Quality Indicators in Laboratory

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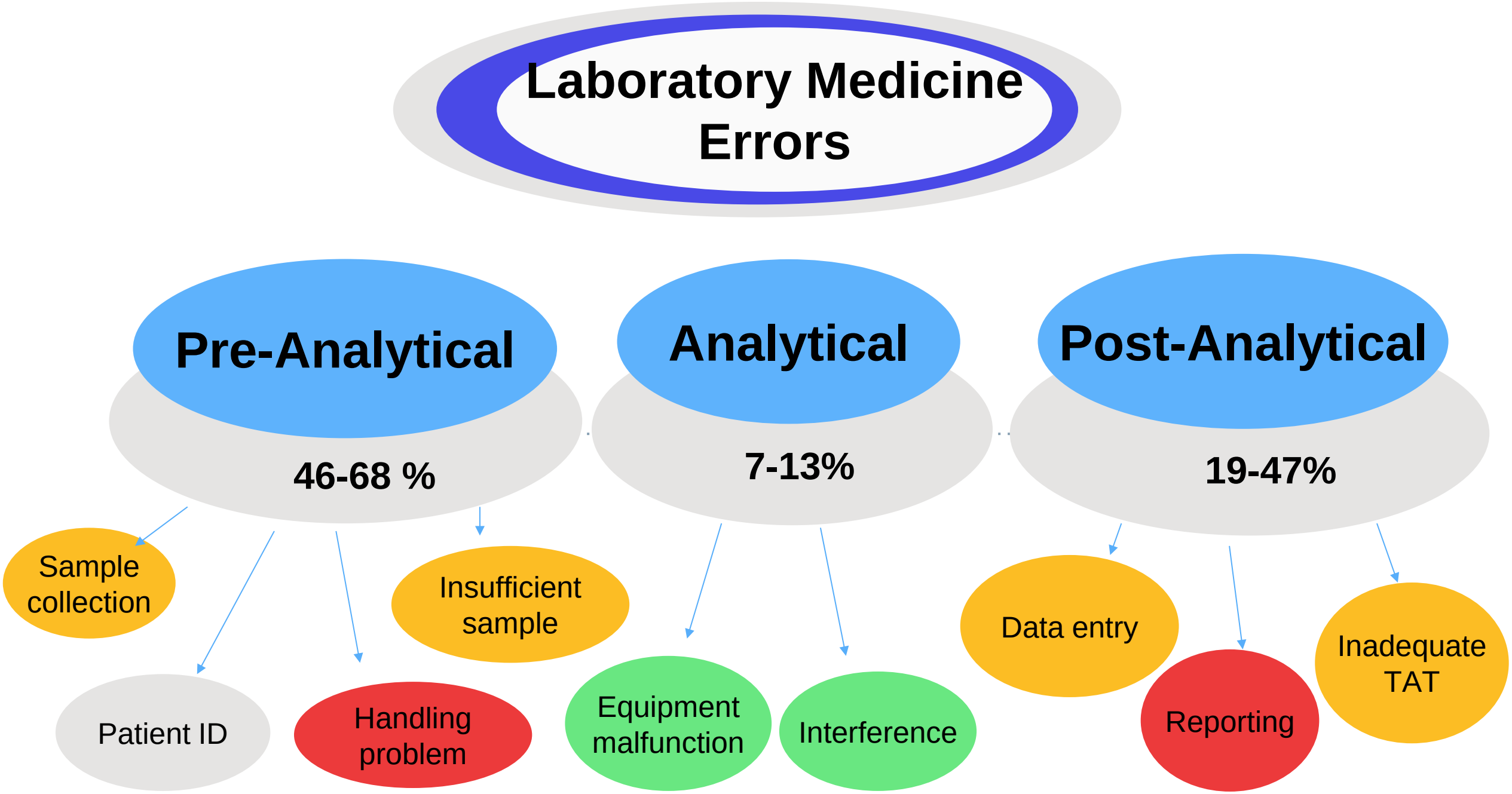
Introduction

Quality Indicators in Laboratory Medicine

- Quality indicators (QI) are about measuring our contribution to patient care
  - ✓Patient safety
  - ✓Clinical effectiveness
  - ✓Patient –centeredness
  - ✓Timely
  - ✓Efficient
  - ✓Equitability

Quality indicators are about doing the right test at right time on the right patient


Laboratory Medicine Errors
Pre-Analytical
46-68 %
Analytical
7-13%
Post-Analytical
19-47%
Sample collection
Patient ID
Handling problem
Insufficient sample
Equipment malfunction
Interference
Data entry
Reporting
Inadequate TAT

Wrong test requested

Right test not requested

Pre- Pre Analytical Errors

Data mis interpreted

Data ignored

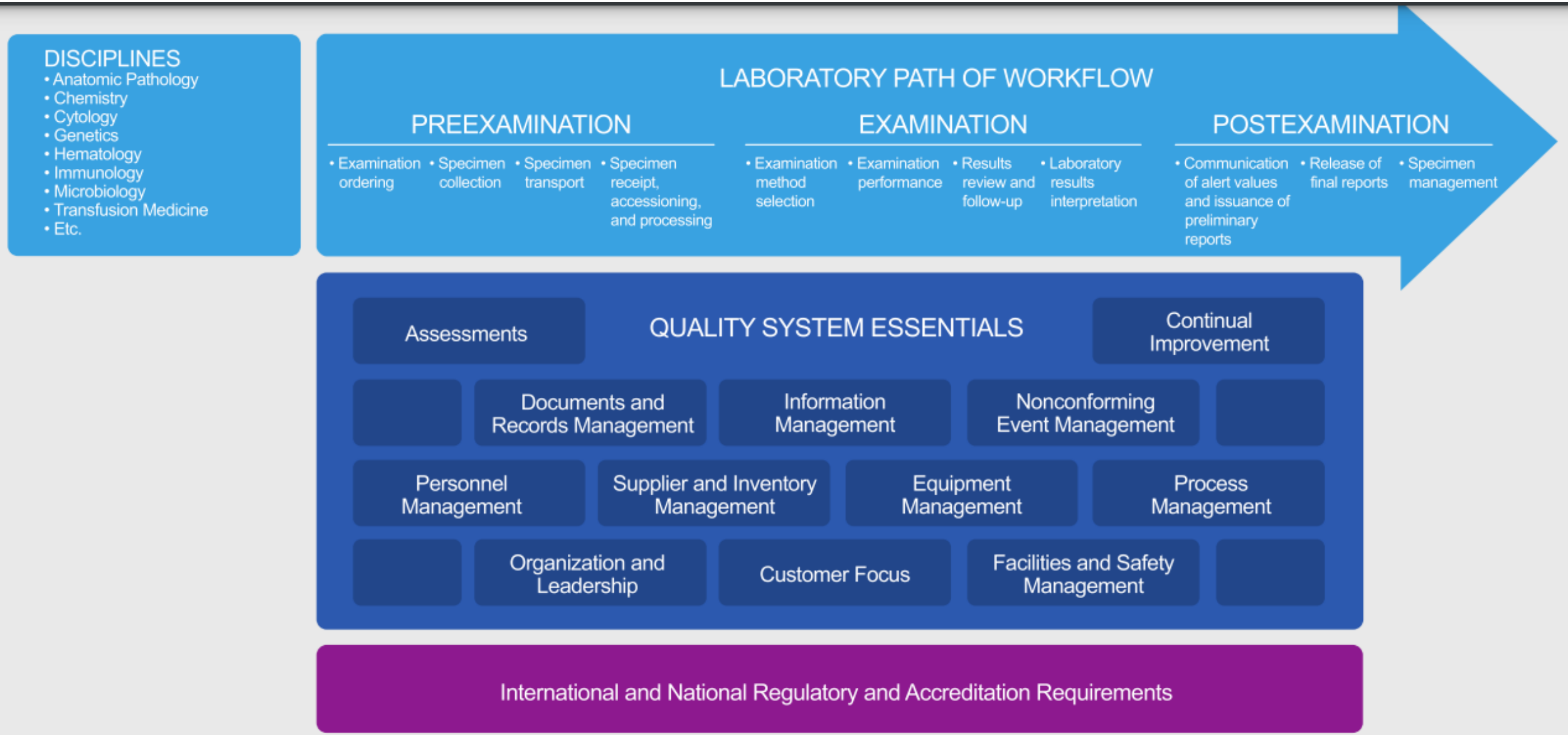
False positive
False negative

Post- Post analytical Errors

- The 12 Quality System Essentials are building blocks necessary to support any laboratory's path of workflow

- If a QSE is missing or poorly implemented, problems will occur in pre-examination, examination and post-examination processes

