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December 20, 2012

Kenneth Shine, M.D.
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The University of Texas System
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Enclosed for your information is a copy of the University of Texas Southwestern Medical Center Internal Audit Report - 12:20 Clinical Trials Billing (Velos/Epic Implementation).

I concur with the auditors' recommendations. Three recommendations have been implemented and one is in process.

Sincerely,

Daniel K. Podolsky, M.D.

Enclosure

cc: Arnim E. Dontes
J. Michael Peppers
Eva Narten

The University of Texas Southwestern Medical Center

Internal Audit Report 12:20
Clinical Trials Billing (Velos/Epic Implementation)

December 20, 2012

Office of Internal Audit
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University of Texas Southwestern Medical Center
Internal Audit Report 12:16
Clinical Trials Billing (Velos/Epic Implementation)
FY 2012

Audit Report - DRAFT
December 20, 2012

Daniel K. Podolsky, M.D., President
The University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard, MC 9002
Dallas, Texas 75390-9002

Dear Dr. Podolsky:

The University of Texas Southwestern Medical Center (Medical Center) Office of Internal Audit has completed its Clinical Trials Billing (Velos/Epic Implementation) audit as detailed below.

Executive Summary

The primary objective of the Clinical Trials Billing Velos/Epic Implementation audit was to assess the system interface under development and to evaluate the proposed control environment pertaining to the clinical trials workflow and related billing process. The audit further assessed the methodology of standards and controls applicable to the project development life cycle.

The audit found that the control design over the Velos/Epic implementation project for Clinical Trials Billing is adequate as evidenced by the Medical Center Project Management Office (PMO) adopting an approach that incorporates the project lifecycle framework and standards endorsed by the Project Management Institute (PMI). These globally accepted standards provide guidelines, rules and characteristics for project management and when consistently applied, enhance the achievement of professional excellence and organizational strategic objectives. The PMI project management framework recognizes a project with a definitive beginning and ending point, which creates a unique set of results and deliverables. Project management under this context represents the application of knowledge, skills, tools and techniques to project activities to meet project requirements, and is accomplished through the integration of the project management processes of initiating, planning, executing, monitoring and controlling, and closing.

To achieve our audit objective we conducted management interviews, performed walkthroughs, reviewed relevant policies and documentation on file including the Velos/Epic Project Charter to understand the project description, goals and objectives, and scope. We studied the lifecycle flow diagram and participated in the PMO project team meetings to determine control requirements were functioning as intended. We

performed limited testing where applicable to validate the integrity and reliability of data. The PMO Office represents a relatively new function from within the Heath System Information Resources Division (HSIR) and Information Resources Department (IR), and has been in operation in the past two years. Control requirements are being updated and new requirements introduced to build on the level of effectiveness.

The audit has identified opportunities to further enhance the PMO process. 1) We recommend adherence with the project lifecycle approach and organizational policies in documenting capital justification and initial budget approval during project development, formal IR approval and information security assessment signoff for new project requests, documentation of Project Charter approval, more effective utilization of the Planview software in monitoring actual and budgeted resources. 2) Test scripts development, execution and results reporting should be reemphasized; we further recommend the incorporation of a formal test plan approach and end user acceptance testing in the PMO process. 3) For those research studies created in the Velos Clinical Trials Management System we recommend reemphasis of required input fields with all research departments and system users; we further suggest the establishment of formal guidelines for the management of test data and test studies. 4) Regarding project issues tracking and communication, we recommend continued collaboration to achieve consensus by senior leadership in the timely resolution of high risk issues.

Background

Clinical trials represent biomedical or health-related research studies involving human subjects. The primary purpose of a clinical trial is to identify a better way to prevent, diagnose or treat a disease. Participants in a clinical trial receive drugs or procedures that already have been researched in successful laboratory and/or non-human studies.

Clinical trials are conducted according to a predefined protocol that describes what types of patients may enter the study, schedules of tests and procedures, items and services to be administered including drugs and dosages, length of study, as well as outcomes that will be measured. Participation in research studies is voluntary. Patients are provided with an informed consent document that explains risks and potential benefits associated with the study. Clinical trials help the patients play an active role in their own health care, gain access to new research treatments before they are widely available, obtain expert medical care at healthcare facilities during the trial, and make contribution to medical research.

