Appropriate Utilization of Laboratory
Tests Through a Diagnostic
Management Team:
Clinical and Financial Benefits

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The Activity of a Diagnostic Management Team:

To Make Certain
Everyone Knows the
Basics From the Start

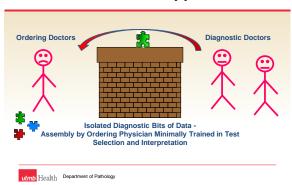


Instead of "throwing test results over the wall to treating physicians"

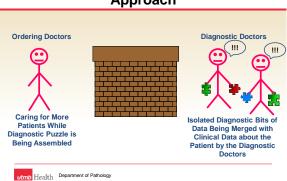
The DMT puts together the diagnostic puzzle and generates a diagnosis or short list of diagnostic options and provides the information to the treating healthcare provider.



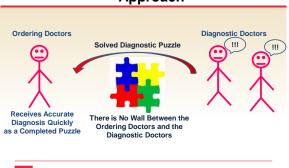
Conventional Approach



Diagnostic Management Team Approach



Diagnostic Management Team Approach



Instead of providing information that is a set of numbers, difficult to understand abbreviations of test names, or simple "positive" or "negative" answers, an understandable narrative report is delivered.

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Data Presentation in the
Medical Record for
Coagulation Studies Prior to
Initiation of the
Patient-specific, Expert-driven
Coagulation Interpretation

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June 30, 2010

Pat-PT: 13.9 PT-inr: 1.1 PTT-pt:

43.6* PooINP: 28.1 P+N0Hr:

38.3 P+N1Hr: 36.2 P+N2Hr:

35.9 Pat-TT: 15 F8Act:

95 F9Act: 102 RVVT:

1.5* DRVVT: Lupus

Anticoagulant Confirmed DMX:

1.3 F11Act: 96 F12Act: 54

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Report in the Medical
Record After Initiation of the
Daily Rounds to Interpret All
Complex Evaluations from
the Special Coagulation
Laboratory

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July 1, 2010

This patient has an elevated PTT, with a normal PT/INR and normal thrombin time.

A PTT mixing study failed to correct into the normal range. These results were consistent with the presence of an inhibitor (such as a lupus anticoagulant) in the sample.

The Dilute Russell Viper Venom time (dRVVT) is used for detection of Lupus Anticoagulant, and the test was positive, indicating the presence of Lupus Anticoagulant.

Taken together, this is a patient with a prolonged PTT based upon the presence of a lupus anticoagulant. There is no increased bleeding risk in this patient, despite the prolonged PTT.

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Official Definition: Diagnostic Management Team (DMT)

Unless <u>all</u> four of the following are met, a group cannot be designated as a DMT

- Team must meet frequently and regularly and provide patient specific reports with no request required to provide an interpretation
- 2. Report must be delivered before or during the time when treatment decisions are made

Official Definition: Diagnostic Management Team (DMT)

- 3. Report must consider the clinical context in which the diagnostic tests are ordered, and attempt to synthesize all relevant diagnostic test results
- 4. Report must be entered into the patient's medical record

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Thousands of departments have clinical service lines

Outside of traditional anatomic pathology and radiology

That meet two or three of these criteria.

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It is a Diagnostic Management Team Activity of Just a Case Conference?

A True DMT

All Current Cases
Discussed & Have a
Narrative Interpretation
Generated & Entered in
Patient's Record

All Cases Discussed with Charted Narratives & Optimized Test Selection with Continuous Enhancement

All Cases Discussed with Narratives in Chart and Optimized Test Selection in Place

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Besides providing a patient-specific, expert-driven narrative of a complex clinical evaluation, what else does a DMT accomplish?

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The Diagnostic Management Team Greatly Optimizes Lab Test Utilization

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Questions to be Addressed:

- How does the DMT impact overutilization and underutilization of laboratory results?
- Is a group of experts valuable to physicians who have little current expertise in test selection?

Questions to be Addressed:

- Is overutilization or is underutilization of laboratory tests more costly considering the total patient encounter?
- How is the cost of overutilization assessed and is that accurate?
- How is the cost of underutilization assessed and how precise can this assessment be?

