ERROR reduction in the Clinical Laboratory

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"I have been struck again and again by how important measurement is to improving the human condition."

- Bill Gates

"Measurement is the first step that leads to control and eventually improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it."

- H. James Harrington

Clinical Laboratory Errors

- Pre-analytic steps (order, transmission of the order to the lab, patient preparation and identification, sample collection, and specimen processing)
- Analytic (assay producing the result)
- Post-analytic steps (transmission of the lab data to the provider)

Most common errors at Atlanta VAMC

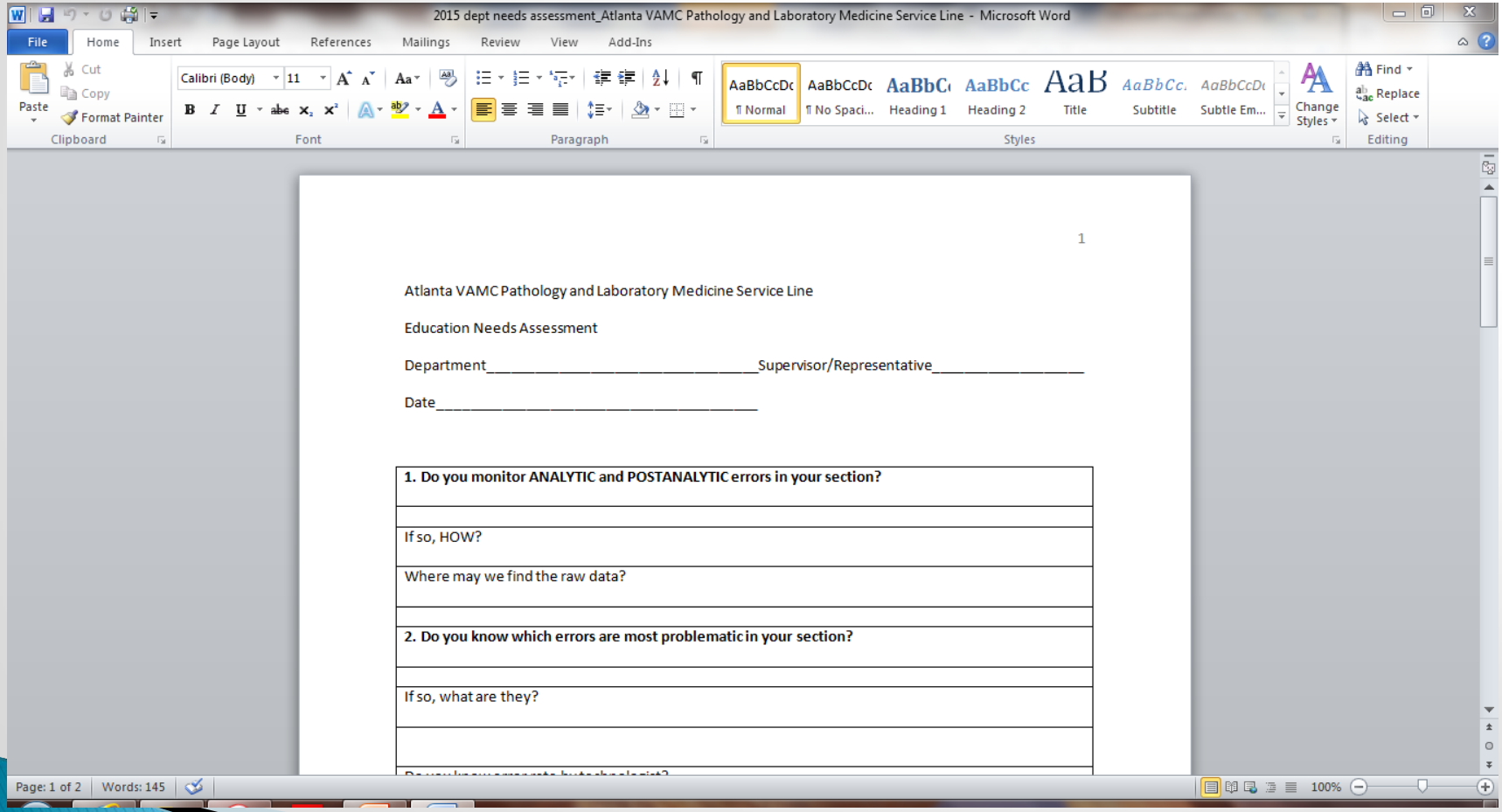
- **Pre-analytic**: mislabeled, unlabeled, hemolyzed, clotted; NSR (no specimen received)
- **Analytic**: QC issues, failure to follow SOP
- **Post-analytic**: Manual data entry reporting errors, erroneously accepting interface flags without investigating, no notification comments on report

Example of why important to call all corrected results: The provider cuts/pastes your report into his CPRS notes. You did not call corrected report. The error goes unnoticed to next provider reading the note.

