



LifeLabs and ColonCancerCheck Program

Executive Summary

In January 2008, the Ministry of Health and Long-Term Care (MOHLTC), in collaboration with Cancer Care Ontario (CCO) launched **ColonCancerCheck** (CCC), a provincial screening program designed to detect colorectal cancer at an early asymptomatic stage, thereby reducing the rate of mortality. One of the ways the program supports this goal is by providing funding to screen all average risk men and women 50 years and older using the Fecal Occult Blood Test (FOBT). When caught early through regular screening, the mortality rates due to colorectal cancer will be reduced.

LifeLabs is a Canadian company with nearly 50 years experience serving the health needs of Canadians providing laboratory testing services, which help physicians and other healthcare providers in the prevention, diagnosis, treatment and monitoring of disease and illness in patients. LifeLabs is part of the ColonCancerCheck program assisting physicians and pharmacists in supporting the needs of patients under the ColonCancerCheck program by:

- **Distribution:** Supplying the Fecal Occult Blood Testing (FOBT) collection kits used exclusively for individuals who qualify under this program;
- **Testing:** Processing FOBT using the new standardized kit for patients referred to us for testing under the ColonCancerCheck program; and
- **Information Management:** Delivering the results of ColonCancerCheck FOBT to physicians and to Cancer Care Ontario

Most LifeLabs departments collaborated to operationalize ColonCancerCheck into the business, including Operations (Client Services & Testing), Medical-Scientific personnel, Quality and Regulatory Affairs, Supply Chain Management, Lean Sigma, Human Resources, Information Technology, Communications and Finance.

LifeLabs' St.Catharines (Schmon Parkway) testing laboratory was chosen as a Centre of Excellence in colorectal screening because of its ability to accommodate the anticipated volumes, its experience handling fecal occult blood testing and its consistent delivery of high level of quality service.

Delivery of specimens was set up so that completed ColonCancerCheck kits could be sent by the patient via Canada Post to Schmon Parkway, dropped off at any one of LifeLabs' 130 Patient Service Centres (PSCs) throughout Ontario or picked up by LifeLabs' couriers at physicians' offices. Completed kits that are left at the PSCs or doctors' offices are then placed in clear interoffice envelopes and transported once a day to the testing site. CCC tests are data entered into a separate Intrlab module (LifeLabs' Laboratory Information System) by data sort staff. Test results are reported to the ordering physician and are uploaded daily to Cancer Care Ontario.

It was recognized early on that the current process was not necessarily going to be appropriate for the new program due to volume and result reporting expectations. A Kaizen (a change for the good) event was initiated to take the program requirements and modify the existing process to provide a more efficient and effective process for the program. The event was based on the SCORE™¹ methodology (Select - Clarify - Organize - Run – Evaluate) where Principles of Lean are combined with the structure of Six Sigma to deliver a more formalized approach to implementing and measuring the success of the program.

¹ Trade mark of Breakthrough Management Group International

Having identified a clear business need, Lean Sigma resources were allocated to facilitate the Kaizen event. The first step was to review the existing process with the personnel at the St. Catharines Testing Laboratory which was to become the central processing location (Appendix 1). Video was taken of the existing process and initial measurements on cycle times, resources, physical steps and process steps were generated. A value-stream map, spaghetti diagram and process map were the tools used to capture this information.

After the initial data collection was done on the existing process, further clarification was achieved by seeking out the new program requirements. With the program information and process information in hand, a three-day event was scheduled and conducted.

The three day event involved members from Operations (both client services and testing), Environment, Health and Safety, Quality and Regulatory Affairs and Lean Sigma. The group reviewed all the initial process information and conducted some validation of process steps during the event. The group was challenged to then modify the existing process to reduce the waste identified in the process and incorporate the program requirements into the new design. The group modified layout, equipment, job functions, data entry and results reporting to achieve the final design. Once finished with the new design and a simulation was run to ensure the expected benefits of the new process were achieved. On completion of the Kaizen event an action list was given to the team for implementation. (Appendix 2). The end result of the work was a reduction in cycle time per test by 279% improvement, Value Added Steps improvement from 1.21% to 3.38% (279% improvement) and reduced physical movement from 4888 steps to 1501 steps (326% improvement). (Appendix 3)

In order to ensure that our employees were adequately trained to the methodology used to develop and interpret the slides used for the Colon Cancer Check program, an extensive training program was designed and implemented.

Job specific trainers, seniors and supervisor were brought into the central testing laboratory (IRL) for a one day session put on by Immunostics; the vendor of the Colon Cancer Check program FOBT kits. The session was comprised of both theory and hands on use of the kit.

During this session participants were required to develop and correctly interpret slide cards that had been impregnated with various quality control samples. Participants were tested on the theory as well as their ability to accurately interpret the results during the hands on portion of the day.

Detailed Standard Operation Procedures (SOPs), training modules, job aids and direct observation competency checklists were developed by QRA based on the OAML approved CCC-FOBT templates. Written quizzes based on the SOPs as well as a slide image quiz were designed and published in the learning management system (LearnShare) to assess competency of staff who would be performing the test.

