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Title of Project:

Evidence-based Contingency Planning for Electronic Health Record Downtime

Principal Investigator and Team Members:

PI: Christian Wernz, PhD
Co-I: Raj Ratwani, PhD
Co-I: Terry Fairbanks, PhD
Other: Ethan Larsen, PhD; Allan Fong, MS; Carlos Rivera, BS; Dan Hoffman, BS

Organization:

PI: Virginia Commonwealth University (VCU) – 06/2017-07/2018
Virginia Tech – 08/2016-05/2017
Co-Is: MedStar Institute for Innovation

Inclusive Dates of Project:

08/01/2016-07/31/2018

Federal Project Officer:

Bryan Kim, PhD

Acknowledgment of Agency Support:

This research has been funded by the Agency for Healthcare Research and Quality (AHRQ)

Grant Award Number

R21 HS24350-02 (initially, prior to 06/2017: R21 HS24350-01A1)

Structured Abstract

Purpose: To assess the clinical and operational implications of electronic health record (EHR) downtimes and to develop an evidence-based analytical tool that supports practitioners in the creation of effective downtime contingency plans.

Scope: EHR downtime was studied in the emergency department and clinical laboratory at two hospitals.

Methods: Collection and analysis of archival and observational data of downtime events, supplemented by stakeholder interviews. Development of a computer simulation model to assess the performance of various downtime contingency plans.

Results: Downtime risks include delay of care, increase in medical error, and disruption in communication. Effective downtime contingency plans can reduce these risks. Computer simulation can assess the performance of various downtime contingency plans and can inform and improve current practice.

Key Words: Electronic health record, health information technology, computer simulation, patient safety, downtime, contingency planning

Purpose

To assess the clinical and operational implications of electronic health record (EHR) downtimes and to develop an evidence-based analytical tool that supports practitioners in the creation of effective downtime contingency plans.

Specific Aim 1: Collect and analyze data to quantify how laboratory and ED operations, including patient safety, are impacted by EHR downtime. Data is obtained from existing hospital datasets, and is enriched by process observations and interviews with stakeholders. The results of the data analysis will serve as input for the simulation in Specific Aim 2.

Specific Aim 2: Develop a computer simulation that replicates laboratory and ED operations during EHR uptime and downtime. Calibrate and validate the simulation with data analyzed in Specific Aim 1. Use simulation model to compare uptime and downtime operations, and assess and improve various downtime contingency plans.

Scope

EHR downtime was studied in the emergency department and clinical laboratory at two hospitals.

Background: EHR systems have been installed in the majority of hospitals and private practices. With the prevalence of EHRs, system downtime is a growing area of concern and is coming to the forefront of research in health information technology (IT) and health services management. Downtime is any period of unavailability or decreased functionality in the EHR system and, unfortunately, is not an uncommon event.

Downtime can result from events internal or external to the IT infrastructure of the healthcare provider. Internal and unexpected downtime events can be caused by EHR system failures, or software and hardware problems in the wider IT network of the healthcare provider. In addition to unexpected downtimes, planned downtimes are often necessary to perform system upgrades and updates. External downtime events can be caused by the EHR vendor. Generally, healthcare providers choose not to run their own data management systems, but purchase this service from the EHR vendor. EHR data is typically stored offsite at centralized data warehouses. Problems with Internet connectivity, or problems at the vendor's data warehouse, can result in limited or no data access for the healthcare provider. Finally, downtimes can be caused by catastrophic events, such as earthquakes, fires, hurricanes, and flooding, or by terrorism, including cyber-attacks.

While EHR vendors are working to prevent downtime events by increasing reliability of hardware and software, healthcare providers will continue to experience downtimes, both planned and unplanned, and must have effective contingency plans in place. There is surprisingly little guidance in the literature or from EHR vendors on best practices for EHR downtimes. Regulatory mandates and recommendations for downtime contingency planning exist (CMS, HIPAA, IOM), but are vague, insufficient and not instructive. Regulations simply require that a procedure be on file; performance requirements are not specified.

