



Analytical systems: Cambodian scenario

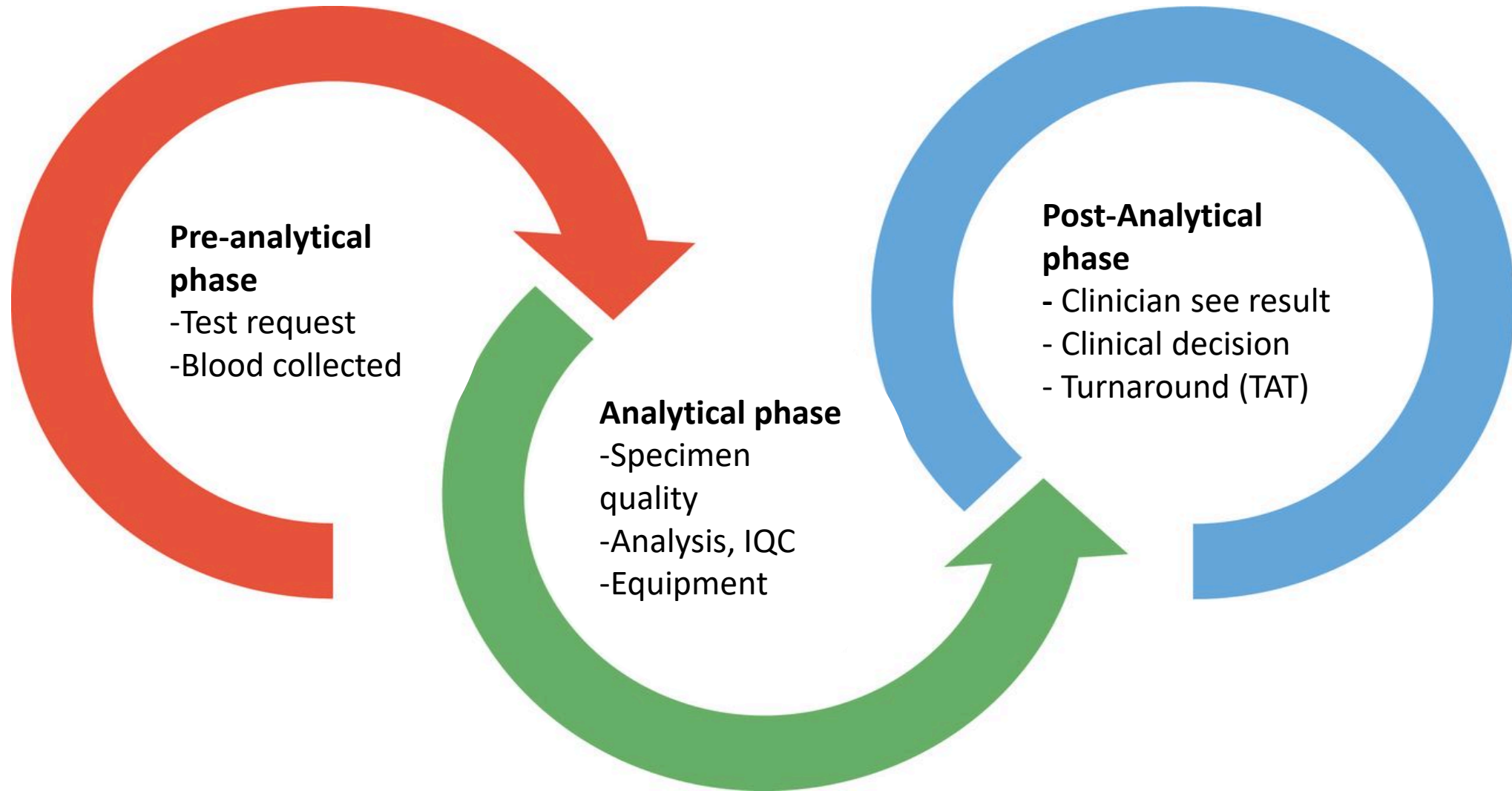
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Outline

- Laboratory Processes
- Snapshot of analytical systems in laboratories
- Define good laboratory quality

Laboratory processes



Snapshot of analytical systems in laboratories

Hematology analyzers

Analzyer	Lab 1	Lab 2	Lab 3	Lab 4	Lab 5	Lab 6	Lab 7	Lab 8	Lab 9
SYSMEX-KX21			√	√		√		√	
SYSMEX-XP100	√	√	√	√		√	√	√	√
SYSMEX-Xs500i					√				
SYSMEX-Xn550					√				
ABX Miros ES 60 (Horiba)							√		
BC-3000Plus (Mindray)							√		
Medonic M32 (Sweden)		√							√

Biochemistry analyzers

Analzyer	Lab 1	Lab 2	Lab 3	Lab 4	Lab 5	Lab 6	Lab 7	Lab 8	Lab 9
Stat Fax 3300 (USA)	✓	✓	✓	✓			✓		
Pentra C400 (Horiba)			✓✓			✓			
Pentra C-200 (Horiba)									✓✓
Humalyzer 3000			✓						
Express Plus Bayer					✓✓				
Mindrayer BA-88A		✓					✓	✓	
Humanalyzer primus						✓			