Quality and Regulatory Affairs (QRA) visited the location to review the SOPs, as well as the training and competency assessment checklists and quizzes for employees not able to attend the vendor training. All employees working in the CCC-FOBT program were trained on the LifeLabs SOPs and training documents and assessed to ensure their competency before being assigned to the bench.

Results of the effort were fully realized in April 2008, when the program was initiated. Review of the results indicated the benefits were being delivered as expected.

Kaizen Event Overview

Business Case

The new FOBT program being implemented by the Provincial Government is a significant opportunity to increase revenue for the business as well as an opportunity for the business to show it can deliver value to the Provincial government with new testing programs. Since the Provincial Government is our largest customer, it is clear that addressing these issues is a business priority. Also, increasing revenue growth is a key objective for the organization.

Voice of the Customer (VOC)

The Provincial Government is the main customer of this process. On-going communications with their FOBT program representatives has given us a clear understanding of their needs. Their measures have been clearly identified and reporting considerations have been taken into account with the new process requirements.

Problem Statement

A new FOBT program is being initiated by the government with start-up for April 2008. The program will involve significant new volumes and require changes in the process activities to meet requirements. The current process also has several inefficiencies which need improvement. These include excessive movement, low value add activities and high labour requirements.

Goal/Objective Statement

Improve Value Added vs. Non-Value Added activities from 1.21% to 2.06% by April, 2008

Reduced number of steps from 4888 to 1466.4 by April, 2008

Maintain current cycle time of processing tests by April, 2008

Scope

The project is limited to the FOBT program testing. There is current FOBT testing but this was kept out of scope for the purpose of this kaizen event. Non-program FOBT testing would be moved to a process similar to program work at some point. The process of delivering samples to the location remains out of scope but everything from the point of delivery at the facility to the final result being reported is in scope. This clear scope should ensure against any creep in new requirements or additional items to consider. There are virtually no constraints to the process other than the timeline. There is a firm April, 2008 start date for the program.

Benefits - Primary and Secondary Metrics

Primary/Secondary Metric	Baseline	Actual	Goal	% Improvement Toward Goal
Value Add vs. Non-Value Add Work	1.21%	3.38%	2.06%	279%
Reduce # of Steps	4888	1501	1466.4	97.7%

Summary of Changes Made to Affect Improvement

The following changes were implemented that allowed the system to realize its current benefits:

- Layout of process area
- Cell design concept for additional capacity
- Implemented smaller batch sizes to meet test result determination criteria
- New electronic pipette to reduce repetitive strain injury
- Trays to support easy transport of test batches
- Implemented batch reporting at time of resulting
- Had technicians apply solution to test slides vs. technologist, which are a scarce skill resource
- Batched daily work to optimize resource work hours while maintaining process time requirements

Timeline

Completion dates and project's major milestones and deliverables

	Start	Select	Clarify	Organize	Run	Evaluate
Planned:	Jan 30, 08	Jan 30, 08	Feb 6, 08	Feb 12, 08	Feb 13, 08	April, 08
Actual:	Jan 30, 08	Jan 30, 08	Feb 6, 08	Feb 12,08	Feb 13, 08	April, 08

Team Members for Kaizen Event

Name	Functional Area	Expertise
Joanna Ellis	RBM	Operations
Pam Williams	RBM	Operations
Frank Colosimo	Testing Supervisor	Operations
Lucy Cortina	Data Entry Supervisor	Operations
Angela Woodcock	Client Services Manager	Operations
Adina Nenu	FOBT Testing	Operations
Louise Wynne	EHS	Ergonomics
Mary Costantino	QRA	Quality Requirements
Tracey Watson	FOBT Testing	Operations
Teresa Collevocchio	FOBT Testing	Operations
Michael Hartman	Lean Sigma	MBB
Michael Mladjenovic	Lean Sigma	MBB

Other Organizational Benefits (Not measured or not measurable)

The organization recognized the benefit of using Lean Sigma tools with new process designs. This was evident in a follow-up request to consider how to improve rejection rates with the testing after initial implementation. These rejection rates were an unknown with project initiation but now have some data to support future actions.

Rejection Criteria for FOBT

An FOBT kit that is not processed due to the fact that (1) The slide card is not labeled with a name and/or date of birth, (2) The name and/or date of birth on the slide card and the requisition do not match, (3) The slide card arrives without a requisition, (4) The requisition is received without a slide card, (5) The specimen is received more than 21 days from the date of first stool collection, (6) The slide has exceeded the manufacturer’s recommended expiry date, or (7) The slide card is damaged.

The top causes that created the rejected specimen were thought to be:

- Patient and physician not reading instructions
- Language barrier
- Physician Understanding
- Misinterpretation of Information
- Overall program design (visual instructions)

LifeLabs had internal sessions to determine how changes or enhancements to the program would reduce rejection rates. The solutions were prioritized based on potential impact on defects, lead-time, complexity, labour, cost and timeframe to implement. These solutions provided the basis for the recommendations shared with the MOHLTC and CCO.

In the short term, LifeLabs sent communications to their physicians who addressed “frequently asked questions” and physician and patient requirements. LifeLabs also modified SOPs to allow for re-alignment of dates as acceptable practice (i.e. use of judgment)

This includes:

- Switching of month & day
- Putting current year as year of birth
- Missing the year

Continuing to communicate and educate internally and externally has helped to reduce rejection rates.