Among healthcare providers, hospitals are particularly susceptible to downtime events given the complexity of their EHR systems. In addition, delays in time-sensitive care can result in serious patient safety hazards. Given the complexity of and reliance on EHR systems in hospitals, effective contingency plans are crucial.

The focus of our research is on the downtime procedures in hospital settings, with particular attention to the laboratory and the ED given that these clinical areas require the rapid communication of information and their activities are significantly hindered by EHR downtimes.

The clinical laboratory is the foundation for most of the medical procedures that take place in the modern hospital. An estimated 7 billion laboratory tests are performed in the United States each year. Within the hospital, laboratory reports are consulted for 70% of medical diagnostics. Emergency medicine is particularly reliant on rapid laboratory testing. Delays in the laboratory can be a major source of medical error that negatively impact patient outcomes.

Seventy-two percent of providers are currently meeting the meaningful use requirement to have computerized physician order entry (CPOE) integrated into their EHR

system. CPOE allows physicians to order laboratory tests directly and receive results through this system.

Emergency physicians rely on laboratory results for clinical decision-making, and any delays or errors in the laboratory can have a dramatic impact on how quickly and safely a patient in the ED is treated. Because nearly all laboratories rely on CPOE and the EHR system to receive physician orders and to send results back to physicians, any EHR downtime will result in delays in laboratory testing and reporting.

Research on EHR downtime, particularly in acute hospital settings, is in its infancy. We do know that EHR downtimes can be frequent, unpredictable, and pose threats to safety and quality. A study surveying 50 hospitals discovered that almost every responding hospital had experienced some unplanned downtime event within the past 3 years. Seventy percent of the hospitals indicated that they experienced an unplanned downtime longer than 8 hours. Worse still, three hospitals responded that downtime was the cause for injuries and negative outcomes for one or more patients. There is also a financial cost to these downtimes. A study focused on small private practices estimates that downtime costs are approximately $500 per physician hour.

Hurricane Sandy, although an extreme scenario, reminded many of the need for detailed and comprehensive downtime planning. Widespread damage to hospitals resulted in lost network connectivity and power outages, and EHRs were rendered useless. In many hospitals, the downtime procedure documentation was in electronic form only and thus not accessible. Only few staff members present in the hospital were capable of enacting the downtime procedures without referencing the unavailable manual.

EHR downtime affects laboratory turnaround time. With modern health IT systems capable of reporting test results as soon as they are completed, physicians have become accustomed to the rapid turnaround. During and after a downtime event, turnaround time can extend to hours as the lab falls behind with a backlog of specimens. Typically, the testing equipment in the laboratory is networked into a laboratory information system (LIS), which processes the results and communicates them back to the EHR for physician review. During normal operation, the flagging of critical results on tests are handled based on preset tolerances, and tests are indicated as critical in the EHR before the physician reviews them. During downtime, paper reporting methods become necessary, and results have to be reported to clinicians by fax or phone instead of through the EHR. Physicians waiting for reports are not always notified that the EHR is down and generally are not easily contacted by phone or fax. Consequently, patients in emergent situations, whose diagnosis depends on timely laboratory results, are exposed to significant risks.

Clearly, laboratory availability and turnaround time affects patient safety, but to date, research has primarily focused on clinician and laboratory personnel errors in test selection, execution and interpretation. Few studies have focused on the impact of delays in reporting of results, and even fewer studies have systematically examined the impact of EHR downtime on the laboratory and other clinical areas, such as the ED, that rely on the laboratory.

Participating organizations: The healthcare organizations which participated in this project were MedStar Good Samaritan Hospital (MGSH) and MedStar Washington Hospital Center (MWHC). MGSH is a suburban acute care hospital with 287 beds located

in Baltimore, MD. MWHC is a large urban hospital with 926 beds in Washington DC. The target hospitals were chosen because of their differing environments and workloads. MWHC, with its burn unit and Level I trauma center, sends different types and larger volumes of requests to the clinical laboratory than the ED at MGSH. MGSH, on the other hand, provides centralized microbiology laboratory services to the four Baltimore area MedStar hospitals. MGSH receives specimens by courier that need testing in the specialized areas of the laboratory.

