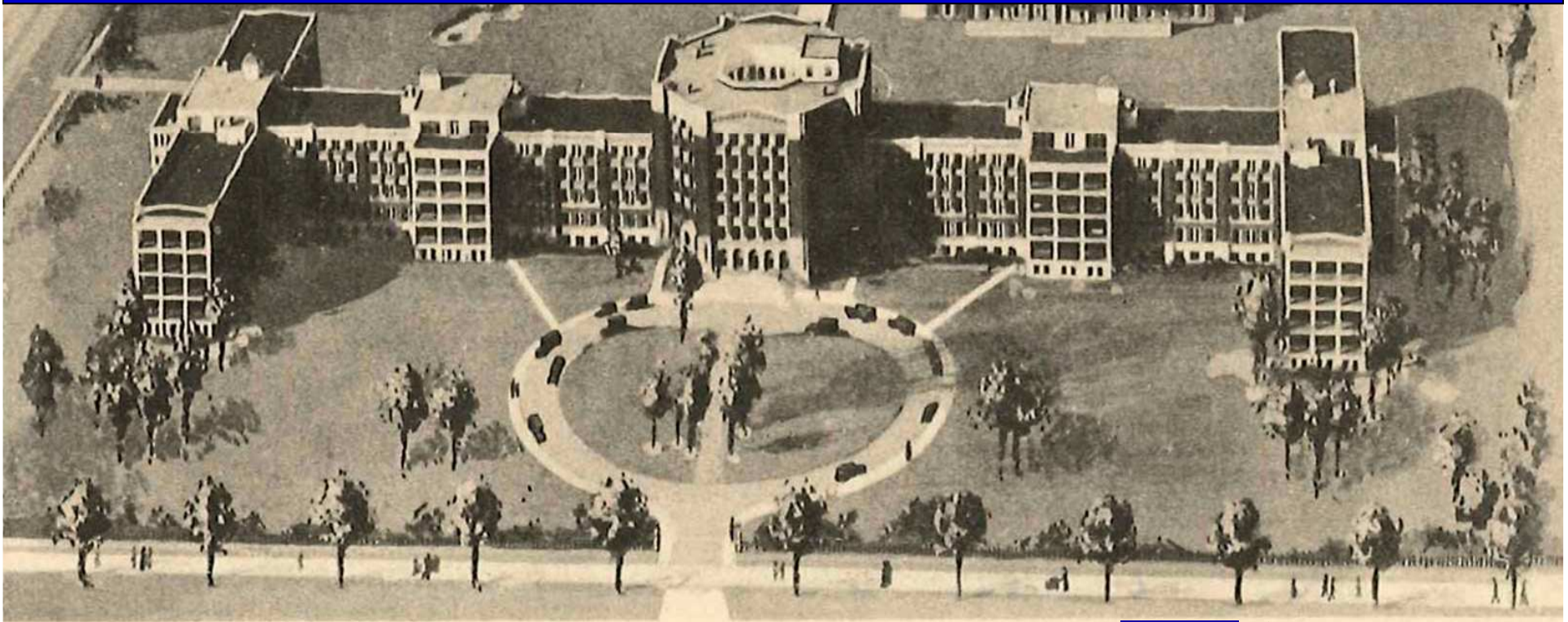


Preparing for Precision Medicine: Lessons in the Transformation of Anatomic Pathology at Henry Ford Health



Henry Ford Hospital 1921

Executive EDGE, Toronto, October 8, 2013



Richard J. Zarbo, MD
DETROIT, MICH.

Pathology and Laboratory Medicine

Disclosure

Various companies, technologies and
platforms will be discussed

The presenter has no conflicts of interest

Personalized Medicine

- Profiling the individual for therapy specifically tailored at the level of cellular
 - Genes (genome)
 - Proteins (proteome)
 - DNA
 - RNA
 - Small signaling molecules (metabome)
- ***Preservation of molecules for assay***
- ***Immediate answers for therapy***

1903-2003

Lab as Supplier makes.....

Diagnostic Reports & Lab Test Results

and we say you can have it-



1.Fast



2.Accurate



3.Cheap

But choose any 2 of the 3

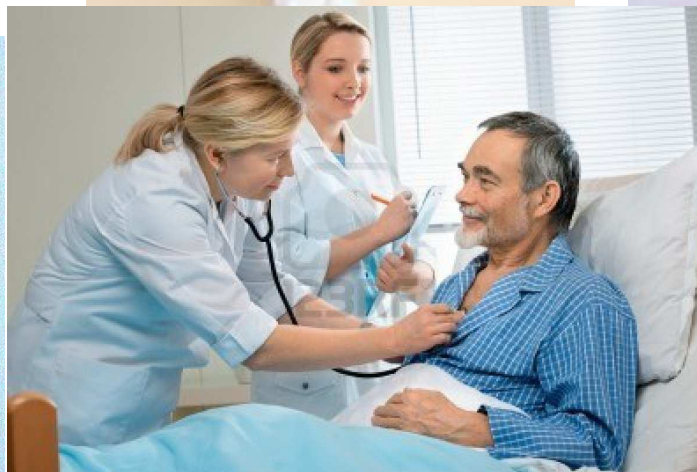
The customer wants.....

ALL



2013-beyond

What Do Customers Want in 2013?



MORE

1. Fast

2. Accurate

3. Cheap



4. Safe



5. Molecular friendly



The customers want.....



Tailored specifically to them

The AP Challenge

“We cannot solve our problems
with the same thinking we used
when we created them.”

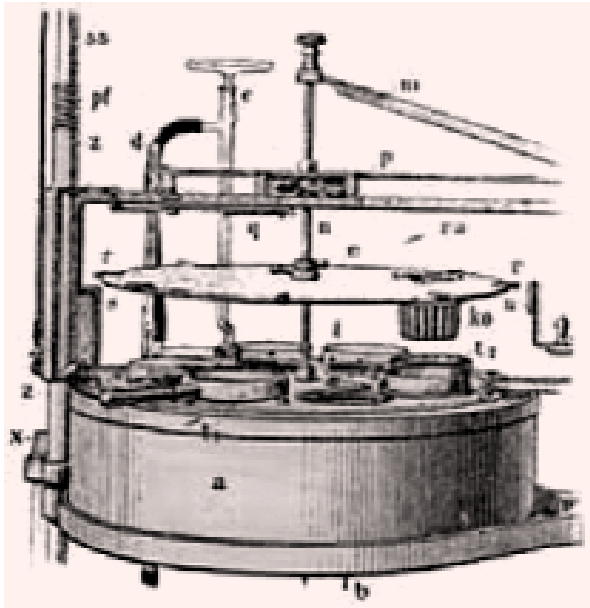
-Albert Einstein

~~The way it was is !~~

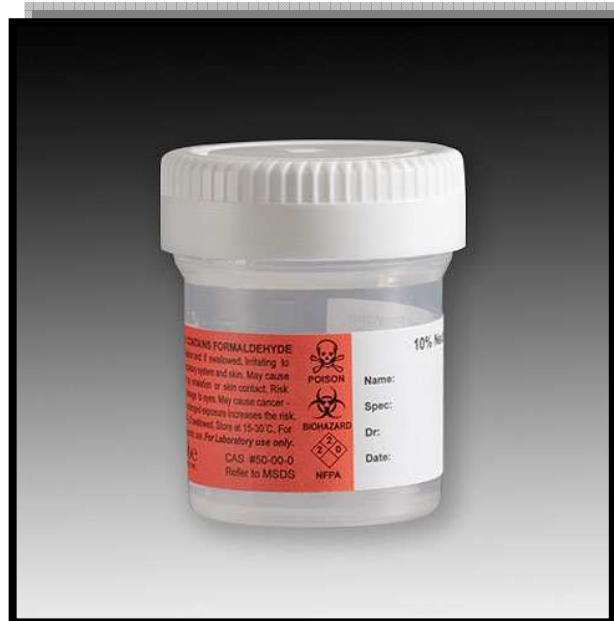


Cycle time = 14 hrs

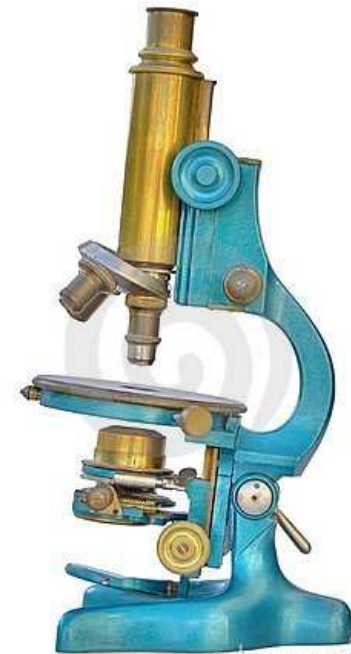
Cycle time = ? hrs



1909
Arendt



1893
Blum



1850s
Virchow

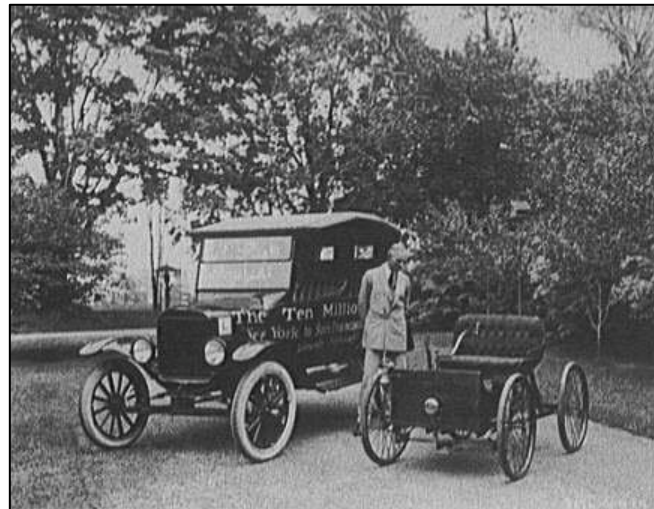
How do we fix this?

- Challenge status quo
- Out-of-the-box thinking
- Lean processes (faster, cheaper, accurate)
- New technology
- Quality Control of currently uncontrolled pre-analytic specimen variables

LESSON

“Say you can, say you can’t.
Either way you are right.”