Clinical trials billing is highly complex due to the nature and scope of these research studies and often more than one entity is responsible for the costs incurred in a trial. This can include government and non-government sponsors, private insurance companies, Medicare/Medicaid contractors, and the patients themselves. A study may include the routine medical treatment or standard of care for a condition which a patient would receive whether or not the person participates in the clinical trial. These are generally billed to the patient or their insurer. If a sponsor provides funding for these items then they may not be billed to the patient or his insurer. Protocols with services, drugs, devices or treatments that are solely for research purposes are generally paid by

the Trial sponsor and may not be billed. Costs related to complications caused by participation in a clinical trial may be the responsibility of the sponsor, the patient or his insurer as specified in the sponsor contract and the informed consent signed by the research subject. Further, the Centers for Medicare and Medicaid Services (CMS) has its own rules and requirements regarding payment of claims of Medicare patients enrolled in clinical trials. CMS covers routine costs in qualifying trials as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

The responsibility for promoting and supporting research activities and monitoring compliance requirements within the Medical Center is delegated by the Office of the President to Research Administration reporting to Academic Affairs. Research policies emphasize adherence to high ethical standards in the conduct of medical research by faculty and staff members and require Institutional Review Board (IRB) approval for studies involving human subjects. The Principal Investigator (PI) of a clinical study is responsible for coordinating with Research Administration and assuming overall responsibilities including study plan and budget development, obtaining necessary approval, enrolling patients, administering therapeutic services, and communicating results in accordance with requirements. Research Administration coordinates with the Medical Center Office of Compliance to administer a billing compliance program ensuring compliance with governing rules and regulations. Federal regulations applicable to clinical trials include 21 Code of Federal Regulations (CFR) governing food and drugs administered by the Food and Drug Administration (FDA), and 45 CFR governing protection of human subjects and personal health information administered by the National Institute of Health (NIH). Both agencies are part of the Department of Health and Human Services (HHS). The Medical Center receives annual research grant funding of more than $417 million from governments, foundations, individuals and corporations.

The Medical Center acquired the Velos clinical trials management system, an internet enabled application in April 2010. Professional and Hospital billing is currently processed through the Epic Practice Management software and Resolute billing module. The Medical Center clinical systems currently do not support integration of research protocols and clinical care. Additionally, Velos research information central repository and Epic electronic medical record are not integrated. The Velos/Epic integration project is to ensure the transparency of research data, patient safety and billing compliance. The Velos/Epic system interface is designed to establish, identify and synchronize research study records and patients participating in clinical trials. Patients are registered and enrolled to research studies in Velos. Patient scheduling, association with a research study and ordering research procedures are processed in Epic. Laboratory, Radiology, Pharmacy and other services obtained in the context of clinical research are ordered and captured in Epic except when excluded by the research protocol or regulatory requirements. Patient charges are then segregated and reviewed prior to billing to sponsors and payers of clinical trials. Approved Velos/Epic project solutions include:

- Creation of a research study in Velos and establishment of the same record in Epic via a system interface; study activation in Velos to enable patient enrollment.
- Patient registration and enrollment in Velos including real time search of the patient's medical record number (MRN) in the Master Patient Index, association of the patient to the study in Epic via interface and return confirmation to Velos. If the patient does not have a MRN, the process will include contacting Registration to manually create a MRN.
- Identification of research patients in Epic through a research flag on the patient form header, plus status designation of active or inactive. Synchronization of study patients via system interface to include disassociation of patients from studies in Epic when this is accomplished in Velos.
- Results of research orders in Epic with the default value in Epic unless overruled by the PI and/or Research Coordinator due to criteria unique to the patient records.
- A patient encounter in Epic with one or more charges related to research will be flagged as a research visit and all charges from that encounter will go to a work queue for further review and segregation into research or standard of care.

