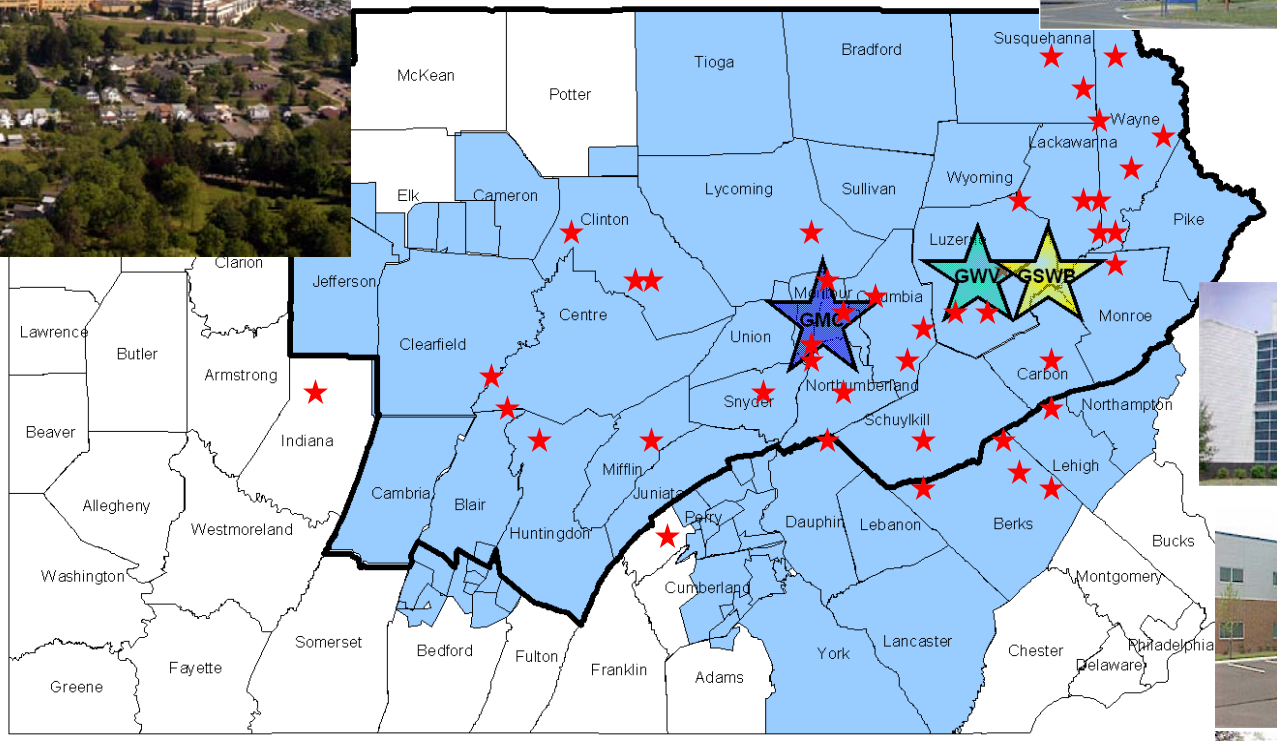
Jay B. Jones, Ph.D. DABCC

Dr. Jones has served as the Director, Geisinger Regional Laboratories since 1985 and the Director, Ancillary Testing Program for Geisinger Medical Center's Division of Laboratory Medicine since 1992. Concurrently, he has also held the position of Director, Chemistry and Toxicology since 1981.

Process Improvement for Critical and Point of Care Testing (CPOCT): A "Lean" Perspective.

Jay B. Jones, PhD DABCC
Director, Regional Labs and Chemistry
Geisinger Health System
Danville, Pennsylvania

Geisinger Health System



Geisinger Hospitals– Provide Primary/Secondary/Tertiary Care

GMC Geisinger Med. Ctr.