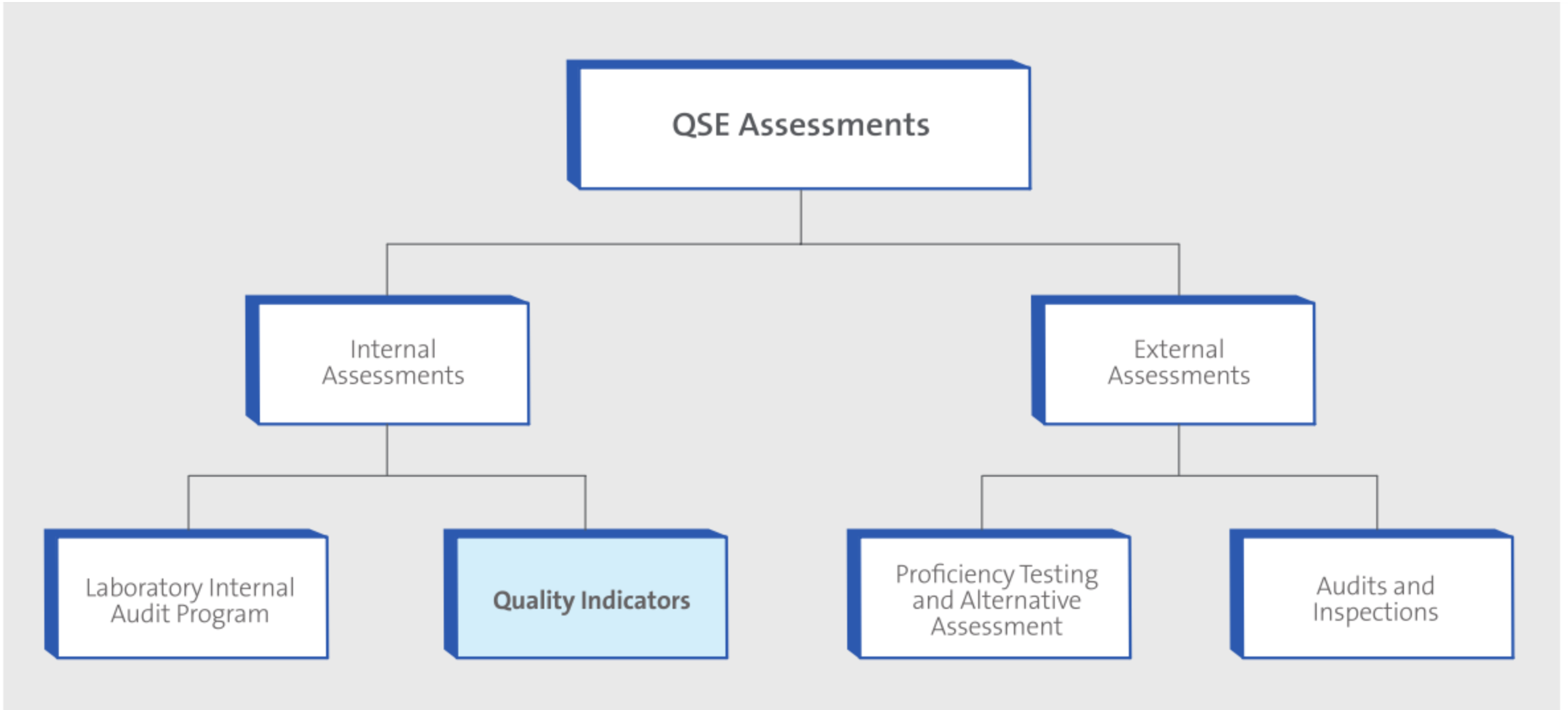
- For example, If a laboratory does not measure the turnaround time for specific examinations, it cannot effectively assess whether it is meeting costumer expectations


DISCIPLINES
• Anatomic Pathology
• Chemistry
• Cytology
• Genetics
• Hematology
• Immunology
• Microbiology
• Transfusion Medicine
• Etc.
LABORATORY PATH OF WORKFLOW
PREEXAMINATION
• Examination ordering
• Specimen collection
• Specimen transport
• Specimen receipt, accessioning, and processing
EXAMINATION
• Examination method selection
• Examination performance
• Results review and follow-up
• Laboratory results interpretation
POSTEXAMINATION
• Communication of alert values and issuance of preliminary reports
• Release of final reports
• Specimen management
QUALITY SYSTEM ESSENTIALS
Assessments
Continual Improvement
Documents and Records Management
Information Management
Nonconforming Event Management
Personnel Management
Supplier and Inventory Management
Equipment Management
Process Management
Organization and Leadership
Customer Focus
Facilities and Safety Management
International and National Regulatory and Accreditation Requirements

- Quality system essentials assessments in laboratories involve both internal and external evaluations

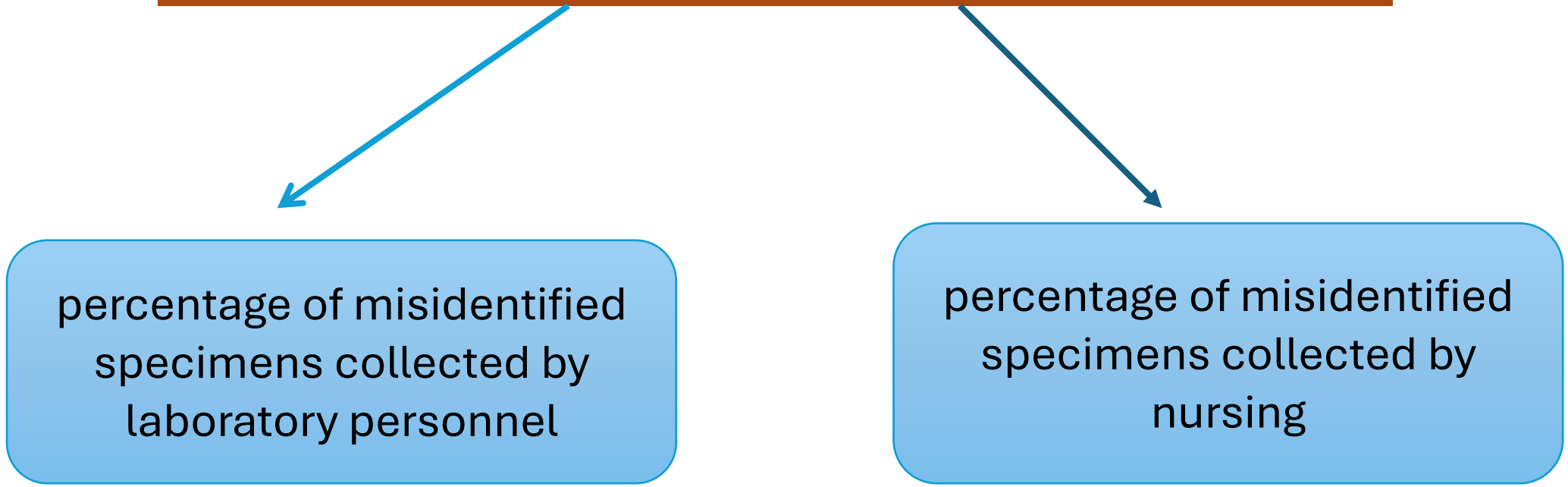
- One program for internal assessment is the development and use of laboratory quality indicators

- Quality indicators in laboratory processes are metrics that provide measurable and interpretable information regarding performance
- They are used to make decisions about laboratory quality and opportunities for improvements


QSE Assessments
Internal Assessments
External Assessments
Laboratory Internal Audit Program
Quality Indicators
Proficiency Testing and Alternative Assessment
Audits and Inspections

- Properly designed quality indicators stimulate continual improvement by providing clear, actionable data to avoid producing confusing and misleading information that could lead to increased work and poor decision-making

