Auto-Validation
*Don’t “Rule” It Out!*

Elinore Craig
Product Manager, IT Integration

**Agenda**

- Barriers to auto-validation
- Success stories
- Overcoming the barriers
About half of respondents report they are not broadly auto-validating across routine lab sections. Of those, roughly half selected the response, "Haven't had time to figure it out".
Obstacles

- Unrealistic expectations
  - Competing projects or lack of focus
  - Trying too much, too fast
  - It takes a village ......

- Human
  - Low appetite for change
  - Concern for job security
  - Don’t trust software

- Vendor
  - LIS interface not available when middleware delivered
  - Doesn’t understand workflow
  - Limited lab testing experience

Implementing Auto-validation

- Plan
  - Scope, goals & measurements
  - Regulatory considerations
  - Continuous process improvement
  - Business case

- Identify stakeholders and form team
  - Lab manager / director, medical director, techs from across shifts, rules builder and administrator, LIS analyst, IT department, LIS vendor

- Select platform
  - Instrument, LIS, Middleware
Implementing Auto-validation, cont’d

- Select lab section & instruments
- Map workflow and plan rules
  - Take opportunity for process improvement
- Develop validation plan
- Execute test plan and refine rules

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Chemistry Rule Flowchart

Hematology Rules

- ISLH Consensus Rules
  - www.islh.com
- If Neonate AND First Sample THEN perform Slide Review
Implementing Auto-validation, cont’d

• Update SOPs
  – New SOP for auto-validation workflow
  – Review all SOPs for impact

• Develop go-live checklist
  – Include a rule back-out plan

• Train operators
• Go-live

Success Stories
Real Life Auto-validation Stories
Not using auto-validation (yet)

- Two-hospital, community based (132 beds and 25 beds)
  - Middleware came with the instrument, first used for data concentrator and specimen archiving
  - Holdups for auto-validation:
    - “It will takes blocks of my time”.
    - New middleware version allows testing without turning off instruments.

I intend to use middleware rules for auto-validation because the flexibility of the rules is amazing.

..... Lab Supervisor

Real Life Auto-validation Stories
General (LIS) solution for auto-validation

- Multi-hospital, 6MM billables/yr, largest lab is 290 FTE
  - Started ~ 10 years ago w/ coag
  - Now live on almost every instrument
  - Outcomes:
    - ED TAT reduced from 40 min to 25-27 min

A few years ago when we switched to <<vendor>> we had auto-validation off for a couple weeks, and the workload was horrendous …We could not have achieved TAT and productivity goals without auto-validation.

..... Lab Director
Real Life Auto-validation Stories  
Middleware specific to instrument & department

• Multi-site system, 2,000 beds with large outreach / reference
  – Goals
    • Eliminate sample handling steps
    • Decrease ED TAT
    • Add capacity in order to increase outreach business
  – Outcomes:
    • Specialized hematology rules provided by Sysmex WAM reduced slide review rates by 29%
    • Reallocated 2.5 FTE while increasing throughput
    • Stat CBC orders decreased by 1/3
    • “Noise level” decreased – fewer phone calls requesting pending results

Real Life Auto-validation Stories  
Middleware specific to instrument & department

• 4 hospitals with 3 lab testing sites
  – Level II trauma center
  – ~900 beds, children’s hospital
  – 11 outpatient testing sites
    • 3 support Oncology
    • 4 support an Urgent Care
  – Standardized across the system
  – One Sysmex WAM database
• Stat CBC TAT: 80% are < 10 min, 96% <20 min.
• CBC auto-validation rate = 82%
Would You Auto-Validate This?

### 88 year old male
- Normal results, no delta failures
- Rules allowed auto-validation

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
<th>Normal Range</th>
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<th>Female</th>
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<tr>
<td>WBC</td>
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<tr>
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<tr>
<td>PLT</td>
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Would You Auto-Validate This?

### 43 year old female
- Low MCV
- If MCV Delta > +/- 5 within 120 days, hold for review
- Recent previous result within 5 so results auto-validated

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<tr>
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Would You Auto-Validate This?

- 78 year old male
- Critical HGB value
- If HGB < 8.0 rerun to confirm
- Rerun confirmed the result, 2nd result auto-validated

Still Doing Manual Platelets?

- March of 2010: 2,334 Phase Platelet counts
- March of 2013: 3 Phase Platelet counts
  - Decrease of 2,331 Phase Platelet counts
  - Instead reported 1,710 Optical Platelet counts
Rules Do It Seamlessly

If PLT Abn Dist flag is present AND PLT < 99 AND Retic% is not present, then reflex Optical Platelet

Rules for Success
## We’re LIVE!  Now What?

- Continuous process improvement
  - Monitor rules performance
  - Change management
    - Rules changes
    - Software updates
    - Training programs
- Vendor support
  - Hotline – 24/7
  - Competent clinical support personnel
  - Remote support
  - Ongoing education resources

## Review the Obstacles

- Unrealistic expectations
  - Competing projects or lack of focus
  - Trying too much, too fast
  - It takes a village …..
- Human
  - Low appetite for change
  - Concern for job security
  - Don’t trust software
- Vendor
  - LIS interface not available when middleware delivered
  - Doesn’t understand workflow
  - Limited lab testing experience
Overcoming the Obstacles

- Unrealistic expectations
  - Adequate planning to identify scope and resource requirements
  - Communicate resource needs and impacts
  - Buy-in from all stakeholders

- Human
  - Communicate goals and benefits
  - Proof of concept – engage users in design & testing
  - Effective change management – keep them engaged

- Vendor
  - Pick the solution that’s the right fit for your lab and your goals
  - Communicate your needs & ensure vendor can meet them
  - Timely involvement, especially if you need new interfaces or consultant help

Vendor Fit

- Product
  - Rules library ("starter kit")
  - Detailed test instructions, test plans and tools
  - General solution vs. one tailored for your instrumentation

- People
  - Clinical experts who understand workflow and middleware goals
  - IT & network expertise

- Services
  - Integrated implementation support:
    - Project management
    - Training rules definition
    - Clinical experts to assist with creating rules
  - Go-live and post live support 24/7
  - Ongoing education resources
**Intelligent Rules Engine**

- Rules on the patient level
  - Location, Age, Sex, Diagnosis
- Rules on the order level
  - Physician, Priority
- Rules on the result level
  - Present, outside/inside range, coded comment, flag
  - % or absolute deltas failures
  - Absence / presence of another parameter
- Rule actions
  - Hold for review, perform rerun analysis, create comments, display messages, add or delete tests

**Getting to the Next Level**

Comprehensive Rule Set and Delta Rules
Auto-validation
Multi-Site/Multi-LIS
Lavender Top Management & Tube Sorters, A1c
Manual Diff Mgmt & CellaVision
Management Reports

Sample Handling & Decision Rules for Rerun & Reflex
Experience Counts

8 of the top 10 America's Best Hospitals* use WAM

Summary

• It’s not easy to start
• But the payoff is huge
  – With the right rules in place, auto-validation reduces tech workload, optimizes turnaround time
• Successful implementation requires
  – Change management
  – Proper expectations
  – Allocated resources
  – The right tools
<table>
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Thank you