

EXTRA-ANALYTICAL PHASES

Specific trials by the use of:

→ questionnaire

→ samples

→ medical reports

AND

→ Working groups dedicated

Are they effective ?

EXTRA-ANALYTICAL PHASES

- ➔ The trials are sporadic exercises and they do not monitor the laboratories performances systematically
- ➔ It is difficult to compare and evaluate the laboratories answers because the methods used are different and not standardized
- ➔ The effectiveness of corrective actions implemented to solve unsatisfactory performance are not evaluated because the trials are occasional

EXTRA-ANALYTICAL PHASES

Can Quality Indicators monitor and assess the quality of the activities of the extra-analytical phases?

Can they be managed by the EQA Organizers?

TODAY

Laboratory Medicine Quality Indicators

A Review of the Literature

Shahram Shahangian, PhD, MS, and Susan R. Snyder, PhD, MBA

Clin Chem Lab Med 2006;44(8):750-759 © 2006 by Walter de Gruyter • Berlin • New York, DOI 10.1515/CCLM.2006.123

Review

Errors in clinical laboratories or errors in laboratory medicine?

Mario Plebani*

Department of Laboratory Medicine, University Hospital of Padova and Center of Biomedical Research, Castelfranco Veneto, Italy

Keywords: errors; intra-analytical; laboratory medicine; mistakes; post-analytical procedures; pre-analytical; total testing process.

Clin Chem Lab Med 2006;46(8):xxx-xxx © 2006 by Walter de Gruyter • Berlin • New York, DOI 10.1515/CCLM.2006.225

Quality indicators and specifications for strategic and support processes in laboratory medicine

Carmen Ricós^{1,*}, Carme Biosca², Mercè Ibarz³, Joana Minchinela⁴, M^a Antonia Llopis⁴, Carmen Perich⁵, M^a Jesus Alsina⁴, Virtudes Alvarez⁶, M^a Vicenta Doménech⁷, Rosa M^a Pastor⁸, Mireia Sansalvador⁹, Gloria Trujillo Isern⁹ and Conrad Vilanova Navarro¹⁰

¹ Laboratoris Clinics Hospital Vall d'Hebron,

prehensive vision of a subject that could motivate further research and advances in the quality of laboratory services.
Clin Chem Lab Med 2006;46

Keywords: laboratory processes; quality indicators; quality management; quality specification.

Clin Chem Lab Med 2007;45(5):672-677 © 2007 by Walter de Gruyter • Berlin • New York, DOI 10.1515/CCLM.2007.122

Quality indicators and specifications for key processes in clinical laboratories: a preliminary experience

M^a Jesus Alsina Kirchner¹, Virtudes Alvarez Funes², Carme Biosca Adzet³, M^a Vicenta Doménech Clar⁴, Mercè Ibarz Escuer⁵, Joana Minchinela Girona⁶, Rosa M^a Pastor Barellas⁶, Carmen Perich Alsina⁷, Carmen Ricós Aguilà^{8,*}, Gloria Trujillo Isern⁹ and Conrad Vilanova Navarro¹⁰

exceeding the specification (0.8%); specifications for the other three well-recognized indicators (imprecision, bias and total error) are not the subject of this study. For the postanalytical phase, the indicators (and specifications) include duplicate hard copies of reports sent to centers or clinical units (1.6%), failure in critical value reporting (0.5%), reports exceeding

Clin Chem Lab Med 2006;44(4):358-365 © 2006 by Walter de Gruyter • Berlin • New York, DOI 10.1515/CCLM.2006.073

Review

Preanalytical variability: the dark side of the moon in laboratory testing

Giuseppe Lippi^{1,*}, Gian Cesare Guidi¹, Camilla Mattiuzzi² and Mario Plebani³

The medical error

Clin Chem Lab Med 2006;44(2):150-160 © 2006 by Walter de Gruyter • Berlin • New York, DOI 10.1515/CCLM.2006.026