Example : Poor patient identification

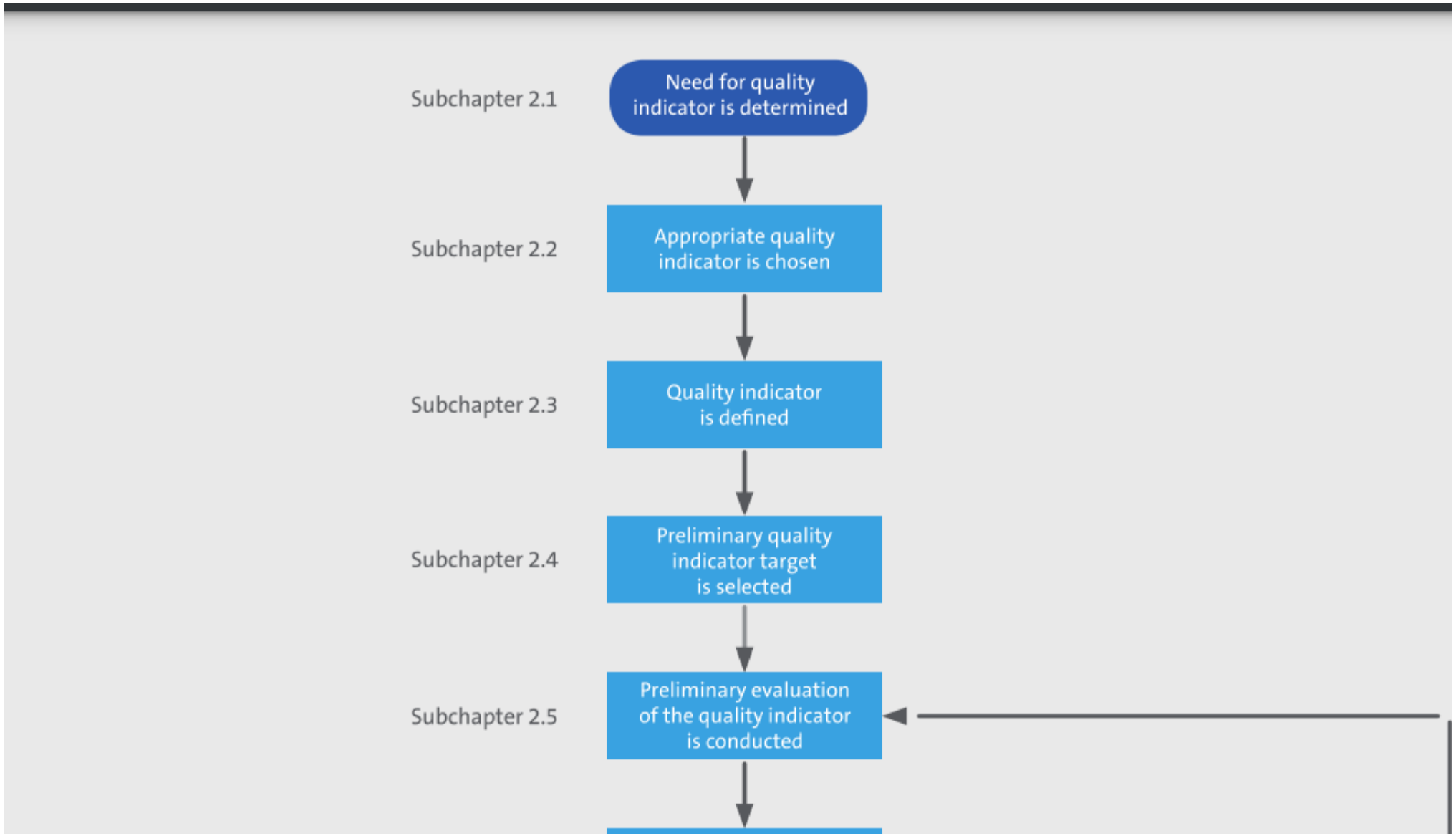


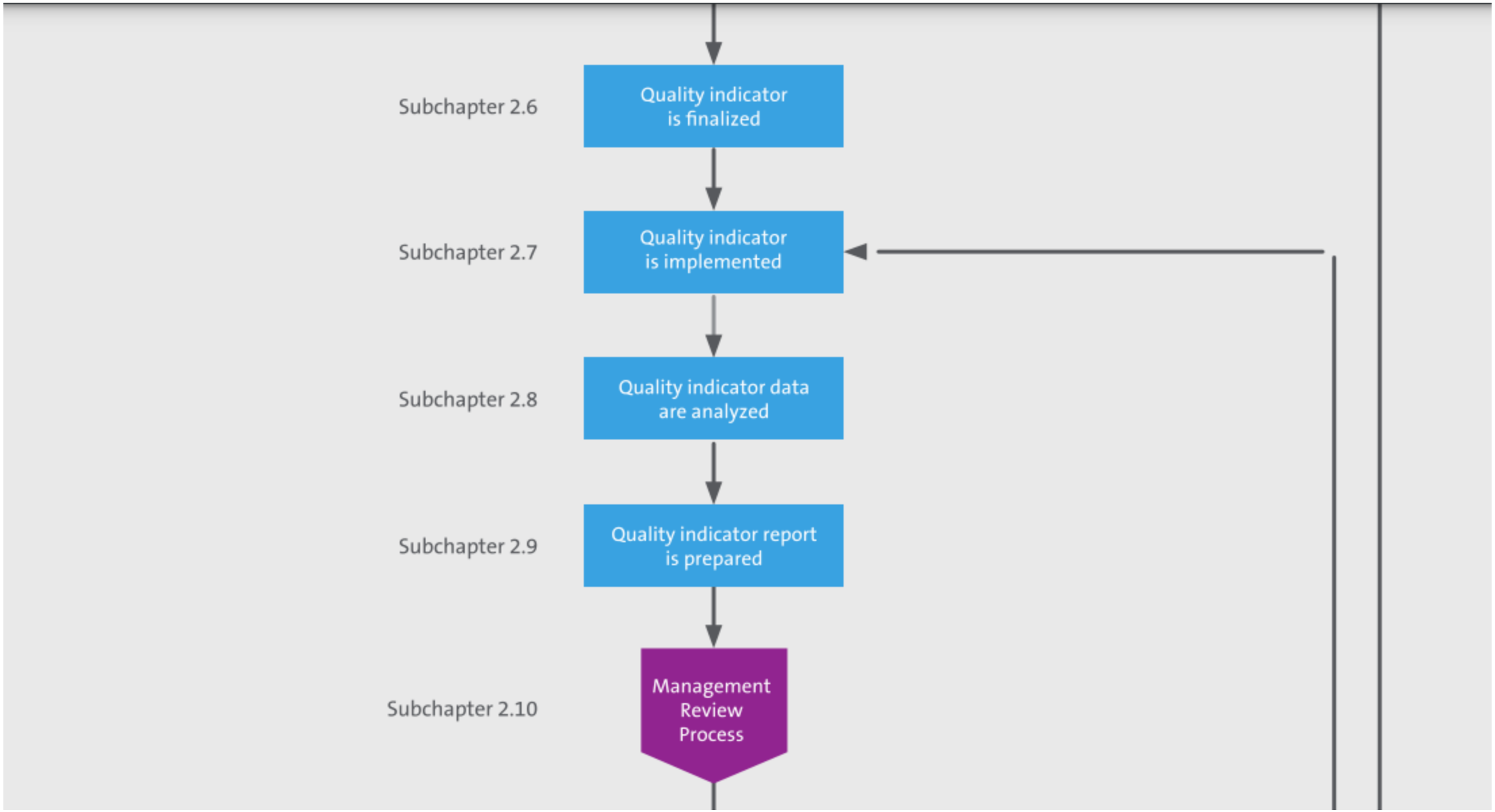
Process to Develop and Use Quality Indicators

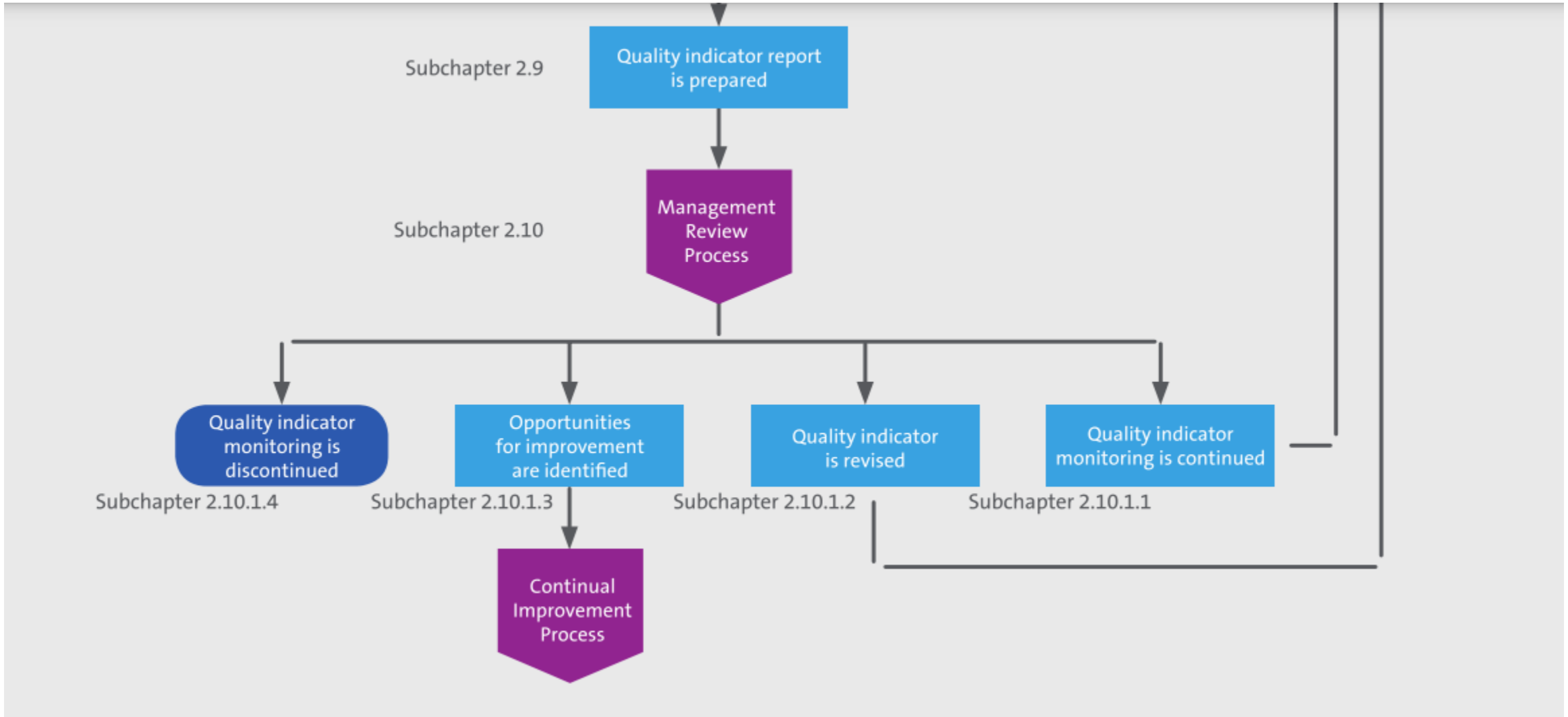
- While universal monitoring of laboratory services is ideal for ensuring quality and compliance, it is often impractical
- Laboratory management should decide which process should be monitored and how the frequency should be

Poor quality increases costs while higher quality reduces costs

Utilizing meaningful quality indicators can effectively enhance quality while ensuring resources are used efficiently


Subchapter 2.1
Need for quality indicator is determined
Subchapter 2.2
Appropriate quality indicator is chosen
Subchapter 2.3
Quality indicator is defined
Subchapter 2.4
Preliminary quality indicator target is selected
Subchapter 2.5
Preliminary evaluation of the quality indicator is conducted


Subchapter 2.6
Quality indicator is finalized
Subchapter 2.7
Quality indicator is implemented
Subchapter 2.8
Quality indicator data are analyzed
Subchapter 2.9
Quality indicator report is prepared
Subchapter 2.10
Management Review Process


Subchapter 2.9
Quality indicator report is prepared
Subchapter 2.10
Management Review Process
Quality indicator monitoring is discontinued
Subchapter 2.10.1.4
Opportunities for improvement are identified
Subchapter 2.10.1.3
Quality indicator is revised
Subchapter 2.10.1.2
Quality indicator monitoring is continued
Subchapter 2.10.1.1
Continual Improvement Process