– Henry Ford



1924

Faster

Business of Healthcare

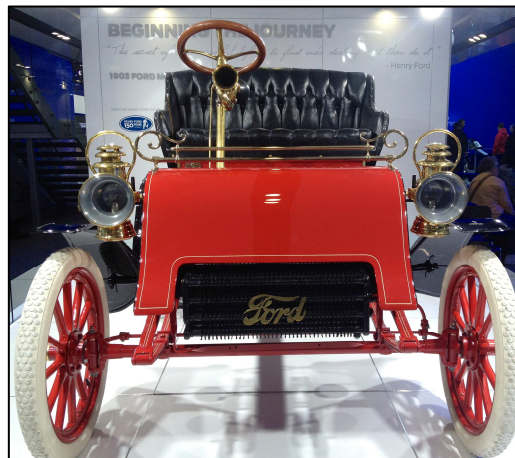


LESSON

Lean Principle- Time Waste

“Time waste differs from material waste in that there can be no salvage. The easiest of all wastes, and the hardest to correct, is the waste of time, because wasted time does not litter the floor like wasted material.”

— Henry Ford



The Vision & Means & Goals

- All specimens from any Operating Room within the Henry Ford Health System are transported, grossed and processed within the day of surgery at Core Anatomic Pathology Lab
- Continuous flow processing for Biopsies & Large Specimens using Lean processes with short cycle times
- 80% of all Biopsy reports within 2 days & all Large specimens reports in 3 days

Reduce Waste =
Cheaper & Faster

Common, Continuous Problem Solving Culture

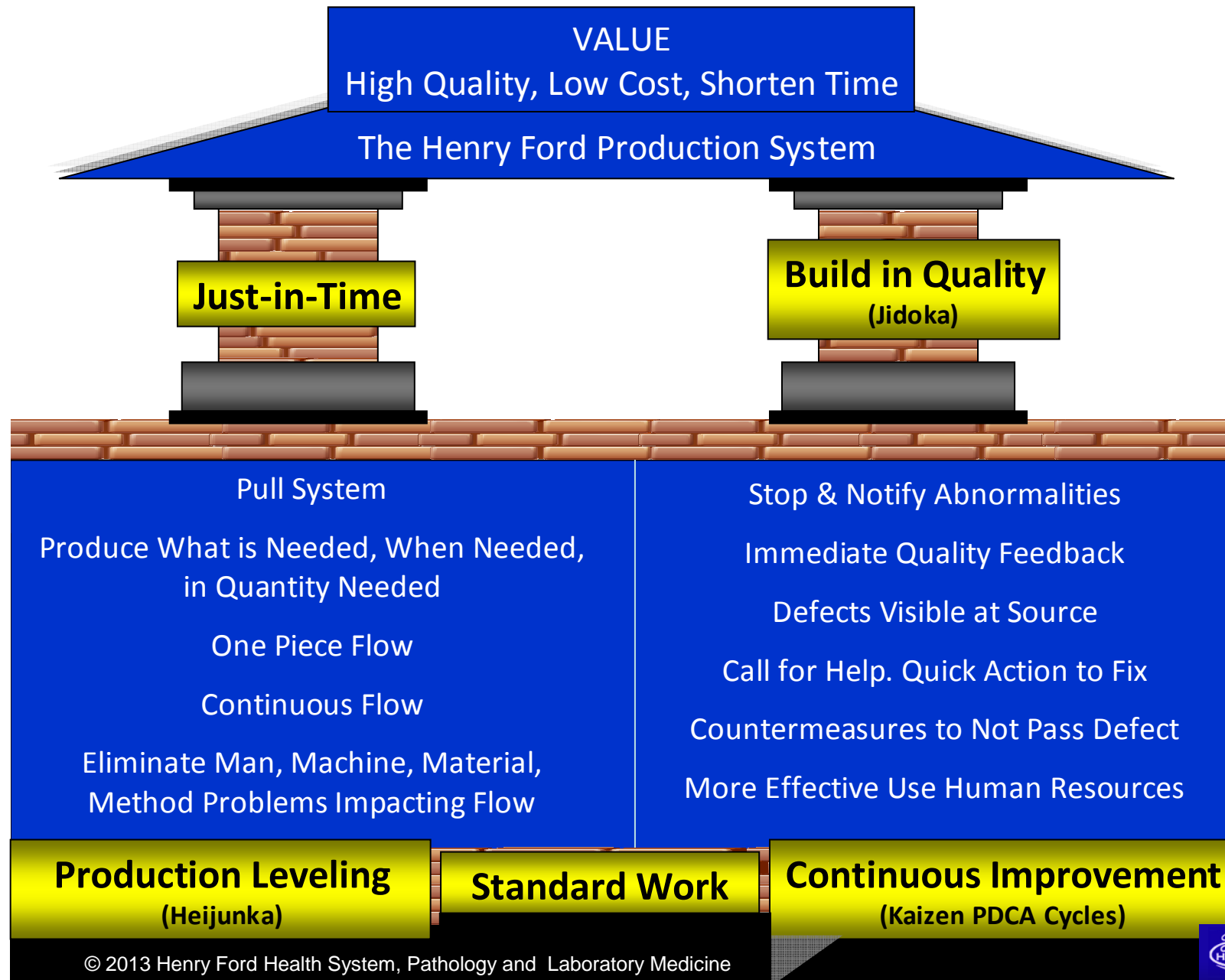


Henry Ford
Production System

“Most people spend more time and energy going around problems than in trying to solve them.”

-Henry Ford

Foundations of Lean Production



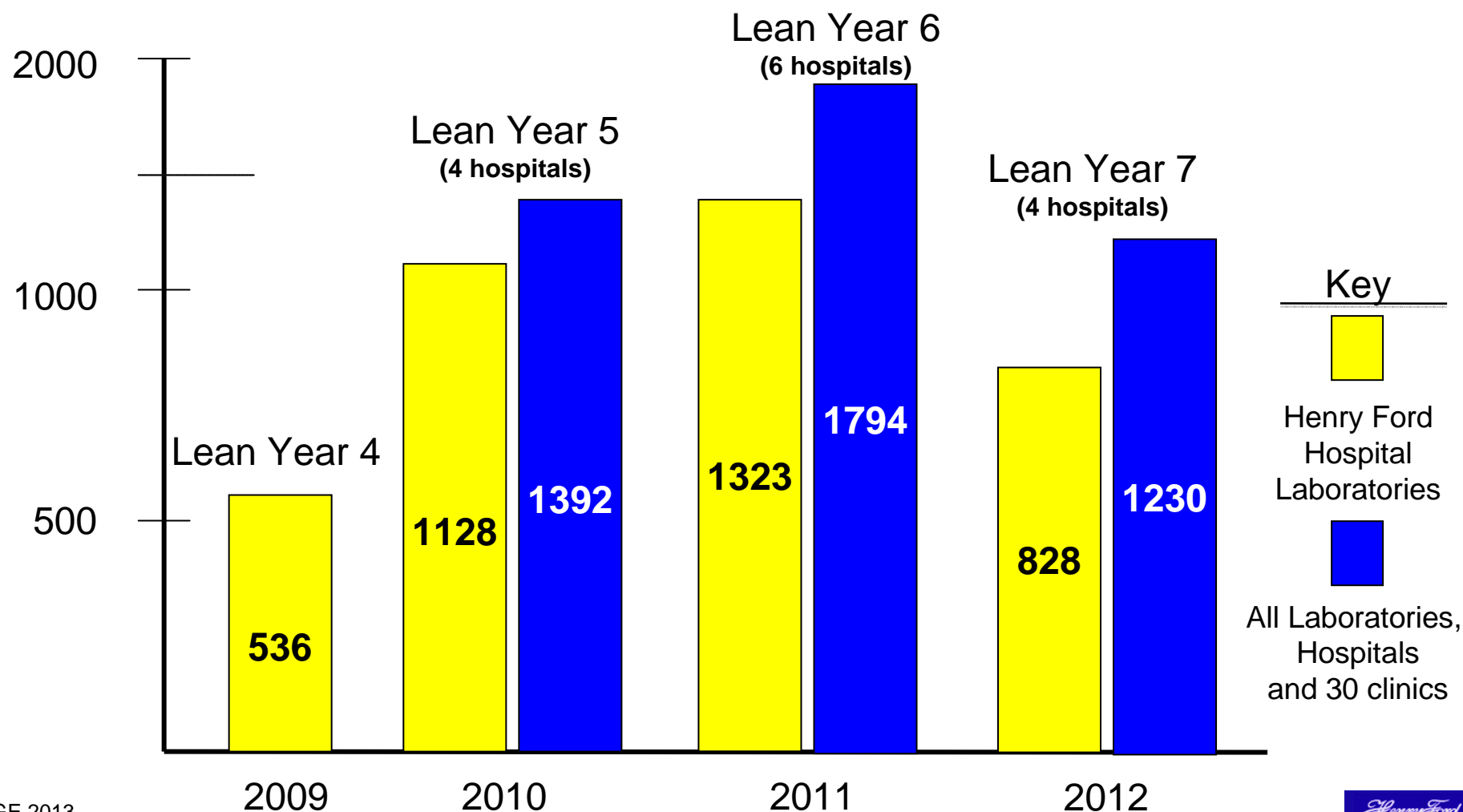
LEVERAGING PRODUCTIVITY OF TEAMS

**Empowered
Work Teams**

Total Process Improvements

Pathology & Laboratory Medicine Service Line

Henry Ford Production System



LESSON

“Getting good players is easy.
The hard part is getting them to play
together.”

