The Diagnostic Management Team and More at Vanderbilt:
Moving Lab Medicine Closer to the Physicians and Patients to Deliver More Value

Michael Laposata, MD, PhD

Edward and Nancy Fody
Professor of Pathology
Professor of Medicine
Vanderbilt University School of Medicine
I have no conflicts of interest relevant to this talk

Michael Laposata, MD, PhD
A patient is taken to the operating room for removal of the right kidney because of renal cell carcinoma

The surgeon mistakenly removes the left kidney

What is the likelihood that this error will go unrecognized?
A patient with breast cancer is given 4 times a standard dose of chemotherapy as a result of a transcription error.

The patient dies from the overdose of the chemotherapeutic agent.

What is the likelihood that this error will go unrecognized?
A patient presents to the emergency room with shortness of breath

The emergency room physician believes the patient has asthma and discharges the patient with nebulizer treatment for asthma

The patient actually has a pulmonary embolism, and the emergency room physician fails to order a diagnostic test for pulmonary embolism, the D-dimer test

The pulmonary embolism increases in size and the patient collapses and dies in the parking lot because anticoagulation was not instituted
What is the likelihood that:

The patient’s family is aware that this is a preventable death?

Other doctors in the hospital and risk management experts in the hospital recognized this is a preventable death?

The doctor who made the error recognizes that the death was preventable?
How often are errors in test selection and result interpretation major causes of morbidity and mortality?

Probably tens of thousands of times every year in America – and this presentation describes how to address this problem.
Outline of the Presentation

1. Presentation of the Clinical Problem
2. The Diagnostic Management Team at Vanderbilt: What it does and how it was created
3. The Existing and Planned Diagnostic Management Teams at Vanderbilt
4. Coagulation Rounds: An example of the DMT in action
5. Concluding Thoughts
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Has the right test been ordered?

Error between result receipt and action?

Action

Ordering

Collection

Identification

Transportation

Preparation

Analysis

Reporting

Interpretation

The nine steps in the performance of any laboratory test. The brain-to-brain turnaround time loop.

Lundberg, 1981
An educational mismatch with medical practice competency which has long needed correction

What medical students are taught about the diagnostic tests they will use in practice?

- Anatomic pathology tests
- Radiology tests
- Clinical laboratory tests

What diagnostic tests do doctors order in practice and are required to interpret the test results by themselves?

- Anatomic pathology tests
- Radiology tests
- Clinical laboratory tests
Radiologists do not give an MRI image back to the ordering physician without an interpretation

Anatomic pathologists do not give biopsies back to surgeons without interpretation
Why is it acceptable for clinical laboratorians to give complex clinical laboratory test results back to physicians without interpretation – When they know just as little about the test results - beyond the most routine ones - as they do about images in radiology and histopathology?
Laboratories make it even more difficult to because – they call the same test by many different names

<table>
<thead>
<tr>
<th>Names for the test to measure the function of an important coagulation-related protein- von Willebrand factor</th>
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<tbody>
<tr>
<td>Ristocetin cofactor</td>
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<tr>
<td>Von Willebrand factor</td>
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<tr>
<td>Von Willebrand factor function</td>
</tr>
<tr>
<td>Factor VIII-related activity</td>
</tr>
<tr>
<td>Functional von Willebrand factor</td>
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<td>VWF activity</td>
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<td>VWF: RCoF</td>
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<tr>
<td>VWF function</td>
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<tr>
<td>VWF, functional</td>
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<tr>
<td>F VIII – related act</td>
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</table>
A doctor wants to know if a patient has vitamin D deficiency – Which **single** test of all the ones listed below with the name vitamin D should be ordered?