Lab General SOP: We must notify provider. Document in VISTA.

How did we learn this?

Occurrence report logs / March 2015: Needs assessment



Rates are nice, but…

Even if the rate of errors/total reports is within acceptable predetermined benchmark, an error is an error.

Each error adversely affects the patient report in some way.

Error rates may be ***misleading***. Example: Microbiology pilot project. Drilling down to the specific errors, rates, and technologists revealed much useful information. Much like epidemiology, where attack rates (new cases/those at risk) during epidemics are useful. (Overall rates may not demonstrate an epidemic or a traceable problem.)

CLIA: Clinical Laboratory Improvement Act 1988

- Allows CAP (College of American Pathologists) to inspect / enforce clinical laboratories in the U.S.
- The Joint Commission (THC) may also perform tracers to determine if a problem/concern originated in the laboratory…
- VAMC is under CLIA rule. VHA Handbook 1106.01 2008 (p. 8)

CAP GEN.16902 QM Implementation Phase II

For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is reviewed annually for effectiveness.

NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.

Evidence of Compliance:

✓ Evidence that the plan has been implemented as designed requires all of the following:

- quality measurements/assessments specified in the plan are being substantially carried out;
- there is evidence of active review of quality measurements;
- if target performance levels are specified in the plan and the targets are not being met, there is documented follow-up action;
- any interventions/changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay documented; **AND**
- any communication of information that is required by the plan have taken place

CAP GEN.16902

"Need to establish specific benchmarks and trend individual data by pre-analytic, analytic, and post-analytic phases. You have divided the occurrences as defined by Type A and Type B, but you must go further." Jan. 2015 CAP Inspector

- Use our current program (collection of data on "OCCURRENCE REPORTS")
- Per CAP: Decision to "drill deeper" by benchmarking errors by type, by section, and by technologist
- Pilot project immediately implemented in microbiology.
- Other lab sections added; each section chooses at least one item to monitor/benchmark.

What is important?

- Ensure the **primary goal** is met: Meeting CLIA/CAP/VA laws, rules, and guidelines.
- Standardize by creating a **MODEL** for our entire laboratory.
- Demonstrate accountability for our errors.

OVERARCHING GOAL:

To serve our patients well.

How? By reducing/ eliminating analytic and post-analytic errors.

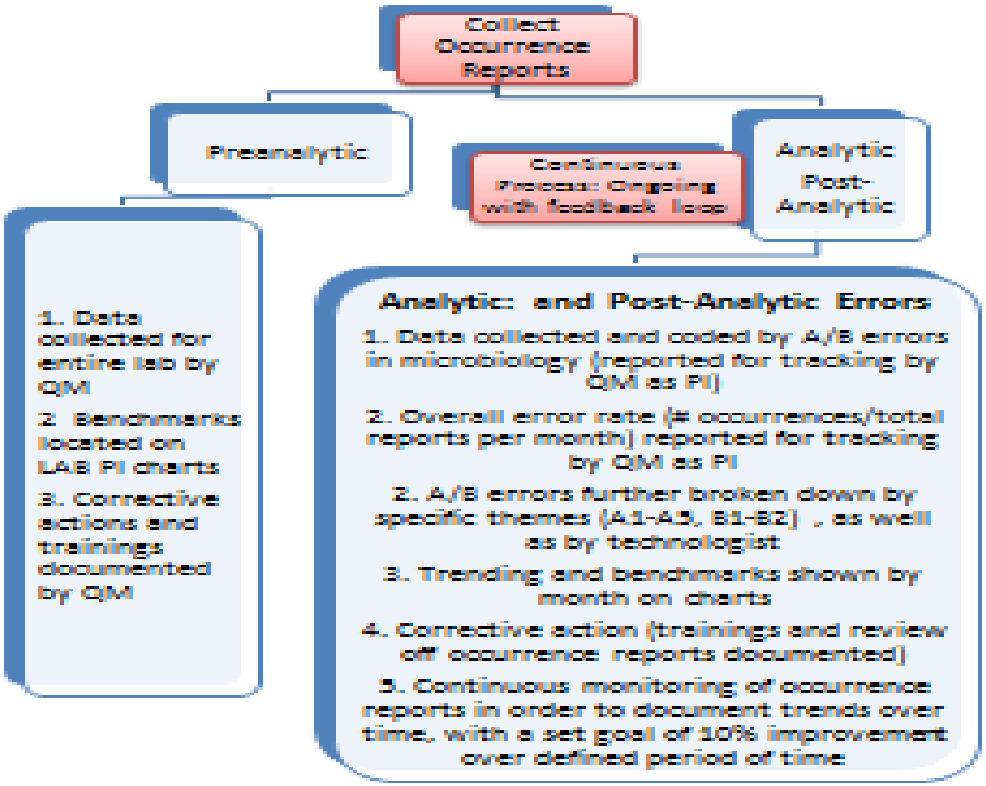
Reminder: VA CORE VALUES include:

