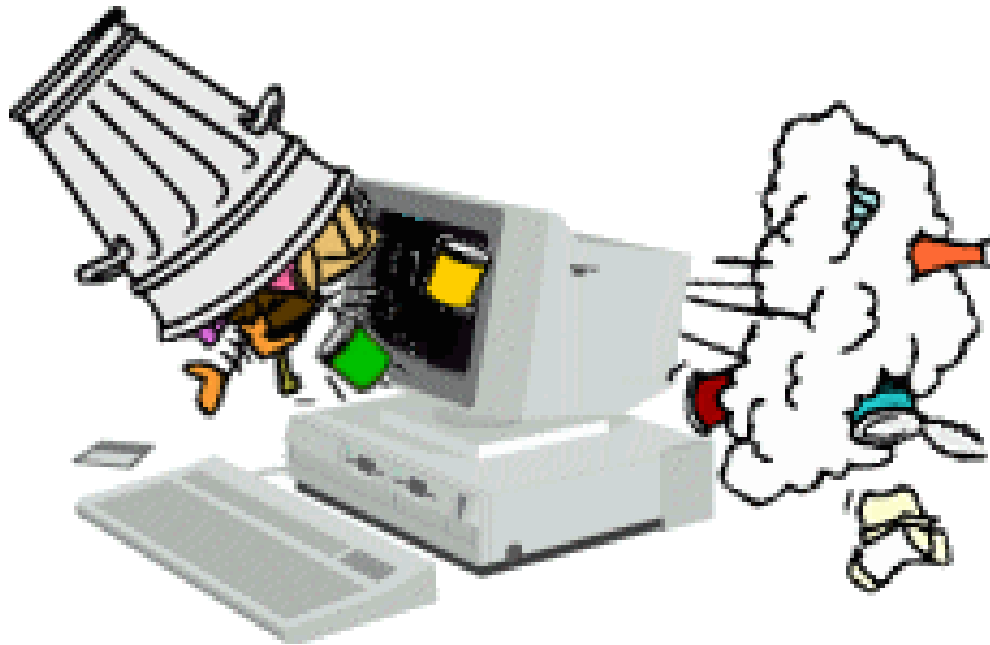


# Garbage in garbage out!

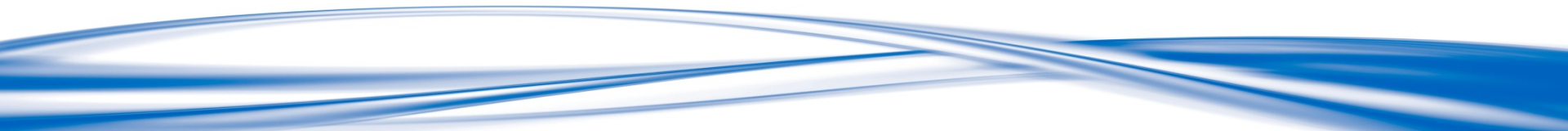


Dr Mike Cornes: Principal Clinical Scientist  
Royal Wolverhampton NHS Trust

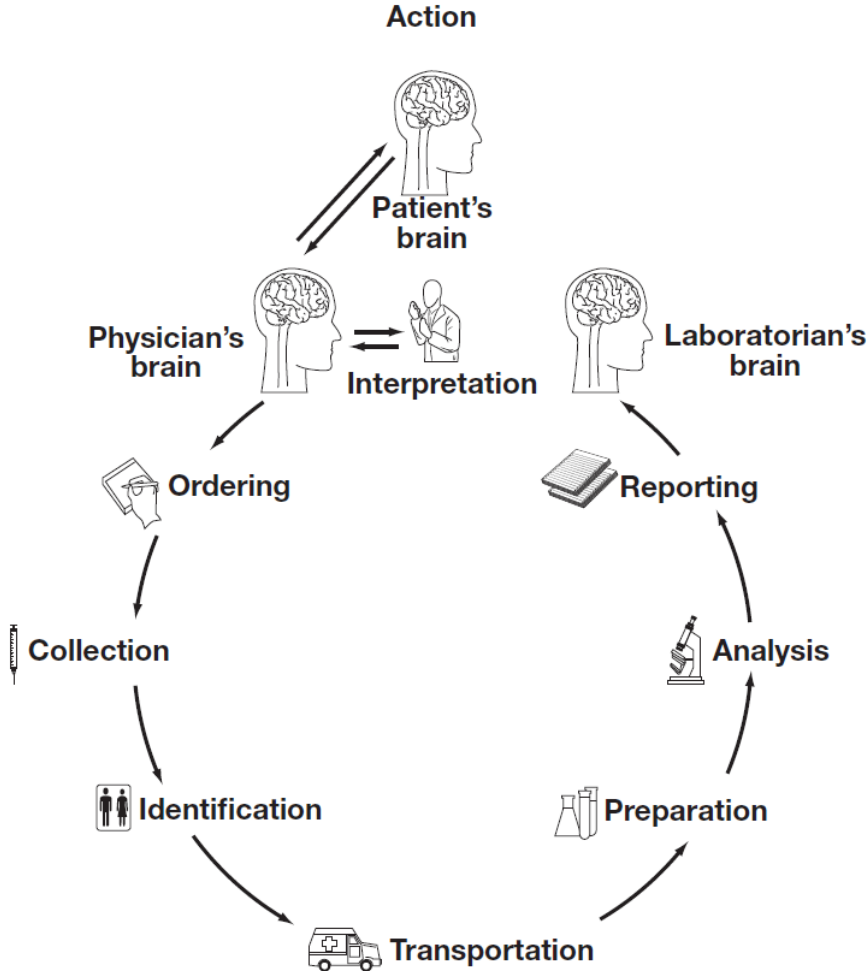




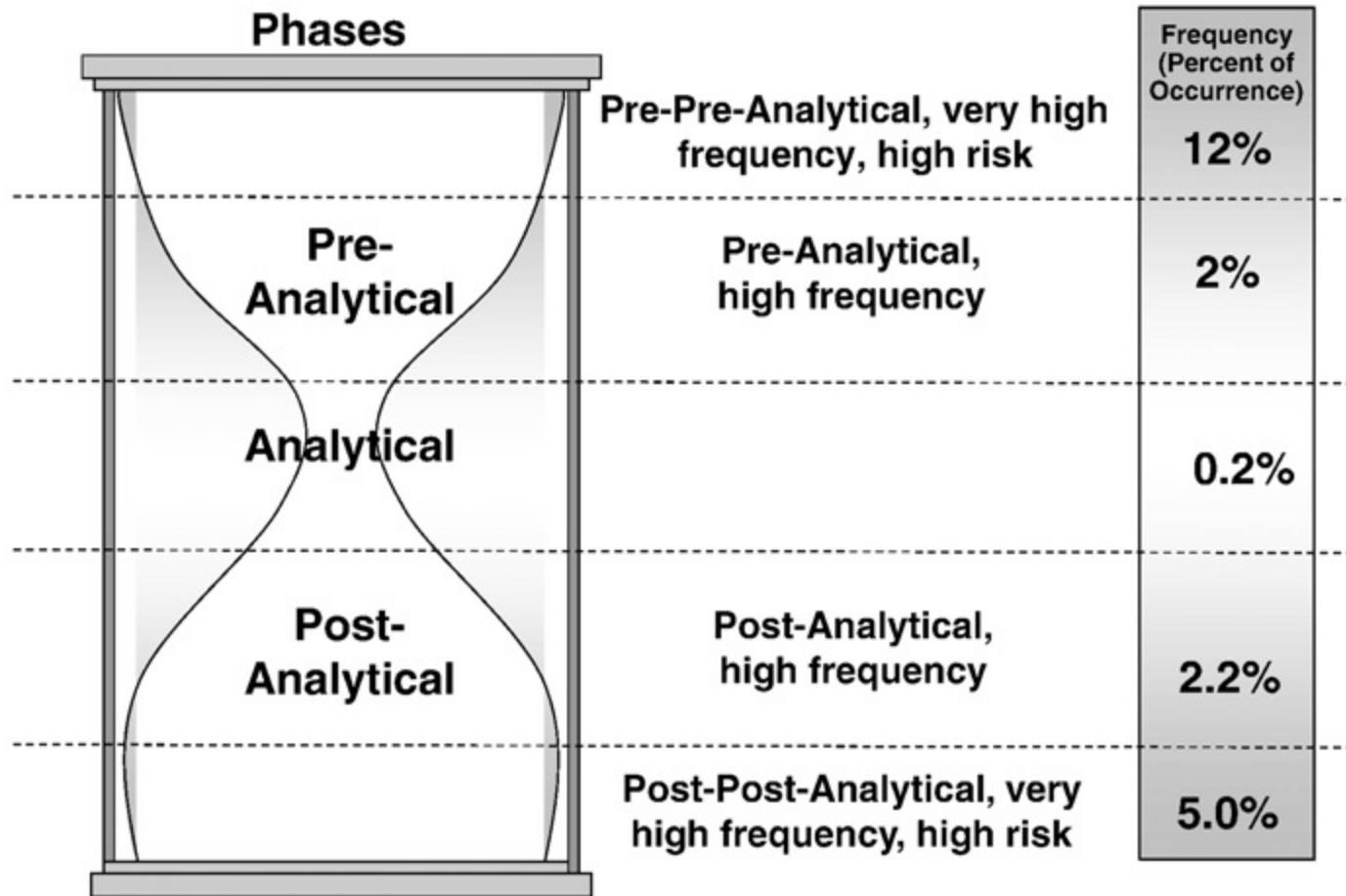
# Overview

- Background
  - Current initiatives
  - How to do it?
  - How to present it?
  - Consequences of poor quality
  - UK situation
  - NEQAS scheme
- 