-Casey Stengel

Baseball manager and philosopher

Creating Flow = Faster

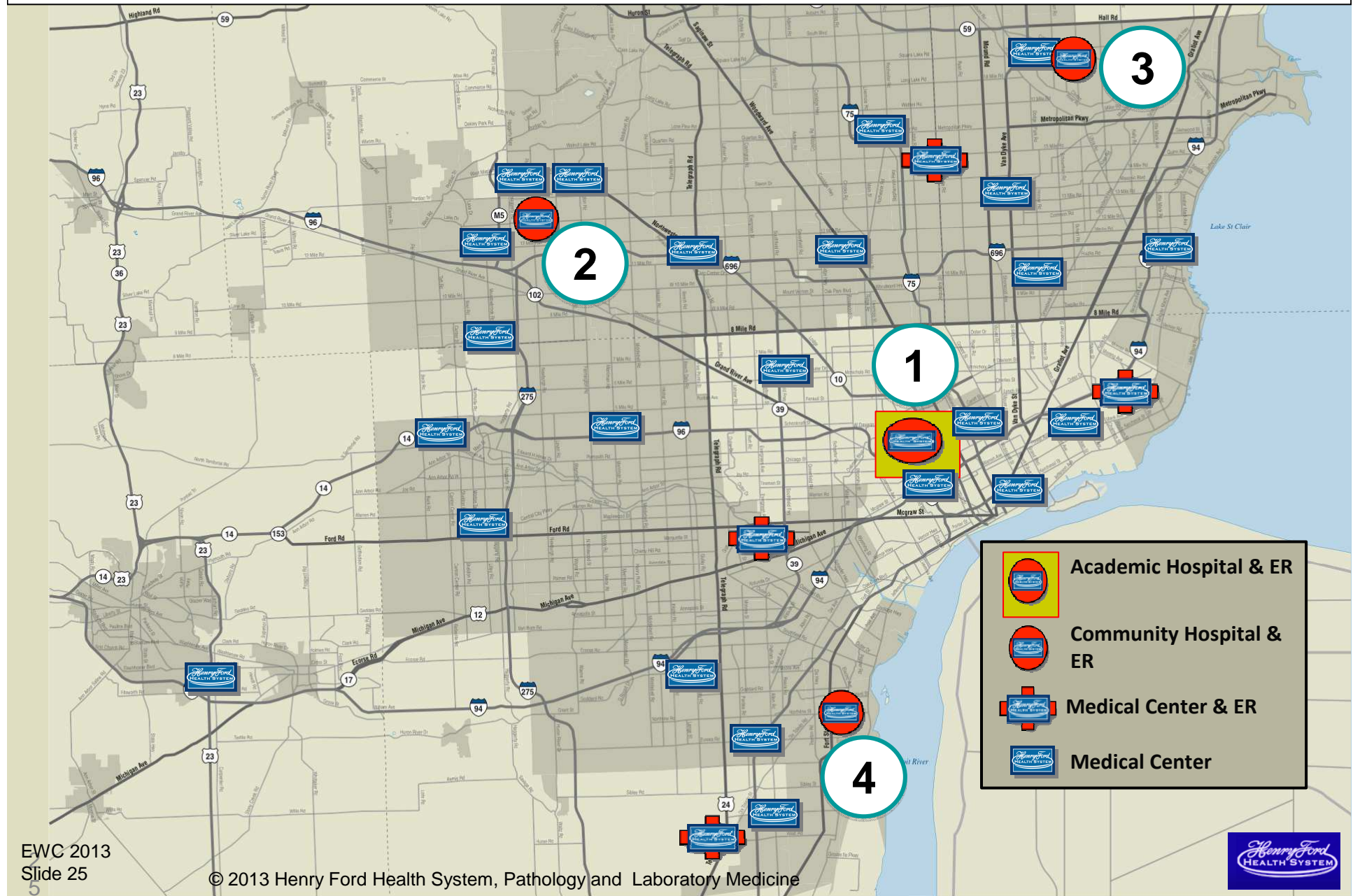
Strive for the IDEAL Condition

Delivery of products & services should pursue the Ideal

Production that is

- **Defect Free** (goal is zero, meets customer expectation)
- **On demand** (supplied when you want it, in right version)
- **Immediate** (now, no waiting)
- **One at a time** (single piece flow, batch size of 1)
- **Continuous flow** (no batches, queues)
- **Minimal waste** (materials, labor, energy, other resources)
- **Safely for every employee**

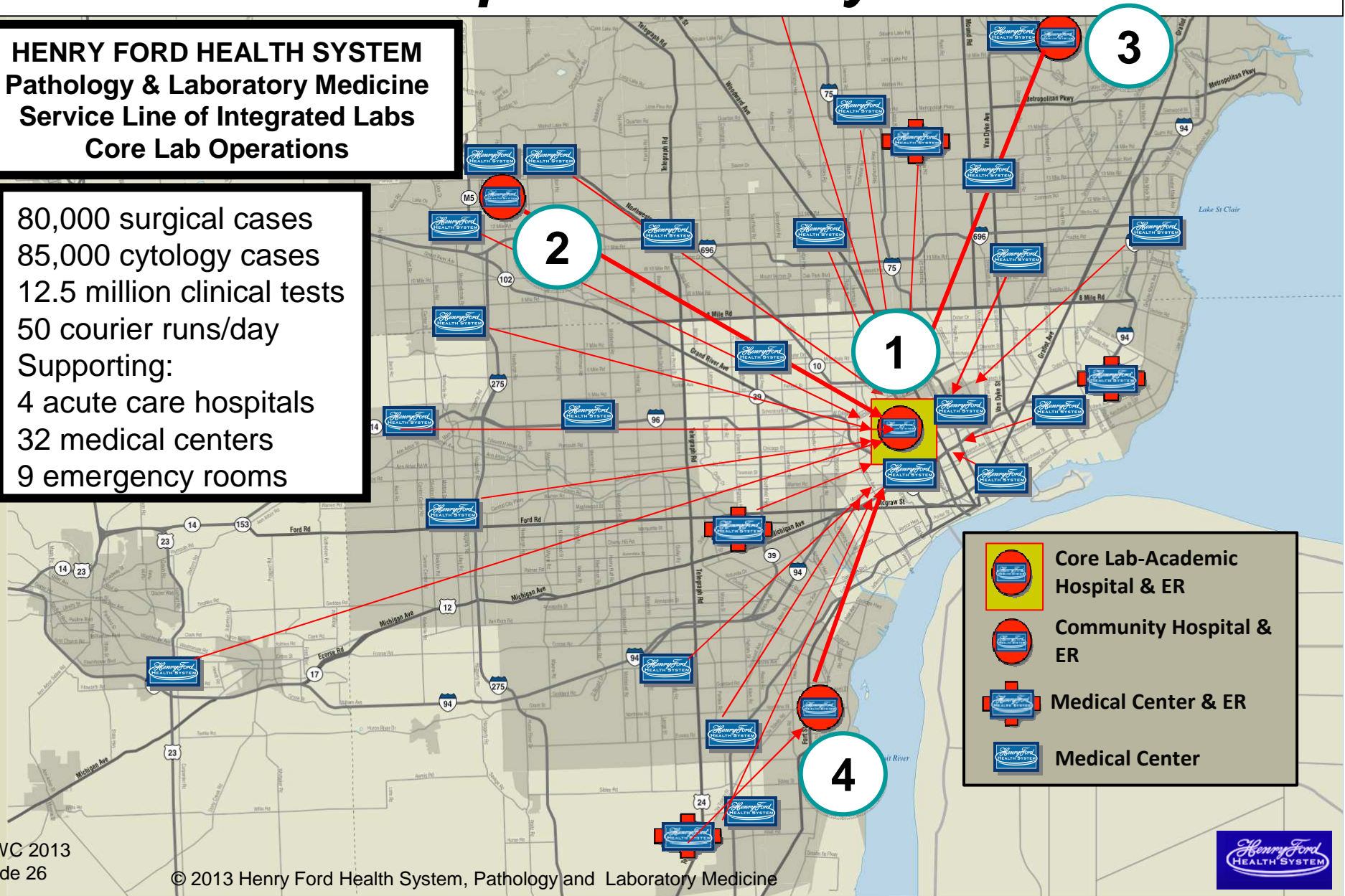
36 Laboratories of Henry Ford Health System



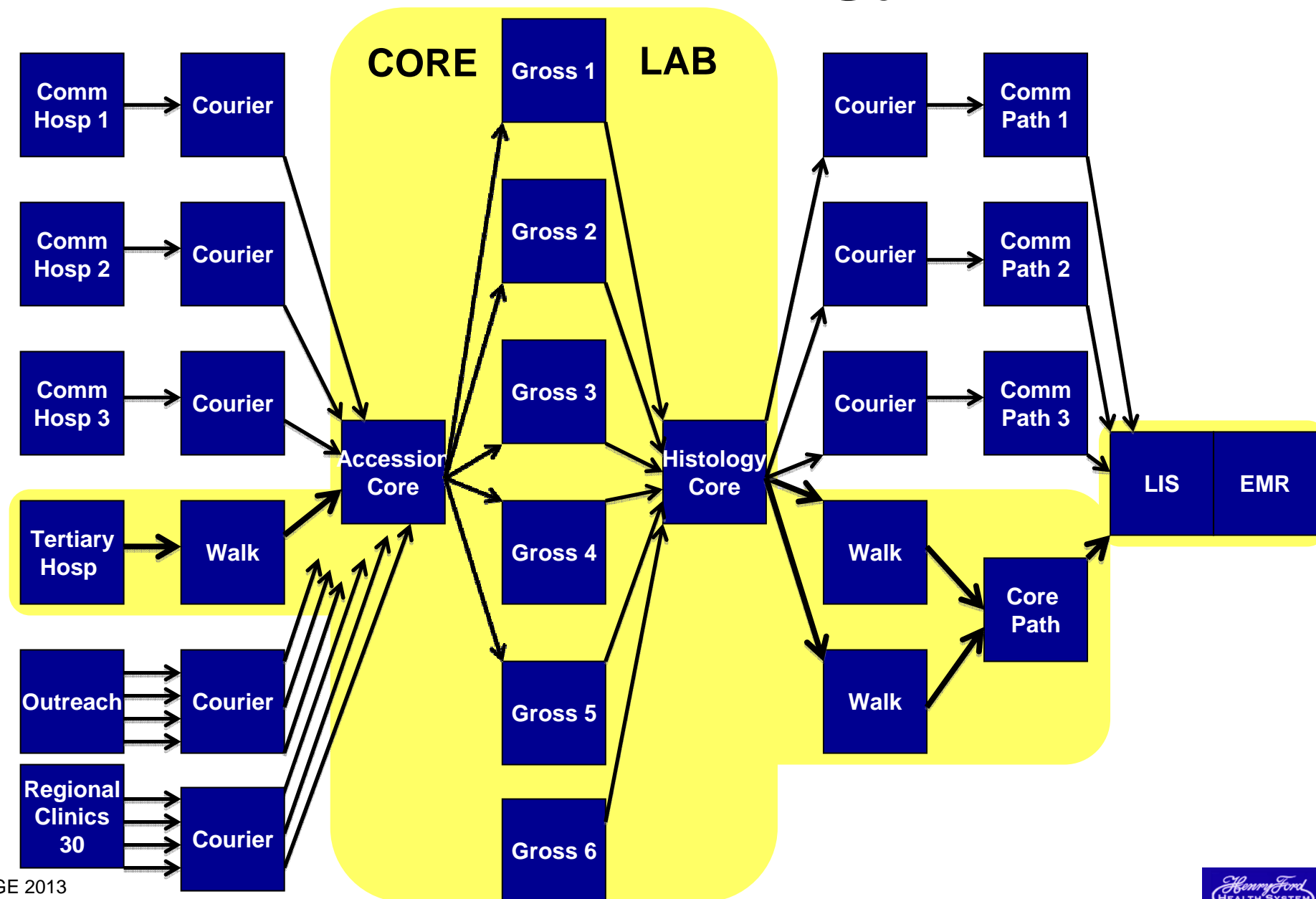
13 Core Laboratories- Consolidated Hub & Spoke Delivery Model

