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.[3]
- 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.[4]
- There is a substantial economic impact due to indirect costs in laboratory developed tests in flow cytometry laboratories.[5]
- 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 annual process time and 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 tests).
- 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.

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 77.6%; 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.

<table>
<thead>
<tr>
<th>Step</th>
<th>% Total Annual Time for Manual Steps</th>
<th>% Change in Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compensation</td>
<td>3.4%</td>
<td>51.7%</td>
</tr>
<tr>
<td>Specimen Preparation</td>
<td>45.2%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Screening Cocktail Preparation</td>
<td>6.2%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Run Screen Test</td>
<td>52.3%</td>
<td>18.5%</td>
</tr>
<tr>
<td>Prepare and Run Reflex Test</td>
<td>38.2%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Total Annual Error Prone Steps</th>
<th>% Error Prone Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compensation</td>
<td>1020</td>
<td>95.3%</td>
</tr>
<tr>
<td>Screening Cocktail Preparation</td>
<td>3104</td>
<td>100.0%</td>
</tr>
<tr>
<td>Run Screen Test</td>
<td>5319</td>
<td>55.6%</td>
</tr>
<tr>
<td>Prepare and Run Reflex Test</td>
<td>5319</td>
<td>0.0%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>12762</td>
<td>NA</td>
</tr>
</tbody>
</table>

REFERENCES:

2. Becton Dickinson and Company, Mississauga, ON, Canada.
3. St. Michael’s Hospital, Toronto, ON Canada.

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