

EQALM SYMPOSIUM 2009
Quality requirements and quality goals
Kaiserin-Friedrich-Haus, 1.-2. July in Berlin, Germany



**Post-analytical factors
and their influence
on analytical quality
specifications**

Henk MJ Goldschmidt
Wednesday 01 July 2009



- ↳ **Introduction**
- ↳ Summary
- ↳ Medical loops
- ↳ Error management
NEXUS
- ↳ Post(-post)-analytical
recommendations
- ↳ Conclusions



Post-analytical factors and their influence on analytical quality specifications

Post-(post-)analytical factors:

1. Reporting
2. Interpretation
3. Overall error management
4. Throughput times
5. Context fit
6. Critical difference ($1/4 BV_{ij}$, zero error)
7. Follow up

Their influence on analytical quality specifications:

1. Define graphics
2. Clinical outcome indicators
3. Define redundancy
4. Define logistical checks
5. Check and double check
6. Define patients context
7. Provide consultation routinely



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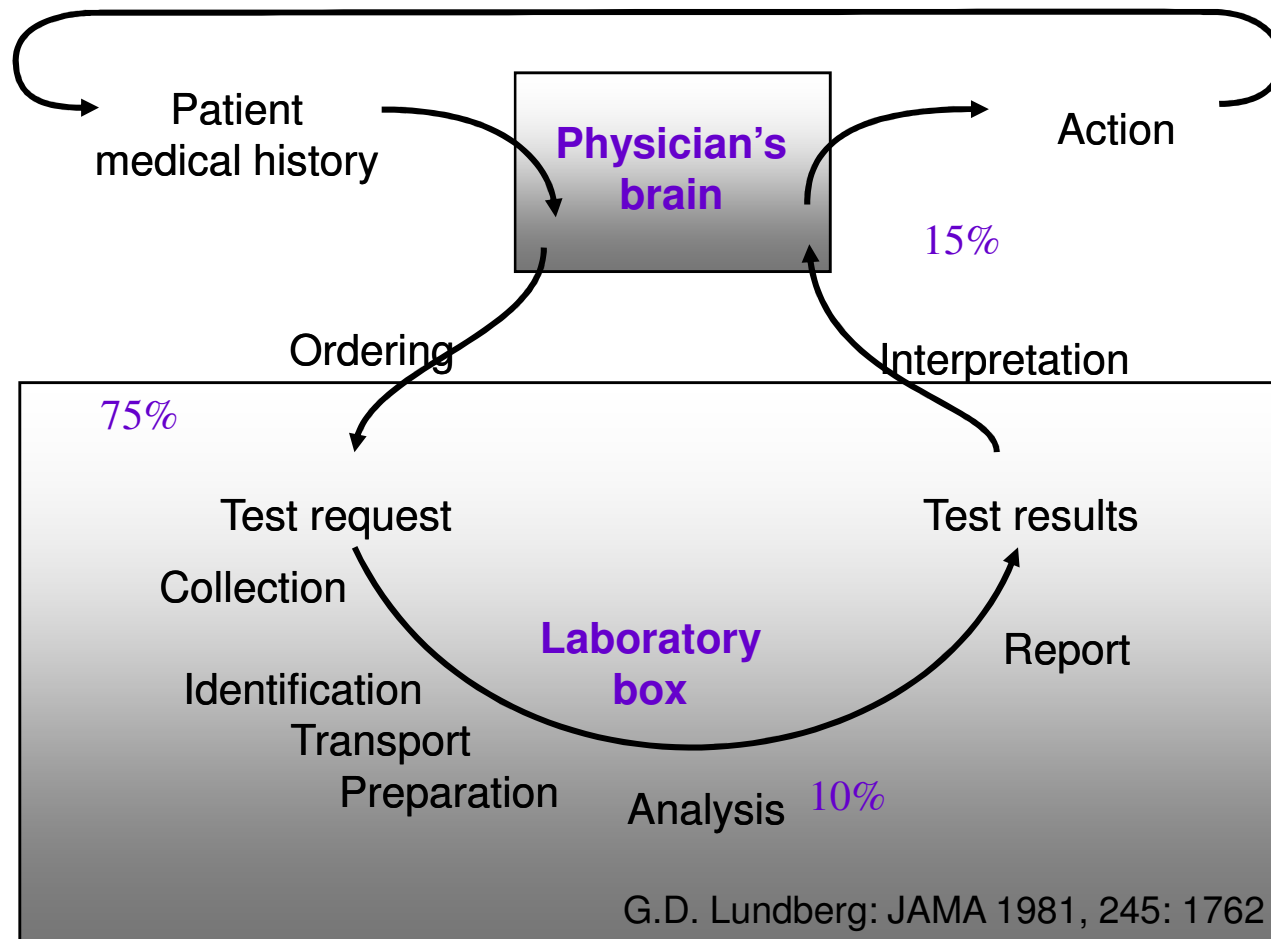
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UPDATE, overview

- It started with time dependencies (first within the lab, than outside, att.f.)
- Lundberg: loop PA-A-PA
- Goldschmidt and Lent:
Data + Context → Information (CFV)
- Goldschmidt: loop PPA-PA-A-PA-PPA
- Weggeman: $K = I * ESA$
- Error budget calculation
- NEXUS model

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The brain-to-brain information loop

