MAYO CLINIC

Positioning the Laboratory to Integrate Clinical Care:

New Approaches to Interactive Test Ordering and Reporting

William G. Morice, M.D., Ph.D.
Chair, Division of Hematopathology
Mayo Clinic, Rochester, MN

MAYO CLINIC

Before creating a solution, you should first identify the problem you are solving

Axiom #1

The Book of Medical Knowledge & Future Horizons of Medical Care

- Future of medicine centered on synthesizing and coalescing information
  - For individuals across multiple episodes of care
  - For groups of individuals to understand risk and determine efficacy of intervention
- This knowledge will be used to create“individualized” prevention and treatment plans
- This knowledge will be used to evaluate the competence of individual care providers

MAYO CLINIC

The Book of Medical Knowledge & Laboratory Services

- Pathology & Laboratory Services are a primary engine for creating medical knowledge
  - Over 50% of MR information from Lab Medicine
- Pathology & Laboratory Services are an important frontier for “individualized” patient care:
  - Genetic risk profiling
  - Patient-specific cancer treatments (mSMART)
- The variety, complexity, and “information density” laboratory tests is rapidly expanding

MAYO CLINIC

Laboratory Physicians, Medical Care, and Information Delivery

- The central role of the lab in creating knowledge creates unique opportunities for Lab Professionals
- To take advantage, Lab Professionals must be active participants in patient care
- To take advantage Lab Professionals must help identify current challenges in medical care
- Lab Professionals must participate in design of the tools which deliver the care we provide
  - Increased opportunity for unnecessary testing
  - Increased need for contextual result interpretation

MAYO CLINIC

MAYO CLINIC

If the solution is more complicated than the problem, then you are probably not solving the problem you think you are.

Axiom #2

The Position of the Lab in Clinical Care
Why aren't we at the table?

- Facilitating Over-Utilization:
  - "The Doctor knows (or should know) what they want"
- Driving Over-Utilization:
  - Volume-driven sales and marketing approaches
- Adding to the cost of care
  - Hidden cost: positive result for an unneeded test
  - Fragmented reports not calling out significant findings
- These issues ALL decrease the perceived and actual value of our specialty

MAYO CLINIC

Positioning of the Lab: Moving Forward

- Need to be proactive in guiding test ordering
  - Simplify offerings around clinical questions
  - Algorithmic approach co-created with clinicians
- Need to assimilate inter-related results into a single report
- Need to provide meaning to groups of individual results rather than just interpretation of the data
- Need to create systems that holds, links, collates, and integrates orders and results

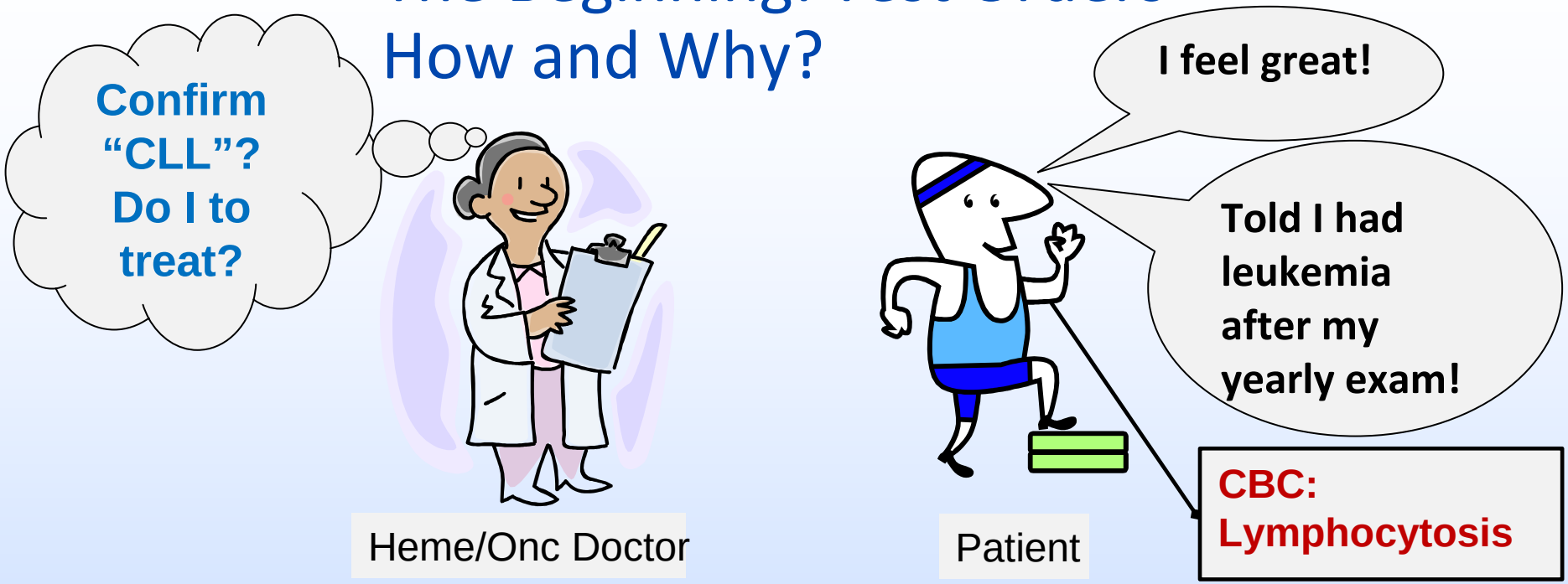
MAYO CLINIC

Positioning Lab to Add Value

- Must understand the context in which tests are ordered
- Must be cognizant of how the information is being used in patient care
- Must understand changing cultural paradigms for how information is accessed and delivered

MAYO CLINIC

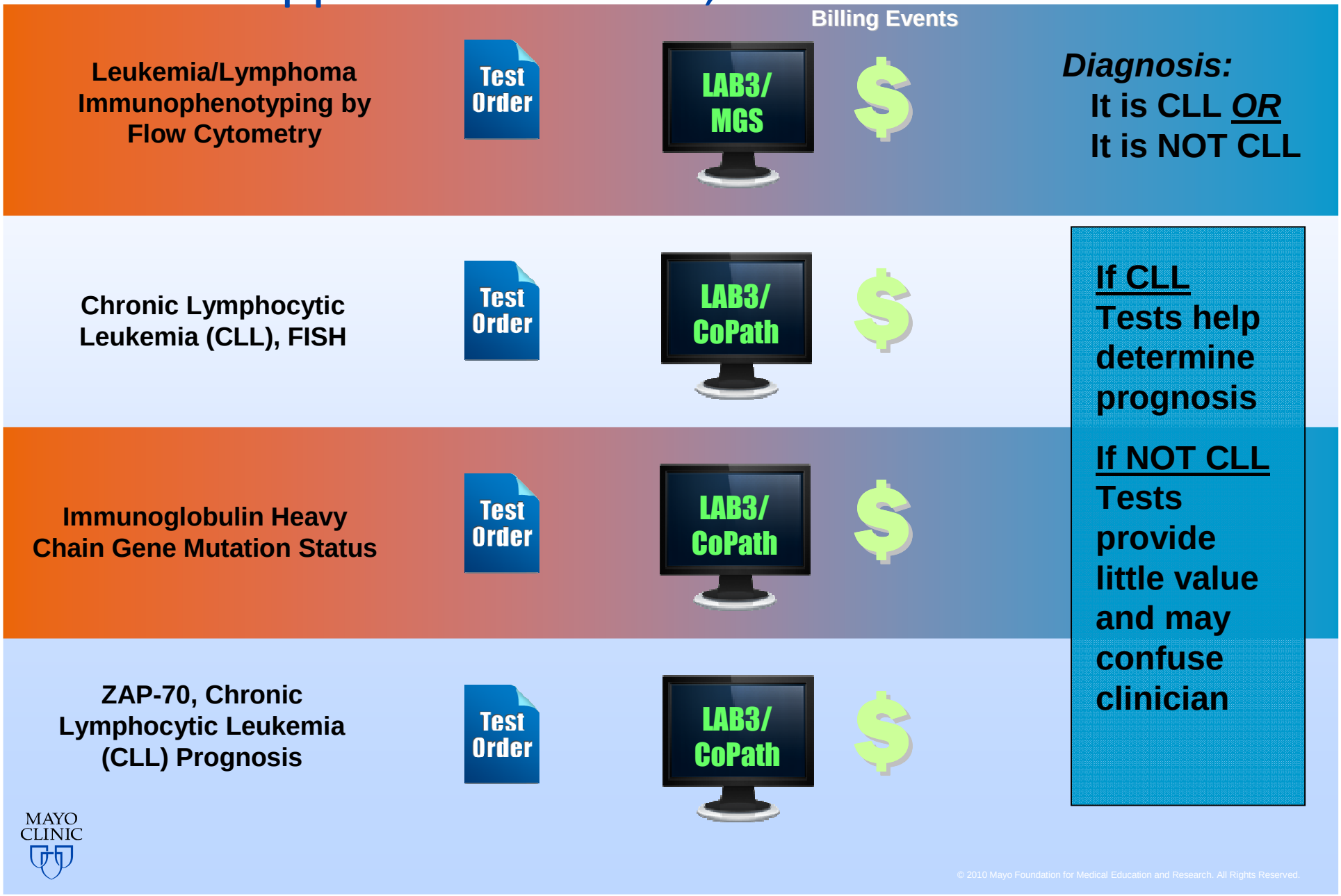
The Beginning: Test Orders How and Why?



