

# *Key Incident Monitoring & Management Systems*

## *K&MMS*

Alan Bateman





# RCPA QAP Enrolments



# *Outline*

- ❖ History / Objectives / Why
- ❖ Data from 2010 / 2011
- ❖ Reports
- ❖ Risk Matrix
- ❖ Haemolysis Survey

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# K&MMS History

## ➤ AIMS

- Voluntary reporting system

## ➤ PIMMS

- Constructed logical map of pathology processes
- Identify likely failure points

## ➤ KIMMS

- Identified highest frequency failure points & classify

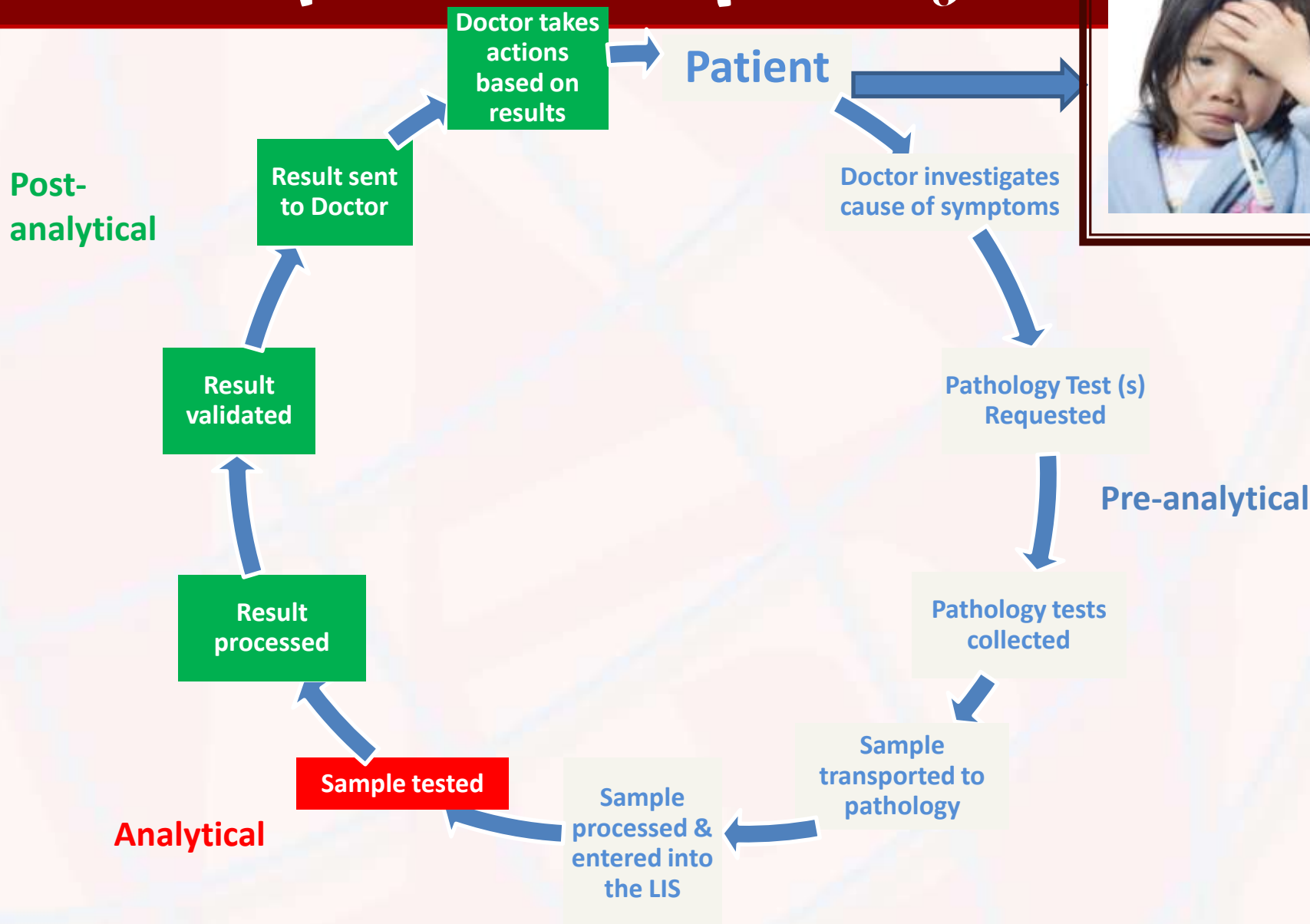
## ➤ SKIMMS

- Summary of KIMMS & very similar to this pilot
- Top 4-5 failure points identified by frequency or importance
- Pilot run through QASEC, 6 sites, 4 completed