GWV Geisinger Wyoming Valley

GSWB Geisinger South Wilkes Barre

Geisinger Med. Grou

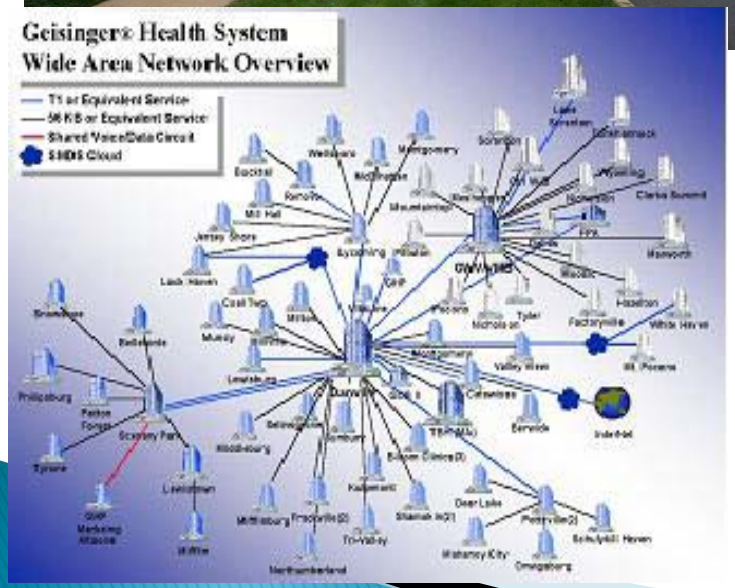
GHP Service Are

GHS Service Are

“Lean” for Process Improvement (2 Examples)

1) Accessible enterprise POC Prothrombin time (PT-INR) testing to avoid strokes (e.g. “Coag Clinics”)
2) Highly efficient and integrated enterprise whole blood/blood gas testing to support CV Surgery (e.g. paperless, wireless, IGO)

Organized EHR & LIS in the Geisinger Enterprise



- $80M+ spent on EHR (EpicCare)
- WAN routers connect to Data Center and “Rack & Stack” Virtual Client Servers (including SunQuest)
- 28 CS apps from Lab alone

What is “Lean”

- Process efficiency defined and practiced by Toyota, Japan
- Value stream mapping (removing waste)
- Process mapping from test(s) ordering to integrating the test result(s) into practice
- Improving the test process in terms of time, people, materiel, quality, outcome value
- Regarded as a method to cut costs

POCT vs. Core Lab "Lean"

- Patient centric
- Starts when the patient enters the door
- (Pre-, Post-) Analytical concurrent
- Single piece flow
- "Real-time" to treatment
- On the spot clinically

- Specimen centric
- Starts when the specimen enters the lab
- (Pre-, Post-) Analytical sequenced in "legs"
- Batched
- "Requeing" required for treatment
- Remote clinically

POCT vs. Core Lab "Lean"

- Test acuity is driver to POC (ABGs, PT-INR)
- Specimen prep is driver to Core Lab
- Turnaround time is driver to POC
- Instrument sophistication is driver to Core Lab

- Expense assessed for **total cost to treatment** may drive to POCT (**total process and total value stream mapping**)

Top Ten "Lean" POCT Attributes

10. POCT consumes less paper and less space storing paper
    - No specimen labels
    - No work lists
    - No requisitions
    - No instrument printouts
    - Etc.

Top Ten "Lean" POCT Attributes

9. POCT performed on "fresh" patient specimen without processing of tube(s)
   - No specimen tube (assuming it's the right one)
   - No centrifuge (space, noise, maintenance)
   - Fewer processing artifacts (temperature, changes with transport & storage time)
   - Closer to in vivo

Top Ten "Lean" POCT Attributes

8. POCT is mobile and easily deployable
   - Can move with clinical service
   - Can be shared between services & operators
   - Good backup system(s) for multiple locations
   - Can travel with patient (e.g. ECMO)
   - Rapid implementation and training

Top Ten "Lean" POCT Attributes

7. POCT is less of a biohazard
   - Specimen contained in test element
   - POCT goes into isolation environment; specimen doesn't come out
   - Less unused specimen to landfill or incinerator
   - No broken tubes or aerosols

Top Ten "Lean" POCT Attributes

6. POCT consumes less patient specimen
   - Most of the specimen is wasted in even 3 mL tubes
   - Blood conservation key in neonates
   - Blood conservation being considered more for all patients

Top Ten "Lean" POCT Attributes

5. POCT improves turnaround time (TAT)
   - Focus on problem areas (e.g. ED)
   - Can be used selectively (e.g. trauma cases but not general ED)
   - TAT on POCT device typically the analytical time (no need to account)
   - POCT often only option because of logistics

