Pre-Analytical Error In Clinical Laboratory & It's Corrective Measures

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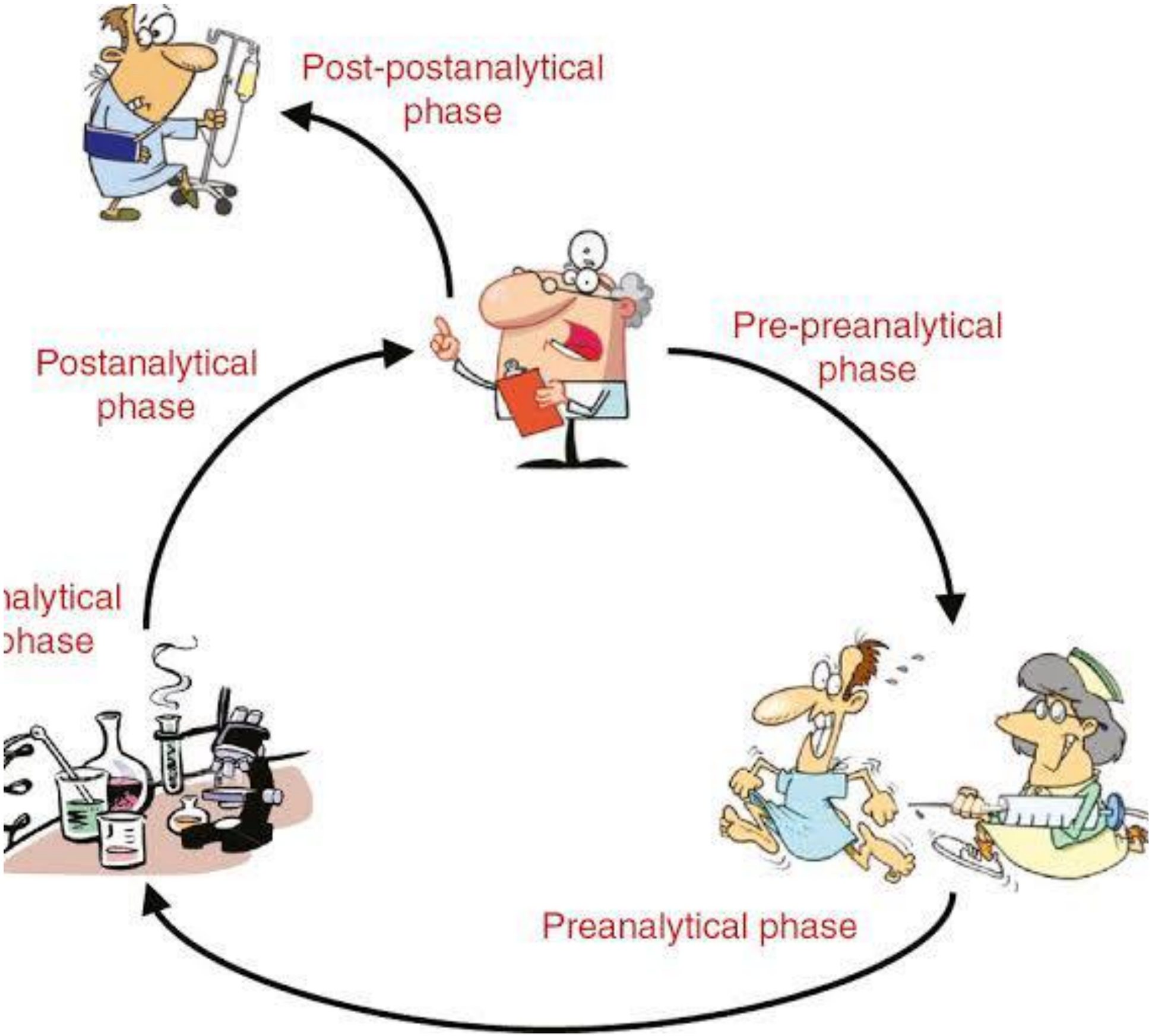
Post-postanalytical phase
Pre-preanalytical phase
Postanalytical phase
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Preanalytical phase