Vitamin D  
Vitamin D2  
Vitamin D3  

25 hydroxy vitamin D  
25-OH vitamin D  
25 hydroxy vitamin D2  
25-OH vitamin D2  
25 hydroxy vitamin D3  
25-OH vitamin D3  

1,25 dihydroxy vitamin D  
1,25-diOH vitamin D  
1,25 dihydroxy vitamin D2  
1,25-diOH vitamin D2  
1,25 dihydroxy vitamin D3  
1,25-diOH vitamin D3  

*And these test names are also presented as abbreviations in multiple different ways!*

*Why don’t we make it easy for a doctor to select the one test which indicates whether or not the patient is vitamin D deficient?*
Consequences of the Vast Array of Testing Options

Doctors pick unnecessary tests or miss the necessary ones

Dozens of approaches emerge for diagnosis of the same condition – some better than others

The correct diagnosis may be achievable promptly, but it is missed or very commonly delayed, with adverse clinical consequences to the patient and/or adverse financial consequences to the institution
EFFECTIVENESS OF CHRONIC PLAVIX THERAPY

Response to Plavix

Clopidogrel nonresponsiveness is associated with increased risk of thrombotic events and correlates to poorer clinical outcomes.

% Patients with Recurrent CVS Events at 6 Months

INHIBITION OF PLATELETS BY CLOPIDIGREL: INHIBITION AT THE ADP RECEPTOR

CLOPIDIGREL → LIVER CYP2C19 → CLOPIDIGREL METABOLITE

ADP Receptor

PLATELET
Genetic Studies

for Cyp2C19 loss of function alleles in the liver –

that convert Plavix to its active metabolite –
can identify patients who do not have an anti-platelet effect from Plavix

Many Alleles for CYP 2C19 – Plavix metabolism May Be Difficult to Assess

<table>
<thead>
<tr>
<th>Allele Name</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP 2C19*1</td>
<td>Wild-type/normal</td>
</tr>
<tr>
<td>CYP 2C19*2</td>
<td>nonfunctional</td>
</tr>
<tr>
<td>CYP 2C19*2B</td>
<td>nonfunctional</td>
</tr>
<tr>
<td>CYP 2C19*3</td>
<td>poor metabolism of compounds like proguanil - with implications for malaria prophylaxis</td>
</tr>
<tr>
<td>CYP 2C19*4</td>
<td>nonfunctional</td>
</tr>
<tr>
<td>CYP 2C19*5</td>
<td>poor metabolizer</td>
</tr>
<tr>
<td>CYP 2C19*6</td>
<td>nonfunctional</td>
</tr>
<tr>
<td>CYP 2C19*7</td>
<td>nonfunctional</td>
</tr>
<tr>
<td>CYP 2C19*8</td>
<td>nonfunctional</td>
</tr>
<tr>
<td>CYP 2C19*17</td>
<td>ultra-rapid metabolizer</td>
</tr>
</tbody>
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SNPedia, 2011
At Vanderbilt alone, there is a potential savings of close to $1.5 million annually from avoidance of adverse events with Plavix – national savings in billions of dollars

**Clopidogrel (Plavix)**

6400 patients on medication x 60 adverse events avoided per year x $25,000 per adverse event = an estimated savings of $1.5 million
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The Diagnostic Management Team at Vanderbilt:

What it does

How it was created
What does a diagnostic management team do?

Conventional approach:

Tests are ordered and these bits of data are “tossed over the wall” to the physician who orders the tests.

The physician who orders the tests is responsible for synthesizing clinical and laboratory data to achieve a diagnosis, often in a limited timeframe.
Conventional Approach

Ordering doctors

Diagnostic doctors

Isolated Diagnostic Bits of Data - Assembly by Ordering Physician Minimally Trained in Test Selection and Interpretation
Example: Treating physician has a patient with a prolonged PTT and must order the correct tests and no unnecessary tests to explain the prolonged PTT preoperatively – with many tests from which to choose, some of which are expensive.
The treating physician often fails to select the correct tests to complete the diagnostic puzzle.

The doctor ordered these 13 tests but still has no diagnosis – puzzle incomplete.

Delayed diagnosis increases expense and leads to poor patient outcome.
What does a diagnostic management team do?

