A Key to Successful EHR Implementation - Quality Assurance and Independent Verification and Validation

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Effectively implementing an electronic health record (EHR) system that meets the meaningful use criteria defined by the American Recovery and Reinvestment Act of 2009 (ARRA) is critical to any provider institution’s future success.

Many providers are looking beyond meaningful use requirements to improve quality of care and operational effectiveness through a sustainable transformation of their clinical, operational, and financial processes, as well as the critical IT platforms that support those processes.

Providers undertaking EHR implementations, for example, are also looking for guidelines to evaluate the likely success of the EHR project and to compare the initiative’s progress with the stated deadlines and financial milestones.

To address these concerns, a growing number of providers are utilizing a project management philosophy known as Quality Assurance/Independent Verification and Validation (QA/IV&V).

QA/IV&V provides an objective, independent assessment of a project’s potential risks and performance, as well as the quality of its management, deliverables, and related processes. QA/IV&V’s risk-based approach can help provide an early warning of conditions that might cause problems during implementation and bring them to the attention of management.

QA/IV&V can help identify potential areas of high risk, and can help ensure the EHR project is designed properly. This often includes evaluating the provider’s implementation and change management plans, training schedule, how data is collected, and monitoring whether the actual implementation is on track to deliver the benefits highlighted in the project plan.

Because QA/IV&V is delivered independently of the vendor’s project management and implementation teams, interested stakeholders including the project sponsor, steering committee, and senior management can rely on the multidisciplined QA/IV&V team to provide objective feedback.

By gathering relevant data, analyzing that data to develop performance improvement guidance, and providing continuous improvement recommendations throughout the project, QA/IV&V can help significantly increase the likelihood that the project will meet its objectives while remaining on time and on budget.
EHR systems offer a number of compelling clinical and financial benefits to healthcare providers. EHR systems, for instance, can provide practitioners with consistent access to standardized data that improves the safety, quality, and efficiency of the care that is delivered.

ARRA provides significant incentives for providers that are able to demonstrate meaningful EHR compliance within the Centers for Medicare and Medicaid Services (CMS) timetables (as well as penalties to those that are unable to demonstrate compliance). In addition, a well-implemented EHR will be mandatory in meeting the requirements of CMS’s Value-Based-Purchasing and Accountable Care Organization guidelines.

Electronic data can also be shared with, and enhance the effectiveness of, the provider’s business- and revenue-related processes. Under CMS rules, eligible healthcare providers and professionals requesting incentive payments will need to use a certified EHR technology to exchange electronic health information to improve the quality of care, to submit clinical quality measures and other data to CMS or other regulatory bodies and for a variety of functional areas including exchanging information related to:

- Computer provider order entry
- E-prescribing
- Recording patient demographics and vital signs
- Maintaining up-to-date problem lists
- Verifying insurance eligibility and submitting claims electronically
- Exchanging key clinical information electronically
- Implementing specific privacy and security capabilities.

Increasing the pressure to get an EHR implementation right the first time, ARRA provides significant penalties for providers that are unable to demonstrate meaningful EHR compliance within the CMS timetables.
Beyond an IT project

“Given the complexity of an EHR implementation, progressive-minded providers are looking beyond IT and systems vendors for an independent assessment of their EHR initiatives.”

While the temptation may be strong to consider EHR as another (albeit very large) IT project, most providers realize EHR also provides a timely opportunity to both improve patient care and reduce costs.

Many providers are looking beyond ARRA’s meaningful use requirements to improve care and operating efficiency through a sustainable transformation of their clinical, operational, and financial processes, as well as the critical IT platforms that support those processes.

In addition to clinical improvements, EHR can provide a number of process- and business-related benefits to providers that seize the EHR opportunity and revamp their operations, systems, and processes to eliminate redundancy and improve overall operations.

As with other transformative projects, a successful EHR implementation has to include a comprehensive needs assessment that balances clinical, operational, and financial considerations, an implementation plan, training, and post-implementation monitoring.

In addition, achieving meaningful use of EHR will often involve interdependencies with other large IT initiatives such as ICD-10. Many providers have several large process- and technology-improvement efforts underway, which increases pressure not only to manage and implement each project effectively on its own, but also to identify potential challenges in one initiative that could affect another.

Given the complexity of an EHR implementation, progressive-minded providers are looking beyond IT and systems vendors for an independent assessment of their EHR initiatives.

Providers are looking for ways, for example, to help ensure the EHR project is well-designed, has a well-thought-out implementation and change management plan, training schedule, is focused on how the data is collected, and that the actual implementation is delivering the benefits called for in the project plan.

In short, many are looking for an independent, objective oversight process to help ensure the project’s technical, operational, and financial goals are being met. To address these concerns, a growing number of providers are turning to a project management philosophy known as Quality Assurance/Independent Verification and Validation (QA/IV&V).