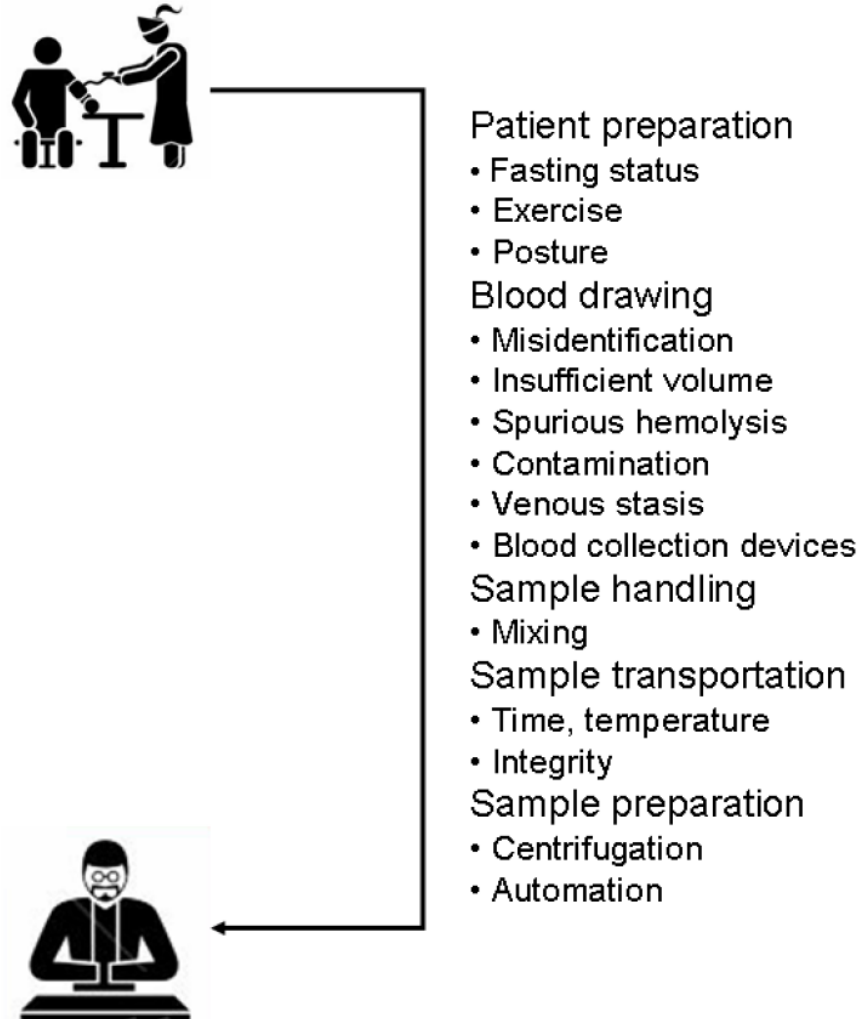




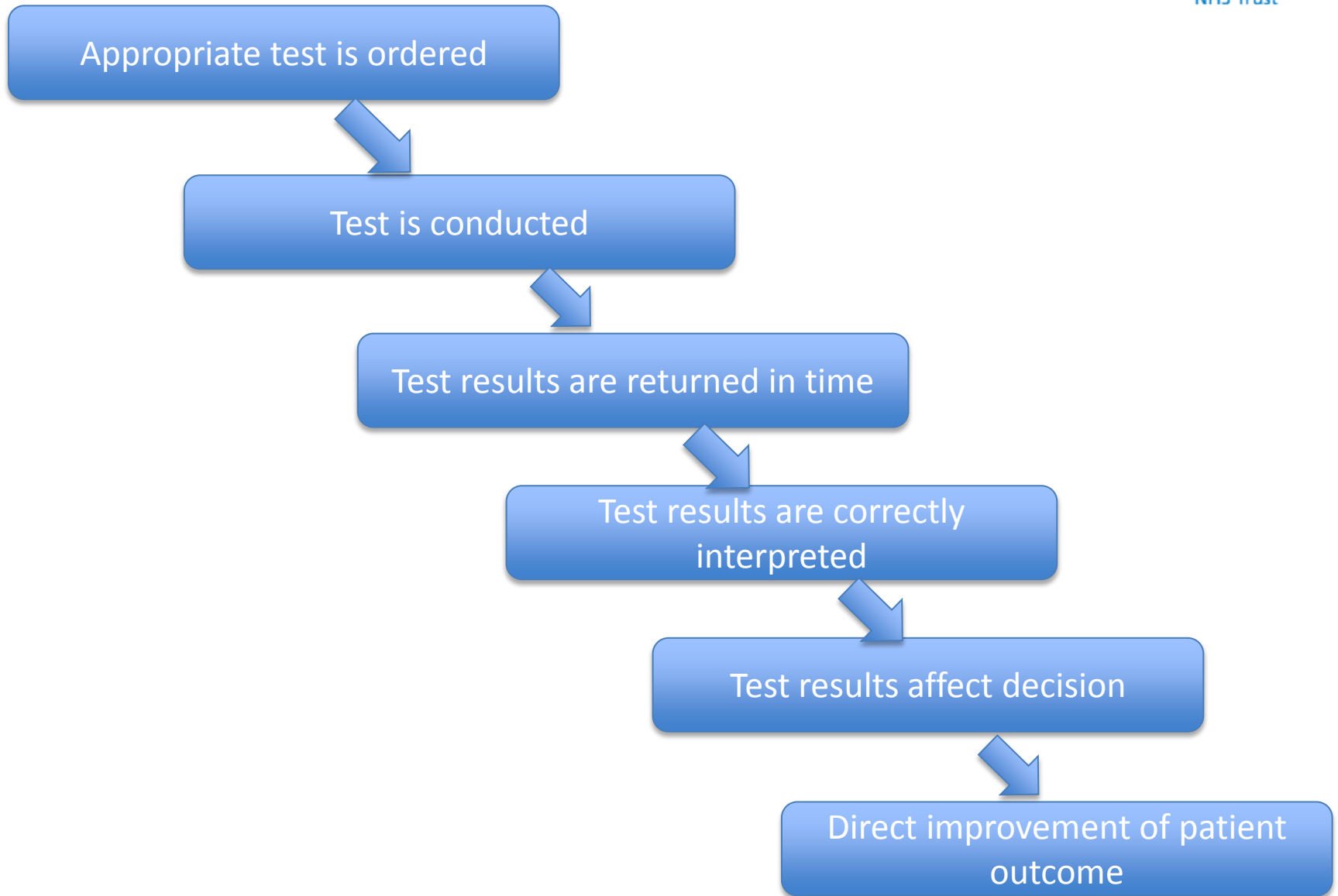
**Figure 1** The brain-to-brain loop for laboratory testing 40 years later.



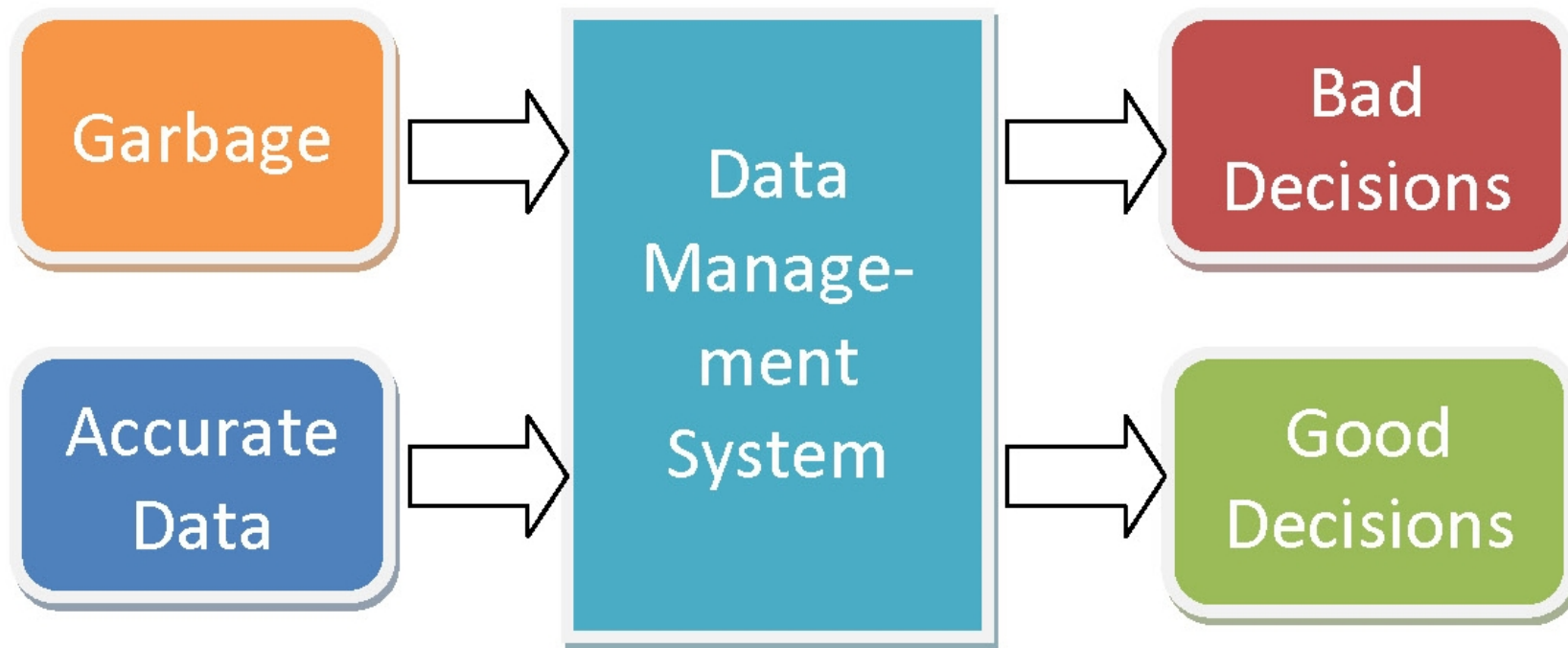
**Fig. 2.** Error stratification in the total testing process (from reference 40, modified).



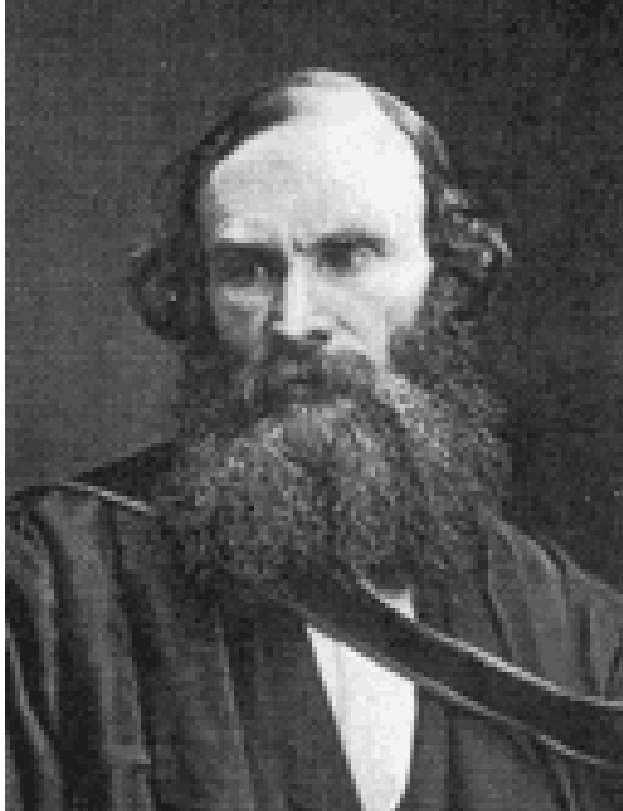
**Figure 2.** The leading causes of preanalytical variability.







## Sir William Thomson (Lord Kelvin)



1824 - 1907

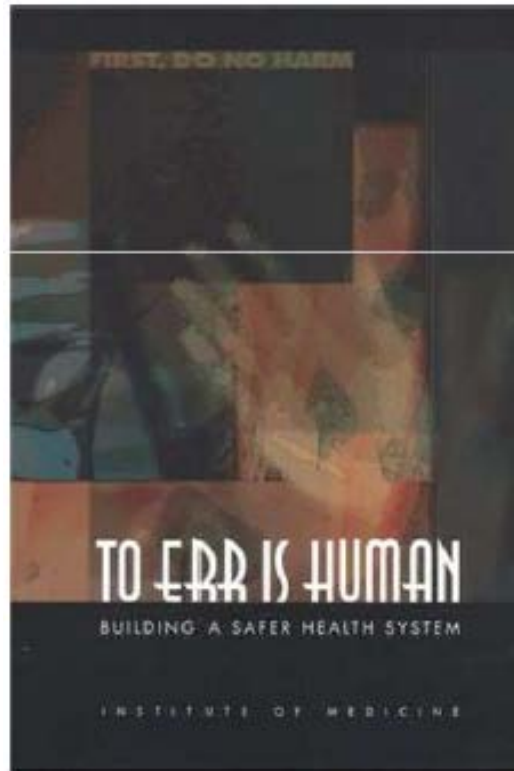
"To measure is to know."

"If you can not measure it, you can not improve it."

# Key Performance Indicators

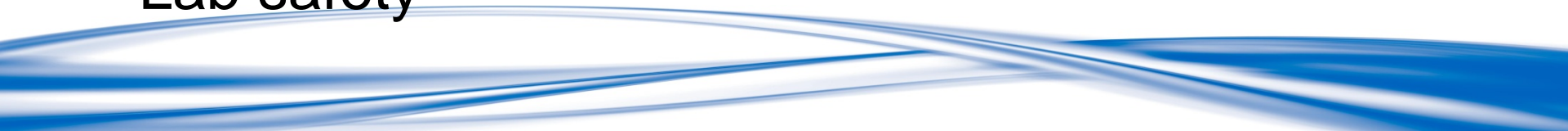


The Institute of Medicine report, *To Err is Human* galvanized a dramatic increase in concern about adverse events and patient safety at an international level.