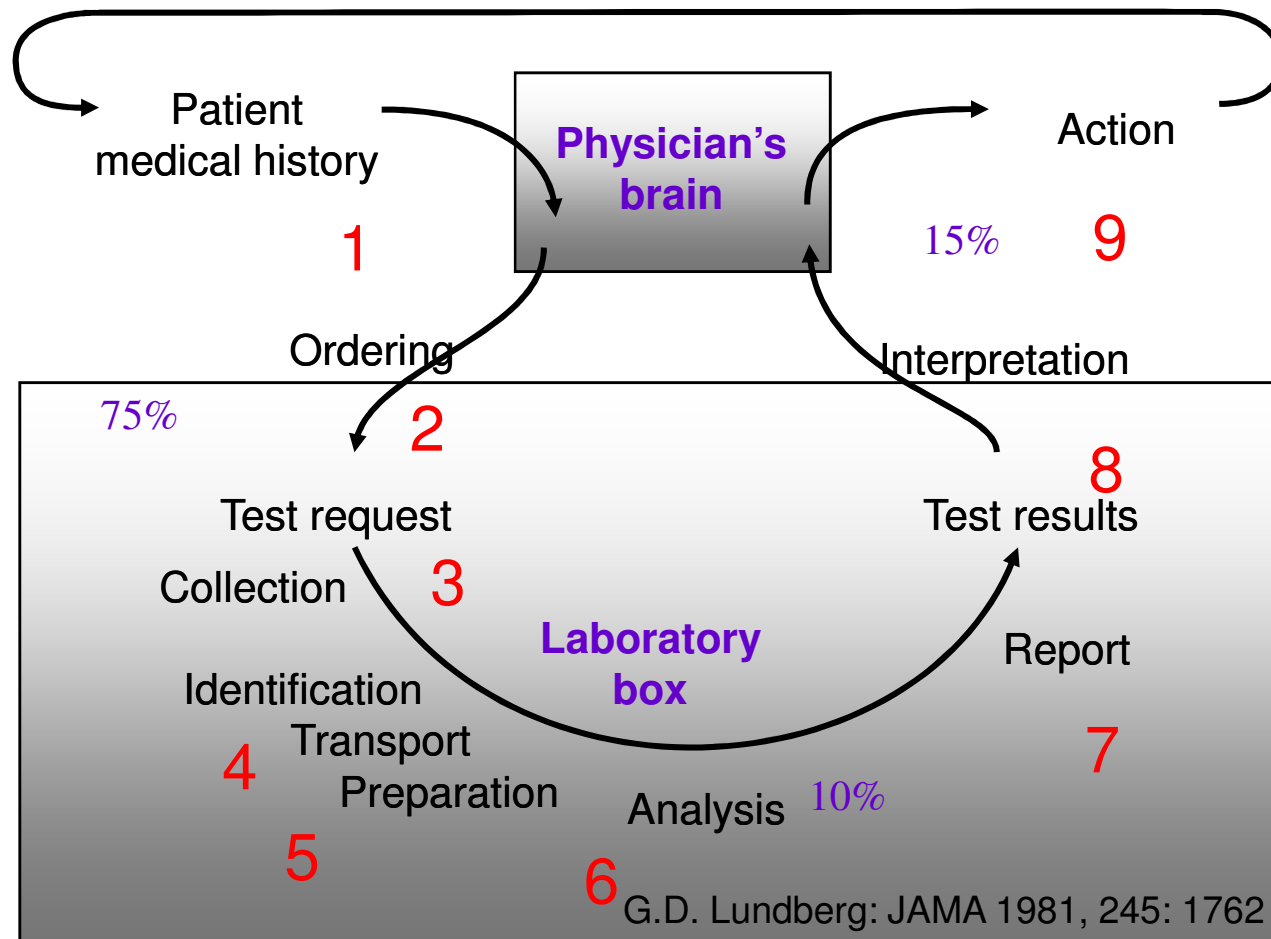


relative error rate

types of errors: sporadic, systematic and analytical

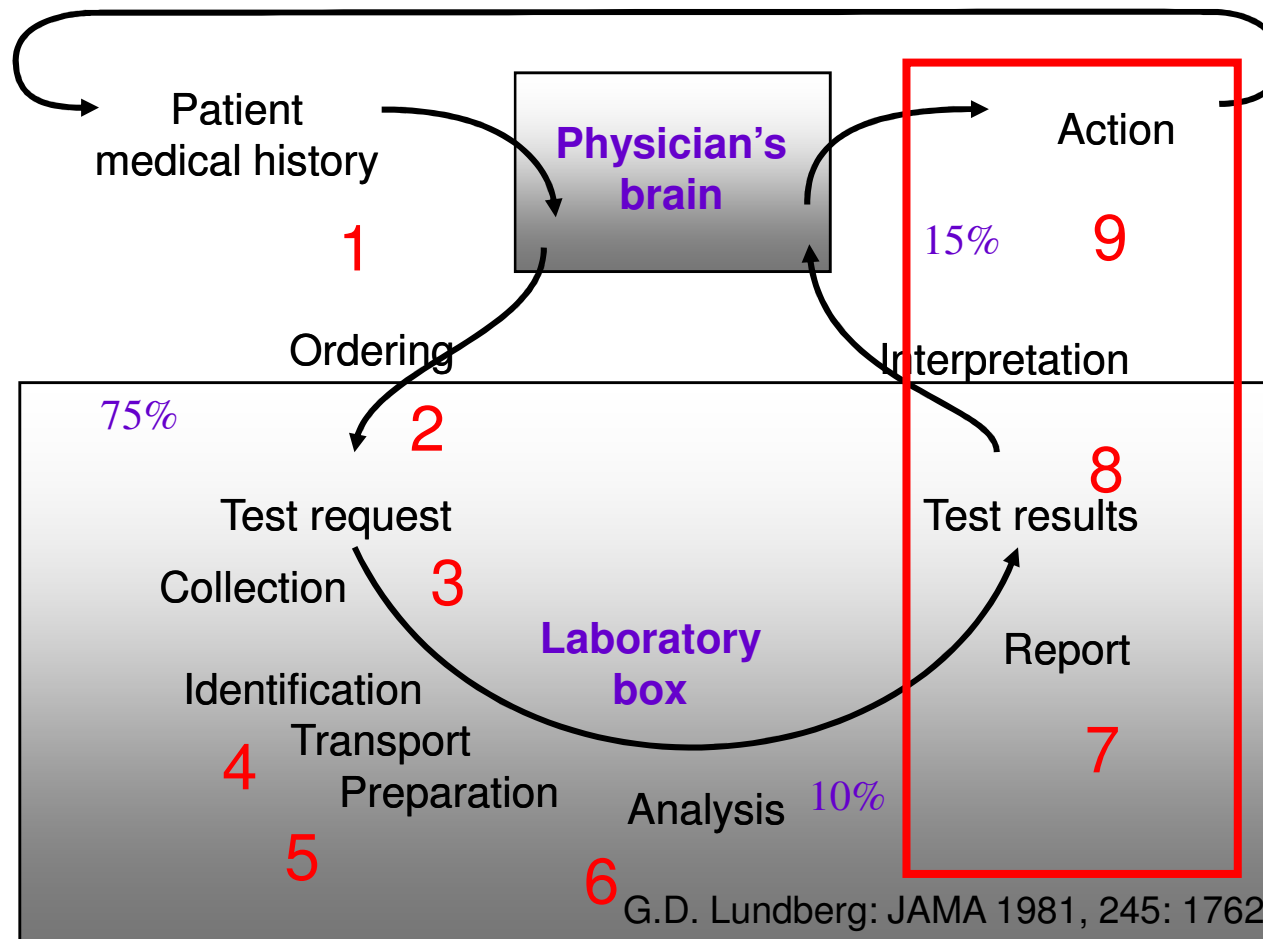
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