The MedStar Health network, composed of ten hospitals and operating more than 120 entities, uses Cerner Corporation's EHR system, MedConnect. In addition to being the EHR vendor, Cerner also provides the data storage service. Patient data is accessible via an Internet connection from a Cerner server farm facility in the Midwest. This situation is typical and chosen by most healthcare systems irrespective of their EHR supplier.

Cerner does have a software solution in the event that the Internet connection to their data is disrupted. The hospital has a local backup of the database from the last 24 hours of operation. However, information can only be read from the EHR, but new information cannot be entered (i.e., read-only). Changes must wait until the connection is reestablished, and the backup may only contain data from recently accessed records. Thus, new lab orders from the ED and new lab results from the clinical laboratory cannot be communicated electronically during a downtime event.

Methods

Collection and analysis of archival and observational data of downtime events, supplemented by stakeholder interviews. Development of a computer simulation model to assess the performance of various downtime contingency plans.

Data Collection and Analysis: We used a combination of qualitative and quantitative data from archival process datasets, process observations and stakeholder interviews. Multiple data sources and data triangulation helped to reduce problems such as missing, incomplete or unreliable data, and enabled cross-validation and consistency checks.

Triangulation has been used in healthcare research in situations where quantitative data is desired in combination with qualitative data, such as in performance evaluations. In our research, quantitative, archival data obtained from the EHR system was combined with qualitative and quantitative data from process observations and interviews with stakeholders. Process observations provided high fidelity and detailed data recordings, while interviews allowed us to obtain estimates of data that were not otherwise available.

In the statistical analysis of the enriched dataset, we obtained statistical distributions of variables, not just mean values. Distributions are necessary for probabilistic risk analyses and were the input to our simulation. Statistical methods included descriptive methods, linear and logistic regression, analysis of variances (ANOVA), t-tests and related hypothesis testing methods.

Archival Data: Since clinical laboratory quality metrics are required by the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP), we had access to a detailed and comprehensive archival dataset to assess laboratory operations during EHR uptime (i.e., normal operations) and downtime. A key performance metric of the *laboratory is turnaround time,* which is the time from specimen arrival in the laboratory to reporting of results. Other metrics included *specimen backlog count* and *throughput* count. Similar to the laboratory, the EDs have several established metrics that are used to measure its performance. We focused on door-to-doc time, patient backlog, and arrival rate.

Observations: In addition to analyzing the archival data, the research team conducted observations in the laboratories and the EDs during uptime and downtime. In the laboratories, the research team observed specific workstations, such as the accessioning where most specimens are brought into the lab. Focusing on specific workstations allowed us to capture the nuanced operations of the laboratories that are not reflected in the EHR data. We assess specimen travel time, specimen backlog, and accessioning load.

The research team observed scheduled downtime events and drills. Unfortunately, during the course of the study no unplanned downtime events occurred. In the eventuality of one occurring, a “scramble” plan had been established by the researchers to ensure that personnel could be operationalized rapidly with the appropriate support necessary in the ED and laboratory.

Interviews: The interview sessions for the study were comprised of 17 personnel from the laboratory and ED. Over several days, multiple sessions were conducted to accommodate participant schedules. The sessions were intended to be conducted as

larger focus groups; however, due to scheduling and work coverage restrictions, all sessions were conducted with only one or two participants at a time. ED interviews focused on physicians and nurses; laboratory sessions focused on technicians from the core laboratory and supervisors. The interviews focused on feedback from stakeholders about their perceptions of downtime operations, desires for potential improvements, and the activities that take place during downtime.

Simulation: The simulation was implemented as a coupled agent-based and discrete simulation in AnyLogic® software. Agents represent patients and clinical staff. The discrete-event simulation elements captured process flow in the laboratory.

In the ED, the process was as follows. Arriving patients were classified according to their emergency severity index (ESI) and were then seen by the nurse and the physician. Figure 1 shows a screenshot of the simulation model for the ED.