Top Ten "Lean" POCT Attributes

4. POCT is less expensive in many situations
   - Improves patient compliance & hence lessens costly adverse outcomes
   - Saves processing time & resources in lab
   - Look for expensive clinic time savings (e.g OR time)
   - Clinic and patient may enjoy the "bang" for the lab's buck

Top Ten "Lean" POCT Attributes

3. POCT less likely to produce a medical error
   - Patient physically scanned (few mis-IDs)
   - Operator physically scanned
   - Few if any handoffs of requests/results
   - Critical results not delayed or lost
   - Medical procedures safeguarded (e.g. creatinine with interventional radiology)

Top Ten "Lean" POCT Attributes

2. POCT saves provider time & effort
   - Less queuing up of previous patient encounter
   - Less CRT look up time & distraction
   - Less brain drain to associate lab results to clinical situation
   - More efficient clinical response

Top Ten "Lean" POCT Attributes

1. **POCT enables integration of testing into clinical flow & clinical judgment**
   - "choreography" into clinical process
   - More likely to influence treatment
   - Impact on clinical outcome amplified
   - Immediacy and proximity makes POCT a clinical tool like a stethoscope

Example 1 – Geisinger Health System "Coag Clinics"

- 9000+ Active Patients; 30,000+ Total Patients
- 15+ locations staffed by 22 FTE pharmacists; CLIA certificates owned by System Lab
- ~14,000+ Encounters per month
- 1.53 encounters per patient per month
- 200 – 300 new patients per month
- >2% per month growth rate
- 70% of INR's within Therapeutic Range

7-10 Minute Patient "Coag Clinic" Visit

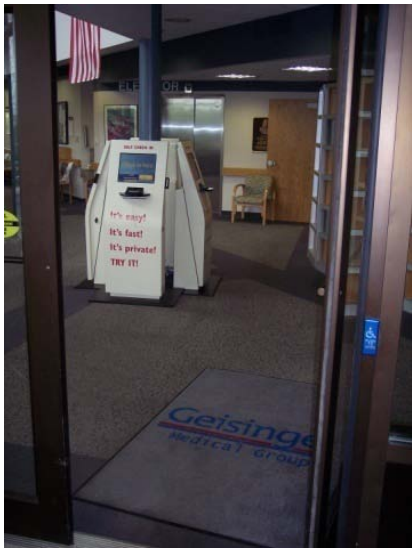
- Patient Registers in lobby("Check in" at Kiosk)
- Pharmacist Sees Appt in EpicCare EHR
- Pharmacist Greets patient in waiting area
- Pharmacist Chats, gets patient history, Finger sticks
- Pharmacist matches patient "story" with PTINR result
- Pharmacist presents card with PTINR result, dose adjustment, next appt schedule to patient
- Any other questions? Bye.

Touch and Swipe Registration Kiosks in Lobbies

- http://www.geisinger.org/locations/gw/mv/index.html

Regional Anticoagulation Clinics

- 10 CLIA certificates
- Pharmacy does PTINR
- Lab billing/purchasing
- LIS connectivity
- Pharmacy tracks utilization & outcome



“Lean” Tends to be Visual

Make sure you get what your doctor prescribes.

For your protection, tablets are clearly marked with the COUMADIN® (Warfarin Sodium Tablets, USP) Crystalline name and dosage strength to help avoid confusion with your other medications.

