

Pre-analytical Errors

Make a difference

Author: Kathy Bayley, PathWest Laboratory Medicine WA

1. Overview

This document has been compiled to provide information about pre-analytical errors to enable the education of sample collectors, both internal and external to the pathology laboratory, on the importance of the pre-analytical phase of pathology testing. This document also contains some ideas on how to reduce pre-analytical error rates.

2. Pathology Laboratory Role

Pathology laboratories provide many complex services such as:

- Diagnostics testing
- Clinical services
- Consultation services
- Sample collection
- Courier services

The main aim for the **diagnostic service** is to:

To get the correct result, on the correct patient, to the requesting doctor without unnecessary delays

It is also the role of the laboratory to:

To protect patients from any wrong or potentially wrong results.

The pathology laboratory has many very established mechanisms within the laboratory to ensure the quality and integrity of the samples and the test results are accurate. These mechanisms are in the form of policies and procedures which are implemented in a quality system framework. This framework is governed by NPAAC (National Pathology Accreditation Advisory Council) and enforced by NATA (National Association of Testing Authorities). This is all very good but if the sample collector has not performed their part of the procedure correctly it doesn't matter how good the laboratory is, the result will not be correct.

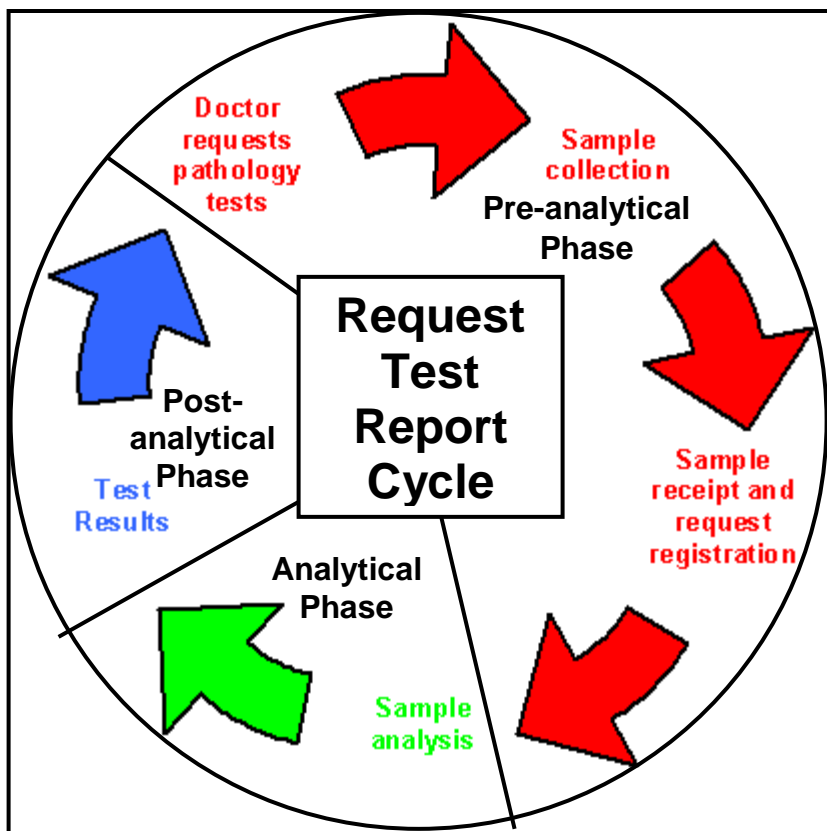


Diagram 1: Phases of Request-Test-Report Cycle

A vital part to getting the correct result on the correct patient is the initial patient's identification; sample collection and sample labelling which occur in the pre-analytical phase (see **Diagram 1**).

Unfortunately not all sample collectors are under the direct control of the pathology laboratory which presents a difficult challenge when trying to enforce correct procedures. Even though pathology have no direct control it is vital that the pathology laboratory educates and communicates with these collectors to ensure sample integrity, for optimal patient safety and care.

Errors that occur in this phase are called pre-analytical errors.

3. Pre analytical Errors

Pre-analytical Error is anything that occurs before a sample is analysed that may compromise the accuracy or integrity of the result

There are two main types of pre-analytical errors:

1. Identification Problems
2. Sample Problem

3.1 Identification Problems

Correct identification of a sample is very important as it is the link between the patient and the tests the doctor has requested to be preformed.

When a sample is being collected, the Collector has a very important task to ensure three aspects of identification are correct and identical. They check the patient identification matches the request by a verbal check and by the identification band (if present) and then that the samples collected are labelled with the sample identification, at the bedside. This allows for a three-way check illustrated in **Diagram 2**. As soon as the sample leaves the patient's side the sample label is the only definitive link back to the patient and so it is so vital that the Collector performs this task accurately and consistently.

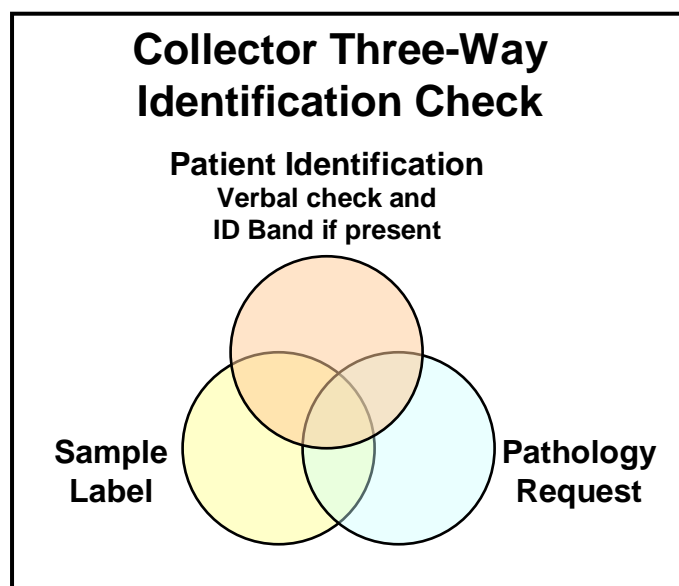
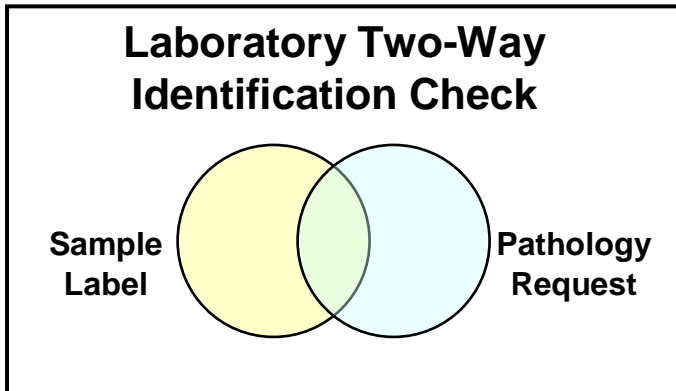


