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Observational Study Examining the Impact Of Dried Tube Technology On Annual Process Time and Error-Prone Steps In Flow Cytometric Immunophenotyping

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Introduction

- In Canada, hematological malignancies make up 9% of estimated direct healthcare costs related to cancer of $3.8 billion.[1]
- The diagnosis of hematological malignancies relies on multiple modalities, including flow cytometry, which historically lacks a standardized workflow that can generate sources of error in both optimal antibody selection and the (manual) pipetting of reagents.[2]
- There is a substantial economic impact due to indirect costs in laboratory developed tests in flow cytometry laboratories. [3]
- Insufficient published evidence exists that quantifies inefficiencies and potential error-prone tasks.

Objective

This serialized observational study, using Lean methodology, was designed to quantify the impact of dried antibody technology, specifically custom BD™ Lyotubes*, on annualized process time and effect on the reduction of error-prone steps. Both of these metrics can help define the quality and productivity of human resource use.

Method

- Two successive observational studies using Lean principles were performed in a public Canadian acute care flow cytometry laboratory. Workflow tasks from sample preparation through to analysis, were videotaped, reviewed and mapped during both pre- and post-implementation of custom BD Lyotube antibody tubes. Pre-implementation data gathered in April 2015 established baseline test metrics utilizing in-house liquid reagent cocktails with post-implementation comparison data collected October 2016. Total process time, hands-on-time, manual steps and error-prone tasks were quantified.
- Evaluated processes included in this analysis are compensation, sample preparation, cocktail and reagent preparation, and running of patient samples (screening and reflex tubes).
- Total opportunities for error in the workflow were identified as steps involving the manual efforts of pipetting, dispensing reagent, and labelling tubes.
- Annual estimates were based on monthly compensation, 48 screening tube cocktails produced, and 50% of annual screening test volume (lymphoid and myeloid lineages) subjected to reflex testing.

Out of Scope:

- Evaluation of error-prone steps did not include tasks with inherent subjectivity, such as analysis and reporting.
- Investigating errors, such as troubleshooting incorrectly pipetted antibody cocktails or potential specimen-collection irregularities, were not included in the processing-time portion of this study.
- Process time for inventory management and error-prone steps in logging or quality control of reagents were not measured.

Conclusion

Implementation of BD™ Lyotube technology demonstrated a beneficial impact that was quantifiable for both annual process time and annual error-prone steps. In these four workflow processes alone, a 17.6% recovered process time enables the laboratory to better manage increasing test volumes or explore the development of additional flow cytometric tests with existing human resources. Furthermore, error-prone steps were reduced in the most common task, running the *screen test,* realizing a reduction of 55.6%. Lean methodology provides a meaningful tool in assessing direct impact to productivity and effectiveness and would be valuable in measuring additional aspects of resource utilization in the flow laboratory.

*** BD Lyotubes are BD customer designed tubes labeled for research use only.**

Workflow in Flow Cytometric Immunophenotyping

Setup: Instrument Compensation
- Label tubes
- Dispense capture beads
- Pipette antibodies

Sample Collection and Preparation
- Collect specimen
- Prepare Specimen
- Do cell counts

Screening Test and Cocktail Prep
- Label cocktail vial
- Pipette antibodies to cocktail
- Log reagent lot used

Run Screen Test
- Pipette out cocktail
- Add sample
- Acquire sample
- Analyze and print

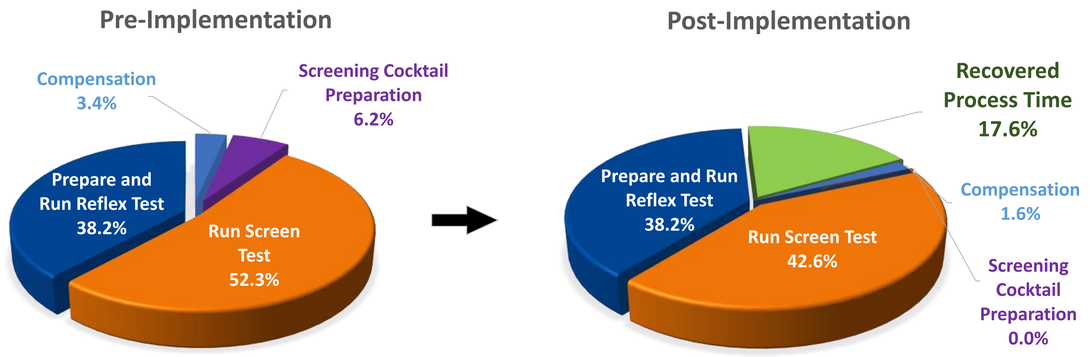
Run Reflex Test
- Pipette out antibodies
- Log reagents
- Add sample
- Acquire sample
- Analyze and print