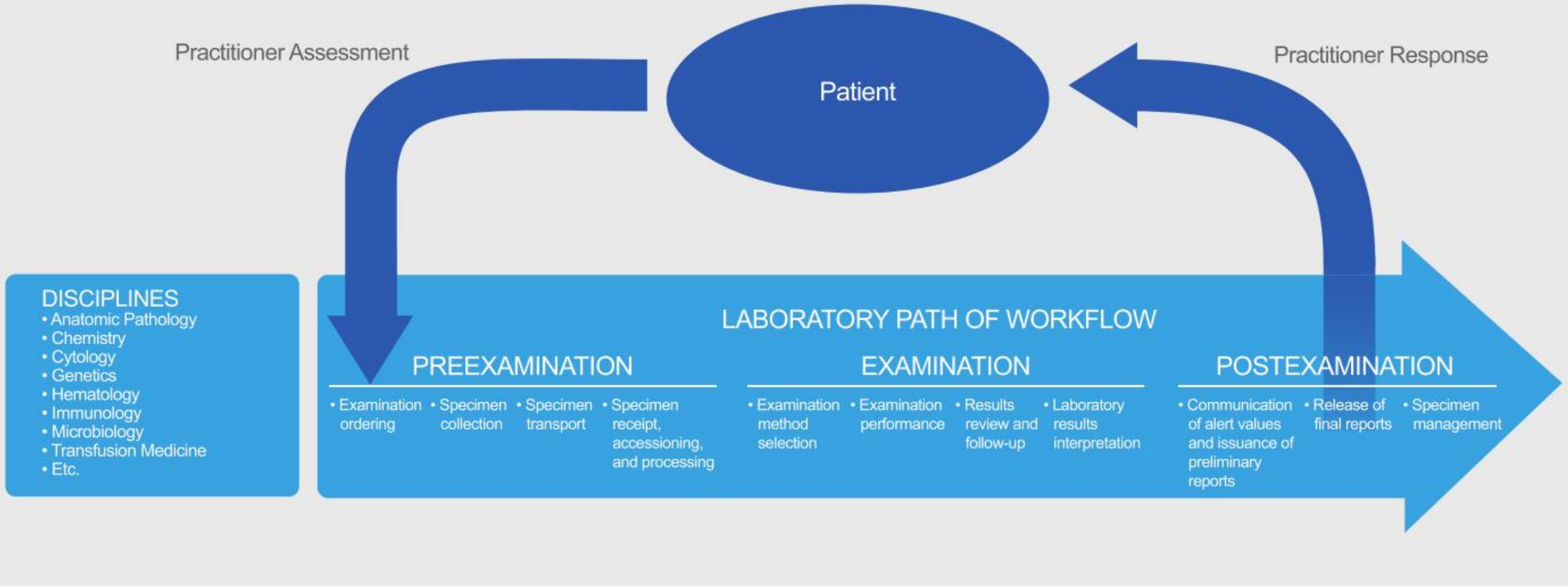
- The need for quality indicators arises from the fallowing sources:
  - Costumer expectations
  - Organizational expectations
  - Regulatory and accreditation requirements
  - Laboratory Quality Management Systems process

Customer Expectations

Laboratory should ensure that expectation of external customers, such as practitioners, patients, and other laboratories as well as inter laboratory customers (personnel) are fulfilled

Turnaround time (TAT) is a crucial laboratory quality indicator in meeting customers' expectations for timely results

critical value reporting


Practitioner Assessment
Patient
Practitioner Response
DISCIPLINES
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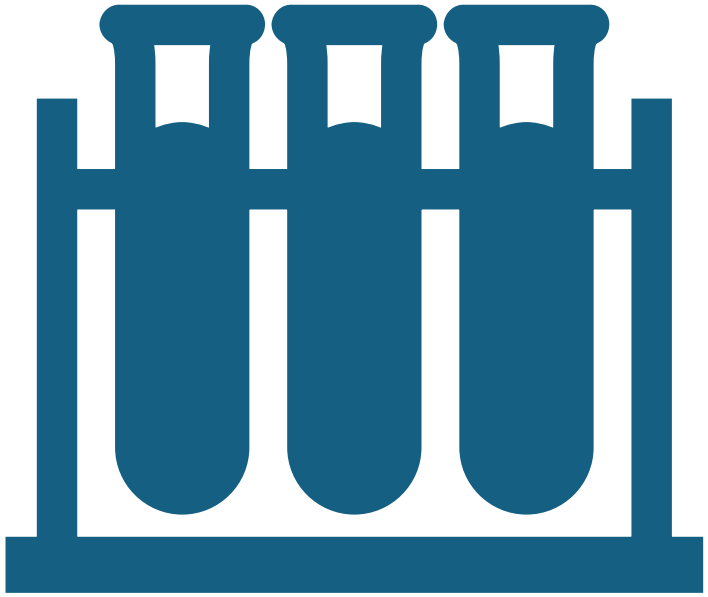


- The scope of the laboratory's quality indicators should include:
  - The appropriateness of examinations ordered, also known as test utilization
  - The pre-examination, examination, and post-examination processes
  - The appropriateness of practitioner responses to laboratory results and reports

Utilization

- The laboratory director plays a crucial role in ensuring that healthcare practitioners order the correct examinations for patients. This includes collaborating with practitioners to verify that the appropriate tests are chosen and ordered correctly

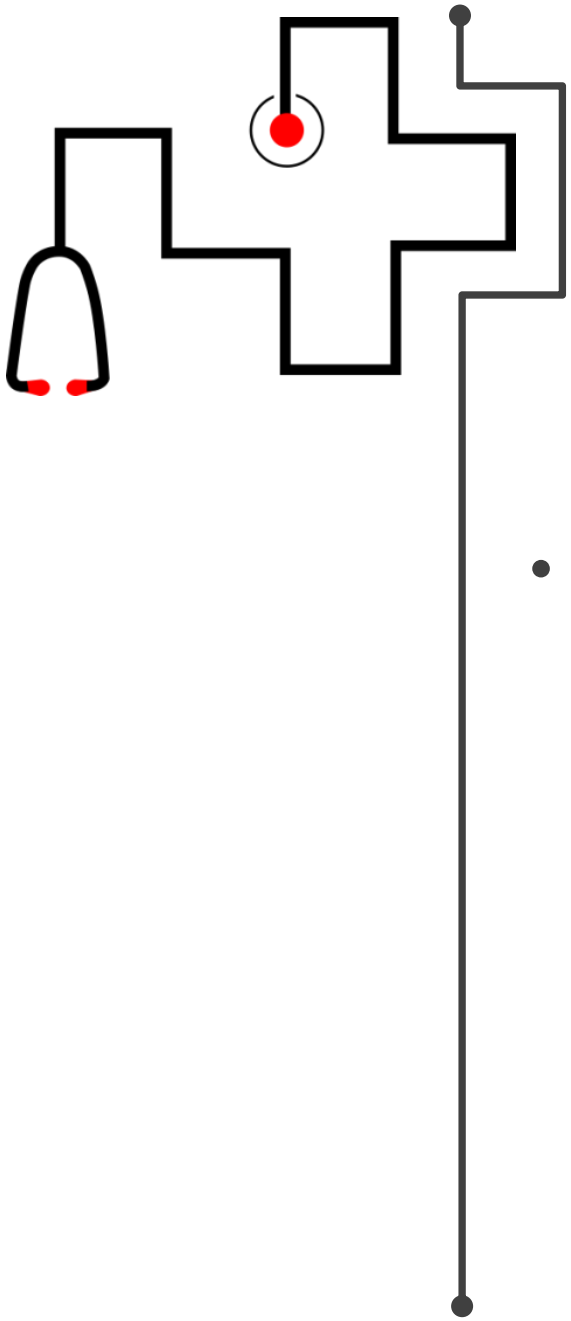
Utilization

- This involves ensuring that non-beneficial tests are not ordered, and that appropriate screening or monitoring tests are being employed at recommended intervals

Diagnostic Algorithms for Utilization

- A group of laboratory directors and practitioners develop which tests are appropriate for specific patient presentations
- As an example, what diagnostic tests are needed during an inpatient visit for children with congenital heart defects

- The limitation is patient to patient variables that may alter the appropriateness of the requested tests
- In out-patient setting the financial incentive to ‘save money’ is less prominent



Practitioners respond to laboratory results and reports

- Monitoring the effectiveness of patient interventions

- Examples: Evaluation of actions after reporting critical value, Evaluation of critical glucose level provided through POCT which are not confirmed by laboratory methods

Selection of Indicators

When selecting a specific quality indicator, a laboratory should consider the reasons for monitoring by answering questions such as:

- **Is the test results are critical to immediate patient care?**
- **Is it a complex process with many activities?**
- **Is it a highly automated system or a manual process?**
- **Is it a subject to repetitive problems that place a strain on laboratory resources?**

Examples of Quality Indicators for laboratory's Path of workflow

Determine rate of, source of, and reasons for the following:

PRACTITIONER ASSESSMENT
Practitioner Assessment
• Unstated reasons for examination orders • Unstated reasons for blood component and blood product orders • Inappropriate reasons for examination orders • Patient consent not obtained when required (eg, genetic testing)

PRE-EXAMINATION PROCESSES

Examination Ordering
• Requests for obsolete or unnecessary examinations • Examination requests without required or critical information • Duplicate examination orders • Verification of physician orders to results of point-of-care examinations

Specimen Collection
• Locations or sites without current specimen collection instructions • Patients without appropriate identification at time of specimen collection • Patients inappropriately prepared at time of specimen collection (eg, nonfasting, medication not taken) • Unsuccessful phlebotomy attempts by phlebotomist* • Specimens collected from inappropriate collection sites (eg, IV line)* • Outpatient waiting time

Specimen Transport
• Specimens delayed in transport • Specimens transported under inappropriate conditions (eg, frozen samples not on dry ice) • Specimens lost in transport

Specimen Receipt, Accessioning, and Processing
• Blood, body fluid, and tissue specimens that do not meet the laboratory's established specimen acceptance criteria (for each of the following reasons and any other, as needed): – Without necessary special handling or preservation – Without appropriate accompanying order or document – Collected at improper time – Collected from incorrect source – Collected from wrong patient – Collected in wrong container type – Labeled with incomplete or wrong information – Unlabeled – Insufficient quantity* (eg, coagulation tube incompletely filled, insufficient specimen for examinations ordered) – Specimen quality issues discovered at specimen processing (eg, clotted, hemolyzed) • Blood volume adequacy for blood culture* • Specimens with chain of custody problems • Specimen handling errors that render the specimen unusable • Cycle time for resolving specimen problems • Accessioning and data entry errors by specimen reception personnel