Pre-Analytical Error

Most critical Phase

Chances of Error

In

Pre-Analytical Error = Approx. 50 - 70 %

Analytic error = 10 - 15 %

Post Analytical Error = 20 - 30 %

Pre-Analytical Error

Most Common Area

- Missing sample and/or Test request
- Wrong or Missing identification
- Contamination from infusion route
- Haemolysed, clotted, and insufficient samples
- Inappropriate containers
- Inappropriate blood to anticoagulant ratio
- Inappropriate transport and storage conditions.

Pre-Analytical Error

Most Common Area

- **Error in Patient Preparation**
  - ✓ Fasting is require
    - GGT
    - Lipid Profile
  - ✓ With Specific Cardiac Markers - Specific Peak Hours
  - ✓ Effect of Medicine
    - Not take Oral Hypo-Glycemic medicine before FBS,PP2BS

Pre-Analytical Error

- **Sample Registration - LIS**
  - ✓ Wrong Entry - Manual Registration - Transcription Error
  - ✓ Entry Without UHID / MRD
  - ✓ Out of Scope test is accepted
  - ✓ LIS failure
  - ✓ No or Wrong Barcode
- **Sample Request - Missing / Un-identifiable**
  - ✓ Mismatch UHID
  - ✓ Un-identifiable Parameter - Full Lipid Profile
  - ✓ No / Inadequate patient's clinical

Pre-Analytical Error

◉ Error in Sample Collection

✓ Wrong Collection Site

- ABG collection site - Venous sample
- FNAC from Wrong site
- Collection from Infusion Site -
    - Total Parental Nutrition - RL infusion

✓ Wrong Collection Time

- FSH / LH / GGT / Lipid Profile

Pre-Analytical Error

◉ Error in Sample Collection

✓ Wrong Vacuette

✓ Routine Biochemistry in EDTA

- Dis-arrange Electrolyte - High Potassium , Low Calcium

✓ Wrong Preservative Ratio

- ABG - Clotted Sample
- APTT/PT , ABG - Wrong interpretation
- Faulty Vacuum in Vacuette - Inadequate Sample Preservative Ration

Pre-Analytical Error

◉ Error in Sample Collection

✓ Wrong Method of Collection

- Spirit wet area - Haemolysed Sample
- Small Needle - High Potassium , Enzymes, Low Cell Count
- Forceful - Aspiration & Emptying
- Tight tourniquet - Collection with Unreleased tourniquet

Pre-Analytical Error

◉ Sample Transportation

- ✓ Haemolysis due to High temperature & Shaking
- ✓ Long Distance - Increase TAT
- ✓ Slide / Vacuttee - Not Secure
- ✓ Cross contamination

Pre-Analytical Error

◉ Sample Centrifugation - Accession

- ✓ Wrong / High Speed - Haemolysed - Leakage - Contamination
- ✓ Imbalance

Pre-Analytical Error

◉ Sample Shorting

✓ No Secondary Sample Identification

✓ Same tips - Carry Over of the sample during Separation

✓ Re - utilisation of Aliquot

- Contamination with Glycerol - HOCL
  - High Glucose, Uric acid, Cholesterol (POD Reaction)

Pre-Analytical Error

◉ Environmental Condition

✓ Temperature of Collection area

✓ Improper Light

- Visibility of vein decrease

✓ Privacy

- Patient does not reveal the history

✓ No availability of Comfortable Chair

- Syncope - Incomplete collection

Quality Indicator of Pre-Analytical Area

1. Number of requests with **clinical question** (%)
2. Number of **appropriate tests** with respect to the clinical question (%)
3. Number of requests without **physician's identification** (%)
4. Number of **unintelligible requests** (%)
5. Number of requests with erroneous **patient identification** (%)
6. Number of requests with erroneous **identification of physician** (%)
7. Number of requests with errors concerning **test input** (%)

