Next Generation Laboratory Automation Systems: Further Improvements in Laboratory Efficiency

http://marc.med.virginia.edu http://medicalautomation.org

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### Disclosure

 Grants – Abbott, Beckman Coulter, Ortho Clinical Diagnostics, Tecan, Hamilton, Perkin Elmer

- Consulting Abbott, Bayer, BD, Dade Behring, Roche
- Travel costs Ortho Clinical Diagnostics

### Objectives

Examine current process improvement methods in the context of automation

- Reveal current laboratory automation bottlenecks and technological solutions
- Discuss automation in non-traditional laboratory disciplines and their integration into the core laboratory

### What is Medical Automation?

- Process Planning
  - Simulation modeling
  - Process optimization
- Process Monitoring
  - Speed of service delivery
  - Length of queues
- Process Management
  - Process streamlining
  - Process automation
- Process Outcomes
  - Quality metrics
  - Health improvement
  - Patient and provider satisfaction





# The **Future of** Healthcare is Technology **Enabled**



# New Medical Communication Paradigms





Vocera<sup>TM</sup>



2007

# New Diagnostic Paradigms Ingesti

#### Ingestible pill camera



Colonoscopy 2005 Colonoscopy 2007

7

# Simpler and Better Diagnosis









**Intestinal Bleed** 

Given Imaging.com

# **Future Pill Technologies**

Micro- optoelectromechanical systems (MOEMS) - Given **Imaging/Olympus** Chemical Analysis - SmartPill Photonics Assessment – MTC/Infotonics







# New Treatment Paradigms









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# **Surgical Robotics**







# Future Surgical Techniques

- Standardize surgical protocols and outcome in remote locations
- Image guided surgery, Natural Orifice Surgery





### Home Diagnostic Medicine 2008



### **Clinical Laboratory of the Future**

Inova Reference Laboratory Northern VA



Chemistry

Anatomic Pathology

Molecular <sup>14</sup>

### **Quality Management Through Automation**

- Automation standardizes testing processes
- Instantaneous measures of performance
  - Precision, Accuracy, Population norms
- Automation can help evaluate performance data and provide instant alerts

# Laboratory Quality and Efficiency Processes

#### Six Sigma

- Juran, Deming, Six Sigma
- Measurement, Evaluation, Adjustment
- Lean
  - Maximize value added steps, minimize wasteful steps

#### Toyota

- Culture of continuous improvement
- Just-in-time, long term, standardized solid processes
- Medical Automation
  - Technology monitored and optimized process management
  - Contains the medical centric parts of Six Sigma, Lean and Toyota



Lean and **Non-linear** Laboratory Engineering

- Examine the waste in your process
- Redesign for minimal steps
- > 40% savings in costs without automation hardware



Lean



# **The Missing Link**

Accessioning automation

- Front End Automation (Gene Pawlick, MD)
- Sample inspection (Charles Hawker, PhD)
- RFID (Bill Neeley, MD)
- Centrifugation



# Centrifugation Options

AutofugeMultifugeSpeedyfuge



# Autofuge<sup>™</sup> (bioSys<sup>™</sup>)



- Reduced automation and maintenance
- High throughput at 425 tubes per hour
- Eliminates need to weigh tubes, or wait for balanced loads
- Both stand alone and automation versions available

# Lean Design and Automation

 Linear arrangement of accessioners
 Linear flow of specimens with batch takeout for analysis



Sonic Healthcare, Sydney, Australia Slide courtesy of Alan Lloyd

#### Laboratory Costs Slide courtesy of Ortho Clinical Diagnostics

Labor 58%

- Analytical 41%
- Pre-Analytical 11%
- Post-Analytical
   5%
- Reagents 27%
- Everything else 15%



Sources: NCCLS GP11-T, Cost Accounting in the Clinical Laboratory: Tentative Guideline, December 1993 "Assessing the Real Cost of Analyzer Ownership", Gerald Catanese, American Clinical Laboratory, June 1993 "Buying Lab Equipment: Comparative Analysis Reveals Operating Costs", E.V. Bunata, Materials Management in Healthcare, September 1992

