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INVESTIGATING, CATEGORISING AND HIGHLIGHTING QUALITY FAILURES IN MEDICAL LABORATORIES

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ABSTRACT

The prevalence of laboratory errors is approximately 0.011%-0.7% in all test results. The laboratory is a key in-patient diagnosis. Therefore, this error rate may be significantly detrimental to patient care. Laboratories have spearheaded endeavours to improve patient safety by implementing a series of improvements such as analytical quality control programmes and expanding the automation of manual processes. All laboratories must have well-established systems capable of identifying and addressing quality failures. This entails a system-led approach that strives to highlight and rectify policy or weak procedural points instead of simply assigning blame. Quality failures can be categorised by cause (the stage at which the issue arose in the testing pathway) and graded on a five-point scale by severity. The severity grade indicates both the actual and potential (worst case scenario) impacts ('A' and 'P' scores) on the patients' outcomes. Typically, the 'A' and 'P' scores are slanted towards low and high adverse impacts on patients, respectively. This further underlines the necessity for laboratories to be constantly vigilant. This implementation of this categorisation and grading system is straightforward and can be a beneficial tool for performance monitoring and evaluation

1. Introduction

The Institute of Medicine (IOM) published a ground-breaking report entitled *'To Err is Human: Building a Safer Health System'* (1999), which informed the public, healthcare professionals, and regulatory bodies about patient safety and quality of healthcare (Corrigan, Greiner, & Adams, 2004; Phillips, DuPree, & Chassin). According to the IOM, up to 98,000 deaths each year in the US was caused by medical error. While there has been some contention about whether this figure is accurate, there is little argument that significant challenges surround the issues of preventable morbidity and mortality attributable to errors of omission or commission in healthcare provision (James, 2013). There is ambiguity as to how clinical laboratories influence patient morbidity and mortality (Bedell et al., 2000). Nevertheless, as between 80%-90% of all diagnoses are based on laboratory tests, it is clear that errors made in the laboratory may be highly detrimental to patient care (Plebani, 2009). For many years, laboratory professionals have spearheaded endeavours to decrease the medical error rate by implementing internal quality control systems and external quality assurance programmes. Recent surveys have consistently reported an error prevalence of between 0.012%-0.6% of all test results and indicate that there is a greater risk of error in the pre-and post-analytical stages than in the analytical stage itself (Harrison, 2009; Organization, 1998). Over the last decade, error rates have decreased; however, there is no universally acknowledged acceptable error rate; hence medical laboratories do not have a definitive quality target (Haak et al., 2019; Law et al., 2021; Søreide & Deshpande, 2021). Commencing with selecting the test(s) and finishing with delivering a properly interpreted report to the clinician who requested it, the laboratory test pathway is a multifaceted process that could benefit from being distilled into several steps. Each step encompasses at least one procedure, and the entire process depends on numerous employees of both the laboratory and other departments working together promptly (Fig. 1).

Patient care can be negatively affected if there is a failure in quality during any of these steps. The existing knowledge of laboratory errors originates primarily from paradigms from the cognitive and behavioural psychology fields (Ellwart et al., 2019). One such paradigm is the 'person approach', which contends that human errors are sloppiness or inattentiveness (Dyer, 2020). The typical response to an error occurring is to blame the responsible human operator (who is generally easily identifiable). The underlying message is that higher levels of management are not guilty in any way for said error. This response is embedded in human behaviour and can be a sense of emotional satisfaction - at least for those assigning the blame. It is an element that is present in all aspects of daily life. However, assessing this paradigm as a beneficial theoretical construct highlights that its weakness is that humans are, and always will be, imperfect, and it disregards the fact that by their nature, many work situations will have a high rate of error, which is confirmed by the widespread

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observation that the same errors are frequently made by different people (Moray, 2018; Pereira, Bertolini, Teixeira, Silla Jr, & Costa, 2020; Senders, 2018). Laboratory professionals are highly trained, devoted, and diligent employees, and are carrying out their roles in a challenging environment whilst providing a high-quality service (i.e., error free). A more fitting paradigm is the 'systems approach' which contends that errors occur because of flawed systems rather than the previously mentioned sloppiness or inattentiveness of the individuals involved (Ervin, Welsh, Batie, & Carpentier, 2003; Moray, 2018; Murray, 2019). Effectively designed systems must account for human imperfection and include suitable checks to identify and avert errors.

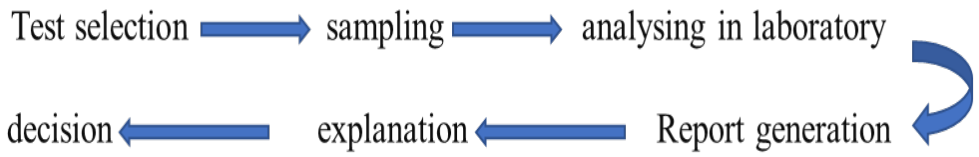

Figure: 1 The laboratory test pathway.

