Article Title: The role of hematologists in a changing United States health care system

Short title: The role of a systems-based hematologist

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Abstract
Major and ongoing changes in United States health care financing and delivery have altered opportunities and incentives for new physicians to specialize in non-malignant hematology. At the same time, effective clinical tools and strategies continue to rapidly emerge. Consequently, there is an imperative to foster workforce innovation to ensure sustainable professional roles for hematologists, reliable patient access to optimal hematology expertise, and optimal patient outcomes. The American Society of Hematology (ASH) is building a collection of case studies to guide creation of institutionally supported systems-based clinical hematologist positions that predominantly focus on non-malignant hematology. These roles offer a mix of guidance regarding patient management and the appropriate use and stewardship of clinical resources, as well as development of new testing procedures and protocols.

Background
Non-malignant hematology research continues to reveal new insights and interventions and there is growing demand for clinical expertise to guide appropriate use of the emerging approaches and tools. Simultaneously, United States health care is undergoing major structural and financial changes, including shifts in the traditional roles and incentives for many physicians with hematology training. In response, the American Society of Hematology (ASH) sought opportunities for hematologists to optimally contribute in the emerging 21st century health ecosystem through a novel and sustainable role, the systems-based clinical hematologist. We define a systems-based hematologist as a specialty-trained physician, employed by a hospital, medical center or health system, who optimizes individual patient care as well as the overall system of health care delivery for patients with blood disorders. From 2011-14 at least a dozen drugs have received marketing approvals for non-malignant hematology indications. These innovations, often associated with very high costs, require expert interpretation and guidance for clinically appropriate utilization, especially with the aging and medically complex population.

The need for a systems-based clinical hematologist is also driven by shifting payment incentives, changes in the workforce providing specialized care for non-malignant hematology problems, and changes in training. In at least some settings, changes in physician payment and organization, such as occurs with creation of accountable care organizations (ACOs), have reduced the incentives for primary care physicians to manage even common hematology cases, which compounds any shortage of hematologists by increasing demand for consultation (Stanley Schrier, Stanford School of Medicine, Personal interview, 30 January 2014; Lowell Schnipper, Beth Israel Deaconess Medical Center, Personal interview, 1 May 2014). Other specialists, including experts in medical oncology, clinical pathology, and transfusion medicine, as well as internists and pediatricians without any hematology training, are being called in to address aspects of non-malignant hematology. While all contribute, the rapid evolution and complexity of the field supports the key role for the Board certified hematologist in assuring that a community or health system can reliably deliver optimal care to the hematology patient. The undervaluing of non-malignant hematology expertise is not just an issue in the United States, but also in Canada, Europe and elsewhere.
While there is an increase in hospitalist and systems-based training and practice involving several other specialties, most hematology academic training programs have merged with oncology fellowships, with a resulting diminished focus on non-malignant hematology as a separate, sustainable discipline. Complicating this, the Accreditation Council for Graduate Medical Education (ACGME) no longer mandates the numbers of months of non-malignant hematology training that is required for a hematology-oncology fellowship program to be certified, and many no longer conform to the traditional one third non-malignant hematology, one third malignant hematology, one third solid tumor oncology model. Further, as many “classic” hematologists trained in prior decades reach the age of retirement, many newly minted physicians focus elsewhere as a principal specialty. Consequently, the time is appropriate to identify career pathways that attract and enable physicians to practice non-malignant hematology in a sustainable manner.

Not surprisingly, only a few descriptions of systems-based clinical hematology roles currently exist in the published literature. However, complex patients are increasingly prevalent and require familiarity with high acuity settings and specialized insights into the work-up and management of multifaceted hematologic conditions and complications.

Beyond the reported literature, we have identified several existing and emerging examples of hematologists in hospital and health system environments who have created practice roles and relationships that provide this critical clinical hematology expertise. Based on our observations, there is not a single role description for a systems-based clinical hematologist. Rather, the key theme is flexible adaptation to combine individual expertise and interest with larger health system needs. For instance, in addition to patient consultations, the systems-based clinical hematologist might establish and promote policies and education programs that identify hematological issues accurately and early, thereby avoiding anticipatable complications. This individual might help develop care pathways to assure the appropriate management of hospitalized patients with bleeding, thrombosis, and cytopenias. A systems-based clinical hematologist could also provide input into the appropriate use and interpretation of genomic testing and provide best strategies for how to counsel and follow individuals with an inherited predisposition for marrow failure, hematological malignancy, or thrombosis. By responding to the emerging incentives to favor high value services over a high volume of services, there is great potential that input from a systems-based clinical hematologist would result in improved stewardship of existing and emerging therapies, leading to more cost effective care both locally and regionally.

Although this forum focuses on the United States health care system, similar issues exist elsewhere, including outside of Canada and Europe. For example, Dr. Andrew Roberts commented that in Australia where hematologists have traditionally been trained dually as internists and hematopathologists, “clinicians with high-level expertise in care of acute and chronic non-malignant hematology have been squeezed out of appointments in both diagnostic laboratories and hospital departments dominated by subspecialized malignant hematology” (Andrew Roberts, Royal Melbourne Hospital, Personal communication, 27 January 2015). Although academic centers need a person fulfilling the roles described above, he feels that “the inertia of how appointments are funded and made into traditional
departments is a major barrier to filling this void.” Dr. Eduardo Rego commented that in Brazil, many of the hematologists who practice in blood banks belonging to the public health system network diagnose and manage patients with hemoglobinopathies, hemophilias and other coagulopathies; and in the north and northeast regions of the country, internists and pediatricians without any hematology training often care for these patients (Eduardo Rego, Ribeirao Preto School of Medicine, University of Sao Paulo, Personal communication, 28 January, 2015). Paradoxically, only 50 to 60% of the hematology fellowship positions are filled, which further contributes to this lack of hematologists, and suggests that practicing hematology is considered not as desirable or secure as practicing solid tumor oncology. Therefore, the concept of systems-based clinical hematologists should be applicable world-wide.

The systems-based hematologist role could be filled by a single individual or split between several hematologists with partial support to each participant. Thus an individual hematologist might combine a systems-based position with outpatient practice or with clinical or translational research activities. As health care delivery models continue to evolve as a result of payment changes and new medical care delivery organizations, it seems likely there will be expanding opportunities to pilot this role and thus promote new career opportunities for hematologists.

Interviews
To understand their progress and challenges, semi-structured hour-long interviews were conducted by one of the investigators with 14 innovating clinical hematologists identified either by ASH or by other interview participants. The project was reviewed and determined to be exempt from institutional review board (IRB) oversight. Two webinars were also convened, bringing together interview participants plus additional leading hematologists to refine and comment on the preliminary compilation of findings.

Key interview findings include:

- These prototype systems-based hematologists have a core clinical focus on non-malignant hematology and augment this with a diverse range of other professional activities.
- Although the portfolios varied, they generally fit four patterns:
  - Fulltime Clinical Practice (e.g., consultant practice, outpatient clinic-based, academic clinical service attending)
  - Academic Practice (e.g., clinical/bench researcher, fellowship training director, clinical educator, medical education researcher, other academic administrator)
  - Quality Management plus Practice (e.g., guidelines and protocols, resource stewardship and formulary management, patient safety and malpractice mitigation)
  - Service Director/Management plus Practice (e.g., anti-coagulation clinics, hemophilia center, sickle cell center, apheresis, transfusion medicine, special coagulation laboratory, bone marrow interpretation)
- Participants worked across a diverse set of institutions (e.g., integrated delivery system, academia, hospital/hospital system, large hematology/oncology group) and included salaried and non-salaried physicians plus capitated and fee for service payment systems.
- They also described widely varying relationships with medical oncology colleagues and practices that were driven by their local institution and community needs.
The range of clinical hematology expertise included transfusion management, anticoagulation oversight, and understanding how and whether to work up a cytopenia or possible hypercoaguable state. Since all of these areas are dynamically evolving, for example because of newly available medications such as dabigatran, rivaroxaban, and apixaban, all participants commented on the need to develop, systematically track, and communicate emerging clinical and operational insights within larger practice communities. These institutionally-based clinical hematologists also frequently are engaged in various other systems-based roles, such as an information technology specialist, hospital quality control officer, and safety officer. Several areas for a clinical or quality improvement that were noted repeatedly in the interviews are listed in Table 1.

Innovative new models for sustainable non-malignant hematology practice

Further examination characterized four representative activities and their supporting rationales. These examples of a systems-based hematologist are not intended to be all encompassing or even necessarily the most compelling across all settings; rather, they illustrate elements upon which a more complete role must be built and required within a high value health care delivery system.

The specific examples range from discrete tasks that are firmly supported by evidence of impact on both quality and cost, such as the management of heparin-induced thrombocytopenia (HIT), to more anticipatory development of discrete responsibilities, such as the delivery of non-malignant 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 (Table 2). These components could 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.

Heparin-induced thrombocytopenia (HIT)

Heparin-induced thrombocytopenia, while relatively uncommon, can result in substantial morbidity, mortality and costs, especially if not readily recognized and managed appropriately. Suspicion for HIT is typically triggered by a falling platelet count in the setting of heparin administration. Diagnosing HIT requires specialized testing services and treatment often involves intravenous administration of direct thrombin inhibitors (DTIs), which carry both a high cost and a risk of causing hemorrhage. Inappropriate laboratory testing and incorrect diagnosis can result in unnecessary DTI use, prolonged hospital stays, and misallocation of laboratory resources. There are several HIT interventional approaches currently used in practice. One focuses on implementing quality improvement and economic outcome initiatives and the other is a recognition and management protocol. The systems-based hematologist could create overall value and care improvement by implementing care pathways that reduce unnecessary heparin exposure, optimize the application of laboratory testing for suspected HIT, and reduce unnecessary DTI use in patients.

