Effective Use of Decision Rules in the Hematology Laboratory

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New York
Presentation Outline

• History of laboratory testing
  • Manual, analytical automation, peri-analytical automation, automated information processing
• Hematology processes and decisions
• Hematology Consensus Group
• Implementation of consensus rules
• Middleware and LIS
In The Early Days:

- Manual reagent preparation
- Manual procedures
  - Reagent & sample pipetting, reagent mixing, precipitation, separation, etc.
- Manual calibrants, controls
- Manual colorimetry
  - Adjustments
  - Readings
- Manual calculations
  - Handwritten
  - Log tables
  - Slide rules
Manual Colorimetry (1967)
Remember The Slide Rule?
Improving Accuracy
In The Early Days:

- Manual colorimetry
- Manual calculations
  - Written
  - Log tables
  - Slide rules
- Manual review for validity
  - Individual decisions
  - Individual performance important
  - Weariness factor
  - Inter-individual inconsistency
The Last Four Decades:

- Analytical automation
  - Progressive improvement
  - Enhanced sophistication
  - Ubiquitous in clinical labs
- Peri-analytical automation
  - Pre- and post-analytical
  - More recent
  - Mainly robotics
- Information processing
  - Mainly post-analytical (reporting)
  - Recently peri-analytical (validity assessment)
  - Expert systems
Analytical automation

- Slow improvement - close to a plateau?

**Chemistry Productivity for Specimens & Tests**

- Orange line: Tests/employee/yr
- Green line: Specs/employee/yr

<table>
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Automated Core Laboratory
Peri-analytical automation

- Major improvement in productivity

**Chemistry Productivity for Specimens & Tests**

- Tests/employee/yr
- Specs/employee/yr
Automated Hematology Laboratory
Hematology Productivity

Tests per employee

1998 1999 2000 2001 2002 2003

Peri-Analytical Automation
What’s The Next Big Opportunity?

- Automated decision rules
  - Autoverification
  - Automated reflex testing
- Applicable to labs with LIS
- Applicable to some labs with automated analyzers but not a good LIS
- Next big thing for labs with peri-analytical automation
- Quality, service and cost benefits
Hematology Process Summary

- 10.8 FTE’s for 3 shifts, 5 day week
- Total worked hours: 403 hours/week
  - Supervision, training, scheduling: 36 hours (9%)
  - Operations total 148 (37%)
    - Reagents & maintenance: 54 hours (13%)
    - Analyzers: 47 (12%)
    - Robotics: 16 (4%)
    - Specimens: 31 (8%)
  - Manual analysis & smear prep: 72 hours (18%)
  - Total Review: 147 hours (37%)
    - Result review: 72 hours (18%)
    - Smear review: 75 hours (19%)
- Note: Prior to autoverification
Results of Application of Mount Sinai Autoverification & Review Criteria in Hematology

- Autoverify if all analyzer results normal
  - 6.25% were autoverified
- Smear review for analyzer flags and also other criteria
  - 27% required smear review
- Manual WBC differential if indicated
  - 8.4% required manual differentials
Validation (Verification) Process

- Validate the test result
  - Review QC results for the run
  - Review analyzer performance
  - Perform delta check
    - New result may be similar to previously known abnormal results
    - Specimen drawn from wrong patient or sample integrity problems (e.g. IV line)
- Compare related test results
- A multitude of variables
Actions

• Actions
  • Validate (verify) the result and report
  • Repeat the analysis
  • Dilute and re-run the sample
  • Perform reflex test
• For most labs, (chem, endo, immuno, etc)
  • actions involve the same analyzer
  • reflex testing is minimal (e.g. HIV)
• Hematology is more complex
What Makes Hematology Special?

- What to do after automated CBC and differential results have been produced
  - Verify and report
  - Repeat with or without dilution on the same or other analyzer
  - Examine a smear
  - Visual differential count
  - Manual platelet count
  - Other follow up tests
Principles for Review

- Reduce the number of samples requiring review to the greatest possible extent
- Analyzers are fast, with low cost per test
- Humans are smart but slow, with high labor cost; and good ones are becoming harder to find!
- Analyzer false positives mainly cause more work; false negatives can harm the patient
- Criteria for review
  - What’s safe?
  - What’s most effective?
  - How do we know?
  - Is one lab’s experience enough?
HEMATOLOGY CONSENSUS GROUP 2002
Mission