Opinion Paper

Laboratory network of excellence: enhancing patient safety and service effectiveness

Mario Plebani^{1,*}, Ferruccio Ceriotti², Gianni Messeri³, Cosimo Ottomano⁴, Nicola Pansini⁵ and Pierangelo Bonini⁶

Introduction

Laboratory medicine can be considered a pioneer medical discipline. To promote quality, it has intro-



Pre-analytical errors in three Italian Laboratories

	Laboratory 1, ppm		Laboratory 2, ppm		Laboratory 3, ppm	
	Inpatients	Outpatients	Inpatients	Outpatients	Inpatients	Outpatients
Hemolyzed sample	3286	100	4300	120	1105.5	621
Insufficient sample	1200	50.1	1250	34.5	995.3	149.6
Incorrect sample	705.9	142.2	823.5	80.7	490.2	235.9
Clotted sample	306.5	39.3	380.7	40.5	928.9	414.3
Incorrect identification	111	0.4	31.3	0.65	NA	NA
Empty tube	92	3.9	80.7	–	4488	759.6
Lack of signature (blood group)	103.0	0	NA	85.0	NA	NA
Lack of or wrong compilation accompany- ing module	46.0	0	127.5	0	NA	NA
Sample not in ice	29.0	2.9	148.9	3.8	250.3	126.6
Tube broken in the centrifuge	22.0	17.7	25.8	27.7	NA	NA
Urine not acidified	9.2	0	155.3	2.9	NA	NA
Urine volume not indicated	1.9	0	187	3.8	118	28.0

Tests registered during a 1-year period: laboratory 1, 258,3850 for inpatients and 2,032,133 for outpatients; laboratory 2, 3,560,135 for inpatients and 2,870,253 for outpatients; laboratory 3, 2,876,524 for inpatients and 173,764 tests for outpatients. NA, not applicable; ppm, parts per million.

The College of American Pathologists Q-TRACKS



Q-TRACK

Performance indicators

Patient identification
accuracy

- Wristband
- Breakdown of Wristband error types (%)

● Blood culture
Contamination

- Total contamination rate (%)
- Neonatal contamination rate (%)
- Other contamination rate (%)

● Laboratory specimen
acceptability

- Specimen rejection rate (%)
- Breakdown of rejection reason (%)

● In-date blood
product wastage

- Overall wastage rate (%)
- Other blood components wastage rates (%)
- Breakdown of wastage reason (%)

The College of American Pathologists Q-TRACKS



Q-TRACK

Performance indicators

- Gynecology
cytology outcomes:
biopsy correlation
performance

- Predictive value of a positive cytology (%)
- Sensitivity (%)
- Screening/interpretation sensitivity (%)
- Sampling sensitivity (%)
- Percent positive for ASC-US interpretations
- Percent positive for ASC-H interpretations
- Percent positive for AGC interpretations

- Satisfaction with
outpatient specimen
collection

- Patient satisfaction score
- Percentage of patients "more than satisfied"

- Stat test turnaround
time outliers

- Stat TAT outlier rate (%)
- Breakdown of outliers by shift (%)
- Breakdown of outliers by day of week (%)

The College of American Pathologists Q-TRACKS



Q-TRACK

Performance indicators

Morning rounds inpatient test availability	- Morning rounds reporting compliance rate (%)
Critical values reporting	- Inpatient critical value reporting rate (%) - Outpatient critical values reporting rate (%)
Turnaround time (TAT) of troponin	- Median TAT of troponin measured from the time - time troponin is ordered to the time the result is - made available to ED personnel - Percentage of troponin results reported by each - institution's established reporting deadline
Corrected results	- Test result correction rate (%)
Outpatient order	- Outpatient order entry error rate (%)
Entry error rate	- Order entry error rates by category (%)

EXTRA-ANALYTICAL PHASES

How laboratories to collect, treat, and evaluate their data of Quality Indicators ?