Stakeholders of the Velos/Epic implementation project include Medical Center PIs, Research Coordinators, IRB, Patients, Providers, Ambulatory Clinics, Inpatient units, Professional and Hospital Billing departments, Patient Registration, Research visit scheduling staff, Research billing staff, Research clinical staff, Research Administration/Departmental Executives, and others. This project has sponsorship from management of Academic Information Systems (AIS) and receives guidance regarding scope, budget and resources from the Project Governance body and Research Steering Committee. This Governance body has senior management representation from Academic and Health System Administration, Research Administration, Hospital and Professional Billing departments, IR Department management and the Compliance Office.

The Project Management Office/Business Systems (PMO) from within HSIR is responsible for the overall management of the Velos/Epic Implementation project with contribution from AIS. Both HSIR and AIS Divisions are located in the IR Department and report to the Vice President of IR. This project includes comprehensive communications and training for all clinical research workflows and impacted end-users. The project has a start date of September 2011 and consists of three phases: Phase 1 pertains to study record and patient flagging in Epic through Velos which was completed in February 2012, Phase 2 includes research patient visits, orders, results and billing with completion date of September 2012, and Phase 3 covers research visit documentation with a target live date of Q4 2012.

Audit Objectives

The primary objective of the Clinical Trials Billing Velos/Epic Implementation audit was to assess the system interface under development and to evaluate the proposed control environment pertaining to the clinical trials workflow and related billing process.

The audit further assessed the methodology of standards and controls applicable to the project development life cycle.

Scope and Methodology

The audit covered March through July 2012 and focused primarily on Project phases 1 and 2. The scope of the engagement included Internal Audit staff functioning in an independent capacity in system implementation. As independent members of the project management team, we assessed proposed controls, identified where controls were required and determined adequacy.

We recorded control issues as they were identified during project related meetings and working sessions, documented solutions by the project team, followed up and verified completion or resolution. We assessed project planning, execution, monitoring and control within the HSIR PMO environment. The audit included applicable testing to validate the integrity of information, results and records.

This audit is a risk-based tier two audit from fiscal year 2012 audit plan. Our examination was conducted according to guidelines set forth by The University of Texas System's Policy UTS 129 "Internal Audit Activities", the Regents' Rules and Regulations, and the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*.

In order to achieve the objectives of this audit, the following procedures were performed:

- We conducted interviews with management members of PMO/Business Systems, AIS and Research Administration.
- We reviewed Research Administration policies and procedures including those governing clinical trials billing, applicable rules and regulations.
- We reviewed the Velos/Epic Project Charter to gain an understanding of the project problem statement, project description and scope, goals and objectives, project organization, authority and milestones.
- We assessed the documented critical success factors of the project, management assumptions, project constraints and major risk factors.
- We participated on the project team, attended team meetings and reviewed meeting notes, issues reported and decisions taken.
- We gained access to the PMO and project's central repository locations (SharePoint sites) to review project requirements documentation, functional specifications, risk assessment/management plan, budget and staffing resources.
- We accessed the Planview system established by IR to review the documentation and methodology for the management of the project lifecycle.
- We performed limited reviews of study records established in Velos.
- We observed the processing steps to activate a research study in Velos, register and enroll approved patients into studies. We verified the system interface was functioning as intended in Epic.

AUDIT RESULTS/RECOMMENDATIONS

The management of a project includes requirements identification, establishment of clear and achievable objectives, balancing the competing demands or constraints for quality, scope, time and cost, and adapting the specifications, plans, and approach to the different concerns and expectations of the various stakeholders. The PMI project management methodology applies knowledge, skills, tools and techniques to project activities to meet project requirements. The PMO has adopted this project lifecycle approach, which ensures a framework for project monitoring, control and accomplishment of organizational objectives. Recommendations are detailed below.

1. **Project Lifecycle**

   The PMO Office was organized and has been in operation for approximately two years. There is overall adherence to the PMI framework in the management of the Velos/Epic implementation project. Control requirements are being updated and new requirements introduced to build on the current level of effectiveness. These include an information security risk assessment of a proposed system or application during project initiation, a formal change control process involving the management of all proposed changes to the cost, schedule or scope of a project, plus a project quality checklist to be reviewed during a project's lifecycle. Opportunities include the following:

   a. Project Initiation - Capital Justification and Initial Budget Approval.

