



Overview on Laboratory Errors and Potential Implications for Clinical Trials

Giuseppe Lippi, Verona, Italy

Secretary of the European Federation of Laboratory Medicine (EFLM)



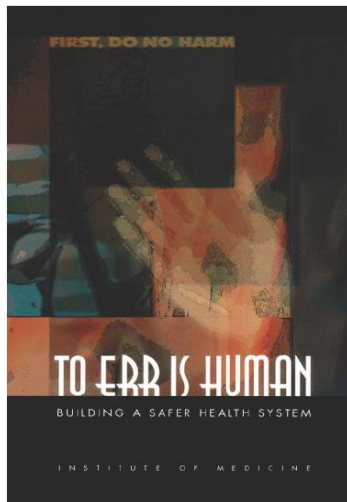
Medical error: definition

Can J Surg, Vol. 48, No. 1, February 2005

Defining medical error

Ethan D. Grober, MD, MEd;* John M.A. Bohnen, MD†

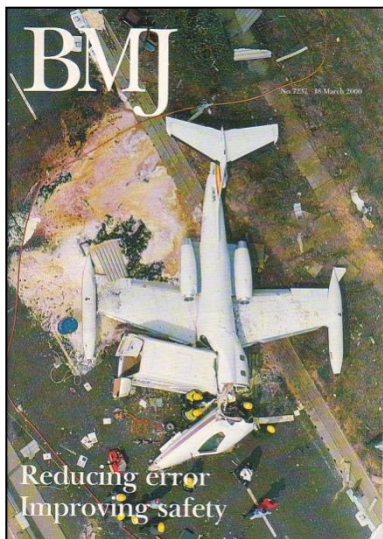
1. Failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an aim (an error of planning).
2. An unintended act (either of omission or commission) or one that does not achieve its intended outcome.
3. Deviations from the process of care, which may or may not cause harm to the patient.



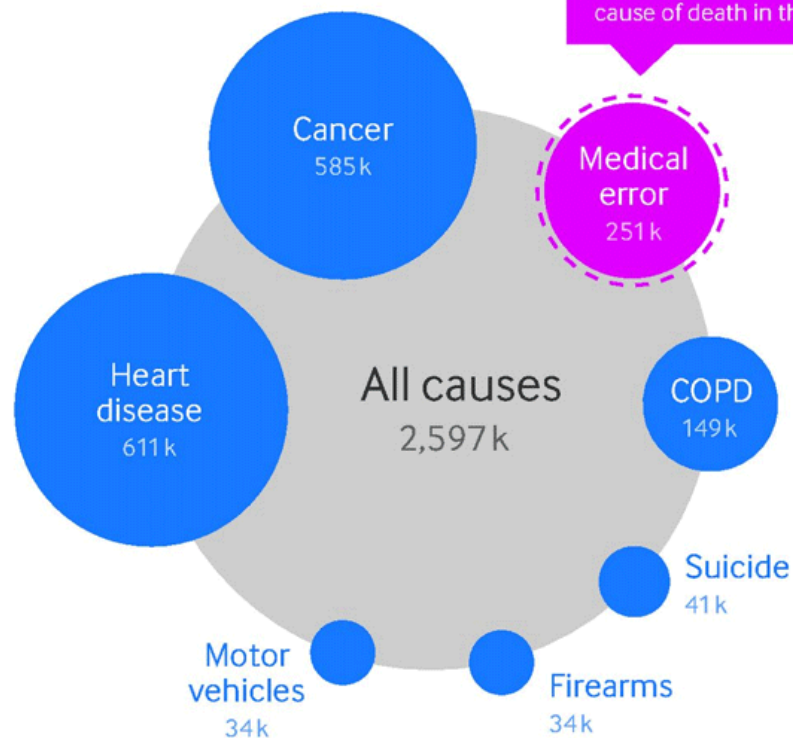
**National Academy of Sciences
INSTITUTE OF MEDICINE - 1999**
**To Err is Human: Building a Safer Health
System**

**From 44.000 to 98.000 US Americans die each
year for errors occurring during hospital stay.**

**Altogether, medical errors account for more
death than road accidents, plane crashes,
suicides and poisonings.**



Causes of death, US, 2013



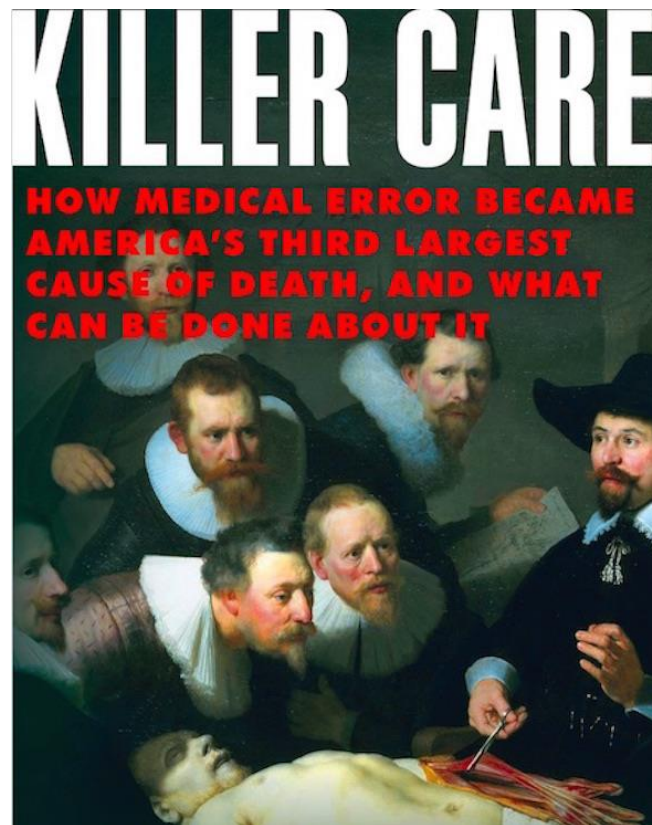
Based on our estimate, medical error is the 3rd most common cause of death in the US

However, we're not even counting this - medical error is not recorded on US death certificates

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Data source:

http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf



Killer Care: How Medical Error Became America's Third Largest Cause of Death, and What Can Be Done About It. Lieber JB, OR Books, 2015.



The irreplaceable value of laboratory diagnostics: four recent tests that have revolutionized clinical practice

Giuseppe Lippi

LABORATORY MEDICINE KEYNOTES

- Laboratory medicine is defined as a science devoted to generate clinically useful information by analyzing the concentration, composition and/or structure of analytes in biological fluids
- Laboratory diagnostics is now providing an almost invaluable contribution to the clinical decision making.
- It is now incontestable that many clinical diagnoses cannot be made without laboratory data.

Do we make errors in clinical laboratories?