This approach focuses on systems or systems design failures rather than human failures. It shifts the emphasis from the employee to the system. This approach helps to enhance workplace culture. Under the 'person approach', there is a fear of being blamed for errors, which undoubtedly fosters a fault-finding and negative atmosphere that inhibits error reporting. Conversely, a 'systems approach' facilitates a more productive interaction with employees to detect the weaknesses in the policies and procedures (Clacy, Goode, Sharman, Lovell, & Salmon, 2017; Salmon et al., 2014). However, the fact is that the 'person approach' is deeply entrenched (especially the tendency to assign blame to individuals); therefore, a significant component of optimising a 'systems approach' is to promote a blame-free and open laboratory environment.

2. Definition of Laboratory Error

As per the IOM, there are two types of medical error: firstly, an execution error, which is when an action fails to be completed as planned, and secondly, a planning error, which refers to the wrong plan being used to accomplish the aim (Armitage, 2009; Loeb, 2000). However, there is no universally accepted definition of laboratory error. Numerous terms are interchanged in the literature, such as 'error', 'blunder', and 'mistake'. The common element is that they all encompass negative inferences of blame, personal failure, and responsibility. Critical terminology such as this inhibits a productive 'systems approach' from being implemented, as it promotes a blame culture and decreases the likelihood that employees will report errors. Thus, a term such as 'Quality Failure' may be more effective due to its more neutral tone (Carayon et al., 2006). In a laboratory testing pathway (see Fig. 1), a quality failure is essentially any failure to meet the target quality required for optimum patient care at any stage in the pathway, from the initial test selection to the return of a suitably interpreted report to the requesting clinician. Rather than focusing on processes and procedures, this definition emphasises patient care and outcomes.

3. Challenges in Recognising and Reporting Quality Failures

Laboratories must recognise quality failures when they arise, as doing so aids in identifying the weak points in the laboratory's policies, procedures, and environment that could be detrimental to patient care. It facilitates quality improvement by developing and prioritising corrective action. Figure 2 depicts the primary components of the quality improvement pathway. It begins with recognising a quality failure and ends with suitable corrective action being taken. This corrective action could include, for example, procedures being modified, the work environment is improved, and additional training for laboratory personnel. Each step of the quality improvement pathway contains potential barriers. Arguably, the most significant is first, not recognising when a quality failure occurs, and secondly, not reporting the quality failure to someone who can investigate and implement corrective action. There are several reasons why quality failures may come to light, including user complaints, experienced and trained employees highlighting unusual findings, and the utilisation of systematic processes to identify idiosyncrasies. Some examples of these systematic processes include analytical quality control programmes, auditing, IT-based systems such as delta checking, minimum acceptable labelling criteria, quality assurance programmes, and sample or request form concordance checks (Heikkilä, 2016; O'Kane, 2009). The success rate of these systematic processes in identifying quality failures is uncertain; however, it is unlikely to be close to 100%. Therefore, employee vigilance is, and always will be, key. A core component of recognising quality failures is the laboratory culture. A productive culture in which questions and evaluation are encouraged, work is thoroughly appraised, and patient safety is prioritised will increase the detection of quality failures. However, it is frequently the case that detecting quality failures does not necessarily mean they will be reported to the appropriate person to initiate corrective action. The reasons for this are multifaceted and varied; for instance, the quality failure is deemed inconsequential, the patient was not harmed, there is no formal reporting mechanism in place, and there is a fear of being blamed. Once again, the laboratory culture is a key factor. A person approach focusing on assigning blame will dissuade employees from reporting instances that more senior staff members have not spotted (Tompson, Belur, & Jerath, 2021). Consequently, this means missed opportunities to identify procedural and other weak points. To establish an environment where quality failures are detected and reported, a culture that promotes a productive and judicious attitude to work must

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be fostered. This will create an atmosphere in which the central focus is on identifying quality failures to improve patient safety (Sahay & Willis, 2021). Positive feedback is essential to promote employee engagement and activeness. Additionally, there must be quantifiable proof that reporting quality failures lead to corrective action such as improvements to policies, processes, and the laboratory environment.

Figure: 2 The quality improvement pathway.