Diagram 2: Collector Three-Way Identification Check



When the sample reaches the laboratory the identification of the sample and the pathology request is checked. If these two identifications do not match, the identity of the sample is compromised. With only this two-way check there is no way to determine the correct identity on the sample (see **Diagram 3**). When this occurs this is an **identification problem**.

Diagram 3: Laboratory Two-Way Identification Check

There are 5 main **identification problems** as defined by RCPA KIMMS (Key Incident Management and Monitoring System) Quality Assurance Program.

- Unlabelled sample
- Mislabelled sample – any mismatch or discrepancy of identification
- Insufficiently labelled sample – less than two identifiers
- Transfusion labelling requirements – no collector signature, no time and date of collection
- Sample suspected to be from wrong patient – wrong blood in tube

Four of the five identification problems are easily detected by the laboratory when the sample and request are examined upon receipt. The samples can be prevented from progressing to the analysis phase. But why is this important?

The consequence of processing a sample with an identification problem is that the result can get allocated to the incorrect patient.

If results are allocated to the incorrect patient this can lead to:

- Unnecessary treatment or investigations
- Lack of treatment
- Death

The greatest risk of causing a patient’s death is due to an identification problem that has no definitive way for the laboratory to detect. This type of identification problem is “Sample suspected to be from wrong patient” or sometimes referred to as “Wrong Blood in Tube”.

This is where the identification on the sample label and request match but the sample inside the tube/container is from a different patient. (See **Photo 1**)

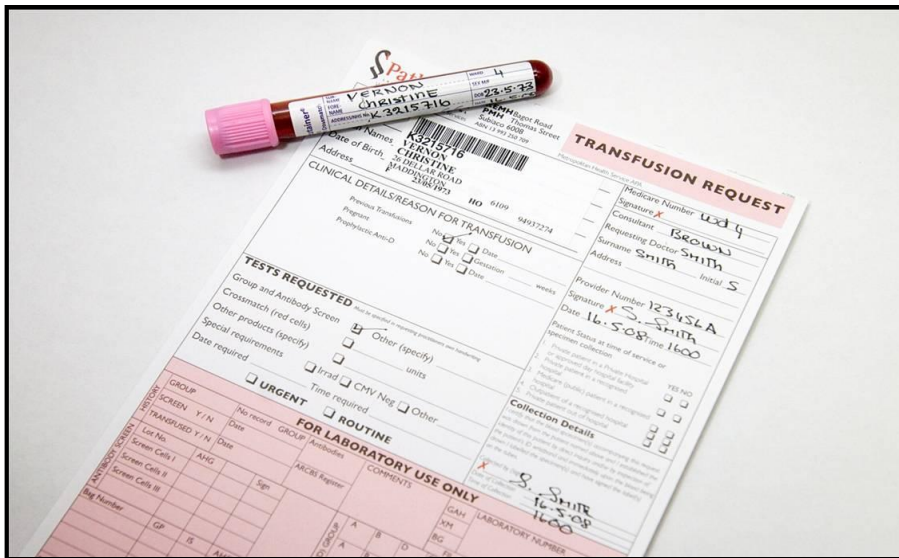


Photo 1: “Sample suspected to be from wrong patient” error also referred to as “Wrong Blood in Tube”

Looking at this sample and request from the laboratories point of view, the identification matches and therefore the sample will be allowed to proceed to the analytical phase. In reality the sample inside the container does not belong to the patient that it has been so carefully labelled with. This error will result in the patient on the label receiving the wrong result. In cases involving blood transfusion, this could result in the death of the patient.

This error occurs when the Collector does not follow the correct procedure and does not perform the three-way check previously described. Once this error has occurred it is very difficult for the laboratory to detect. The only way to detect this error is by “chance”.

Some mechanisms that help detect wrong blood in tube errors -

- Historical blood grouping not matching
- Serial laboratory testing – significant change in parameters that are not consistent with previous results.
- Diagnosis history – current results are not consistent with diagnosis e.g. cancer or a syndrome
- Doctor / Nurse / Collector realise that they may have made a mistake and they contact the laboratory.
- Doctor phones for a result and the sample is not recorded as being received yet the doctor is certain the sample was collected from the patient.

These mechanisms for Wrong Blood in Tube error detection are far from adequate and many of these errors will remain undetected resulting in the test results being allocated to the wrong patient.

How can we stop a patient getting the wrong test results?

The only answer to this question is for the laboratory to have zero tolerance of identification errors.

Zero Tolerance is rejecting all samples that have a compromised identity. This will ensure the correct result is being reported on the correct patient. It also reinforces the importance of patient and sample identification to the Collector, ultimately reducing the likelihood of “Wrong Blood in Tube” errors.

The only exception to this policy should be “**irreplaceable samples**”. These are samples that cannot be readily repeated and should still be processed.

Some examples of irreplaceable samples are: biopsies, surgical samples, blood gas samples and lumbar puncture samples. When results are issued on these samples it is vital that the compromised identification of the sample is documented. This alerts the requesting doctor to the identification problem and allows them to consider this fact when interpreting the result.

