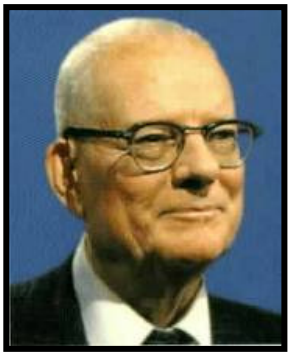
Annex 15-A: W. Edwards Deming 14 Points for Quality



1. Create constancy of purpose for improvement.
2. Improve constantly and forever.
3. Adopt the new philosophy.
4. Cease dependence on mass inspection.
5. End the practice of awarding business on price alone.
6. Institute training.
7. Institute leadership.
8. Drive out fear.
9. Break down barriers between staff areas.
10. Eliminate slogans, exhortations, and targets.
11. Eliminate numerical quotas.
12. Remove barriers to pride in workmanship.
13. Institute a vigorous program of education and training.
14. Take action to accomplish transformation.

Annex 15-B: Using a Lean Systems Approach to Improve Time to Reporting of Positive Blood Cultures

INTRODUCTION Leans Systems Approach (LSA) improves process by identifying each step, removing non-value added steps, and eliminating waste. The benefits of applying such principles include a more efficient and timely delivery of product. The time to reporting of microbiology results using traditional culture-based phenotypic methods is complicated by the dependence on the growth rate of organisms for both initial detection and subsequent identification, often considered the limiting factor to timely reporting. We were interested to use LSA in our laboratory to assess the impact on the time to reporting of results.

The Microbiology laboratory at Vancouver General Hospital (VGH) is a full service regional laboratory. We receive 47,000 blood cultures annually, which are tested using the BACTEC 9240 blood cultures system. Given the importance of timely blood cultures results and the numbers of blood cultures performed in our laboratory, any potential improvements in blood cultures processing would have a high clinical impact. Preliminary review revealed a delay in turn around time from first notification of a positive culture to the finalized result.

METHODS The steps of LSA were followed:
1) process selected, 2) problem statement and objectives developed, 3) team selected and trained, 4) baseline data obtained, and 5) changes implemented and evaluated during the run event.

Blood culture time to reporting was selected for the project according to the following criteria: importance of results, probability of success, visibility of impact, attitude of staff (can vs. can't), and strength of leadership. The project scope was all positive blood cultures from receipt in the laboratory to final results reporting.

Three technologists were dedicated to the project for three months, assisted by an operations director (project champion) and an outside consultant. Two months were spent studying blood cultures processing. The laboratory was cleaned, de-cluttered, and organized to achieve standardization and to decrease unnecessary waiting and motion. Process changes were introduced. The final month was spent to assess the impact of changes. Data collected pre- and post-changes were tabulated and reviewed.

All Microbiology technologists and Medical Microbiologists had the opportunity to provide feedback.

LSA principles and tools were followed. Key tools included:

- "5S" (sort, store, shine, standardize, sustain),
- value stream mapping (capture details of process),
- eliminate/reduce waste (waiting, overproduction, rework, motion, processing, inventory, intellect, transportation),
- spaghetti diagrams (map motion),
- measure times (Cycle time-from beginning to completion, Queue time-wait time between processes, Lead Time-Cycle time and queue time.)

PROBLEM STATEMENT In our laboratory, only 19% of positive blood cultures are finalized with identification and susceptibilities within 24 hours of first signal as a positive blood cultures.

PROJECT SCOPE All positive blood cultures from receipt to final results reporting.

Table 1: Work Flow for Pre-Analytic Processing of Blood cultures, Pre- and Post-LSA.

Pre-LSA: Not standardized	Post-LSA: Standardized
1. Blood cultures received in Laboratory Reception by Tube / Porter / Cooler.	1. Blood cultures received in Laboratory Reception by Tube/ Porter/ Sweeper.
2. Blood cultures sorted, NOT treated as STAT.	2. Blood cultures treated as STAT.
3. Random arrival and log-in of blood cultures in Microbiology.	3. Blood cultures delivered to Microbiology every half hour, and directly by pneumatic tube system.
4. Blood cultures loaded into BACTEC when convenient.	4. Blood cultures accessioned as priority, loaded directly.