*Well, after checking all your test results, I can unquestionably conclude that your problem is that you are **pregnant!***

Laboratory error: definition

A defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting to these

**ISO/TS
22367**

Medical laboratories — Reduction of error through risk management and continual improvement



A Six-Sigma approach for comparing diagnostic errors in healthcare—where does laboratory medicine stand?

Giuseppe Lippi¹, Mario Plebani²

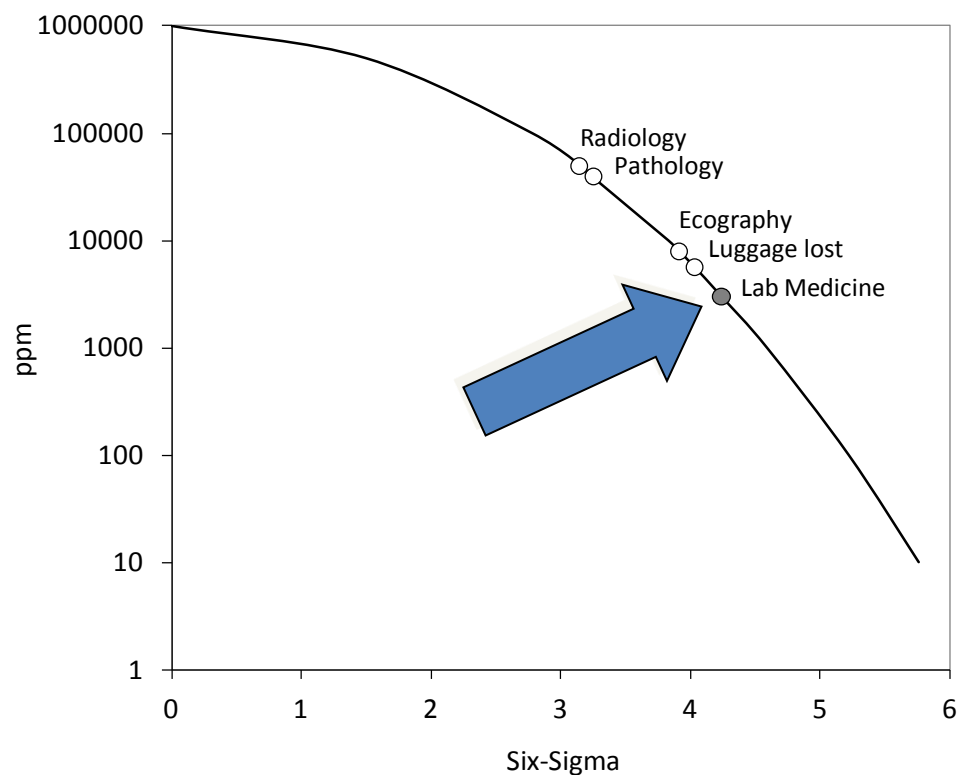
Specialities	Frequency	Six-sigma SD
Radiology	4%	3.25
Pathology	5%	3.14
Ecography	0.8%	3.91
Laboratory	0.3%	4.24
Luggage lost in airport	0.6%	4.03



Ann Transl Med 2018;6(10):180

A Six-Sigma approach for comparing diagnostic errors in healthcare—where does laboratory medicine stand?

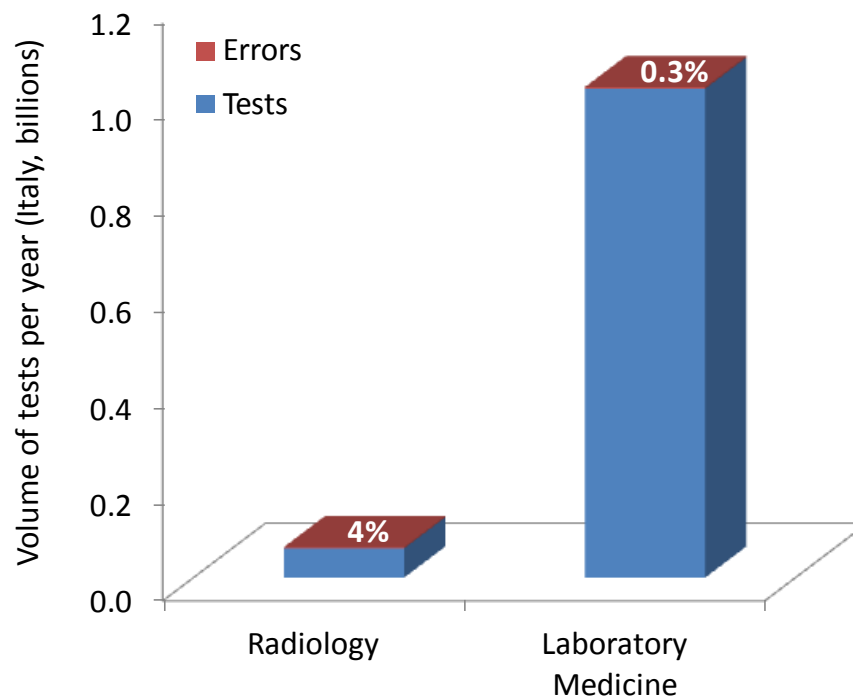
Giuseppe Lippi¹, Mario Plebani²





A Six-Sigma approach for comparing diagnostic errors in healthcare—where does laboratory medicine stand?

Giuseppe Lippi¹, Mario Plebani²



A clinical perspective...

Clinical Chemistry 53:7
1338-1342 (2007)

Errors in a Stat Laboratory: Types and Frequencies 10 Years Later

PAOLO CARRARO AND MARIO PLEBANI*

Table 4. Laboratory errors and patients' outcomes.

	No.	%
Total errors	160	
No effect	121	75.6
Inappropriate intensive care unit admission	1	0.6
Inappropriate transfusion	2	1.3
Further inappropriate investigation	9	5.6
Laboratory tests repetition	27	16.9

An economic perspective...