**T**his 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.

# Benefits of KPI driven quality


- **You cannot improve what you don't measure**
  - Lab test results are only as good as the condition of the specimen allows
    - Garbage in, garbage out!
  - Ensures the result is connected to the right specimen and patient
  - Ensure quality specimen management for accurate test results
  - Lab safety
- 



# ISO 15189:2003

- 4.12.4

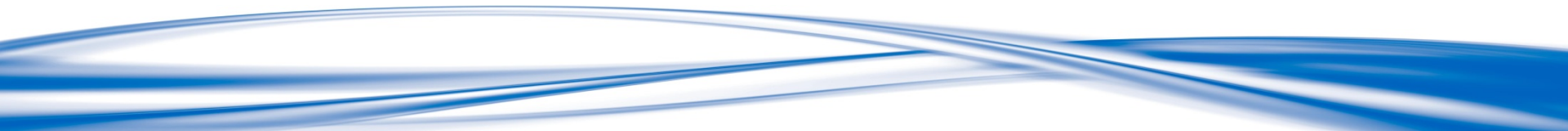
Laboratory management shall implement quality indicators for *systematically monitoring and evaluating the laboratory's contribution to patient care*. When this program identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.



# ISO 15189:2012

The ISO 15189:2012 standard for laboratory accreditation defines the pre-analytical phase as “steps starting in chronological order, **from the clinician's request and including the examination requisition, patient preparation, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins**”

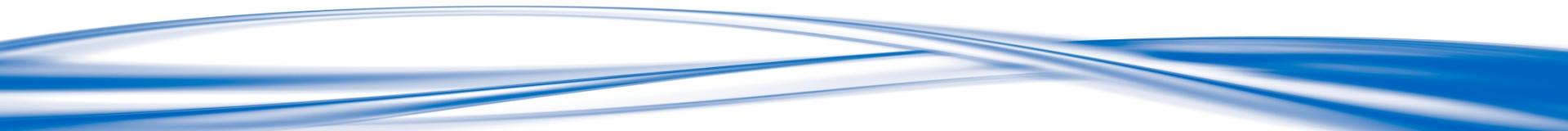
This definition recognizes the need to evaluate, **monitor and improve all the procedures and processes in the initial phase of the TTP, including the procedures performed in the so-called “pre-pre-analytical phase”**



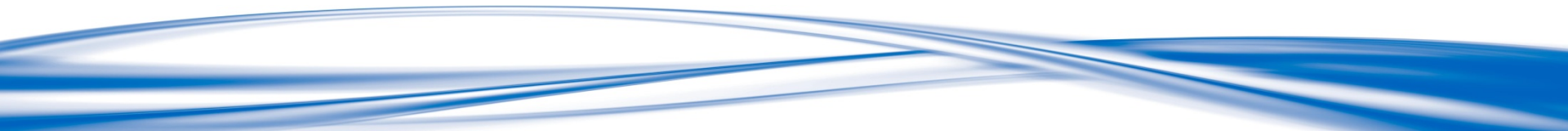
# ISO 15189:2012

- 4.14.7 The laboratory shall **establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination**, examination and post-examination processes
    - EXAMPLE No. of unacceptable samples, number of errors at registration and/or accession, number of corrected reports

**The Process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration**

The indicators shall be periodically reviewed, to ensure their continued appropriateness
- 

# ISO 15189:2012

- 5.4.1 The laboratory shall have **documented procedures and information for pre-examination activities to ensure the validity of the results of examinations**
  - 5.6.1 Appropriate pre and post-examination processes shall be implemented see:
    - 4.14.7,
    - 5.4 (pre),
    - 5.7 (post)
    - 5.8 (reports)
- 

**Table 2**  
Quality indicators selected for the model.

Code	Quality indicators
QI-1	Number of requests with clinical question/total number of requests (in percentage)
QI-2	Number of appropriate tests (with respect to clinical question)/number of requests that report clinical question (in percentage)
QI-3	Number of requests without physician identification/total number of requests (in percentage)
QI-4	Number of unintelligible requests/total number of requests (in percentage)
QI-5	Number of requests with errors concerning patient identification/total number of requests (percentage)
QI-6	Number of requests with errors concerning physician identification/total number of requests (percentage)
QI-7	Number of requests with errors concerning input of tests (missing/added/misinterpreted)/total number of requests (percentage)
QI-8	Number of samples lost-not received/total number of samples (percentage)
QI-9	Number of samples collected in inappropriate container/total number of samples (percentage)
QI-10	Number of samples hemolyzed (haematology, chemistry)/total number of samples (percentage)
QI-11	Number of samples clotted (haematology, chemistry)/total number of samples with anticoagulant (percentage)
QI-12	Number of samples with insufficient sample volume/total number of samples (percentage)
QI-13	Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant (percentage)
QI-14	Number of samples damaged in transport/total number of samples (percentage)
QI-15	Number of samples improperly labelled/total number of samples (percentage)
QI-16	Number of samples improperly stored/total number of samples (percentage)
QI-17	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (percentage)
QI-18	Number of unacceptable performances in EQA schemes occurred for a cause previously treated, per year/total number of unacceptable performances (percentage)
QI-19	Number of tests with CV% higher than selected target, per year/total number of tests (percentage)
QI-20	Number of instrumentation failures causing delay in delivering reports, per year/total number of reports (percentage)
QI-21	Number of reports delivered outside the specified time/total number of reports (percentage)
QI-22	Number of critical values communicated/total number of critical values to communicate (percentage)
QI-23	Average time to communicate critical values
QI-24	Number of interpretative comments, provided in medical report, that impacted positively on patient's outcome (in percentage)
QI-25	Number of guidelines issued in co-operation with clinicians per year



Indicators for pre-analytical phase (percentages).

<b>Appropriateness of test request</b>	Number of requests with <b>clinical question</b> (outpatients)/total number of requests (outpatients)
<b>Patient identification</b>	Number of appropriate requests, with respect to <b>clinical question</b> (outpatients)/number of requests reporting clinical question (outpatients) Number of requests with errors concerning patient identification/total number of requests Number of requests with errors concerning patient identification, detected before release of results/total number of requests Number of requests with errors concerning patient identification, detected after release of results/total number of requests Number of misidentified patients/total number of patients
<b>Request form</b>	Number of unintelligible outpatient requests/total number of outpatient requests
<b>Order entry</b>	Number of outpatient requests with errors in physician's identification/total number of outpatient requests Number of outpatient requests with errors concerning <b>test input</b> (missing)/total number of outpatient requests Number of outpatient requests with errors concerning input of tests (added)/total number of outpatient requests Number of outpatient requests with errors concerning test input (misinterpreted)/total number of outpatient requests Number of inpatient requests with errors concerning test input (missing)/total number of inpatient requests Number of inpatient requests with errors concerning input of tests (added)/total number of inpatient requests Number of inpatient requests with errors concerning test input (misinterpreted)/total number of inpatient requests
<b>Sample identification</b>	Number of samples <b>improperly labeled</b> /total number of samples
<b>Sample collection</b>	Number of samples collected at <b>inappropriate collection time</b> /total number of samples Number of samples collected with <b>inappropriate sample type</b> /total number of samples Number of samples collected in inappropriate container/total number of samples Number of samples with <b>insufficient sample volume</b> /total number of samples
<b>Sample transportation</b>	Number of samples damaged/total number of samples Number of samples transported in inappropriate time/total number of samples for which the transport time is checked Number of samples transported under inappropriate temperature conditions/total number of samples for which the transport temperature is checked Number of samples improperly stored/total number of samples Number of samples lost-not received/total number of samples
<b>Sample acceptance/rejection</b>	Number of contaminated blood culture/total number of blood cultures Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant Number of samples <b>haemolysed</b> (hematology)/total number of samples (hematology) Number of samples haemolysed (chemistry)/total number of samples (chemistry) Number of samples clotted (hematology)/total number of samples with anticoagulant (hematology) Number of samples <b>clotted</b> (chemistry)/total number of samples with anticoagulant (chemistry) Number of samples clotted (immunology)/total number of samples with anticoagulant (immunology) Number of samples haemolysed (immunology)/total number of samples (immunology) Number of lipaemic samples/total number of samples Number of samples unacceptable (microbiology)/total number of samples (microbiology)

Indicators for intra-analytical phase (percentage).

<b>Analytical performance</b>	Number of tests kept under control with EQAS-PT per year/total number of tests provided by service, per year Number of unacceptable performances in EQAS-PT schemes per year/total number of performances in EQA schemes Number of unacceptable performances in EQAS-PT schemes per year occurring in previously treated cause/total number of unacceptable performances Number of IQC values that exceed the selected target, per year/total number of IQC values Number of tests with CV% higher than selected target, per year/total number of tests with known CV%
<b>Instrumentation efficiency</b>	Number of reports with delayed delivery for instrumentation failures, per year/total number of reports
<b>Data entry</b>	Number of incorrect results for erroneous transcription and/or manual entry data in computer system/total number of results requiring transcription and/or manual entry in the computer system

Indicators of post-analytical phase.

<b>Timeliness of results reporting</b>	Number of reports delivered <u>outside the specified time</u> /total number of reports (percentage) Turn Around Time (min) of potassium at 90th percentile (emergency) Turn Around Time (min) of potassium at 90th percentile (routine) Turn Around Time (min) of international normalized ratio value at 90th percentile (routine) Turn Around Time (min) of C-reactive protein at 90th percentile (routine) Turn Around Time (min) of white blood cells at 90th percentile (routine) Turn Around Time (min) of troponin I or troponin T at 90th percentile (routine)
<b>Accuracy of results reporting</b>	<b>Number of outpatients called back for a blood re-collection due to unsuitable samples or incorrect results/total number of outpatients (percentage)</b> Number of corrected reports/total number of reports (percentage)
<b>Timeliness and effectiveness of critical values reporting</b>	Number of <u>critical values of inpatients communicated within an hour</u> (from result validation to result communication to clinician)/total number of critical inpatient values to communicate (percentage) Number of critical values of outpatients communicated within an hour (from result validation to result communication to clinician)/total number of critical outpatient values to communicate (percentage) <u>Time (from result validation to result communication to clinician) to communicate critical inpatient values (min)</u> <u>Time (from result validation to result communication to clinician) to communicate critical outpatient values (min)</u>
<b>Effectiveness of interpretative comments</b>	<b>Number of reports with interpretative comments, provided in medical report, impacting positively on patient's outcome/total number of reports with interpretative comments (percentage)</b>
<b>Effectiveness of clinical audit</b>	Number of guidelines issued in cooperation with clinicians per year

**TABLE 2.** Quality Indicators of the pre-analytical phase (order of priority: 1 = Mandatory; 2 = Important; 3 = Suggested; 4 = Valuable).