The mission of the international consensus group was to develop a set of functional guidelines that would aid laboratories in reducing the number of hematology result reviews and subsequent procedures they are required to perform, without losing any useful clinical data.
Participants - 2002 Consensus Meeting
Indian Wells, California

- Hospital Ramon y Cajal, Madrid Spain
- Liverpool Hospital, Sydney, Australia
- Chinook Health Region, Lethbridge, Alberta, Canada
- University College Hospital, London, UK
- Mt. Sinai Hospital, Toronto, Canada
- Auscorp, Melbourne, Australia
- Oregon Medical Laboratories, Eugene, Oregon, USA
- Childrens Hospital, Denver, Colorado, USA
- Grant Medical Laboratory, Columbus, Ohio, USA
- Mayo Clinic, Rochester, Minnesota, USA
- Alliance Laboratories, Cincinnati, Ohio, USA
- Mt. Sinai, New York City, New York, USA
- Dynacare Seattle, Washington USA
- UC Davis Medical Center, Sacramento, California, USA
- ACL, Milwaukee, Wisconsin, USA
- Barnes-Jewish Hospital, St. Louis, Missouri, USA
2 DAYS IN the HOT DESERT SUN
20 HEMATOLOGISTS
200 SODAS TEAS & COFFEE
2000 LAB RULES
(actually ~ 950)
83 rules we could test in our labs
Consensus Study Protocol

• For each lab:
  • 1000 patient specimens from daily workload over several days
  • Approx 200 specimens which had previous results to test delta rules
  • Recorded all analyzer results, including flags, vote-outs, etc.
  • Reviewed smears from all patients to validate rule performance
  • Compared each lab’s rules with consensus rules
  • Compared efficacy of individual consensus rules
Hematology Analyzers in the Study

- Advia 120 – Bayer
- CellDyn 4000 – Abbott
- Gen*S, LH 750 – Beckman Coulter
- SE-9000, XE-2100 - Sysmex
Definition of Positive Smear
Findings: Morphology

- RBC morphology: 2+/moderate or greater
- Platelet morphology: 2+/moderate or greater
- Platelet clumps: > rare or occasional
- Toxic granulation: 2+/moderate or greater
- Dohle bodies: 2+/moderate or greater
- Vacuoles: 2+/moderate or greater
- Any malarial parasite
Definition of Positive Smear Findings: Abnormal Cell Types

- Blast $\geq 1$
- Metamyelocytes $> 2$
- Myelocytes/Promyelocytes $\geq 1$
- Atypical lymphocytes $> 5$
- NRBC $\geq 1$
- Plasma cells $\geq 1$ or more
Rules Summary

- Rules separated into five main categories
  - WBC parameters
  - Platelet parameters
  - RBC/Hemoglobin parameters
  - Differential parameters (#)
  - Suspect codes/flags
- Neonates
- 1st time samples
- Subsequent sample (< 72 hrs.)
- Total of 41 consensus rules
Some Consensus Rules - WBC

- WBC >4 and <11 with WBC flags: slide review
- WBC >11 and <50 with no WBC flags: verify
- WBC >11 and <50 with WBC flags: slide review
- WBC > 4 <11, first time, no WBC flags: verify
- WBC <4, first time, no flags: slide review
- WBC any, incomplete diff: slide review + count
- WBC < 4, pass delta, same flag except blasts: verify
Some Consensus Rules - Differential

- Neut # < 1.0, first time = slide review
- Neut # < 1.0, pass delta, no blast flag = verify
- Mono # > 1.5, first time or fail delta = slide review
- Mono # > 1.5, pass delta = verify
- Flags: Immature granulocytes, or NRBC, or blasts, or atypical lymphs: slide review
Some Consensus Rules - Platelets

- PLT <100 and first time: slide review
- PLT >100 and <1000 with no PLT flags: verify
- PLT any count and PLT clump flag: slide review
- PLT >100 and other PLT flags, first time analysed: slide review
- PLT <100 and other PLT flags: slide review
- PLT <10 any time: lab SOP, alternate count
Some Consensus Rules - RBC

- HGB < 7, first time = slide review
- HGB > 7, no RBC flags = verify
- MCV > 105, adult, first time, sample < 24 hrs old = slide review
- MCV < 75, pass delta = verify
- RDW > 22, first time = slide review
- RBC fragment flag = slide review
- RBC dimorphic flag = slide review
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<thead>
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<th>Truth Tables for All Laboratories</th>
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<tr>
<td><strong>TOTAL TP FP TN FN</strong></td>
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<tr>
<td>Number 13298 1483 2476 8953 386</td>
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<tr>
<td>% 11.2 18.6 67.3 2.9</td>
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<table>
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<th>REVIEWED # SLIDES</th>
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INTERNATIONAL CONSENSUS GROUP FOR HEMATOLOGY REVIEW

Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis
(Read Online)

<table>
<thead>
<tr>
<th>Delta Definitions</th>
<th>Positive Smear Findings</th>
<th>Consensus Rules</th>
<th>Truth Table</th>
<th>Participating Hospitals</th>
<th>Steering Committee</th>
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</thead>
</table>

The International Consensus Group for Hematology Review is pleased to publish the following guideline:

Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis

Berend Houwen MD, PhD, the founder of ISLH, who passed away recently, recognized the long-standing need for generally accepted guidelines "rules" which could be applied to criteria for review of CBC and differential results from automated hematology analyzers and he addressed it in a visionary manner. He invited twenty experts to a meeting to discuss the issues and agree upon the most appropriate criteria. Beckman Coulter Inc. generously provided an educational grant to fund this meeting and to provide financial assistance for the development of guidelines. Dr. Houwen gathered together hematology laboratorians who represented six countries and seventeen laboratories that were foremost in the use of review criteria. The laboratories included those servicing tertiary care hospitals, oncology hospitals, community hospitals, children's hospitals, hospital laboratories, and independent laboratories.

We encourage laboratorians to explore the application of these rules in their own laboratories and to share their findings with the Consensus Group. Before activating any or all of these rules in your labs for clinical purposes, the Consensus Group strongly advocates testing of each rule in your laboratory setting.

The information on this website includes the rules for review, definitions of delta terms, definitions of what constituted a positive smear finding in this study, a consensus rules results "truth table", contact information for steering committee members, and a list of participating hospitals and laboratories. We thank each of the participating laboratories for taking the time to help determine the rules for this study, collecting and providing the data, reviewing the data analysis for their individual laboratories, and reviewing the attached material prior to publication on this website.

This material will be submitted in expanded form for journal publication within the next few months. Journal reference information will be posted on this website as soon as available.
### Consensus Rules

**Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis**

**Delta Definitions**

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Parameter</th>
<th>Primary</th>
<th>and/or</th>
<th>Secondary</th>
<th>and/or</th>
<th>Tertiary</th>
<th>and/or</th>
<th>Fourth</th>
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<tbody>
<tr>
<td>1</td>
<td>Neonate</td>
<td>First</td>
<td>sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Slide  Review</td>
</tr>
<tr>
<td>2</td>
<td>WBC, RBC, HGB, PLT, Retics</td>
<td>Exceeds</td>
<td>linearity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dilute sample and rerun</td>
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<tr>
<td>3</td>
<td>WBC, FLT</td>
<td>Lower than Lab verified instrument linearity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Follow lab SOP</td>
</tr>
<tr>
<td>4</td>
<td>WBC, RBC, HGB, PLT</td>
<td>Vote Out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Check sample for clot, Rerun sample If persists, perform alternate counting method</td>
</tr>
<tr>
<td>5</td>
<td>WBC</td>
<td>&lt;4.0 OR &gt;30.0</td>
<td>and</td>
<td>first time</td>
<td></td>
<td></td>
<td></td>
<td>Slide Review</td>
</tr>
<tr>
<td>6</td>
<td>WBC</td>
<td>&lt;4.0 OR &gt;30.0</td>
<td>and</td>
<td>delta failed</td>
<td>and</td>
<td>within 3 days</td>
<td></td>
<td>Slide Review</td>
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**Consortium Rules**
# Steering Committee Members - Contact Information

**INTERNATIONAL CONSENSUS GROUP FOR HEMATOLOGY REVIEW**

Suggested Criteria for Action Following
Automated CBC and WBC Differential Analysis

