

Rischi di errore nel Laboratorio Clinico

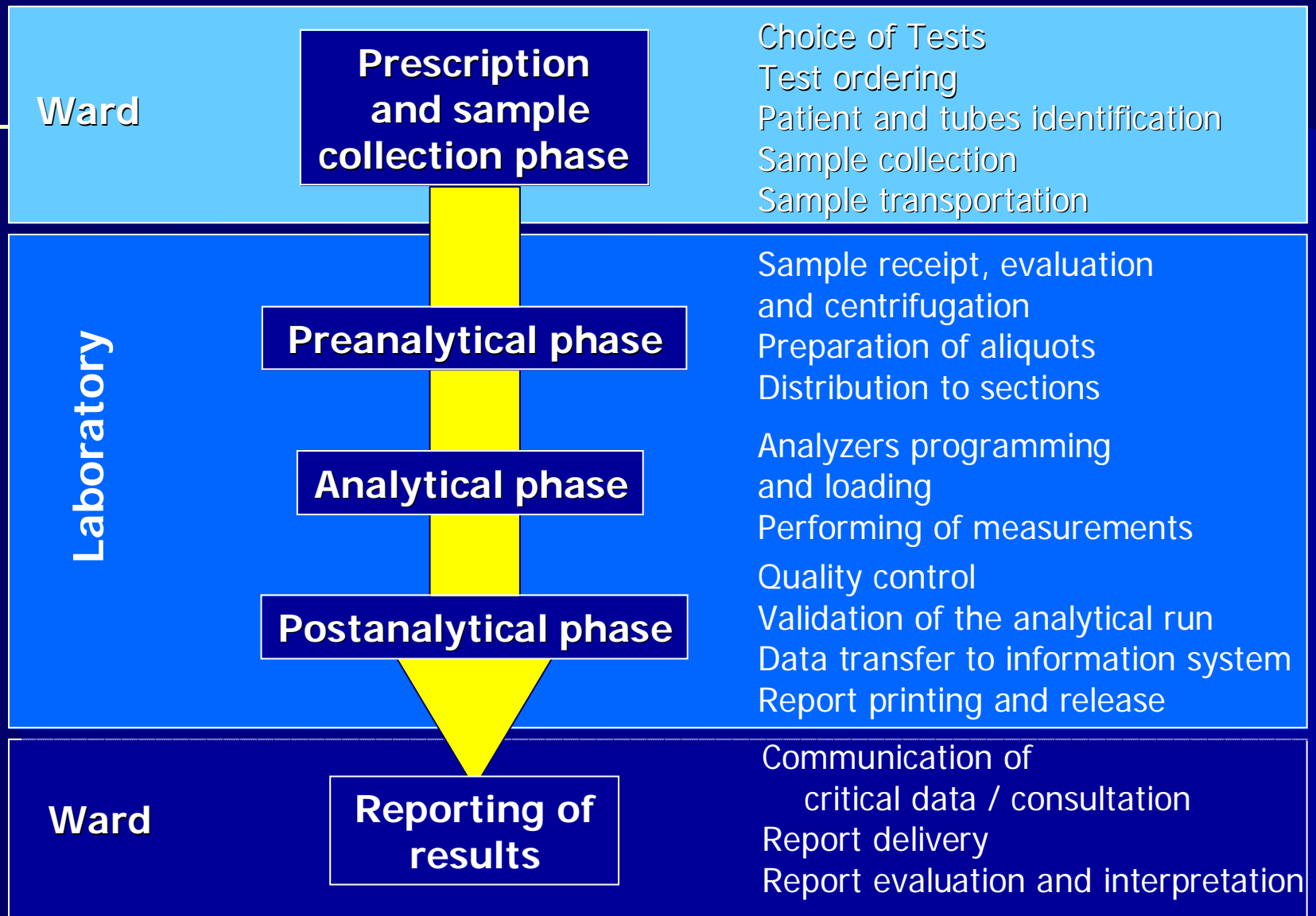
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What is an "*error*" in laboratory medicine?

" Any defect from ordering tests to reporting results and appropriately interpreting and reacting on these"

Laboratory testing process



Review of the literature on laboratory errors

Sector of the laboratory	Lapworth 1994	Goldschmidt 1995	Nutting 1996	Plebani 1997	Stahl 1998	Hofgartner 1999	
	Clinical Chemistry	Whole lab	Primary care	Stat lab	Whole Lab	Molecular genetic On site survey (2 labs)	Molecular genetic Questionnaire
Data collection period	1 year	6 years	6 months	3 months	3 years	10 years	1 year
Numbers of tests	~997000	ND	ND	40490	676564	4234	88394
Numbers of patients	~249000	ND	160.714	ND	ND	ND	ND
N° of errors	120	133	180	189	4135	16	293
Frequency (%)	0.05% of patients		0,11% of patients	0.47% of test results	0.61% of test results	0.38% of test results	0.33% of test results
- pre-analytical phase	31.6%	53%	55.6%	68.2%	75%*	44%	60%
- analytical phase	31.6%	23%	13.3%	13.3%	16%*	31%	19%
- post-analytical phase	30.8%	24%	30%	18.5%	9%*	12.5%	15%
- multiple phases	6%					12.5%	6%
Identification errors	41 (34%)	77 (58%)	ND	5 (2,6%)	ND	ND	ND
Impact on patients' outcome	ND						
-none		43%		74%			63.4%
-mild		23%	13%	19.6%		25%	20%
-moderate		26%	13%	6.4%		50%	10.2%
-severe		8%				25%	6.4%
-very severe		none					

Pre – examination procedures outside laboratory

Risk of Error

Preventive action

Test request (inappropriate)

Guidelines

Patient identification

Use of Wristband

*Automation of the
process*

Test ordering

*Computer written test
requisitions*

Incorrect blood withdrawal

Information / training

Incorrect sample
transportation

Information / training

Pre – examination procedures in lab

Risk of Error	<i>Preventive action</i>
Sample interchange during identification or splitting	<i>Pre-analytical Automation</i>
Tube breaking	<i>Plastic tubes</i>
Acceptance of inappropriate sample	<i>Acceptance / rejection criteria</i>

Examination process

Risk of Error	<i>Preventive action</i>
Blunders Random errors <ul style="list-style-type: none">– <i>Interferences</i>– <i>HAMA or HAAA</i>	<ul style="list-style-type: none">■ <i>Delta check</i>■ <i>Panic limits</i>■ <i>Plausibility algorithms (expert systems)</i>
Excessive imprecision or bias	<ul style="list-style-type: none">■ <i>Internal and external QC</i>■ <i>Appropriate quality specifications</i>■ <i>Proper calibration and maintenance of the analyzers</i>

Post examination processes in lab

Risk of Error	<i>Preventive action</i>
Data input	<ul style="list-style-type: none">■ <i>On line connections</i>■ <i>Delta check</i>■ <i>Panic limits</i>■ <i>Expert systems</i>
Reference intervals (wrong)	<ul style="list-style-type: none">■ <i>Periodical review</i>
Interpretative comments (wrong)	<ul style="list-style-type: none">■ <i>Training</i>

Post examination processes outside laboratory

Risk of Error

Preventive action

Lack or delayed notification of pathological results

- *Definition of specific rules and organization*

Lack of reaction to a pathological result

- *Computerized algorithms*