Example of an appropriate comment to be added to a report of an irreplaceable sample received with an identification problem which has been processed:

Sample received did not meet the minimum labelling requirements. Please take care when interpreting these results. The following person was contacted to confirm the identity of the sample: {free text in Dr/collectors name, date and time}”

3.2 Sample Problems

A **sample problem** is when the sample supplied for testing is not suitable to be used for the tests requested. If these samples were analysed the test result reported will not give an accurate representation of the patient's condition. This may mislead the doctor when interpreting the result for diagnosis or treatment. The laboratories are very good at detecting these problems during the analytical phase. These samples are rejected and repeat samples are requested.

There are several reasons why a sample may not be suitable for testing, as defined by KIMMS (Key Incident Monitoring and Management System) Quality Assurance Program.

- Sample not collected
- Incorrect sample type
- Haemolysed sample
- Clotted sample
- Incorrect fill level of sample – e.g. coagulation tests
- Insufficient sample
- Contaminated sample – e.g. sample taken from drip arm
- Incorrect sample storage or transport

These sample problems are due to collection related issues. Mostly they are due to inadequate collection technique and knowledge of appropriate procedures. In some cases the clinical condition of the patient can also cause these sample problems.

These samples are not suitable to be analysed so they must be rejected and a repeat sample requested.

4. Sample Rejection

Samples with identification problem or sample problems should be rejected. Even though sample rejection protects the patient from getting the wrong result it also causes problems itself.

1. Sub-optimal patient safety and care
2. Create rework

4.1 Sub-optimal patient safety and care

Rejecting a sample compromises the care and safety of patients. Not only is the risk associated with sample recollection (e.g. venipuncture) but there is also the patients state of mind to be concerned about. Many patients will find it very traumatic to have a repeat sample taken. They may assume that the repeat sample collection is due to them being ill and needing more investigations performed, causing them unnecessary stress.

Iatrogenic anaemia is a condition where a state of anaemia is induced due to the treatment or investigations performed on a patient. This condition is quite common in neonates where many regular blood tests are being performed. Sample rejection in this context will only worsen the condition of the patient.

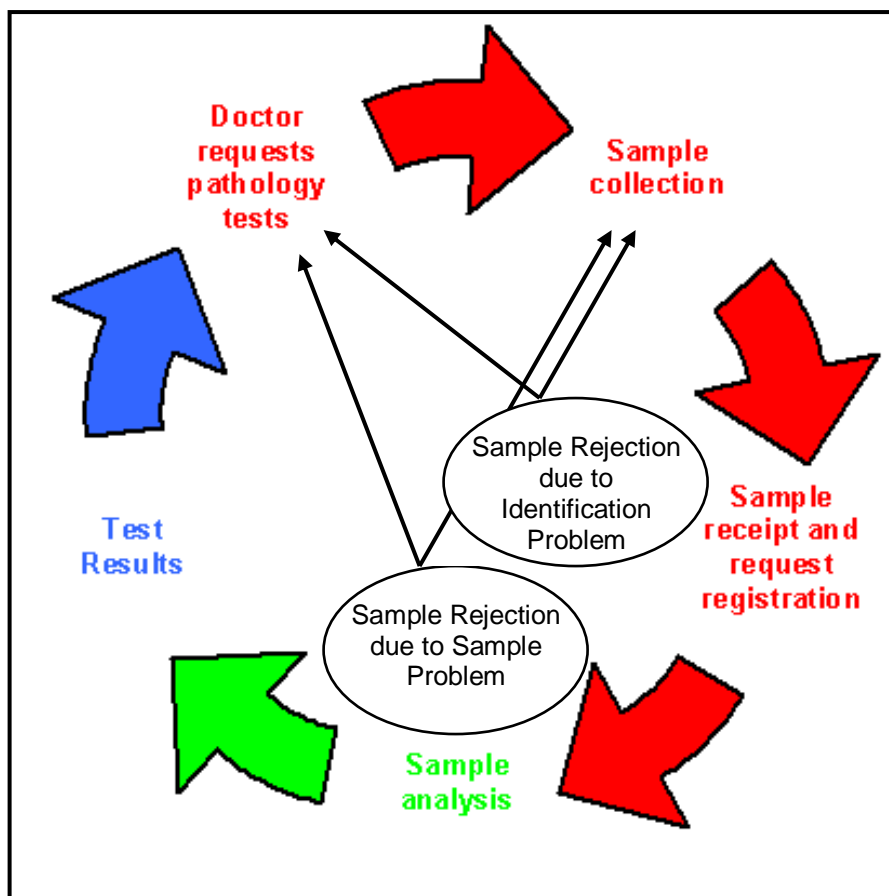
Rejecting samples creates the need for the sample to be recollected and this will delay the test result getting back to the requesting doctor. This may cause a delay in the appropriate treatment of the patient's condition.

In some circumstances samples are collected for pathology testing and the patient's treatment is commenced before the test results are returned to the doctor. If these samples are rejected there is no opportunity to repeat the test for that particular point in time. Rejection of these samples creates a missed opportunity for testing. A common example is if a blood culture sample is rejected and treatment has commenced before a repeat sample is taken, often no bacteria will be isolated. This results in the doctor not knowing what the causative agent was and may affect the patient's treatment regime.

4.2 Rework

Rejecting samples creates rework making the Request-Test-Report Cycle inefficient, wasting time and resources. Sample identification problems are usually identified at Sample Receipt, while sample problems are not usually detected until the Sample Analysis stage. Once these problems are detected, the samples are rejected and a repeat sample is requested. This repeat request is commonly communicated back to the requesting doctor or the collector by laboratory staff. This is demonstrated in **Diagram 4**.

Diagram 4: Request Test Report Cycle Rework



This diagram demonstrates that the rejection of samples causes a large amount of rework from many different sources.

- **Patient's Time** - the patient may live a long way from the collection centre or doctor or may have to organise child care or time off work
- **Collector's Time** – the collector must contact the patient of the recollection and then recollect the sample.
- **Doctor's Time** – The doctor may start to enquire where the test results are.
- **Laboratory's Time** – Staff time requesting repeat sample and staff time reprocessing the new sample when it arrives.

This quote has never been so true:

“There is never time to do it right the first time but there is always time to do it again.”