- Doctor examines patient and reviews preliminary data
- Makes presumptive diagnosis based on data
- Orders additional studies to confirm diagnosis and generate prognostic data

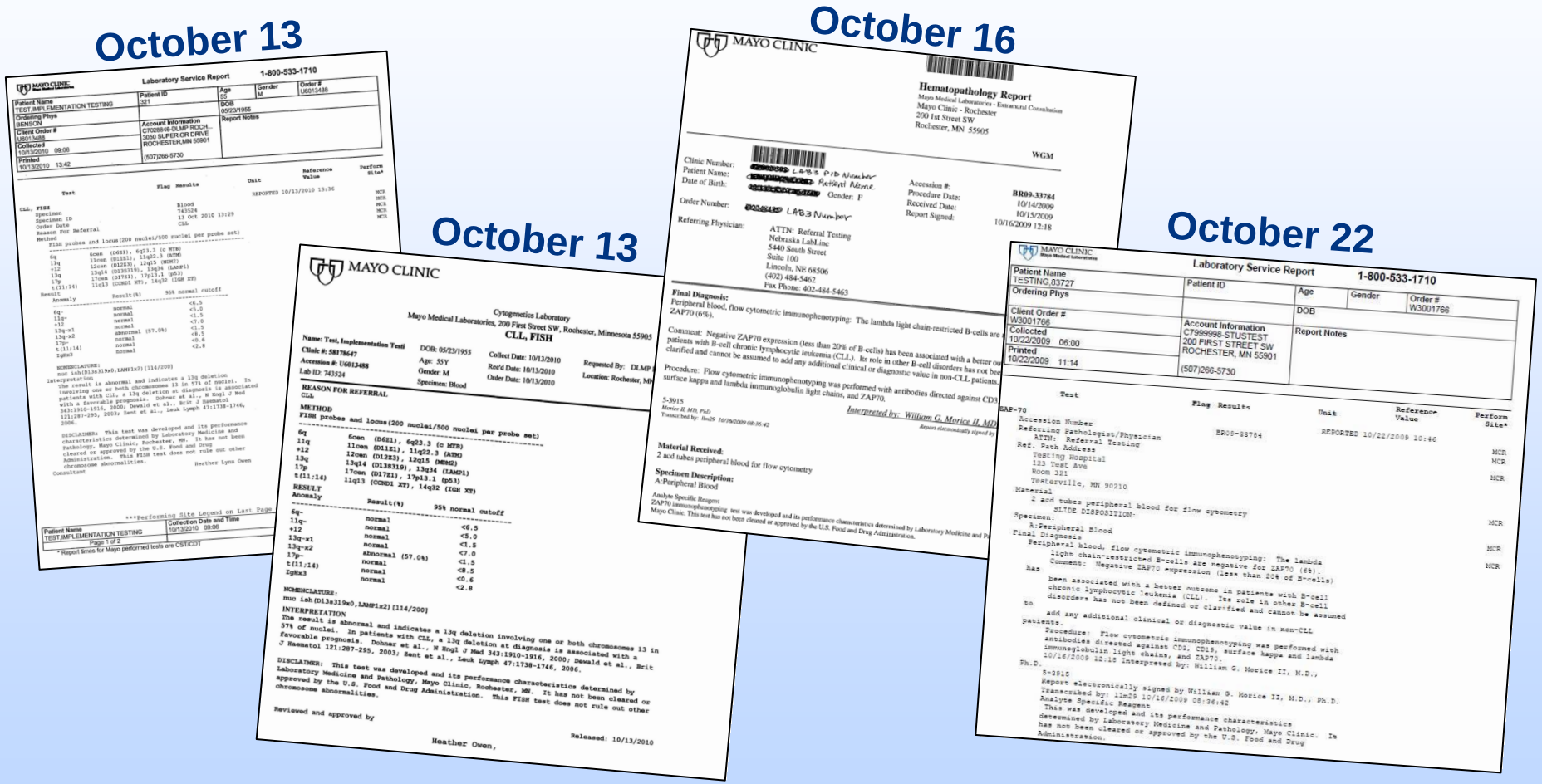
MAYO CLINIC

Current Approach – 4 Tests, 4 Results



MAYO CLINIC

Current Approach – 4 Tests, 4 Results



That doesn't really help …

MAYO CLINIC

What Should Happen

Scenario #1

Leukemia/Lymphoma Immunophenotyping by Flow Cytometry

Result – Not CLL

Billing Event

~~Pending~~ **Canceled**

Chronic Lymphocytic Leukemia (CLL), FISH

Immunoglobulin Heavy Chain Gene Mutation Status

ZAP-70, Chronic Lymphocytic Leukemia (CLL) Prognosis

MAYO CLINIC

What Should Happen

Scenario #2

Leukemia/Lymphoma Immunophenotyping by Flow Cytometry

Result – CLL Confirmed
Prognosis – Standard Risk

Billing Event

Pending Confirmed

Chronic Lymphocytic Leukemia (CLL), FISH

Immunoglobulin Heavy Chain Gene Mutation Status

ZAP-70, Chronic Lymphocytic Leukemia (CLL) Prognosis

Billing Events

MAYO CLINIC

Integrated Report

Integrated Report

The Integrated Report uses results A – D and combines them into a single fully integrated report.

Cell Kinetics

Cell Kinetics

Molecular Hematopathology

Cytogenetics

Integrated Report

Integrated Report E
++++++++++++++++

Result A
==========

Result B
==========

Result C
==========

Result D
==========

MAYO CLINIC

The Integrated Report

MAYO Clinic

Bone Marrow Morphology Analysis

Patient Name: TEST, TEST
Birth Date: 4/7/1993 8:00:00 AM
Age: 17 Y
Gender: Female
Referring Physician: test test
Tel: 0000000000
Fax: 0000000000
Collection Date: 04/21/2010
Treating Physician: Laura Test
Tel: 1111112222
Fax:
Received Date: 04/21/2010
Order #: 100000198
Specimen #:
Case #:
Client Specimen #:
Account #: CLTEST
AP #: P-10-198
Client Lab ID:
Client Hospital ID:
TEST CLINIC**SCC USE
Specimen(s) Received: 2 Block, Wet tissue, 1 Slide, Smear

Clinical Data: Patient has a history of Acute Leukemia.

Body Site: Bone, Left Iliac; Bone, Left Iliac; Bone, Left Posterior Iliac

Diagnosis: Hypercellular marrow 5% with maturing trilineage hematopoiesis.

Reviewing Pathologist: 0000000000

Giemsa | Iron | Peroxidase

Bone Marrow Differential Count

Differential/Aspirate (200 cells counted)

Cell/Signal Type	Cell/Signal Count	Cell Signals Normal Range	Cell/Signal Type	Cell/Signal Count	Cell Signals Normal Range
PRONORMOBLASTS	6	0 - 2	ERYTHROID SERIES	20	15 - 25
PLASMA CELLS	10	0 - 1	MYELOBLASTS	0	0 - 3
PROMEYLOCYTES	0	2 - 8	MYELOCYTES	30	10 - 13
METAMYELOCYTES	22	10 - 15	NEUTROPHILS/BANDS	5	25 - 40

MAYO Clinic

Surgical Pathology Report
ICC Analysis

Patient Name: TEST, TEST
Birth Date: 4/7/1993 8:00:00 AM
Age: 17 Y
Gender: Female
Referring Physician: test test
Tel: 0000000000
Fax: 0000000000
Collection Date: 04/21/2010
Treating Physician: Laura Test
Tel: 1111112222
Fax:
Received Date: 04/21/2010
Order #: 100000200
Specimen #:
Case #:
Client Specimen #:
Account #: CLTEST
AP #: P-10-200
Client Lab ID:
Client Hospital ID:
TEST CLINIC**SCC USE
Specimen(s) Received: 1 Block, Paraffin

Clinical Data: Patient has a history of migraine headaches.