Quality Indicator of Pre-Analytical Area

8. Number of **samples lost**/not received (%)
9. Number of samples collected in **inappropriate containers** (%)
10. Number of samples **haemolysed** (haematology, chemistry) (%)
11. Number of samples **clotted** (haematology, chemistry) (%)
12. Number of samples with **insufficient volumes** (%)
13. Number of samples with inadequate **sample-anticoagulant ratio** (%)
14. Number of samples **damaged in transport** (%)
15. Number of **improperly labelled** samples (%)
16. Number of **improperly stored** samples (%)

Implementation of Quality Indicator

➡Prioritised Quality Indicator

➡Define Bench Mark of Quality Indicator

➡Data Collection

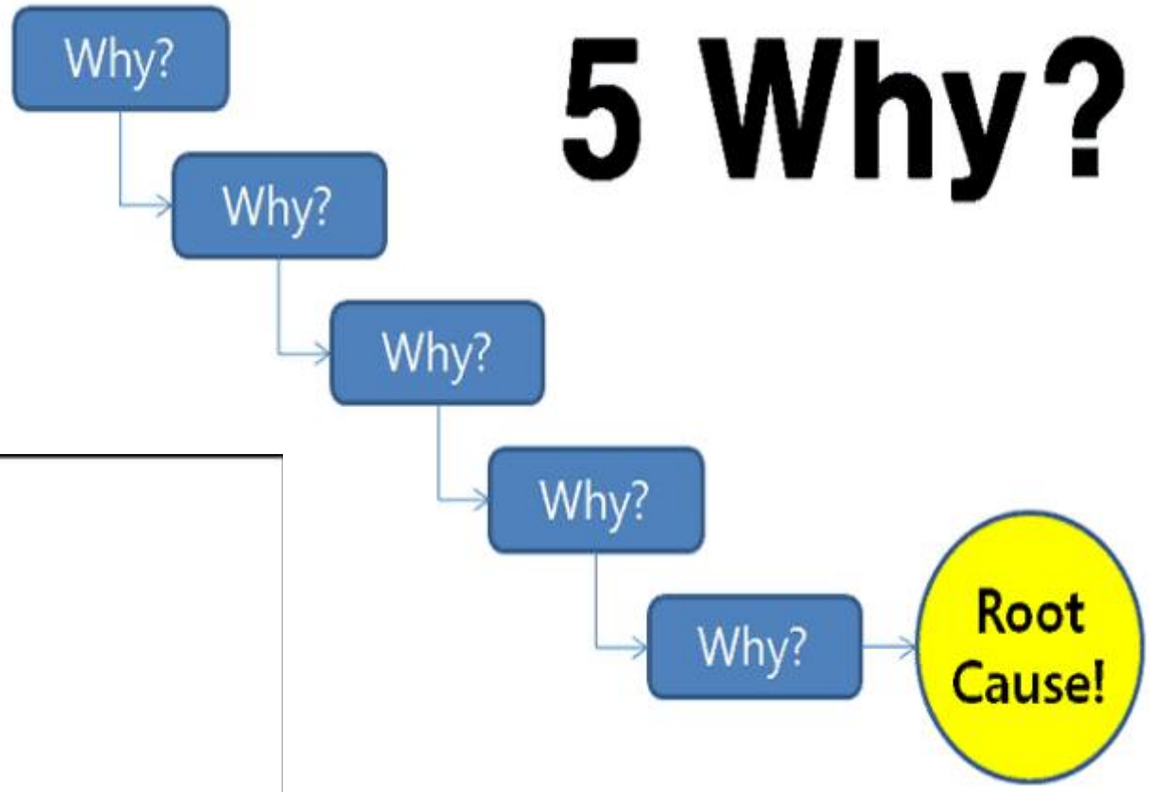
➡Finding Outliers

➡Root Cause Analysis

➡Corrective Action - Preventive Action - Risk Managment

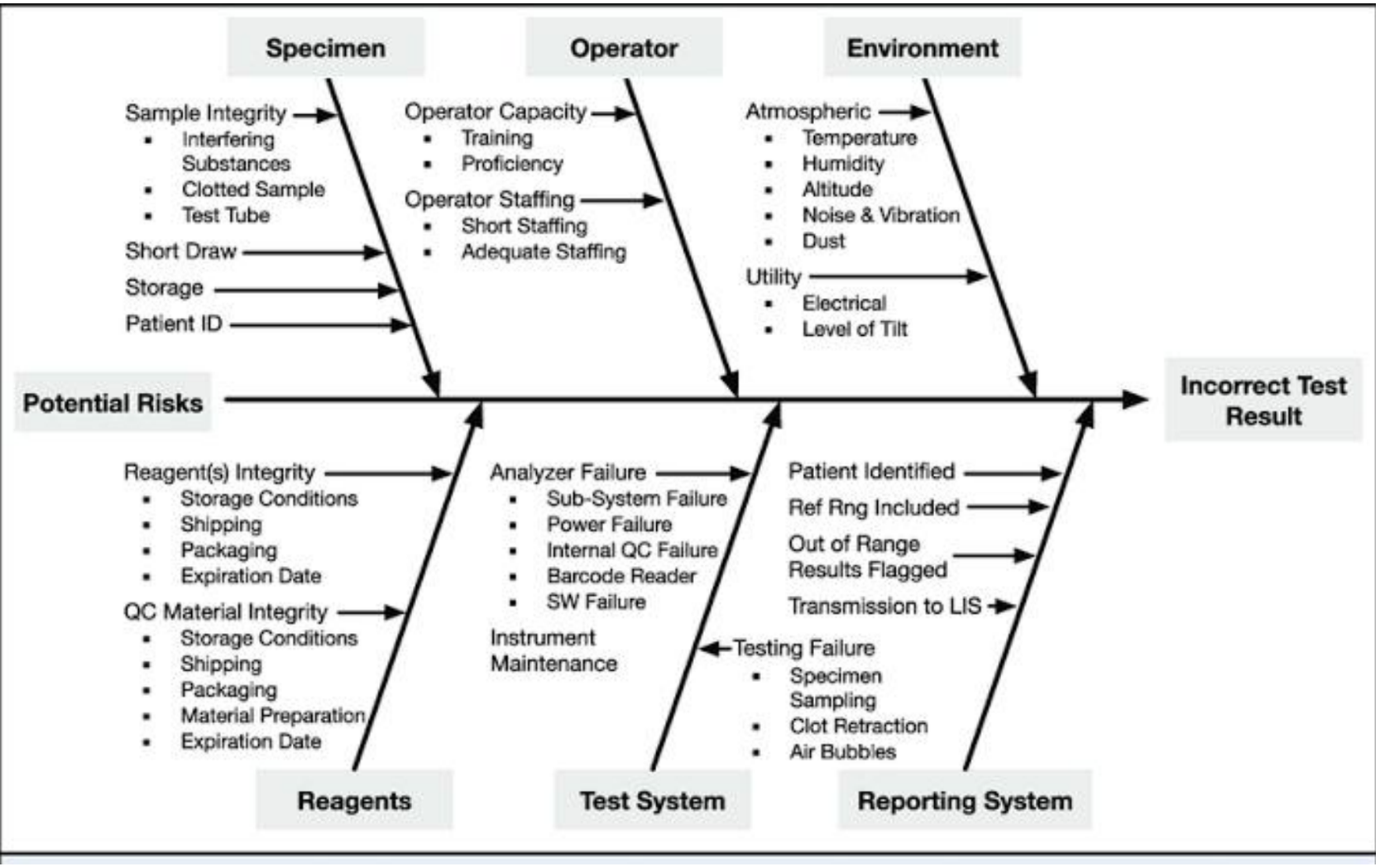
➡Continual Improvement - Updation of Bench Marks

