Why Full Autoverification Generates Big Cost Savings in Labor, Faster TAT, Reduced Errors, and Supports Best-in-Class Lab Operations

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Laboratory Intelligence and Process Optimization
Objectives

• Realize why measuring auto verification by laboratory workload produces a logarithmic return on investment (financially, clinically, and operationally) and proves that <60% AV produces little return.

• Understand how to create a lab-wide AV design plan, and how to determine best options for implementation.

• Comprehend the risk associated with manual verification, poor autoverification design and maintenance, and vendor provided rules-packages.

• Appreciate why and AV project is never truly 'completed' and how LEAN concepts show us how to continuously improve.
Bio

• Clinical Chemistry Technologist (ASCP)
• Bench tech at 500+ bed hospital
• Field Tech Support then SME for Roche chemistry / instruments
• Reagent and Automation product manager
• Lab IT consultant
• Co-authors on AUTO10-A (CLSI Autoverification of Clinical Laboratory Tests Results; Approved Guideline)
• Certified Six Sigma / LEAN Black Belt

• Most recent
• Direct of Lab IT Services for 4th largest US based lab (8 yrs)
• Interfaced hundreds of instruments over large geographical areas
• Built autoverification algorithms and implemented in every lab area
• Architected and led a design time to build a complete homegrown LIS
• Author “A step-by-step process to 95% Autoverification” – CAP Today Dec 2015
• Chairman – CLSI AUTO15 - Department Spec Autoverification – (In review)
Labor and Cost Containment are Lab’s Biggest Issues

MT/MLT 50-80% Vacancy Rate\textsuperscript{1,2,3}  

335,700 open positions in 2016, will grow >40K by 2026\textsuperscript{17}  

20% turnover rate\textsuperscript{3}  
Labs actively recruiting globally  

\textdollar$7,500 / position  

\textdollar$14K if >3 months\textsuperscript{10}
Diminishing Returns of Hardware Automation in the clinical laboratory

Pre 1970s
- No Automation

1970s
- SMAC Analyzer
- Automated Hematology

1980s
- Immunoassay Automation
- LIS interfacing

1990s
- Total lab Automation
- Task targeted automation
- Assay Additions
- RIA -> Automation

2000s
- Molecular Automation
- Assay Additions
- Middleware

Now

Lab Workload

- Manual Processes
- Automated Processes

No Automation
100%
75%
60%
60%
40%
40%

Technology
Manual processes reduce quality

**Medical Error**
Now the 3rd leading cause of death in the US

**2.9 – 26.9%**
Human error rate

**Test Requests Increasing**
Growing at 7% globally

**TAT / DOT**
Lab testing ordered on 41% of all visits AND at least 10% of diagnoses delayed until testing is complete

**Physicians ordering the WRONG tests**
66% Vitamin D orders are ordered incorrectly

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MCKESSON
Where do labs spend their skilled labor

- 65% + Reviewing Results
- 20% Maintenance
- 8% Finding Specimens
- 7% Analyzing Tests / Other
‘Our value is that we TOUCH every single one of our results!!’

- Passengers
  - 400
- Pilots
  - 3
- One of the only planes that can land in 0 visibility
  - Visibility < 50 ft – pilots are NOT PERMITTED to touch controls
Data Automation Eliminates Non-Value Add Activities

Autoverification - The use of algorithms that enable the automatic commenting and releasing of results immediately to the LIS / EMR.

Is NOT – Releasing normal results (common misconception)

Assisted Review- Using instructions, colors, icons to help identify the reason for an exception and the suggested actions for resolution.

Analytics- Continuous improvement using machine learning
‘We’re good, we already have 60% autoverification....’

80 / 20 rule

• How long does it take for you to review / release a result / specimen?
Result Review Statistics for Chemistry
150 Bed Hospital (POST AV Implementation)

- 235,000 Chemistry tests (22,000 specimens)
- Measured from February to March 2019
- Approximately 85% AV

- AVERAGE Time to Review 1 Specimen
  - 5.5 Minutes
  - ~20-25% of total technologist time available
  - >$80K / year
No Current Industry Autoverification Standards (and there won’t be.....)

Overall concepts describing ‘what to think about’

Auto 15 – Autoverification of Medical Laboratory Results for Specific Discipline

- Should be out ~2019
- Shows example algorithms
Autoverification rates <60%
Fully intelligent autoverification is critical to lab survival

- >95% of results
- 'Intelligence' allows for autorelease, autocommenting, tech instructions / etc.

- Error rates at Six Sigma levels (0.009%)
- LabWide

* Average results based on 1000 analyte per day laboratory
Examples

• AST is normal – do you release?
  – Oh, btw… ALT, ALP, GGT – all critically high…
  – Wouldn’t it be nice if the ‘system’ looked at this and held all of them?