How can we find the balance between protecting the patient from incorrect results and rejecting samples that cause sub-optimal patient safety and care and creating rework? The only way is to –

Get it right the first time!

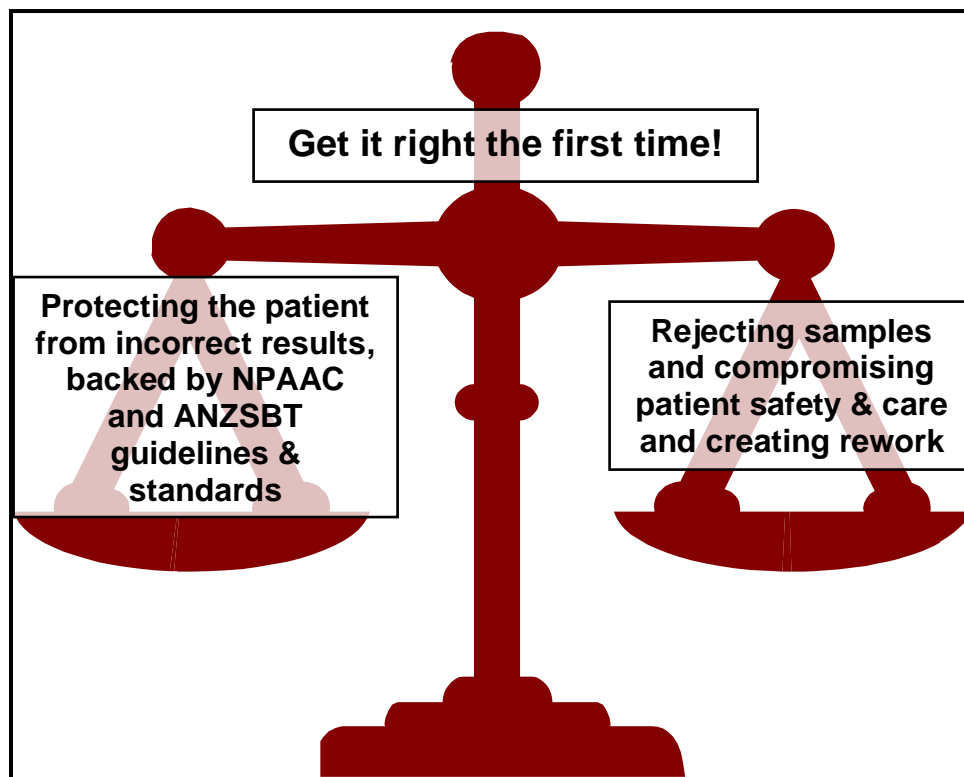


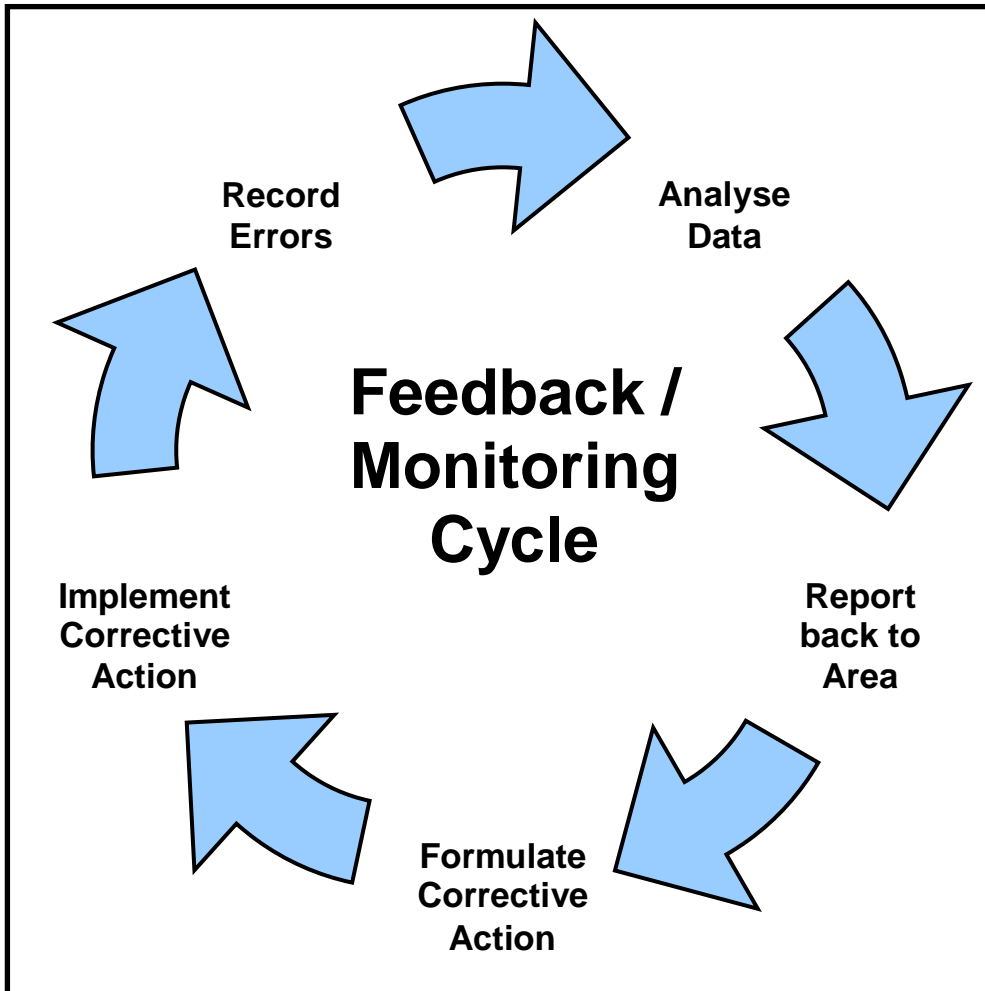
Diagram 5 – Get it right the first time – The balance between protecting the patient from wrong results and sample rejection.