      The Velos/Epic implementation project qualified as capital project with internal labor costs of $690,000 plus software licensing and implementation costs of $17,000, for a total of $707,000. The project received approval from the Health System Leadership and Clinical Research Information System Governance Committee (CRIS); however, documentation of capital budget justification and initial budget approval was not on file. Funding amount and source for some key budget elements did not appear adequately detailed. The internal salary and fringe benefits costs of $690,000 over the two-year project duration pertained to HSIR technical resources and AIS project management resources only. PMO resources required for the management of the project were not budgeted while the PMO Office currently leads this project with AIS contribution. The required capital justification and initial budget forms are being addressed by the PMO Senior Manager supervising the project.

   b. Project Initiation - Information Resources Approval.

      Proposed new projects require the submission of a Project Initiation Form (PIF) describing if the request is for a feasibility study, new or upgrade/enhancement to systems or applications, process/workflow optimization, infrastructure/operations, construction, or other request types. The PIF is to have proposed start and end dates, estimated resource hours, requester and PIF author information, and sponsor information. The PIF requires approval by the executive sponsor(s), IR Division Head and Chief Information Security Officer (CISO). Approval by the

Chief Information Officer (CIO) is further required for project hardware/software costs over $17,000. The PIF for this project was not available and it is being addressed during the audit.

New software/hardware implementation could pose a risk to existing systems or applications. Documentation of vendor specifications and functional requirements ensures that information system projects are implemented in an effective and efficient manner. As best practices, an information security risk assessment is generally performed during project initiation to determine the sensitivity and confidentiality of data and required storage, software/hardware management responsibilities, system user account access, vendor access requirements, network vulnerability monitoring and disaster recovery responsibilities. The aforementioned was not in process during the first phase of the Velos/Epic project. It is now in effect and requires the project manager to conduct an information security risk assessment with the vendor. The completed questionnaire is to be returned to the Information Security Office (ISO) prior to system approval and implementation.

c. Project Planning - Charter.

Project requirements discussed in the Velos/Epic Charter document on file were consistent with professional standards and internal guidelines established by the PMO Office. They included defined project description, problem statement, project goals, objectives and scope, critical success factors and assumptions, project constraints, risks and flexibility. Project funding authority, a governance structure provided through the Research Steering Committee and major project milestones were presented. Information regarding the project organization of executive stakeholders, project team and research coordinator workgroup was provided. Roles and responsibilities of project team members and stakeholders were discussed. However, this Charter document appeared to be a work-in-process. Full descriptions of measurable success factors, project funding amount and source for any required professional services costs were not yet determined. Formal approval was not present.

d. Project Monitoring/Controlling.

The Velos/Epic integration project is a multi-year project with start date of March 2011 and planned end date of Q4 2012. Actual resources allocated to the project are currently processed into the Planview system as a time tracking tool within IR for payroll purposes only. Planview is capable of reporting actual as well as budgeted resources and hours for individual tasks or phases of a project. The PMO Office is moving towards tracking actual versus budget at the project phase or detailed task levels, and it is expected to become a requirement for future projects.

Recommendation

We recommend management of PMO/Business Systems continue assessing the controls relevant to individual project management phases and appropriate improvement steps, specifically:

a. Adherence with the PMO project lifecycle process in reemphasizing the submission of capital justification and initial budget forms during project development. Detailed support should accompany a project proposal to facilitate management review and approval. Documentation of approval and relevant support should be retained for reference.
b. Emphasizing formal IR approval and information security assessment signoff for new project requests and retention of support.
c. Continued emphasis in obtaining formal charter approval and making timely revisions to the charter document to ensure approved changes in conditions and requirements are reflected in the project assumptions, risks, milestones and deliverables.
d. Introduction of a defined budget monitoring process within the PMO project lifecycle including more effective utilization of the Planview system in order to improve the management of actual and budgeted resources.

Management Response

a. As previously stated the PMO is a relatively new organization at the Medical Center. The PMO has implemented and enforced a process whereby documentation for the initiation process which includes but is not limited to budget, justifications and Information Systems Advisory Committee (ISAC) approval. This documentation now resides on each project's SharePoint site for reference and retrieval as necessary.