TODAY ?

Today

Pre-Analytical phase:

Internal Quality Control

Implementation of a **dedicated software** to collect Quality Indicators data

Azienda Ospedaliera Università di Padova

Dipartimento Medicina di Laboratorio

Direttore: Prof. Mario Plebani

Benvenuto
Laura Sciacovelli

Qualità

► Indicatori

Libro di bordo

Segreteria

Progetti

Traceability of user with
username and password

I. T. del Dipartimento Medicina di Laboratorio 2009 - 2011

Dipartimento Medicina di Laboratorio

Laboratory area

Period of time

Sezioni abilitate

Allergologia in Vitro
Ambulatori
Autoimmunità
Biologia Molecolare
Chimica Automatizzata
Chimica Clinica Speciale
Citofluorimetria
Coagulazione
EIA
Ematologia
Formazione
Gestione Qualità

Mesi di riferimento

LUGLIO 2011
GIUGNO 2011
MAGGIO 2011
APRILE 2011
MARZO 2011
FEBBRAIO 2011
GENNAIO 2011
DICEMBRE 2010
NOVEMBRE 2010
OTTOBRE 2010
SETTEMBRE 2010
AGOSTO 2010

Sommario

Grafici

Inserisci

Button to open the page for the data input

Sezione: **Ambulatori**

Inserimento dell'Indicatore di Qualità **IND-20** per il mese di **AGOSTO 2011**

IND-10	<div>Number of requests with errors concerning input tests (missing)</div> <div><input type="text"/> <input type="checkbox"/> Ind. NON valorizzabile</div> <div>Total number of outpatients requests</div> <div><input type="text"/> <input type="checkbox"/> Ind. NON valorizzabile</div> <div>Percentage</div> <div><input type="text"/> <input type="button" value="Calc. %"/></div> <div>Note</div> <div><div>Nessuna nota</div></div> <div><input type="button" value="Ritorna a Sezione e Mese"/> <input type="button" value="Invia IND-20"/></div>
IND-13	
IND-16	
IND-20	
IND-21	
IND-26	
IND-27	
IND-32	
IND-33	
IND-37	
IND-63	
IND-68	

Dipartimento Medicina di Laboratorio

Sezioni abilitate

Allergologia in Vitro
Ambulatori
Autoimmunità
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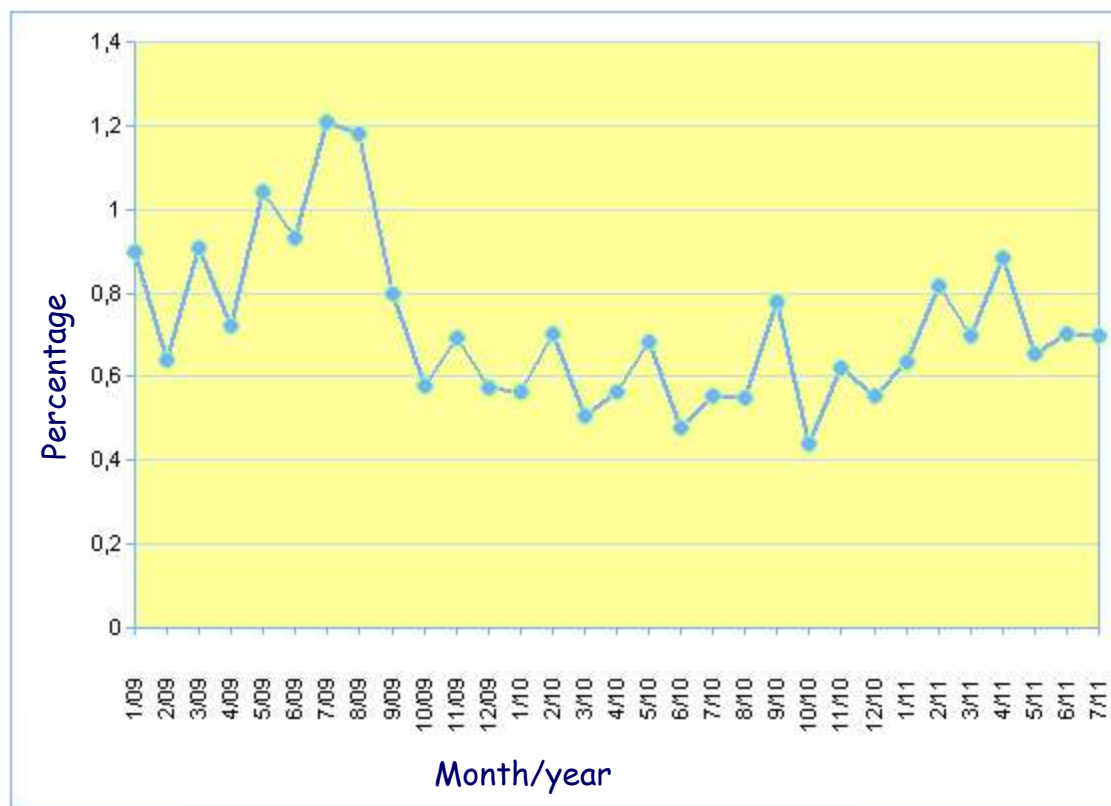
Inserisci