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GHS WESTERN REGION ANTICOAGULATION CLINIC
APPOINTMENT

DATE: _____ TIME: _____

TO CHANGE APPOINTMENT CALL (717) 242-4275
MONDAY THRU FRIDAY 8:00 AM - 5:30 PM

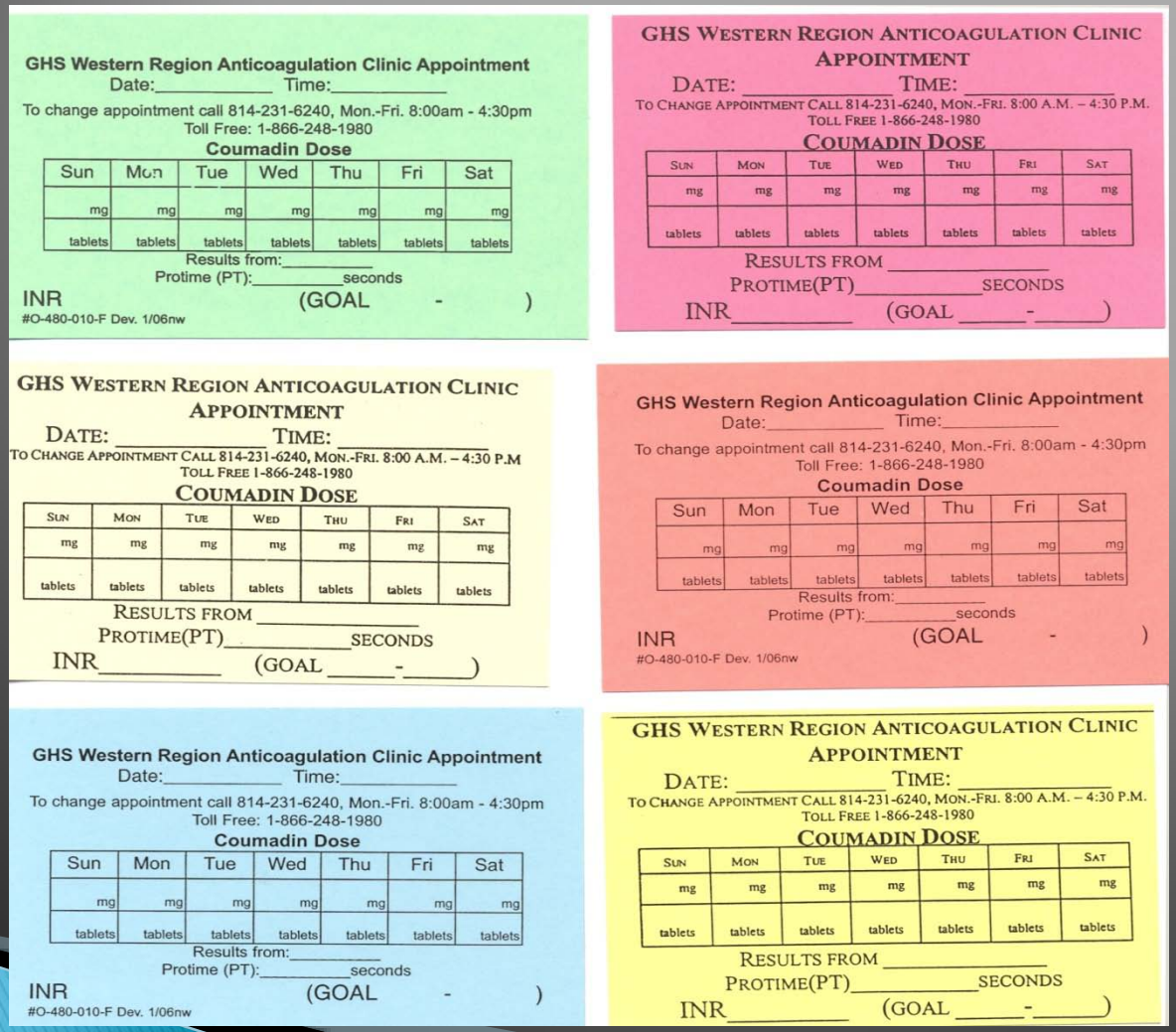
COUMADIN DOSE

SUN.	MON.	TUE.	WED.	THU.	FRI.	SAT.
mg	mg	mg	mg	mg	mg	mg
tablets	tablets	tablets	tablets	tablets	tablets	tablets

RESULTS FROM _____

#A-750-213-F Rev. 11/07js INR_____ (GOAL _____-_____)

Patients carry out next Appointment, Coumadin Dose, & PT-INR with goal



GHS Western Region Anticoagulation Clinic Appointment
Date:_____ Time:_____
To change appointment call 814-231-6240, Mon.-Fri. 8:00am - 4:30pm
Toll Free: 1-866-248-1980
Coumadin Dose

Sun	Mon	Tue	Wed	Thu	Fri	Sat
mg	mg	mg	mg	mg	mg	mg
tablets	tablets	tablets	tablets	tablets	tablets	tablets

Results from:_____
Protime (PT):_____seconds
INR (GOAL -)
#O-480-010-F Dev. 1/06nw

