Poster abstracts

Erythropoiesis-stimulating agents

Impact of limiting erythropoiesis-stimulating agent use for chemotherapy-induced anemia on the United States blood supply

Francis Vekeman,[1] Brahim K. Bookhart,[2] Mei Sheng Duh,[3] R. Scott McKenzie,[2] Patrick Lefebvre,[1] and Catherine Tak Piech[2]

[1] Groupe d'analyse, Ltée, Montréal, Québec, Canada;
[2] Ortho Biotech Clinical Affairs, LLC, Bridgewater, NJ; and
[3] Analysis Group, Inc., Boston, MA

Background Between 1987 and 1997 safety concerns decreased demand for allogeneic blood. Simultaneously, collection declined from 13.6 to 11.9 million units, resulting in a 48% marginal reduction between available supply and demand *(Sullivan MT et al. Transfusion 2005;45:141–148)*. The margin has further declined, exacerbated by procedures used for qualifying fully screened units. Resultant periodic shortages in the blood supply have been moderated by use of erythropoiesis-stimulating agents (ESAs) for patients with chemotherapy-induced anemia (CIA). Here, the impact of limiting the use of ESAs for CIA on the United States blood supply is estimated.

How we did it A top-down modeling simulation compared the number of red blood cell (RBC) units transfused in ESA-treated patients with those that would be transfused if ESAs were discontinued or limited. The result of this analysis was then contrasted with the latest available data from 2004 on the marginal US blood supply. Model inputs from the literature or expert opinion included incident cases of ESA-treated patients with CIA, clinical trial transfusion rates, and volume of RBC units required for ESA-treated and ESA-untreated patients. Sensitivity analyses also were conducted.

TABLE 1

Estimated impact of limiting ESA use on blood supply

	Percent reduction in ESA use			
	25%	50%	75%	100%
Incremental RBC units transfused	118,602	237,203	355,805	474,407
Percent marginal blood supply to cover incremental demand	18%	37%	55%	73%

ESA = erythropoiesis-stimulating agent; RBC = red blood cell

Impact on practice and patients It was estimated that 492,002 incident patients with CIA received a total of 372,809 RBC units despite ESA treatment. Table 1 presents the model predictions.

Looking ahead Limiting ESA use in patients with CIA imposes considerable pressure on the US blood supply and does not consider regional and seasonal variations in the number of available units and donation frequency.

Hemoglobin levels prior to blood transfusions in oncology patients receiving chemotherapy and erythropoiesis-stimulating agents (ESAs): observational data from the Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies (DOSE) registry

Kay Larholt, Tanya Burton, Chris L. Pashos, Brahim K. Bookhart, Catherine Tak Piech, and R. Scott McKenzie

Abt Associates, Lexington, MA, and Ortho Biotech Clinical Affairs, LLC, Bridgewater, NJ

Background Blood transfusions in oncology patients occur at various hemoglobin (Hb) levels based on underlying malignancy, treatment, and comorbidities. Minimal data on Hb levels at which transfusions occur (transfusion triggers) are available.

How we did it Real-world data on ESA-treated patients in US oncology clinics were analyzed from an ongoing, prospective, observational registry, the DOSE registry. Data were collected from participating hospital- and community-based outpatient practices between December 2003 and July 2007. Hb values within 3 days before transfusion were assessed and summarized. If multiple Hb values were recorded, the lowest Hb value was reported.

Impact on practice and patients Of 334 transfusions, 314 had a Hb value reported within 3 days. The transfusion trigger ranged from 5.4 to 11 g/dL. In all, 64% of transfusions occurred at a Hb value $\geq$ 8 g/dL, including 19% occurring at a Hb level $\geq$ 9 g/dL and 4% at a Hb level > 10 g/dL (Table 2). Subgroup analyses by age (< 65 years vs $\geq$ 65 years) and payer type (Medicare vs other) demonstrated similar findings.

Looking ahead In this analysis of DOSE registry data, transfusion triggers in ESA-treated oncology patients varied considerably, with most transfusion events occurring at a Hb level $\geq$ 8 g/dL and approximately 1/5 transfusions occurring at a Hb value $\geq$ 9 g/dL. Further analyses should explore patient characteristics or other factors to explain this variation.

© 2008 Elsevier Inc. All rights reserved.

TABLE 2

Number and percentage of transfusions triggered by different hemoglobin values

	Hemoglobin value triggering transfusion (g/dL)					
	< 7.0	7.0–7.9	8.0–8.9	9.0–9.9	10.0-10.9	11
All patients						
Number of transfusions (%) (n = 314)	14 (4%)	96 (31%)	141 (45%)	48 (15%)	14 (4%)	1 (0.3%)
Subset by age						
Age ≥ 65 years (n = 155)	8 (5%)	47 (30%)	70 (45%)	20 (13%)	10 (6%)	0 (0%)
Age < 65 years (n = 159)	6 (4%)	49 (31%)	71 (45%)	28 (18%)	4 (3%)	1 (1%)
Subset by payer type						
Medicare (n = 150)	8 (5%)	47 (31%)	61 (41%)	22 (15%)	12 (8%)	0 (0%)
Other insurer (n = 164)	6 (4%)	49 (30%)	80 (49%)	26 (16%)	2 (1%)	1 (1%)

Transfusion outcomes among oncology patients initiated with erythropoiesis-stimulating agents (ESAs) at baseline hemoglobin levels of < 10 g/dL vs 10–11 g/dL: observational data from the Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies (DOSE) registry

Kay Larholt, Tanya Burton, Chris L. Pashos, Brahim K. Bookhart, Catherine Tak Piech, and R. Scott McKenzie

Abt Associates, Lexington, MA, and Ortho Biotech Clinical Affairs, LLC, Bridgewater, NJ

Background The 2007 American Society of Clinical Oncology/American Society of Hematology practice guidelines on the use of ESAs in cancer patients continue to recommend initiation of ESA therapy as the hemoglobin (Hb) level approaches or falls below 10 g/dL *(Rizzo JD et al. Blood 2008;111:25–41)*. Observational data on transfusion utilization outcomes in patients initiated on ESAs at different baseline Hb levels have not yet been reported. Transfusion outcomes in chemotherapy-treated oncology patients who were initiated on ESA therapy at a baseline Hb level of < 10 g/dL versus 10–11 g/dL were compared.

How we did it Observational data from an ongoing, prospective registry of ESA-treated patients in US oncology clinics between December 2003 and July 2007 were analyzed. Both hospital- and community-based outpatient practices were included. Data were analyzed from adult chemotherapy-treated patients receiving ≥ 2 doses of an ESA and who had transfusion-related outcomes.

Impact on practice and patients A total of 969 patients (including 341 patients who initiated ESA therapy at a Hb value < 10 g/dL and 628 patients who initiated ESA therapy at a Hb level = 10–11 g/dL) from 48 sites were included. Primary cancer, gender (63% women), and age (mean, 62.6 years) were similar in both groups. A significantly greater proportion of patients started on ESA therapy at a baseline Hb value < 10 g/dL required transfusions, and this group received significantly more units of blood (Table 3). These trends were maintained from day 28 to the end of the study.

Looking ahead Data from the DOSE registry show that initiating ESA therapy at a Hb level of 10–11 g/dL, compared with a Hb level < 10 g/dL, may reduce transfusion requirements and result in improved hematologic outcomes.

TABLE 3

Effect on transfusion requirements of initiating ESA therapy at different hemoglobin levels

	Baseline hemoglobin level		
	<10 g/dL (n = 341)	10–11 g/dL (n = 628)	*P* value
Patients requiring transfusions from day 1 to end of study	31%	14%	< 0.0001
Patients requiring transfusions from day 28 to end of study	16%	9%	0.0008
Mean units transfused/ study patient, day 1 to end of study	0.89	0.44	< 0.0001
Mean units transfused/ study patient, day 28 to end of study	0.44	0.27	0.02
Mean ESA treatment duration (days)	59	58	NS

ESA = erythropoiesis-stimulating agent; NS = not significant

Rare cancers

Head and neck angiosarcoma with pneumothorax secondary to cystic pulmonary metastases

Mohammad Y. Alsawah, Ishmael Jaiyesimi, Michael H. Lazar, and Sharath Bhagavathi

William Beaumont Hospital, Royal Oak, MI

Angiosarcomas of the head and neck are rare, highly aggressive malignant tumors of vascular origin. Pulmonary metastases from these tumors, in the form of parenchymal nodules, are common and can occasionally cause hemothorax secondary to their rupture. We describe a case of metastatic angiosarcoma characterized by multiple small pulmonary cysts without intracavitary growth or bleeding. The rupture of one cyst caused pneumothorax without accompanying pleural effusion. A review of the recent medical literature showed few case reports of malignant metastasis in the form of thin-walled cysts with or without intracystic bleeding or growth. No correlation between the different radiologic forms of pulmonary metastases and certain biologic tumor markers has been investigated yet.

Drug reimbursement

The Medicare Modernization Act of 2003: impact on pharmacy services in community-based oncology practices

Elaine L. Towle, and Thomas R. Barr
Oncology Metrics, Dallas-Fort Worth, TX

Background The Medicare Modernization Act of 2003 (MMA) created the most sweeping reforms to Medicare since the inception of the program in 1965. MMA is most well known for the initiation of a prescription drug benefit for Medicare beneficiaries. Provisions of the MMA also added coverage for screenings and other preventative care services and created health savings accounts. The most significant provisions to the medical oncology community, however, concern payment for drugs and drug-administration services. The changes implemented by MMA have had a dramatic impact on the practice of medical oncology in the community setting.

