



Short Communication

Quality Management in Clinical and Public Health Research: A Panacea for Minimising and Eliminating Protocol Deviations in Research Operations

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Abstract

A quality management system for clinical and public health research operations is indispensable because it ensures the integrity and reliability of research outcomes. By implementing a robust quality management practice in research implementation and operation, research teams can uphold the highest standard of research conduct, thereby enhancing the credibility and trustworthiness of research findings. This paper elucidates the significance and role of a quality management system in clinical and public health research operations and its efficacy in minimising and eliminating protocol deviations and highlights the key steps in setting up a quality management system for research operations.

Keywords: Quality Management System; Protocol Deviation; Clinical Research; Public Health Research.

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Introduction

Clinical and public health research endeavours rely on the use of meticulously designed protocols to generate valid and reliable data. ^[1] Protocol deviations, defined as either minor or major divergence from established ethical standard practices and approved research protocol, pose a significant challenge to the integrity of research outcomes. ^[2-6] Quality management system in research operations serve as a comprehensive approach for mitigating the risk of protocol deviations and maintaining research integrity. ^[7]

Clinical and public health research is a form of research in which human subjects, their data or samples are studied within globally acceptable ethical standard practice to better understand health and disease outcomes. ^[8] Clinical and public health research provides an avenue and opportunity to find new and better ways to detect, diagnose, treat, and prevent diseases. ^[8]

Over time, clinical and public health research has played a vital role in improving our understanding of human health and disease and in the discovery and development of new, safe, and effective treatments. ^[8] However, the ultimate goal of research is to find answers to research questions by generating high-quality data for proving or disproving a hypothesis that forms the outcome of the research. ^[8] High-quality data vis-à-vis high-quality outcomes in research can only be guaranteed when approved research protocols are implemented with minimal or no protocol deviations and are in line with standard global ethical principles and practices. ^[9]

To minimise or eliminate protocol deviations in clinical and public health research, quality management procedures must be implemented in all clinical and public health research operations from the point of protocol development through the data generation process to the reporting of the findings from the research. ^[8]

A quality management system (QMS) in research operations can be defined as a plan or system, including structure and defined responsibilities, which provides a framework for all quality management activities, including quality control, quality assurance, quality improvement and the reporting of these activities. ^[10] It encompasses the organisational structure, responsibilities, procedures, processes, and resources for implementing a quality system for conducting research. ^[11] According to Afifa, ^[12], QMS in research simply implies standardised research procedures with guidelines. These guidelines form the backbone for all procedures to be carried out during the research implementation. Furthermore, the QMS is meant to keep track of all the records, activities, tasks, processes, important events, interactions, inspections, and training that must be administered and controlled throughout the research implementation and the lifespan of the study. ^[12]

Establishing a QMS for clinical and public health research operations is the key to eliminating protocol deviations and ensuring that research objectives are met as expected. ^[12] QMS processes and procedures should be implemented to ensure that established standard operating procedures are strictly adhered to during the implementation of the research by all research team members. ^[12] The QMS ensures that clinical and public health research are implemented according to standardised practices to meet sponsors/funders, research governance, and regulatory and trust requirements during implementation. ^[13]

This paper explores the significance and role of quality management in clinical and public health research operations and its efficacy in minimising and eliminating protocol deviations and highlights the key steps in setting up a quality management system for clinical and public health research operations.

Protocol Deviations in Research Operations

One fundamental tenet of research ethics is to ensure uniform provision of maximal benefits and minimal risks to all subjects in all research operations; hence, the research protocol must be meticulously prepared with ethical principles in consideration, as any deviation from established research procedures may result in reduced benefits or heightened risks to the study participant. ^[3]

A deviation from research protocol is defined as any intentional or unintentional divergence from predetermined research protocol approved by the designated ethical committee. ^[3,13] This refers to instances where procedures outlined in a study protocol are not followed as planned or specified. ^[3,13] These deviations could introduce bias into study results, leading to erroneous conclusions and potentially influencing clinical and public health practices and policy decisions. ^[3] Additionally, deviations may compromise participant safety and welfare, undermine research credibility, and impede scientific progress. ^[3]

Protocol deviations are neither uncommon nor unexpected during research implementation. ^[3,13] They have been conventionally classified as deviations or violations, depending on their impact on the study outcome. ^[3] These deviations can occur at various stages of the research process, including during participant recruitment, data collection, intervention implementation, analysis, and reporting of research findings. ^[2-3] These deviations can arise due to intentional or unintentional human error, unforeseen circumstances, or systemic inefficiencies. ^[3] While some deviations may be minor and have minimal impact on study outcomes, others can significantly affect the validity, reliability, and integrity of research findings. ^[2-3]

A minor divergence from the approved research protocol is categorised as a deviation, while deviations that compromise data quality or jeopardise participant safety are termed protocol violations. ^[3] Deviations are subcategorised as noncompliance, misconduct, or fraud. ^[3] An isolated deviation may be labelled noncompliance, whereas repeated and systematic noncompliance, often disregarding warnings, is classified as misconduct. Noncompliance driven by financial incentives may be deemed fraud. ^[2-3,14]

