

21-401 Beaker AP Post-Implementation Review

EXECUTIVE SUMMARY

In June 2020, MD Anderson implemented Epic Beaker Anatomic Pathology (AP), a laboratory information system that is a module of the Epic. Beaker AP replaced the legacy system, PowerPath, for anatomic pathology lab functions. As a follow-up to the module deployment, Internal Audit performed a post-implementation review over Beaker AP with the following objectives:

- Evaluate progress in achieving objectives of Beaker AP's implementation,
- Assess whether institutional project management and implementation procedures were followed,
- Evaluate key integrations and data transfers between Beaker AP and applicable lab instruments and systems,
- Assess effectiveness of relevant information technology (IT) general controls, and
- Evaluate at a high-level the sufficiency of oversight programs in place designed to identify, promote, monitor, and enforce compliance with applicable regulatory requirements.

Audit Results:

Based on audit procedures performed, the Epic Beaker AP module implementation generally achieved objectives of the project; Internal Audit observed the following notable successes:

- Strong alignment with the MD Anderson Information Technology Project Management and Governance Policy and the Project Management Methodology framework,
- Establishment of post-implementation processes to address end user issues, including Monthly Beaker Steering Committee meetings and utilization of the Cherwell ticketing system,
- Interfaces between Epic Beaker AP, lab instruments, and data repositories were effectively tested through Mapped Record Testing prior to go-live and are actively monitored for errors or failures,
- IT general controls related to user access management, change management, and backup/recovery are operating effectively, and
- Regulatory compliance was considered as part of the implementation and processes have been designed and implemented to enable compliance.

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

Additionally, Internal Audit was made aware of the following opportunities:

- Managing Data Quality - Data quality issues for 100-150 patient cases, where 4 weeks of data was not carried over from PowerPath to Beaker AP and had to be manually recreated by laboratory staff,
- Pre-implementation Report Testing - Key report design issues identified by laboratory management after go-live, one of which required a manual workaround outside of Beaker, and
- End User Training - Issues with laboratory end users and non-pathology personnel failing to understand Beaker AP workflow processes correctly, due in part to a 3-month gap between training and the Beaker AP go-live as a result of COVID-19, as well as non-pathology users not being required to attend trainings but still being involved with the specimen ordering/collection process.

Management Summary Response:

Management agrees with the observations and recommendations and has developed action plans to be implemented on or before 11/30/2021.

Appendix A outlines the methodology for this project.

The courtesy and cooperation extended by the personnel in the Division of Information Services are sincerely appreciated.

Sherri Magnus

Sherri Magnus, CPA, CIA, CFE, CRMA
Vice President & Chief Audit Officer
April 1, 2021

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

Observation 1:**Enhance Direct Communication Plans with Impacted Users****RANKING: Medium**

The communication with laboratory personnel was not sufficient during the Epic Beaker AP implementation. As a result, not all in-progress cases were correctly identified by laboratory personnel during the data validation process and were mistakenly included as part of the bulk upload of finalized patient cases. This possibly impacted between 100 and 150 patient cases. According to management, the lab team had to manually update each of these cases in Beaker AP and recreate the missing data. Management disclosed that this incident was not communicated to IT Support; therefore, no root cause analysis was performed for this incident. Incomplete or missing patient case data could result in a patient safety issue. Our scope and planned procedures did not include the identification or confirmation of actual patient safety concerns. Best practices require implementations include a comprehensive communication plan for all individuals involved in data validation, testing, and end users.

Recommendation:

We recommend enhancing communication plan guidelines for future application and Epic module implementations to enable direct communication with impacted users from the deployment team to limit, prevent, or detect data quality issues. Communication should inform users of their role to enable data quality, including:

- Explicit guidance regarding when legacy systems should no longer be used, if those legacy systems remain available, and
- Expectations for reporting issues and incidents so they can be resolved or evaluated for root cause by IT support.

