Michael Laposata, M.D., Ph.D.

Director of Clinical Laboratories Massachusetts General Hospital Professor, Harvard Medical School

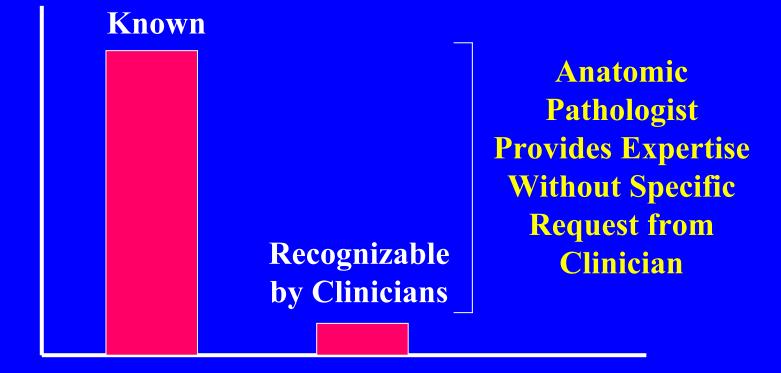
Everyone accepts the fact that the ordering physician cannot interpret a biopsy specimen nor read an MRI, but there is an incorrect assumption, often by pathologists who are in charge of clinical laboratories, that the ordering physician knows precisely what to do with a prolonged PTT or a speckled ANA positive at 1:1280 – **BUT THEY DON'T**

And these tests are ordered far more frequently than any test in AP!!

ANATOMIC PATHOLOGY

1972 & Today

Microscopic Morphologic Diagnoses



LABORATORY MEDICINE

1972

Lab Tests and # Diagnoses
Dependent on Lab Tests

Clinician
Diagnoses Expertise
Known & in Test
Tests Selection and
Available Interpretation

No Difference

LABORATORY MEDICINE

Today

Lab Tests and # Diagnoses
Dependent on Lab Tests

Diagnoses
Known &
Tests Available

Clinician Expertise in Test Selection and Interpretation

BUT No Expert
Advice
Provided
Unless
Specifically
Requested

Most pathologists do know that this is a problem, but specifically someone else's problem because-

-I never learned CP well enough in residency and cannot learn it now
-Unlike AP, I am not sure I'll be paid for doing it
-No one really expects me to do it- I just need to answer an occasional question about a test
-I could get into trouble if I start a turf war over consultation services-better to be referral service to other consult services

Coagulation test interpretations at MGH – How much case experience is necessary to correctly interpret >95% of cases?

Pathology residents on the MGH coagulation service sign out >98% of cases correctly after 2 months – this is > 1200 cases

Visiting pathologists and residents from internal medicine at MGH coagulation rounds report confidence at the 90+% level after 1-2 weeks — this is > 150 cases per week

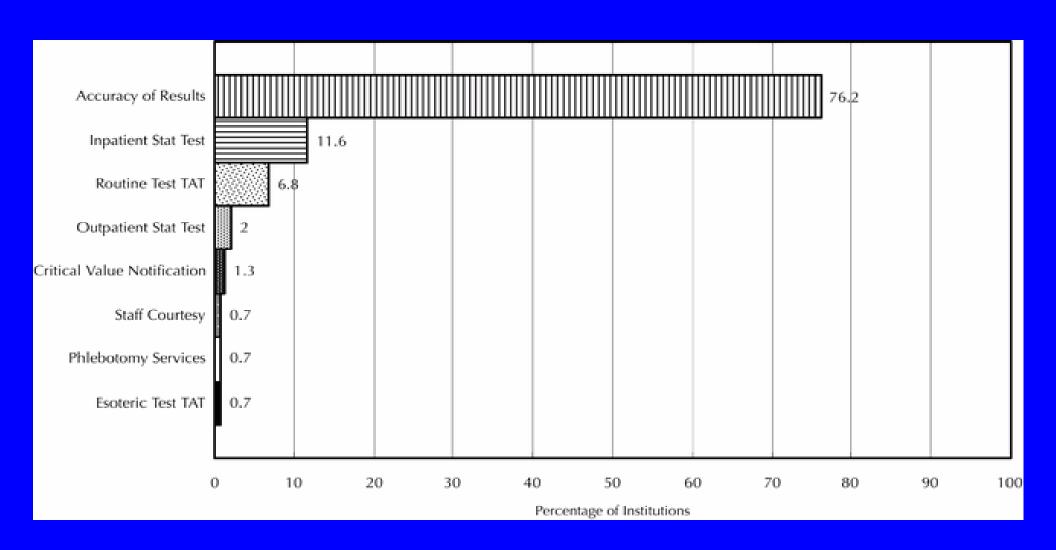
CLINICAL LABORATORY INTERPRETATION CODES

86320-26	Immunoelectrophoresis, serum
86325-26	Immunoelectrophoresis, other fluids
86327-26	Immunoelectrophoresis, 2-dimensional
86334-26	Immunofixation electrophoresis
87162-26	Dark field examination, any source
87207-26	Smear, primary source, for inclusion bodies/parasites
88371-26	Protein analysis by western blot, interpretation
88372-26	Protein analysis by western blot, with probe, interpretation
89060-26	Crystal identification by light microscopy

CLINICAL LABORATORY INTERPRETATION CODES

83020-26	Hemoglobin; electrophoresis
83912-26	Nucleic acid probe, each, with exam and report
84165-26	Protein, electrophoretic fraction and quantitation
84181-26	Western blot interpretation
84182-26	Western blot interpretation, immunological probe for band identification, each
85390-26	Fibrinolysis or coagulopathy screen, interpretation and report
85576-26	Platelet aggregation (in vitro), each agent
86255-26	Fluorescent antibody; screen, each antibody
86256-26	Fluorescent antibody; titer, each antibody

PHYSICIANS' RATING OF MOST IMPORTANT SERVICE ASPECT FOR CLINICAL LABORATORIES – EXPECTATIONS ARE LOW



Arch Pathol Lab Med 129, 1252, 2005

METHODS

Random sample of adults living in 12 metropolitan areas in the United States and asked about selected health care experiences. Written consent received to copy medical records for the most recent two year period and this information used to evaluate performance on 439 indicators of quality of care for 30 acute and chronic conditions as well as preventive care. We then constructed aggregate scores.