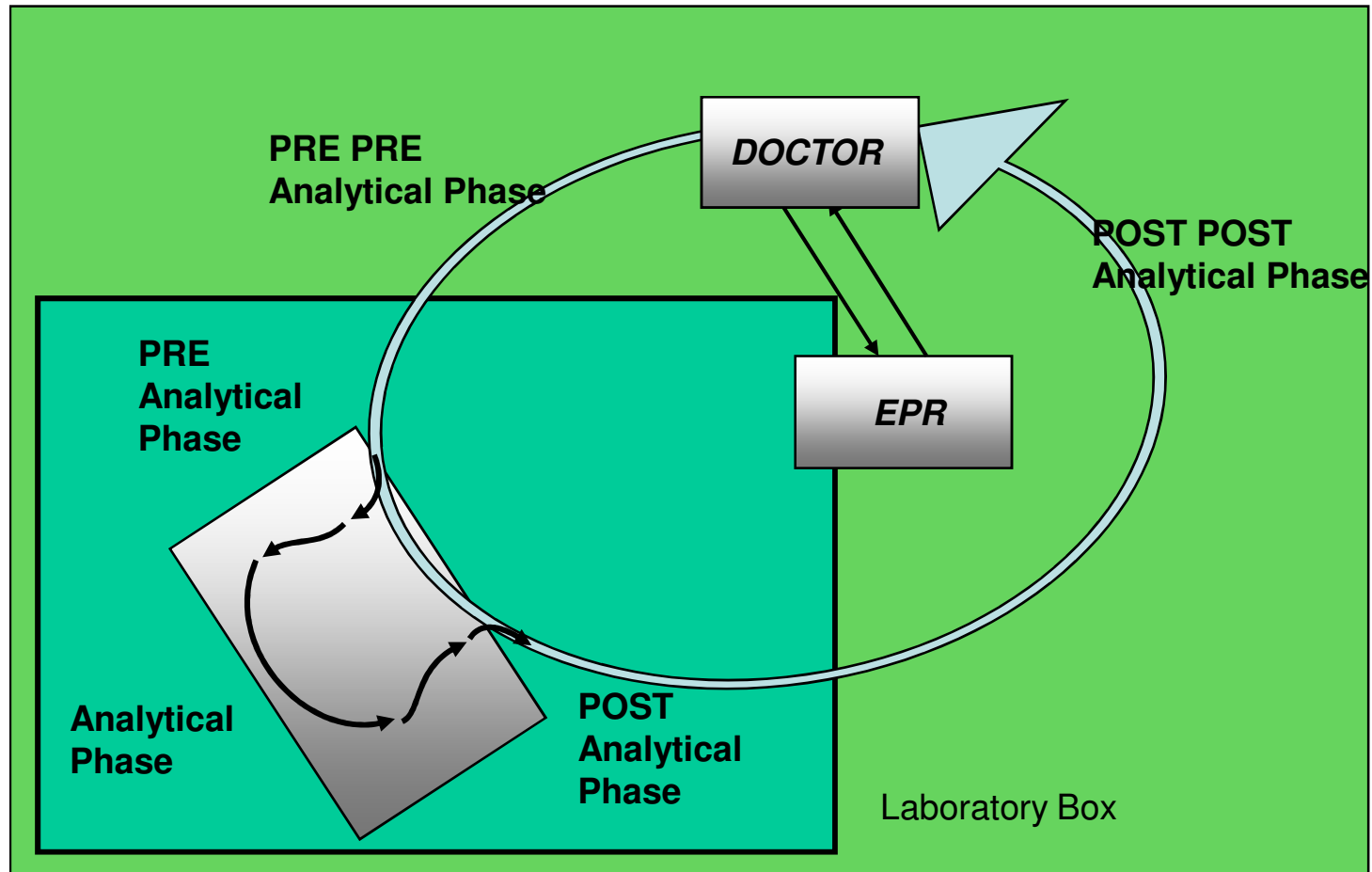
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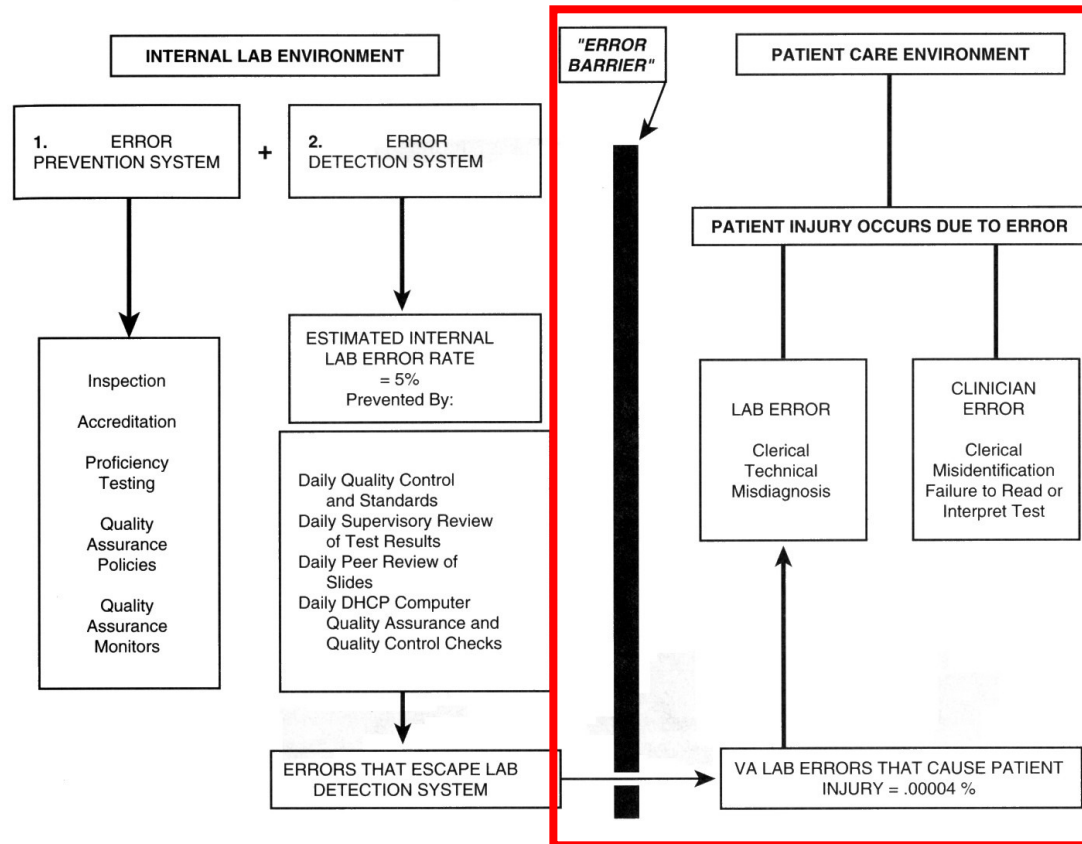
Complete Diagnostic / Therapeutic Loop