Quality indicator	Priority score
<b>a) Appropriateness of clinical request</b>	
Percentage of "Number of requests without clinical question (outpatients) / Total number of requests (outpatients)"	2
Percentage of "Number of inappropriate requests, with respect to clinical question (outpatients) / Number of requests reporting clinical question (outpatients) "	4
Percentage of "Number of inappropriate requests, with respect to clinical question (inpatients) / Number of requests reporting clinical question (inpatients) "	4
<b>b) Patient identification</b>	
<u>Percentage of "Number of requests with errors concerning patient identification / Total number of requests"</u>	1
<u>Percentage of "Number of requests with errors concerning patient identification, detected before release of results / Total number of requests"</u>	1
<u>Percentage of "Number of requests with errors concerning patient identification, detected after issuing results / Total number of requests"</u>	1
<b>c) Data entry of the request</b>	
Percentage of "Number of outpatients requests with errors concerning physician identification / Total number of outpatients requests"	2
Percentage of "Number of unintelligible outpatients requests / Total number of outpatients requests"	3
Percentage of "Number of outpatients requests with errors concerning test input / Total number of outpatients requests"	1
Percentage of "Number of outpatients requests with errors concerning test input (missing) / Total number of outpatients requests"	1
Percentage of "Number of outpatients requests with errors concerning test input (added) / Total number of outpatients requests"	1
Percentage of "Number of outpatients requests with errors concerning test input (misinterpreted) / Total number of outpatients requests"	1
Percentage of "Number of inpatients requests with errors concerning test input (missing) / Total number of inpatients requests"	1
Percentage of "Number of inpatients requests with errors concerning test input (added) / Total number of inpatients requests"	1
Percentage of "Number of inpatients requests with errors concerning test input (misinterpreted) / Total number of inpatients requests"	1
<b>d) Sample identification</b>	
<u>Percentage of "Number of improperly labeled samples / Total number of samples"</u>	1



**e) Sample collection**

Percentage of "Number of samples collected at inappropriate time / Total number of samples"	2
<u>Percentage of "Number of samples collected with inappropriate sample type / Total number of samples"</u>	1
<u>Percentage of "Number of samples collected in inappropriate container / Total number of samples"</u>	1
<u>Percentage of "Number of samples with insufficient sample volume / Total number of samples"</u>	1

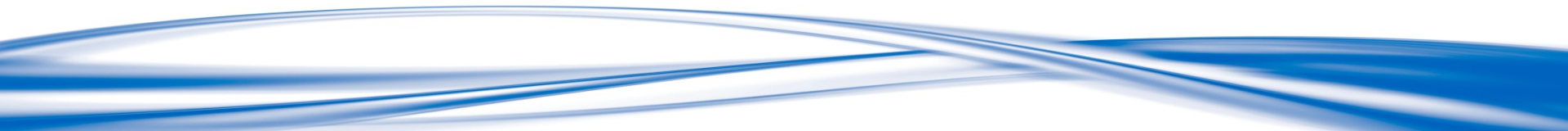
**f) Transport of sample**

Percentage of "Number of damaged samples / Total number of samples"	1
Percentage of "Number of samples transported at inappropriate time / Total number of samples for which transport time is checked"	1
Percentage of "Number of samples transported under inappropriate temperature condition / Total number of samples for which the transport temperature is checked"	1
<u>Percentage of "Number of improperly stored samples / Total number of samples"</u>	1
<u>Percentage of "Number of samples lost-not received / Total number of samples"</u>	1

**g) Suitability of sample**

Percentage of "Number of samples with inadequate sample-anticoagulant volume ratio / Total number of samples with anticoagulant"	1
Percentage of "Number of <u>hemolyzed</u> samples (hematology) / Total number of samples (hematology)"	1
Percentage of "Number of hemolyzed samples (chemistry) / Total number of samples (chemistry)"	1
Percentage of "Number of <u>clotted</u> samples (hematology) / Total number of samples with anticoagulant (hematology)"	1
Percentage of "Number of clotted samples (chemistry) / Total number of samples with anticoagulant (chemistry)"	1
Percentage of "Number of clotted samples (immunology) / Total number of samples with anticoagulant (immunology)"	1
Percentage of "Number of hemolyzed samples (immunology) / Total number of samples (immunology)"	1
Percentage of "Number of <u>lipemic</u> samples / Total number of samples"	1
Percentage of "Number of unacceptable samples (microbiology) / Total number of samples (microbiology)"	1
Percentage of "Number of <u>contaminated blood</u> cultures / Total number of blood cultures"	1

# Quality Indicators Summary

- PID errors
    - Before and within lab
  - Booking in errors
  - Missing tests
  - Inappropriate samples
  - Haemolysed samples
  - Clotted samples
  - Insufficient samples
  - Wrongly labelled samples
  - TAT failures
  - Unacceptable samples
- 



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IFCC - Education and Management Division

## IFCC - Education and Management Division Working Group: Laboratory Errors and Patient Safety

### 9.3.8. Laboratory Errors and Patient Safety (WG-LEPS)

#### Terms of references

The Education and Management Division (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has recently established a new Working Group on "Laboratory errors and patient safety" (WG-LEPS 9.3.8).

The WG mission is to stimulate studies on the topic of errors in laboratory medicine, to collect available data on this topic and to recommend strategies and procedures to improve patient safety.

According to the Chair of the World Alliance for Patient Safety, Sir Liam Donaldson, established by the WHO in 2004, "a focus on addressing errors in laboratory medicine is an important element of the international agenda on patient safety. Timely and accurate laboratory test results are a cornerstone of effective diagnosis and treatment of patients" (Clin Chem Lab Med 2007; 45(6): 697-9).

In the last few years a body of evidence has been collected to demonstrate that many of the errors in laboratory medicine occur in the pre- and post-analytical phases of laboratory testing. Therefore, improving the safety of laboratory testing requires a detailed understanding of the steps involved in the total testing process to identify the hierarchy of risks and challenges to be addressed.

Patient safety is increasingly recognised as a serious problem that requires a globally led approach and the IFCC WG-LEPS should be a tool to improve the knowledge in the field at an international level, and to recommend the development and application of standardised operating protocols.

#### Current Projects

Improving awareness of laboratory professionals regarding the topic of errors and patient safety.

Implementing pilot studies to evaluate laboratory errors frequency and types.

Implementing projects for error reduction through the design of safer procedures and processes.

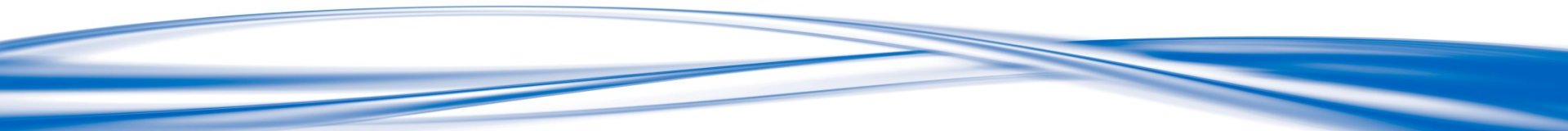
Cooperating with other scientific organizations (WHO, AACC, ASCP, etc) for assuring improvements in the field of patient safety.

Organizing meetings and scientific sessions on the topic of laboratory errors and patient safety.

Supporting the publications of papers on the topic of laboratory errors and patient safety in scientific journals and monographs.

# How to do it?

- Choose your indicator
- Automate extraction
- Develop SOP
  - Include action plan



# Developing Indicators

<b>Objective</b>	What are you trying to measure?
<b>Methodology</b>	<ol style="list-style-type: none"> <li>1. <b>How to capture the data? – flag data</b></li> <li>2. <b>Who (or what) to capture the data?</b></li> <li>3. <b>How often to capture the data?</b></li> </ol>
<b>Set Limits</b>	Acceptable, Concern, Unacceptable Critical
<b>Presentation</b>	Graphic or Text
<b>Interpretation</b>	<p>What does it mean?</p> <p>Who's quality does it reflect?</p>
<b>Limitations</b>	Unintended variables or uncontrollable variables
<b>Action Plan</b>	<p><b>What will I do if it indicates acceptable performance?</b></p> <p><b>What will I do if it does not?</b></p>
<b>Exit Plan</b>	When can I stop measuring?

# Extraction of KPIs

Year	Month	TEXTCODE	ZAP1	ZAPC1	ZAPH1	ZAPM1
2015	8				7	
2015	8	.ANS			2	
2015	8	.CLOT			149	
2015	8	.DIFP		2		
2015	8	.HAZ		2	3	12
2015	8	.ILLS		2		2
2015	8	.INAP		49	24	102
2015	8	.INRQ		10	3	29
2015	8	.INSS		7	469	72
2015	8	.MAT		15	8	21
2015	8	.MISL	41	84	60	36
2015	8	.NOS		333	430	25
2015	8	.NPDS	3	58	41	102
2015	8	.NRQ				70
2015	8	.NUM		2	3	2
2015	8	.SDAT			1	1
2015	8	CLOT			3	
2015	8	-IINS			1	
2015	8	INSUF		1		4
2015	8	KEDTA		1		

# Extraction of KPIs

Year	Month	TESTCODE	CountOfACCNUM	DISCIPLINE
2015		8 ADD2	57	Clinical
2015		8 ADD3	5	Clinical
2015		8 ADDON	1180	Clinical

Year	Month	Description	Clinical Chemistry	Haematology	Immunology	Microbiology
2015		8 Ana Error	2			
2015		8 EDTA Contamination	10			
2015		8 Haemolysed	403	154	3	
2015		8 Icteric	19			
2015		8 Insufficient	62	47	89	27
2015		8 Left on cells	11			
2015		8 Lipaemic	6	2		
2015		8 Pre analytical error	92	5		



# Extraction of KPIs

AN84		AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO
	A	B									
			Decemb	January	February	March	April	May	June	July	August
2	<b>IFCC Quality indicator</b>										
9	<b>PRE-QI-8</b>	Percentage of illegible requests	0.004%	0.003%	0.002%	0.000%	0.002%	0.000%	0.001%	0.000%	0.003%
10		Addons	1055	1088	1009	1093	950	1096	1081	1136	1180
11	<b>PRE-QI-9</b>	Percentage of requests with one call to addon tests	1.866%	1.628%	1.585%	1.548%	1.511%	1.702%	1.522%	1.585%	1.892%
12		add2	36	54	55	50	64	43	47	55	57
13		add3	0	2	0	1	1	4	0	2	5
14	<b>PRE-QI-10</b>	Percentage of requests with further calls to addon tests	0.064%	0.084%	0.086%	0.072%	0.103%	0.073%	0.066%	0.080%	0.099%
15		.nos No sample received with request form. Please repeat if clinically indicated.	298	359	329	319	318	315	344	371	333
16		nosam	0	5	0	1	0	0	0	0	0
17	<b>NotRec</b>	Percentage of requests not received or lost	0.527%	0.545%	0.517%	0.453%	0.506%	0.489%	0.484%	0.518%	0.534%
18		.inap Inappropriate sample received for this test. For correct sample(s) please see Pathology User Guide.	34	66	50	60	44	54	47	51	49
19		EDTA	18	11	14	16	13	21	13	12	10
20	<b>WroTy</b>	Percentage of requests with the wrong sample type sent	0.092%	0.115%	0.101%	0.108%	0.091%	0.116%	0.084%	0.088%	0.095%
21		Haemolysed	481	435	427	485	454	460	452	486	403
22		Hb > 0.5	1991	1988	1897	1942	1780	1793	1425	1447	1602
23	<b>PRE-QI-28</b>	Percentage of requests with haemolysed samples	0.851%	0.651%	0.671%	0.687%	0.722%	0.714%	0.636%	0.678%	0.646%
24	<b>Hem</b>	Percentage Hb > 0.5	3.522%	2.975%	2.979%	2.750%	2.832%	2.784%	2.007%	2.019%	2.568%
25		.clot clotted	0	0	1	0	1	1	0	0	0
26	<b>Clot</b>	Percentage of requests with clotted samples	0.000%	0.000%	0.002%	0.000%	0.002%	0.002%	0.000%	0.000%	0.000%
27		.inss Insufficient sample received to carry out this test.	9	2	2	12	9	16	9	6	7
28		insuff	77	87	107	85	69	143	86	75	62
29	<b>InsV</b>	Percentage of requests with insufficient samples volume	0.152%	0.133%	0.171%	0.137%	0.124%	0.247%	0.134%	0.113%	0.111%
30		ztum	0	0	0	0	0	0	0	0	0
31	<b>DamS</b>	Percentage of requests damaged in transport	0.004%	0.000%	0.002%	0.001%	0.000%	0.002%	0.001%	0.001%	0.003%
32		.ills Illegible information provided on sample container. Clearly provide Surname, Forename, D.o.B. and Hospital number/ NHS number.	2	2	1	0	1	0	1	0	2
33		.mat Details on Sample and Request Form DO NOT match.	13	15	20	23	16	12	16	18	15
34		.npds No patient's details on sample(s). Unsafe to process tests.	70	72	59	62	58	60	51	60	58