HENRY FORD HEALTH SYSTEM
Pathology & Laboratory Medicine
Service Line of Integrated Labs
Core Lab Operations

80,000 surgical cases
85,000 cytology cases
12.5 million clinical tests
50 courier runs/day
Supporting:
4 acute care hospitals
32 medical centers
9 emergency rooms



Anatomic Pathology VSM



The Challenge

Key Problems

- Core AP Lab operations
 - Specimen accession, gross exam, histology, IHC, molecular studies
 - Serving 4 hospitals up to 30 miles away
 - Specimen delivery efficiency
 - Production efficiency
 - Timeliness of slide production & return delivery
- Large specimen resections triaged to Tumor Board presentations at 4 hospitals

Lean Operational Efficiency

- **Continuous flow goal**

- Centralized production for Accession, Gross, Histology, all Stains and Slide disbursement

- **Operational challenges**

Work simplification and mistake-proofing

- **Original condition-** Barcoded operation with transcription-less & paper-less gross, histology and signout
- **Challenge-** same-day metrics of successful production and defect resolution between hospitals

Load leveling

- **Original condition-** 1 histology shift
- **Challenge-** Match courier with specimen availability and workers with volumes of work around the clock

Batch size reduction

- **Original condition-** overnight large specimen batch processors, same-day rapid cycle processing of small biopsies only since 2004
- **Challenge-** rapid cycle processing of large specimens & biopsies

LESSON

Lean Principle- Start with Work Simplification

“Every well thought-out process is simple.”

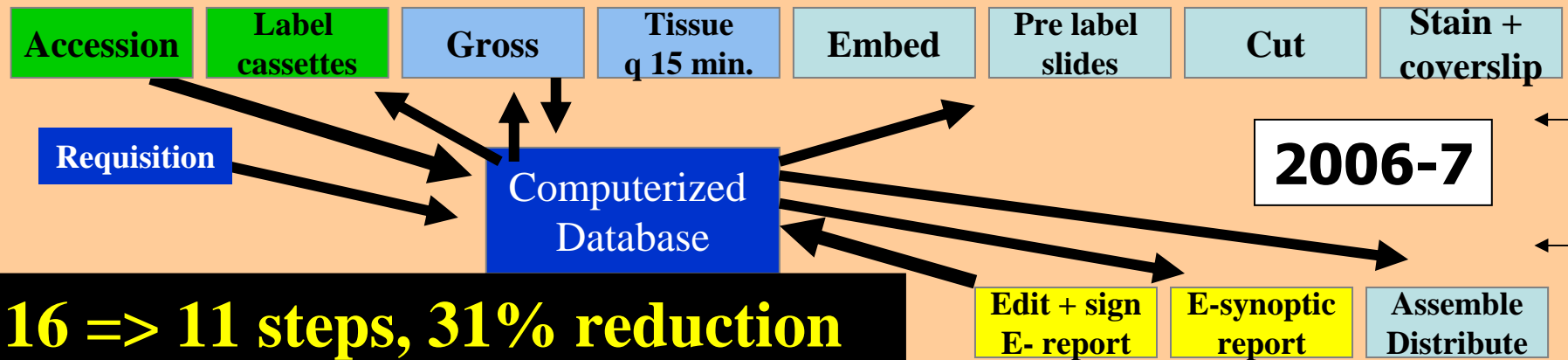
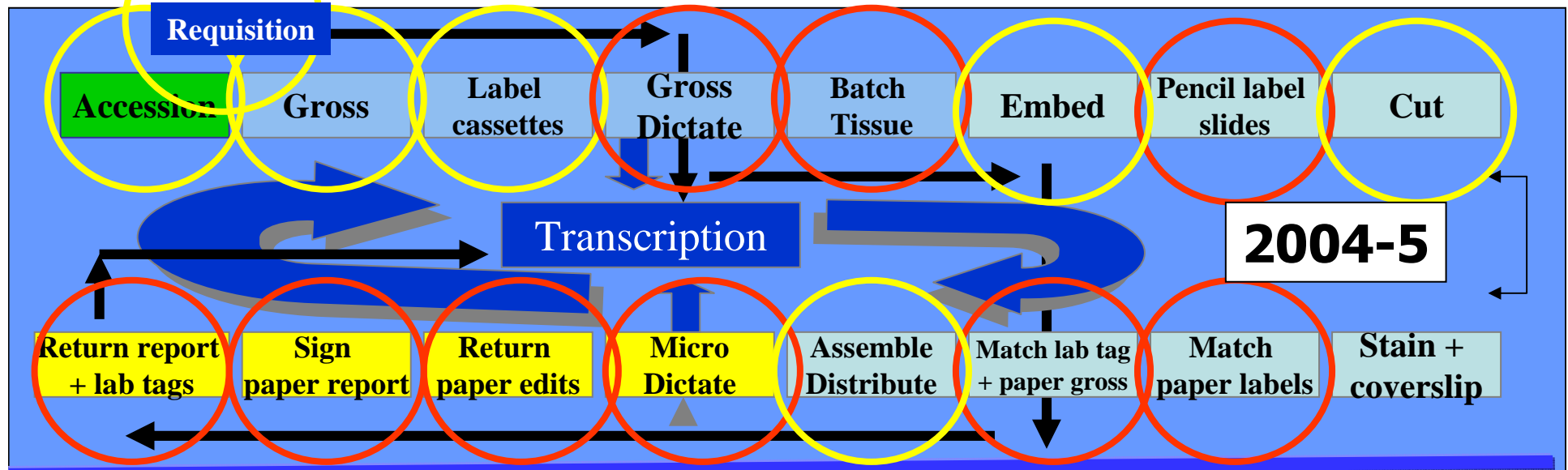
– Henry Ford



Transition to Paperless Barcoded Workflow in AP

Process modified

Process eliminated



16 => 11 steps, 31% reduction

Key Changes 2004-2008

- Work simplification & standardization reinforced by LIS design and barcode technology
 - Elimination of dictation 100% cases (-3 FTE transcription)
 - Gross & Diagnostic templates tied to LIS part types
 - Bar code specified work processes- accession to signout (2006)
 - Barcode design integrated with LIS (partner General Data)
 - Elimination internal mis-IDs (- 1.3 FTE rework)
 - Adopt chemical resistant slide labels (StainerShield DT)
 - Eliminate pencil writing glass slides (-0.37 FTE histotech)
 - Eliminate slide label matching post stain (-1.0 FTE histotech)

Accession

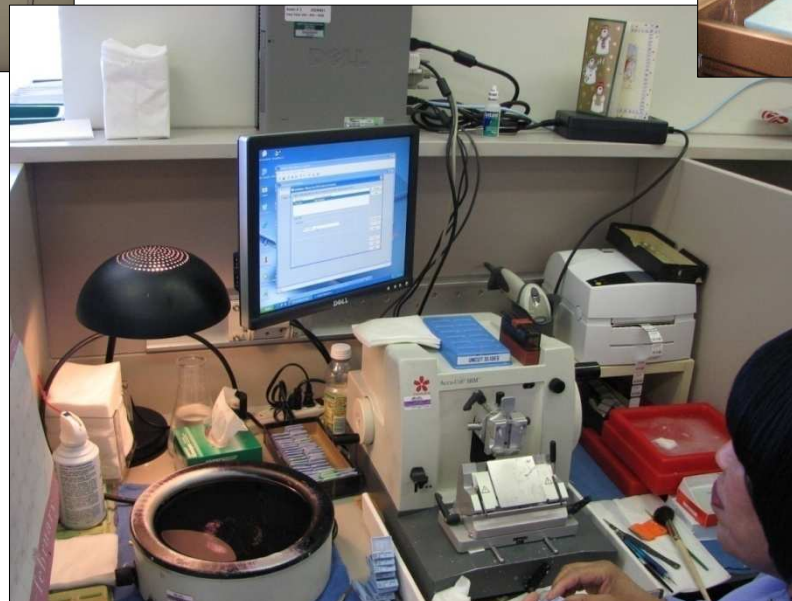
Simplified Activities

All work is highly specified and front-loaded



Key Changes 2004-2008

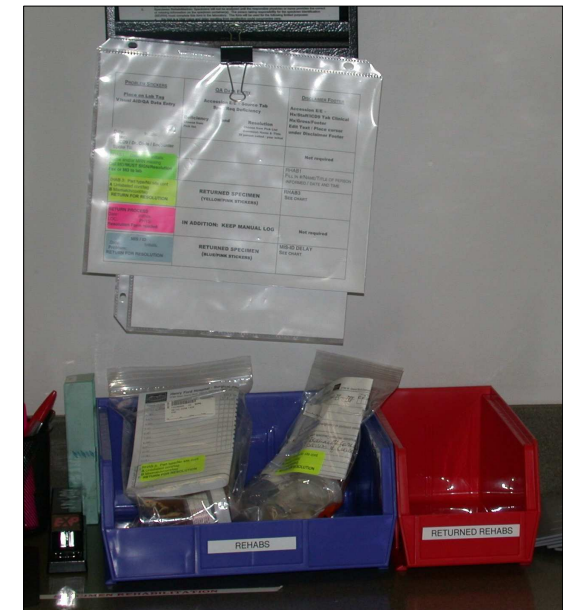
- Laboratory structural redesign, work cell design & standardization



