Automation is Here

Now How Do You Handle All the Data?

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Automation in 2002 (Chem/IA)
Autovalidation for Chemistry and IA in 2003

Life IS Good

Hemo and coag instruments were connected to the middleware solution in summer 2004, but not placed on the automation system.
Coagulation autovalidation started in September 2004.
Hemagram autovalidation started in October.
Differential autovalidation started in Feb 2005.
Hemo was paperless by June 2005.
How do we handle all that DATA?

- Optimizing instrument settings
- Autovalidation set-up
- Using rules wisely – practical application
- Policy and regulations

Optimizing Instrument Settings

- Autodilute once – to the appropriate level
- Auto-rerun
- QC on reagent cassette change
- Flagging – define it at middleware
- Multiple assays – same barcode or not?

What you need for Autovalidation...

- Middleware and LIS
- Rules
- Policy
- Communication
- Tech involvement and acceptance
Basic Autoverification Rule

If a patient result requires an “action” to be taken on that result, then it should NOT be autoverified.

An “action” can be mental or physical.

Real Information

Problem Assays
- QC shifts
- Drifting calibrations
- Repeat testing
- Instrument issues

Comfort Level
- Sample issues
- Hemolysis
- Clots

Repeat testing

5 Filters for Autovalidation

- Quality Control
- Review Ranges
- Delta Checks
- Instrument Flags
- Complex Rules
Quality Control

Is what you are using now working?
Can your middleware stop patient results after a failed QC for a given assay from a given instrument?
Are there assays that can’t be trusted?
Is there some function of “manual” QC currently being done by the techs reviewing patient results?

QC thoughts...

- Don’t rewrite your QC rules
- Set up a program that works for your lab
- Track QC where it makes the most sense for your operations.

Review Ranges

- What results need to be reviewed – and why?
- What “action” are you going to take on that result?
- Do NOT use reference ranges as review ranges
- Pick limits that are useful for multiple populations
Delta Checks

• Use – clinical significant change or identifying incorrectly labeled specimens
• Don’t use them for all assays – be careful
• Apply them to specific populations if possible.

Instrument Flags

• Variety of flags depending on instruments.
• What happens to these flags when results are transmitted to the middleware or LIS?
• Are the flags indicating something that would not be caught by other filters?

Common Flags

- Linear limits
- Lack of calibration
- Insufficient reagent
- Insufficient sample
- Clotted specimens
- Specimen or assay issues
- Error flags - hemo
Complex Rules

Complex rules are combinations of "if" "then" statements, or a set of "or" statements in a sequence, that can cause results to be held or released during the autovalidation process. (Boolean logic)

Example: If hemolysis = or > 2+, then hold K⁺ and LD results.

Examples of Complex Rules

- Some middleware programs use user defined complex rules for range, delta check, flags, etc.
- Holding chemistry results based on interferents (lipemia, icteria, hemolysis)
- Ordering reruns/repeats on results in the gray zone (hepatitis, HIV)
- Reflex orders, algorithms
- Determining if the CBC requires a manual differential or slide review.

Assay Grid

Set up an excel spreadsheet with the review range, the critical values and delta checks clearly defined.
<table>
<thead>
<tr>
<th>Assay</th>
<th>Critical Low</th>
<th>Review Low</th>
<th>Ref. Range</th>
<th>Review High</th>
<th>Critical High</th>
<th>Delta Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glu</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUN</td>
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<td></td>
</tr>
<tr>
<td>Creat</td>
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<td></td>
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<tr>
<td>Na</td>
<td></td>
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<td></td>
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<tr>
<td>K</td>
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<td></td>
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<tr>
<td>Cl</td>
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<tr>
<td>CO2</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Alcohol</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Troponin</td>
<td></td>
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<tr>
<td>Hgb</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
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</tr>
</tbody>
</table>

**Uses for the Assay Grid**

Go to your pathologist with your assay grid in hand. Explain what you decided and why.

Make it part of your autovalidation policy.

**Allow the Rules to work together**
IT Considerations

IT “Team”

- Lab IT person or lab person most familiar with the LIS operations
- Lab techs – who use the system all the time AND who are not afraid of change
- Middleware vendor rep or automation vendor rep
- Hospital IT rep
IT Considerations

- Regulatory Issues
  - Turn On/ Turn Off
  - Audit Trail

- Capability of LIS versus middleware
  - Repeats
  - Delta checks
  - Critical value documentation

IT considerations

- Partial upload vs complete upload
  - Do you allow tests that pass autoverification rules to be filed if other tests on the same specimen are not completed yet or are being held for review?

Partial Upload

<table>
<thead>
<tr>
<th>First results</th>
<th>Clean Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glu 100</td>
<td>Glu 325</td>
</tr>
<tr>
<td>BUN 25</td>
<td>BUN 35</td>
</tr>
<tr>
<td>Creat 1.2</td>
<td>Creat 1.5</td>
</tr>
<tr>
<td>Na+ 135</td>
<td>Na+ 135</td>
</tr>
<tr>
<td>K+ 4.0</td>
<td>K+ 4.0</td>
</tr>
<tr>
<td>Cl 105</td>
<td>Cl 105</td>
</tr>
<tr>
<td>CO2 22</td>
<td>CO2 27</td>
</tr>
<tr>
<td>Ca++ 3.8</td>
<td>Ca++ 10.2</td>
</tr>
</tbody>
</table>
IT considerations

- Ability to make changes quickly
  - Range change
  - Rule turned on or off
  - New rule implemented

Autovalidation Policy

- Define test criteria and approval
- Define filters preventing autoverification
- Define level where filters exist (middleware or LIS or combination)
- Define audit trail identifiers
- Define suspension plan
- Define annual verification requirement
Autoverification Policy

- Tests must meet the following criteria
  - Approved by Pathologist (assay grid)
  - Filters in place in LIS/Middleware
  - Filters must be approved

Filters

The following filters are in place on the XX software that will cause a result to be held
- Results outside Review range
- Results triggering a Delta check
- Results with an Instrument flag (ie. reportable range limit, error, etc.)
- Results of tests where the most recent QC sample result is out of acceptable range or QC hasn’t been run in the past 24 hours.
- Results failing a complex rule

The following filters are in place on the XX software that will cause a result to be held –
- Critical values
- Out of acceptable reporting format
Audit Trail Information

Define the audit trail being used.

How can someone tell if the result was autoverified or manually reviewed?
How can someone identify who reviewed and verified it?

Initial and Yearly Validation

- Scripting
- Range and delta checks –
  - Use CAP or other linearity material
  - Low/high values under same dummy patient name run minutes apart
  - Range flags, delta checks, critical values, out of range
- Complex rules
  - Real patient examples
  - QC material

Final Thoughts

- Autoverification removes the need to look at every result and brings the tech’s attention to those results requiring action.
- Start and work with what is currently being done by the technologists manually.
- When you first start out, don’t invent new rules that you currently don’t use.
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