# Extraction of KPIs

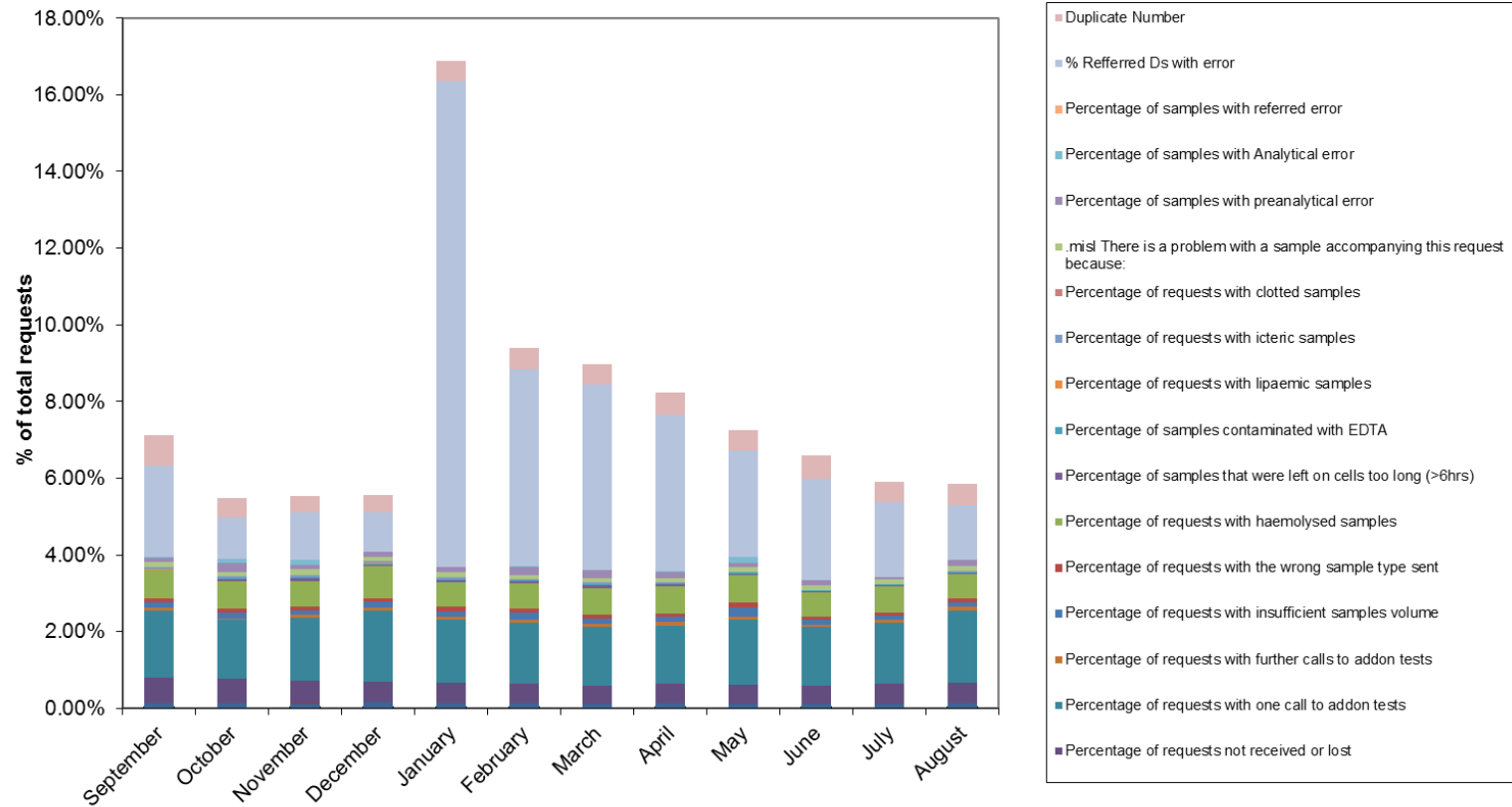
35		.idm Illegible or no NHS/Hospital number. Unique Identifier Required GP requests please provide: NHS Number, Surname, forename and D.o.B. Hospital requests please provide: Hospital / NHS Number, Surname, forename and D.o.B. inappropriately identified requests may not be processed.	3	0	0	1	6	6	5	2	2		
36	PRE-QI-15	Percentage of requests with mislabelled samples	0.156%	0.133%	0.126%	0.122%	0.129%	0.121%	0.103%	0.112%	0.123%		
37		Lip	5	3	3	0	1	1	2	5	6		
38	PRE-QI-33	Percentage of requests with lipaemic samples	0.009%	0.004%	0.005%	0.000%	0.002%	0.002%	0.003%	0.007%	0.010%		
39		Total EQA actionable errors											
40													
41		.dip Details provided DO NOT match existing computer records.	0	0	1	0	0	0	0	1	2		
42		.inrq Insufficient details on request form.	3	3	9	8	5	11	8	7	10		
43		.misl There is a problem with a sample accompanying this request because:	65	81	80	85	67	78	80	94	84		
44		.sdat The collection date for the specimen received is outside the acceptable period for this investigation. Collected:	0	5	0	0	0	0	0	0	0		
45		.haz Hazard! Specimen leaked in transit because sample lid/top inadequately tightened.	2	0	1	1	0	1	1	1	2		
46		.ilrq Illegible information on request form	0	0	1	2	0	0	1	0	0		
47		.nrq No request form received. To avoid delays please ensure the correct request forms are sent.	0	0	1	2	0	1	0	0	0		
48		blk	0	0	0	0	0	0	0	0	0		
49		Ioteric	30	33	13	35	17	11	7	9	19		
50		LOC	14	37	30	56	36	28	14	23	11		
51	ExcTim	LOC	0.025%	0.055%	0.047%	0.079%	0.057%	0.043%	0.020%	0.032%	0.018%		
52		Percentage of requests with Ioteric samples	0.053%	0.049%	0.020%	0.050%	0.027%	0.017%	0.010%	0.013%	0.030%		
53		Percentage of samples that were left on cells too long (>1hr)	0.025%	0.055%	0.047%	0.079%	0.057%	0.043%	0.020%	0.032%	0.018%		
54		Percentage of samples contaminated with EDTA	0.032%	0.016%	0.022%	0.023%	0.021%	0.033%	0.018%	0.017%	0.016%		
55		PAERR	70	101	133	141	90	64	97	36	92		
56		Percentage of samples with preanalytical error	0.124%	0.151%	0.209%	0.200%	0.143%	0.099%	0.137%	0.050%	0.147%		
57	GNV												
14	RAW	Numerical	Percentage	Six sigma	Haem 0.5	Lab errors	Error codes by Dept	Table	Introduction	Calculat			

# Presentation of KPIs

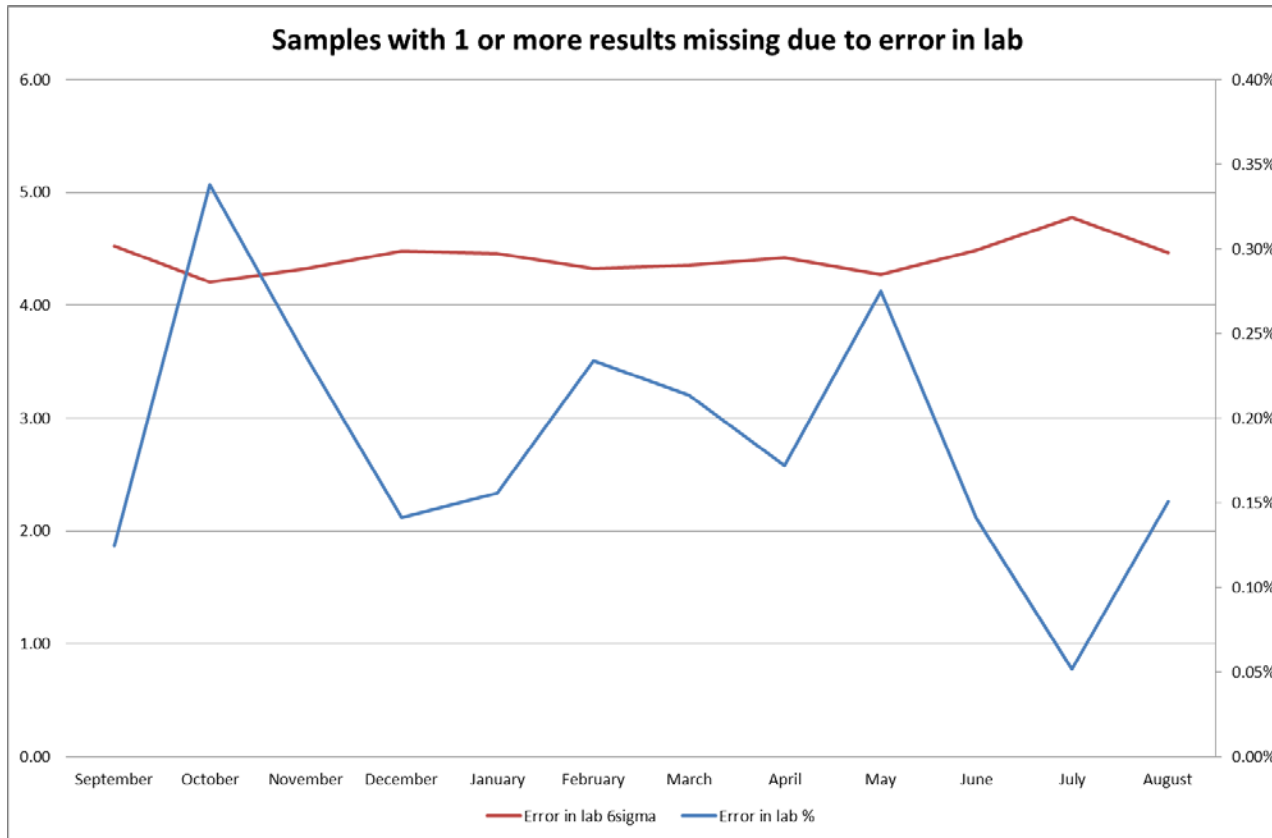
Pathology Directorate KPIs										
Indicator	Target	Area	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Ave
Specimen rejection Green <1.59%, amber 1.59-2%, red >2%		Div1	1.29%	1.34%	1.30%	1.40%	1.39%	1.45%	1.45%	1.37%
		Div2	1.62%	1.71%	1.75%	1.66%	1.74%	1.94%	1.94%	1.77%
		Comm	1.10%	1.55%						1.33%
		GP	1.40%	1.12%						1.26%
Data entry errors Green <1.59%, amber 1.59-2%, red >2%		Central	0.7%	0.0%	0.0%			0.8%	0.0%	0.2%
		Mic	0.1%	0.3%	0.1%	0.0%		0.0%	0.4%	0.2%
Incidents Green 0, red ≥1 greens1,amber2,red>2 green <14, amber 14-25, red >25		Red	0	0	0	0	0	0	0	0
		amber	0	0	0	0	0	0	0	0
		yellow	2	5	2	8	11	12	16	8
		green	8	12	11	15	14	11	4	11
Complaints green0,amber1, red=>2			1	0	0	0	0	0	0	
Document outside review Green <10%, amber 10-20%, red 20%		CP	35.16%	6.98%	3.38%	1.07%	2.27%	2.12%	3.69%	7.8%
		CHE	1.39%	0.97%	0.78%	2.96%	1.37%	1.02%	0.84%	1.3%
		HAE	10.29%	2.64%	7.67%	7.93%	9.64%	0.20%	0.22%	5.5%
		MIC	10.25%	11.00%	10.20%	4.66%	2.20%	1.35%	1.51%	5.9%
		PHL	52%	37%	37%	15%	11%	11%	11%	24.8%
		POCT	14.86%	15.34%	18.86%	23.43%	25.10%	2.86%	22.98%	16.7%
Actions overdue Green 0-1, amber 2, red ≥5		CP	15	11	10	5	8	13	11	10
		CHE	13	4	0	3	7	12	2	5
		HAE	14	9	10	12	1	4	4	8
		MIC	3	1	1	5	28	1	1	8
		PHL	0	0	0	1	1	1	0	0
		POCT	2	3	0	2	3	3	0	2
		CP	6	4	0	2	5	11	12	6
Audits overdue Green 0, amber 1, red ≥2		CHE	0	0	1	0	0	2	1	1
		HAE	4	2	3	1	1	0	0	2
		MIC	3	3	5	3	0	0	0	2
		POCT	10	0	0	0	1	0	2	2
		CP	6	4	0	2	5	11	12	6
EQA poor performance green 0, amber 1, red >1			0	0	0	0	1	0	2	
Bone marrow reporting Green0, amber1, red≥2 Green 0, red ≥1		4-8 wks	8		7	1	4	4	0	5
		> 8 wks	3		0	0	0	0	0	1