• Glucose critically high do you rerun / release?
  – Oh, btw… It’s lower than last glucose done 2 hours ago…
  – Wouldn’t it be nice if the ‘system’ knew this, and didn’t hold this up?

• Albumin is normal – do you release?
  – Oh, btw… it’s higher than the total protein…
  – Now, do you rerun Albumin (3+ times) or wouldn’t it be nice if the ‘system’ told us that there is a rare potential interferant that could cause this (outlined in the package insert.)

• BUN and Creatinine are critically high, do you rerun and call to floor?
  – Oh, btw… this is a dialysis patient…
  – Wouldn’t it be nice if the ‘system’ knew this and didn’t put it on the call list?
# 80% of labs have 0-5% autoverification

<2% of labs have >90% autoverification

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Resources</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No specific industry standards</td>
<td>• MT Vacancy rate</td>
<td>• Antiquated LIS functionality</td>
</tr>
<tr>
<td>• No specific SOPs to review and release analytes</td>
<td>• Result production takes priority over all other projects</td>
<td>• LISs / EMRs not focused on operations of the laboratory</td>
</tr>
<tr>
<td>• Laboratory + IT expertise difficult to find</td>
<td>• Low on the list of tasks</td>
<td>• &gt;50% of labs planning on switching LIS vendors (^19)</td>
</tr>
</tbody>
</table>
How do we know this works
4th Largest Reference laboratory 40K reqs / day

Chemistry Department
  – 10,000 requisitions / day
  – 15 Roche COBAS 8000s
    – 1 lab aid dedicate to maintenance (unskilled labor)
  – >90% AV

  – 1-2 MTs / shift
  – <5 corrected reports / month

*All data and figures were provided by customer. Based on approximations by customer unless otherwise noted. Customer survived by McKesson in 2018
How do we get there?
Our (fillin the blank) vendor is going to provide us rules... we’re good

**Regulations**

IVD manufacturers are regulated by the FDA, including any ‘systems’ that are distributed or resold.

Any change to the ‘system’ in the field could invalidate the FDA approval.

Therefore there is minimal to no customization offered AND functionality is limited.

**Standardized Rules Packages**

DANGEROUS – Assumes that the instrument settings and LIS upload is standard, and it rarely is!

**DI is NOT DI**

DI functionality is a function of vendor. However, most only use connectivity.

**Vendor will remove if and when you decide to change vendors**

Generally, IVD middleware must be on IVD hardware (per regulation). Virus protection is also problematic, thus IDN functionality is generally not possible.
SMART TESTS℠

- **Scope the project**
- **Master algorithm template**
  - **Analyzer (submaster) algorithm template**
  - **Reagent specific algorithm**
- **Tool selection**
- **Translate algorithms into rules**
- **Exceptions review process definition / creation**
- **Substantiate with documentation / validation**
- **Train**
- **Scale**
• Think LOGICALLY

• A programmer’s wife sends her husband to the store. She says, "Buy a loaf of bread. If they have eggs, get a dozen."

• An hour later, he returns home with twelve loaves of bread.
Simple Master Autoverification Algorithm\textsuperscript{12}

Fig. 1. Example of a simple master algorithm
Delta Checks (chemistry only) in a 150 Bed Hospital

- Measured from Feb – March (2019)
- 1393 Delta Checks total (~0.1% of volume)

- Results Modified?
  - 0
- Comments Added / Modified?
  - 0
- Results rejected?
  - 1 (confirmed, but nurse ‘didn’t like it’)
- Added FTE Cost?
  - >$30K
- TAT Impact?
  - >5 min per TEST
  - >7 min per Specimen
Think differently

- Reruns added 30 min of turn around time (on average)

- Results outside acceptable criteria?
  - 0

- It is possible to release initial result, then rerun to confirm?
Analyzer Specific Algorithms

- Derived from Master
- Standardized for Analyzer Specific
  - Result formats (linearity limits)
  - Error Codes

Reagent Specific Algorithms

- Derived from Analyzer Specific
- Most detailed algorithm
Analyzer Specific Algorithm Example

Fig. 2. Example of an analyzer-specific algorithm
Reagent Specific Algorithm Example (TSH)\textsuperscript{12}
Algorithms for Chemistry Tend to Get Very Complex

- Critical Values
- Related Analytes (anion gap)
- Specimen Integrity
- Automatic Comments
LIS

Middleware

Instrument

- SOME LIS’s can get to 50-60% autoverification (not the core strength of an LIS)
- Rules are limited and therefore more error-prone

- A few companies now providing Middleware
- Some can provide ALL of the functionality needed
- However, many vendors don’t connect all lab equipment

