MONITORING ERROR IN THE MEDICAL LABORATORY –

A REVIEW OF THE BC PATIENT SAFETY AND LEARNING REPORTING SYSTEM

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BC PATIENT SAFETY & QUALITY COUNCIL
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Laboratory Error

- 80-90% of all diagnosis are made on the basis of laboratory tests.
- Medical error (IOM): failure of a planned action to be completed as intended
- Laboratory error: any quality failure within the complete pathway from test selection to the return of an appropriately interpreted report.

Identification of Errors in the Clinical Laboratory

- Quality cannot be improved without being measured.
- Incident Report System (IRS); reporting system for collecting data about safety events (incidents).
- Important tool in improving patient safety as it helps identify weaknesses in the system.

BC Patient Safety & Learning System

- Laboratory safety events represent 11% of the more than 250,000 records in the provincial database and are the fourth most frequently-reported type of problem.

Laboratory Error – BC PSLS

- 12,278 safety event reports in the Laboratory category
- 75 hospital-based laboratories in BC
- Included hazards, near misses, and adverse events
- Variables analyzed:
  - Phase of testing process involved
  - Specific problem that occurred
  - "Near miss" or Not near miss
  - Degree of harm to patients

Point of Testing Process

Process		BCPSLS	Carraro, 2007	Plebani, 2006
Pre-analytic	Collections (51%)	76%	62%	70%
	Order processing or handling (25%)			
Analytic		6%	15%	
Post-analytic		18%	23%	30%

- Most laboratory errors occur in the pre-analytical phase

Carraro, P. (2007) Errors in a Stat Laboratory: Types and Frequencies 10 Years Later. Clin. Chem. 53(7)

Plebani, M. (2006) Errors in clinical laboratories or errors in laboratory medicine? Clin. Chem. Lab. Med. 44 (6)750-759

Pre-Analytical

Pre-analytic Process (collections)	%
Unlabelled/mislabelled sample	16.8
Lost/ leaky/ insufficient/ empty/compromised sample	10.1
Delay in sample collection/delivery	8.4
Incorrect procedure/collection time/delivery	5.3
Incorrect patient/body part/sample type	4.5
Sample / requisition discrepancy/ no requisition	2.3
Other	3.7
Total	**51.0**
Pre-analytic Process (clerical/order entry)	**%**
Incorrect test/product ordered; test ordered on incorrect patient	8.8
Incomplete or incorrect information in order/requisition	7.4
Order not combined/processed; duplicate order/no requisition	6.5
Other	2.6
Total	**25.3**

Analytical

Analytical Process	%
Incorrect triage, sorting, direction or handling of sample in lab	1.3
Delay in processing	1.3
Procedure not followed	1.0
Specimen / block / slide mislabelled in lab/damaged	0.9
Instrument / analyzer error	**0.4**
Other	0.7
Total	**5.6**

Post-analytical

Post-analytic Process	%
Incorrect results reported	10.0
Higher than expected turnaround times for results or products	4.2
Results reported to or on incorrect person	2.2
Other	1.5
Total	**17.9**

Approximately 40% of reports filed under "Incorrect results reported" were microbiology results.

Identification errors

- Unlabelled or mislabelled samples → 16.8%
- CAP study*: 1 in 18 identification errors resulted in averse event
- BC PSLS: 1 in 6 (minor – severe), 1 in 61 (moderate to severe) identification errors resulted in adverse event

Identification error	BC PSLS	CAP*
Primary specimen label error	66.1%	55.5%
Initial registration/order entry error	26.6%	22.4%
Other clerical error		12.4%
Other reason for error		4.2%
Aliquot/block/slide label error	1.9%	3.8%
Result entry error	5.4%	1.7%

*Valenstein P. (2006) Identification Errors Involving Clinical Laboratories Arch. Pathol. Lab. Med. Vol 130

Taxonomy

Point of testing process

- Pros:
  - Easy to apply
  - Reproducible
  - Identifies the step on which attention should be focused
- Cons:
  - Does not consider the causative nature of the quality failure

Causation

- Cognitive / Non-cognitive
- Latent / Active
- Preventable/ Non-preventable
- Cons:
  - More difficult to apply

Taxonomy

Degree of harm

Degree of harm	%	O'Kane	Astion
1 - No harm	80.3	75.1	95%
2 - Minor harm	16.7	6.4	5%
3 - Moderate harm	2.8	18.5	
4 - Severe harm	0.2	0	
5 - Death	0	0	

O' Kane M. (2009) The reporting, classification and grading of quality failures in the medical laboratory. Clin. Chim. Acta 404: 28-31

Astion M.L. (2003) Classifying Laboratory Incident Reports to Identify Problems that Jeopardize Patient Safety. Am. J. Clin. Pathol 120: 18-26

Specific harm

367/12278 (3%) events were associated with moderate to severe harm

Specific harm
wrong treatment
patient not properly followed up
patient unnecessarily treated
altered management of pregnancy
patient unnecessarily transfused
patient underwent tubal ligation while pregnant
unnecessary mastectomy
unnecessary removal of prostate
unnecessary surgery
patient arrested
patient died

Taxonomy

Degree of harm - Actual vs. Potential harm

Actual harm

2 prostate biopsies results – Patient A: carcinoma, Patient B: benign

Patient A: radical prostatectomy → reveals no carcinoma

Review patient B: carcinoma

Transcription error – slides were properly labeled.

Potential harm (1 – 4?)

PAP smear results entered on wrong patient history (same last name)

Potential harm

- O'Kane: 67.9% skewed heavily in favor of high potential adverse impact.
- BC PSLS: only 4% moderate – severe potential harm

Near Miss

- Incident that could have caused harm but did not.
- Much more frequent (7 – 100 times) than adverse events.
- Indicators of areas of increased risk.
- 'Cheap' learning tool
- Underreported

Near miss

- BC: 12278 events reported
  - 8568: NOT a near miss (70%)
  - 3710: Near miss (30%)

Degree of harm	Near miss	
	Yes (30%)	No (70%)
1 - No harm	89	72
2 - Minor harm	7	24
3 - Moderate harm	3	4
4 - Severe harm	1	0

Near miss

- *"Patient had no ID band. Lab confirmed patient ID & birth date prior to collection."*

  Near miss? 80% NO 20% YES

"People should know how to report a near miss as well as they know how to press the fire alarm." Ritwik

Ritwik U. Risk-based approach to near miss. Hydroc. Proc. Oct. 2002

BC PSLS - Incident Follow up

- Event reviewed by leader
  - No harm / Minor harm → tracked and trended
  - Moderate harm → analysed by leader; choose appropriate action
  - Severe harm → specific, formal process; critical event investigation
- Action taken
  - 64% recorded an action

Lack of feedback

- *"I would appreciate being contacted to learn what actions are being taken. A lack of response will indicate to me that no action is being taken. I hope you'll excuse my tone but I have some skepticism that these reports are read by anyone."*

  Medical professional

- No record of any action taken

Challenges of IRS

- Barriers to reporting
  - Lack of feedback
  - Fear of negative action
  - Too trivial to merit reporting, "Quick fix".
  - Inadequate system
  - Lack of action
- A stronger link is needed between identifying and mitigating hazards.

Path forward

- Commitment to Patient Safety Culture
  - Encourages identification, communication, and resolution of safety issues
- There must be tangible evidence that quality failure reporting results in action.
- Patient safety incident reporting needs to move from being a research tool to being embedded in health systems.

Thank you!

"What is not reported cannot be thoroughly investigated.

What is not thoroughly investigated cannot be changed.

What is not changed cannot be improved."

Centre for Chemical Process Safety