5. How can we help collectors get it right the first time?

Generally the best way to help collectors to get sample collection right the first time is to ensure they have the appropriate education, training and tools to perform the task required. Many of our collectors are not in the direct control of the pathology laboratory so we have to develop new pathways to get the information across.

The most commonly used method is feedback to each collector when they have made an error. In some circumstances it is very difficult to know the identity of the collector or it is difficult to get in contact with that person because their shift has finished. A more meaningful way of presenting the information is in an aggregated form back to a work area. This takes away the individual blame and emphasizes the improvement aspect of reducing pre-analytical errors.

6. Feedback / Monitoring Cycle



The Feedback / Monitoring Cycle is a five stage cycle that allows evidence based feedback to drive improvement. This cycle also allows the monitoring and evaluation of interventions put in place to improve error rates.

6.1 Record Errors

In order to feedback to collectors it is important to have accurate evidence of the errors that have taken place. The best and easiest way to record pre-analytical errors is in your Laboratory Information System (LIS). LIS vary significantly from laboratory to laboratory but they all allow new test panels to be added. It is possible to create and add an error test panel.

The panel will collect the date and the location of the patient and within the panel you can record the type of error, who was the collector (lab staff / hospital / external depending on your client mix), what action has been taken (sample rejected or still processed) and even the tests that have been effected by this error, all by library codes.

A great way to start is by recording the RCPA KIMMS (Key Incident Monitoring and Management System) Quality Assurance Program error categories. Create a library code for each error. You may need to change the wording into something your staff are familiar with to ensure compliance.

In a hospital situation it is very important you capture the source location of the patient. Source location is the first location the patient presents for that request. This is the most likely location the sample was collected. Many LIS systems update the patient location as the patient moves through the hospital to ensure the report is sent to the correct location.

Diagram 6: Capturing error data using your Laboratory Information System

Source location – location the sample was collected

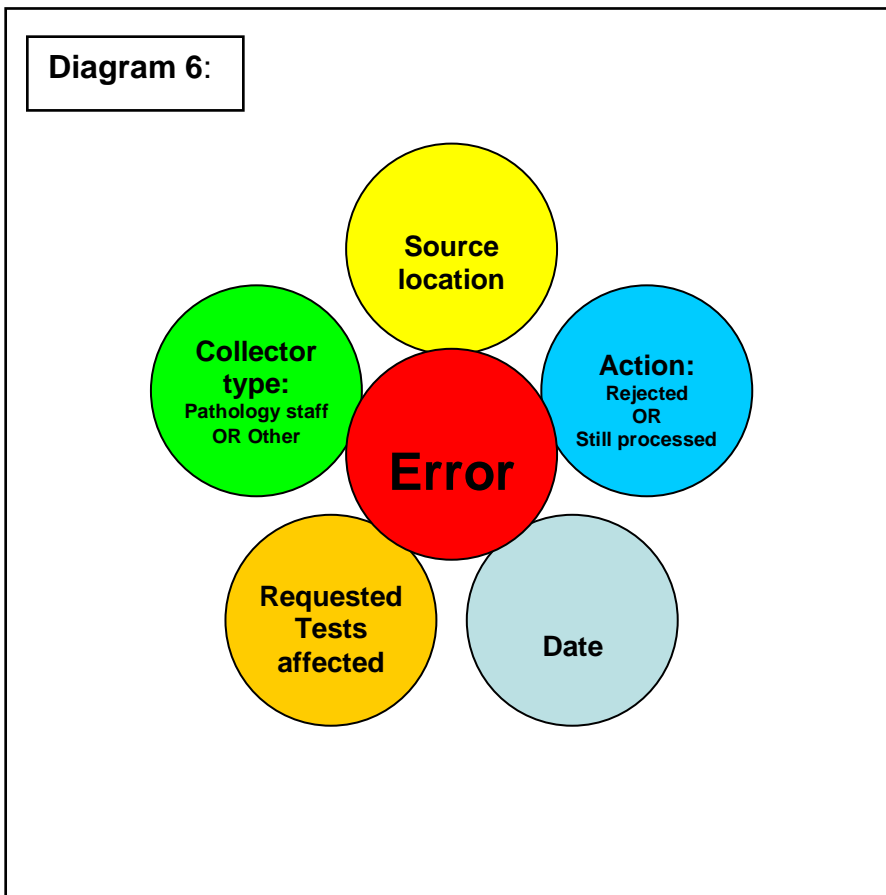
Date – date of sample collection

Collector Type – Record if the sample was collected by laboratory staff, hospital ward staff or external doctor

Action – was the sample rejected or was it still processed as it was classified as an irreplaceable sample

Requested Tests affected – record the requested tests that have been affected by this error.

Example Error is sample clotted and the requested test that was affected by this error was the Full Blood Picture or the error is incorrect fill and the requested test that was affected by this error was Coagulation profile.