© 2013 John Wiley & Sons Ltd, *Int. Jnl. Lab. Hem.*

Prevalence and cost of hemolyzed samples in a large urban emergency department

G. Lippi*, P. Bonelli*, G. Cervellin†

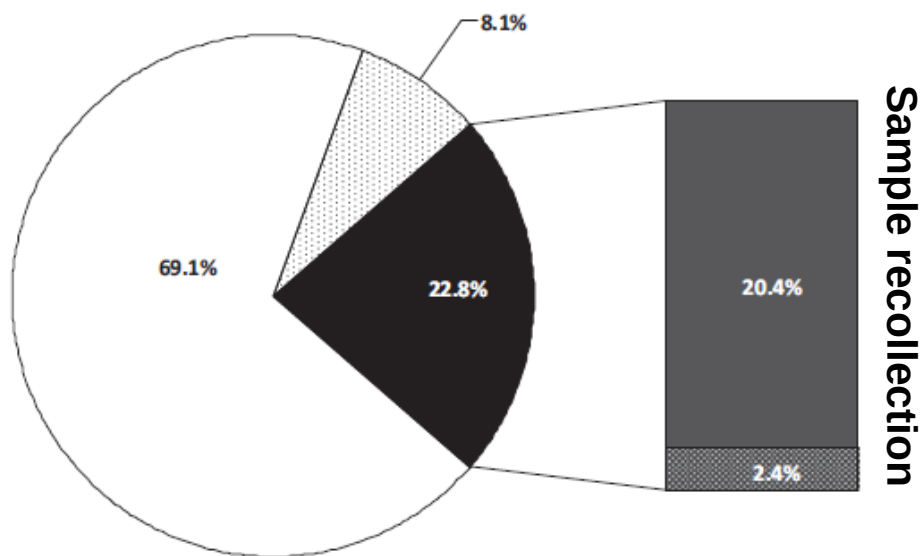


Figure 1. Estimated cost of diagnostic samples collection in a large urban emergency department. □, non hemolyzed samples (material); ▨, non hemolyzed samples (personnel); ■, recollection of hemolyzed samples (material); ▩, recollection of hemolyzed samples (personnel).

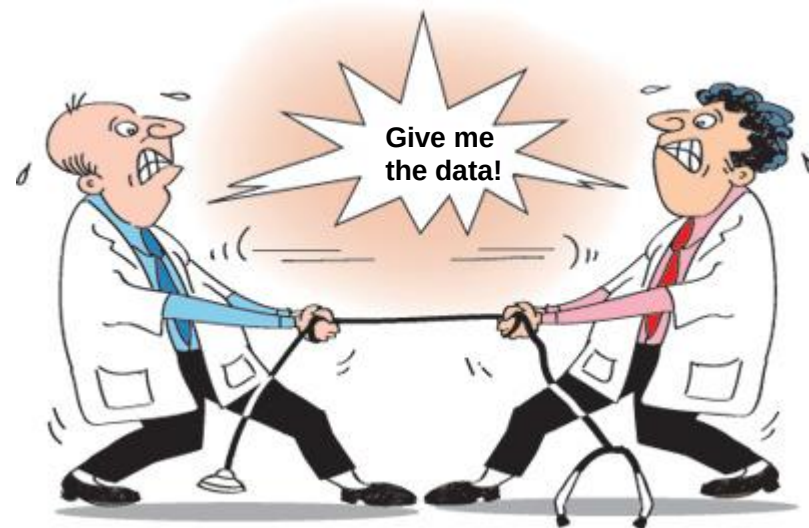
An organizational perspective...

Critical Reviews in Clinical Laboratory Sciences, 2011; 48(3): 143–153

Hemolyzed specimens: a major challenge for emergency departments and clinical laboratories

Giuseppe Lippi¹, Mario Plebani², Salvatore Di Somma³, and Gianfranco Cervellin⁴

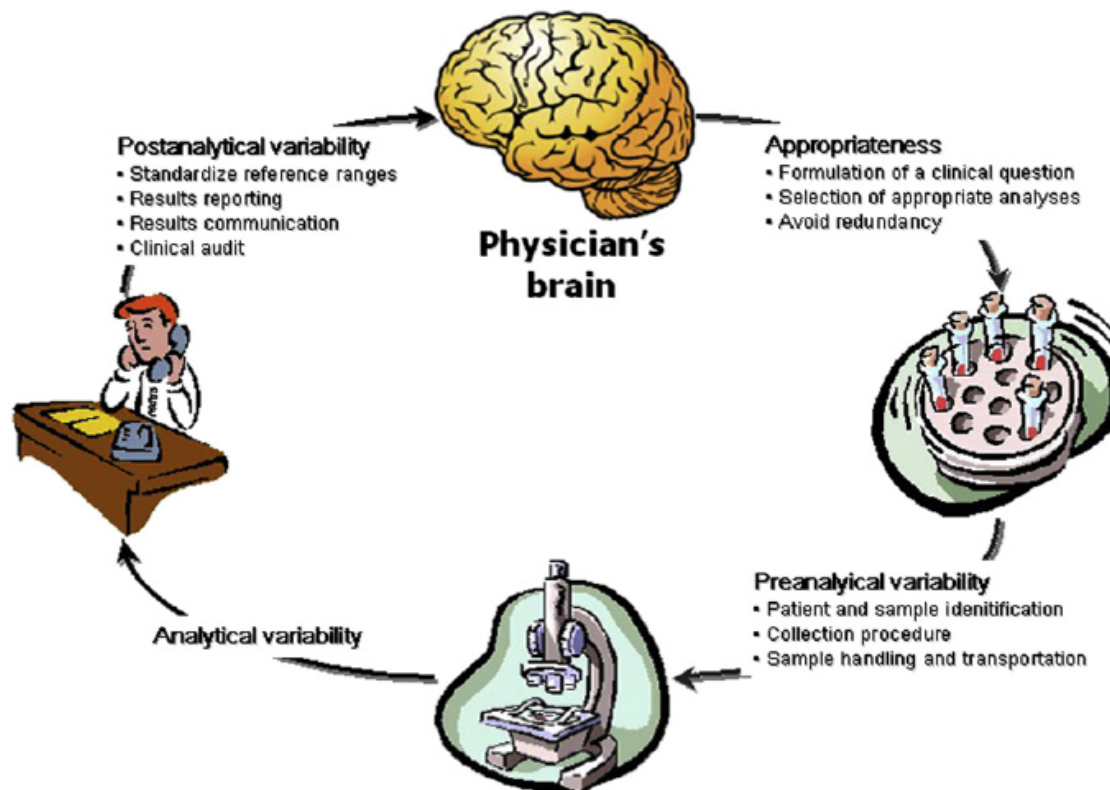
Mildly hemolyzed (≥ 0.3 to 0.6 g/L)	• Potassium • Amino transferases • Lactate dehydrogenase
Moderately hemolyzed (≥ 0.6 to 2.0 g/L)	• Cardiac biomarkers • Beta-human chorionic gonadotropin • Glucose • Creatine kinase • Prothrombin time • Activated partial thromboplastin time • D-dimer
Grossly hemolyzed (≥ 2.0 g/L)	• Virtually all tests



Clin Lab Med 28 (2008) 285–294

Quality Improvement in Laboratory Medicine: Extra-Analytical Issues

Giuseppe Lippi, MD^{a,*}, Roberto Fostini, MD^b,
Gian Cesare Guidi, MD^a



Development of laboratory errors throughout the total testing process.