## ➤ RCPA KIMMS QAP

- Pilots in 2007 and 2008, Full QAP program in 2009.

# Request-test-report cycle



# Recent Articles

*Currently laboratory errors occur more frequently in the extra-analytical phases"*

*Flebanì. M, Carriaro. P.*

*Clin Chem Lab Med 2004*

*"The great majority (88.9%) of quality failures occurred in the pre-analytical phase"*

*O'Kane. M. J., Lynch. P. L., McGowan. N.*

*Am Clin Biochem 2008*

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# K&M&S Objectives

- To establish a national data set for pathology incidents
- To develop the data set to enable participants to measure and monitor pathology incidents
- Set achievable, national benchmarks for good pathology practice
- Educate laboratories on methods to reduce errors
- Raise awareness of safe work practices
- Set standards for best practice

# *K&M&S Definitions*

- Definitions are provided to ensure that the same data is submitted by participants
- Definitions are continuously updated & refined to improve data quality
- Additional categories have been added to capture more specific data for example: precious samples

# Requirements

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

## REQUIREMENTS FOR PARTICIPATION IN EXTERNAL QUALITY ASSESSMENT

(Fourth Edition 2009)

1.	Enrolment in external quality assessment programs .....	4
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NPAAC Tier 3 Standard

**National  
Pathology  
Accreditation  
Advisory  
Council**

# Requirements

## 3. Pre-analytical quality assessment

**S3.1 Documented procedures must be in place for quality assessment of the pre-analytical phase.**

C3.1 Variables which can adversely affect the pre-analytical phase of laboratory testing can include, but are not limited to:

- (a) patient identification
- (b) patient preparation and pre-test information
- (c) confirmation of test requests
- (d) procedures for correct specimen collection
- (e) recording endogenous variables, e.g. drugs, circulating antibodies
- (f) required specimen labelling
- (g) recording of specimen integrity including correct tube fill, haemolysis, lipaemia, icterus
- (h) incorrect specimen collection
- (i) correct specimen transport
- (j) relevant turn around time from collection to receipt and to validation.

**S3.2 The laboratory must identify, document and correct errors in the pre-analytical phase to minimise recurrence.**

**G3.1** **G3.1** Laboratories should be enrolled in an EQA program covering the pre-analytical phase. Laboratories not enrolled in an EQA program should identify high risk areas and compare their data with other laboratories to ensure they demonstrate acceptable performance.

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# *Accessions*

Run	Accessions
Run 1 2010	3,860,160
Run 2 2010	5,513,862
Run 3 2010	5,896,629
Run 4 2010	5,469,028
Run 1 2011	6,605,854
Run 2 2011	6,467,546
Total for 18 Months	33,813,079

# Method of Detection

HOW WAS THE INCIDENT DETECTED?	Jan-Mar			Apr-Jun			Jul-Sept			Oct-Dec		
	All (59)			All (70)			All (69)			All (66)		
	Count	All %	% of Accessions	Count	All %	% of Accessions	Count	All %	% of Accessions	Count	All %	% of Accessions
Complaint (always detected by those outside pathology)	1,203	3.03%	0.03%	2,698	5.33%	0.05%	3,807	5.69%	0.06%	2,420	3.90%	0.04%
Problems detected by the lab, ie by the Quality System	38,531	96.97%	1.00%	47,906	94.67%	0.87%	63,122	94.31%	1.07%	59,588	96.10%	1.09%
Total Feedback	39,734			50,604			66,929			62,008		