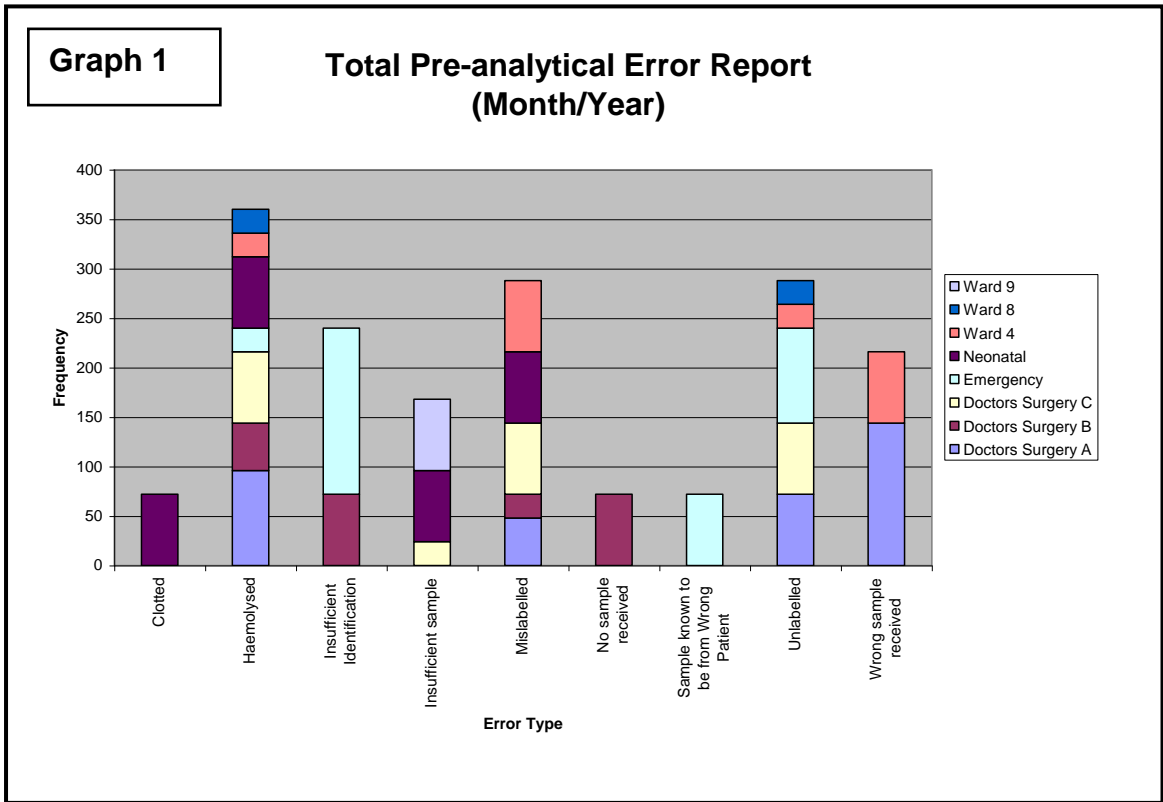


If you can collect this information in your LIS you are able to extract it. Even if your LIS does not have a sophisticated reporting function you can always extract the data as a text file and import it into Microsoft Excel or Microsoft Access to help you analyse the data.

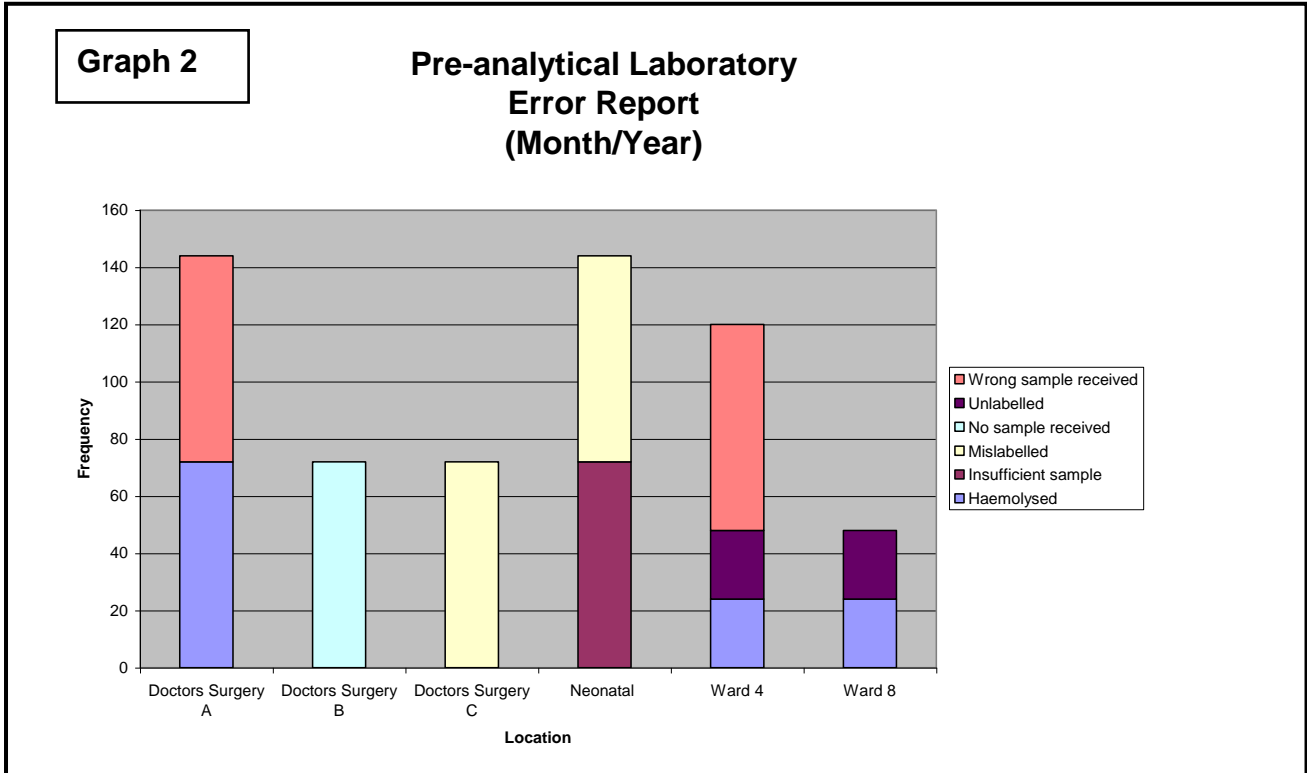
6.2 Analyse Data

The easiest way to analyse the data is import the raw data into Excel or Access and perform some basic manipulation of the data. The best way to view the data is in pivot tables or in graphs.