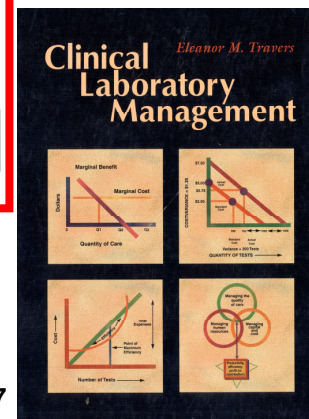
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Quality of the product (medical treatment not the isolated lab test)

WHY LABORATORY ERRORS HAPPEN

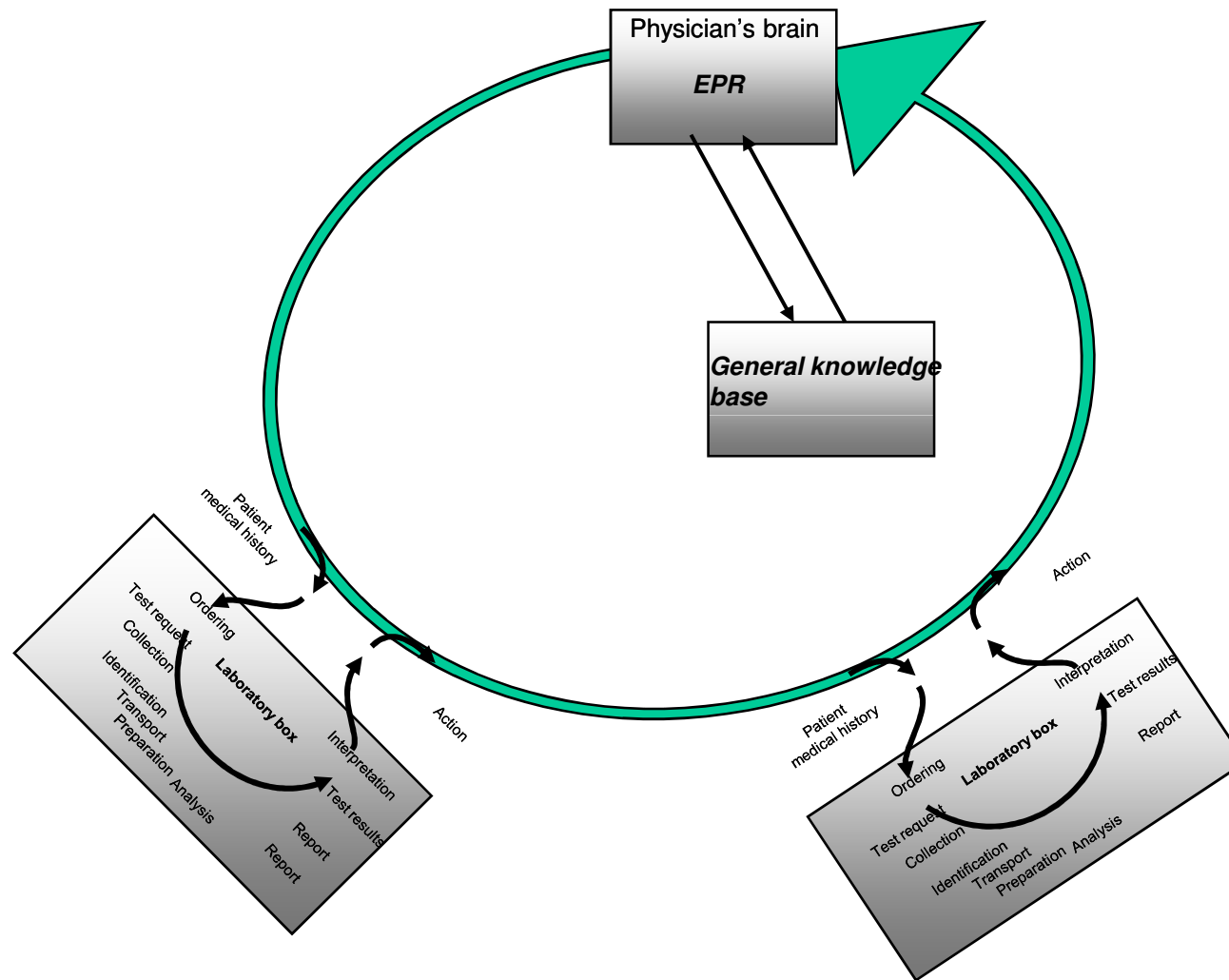


Ref: Travers, Clinical Laboratory Management, p. 769, ISBN 0-683-08376-7, 1997



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The medical laboratory in the medical process