GHS WESTERN REGION ANTICOAGULATION CLINIC APPOINTMENT
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TOLL FREE 1-866-248-1980
COUMADIN DOSE

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mg	mg	mg	mg	mg	mg	mg
tablets	tablets	tablets	tablets	tablets	tablets	tablets

RESULTS FROM _____
PROTIME(PT)_____SECONDS
INR_____ (GOAL _____-_____)

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SUN	MON	TUE	WED	THU	FRI	SAT
mg	mg	mg	mg	mg	mg	mg
tablets	tablets	tablets	tablets	tablets	tablets	tablets

RESULTS FROM _____
PROTIME(PT)_____SECONDS
INR_____ (GOAL _____-_____)

Incidence of Adverse Events

Comparison of GHS data with literature

	GHS Clinics (1)	Reference Anticoagulation Clinics (2)	Usual Practice (non-clinic Patients)*	GHS Non-Clinic Patients (3)
Rate of Bleeding	**8.67%**	15.30%	35.30%	17.10%
Rate of Thromboembolic Events	**1.54%**	3.60%	11.80%	20.60%

(1) Based on 2004-2009 GHS Anticoag data-total of 8847 patients on continous therapy Incidence of Events per patient per year

(2) Bungard TJ, Gardner L, Archer SL. Evaluation of a pharmacist-managed anticoagulation

(3) Based on 2009 GHS data - total of 307 patients on continous therapy

Drug Therapy Compliance 2003

- "Coag Clinic" patient compliance
  - average compliance with warfarin therapy = 82.3%
    - Comparison <50%
  - 57.5% of patients had compliance rates of 90% or greater
    - Comparison <20%

Stroke Prevention

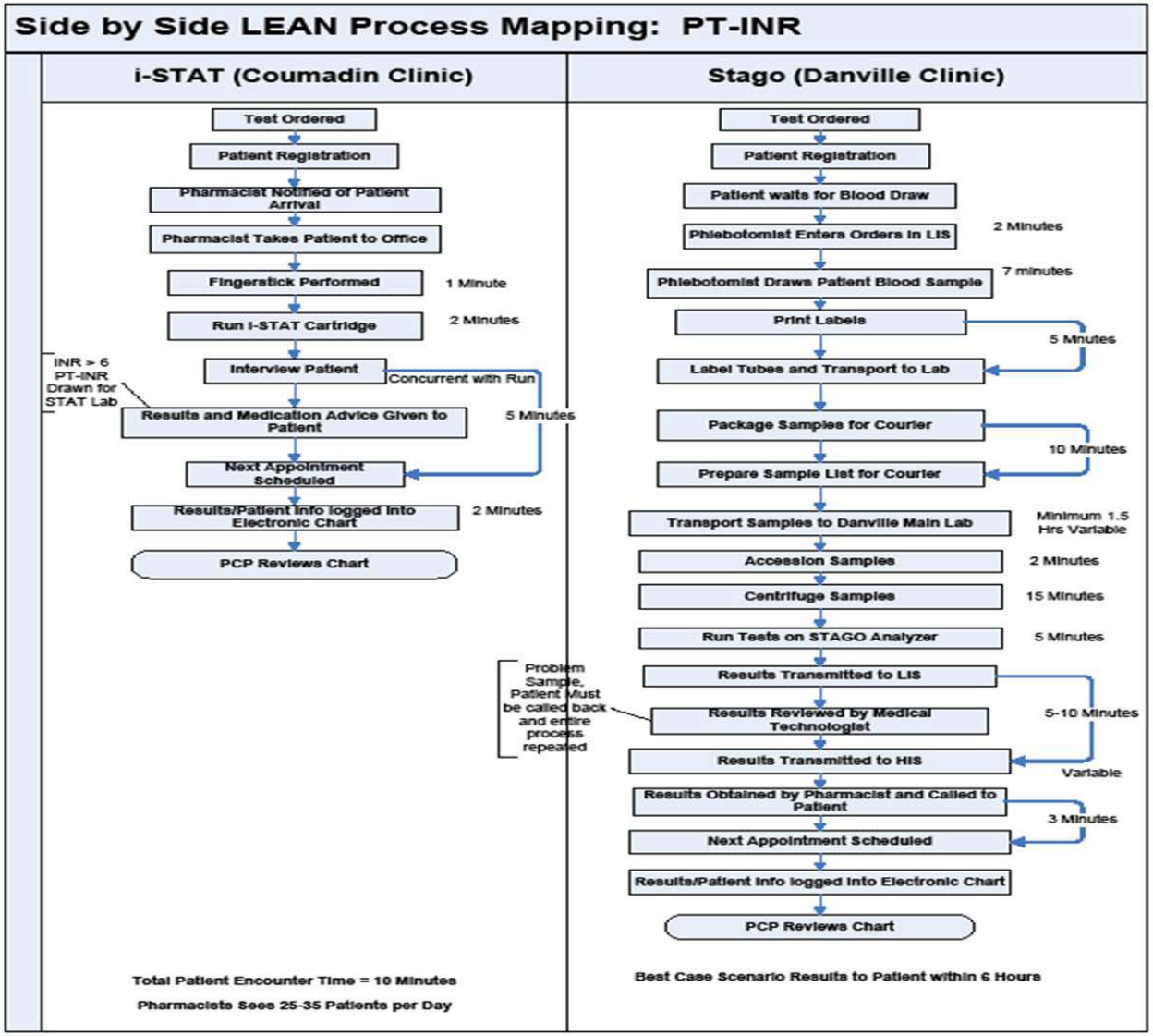
- 3117 patients were actively managed on anticoagulation therapy during calendar year 2009, with a diagnosis of A-Fib
- For each every 33 A-fib patients on anticoagulation therapy 1 stroke per year is avoided
- 94 potential strokes avoided during 2009