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Exploring the iceberg of errors in laboratory medicine

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ABSTRACT

The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories, and currently available evidence demonstrates that the pre- and post-analytical steps of the total testing process (TTP) are more error-prone than the analytical phase. In particular, most errors are identified in pre-analytic and post-analytic steps outside the walls of the laboratory and beyond its control. However, in a patient-oriented approach to the delivery of health care services, there is the need to investigate any possible defect in the total testing process that may have a negative impact on the patient. In fact, in the interests of patients, any direct or indirect negative consequence related to a laboratory test must be considered, irrespective of which step is involved, and whether the error is caused by a laboratory personnel (e.g., calibration or testing error) or by a non-laboratory operator (e.g., inappropriate test request, error in patient identification and/or blood collection). Data on diagnostic errors in primary care and in the emergency department setting demonstrate that inappropriate test requesting and incorrect interpretation account for a large percentage of total errors whenever the discipline involved is radiology, pathology or laboratory medicine. Patient misidentification and problems in communicating results, which affect the delivery of all diagnostic services, are widely recognized as the main goals for quality improvement. Therefore, some common problems affect diagnostic errors, although specific factors characterizing errors in laboratory medicine should lead to preventive and corrective actions if evidence-based quality indicators are developed, implemented and monitored. The lesson we have learned is that each practitioner examine its own total testing process to discover its weaknesses and identify appropriate remedies.

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1. Introduction

Quality measurement in healthcare is shifting from a focus on quality assurance to transparency and accountability for patient care outcomes. Every step in the process of patient care carries a risk of harm and while the dictum "first, do no harm" is a cornerstone in medicine, only relatively recently has unsafe patient care been recognized as a worldwide problem and a significant source of morbidity and mortality [1].

The US Institute of Medicine (IOM) report, *To Err is Human: Building a safer health system*, as well as the UK report *An organization with a memory* [2] galvanized a dramatic increase in concern about adverse events and patient safety at an international level [2]. Subsequent IOM reports, *Creating the quality chain* [4] and *Patient safety: achieving a new paradigm for care* [5] stressed the emergence of patient-oriented care and the fact that complex systems (health care) are characterized by a specialization and interdependency.

Most available data on errors in health care focus on medication-related errors (particularly in hospitals) and related adverse events.

However, in recent years large-scale surveys have demonstrated that patients and physicians perceive that diagnostic errors are a common occurrence and a cause of concern [6]. Throughout the last decade, diagnostic errors have led to the most prevalent type of malpractice claim in the US [7,8]. However, on considering the frequency and impact of diagnostic errors, one is struck by the widespread lack of awareness of this type of medical error. The diagnostic process, which consists of numerous clinical steps, involves several multiple problems, and errors that can harm patients are the result of the alignment of multiple breakdowns which, in turn, stem from a confluence of contributory factors [9].

In the past, clinical laboratories may have lacked information about how such system-wide issues were affecting them and the quality of services delivered. Numerous efforts have been made in recent decades to implement quality indicators for laboratory tests, which focus on either analytical performance or the achievement of specific efficiency targets, such as valuable turnaround time and constrained costs [10]. However, a systematic framework for laboratory quality measurement is either unavailable or still in embryo and, therefore, little information is available on how to demonstrate whether services provided by laboratories, and the use of these services, is safe, timely, efficient, effective, equitable, and patient-oriented. As stated by Nancy C. Elder et al., "the testing process begins and ends with the patient" [11]. A multidisciplinary framework which takes into account the total

Frequency of errors (%) in the main phases of the total testing process.

Year	Author(s)	Pre	Intra analytic	Post	Reference
•1991	Ross et al.	45.5	7.3	47.2	17
•1997	Plebani et al.	68.2	13.3	18.5	18
•2003	Astion et al.	71.0	18.0	11.0	26
•2007	Carraro et al.	61.9	15.0	23.1	19



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Recognizing and Reducing Analytical Errors and Sources of Variation in Clinical Pathology Data in Safety Assessment Studies

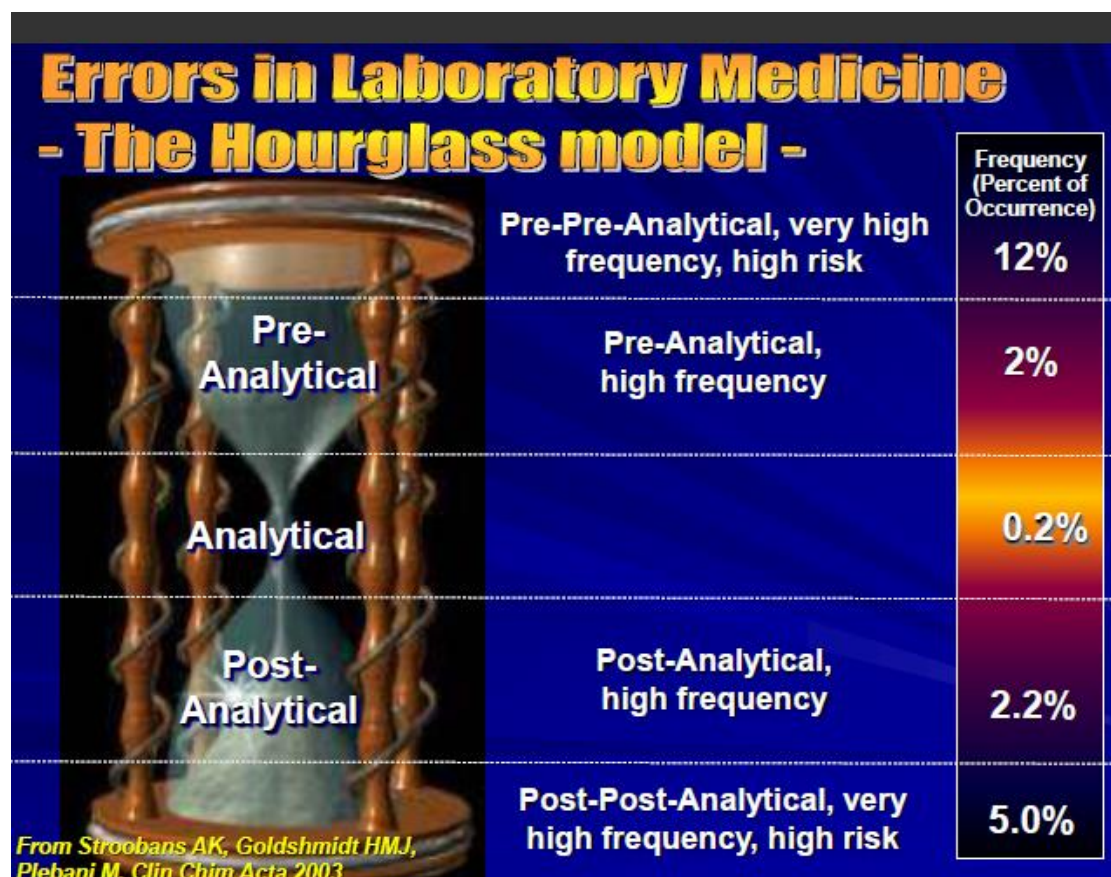
A. E. Schultze¹ and A. R. Irizarry¹

Table 1. Frequency of Diagnostic Testing Errors.