Goldschmidt HMJ
Postanalytical
factors and their
influence on
analytical quality
specifications.
Scand J Clin Lab
Invest 1999; 59: 551-
554

$$K(\text{knowledge}) = I(\text{information}) * E(\text{experiences}) . S(\text{skills}) . A(\text{attitudes})$$

Linking the concepts of biological variation and medical allowable error

Table: Calculated and studied error rates

Phase	frequency of occurrence		justification source
Pre-pre-analytical phase	1:8	12.0 %	own enquiry ¹
Pre-analytical phase	1:49	2.0 %	literature
Analytical phase	1:625	0.2 %	results lab author 1 ²
Post-analytical phase	1:45	2.2 %	literature
Post-post-analytical phase	1:19	5.0 %	own enquiry ³
Overall error rate		20.0 %	see paper for calculation
Error budget that can be afforded		26.9 %	see paper for estimation

1 Interviewing clinicians,
checking for errors in e.g. thinking wrong hypothesis

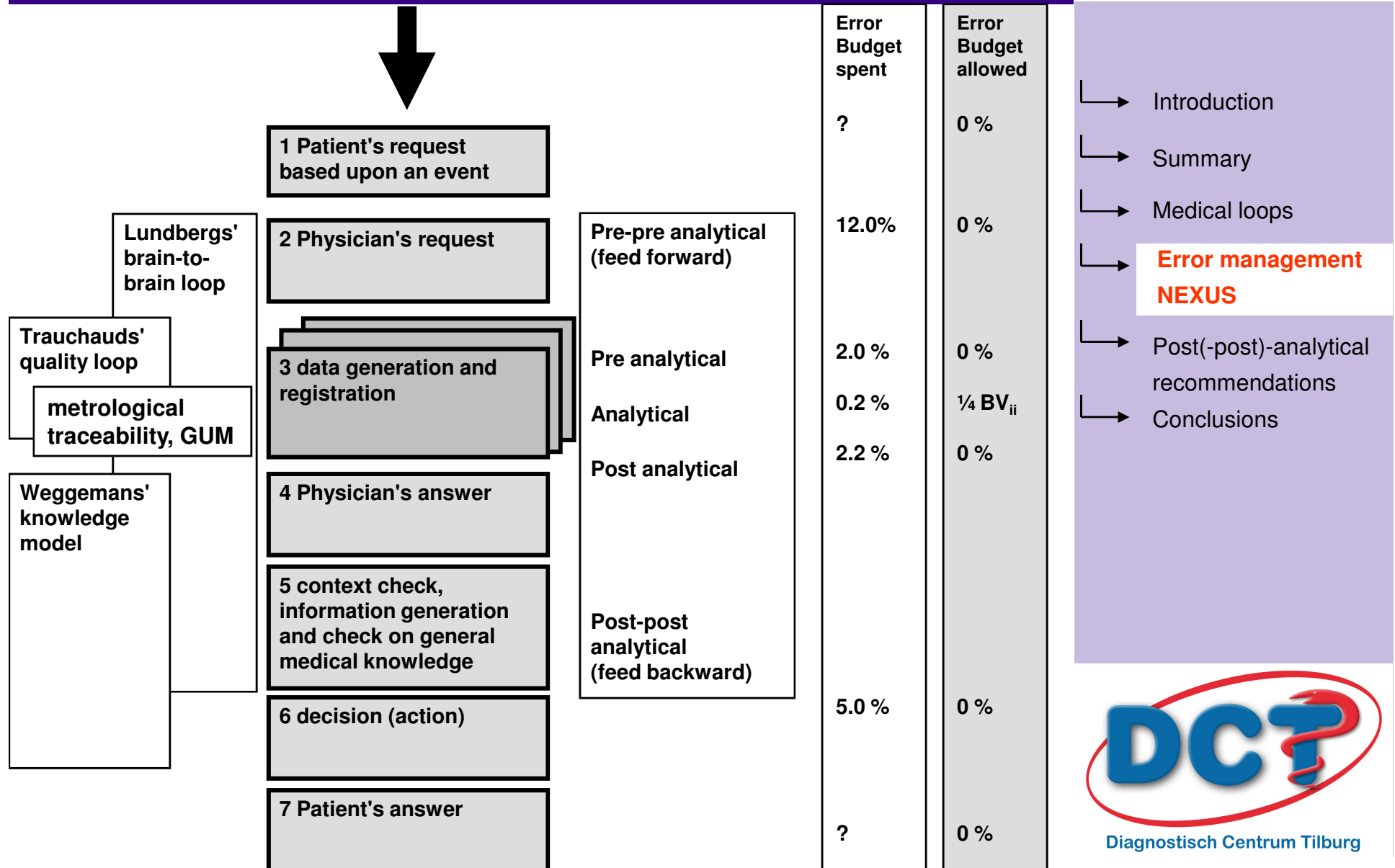
2 Internal, not external, quality control figure

3 Interviewing clinicians, checking for e.g. misinterpretation of results

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NEXUS approach: linking all concepts

Goldschmidt HMJ Clin Chem Lab Med 2004 42(7) 868-873



Linking the concepts of biological variation and medical allowable error

In a way the two approaches are: what is right now practically achievable and what is, from a theoretical point of view, possible.

So the potential of laboratory medicine is given by the biological variance concept.

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Post and post-post analytical steps possible errors linked to potential solutions

Step 7 reporting

7

Transcription errors
Computer errors
Delayed reporting
No delta check done
Conflicting rules
Wrong validation

ICT

check and double check

Step 8 interpretation

8

Interpretation errors

second opinion, interactive
software

No, wrong reflex test
Consultation error

second opinion,
interactive software,
protocol
monitoring software

Delayed consult
Erroneous reference values
Missed interaction test medication
Computer errors
Diagnostic uncertainty

ICT

ICT

check and double check
reduction measurement
variability, other test

Step 9 action

9

Erroneous action
No action taken while was required
Wrong medication
Missed interaction medication
Medical action outside protocol
Computer errors

second opinion

second opinion

protocollary approach

ICT

ICT

check and double check

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Quality of laboratory information

The Stockholm statements:

1999 quality of laboratory results

The Antwerp statements:

2003 quality of laboratory information

Jean-Claude Libeer formulated the following questions:

Is our information useful for patient care?