RESULTS All steps in processing of positive blood cultures were reviewed and value stream mapping was done. Data collected to determine current state revealed that only 20% of positive blood cultures were finalized with identification as positive. Controllable steps in blood culture processing identified to have an impact on this figure were: time to accession blood cultures, time to load blood cultures into automated equipment, time to investigate blood cultures signaled as positive, review of culture for early growth to begin investigations, time to receive, review and release results of identification and susceptibility tests, the number of technologists working on blood cultures at critical points, and the order of work flow on the blood cultures bench. Results are represented in Tables 1-3 and Graphs 1-5.

CONCLUSIONS Applications of LSA have not been widely reported from Microbiology Laboratories. This study demonstrates that LSA can be used to improve the time to reporting of final blood cultures results after initial detection of a positive blood culture. In our study, the percentage of positive results finalized at 24 hours after initial identification improved from 19% to 40%. This benefit was a result of LSA applied to both pre-analytic and analytic blood cultures processes. Heightened awareness

around the importance of expedited blood cultures processing led to much improved handling from collection to entry into the BACTEC, and earlier positivity from time of collection. The blood cultures analytic process was enhanced by standardized work flow, prompt handling of positive blood cultures, early review of growth, and additional technologists assigned to the blood cultures bench during critical times.

LSA led to improvements in other VGH Microbiology processes:

- A cleaner and less cluttered environment in which to work.
- A better organized physical lay-out to decrease extra motion.
- New and standardized workflow processes, posted as appropriate, and very importantly
- **An enthusiastic and energized microbiology laboratory staff.**

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1. Tapping D., et al. 2003. Value stream management for the lean office.
2. BMG. 2002. Lean for transactional business processes.
3. Jacobson, J.M., et al. 2006. Lean and Six Sigma: not for amateurs. Lab Med. 37:78-83.

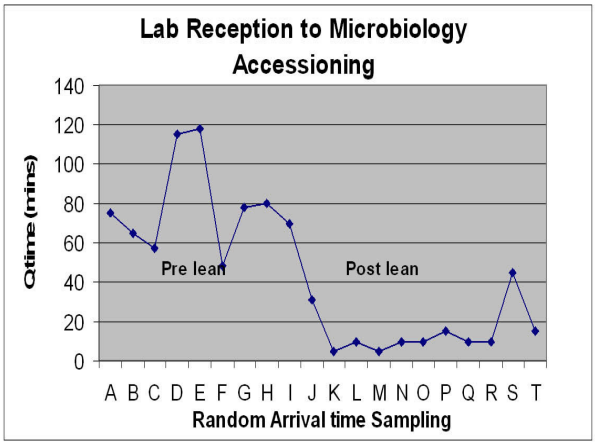
[Notes: 1. This study was originally presented as a poster at the AMMI Canada-CACMID Conjoint meeting held in Vancouver, Feb 2008. It was reformatted as an article for the on-line newsletter CMPT Connections 2008; 12(1):2-4. 2. The terminology examination, preexamination and post-examination is used for analytic by CLSI GP26-A3; 24;36.]

Table 2: Time Measurements Pre-Analytic Processing of Blood Cultures. (Time reductions range: 31- 100 minutes)

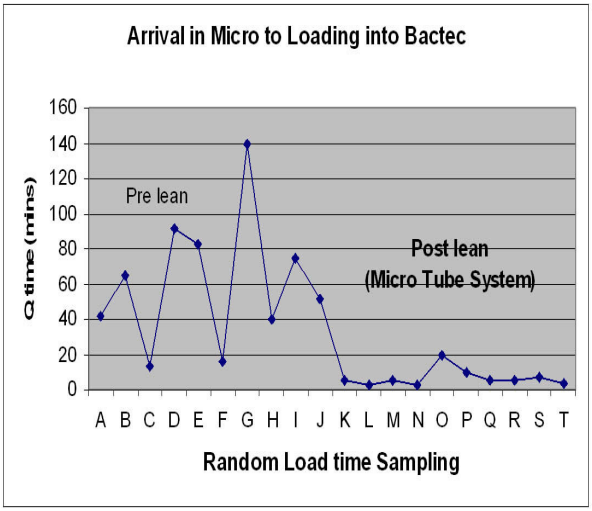
Step in pre-analytic processing of blood cultures	Pre-LSA Time ranges, minutes	Post LSA Time ranges, minutes
Laboratory reception to Microbiology accessioning.	1 to 118	**1 to 45**
Microbiology accessioning to computer log-in.	1 to 71	**1 to 40**
Computer log-in to load into blood cultures system.	1 to 110	**1 to10**