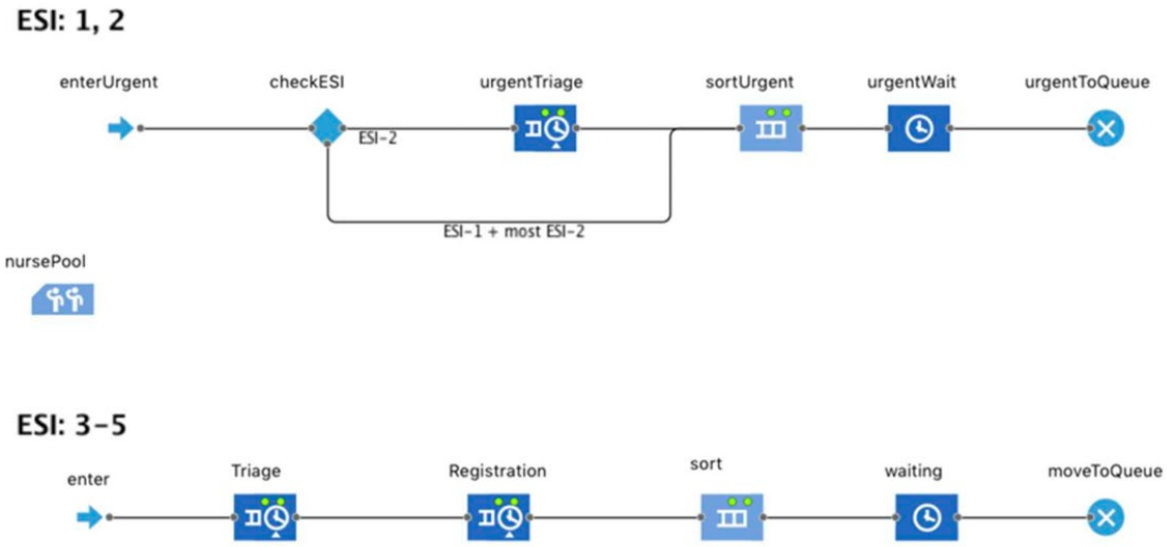

Figure 1: ED simulation model

Should ED patients need laboratory work, their specimens were sent to the laboratory, which as modeled as a discrete-event process. The laboratory process is summarized in Figure 2.

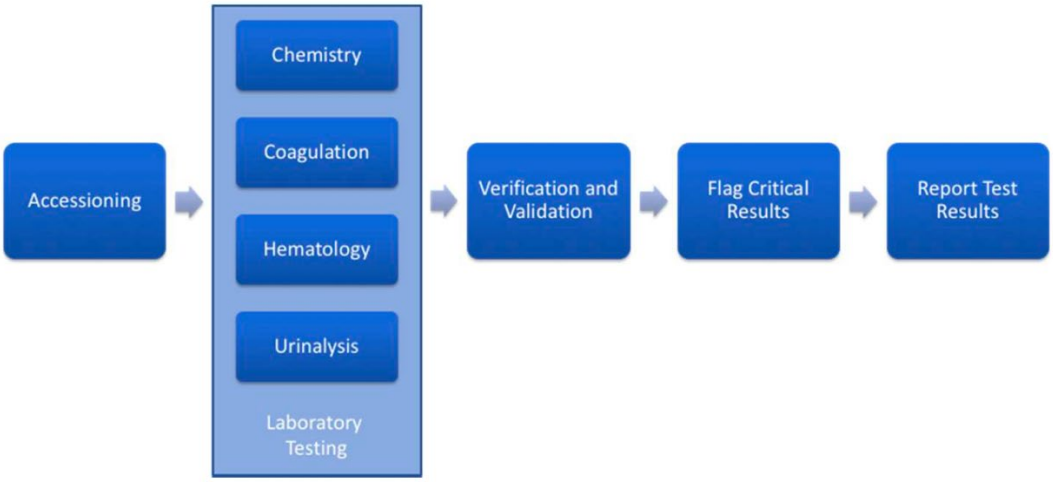

Figure 2: Laboratory process

The simulation was calibrated and baselined to be reflective of a week in September 2015. September 2015 was selected as it represents a window in which the most reliable data was available for comparison to the simulation model. Two separately calibrated simulation models, one for uptime and one for downtime, were developed. For the downtime model, we assessed various downtime protocols. In particular, we studied the limited testing menu for the laboratory and changes in number and roles of support staff.