Preanalytical phase (%)	Analytical phase (%)	Postanalytical phase (%)	Reference
32	32	31	Lapworth and Teal (1994)
53	23	24	Goldschmidt and Lent (1995)
56	13	30	Nutting et al. (1996)
75	16	9	Stahl et al. (1998)
44	31	13	Hofgärtner and Tait (1999)
62	15	23	Carraro and Plebani (2007)
65	8	49	Plebani. (2009)
46–68	7–13	19–47	Hammerling (2012)

LABORATORY ERRORS

The “hourglass” model



Extra-Laboratory ~90%

Within-Laboratory ~10%



Phase of the TTP	Type of error	Relative frequency (%)
Pre-pre-analytical	Inappropriate test request Order entry Patient/specimen misidentification Sample collected from infusion route Sample collection (hemolysis, clotting insuff. volume, etc) Inappropriate container Handling, storage and transportation	46-68.2%
Pre-analytical	Sorting and routing Pour-off Aliquoting, pipetting and labelling Centrifugation (time and/or speed)	3.0-5.3%
Analytical	Equipment malfunction Sample mix-ups Interference (endogenous or exogenous) Undetected failure in quality control	7.0-13%
Post-analytical	Erroneous validation of analytical data Failure in reporting/addressing the report Excessive turn-around-time Improper data entry and manual transcription error Failure/delay in reporting critical values	12.5-20%
Post-post-analytical	Delayed/missed reaction to laboratory reporting Incorrect interpretation Inappropriate/inadequate follow-up plan Failure to order appropriate consultation	25-45.5%



Standardizing *in vitro* diagnostics tasks in clinical trials: a call for action

Giuseppe Lippi^{1,2}, Ana-Maria Simundic^{1,3}, Leocadio Rodriguez-Manas⁴, Patrick Bossuyt⁵,
Giuseppe Banfi⁶

Clinical trials are

conventionally defined as studies:

- carried out in clinical research
- involving human participants
- designed to answer specific questions about biomedical or behavioral interventions
- focused on new treatments such as drugs, vaccines, dietary choices and supplements, changes in life styles, medical devices and biomarkers.

Table 1 Classification of clinical trials

Stage	Primary goal	No. of subjects
Preclinical	Analysis in non-human subjects, to preliminary evaluate efficacy, toxicity and pharmacokinetics	–
Phase 0	Preliminary evaluation of efficacy, effectiveness and safety in healthy volunteers	10–20
Phase I	Preliminary evaluation of efficacy, effectiveness and safety in healthy volunteers	20–100
Phase II	Evaluation of efficacy, effectiveness and safety in patients	100–300
Phase III	Evaluation of efficacy, effectiveness and safety in patients	>300
Phase IV	Postmarketing surveillance	All subjects



Estimation of clinical trial success rates and related parameters

CHI HEEM WONG, KIEN WEI SIAH ANDREW W. LO*

Therapeutic group	All indications (industry)						Probability of success	
	Phase 1 to Phase 2		Phase 2 to Phase 3			Phase 3 to Approval		Overall
	Total paths	POS _{1,2} , % (SE, %)	Total paths	POS _{2,3} , % (SE, %)	POS _{2,APP} , % (SE, %)	Total paths	POS _{3,APP} , % (SE, %)	POS, % (SE, %)
Oncology	17 368	57.6 (0.4)	6533	32.7 (0.6)	6.7 (0.3)	1236	35.5 (1.4)	3.4 (0.2)
Metabolic/ Endocrinology	3589	76.2 (0.7)	2357	59.7 (1.0)	24.1 (0.9)	1101	51.6 (1.5)	19.6 (0.7)
Cardiovascular	2810	73.3 (0.8)	1858	65.7 (1.1)	32.3 (1.1)	964	62.2 (1.6)	25.5 (0.9)
CNS	4924	73.2 (0.6)	3037	51.9 (0.9)	19.5 (0.7)	1156	51.1 (1.5)	15.0 (0.6)
Autoimmune/ Inflammation	5086	69.8 (0.6)	2910	45.7 (0.9)	21.2 (0.8)	969	63.7 (1.5)	15.1 (0.6)
Genitourinary	757	68.7 (1.7)	475	57.1 (2.3)	29.7 (2.1)	212	66.5 (3.2)	21.6 (1.6)
Infectious disease	3963	70.1 (0.7)	2314	58.3 (1.0)	35.1 (1.0)	1078	75.3 (1.3)	25.2 (0.8)
Ophthalmology	674	87.1 (1.3)	461	60.7 (2.3)	33.6 (2.2)	207	74.9 (3.0)	32.6 (2.2)
Vaccines (Infectious Disease)	1869	76.8 (1.0)	1235	58.2 (1.4)	42.1 (1.4)	609	85.4 (1.4)	33.4 (1.2)
Overall	41 040	66.4 (0.2)	21 180	48.6 (0.3)	21.0 (0.3)	7532	59.0 (0.6)	13.8 (0.2)
All without oncology	23 672	73.0 (0.3)	14 647	55.7 (0.4)	27.3 (0.4)	6296	63.6 (0.6)	20.9 (0.3)

Overall success is always **<1/3** of all clinical trials





Alzheimer's Research & Therapy 2014, 6:37

Alzheimer's disease drug-development pipeline: few candidates, frequent failures

Jeffrey L Cummings^{1*}, Travis Morstorf² and Kate Zhong¹

The attrition rate for AD treatment is high, with 72% of agents failing in Phase 1, 92% failing in Phase 2, and 98% failing in Phase 3 in the period observed, leading to an **overall 99.6% failure**.



Standardizing *in vitro* diagnostics tasks in clinical trials: a call for action

Giuseppe Lippi^{1,2}, Ana-Maria Simundic^{1,3}, Leocadio Rodriguez-Manas⁴, Patrick Bossuyt⁵,
Giuseppe Banfi⁶

Laboratory medicine in clinical trials

Laboratory diagnostics plays a foremost role in clinical studies, since it is basically used for:

- Establishing inclusion and exclusion criteria
- Determining baseline parameters
- Monitoring the safety of the participants
- Demonstrating efficacy of investigational product(s)



Standardizing *in vitro* diagnostics tasks in clinical trials: a call for action

Giuseppe Lippi^{1,2}, Ana-Maria Simundic^{1,3}, Leocadio Rodriguez-Manas⁴, Patrick Bossuyt⁵,
Giuseppe Banfi⁶

Laboratory medicine in clinical trials

There is now widespread recognition of the fact that many promising treatments or biomarkers are “***lost in translation***” on their route from basic research to routine practice due to unwarranted bias emerging from analytical and especially extra-analytical activities.

Biostatistics (2019) **20**, 2, pp. 273–286

Estimation of clinical trial success rates and related parameters

CHI HEEM WONG, KIEN WEI SIAH ANDREW W. LO*

A simple question emerges looking at this data....

How much of this failure rate is attributable to laboratory errors?