Do we know what clinicians want?

Do clinicians know what we can offer?

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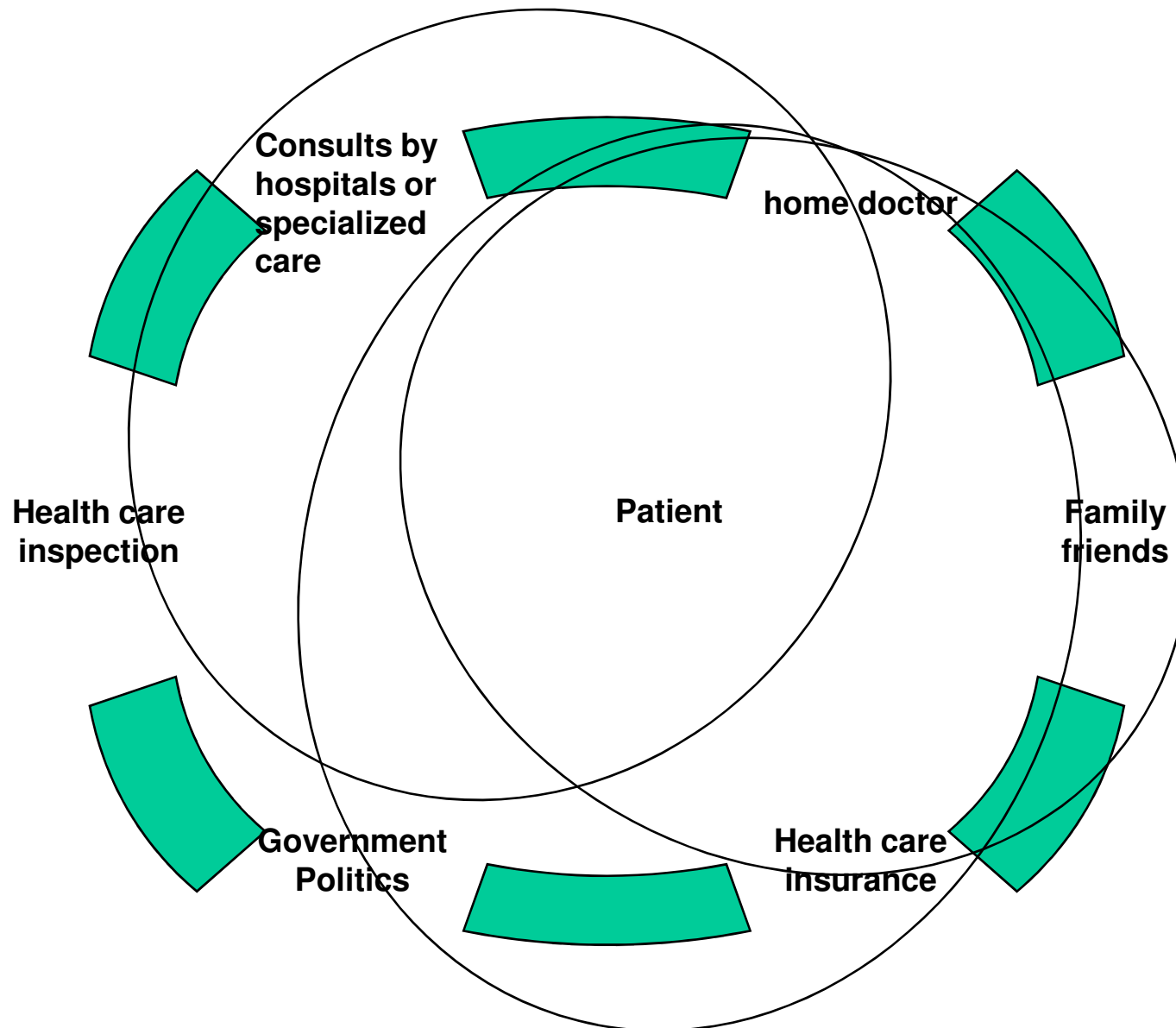
The patient in the lead: all involved

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The patient in the lead: all involved



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RECOMMENDATIONS

1. Use graphics to report
2. Use clinical outcome indicators
3. Use redundancy
4. Use logistical checks
5. Check and double check
6. Define the patients context
7. Provide consultation routinely

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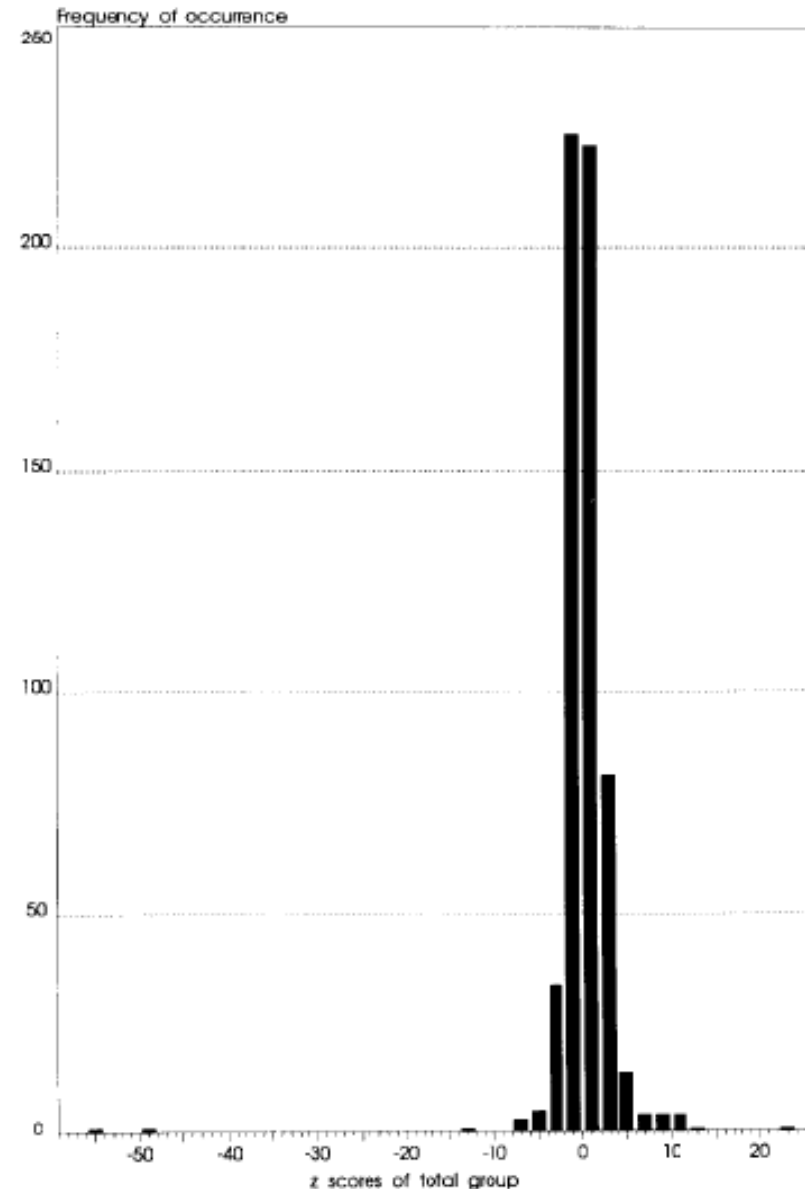
The guessing experiment