   Implementation Status: Implemented
   Implementation Date: June 15, 2012

b. The security assessment process was not in place during the implementation of Phase 1 of this project. The PMO along with the HSIR Security team have developed a security assessment which documents the protection of PHI along with outlining vendor access to the system. This document is presented to the ISAC committee for approval and must receive final approval from the security team prior to project execution. This document along with the approvals is retained on the project SharePoint site. The Project Initiation Form (PIF) is under review by the HSIR Directors in the bi-monthly capital project prioritization meetings. Target implementation is March 2013.

   Implementation Status: In Process
   Implementation Date: March 31, 2013

c. Project scope changes are to be addressed through a change management process. This process was not in place during project phase 1 but it has since been implemented. Currently, if there is any change in project scope, schedule or budget a change management form must be completed by the project manager and submitted to the HSIR Director responsible for the project for approval. Once approval is received the form is then sent to the PMO Senior IR Managers and placed on the project SharePoint site. Then all project documentation is updated as necessary. Documentation of Project Charter approval by the Project Sponsor was obtained on September 3rd.

Implementation Status:	Implemented
Implementation Date:	September 03, 2012

d. It is the project manager's responsibility to manage the hours charged to their project by the resources assigned. There is a current initiative within HSIR to improve our ability to capture actuals versus estimates. The current version of Planview does not address this need adequately. The PMO is in the process of upgrading the Plan View software to include a resource module which will give us the ability to track actual vs. estimated work effort. Phase 1 upgrade will cover the time reporting and review process including classification by work types (support or projects). Target completion for phase 1 is March 2013. Phase 2 upgrade will cover actual versus budgeted resources with target date of July 2013.

Implementation Status:	In Process
Implementation Date:	July 30, 2013

Responsible Personnel:
Assistant Vice President, PMO/Business Systems & CIO, University Hospitals

2. Test Standards

Velos/Epic integration project phase 1 includes the creation of research study records in Velos and establishment of the same records in Epic through system interface, registration and enrollment of research patients to a study in Velos and association of patients to the same study in Epic via interface from Velos. Phase 1 elements further include synchronization of research patient records between Velos and Epic via interface and disassociation of patients from study in Epic when they are off study in Velos. The PMO project management methodology includes test scripts development, performing required testing, acceptance and signoff during the execution phase of a project.

Project phase 1 testing was conducted prior to the go live date of February 27, 2012. Results of functional testing performed by assigned testers, whether passed or failed, and test dates were summarized on a spreadsheet. However, they did not

capture the level of details, expected and actual outcomes for individual testing scenarios and test steps outlined in the project test scripts. This test matrix provided instructions and steps for validating basic system functionality associated with user entry (five test specifications), testing system interface for specific workflow exceptions (four test specifications), testing miscellaneous attributes in Velos and Epic (two test specifications). The design in the project test scripts for testing basic system functionality was sufficient, while the design for testing one specific workflow exception and testing miscellaneous system attributes was not completely built. There was no documented test plan approach; evidence of end-user acceptance test results and signoff was not available.

Successful test management requires the development of a comprehensive test plan and testing strategy. A test plan represents a systematic approach to testing system software or hardware and generally incorporates test coverage, test methodology and responsibilities. Essential test plan elements include purpose and scope of testing, relevant software risk issues, technical functions to be tested, features and risk levels to be tested, detailed testing strategy, roles and responsibilities of testers and end-users, acceptance testing and signoff. Test plan documentation provides detailed descriptions of the test procedures and goals, test scripts matching work scenarios in the production application(s), pass/fail criteria appropriate to the test plan level, execution and error logs. Expected deliverables generally include a summary report of tests performed, exceptions and corrective actions. Appropriate approval by the project team and project sponsor is needed to implement the test plan.

Recommendation

Test scripts development, execution and results reporting should be reemphasized to responsible project team members to ensure fulfillment of test objectives and adherence with project requirements. Documentation of end user acceptance should be retained. We further recommend the incorporation of a formal test plan approach in the PMO process. The test plan should include items/functions and features to be tested and software risk issues, planning risks and contingencies, a comprehensive testing strategy that includes test cases or scenarios developed to meet the objective for each test phase, testing levels, required resources and responsibilities, test deliverables, appropriate management buyin and approval.