Examples of analyzers in laboratory



Define good laboratory quality

Parameter			
Accuracy			
Reliability			
Timeliness of results			

Define good laboratory quality

Parameter	Operation level	Clinical Decision	ISO 15189
Accuracy	Correlation studies	Diagnosis	4.13 Control of records 5.6.4 Comparability of examination results
Reliability			
Timeliness of results			

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Accuracy	Correlation studies	Diagnosis	4.13 Control of records 5.6.4 Comparability of examination results
Reliability	Precision (CV%)	<ul style="list-style-type: none">• Monitoring (Repeat visits)• Prognosis	5.3.2.7 Reagents and consumables records
Timeliness of results			

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Accuracy	Correlation studies	Diagnosis	4.13 Control of records 5.6.4 Comparability of examination results
Reliability	Precision (CV%)	<ul style="list-style-type: none">• Monitoring (Repeat visits)• Prognosis	5.3.2.7 Reagents and consumables records
Timeliness of results	Turn-around time (TAT) Example SOP: Contingency plan	Appropriate treatment	4.1.2.1 Management commitment - uninterrupted testing services

Different types of analyzer: What are critical factors on quality and cost?

Different Analyzer	Correlation studies	Impact on quality	Impact on cost
1	NA	<ul style="list-style-type: none"> -Good contingency plan -Communication record 	<ul style="list-style-type: none"> -Sufficient for small laboratory -TAT may be prolonged
2+	Yes	<ul style="list-style-type: none"> -Record on reagents & consumables -Correlation studies documentation -IQC for each analyzer 	<ul style="list-style-type: none"> -Keeping different sets of reagents/consumables -Staff training & competency -Cost of reagents for comparison studies -Management of IQC (increase staff time and cost of QC materials)

Different reagents, different vendors

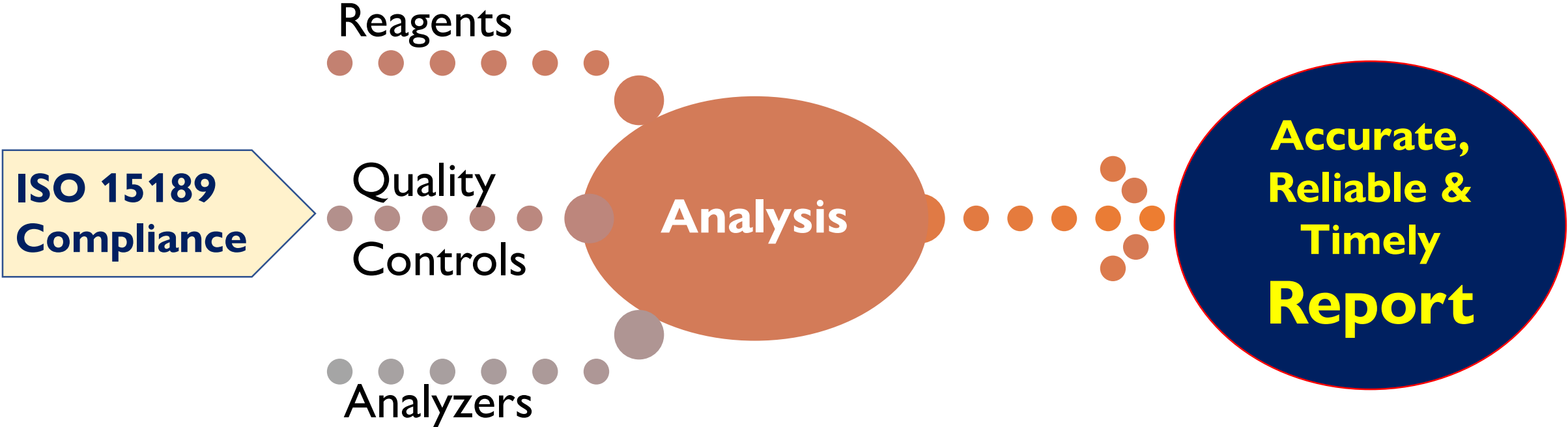
Example: Lab 7; Biochemistry; Mindray BA-88A

Tests	Reagents vendors
Glucose , Triglycerides,	Human
Cholesterol, Creatinine,	Analyticon
Transaminases, Total protein	Cypress

Different reagents: What is the impact on quality and cost?

Impact on quality	Impact on cost
<ul style="list-style-type: none">• Record on reagents & consumables• Correlation studies for reagents documentation• IQC for each reagents	<ul style="list-style-type: none">• Keeping different sets of reagents/consumables• Time on staff training & competency• Cost of reagents and time for comparison studies• Management of IQC (increase staff time and cost of QC materials)

Summary of analytical processes



Summary on quality management

Proposal	Operational activity	Impact
Similar model analyzer	Minimize variables such as imprecision CV%.	Clinical decision on patient monitoring.
Quality control with appropriate ranges for test	Reduce number of QC runs to establish the range.	Reduce QC cost and wastage.
Reagents from same manufacturer	Reduce reagent verification studies and correlation.	Reduce reagent cost, wastage and error.

Thank you



- ✓ Bureau of Medical Laboratory Services, Department of Hospital Services, Ministry of Health, Cambodia
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