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Diagnostic Management Team Activities Optimizing Lab Selection

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Take Clinical Context and Diagnostic Goals



Obtain the Correct Diagnosis Rapidly And

Using All the Necessary Tests to Reduce Underutilization and No Unnecessary Tests to Reduce Overutilization

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Survey Response Concerns of Ordering Physicians on Clinical Laboratory Issues

Concerned about overtesting patients

42.6%

Concerned about undertesting patients

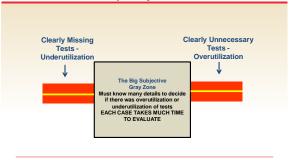
18.7%

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The determination whether overutilization or underutilization of laboratory tests has occurred is (for the most part) made as a general conclusion by individuals who are perceived, or perceive themselves to be, EXPERTS.

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Can You Decide About Appropriateness of Utilization (Over <u>or</u> Under) if You Are Not an Expert in the Specialty for a Case?



Even Among Experts, Controversy Exists Regarding Test Utilization for the Questions:

Is Factor XII testing necessary?

How many lupus anticoagulant tests should be performed?

Are both Anticardiolipin and Anti-Beta 2 Glycoprotein I tests redundant?

Should Factor XI testing only be performed for patients of Ashkenazi Jewish descent?

And at least 10 more ...

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It is difficult, especially for non-experts, to decide if overutilization or underutilization has occurred

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To obtain the most meaningful decisions on whether over or underutilization has occurred, experts must make a conclusion in clinical context and real time for individual cases



Initial Analysis by Experts in Real Time Regarding Test Utilization in Coagulation

Total Patient Cases	200 cases	
Analyzed		
Diagnostic errors	155	
No errors	45	

Frequency of Diagnostic Errors



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Courtesy of Mayukh K. Sarkar, Ph.D., MSL(ASCP)^{CM}

Comparison with Studies on Overutilization vs. Underutilization

	Sarkar et al	Zhi M et al, (2013)	McGlynn et al, (2003)
Overutilization	16%	20.6%	Did Not Measure
Underutilization	44%	44.8%	45.1%

Only 55% of the patients received appropriate quality care because of underutilization of diagnostic tests

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Courtesy of Mayukh K. Sarkar, Ph.D., MSL(ASCP)CM

The Cost of Overutilzation

Routine Tests

Eliminate 25% of Complete Blood Tests

If this equals 25k tests per year
If the total cost to the lab is \$10 per test

This \$250k per year so For a lab budget of \$25M

This is a savings of 1% of the laboratory budget



Expensive Send-out Tests

Eliminate 10% of genetic tests, which have a rapidly growing number of indications

If this equals 500 tests per year
If the charge to the Laboratory/Institution
is \$5k per test

This is \$2.5M per year So, for a lab budget of \$25M, This is a savings of 10%

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Therefore, the send-out budget is a better financial target, but the arguments against excess routine testing are strongly evidence-based



At the same time, "the diagnostic odyssey" of exome analysis for patients, especially neonates, is being increasingly shown to reduce mortality

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If this grows, does the lab budget goes way up while the total cost of care goes down? Five years ago, who would have thought a total exome sequence to evaluate a floppy baby made any sense?

It is now almost a standard of care.

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What was once considered overutilization may become a problem of underutilization

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Underutilization:

Failure to order tests to establish diagnosis

This counts as a diagnostic error:

<u>Delayed</u> or Missed Diagnosis

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Why the Cost of Underutilization is Large and Unknown

What is underutilized?

Clinical History

Inadequate questioning of patient (saves ten minutes of encounter time: \$100-250)

> <u>Lab Tests</u> No D-Dimer Ordered (saves \$25-50)

Imaging Study
No compression ultrasound
(saves \$250-500)

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Patient History:

Right leg slightly swollen

with a history of deep vein thrombosis: Remains

undiagnosed

The immediate effect is a savings of \$375 to \$800

But what are the costs?

Impossible to know but possible to estimate.

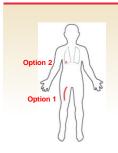
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What are the Possible Outcomes in Care and Cost for this Scenario?