Study Limitations: The limitations of the study can be categorized according to four categories: study site selection, data availability, participant selection and simulation modeling.

Study site selection: Our results are based on the processes and data of two hospitals. Expanding the analysis to more hospitals would provide necessary insights for rare events, in particular those that harm patients.

Data availability: As data collection proceeded, artifacts were found in the normal operation EHR datasets which impacted the quality of the raw EHR data. These artifacts were identified by patients with abnormally long total treatment times, i.e., measured in days or even weeks. Another artifact was laboratory tests that were reported significantly faster than they physically could have been completed, e.g., a 45-minute chemistry test reported in 15 minutes. We suspect that these data abnormalities represent an artifact of the way the EHR was built, scripting together several independent programs. The master EHR database has entries for every interaction, but the data itself may be representing the time the data was written rather than the time the action took place. While the data was cleaned for identified abnormalities through consultation with subject matter experts in the hospitals, there is still potential for irregularities remaining in the dataset.

Review of paper records found that stated downtime procedures were not being adhered to during downtime events. Many of the paper records lacked information that was expected to be present. Therefore, we may not have obtained the full picture of downtime effects.

*Participant selecti*on: Participants for interviews were recruited based on a volunteer basis, and sessions conducted during work hours. While a balanced number of

participants across roles and sites was sought, the result was an imbalanced participant pool across sites. Due to the presence of a workers' union at one of the hospitals, contacting and conducting sessions with the nursing staff there was not possible. Therefore, the nursing interview data only represents the opinions and experiences of one of the hospitals.

Participants were recruited as they volunteered for sessions when the researcher was available. Hospital employees coordinated amongst their coworkers to manage shift and care coverage to participate, causing the initially designed focus groups to be conducted as interviews. The incentive for stakeholders to participate was only the potential for improvement to their work environment; future research may benefit from additional incentive to encourage greater participation.

Simulation modeling: The simulation model was created and calibrated based on the available data. We were able to validate and verify the model for normal operation based on this data. Downtime records, however, were not as comprehensive and reliable as the normal operation data. Therefore, data estimations had to be performed and a comprehensive validation was not possible.

Results

Downtime risks include delay of care, increase in medical error, and disruption in communication. Effective downtime contingency plans can reduce these risks. Computer simulation can assess the performance of various downtime contingency plans and can inform and improve current practice.

Stakeholder interviews confirmed that downtime is disruptive to the organizational processes and adds considerable stress to the workforce. Neither of the target hospitals had any reportable events or fatalities related to their previous downtimes.

In our archival data analysis, we searched 80,381 voluntary patient safety reports from January 1, 2013 to January 10, 2016 and could identify 76 downtime related incident reports.

Our finding show that the laboratory category had the greatest number of reported downtime incidents, accounting for 48.7% (n=37) of the explicit downtime reports, followed by medication administration with 14.5% (n=11) of reports. Specifically, the following occurrences were reported (Table 1).

Table 1 – Clinical Care Processes Impacted by Downtime

Care Process	Sub Category	Definition	Freq of Occurrence
Laboratory	*Patient Identification*	Improper continuity of patient identification from collection to testing	9
	Lab Ordering	Complications to order placement and receipt	2
	Specimen Labeling and Tracking	Specimen was misplaced or mislabeled	11
	Results Reporting	Transmission of results from the laboratory to the clinician	8
	General	General descriptions of downtime issues with the lab (e.g. the lab results were slowed due to downtime)	7
Imaging	*Image Ordering*	Complications to order placement and receipt	1
	Image Transfer	Relaying Image to necessary staff for interpretation	1
	Results Reporting	Transmission of imaging study results to clinician	2
Medication	*Issue Entering Order*	Placement of medication order disrupted	3
	Administration	Includes: delay, wrong dose, wrong medication, and medication tracking	8
Patient Registration		Issue caused patient registration to be disrupted or incomplete	4
Hand-off / Transfer of Patient		Issue transferring patient or handing off patient at shift change	4
Documentation		Unable to document patient information	3
History Viewing		Unable to view past patient information	1
Delay of Procedure		Delay to medical procedure due to downtime	2
General Delay of Care (no specific process mentioned)		Incident reports that described overall difficulties with downtime operations without specific details (e.g. downtime caused delays in patient care)	10