Histogram of 611 Z-scores of clinical test results of 3 outpatient clinics and 4 physicians. The Z-scores are the context fits a particular clinical chemical test result.

In:

Chemometrics and Intelligent Laboratory Systems 28 (1995) 181-192 From data to information: how to define the context?

H.M.J. Goldschmidt and R.W. Lent.



Chemistry / Hematology

Exemple 1 (Biochimie)

VALAB - expert -

Valider Consulter Paramètres Configurer Session

No : Nom : SGL
 Né(e) le : 31/08/1968 Date Examen : 30/03/92 09h
 Sexe : F Cont.d'urgence : NON Cont.Hosp. : OUI

Origine dossier : néphrologie

Paramètre	Valeur	Unité	Normale	Date	Heure	Statut
Sodium	139	mmol/l	*137	29/03/92	00h	○
Potassium	*6.5	mmol/l	*5.1	29/03/92	00h	○
Chlorures	103	mmol/l	99	29/03/92	00h	○
Bicarbonates	23	mmol/l	25	29/03/92	00h	○
Protéines	*62	g/l	70	29/03/92	00h	○
Balance ion.	97.38	ss unité	100.7	29/03/92	00h	○
Urée	*35	mmol/l	*20	29/03/92	00h	○
Créatinine	*663	µmol/l	*423	29/03/92	00h	○
Glucose	*7.28	mmol/l	5.56	29/03/92	00h	○
Acide urique	*460	µmol/l	360	29/03/92	00h	○
Cholestérol	5	mmol/l	5.2	29/03/92	00h	○
Triglycérides	*1.5	mmol/l	1.33	29/03/92	00h	○
Calcium	*1.75	mmol/l	*2.2	29/03/92	00h	○
Phosphore	*1.45	mmol/l	*1.37	29/03/92	00h	○
Fer	15	µmol/l	18	29/03/92	00h	○
Phosphatas.alc.	97	UI 37°	88	29/03/92	00h	○
GGT	55	UI 37°	45	29/03/92	00h	○
Bilirubine tot.	3	µmol/l	2.1	29/03/92	00h	○
TGP	22	UI 37°	28	29/03/92	00h	○
TGO	34	UI 37°	31	29/03/92	00h	○
LDH	489	UI 37°	511	29/03/92	00h	○
CK	77	UI 37°	86	29/03/92	00h	○

Informations sur le paramètre

Potassium

Bornes...
 Bornes de normalité : 3.50 <> 4.80
 Bornes extrêmes : 2.88 <> 7.50

Trace de l'expertise

Influence positive :
 Créatinine
 Origine dossier
 Balance ion.
 Chlorures
 Bicarbonates
 Protéines
 Contexte hospitalier

Influence négative :
 Potassium

Fermer

Supprimer
 Modifier
 Détails...

Bilan validé

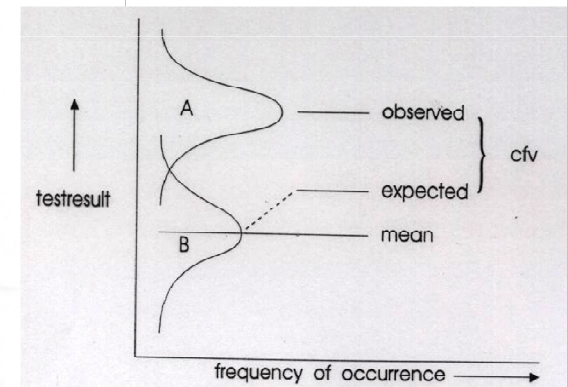
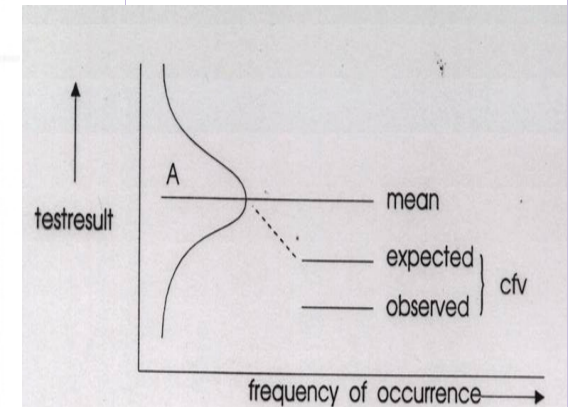
Fermer

Stop.