# Presentation of KPIs

Chemistry error numbers

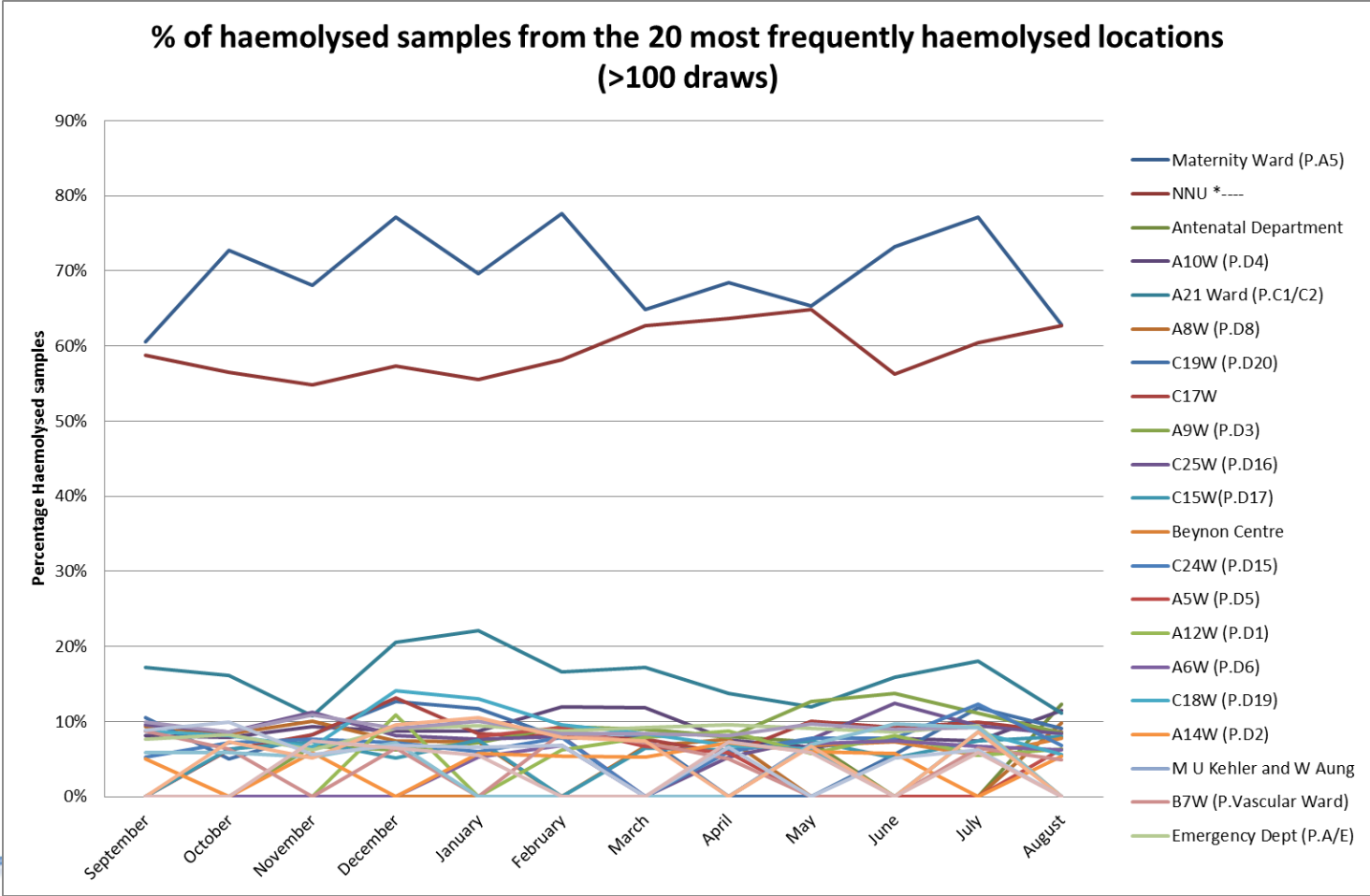


# Presentation of KPIs



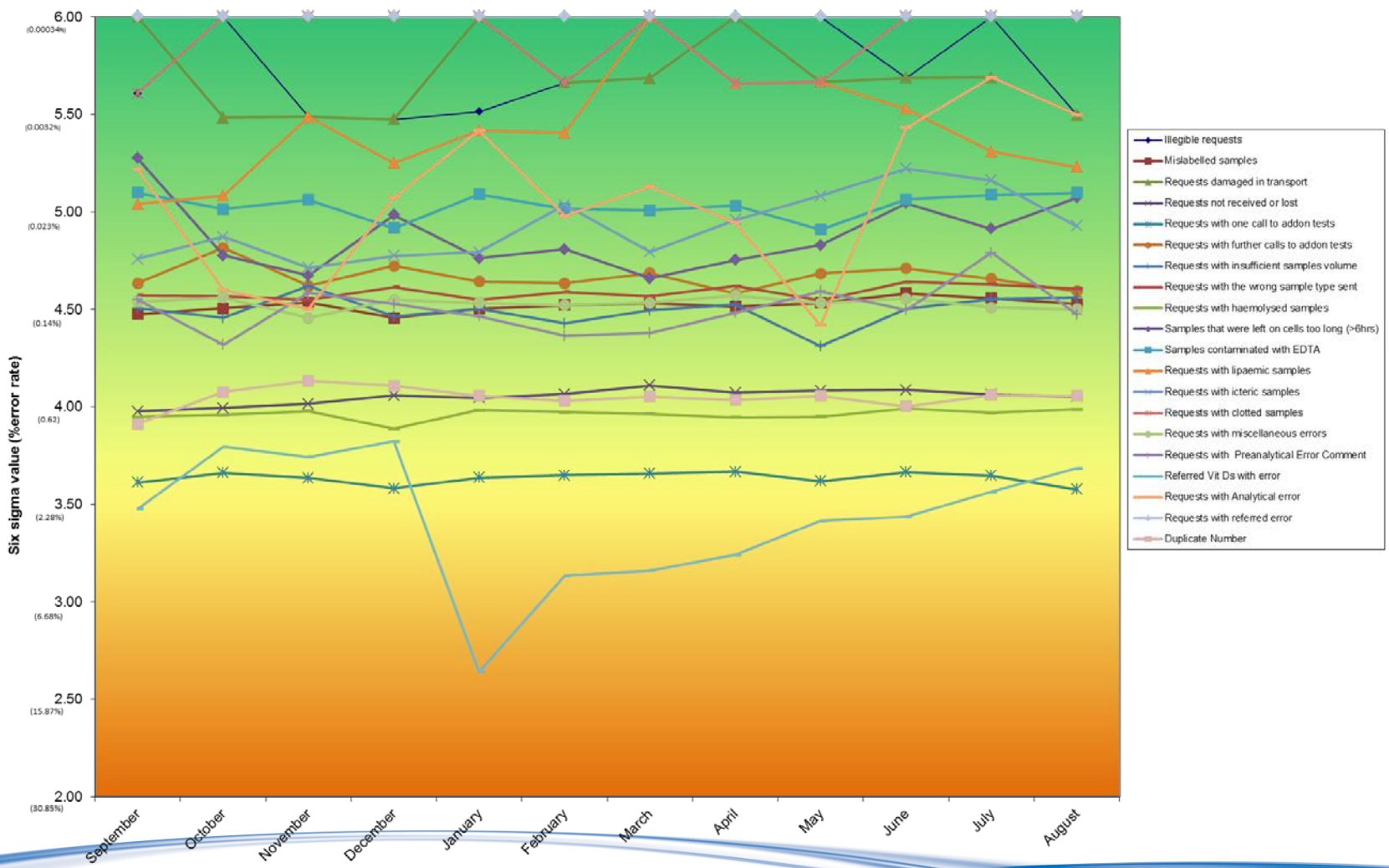


# Presentation of KPIs



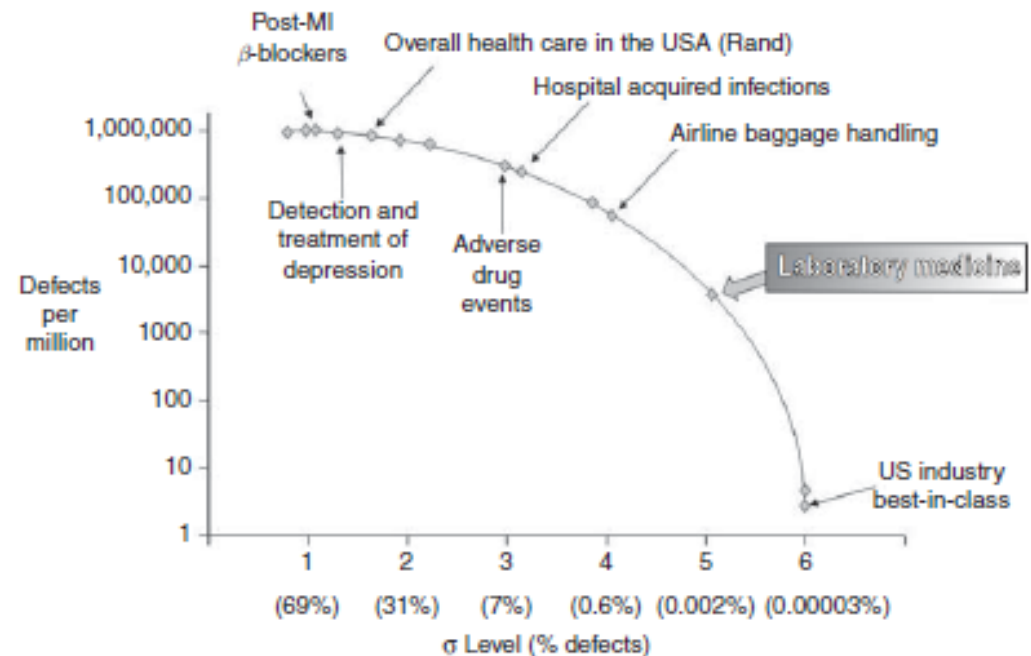
# Presentation of KPIs

Six Sigma values for lab errors



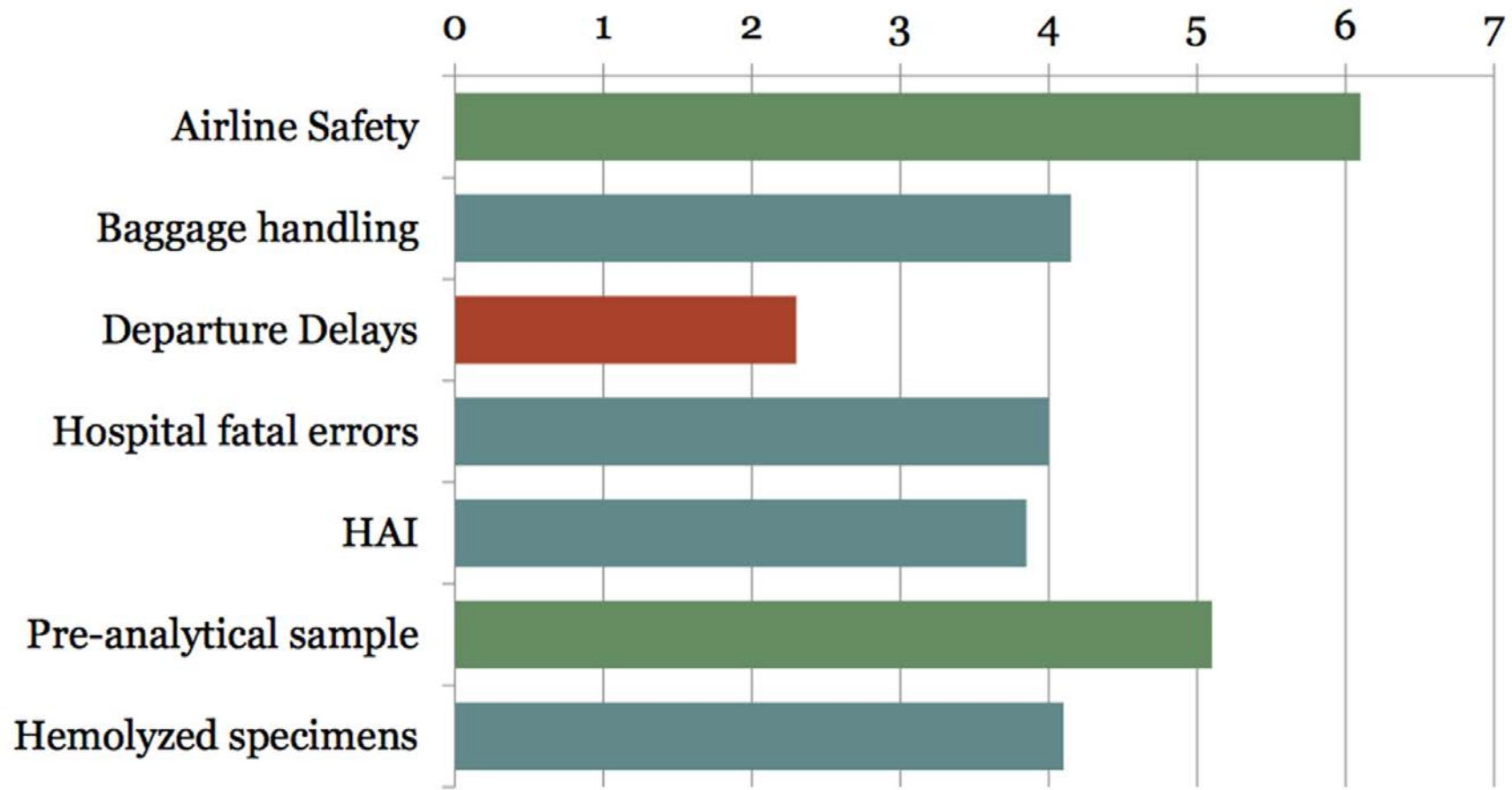
# Six Sigma

Sigma	Spelling
7	1 misspelled word in all of the books contained in several large libraries
6	1 misspelled word in all of the books contained in a small library
5	1 misspelled word in a set of encyclopaedias
4	1 misspelled word in a book chapter
3	1.5 misspelled words per page in a book
2	25 misspelled words per page in a book
1	170 misspelled words per page in a book



The detection and prevention of errors in laboratory medicine

Mario Plebani



# Effect of continual KPI monitoring

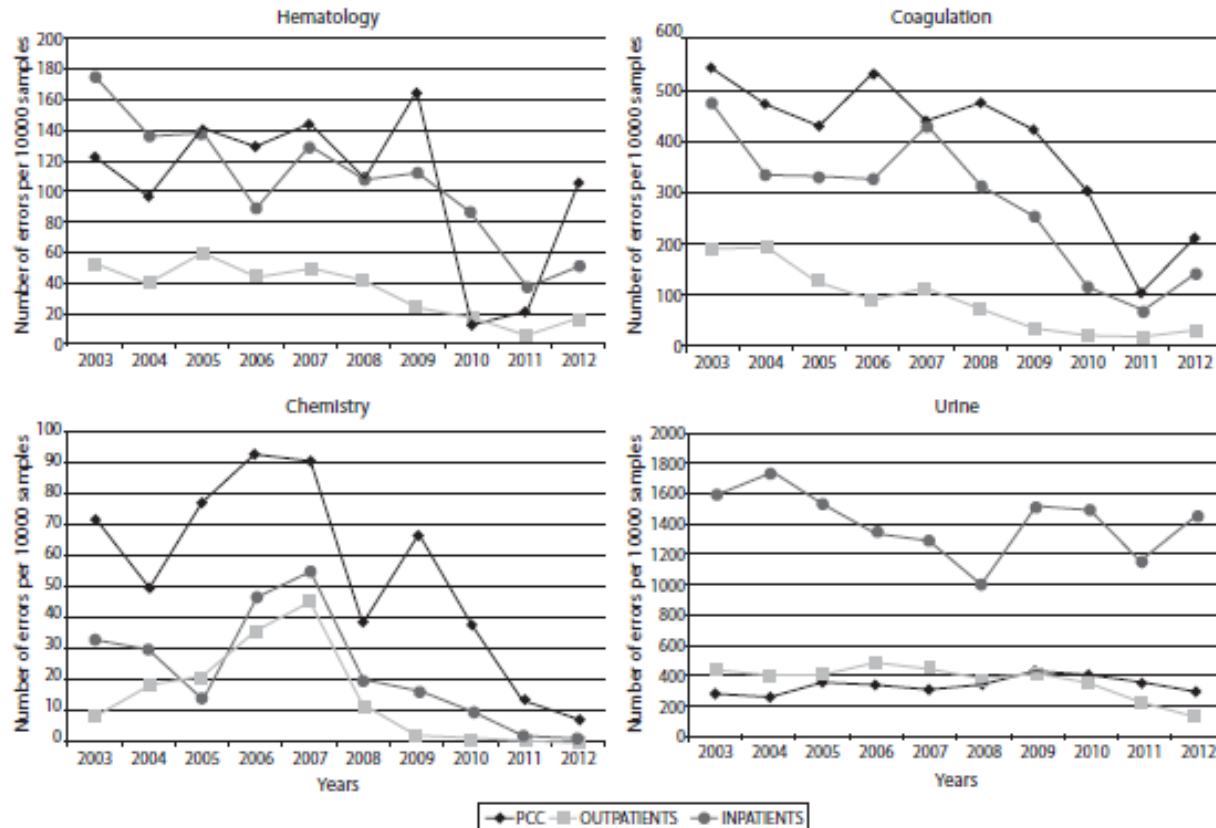


FIGURE 2. Annual global indicator results in every type of patient: Shows the sum of all types of preanalytical errors with respect to every sample collected in inpatients, outpatients and primary care patient's samples.



# Costs of poor practice

- That 70% value
- VALUE?
  - Clinical Value
  - Economical Value
  
- NET VALUE = benefit – harm
  - Increase benefits (Difficult)
  - Decrease harm

VIEWPOINT



OPEN ACCESS

## When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine

Paul L Epner,<sup>1</sup> Janet E Gans,<sup>2</sup> Mark L Graber<sup>3</sup>

Instead of studying the process defects, we should focus more on studies that show a reduction of harm and cost.