# Sample Misidentifications 2010

Statistics Summary KIMMS 2010	Jan-Mar			Apr-Jun			Jul-Sept			Oct-Dec		
	All (59)			All (70)			All (69)			All (66)		
PRE-ANALYTICAL (before results released)												
IDENTIFICATION PROBLEMS (count all as potential harm)	Count	All %	% of Accessions	Count	All %	% of Accessions	Count	All %	% of Accessions	Count	All %	% of Accessions
Sample suspected to be from wrong patient (wrong patients blood in tube)	241	2.19%	0.01%	999	6.45%	0.02%	1,030	5.75%	0.02%	1,060	6.04%	0.02%
Unlabelled samples	3,371	30.70%	0.09%	4,605	29.74%	0.08%	4,990	27.87%	0.08%	4,759	27.14%	0.09%
Fewer than 2 identifiers initially supplied	1,973	17.97%	0.05%	2,330	15.05%	0.04%	3,747	20.93%	0.06%	2,983	17.01%	0.05%
Any mismatch or discrepancy of identifiers (major or minor)	3,222	29.34%	0.08%	4,545	29.35%	0.08%	5,081	28.38%	0.09%	5,337	30.43%	0.10%
Any within laboratory failure of ID	119	1.08%	0.00%	139	902.00%	0.00%	263	1.47%	0.00%	253	1.44%	0.00%
Transfusion issues-not covered in other categories	1,647	15.00%	0.04%	2,057	13.29%	0.04%	2,293	12.81%	0.04%	2,483	14.16%	0.05%
Sample misidentifications not classified above	407	3.71%	0.01%	808	5.22%	0.01%	499	2.79%	0.01%	662	3.77%	0.01%
TOTAL Pre-analytical errors	10,980			15,483			17,903			17,537		
IDENTIFICATION errors as % of ACCESSIONS			0.28%			0.28%			0.30%			0.32%

# Sample Rejections 2010

Statistics Summary KIMMS 2010	Jan-Mar			Apr-Jun			Jul-Sept			Oct-Dec		
PRE-ANALYTICAL (before results released)	All (59)			All (70)			All (69)			All (66)		
<b>SAMPLES REJECTED</b>	Count	All %	% of Accessions	Count	All %	% of Accessions	Count	All %	% of Accessions	Count	All %	% of Accessions
Samples rejected due to misidentification issues	5,495	14.85%	0.14%	7,275	14.73%	0.13%	8,989	15.23%	0.15%	8,754	15.26%	0.16%
Incorrect patient preparation	168	0.45%	0.00%	183	0.37%	0.00%	451	0.76%	0.01%	604	1.05%	0.01%
Sample haemolysed	5,683	15.36%	0.15%	7,358	14.90%	0.13%	8,688	14.72%	0.15%	8,246	14.38%	0.15%
Sample clotted	4,372	11.81%	0.11%	6,134	12.42%	0.11%	6,957	11.79%	0.12%	6,729	11.73%	0.12%
Incorrect fill level of sample	2,071	5.60%	0.05%	3,760	7.61%	0.07%	2,718	4.61%	0.05%	2,569	4.48%	0.05%
Insufficient sample	2,560	6.92%	0.07%	3,307	6.70%	0.06%	5,660	9.59%	0.10%	5,808	10.13%	0.11%
Incorrect sample storage or transport	1,047	2.83%	0.03%	1,399	2.83%	0.03%	1,456	2.47%	0.02%	1,680	2.93%	0.03%
Specimen not collected	8,853	29.92%	0.23%	12,144	24.59%	0.22%	13,591	23.03%	0.23%	13,673	23.84%	0.25%
Incorrect specimen type	2,191	5.92%	0.06%	2,911	5.90%	0.05%	3,907	6.62%	0.07%	3,477	6.06%	0.06%
Registration of test error	1,658	4.48%	0.04%	1,340	2.71%	0.02%	2,607	4.42%	0.04%	1,893	3.30%	0.03%
Other (please specify)	2,911	7.87%	0.08%	3,566	7.22%	0.06%	3,983	6.75%	0.07%	3,919	6.83%	0.07%
<b>TOTAL SAMPLE REJECTIONS</b>	37,009			49,377			59,007			57,352		
<b>REJECTIONS as % of ACCESSIONS</b>			<b>0.96%</b>			<b>0.90%</b>			<b>1.00%</b>			<b>1.05%</b>

