Power of lean methodology in clinical laboratory application, a story of process improvement

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Abstract

We use flow cytometry crossmatch (FCXM) assays to deliver the final compatibility check, which enables clinicians to decide whether to proceed or withdraw organ transplantation as a therapeutic modality. The FCXM is time consuming and in an effort to improve the process, we implemented a lean approach to optimize the assay, focusing on cell isolation cycle time.

The impact was a 18% reduction in TAT

Improvement in patient experience using 50% less blood volume

The time saved at the start of the process provided the transplant team with more time to support decision making related to the transplant process.

Background

FCXM is decision tool enabling 'go, no-go' decisions to be made. It is lengthy to perform predominantly related to the cell isolation process which is a pre-requisite to the test. Previously, we used a density gradient method to isolate cells which took 75 minutes of process time, yielding a purity of approximately 90%.

A downside of this method is a minimum requirement of 32 mL of blood for the FCXM assay.

Plan Explore opportunity

In an effort to improve the process and reduce the time and volume of blood required, we explore employing an alternative pre-analytic cell isolation methodology that current literature supported as superior aiming to:

Reduce test cycle time

Improve patient experience

Do Implementation

We validated a new cell isolation method (EasySep direct lymphocyte enrichment) that required:

16 ml blood

30 minutes cycle time

As shown in figure1:

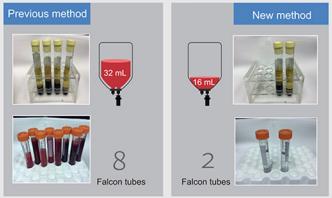

Figure 1. Blood volume comparison between the previous and new cell isolation methodology for FCXM

Check Results

We compared Cycle Time (CT) "processing" and Takt Time (TT) "sample received to verified" before and after change (figure 2 &3). Blood volume difference was calculated (Figure 4)

Act Adopt

Lean offers a powerful set of tools for laboratories to use.
The new method (EasySep direct lymphocyte enrichment) was subsequently adopted which resulted in:

- Reduced pre-analytical process time from 75 down to 30 minutes (60% reduction).
- Better patient experience due to less blood being taken (50% less blood volume required).

HLA Laboratory technologists and management were thrilled with the change as on-call time decrease by an hour, improving work-life balance.

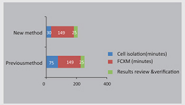

Figure 2. Process time in minutes for the previous and new methods, with time on the x-axis.

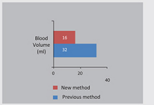

Figure 3. Difference In blood volume collection between the previous and new methods with volume on the x-axis

	Previous method	New method	Difference
Cycle Time (CT)	224 minutes	179 minutes	45 minutes (20%) reduction
Takt Time (TT)	249 minutes	204 minutes	45 minutes (18%) reduction
Blood volume collected	32 ml	16 ml	16 ml (50%) reduction

Table 1. Summary of differences between the previous and new methods for Cycle Time (CT) and Takt Time (TT).