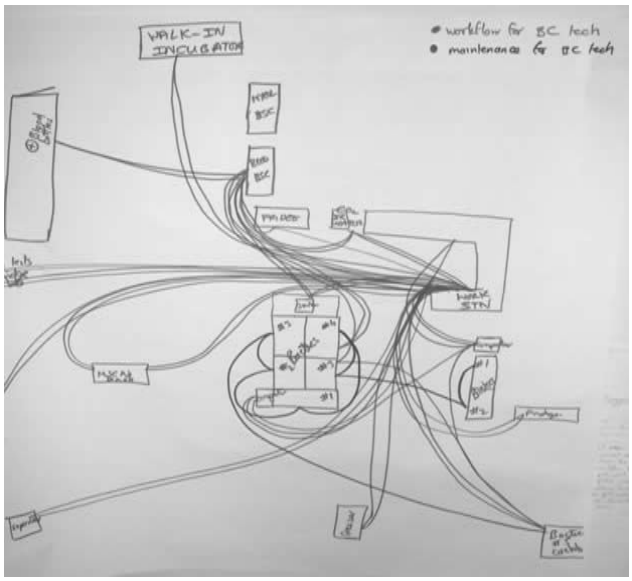
Table 3: Work Flow for Analytic Processing of Blood Cultures, Pre- and Post-LSA.

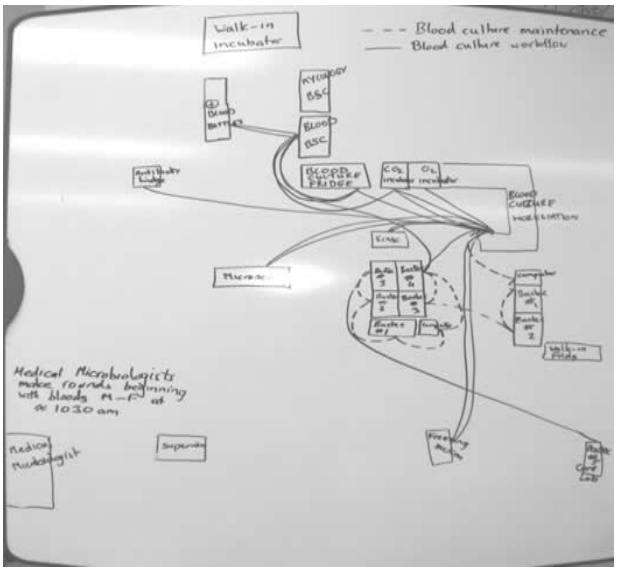
Pre-LSA: Not standardized	Post-LSA: Standardized
1. Blood cultures not staffed to accommodate busy work periods.	1. Blood cultures helper assigned 0600 to 0800.
2. No protocols for order of work flow.	2. Protocols established standardized order of work.
3. Review of plated cultures for early set-up inconsistently performed, or done too early in the day.	3. Review of plated cultures standardized to be done at 1400 and 1630 (early set-up of biochemicals and susceptibility tests).
4. Positive signal from machine not monitored on afternoon shifts when staff in other laboratory areas.	4. Monitor frequently to better detect positive signal when working in areas away from the BACTEC machines.