Deep vein thrombosis accounts for leg swelling. Patients mainly 20 years of age and older

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Options 1 and 2



Option 1:

- Clot stays in leg
- Active fibrinolysis and clot dissolves on its own
- Cost: < \$2000

Option 2:

- · Small embolism-asymptomatic
- Cost: < \$2000

Options 3 and 4

Option 3:

- · DVT enlarges inducing permanent post-phlebitic syndrome
- Cost: \$100k to 150k/yr for up to 2-3 years and \$20-50k for decades

Option 4:

- · Symptomatic pulmonary embolism: Major lung infarction
- Cost: \$100k to 200k/yr for 2-3 years, and \$20-50k for decades



Options 5 and 6

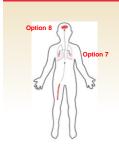
Option 5:

- · Patient has patent foramen ovale (PFO)
- DVT goes to brain instead of lungs
- Minor-to-moderate stroke
- Cost: \$100k to 200k/yr for 2-3 years and \$20-50k for decades

- Option 6:
 Patient has PFO
- · Large embolus produces major disabling stroke
- Cost: \$200-500k/yr for 2-3 years, and \$50-100k for decades

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Options 7 and 8



Option 7:

- Lethal pulmonary embolism
- One time cost: < \$2000

Option 8:

- Lethal stroke
- One time cost: < \$2000

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Approximate Financial Analysis for 500 Bed **Hospital with One DVT Complication**

Options 3, 4, and 5

182 events x \$50k/year = \$ 9,100,000

Option 6

12 events x \$500k/year = 6,000,000

\$15,100,000

If 10% of Complications are Prevented, \$1,500,000 Saved - Could Hire 6-8 Experts A \$200k/yr per DMT Expert

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This centers the target for major cost benefits

Along with the obvious clinical outcome benefits

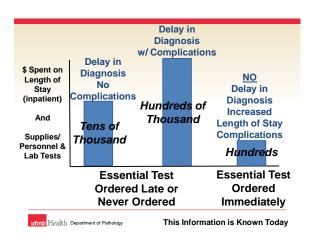
On underutilization of lab tests rather than overutilization

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Does the patient's death help the bottom line?

However,

Mortality statistics are likely to create a bad safety score that indirectly cause loss of revenue



Distribution of Options 1-8 in Different Institutions

The cost evaluation varies by institution

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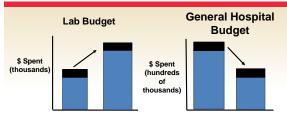
All of These Cost Far More than \$300-800 Saved Per Case by Underutilization



This Information is Known Today

Which Budget Changes When An Extra Necessary Test is Ordered to Make an Accurate Diagnosis Quickly?

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Does the Lab Director Lose Credibility Because the Lab Budget Increased?

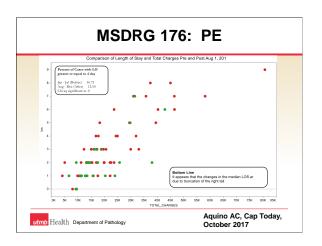
Hospital Administrators with Little Clinical Knowledge Might Say "Yes"

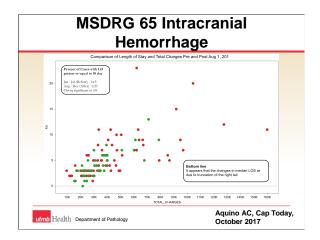
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Before and After Coagulation DMT:

What is the Impact of the Length of Stay in the Hospital for Pulmonary Embolism and Intracranial Hemorrhage?

R. Lawrence Van Horn, Ph.D, MPH, MBA
Assoc. Prof. of Economics and Management
Exec. Dir. Of Health Affairs
The Owen Graduate School of Business Administration
Director, Office of Sustainable Health Care Finance
Institute of Medicine & Public Health
School of Medicine





The Identified Obstacles to DMT Creation:

The Roadmap to Institute Improved Care at Lower Cost

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So, why has there been no emphasis, except from a limited number of motivated individuals, to create DMTs?

Especially when they are desirable to treating healthcare providers who are unfamiliar with costly and complex diagnostic tests?

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Problem #1 Not Enough Experts?