ADHERENCE TO QUALITY INDICATORS, OVERALL AND ACCORDING TO TYPE OF CARE AND FUNCTION

Variable	No. of Indicators	Percentage of Recommended Care Received (95% CI)
Overall care	439	54.9 (54.3 – 55.5)
Type of Care		
Preventive	38	54.9 (54.2 – 55.6)
Acute	153	53.5 (52.0 – 55.0)
Chronic	248	56.1 (55.0 – 57.3)
Function		
Screening	41	52.2 (51.3 – 53.2)
Diagnosis	178	55.7 (54.5 – 56.8)
Treatment	173	55.7 (54.5 – 56.8)
Follow-up	47	58.5 (56.6 – 60.4)

N Engl J Med 2003; 348:2635-45

ADHERENCE TO QUALITY INDICATORS, ACCORDING TO MODE

Mode	No. of Indicators	Percentage of Recommended Care Received (95% CI)
Medication	95	68.6 (67.0 – 70.3)
Immunization	8	65.7 (64.3 – 67.0)
Physical Examination	67	62.9 (61.8 – 64.0)
Laboratory Testing or Radiography	131	61.7 (60.4 – 63.0)
Surgery	21	56.9 (51.3 – 62.5)
History	64	43.4 (42.4 – 44.3)
Counseling or Education	23	18.3 (16.7 – 20.0)

N Engl J Med 2003; 348:2635-45

ADHERENCE TO QUALITY INDICATORS, ACCORDING TO CONDITION

Condition	Percentage of Recommended Care Received (95% CI)
Breast Cancer	75.7 (69.9 – 81.4)
Coronary Artery Disease	68.0 (64.2 – 71.8)
Hypertension	64.7 (62.6 – 66.7)
Congestive Heart Failure	63.9 (55.4 – 72.5)
Cerebrovascular Disease	59.1 (49.7 – 68.4)
Chronic Obstructive Pulmonary Disease	58.0 (51.7 – 64.4)
Depression	57.7 (55.2 – 60.2)

ADHERENCE TO QUALITY INDICATORS, ACCORDING TO CONDITION

Condition	Percentage of Recommended Care Received (95% CI)
Asthma	53.5 (50.0 – 57.0)
Benign Prostatic Hyperplasia	53.0 (43.6 – 62.5)
Hyperlipidemia	48.6 (44.1 – 53.2)
Diabetes Mellitus	45.4 (42.7 – 48.3)
Headache	45.2 (43.1 – 47.2)
Urinary Tracy Infection	40.7 (37.3 – 44.1)
Community-acquired Pneumonia	39.0 (32.1 – 45.8)
Sexually Transmitted Diseases or Vaginitis	36.7 (33.8 – 39.6)
Dyspepsia and Peptic Ulcer Disease	32.7 (26.4 – 39.1)
Atrial Fibrillation	24.7 (18.4 – 30.9)
Hip Fracture	22.8 (6.2 – 39.5)
Alcohol Dependence	10.5 (6.8 – 14.6)

N Engl J Med 2003; 348:2635-45

THE LIST OF LABORATORY MEDICINE INTERPRETIVE ROUNDS AT THE MGH – MINIMAL TURF ISSUES HAVE OCCURRED

Currently active-

Coagulation

Autoimmune disease

Hemoglobinopathy/Anemia

Transfusion reactions &

Complex transfusion cases

Serum protein analysis

HIV

Hepatitis

To be reactivated-

Toxicology

Needed but not created-

Endocrinology

Needed and being created-

Cardiovascular risk

Not all lab test results need an interpretation –

Which tests or panels of tests provide clinically valuable information?

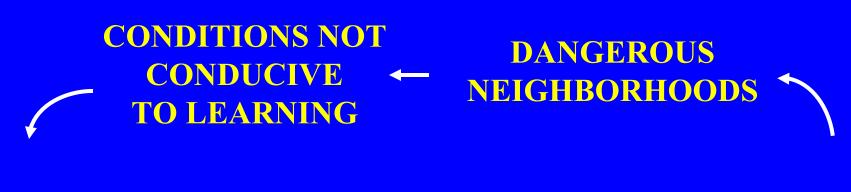
How much diagnostic complexity should be present so that an interpretation provides information not known to the ordering physician?

Who suffers without a laboratory medicine consult service that addresses correct test selection and result interpretation? Not the pathologists.

The patient, of course, whose care is subject to the variable knowledge of non-experts in laboratory medicine.

And the primary care doctor who wants to deliver optimum care in a healthcare system that discourages input from pathologists in test selection and result interpretation.

THE VICIOUS CYCLE: AMERICAN SOCIETY



LACK OF EDUCATION

INCREASE IN CRIME



ABSENCE OF SKILLS

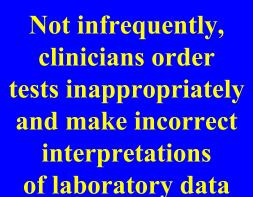
NO GAINFUL
EMPLOYMENT



THE VICIOUS CYCLE: LABORATORY MEDICINE FOR THE PAST 30 YEARS

Clinicians perceive need for advice on selection and interpretation of laboratory tests, but no expertise in pathology department available

Less than optional quality of care and increased cost to manage patient



received by pathologists on laboratory test use and interpretation

No consults

No support for pathologists to teach appropriate laboratory test selection and interpretation to residents

No competency among residents to meet need for 24 hr/7 day consult service



A big problem is that those pathologists interested in optimizing care and minimizing errors in the clinical laboratory are addressing the issues within the walls of the laboratory. This approach misses the major source of error — the improper selection of tests and incorrect interpretation of test results—

High frequency errors which occur outside the laboratory.

Has the right test Error between result been ordered? receipt and action? Action **Interpretation Ordering Collection** Reporting **Analysis Identification** Transportation \rightarrow Preparation The nine steps in the performance of any laboratory test. The brain-to-brain turnaround time loop.

Lundberg, 1981

Are serious errors really being missed – ones that might be prevented if the complex lab results are not automatically interpreted by a knowledgeable pathologist -

without requiring a call from the ordering physician?

ERRORS AS A RESULT OF INCORRECT TEST SELECTION OR MISINTERPRETATION OF TEST RESULTS

Bleeding disorders missed in children whose fathers were accused of child abuse – 2 cases Misinterpretation of results by an obstetrician that led to termination of a pregnancy with a normal fetus Failure to identify a factor deficiency prior to neurosurgery that led to major neurologic deficiencies Misidentification of a lupus anticoagulant as a factor VIII inhibitor and treatment with factor VIII concentrate Inadequate anticoagulation with heparin because of the presence of a lupus inhibitor that elevated the PTT value prior to anticoagulation AND MANY, MANY MORE....