Body Site: Lymph Node

Interpretation: Stage IV neuroblastoma. This interpretation is based on histological features seen in an excised lymph node mass.

Comment: This analysis is an adjunct to the evaluation of the referring physician and does not represent a final diagnosis.

H&E

Marker	Marker Comment	Result
NB84a	Neuroblastoma	Positive-Cytotrophoblast/Villi stroma

Electronically Signed By: LAURA DE LA MIRANDA SCC
Employee
Date: 4/22/2010 9:05 AM

This test was developed and its performance characteristics have been determined by Mayo Clinic. It has not been cleared or approved by the FDA. The FDA has determined that such clearance or approval is not necessary. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing.

MAYO CLINIC

Integrated Test Ordering and Reporting

- Is this the end or the beginning?
- How do you integrate information that is not there?

MAYO CLINIC

SHREK, ONIONS, and Consultative Laboratory Medicine

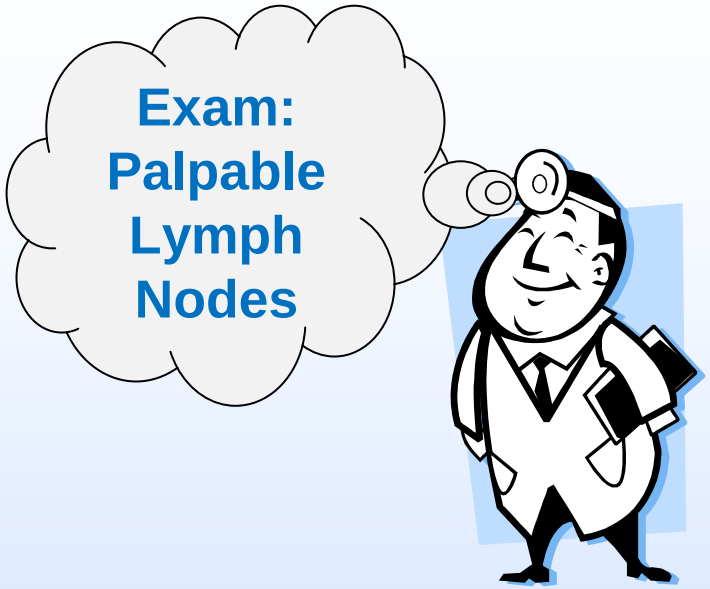
MAYO CLINIC

Consultative Laboratory Practice: Different Layers

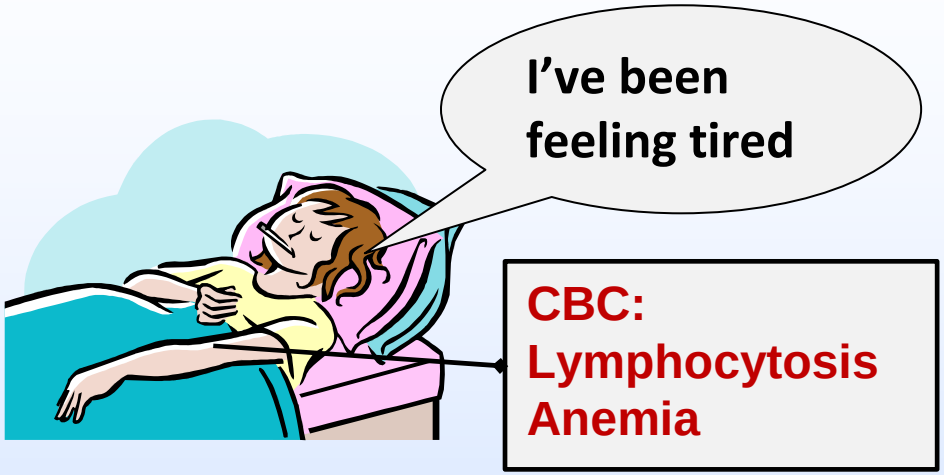
- TECHNICAL: Request for assistance in creating data or verifying methods of data creation
- INTEPRETIVE: Request for assistance in interpreting data to generate an individual result
- INTEGRATIVE: Request to assist in reviewing and collating group of individual results
- SUPPORTIVE: Request for assistance in using knowledge to guide the selection of individual tests to appropriately answer clinical questions

MAYO CLINIC

The Beginning: How are Orders Created?



Primary Care Doctor



Patient

- Doctor examines patient and reviews preliminary data
- Creates differential diagnosis (List) based on data
- Orders additional studies to narrow list into specific diagnosis

MAYO CLINIC

Differential Diagnosis & Test Ordering

Differential Diagnosis	Ordered Tests
• Viral Infection (80%)	• Viral Serologies
• Autoimmune Disease (5%)	• Autoimmune Serologies
• Lymphocytic Leukemia (5%)	• Leukemia Flow Cytometry
• Immunodeficiency (5%)	• Immune Function Tests
• Something else (5%)	• Round 2

MAYO CLINIC

Integrated Report

Cell Kinetics

Cell Kinetics

Molecular Hematopathology

Cytogenetics

Integrated Report

How can we integrate what does not exist and should?

