Jay B. Jones, Ph.D. DABCC

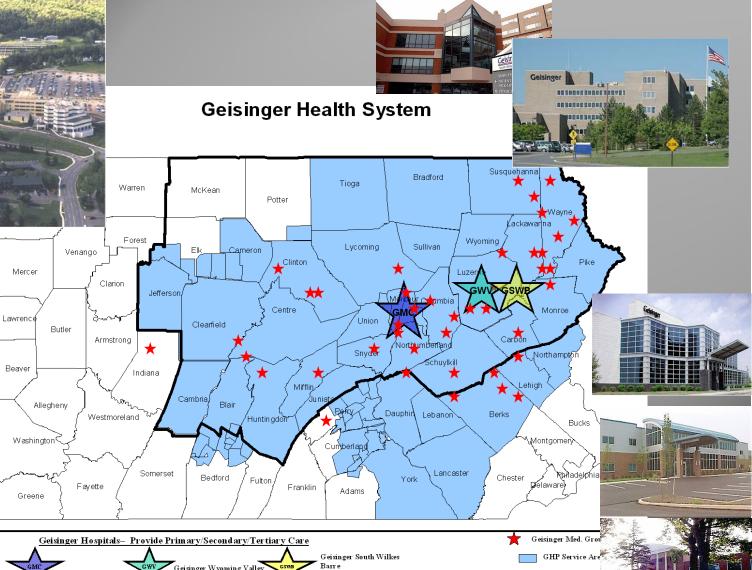


Dr. Jones has served as the Director, Geisinger Regional Laboratories since 1985 and the **Director**, Ancillary Testing **Program for Geisinger Medical** Center's Division of Laboratory Medicine since 1992. Concurrently, he has also held the position of Director, Chemistry and Toxicology since 1981.

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



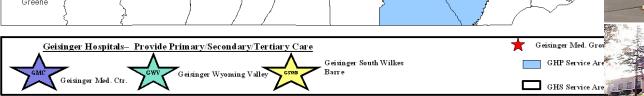


















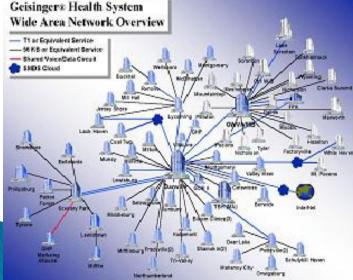


"Lean" for Process Improvement (2 Examples)

- 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, OE/RR)

Organized EHR & LIS in the Geisinger Enterprise





- \$80M spent on EHR (EpicCare)
- WAN routers connect to Data Center and "Rack & Stack" Client Server LIS (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 (<u>total process and total</u> value stream mapping)

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

- 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 <u>in vivo</u>

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

- 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

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

- 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

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

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)

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

- 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"

- > 7,057 Active Patients; 25,792 Total Patients
- 8+ locations staffed by 14 FTE pharmacists;
 CLIA certificates owned by System Lab
- ~11,000 Encounters per month
- 1.53 encounters per patient per month
- 175 250 new patients per month
- >1% 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.geisinge r.org/locations/const /gw/my_visit/mv_we lcome.html



Touch and Swipe Registration Kiosks in Lobbies

- Typically 4 kiosks clustered in lobby
- Patients prefer kiosk registration rather than waiting in line at a desk
- Pharmacist via EHR screen sees patient is on the way to waiting area and frequently greets them there before they sit down



Regional Anticoagulation Clinics

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





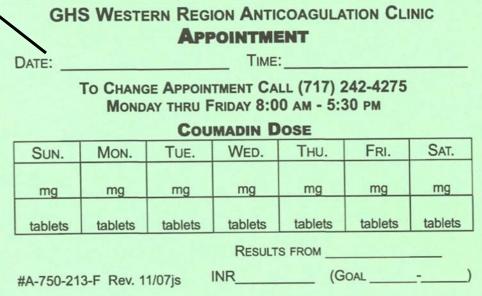
"Lean" Tends to be Visual

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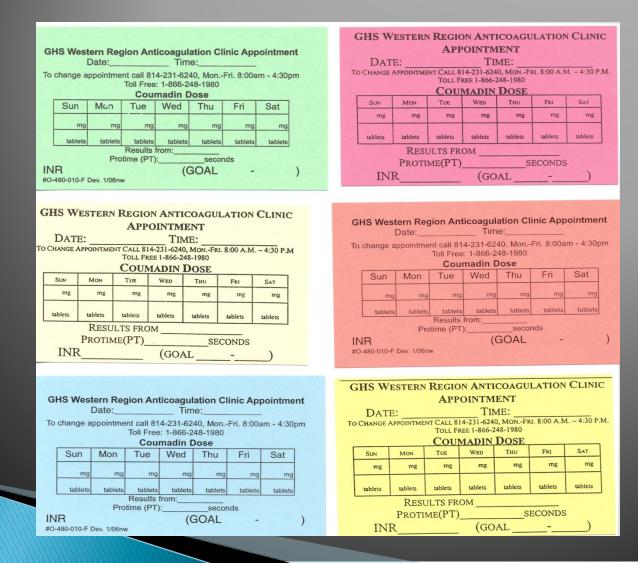
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For your protection, tablets are clearly marked with the COUMADIN[®] (Warfarin Sodium Tablets, USP) Crystalline name and dosage strength to help avoid confusion with your other medications.