Increased cost of care from lab tests & technologist labor

Delay in time to diagnosis with increased length of stay for inpatients

INCORRECT LABORATORY TESTS ORDERED OR MISINTERPRETATION OF TEST RESULTS

Physician time lost in assessment of incorrect tests

Clinical consequences and emotional distress from unnecessary procedure or misdiagnosis

Changes in the Scope of Care Provided by Primary Care Physicians

Physicians' Assessments of the Appropriateness of Primary Care Physicians' Scope of Care

Scope of Care	Primary Care Physicians (N=7015)	Specialists (N=5092)
Greater than it	24 + 0.8	38 + 0.8

N. Engl. J. Med, Dec. 23, 1999

I have a case of a 25 year old woman who is interested in oral contraceptive use. I will only recommend them if I know that she does not have a risk factor for thrombosis —

Can you tell me which tests I should order to assess hypercoagulability in this case?

Platelet Specific PLA-1 Antigen (526)
Platelet Factor 4 (504)
Protein C
Activity (035) Antigen (036)
Antigen/F VII Ratio (067)
Protein C Inhibitor (PAI-3)* (717)
Protein S
Activity (088)
Antigen Total (038) Antigen Free (087)
Antigen/F VII Ratio (059)
Protein C and S
Activity (149) Antigen (142)
Antigen/F VII Ratio (032)
Activity and Antigen (204)
Proconvertin Prothrombin Assay (084)
Prothrombin Consumption (PF3) (503)
Prothrombin Fragment 1+2 (718)
Prothrombin Time (080)
Prothrombin Time Mixing Study (116)
Reptilase Time (610)
Stypven Time (611)
Thrombin Time (807)
Thrombin Time Mixing Study (813)
Thrombin-ATIII Complex (714)
Thrombus Precusor Protein* (209)
Ussue Factor Pathway Inhibitor An 1/147
Ussue Plasminogen Act Antigen (125)
Tissue Thromboplastin Inhibition (804)
von Willebrand Factor
Activity (114) Antigen (113)
Multimers (117)

F VIII Human (Bethesda) (701)
☐ F VIII Porcine Screen (703)
FIX (Bethesda) (704)
☐ Fibrin Monomer (202)
Fibrinogen
☐ Activity (200) ☐ Antigen (199)
Fibrin(ogen) Degradation Products (201)
☐ Fibrinopeptide A (086)
Fletcher Factor
Prekallikrein Assay (121)
☐ Prekallikrein Screen (120)
Heparin Adsorption of Plasma (135)
Heparin Anti-Xa Assay
☐ Unfractionated (600)
☐ LMWH (602)
Heparin Cofactor II* (133)
Heparin-Induced Antibody
Antibody* (522) Antibody Titer* (528)
☐ Heparin Solution Quantitation (139)
Hexagonal Phospholipid Neut. (144)
High Mol Wt Kininogen Assay (123)
Homocysteine (Serum) (727)
Homocysteine (Urine) (729) Kaolin Clotting Time (056)
☐ Kaolin Clotting Time (056)
Lipoprotein(a)* (715)
Plasminogen Activator Inhibitor-1 (126)
Plasminogen Activator Inhibitor-2* (140)
☐ PIVKA-II* (726)
Plasminogen
Activity (400) Antigen (408)
Platelet Neutralization Procedure (805)
Platelet Antibody
☐ Direct (523)
☐ Screen (520) ☐ Platelet Specific (524)

Activated Protein C Resistance (716)
alpha-2-Antiplasmin Assay (039)
Anticardiolipin Antibody
☐ IgG, IgM (034) ☐ IgA (164)
Antiphosphatidylserine (153)
Antithrombin
Activity Plasma (030)
Antigen Plasma (033)
Activity Serum (031)
☐ APTT (040)
APTT Mixing Study (806)
U beta-Thromboglobulin (085)
C4b Binding Protein* (160)
Cryofibrinogen (203)
D-Dimer
Quantitative (405)
Semiquantitative (404)
☐ Dilute Russell's Viper Venom Test (057)
☐ Euglobulin Lysis Time (401)
Factor Activities
☐ F II (100)
☐ FV(101) ☐ FX(105)
☐ F VII (102) ☐ F XI (106)
☐ F VII (102) ☐ F XI (106) ☐ F VIIa* (activated Factor VII) (111)
☐ F VIII (103) ☐ F XII (107)
\Box FIX (104) \Box FXIII* (108)
Factor Antigens
☐ F VII* (112) ☐ F IX (205)
□ FX* (206)
Factor V Mutation (Leiden) (719)
Factor VIII Concentrate Quantitation (058)
ractor inactivators
Inhibitor/Inactivator Screen (700)
☐ F V (Bethesda) (706)
F VIII Porcine (Bethesda) (702)

SPECIAL COAGULATION LABORATORY

One check mark in the correct box and all the correct tests are performed on the same blood sample

MASSACHUSETTS GENERAL HOSPITAL 55 Fruit Street, Boston, MA 02114 Please check one: INPATIENT	Date Req Area PATIENT IDENTIFICATION REQUIREMENTS:
SPECIAL COAGULATION OUTPATIENT LABORATORY REQUISITION RESEARCH	FULL NAME, MEDICAL RECORDS NUMBER, GENDER, DATE OF BIRTH
Date Collected: Time Collected: Phleb: Completed by:	
ORDERING PROVIDER NAME: MGH PROVIDER NUMBER	P_
Specimen Type: CODE/DX REQUIRED FOR OUTPATIEN	ит
Special Billing #: (Peoplesoft # starting with "9")	
Check all that apply. b = 4.5ml Blue on ice r = 3ml red 3b 1r Prolonged PT/PTT Panel or Mixing Studies* (See Back)	
2b 1r Antiphospholipid Antibody Panel (See Back) 2b Lupus Anticoagulant*	Attention: All services ordered for the patient must meet the definition of medical necessity (i.e., required to diagnose or treat an illness or injury). Documentation must be sufficient to demonstrate same.
1r Anticardiolipin Antibody	REFER TO BACK FOR PARTIAL DIAGNOSIS LIST
3b 1r Hypercoagulation Panel* (See Back) (Check here if on Coumadin]	 Platelet Aggregation Studies must be scheduled in advance at 726-3900 (No Ice) (Patient must not have take
1b Thrombin Time* Reptilase Time	aspirin within 8 days of test)
3b von Willebrand Panel (See Back)	Patient Information
2b Factor Assay* (Specify Factors)	Current Anticoagulants: Coumadin Heparin Loveno
1b Heparin-induced thrombocytopenia (HIT) assay	☐ Fragmin ☐ Hirudin
1b Anti-Xa Assay (Must circle one Anticoagulant to specify:	☐ Argatroban ☐ Fondaparinux
Fragmin, Lovenox, Heparin, Fondaparinux or	None Other
1b Chromogenic Factor X (Must be on Coumadin)	Thrombosis
Other (please list)	Bleeding Past Current None
	* Hirudin or Argatroban interfere 70130 (1