Stroke Prevention

- Cost per Acute Stroke approximately $12,000 for initial event
  - $1,128,000 annual cost avoidance
- Ongoing care costs are approximately $3500 per patient per year
  - $329,000 per patient per year cost avoidance
- Cost avoidance associated with stroke prevention more than pays for annual cost of the program

Lab's Role in "Coag Clinic"

- Provide/maintain instruments
- QC/PT/CLIA regulatory compliance
- Result reported through LIS to EHR, with billing of outpatient CPT revenue to lab
- Lab highly regarded senior leadership as providing integral patient service at POC
- Pharmacy gets most of the credit and truly values and trusts the lab


Side by Side LEAN Process Mapping: PT-INR
i-STAT (Coumadin Clinic)
Test Ordered
Patient Registration
Pharmacist Notified of Patient Arrival
Pharmacist Takes Patient to Office
Fingerstick Performed
1 Minute
Run i-STAT Cartridge
2 Minutes
INR > 6 PT-INR Drawn for STAT Lab
Interview Patient
Concurrent with Run
Results and Medication Advice Given to Patient
5 Minutes
Next Appointment Scheduled
Results/Patient Info logged into Electronic Chart
2 Minutes
PCP Reviews Chart
Total Patient Encounter Time = 10 Minutes
Pharmacists Sees 25-35 Patients per Day
Stago (Danville Clinic)
Test Ordered
Patient Registration
Patient waits for Blood Draw
Phlebotomist Enters Orders in LIS
2 Minutes
Phlebotomist Draws Patient Blood Sample
7 minutes
Print Labels
5 Minutes
Label Tubes and Transport to Lab
Package Samples for Courier
10 Minutes
Prepare Sample List for Courier
Transport Samples to Danville Main Lab
Minimum 1.5 Hrs Variable
Accession Samples
2 Minutes
Centrifuge Samples
15 Minutes
Run Tests on STAGO Analyzer
5 Minutes
Results Transmitted to LIS
Problem Sample, Patient Must be called back and entire process repeated
Results Reviewed by Medical Technologist
5-10 Minutes
Results Transmitted to HIS
Variable
Results Obtained by Pharmacist and Called to Patient
3 Minutes
Next Appointment Scheduled
Results/Patient Info logged into Electronic Chart
PCP Reviews Chart
Best Case Scenario Results to Patient within 6 Hours

ABGs and Whole Blood Chemistries in the CV OR

- Anecdotal “15 minute TAT” from surgeons
- Traditionally tracked In-Lab 2.5 min. TAT

==========

- Observational “lean” process mapping in OR/lab
- TAT study confirmed 15 min. TAT
- Process improvements designed & prototyped
- Information Technology updates being implemented
- Rolling out process improvements to Enterprise