EXAMINATION PROCESSES

Examination Performance
• Problematic instrument-to-instrument correlation • Incomplete test runs by instrument (ie, technical problems) • Invalid test runs by instrument (ie, failed calibration, unacceptable quality control results) • Repeat examinations due to operational factors (see second and third bulleted items in this section) • Examination cancellation after testing* (eg, IV fluid contamination, practitioner order to cancel) • Blood culture contamination rate* • Urine culture contamination rate* • Discrepancies between blood type at serological examination and the historic record for the same patient • Histology slide recut rate

Laboratory Results Interpretation
• Disparities in diagnosis between: – Frozen section and final diagnosis – Cytological and pathological diagnosis by selected organ system (eg, fine-needle biopsy correlation with tissue diagnosis) – Cell types and/or inclusions identified in blood and body fluids* • Concordance with surgical pathology cases reviewed elsewhere • Correlation between cytotechnologist and pathologist results • Anatomic pathology misdiagnosis • Cytopathology misdiagnosis

Post- EXAMINATION PROCESSES

Communication of Alert Values and Issuance of Preliminary Reports
• Alert values not reported or not documented • Unmet TATs of specified examination results for: – ED: cardiac injury markers, blood alcohol, others as agreed – Surgery department frozen section results – Other specified areas with which the laboratory has an agreed-on time (eg, intensive care units)

Release of Final Reports

- Unmet TATs of autopsy final reports
- Delayed reports
- Surgical pathology report adequacy (ie, inclusion of all expected information)
- Disparities between information in the preliminary and final reports
- Results reported without appropriate disclaimers or related comments
- Corrected reports in each laboratory discipline due to reporting errors
- Amended reports due to reporting errors in:
  - Anatomic pathology
  - Cytopathology

Specimen Management
Unable to retrieve retained specimen materials: • Blood • Body fluids • Tissues • Blocks • Slides • Other (specified)

Additional consideration for selecting QI

- Problem-prone
- High volume
- High risk
- High cost

Additional consideration for selecting QI

- Normally stable process which the failure could cause potential serious conquenses for patients
  - ✓Wrong blood component administration
- Complex workflow processes that involve multiple inputs
  - ✓The correct time of specimen collection in drug levels
- Process with recent revision (such as TAT)

Table 2. A Set of Laboratory Quality Indicators for Perpetual Monitoring of the Path of Workflow*

Path of Workflow Phase	Recommended Indicator
Practitioner assessment	• Appropriateness of examination orders
Preexamination	• Accuracy of patient identification at the time of specimen collection • Accuracy and completeness of examination/test requests • Numbers and sources of, and reasons why specimens do not meet the laboratory's acceptance criteria
Examination	• Number of specimens lacking sufficient quantity at examination • Number of and reasons for repeat examinations, by examination • Number of times and reasons for failures of calibration materials or controls for a given instrument or test system • Number of times and reasons for technical failures of a given instrument or test system
Postexamination	• Completeness of laboratory reporting of critical values • Numbers and types of reporting errors (eg, corrected reports after issue, amended surgical pathology report due to diagnostic error) • Numbers and types of specimens that cannot be retrieved during postexamination storage
Practitioner response	• Number and source of failures to review and act on significant examination results before patient is discharged

* This list represents suggestions from the authors only, not from their respective organizations or any regulatory or accreditation organization.

Data Collection Plan

Now quality indicator is defined....

Data Collection Plan

- Data collection should be precise and specific
- Example: Urine culture contamination data should contain age , sex and collection method
- Data sampling may be performed for subset of QI

Table 4. Part II: Indicator Development and Data Collection*

Field on Indicator Development Form	Description
(A) Identify the function(s)/person(s) responsible for collecting the data.	Describe who will collect the data. This activity could be the responsibility of a quality unit in a large laboratory but may instead be the responsibility of one or more individuals in a smaller laboratory.
(B) Select the time frame for data collection: If **retrospective,** specify data time frame. If **concurrent,** specify frequency of data collection.	Retrospective data are historic and should be available. Concurrent data are collected in real time as the indicator event occurs. Specify how often the data will be collected, eg, hourly, daily, weekly, as appropriate.

(C) Specify any baseline measurement for this indicator and the time period from which the baseline is obtained.	Baseline (eg, retrospective) data indicate prior performance. A baseline can also be obtained during preliminary evaluation. Include the time period of the baseline measurement. Baseline data are used to compare the current state with a future state.
(D) Specify the type of data to be collected.	Data generally are classified as attribute or variable: • Variable data are measured and plotted on a continuous scale (see Subchapter 2.8.3.1). • Attribute data are counted as discrete items or events (see Subchapter 2.8.3.2).

(E) Specify whether stratification for any potential subgroup or category is needed for this indicator.	Identify the unique characteristics, potential subgroups, or categories expected to be present in the data that could influence interpretation of the indicator.
(F) Describe any needed data sampling.	Describe the specific sample, eg, "The data from every *n*th sample will be collected on Mondays, Wednesdays, and Fridays for the month of October 20XX." Select a sample that will be an accurate representation of the whole.

Indicators Analysis

Data Display on Charts

- Presenting collected data in tables can be challenging, as raw numbers are often not easily interpretable. Graphics, such as charts and graphs, help transform these raw data into clearer and more understandable information

Preliminary Quality Indicator Target Is Selected!

Preliminary Quality Indicator Target

- Each indicator typically has a target that defines the desired performance level
- Each indicator has a threshold that, when crossed, taking action is needed
- Each objective requires specific measurements to effectively monitor progress toward its respective goal

Table 6. Important Relationships in Quality Indicator Development

	Purpose	Question	Example
Goal	States how the strategic plan can be accomplished	"What do we do to achieve our strategic plan?"	Improve customer satisfaction
Objective	Specifies an action that, when achieved, will help fulfill a goal	"How will we know if we are achieving our goals?"	Reduce TAT of cardiac markers to the ED by 30% within 4 months
Indicator	Measures performance of the work process involved in the objective	"How close are we in achieving the objective?"	Data measuring time from specimen collection to release of results
Target	Reflects desired performance or expectations	"What performance level are we trying to accomplish?"	25 minutes or less
Threshold	Triggers an improvement action	"What is the poor performance level that, when exceeded, warrants our taking action?"	More than 35 minutes

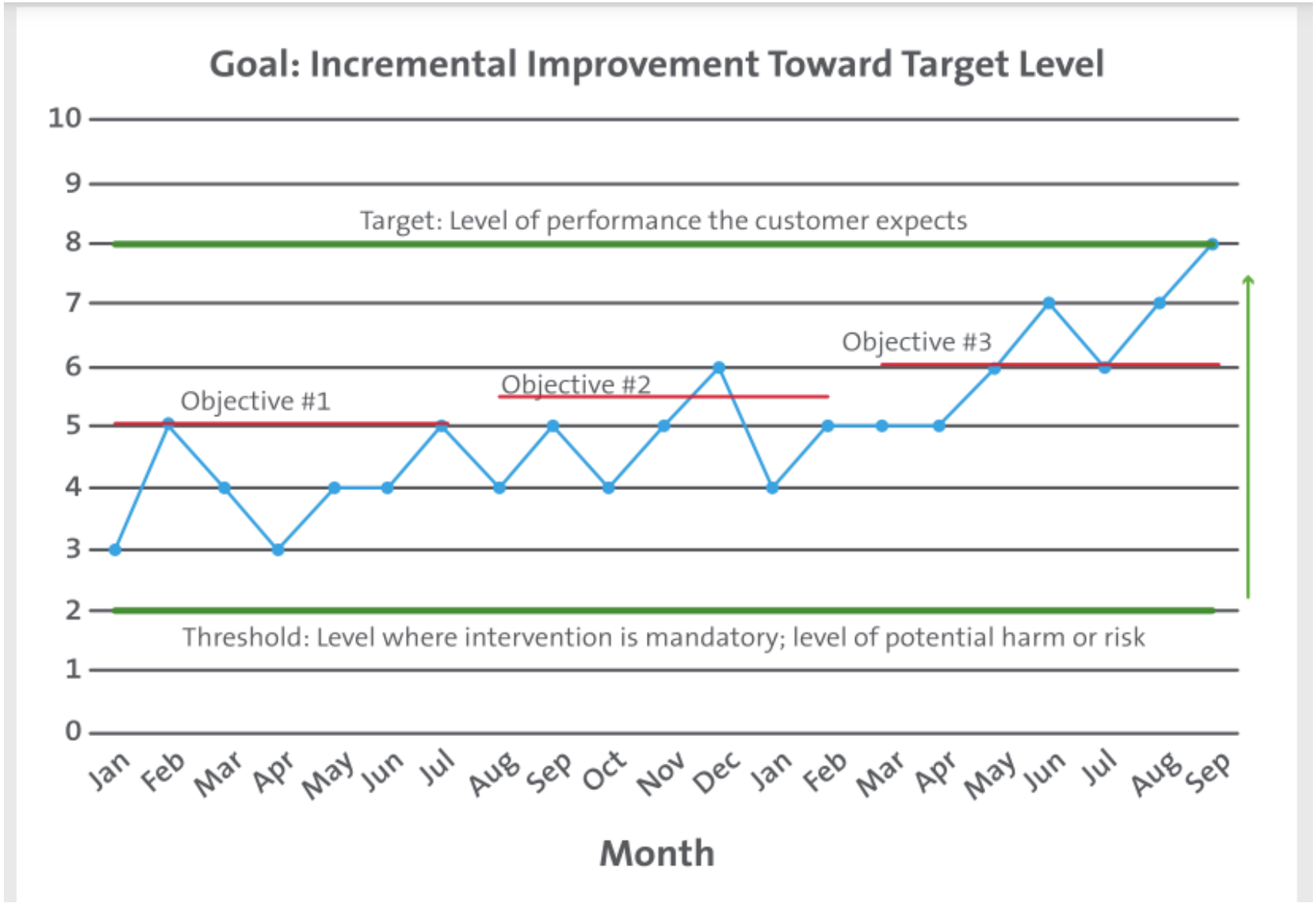
Abbreviations: ED, emergency department; TAT, turnaround time.