# Overall Incident Rate 2010/2011

2010				2011	
Run 1	Run 2	Run 3	Run 4	Run 1	Run 2
1.22%	1.21%	1.41%	1.39%	1.38%	1.53%



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# Web Based Report

Lab Report (Page 1) Lab Report (Page 2) Lab Report (Page 3) Lab Report (Page 4) Lab Report (Page 5) Lab Report (Page 6) Lab Report (Page 7) Lab Report (Page 8)

## PRE-ANALYTICAL PHASE

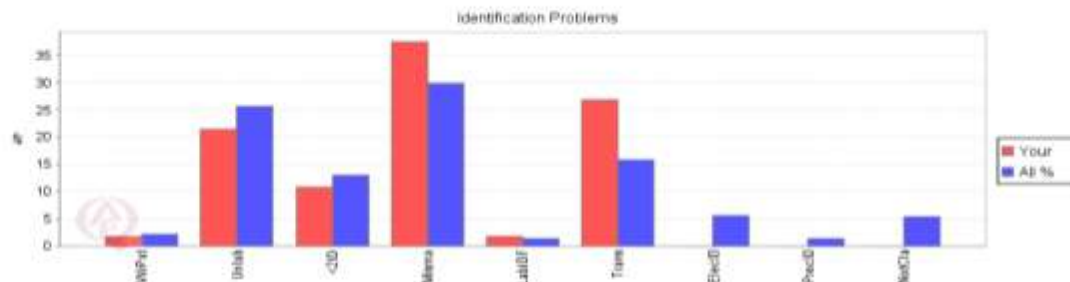
### Identification Problems

The number of participants submitting data for Run 1 2011 were similar to those at the end of 2010 with 71 submissions received. "Any mismatch or discrepancy of identifiers" was the highest reported category of identification problems for Run 1. "Unlabelled samples" and "Transfusion issues-not covered in other categories" were the other two major sources of identifications problems this Run, and these three categories continue to be the highest recorded types of identification errors.

This is the first Run where KIMMS has collected information regarding previous ID issues and ID errors on e-requests. Although there were only a few participants that reported data in these categories, it should be noted that over 800 electronic ID errors were recorded from 1 laboratory alone. This will be an interesting category to monitor.

The data from the Risk Matrix (separate sheet) shows that the two largest areas of risk for ID problems Run 1 across all data submitted are "Transfusion Samples" and "Suspected wrong blood in tube" with 4.9% and 4.3% respectively of risk across all categories.

Various ID problems were included in the sample rejection "Other" category. We will add a "specify other" category for ID for Run 2 2011 to allow participants to indicate what errors are included in the "Sample misidentifications not classified" category. Please record all transfusion ID errors in the appropriate ID category for the problem or if the problem does not fit any of the categories please record it in the "Transfusion issues - not covered in other categories".



Assessors		#000		#0001		#00000	
PRE-ANALYTICAL (before results released)		Key		Year Count		Year % Acc	
IDENTIFICATION PROBLEM (insert all as potential harm)		Year Count		Year % Acc		All Count	
Sample suspected to be from wrong patient	WPt	1	1.79	0.00	484	2.2	0.01
Unlabelled samples	Unlab	10	21.43	0.00	4,649	25.56	0.07
2 identifiers initially supplied	CID	8	16.71	0.01	2,388	13	0.04
Any mismatch or discrepancy of ID	Mism	21	37.90	0.03	5,426	29.81	0.06
Any within laboratory failure of ID	LabID	1	1.79	0.00	261	1.45	0
Transfusion samples	Trans	18	26.79	0.02	2,071	18.78	0.04
Sample misidentifications not classified	NoCI				368	0.3	0.01
ID errors e-requests	ElecID				1,080	5.91	0.03
Previous ID prob	PrevID				257	1.41	0
Total Pre-analytical errors		56			16,136		
IDENTIFICATION errors as % of ACCESSIONS					0.09		0.28

## KIMMS - 2010-4

## PRE-ANALYTICAL PHASE

## Identification Problems

'Any mismatch or discrepancy of identifiers' was again the highest reported category of over 30% of errors recorded in this category. Both the aforementioned category and 'Unlabelled samples' contributed to between 56% - 60% of the Pre-analytical identification problems reported for each run of the 2010 cycle.