Quality improvement should focus on reducing patient harm rather than process defects.

# Causes of Harm

## Box 1: Five causes taxonomy of testing-related diagnostic error

- ▶ An inappropriate test is ordered
- ▶ An appropriate test is not ordered
- ▶ An appropriate test result is misapplied
- ▶ An appropriate test is ordered, but a delay occurs somewhere in the total testing process
- ▶ The result of an appropriately ordered test is inaccurate

*most frequent*

- ▶ Patient harm due to the laboratory testing

# Specimen rejection related harm

- Repeated sampling:
  - 86.8% of rejected blood specimens led to repeated phlebotomy.
  - 13.8% of rejected urine specimens required recatheterization of the patient to collect a new urine sample.
  - inconvenience and discomfort for the patient, potential for patient complications.
- Delay in reporting of the results:
  - the median specimen processing delay was 65 minutes
  - potential for the failure to provide adequate care in a timely manner

# Reducing Costs

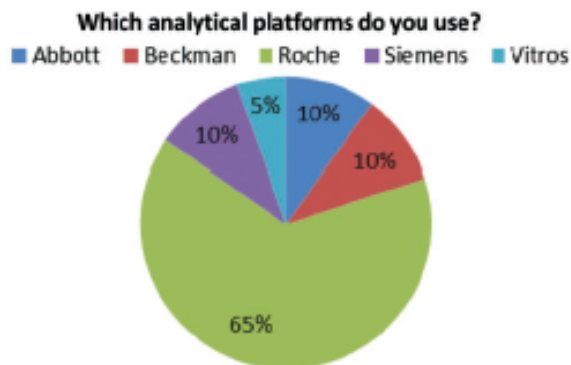
- A study was performed in a London teaching hospital
- the estimated cost of repeating haemolysed specimens, based on an average of 60 admissions per day, was **£4355 per month**, plus additional time and equipment costs.
- This cost-saving would fund at least one dedicated Emergency Department phlebotomist.



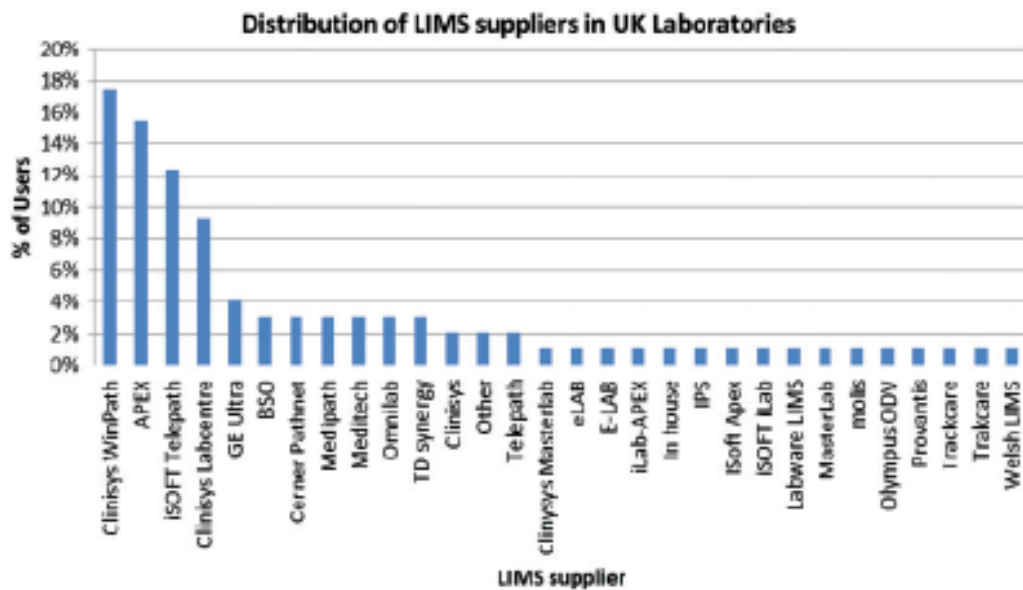
# Cost

- 48% of hyperammonemia cases are false positive
- most common causes are capillary sampling and delayed transport
- False positives lead to:
  - additional diagnostic workup, patient discomfort, LOS
  - increased cost