Integrated Report

Integrated Report ?
++++++++++++++++

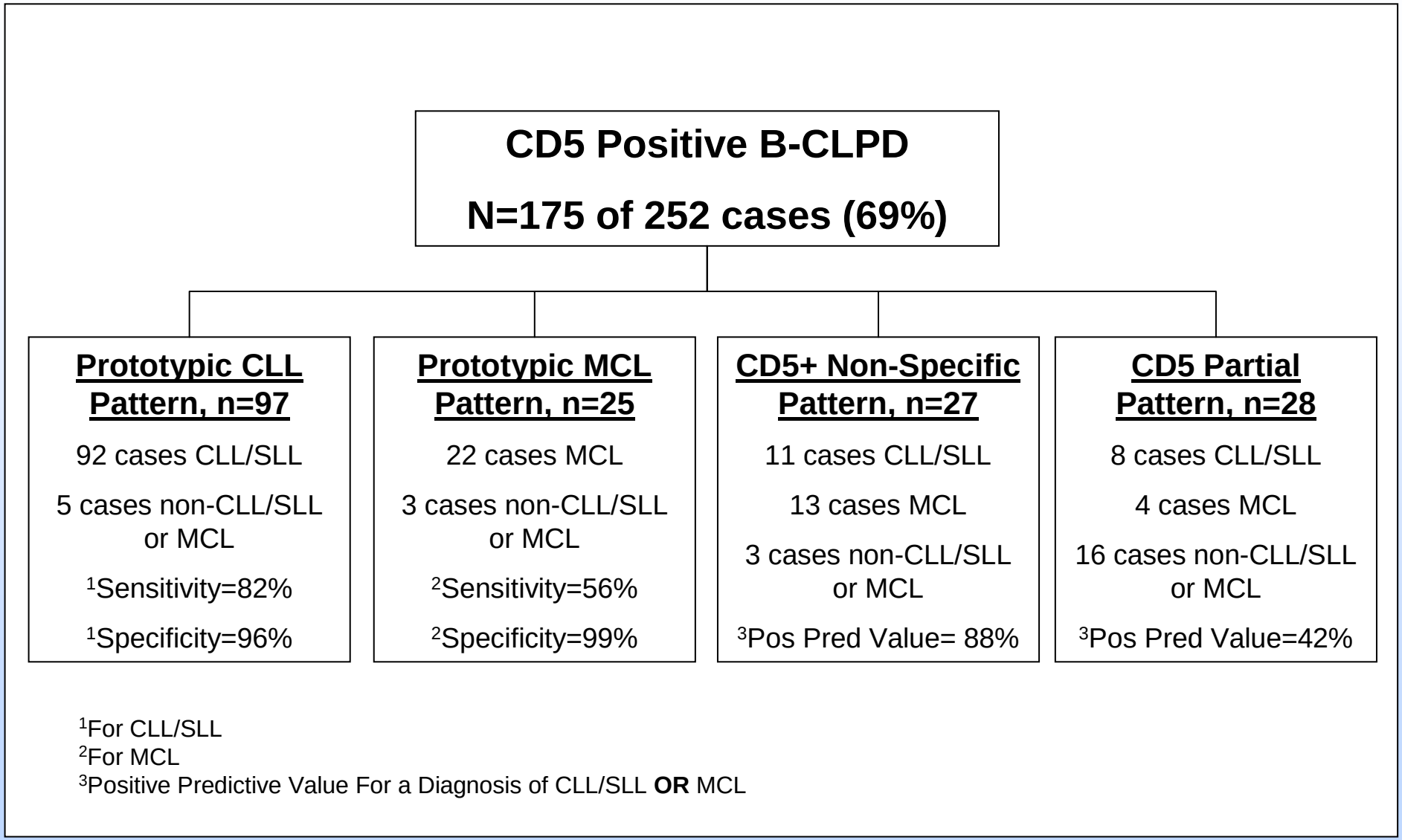
Result A CLL
==========

CLL Prog Result ?
==========

CLL Prog Result ?
==========

CLL Prog Result ?
==========

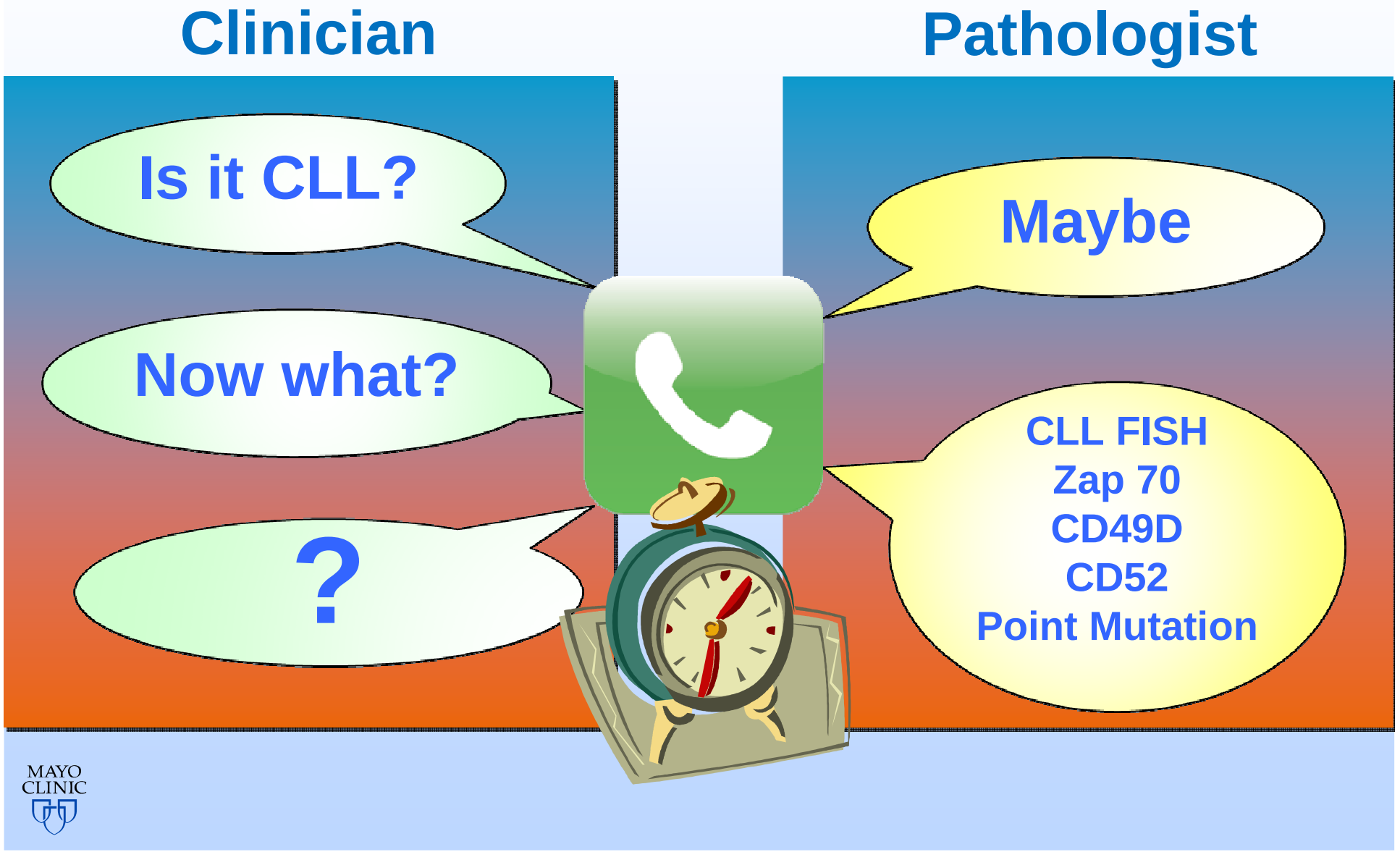
MAYO CLINIC



[1]For CLL/SLL
[2]For MCL
[3]Positive Predictive Value For a Diagnosis of CLL/SLL **OR** MCL

MAYO CLINIC

Current Approach – 1 Test, Now What?