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</table>

<table>
<thead>
<tr>
<th>Dr. Elkin Simson</th>
<th>Ms. Stefanie L McFadden</th>
<th>Mr. Patrick W Barnes</th>
<th>Professor Samuel J Machin</th>
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<tbody>
<tr>
<td>Elkin Simson</td>
<td>Dr. Elkin Simson</td>
<td>Mt. Sinai Hospital</td>
<td>New York, NY USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>212-659-8181</td>
<td><a href="mailto:elkin.simson@mrsnyuhealth.org">elkin.simson@mrsnyuhealth.org</a></td>
</tr>
<tr>
<td>Stefanie L. McFadden</td>
<td>Ms. Stefanie L McFadden</td>
<td>Laboratory Consultant,</td>
<td>Columbus, OH USA</td>
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<tr>
<td></td>
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<td>614-579-5999</td>
<td><a href="mailto:stef@slh.org">stef@slh.org</a></td>
</tr>
<tr>
<td>Patrick W Barnes</td>
<td>Mr. Patrick W Barnes</td>
<td>Barnes Jewish Hospital,</td>
<td>St Louis MO USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>314-352-5048</td>
<td><a href="mailto:PWB02580@bjc.org">PWB02580@bjc.org</a></td>
</tr>
<tr>
<td>Samuel J Machin</td>
<td>Professor Samuel J Machin</td>
<td>University College Hospital,</td>
<td>Dept. of Haematology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>London UK</td>
<td><a href="mailto:samuel.machin@ucl.ac.uk">samuel.machin@ucl.ac.uk</a></td>
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How To Implement Consensus Rules?
Reality Bytes

- Fewer Medical Technologists
- Fewer Medical Technology Schools
- Average age of an MT is 50
- More generalists than specialists
- Instruments are much more automated than at any other time
- More tests per tech than at any previous time.
A Typical Day

Reporting 200-400 patient profiles per shift
While.....
The phones are ringing, the boss wants more – now, residents walk in to look at a smear...

With all of the high tech equipment in most labs today - *What are the technologists spending most of their time on?*
Data Review

Reviewing each result in light of **RULES**

- Normal Ranges
- Critical Values – IP and OP
- Delta Checks
- Relationship of parameters (eg. RBC, HGB, HCT)
- Dilution Needs or Manual processes
- Laboratory Review Policies
- Pathology Review Policies
- Rules for specific units or physicians
How does everyone know the rules?

The Procedure Manuals!

Reality check:

Posted sheets on instruments, cabinets, counter tops, inside lab coats, memory……..
Automated Hematology Analyzers

My hematology analyzer is faster than your hematology analyzer......

*Does it really matter that it can do over 100 samples per hour if your brain can only go 35?*

So - What’s the answer??
Automation of the Review Process

Maximizes instrument capabilities and logic rules while minimizing patient risk

- Reduce technologist interventions
- Reduce turn around time (TAT)
- Apply rules in a standardized way
- Consistent decision making by all staff
- Increases the comfort level of generalists
- Decreases tech time of asking “what do I do now” to the senior staff, thus decreasing total turn around time.
Software Solutions

- LIS
- Middleware + LIS
Middleware (Middle-Hemeware)

- Software between the analyzer and the LIS.
- Information from the analyzer is sent to the middleware.
- Middleware software contains all the laboratory’s rules.
- Middleware applies the rules to each sample.
- Middleware sends the automatically validated results to the LIS, holding back the non-validated samples for technologist review.
- Displays data for samples held back.
Middle-Hemeware Displays

- Histograms and cytogram scatterplots
- Previous results
- Instrument comments
- “Next Steps” for staff
- Which rules were triggered and the data that met that criteria.
- Viewable at cell counting workstation, differential workstation and at various other locations (e.g. manager’s office, hematopathologist’s office)
- Specimen results are stored with their respective histograms, scatterplots and all comments.
Advantages of Middle-Hemeware

- Increased focus on abnormal samples
- Increased release rate
- Flexible system (add tests, comments)
- One instrument interface to LIS (standardizes interface specs)
- Easier creation of rules
- Rules can be more complex - increases the autovalidation rate
- Review complete data from multiple analyzers at one workstation
**Beckman Coulter Test Results and Graphics: Ingles, Lauren (30008)**