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Beyond an IT project

Electronic Health Records: Providers’ Priority

KPMG's QA/IV&V approach is focused on mitigating overall program risk.
Benefits of QA/IV&V

QA/IV&V is a widely accepted framework that provides a strategic and independent approach to project management and implementation. QA/IV&V provides an objective assessment of a project’s risks and performance as well as the quality of its management, deliverables, and related processes.

QA/IV&V’s risk-based approach can help identify conditions that might cause problems, bring them to the attention of management, and focuses on preventing the areas of highest risk.

QA/IV&V begins at the outset of a project—when risks can be foreseen, prioritized, and addressed—and continues throughout the project life cycle.

By gathering relevant project data, analyzing that data to develop performance improvement guidance, and providing continuous improvement feedback to the project, QA/IV&V can significantly increase the likelihood that the project will meet its objectives on time and on budget.

Throughout the project’s planning, design, building, implementation, and monitoring phases (see diagram on page 3), QA/IV&V helps ensure that clinical stakeholder requirements and governance are addressed early in the project life cycle, and helps identify risks before they become full-blown problems.

In addition, if problems are identified, QA/IV&V can help identify the root causes so mistakes are not repeated.

Finally, its emphasis on measuring project outcomes can improve project processes and results by raising critical questions:

- Do project deliverables meet industry standards?
- Is the project on time, within budget, and delivering the required scope?
- Are the expected outcomes and benefits being achieved?

Because QA/IV&V is delivered independently of the vendor’s project management and implementation teams, the project sponsor, steering committee, and senior management can rely on the QA/IV&V team to provide objective feedback throughout the project life cycle.

Potential EHR implementation risks

As with any large transformation project, an EHR initiative carries a number of implementation risks. Because EHR projects touch so many aspects of the patient and provider experience, there are, unfortunately, a variety of ways in which a project can fail to deliver the expected benefits:

- **Insufficient or inadequate planning**: Instead of treating EHR as a vendor-driven initiative, it is critical to consider the varied needs of the clinical providers and operational professionals who will interact with the EHR system.

- **Meaningful use incentives**: Providers unable to demonstrate meaningful use will not receive incentive dollars, and will be subject to financial penalties for failing to meet CMS timetables.

- **Scope**: EHR implementations focused solely on Stage 1 requirements may face significant challenges in achieving the anticipated success metrics including improvements in patient care and meeting future government, third-party and Stage 2 and 3 requirements.

- **Corrective costs**: Any operational deficiencies discovered after the EHR system is implemented will require additional expense and lead to delays.

- **Vendor shortage**: Many EHR vendors are trying to complete implementations simultaneously at different healthcare systems, so the pool of experienced professionals may be overtaxed.

- **Operational disruptions**: Providers must design, test, and implement new records systems, reporting standards, data formats, and business processes while still meeting the expected standards of patient care and operational efficiency.

- **Data conversions**: Preparing existing data in a format that can be read by the new system, and shared with payors and other providers, presents a technological and operational hurdle.

- **Change management**: Critical change management issues, including staff training and an institutional communications plan, must be factored into the overall project plan.

Given the unique nature of EHR, the information contained within those records simply has to be accurate and up-to-date. Relying on outdated, incomplete, or inaccurate information can compromise the quality of clinical decisions and lead to adverse outcomes.
QA/IV&V phases

1. Project process assessment
The QA/IV&V project process assessment focuses on the methods, practices, and tools used by the project management team to plan, execute, monitor, and control the project. This assessment is a critical early step in completing the project on time and on budget, while meeting the project goals as well as its clinical and business requirements.

While specific factors will vary among projects and providers, common steps and deliverables during this phase include identifying key clinical, financial, and management stakeholders, and interviewing those stakeholders to ensure everyone’s goals and expectations are in alignment.

This phase will typically include the creation of a project governance structure, as well as a detailed review of the project documentation. Identifying potential gaps as early in the project’s life cycle as possible reduces the opportunity for problems to cascade, as well as the need for rework and changes to the project’s design or intended functionality.

2. Project management assessment
The QA/IV&V project management assessment is designed to help remedy the issues that arise when projects do not use leading project management practices. This assessment focuses on assessing the methods used by the project team to execute its plan (business process development, organizational change, technology integration, and internal controls).

As in the project process assessment, a variety of methods — interviews, informal conversations, and reviews of project schedules and other documents — are used to assess the project’s scope, schedule, and cost. This assessment often includes other critical success factors including technology integration, communications and training during and after the implementation phase, and other process or organizational impacts that need to be considered.