- The problem specific to the US is the inordinate financial incentive for pathologists to perform only surgical pathology and cytopathology
- Today, there are few "true" <u>pathologist</u> experts in the US in laboratory medicine knowledgeable enough to lead a DMT

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When Anatomic
Pathology Earns \$300400k, and Clinical
Pathology Earns
\$100k, Keep in Mind:

"Most pathologists enter the workforce owing at least \$140,000, and plenty owe far more. It is not uncommon for 2-physician couples to accrue more than half a million dollars in loans during their training years."

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Arch Pathol Lab Med 142:13, 2018

Because of this, there are simply not enough pathologists, even in many academic medical centers, to form DMTs

There must be at least two leaders in an individual service line to provide DMT services on a daily basis, due to vacations and travel

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Problem #1 Proposed Solution

If experts from healthcare systems, which involve many hospitals are also considered, virtually every system has enough individuals in all of the diagnostic areas to staff multiple, frequently used DMTs.

The experts may be MD/DO or non-MD.



Problem #2
Little or No Payment for DMT-directed Test
Utilization or More Rapid and Acute Diagnoses

A major problem in the US and other countries where private insurance companies determine activities which are deserving of payment, is that the provision of a patient-specific, expert-driven interpretation of laboratory tests merits an insignificant payment or no payment at all.

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Hospital leaders who do not know clinical medicine are more likely to be influenced by a revenue stream of \$100k than a saving opportunity of \$1M

Thereby

Undervaluing experts who <u>save</u> dollars by actively managing test use.



In addition, only MD pathologists, even if they are not experts in a particular field, are allowed to bill for consultative services related to the selection of tests and the interpretation of test results

While true non-MD experts are not paid.

This greatly limits the participation of non-MD true experts which can substantially contribute to the generation of a rapid and accurate diagnosis

In countries where healthcare is supported by the government, this consideration is irrelevant



Problem #2 Solution

Payment for optimized test selection and improved speed and accuracy of a diagnosis must be reimbursed, independent of the degree of the expert, incentivize experts to perform this critical task

Does this payment come from the hospitals? Insurance companies?

A fair and consistent payment mechanism must be identified.

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Problem #3 Increased Liability for Medical Care

- A major problem, particularly in the US, involves the high number of lawsuits directed at healthcare providers
- Countries in Western Europe, by and large, understand the fallibility of healthcare providers in a way that reduces the litigious climate of medical practice



Problem #3 Solution

It is a fact of life in the US:

Learn how to provide
evidence-based conclusions
and accept you will be
challenged when a patient
has a bad outcome

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Problem #4 Lack of Interest in a DMT Role by True Experts

What keeps the non-MD laboratory directors from leadership roles in DMTs?

Is there concern if these roles are avoided that such individuals will be excluded from faculty level service roles in hospitals?



Looking Ahead

What is the future for Laboratory Directors, MD and non-MD, who do not lead a DMT?

A recent report regarding the value of clinical chemistry training in pathology training programs in the US suggests that if leaders in clinical chemistry, mostly non-MD individuals, do not pursue leadership in DMTs, that their roles will be lost in medicine.

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Pathology's Stepchild Richard E. Horowitz, M.D. Sarah M. Bean, M.D.

"Clinical chemistry isn't very alluring!"

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Arch Pathol Lab Med 141:186-189, 2017 and 141:203-208, 2017

"Participating in a . . . type of diagnostic management team during training would be an excellent experience for subsequent community hospital practice."



Arch Pathol Lab Med 141:186-189, 2017 and 141:203-208, 2017 Many reasons have been offered as to why pathologists and non-MD laboratory experts do not want to create and lead DMTs.



Why Lab Leaders Do Not Start a DMT?

- 1. Not comfortable making a final diagnosis
- 2. Unwilling to accept call on nights and weekends
- 3. Worry about loss of court case as a nonexpert
- 4. Would limit my research program
- 5. Would not be compensated

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Why Lab Leaders Do Not Start a DMT?

- 6. No one to fill in when I am out of town
- 7. Need to see DMT process at least once
- 8. As a generalist, I cannot know everything asked of me
- 9. My personality is not suited to comfortable communication with treating physicians

Can Non-MD Experts Lead a DMT?

