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Designing clinical audits to support compliance activities

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Auditing is a key component of an effective healthcare compliance program and should be based on a risk assessment that examines the specific risks to the organization. Continuous improvement, periodic testing, and review are expected activities of a compliance program.[1] Designing effective audit tools will provide data in a format that supports analysis of potential risks and tracks responses to identified concerns.

The purpose of the audit will drive the design of the tool. A wide-ranging tool with many indicators may be needed to evaluate a new clinical program with little historical data. A focused review with a limited number of audit questions is appropriate for specific risk areas. Overall, the goal is for relevant data to be captured in a consistent and objective manner. This will improve the organization's ability to evaluate and respond to the identified concerns.

When multiple risks are identified, a large audit plan can be divided into a series of audits. Potential audit areas are rank ordered based upon decreasing risk, and then subsequently audited in a sequential manner. This is a recommended process for large audits that need to be completed for multiple units. The challenge with a large audit is the time it takes for completion. If there is a risk that not all units will be audited in the expected timeframe, breaking the audit tool into smaller components will provide time to address high-risk areas in all locations.