14 – 205 Operational Assessment - ChemoCato

Strategic Area: Information Technology, Pharmaceutical
Risk Type: Operational
Audit Manager: Betty Kaczmarek, PharmD

Overview:

Chemocato is an integrated pharmacy software solution for oncology therapy that can provide support throughout all stages of therapy management: from therapy planning, to current therapy prescribing, to the preparation of cytotoxic drugs and other critical medications. Chemocato can operate as a stand-alone application in small pharmacies, or can integrate different nursing units and physician offices in large hospital networks. Chemocato was implemented in MD Anderson’s R2 pharmacy in October 2012, and became the first American site to utilize the application.

At MD Anderson, Chemocato is used to support several stages of the oncologic medication use process: oncologic medication preparation, inventory management and preparation verification. At the time of this audit, Chemocato was in use for MD Anderson’s adult, outpatient chemotherapy treatment in the main pharmacy. MD Anderson plans to implement Chemocato during the last week of June 2014 at three additional pharmacy locations.

Chemocato is interfaced with one application, GE Healthcare’s Centricity, MD Anderson’s primary clinical application for entering medication orders, medication administration records, and tracking clinical orders. Chemocato acts as an interactive assistant, guiding technicians through the production process. Additionally, it is used by chemotherapy pharmacists and technicians but is accessible to some IT personnel, most of whom are granted read-only access, amounting to approximately 60 total users. The Core Clinical Systems team provides functional IT support for the application, including user security access provisioning, end user trouble shooting, and response to emergency situations.

Audit Results Summary:

Internal Audit found that MD Anderson has established controls to support the Chemocato application, with processes and procedures to evidence control design and operation. Through our procedures, we noted Chemocato has a strong control environment with many control processes related to operations and change. Details of our results are as follows:

Interfaces

Internal Audit obtained an understanding of Chemocato’s primary interface, an inbound interface from Centricity to Chemocato, and noted that the interface is functioning effectively. In addition, the functional user group and supporting IT team have effective processes in place to identify and resolve errors encountered with the interface.
General Chemotherapy
Internal Audit found that MD Anderson has incorporated best-practice pharmaceutical standards, such as a three pharmacist review of oncologic medication orders. Internal Audit also observed chemotherapy preparation at MD Anderson’s R2 pharmacy, and noted that the pharmaceutical team appropriately handled oncologic medication and utilized appropriate safety equipment for oncologic medication preparation.

Chemocato
Internal Audit gained an understanding of the operational procedures followed as they relate to gravimetric preparation of chemotherapy using Chemocato. All pharmacists and technicians using Chemocato must undergo a practical training session prior to utilizing the software in chemotherapy preparation. It is important to note that effective procedures are in place to calibrate and maintain gravimetric scales with logical access to Chemocato's database appropriately restricted as well. Furthermore, there are various effective automated controls throughout the mixing process facilitated via bar code scanners and gravimetric weight tolerances.

Additionally, the Chemocato Pharmaceutical team has performed Failure Mode Effects and Analysis (FMEA) for several Chemocato-specific functions, including: Ordering, IV Production & Process, Pharmacist Workflow, Inventory Management, and Master Data. In performing the FMEAs, the team identifies failure modes and compensating controls to mitigate the risk associated with the identified failures and their effects.

Management Summary Response:

No observations were identified as part of the Chemocato assessment.

Number of Priority Findings to be monitored by UT System: None

A Priority Finding is defined as “an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.”

The courtesy and cooperation extended by the Pharmaceutical and Core Clinical Systems were sincerely appreciated.

Sherri Magnus, CPA, CIA, CFE, CRMA
Vice President & Chief Audit Officer
August 26, 2014
Appendix A

Objective, Scope and Methodology:

The objective of this internal audit was to assess controls for the Chemocato application against established policies and procedures. Our assessment focused on various controls including interface monitoring/processing, general chemotherapy, and Chemocato application controls. The scope of this internal audit was focused on both the design of controls and execution of those controls operated by MD Anderson personnel. The internal audit coverage period was from September 1, 2013 to June 17, 2014.

Our procedures included the following:

- Interviewed key personnel within the Pharmaceutical and Core Clinical Systems teams for the Chemocato application.
- Gained an understanding of Institutional Policies and Procedures and compared to Chemocato’s current control environment for the following areas:
  - Interfaces
  - General Chemotherapy
  - Chemocato

Our internal audit was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing.