



HEALTHCARE AND HUMAN SERVICES POLICY, RESEARCH, AND CONSULTING—WITH REAL-WORLD PERSPECTIVE.

Systems-Based Clinical Hematologist Project

Business Case Portfolio

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Table of Contents

Executive Summary	1
Logic Model- Opportunity for Benign Hematology Interventions and Roles	2
Opportunity Area 1: Heparin-Induced Thrombocytopenia (HIT).....	5
Context/Problem Statement	5
Intervention Logic Model	5
Knowledge Base	6
Key Intervention Features	7
System Requirements and Investments	7
Potential Barriers.....	7
Potential Impacts.....	8
Opportunity Area 2: Use of Plasma Infusion in the Management of Thrombotic thrombocytopenic purpura (TTP).....	9
Context/Problem Statement	9
Intervention Logic Model	9
Key Intervention Features	10
System Requirements and Investments	10
Potential Barriers.....	11
Potential Impacts.....	11
Professional Role 1: Medical Director for Hemostasis/Thrombosis Stewardship.....	12
Context/Problem Statement	12
Intervention Logic Model	12
Key Intervention Features	13
System Requirements and Investments	13
Potential Barriers.....	14
Potential Impacts.....	14

Professional Role 2: Benign Hematology Consultation and Management in an ACO Environment.....	15
Context/Problem Statement	15
Intervention Logic Model	15
Knowledge Base	15
Key Intervention Features	16
System Requirements and Investments	16
Potential Barriers	17
Potential Impacts.....	17
Summary and Potential Next Steps.....	18
Appendix A	19

Executive Summary

On behalf of the American Society of Hematology (ASH), The Lewin Group has examined and sought to help refine a new role for 21st century hematologists – the systems-based clinical hematologist. The intent of this effort is to identify emerging career opportunities for health system and hospital based hematologists and to provide guidance on pursuing those initiatives. At the core of this concept is the projected need for easily accessible expertise and leadership in the increasingly complex domains of clinical hematology.

The first phase of the study identified what is occurring ‘in the field’ among innovators of this new hematology role through an environmental scan of peer-reviewed and grey literature and a series of interviews with practicing and innovating hematologists. Several common areas of focus were identified including areas for creating quality improvement and guidelines as well as the appropriate use of resources. The second phase of the study has further examined the policy and operational underpinnings of the expansion of systems-based hematology roles.

Business cases have been developed to illustrate two examples of specific interventions as well as two more comprehensive professional roles for systems-based hematologists. The featured examples are not intended to be all encompassing or even necessarily the most compelling across all settings, but rather to provide illustrations of elements upon which a more complete role could be built and justified.

The expectation is that there are likely several similar building blocks and approaches to assemble components into professional roles; how they are best combined and pursued will be a reflection of both the institutions involved and the leaders assembling these opportunities.

Logic Model- Opportunity for Benign Hematology Interventions and Roles

On behalf of the American Society of Hematology (ASH), The Lewin Group has examined and sought to help refine a new role for 21st century hematologists – the systems-based clinical hematologist. The intent of this effort is to identify emerging career opportunities for health system and hospital based hematologists and to provide guidance on pursuing those initiatives. At the core of this concept is the projected need for easily accessible expertise and leadership in the increasingly complex domains of clinical hematology. While such a professional role may initially be best suited to an academic center, a large acute care hospital or an integrated care system, we would expect that the ongoing consolidation of small and medium size hospitals and the emergence of more integrated systems of care, such as Accountable Care Organizations (ACOs), set the stage for a more generalized examination of this role.

Motivated by the experiences of several innovators who have been testing some of these interventions and roles in limited settings, ASH is interested in ultimately designing and promoting a new and generalizable career pathway for hematologists, based on the idea that a hospital or systems-based clinical hematologist is a critical part of the health care team. Such a role could be filled by a single individual or split between several hematologists. The systems-based clinical hematologist would ideally establish and promote policies and education programs that identify hematological issues accurately and early, thereby avoiding anticipatable complications. This individual would provide guidance on the appropriate evaluation and management of hospitalized patients with bleeding, thrombosis, and cytopenias. ASH expects that there will be different institutional drivers for creating designated benign hematologist roles including, but not limited to, changes in payment models such as formation of ACOs, or confronting institutional ‘pain points’ such as concerns over appropriate use of tests and expensive or high-risk interventions. Further, a systems-based hematologist could also provide input into the appropriate use and interpretation of molecular testing. As health care delivery models continue to evolve as a result of the Affordable Care Act (ACA), ASH believes there will be expanding opportunities to pilot this new role and promote new career opportunities for hematologists.

The focus of this initiative is on hematologists who do not also practice primarily as medical oncologists. The included expertise can range across diverse aspects of care such as transfusion management, anticoagulation oversight, and understanding how and whether to work up a cytopenia or possible hypercoaguable state. As all of these areas are dynamically evolving, there is also a need to develop, systematically track, and communicate emerging clinical and operational insights within larger practice communities. The robust positioning of an institutionally based clinical hematologist could also entail such multiple system-based roles as an information system specialist, a hospital quality control officer, and safety officer. A crucial role of likely growing importance would be to ensure appropriate use of increasingly effective, yet also expensive, interventions without adversely impacting quality of care. Finally, peer and patient education would be one of the more frequently employed interventions. Educational efforts include traditional activities such as conference presentations, student and house staff teaching sessions, and written guidelines but also may bridge to innovative uses of media and other resources to inform and engage both providers and patients.

The first phase of the study identified what is occurring ‘in the field’ among innovators of this new hematology role. In Phase 1 we completed an environmental scan of peer-reviewed and grey literature and a series of interviews with practicing and innovating hematologists. The intent of the environmental scan and interviews was to identify the current state of the art including the core competencies and clinical portfolios of current institutionally based clinical hematologists, how are they performing their role, and what type of job description and environment exists for them. The interviews were designed to systematically capture what is occurring in these settings and understand how novel and transferable this role is for other settings. Within the scope of work being addressed across the innovators interviewed, several areas of focus were noted repeatedly. These include the following:

Common Areas of Focus
Quality Management/Guidelines
Heparin Induced Thrombocytopenia (HIT) screening and management
Treatment of bleeding in the anticoagulated patient
Sickle cell disease management and day hospitals
Appropriate Use of Resources
Appropriate use of transfusion services and products
Clotting factor management (factor VII, PCCs)
Standardization of anticoagulation practices
Infusion protocols
Genomic testing
Growth factors
Pre-op hematology evaluation/anemia in the elderly

The second phase of the study has further examined the policy and operational underpinnings of the expansion of systems-based hematology roles. Based on the interviews from Phase 1 of the study, additional outreach, and information received following the ASH Annual Meeting in December 2013, the Lewin team worked with ASH to identify four representative systems-based hematology activities around which supporting rationales have been built, and that can be summarized as opportunities.

Target Opportunities
Quality Management/Guidelines
HIT screening and management
Appropriate Use of Resources
Reducing plasma utilization for Thrombotic thrombocytopenic purpura (TTP)
Professional Roles
Blood and platelet transfusion stewardship
Hematologists in Accountable Care Organization (ACO) settings

These components can be used in conjunction with one another or on their own to support discussion with hospital and health system administrators for direct financial support for a systems-based hematologist. Lewin created a standardized business case template that was used across the four topics when compiling information. This template can be found in **Appendix A**.

The featured case examples are not intended to be all encompassing or even necessarily the most compelling across all settings; rather, they provide illustrations of elements upon which a more complete role could be built and justified. We have also summarized two examples of where somewhat broader innovation has led to new system-supported roles to meet a portfolio of identified patient care needs. The expectation is that there are likely several similar building blocks and approaches to assemble components into professional roles; how they are best combined and pursued will be a reflection of both the institution and the leaders assembling these opportunities. Finally, the inclination and ability of institutions to ‘take the plunge’ and fully create a position will vary. Some settings will likely begin smaller than others, with pursuit of an intervention like HIT management, perhaps in a quality improvement context, then, ideally, building up to institutional support of a larger designated physician role.

The intersection of the scale of the four examples discussed in this paper and the extent of evidence and experience for building business cases around them is presented in the matrix below.

		Degree of Evidence and Existing Experience	
		Early/More Speculative	More Established
Scale	Large/Professional Role	Benign Hematology Consultation and Management in an ACO Environment	Medical Director for Hemostasis/Thrombosis Stewardship
	Small/Individual Initiative	Reducing Plasma Utilization for Thrombotic Thrombocytopenic Purpura (TTP)	HIT Screening and Management

Opportunity Area 1: Heparin-Induced Thrombocytopenia (HIT)¹

Context/Problem Statement

Heparin-induced thrombocytopenia, while relatively uncommon, can result in substantial morbidity, mortality and costs, especially if not readily recognized and managed appropriately. As the understanding of HIT has evolved substantially over the last 2 decades and management has been enabled by availability of newer but expensive alternatives to heparin, prompt systematic recognition of HIT plus experience in using both heparin and alternative agents offers the opportunity for both care improvement and appropriate stewardship of resources.

HIT is divided into two major types. Type 1 HIT is benign and self-limited and characterized by a mild drop in the platelet count within two days of heparin administration, which partially or completely self-corrects with continued heparin administration. Type 2 HIT, however, is more serious and requires intervention on the part of the clinician to avoid serious harm to the patient. Type 2 HIT is the result of the formation of antibodies directed against epitopes on the antigen complex of heparin combined with platelet-factor 4 (PF4). The diagnosis of HIT requires clinical suspicion and is triggered by a falling platelet count in the setting of heparin administration.²

Major systems costs associated with HIT are diagnostic testing, intravenous anticoagulation therapy, and increased hospital length of stay. Testing for HIT requires specialized testing services, and treatment involves intravenous administration of direct thrombin inhibitors (DTIs) which are expensive agents. HIT has been associated with a prolonged length of hospital stay (sometimes up to 2 weeks) and the need for continued outpatient anticoagulant therapy for up to 30 days. Hospitalization costs for patients developing HIT in a university affiliated tertiary care hospital were over \$40,000 greater than those incurred by case matched controls without HIT.³ In another study, reimbursement for patients with HIT did not completely cover hospitalization-associated costs, resulting in net losses to the hospital of up to \$14,000-\$20,000 per patient depending on the payer.⁴

Intervention Logic Model

The purpose of this intervention is to reduce unnecessary heparin exposure, improve diagnostic accuracy, reduce unnecessary DTI use in patients with low pre-test probability, and reduce the length of hospital stay by targeting use of low-molecular weight heparin for deep vein thrombosis (DVT) prophylaxis and use of rapid turnaround assay for HIT diagnosis. The intervention should also include a hematologist review of all suspected cases of HIT, pharmacy

¹ Information initially drafted and compiled by Nathan Connell, MD., Teaching Fellow in Hematology and Oncology, Department of Medicine, Alpert Medical School of Brown University

² Connell NT and Sweeney JD. Does my patient have a life- or limb-threatening thrombocytopenia? Hematol Oncol Clin North Am. 2012 Apr;26(2):369-82

³ Creekmore FM, Oderda GM, Pendleton RC, Brixner DI. Incidence and economic implications of heparin induced thrombocytopenia in medical patients receiving prophylaxis for venous thromboembolism. Pharmacotherapy. 2006 Oct;26(10):1438-45.

⁴ Smythe MA, Koerber JM, Fitzgerald M, Mattson JC. The financial impact of heparin-induced thrombocytopenia. Chest 2008 Sep;134(3):568-73.

review/approval of DTI use based on protocol/guidelines and an algorithm-based approach to reduce inappropriate diagnostic test ordering.

While unfractionated heparin is cheaper for each unit of heparin administered, it requires frequent nursing administration, and may have increased potential for refusal by patients due to additional injections. Use of a low-molecular weight heparin is likely to be more consistently administered and therefore more effective in reducing venous thromboembolisms (VTEs) in hospitalized patients. It is also associated with a significant reduction (~95% risk reduction) in HIT.

Implementation of a rapid turnaround assay for HIT, if clinicians are trained to interpret the assay properly, will allow more accurate patient categorization and appropriate use of treatment modalities. Patients with a low pre-test probability of HIT do not require DTI therapy. Routine documentation of the estimated pre-test probability in conjunction with ordering of DTI therapy can be reinforced by hospital guidelines. In combination, appropriate HIT testing, risk documentation and periodic review of prescribing practices supports appropriate use resulting in reductions in DTI administration costs.

Knowledge Base

There are several HIT interventions currently used in current practice.

The heparin-induced thrombocytopenia task force model: implementing quality improvement and economic outcome initiatives: Heparin-induced thrombocytopenia is a costly but potentially preventable complication associated with the use of heparin. Based on a 1% to 3% incidence of HIT, the total cost and potential financial loss due to HIT complicating open-heart surgery is estimated to range from over 100 to 300 million dollars and from over 33 to 100 million dollars annually, respectively, in the United States. To minimize the personal and economic cost of HIT, the Charleston Area Medical Center (CAMC) HIT Task Force developed institutional guidelines for diagnosis and treatment, educated medical staff and patients, and took measures institution-wide to reduce patient exposures to heparin.⁵

Development and implementation of a comprehensive heparin-induced thrombocytopenia recognition and management protocol: In keeping with the Joint Commission's National Patient Safety Goal (NPSG) for anticoagulant therapy (goal 03.05.01), a multidisciplinary working group conducted a needs assessment to identify areas for improvement in the Center's HIT management practices, particularly the use of DTI therapy (an issue not specifically addressed by NPSG 03.05.01). The resulting action steps included (1) the implementation of a detailed protocol for the recognition and management of HIT, as well as guidelines on the use of the DTIs, (2) more efficient use and optimized documentation of initial and confirmatory tests in the electronic medical record (EMR), and (3) the education of pharmacists, nurses, and physicians on the use of the HIT protocol, with initial and ongoing case-based competency testing of pharmacy staff. Early post-implementation experience indicated that the protocol and associated activities have resulted in improved DTI prescribing and dosing, HIT documentation,

⁵ Frame JN. The heparin-induced thrombocytopenia task force model: implementing quality improvement and economic outcome initiatives. Semin Hematol. 2005 Jul;42(3 Suppl 3):S28-35

and patient education practices while expanding pharmacists' involvement in ensuring optimal, cost-effective management of patients with HIT.⁶

Key Intervention Features

The key actors for this intervention are clinicians (e.g., primary care physicians, hospitalists, surgeons, and hematologists), laboratory technicians, pharmacy specialists and nursing staff.

Changes will need to be made to the preferred VTE prophylaxis guidelines and it will be important to implement a computer-assisted algorithm to assist with this. The first step should be to review and update the hospital guidelines to include recommendation for hematology consultation in suspected cases of HIT. As the review and update of hospital guidelines often takes between 4 to 6 months, implementation of information technology (IT) algorithms, clinician and nursing education and pharmacy review and training should occur concurrently. Pharmacy review and training takes 1 to 2 months, clinician and nursing education takes from 2 to 4 months. The final step is data collection and analysis to determine the outcome(s) of the intervention which will take from 6 to 12 months.

Through data collection and analysis, organizations will be able to determine the rate of HIT diagnosis, the average length of stay for medical and surgical patients, the amount of DTI administered (and in turn, associated costs) and the number of positive HIT assays as a proportion of the total number of assays sent.

The desired outcomes for this intervention are a 10% reduction in HIT, a 5% reduction in length of stay for medical and surgical patients, a 25-50% reduction in the amount of DTI administered and a 20% increase in the proportion of HIT assay positivity as a fraction of the number of assays sent, indicating more appropriate use of diagnostic test ordering.

System Requirements and Investments

Necessary roles and corresponding skills sets include a designated systems-based hematologist reviewer, pharmacy and nursing liaisons, pharmacy experience, and an IT liaison.

IT requirements include clinical algorithm development and reference management. Also, it is important to integrate pharmacy flags into charts for review.

Potential Barriers

Changes in use of anticoagulants for dialysis and cardiac surgery and changes in VTE prophylaxis clinical practice may be necessary. Also, it will be necessary for there to be appropriate recognition and application of the diagnostic test algorithm.

An IT support mechanism to improve appropriate use of diagnostic testing is necessary. Pharmacy will also need to be able to review laboratory data to support the use of DTI.

⁶ Smythe MA, Mehta TP, Koerber JM, et al. Development and implementation of a comprehensive heparin-induced thrombocytopenia recognition and management protocol. Am J Health-Syst Pharm. 2012 Feb 1; 69: 241-8.

Potential Impacts

Patients with early recognition of HIT and DTI treatment will have improved outcomes. Further, any reduction in unnecessary DTI use as a result of appropriate testing will reduce the overall risk of major bleeding associated with this group of anticoagulants.

An additional motivation for not over-diagnosing HIT, especially for large hospital systems, is the challenge inherent in managing anticoagulation for the truly HIT affected patient through surgery. If a procedure is done with anticoagulation, such as operations involving cardiac bypass, DTI use is less familiar to surgeons and difficult to monitor. DTIs are also not easily reversed if excessive bleeding occurs during their use. Further, if DTIs are held during surgery and begun post-op and then the patient needs to return emergently to the operating room, bleeding control can be problematic. Finally, if re-initiation of anticoagulation post op is delayed the risk of clotting increases.

Appropriate use of DTIs will also reduce overall medication costs. For instance, Argatroban, one of the commonly used DTIs, can cost over \$1,000 per day as compared to \$4-\$6/day for unfractionated heparin therapy.⁷ As noted previously, patients with HIT will have a longer hospital stay, incurring substantially higher hospital-associated costs, which could result in a net loss to the hospital after reimbursement of up to \$20,000 per patient depending on the payer.⁸

Patients benefit from reduced anxiety related to diagnostic workup and anticoagulation administration, a decreased length of stay and fewer injections for VTE prophylaxis. This will lead to reduced complications from hospitalization and improved patient satisfaction, both of which can lead to physician satisfaction. Also, rapid turnaround of diagnostic testing improves the clinician's ability to confirm and/or exclude a diagnosis of HIT.

⁷ These costs are institution specific to Rhode Island Hospital.

⁸ Smythe MA, Koerber JM, Fitzgerald M, Mattson JC. The financial impact of heparin-induced thrombocytopenia. Chest 2008 Sep;134(3):568-73.

Opportunity Area 2: Use of Plasma Infusion in the Management of Thrombotic thrombocytopenic purpura (TTP)⁹

Context/Problem Statement

Thrombotic thrombocytopenic purpura is a devastating illness with mortality approaching 90% if not diagnosed and treated early. Treatment involves invasive procedures to remove circulating plasma volume and replace with plasma obtained from blood donors. In some instances, 25-50% of a health system's yearly plasma volume may be utilized for a few patients with TTP. This project aims to reduce plasma utilization for TTP by implementing a rapid turnaround assay for ADAMTS13, the enzyme involved in the pathophysiology of TTP. Though not fully established as the gold standard, assays for ADAMTS13 can be used in conjunction with clinical judgment to improve the upfront diagnosis of TTP.

Intervention Logic Model

Acquired idiopathic thrombotic thrombocytopenic purpura is a thrombotic microangiopathy with a high mortality (>90%) unless plasma exchange is implemented quickly. TTP is caused by a severe deficiency (<5% activity) of the metalloproteinase ADAMTS13, which is responsible for cleaving large multimers of von Willebrand factor (vWF). This deficiency is due either to a congenital deficiency or an autoantibody inactivating the N-terminal active site region of the enzyme. Absence of ADAMTS13 leads to the presence of abnormal ultrahigh molecular weight vWF, in turn causing platelets to aggregate in small vessels resulting in organ ischemia.¹⁰ In almost all cases, ADAMTS13 activity of less than 5% can be demonstrated on the serum of patients suspected of having TTP. Typically, TTP is a clinical diagnosis with a reported pentad of thrombocytopenia and microangiopathic hemolytic anemia along with renal and neurologic dysfunction and fever. One review, however, found that only 3% of patients have the full pentad at presentation, so the diagnosis is often uncertain.¹¹

Therapeutic plasma exchange with either ABO compatible fresh frozen plasma, 24-hour frozen plasma, or cryosupernatant plasma is the therapy of choice, as it reduces the mortality from 90% to approximately 13%.¹² In spite of the availability of a confirmatory diagnostic test, many patients do not receive confirmation of the diagnosis until days or weeks after presentation because of the long turnaround time for the ADAMTS13 activity assay. Currently, the assay is only performed in specialized laboratories and usually has a turnaround time (TAT) of 10-14 days. Since TTP remains a clinical diagnosis, and given the high mortality associated with withholding treatment, many patients receive plasma exchange unnecessarily in an attempt to capture all patients with the diagnosis who would benefit from the therapeutic intervention.

⁹ Information initially drafted and compiled by Nathan Connell, MD., Teaching Fellow in Hematology and Oncology, Department of Medicine, Alpert Medical School of Brown University

¹⁰ Connell NT, Sweeney JD. Does my patient have a life- or limb-threatening thrombocytopenia?

¹¹ George JN. How I treat patients with thrombotic thrombocytopenic purpura: 2010. Blood 2010;116:4060-9.

¹² von Baeyer H. Plasmapheresis in thrombotic microangiopathy-associated syndromes: review of outcome data derived from clinical trials and open studies. Therapeutic apheresis: official journal of the International Society for Apheresis and the Japanese Society for Apheresis 2002;6:320-8.

In 2009, the Rhode Island Hospital system utilized approximately 50% of all plasma transfused for 16 patients with suspected TTP. A review of data from the Oklahoma TTP Registry showed that during a 3 year time period, 17% of patients undergoing plasma exchange for TTP had a complication directly attributed to the exchange process rather than the underlying illness.¹³ Due to limited availability of certain ABO plasma such as Group AB and Group B, blood products can be scarce resources; even small reductions in utilization by one part of a hospital system can give greater flexibility to areas where the blood product is needed the most.

Intervention targets are hematologists and transfusion medicine specialists with the desired result of a 10% reduction in plasma utilization for TTP and better up-front diagnosis of patients with thrombotic microangiopathies.

Key Intervention Features

The main actors for this intervention are the Special Coagulation Laboratory director, the Transfusion Medicine Service director, the Clinical Apheresis Service director and hematologists.

It takes between 6 and 12 months to acquire, validate, and fully implement rapid turnaround testing in a special coagulation laboratory. Validation should include sending simultaneous samples to outside reference laboratories in order to establish that the assay, in conjunction with the training done by staff, would have a tight correlation with the reference labs. Once it has been implemented, it will take 1 to 2 weeks to train hematologists before data collection can begin. Twelve to 18 months should be allowed for data collection and evaluation. The assay used by Rhode Island Hospital is a commercially available assay which uses a peptide substrate with a susceptible Met-Tyr peptide bond which is cleaved by the ADAMTS 13 in the patient's plasma.

The goal of the intervention is to reduce plasma utilization for TTP by 10% with the mortality for TTP patients at or below the published mortality rate.

System Requirements and Investments

A systems-based hematologist is needed to coordinate efforts from multiple departments and services with a skills set that includes the ability to validate and implement a new diagnostic test. This includes a strong understanding of data analysis, both methodologically speaking with respect to study design, and with respect to statistical analysis.

Hospitals or health care centers will need an IT tracking system for transfusion data as well as a laboratory data management system for the new test implementation.

¹³ Som S, Deford CC, Kaiser ML, et al. Decreasing frequency of plasma exchange complications in patients treated for thrombotic thrombocytopenic purpura-hemolytic uremic syndrome, 1996 to 2011. *Transfusion* 2012.

Potential Barriers

Potential barriers to implementation include resistance or push back to changing the current clinical practice as well as hesitancy to use assay results to guide clinical practice. Technical barriers could include access to the necessary data management systems and the availability of the test on nights and weekends due to the specialized nature of the assay and the need for trained laboratory staff.

Potential Impacts

This intervention has the potential to positively impact the quality of care given, the cost of care and the experience of both the patient and the clinician.

A rapid turnaround assay can provide the correct categorization of patients at the time of presentation while reducing the unnecessary utilization of a scarce resource. By having an accurate up-front diagnosis, patients avoid unnecessary exposure to blood donor plasma, and are therefore less likely to experience transfusion-related infections, allergic reactions and circulatory overload. Also, central venous catheters are used to perform the plasma exchange, and these are at high risk for catheter-associated infections, bleeding complications, catheter-associated thrombosis and pneumothorax. By confirming or excluding the diagnosis early, physicians are able to start the appropriate treatment sooner. If the assay results do not support the diagnosis of TTP, the physician can actively pursue alternative diagnoses (e.g., malignant hypertension, atypical hemolytic-uremic syndrome [HUS]).

The impact of this approach on costs of care will vary by location and institution. As an example of both an approach to savings projections and the potential impact of this approach, in the Rhode Island Hospital system, the estimated costs for each plasma exchange are approximately \$3,000. For the State of Rhode Island, there are an estimated 7 patients who received exchange each year but did not actually have TTP. Given that the mean number of exchanges for patients without TTP was 11 at Rhode Island Hospital, appropriate intervention resulting in avoidance of exchange would result in a potential exchange-related cost savings of approximately \$33,000 per patient at this institution or an annual exchange-associated cost savings of approximately \$231,000.

Professional Role 1: Medical Director for Hemostasis/Thrombosis Stewardship¹⁴

Context/Problem Statement

The hemostasis/thrombosis stewardship program is designed to broadly and systematically address coagulation-related disorders in an academic medical center with a team consisting of one 30-40% full-time equivalent (FTE) hematologist, possibly supported by one 100% FTE pharmacist, and administrative staff. The program is intended to foster collaboration across medical departments to promote appropriate and cost-effective use of new and established anticoagulants and clotting factors, agents that often have a narrow therapeutic window for both effectiveness and safety and which can be very costly.

Some examples where a systems-based hematologist can foster appropriate and safe practice include:

- Implementation and adherence to effective regimens for prophylaxis and treatment of deep venous thrombosis and pulmonary embolism.
- Informed use of oral anticoagulants. Patients with atrial fibrillation and their clinicians should understand the potential value and hazards of both traditional and newer approaches for oral anticoagulants. For instance, lack of the need for regular monitoring, a potentially desirable feature of the newer agents in comparison to warfarin, does however place more onus on the patient to ensure that medication is taken properly, and the fact that the majority of new oral anticoagulants cannot be easily reversed if bleeding does occur is a conversation that should be held with all interested parties.
- The evaluation and management of suspected HIT is often highly variable. When indicated, a DTI can be used for patients with, or at risk of developing HIT. However, appropriate use of DTIs requires careful risk assessment, laboratory testing, and coordination across clinical specialties. (See also Opportunity Area 1: Heparin Induced Thrombocytopenia (HIT), pages 5-8.)
- Clotting factor concentrates tend to be prescribed at higher doses than actually required, particularly during nights and weekends.

Intervention Logic Model

This program will promote improved prevention, diagnosis and management of thrombosis and pre-thrombotic disorders, guide the appropriate situational use of anticoagulants and clotting factor concentrates, and insure consistent institutional knowledge of recent advances in testing and treatments. A hemostasis/thrombosis stewardship program will foster closer ties between key stakeholders, including hematology, pharmacy and laboratory medicine. It will help ensure

¹⁴ Information for this description was provided in part by Nancy Berliner, MD; Chief, Division of Hematology, Brigham and Women's Hospital; Professor of Medicine, Department of Medicine, Harvard Medical School and by Janis Abkowitz, MD, Hematology Division Head, Clement A. Finch Professor of Medicine, and Adjunct Professor of Genome Sciences at the University of Washington

clinical guidance is incorporated into the work flow (e.g., a pharmacist provides consultation and the information is inserted into the chart), that formulary guidelines for the use of new agents are established and that guidelines for clotting factor use in patients with hemophilia and other clinical situations are established. As a particular focus for resource stewardship, the program also helps ensure that work-ups for HIT are aligned with clinical indications, that work-ups necessary to diagnose HIT are available every day, and that DTIs are used appropriately.

Key Intervention Features

The primary actors in the intervention are clinicians from hematology, pharmacy, cardiology/cardiac surgery and laboratory medicine.

The first step to developing a stewardship program is to identify the baseline level of related system-wide resource use and spending and to project, based on evidence-based practices, potential improvements in quality of care, patient safety and cost savings expected to result from the program. All stakeholders should be actively engaged in order to develop strong relationships among the designated stewardship staff as well as other impacted clinicians and hospital administration. It's important that all stakeholders are exposed to and "buy in" to the proposed program.

The program can include:

- Ongoing medical literature review, including clinical trials, drug approvals, and cost or clinical effectiveness studies.
- Development of evidence-based clinical guidelines for the appropriate use of anticoagulants and clotting factor.
- Education of patients and colleagues on new options and best practices.
- Implementation of decision support within EHR/EMR systems that support appropriate practice and are compatible with existing clinician workflows.
- Bridging of care between outpatient care and procedures or hospital-based care.

System Requirements and Investments

The program, as implemented at Brigham and Women's Hospital in Boston, is set up to support a 40% hematologist FTE position. This individual will serve as the program director. In addition, along with some administrative support, a 100% pharmacy FTE is required for the program to closely follow, teach and monitor patients along with other program support activities. At the University of Washington, 0.3 FTE is funded for the Medical Director of Anti-Coagulation and Thrombosis Disorders.

Collaboration with leadership and management of EHR/EMR and other clinical information systems is ideally required for effective use of online decision support.

The program design builds upon the expectation that the director of the hemostasis/thrombosis stewardship program is a dedicated, well-respected resource for other clinicians and is interested in, and able to stay up to date with, new medical research, drug approvals, and clinical trials.

Potential Barriers

Lack of buy-in among clinical staff, both within the hematology department and in other departments with which the program will interact, could be a barrier to program success.

EHR/EMR systems may or may not be fully implemented at all organizations, so that component of the intervention may not be possible initially.

It is also important to acknowledge that all aspects of the stewardship program will not be universally applicable to all organizations (e.g., guidelines for benign hematology-centric practice may not be directly applicable in a Cancer Center setting due to specific patient needs and interactions with chemotherapy drugs).

Potential Impacts

With the influx of new compounds, therapies, and treatments, patients and providers alike must be kept abreast of developments in research and application in practice. Forming a team dedicated to clinical guideline development and patient/colleague education will ensure that best practices based on the most recent clinical publications, patient outcomes, and cost efficacy are implemented uniformly across the organization, ultimately increasing patient safety and limiting unnecessary expenses.

Preliminary measurable impact on targeted practices, such as HIT work-up and management are projected as early as 3-4 months post-stewardship implementation. After one year, it is expected that the stewardship impact on previously excessive resource use will offset program costs.

Professional Role 2: Benign Hematology Consultation and Management in an ACO Environment¹⁵

Context/Problem Statement

The current business and regulatory environment is driving practice consolidation across medical specialties. Hospital systems are incorporating local practices, and ACOs are being formed, leading to increases in the number of patients being served within a defined system of care. Due to both changes in payment policies and increased workload requirements related to practice redesign, incentives for primary care clinicians to fully work up and manage common hematology related problems such as anemia and other cytopenias are being diminished, leading to an increased number of referrals for benign hematology conditions. Further, as traditional care and referral patterns are also disrupted, unless this consolidation fully anticipates specialty care demands, increased need for benign hematology services is projected to occur in at least some care systems. This situation also may be affected by consolidation of practices focused on medical oncology that in the past have also served patients with hematology issues. The scope of the challenge is yet unknown and will depend to no small extent on the local health care system's unique patient population and referral traditions.

However, this phenomenon has been observed at a few large university systems experiencing effects of community consolidation in their practices and may provide insight and guidance if, and as, similar disruptions arise at other institutions. Without planning for such changes, the volume of benign hematology consultation requests may quickly outpace the capacity to provide such services. While benign hematology services are critical, and the patient care needed often cannot be met by internal medicine clinicians, hematology revenue streams are much harder to project. Therefore, benign hematology practice areas are becoming inundated with requests without the needed staff to support the influx.

Intervention Logic Model

The purpose of this intervention is to prepare for a potential influx of new benign hematology referral patients and therefore avoid a backlog of consultations. The desired result is organized patient flow and advance planning to eliminate patient volume issues.

Knowledge Base

Beth Israel Deaconess in Boston has its own evolving and growing health network and has purchased many local physician practices. As a result, Dr. Lowell Schnipper, the Chief of the Division of Hematology and Oncology at Beth Israel, has reported a growing volume of benign hematology consultations confronting his division and exceeding prior capacity for addressing referrals. The majority of clinicians in the division are mainly oncology-focused, have substantial research commitments supported by NIH Research Project Grants (R01s), and are less inclined or available to manage benign hematology consultations. Because this changing pattern of care

¹⁵ Information for this description was provided in part by Stanley Schrier, MD, Professor of Medicine (Hematology), Emeritus, Stanford University and by Lowell Schnipper, MD, Theodore W. and Evelyn G. Berenson Professor, Department of Medicine, Harvard Medical School; Chief, Hematology/Oncology, Beth Israel Deaconess Medical Center; Clinical Director, Beth Israel Deaconess Medical Center Cancer Center, Beth Israel Deaconess Medical Center

had not been fully anticipated, they have had to seek assistance from outside the system, hiring external individuals, paid on a monthly basis, to help cover the excess demand for inpatient and outpatient benign hematology consults. Only recently has a successful business case been formulated for hiring a benign hematologist internally to fill this role. They have recently hired a full-time salaried clinical position to focus on benign hematology clinic and referral work.

Dr. Stanley Schrier noted Stanford is also seeing a similar increased need for benign hematology consultations in their newly emerging and growing ACO-associated population.¹⁶ This need for hematology care is amplified for the Medicare beneficiaries included within the ACO; for instance, it is estimated that 5% of their Medicare ACO population will have anemia and a similar proportion may merit evaluation for a myelodysplastic syndrome.

Key Intervention Features

The main actors in this intervention are the clinicians in divisions of hematology/oncology, university faculty in hematology (if the organization is an academic institution), primary care providers in newly acquired practices, and hospital administration.

The first necessary step is to perform research to better understand the scope of the problem. It is necessary to know the number of patients involved, their medical histories, and the hematology proficiency, inclination and capacity for hematology evaluation and management of the primary care providers in the new practices. The hospital administration needs to be alerted of the incoming demand and decisions made on how best to remedy the situation and deal with the influx.

Innovators suggest that this emerging benign hematology challenge may also present an opportunity to take advantage of online e-consults. Telemedicine is evolving due to necessity and allows for new forms of communication and consults not constrained by geography, time or place. Since the acquired practices will likely be geographically dispersed, it may be much more feasible to consolidate the benign consultative roles into a single individual if benign hematology consults can be carried out via web or teleconference.