With respect to downtime adherence, we obtained the following results. Of the 76 incidents, 46% (n=35) indicated that downtime procedures were either not followed or were not in place. Only 27.6% (n=21) of incidents indicated that downtime procedures were successfully executed, and 26.3% (n=20) had insufficient information to determine if downtime procedures were present or followed.

Through the simulation, we could document the expected difference in key performance indicators for uptime vs. downtime. The results shown in Table 2 are based on 1,500 iterations with stochastic variable inputs.

Table 2: Comparison of Normal vs. Downtime Simulation

	Normal Control	Downtime Control
Door to Doc (min)	(M=75.35, SD=22.06)	(M=1418.04, SD=263.79)
Total Treatment Time (min)	(M=255.45, SD=41.86)	(M=1731.50, SD=247.07)
Lab throughput (count)	(M=7311.61, SD=99.20)	(M=4529.40, SD=67.03)
Critical Calls in 15min (%)	(M=99.99, SD= 0.022)	(M=78.78, SD=2.88)
Chemistry TAT (min)	(M=44.85, SD=23.89)	(M=3637.57, SD=129.39)
Coagulation TAT (min)	(M=28.32, SD=2.99)	(M=2041.41, SD=116.36)
Hematology TAT (min)	(M=21.39, SD=3.29)	(M=2724.59, SD=127.03)
Urinalysis TAT (min)	(M=36.88, SD=2.79)	(M=1424.81, SD=95.20

Based on these simulation models, we assessed the benefits of a limited laboratory testing menu during downtime. Table 3 summarizes the expected performance, which shows significant workload reductions.

Table 3: Workload for limited testing menu during downtime

Key Performance Indicator	Optimal Experiment	Improvement vs Control
Door to Doc Time	40% Workload Reduction	95% (-1336 min)
Total Treatment Time	50% Workload Reduction	85.2% (-1466.08 min)
Laboratory Throughput	No Plateau	
Critical Results Reported within 15 min	No Plateau	
Chemistry Turnaround Time	No Plateau	
Coagulation Turnaround Time	40% Workload Reduction	98.5% (-2012.65 min)
Hematology Turnaround Time	40% Workload Reduction	99% (-2700.67 min)
Urinalysis Turnaround Time	40% Workload Reduction	97.4% (-1388.96 min)

Workload reduction of 40% and more significantly reduce the door-to-doc time in the ED. Figure 3 shows the benefits of various work load reductions as predicted by our simulation.

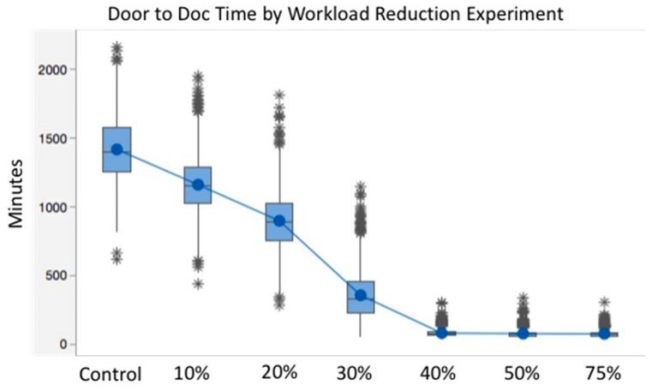

Figure 3: Impact of workload reduction on door-to-doc time

Further, we assessed the benefits of additional staffing during downtime. To illustrate the results, we show the results of four different scenarios (experiments) with additional staff and lab technicians. The computational experiments were performed as shown in Table 4.

Table 4: Variable staffing experiment

Experiment	Support Staff	Additional Chemistry Technicians
1	1	0
2	1	1
3	2	1
4	2	2

The experiments showed that significant benefits were achieved with one additional staff member and one additional lab technician. Figure 4 compares the door-to-doc time for the four different experiments.