Are there potential solutions to the problem of incorrect ordering of tests and misinterpretation of test results from the clinical laboratory?

If yes, have they been proven to work in a clinical setting?

STRATEGY #1

Use reflex testing as much as possible to increase appropriateness of test selection



1 Check in Box for Prolonged PTT Panel Initiates Use of This Test Selection Algorithm

Prolonged PTT Evaluation

Degrade heparin in sample and repeat PTT - if the PTT normalizes, heparin is the cause

PTT mixing study (1:1 mix of patient:normal plasma)

PTT Normalizes

Factor deficiencymeasure factors VIII, IX, XI, and XII PTT remains prolonged

Inhibitor, most commonly Lupus anticoagulant; may be a Factor VIII inhibitor if PTT mixing study first normalizes and then becomes prolonged

Perform tests for specific inhibitors suggested by results of PTT mixing study

IN THE ABSENCE OF REFLEX TESTING

To minimize the number of lab tests-

Example: Patient with a prolonged PTT of 65 seconds

Assumption: Physician orders all tests relevant to the most likely diagnostic possibilities

IN THE ABSENCE OF REFLEX TESTING

 $\overline{\text{VISIT 1: PTT}} = 65 \text{ seconds}$

VISIT 2: New sample collected for PTT mixing study

Result: Corrects into normal range

VISIT 3: New sample collected for Factor VIII, IX, XI, XII assays

RESULT: Factor XI low at 3% of normal; factors VIII, IX, and XII normal

DIAGNOSIS: Factor XI Deficiency

Visits: 3 # Tests Performed: 6

IN THE ABSENCE OF REFLEX TESTING

To minimize the number of patient visits-

Example: Patient with a prolonged PTT of 65 seconds

Assumption: Physician orders all tests relevant to the most likely diagnostic possibilities

IN THE ABSENCE OF REFLEX TESTING

TESTS TO MAKE DIAGNOSIS:

PTT mixing study, assays for factors VIII, IX, XII, XII, lupus anticoagulant screening assay and confirmatory assay, Bethesda Unit assay for factor VIII inhibitor

DIAGNOSTIC POSSIBILITY 1: Factor deficiency

DIAGNOSTIC POSSIBILITY 2: Lupus anticoagulant

IN THE ABSENCE OF REFLEX TESTING

DIAGNOSTIC POSSIBILITY 3:

A potentially lethal bleeding disorderfactor VIII inhibitor

Bethesda unit assay for quantitation of a factor VIII inhibitor is highly complex!

Visits: 1

Tests Performed: 9, with most tests not necessary to establish diagnosis

Test ordered on Requisition	Initial Test Performed	Criteria for Reflex	Test Ordered by Reflex
Lupus anticoagulant	Screen	Positive Screen	Lupus anticoagulant confirmation; anticardiolipin antibody added if red top received even if lupus anticoagulant is negative
Protein C	Protein C functional	<70% activity	Antigenic Protein C
Antithrombin III	Functional antithrombin III	<70% activity	Antigenic antithrombin III
Protein S	Functional Protein S	<70% activity	Free Protein S antigen, fibrinogen and functional FVIII activity
Activated protein C resistance or Factor V Leiden	Activated protein C resistance	≤2.1	Factor V Leiden by DNA assay
Prolonged PT Evaluation (mixing studies)	PT, removal of heparin if PTT also prolonged, mixing study	Mixing study normal, prolonged, or "fades"	Factor assays, lupus anticoagulant, and/or factor inhibitor tests if indicated
Prolonged PTT Evaluation (mixing studies)	PTT, removal of heparin, mixing study	Mixing study normal, prolonged, or "fades"	Factor assays if mix is normal; lupus anticoagulant if mix is prolonged, factor VIII if mix "fades"; all three tests if mix results inconclusive; factor inhibitor tests if indicated
Multiple individual hypercoagulation tests	As ordered	Patient not on coumadin or other reason for not performing tests	If missing a test from the usual screen (activated protein C resistance, protein C, protein S, antithrombin), it will be included
Reptilase time	Reptilase time	> 24 seconds	Fibrinogen Degradation Products (or D Dimer), Fibrinogen

The MGH clinical laboratory currently uses about 100 reflex test algorithms in all areas of laboratory medicine —

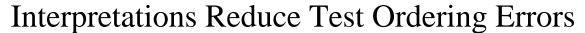
Most are locally generated and once approved by the MGH medical policy committee are rapidly implemented.

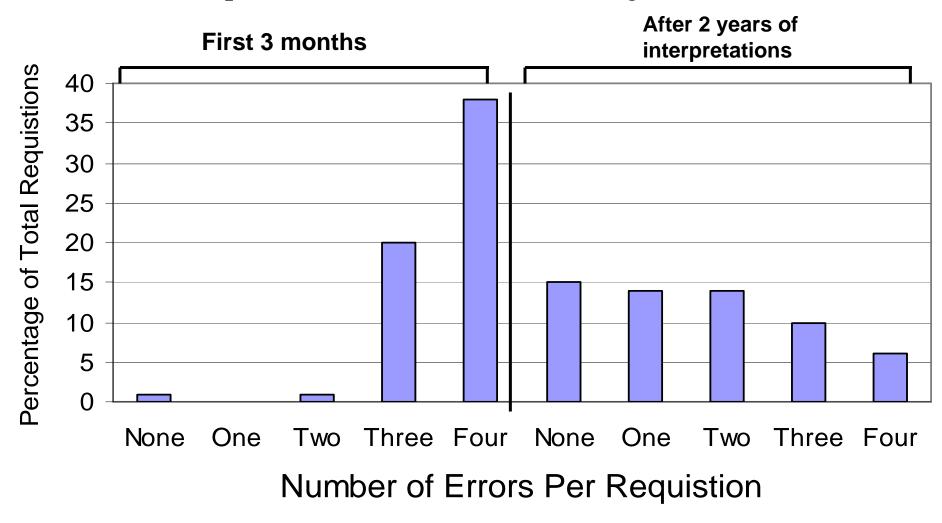
Every proposed algorithm has been approved by the committee and new ones are presented each year