System Requirements and Investments

The goal, if justified by projected workload driven by practice reorganization, would be to hire a benign hematologist who would handle the inpatient and outpatient consults. Some institutions are considering fulfilling this role with hematology fellows late in their specialty training.

Beth Israel Deaconess has created a full-time salaried clinical position in order to hire a benign hematologist. The necessary Relative Value Unit (RVU) generation for supporting this position was estimated by projecting the number of ambulatory sessions a clinician would cover and the number of inpatients he or she would see and manage.

¹⁶ Minimum of 5,000 Medicare patients

The focus of the position will necessarily reflect the clinical needs of the hospital system or institution and the domains already occupied by other specialty areas (clinical pathology, internal medicine, etc.). For example, at Beth Israel, the newly created benign hematology position will most likely deal with hemostasis/thrombosis issues and stewardship about 50% of the time. It will also be necessary for the hired individual to handle complicated coagulation problems that can arise in other organizational specialty areas such as liver transplants, obstetrics, and cardiovascular care.

Potential Barriers

Communication, collaboration, and transparency between the hematology faculty and the hospital administration could be identified as challenges. The hospital's practice expansion agenda may not always be clearly communicated to the faculty or parties responsible for benign hematology consultation and hiring clinical staff focused on benign hematology care may be more difficult given their somewhat lower billing potential than peers primarily focused on malignant hematology or oncology care.

There are also risks if the RVUs for the created position do not meet the projection. Innovators project that it may take 1 to 2 years for referral patterns and work load to stabilize.

This new opportunity has only recently arisen and the scope of the challenge is not entirely clear. No official surveys or research have been done to identify the new patients, their history of care, and how their hematological issues have been dealt with in the past. Additionally, it is unclear from where individuals to fill this inpatient/outpatient consultative role might be sourced.

Potential Impacts

In the face of a projected consultation capacity shortfall, a designated benign hematologist can insure that patients have more timely access to benign hematology expertise. From an operational perspective, this would prevent a backlog of consultations and a potentially stressful work environment if consultation capacity is inadequate.

On balance, justification for such a role will require a demonstration that hiring a benign hematologist to handle the influx would be less costly than contracting additional, external benign hematology referral resources, if they are available, in the community served.

Summary and Potential Next Steps

The examples that have been developed range from circumscribed areas of focus that are firmly supported by evidence of impact on both quality and cost, such as the management of HIT, to more anticipatory development of roles, such as the delivery of benign hematology services in the ACO environment where practice change is being driven by alterations in patient referral patterns due to aspects of health care reform. The emerging role for stewardship of hemostasis- and thrombosis-associated care is taking root in more than one organization, while leverage of the strategy embedded within Opportunity Area 2: Use of Plasma Infusion in the Management of Thrombotic thrombocytopenic purpura (TTP) is a relatively early innovation available for, but awaiting, more widespread adoption and refinement.

The expectation is that there are likely several similar building blocks and approaches to assembling components into professional roles; how they are best combined and pursued will be a reflection of the institutions involved, and the inclination of the leaders assembling these opportunities to begin in a more limited fashion or to propose more comprehensive professional roles.

There are additional opportunities for further analysis and development of the importance and potential impact of systems-based hematologists on three levels:

- 1) *Projects and initiatives:* Several additional examples of specific topic-based use cases can be further developed into business cases; several additional examples were noted in Phase 1 of this project.
- 2) *Professional roles:* ASH members should commit to continue to collect, characterize and communicate where innovative systems-based hematology roles are being developed.
- 3) *The patient population served:* As reflected by the professional roles being developed in response to the changing payment environment, including the emergence of ACOs, planning for optimal leverage and location of benign hematology practices is increasingly a population medicine challenge. Based on the emerging scope of important benign hematology activities and the relative frequency of affected patients, it should be feasible to develop and test model(s) of likely population composition and size necessary to sustain a systems-based hematologist role assembled from among the various components.

Finally, the inclination and ability of institutions to ‘take the plunge’ and fully create a position will vary. Some settings will likely begin smaller than others, with pursuit of an intervention like HIT management, perhaps in a quality improvement context, then, ideally, building up to institutional support of a larger designated physician role.

Appendix A

Benign Hematology Intervention Business Case Template: Critical Elements

1. Context/Problem Statement (Target for the intended change)
2. Intervention logic model (text and/or flow diagram)
 - a. Higher level rationale for the intervention
 - b. Intervention target(s)
 - c. Desired result
3. Knowledge base (if applicable)
 - a. Example(s) from current practice
 - b. Literature examples
4. Key Intervention Features
 - a. Actors
 - b. Sequence of activities
 - c. Time frame
 - d. Measures of impact and success
5. System requirements and investments
 - a. Skills
 - b. Position/roles
 - c. Salary/payment model
 - d. IT
6. Potential barriers
 - a. Social/political
 - b. Technical
7. Potential Impacts
 - a. Quality of care
 - b. Cost
 - c. Patient experience
 - d. Clinician experience