

This repository allows the organization to operate without need for paper records, because information exchange between actors or systems is facilitated by these documents. For instance, for ancillary systems like imaging or laboratory, order is no longer paper-based but a digitally signed CDA R2. Likewise, result reports are not printed, but reviewed directly in the EHR through a CDA R2 sent by the ancillary service.

Since 2012, and based on this implementation, all procedures and communications for healthcare continuity while systems recover from a meaningful interruption have been redesigned, mainly for the inpatient setting. Two levels of contingency were identified:

- Level 1 is the application level, when only the EHR is not available. Causes might be a problem with the deployment of a new version or server issues. The rest of the computing infrastructure is available: database, networking, electricity, etc.
- Level 2 is total impact. Usually this level of contingency occurs when the database server is down or halted during upgrades or maintenance, or during data center problems affecting the server farm or storage, network outages or natural disasters.

The decision was to leverage the redundancy generated by the document repository to support contingency processes.

Design

A laboratory function study was performed to evaluate effectiveness and 20 Level 2 contingency tests were run on different days and at varying times. Time was randomized from the last execution to the start of simulated system downtime.

This involved simulating system downtime on 20 occasions at different times of day and comparing each prescription that each patient had at the time of the simulated downtime with the current list of prescriptions in real time. For example, if the list had been generated at 12:00 am and the system went down at 12:16 am, prescriptions during those 16 minutes were compared for additions or modifications.

Results

In order to mitigate the first level of contingency, a CDA navigator was developed, having as indexes some of the elements in the CDA header (metadata).

Table 1

Document date	/ClinicalDocument/effectiveTime/@low
Document type	/ClinicalDocument/code/@code
Service	/ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization/id/@extension and /ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization/id/@assigningAuthorityName
Patient id	/ClinicalDocument/recordTarget/patientRole/id/@extension
Patient root	/ClinicalDocument/recordTarget/patientRole/id/@root
First name	/ClinicalDocument /recordTarget/patientRole/patient /name/@given [1]
Last name	/ClinicalDocument /recordTarget/patientRole /patient/name/@family

Using this index, a tree is generated, and this tree is accessed based on patient information. From the tree root (target patient), timeline for inpatient (day by day) can be navigated. After selecting a specific date, the caregiver can access all documents for the visit grouped by document type and service.

This application is deployed on a different server from the EHR, and with a different and redundant database. If by any chance the EHR is not available, the document-based EHR at least can be retrieved.

Figure 1 – CDA Navigator

The second level of contingency assumes a total lack of database support, application server support, and electricity or network connections.

In this extreme case and only for inpatient and emergency care (average 720 beds), the question of which information is most critical for healthcare delivery to minimize risk to patients was evaluated on a consensus basis.

In this regard, two elements were key: access to the patient's prescriptions (medications, dosages, etc.) and proper labeling for laboratory samples.

Based on this requirement, an application was designed that accessed the document repository every 30 minutes for the latest medication and sampling label information for each inpatient.

Each computer running the application devotes local disk space to a folder tree organized by department and inpatient location and containing every prescription CDA and label information for each location.

This temporal repository is composed of two folders. The system alternates storage of the document between them. This application runs redundantly on several computers in strategically selected locations, and can only be used in contingency situations. These computers have a local printer and connection to backup power, with uninterruptible power source (UPS) and supplies of printer paper.

In the event of natural disasters, application server downtime, database downtime, or any other contingency, these computers can be used to print prescriptions and labels so that critical healthcare delivery can continue uninterrupted.

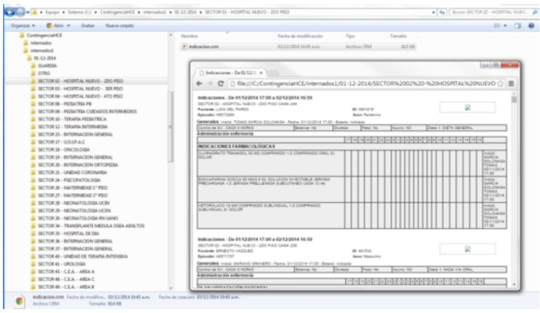

Figure 2 – File Explorer for Level 2 Contingency

Creating this backup requires querying the relational system and generates an average of 18 queries involving 44 tables for each patient. With an average of 720 beds, 12,960 queries would be needed every 30 minutes, which then would need to be turned into HTML for on screen rendering.

Using the CDA repository, only 1 query is needed, involving a snapshot of the current active inpatients or emergency care episodes, and the query to the document repository for the URL for the patient's last prescription CDA. Rendering the information only requires transformation of the XML using an XSLT stylesheet.

The downtime record between March 2012 and June 2014 is presented in Table 2. This table shows dates and times when the EHR was not available, and for how long. The column 'Type' indicates if the lack of EHR was programmed or not, and then the cause. The column "Level" indicates the severity level assigned to the cause and for each event, the quantity of pages printed.

Table 2 – Downtime Record and Pages Printed

Date Begin Time	Duration (Hrs.)	Type *	Motive	Level	Pages
08/03/12 09:15	05:55	U	EHR bug	1	365
05/04/12 23:10	02:00	U	DB issue	2	301
07/04/12 20:00	02:00	P	DB mainte-nance	2	10
27/04/12 09:50	06:15	U	EHR bug	1	303
12/05/12 22:40	07:50	P	Upgrade DB	2	1254
09/06/12 22:00	07:00	P	Upgrade Server memory	2	867
29/12/12 05:30	04:30	U	EHR bug	1	425
23/04/13 05:30	25:01	U	Shut-down power	2	1450
26/04/13 12:30	01:00	U	Router down.	2	23
27/04/13 18:00	03:00	P	Server mainte-nance	2	150
25/05/13 16:00	05:05	P	Server mainte-nance	2	1050
15/06/13 17:00	07:38	P	Server mainte-nance	2	1080
26/07/13 20:00	13:30	P	New DB cluster	2	1250
14/09/13 18:00	02:00	P	Update switches firmware	2	306
11/01/14 02:00	04:30	P	Update switches firmware	2	309
24/06/14 12:10	01:10	U	DB issue	2	124

*Type: U: Unplanned - P: Planned

As an example, a change of servers' operating system produced downtime of 13:30 hours. In this contingency, all prescriptions were printed, and 1,250 sheets of paper were used to print 759 prescriptions in 1 hour 15 minutes.