As indicated in the last report, there have been some amendments made for 2011. The following two categories have been added due to their high volume/risk:

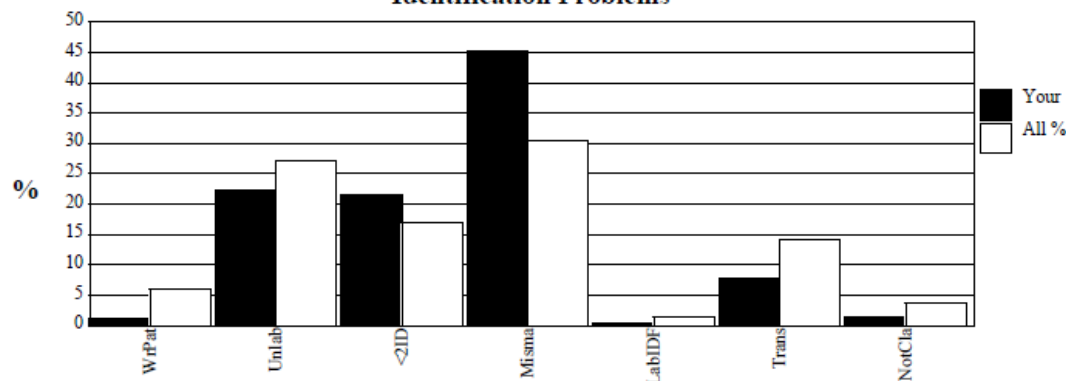
- **ID errors on electronically requested samples** - Error in one or more patient identifiers in an electronic request or an electronically requested sample
- **Precious / semi-precious unlabelled / mislabelled samples** - Any Precious / semi-precious sample or request that is mislabelled / unlabelled. E.g. fine needle aspirate, biopsy, CSF, amniotic fluid, surgical samples, cord blood, blood bank samples etc.

Due to the introduction of the above Precious / semi-precious category, the following categories have been amended accordingly:

- All other unlabelled samples
- All other samples - Any mismatch or discrepancy of identifiers (major or minor)

Please ensure you review the updated definitions / examples for the 2011 data collection cycle.

Identification Problems



Accessions 128939 All (66) 5469028

PRE-ANALYTICAL (before results released)								
IDENTIFICATION PROBLEMS (count all as potential harm)	Key	Your Count	Your %	Your % Acc	All Count	All %	% of Acc	
Sample suspected to be from wrong patient (Wrong blood in tube)	WrPat	10	1.08	0.01	1060	6.04	0.02	
Unlabelled samples	Unlab	206	22.34	0.16	4759	27.14	0.09	
Fewer than 2 identifiers initially supplied	<2ID	199	21.58	0.15	2983	17.01	0.05	
Any mismatch or discrepancy of identifiers (major or minor)	Misma	418	45.34	0.32	5337	30.43	0.10	
Any within laboratory failure of ID	LabIDF	5	0.54	0.00	253	1.44	0.00	
Transfusion samples	Trans	72	7.81	0.06	2483	14.16	0.05	
Sample misidentifications not classified above	NotCla	12	1.30	0.01	662	3.77	0.01	
<b>Total Pre-analytical errors</b>		<b>922</b>			<b>17537</b>			
IDENTIFICATION errors as % of ACCESSIONS				<b>0.72</b>			<b>0.32</b>	

## KIMMS - 2011-1

### ALL PARTICIPANTS SUMMARY:

Issue	% of Accessions	Breakdown of Problem
Pre-analytical identification problems	0.28	1 in 3 sample misidentification problems are due to a mismatch or discrepancy of ID 1 in 4 sample misidentification problems are due to unlabelled samples 1 in 6 sample misidentification problems are due to transfusion samples not otherwise classified
Pre-analytical rejections	1.02	1 in 5 samples are not collected 1 in 5 samples are haemolysed 1 in 8 samples are rejected due to misidentification issues
Post-analytical incidents	0.08	3 in 5 post-analytical incidents are due to "Report retracted because of an error after release"
Overall incident rate	1.38	71 laboratories recorded 90883 incidents from 6605854 accessions.