Management Response

a. The PMO has recently implemented a test plan to be completed during the planning phase of the project lifecycle. The test plan outlines the scope, quality objectives, roles and responsibilities, test execution assumptions, constraints and milestones. This is to be communicated to all project team members and customers who will have testing deliverables. The plan also needs to receive approval from the HSIR Director responsible for the project. Testing risks and issues are maintained on the project's risk register log and issues list. Testing scenarios are identified and scripts are created by the

project team. Scenarios and scripts receive acceptance approval by the customer prior to the beginning of the testing phase. Formal customer acceptance that testing goals and objectives have been met is now required.

Implementation Status:	Implemented
Implementation Date:	June 15, 2012

b. User acceptance signoff was not in place during Velos/Epic Project phases.

The original plan for user acceptance testing for Phase 2 was as follows:

- ObGyn - include in the portion of testing that is specific to the department billing personnel (i.e. SOC charges routing to the department work queue).
- Internal Medicine - include in the portion of testing that is specific to the department billing personnel (i.e. SOC charges routing to the department work queue).
- Cancer Center - include in hospital billing work queues
- Urology - include in registration & scheduling research only and mixed visits (Ambulatory Clinic)
- Simmons Comprehensive Cancer Center - include in registration & scheduling research visits

While there was internal testing by Velos and Epic Teams in the development environments (all documented via email), the end user testing was not completed before go-live date for Phase 2.

The current PMO methodology now includes end user testing and acceptance sign-off. All test records are retained on the project SharePoint site for reference and retrieval. Epic currently has a testing environment referred to as TST which is used for testing of any new application functionality, upgrades and/or modifications to code.

Implementation Status:	Implemented
Implementation Date:	September 29, 2012

Responsible Personnel:
Assistant Vice President, PMO/Business Systems & CIO, University Hospitals
Assistant Vice President, Academic Information System

3. <u>Velos Studies</u>

Velos-Epic integration project Phase 1 implementation covered registration of research studies and patients in Velos and creation of this information in Epic through interface. Project Phase 1 was completed and production commenced during February-March 2012. Existing study records of major research centers and departments have been established in Velos. Registration of new studies and patients by research departments is in progress.

A system download through April 27, 2012 obtained from AIS listed 3,343 open and 842 closed or terminated studies in Velos. Open studies pertained to active and inactive records in various build stages of the IRB, Coverage Analysis and Study phases, and included 663 IRB approved studies plus 54 studies with "Active/Enrolling" status. The following attributes were observed for open study records:

a. Required (mandatory) input fields displaying no values: "Study Contact", PI "Specialty", "Research Type", "Research Phase", "Study Sponsor" and "Blinding." "Research Type" denotes the type of funding source (academic, institutional, private nonprofit/for profit, public local/federal, etc.) and "Study Sponsor" identifies the sponsoring organization.
b. PI "Department" not specific and/or PI "Specialty" missing.
c. Study status of "IRB - Approval Lapsed" but showing "Active for Enrollment" date (3 cases); and "Study - Enrollment Complete" with "Active for Enrollment" date, but no human subjects enrolled (22 cases).
d. Test studies (8 in production environment).

(3a, 3b and 3c) were consistently associated with legacy studies that underwent data conversion and migration from the legacy systems to Velos during project Phase 1 implementation, while the remainder pertained to new studies set up by end users. Test study records identified in (3d) were created by system users for conducting functional testing and validation that the system integration was working as intended. According to AIS, the project implementation planning began with the prerequisite that there were to be separate production and test environments. This requirement was subsequently dropped due to resource limitations. Currently, test studies are distinguished from true studies based on the "test" designation indicated in the study title. There are no formal guidelines for the management of test data. Users with create/update capability can set up test studies and system administrator preapproval is not required.

Recommendation

We recommend the Project Sponsor and Research Administration collaborate to formally communicate to all research departments of the need to revisit and update study records established in Velos. Required input fields should be reemphasized to all users. We further recommend management establish and maintain a set of formal guidelines for the management of test data and the conduct of acceptance testing. They should incorporate best practices including administrator approval, control and disposition of test records. Acceptance testing by end-users should be performed in an environment that is capable of fully simulating the production environment, functions, and features that the application must support. Details that cannot be replicated in the test environment should be documented as known risks upon release to a production environment.