4. Significance of Quality Failures' Categorisation and Grading

Reporting quality failures should result in enhanced policies, processes, and/or the laboratory environment, with the goal of improving patient safety. This goal would benefit from implementing an appropriate system for categorising quality failures by cause and grading by severity, as this will illuminate where exactly corrective action should focus and where quality improvement should be prioritised. Furthermore, continual monitoring of quality failure trends will facilitate the evaluation of the corrective actions' effectiveness. Numerous approaches have been employed to categorise quality failures by cause. Of them, the most prevalent and straightforward categorises the failures according to where in the testing process they arise, i.e., the pre-analytical, analytical, or post-analytical stage, with subsequent subdivision to denote the step it occurred [3, 4, 6]. This approach is basic and does not account for the causative nature, for instance, whether it was cognitive or non-cognitive or latent or active [15]. Nevertheless, a benefit is that it is easily applied, reproducible, and quick to determine which step in the testing pathway requires attention. Another classification system is ISO/PDTS 22367, which in addition to the previously mentioned factors, considers others such as avoidable or unavoidable and attempts to quantify the impact on the patient [12]. While this system offers a more in-depth overview of individual quality failures, it is more complicated, and its application is likely more challenging.

It appears to be the case that only a small number of quality failures in laboratories harm patients, and unsurprisingly, they are the priority of risk management activities. Nevertheless, there are significant opportunities to learn from most quality failures, despite minimal direct influence on patient care. It may simply be down to chance that most quality failures do not lead to negative clinical outcomes. For instance, the quality failure could have been identified and addressed before a report was issued, or an inaccurate test result did not differ substantially from the actual result. More extreme examples of quality failures are often called 'near misses', but the less drastic are generally ignored by laboratory and clinical employees due to their insignificance in the grand scheme. The key point is that any quality failure of any magnitude could signify weak points in policies or procedures that may not lead to actual patient harm in one scenario but may do so in another. Consider, for instance, a sample labelling error in a clinical area: in one scenario, the laboratory employees identified the error as the delta check showed that the test results did not correspond to other results produced recently for the same patient [17]; however, in another scenario, an inaccurate report was issued because there were no prior results to compare. Sample labelling errors such as this in clinical areas are widely deemed difficult to identify with standard laboratory quality management processes.
Consequently, present an extremely high risk to patient safety. Hence, any system grading the severity of quality failures must consider both the actual patient harm and the potential worst-case outcome. The severity of each quality failure can be described by assigning both an A and P score (i.e., the actual and potential adverse impacts on the patient, respectively) [16]. The same five-point severity scoring scale could be used to measure both the A and P scores according to the patient outcome [16], as follows:

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1. No amendment to patient management; no negative clinical outcome
2. Minor amendment to patient management; no negative clinical outcome
3. Minor negative clinical outcome
4. Medium negative clinical outcome
5. Major negative clinical outcome

The following offers some examples of score assignments:
A recurrent issue with an ion-selective electrode caused a sample with a potassium level of 4.4 mmol/l to be reported as 4.1mmol/l. Later that day, a series of samples were rerun due to abnormal internal quality control results, which caused the quality failure to be identified. As the quality failure did not lead to unfounded patient management amendments, there was no negative patient impact; hence, an A score of 1 was assigned. However, a quality failure such as this could potentially lead to a major negative patient impact, such as a failure to diagnose hypo- or hyperkalaemia correctly; thus, a P score of 5 was assigned.

It had been determined that an in-patient with hyponatraemia should be discharged if their serum sodium concentration had increased to N 135 mmol/l. A non-urgent sample was sent to the laboratory; however, it was misplaced for a short time at specimen reception, which caused analysis to be delayed by an hour. Consequently, there was a short delay in discharging the patient. This quality failure was assigned an A score of 2 as there was a minor amendment to patient management, but there was no negative clinical impact. It was also assigned a P score of 3 due to the potential for a minor negative clinical impact because of the short delay in analysing the non-urgent sample. The laboratory was given a sample that had been labelled incorrectly. Specifically, the patient details on the specimen bottle and the request form did not match. The sample was rejected, and the laboratory requested a repeat sample. An A score of 3 was assigned as there was a minor negative clinical impact due to the necessity to carry out another venepuncture. A P score of 5 was assigned due to the potential major ramifications of a sample being labelled incorrectly.

5. Assessment of the Categorisation and Grading System

The clinical biochemistry laboratory in Altnagelvin Hospital, Northern Ireland, was used to assess how straightforward an undertaking it is to integrate a quality failure reporting, categorisation, and grading system into standard laboratory operations [16]. Altnagelvin Hospital's laboratory provides services to a wide variety of clinical specialities. The employees utilise up-to-date automated equipment and partake in a wide variety of quality assurance programmes (both internal and external). All laboratory employees were urged to detect and report any quality failures as a component of their normal operations. All quality failures required the completion of a standard proforma, and subsequently, the failure was investigated, and suitable action was agreed with the chief biomedical scientist or department head. Quality failures highlighted by users of the services were reported in the same manner. Every quality failure was categorised according to the phase of the testing pathway in which it originated, and A and P scores were allocated. Corrective action was then prioritised accordingly. The department held a quality meeting each month during which the identified quality failures were discussed and reviewed. Information sessions were held for employees about the process of quality failure reporting and the significance of integrating it into normal laboratory operations.

