Risk-Based Quality Control Practices: ISTAT INR/PT

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Objectives

Review Laboratory testing processes:

- Preexamination (Preanalytical)- instrument and quality control
- Examination (Analytical)- User Training & Competency
- Postexamination (Postanalytical)- Monitoring Compliance

Pre-examination(Preanalytical) Risk Assessment Principle

- Procedure and Policy
- User Training and Competency
- New POC instrument validation
- New cartridge shipment lot verification
- On-going patient correlations between iSTAT and Lab equipment

Preexamination (Preanalytical) – Procedure and Policy

Risk:

- Does the procedure define the intended patient population(s)? For example: i-STAT INR testing is used to monitor Coumadin therapy patients at the Oral Anticoagulation Clinic
- Does the policy include situations when patient i-STAT INR result is to be checked by the Clinical Laboratory instrument? For example: Patient i-STAT INR result> 4.0 or inconsistent with current patient Coumadin therapy must be checked by drawing a fresh blood sample to the Clinical Laboratory. Clinical Lab INR result will be reported and used for patient treatment

Preexamination(Preanalytical)- New i-STAT Instrument Validation

Risks:

- Erroneous results from faulty analyzer may lead to improper patient care, **but** extensive requirements for validation delay delivery of new instruments to POC users

Preexamination(Preanalytical) – New POCT Instrument Validation

Progression of i-STAT Quality Control Policy:

- 1997 - 2005: Only Electronic QC (internal and external electronic simulator)
- 2005 – 2012: Equivalent Quality Control Option 1 - Electronic QC; liquid QC ten days twice per day for twenty data points; linearity (Expensive!)
- 2013 to present: Electronic QC; liquid QC two days five times per day for ten data points; linearity (Expensive!)
- Proposed QC Plan: Compare new instrument to one reference meter using electronic QC only (programmed every 8 hours). Assessment and data collection in progress

Preexamination(Preanalytical)- i-STAT and Lab Instrument Patient Result Bias

Risks:

- Bias between i-STAT and Clinical Lab instrument(s) can impact patient care @ the Oral Anticoagulation Clinic where patients are monitored for Coumadin dosages

Preexamination(Preanalytical)- Laboratory Coagulation Instruments

Risks:

- Variation of INR for the Lab instrument due to different thromboplastin sources and lot-to-lot variation
- Multiple Lab instruments can create additional result bias

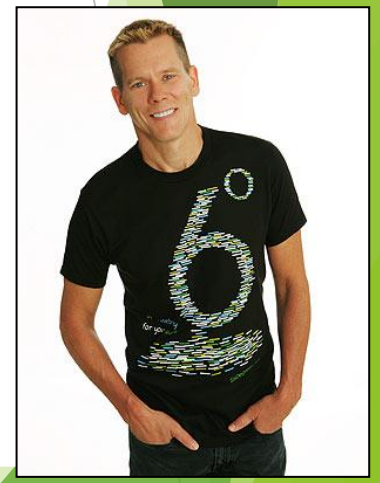
Preexamniation(Preanalytical)- New i-STAT cartridge shipment lot verification and on-going result comparison to Lab instrument(s)

- For i-STAT instrument - run a patient sample(vary with low, medium and high value) when receiving a new shipment lot to check for lot-to-lot variation
- Perform monthly patient sample correlations (rotate using low, medium and high values) between i-STAT and Lab equipment
- Pay attention to the pharmacists when they have concerns/questions with patient INR results. Contact vendor immediately

Examination(Analytical) – User Training and Competency

Risks: (6-elements of competency assessments)

- Specimen collection
- Instrument function
- Test performance
- Result reporting
- Quality assessment
- Problem solving



Post-examination-
Point-of-Care Testing Concerns

Risks:

- Incorrect patient identification.
- Electronic QC and liquid QC out-of-range incidents and corrective actions
- Cartridge storage temperature documentation and corrective actions
- Proficiency testing compliance
- POC units are alerted of on-going compliance status

Quality Assessment Strategy- Monthly Compliance Reports

Risks:

- Lack of accurate monitoring may allow improper testing activities to persist, with potential for patient harm .
- Detailed monitoring taxes limited POCT resources, and many items have less risk to patients than others.
- Create Risk Acceptability Matrix

Quality Assessment Strategy- Monthly Compliance Reports

Question#	Scoring: NA, Pass or Fail	Grading Checklist Questions	High Impact category	Medium Impact category	Low Impact category
1	Fail	Training /Certification/Competency are current	3		
2	Pass	Results entered with correct patient identification (MRN#)	3		
3	Pass	Completed QC (i.e. QC completed per specified frequency)	3		
4	Pass	Out-Of-Range QC have notations (i.e. corrective actions were noted with the repeated QC)	3		
5	Fail	All patient manual results in EMR have appropriate test notations (i.e. lot#, expiration date, internal QC result, etc.)		2	
6	Pass	Testing materials (reagent /test kits) were validated by POCT dept.		2	
7	Pass	Temperature logs (complete and Out-Of-Range readings have corrective actions noted)		2	
8	Pass	No reagents expired		2	
9	Pass	Reagent dated legibly by user		2	
10	Pass	Infection control OK		2	
11	Pass	Procedure/Policy available			1
12	Fail	Patient data/results were complete in EMR (i.e. all of the results obtained were recorded)			1

Quality Assessment Strategy- Monthly Compliance Reports

- Unit judged to be out of compliance if any one of the “high” impact items fails, or if any two items fail, regardless of impact.
- First failure triggers response from POCT committee.
- Heightened response, with four months of failure within a rolling twelve month period triggering loss of POCT privileges

Tackling Risk Management

- Risk assessment for each testing phase
- It is a continuous process

Questions?

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