The Diagnostic Management Team Approach:

Physicians order tests by requesting evaluation of abnormal screening test or clinical sign or symptom

The expert physician and colleagues in the DMT synthesizes the clinical and laboratory data and provides a narrative interpretation based upon medical evidence –

not only when requested -

but for every case in that DMT
Diagnostic Management Team Approach

Ordering doctors

Caring for More Patients While Diagnostic Puzzle is Being Assembled

Conferring Diagnostic doctors

Isolated Diagnostic Bits of Data Being Merged with Clinical Data about the Patient by the Diagnostic Doctors
DMTs take all cases –
not only ones presented for consultation

For coagulation – every evaluation emerging from the special coagulation laboratory

For hematopathology – every case

For microbiology – every “sentinel” case

For transfusion medicine - every case involving transfusion reactions, massive transfusion, errors in handling, and Rh incompatibility
Diagnostic Management Team Approach

Ordering doctors

Conferring Diagnostic doctors

There Is No Wall between the Ordering Doctors and the Diagnostic Doctors

Solved Diagnostic Puzzle

Receives Accurate Diagnosis Quickly as a Completed Puzzle
The DMT receives the order to evaluate the prolonged PTT. The DMT decides that only 7 tests are needed to complete the diagnostic puzzle to explain the prolonged PTT.
The DMT rapidly completes the diagnostic puzzle—
Faster diagnosis translates to lower expense and better patient outcome.
The treating doctor needs a diagnosis and not just test results –
And now knows exactly what to do

Evidence based diagnostic conclusions and treatment recommendations are provided by the DMT, for each individual patient

This patient has Factor XII deficiency to explain the prolonged PTT value.

There is no predisposition to bleeding with deficiency of this coagulation factor.

There is no need to transfuse fresh frozen plasma prior to surgery.

The patient is cleared to undergo surgery.
It is not a diagnostic management team activity if any of the following are true

• The interpretation does not consider clinical information
• The service does not meet on a regular schedule
• The interpretation is not written or not included in the medical record
• The interpretation is so self evident that it is not clinically valuable for the treating physician

For example: The interpretation only provides a report of tests results as abnormal but fails to explain why
Barriers to Diagnostic Management Team Creation

And how they have been overcome at Vanderbilt
Why Are National Barriers Not Barriers At Vanderbilt?

Failure of institutions to recognize the clinical and financial benefits of advice on test selection and result interpretations on the total patient encounter.

Anatomic pathology interpretation: Professional fee pays $300
Clinical laboratory interpretation: Professional fee is $0 and the savings from a more rapid and more accurate diagnosis is $3000
Almost no one understands this in 2014
Too few classically trained experts in laboratory medicine are to provide clinically useful advice.

Vanderbilt has made certain that there is a large group of local experts (doctoral and non-doctoral) in laboratory medicine for the DMT –

The main criterion for hiring a doctoral lab director is NOT the degree (MD, PhD, DCLS?) – it is the ability to increase the speed and accuracy of diagnosis – the professional fee for the interpretation is irrelevant to the DMT concept.
If payment for the consult is less relevant than the savings from a quick and accurate diagnosis, all qualified individuals should be invited to help establish the correct diagnosis.
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The Existing and Planned Diagnostic Management Teams --

at Vanderbilt
Hematopathology Dashboard: Pre-historic (ca. 2010)

From Dr. Adam Seegmiller
Hematopathology Dashboard: Modern Version

From Dr. Adam Seegmiller
Reflex Testing in Hematopathology

- At the time of bone marrow biopsy, the oncologist orders “bone marrow testing panel”

- Pathologist:
  - Consults electronic medical record and patient flowsheet for history and previous test results
  - Reviews bone marrow morphology
  - Orders appropriate cytogenetic and molecular tests

- The oncologist retains the option to order tests “a la carte”
Fractional weekly utilization of the bone marrow testing panel vs. a la carte ordering - after Hematology DMT implementation

Courtesy of Dr. Adam Seegmiller and colleagues
Significant Savings with Reflex Testing in Hematopathology

- Cost per marrow is $284 less for reflex testing.
- Yearly savings (>1800 bone marrows) exceeds $800,000 at Vanderbilt alone.