MGH experience with detectable errors in test selection by clinicians

Test selection errors by commercial laboratory clients for hypercoagulable states

The clients were not given the opportunity for reflex testing and forced to select individual tests from a large test menu



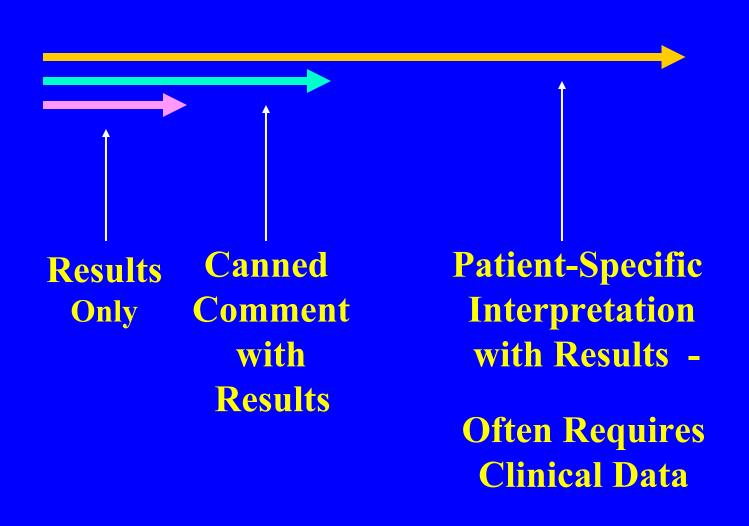


Arch. Pathol. Lab. Med. 2004. 128:1424-1427

STRATEGY #2

Provide patient-specific narrative interpretations of the test results, as done in Anatomic Pathology and Radiology, for complex evaluations in many areas of Laboratory Medicine, obtaining clinical information when necessary to enhance the speed and accuracy of the interpretation.

LABORATORY MEDICINE INTERPRETATIONS: LEVELS OF DIAGNOSTIC INFORMATION



Many pathologists and many clinical laboratories claim that they do interpretations BUT IN ALL CASES I HAVE SEEN

- -The interpretation is a canned comment if provided systematically OR
- -The interpretations are only done if the pathologist is called with a question and this is at best a very small percentage of the questions in the head of the ordering physician regarding test selection and result interpretation OR
- -The interpretations are not done regularly as would be expected with frozen sections in AP

RESIDENT'S MEDICAL INFORMATION NEEDS IN CLINIC: ARE THEY BEING MET?

Am J Med. 2000; 109:218-223.

"In this study, our objective was to determine the frequency, characteristics, and pursuit of residents' medical information needs in clinic by interviewing them immediately after each patient encounter."

ASSOCIATIONS BETWEEN A RESIDENT'S PERCEPTIONS OF A CLINICAL QUESTION AND THE LIKELIHOOD THAT THE ANSWER WAS PURSUED

Number of Questions Pursued/ Number of Questions (Percent)

I am uneasy about 29/96 (30)

this problem

Perception

I must obtain the 22/65 (34)

answer urgently

The answer would 58/192 (30)

change management

Without the answer, my 33/93 (36)

patient could be harmed

ASSOCIATIONS BETWEEN A RESIDENT'S PERCEPTIONS OF A CLINICAL QUESTION AND THE LIKELIHOOD THAT THE ANSWER WAS PURSUED

Perception

Number of Questions Pursued/ Number of Questions (Percent)

The answer will help 76/262 (29)

me manage other patients

The answer will benefit my 79/270 (29)

general knowledge

This problem involves 32/76 (42)

malpractice risk

My patient expects to know 52/136 (38)

the answer

The answer definitely exists 57/196 (29)

INNOVATIVE USE OF TECHNOLOGY HELPS CLINICIANS USE BEST PRACTICES

"There are an estimated 20,000 medical journals offering updates on various medical specialties.

Partly because of the overload of information, most physicians rely on what was current during their own education for what they do."

Christakis et al. Pediatrics, 107, E15, 2001

Guessing at the correct answer is far more common than seeking a consultation from an expert –

And guesses are made for the most serious of clinical decisions and the patient is usually unaware that the physician is guessing.

The income from performance of interpretations of results from the clinical laboratory –

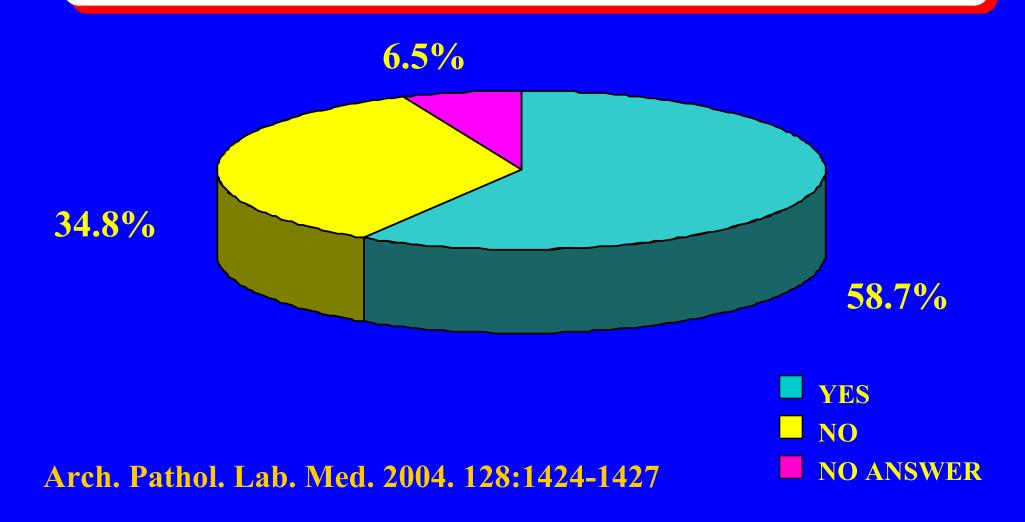
including the microscopic interpretations that fall within the clinical laboratories like peripheral blood smears and gram stains

 is not great enough to drive the majority of pathologists into this activity. 1996 Survey of MGH physician experience with narrative interpretations of complex laboratory evaluations in coagulation