Root Cause Analysis



5 Why?

5' why technic



Ishikawa Technic

5 Why Technic of Root Cause Analysis

Error in Pre-Analytical Area

More than 10% Sample Haemolysed (Violation of Bench Mark) in October 2023

5 Why Technic	Scenario - 1
1st Why	**New transport bag** was introduced and it unable to maintain temperature
2nd Why	Laboratory management has **not taken working demo** before purchase
3rd Why	**Vendor** for transport of bag was **well known**, old and faithful.
4th Why	Vendor **evaluation was not don**e with proper benchmark and it was just done on paper for NABL assessment.
5th Why	NABL accreditation process was implemented in laboratory from **consultant** - **(Root Cause)**
Corrective Action	Management asked Vendor to **correct transport bag** immediately for temperature maintaining facility.
Preventive Action	Management asked his most competent and sincere laboratory person for "**4 Days Internal Auditor Training** as Per ISO 15189:2022 **&** set **priority for appointing** employee who has competency related ISO15189

5 Why Technic of Root Cause Analysis

Error in Pre-Analytical Area

More than 10% Sample Haemolysed (Violation of Bench Mark) in October 2023

5 Why Technic	Scenario - 2
1st Why	Most of sample collection is done by **untrained staff.**
2nd Why	Most of the sample are received from **referring hospital** and their nursing staff are not trained for sample collection and transportation.
3rd Why	Laboratory management has focused on **training of their own phlebotomist.** **(Root Cause)**
4th Why	————————
5th Why	————————
Corrective Action	Laboratory management asked their trained **phlebotomist** to remain at hospital at **peak hours of the hospital**.
Preventive Action	Laboratory management asked hospital management to give **chance /slot to train their nursing staff** for sample collection during any of their own training session.

5 Why Technic of Root Cause Analysis

Error in Pre-Analytical Area

More than 10% Sample Haemolysed (Violation of Bench Mark) in October 2023

5 Why Technic	Scenario - 3
1st Why	In Civil Hospital, Collected sample are brought by ward-boy **without cold chain**
2nd Why	Cold chain box are available but nursing staff does **not using it.**
3rd Why	Previously purchased cold chain box are **stolen.**
4th Why	Nursing incharge was **not** maintaining log-book for "**Cold Chain Box Log**"
5th Why	Nursing staff is **not sensitised to maintain** sample transportation log as well as sample transport bag log. **(Root Cause)**
Corrective Action	**Laboratory director** has **taken charge** and responsibility of all their "Cold Chain Box" and Started using it with maintaining it's traceability and log.
Preventive Action	**LD asked hospital admin to arrange sensitisation training about related Good Laboratory Practice for Nursing Staff. & asked Medical Superitendent to purchased GPS sensory for "Cold Chain Box", to track transport box, TAT and to evaluate activity of Ward-Boy.**