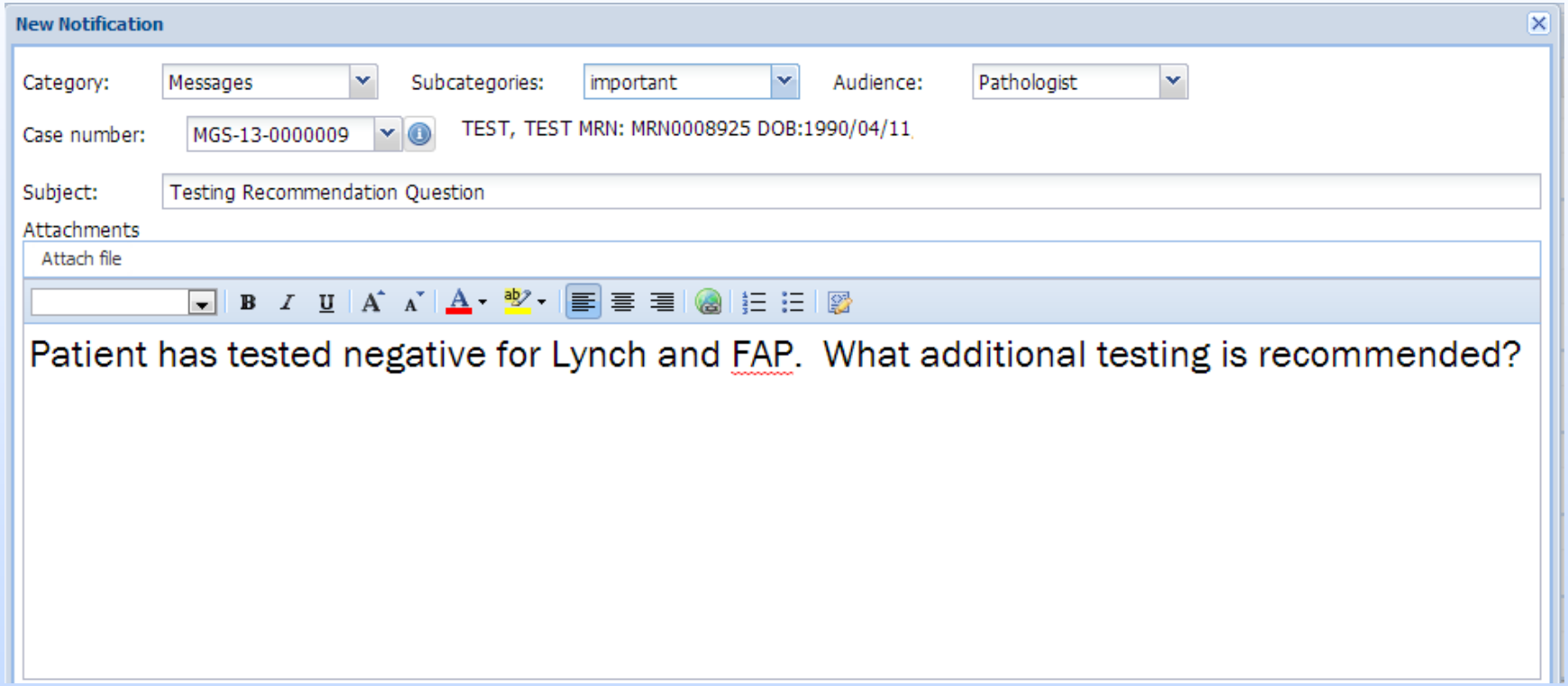


MAYO CLINIC

That doesn't really help either…

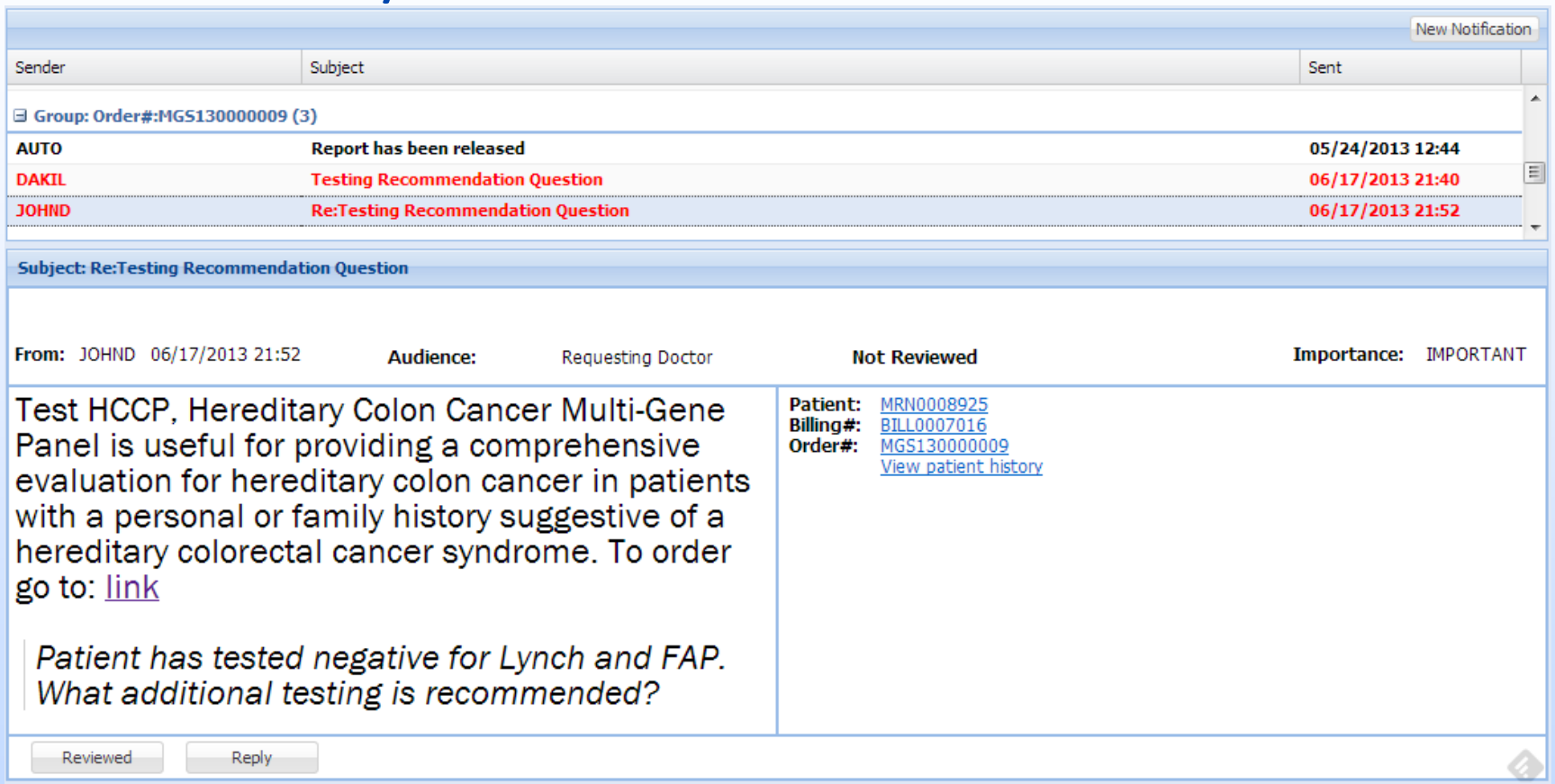
MAYO CLINIC

Testing Recommendation Question



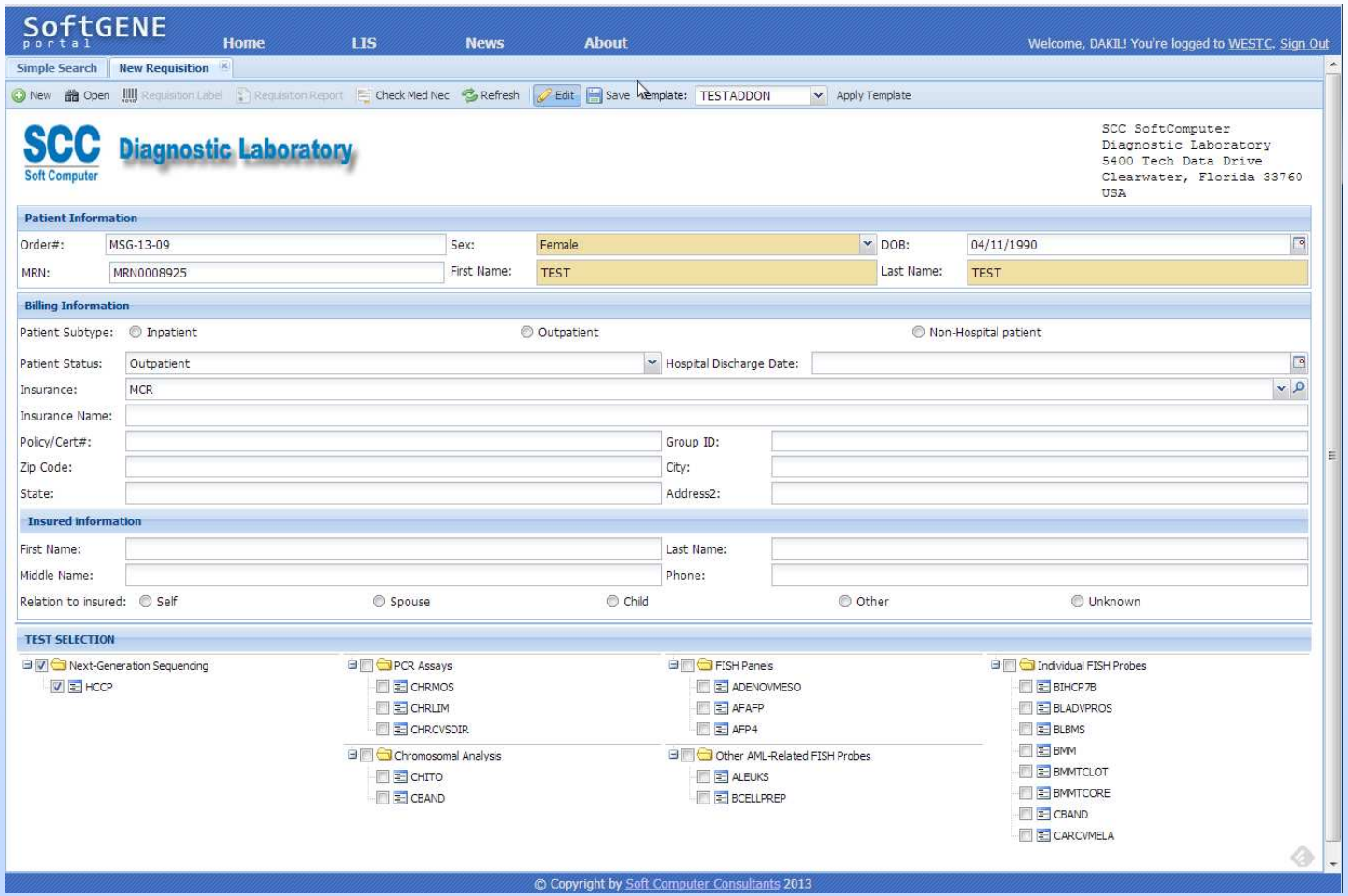
MAYO CLINIC

Notification/Conversation Thread



MAYO CLINIC

Provider Orders HCCP and Submits Billing Information



MAYO CLINIC

Mayo Clinic Integration of Laboratory Information : Collaborative Laboratory Integrated Reports (CLIR)