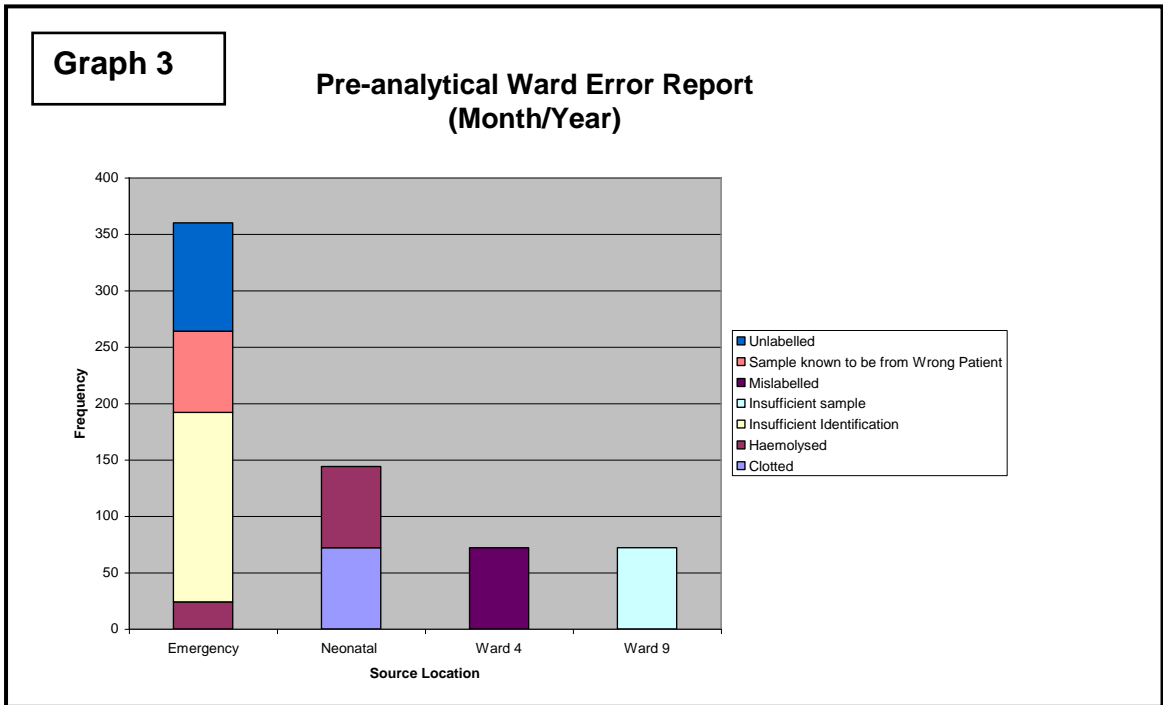
The data and resulting graphs can be manipulated to demonstrate different problems. The graphs should be designed to show a target audience the data they are interested in.



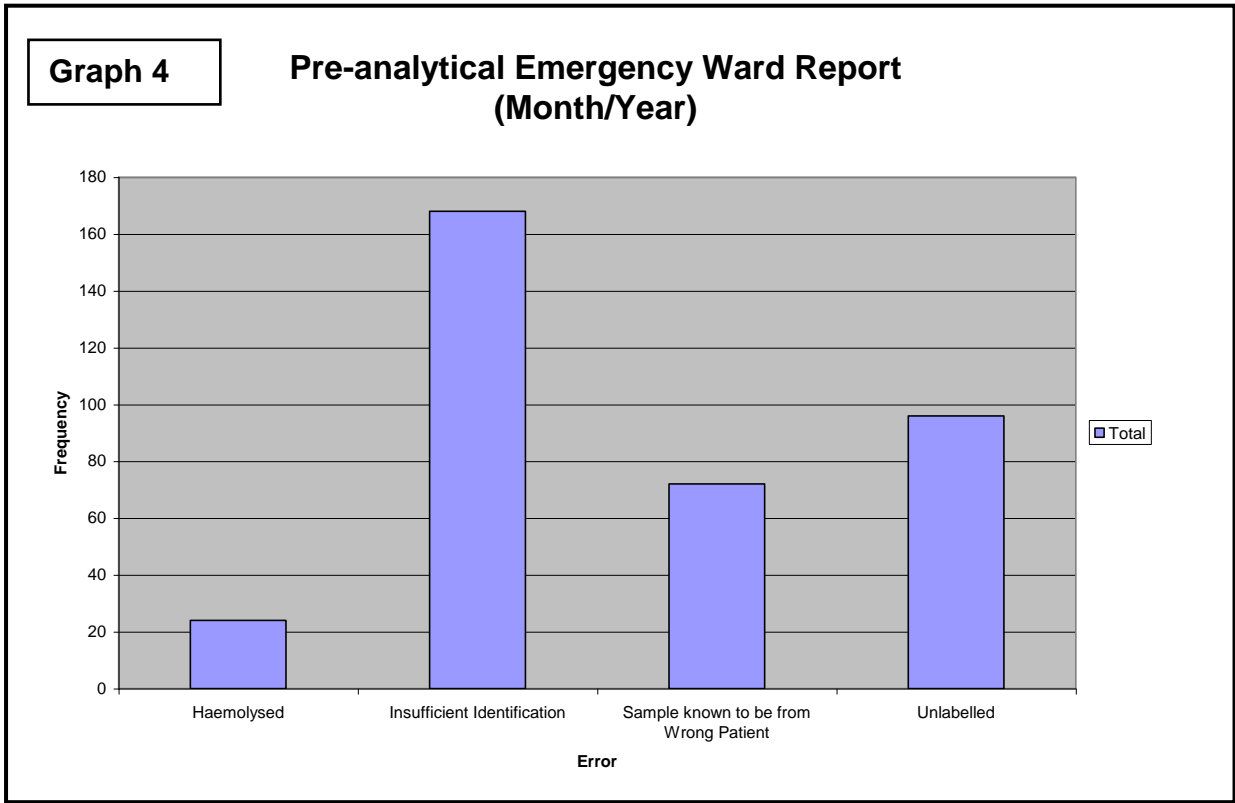
Graph 1 shows the total pre-analytical errors recorded for a month. This report type may be useful for the Pathology Laboratory Management to help identify what are the most common mistakes and where they are occurring.