Management Response

For (3a, 3b and 3c) - A formal mechanism for communication to all appropriate research team members was not in place for Phase 1 of this project. The Offices of Research Administration, Compliance and Academic Information Systems have worked jointly with the Medical Center's Internal Communications to implement a Research Administration and Compliance Communications Plan to track the research community so we can better identify the targets of necessary communications and to define methods of communication.

Implementation Status:	Implemented
Implementation Date:	September 29, 2012

A project has been started to create processes and procedures to manage data in Velos to ensure data integrity. This project will include a review of required fields and the data definitions for those fields, creation of specifications for monitoring reports, development of these reports, identification of resources to use the reports and procedures for corrective action for data discrepancies. The above described communication mechanism will be used to alert the user community of any changes and these items will be incorporated into the currently existing Velos training documents and classes.

Implementation Status:	Implemented
Implementation Date:	September 29, 2012

For (3d) - All referenced test studies but one were removed. Within Velos there is now one test study in the production environment that is used as final testing and this known study is excluded from all reporting that is done from Velos. In addition, there is a Velos test environment that was created as a copy of the production environment when an upgrade is made, and any changes to the environment go through development, test and then production to ensure that test and production are in sync. End user testing and acceptance sign-off requirements are now in place.

Implementation Status:	Implemented
Implementation Date:	June 11, 2012

Responsible Personnel:
Assistant Vice President, Academic Information System
Vice President, Research Administration

4. Issues Tracking

Successful project management relies on the constituent processes, interactions among key stakeholders and timely direction by the project governance body to achieve consensus in guiding a project. The PMI approved project management lifecycle process includes interactive components that ensure the specifics for a project are defined and objectives accomplished based on the level of complexity,

risk, size, timeframe and access to resources, historical information, and project management maturity continuum. As new project information is established additional dependencies, requirements, risks, opportunities, assumptions and constraints are identified and resolved. Involvement of project governance members through an integrated approach creates an environment that facilitates project member contributions during all project phases ensuring desirable outcomes. Project Phase 2 had a target live date of September 29, 2012. A project request for the creation of a centralized staff to review the research charge level work queues was recently approved by senior management. This request had a designated critical priority level. Several risk areas with high priority and active monitoring status remain active on the PMO issues list. These potential barriers could create opportunities as definitive courses of action are agreed upon and approved for implementation.

a. Research patient scheduling and billing.

   Some research departments or specialties currently do not schedule research patient visits in Epic. In order for the research visit to be associated to the study, the patient encounter has to be scheduled in Epic. Clinical Trials Billing Compliance Policy (Research Policy 153) currently in effect, requires all clinical trials with IRB approval be registered in an approved clinical trials management system. However, the scope of this Policy does not apply to research visit scheduling or billing. Additionally, research charges are not being entered through Epic for many Departments. An official determination has not been made if all Departments are to use Epic for research billing. The project Phase 2 implementation fall back plan is that some research billing will stay on paper.

b. System access and user roles of Research Coordinators (RCs).

   Not all RCs currently have access to Epic or use the system to schedule research visits. The number and identity of RCs including their appropriate security levels have not been established. RCs currently have varying responsibilities based on the studies they are associated with. RCs are to assist their PI in the management of a clinical trial from study proposal to review and approval, activation, scheduling patient visits, recording research activities, results reporting and closeout. Other essential responsibilities of RCs can include processing inter-departmental payment, billing study sponsors and performing accounts receivable reconciliation. Administration of Epic user training could be impacted if the required number of participants or level of training is not established. A listing of all RCs is to be generated through the Office of the Project Sponsor. Epic security levels are rescheduled for Phase 3.

c. Research order sets.