Obtaining Valid Laboratory Data in Clinical Trials Conducted in Resource Diverse Settings: Lessons Learned from a Microbicide Phase III Clinical Trial

Tania Crucitti^{1*}, Katrien Fransen¹, Rashika Maharaj², Tom Tenywa³, Marguerite Massinga Loembé^{4,5,6}, Kailapuri Gangatharan Murugavel⁷, Kevin Mendonca⁸, Said Abdellati¹, Greet Beelaert¹, Lut Van Damme^{9,10}

RESULTS: Overall, good results were observed. However, **discordances between the reference and site laboratories were identified for HIV and CT/NG results**. One particular site experienced difficulties with HIV rapid testing shortly after study initiation. At all sites, **DNA contamination was identified as a cause of invalid CT/NG results**.



Recognizing and Reducing Analytical Errors and Sources of Variation in Clinical Pathology Data in Safety Assessment Studies

A. E. Schultze¹ and A. R. Irizarry¹

Table 2. Serum Glucose Concentrations (mg/dl).

Time (hr)	Dog 1	Dog 2	Dog 3
0.5	103.5	98.3	109.7
1	98.2	93.8	105.8
2	95.4	87.6	100.1
4	83.7	74.3	79.1
8	61.6	43.8	41.5
16	38.8	6.9	4.4
24	17.3	<2.0	<2.0



Clinical Chemistry 53, No. 8, 2007

The Paradox in Translational Medicine

Giuseppe Lippi

There is a serious concern regarding reliability and reproducibility of results because of sample handling; preanalytical variability may influence profiles of some biomarkers. Therefore, the most feasible and standardized collection procedures should be established.

Ann Transl Med 2016;4(9):181

Standardizing *in vitro* diagnostics tasks in clinical trials: a call for action

Giuseppe Lippi^{1,2}, Ana-Maria Simundic^{1,3}, Leocadio Rodriguez-Manas⁴, Patrick Bossuyt⁵,
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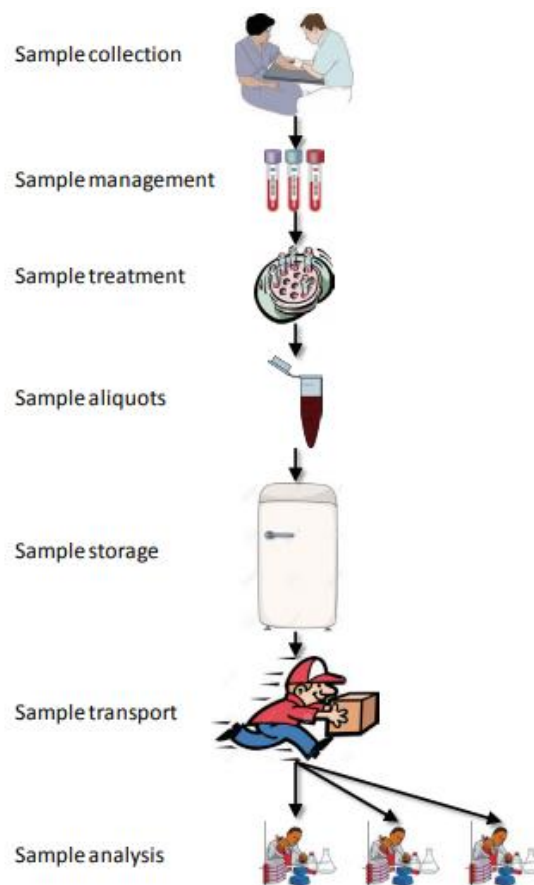
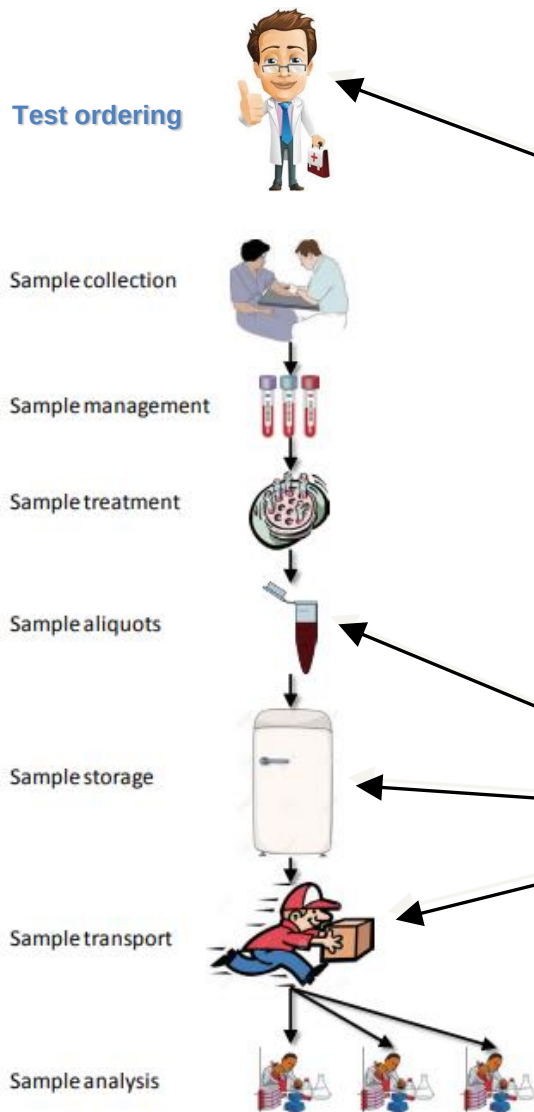


Figure 1 The total testing process in clinical studies.



And what about **appropriateness** of test scheduling in clinical trials?

Most (if not all) trials are still based on old and obsolete tests, such as

- **Urinary β -HCG** for suspected pregnancy
- **CK-MB** for ruling out ACS
- Etc...

Some of these steps are **HIGHLY SPECIFIC** in clinical trials

Figure 1 The total testing process in clinical studies.