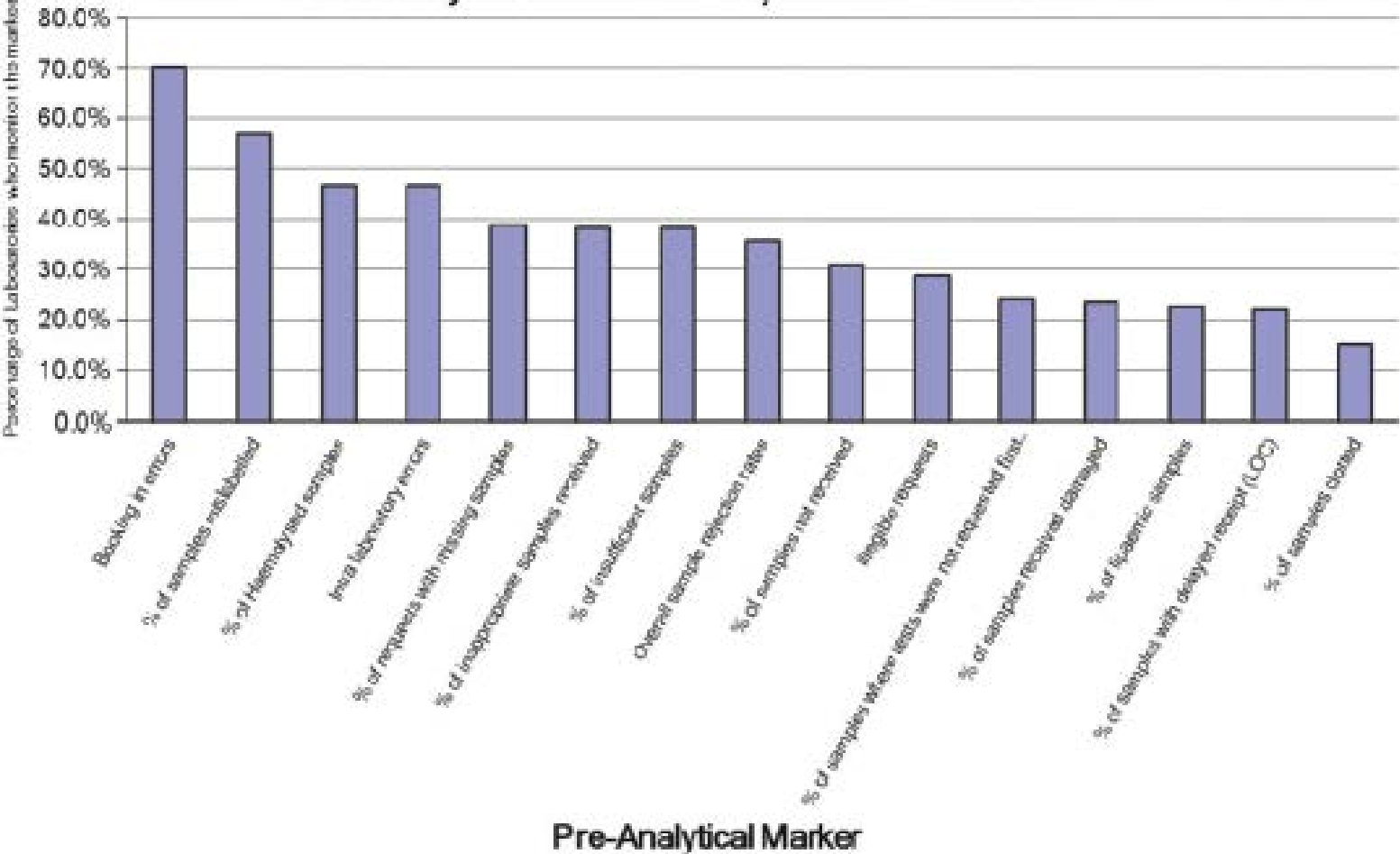
# Current UK situation



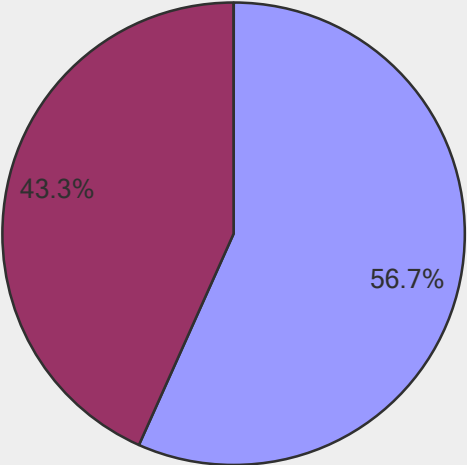
**Figure 2.** Laboratory analytical platforms in use in UK clinical laboratories surveyed.



Pre-Analytical markers currently monitored in the UK

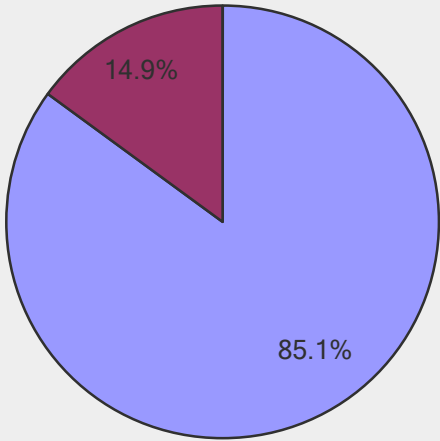


How do you count requests?



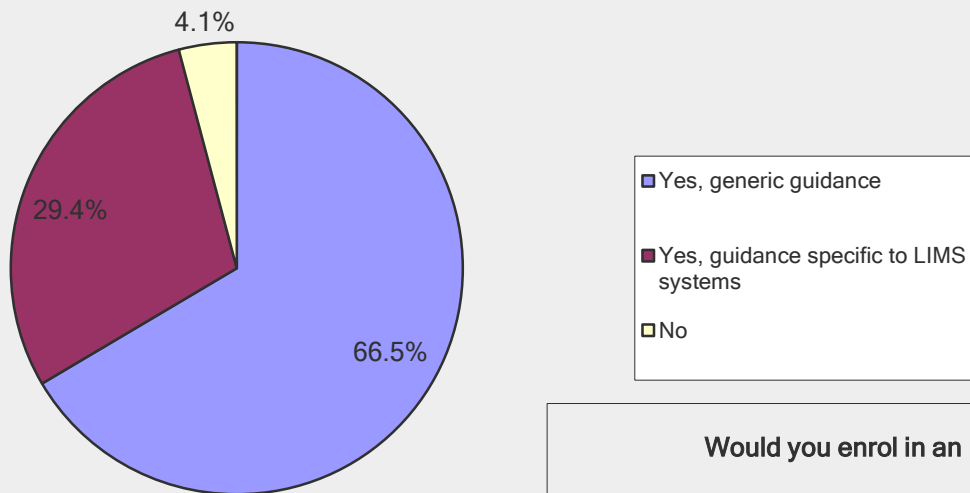
- Each sample has a separate accession number.
- Each request has a separate accession number.

Do you use automated HIL indices?

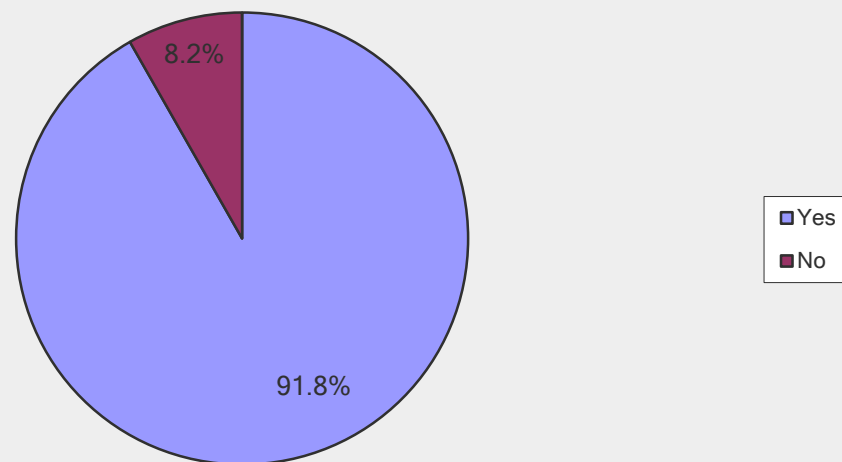


- Yes
- No

Would you be interested in any guidance documents on the best approach to collect data to ensure standardisation?



Would you enrol in an EQA scheme to compare pre-analytical error rates with other institutions?



# NEQAS scheme



Pre & Post Analytical Quality Monitoring Service

Test site :

Distribution : 4

Date : 31-Aug-2015

Page 1 of 12

Distribution Summary

This is a preliminary report.

Please check the completeness and accuracy of your data - additions and amendments may be made via the Results button.


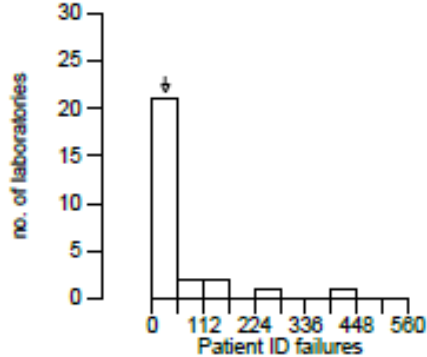
Thank you!

Barbara De la Salle and David Bullock  
29 September 2015

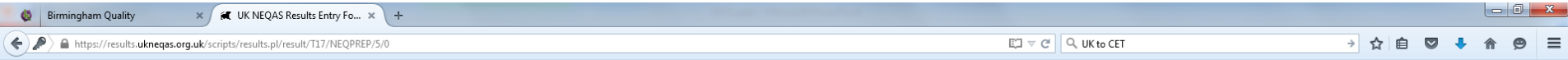
	Failures	Opportunities	Defects/million	Yield	Sigma
Patient ID failures	3	84189	35.6	99.996	5.47
Sample ID failures	3	84189	35.6	99.996	5.47
Sample type/container failures	122	84189	1449.1	99.855	4.47
Sample volume failures	7	84189	83.1	99.992	5.26
Sample time/temperature critical failures	OMIT				
Blood sciences quality rejections					
Microbiology quality rejections	256	84189	3040.8	99.696	4.24
Contaminated blood cultures					
TAT failures					
Corrected reports					
Critical value reported over 1 hour from validation					



# NEQAS Scheme

	Pre & Post Analytical Quality Monitoring Service		Test site :								
	Distribution : 4	Date : 31-Aug-2015	Page 2 of 12								
	Analyte : Patient ID failures										
Spec. Pool	Pool description / Treatments / Additions		<input type="checkbox"/> All methods  Your A score is Your B score is Your C score is  The A limit is The B limit is +/- The C limit is								
<b>Specimen : Extend Pilot</b> All methods [ALTM]	<table border="1"> <thead> <tr> <th>n</th> <th>Mean</th> <th>SD</th> <th>CV(%)</th> </tr> </thead> <tbody> <tr> <td>27</td> <td>50</td> <td>95</td> <td>189.9</td> </tr> </tbody> </table>	n	Mean	SD	CV(%)	27	50	95	189.9		Your result 3  Target value ()  Your specimen: %bias transformed bias Accuracy Index  Method Principle mean [GLTM]  Method mean [MLTM]
n	Mean	SD	CV(%)								
27	50	95	189.9								

# NEQAS SCHEME



United Kingdom National External Quality Assessment Schemes

[UK NEQAS Website](#) [Results and Reports](#) [Switch Lab/ID](#) [Help](#)

## Results Entry

Scheme: **Pre & Post Analytical Quality Monitoring Service**  
 Distribution: **5**  
 Input from: **01-10-2015**  
 Return results: **30-11-2015**

Laboratory: **T17**

Mnemonic:

	Extend Pilot		Extend Pilot
Period covered (days)	<input type="text"/>	Total microbiology samples received	<input type="text"/>
From (dd/mm/yy)	<input type="text"/>	Microbiology sample quality rejections	<input type="text"/>
To (dd/mm/yy)	<input type="text"/>	Total blood cultures received	<input type="text"/>
Total patient testing requests received	<input type="text"/>	Contaminated blood cultures	<input type="text"/>
Patient ID failures	<input type="text"/>	Total reports with agreed TAT	<input type="text"/>
Total samples/specimens received	<input type="text"/>	TAT failures	<input type="text"/>
Sample ID failures	<input type="text"/>	Total reports issued	<input type="text"/>
Sample type/container failures	<input type="text"/>	Corrected reports	<input type="text"/>
Sample volume failures	<input type="text"/>	Total critical values reported	<input type="text"/>
Total time/temperature critical samples	<input type="text"/>	Critical value reported over 1 hour from validation	<input type="text"/>
Sample time/temperature critical failures	<input type="text"/>		
Total blood sciences samples received	<input type="text"/>		
Blood sciences sample quality rejections	<input type="text"/>		

\* Indicates analyte for which you are not registered

Specimen received:  (dd/mm/yy)

Q1. What LIMS system is in use for your laboratory?

Q2. Do you count samples by request (ie a single accession number is allocated irrespective of how many tubes are received) or by sample tube (ie each physical sample receives a separate accession number)?

Q3. Do you record errors electronically within your LIMS, electronically in another system (eg QPulse or Datix), manually, or some combination?



# NEQAS scheme data

Do you count samples by request (ie a single accession number is allocated irrespective of how many tubes are received) or by sample tube (ie each physical sample receives a separate accession number)?	
REQUEST	23
TUBE	15

Do you record errors electronically within your LIMS, electronically in another system (eg QPulse or Datix), manually, or some combination?

# Summary

- To improve quality you must first measure it
  - Uniquely placed to collect data on sample and request quality
  - Process needs to be robust and consistent
    - Set up codes
    - automate
  - There must be a plan to act on poor data
  - Participation in an EQA scheme allows comparability with other labs and will drive down errors
- 