From Adam Seegmiller
Survey of 22 clinicians who Interacted with the Hematopathology DMT at Vanderbilt – Positive Response

I am aware of the option to order a bone marrow testing panel.

I trust the pathologists to order appropriate tests for my patients.

I have read the SOPs for bone marrow test ordering.

I trust the SOPs to help the pathologists choose the right tests at the right time for my patients.

I prefer to be the individual primarily responsible for deciding which tests should be ordered on my patients.

0% 20% 40% 60% 80% 100%

Disagree
Neutral
Agree

*Courtesy of Dr. Adam Seegmiller and colleagues*
Interpretations by the Microbiology Diagnostic Management Team

- Clinically significant combinations of pathogen and site of detection
- Unusually virulent pathogen or strain
- MDR antimicrobial susceptibility pattern
- Unexpected antimicrobial susceptibility or resistance
- Findings suggestive of treatment failure
- Infection control or public health issues
- Findings suggestive of underlying pathology
- Concern for rapid disease progression
- Conflicting, confusing, or ambiguous results
- Any result that a technologist considers atypical or concerning with respect to patient well-being

From Dr. Jim Chappell
The National Fungal Meningitis Outbreak

Caused by injections of steroid preparations contaminated with *Aspergillus Fumigatus*

- 730 cases in 20 states
- 51 deaths
- Index case identified at Vanderbilt

The Microbiology DMT at Vanderbilt helped terminate this huge outbreak

Drs. Carol Rauch, Jim Chappell, and Chuck Stratton, along with others
The National Fungal Meningitis Outbreak

• The DMT started with a diagnosis of meningitis and promptly identified that the source of the problem was contaminated steroid preparations. The DMT promptly determined that the cause of the meningitis was *Aspergillus Fumigatus*.

• The DMT learned that the patient was not immunocompromised, had just received epidural steroid injections and had lumbar level abscesses.

• The DMT determined that it was a true infection of the steroid preparation and not a laboratory contaminant.
The National Fungal Meningitis Outbreak

• The DMT initiated and completed antigenic and other tests to support the conclusion that the pathogenic agent was *Aspergillus*

• The DMT worked closely with the Tennessee Department of Health which ultimately led to announcements and recalls of the infected steroid preparations

• The DMT participants were invited by the *New England Journal of Medicine* to prepare a publication to document the case and raise awareness of the national problem, and this paper was finalized within 1 month of the DMT discussions at Vanderbilt
Transfusion Medicine Rounds – Predominant Case Material

- Transfusion Reactions
- RBC Antibody Identifications
- Massive Transfusion Protocol Review
- Case discussions about patients receiving out of group platelet transfusions to determine the need for Rh Immune globulin
- Real time review of errors related to cases with transfusions
The landscape within the current vision at Vanderbilt – a 3 year plan for the clinical laboratory DMTs

- Coagulation
- Transfusion Medicine
- Microbiology
- Endocrinology
- Toxicology
- Autoimmunity
The landscape within the current vision at Vanderbilt – a 3 year plan for the anatomic pathology DMTs

- Hematopathology
- Breast Cancer
- Neuropathology
- Renal Pathology
- Lung Cancer
- Other cancers – GI, Prostate, Others with valuable molecular and genetic testing that directs therapy
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Coagulation Rounds

Multiple Attendings

Coagulation Lab

Expert Driven, Patient Specific Diagnostic Interpretation

Diagnostic Test Selection Algorithms
Selected by Treating Physicians

Financial Benefits:
On Test Selection
On Diagnosis
But Difficult to Quantify

Neurology
Cardiology
Hematology
Oncology
Ob-Gyn
Rheumatology
Coagulation Rounds

Logistics

Case Material
Early AM:
Resident on service confers with special coagulation technologist to identify cases for evaluation