**Patient:** Ingles, Lauren

**SID:** 30008

**Location:** Orchard Main Lab

**Provider:** Rogers, Craig

**WBC** 23.6 × 10^9/L

**NE %** 74.7

**LY %** 19.5

**MO %** 2.4

**EO %** 1.5

**BA %** 1.9

**NE #** 17.7 × 10^9/L

**LY #** 4.6 × 10^9/L

**MO #** 0.6 × 10^9/L

**EO #** 0.4 × 10^9/L

**BA #** 0.5 × 10^9/L

**RBC** 5.12 × 10^12/L

**HGB** 18.9 g/dL

**HCT** 54.9%

**MCV** 107.2 fl

**MCH** 37.0 pg

**MCHC** 34.5

**RDW** 17.7

**PLT** 205

**MPV** 8.1

**Suspect/Definitive/Conditional Flags**

- Ne Blasts
- WBC Interference
- Sample Not Validated

**Suggested Action**


**RBC Histogram**

**PLT Histogram**

**WBC Threshold Monitor**

**Panels in Order:** RBC with Differential (Approved)

**Approved:** 8/24/2000 5:18 PM TR

**Cass/Pos:** 000000

**Date/Time:** 8/24/2000 2:39 PM

**Aspiration Mode:** Manual

**Instrument:**

**Buttons:**
- Browse Reruns
- Reflex Orders
- Rerun Results
- Comments
- Print
- Rules
- Approve
- Refresh
- Close
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**Hematology**

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<td>I MHGB</td>
<td>15.1</td>
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<td>I MCV</td>
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<tr>
<td>I MCHC</td>
<td>33.2</td>
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<tr>
<td>I RDW-CV</td>
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<td>I PLT</td>
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<td>I NEUT#</td>
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**RACK**

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<td>TUBE</td>
<td>1</td>
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<tr>
<td>Accession DT</td>
<td>2003-09-09</td>
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<tr>
<td>Doctor</td>
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**DIFF**

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<tr>
<td>I MON#</td>
<td>0.32</td>
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<tr>
<td>I MONO%</td>
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<tr>
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<td>0.16</td>
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<tr>
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<tr>
<td>I BASO%</td>
<td>0.6</td>
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<tr>
<td>I RET#</td>
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<tr>
<td>I RET%</td>
<td>0.12</td>
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**WBC/BASO**

- IMI
- RET
- NRBC

**RBC**

- PLT
- PLT-O
- NRBC

**PLT**

- 62 Various WBC Flag
- Perform Manual Diff
- WBC Abn Scattergram

**NRBC**

- Various WBC Flag
- Perform Manual Diff
- WBC Abn Scattergram
### QC Results - ABX1 Low Control

**Date:** 9/5/2005

#### ABX1

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<tr>
<th>Test</th>
<th>Ref Values</th>
<th>Actual Values</th>
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<td>Mean</td>
<td>Low</td>
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<tr>
<td>WBC</td>
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<tr>
<td>RBC</td>
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<td>HGB</td>
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<tr>
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</tr>
<tr>
<td>RDW</td>
<td>15.2</td>
<td>11.9</td>
</tr>
</tbody>
</table>

#### Graph

**WBC Data Points 25**

- Assay Limits
- 3SD
- Mean
Tech Instructions

- Standardizes Next Steps for Techs
- Can be as simple as “scan slide”
- More complex: R/O cold agglutinin or lipemia per lab SOP # 566.
- Displays on Results screen – easily visible to techs.
- Useful to all staff from senior to new techs.
HGB Consensus Rule

Consensus Rule #9

HGB is less than 7.0g/dl or > 2g/dl above upper reference range for age and sex.

Tech instructions: Slide Review if first time. Verify sample integrity if indicated.
Rules example #2

Consensus rule #35
Atypical/Variant Lymph Flag (suspect comment)
Tech Next Step: Slide Review

Easily handled by Middle-Hemeware

Handled by LIS if it can accept instrument comments and histograms and can display tech instructions
Rules example #3

Parameter Combinations

Consensus Rule #36
Atypical/Variant Lymph Flag, with previous confirmed result and positive delta flag for WBC.

Tech instruction: Slide Review

Able to write this rule in Middleware, difficult in LIS systems
Rule Example #4

Tailoring the consensus rules to physicians

Consensus rule #4: WBC <4.0 or > 30.0 and first time
Tech instruction: Slide Review

WBC <4.0 or > 20.0 and Dr. Jones
Tech instruction: Slide Review
Summary: Realized Benefits of Middle-Hemeware

- Able to view multiple hematology analyzers from one workstation, with no paper printouts
- Easier creation of rules than most LIS systems – can specify rules for suspect flags, as well as combination of parameters.
- Standardized rules for review
Summary: Realized Benefits of Middle-Hemeware

- Decreased overall turn around time
- More work per technologist without stress & errors
- When reviewing results, all information is at hand, not just the numbers.
- Increase auto-validation rate
- Technologists able to spend more time focusing on abnormal samples
Conclusions

- The hematology laboratory is a more complex operation than most
- Standardization of decision rules has been initiated
- Automation of rules is available
- In most situations, Middleware provides a preferred solution