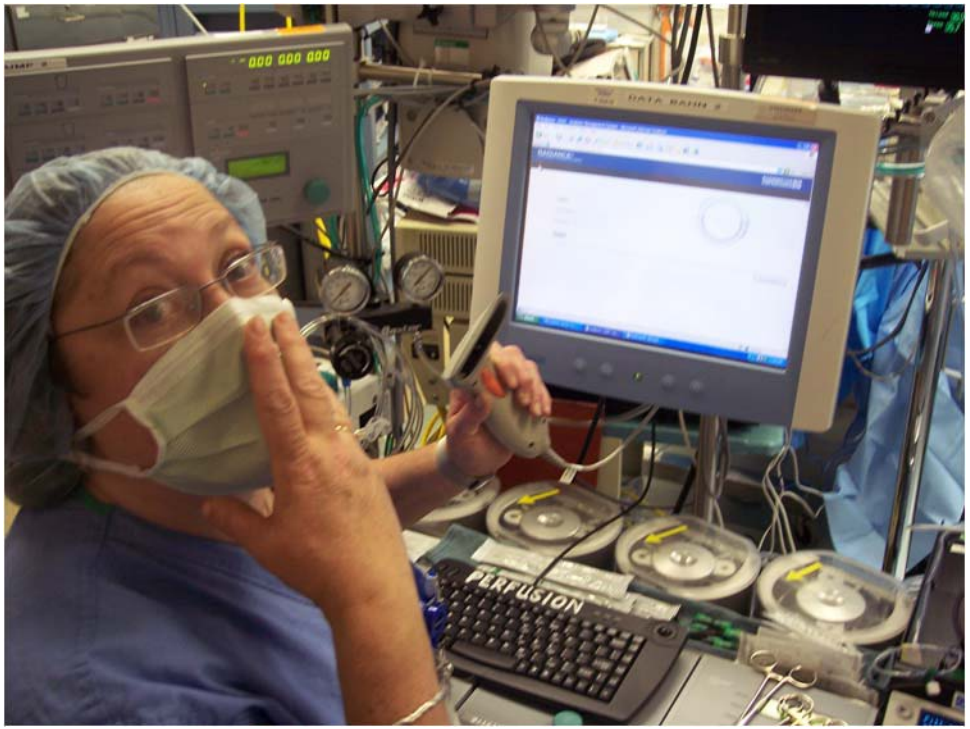
Lean Process Study "Kaisons"

- 15 min. TAT correct!
- CV OR clerical tasks distracting; need GPS model
- Perfusionists need to stay with pump; POCT distracting
- IT solutions needed (e.g. IGO)
- Tube system inconsistent
- CV OR has enterprise team
- 5 min "Vein to Brain" Aim

Components of Turnaround Time from "Vein to Brain" (V to B)"

A. CV-OR (min:sec)	Mean	Minimum	Maximum
1) Specimen Collection	1:48	0:35	3:30
2) Test Ordering	1:44	0:53	3:05
3) Results Receipt	3:54	0:59	6:23
Total "V to B" TAT	15:23	12:12	22 :16
B. Stat Lab (min:sec)			
1) Specimen Receipt	1:41	0:31	3:41
2) Specimen Testing	0:36	0:20	1:16
3) Result Reporting	1:37	0:45	4:24
Total "In Lab" TAT	2:36	1:19	5:36
C. Pneumatic Tube (min:sec)			
1) Derived Transport Time	4:08	1:40	9:55