Early AM till 4 PM:
Resident reviews lab data as it becomes available and clinical details for all patients being evaluated; follows up with clinical or laboratory questions for these cases as necessary; creates preliminary interpretation.
The Logistics of Coagulation Rounds

4 PM:
Attending, coagulation resident, other trainees discuss each case – with relevant teaching points made by attending – and interpretation finalized. Result into patient’s electronic record immediately.
Data presentation in the medical record for coagulation studies prior to initiation of the patient specific, expert driven coagulation interpretations

JUNE 30, 2010  VANDERBILT UNIVERSITY

The Dilute Russell Viper Venom time (dRVVT) is used for detection of Lupus Anticoagulant. Hemolysis, deficiencies or inhibitor of Factors II, V and X, high Factor VIII level (>200%), Heparin level >1 IU/ml, some LMWH, Coumadin and other Vitamin K antagonists may interfere with test results. In order to determine etiology of prolonged dRVVT, a mixing study was performed showing no dRVVT correction, indicating the presence of Lupus Anticoagulant.
Report in the medical record after initiation of the daily rounds to interpret all complex evaluations from the special coagulation laboratory.

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.
Attendees at the Coagulation DMT and their responsibility

- The trainee(s) – usually a pathology resident and occasionally a hematology-oncology fellow or a medical student under the guidance of a resident or fellow

Reviews the medical record for each case to collect information relevant to coagulation issues

And provide a draft patient specific interpretation of the laboratory test results in clinical context
Attendees at the Coagulation DMT and their responsibility

- **The attending laboratory director**

  Reviews presented cases and interpretations drafted by the trainee,

  For immediate inclusion into the medical record when finalized at rounds
Attendees at the Coagulation DMT and their responsibility

• The Medical Technologist

Provides input on interpretation of test results when there is a relevant question such as:

Result is influenced by the methodology
Sample was partially compromised
Attendees require education about assay
A series of suspicious results suggest the possibility of a laboratory error
Role of the Information Scientist in the DMTs

- Information scientist is in attendance 2 times per week at the coagulation DMT
- The activity is to provide patient-centered, expert-driven, evidence-based medicine literature support to the DMTs when relevant clinical questions arise
- DMT database tool contains the answers to questions posed at the DMT rounds and is constructed for reuse and distribution of information to others

Provided by Tracy Shields
Two ways to ask clinical questions or suggest topics:
1) through the electronic medical record, and
2) through the DMT tool

Selected list of library resources

Provided by Tracy Shields
Guidelines from a chapter of the American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (6th Edition) include the following recommendations for the treatment of superficial vein thrombosis (Kearon et al. 2008):

“For patients with spontaneous superficial vein thrombosis, we suggest prophylactic or intermediate doses of LMWH [low molecular weight heparin – ed.] (Grade 2B) or intermediate doses of UFH [unfractionated heparin – ed.] (Grade 2B) for at least 4 weeks. We suggest that as an alternative to 4 weeks of LMWH or UFH, VKA [vitamin K antagonist – ed.] (target INR, 2.5; range, 2.0 to 3.0) can be overlapped with 5 days of UFH and LMWH and continued for 4 weeks (Grade 2B). We suggest that oral NSAIDs should not be used in addition to anticoagulation (Grade 2B). We recommend medical treatment with anticoagulants over surgical treatment (Grade 1B).

Remark: It is likely that less extensive superficial vein thrombosis (ie, where the affected venous segment is short in length or further from the saphenofemoral junction) does not require treatment with anticoagulants. It is reasonable to use oral or topical NSAIDs for symptom control in such cases."

These guidelines cite numerous other studies and a Cochrane review of treatment of superficial thrombophlebitis (Di Nisio et al. 2007). Other authors (Carrero-Vidal et al. 2010; Kitchen 2011) note other existing factors such as site and concurrent deep vein thrombosis for consideration with regard to treatment selection. Kitchen (2011) notes that “I treat the majority of patients with a clinical diagnosis of SVT [superficial venous thrombosis – ed.] on an equal footing as patients with other VTE [venous thromboembolism—ed.]"