Table: 1 Breakdown of quality failures by cause.

Pre-analytical phase Analytical phase	87.6 %
Post-analytical phase	11.1 %
Post-analytical phase	1.3 %

Table: 2 Severity of quality failures—distribution of 'A' and 'P' scores.

Severity	'A' score [%]	'P' score [%]
1	75.1	0.7
2	6.4	10.8
3	18.5	16.0
4	0	4.9
5	0	67.9

The laboratory received 741,988 requests over a duration of 30 months. During this time, a total of 658 quality failures were recorded, equating to a rate of 0.089% of all requests. Additionally, the monthly range was 0.036%-0.095%. If the actual rate of quality failures over these 30 months was relatively constant, this monthly variation could indicate the level of recognition fluctuating, incomplete reporting, or a combination of the two.

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Throughout the 30 months, most of the quality failures (87%) transpired overwhelmingly in the pre-analytical stage (Table 1). The most prevalent was incorrect or incomplete specimen or specimen request form labelling. The proportion of pre-analytical quality failures is above the level documented in the existing literature [4-14]. No definitive reason for this has been established. Still, it could be due to a reporting bias or that advances in laboratory technology have decreased the number of quality failures arising in the analytical and post-analytical stages. The data on the seriousness of quality failures is noteworthy. Most quality failures (75.1%) were not deemed to have had any negative effect on patient care and were thereby assigned an A score of 1, which, as detailed earlier, is the lowest possible score representing no amendment in-patient management and no negative clinical outcomes (see Table 2). There were two reasons for this: firstly, the quality failure was immaterial, or secondly, the existing laboratory checks had identified the quality failure before releasing the result. Conversely, the P scores allocated were much higher, representing the high risk of negative impact; in fact, 67.9% of all quality failures assigned a P score of 5, the highest score, reflecting a very high risk of a negative clinical outcome. Quality failures that do not lead to actual patient harm may suggest defective protocols or processes, which could be harmful to the patient in a diverse scenario. Quality failures are essentially an opportunity to review the protocols and procedures and the P score. This emphasises the possible clinical risk, which subsequently aids in establishing where the priority for corrective action should lie. It was verified that A and P scores could be assigned with consistency and reproducibility, with kappa statistics for between observer agreement of 0.98 and 0.78 for A and P scores, respectively [19]. Furthermore, it was confirmed that a quality failure reporting, categorisation, and grading system could be a valuable supplementary tool to monitor quality in the laboratory. Some examples of the following corrective actions included analytical quality control management, the implementation of technology to scan request forms (resulting in a 90% decrease in data transcription errors), reporting of critical value, modification of the processes for sample handing at specimen reception, and updated information for phlebotomy personnel.

6. Conclusion

Medical laboratories are a core component of in-patient diagnoses and management; hence, laboratory quality failures are a significant issue due to the potential for patient harm. Laboratories have endeavoured to increase patient safety by implementing a series of improvements focusing primarily on the analytical stage. The improvements include introducing analytical quality control programmes and the expanded automation of manual processes. Evidence shows that there has been a decrease in the rate of quality failures over the last decade. Technological advances could further reduce this rate, but fundamentally, laboratory staff must be constantly vigilant and conscientious in investigating and reporting possible quality failures. This will be promoted by establishing a culture of openness in the laboratory and implementing an approach that prioritises identifying and addressing weak points in policies and procedures instead of blaming individual personnel. It is essential that all laboratories monitor the rates of quality failures and alter and strengthen their policies and procedures or amend the laboratory environment accordingly to decrease the possibility of failure repetition. Categorising quality failures by cause (i.e., pre-analytical, analytical, and post-analytical phases) enables the step in the testing pathway in which the error occurred to be illuminated, which is beneficial in performance monitoring. Furthermore, grading the severity of the quality failures is advantageous as it prioritises corrective action. A five-point scale can be used to assign the ‘A’ and ‘P’ scores for each quality failure according to the impact on patient care. The A score represents the actual impact on the patient, whereas the P score represents the possible worst-case scenario that could result from the quality failure. Six hundred fifty-eight quality failures that occurred over 30 months in the clinical biochemistry laboratory of Altnagelvin Hospital in Northern Ireland were reviewed. It was confirmed that the application of the grading system was straightforward and consistent. The A and P scores trended towards the low and high negative impact on patient care, respectively. The risk of harm to patients due to quality failures emphasises the necessity for employees to be vigilant and that effective processes and checks must be in place in the laboratory.

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