Management's Action Plan:

Executive Leadership Team Member: Craig Owen
Division/Department Executive: Wes Vanderhoofven
Owner: David Duplichen
Implementation Date: 9/1/2021

Management communication plans will include more direct communications to impacted end users around conversions and transition between systems.

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

Observation 2:**Enable Report Design and End User Acceptance****RANKING: Medium**

Several Laboratory Managers expressed that key reports in Beaker AP did not meet their expectations, and in one instance necessitated the use of manual workarounds. Primary concerns raised by laboratory personnel included report formatting/display issues, lack of desired data fields and incorrect data pulls for some reports. Laboratory personnel expressed issues with the Patient History Report and Notes (90 Days) Report, as the information in these two reports needs to be consolidated into a separate report. Internal Audit was also informed of issues with the Turnaround Time Report, as it was not configured to calculate metrics needed for College of American Pathologists reporting, resulting in manual calculation by the Lab team using spreadsheets. The approach for key reports included Beaker AP Reporting Analysts meeting with designated end users during face-to-face meetings to walk through and validate reports. End users did not have consistent hands-on opportunities to evaluate reports independently prior to go-live.

It should be noted that report enhancements are currently being addressed by the Beaker AP team and validated by end users. Major reporting concerns raised by end users are tracked through Cherwell tickets and discussed/evaluated during monthly Beaker Steering Committee meetings.

Recommendation

In the short-term, IT should continue to coordinate with laboratory personnel to identify, prioritize, and implement enhancements with key reports through the Beaker Steering Committee and Cherwell ticketing process. For future implementations and any new or modified reports in Beaker AP post go-live, recommend that end users test reports independently through hands-on generation and review in addition to guided walkthroughs provided by report developers. The independent generation and review testing process should increase the likelihood that issues are identified, and end users are able to express concerns to report developers sooner.

For system implementations where regulatory compliance or critical business processes are dependent on effective reporting, recommend incorporating report testing into the foundational training for relevant end users. To do so, this may involve accelerating the timing of report testing in the pre-implementation testing plan or generating test data for report testing purposes.

Management's Action Plan:

Executive Leadership Team Member: David Jaffray

Division/Department Executive: Craig Owen

Owner: Janna Baganz

Implementation Date: 11/30/2021

Management will continue the post-implementation process to collect feedback and develop report enhancement requests from end users for Epic Beaker AP as this process has been effective.

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

For future system implementations, including new Epic modules, Management will require project stakeholders/customers to designate operational and report/data analyst resource(s) to support the implementation project team with key report development and approval. The designated individual(s) will serve as subject matter and content experts acting as liaisons between the project team and the business. Designated individual(s) will be responsible for developing a sufficient understanding of the new system's capabilities and workflows to ensure satisfactory mapping of report development to business requirements prior to go-live.

Observation 3:**Ensure End Users and Stakeholders are Adequately Trained****RANKING: Medium**

Internal Audit noted that there were issues with end-users properly following Beaker workflows after go-live, such as failing to mark a specimen as "Gross-Complete" or failing to document specimen collection date/time. Issues with non-pathology personnel also came up, as they were not always aware of changes to the specimen ordering and collection process in Beaker AP, as compared to PowerPath. These issues resulted in processing delays and required lab personnel time to investigate and resolve. While all pathology users were required to complete assigned trainings and a knowledge assessment to obtain access to the system, Beaker AP workflow procedures were not consistently followed by users after go-live. Non-pathology users were not required to take Beaker AP training, as their overall job functions did not heavily involve Beaker AP; however, these users were still involved with the specimen collection process.

It should be noted that end user engagement with training was also impacted by the forced switch from a classroom environment to virtual sessions, due to the impact of COVID-19. As some laboratory personnel were not as experienced with using virtual conferencing, this resulted in additional complications during trainings. COVID-19 also resulted in a multiple month gap between user training and the go-live of Beaker AP, which impacted user retention of training information for some users. The pandemic also prevented planned in-person Epic expert support in labs during the typical hypercare period (period of about 30 days after go-live) that would have provided hands-on support for users and accelerated adoption and issue resolution.