Understanding and addressing protocol deviations in clinical and public health research operations are essential for maintaining the quality and credibility of research outcomes. ^[2-3, 14] Researchers must document and report deviations transparently, adhering to established guidelines and regulatory requirements. ^[2-3,14] Transparency in reporting deviations enables stakeholders, including funding agencies, peer reviewers, and journal editors, to assess the potential impact on study findings and interpret results appropriately. Moreover, proactive measures could be implemented during the developmental stages of all research to minimise the occurrence of protocol deviations. ^[2-3,14] This includes comprehensive training of research staff, robust monitoring and oversight mechanisms, clear communication of protocol requirements to all stakeholders, and flexibility in protocol design to accommodate real-world challenges while ensuring scientific rigor. ^[3]

Common Protocol Deviations in Clinical and Public Health Research

Some common protocol deviations in clinical and public health research are highlighted as follows:

Nonadherence to protocol procedures: This involves instances where researchers fail to adhere strictly to the procedures outlined in the approved research protocol. Nonadherence can occur due to oversight, lack of training, or other external factors affecting research implementation. ^[14-15]

Incomplete documentation: Failure to document study procedures, interventions, or participant data accurately and comprehensively can lead to incomplete or missing data, compromising the integrity of the study findings. ^[14-15]

Participant eligibility criteria: Deviations related to participant eligibility criteria occur when individuals who do not meet the specified inclusion criteria are enrolled in the study or when eligible participants are excluded erroneously. [14-16]

Informed consent issues: Protocol deviations related to informed consent include failure to obtain informed consent from participants or obtaining consent improperly, such as coercion or inadequate disclosure of study risks and benefits. [14-16]

Data collection errors: Errors in data collection, including inaccurate measurements, data entry mistakes, or missing data, can occur due to human error or equipment malfunction, leading to compromised data quality. [14-15]

Intervention delivery: Deviations in intervention delivery involve variations from the planned administration or execution of study interventions, such as incorrect dosages, timing, or delivery methods. [14-15]

Adverse event reporting: Failure to report adverse events promptly and accurately or inaccurately, categorising events can lead to underestimation or misrepresentation of safety risks associated with study interventions. [14-16]

Data analysis and reporting: Deviations in data analysis and reporting include selective reporting of results or failure to disclose conflicts of interest, leading to biased or misleading study conclusions. [14]

Ethical and regulatory compliance: Failure to comply with ethical principles and regulatory requirements, such as institutional review board (IRB) approvals, data protection regulations, and reporting guidelines, constitutes protocol deviations with serious implications for research integrity and participant protection. [2, 4-6, 14-15]

Therefore, by identifying and mitigating all protocol deviations, researchers can enhance the reliability, validity, and ethical conduct of clinical and public health research studies.

The Role of Quality Management System in Research Operations

A quality management system plays a pivotal role in mitigating the risk of protocol deviations and ensuring adherence to an approved research protocol. It plays a crucial role in ensuring the integrity, reliability, and ethical conduct of clinical and public health research operations. The following are the key roles of a quality management system in research operation activities:

Ensuring compliance: Quality management ensures that research operations adhere to regulatory requirements, ethical guidelines, and industry standards. This includes obtaining appropriate approvals, maintaining documentation, and conducting research following established ethical guidelines. [10, 17-18]

Data integrity: Quality management ensures the accuracy, completeness, and reliability of the data collected during research activities. This involves implementing robust data collection, storage, and analysis procedures to minimise errors and bias. [10, 17-18]

Participant safety: Quality management prioritises the safety and well-being of research participants. This includes implementing measures to minimise risks, ensuring informed consent, and monitoring participant health throughout the research process. [10, 17-18]

Resource optimisation: Effective quality management helps optimise the use of resources, including personnel, equipment, and funding. By streamlining processes, identifying inefficiencies, and minimising waste, research operations can achieve better outcomes within budgetary constraints. [10, 17-18]

Continuous improvement: Quality management promotes a culture of continuous improvement, where research processes are regularly evaluated, monitored, and refined. This allows for the timely identification of issues or deviations, corrective actions, and preventive measures to enhance overall research quality. [10, 17-18]

Risk Mitigation: Quality management involves proactive risk assessment and mitigation strategies to identify and address potential threats to research integrity or participant safety. This may include contingency planning, protocol modifications, or addressing emerging ethical concerns. [10, 17-18]

Quality Management System in Research Operations: Key Benefits

The implementation of a QMS in clinical and public health research operations offers several benefits, contributing to the overall success and integrity of research endeavors. The following are some of the key advantages:

Enhanced research quality: A well-implemented QMS ensures that research activities are conducted according to established standards, protocols, and regulatory requirements. This promotes consistency, accuracy, and reliability in data collection, analysis, and reporting, leading to higher-quality research outcomes. [10, 18-20]

Compliance and regulatory adherence: A QMS helps ensure compliance with relevant regulatory guidelines, ethical standards, and institutional policies governing research. By documenting procedures, obtaining necessary approvals, and maintaining comprehensive records, research operations can demonstrate adherence to regulatory requirements. [10, 18-20]