- **Integrity**: Adhere to the highest professional standards.
- **Commitment**: Fulfill my individual responsibilities and organizational responsibilities.
- **Excellence**: Strive for the highest quality and continuous improvement. Be thoughtful and decisive in leadership, accountable for my actions, willing to admit mistakes, and rigorous in correcting them.

Microbiology Laboratory

Flowchart: Occurrence Reports and QA

FLOWCHART



Preanalytic, Analytic, Postanalytic

- Data collected by Madeline AND Julie. **Occurrence Reports**
- I-drive Excel spreadsheets for data
- Occurrence reports sent on to supervisors for response and corrective action documentation – returned to Julie.
- Filed in office upon conclusion of investigation – kept for at least 2 years

NEW: These items will become part of the overall MODEL.

Measuring errors

Laboratory Occurrences by Section/Shift and by Technologist

Refer to new bar graphs (I-drive, Quality Management folder, restricted access)

Note: Benchmarks

EXCEL GRAPHS

Corrective Action to decrease/eliminate medical errors

1. **Learning**: CEs, training (and enhanced vigilance), competencies

2. **Engineering controls**: Strategies to avoid lapse in memory, fatigue, distractions (use checklists, memos, warning labels, memory aids, highlighter)

3. **HR intervention**: Mismatch of technologist with job skills (temporary or long-term); reckless behavior

We will work with primarily with learning.

Reference: Post-analytic errors: Cases, Concepts, & Interventions
https://www.youtube.com/watch?v=8L61TLBDL3Y Michael Astion, MD, PhD

According to VA National Center for Patient Safety:
Interventions may be difficult. Software enhancements (IF they work), LEAN, interfaces (IF they work), are examples…

Sources of error

- **Cognitive Errors** (mistakes – due to poor knowledge or judgement)

- **Noncognitive Errors** (slips / lapses due to fatigue)

Our focus will be on Cognitive Errors. Prevention may be achieved by increased training, competency evaluation, and process aids (use of checklists, procedure summaries)

Reference: Dasgupta, A. & Sepulveda, J. (2013). Accurate Results in the Clinical Laboratory: A guide to error detection and correction. Elsevier: New York.

Learning: Two types

- **Single-loop learning**: A simple error-and-correction process. Problem-solvers adjust behavior and work processes in response to changing events or trends.

- **Double-loop learning:** Problem-solvers attempt to close the loop (and eliminate problems) by questioning and modifying / changing the underlying structure of the system.

Reference: Shortell, S. & Kaluzny, A. (2006): Health Care Management: Organization Design and Behavior, 5th ed. Chapter 12, Organizational Learning, Innovation, and Change. Thomson – Delmar Learning, New York.