# The Lab of the (Near) Future

- Pre-labeled phlebotomy with automatic sample logging technology (e.g. RFID)
- Appropriate sample collection for disease state and time Process Control
- Rapid transportation, accessioning, and processing
- Analytical excellence
- Synoptic reporting
- Storage for reuse or research biorepository

### **Phlebotomy Tray Preparation**

 Visual tube inventory
 Automated reorder
 Linked to LIS to generate labeled tubes
 Eliminates errors

> BC-ROBO – mini 40 Multi-tray system



### **Clinical Laboratory of the Future**



Chemistry

Anatomic Pathology

Molecular 26

### Modular Point-in-space Sampling



### **Optimal LIS – Process Control Interface**

Minimize the need for interface development Allows LIS to evolve into Process Controller



See: Rod Markin, MD, PhD The LIS Continuum

### **Laboratory Automation Options**

Company	Name	USA/Eur/Asia- Aust.	1 <sup>st</sup> Install – 2006 Contracts
A&T Corporation	Clinilog	0/0/85	<b>1993 -10</b>
Abbott	Accelerator	2/13/0	2005 -36
Beckman Coulter	Power Processor	285/70/60	1998 -51
Dade Behring	StreamLAB AW	0/0/0	2002 -0
Integrated LAS	Efficiency Series	1/0/0	2003 -1
Olympus	OLA2500 LAS	40/200/3	2003 -7
Ortho Diagnostics	enGen	5/18/0	2000 -16
Roche	MODULAR Pre-analytics	s <b>50/109/105</b>	2000 -34
Siemens	Advia Labcell	20/46/10	<b>1998 -16</b>
Sysmex Amer.	HSTN	100+/1000+	1991 -50
Thermo	TCAutomation	5/43/0	2000 -0

Source: CAP Today, March 2007 Annual Automation Survey

# Has Lab Automation Lived Up to the Expectations of U.S. Users ?

	<u>Front-End</u>	<u>TLA</u>	<u>Combined</u>
Absolutely Yes	37%	41%	39%
Mostly Yes	37%	34%	36%
SubTotal	74%	75%	75%
Satisfactory	22%	22%	22%
No	4%	3%	3%

Survey from Diagnostic Testing & Technology Report (Washington G-2 Reports) October 2005

# How Many Systems are Installed in the USA?

32% of laboratories have installed automation (estimated 525 labs)
 66% TLA, 34% pre-analytics
 25% have purchase plans in place

Survey from Diagnostic Testing & Technology Report (Washington G-2 Reports) October 2005, N = 188

### Advances in LAS / Instrument Process Control

- Partial Process Control
  - Process controller knows when sample has arrived at the instrument, and data is reported
- Total Process Control
  - Instrument availability
  - Sample status
  - Instrument alarms, flags, status, and warning messages

Vendor	<b>Total Process</b> <b>Control</b>	<b>Partial Process Control</b>
Abbott	Architect	Centaur, Tosoh
	Axysm	Sta-R
Bayer	1640/2400	Sta-R
	Centaur	
Beckman	Synchron	Sta-R, Modular,
	CXI, LXI	Tosoh, CA7000
Dade	Vista, CA7000	Centaur, Tosoh
	RXL, Cobra	
Roche	DP, PP, Cobas	33

### 4<sup>th</sup> Generation Laboratory Automation

- Modular open architecture
- Process Management
  - Communication between LIS and LAS
  - Current status of automation system and analyzers
  - Optimization of sample distribution
  - Prioritization of STAT samples
  - Graphical user interface
  - Alerts for low reagents and consumables
  - Alerts for maintenance and error conditions
  - Allows post analytical specimen archiving and retrieval

### 4<sup>th</sup> Generation Laboratory Automation

#### Intelligent sample management

- Automated sample inspector
- Bar code/matrix code/RFID reading
- Intelligent sample routing
- Centrifugation
  - User definable parameters (speed, temperature, time)
  - Multiple centrifuges with >500 tubes/hr. capacity
  - Dedicated STAT centrifuge
- Decapper 1 second per tube
  - Closure independent Hemaguard, rubber stopper, and screw cap