Developing Objectives

EXAMPLE:

Poor objective: "Reduce current blood culture contamination rate of 0.5% by half."

SMART objective: "Reduce (age-specific) blood culture contamination rate to < 0.25% within six months."


Goal: Incremental Improvement Toward Target Level
10
9
8
7
6
5
4
3
2
1
0
Target: Level of performance the customer expects
Objective #1
Objective #2
Objective #3
Threshold: Level where intervention is mandatory; level of potential harm or risk
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Month

Data Analysis for Improvement

Table 10. Reasons for Delayed Release of Laboratory Results: Unsorted Data

Defect*	Days							Total
	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	
Incomplete requisition	3	3	5	4	5	7	6	33
Incorrect result reported	0	0	0	1	0	0	0	1
Incorrect transport temperature	1	0	0	1	1	1	1	5
No requisition	1	1	0	0	1	1	1	5
No specimen source	2	1	3	1	1	2	0	10
Specimen lost in transit	0	1	1	0	1	1	0	4
Unlabeled specimen	8	6	5	3	3	1	2	28
Total	15	12	14	10	12	13	10	**86**

* Items in "Defect" column are arranged alphabetically, not by prevalence.

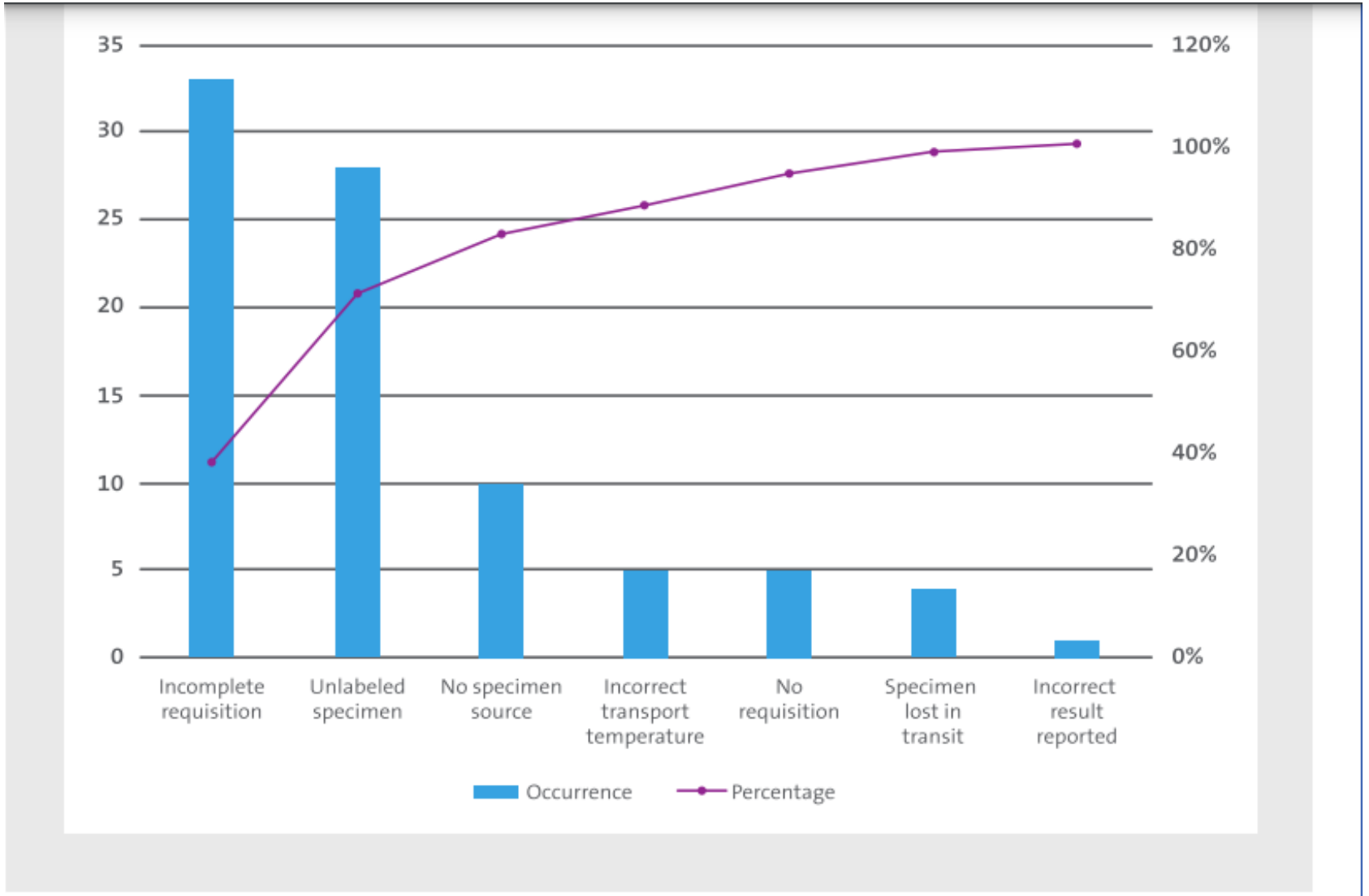
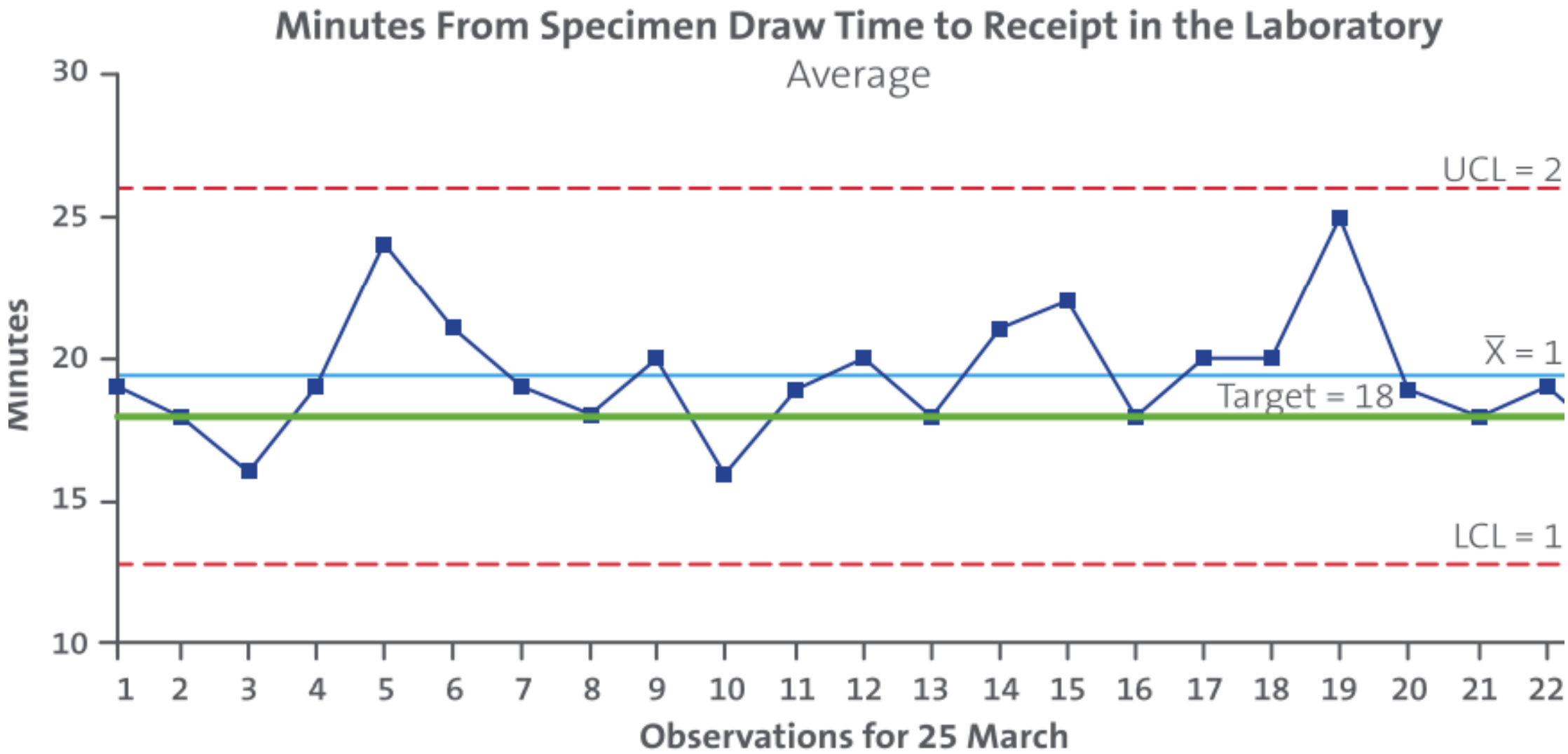
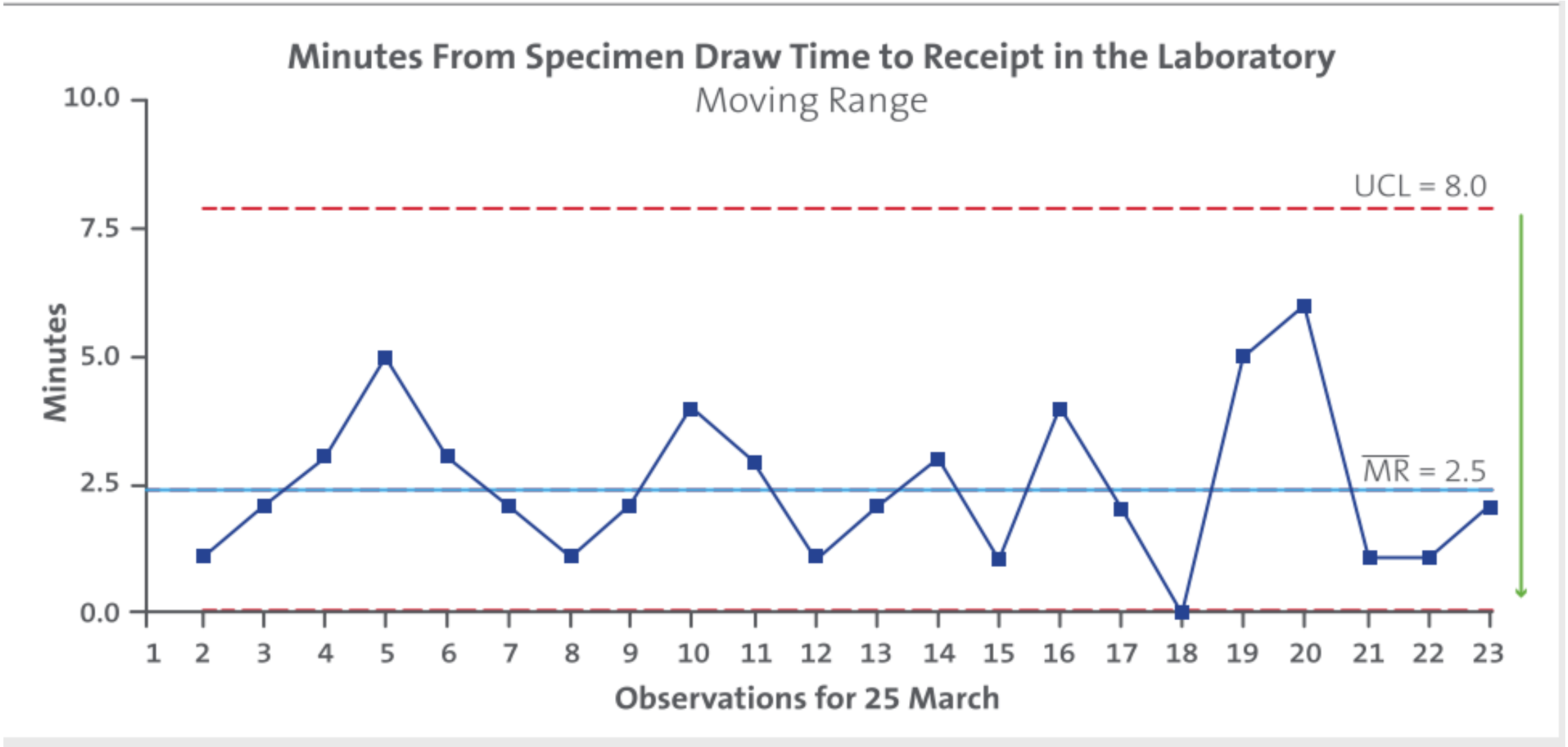