A major problem is that non-MD experts feel uncertain about their knowledge of clinical medicine.

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Can Non-MD Experts Lead a DMT?

The perception by non-MDs that MD experts have indepth knowledge into all clinical presentations and all diagnostic procedures is incorrect.

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Can Non-MD Experts Lead a DMT?

Expert level information can be learned by non-MDs in a matter of months, and then as more cases are encountered, the expertise grows.

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Problem #4 Solution

Take whatever you feel you know the best and start a DMT for that group of patients

however limited it may be

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Examples

Thyroid test abnormalities in pregnancy, instead of all thyroid disorders

Toxicology for pain management, instead of all of toxicology

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Problem #5
DMTs are Not Relevant to
Anatomic Pathology Practice

Why has there never been wide dissemination of DMTs that involve consideration of anatomic pathology findings alongside findings in radiology and genetic testing?

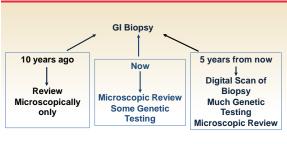
Most anatomic pathologists enjoy an income sufficient enough to discourage them from developing additional content knowledge outside of traditional anatomic pathology.

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In the US at least, there is no incentive to provide a synthetic report that includes histologic and radiologic findings, and when relevant, genetic findings.

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What is Changing Right Now in Anatomic Pathology?



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Problem #5 Solution

Use the latest technology and provide for more than recognition of an image through a microscope

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A New Role for the DMT:

The Diagnostic and Management Autopsy (DMA)



A New Kind of Autopsy for the 21st Century

Arch Pathol Lab Med 141:887-888, 2017



My good friend's husband died several days ago.

He had coronary artery disease with a thrombosed stent demonstrated by coronary angiography just 8 days before he passed away at home.

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Arch Pathol Lab Med 141:887-888, 2017

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Arch Pathol Lab Med 141:887-888, 2017

When he died, the medical examiner asked his family whether there was interest in an autopsy because her office did not require one.

His wife was pleased to avoid an autopsy.



Arch Pathol Lab Med 141:887-888, 2017

I wanted to know more about his thrombosed stent and treatments, especially as they pertain to my expertise with antiplatelet agents.



Arch Pathol Lab Med 141:887-888, 2017

I also wanted to know why it seemed he could wait up to "a couple of months" before undergoing a coronary artery bypass.



Arch Pathol Lab Med 141:887-888, 2017

In addition, did his caregivers consider pharmacogenomic studies to determine whether he was sensitive to Plavix to maintain stent patency, or was he resistant as a result of a mutation in the CYP2C19 gene affecting 15% of people receiving this medication?



Arch Pathol Lab Med 141:887-888, 2017

Finally, I wanted a small piece of liver from a postmortem biopsy, not an autopsy, to be retained for future genetic studies should we learn of new heritable syndromes associated with atherosclerosis in the future.

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Arch Pathol Lab Med 141:887-888, 2017

My questions are not the focal point of a traditional autopsy,

which does not routinely involve consulting with a group of experts in vascular disease and coagulation



Arch Pathol Lab Med 141:887-888, 2017

The DMA would involve an expert-driven review of the patient's diagnostic studies to determine if there was underutilization of the necessary tests



Arch Pathol Lab Med 141:887-888, 2017

The editorial suggests that a "diagnostic and management autopsy" (DMA) by DMT experts should accompany virtually every death



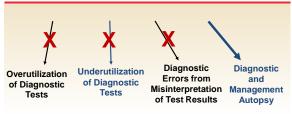
Arch Pathol Lab Med 141:887-888, 2017

Concluding Thoughts



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The Diagnostic Management Team A Group of Experts in One or More Diseases



The Emergence of the Pathologist in Health Care is Happening Now

When You Are a Patient, Which One Do You Want?

Diagnosis without a DMT	Non-experts Providing Most of the Care, Faced with Hundreds of Tests Unfamiliar to Them and with No One To Advise Them
Diagnosiswith a DMT	Experts Directing Diagnostic Testing and Knowledgeably Interpreting Test Results