Delivering improved efficiency and patient outcomes through the implementation of the BD Totalys™ System and the BD MPD™ Process.

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Introduction

In 1986, Denmark implemented a national cervical cancer screening program. As part of the continuous optimization of the program, a 2012 government guideline called for the transition from conventional pap smears to liquid-based cytology (LBC). The goal: to improve the quality of results by reducing the number of unsatisfactory specimens.

We at the Naestved Hospital Institute of Pathology, decided to take a system-based approach to implementing liquid-based testing. As a consolidation of Danish cytology laboratories was taking place at the same time, optimizing the process was an important additional requirement. With Naestved set to become one of five regional centers performing cervical cancer screening, the laboratory had to tackle the dual challenge of increasing both diagnostic quality and laboratory productivity.

Background

We are one of five regional centers in Denmark performing cervical cancer screening. The Pathology Department of Sjaelland is made up of 3 labs processing 60,000 cytology tests a year , We processes about 20,000 cytology tests per year in accordance with the national guideline of cytology as a primary means of screening with HPV reflex.

Firstly the laboratory had to meet the Danish quality standard for liquid-based cytology. That meant going from an unsatisfactory rate of 4.4% with conventional pap smears to less than 1.5%.

Secondly, Danish guidelines require that results are provided within 10 days of sampling

Thirdly, a consolidation of 3 cytology laboratories was set to take place. With Naestved taking on the workload of two other laboratories without additional resources

Naestved vision and goals

Move from Conventional Cytology to LBC
- Improve quality and consistency of results
- Decrease slide screening time

Improve Turn Around Time (TAT)
- Optimize Full Time equivalents (FTE) productivity
- Implement streamlined workflow
- Consolidate cytology testing to one site

Measure Predict Deliver – Moving to the BD Totalys ™ solution.

To support our transition to the BD Totalys ™ solution a BD expert team "(lean, IT, Application, project manager)"and Axlab [BD distributor in Denmark] used the BD MPD™ ("Measure, Predict, Deliver") process to :

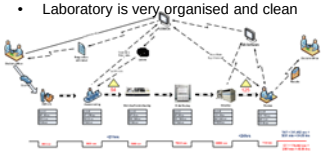
- Understand the current state Conventional cytology process. Identifying any best practice and possible road blocks to a success full implementation
- Develop a ideal future state and predict the impact of the new technology on our process and resources
- To propose support to our laboratory during the implementation phase by providing training and education focused on meeting our vision and goals. Thus enabling us to realise the full benefits of the new technology on completion of installation.

Measure – Conventional Cytology process observations

The BD expert team worked closely with the Naestved laboratory team to observe the Conventional Cytology process with an annual workload of 20,000 cases.

The observations of the current state Convectional Cytology process highlighted a number of best practices

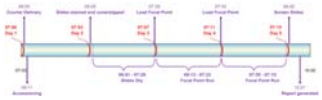
- All samples arrive pre-accessioned
- Streamlined information flow
- Laboratory is very organised and clean



The Value Stream Map (VSM) Shows the flow of samples through the process. Identifying issues where the flow is interrupted.

The conventional process VSM shows a Turn Around Time (TAT) of 94.5 hrs and a process Cycle Time (CT) of 49.85 hrs. The flow of the samples is being interrupted at 2 points in the value stream:
- Up to 21 hrs between accessioning and staining
- Up to 24 hrs between imaging and review / screening

A typical time line for the flow of a case through the process.



The process CT is broken down in to Hands on Time (HOT) and Walk Away Time (WAT). In the conventional process the HOT equals 197.46 minutes and WAT 2795.93 minutes (including BD FocalPoint™ imaging).

20,000 cases were being processed 2.5 Full Time equivalents from sample deliver to primary screening results.

Predict – A customized Proposal for Naestved

BD's LEAN and IT specialists analysed our current laboratory process and IT infrastructure and developed a future state process and VSM.