Button to open the page for the inserted data showing (graphic)

Sezione: Ambulatori

Quality Indicator 20: Percentage of "Number of requests with errors concerning input tests (missing)/Total number of requests"

IND-10
IND-13
IND-16
IND-20
IND-21
IND-26
IND-27
IND-32
IND-33
IND-37
IND-39
IND-63



Results

Quality Indicators data collected in the last years

<i>a) Formulation and input of request</i>											
QI		2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
	OUTPATIENTS REQUESTS CHECKED	4029	2099	4734	2248	6060	13467	11357	41764	88357	94121
10	Percentage of "Number of requests with errors concerning patient identification/Total number of requests"	0.29	0.14	0	0	0	0.01	0	0	0	0
13	Percentage of "Number of requests with errors concerning physician identification/Total number of requests"									0.004	0
20-26-32	Percentage of "Number of requests with errors concerning input of tests/Total number of requests"	0.78	0.61	0.87	1.3	2.19	1.08	0.573	1.33	2.03	0.89
20	Percentage of "Number of requests with errors concerning input of tests (missing)/Total number of requests"									0.88	0.58
26	Percentage of "Number of requests with errors concerning input of tests (added)/Total number of requests"									0.79	0.09
32	Percentage of "Number of requests with errors concerning input of tests (misinterpreted)/Total number of requests"									0.36	0.27
	Other errors	0.04	0.19	0.46	0	0.26	0.1	0	0.02		
	TOTAL ERRORS	1.14	0.95	1.18	1.3	2.45	1.2	0.573	1.35	2.1	0.89

Results

QI	OUTPATIENTS REQUESTS	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
10 - 13 - 20 - 26 - 32	Percentage of "Number of requests with errors concerning patient identification, physician identification, input of tests /Total number of requests"	1.14	0.95	1.18	1.3	2.45	1.2	0.573	1.35	2.1	0.89



State-of-the-art

Limits to evaluate the performance

Performance			
Optimum	Desirable	Minimum	Unacceptable
<0.5	0.6 – 1.0	1.1 – 1.5	>1.5

EXTRA-ANALYTICAL PHASES

How EQA Organizers can provide an
evaluation of laboratories Quality
Indicators data?

TODAY



Today

Pre-Analytical phase:

External Quality Assessment

MODEL OF QUALITY INDICATORS

Aim

to define a model of quality indicators to apply in different laboratories in order to decrease the error rates in the Total Testing Process

Key processes

Pre-analytical

16 QI

Intra-analytical

4 QI

Post-analytical

5 QI