Thrombotic thrombocytopenic purpura (TTP)

Thrombotic thrombocytopenic purpura is a devastating illness with mortality greater than 90% if not diagnosed and treated early. Treatment involves substantial plasma replacement. In some instances,
25-50% of a health system’s yearly plasma volume may be utilized for a few patients with TTP (N.T.C. and Joseph D. Sweeney, unpublished data, December 18, 2013). 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.\(^{19}\) Therapeutic plasma exchange can reduce the mortality from 90% to approximately 13%,\(^{19}\) although complications from plasma exchange are not uncommon.\(^{20}\)

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). Currently, the assay of this enzyme in specialized laboratories often has a turnaround time of 10-14 days. Though not a gold standard, assays for ADAMTS13 can be used in conjunction with clinical judgment to improve the upfront diagnosis of TTP. Local implementation by a systems-based hematologist of a rapid turnaround assay for ADAMTS13 may reduce system-wide plasma utilization for TTP. This approach to stewardship, which is available in some academic institutions, is awaiting more widespread adoption.

Medical director for hemostasis/thrombosis
There are several examples of systems-based hematologist-led organizational hemostasis/thrombosis stewardship programs that are designed to broadly and systematically address coagulation-related disorders within a medical center or delivery network. Mostly located in academic medical centers, these programs are designed to foster collaboration across medical specialties 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. Examples of how 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, evaluation and management of suspected HIT and correct use and dosages of clotting factor. This opportunity is amplified by the influx of new compounds, therapies, and treatments, where patients and providers alike must be kept abreast of developments in research and application in practice.

Non-malignant hematology consultation in an ACO environment
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. Concurrently, incentives are being diminished for primary care clinicians to fully work up and manage common hematology-related problems such as anemia and other cytopenias, leading to an increased number of referrals for non-malignant hematology conditions. This phenomenon has been observed at a few large university systems experiencing effects of community consolidation in their practices (Stanley Schrier, Stanford School of Medicine, Personal interview, 30 January 2014; Lowell Schnipper, Beth Israel Deaconess Medical Center, Personal interview, 1 May 2014) and may provide insight and guidance if, and as, similar disruptions arise at other institutions.
In the face of a projected consultation capacity shortfall, a designated and funded non-malignant hematologist can insure that patients have more timely access to hematology consultations. Justification for such a role by a health system or clinic will require a demonstration that hiring a hematologist to handle the influx of consultations would be better integrated and ideally less costly than contracting additional, external non-malignant hematology referral resources, if they are available, in the community served. This is especially important because hematology encompasses many rare disorders for which phase 3 studies and level 1 evidence do not exist, and thus physiological insights, synthesis of the literature, and clinical judgment are critical for patient care decisions. This may explain why the “How I Treat” article series published in Blood is accessed so frequently. For the 33 articles published within the past 2 years, there were 2095 mean hits per article per month (range 787-4975).

Next Steps
The expectation is that there are likely several similar building blocks and approaches to assembling components into robust and attractive professional roles; how they are best combined and pursued will be a reflection of the institution’s and health system’s needs and the inclination of the leaders and innovators involved. Also, as planning for optimal leverage and location of hematology practices that focus on non-malignant hematology is increasingly a population medicine challenge, 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.

We anticipate that the ability of institutions to fully create a position will vary. Some settings will likely begin small, 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 clinical hematologist role. ASH is interested in learning of innovations both small and large that have proven their value in improved patient care.

We see this is a unique opportunity for hematologists to design new models for care delivery and demonstrate their ability to improve clinical outcomes while maintaining or reducing costs. We recommend that health systems evaluate the outcomes, using established epidemiologic methods such as policy analysis, health-technology assessment, time-series analysis and quality of life assessment. Also, diagnostic and therapeutic algorithms should be evaluated based on decision models incorporating outcomes and costs. The informal evaluation and sharing of best-practices will be equally valuable. ASH is collecting business plans that justify these roles and will anonymize them and make them available to Society members to use in negotiations at their institutional sites.

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Authorship
Contribution: Paul Wallace directed the interviews and research. All authors assessed the data and contributed to the preparation of the manuscript.

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References


Table 1. Common areas of focus for clinical or quality improvement noted in interviews with hematologists

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<th>Common Areas of Focus</th>
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<td>Quality Management/Guidelines</td>
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<td>Heparin-induced Thrombocytopenia (HIT) screening and management</td>
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<td>Treatment of bleeding in the anticoagulated patient</td>
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<td>Sickle cell disease management and day hospitals</td>
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<td>Appropriate Use of Resources</td>
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<td>Appropriate use of transfusion services and products</td>
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<td>Clotting factor management (factor VIIa, prothrombin complex concentrations)</td>
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<td>Standardization of anticoagulation practices</td>
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<td>Infusion protocols</td>
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<td>Genomic testing, assessing risk and designing follow-up</td>
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<td>Optimal use of growth factors</td>
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<td>Pre-operative hematology evaluation/anemia in the elderly</td>
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Table 2. Four representative models assessed by scale of activity and the degree of evidence and existing experience

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<th>Degree of Evidence and Existing Experience</th>
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<td>Early/More Speculative</td>
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<td>Scale</td>
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<td>Role</td>
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<td>Small/Individual Initiative</td>
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