VALAB - expert -

NTD :128
 NDE :128
 NDV :100

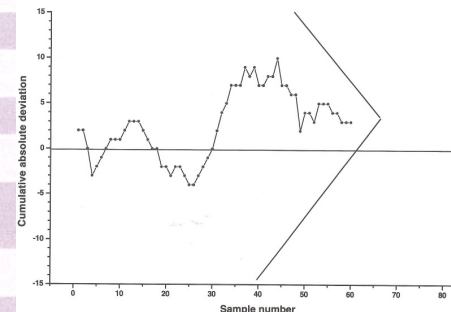
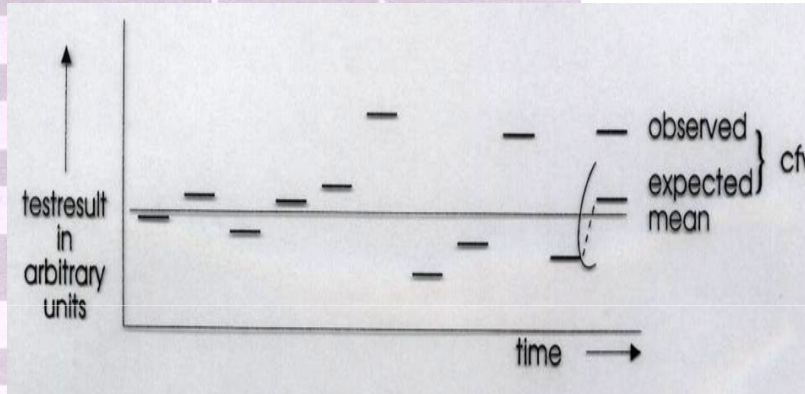
EREMS



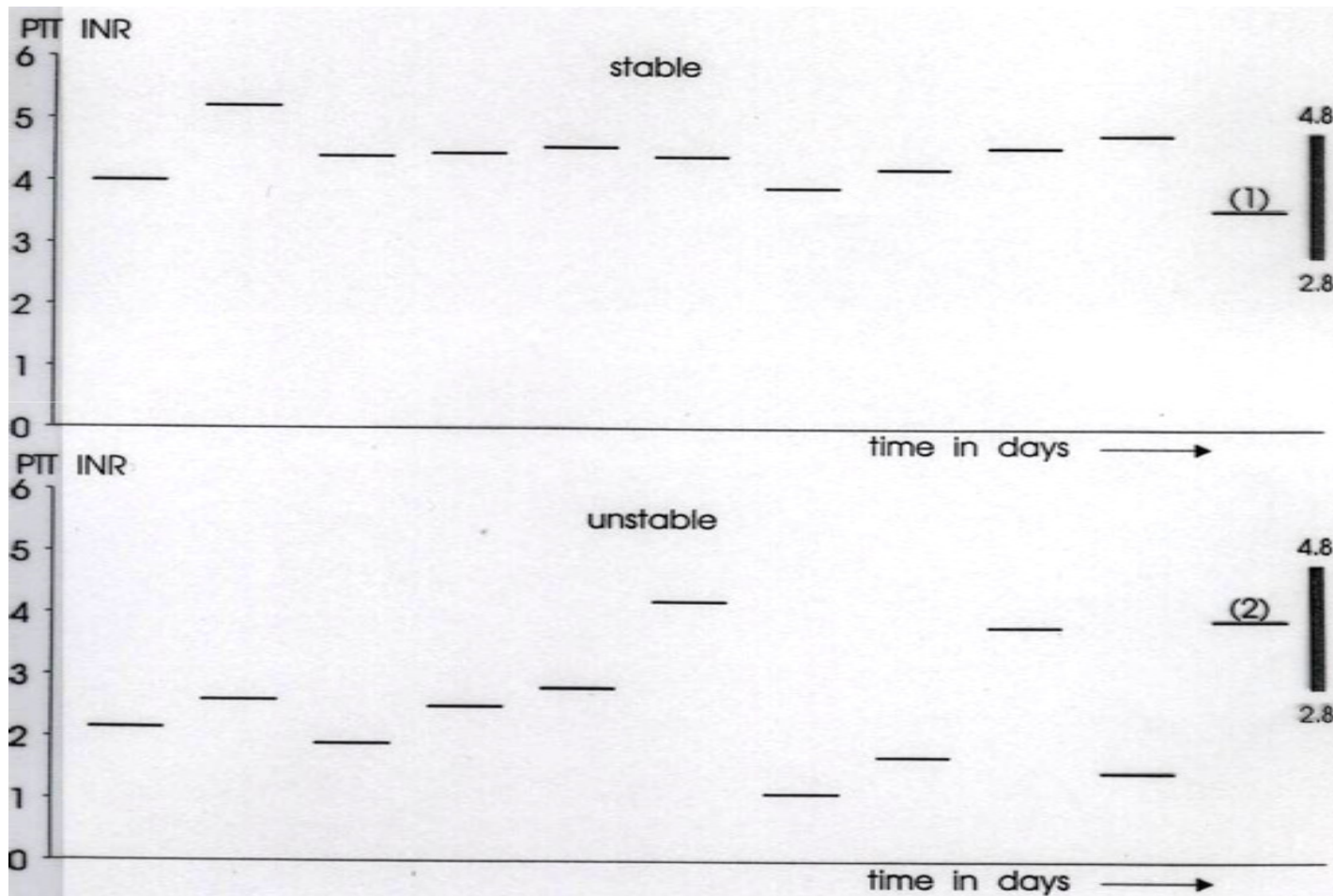
<http://www.ifrance.com/valab/>

Coagulation

Coagulation		Site:	Method:			
Date	Accn#	Analyte/Flag being tested	Results	Problems identified	Changes made	Test performed by
		Normal patient should autoverify				
		PT < 9.2				
		PT > 43.1				
		INR < 0.9				
		INR > 4.4				
		# Delta check PT				
		> 24 hours from collection				
		PTT < 22.3				
		PTT > 37.0				
		# Delta check PTT				
		> 4 hours from collection				
		HPTT < 22.3				
		HPTT > 100.0				
		> 4 hours from collection				
		# Delta check HPPT				
		FGN < 100				
		FGN > 500				
		# Delta check FGN				
		> 8 hours from collection				
		NCD				
		LNCD				
		Difference check				



Context geared



Goldschmidt, H.M.J. and Lent R.W.,

Chemometrics and Intelligent Laboratory Systems 28 (1995) 181 - 192

Define *personalized* analytical specifications

- It's time to recognize the physician as well as the patient
- Use comprehensive models
- Use time dependencies
- Use autovalidation and autoverification
- Bring the quality upto the new level:
 - systematic errors: zero
 - random errors: $\frac{1}{4} BV_{ii}$

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→ Summary



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