In the contingency Level 1 case, even though the CDA browser was used, the critical care units and emergency care areas preferred to print out the prescriptions in order to be able to make written notes of instructions and any other changes.

Details of each test simulation are presented in Table 3, including the time elapsed since last generation (mins), the number of inpatients at that moment, records that matched at the simulated downtime and the differences found.

Table 3 - Evaluation Cases

Case #	Minutes elapsed since last generation	Inpatients at down-time	Matches	Diffe-rences
1	2	654	650	4
2	10	695	667	34
3	18	712	668	44
4	25	730	666	64
5	5	759	723	36
6	12	759	707	52
7	26	762	686	76
8	5	771	759	12
9	5	721	697	24
10	15	678	630	48
11	14	699	643	56
12	10	712	680	32
13	17	734	686	48
14	5	723	707	16
15	15	745	709	36
16	13	711	671	40
17	22	733	657	76
18	5	732	712	20
19	1	722	722	0
20	25	745	673	72
		14,497	13,713	784

The differences were evaluated in each case: how many were caused by a patient being admitted or discharged, how many were caused by a change in medications. Medications for newly admitted patients and missing updates were deemed errors. New inpatients with no medications and discharged patients still in the contingency system were not deemed errors.

For example, for the second case, 34 differences were found, 22 of them due to patients admitted during the 10 minutes from the listing generation but with no prescription, 6 patients with their prescriptions updated, 13 patients discharged and 3 patients had new prescriptions. The evaluation result is presented in Table 4.

Table 4 – Evaluation Results for Contingency Listing

Case #	Diff.: New Admissi on	(1) Diff. Medicat ion Change	Diff.: Dischar ged patient	(2) New patient with prescripti ons	Errors (1) + (2)
1	1	1	2	0	1
2	12	10	6	6	16
3	22	6	13	3	9
4	34	10	17	3	13
5	18	3	15	0	3
6	26	4	20	2	6
7	8	10	55	3	13

8	6	3	3	0	3
9	12	3	9	0	3
10	22	2	20	4	6
11	29	6	19	2	8
12	16	5	11	0	5
13	23	10	6	9	19
14	8	2	6	0	2
15	17	5	12	2	7
16	20	7	13	0	7
17	39	17	16	4	21
18	10	3	7	0	3
19	0	0	0	0	0
20	36	9	23	4	13
	359	116	273	42	158

The results show that printed prescriptions concur in 98.91% (14,339/14,497) of those registered in the EHR.

The relationship between the time elapsed since the last generation and the differences found after downtime are presented in Figure 3.

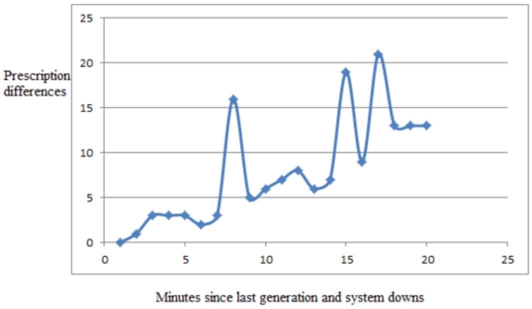

Figure 3 – Differences (Time)

Discussion

This architecture allows information to be available from all delivery care locations, and allows every actor requiring the information to access it.

The printing process has a predefined sequence for the various locations, prioritizing critical care units, emergency care, pediatric care, and then other services.

The more time elapses between the generation of the latest list and the EHR unavailability, the greater the difference in the prescription record. Although the medical staffs understand that any changes made in less than 30 minutes could be re-prescribed, they are aware that the nurse work based on the lists received and these should be corrected manually after the EHR disruption.

In the real scenario, other times should be evaluated because doctors do not make decisions on every patient immediately after the system goes down. Other changes could have been made during the downtime and will not be represented in the print version (prescriptions, bed changes, etc.). So we have two mechanisms that generate gaps between the information documented and the reality: gaps between the last local backup and the down time and gaps between the down time and the moment at which the caregiver uses the print version.

This study evaluated the differences between Point 1 and Point 2. The effectiveness of this architecture at Point 3 is pending evaluation and will be the subject of a future study.

The alternating folder strategy was required because in one of the tests if network connectivity or power was interrupted just when the folder was being generated, its structure could be corrupted. If this happens, the other folder can be accessed.

Prescription printed forms are used mainly by the nurses to ensure care continuity for patients. They continue recording their actions there in order to update the EHR when the system comes back, or scanned as part of the care record.

One limitation, as shown by the evaluation of the results, is that not all the information is available because there can be changes between the executions of the refresh process: patient transfers, new prescriptions, admissions or discharges.

No other experience in creating this kind of repository was found in the literature, either as a redundant repository or for use on a contingency basis.

Conclusion

Downtime in information systems, both planned and unplanned, is inevitable, even in the healthcare environment, where systems need to be available 24-7-365. Implementing tools such as the one presented in this paper provides contingency plan support and helps mitigate many risks that threaten information availability at the point of care.

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