Improved participant safety and ethics: A QMS prioritises participant safety and ethical considerations in research activities. By implementing a robust protocol for informed consent, participant monitoring, and risk assessment, research operations can minimise potential harm to participants and uphold ethical principles. [10, 18-20]

Efficiency and resource optimisation: Streamlining research processes through a QMS improves operational efficiency and resource utilisation. By standardising procedures, identifying inefficiencies, and eliminating redundant activities, research operations can maximise productivity and minimise waste of time, resources, and funding. [10, 18]

Risk management and mitigation: A QMS facilitates proactive identification, assessment, and mitigation of risks associated with research activities. By conducting risk assessments, implementing preventive measures, and developing contingency plans, research operations can minimise the impact of potential threats on project timelines and outcomes. [10, 18-20]

Continuous improvement culture: Implementing a QMS fosters a culture of continuous improvement within research teams. By regularly evaluating processes, soliciting feedback, and implementing corrective actions, research operations can identify areas for enhancement and drive ongoing performance improvement. [10, 18]

Enhanced collaboration and communication: A QMS promotes effective communication and collaboration among research stakeholders, including investigators, sponsors, ethics committees, and regulatory authorities. By establishing a clear channel of communication, sharing information transparently, and fostering collaboration, research operations can facilitate smoother project execution and achieve better outcomes. [10, 18]

Overall, a well-designed and effectively implemented QMS is essential for ensuring the quality, integrity and success of clinical and public health research operations, ultimately contributing to advancements in scientific knowledge and improvements in public health outcomes.

Steps in setting up a Quality Management System in Research Operations

Addressing and preventing protocol deviations requires proactive measures such as setting up a QMS, which includes comprehensive protocol training for research staff, robust monitoring and oversight mechanisms, regular audits and quality control checks, and transparent reporting of deviations in research publications. ^[10, 17-20]

Setting up a QMS for clinical and public health research projects involves several essential steps to ensure research integrity, compliance with regulatory requirements, and the delivery of high-quality outcomes. The primary components of a QMS include quality management planning, quality control, quality assurance and quality improvement. ^[15, 18-20] The key steps in setting up a QMS have been categorised under these components, as shown in **Fig. 1** below.

Understand regulatory requirements: Begin by familiarising yourself with the regulatory standards and guidelines relevant to clinical and public health research, including those from government agencies, funding bodies, and ethical review boards. ^[15-16]

Define quality objectives: Clearly, outline the quality objectives of the research project, including specific goals related to data integrity, participant safety, ethical considerations, and regulatory compliance. ^[15-16]

Identify the key processes: Identify the key processes involved in the research project, from study design and participant recruitment to data analysis and reporting. These processes, including workflow diagrams, are documented in detail to ensure clarity and consistency in execution. ^[15-16]

Establish quality policies and procedures: Develop comprehensive policies and procedures that govern all aspects of the research project, including data collection, management, analysis, and dissemination. These policies should align with regulatory requirements and best practices in clinical and public health research. ^[15-16]



Figure 1: Steps in setting up a Quality Management System in Research Operation

Document control: Establish a robust document control system to manage all project-related documentation, including the study protocol, standard operating procedures (SOPs), consent forms, and data management plans. All the documents should be version-controlled, easily accessible, and regularly updated as needed. [15-16]

Assign responsibilities: Clearly, define roles and responsibilities for all project team members involved in implementing the QMS. Designate individuals or teams responsible for overseeing quality assurance activities, monitoring compliance, and addressing deviations or nonconformities. [15-16]

Implement training programs: Develop and implement training programs to ensure that all project staff members are adequately trained in QMS policies, procedures, and protocols. Ongoing training and support should be provided to reinforce compliance and promote a culture of quality within the research team. [15-16]

Establish quality metrics: Define key performance indicators (KPIs) and quality metrics to measure the effectiveness of the QMS and monitor progress towards quality objectives. Regularly collect and analyse data on these metrics to identify areas for improvement and take corrective actions as needed. [15-16]

Internal audits: Regularly conduct internal audits of the QMS to assess compliance with established policies, procedures, and regulatory requirements. Any nonconformities or areas for improvement should be identified, and corrective and preventive actions such as retraining should be implemented where necessary. [15-16]

Continuous improvement: Foster a culture of continuous improvement within the research team by encouraging feedback, sharing lessons learned, and implementing best practices. Regularly review and update the QMS to reflect changes in regulations, technology, or project requirements. [15-16]

By following these steps, clinical and public health research projects can establish a robust QMS that promotes research integrity, enhances compliance, and ensures the delivery of high-quality outcomes, ultimately contributing to improved health outcomes and scientific advancement.

Conclusion

A quality management system in research operations serves as the cornerstone of clinical and public health research operations, offering a comprehensive framework for minimising and eliminating protocol deviations. By prioritising protocol adherence, training, documentation, monitoring, and continuous improvement, research teams can uphold the highest standards of research conduct, thereby enhancing the credibility and trustworthiness of study findings.

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