- Linear flow
- U-shaped individual workcells

Key Changes 2004-2008

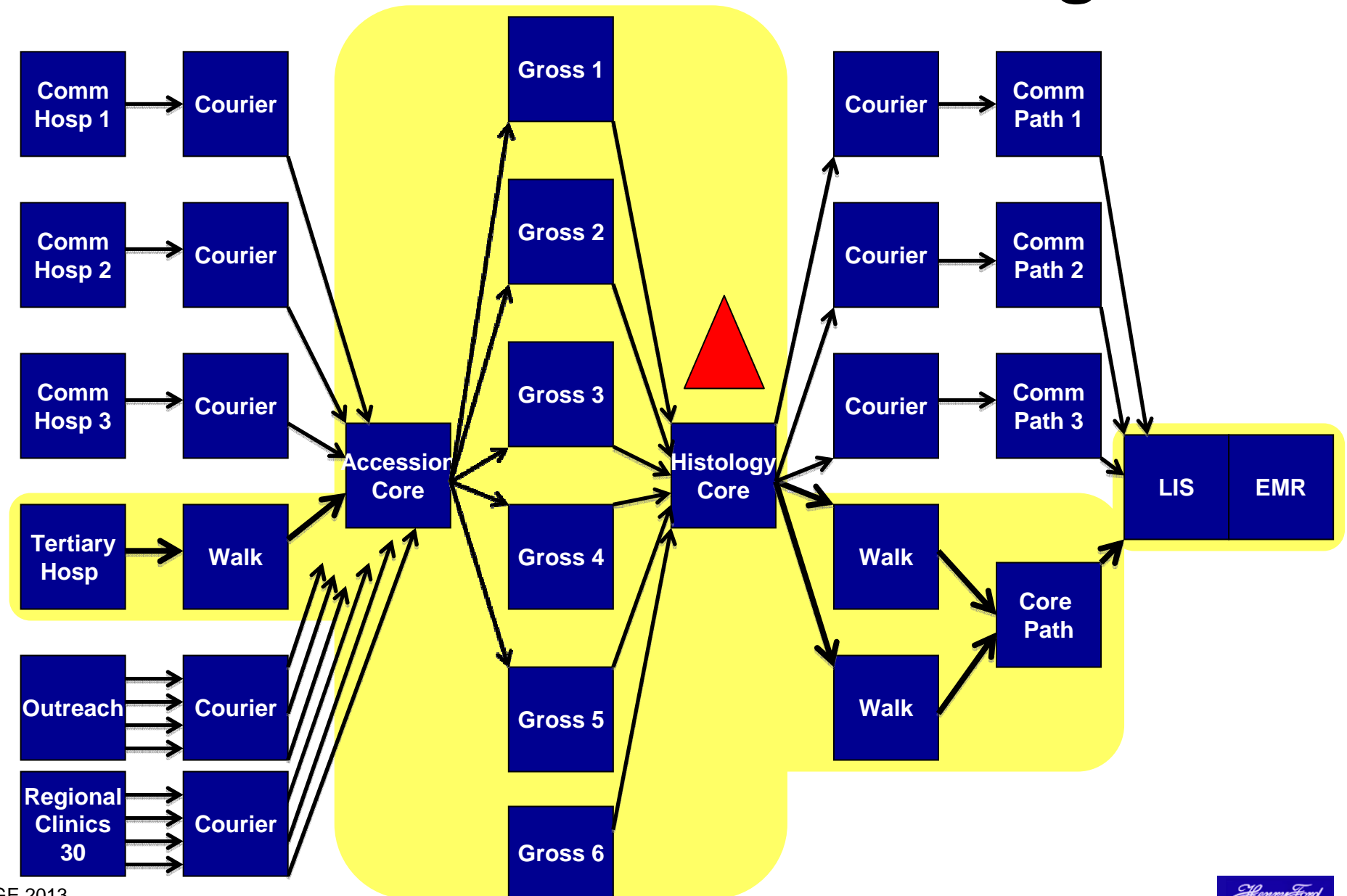
- Organized workflow, visual standard work, priority specimen streams



Safer Work Simplification Redesign



AP Bottlenecks & Challenges



Histology Core

- Resolving the bottlenecks
 - 2.5 shifts (20 hours) (5AM-1AM)
 - Standard work, barcode driven, LIS integrated
 - Small batches, pull
 - Daily maintenance kaizen
- Lean aligned technology

- **Rapid cycle times**
- **Adapted to small batches**
- **Continuous Flow Production**
- **Closer to ideal flow one at a time**

In Search of a Batch

7 AM AP Core Lab- Accession & Gross



To be accessioned
same day arrival

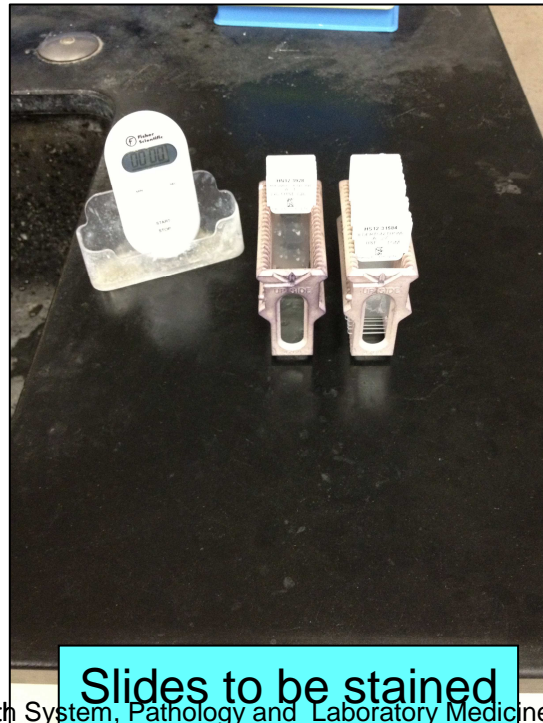
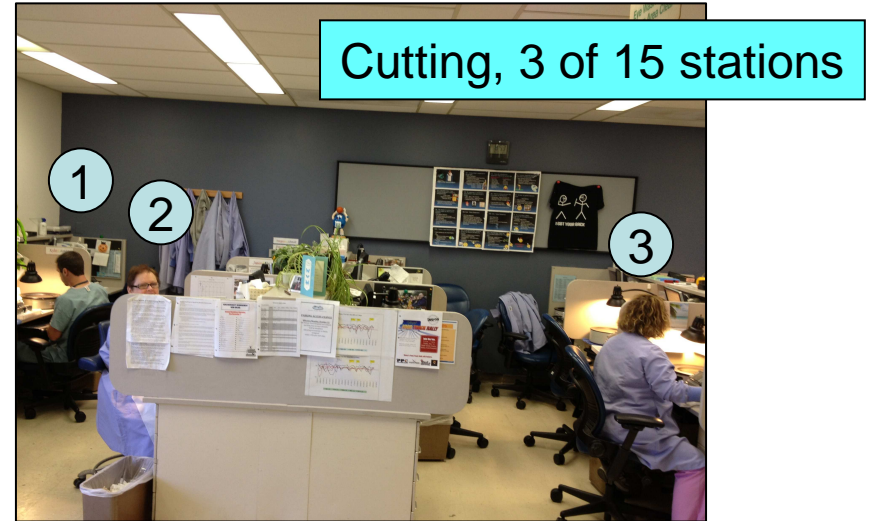


Accessioned
previous evening

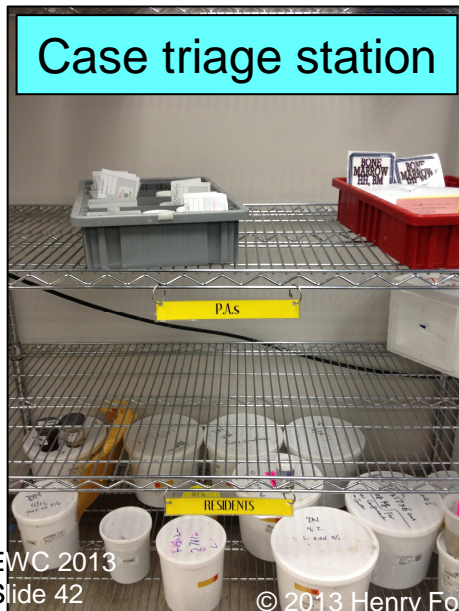


Gross from
previous evening

7 AM AP Core Lab- Histology

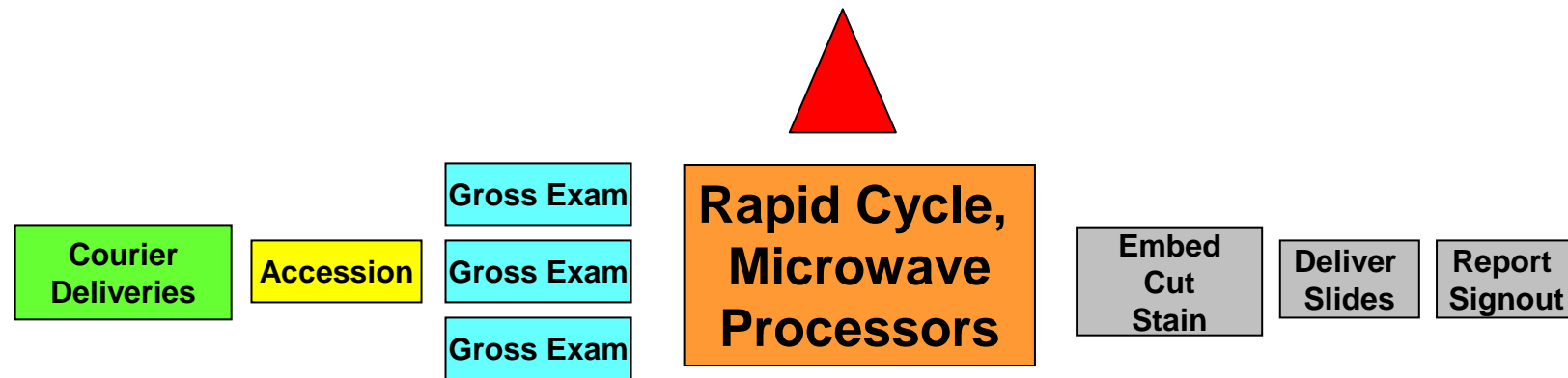


4 PM AP Core Lab- Level Load, Pull



Continuous Flow Promoted by Technology

Small Batches, Rapid Cycle Times Promote Flow



MoTown Motion- Continuous Flow

Bergamo Boulevard



Woodward Avenue



Processor Finish Time	Convntnal Overnight Medium	Convntnal Overnight Large 1	Convntnal Overnight Large 2	Convntnal Overnight Breast	Convntnal Overnight Prostate	Convntnal Midday Medium	Microwave Biopsy
4am							
5							
6							
7							
8							
9							
10							
11							
12pm							
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12am							
1							
2							

