What is Non-Conformance Management?

The laboratory's quality management system (QMS) is the bedrock in meeting quality objectives. The QMS governs all laboratory activities and addresses all processes to ensure accurate and timely service delivery to patients. One fundamental element of a QMS is a process to manage non-conformances. The goal is to cultivate an environment in which occurrences can be detected, reported, and the outcomes used to improve the quality of laboratory services.

A non-conformance, in its simplest terms, is a failure to meet requirements. It occurs when there is a detour (unintentional or deliberate) from established practice, policies, and procedures, resulting in a product or service that does not meet defi ed expectations. In the laboratory, examples include:

- Unlabeled/mislabeled specimen
- Missing specimen
- Specimen preparation error
- Equipment out of specifi ation
- Delay in turnaround times
- Incorrect delivery of critical report

A non-conformance can be minor (adherence to policy/process or procedures is inconsistent or the requirement is met in practice, but

required documentation is missing or incomplete) or major (has the potential to directly impact patient safety or an examination), but each can impact product quality or patient safety.

By managing non-conformances, we can learn about laboratory errors from the most critical to the mundane and improve quality from the ground up. In my experience, the best way to approach managing non-conformances is through the "five W's" of effective non-conformance reporting.

1: Why Report?

It is a requirement by standards and accreditation bodies to have a system for detection and reporting of non-conformance. For example, IQMH Accreditation Standard Section IIA.2 states "The quality management system shall encompass all management activities and processes relating to quality assurance: (h) investigation of non-conformities." It is also a proven method of continuous quality improvement (CQI) by which error waste and ineffici cies are reduced and quality and safety principles are implemented and sustained. So, a robust but effici t reporting process must be built into every laboratory system to guard against underreporting or errors.

2: Who Should Report?

Ideally, the person who detected the non-conformance should report the occurrence as close to the time of the event as possible. Th s individual has the closest perspective to the details that led up to the event, the event itself and any immediate actions needed to contain the issue. However, the review and investigation stage on non-conformance management must be open to various stakeholders to ensure a wide range of perspectives can be part of the resolution.

3: When to Report?

In non-conformance reporting, the clock is ticking. Critical and major non-conformances must be reported within 24 hours of detection. The longer it takes to report the error, the more potential there is to: allow subsequent errors to occur; lose essential information concerning the event; and have staff unavailable to recall the details of the event.

However, non-conformances may be identifi d during internal audits of the management system and laboratory activities, management review, document reviews, customer or supplier audits, or external assessments by regulatory or accreditation bodies.

4: What to Report?

Ultimately, the biggest challenge for laboratory staff is what is considered reportable. For minor non-conformances, a simple track and trend of such events is enough to raise a flag if recurrence is noted above a threshold. The process should use a standardized, systematic approach to help identify and assess potential risk or failure that exists in a process, and to identify which errors need be reported. Looking at each error with the lens of its potential impact on the product or service if the error went undetected is helpful in determining said risk.

Once a non-conformance is deemed reportable, the documentation must capture specific details such as date, time, area, involved staff and a brief summary of the non-conformance. Any non-conformance should be suffici tly documented to ensure there is traceability of all steps and actions taken and signatures of those involved in the capture, review and approval of the report.

5: Where Next? A Risk-Based Approach

Using a risk matrix to assign a risk rating is an effective tool, as it allows staff to adopt a proactive approach to non-conformance reporting and enables the identifi ation of potential non-conformities. Additionally, this prepares staff to react objectively when faced with the question "to report or not report?" and empowers staff o implement corrective actions.

After the 5 W's

There is a well known quote that the definition of insanity is to repeat the same mistakes and expect different results. A lack of effective non-conformance management in your quality system may feel the same. Reporting is essential, but without timely follow up, investigation and process change to ensure effective outcomes will be futile, if actions to correct the error at its core are not performed. Change outcomes must be linked with learning to avoid the same pitfalls in the future. Follow these key guidelines to ensure effective outcomes after the 5 W's.

If the non-conformance is major, perform a detailed investigation and root cause analysis. Involve a number of subject matter experts, including the supervisor and the quality and medical director, to determine the source of the non-conformance and make recommendations to mitigate further opportunity for recurrence. The investigation may involve a physical walk through the steps in a process, to follow the "breadcrumb trail" and find the reason for the non-conformance.

Management should review major non-conformances, and ensure the medical/scientific director has had the opportunity to view reports at a monthly quality meeting and the annual report. Minor non-conformances should also be available for review if required.

When implementing preventative change, there will be documentation in the non-conformance report that speaks to the actions (short and long term) needed to guard against further incidences of the same or similar non-conformance. Remember to follow the change control process to ensure modifi ations to policies, processes and procedures are done in a controlled manner.

Typically, it is the role of the quality manager to assign a tracking number to the non-conformance and file in the QMS, as well as an individual for follow up with the department issuing the non-conformance. Their follow up will be a guide as to whether the fix is working. If there are still problems, then a new corrective action plan is required and the non-conformance must remain open for further investigation.

Finally, it is best to present individual and cumulative data on the type, origin, and severity of corrective actions taken at local quality assurance meetings, so that trend analysis can highlight any ongoing concerns. Reports and summaries should also be shared with appropriate staff to ensure knowledge and ensure full transparency.

In our busy and resource strained laboratories, quality and accreditation will always require non-conformance reporting systems. As laboratory teams, we have an obligation to ensure that errors are easily reported and not missed or under reported. It is vital that we all understand the rationale for safe and effective non-conformance handling. Teams should benefit from a review of the five key principles (why, who, when, what and where next) of non-conformance reporting.

Using a risk-based approach and continuous quality improvement goals, together with standardized methods, will ultimately help focus our attention on the advantages of maintaining a user-friendly non-conformance reporting and management system. J

EDWIN BRINDLE, MSc, MLT
Quality Manager, Cellular Therapy &
Transplantation, Hamilton Health Sciences