#### COMMENTS:

**Further information on the following:**

**How the incident was detected?** The laboratory quality systems captured 95% of incidents.

**Major areas of risk?** Haemolysed samples and Report retractions were the areas of greatest risk for this survey (see risk matrix)

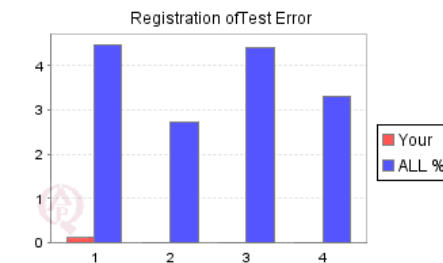
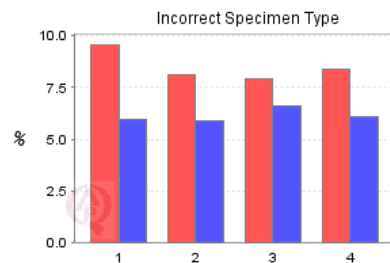
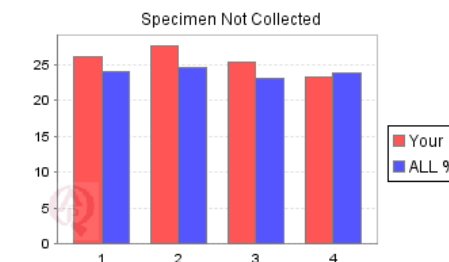
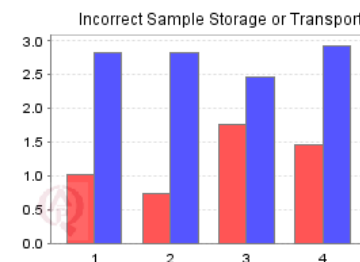
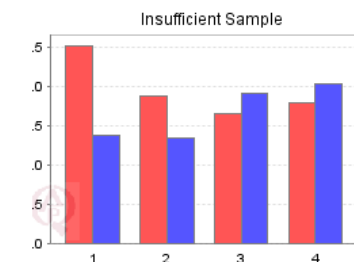
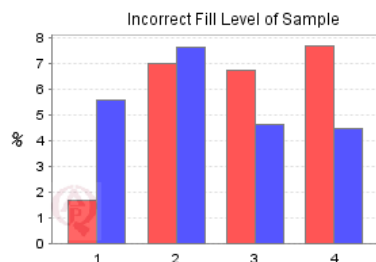
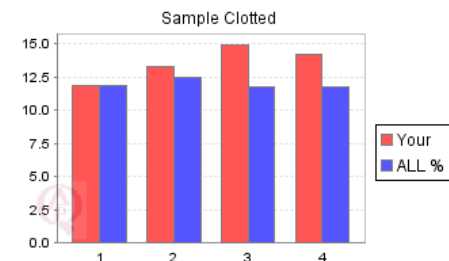
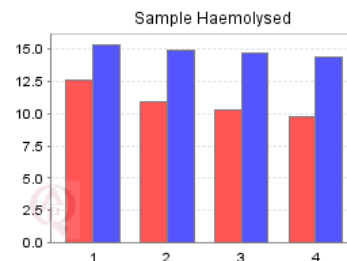
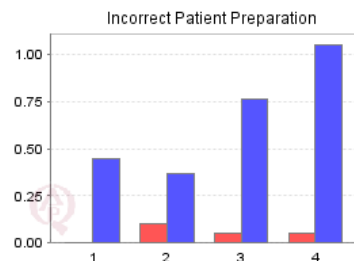
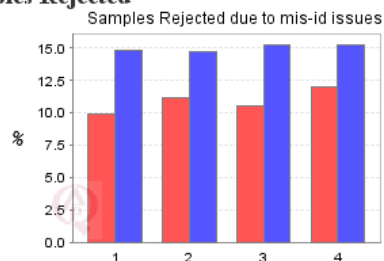
**Root cause of incident?** 60% of incidents had their source outside the laboratory, so pathology needs to focus their attention to these areas.