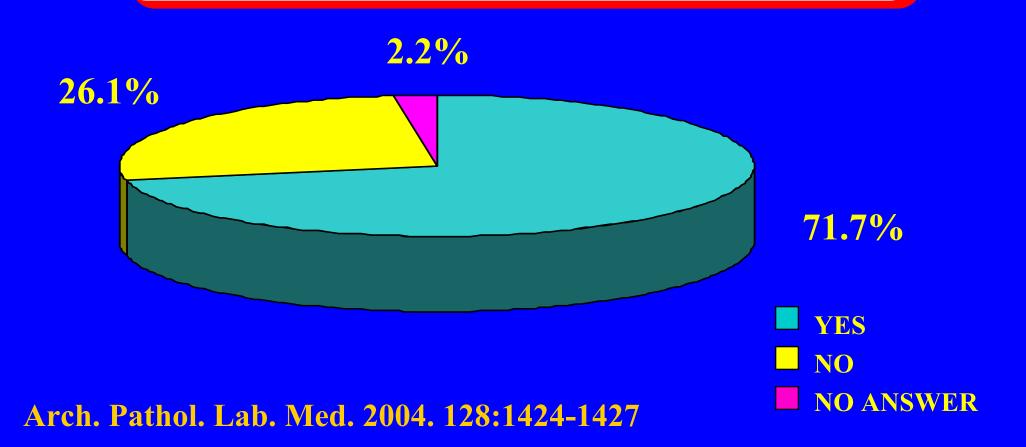
Ordering physicians sent a narrative interpretation of one their own cases Clinicians asked to respond to several questions about the interpretation

46 Of 100 surveys returned

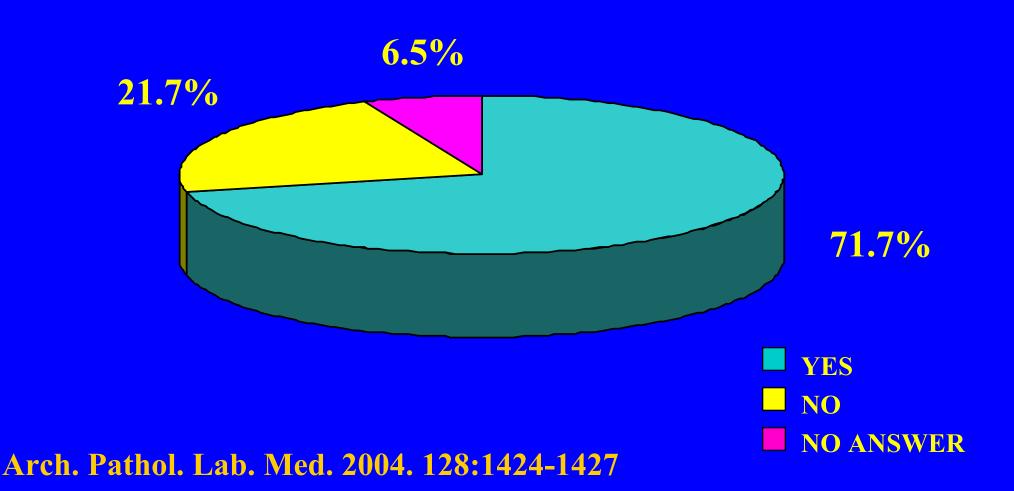
THIS INTERPRETATION SHORTENED THE TIME TO A DIAGNOSIS?



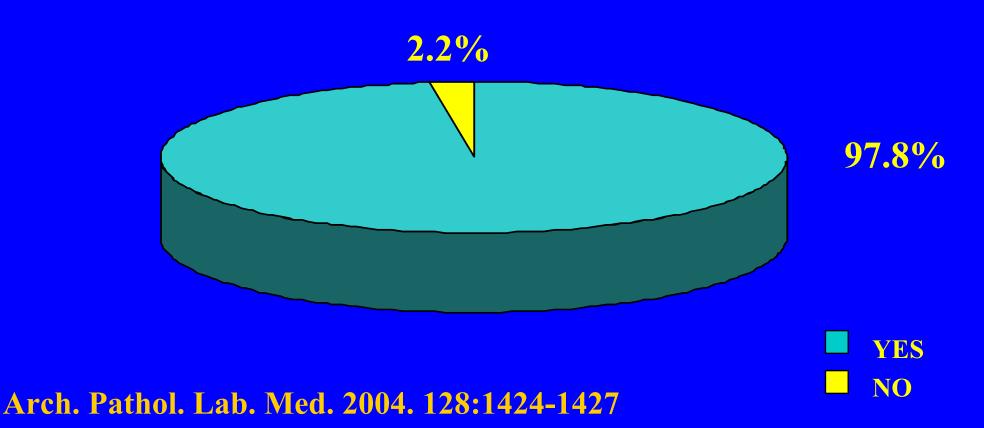
THIS INTERPRETATION PROBABLY REDUCED THE NUMBER OF LABORATORY TESTS REQUIRED TO MAKE A DIAGNOSIS?



THIS INTERPRETATION HELPED AVOID A MISDIAGNOSIS?



DO YOU FIND THESE INTERPRETATIONS USEFUL OR INFORMATIVE?



