## Automation and Process Re-Engineering are Required to Achieve Six-Sigma Quality: Our 27-Year History of Continuous Improvement

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## **Disclosure and Objectives**

Charles D. Hawker is retired and has nothing to disclose. Bonnie L. Messinger and David N. Rogers are employees of ARUP Laboratories.

#### Objectives:

After completing this activity, the participant will be able to...

- Define various process improvement actions and describe how they impact non-analytic quality metrics.
- Describe the role of automation in improving non-analytic quality.
- List three activities to improve non-analytic quality in their own laboratory.







1. Introduction

- 2. Eight automation stages
- 3. Nineteen process improvement steps
- 4. Results over 27 years
- 5. Conclusions





# Realistic Error Rates: It is difficult to have better than a 1/1000 error rate without advanced design and technology

Method of Ensuring Accuracy Clear processes, reliance on education, training, vigilance	<u>Example</u> Hand washing
The above plus reminders, checklists, communication, retraining, competency testing,	Mislabeled specimens Requisition order errors Sub-optimal specimens
The above plus standardiza- tion, error-proofing, elimina- tion of fatigue & distractions	Lost specimens Corrected reports
The above plus automation, robotics, software enhance- ments, advanced process design	Bar code reading Interfaced result entry
	Method of Ensuring Accuracy Clear processes, reliance on education, training, vigilance The above plus reminders, checklists, communication, retraining, competency testing, processes reflecting human behav The above plus standardiza- tion, error-proofing, elimina- tion of fatigue & distractions The above plus automation, robotics, software enhance- ments, advanced process design

Source: Michael Astion, Univ. of Washington, based on a report by Resar, RK: Making noncatastrophic health care processes reliable: learning to walk before running in creating high-reliability organizations. *Health Serv. Res.* 2006;41:1677-1689





## Introduction

- Six-Sigma quality is extremely difficult to achieve in clinical laboratories because there is so much manual handling and variation in inputs.
- Since our founding in 1983, our laboratory has monitored numerous quality indicators, both analytic and non-analytic.





## Introduction

- One indicator, lost samples, has shown continuous improvement over the past 27 years as a result of extensive automation and process re-engineering and in a number of months has exceeded Six-Sigma levels.
- In order to achieve Six-Sigma quality, we believe both automation and process reengineering are required.





## **Automation Stages**

- A. 1998 The first track (MDS AutoLab)
- B. 2003 Two story freezer automated storage and retrieval system (AS/RS)
- C. 2004 Major expansion of track system
- D. 2004 Two Motoman storage sorting robots





## **Automation Stages**

- E. 2006 Addition of four sorters to track
- F. 2009-10 Sort-to-Light automated system for sorting manual specimens
- G. 2010 ATS 4000 per hour automated storage sorter
- H. 2014

New track system: MagneMotion MagneMover LITE<sup>®</sup> with 20 robots





#### A RUP Automation, November 17, 1998 2000 specimens/hour, 30 workstations, 4 sorters













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#### **Process Improvements & Engineering Controls**

- 1. 1992 Lost specimen checklists
- 2. 1997 Standard tubes
- 3. **1997** Single-piece flow
- 4. 1998 Raised edge workstations

5. 1999 Programming change to prevent storage of in-process samples





**Process Improvements & Engineering Controls (2)** 

- 6. 1999 Redesign and move of waste receptacles
- 7. 2000 Skirting material installed around equipment
- 8. 2003 Realigned light fixtures
- 9. 2005 Checklist revision protocol

10. 2009 Daily visual sweeps

**Process Improvements & Engineering Controls (3)** 

- 11. 2010 Lost specimen pattern analysis
- 12. 2010 Specimen Processing "pods" (teams)
- 13. 2011 Paraffin tissue and extracted nucleic acid transport submission kit
- 14. 2011 Barcode scans for batch receipt of shipments





**Process Improvements & Engineering Controls (4)** 

#### 15. 2012 Big data reports

## 16. 2013 Installed multiple video cameras

## 17. 2014 Clean line of sight

# 18. 2017 Extended "big data" with a "No Track Event" report

## 19. 2018 Green, tagged bags for S.P. waste







#### 6 WASTE RECEPTACLE FITTED WITH ROUNDED COVER AND NARROW SLIT

## 7 SKIRTING MATERIAL INSTALLED AT EQUIPMENT BASE (OUTLINED IN RED)



#### 12 SPECIMEN PROCESSING WORKSTATIONS ARRANGED IN A "POD" OF FOUR



#### 13 PARAFFIN TISSUE AND EXTRACTED NUCLEIC ACID TRANSPORT SUBMISSION KIT



#### **16 USE OF VIDEO CAMERAS**



#### **19 WASTE RECEPTACLE FITTED WITH GREEN BAG**

## Six-Sigma

- 3.4 defects per million opportunities (DPMO)
- Estimated average hand-offs/specimen = 6
- Each hand-off = Lost Sample "Opportunity"





## Six-Sigma

For consistency and comparison over time, we used units in place of opportunities.

- 1) Billed units (1.6 per specimen)
- 2) Specimens

## "Opportunity"

- Chances per unit for a defect
- Independent of other opportunities
- Measurable and observable
- Relates directly to "Critical to Quality" (CTQ)





#### LOST SAMPLES PER 1,000,000 BILLED UNITS



Lost Specimens Per 1,000,000



## What You Can Do In Your Lab

- Reducing lost specimens is about tracking, even without automation.
- The LIS can be used to track specimens from Specimen Processing (*Central Collect* status) to lab sections (*In Lab* status). It requires an extra bar code read in the labs to verify the receipt of the specimen.
- For specimens being transported to the lab from clinics or affiliated hospitals, consider using bar codes to create transfer lists.





## What You Can Do In Your Lab

- Require employees to "check out" specimens from a centralized storage system for archived specimens before giving them the location (box/rack #, row #, column #).
- Design specimen processing areas to minimize opportunities for errors (misplaced specimens).
- Implementing small improvements in an iterative fashion leads to continuous improvement.





## **Summary**

## Steady improvement for 27 years

- Re-engineering and behavioral controls
  - Foundation for iterative improvement
  - "Don't automate a broken process"
- Automation
  - Boosts improvement potential to 6 Sigma levels