3. Deliverables assessment
Project deliverables need to adhere to project, clinical, and business requirements, as well as agreed-upon technical standards. The deliverables assessment examines the specific results of project deliverables by focusing on the adherence to project requirements, standard industry processes, and technical standards for each deliverable.

This phase typically includes a comparison of the project plans with the provider’s clinical and financial requirements, leading industry practices, and the provider’s IT resources.

From a technology standpoint, this may include identifying the systems, interfaces, and operational processes that will be affected by the EHR implementation, the provider’s infrastructure capabilities, internal controls, and integration with other clinical and financial systems.

Defects that can be uncovered through deliverables assessment might include, for example, omission of requirements in design or test cases, errors, data format incompatibility, security vulnerabilities, incomplete planning, or other potential issues.

4. Risk assessment
The QA/IV&V function proactively and systematically identifies conditions that might damage the ability of the project to achieve its goals. Focus is provided on strategy and governance, project management, business processes, organizational change management, and other critical success factors.

This typically includes interviews with stakeholders, attending design and project update meetings, ensuring project design or scope changes are documented, and other factors.

5. Performance assessment
Each activity includes processes for gathering performance data about project processes, deliverables, risks, and other factors; analyzing the data to develop performance improvement guidance; and providing continuous improvement feedback to help project leaders meet the project’s performance objectives.

QA/IV&V helps improve the project’s management by reviewing processes and practices, and providing feedback—with the ultimate effect being that those processes become consistent with leading practices, which results in a higher level of assurance of overall project success for key stakeholders.
Importance of objective QA/IV&V

When using QA/IV&V during an EHR implementation, providers should pay close attention to long-term monitoring, the need for diverse skills, and the importance of an independent assessment.

QA/IV&V can help ensure that the project is consistent with the provider’s strategic priorities and on track to meet its performance objectives, and that resources required for project success are available.

As we noted earlier, a complex IT project requires many functions to succeed, including strategy and governance, project management, business process development, organizational change, technology integration, and more.

To address these aspects, the QA/IV&V team generally involves multidisciplined professionals with knowledge across a wide range of areas. The QA/IV&V team should have the resources to evaluate practices and deliverables for each project component, according to the project documents and agreed-upon standards.

Retaining a QA/IV&V team that remains independent of the vendor’s project management and implementation teams allows the project sponsor, steering committee, and management to receive objective feedback throughout the project life cycle.

**EHR benefits to providers**

By increasing providers’ access to updated information, and improving the quality of that data, an EHR system can transform the clinical process and create the following benefits:

- Improve patient safety, quality of care, and efficiency
- Provide electronic access to ambulatory and inpatient records
- Increase physician/hospital integration through collaboration and patient care coordination
- Transform care delivery by improving coordination throughout the continuum of care
- Improve revenue and operating margins through enhanced clinical documentation and charge capture
- Enhance data quality to better meet payor requirements and improve the payment process
- Reduce administrative overhead that can result in delayed or denied claims
- Enable meaningful institutional efforts at becoming “accountable care capable”
KPMG’s Healthcare’s QA/IV&V services provide independent oversight that can help make a difference between success and failure at each phase of the project life cycle, from initial approval through long-term service delivery.

Through the application of QA/IV&V assessments—focused on risk, project management, deliverables, performance, and process improvements—the KPMG Healthcare QA/IV&V team can provide collaborative assistance to the project team and help ensure that the organization “builds the right EHR system” and “builds the EHR system right.”

Key to the success of the QA/IV&V approach are a multidisciplined team; a comprehensive scope that mirrors the project’s clinical, operational, and financial goals; and an appropriate level of independence.

Healthcare providers can minimize risks, lower overall costs, and significantly increase the likelihood of success if they include QA/IV&V components as part of their mission-critical projects.
About KPMG Healthcare

With nearly 850 experienced professionals and over 90 partners, KPMG Healthcare in the U.S. annually serves over 1,000 healthcare clients, and has performed meaningful work across the entire spectrum of healthcare players — from major government health agencies, to public and private insurers to the top U.S. healthcare systems. We use this experience to help healthcare organizations see themselves more clearly in the midst of unprecedented flux, assessing not only where they are today, but where they’d like to be in the future. We can help you identify and understand the complexities and risks inherent in healthcare transformation and help turn them into opportunities. We can help you recognize what you need to do and provide the tools, techniques, and experience to help you get there.

About the KPMG Healthcare & Pharmaceutical Institute

The KPMG Healthcare & Pharmaceutical Institute provides a forum for healthcare business leaders to gain insight into emerging issues, consider approaches to help balance risk and controls and improve performance, and further explore the accelerating transformation within the healthcare industry, both domestically and globally. Please visit kpmghcpharainstitute.com to browse the Institute’s resources and join as a member.

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