A randomized, placebo-controlled, double-blind trial (Comparison of Arixtra in Lower Limb Superficial Vein Thrombosis with Placebo [CALISTO]) published in 2010 compared fondaparinux to placebo in patients with acute, symptomatic lower-limb superficial vein thrombosis 5 cm or greater in length (Decousus et al. 2010). Treatment with fondaparinux (2.5 mg once daily) or placebo was administered for 45 days, and patients were followed for 30 days after discontinuing treatment. Incidence of symptomatic pulmonary emboli, deep vein thromboses,
Explanations from Coagulation Rounds

Why the patient is bleeding

**Why the patient is clotting**

Does the patient have an immediate risk of catastrophic thrombosis from selected coagulation disorders

**Why the woman cannot carry a pregnancy to term**

How to manage and monitor anticoagulant therapy

Is there an underlying bleeding disorder in a bruised child

And many more
To reduce diagnostic error and save money while improving patient outcomes -

“ Just DMT all of the Pathology Services “
Before and After Coagulation DMT –
What is the Impact of Length of Stay in
the Hospital for Pulmonary Embolism
and Intracranial Hemorrhage?

R. Lawrence Van Horn, Ph.D, MPH, MBA
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Exec. Dir. Of Health Affairs
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School of Medicine
MSDRG 176: PE

Comparison of Length of Stay and Total Charges Pre and Post Aug 1, 2010

Percent of Cases with LOS greater or equal to 4 days
- Jan - Jul (Before) 36.75%
- Aug - Dec (After) 12.50%
Chi-sq significant at .05

**Bottom Line:**
It appears that the changes in the median LOS are due to truncation of the right tail.
Comparison of Length of Stay and Total Charges Pre and Post Aug 1, 2010

Percent of Cases with LOS greater or equal to 10 days
Jan - Jul (Before)  14.5%
Aug - Dec (After)  2.25%
Chi-sq significant at .05.

Bottom line: It appears that the changes in median LOS are due to truncation of the right tail.
“Diagnostic Latency” - I

• Tests ordered when patient admitted on Monday.

• Results back Tuesday with several abnormal results.

• Action taken on Wednesday with further evaluation.
“Diagnostic Latency” - II

- Diagnosis and discharge plan on Thursday. Patient gone by 3 PM.

Length of Stay: 4 days
No Diagnostic Latency - I

• Tests ordered when patient admitted on Monday.

• Results to coagulation rounds with preliminary interpretation by coagulation resident Monday at 4:00 p.m.

• Patient specific, expert driven narrative completed by 6:00 p.m. Monday and into medical record.
No Diagnostic Latency - II

- Further evaluation Tuesday.
- Discharge on Wednesday.

Length of Stay: 3 days

Limiting factor for some evaluations: Not all assays done daily Monday-Friday, delaying narrative and increasing length of stay.
Annual Savings for Clinical Situations Presented

1. Pharmacogenomics testing for Plavix: 1.5 million dollars

2. Unnecessary testing for leukemia: 0.88 million

3. Reduced length of stay for Pulmonary Embolism: 200 cases per year and $2000 reduction is 0.4 million

4. Oncologists seeing 1000 more patients annually with revenue of (minimum) $300 per visit: 0.3 million

The total for just these examples is about 3 million dollars at Vanderbilt

These are 4 examples involving 3 diseases – But there are hundreds of diseases where such reductions are possible – collecting the information for each case requires dozens of hours
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If you are seriously ill with an unknown diagnosis, you want -

An expert in the field

With current knowledge

Directing your evaluation in real time and explaining it all to you

This is the diagnostic management team – which needs to serve all those in need, not just those in a place where it exists
Acknowledgements

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DMT Attendings
Nearly 20 to date

Technologists attending DMTs
Multiple technologists in coagulation and transfusion medicine

Director of trainee activities at the DMT
Dr. Bob Hoffman