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

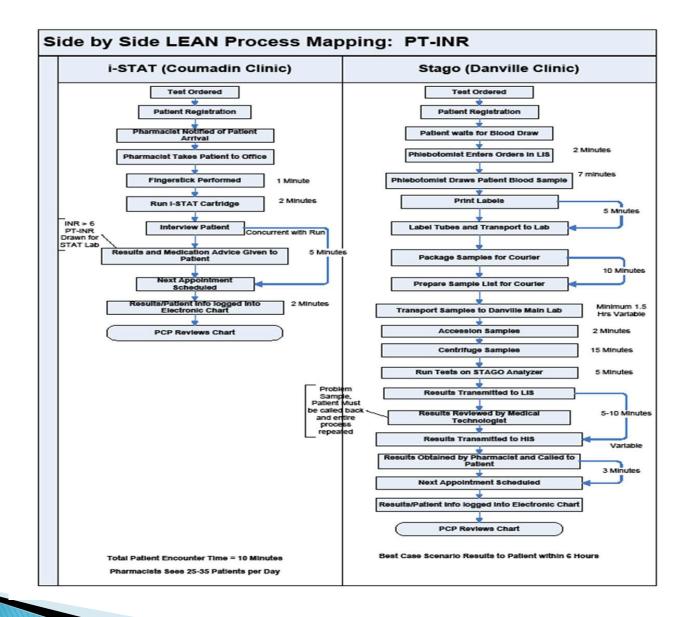
- 3117 patients were actively managed on anticoagulation therapy during calendar year 2009, with a diagnosis of A-Fib
- For each every 33 A-fib patients on anticoagulation therapy 1 stroke per year is avoided
- 94 potential strokes avoided during 2009

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



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) 1) Specimen Collection 2) Test Ordering 3) Results Receipt	<u>Mean</u> 1:48 1:44 3:54	<u>Minimum</u> 0:35 0:53 0:59	<u>Maximum</u> 3:30 3:05 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				
<u>C. Pneumatic Tube (min:sec)</u>							
1) Derived Transport Time	4:08	1:40	9:55				

Efficient, Safe Order Entry



1. Patient Barcode

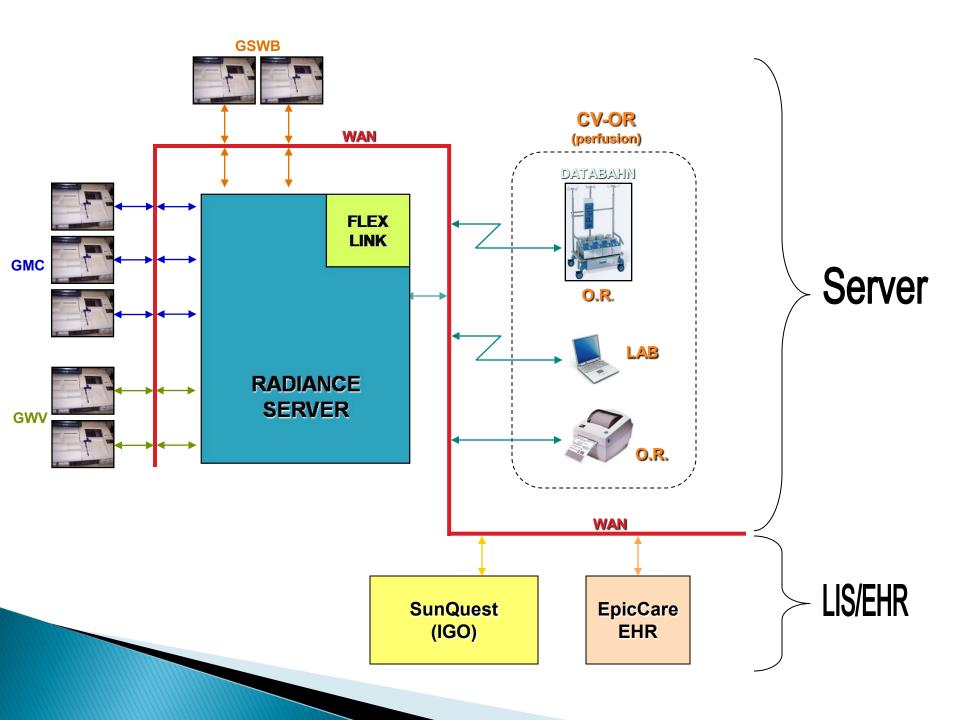






3. Operator Barcode





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