Result

Lost the kingdom

Therefore

Why

Lost the battle

Therefore

Why

One less warrior

Therefore

Why

One less horse

Therefore

Why

Horse lost a shoe

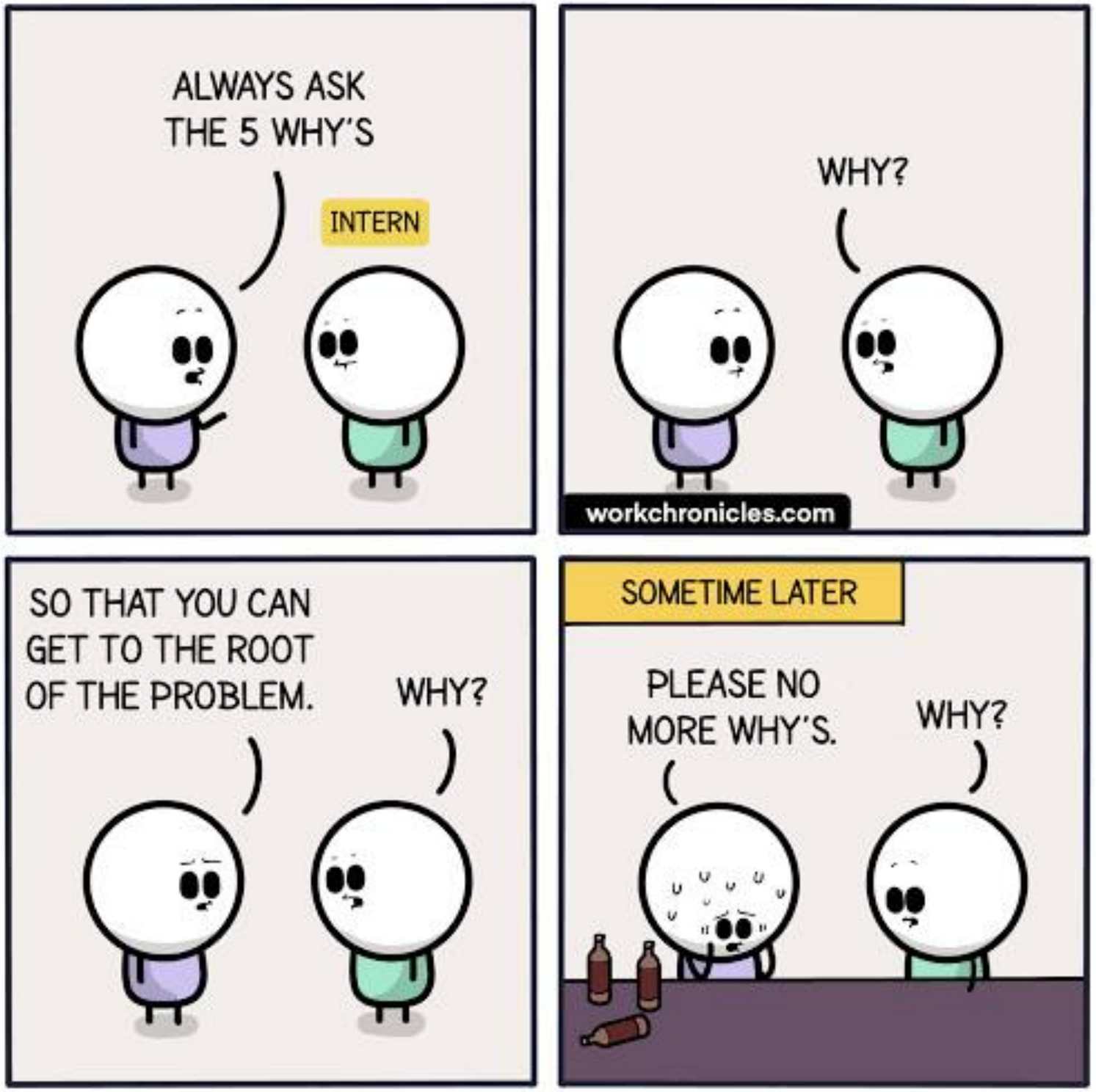
Therefore

Why

Not enough nails

Start

Root Cause



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Pre-Analytical Error

Risk Management - Most Important As Per ISO 15189:2022

- **Patient Preparation** = History Taking and Remarks in Request
- **Sample Request** = Request in Software , Verified & Valid LIS - HIMS
- **Sample Collection** = Good Vacutainer , Repeated Training of Phlebotomist
- **Sample Transport** = Reduce Transportation Time, POCT, Cold Chain
- **Sample Registration** = LIS - Validation - Verification
- **Sample Centrifugation** = Training - SOP - Calibration
- **Sample Shorting** = Automation - Barcode - Use of Primary Sample
- **Environment** = Light , Temperature , Humidity, Privacy , Reclining Chair

Thank You Very Much.

Meril ACADEMY

Diagno SPHERE

A DIAGNOSTIC REVOLUTION

My Special Thanks

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