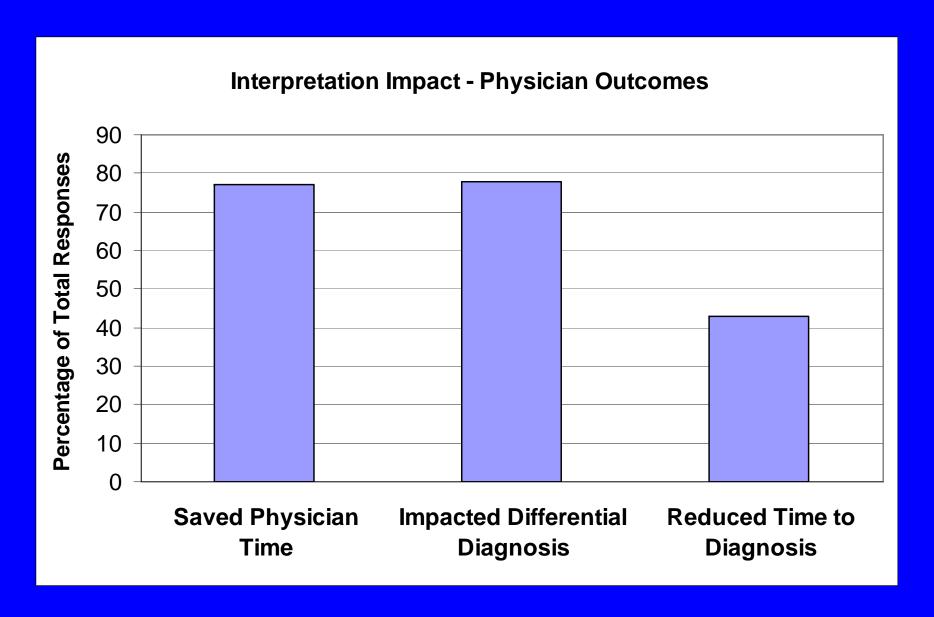
2000 Survey of MGH physician experience with narrative interpretations of complex laboratory evaluations in coagulation

Ordering physicians electronically sent a narrative interpretation of one their own cases

Clinicians asked to respond electronically to several questions about the interpretation