   A decision by senior leadership has not been reached regarding the use of research order sets, which could be due in part to some areas of research not

completing a coverage analysis. Such review is performed of protocol-related documents during the pre-trial phase to establish if all patient care costs related to a study are covered by the study sponsor, patients, third-party payers or other funding sources. Order sets are to expedite the ordering process for a common research scenario and are associated with the protocol on which a clinical trial is based. They typically follow an approved format and are designed to safeguard the health of the patients as well as answering specific research questions. Research Policy 153 requires the completion of an appropriate coverage analysis for clinical trials involving human subjects and billing of a sponsor, a clinical department, a third-party payer or patient. The current project implementation plan is to go live with research studies that completed a coverage analysis for Phase 2 and defer the feasibility of order sets into Phase 3.

d. Research rate schedule.

A research fee schedule has not been loaded into Epic to facilitate professional service charges and billing. The expectation of management is an approved research charge master for hospital charges and research fee schedule for professional services will be developed by the Medical Center and its affiliates for budgeting and billing purposes. Research fee schedule implementation is under discussion by the Project Sponsor and Research Administration for project phase 3.

Recommendation

The issues are due to varying billing processes and practices employed by the research departments, clinical and hospital entities. Each area impacted by the implementation project has different governance. There is no centralized decision maker that can make a determination when issues are escalated, which has slowed the project progress. Collaboration and consensus by senior leadership would ensure timely accomplishment of the following:

a. Implementation of formal guidelines or policies for scheduling research appointments and billing.
b. Identification of RCs, appropriate Epic system access levels and training requirements.
c. Determination of the use of research order sets relative to the coverage analysis requirements referenced in Research Policy 153.
d. Implementation of research fee schedules in Epic.

Management Response (Project Steering Committee through Project Sponsor)

a. Formal guidelines or policies for scheduling research appointments and billing.

Epic Tip Sheets have been provided with instructions on scheduling research appointments. Research billing will not be done using Epic. Billing personnel will continue to bill research charges in the same manner as they do today.

Implementation status: Implemented
Implementation Date: September 29, 201

b. Identification of RCs, required Epic system access and training requirements.

The rollout plan for Epic Research Billing does not require anyone who does not currently schedule or bill for research to do so, thus, the process will continue with current access. Schedulers have been provided Epic Tip Sheets explaining the research visit flag and those who are doing the research billing will continue to bill as they have in the past with research charge information being sent to them from the Office of Research Facilitation who will be handling the Epic research work queues.

Implementation Status: Implemented
Implementation Date: September 29, 2012

c. Use of research order sets relative to the coverage analysis requirements outlined in Research Policy 153.

The project team determined not to require research order sets, with recommendation from the EVP of Health System Affairs.

Implementation Status: Completed and Closed
Implementation Date: August 19, 2012

d. Research fee schedules in Epic.

As Research Billing will not be done using Epic, the approved Research Rate List is not scheduled to be loaded in the system. When standard-of-care services related to clinical trials are billed using Epic, the already-loaded physician fee schedule (for Physician Practice Plan services billing) and charge master (for University Hospital services billing) would be used.

Target Implementation Date: Completed and Closed
Implementation Date: August 19, 2012

Responsible Personnel:
Assistant Vice President, Academic Information System

Conclusion

We have concluded that the control design over the Velos/Epic implementation project for Clinical Trials Billing is adequate as evidenced by the Medical Center PMO adopting an approach that incorporates adequate project lifecycle framework and standards.

In order to continue to improve the level of effectiveness, we made recommendations related to the following: 1) Adherence with the project lifecycle approach in requiring documentation of project and budget approval during project development, information security assessment signoff, Project Charter approval and more effective utilization of the Planview software in monitoring actual and budgeted resources, 2) Comprehensive test scripts development, execution and results reporting, incorporation of a formal test plan approach and end user acceptance testing in the PMO process, 3) Reemphasis of required input fields of research studies in Velos and establishment of formal guidelines for administering test data and test studies, and 4) Continued collaboration to achieve consensus by senior leadership in the monitoring and timely resolution of project high risk issues.

We appreciate the courtesy and cooperation from the PMO Office, Project team members and executive sponsor, Project Steering Committee, HSIR and AIS management, and Urology Department Clinical Nursing Administration staff.

Andrea Claire, JD, MBA, CIA - Manager of Internal Audit
Van Nguyen CPA - Supervisor of Internal Audit

660 Audit Hours Expended

Sincerely,

Eva Narten, CPA, CIA, CISA
Assistant Director of Internal Audit

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