Figure 7. Pareto Chart of Sorted Data for Different Nonconformance Types Resulting in Delayed Release of Laboratory Results. In this figure, the bar height represents the number of nonconformances on the left axis and the line is cumulative frequency of occurrence on the right axis.

- Levey-Jennings control charts are widely used in laboratory settings for plotting Quality Control (QC) data derived from automated examination instruments. These charts can also be effectively adapted for analysing quality indicator data


Minutes From Specimen Draw Time to Receipt in the Laboratory
Average
UCL = 2
X̄ = 1
Target = 18
LCL = 1
Minutes
30
25
20
15
10
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
Observations for 25 March


Minutes From Specimen Draw Time to Receipt in the Laboratory
Moving Range
10.0
7.5
5.0
2.5
0.0
Minutes
UCL = 8.0
$\overline{MR}$ = 2.5
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
Observations for 25 March

Control Chart Interpretations

- Quality indicator data showing any of this patterns require immediate investigation and resolution:
  - ✓Data point outside the control limits
  - ✓Multiple points in row continuously increasing or decreasing (Trend)
  - ✓Multiple points in the same side of median (shift)

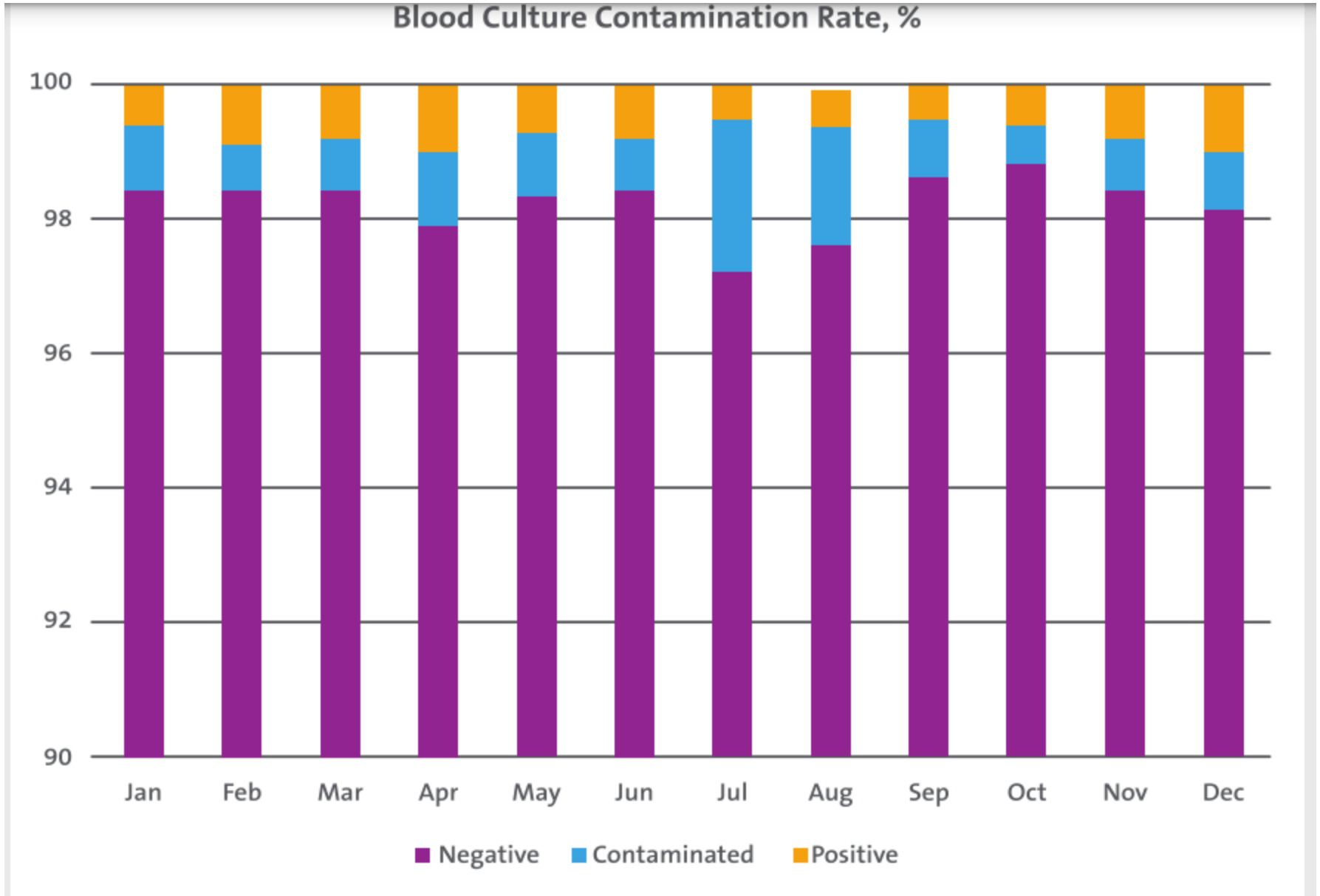
Example : Blood Culture contamination

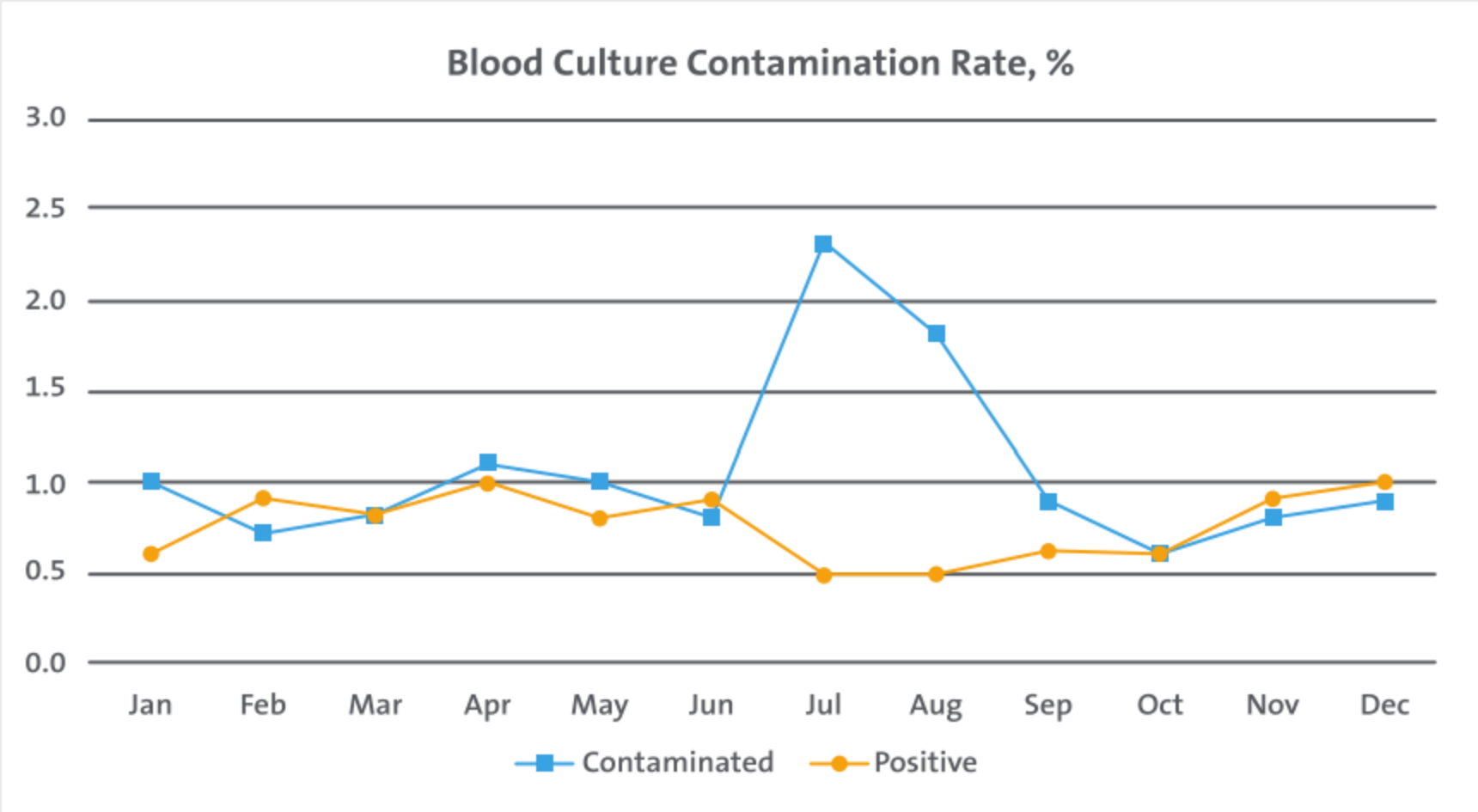
Table 11. Data Presentation in Table Format (Value)

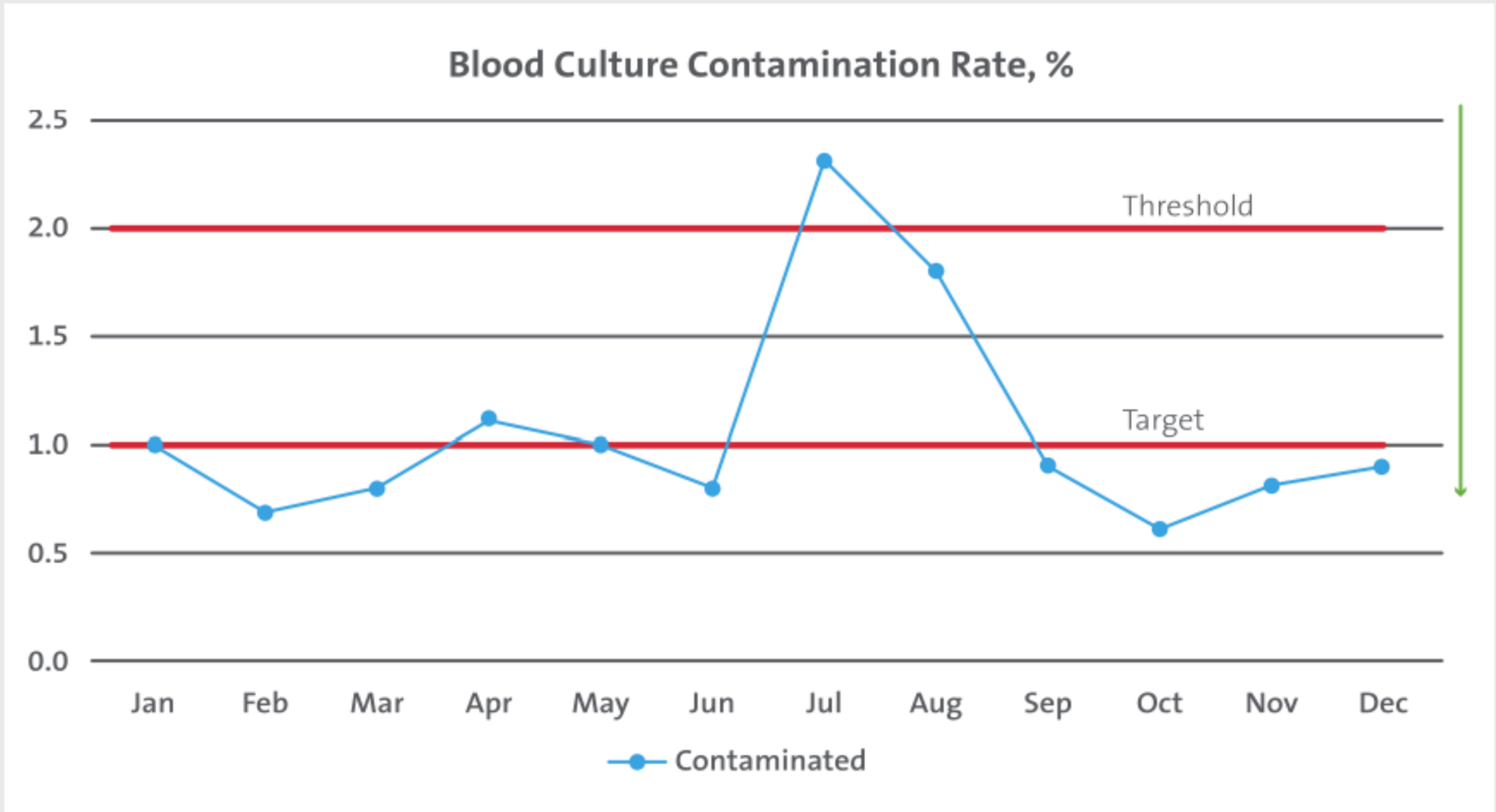
Month	Negative	Contaminated	Positive	Total
January	1574	16	10	**1600**
February	1580	11	14	**1605**
March	1573	13	12	**1598**
April	1566	18	16	**1600**
May	1574	16	12	**1602**
June	1594	12	14	**1620**
July	1506	36	8	**1550**
August	1489	28	8	**1525**
September	1577	14	9	**1600**
October	1605	10	10	**1625**
November	1574	12	14	**1600**
December	1568	14	16	**1598**

Table 12. Data Presentation in Table Format (Percent)

Month	Negative	Contaminated	Positive	Total
January	98.4%	1.0%	0.6%	**1600**
February	98.4%	0.7%	0.9%	**1605**
March	98.4%	0.8%	0.8%	**1595**
April	97.9%	1.1%	1.0%	**1600**
May	98.3%	1.0%	0.8%	**1602**
June	98.4%	0.7%	0.9%	**1620**
July	97.2%	2.3%	0.5%	**1550**
August	97.6%	1.8%	0.5%	**1525**
September	98.6%	0.9%	0.6%	**1600**
October	98.8%	0.6%	0.6%	**1625**
November	98.4%	0.8%	0.9%	**1600**
December	98.1%	0.9%	1.0%	**1598**


Blood Culture Contamination Rate, %
100
98
96
94
92
90
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Negative
Contaminated
Positive


Blood Culture Contamination Rate, %
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Contaminated