Before

Cycle Time
10-12 hrs

Cycle
Time
4 hrs

Cycle
Time
1.5 hrs

Histology Processing Flow

Conventional
Overnight processing
Large & Medium & Derm

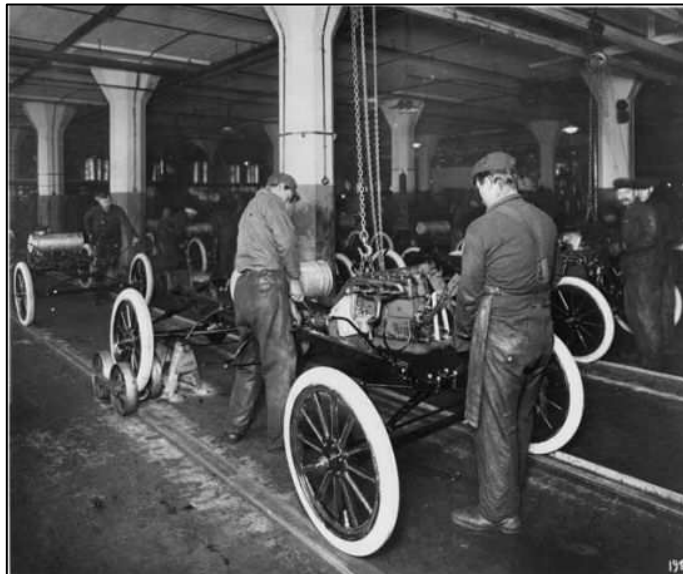
Microwave
Same Day processing
Biopsies
from previous day
and
early same day Biopsies
in mornings
except Prostate and Breast

Processor Finish Time	Convntnal Overnight Cell Block	Convntnal Overnight Large 1	Convntnal Overnight Breast	Convntnal Overnight Large 2	Convntnal Midday Large	Microwave Large 1	Microwave Large 2	Microwave Macroblock Prostate 1	Microwave Macroblock Prostate 2	Microwave Biopsy 1 Biopsy 2
4am			Histology Processing Flow							
5										
6										
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10										
11										
12pm	Cycle Time 10 hrs									
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LESSON

“It’s the work,
not the man that manages.”

-Henry Ford

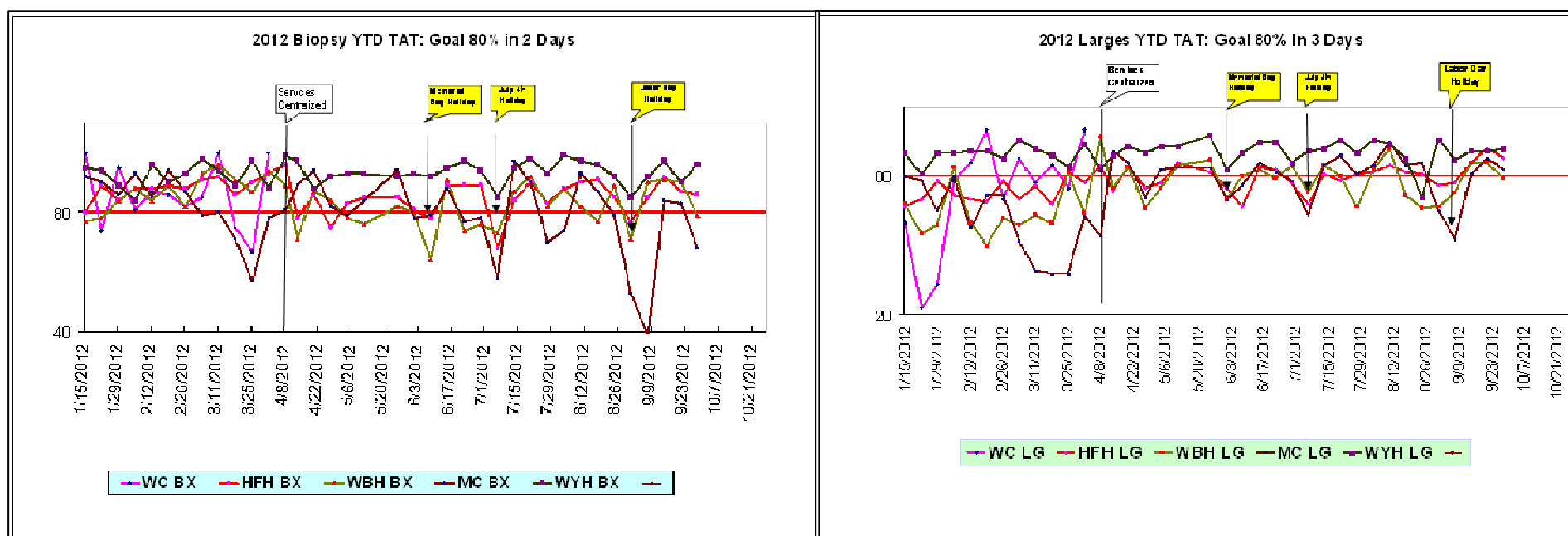


Time Outcome

Surgical Report Times

All Small Biopsies
80% within 2 days

All Large Specimen Resections
80% within 3 days



LESSON

Don't Be Overwhelmed

“Nothing is particularly hard
if you divide it into small jobs.”

– Henry Ford



Safer

Now that we have a functional System of Work

- What is the next vision?



Defect Free
On demand
Immediate
One at a time
Continuous flow
Minimal waste

➤ ***Safely for every PATIENT***

Barcode Specified Work Processes

Henry Ford Hospital - Surgical Pathology
2799 West Grand Blvd., Detroit, Michigan 48202 ph: 313-916-2357 Date of Surgery: 8-4-08 ☐ IPD ☐ OPD

Tissue or Specimen Anatomic Site and Procedure: ICD-9 DX CODE (PLACE PATIENT LABEL HERE)
1. (A) Colon, Sig. 211.3 MRN 80098630900
2. (B) Colon, Desc. 211.3 NAME PAN, Peter
3. (C) Stomach, Bx. 53.5.4 DOB
4. (D) Suffix:
5. (E) Send diagnostic report to:
6. (F) Doctor name: TEST Dr. Code:
7. (G) Biopsy # or office lab
8. (H) Additional Copy to: Dr.
9. (I) Biopsy # or office lab
10. (J) Biopsy # or office lab
11. (K) Biopsy # or office lab
12. (L) Biopsy # or office lab

Clinical History/Radiologic findings: Jimmy Hx of Colon Cancer
Pre-Op/Post-Op diagnosis:

MUST COMPLETE 26079 Rev.

PAN, PETER
MRN: 80098630900
HS08-100082

1

Specimen container

2

3

Tissue cassette

4

Glass slide

HS08-100082
PAN, PETER
A-1
Lev 1 H&E JMT
Henry Ford Hosp.

HS08-100082
PAN, PETER
B-1
Lev 2 H&E JMT
Henry Ford Hosp.

HS08-100082
PAN, PETER
C-1
Lev 1 H&E JMT
Henry Ford Hosp.

HS08-100082
PAN, PETER
C-1
Lev 2 H&E JMT
Henry Ford Hosp.

HS08-100082
PAN, PETER
C-1
Lev 4 Blank JMT
Henry Ford Hosp.

This case is submitted in 3 specimen containers consisting of:
part A - sigmoid colon biopsy,
part B - transverse colon biopsy and
part C - stomach biopsy with standing preorder for Helicobacter pylori immunostain.

Protocol driven information is reflected in the slide labels dictating 2 levels cut for each part.

The stomach biopsy protocol, part C, calls for an additional 2 blank slides to be cut, one for the immunostain & a 4th left unstained.

All barcodes generated at Accession & Microtome

Changes in Mis-identifications In-Process

Pre (2006) and Post Barcode (2007) Specified Workflow Conditions

	2006 Volume By Category	2006 No. Defects (rate)	2007 Volume By Category	2007 No. Defects (rate)	
Surgical Cases	2,694	45 (1.67%)	2,877	18 (0.63%)	62% (p< 0.001)
Specimen Parts	4,413	10 (2.3%)	4,725	11 (2.3%)	0% NS
Tissue Cassettes	8,776	5 (0.057%)	9,167	5 (0.054%)	5.3% NS
Slides	14,270	30 (0.21%)	17,927	2 (0.011%)	95% (p<0.001)

NS= not significant, Chi-square test

The Henry Ford Production System. Reduction of Surgical Pathology In-Process Misidentification Defects by Bar Code Specified Work Process Standardization. Zarbo RJ, Tuthill JM, D'Angelo R, et al
AJCP 2009;131:468-477

Now that we have a functional System of Work

- What is the next vision?



Defect Free
On demand
Immediate
One at a time
Continuous flow
Minimal waste



***Safely for every
EMPLOYEE***

What does Kielbasa

Employee safety and pre-analytic specimen quality have in common?





New Condition New Vision & Means & Goals

- Reduce employee exposure to formalin in Operating Room Suites and Laboratory
- Reduce use of formalin in transport of large specimens to Core Lab from Community Hospitals
- Reduce cost of formalin use and disposal
- Cut all tissues in the fresh state to:
 - Use rapid cycle microwave processors throughout day
 - **Provide better control over fixation type & times**
 - Use less formalin to fix and store

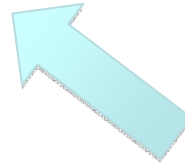
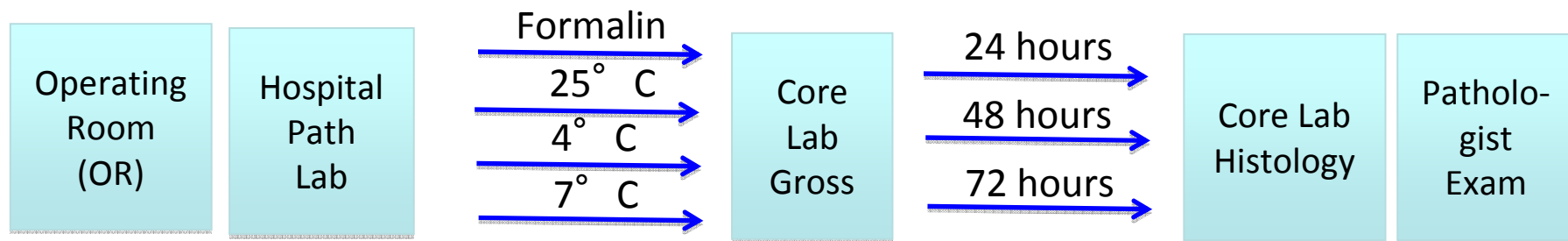
Minimize Formalin