GOALS

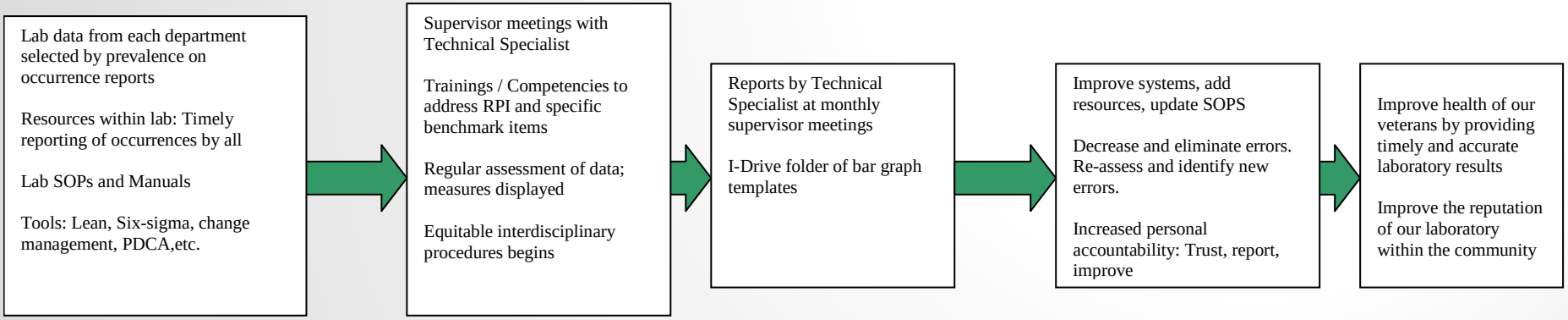
Through learning: Achieve error minimization using tools such as Total Quality Management (TQM), Continuous Quality Improvement (CQI), Root Cause Analysis (RCA), etc.

In order to:

- Improve the health of our veterans by providing timely and accurate laboratory results, and
- *Improve the reputation* of our laboratory in they eyes of our veterans, providers, and community as a whole

Logic Model: **ATLANTA VAMC - Creating a High-Reliability Organization (HRO), 2015**
Goal: **Clinical Laboratory Error Reduction /Elimination thru ROBUST PROCESS IMPROVEMENT (RPI)**

ASSUMPTIONS:
1. Employees representing each department as defined by lab administration will attend meetings, trainings, and competencies as required
2. Meetings to be held at least quarterly
3. Laboratory supervisors and leaders will measure, collect, and depict data, allowing for completion of feedback loop



(Planned work……) (Intended results……)

Change must include:	Obstacles include:
1. Leadership's commitment 2. Culture of safety throughout entire lab and beyond 3. Deployment of process improvement tools and methods 4. Must move beyond tabulation of results to take effective action	1. Poor communication within and between all team members 2. Poor hand-off communications (incomplete or inaccurate) 3. Desensitization; ongoing culture of low expectations 4. Eliminate intimidating behavior – no "snitch" mentality. Must identify all errors in order to make improvement 5. Time: How fast can important change be made?

Reference: Chassin, M. & Loeb, J. (2013). High-reliability health care: Getting there from here. The Joint Commission. The Milbank Quarterly, 91 (3), 459-490. Wiley Periodicals Inc. on behalf of Milbank Memorial Fund.

So, what do we do?

- Keep accurate data using occurrence reports.
- (Report extraneous data to Julie via Outlook email by 5th of each month.)
- Julie will input data using Excel bar and line graphs in I-drive
- Whenever a particular item count moves above the benchmark, a corrective action (training) will occur.
- Following month's data / bar graphs will be inspected for improvement; has item in question moved below the benchmark?
- If not, SUPERVISOR will need to respond to Corrective Action request. (examples: Did you retrain technologist? Did you change process?)
- Annually: Reassess Quality Improvement items in each laboratory section. Determine if new or different items / changes in benchmarks are required. Provide a summary report at close of fiscal year.

We need:

- To *change the paradigm*
- Commitment from Leadership and Staff

If you see an error or concern with our laboratory testing (at any phase), report it (on an occurrence report).

…Does this next slide topic look familiar?

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- MARTA Police Mission
- The Department
- See Something, Say Something
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Timeline for dissemination

Every month:

- One meeting time scheduled for Lab representatives of the **Lab Subcommittee ALL HAZARDS**; certain specific items (safety/waste/callback cascade) may be reported at this meeting (beginning JUNE 15 @8am)

- Full report (view the current bar graphs from I-drive) at each monthly **supervisor meeting**. (Specific outliers will be discussed with individual supervisors in a private setting.)

- **QM PACKET:** Full report and SUMMARY of how we are doing reported to the QM, Chief Medical Technologist, and Pathology at beginning of each month. (Did we meet our objective? If not, what is going to change? Have we had trainings or SOP in-services?)

- A second meeting date/time has been blocked out for education (CE, training, etc.)… can be section-specific, or general (safety, for example). Beginning June 15@3pm.

LISTEN… This is important information!

https://www.youtube.com/watch?feature=player_embedded&v=i1HlQ7Yp-BI

“Coming together is a beginning; keeping together is progress; working together is success.”

–Henry Ford

The End

Thank you!