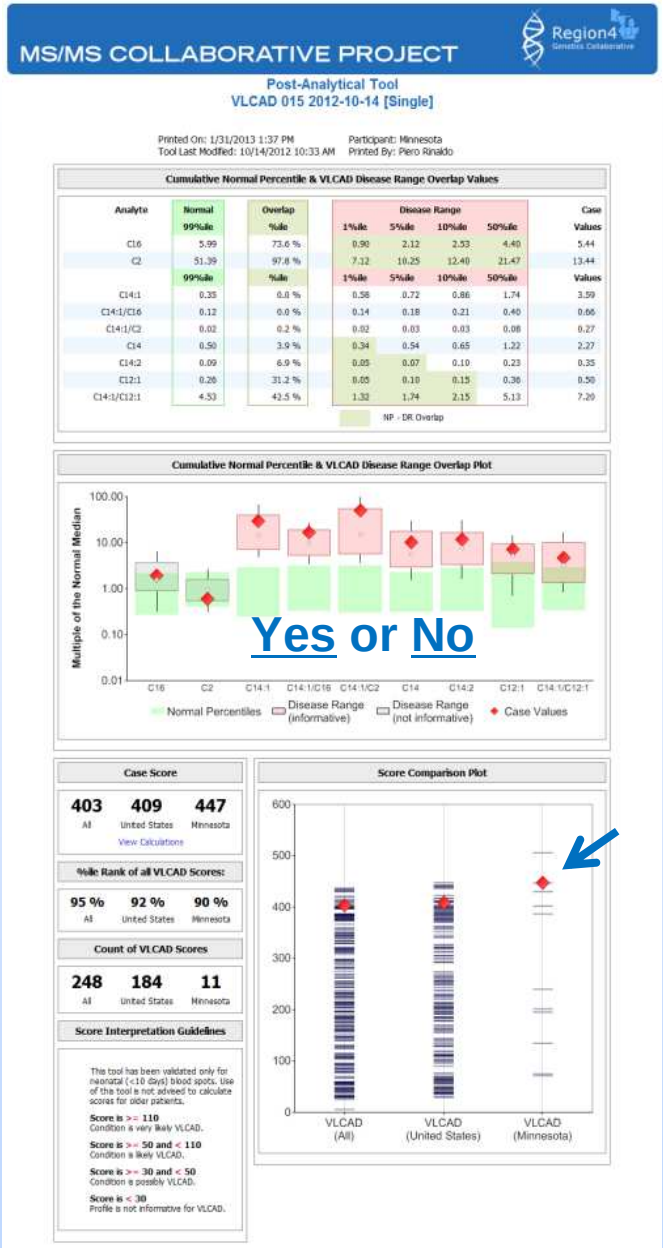
- A Mayo-led, worldwide collaborative project to improve the post-analytical interpretation of mass spec. newborn screening results (134 results per patient)
- Based on multivariate pattern recognition software that generates post-analytical interpretive tools

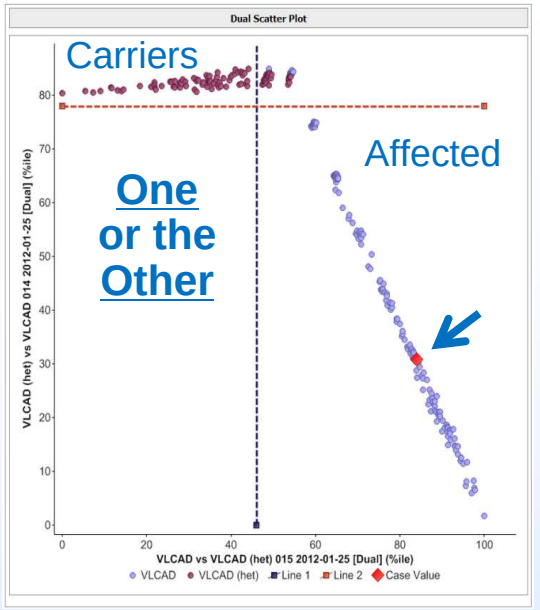
MAYO CLINIC

CLIR Tools

2012-2013 (YTD) UTILIZATION

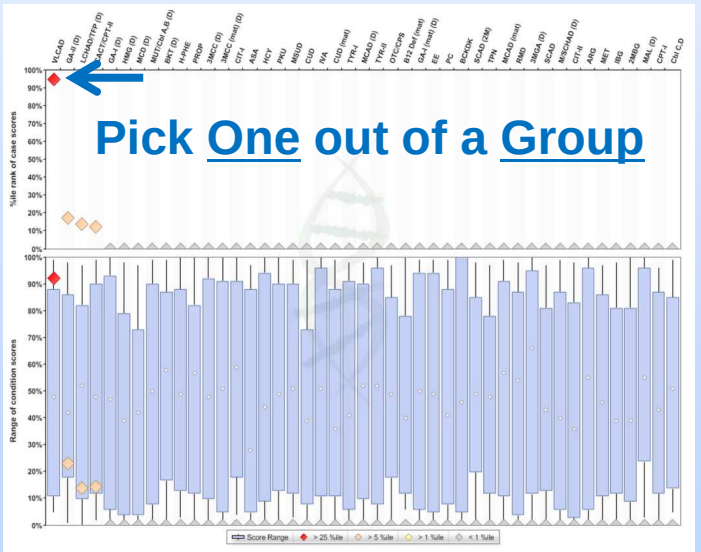
195 sites
52 countries
>58 million calculated scores





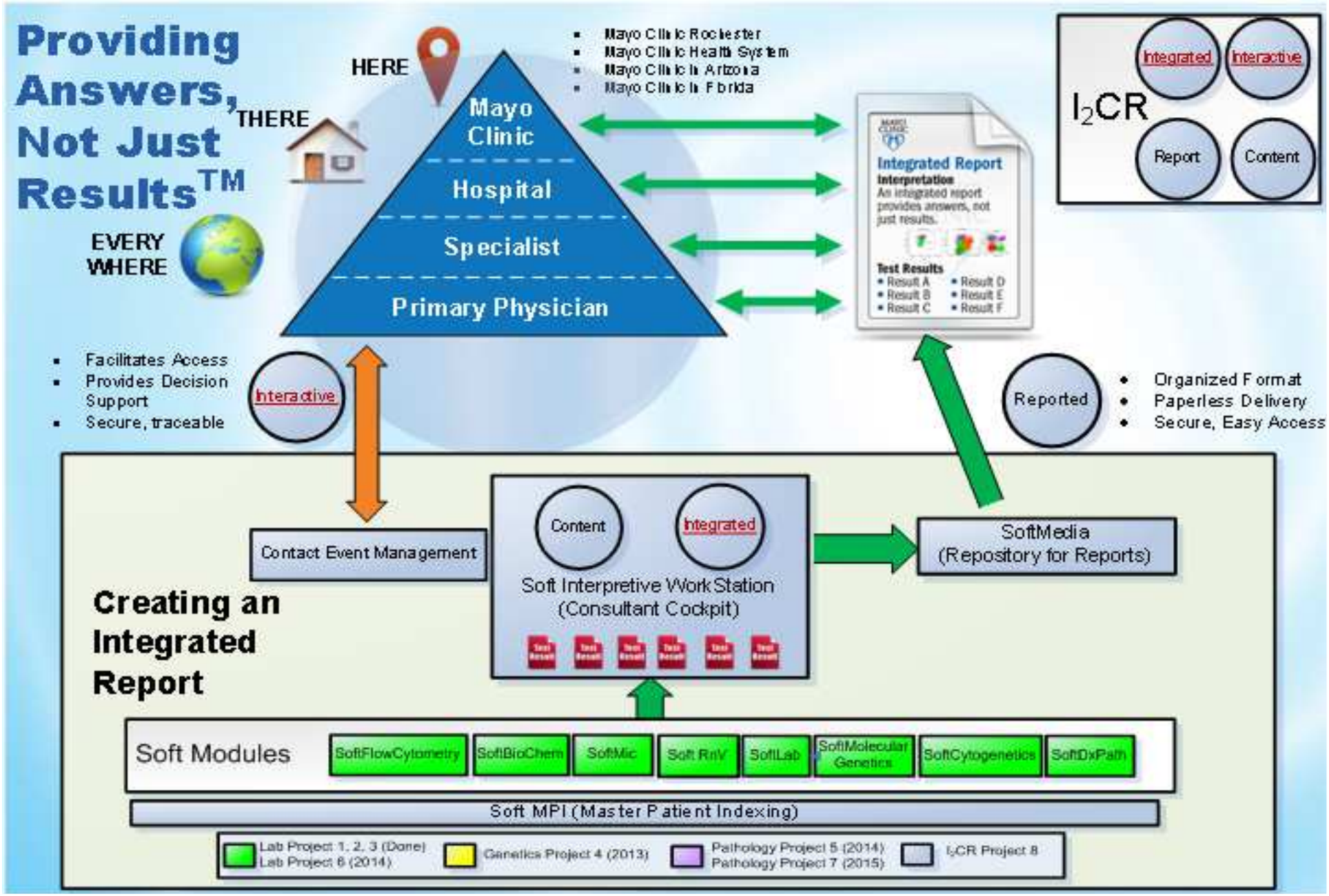
McHugh DMS et al. (2011) Clinical validation of cutoff target ranges in newborn screening of metabolic disorders by tandem mass spectrometry: A worldwide collaborative project. Genet Med 13:230-254.