Validation Schemes

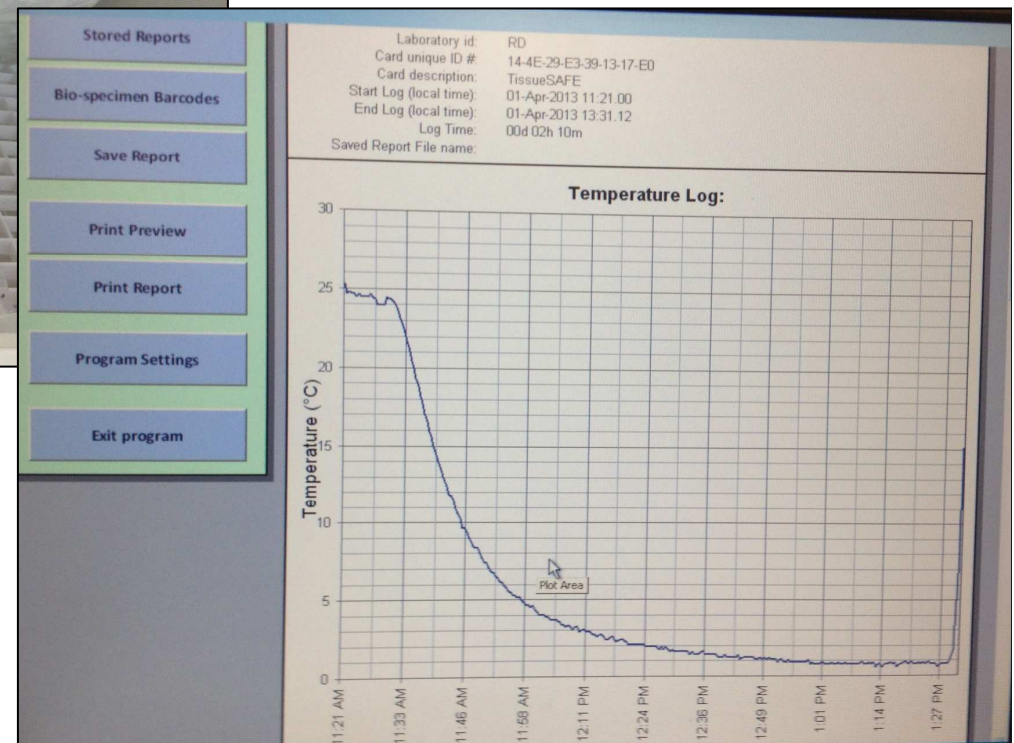
Main & Community Hospital Specimens

Formalin vs Temperature and Time Held Under Vacuum Before Processing

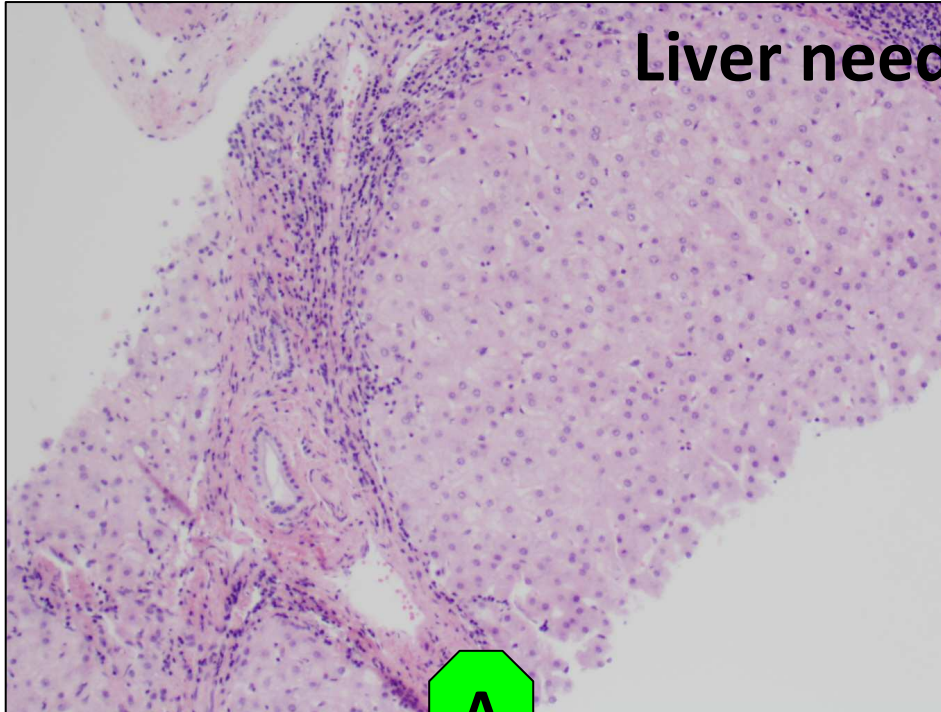


Specimen transport from ORs of Main hospital to Frozen Section Room in OR and from Community hospital 25 miles away to AP Core Laboratory

Compare paired samples of immediately formalin fixed to vacuum sealed



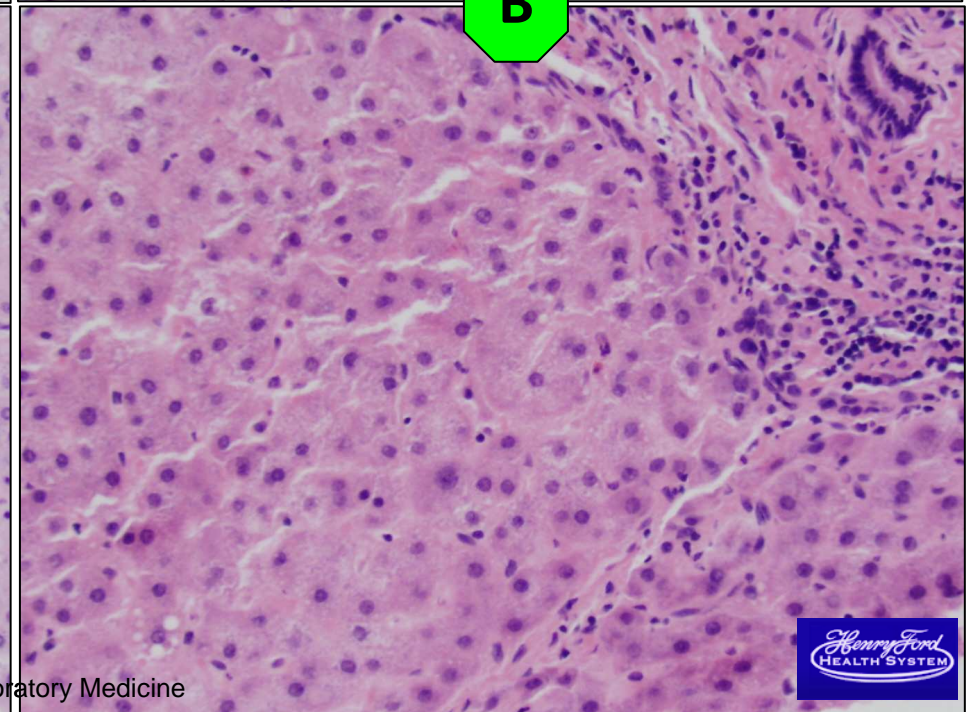
Liver needle biopsies



A



B



Large Specimens	1 acceptable	2 Inferior	3 unacceptable
Appendix	4		
Brain	1		
Colon	11		
Gall bladder	14		
Heart	1		
Kidney		1	
Liver	4		
Lung	3		
Prostate TURP	1	1	
Skin	3		
Small bowel	3	1	
Stomach	20		
Soft tissue	2		
Thyroid	7		
Uterus	28	1	
Tonsils	13		
Miscellaneous*	7	* Miscellaneous hemorrhoid, hydrocele, heart valve, artery, endometrium	
Total	122	4	0

TissueSafe

Milestone Medical

Histologic Assessment of Large Specimen Morphologic Preservation



HEMATOXYLIN AND EOSIN

1= ACCEPTABLE FOR
DIAGNOSIS

- 2= INFERIOR QUALITY
- 3= UNACCEPTABLE FOR
DIAGNOSIS

Safer
+
Cheaper



Year Estimated Formalin Related Savings

Community Hospital, 8900 surgical cases

Seal Select Large specimens Only

- 135 fewer gallons of formalin used
- Cost reduction in purchased formalin:
 - \$5.50 per gallon
- Cost reduction in combined formalin disposal:
 - \$7.00 per gallon
- Cost plastic sealing bags = cost plastic buckets
- Total cost savings for 1 year = \$1688
- Safety in reduced exposure to carcinogen
= priceless

SealSafe

Milestone Medical





Histologic Assessment of Morphologic Preservation in Storage

**1:1 and 2:1 formalin:tissue weight ratio
24, 48, 72 hours under vacuum at room temperature**

Specimens	1 Acceptable 24 hours	1 Acceptable 48 hours	1 Acceptable 72 hours	2 Inferior or 3 Unacceptable	
Colon	1	1	1	0	• 1=
Gall bladder	2	2	2	0	• 2=
Small bowel	1	1	1	0	• 3=
Thyroid	1	1	1	0	• UNACCEPT-
Uterus	5	5	5	0	• ABLE FOR
Total	10	10	10	0	• DIAGNOSIS

Old World- New World



Disposal requires formalin
decanting & tissue
separation offsite



- Formalin spill in lab w/Spill X Neutralizer treatment
- Clean-up costs \$2,500
- Lab evacuated for clean-up

Pilot

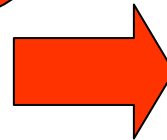
1 week- Space & Disposal Savings



- Formalin used in specimen storage
↓ 9 gallons/wk or 468 gallons/yr
- Formalin Cost reduction to Lab/year
↓ \$2594
- Shelf space reduction
↓ 43%
- Institution combined Formalin/Tissue disposal savings/year \$1.70 ➔ 75 cents/lb
↓ \$51,000