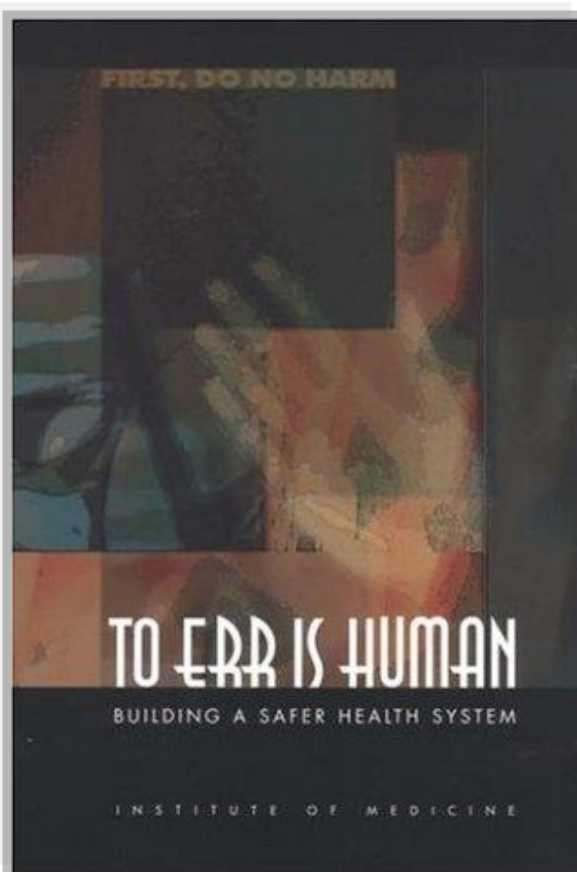


Clin Chem Lab Med 2016; 54(1): 1–3

Editorial

Giuseppe Lippi, Mario Plebani and Mark L. Graber

**Building a bridge to safe diagnosis in health care.
The role of the clinical laboratory**

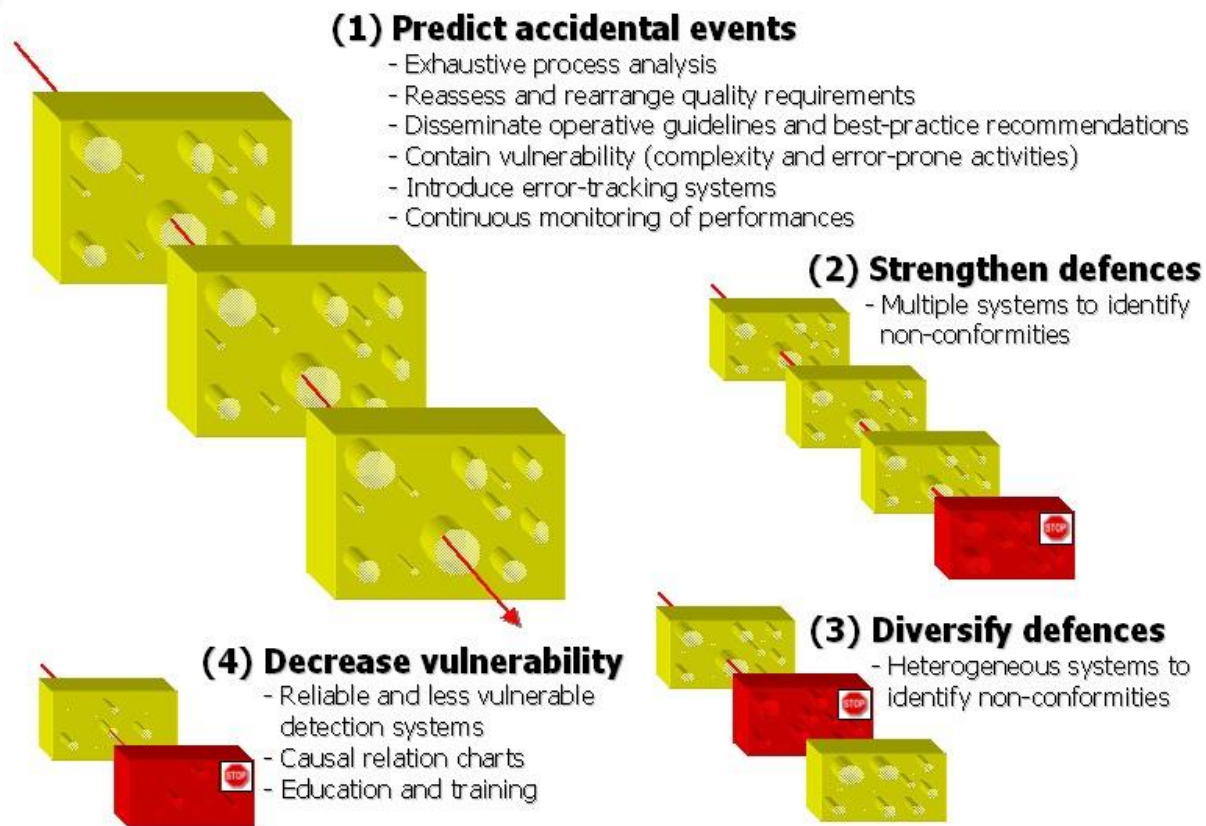


1 **A Comprehensive Approach to Improving Patient Safety**

This report proposes a comprehensive approach for reducing medical errors and improving patient safety. The approach employs market and regulatory strategies, public and private strategies, and strategies that are implemented inside health care organizations as well as in their external environment. To achieve a threshold improvement in patient safety, all of these strategies must be employed in a balanced and complementary fashion.

Risk management in the preanalytical phase of laboratory testing

Giuseppe Lippi* and Gian Cesare Guidi





Clin Lab Med 28 (2008) 285–294

Quality Improvement in Laboratory
Medicine: Extra-Analytical Issues

Giuseppe Lippi, MD^{a,*}, Roberto Fostini, MD^b,
Gian Cesare Guidi, MD^a

Development of a multifaceted risk management strategy to enhance quality in the total testing process

1. Systematic analysis of **workflows and bottlenecks** in the system:
 - Elimination or redesign of **flawed/mishandled** procedures
 - Identification of **solutions** to suit local circumstances.
2. Do **not blame** individuals.
3. Continues **process monitoring** through development and implementation of suitable “**error tracking systems**”.
4. Continuous **education** through *reliable recommendations, improved communication, interpretive rounds* within and outside the laboratory.
5. Definition and implementation of representative **quality indicators** and **outcome measures**.



Leading “preanalytical” issues in clinical trials

- Are there precise procedures for **specimen collection**?
- Is there unique **identification** of the patient/ the specimen?
- Date and time of **collection** are recorded?
- Is the **type** of specimen clearly defined?
- Which are the **investigations** requested?
- Are there procedures for specimen **transport**?
- Have date and time of **receipt** been recorded?
- Has **clinical information** been provided?