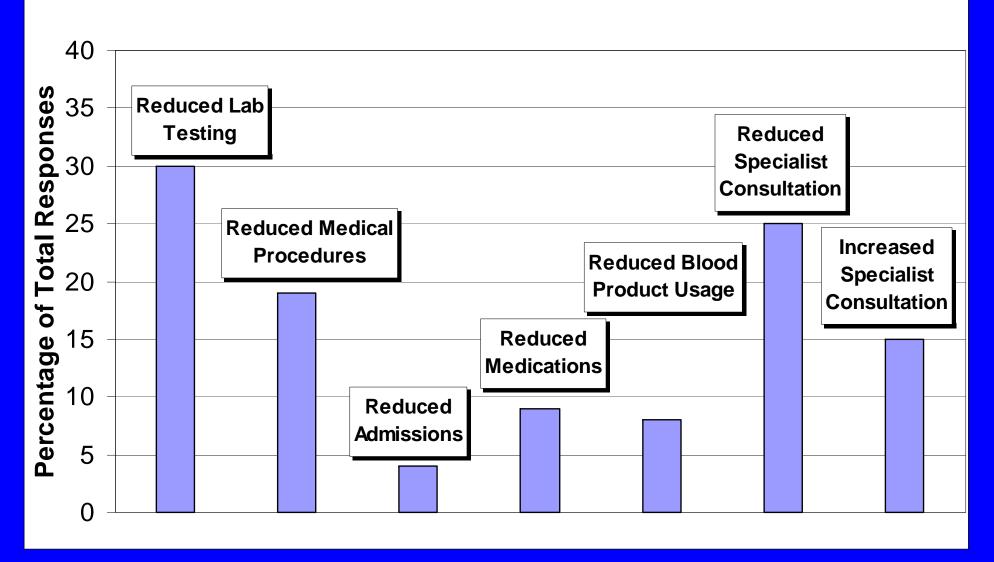
100 of 100 surveys returned

Arch. Pathol. Lab. Med. 2004. 128:1424-1427



Arch. Pathol. Lab. Med. 2004. 128:1424-1427

Interpretation Impact Medical Utilization

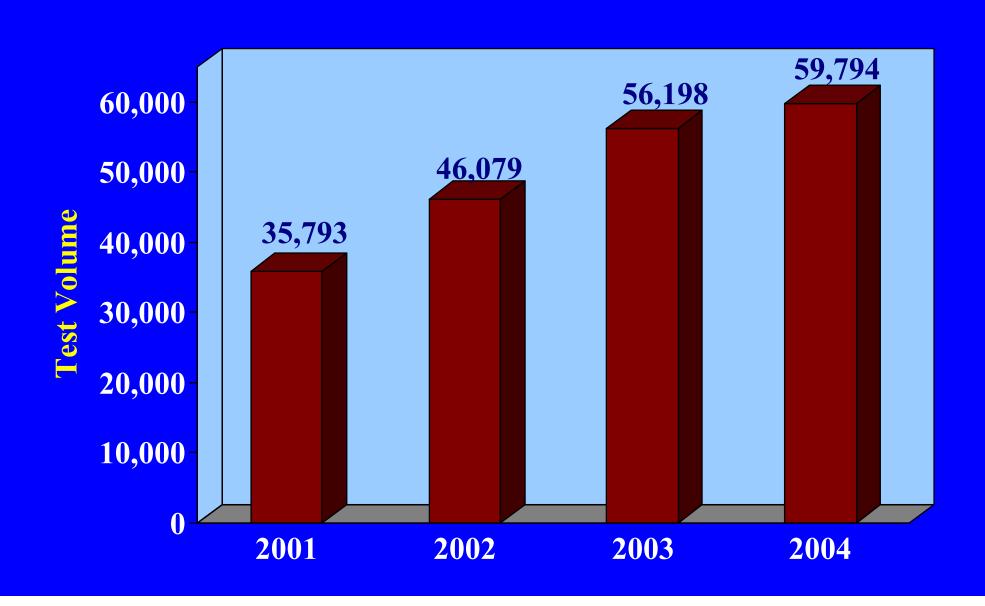


Arch. Pathol. Lab. Med. 2004. 128:1424-1427

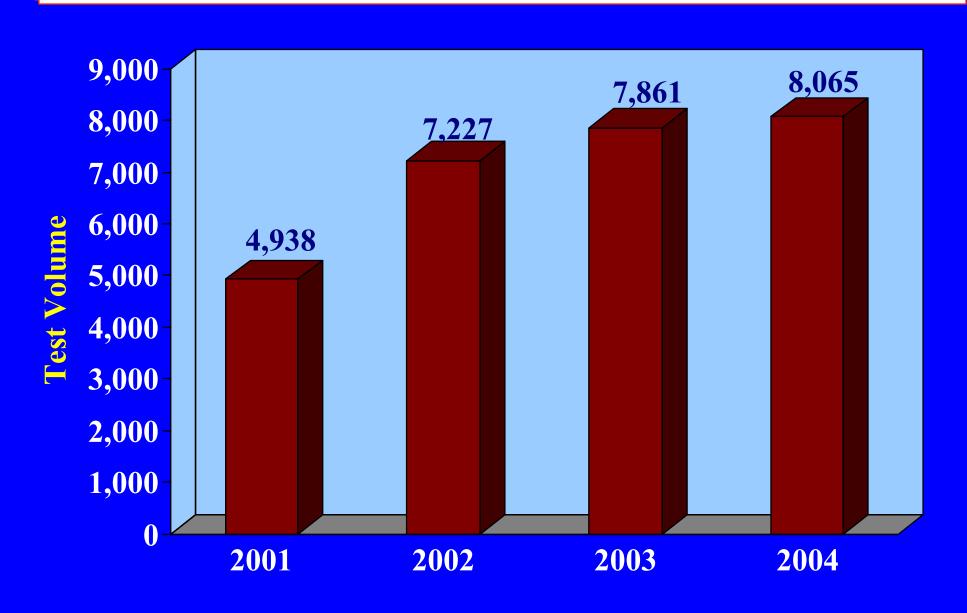
So with this kind of evidence of improved clinical outcome and wide support from clinicians ordering tests in an actual clinical setting, is the provision of systematically provided, patient specific, expert driven

interpretations increasing the test volume and thereby increasing the number of promptly and accurately diagnosed cases?

TOTAL SPECIAL COAGULATION TESTS AT MGH



PATIENT-SPECIFIC INTERPRETATIONS OF COMPLEX COAGULATION EVALATIONS AT MGH



The ramp up for this service is slow – in our institution we did 9 cases the first week the interpretation service was implemented and the entire first year showed similar activity –

Some might perceive low case volume initially as a reason to not initiate or discontinue the service if it is implemented.

A service never implemented never becomes valued

Pathologists hear mostly about overuse of tests, which are primarily the routine tests ordered daily, without consideration of their true value —

This is different from a series of focused tests that shorten the time to diagnosis and improve the accuracy of diagnosis — thereby saving money and improving clinical outcome.

REQUEST FOR IMPLEMENTATION OF PROGRAM TO REDUCE LABORATORY ERRORS

From General Clinicians

- 1. Make the service available and easy to use
- 2. Request for subspecialist cooperation
- 3. Quality and efficiency are driving forces

BARRIERS TO IMPLEMENTATION OF PROGRAM TO REDUCE LABORATORY ERRORS

From Pathologists

- 1. Lack of expertise by pathologists
- 2. Fear of subspecialist response
- 3. No expectation of payment
- 4. Complacency with canned comments
- 5. Lack of interest by academic pathologists

PATHOLOGIST MEAN NUMBER OF HOURS WORKED PER WEEK IN CLINICAL PATHOLOGY AND ADMINISTRATION SERVICES, BY REPORTING YEAR

	Mean Hours				
Type of Service	2004	2002	<u>2000</u>	<u>1998</u>	<u>1996</u>
Clinical Pathology services for which a separate bill is issued	2.9	2.7	2.6	2.6	4.1
Clinical pathology services for which no separate bill is issued	7.7	7.8	7.4	8.7	8.5
Total hours per week in clinical pathology services	10.6	10.5	10.0	11.3	12.6
Total hours worked per week	49.4	48.7	48.2	48.0	48.5

2004 CAP Practice Characteristics Survey Report

CHANGE IN AMOUNT OF CLINICAL PATHOLOGY-RELATED SERVICES COMPARED TO TWO YEARS AGO, BY REPORTING YEAR

	Percentage of Pathologists								
Amount of Clinical Pathology Services									
Compared to Two Years Ago		2004	2002	2000	1998	1996	1994		
More		24	28	21	25	23	25		
Same		55	48	54	49	53	56		
Less		10	13	16	16	17	10		
Did not perform clinical path two years ago and still don't		11	10	8	10	6	8		
No Answer		*	1	1	*	1	1		
Total		100	100	100	100	100	100		
*Less than 1%									

2004 CAP Practice Characteristics Survey Report

The current CAP practice data indicate that the vast majority of pathologists do little clinical pathology and many of those that do don't bill professionally for it – possibly because the activity is lab management and not clinical consultation.

Most pathologists think they are doing more CP every year, but really aren't by their own data on practice time distribution AP vs. CP.

People tend to overestimate the time spent on activities that they do not like.

WHAT CAN BE DONE NOW – WITH A NATIONAL SHORTAGE OF EXPERT PATHOLOGISTS IN LABORATORY MEDICINE?

Create a national group of experts in the areas of Laboratory Medicine to provide the narrative interpretations (A "Supreme Court") and link the experts to the physicians requesting advice and their pathologists through a web-based Internet service

A National Lab Medicine Consultative Service?



- •Requests interpretation
- •Views completed interpretation

- Assembles case
- Presents case to pathologist
- Manages case flow

•Creates interpretation

Software is commercially available to expedite the generation of narrative reports BY

- -Linking the interpreting pathologist to other experts
 - -Assisting the interpreter in arriving at the correct clinical conclusions.

LABORATORY MEDICINE ACTIVITIES: THE ROAD TO INDISPENSIBILITY

Program in Lab Medicine

Teaching Answer Questions on Laboratory Related Issues

Provide Interpretive Service for Complex Test Batteries Independent of Requests from Clinicians

Necessary to pass board examinations

Necessary to gain visibility in patient care

Necessary to gain indispensability in patient care

Where do the path and lab societies stand?

-CAP has taken no leadership role in advancing this activity for pathologists -AACC is not actively interested, presumably because PhD laboratory scientists cannot be paid for interpretations -ASCP is not closely connected with issues of daily pathologist practice -Some state societies of pathology are interested but appear more focused on the revenue from interpretations than the lack of **CP** knowledge of pathologists

Is this problem a topic of active discussion by any of the agencies that are concerned with the quality of clinical care –

particularly the Institute for Quality in Laboratory Medicine?

Medical error from incorrect laboratory test selection and result interpretation is rapidly becoming a more serious problem as the test menu becomes larger and more complex-particularly with the growth of molecular diagnostics.

Will the Services Desired by Clinicians Ever be Provided?

Institute for Quality in Laboratory Medicine?

7

Patient specific,
proven value added
narrative
interpretations by
expert clinical
pathologists
at the
Massachusetts
General Hospital

Growth of programs outside MGH by MGH trained pathologists

Medical error reduction becomes associated with financial benefits