8.8
shelves

5
shelves



LESSON

New Technology

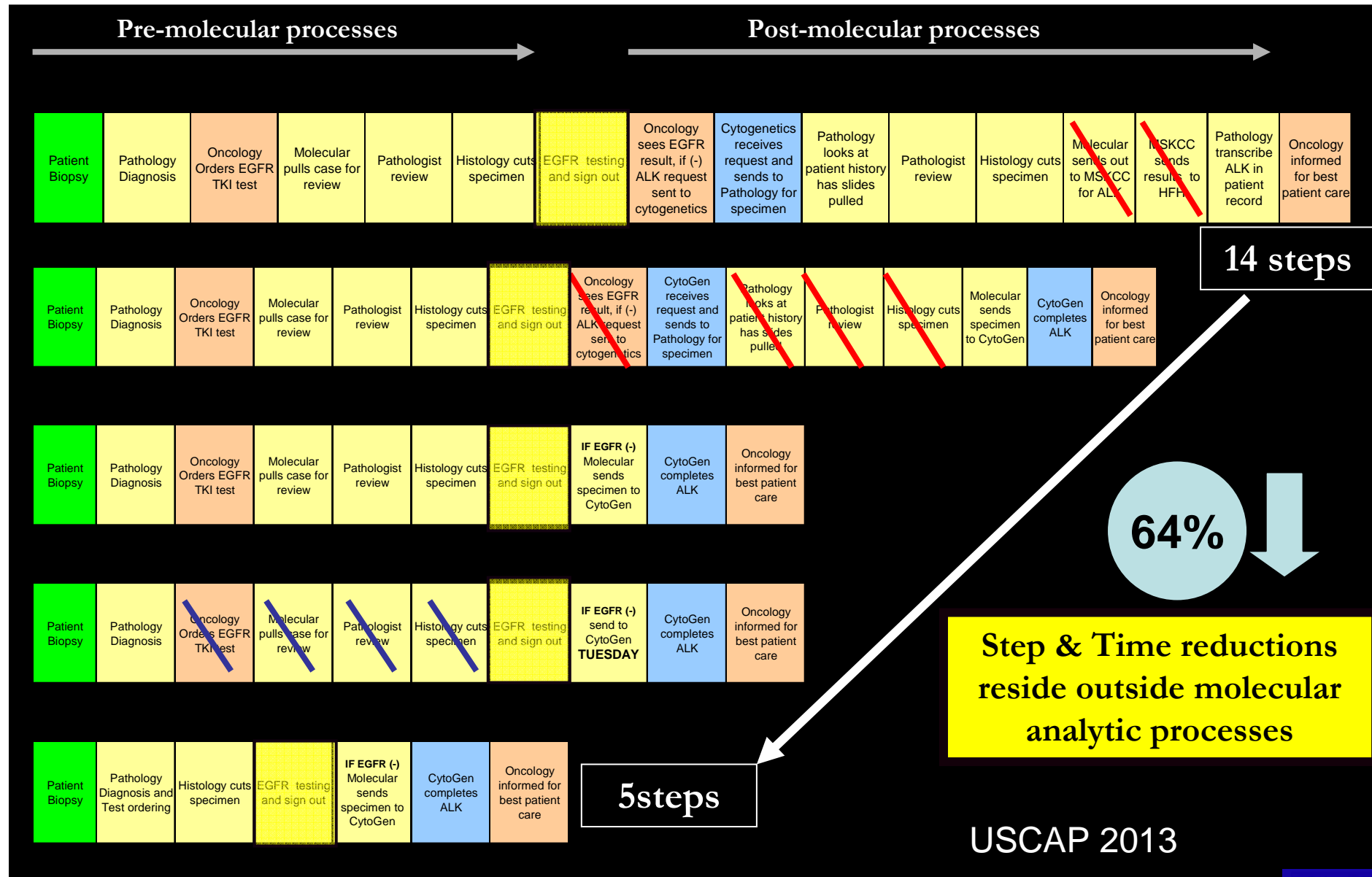
“Your methods are formed by what you are trying to do; they do not determine your purpose. To my mind it is starting wrong to put methods ahead of purpose.”

– Henry Ford



Fast & Accurate for Molecular

EGFR and ALK Testing Protocols-Cycle Time Reductions



Key Interventions & Their Impact

TAT Interval Diagnosis to Treatment Decision

61
days

Cycle 1: MEDICAL NEED ESTABLISHED
EGFR done in-house / ALK a send out test

35
days

Cycle 2: ALK TESTING BROUGHT IN-HOUSE

17
days

- **Cycle 3: BETTER CLINICIAN AWARENESS**
– ALK reflex in place

12
days

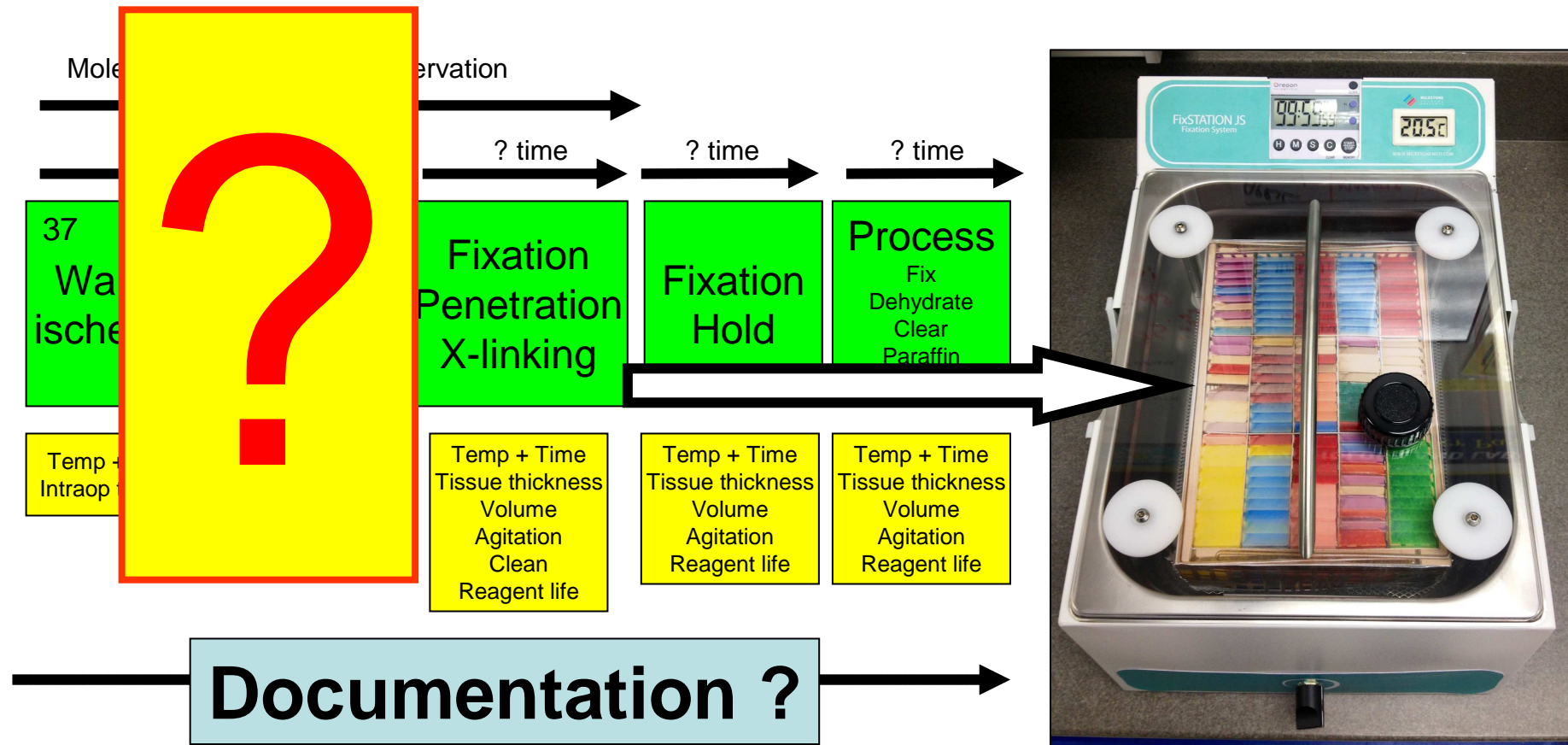
- **Cycle 4: REDESIGN SPECIMEN HANDOFFS**

10
days

- **Cycle 5 - Ideal: AUTHORIZE PATHOLOGISTS TO ORDER EGFR**

Current recommended standard TAT per CAP/AMP/IASLC = 10 days

PreAnalytic Specimen Quality Variables Determine Success in Molecular Testing



LESSON

***When it comes to tissue preservation
for personalized medicine***

“Well done is quickly done.”

-Julius Caesar

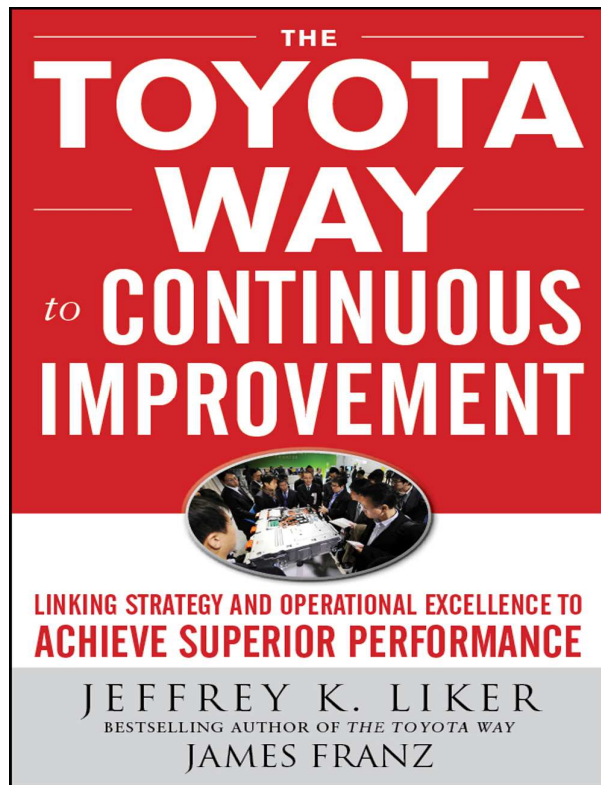
But only if controlled for quality variables

Author, General, Politician

Continuous Improvement in Anatomic Pathology

“We know from the changes that have already been brought about that far greater changes are to come, and that therefore we are not performing a single operation as well as it ought to be performed.”

— Henry Ford



**“Relentlessly
pursuing
perfection!”**

Chapter 9
**Bringing Ford’s Ideas
Alive at Henry Ford Health
System Labs through
PDCA Leadership**

