Quality Management – Improving the Process

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Background

Quality Management is an overall system for evaluating clinical research processes, managing the protocol activities and accuracy of the data collected, and ensuring the protection of human subjects. Quality Management activities in clinical research are part of an on-site management tool to measure, evaluate and improve site performances. These measurements are achieved by implementing quality control and quality assurance checks across the continuum of the protocol.

Quality control activities are performed in real time to verify that protocol procedures and data management meet quality standards. Quality control checks provide opportunities for real-time corrective action.

Quality assurance activities are routine, retrospective. Along with quality control activities, quality assurance checks provide a broader evaluation of performance of clinical research processes and documentation. Additionally, these internal evaluations prepare for and complement site monitoring visits.

Objectives

The primary goals of quality management are:

• Protection of human subjects.
• Site management of clinical research processes.
• Data are accurate and verifiable.
• Public confidence.
• Establishment of best practices for healthcare delivery systems resulting from research.

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<thead>
<tr>
<th>Quality Management Process</th>
<th>Nursing Process</th>
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<tr>
<td>Assess the protocol</td>
<td>Assess</td>
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<tr>
<td>Plan QM process</td>
<td>Diagnose</td>
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<td>Implement plan activities</td>
<td>Plan</td>
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<td>Evaluate effectiveness</td>
<td>Implement</td>
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<td>Evaluate</td>
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Table 1: The quality management process in research very closely resembles the process in nursing

Methods

Performing quality management requires:

• Internally monitoring the conduct of the protocol as approved and intended by continuous quality reviews.
• Analyzing quality reviews toward minimizing error repetition and correction and maximizing efficient internal processes.
• Using results of quality reviews, error identification and correction to train research staff.
• Establishing preparedness and readiness for any external audit by organizing operations, processes, and documentation.

Results

By implementing an effective Quality Management process, the primary objectives can be measured, analyzed and applied toward establishing standards of excellence and best practices.

Resources

American Society for Quality – http://www.asq.org/
Agency for Healthcare Research and Quality (AHRQ) – http://www.ahrq.gov/
Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials – http://www.aamc.org/research/