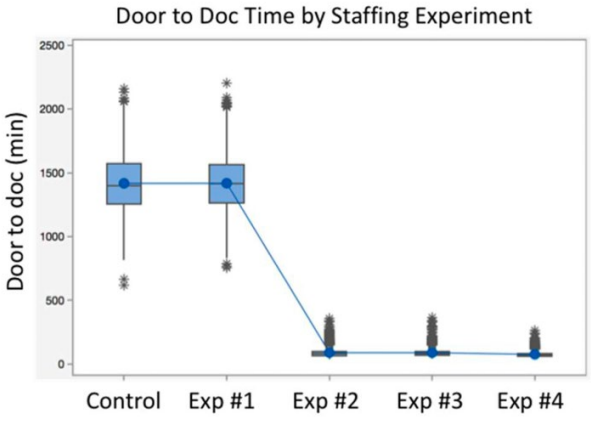

Figure 4: Impact of staffing on door-to-doc time

For experiment 2, Table 5 summarized the improvements in terms of door-to-doc time. Similar analyses were performed for the other KPIs.

Table 5: Performance improvement through additional staffing

Key Performance Indicator	Optimal Experiment	Improvement vs Control
Door to Doc Time	1 Support + 1 Tech	93.6% (-1328.16 min)
Total Treatment Time	1 Support + 1 Tech	82.4% (-1426.65 min)
Laboratory Throughput	1 Support + 1 Tech	58% (+2636.52 units)
Critical Results Reported Within 15 min	1 Support + 1 Tech	16.4% (+12.95 % called)
Chemistry Turnaround Time	1 Support + 1 Tech	88% (-3193.18 min)
Coagulation Turnaround Time	1 Support + 1 Tech	95.6% (-1952.06 min)
Hematology Turnaround Time	1 Support + 1 Tech	96.1% (-2618.57 min)
Urinalysis Turnaround Time	1 Support + 1 Tech	93.5% (-1332.97 min)

In conclusion, the simulation study documents the benefit of testing downtime contingency plan through a computer simulation. The approach allows to quantitatively assess the benefits of different interventions – without negatively impacting clinical operations – and enables optimal trade-off decisions between resource deployment and performance outcomes. Further details of our findings can be found in the publications listed in the next section.

List of Publications and Products

Journal Publication:
Larsen E, Fong A, Wernz C, Ratwani R. Implications of Electronic Health Record Downtime: An Analysis of Patient Safety Event Reports. *Journal of the American Medical Informatics Association 2018;* 25(2):187-191. PMID: 28575417

PhD Dissertation:
Larsen E. Macroergonomics to Understand Factors Impacting Patient Care During Electronic Health Record Downtime [dissertation]. Blacksburg, VA: Virginia Tech; 2018.

Conference Proceeding:
Larsen, E, Haubitz C, Ratwani R, Wernz C. Improving Electronic Health Record Downtime Contingency Plans with Discrete-Event Simulation. *Proc. 49th Hawaii International Conference on System Sciences (HICSS-49)*. 2016 January; Kauai, HI. 2016:3179-3188.

Conference Presentations:
Larsen E, Ratwani R, Wernz C Downtime of Electronic Health Record Systems and Its Impact on the Clinical Laboratory and Patient Care. *Conference on Health IT and Analytics (CHITA)*, Washington, DC, 2017 November.

Larsen E, Haubitz C, Wernz C, Ratwani R. Improving Electronic Health Record Downtime Contingency Plans with Discrete-Event Simulation. *49th Hawaii International Conference on System Sciences (HICCS-49)*, Kauai, HI, 2016 January.

Journal Publications in Preparations (not yet published):
Larsen E, Hoffman D, Rivera C, Kleiner BM, Wernz C, Ratwani R. Continuing Patient Care During Electronic Health Record Downtime.

Kulkarni AU, Larsen E, Rivera C, Ratwani R, Wernz C. Developing Electronic Health Record Downtime Contingency Plans through a Coupled Agent-based and Discrete-event Simulation.