- SOME instruments have LIMITED rules (e.g. hematology)
- Not an overall lab solution, but should be used if it makes sense

Tools Options
Sure we have ‘Autoverification’ - we can do that too!
Translate Algorithm into Rules

- Implement / install tool (if needed)
- Add rule nomenclature on algorithm
- Name rules appropriately
  - Good practice would be to reference the version of algorithm and the step number
    - Test name, reagent specific algorithm version, step name, then something about the rule (e.g. GLU-alg 1.2-step 8-Check ver high limit)
- BEWARE of ‘Rules-Packages’
  - These usually are dangerous pitfalls and will not get you to these levels
  - There are no industry approved autoverification standards
Exceptions Review

- Use colors / visual cues
- Utilize technologist input
- The defined process WILL change overtime
  - Allow / Expect for change

5/1/19
Autoverification rules must be tested, validated, and documented

Build common forms and a process for validation

Begin with simulations then real patients (where available)

Provide the following documentation

- Algorithm with note to what is being tested
- Instrument print out
- Audit trail within the tool
- Final result printout

CAP requires autoverification revalidation every year

- Create an SOP / process for revalidation
- Note that the tool selected should make this easy

5/1/19
Autoverification is an ongoing process
  ➢ Utilize Kaizen
➢ Use the first experience to build processes, forms, etc.
➢ Continue to a more sophisticated platform
➢ Continually obtain metrics
  ➢ % Autoverification, Errors, TAT, Cost, etc.
➢ Scale your algorithms as you hone your process
➢ Meet regularly to address issues, suggestions, process improvements, etc.
Other Notes

- **Recommended order of projects**
  - Coagulation
  - Hematology
  - Immunoassay
  - Chemistry
  - Toxicology
  - The rest

- **Reportable calculations**
  - should be performed AFTER each component is autoverified. The calculation should then have its own algorithm

- **Package inserts / bulletins**
  - Review as you build reagent algorithms
  - Get rid of ‘wall paper’
# Hospital Example after implementing AV
(114 bed community hospital – WITH Hardware automation)

<table>
<thead>
<tr>
<th>Actions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-allocated 1.5 FTE to different roles</td>
<td>~$9K / month, 350 hours saved</td>
</tr>
<tr>
<td>Overtime reduction (1.5 hrs / day @ $42.75)</td>
<td>~$2,000 / month, 50 hours liberated</td>
</tr>
<tr>
<td>12 phone calls / day -&gt; 2 ~ 1 hour per day</td>
<td>~$1K / month, 30 hours saved</td>
</tr>
<tr>
<td>Supervisor involvement in difficult issue</td>
<td>~$1000 / month, 15 hours saved (supervisor hours)</td>
</tr>
<tr>
<td>Misc savings (reruns, stat reductions, etc.)</td>
<td>~$3K - $5K / month, 20+ hours saved</td>
</tr>
<tr>
<td>Eliminated two open FTEs, hired Biology majors in lieu of MTs</td>
<td>~$10 K / month + 100 hours</td>
</tr>
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Corrected Report Reduction

![Corrected Reports / Month](chart)

- 156 /yr → 85 / year

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Additional Benefits

- **Capacity increase ~7% plus per year**
- **Clinician Satisfaction increased**
- Reporting has proven underlying issues:
  - TAT for specimens to lab
  - Re-run statistical difference
- **Technologist Satisfaction increased**
- **Reduced Turn around time by 30%**
Specimen Retrieval

Save hours per week finding specimens and reduce redraws

Find samples < 1 min – anywhere in the lab

Customized dynamic stat and pending screens for added efficiency with fields like “Last Known Specimen Location”

All areas of the lab – plates, slides, long term studies, binders, etc.

Integrated system ensures that pendings or add-ons are not stored

Use for ‘rainbows’ and specimens that aren’t accessioned
**Electronic Maintenance Management**

Ensure no maintenance item is missed, and eliminate waste

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>LAB-Wide</strong> Equipment, Facilities, etc.</td>
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<tr>
<td><strong>Supervisor Sign-off</strong></td>
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<th><strong>Integration with instrumentation:</strong></th>
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<tr>
<td>• Items can be triggered based on ‘cycles’</td>
</tr>
<tr>
<td>• Interfaces can be shut down automatically if maintenance is incomplete</td>
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<td>• Single click reports with issue tracking</td>
</tr>
<tr>
<td>• Failures trigger additional maintenance items</td>
</tr>
<tr>
<td>• <a href="#">Link to videos, PDF, manuals, web, etc.</a></td>
</tr>
<tr>
<td>• <a href="#">Add attachments to maintenance items</a></td>
</tr>
</tbody>
</table>
Questions?
Sources

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