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AND LABORATORY MEDICINE



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Working Group: Preanalytical Phase

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Chair



Giuseppe Lippi
first term 2019-2020

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EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
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COLABIOCLI

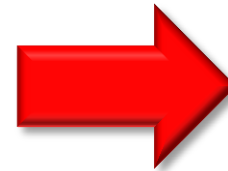
Ana-Maria Simundic*, Karin Bölenius, Janne Cadamuro, Stephen Church, Michael P. Cornes, Edmée C. van Dongen-Lases, Pinar Eker, Tanja Erdeljanovic, Kjell Grankvist, Joao Tiago Guimaraes, Roger Hoke, Mercedes Ibarz, Helene Ivanov, Svetlana Kovalevskaya, Gunn B.B. Kristensen, Gabriel Lima-Oliveira, Giuseppe Lippi, Alexander von Meyer, Mads Nybo, Barbara De la Salle, Christa Seipelt, Zorica Sumarac and Pieter Vermeersch, on behalf of the Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI)

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling



CHECKLIST STRUCTURE

- ✗ BRIEF
- ✗ EASY TO READ
- ✗ PRECISE
- ✗ EFFICIENT
- ✗ TO THE POINT
- ✗ EASY TO USE
- ✗ PROVIDE REMINDERS

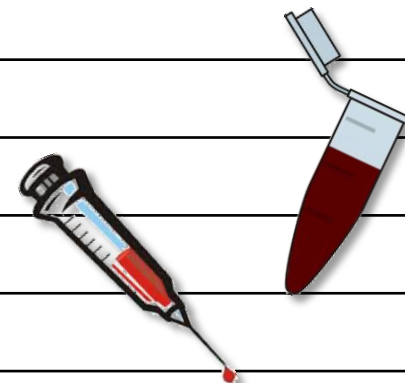


**A GOOD
CHECKLIST MUST
BE PRACTICAL!**



THE PHLEBOTOMY CHECKLIST

N.	ITEM
1)	Are you wearing personal protective equipment (ppe)?
2)	Has the patient remained seated for not less than 5 min?
3)	Did you check the identity of the patient?
4)	Did you check that the identity of the patient matches the blood tubes labels?
5)	Did you label blood tubes before venipuncture?
6)	Did you prepare all the necessary material before blood drawing?
7)	Did you assemble the blood collection device?
8)	Did you apply the tourniquet for less than 2 min?
9)	Did you avoid to insist in case of difficult venipuncture?
10)	Did you fill blood tubes at their nominal volume?
11)	Did you gently mix blood tubes after collection (at least 4-6 times)?
12)	Did you safely discard potentially infectious material?





OBSERVATIONAL STUDY



An observational study was planned to verify whether the implementation of the phlebotomy checklist in different **phlebotomy centers** (i.e., outpatient clinics) and **emergency departments** may be really effective to reduce preanalytical errors during venous blood collection.

CHARACTERISTICS OF THE ITALIAN MULTICENTER OBSERVATIONAL STUDY

7 Phlebotomy Centers	Desenzano del Garda General Hospital, Padova University Hospital, Parma University Hospital, Pordenone General Hospital, Trento General Hospital, Verona University Hospital and Verona General Hospital
4 Emergency Departments	Desenzano del Garda General Hospital, Parma University Hospital, Pordenone General Hospital and Trento General Hospital
2 Observational periods of 3 months each	June-August 2014 without phlebotomy checklist September-November 2014 with phlebotomy checklist
Period of training	Personnel was appropriately trained about the content of the phlebotomy checklist, and asked to follow the items before each venipuncture
Blood collection device	All centers used the same type of blood collection device

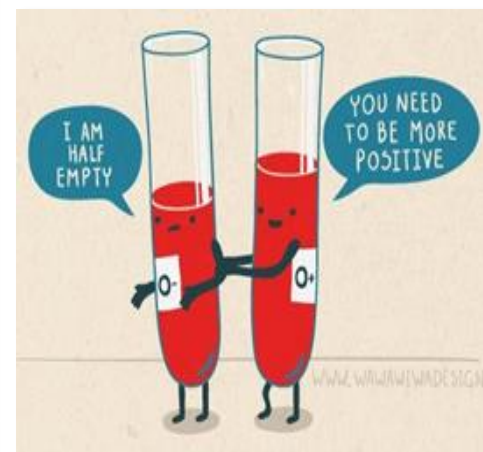


PREANALYTICAL QUALITY INDICATORS

In agreement with recent recommendations, the following preanalytical quality indicators were monitored throughout the two study periods:

PREANALYTICAL QUALITY INDICATORS

- 1) identification errors
- 2) samples received in inappropriate containers (i.e., wrong blood tube)
- 3) blood tubes inappropriately filled (for sodium citrate blood tubes)
- 4) hemolyzed samples (for clinical chemistry testing)
- 5) clotted samples (for EDTA and sodium citrate blood tubes)





RESULTS



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A multicentre observational study evaluating the effectiveness of a phlebotomy check-list in reducing preanalytical errors

Giuseppe Lippi¹, Iole Caola², Gianfranco Cervellin³, Anna Ferrari⁴, Bruno Milanese⁵, Margherita Morandini⁶, Elisa Piva⁷, Claudio Ramponi⁸, Davide Giavarina⁹

After the introduction of the phlebotomy checklist:

- the rate of **preanalytical errors** was found to be **significantly decreased in phlebotomy centers** (0.04% versus 0.05%, $p=0.001$; OR, 0.77 and 95% CI, 0.66-0.90), **but** remained virtually **unchanged in emergency departments** (0.83% versus 0.82%; $p=0.841$; OR, 1.01 and 95% CI, 0.95-1.07);
- a **significant decrease** of errors was achieved **for identification errors and clotted specimens** in both phlebotomy centers and emergency departments; but a **significant reduction of hemolysis** was noticed in **phlebotomy centers** alone;
- overall, the **risk of identification errors** was reduced by approximately **70%** (OR, 0.31 to 0.34), and **clotted specimens** decreased by **more than 30%** (OR, 0.55 to 0.69).

PCs
EDs



CHECK-LIST IN LABORATORY MEDICINE: AN IMPORTANT TOOL TO IMPROVE THE PATIENT SAFETY

A. Aita¹, R. Marin¹, E. Piva², L. Sciacovelli², M. Plebani¹

Methods. Implementation of a Check list (CL) on blood collection procedures in 3 outpatients phlebotomy sites involving 25 physicians and 15 nurses for 1 month.

Results: The percentage of points filled were respectively:

- 100% patient identification
- 100% label-sample-identification matching
- 58-78% vein selection
- 97-98% needle selection
- 83-91% tourniquet application time
- 98-99% tubes filling
- 97-99% tubes mixing
- 1-33% sample transport

Conclusions: The CL is a support tool to prevent and reduce procedural errors, in order to ensure the patient safety.



Standardizing *in vitro* diagnostics tasks in clinical trials: a call for action

Giuseppe Lippi^{1,2}, Ana-Maria Simundic^{1,3}, Leocadio Rodriguez-Manas⁴, Patrick Bossuyt⁵,
Giuseppe Banfi⁶

Table 2 Major hurdles for establishing high quality laboratory testing in clinical trials

Heterogeneity of current guidelines and recommendations for the testing process

Little evidence exists that basic pre-analytical, analytical and post-analytical requirements are defined as mandatory quality prerequisites in clinical trials

Current guidelines and recommendations are specifically designed for routine laboratory testing

Clinicians', patients', nurses' and diagnostic companies' perspectives are not thoughtfully integrated in laboratory best practices



Ann Transl Med 2016;4(3):59

The impact of preanalytical variability in clinical trials: are we underestimating the issue?

Giuseppe Banfi¹, Giuseppe Lippi²

Yes!
WE'RE