RESULT: Annual Recovered Process Time

BD Lyotube technology impacted time in three of the four baseline workflow processes: *screening cocktail preparation* time was eliminated; *compensation* time was reduced by 51.7%; and hands-on time in *running screen tests* (including analysis time) was reduced by 18.5%, impacted by the elimination of pipetting cocktails. *Prepare and run reflex testing* time was unaffected.

Measured process time for these four processes demonstrated an overall recovery of annual process time of 17.6%; the majority owing to reduced hands-on time *running screen tests* at 9.7%, 6.2% was from eliminating *screening cocktail preparation*, and 1.8% from a reduction in time spent performing *compensation*.

Step	% Total Annual Time for Manual Steps		% Change in Time
	Study No.1	Study No.2	
Compensation	3.4%	1.6%	51.7%
Specimen Preparation	45.2%	45.2%	0.0%
Screening Cocktail Preparation	6.2%	0.0%	100.0%
Run Screen Test	52.3%	42.6%	18.5%
Prepare and Run Reflex Test	38.2%	38.2%	0.0%

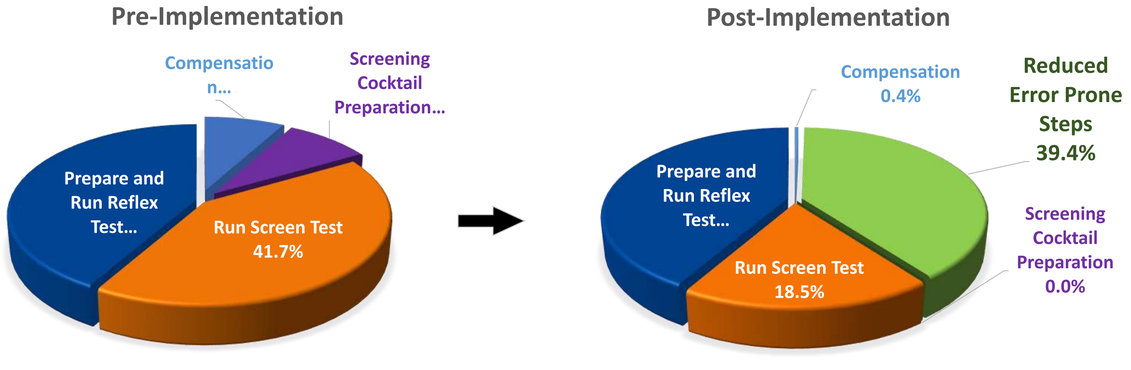


RESULT: Annual Error-Prone Step Reduction:

Of the four workflow processes assessed in pre-implementation, a majority of total error-prone steps measured were credited to *running the screen test* and subsequent *reflex (add-on) testing* at 83.4%. In post-implementation, 100% of the error-prone steps associated with *creating the cocktail* were eliminated while the *preparation and running of reflex testing* was not impacted. Error-prone step reduction in *compensation* tasks and *running the screen test* were quantified at 95.3% and 55.6% respectively.

Of the three impacted processes (compensation, screening cocktail preparation, and running screen test) a substantial annual error-prone step reduction of 67.6% (from 7443 to 2412) was observed, with the remaining error-prone steps still attributed to *running reflex tests*.

Step	Total Annual Error Prone Steps		% Error Prone Reduction
	Study No.1	Study No.2	
Compensation	1020	48	95.3%
Screening Cocktail Preparation	1104	0	100.0%
Run Screen Test	5319	2364	55.6%
Prepare and Run Reflex Test	5319	5319	0.0%
TOTAL	12762	7731	NA



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