Marquardt G et al. (2012) Enhanced interpretation of newborn screening results without analyte cutoff values. Genet Med, 14:648-654.

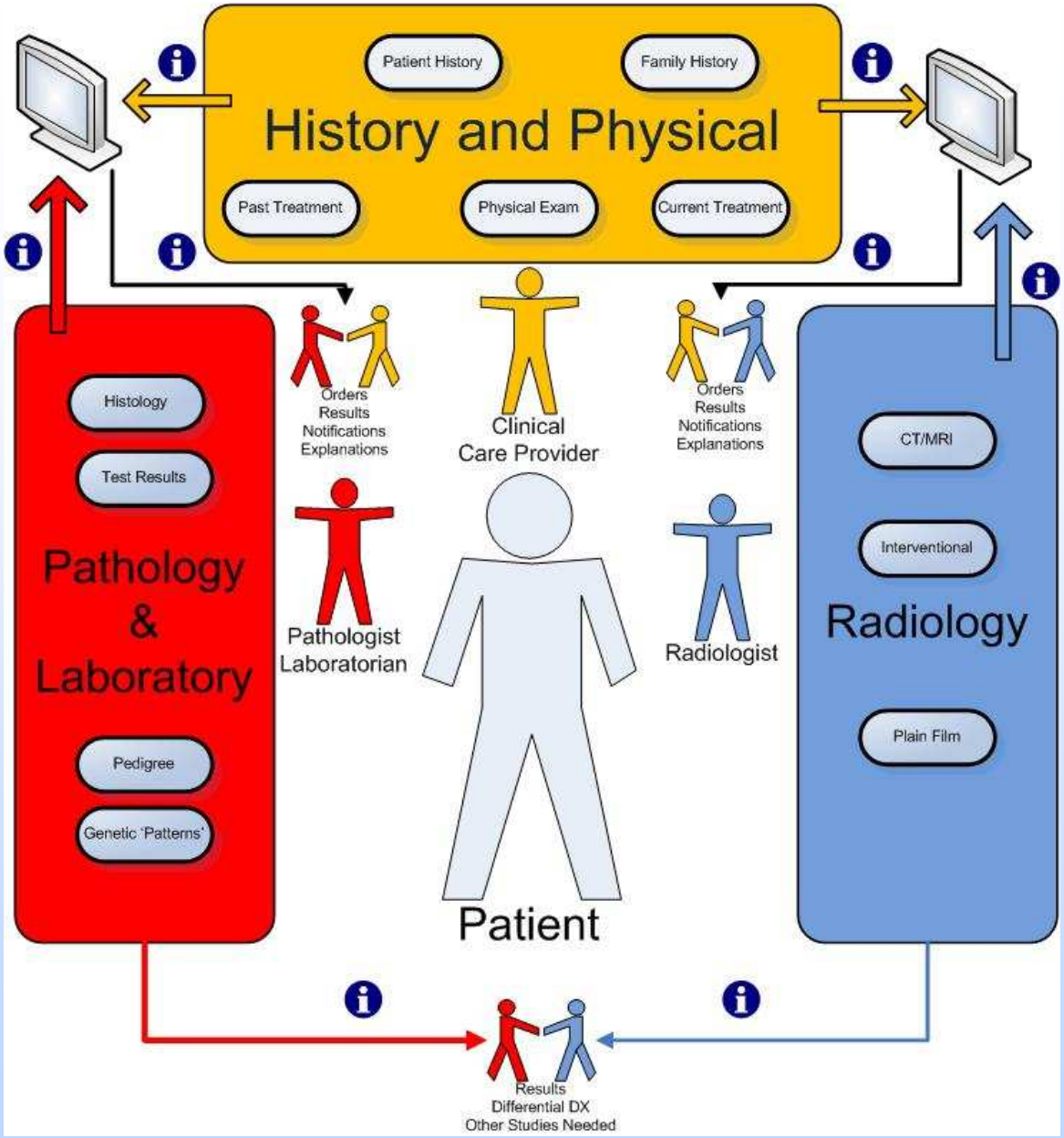


MAYO CLINIC

Building Tools to Add Value



MAYO CLINIC


Patient History
Family History
History and Physical
Past Treatment
Physical Exam
Current Treatment
Histology
Test Results
Pathology & Laboratory
Pedigree
Genetic 'Patterns'
Orders
Results
Notifications
Explanations
Clinical Care Provider
Pathologist Laboratorian
Patient
Orders
Results
Notifications
Explanations
Radiologist
CT/MRI
Interventional
Radiology
Plain Film
Results
Differential DX
Other Studies Needed

Cervical Cancer Prevention:
Do we need to think of a different system?

Problem: Although cervical cancer is highly preventable, it still continues to be a leading cause of death.

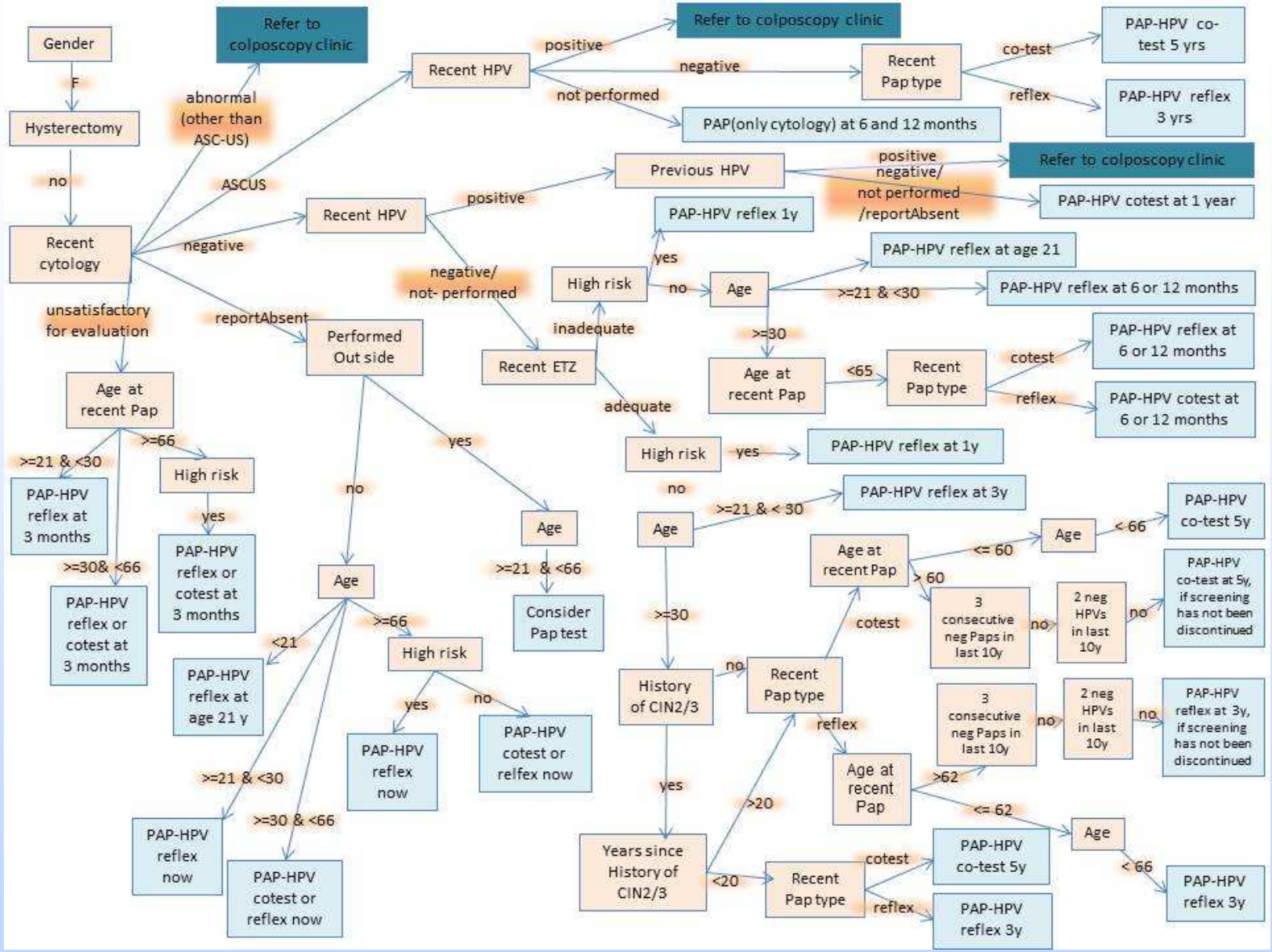
More than half of the women diagnosed with cervical cancer were found to have inadequate screening

*Guidelines for cervical cancer are **complex** and not easily recalled by health providers.*

Solution: Clinical Decision Support Service incorporated into pathology report, to remind optimal care.