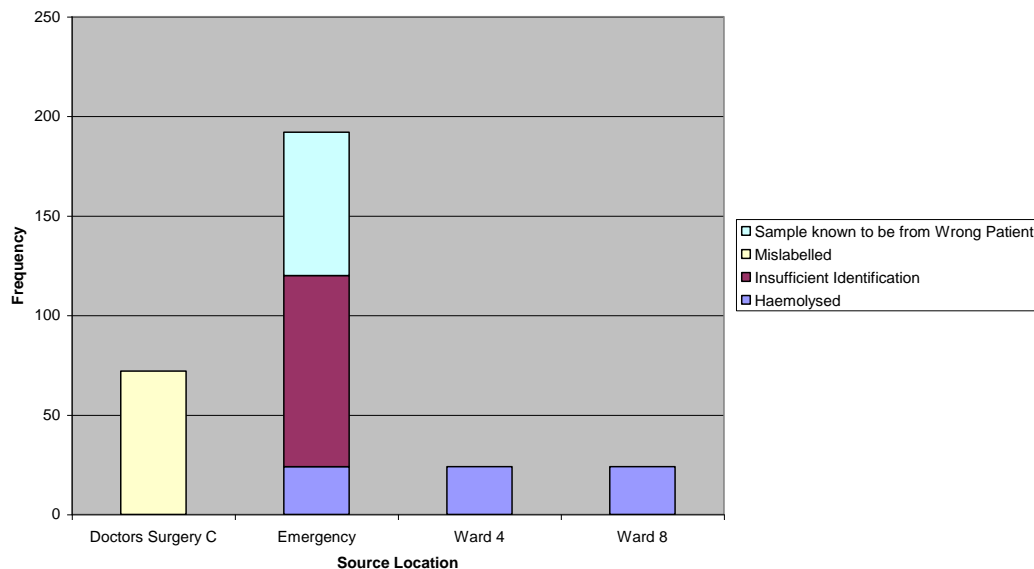
Graph 2 shows the pre-analytical errors performed by Pathology Laboratory’s collection staff. This report may be useful to collection staff managers. It can help identify what the most common errors are and where the errors are occurring.



Graph 3 shows the pre-analytical errors performed by hospital ward staff. This report may be useful to hospital management to help identify areas that need to reduce the frequency of errors.



Graph 4 shows the frequency of each error type for a particular area. This is useful to monitor the frequency of errors when interventions have been implemented.

Graph 5**Pre-analytical Transfusion Medicine Report
(Month/Year)**

Graph 5 utilises the Tests affected by the error. This information enables a discipline specific report to be produced. This example shows a Transfusion Medicine Report and only has captured the errors related to transfusion medicine tests. This report can be used by Transfusion Committees to help monitor error rates.

From these examples it is easy to see that there are many ways to present the same data. It is important to find the most useful way to display the data for the audience of the information.

6.3 Report back to Area

It is important to regularly feedback the error information in a format that is easily understood, to the source of the errors. This allows aggregated data to be accessed and the problem to be acknowledged in a non-threatening way.

A good place to start is with internal management meetings. Look at the overall information and the areas that are within the direct control of the laboratory e.g. Laboratory Sample collectors.

Next it is possible to take this information and present it at an external meeting. Some common forums are:

- Hospital Medical Advisory Committees
- Hospital Operations Meetings
- Emergency Department Meetings
- General Practitioner Education Sessions

Some area will immediately respond and set up a working group to focus on the issues demonstrated by the data. In the example of a hospital working group, it is ideal if this group has representation from pathology, nurses and doctors from the areas that have the highest error rates. This will enable the group to devise appropriate interventions and recommend procedure change if required.

6.4 Formulate Corrective Action

Some areas will want the error data regularly reported to them and they will internally formulate corrective actions to reduce pre-analytical error rate.

Other areas will want pathology help to formulate interventions. There are some key aspects to keep in mind if pathology is involved.

- Don't try to tackle all the problems at once. Do the most common errors first.
- Make sure you have representation of the different collection staff relevant to the area.
- Brainstorm ideas why this error may be occurring and try to get to the root cause. A procedure or process may have to be altered or the procedure may need to be re-enforced with education.
- Target education to a specific area or topic
- Develop and use targeted education tools like posters or screen saver education (concept developed by King Edward Memorial Hospital Quality and Safety Group in Western Australia)
- Develop targeted education sessions. Create a power point presentation focusing on preventing pre-analytical errors.
- Target new clinical staff at orientation forums
- Presentations to Medical and Nursing Student
- Competencies – In some areas where collection technique and processes are vital a competency package may be useful (e.g. neonatal wards). This package can contain a theoretical session on sample collection as well as a practical component.

6.5 Implement Correction Action

Once the corrective action has been formulated and created it is important to record the location and date the intervention was started so the success can be monitored.

6.6 Monitoring

Now that an intervention has been put in place it is important to continue to record the pre-analytical errors (back to the **record** stage of the **Feedback / Monitoring Cycle**). This will provide evidence of the impact the intervention has made on the pre-analytical error rate.

It is important to evaluate the success of the intervention after an agreed timeframe. Not all interventions will reduce the pre-analytical rate. Some interventions may need more time before evidence of error reduction is seen. Some interventions may need to be adjusted to get the desired outcome while others may not work at all. It is important to record the effectiveness of all interventions. The ones that significantly reduce error rate can be applied to other areas while the ones that don't work can be recorded so they are not repeated in the future.

It is important to feedback this information to the area so the all staff are aware of how the interventions are affecting the pre-analytical error rate of their area. This encourages staff to engage in the improvement process and may encourage new ideas from the staff to reduce error rates. This continual feedback also raises the awareness of the problem and this will help to reduce error rates.

Generally one intervention will not produce sustainable error reductions. To get best results periodic interventions and training should be introduced using a variety of methods to maintain focus on this problem. For example: first month may be an educational presentation focusing on pre-analytical error followed by the next month having a poster campaign then following up with the introduction of a computer screen saver. Using this method there is always something new for the staff to read and focus on, re-enforcing the correct sample collection message.

7. Conclusion

- It is important to keep sample acceptance standard high for patient safety.
- It is important that repetitive errors are not allowed to keep occurring when most are easily preventable.
- It is important to monitor pre-analytical errors to identify deficiencies and monitor success.
- It is important to continually educate internal and external sample collectors, giving them not only the skills but the understanding of the consequences of pre-analytical errors.
- Reducing pre-analytical errors not only optimises patient safety and care but also improves efficiency of the pathology laboratory service by reducing rework.