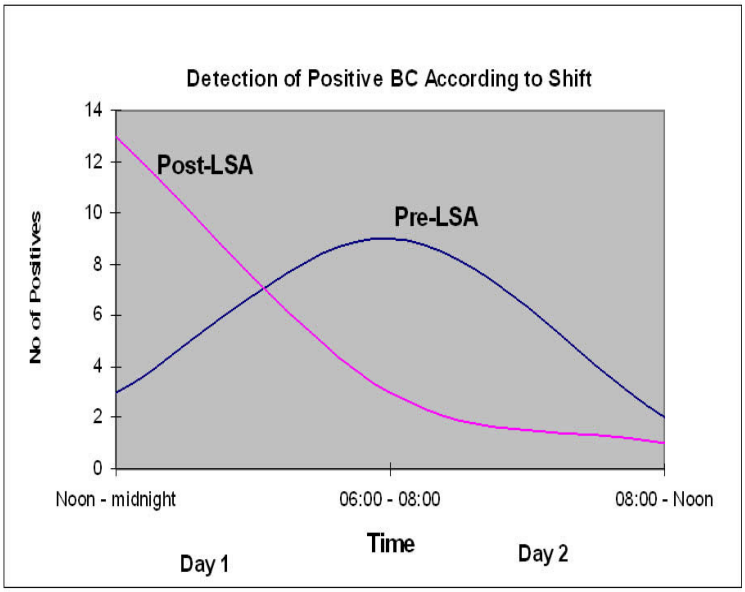


Graph 1 (above), graph 2 (below): Decreased time to enter blood cultures into BACTEC.







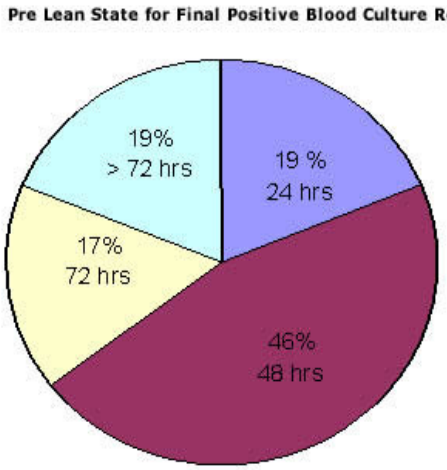


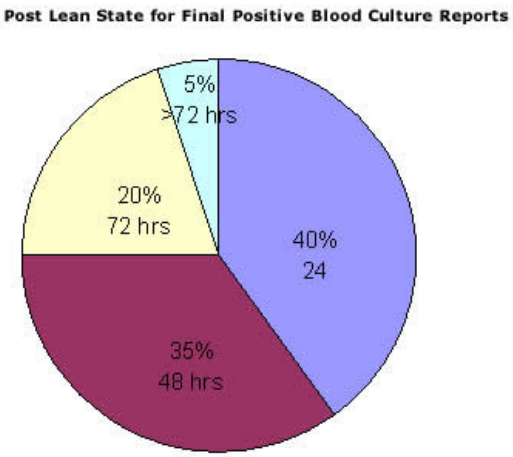
Spaghetti Diagrams (above): illustrate decreased motion with improvement in physical lay-out.

(top left) Pre LSA

(top right) Post LSA

Graph 3 (left): Expediting blood cultures into BACTEC: more positive blood cultures detected during regular operating hours, decreasing time to initial positive from time of collection.





Graphs 4 and 5 (above): Time to finalize results at 24 hours after initial positive improved from 19% to 40%.

Annex 15-C: Quality Indicators and ISO

ISO 9001: 2000 (5.4.1)
Top management should ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be *measurable* and consistent with the quality policy.

ISO 9001:2000 (8.4)
The organization shall determine, and collect and analyze appropriate data to demonstrate suitability and effectiveness of the quality management system and evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to:

- customer satisfaction
- conformity to product requirements
- characteristics and trends of processes and products including opportunities for preventive actions
- suppliers.

ISO 15189:2003 (4.12.4)
Laboratory management shall implement quality indicators for *systematically monitoring and evaluating the laboratory's contribution to patient care*. When this program identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

Annex 15-D: Quality Indicators Examples

The total testing process (pre-examination, examination, post-examination) includes all activities from the physician's decision to order a laboratory test through the return of information for patient care.

The following examples of quality indicators can be used in a laboratory total testing process.

- ordered test is appropriate for patient care
- patient consent appropriately collected
- physician written order received with every sample
- cost benefits assessment for laboratory examination menu
- patient identification and its accuracy
- preparation of patient for specimen collection
- appropriate sample container
- timing of sample collection
- phlebotomy success
- sample integrity
- sample quantity
- sample transportation
- accuracy of sample identification
- condition for sample storage
- quality control
- external quality assessment or proficiency testing program
- time to first result availability
- result reporting accuracy
- adequacy of information for interpretation of laboratory tests
- report delivery turnaround time
- consistency of critical values reporting
- result interpretation by physician
- sample contamination
- laboratory injuries or accidents
- competency of laboratory personnel
- patient's satisfaction with laboratory services
- physician's satisfaction with laboratory services