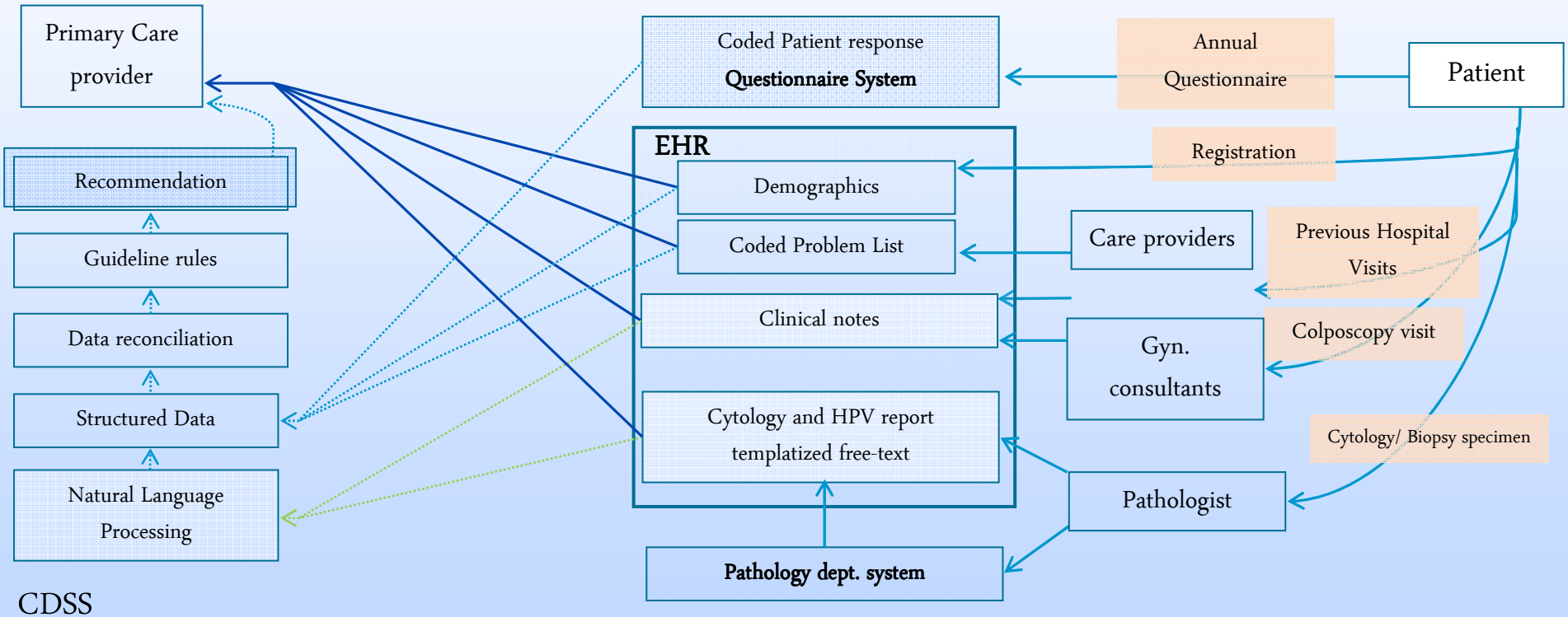
MAYO CLINIC

Decision logic for Pap derived from the care process model

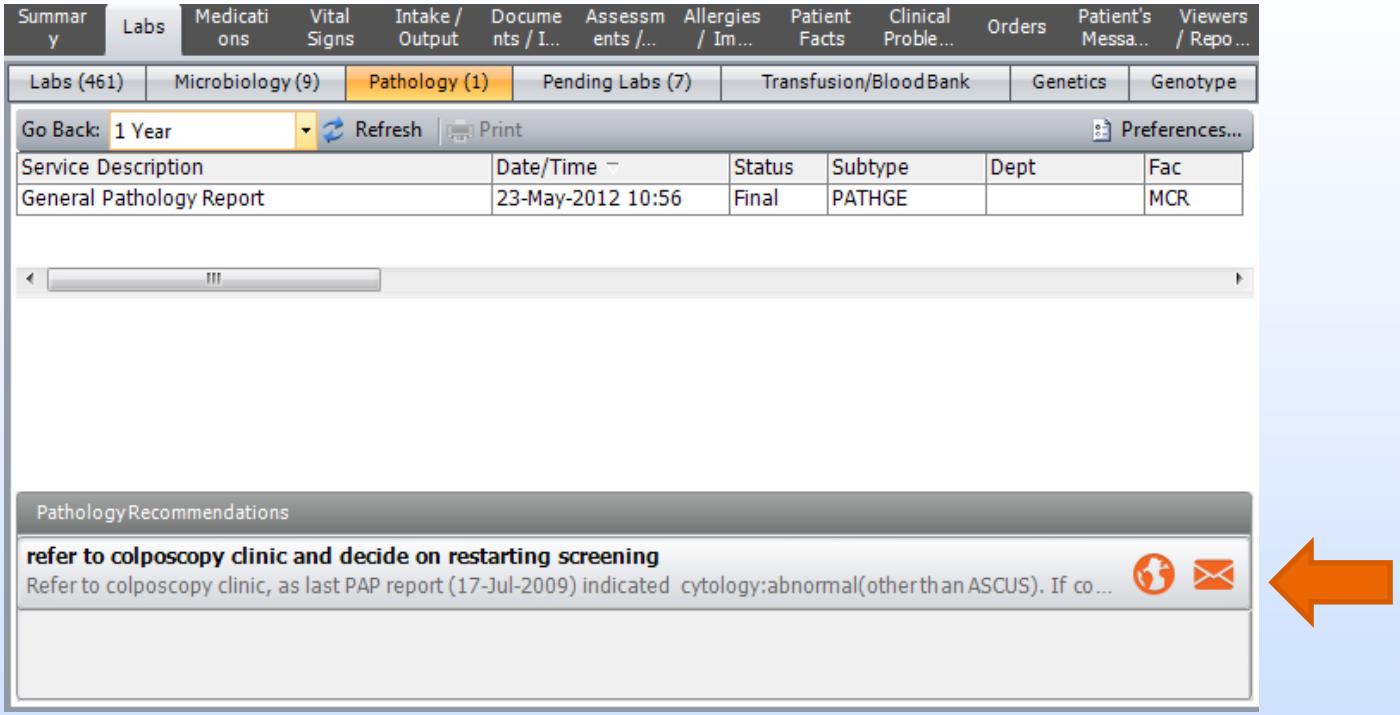


MAYO CLINIC

MAYO CLINIC


Primary Care provider
Recommendation
Guideline rules
Data reconciliation
Structured Data
Natural Language Processing
CDSS
Coded Patient response
Questionnaire System
EHR
Demographics
Coded Problem List
Clinical notes
Cytology and HPV report templatized free-text
Pathology dept. system
Annual Questionnaire
Patient
Registration
Care providers
Previous Hospital Visits
Colposcopy visit
Gyn. consultants
Cytology/ Biopsy specimen
Pathologist

New generation PAP Reporting Using CDSS



- 25 Users, 175 cases, 87% accuracy
- All errors corrected after ID'ing rule deficiecies
  - *J Am Med Inform Assoc* 2013;**20**:749-757

MAYO CLINIC

Positioning the Laboratory to Add Value: Who Benefits (ROI)?

- #1: The Patient
  - Increased accuracy
  - Fewer office visits, get diagnosis more quickly
- Clinical Care Provider: Clearer understanding of tests ordered, results, meaning for patient
- Laboratory
  - Increased value of service provided
  - Decreased number of non-reimbursed tests
- Healthcare System
  - Optimized utilization eliminates waste
  - Potential to broadly integrate patient information

MAYO CLINIC

Thank You to:
Dr. Piero Rinaldo, CLIR
Dr. Rajiv Chaudry, CDSS
Dr. Matthew Howard
The Organizers
And Audience!

Questions?