Recommendation

We recommend that system implementation guidelines be adjusted to specify that end-user training must be completed within 60 days of system go-live to increase the likelihood of training knowledge retention. For functions indirectly impacted by a system implementation, like non-pathology functions for Epic Beaker AP, consider adjusting communication plans and training plans to incorporate those functions for improved awareness of upcoming changes and provide instruction on any changes to procedures, processes, or workflows to reduce the impact of the system implementation on those functions.

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

Management's Action Plan:

Executive Leadership Team Member: David Jaffray
Division/Department Executive: Craig Owen
Owner: Michael Bersin
Implementation Date: 06/01/2021

COVID-19 was unprecedented and had a major impact on the Beaker AP project timeline and activities. The project go-live was moved three months from April to July. A significant portion of the clinical staff had already begun training when the decision was made to move the project. Additionally, our training staff was not allowed to be onsite during go live to ensure protection of our patients and staff. Our training team quickly pivoted all training (not just Beaker) from physically in classroom to holding virtual classes. Our IS Training standard is for end users to complete training within 60 days of a go-live. If we have an event occur again that changes the go-live date significantly after training has begun, the IS Training team will work with operational leadership to schedule refresher training courses and encourage utilization of the training playground environment.

For functions and groups indirectly impacted by a project implementation, we will work with operational leadership to include them in our Go Live Readiness Assessment (GLRA) process to help ensure leadership awareness and operational readiness prior to go live. We will also work with our change management and communication teams to promote educational materials, including our OneConnect Central SharePoint site. For implementations where we do not have onsite assistance, we will offer virtual labs to help users at go live and partner with operational super users to support them.

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

Appendix A

Objective, Scope and Methodology:

The overall objective of this engagement was to assess the effectiveness of the Beaker AP implementation. The scope of this engagement focused on validating if project objectives were met, determining if project management practices were used efficiently, assessing the effectiveness of integrations with other systems/devices, evaluating the effectiveness of IT general controls, and evaluating how regulatory compliance needs were considered.

Our procedures included the following:

- Conduct information-gathering interview(s) with key contacts to understand how Beaker AP is being utilized and how well it meets end user needs.
- Identify instances where Beaker AP is not being used as intended, determine potential improvement opportunities, and identify areas of risk and concern for Beaker AP.
- Review Beaker AP project management documentation to validate implementation procedures aligned with MD Anderson Cancer Center project management standards.
- Determine processes in place to communicate, address, and resolve any perceived or actual issues with Epic Beaker.
- Identify the methods by which data is processed, manipulated, and transferred to and from other systems, validate user acceptance testing is performed, and ensure management approval was attained prior to migration to production environments.
- Hold discussions with key contacts to determine change control, data backup and recovery, and user access provisioning processes in place.
- Test IT general controls relating to change management, data backup and recovery, and user access provisioning to ensure effectiveness of controls in place.
- Determine regulatory compliance policies Beaker AP is required to follow and validate processes and procedures in place enforce compliance with those policies.

Criteria considered by Internal Audit for this assessment included, but was not limited to, the following:

- Adherence to institutionally defined project management and system implementation procedures
- Adherence to institutionally defined end-user training requirements, including time between trainings and go-live
- Adherence to best practices for key report testing, including hands-on testing and approval of the reports by end-users
- Adherence to best practices for communication plans for all individuals involved in data validation, testing and end users
- Adherence to best practices for monitoring system interfaces for failures and
- Adherence to institutionally defined processes for IT General Controls

Please note that this document contains information that may be confidential and/or exempt from public disclosure under the Texas Public Information Act. Before responding to requests for information or providing copies of these documents to external requestors pursuant to a Public Information Act or similar request, please contact the University of Texas MD Anderson Cancer Center Internal Audit Department.

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

The internal audit function at MD Anderson Cancer Center is independent per the *Generally Accepted Government Auditing Standards* (GAGAS) requirements for internal auditors.

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.*”