Positive


Blood Culture Contamination Rate, %
2.5
2.0
1.5
1.0
0.5
0.0
Threshold
Target
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Contaminated

Quality Report for XYZ Hospital (Laboratory 2), December 20XX

The laboratory quality report lists quality metrics used to monitor each laboratory's performance to identify opportunities to improve efficiency, effectiveness, and patient safety.

	Rejection Rate, %[1]		Blood Culture Contamination Rate, %[2]			ED TAT[3]	Critical Calls[4]	PT[5]	Blood Product Wastage Rate, %[6]
	Floor	Laboratory	ED	RN	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory
Target	< 0.35%		< 1%			> 90%	> 99%	99% accurate	0.25%
Threshold	G = < 0.52% W = 0.52% to 1.21% R = > 1.21%		< 2%			≥ 80%	≥ 98%	97% accurate	G = < 0.62% W = 0.62% to 3.36% R = > 3.36%
Period	January 20YY		January 20YY			January 20YY	January 20YY	4th Quarter 20XX	January 20YY
Laboratory 1	0.04	0.19	3.8	0.0	1.0	72	100.0	97.5	4.00
Laboratory 2	0.90	0.24	2.9	0.0	1.0	89	99.6	100.0	1.30
Laboratory 3	0.70	0.40	2.9	0.0	1.5	92	100.0	99.4	0.60
Laboratory 4	0.62	0.45	2.9	2.1	1.3	43	99.6	98.2	4.35
	Preexamination					Examination		Postexamination	No examination

[1] Rejection rate: percent of general hematology and chemistry specimens rejected for testing.
[2] Blood culture contamination: percent of blood cultures that grow bacteria likely to represent contaminants.
[3] ED TAT (select tests): order to result; percentage ≤ 60 minutes.
[4] Critical calls: percent of critical test values successfully reported/called.

To be completed by the laboratory			
Variance Explanation (positive or negative)			
Laboratory 2: • ED blood culture contamination rate 2.9% (threshold < 2%). Previous 2 months met objective; data indicate contaminated samples drawn by temporary nurses during personnel shortage.			
Corrective Action Recommendations for Improvement (explain corrective actions for above):			
Laboratory 2: • ED blood culture contamination rate (2.9%). Review training of temporary personnel in blood culture collection practices.			
Prepared and submitted by:	[name], Quality Manager	Date:	January 20XX

Abbreviations: ED, emergency department; PT, proficiency testing; RN, registered nurse; TAT, turnaround time

Each quality indicator in a report should include the following important information:

- Data collection
  - Time period
  - Method
  - Limitations
- Information
  - Presentation
  - Interpretation
- Conclusion as to whether the laboratory met, exceeded, or failed the indicator objective or target
- Recommendations for needed actions and interventions