### Key Incident Monitoring & Management Systems

# Cumulative Report

## C-PreAnalytical Samp Reject

### Samples Rejected





# Other Reports

- ❖ Top 3 Graphs – Development / Improvement
- ❖ Comparison Graphs – Testing Phase
- ❖ Supervisor Reports – Testing phase

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- ❖ Haemolysis Survey

# *K&MMS Risk Matrix*

A Risk Matrix has been developed to replace the Harm Categories used by KIMMS.

Old Categories:

- Actual harm
- Potential harm
- Recollection Risk

# K&MHS Risk Matrix

PRE-ANALYTICAL IDENTIFICATION INCIDENTS	Run 1	Run 2
Sample suspected to be from wrong patient (Wrong blood in tube)	4.30%	3.00%
Transfusion samples	4.90%	5.10%
TOTAL IDENTIFICATION INCIDENTS	15.30%	13.70%

# K&MHS Risk Matrix

PRE-ANALYTICAL SAMPLES REJECTED	Run 1	Run 2
Sample haemolysed	21.60%	26.60%
Incorrect fill level of sample	4.50%	3.90%
Specimen not collected	6.10%	5.60%
Registration of test error	7.60%	8.20%
TOTAL SAMPLES REJECTED	61.40%	63.80%



# K&MHS Risk Matrix

POST ANALYTICAL	Run 1	Run 2
Report Retracted	17.80%	18.00%
TOTAL POST ANALYTICAL	23.40%	22.60%

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# Haemolysis Survey

- One of the biggest problems identified to date for Sample Rejections is **haemolysed samples**
- Data being returned for this category appears to be inconsistent with some laboratories not reporting Haemolysis if some tests were performed.
- The RCPA KIMMS QAP surveyed laboratories to assist in the development of a haemolysis position statement.

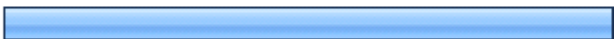

# Haemolysis Survey

## 24. Does your laboratory submit data to KIMMS QAP?

		Response Percent	Response Count
Yes		37.2%	42
No		62.8%	71
answered question			113
skipped question			201




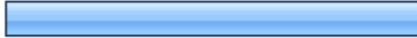
# Haemolysis Survey

**4. Does your laboratory have a reject/accept policy for haemolysed samples? (where "sample rejection" is "no analytical result reported for any requested test on the accession").**

		Response Percent	Response Count
Yes		81.3%	244
No		18.7%	56
answered question			300
skipped question			14









# Haemolysis Survey

## 6. How do you determine if a sample is haemolysed?

		Response Percent	Response Count
No formal method in place		3.3%	10
Visual check – unaided		32.1%	96
Visual check – comparison to a colour chart		9.4%	28
Haemolysis Index – as per laboratory instrumentation		55.2%	165
answered question			299
skipped question			15

# Haemolysis Survey



9. What percentage of haemolysed samples originate from the following areas of your institution? (e.g. Emergency 50%, Surgical 10%)

		Response Percent	Response Count
Emergency Department		73.3%	165
Maternity Ward		32.4%	73
Paediatric Ward		42.7%	98
Intensive Care Ward		44.4%	100
Surgical Ward		40.9%	92
Outpatients		40.4%	91
General Practitioners		53.3%	120
Collection centres		59.1%	133
answered question			225
skipped question			89



# Haemolysis Survey

## 19. How are haemolysed samples recorded?

		Response Percent	Response Count
Recorded manually		28.4%	25
Code added to LIS – extract data for review		71.6%	63
	Other (please specify)		11
	answered question		88
	skipped question		226

# Australian Pre-analytical Network

## Knowledge creation and innovation

"Our members come from broad industry backgrounds with a range of experiences to share".

"Changes are occurring all of the time in our industry as technology, the political arena, and perhaps more importantly, attitudes, change".



### Best Practice

"As an independent forum, we can provide the platform for our members to share their quality and best practice ideas"



Australian  
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**Network**



APaN

[www.apan.com.au](http://www.apan.com.au)

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# Acknowledgements

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# Questions



# Thank You!