### 4<sup>th</sup> Generation Laboratory Automation

- Recapper 1 second per tube
  - Foil Seals
  - Reseal after sampling capability
- Specimen scanner 1 second per tube
  - Serum vs plasma (which anticoagulant) vs urine
  - Clots, fibrin, hemolysis, icterus, lipemia
  - Correct tube type, specimen temperature
  - Heights of serum vs air and cells vs serum interfaces
- Specimen sorter 1 second per tube
  - Intelligent Pre and post analytical sorting
  - Conveyor 1 meter per second
  - Fast shuttle and bypass capabilities
  - Short term storage with recall, Error handling
- Post analytical storage and retrieval

### Inventory Management

Inventory Management

- Automated forecasting based on current and past utilization
- Link to storeroom inventory with automated ordering

- Overstocking with utilization-billing



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### Automated Biorepository

Reduce your operational and financial burden Accelerate the availability of bio-specimens for repeat, reflex, add-on Facilitate medical/research collaboration Achieve consistent highquality samples and data Ensure patient privacy



### Automated Storage and Retrieval

#### Inpeco, Milano, Italy

#### **Beckman Coulter**

#### **Hamilton Robotics**





# Non-Traditional Laboratory Automation



### Anatomic Pathology

### Molecular Biology



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### Automated Molecular Diagnostics

- Over 550 samples per 8hr shift for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*
- Automated sample extraction amplification, reading, and LIS reporting
- Pipetting transfers without the use of syringe pumps and tubing
- Isothermal SDA technology



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### Automation in Anatomic Pathology

Less routine
 More subjective
 Requires individualized attention to each patient case



# **Commercial Players**

#### **Clinical Pathology**

- A &T Corporation
- Abbott Diagnostics
- Bayer Healthcare Diagnostics
- BD
- Beckman Coulter
- Dade Behring
- Olympus America
- Ortho-Clinical Diagnostics
- Roche Diagnostics

#### Anatomic Pathology

- Cellient
- Dako
- Leica
- Milestone
- Roche
- Sakura Finetek
- Ventana Medical Systems

### Automation in Tissue Preparation: Tissue-Tek Xpress

- Automated tissue embedding
- Continuous flow operation
- ~120 samples/hr throughput
- Tissue is uniformly fixed using microwave enhanced mixing
- Reduces formalin and xylene use by 80%
- Preserves DNA and RNA

Tissue-Tek Xpress, Sakura Finetek, U.S.A., Inc. <http://www.sakuraus.com>



### Tissue Tek Xpress™



Reagent 1 Microwave fixation and dehydration





### Sakura Fineteck



Reagent 2 Dehydration and clearing

Circular microwave action and bubble dispersion

Reagent 3 Clearing and paraffin embedding

11 11





Reagent 4 Final paraffin embedding

Morales AR, Nassiri M, Kanboush R, Vincek V, Nadji M. Am J Clin Pathol. 2004;121(4):528-536.

### **H&E Slide Preparation**

80% of total slides are stained with H&E
Estimated market: 500-600M slides per year
A market desperately in need of automation





### Automated Slide Preparation

 Up to 80% labor reduction using pallet approach (25 slides)

- 20 tray capacity (500 slides)
- Time to first result in 35 minutes, 200 slides/hr
- Unattended preparation of 500 slides



Ventana, Symphony™ www.ventanamed.€om

### What I didn't Cover

Cell Based Assays
 Automated Proteomics
 Mass spectroscopy from tissue sections





#### ProLink Express TM



### Summary and Conclusion

- Systems integration (hardware and software) and process consolidation are the keys to success
- It will be important to develop an economic model for return on investment in terms of real dollars and improved service
- Automation initiatives need to measure improvements to quality, and efficiency
- All areas of the laboratory can benefit from automation

# The Future of Laboratory Medicine

- Continued economic pressure for integration of analytical processes
- Increased development and use of efficiency tools
- Incorporation of anatomic, molecular, proteomic, and cell based assays in the central laboratory
- Emerging use of proteomics for detection and staging of occult disease
- Merging of medical imaging and diagnostics
- Growing appreciation for the role of Laboratory Medicine in home diagnostics

# Dealing With the Technologist Shortage



# Thank you

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