The future state VSM shows a TAT = CT of 30.3 hrs . With the blocks to the flow of the samples removed from the process.
- Slide Drying time reduced to 60 mins
- Vials processed on BD Multiprocessor ™ immediately after accessioning.
- Slides imaged every day

Predicted WAT 1440 minutes and CT 85.01 minuets (48.5 % WAT reduction 56.94% CT reduction) . HOT is excl. any maintenance and cleaning

Predicted productivity based on the future state process for 60,000 LBC samples. 1.5 FTE's based on split shifts

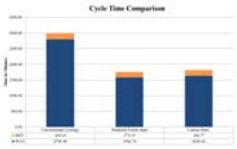
- 1 FTE helps Accessioning in the morning 7.45am -11.45am (4hrs)
- 1 FTE runs Cytology lab 8.40am – 3.30pm (= 7hrs incl. 3 hrs released for other activities and breaks)

Deliver and Sustain – BD Totalys ™ LBC process re- observations

BD's LEAN specialists re-observed our newly established BD Totalys™ LBC process once a steady state was achieved with in the laboratory.

The LBC process VSM shows a TAT of 46.3 hours and CT of 30.3 Hrs . This represents a 51.19 % reduction in TAT and 39.22 % reduction in CT. The additional 16hrs in the TAT results from a decision to hold samples between slide drying and imaging.

The BT Totalys ™ process has a HOT of 186.77 minutes (4.7% reduction) and a WAT of 1629.43 minutes (41.71 % reduction). HOT is excl. any maintenance and cleaning



These observations confirmed that the BD Totalys ™ solution and LBC process had enabled us to achieve our project quality, Turn around Time and efficiency goals by realising the predicted outcomes and process improvements.

We recorded the process flow of a typical working day where they are able to process 288 LBC samples on the BD Totalys MultiProcessor ™ in 4 hours

Run	On Totalys MultiProcessor	Off Totalys MultiProcessor
1	07:15	08:24
2	07:17	09:17
3	08:33	10:00
4	09:20	10:55
5	10:20	11:40
6	11:08	12:24

LEAN – best practice

During this project we were able to maintain and introduce a number of LEAN best practices and tools to further enhance the management of the new automated process these included , but not limited to:

Visual Management
BD Totalys MultiProcessor ™and SlidePrep ™ trays identified with a coloured dot to enable easy management of vials and slides throughout the process.

Single piece flow in data accessioning
Accessions the sample, completes data entry, labels the vial and C-Tube, and print the slide for each request. Placing the vial, C-Tube and slide in the appropriate tray before moving on to the next request.

Ergonomic Workstation layout
The workstation has been designed so that the whole task can be done easily with everything required to complete the activity easily accessible

The BD Totalys MultiProcessor ™ tray holder places the tray at the ideal height to place vial and C-tube in the tray with out reaching or bending over.

Summary

•. Consolidated the processing of cytology samples , totalling 60,000 per annum, from three laboratories Naestved, Slaegelse, Roskilde , each processing 20,000 cytology samples a year to one site at Naestved.
- •Cytology process moved to one site, Naestved , reducing process complexity and the need to transport slides through the network.

• Improve the quality and consistency of cytology slides and results
- •Implementation of the SurePath Liquid Based Cytology for consistent high quality cytology slides and a 72% reduction of Unsat results.
- •Implementation of Guided Screening in conjunction with BD FocalPoint ™ imaging to delivering a high quality standardised screening process
- •Automatic positive patient ID insuring chain of custody throughout the process

• Reducing the time to result to comply with national guidelines
- Improved time to result. Cytology turn around times (TAT) – 51.19% reduction in TAT 94.85hrs to 46.3hrs
- Reduction in process cycle times by 39.22% - 49.85hrs to 30.3hrs
- Meeting national turn around guidelines of 10 days from receipt – Current TAT <=7 days.

• Process the 60,000 samples a year within the available resources at Naestved
- Sample accessioning , Data Entry and preparation managed by 1.5 FTE at Naestved for 60,000 samples
- Implementation of a new Cervical Screening HPV protocol.

Process designed to manage / identify and process samples identified for HPV testing post Cytology aliquot.

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