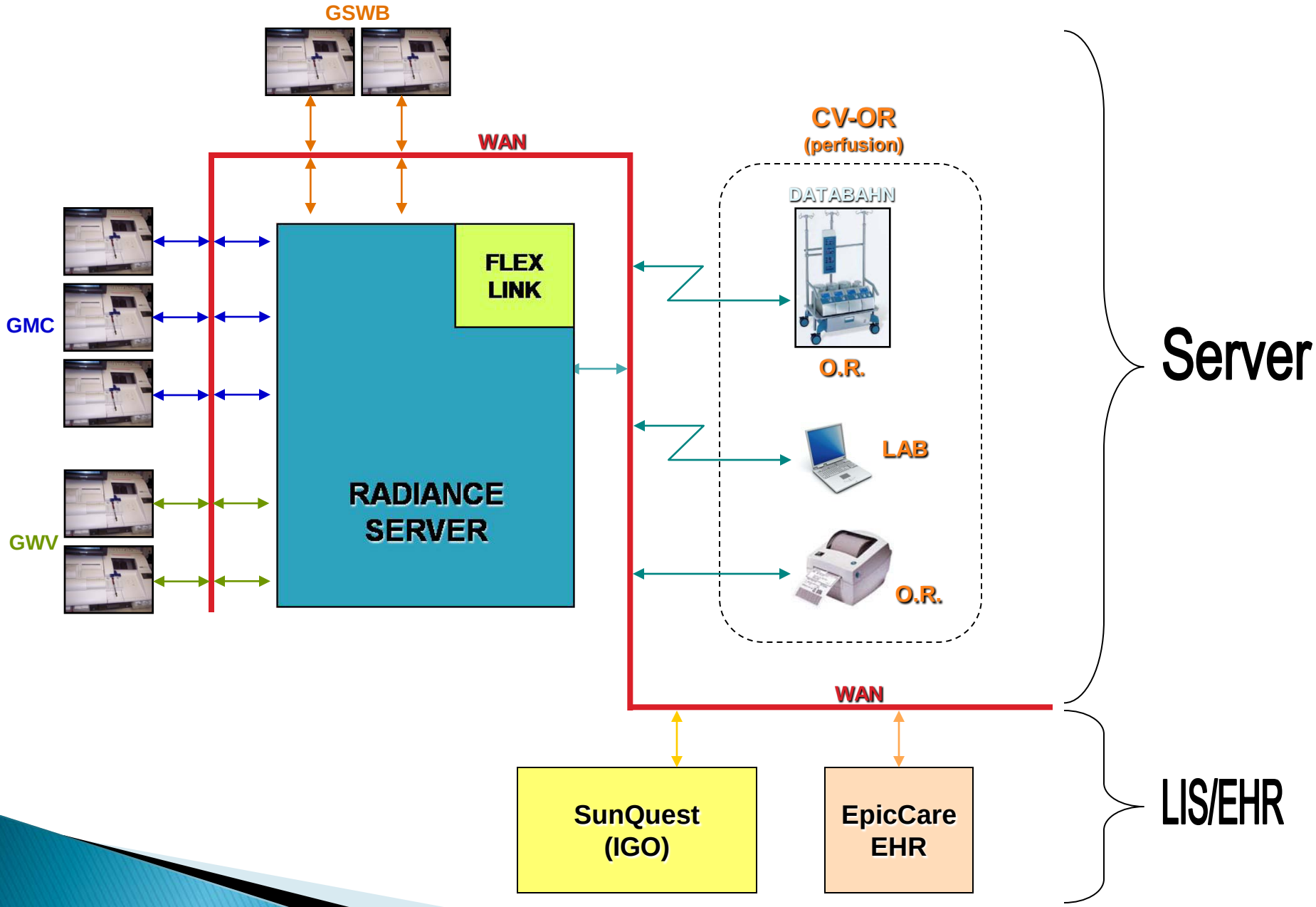
Efficient, Safe Order Entry



1. Patient Barcode

2. Syringe Barcode

3. Operator Barcode


GSWB
WAN
CV-OR
(perfusion)
DATABAHN
FLEX
LINK
GMC
RADIANCE
SERVER
O.R.
LAB
GWV
O.R.
WAN
Server
SunQuest
(IGO)
EpicCare
EHR
LIS/EHR

IVD Industrial Connectivity Consortium (IICC) www.ivdconnectivity.org

- Similar to Connectivity Industrial Consortium (CIC) that created POCT1-A
- Funded by top 7 instrument vendors
- Adopted specifications (i.e. HL7 2.x, IHE, CLSI, etc) for interoperability
- Architecture to include instrument generated orders (IGO) similar to POC instruments (instruments become “smarter”)

Conclusion:

1) POCT is innately “Lean”

2) “Coag Clinics” are a prime example of a “Lean” process improving economic & clinical outcomes

3) “Lean” study of enterprise lab support of clinical services will produce improved efficiency (e.g. CV-surgery)

4) “Leaning” processes around information systems will continue as a prime lab objective