How we did it Oncology Metrics collected data from two independent data sources from 2004 through 2006. The Oncology Circle is a knowledge-sharing national network of community-based oncology practices facilitated by Oncology Metrics. Oncology Circle practices provide financial and operational data to Oncology Metrics twice a year; Oncology Metrics aggregates this practice management and financial information and provides benchmarking services to enable members to improve their operational and financial performance. In addition to the Oncology Circle, Oncology Metrics has implemented a benchmarking survey for community-based oncology practices on behalf of a national drug distributor. Both the Oncology Circle and the benchmarking survey rely on self-reported data from community oncology practices.

Impact on practice and patients Survey results show an annual increase in the cost of drugs per full-time equivalent (FTE) medical oncologist of approximately 20% from 2005 to 2006. Drug cost as a percentage of total practice cost has also risen, although at a less dramatic rate. Drug margin as a percentage of drug cost began to drop when MMA was implemented in 2004. We saw gradual drops from 2003 to 2004 and again from 2004 to 2005. The change from 2005 to 2006 was far more dramatic, averaging 16%–18%. Nationally, we have observed a decrease in drug margin as a percentage of drug cost of approximately 30% from 2002 to 2006. Practices have implemented a variety of strategies in response to these changes, including decreasing inventory levels, more aggressively managing drug purchasing, closing satellite offices, and implementing staff changes.

Looking ahead Community-based oncology practices continue to respond to the impact of MMA. Data from national surveys show a dramatic impact on drug margins, with a corresponding impact on operations and the practices' bottom line. Practices must continue to monitor these issues closely and make changes in their practice in response to these economic pressures.

Complementary/alternative medicine

The prevalence of the use of complementary/alternative medicine by cancer patients

Rajesh Thirumaran, Paul Gilman, and Mary Denshaw Burke
Lankenau Cancer Center, Wynnewood, PA

Background Complementary and alternative medicine treatments are believed to be prevalent, and their use is considered to be increasing. This study was done to assess their prevalence and the reasons for their use.

How we did it Subjects were cancer patients attending the outpatient clinic of the Lankenau Cancer Center, Wynnewood, PA. After obtaining written informed consent, we asked patients to complete a self-administered questionnaire on their knowledge and use of complementary/alternative medicine.

Impact on practice and patients Of the 50 participants, 70% of the patients had used at least one complementary/alternative medicine approach. Use was greatest for high-dose vitamin therapy and herbal therapy. Most patients had learned about complementary/alternative medicine from another cancer patient.

Looking ahead The use of complementary and alternative medicine is common among cancer patients. Given the number of patients using this approach, more research needs to be done to determine the possibility of complementary medicine-chemotherapy interactions.

The "AboutHerbs" Web site

K.S. Yeung, J. Gubili, and B.R. Cassileth
Integrative Medicine Service, Memorial Sloan-Kettering Cancer Center, New York, NY

Background Use of dietary supplements has been on the rise over the past 2 decades. Surveys show that a majority of cancer patients use supplements during and after treatment in hopes of cure and for symptom relief. However, the safety and efficacy of most herbal remedies have not been studied. Further, there is potential for herb-drug interactions. For example, when taken concurrently, St. John's Wort can lower the plasma levels of irinotecan (Camptosar), a chemotherapy drug, by almost 40%. Botanicals that exhibit estrogenic effects may stimulate proliferation of hormone-sensitive cancers. Information on herb-drug interactions is essential but is not easily available to oncology professionals.

How we do it The Integrative Medicine Service at Memorial Sloan-Kettering Cancer Center developed a free Web site, "AboutHerbs" (http://www.mskcc.org/aboutherbs), that offers evidence-based, timely, and objective information about dietary supplements and unproved cancer treatments. The Web site contains 228 monographs and is updated regularly.

Impact on practice and patients "AboutHerbs" registers one million hits annually. Practitioners and patients use this Web site as a source of reliable, updated information about dietary supplements. The "AboutHerbs" team also responds to inquiries on a daily basis.

Looking ahead The "AboutHerbs" Web site will continue to provide valuable information about herbs, vitamins, dietary supplements, and unproved methods of cancer treatment. A list of herbs that interact with cytochrome P450 (CYP) enzymes or have estrogenic effects is in preparation. This Web site serves as a quick reference to over-the-counter remedies, unconventional methods, and herb-drug interactions in cancer care.

Oncology treatment guidelines

Use of treatment guidelines to create chemotherapy selection and patient care tools for community oncology practices

C.G. Baker, K.B. Whitlock, I.A. Aksamit, J.W. Ganz, L. Friedman, S.W. Angelides, N.L. Martinez, and K.A. Bergstrom
McKesson Corporation/National Oncology Alliance, San Rafael, CA

Background The resources required to evaluate evidence supporting chemotherapy or supportive care treatments, standardize care, and create patient care tools are generally unavailable to community oncology practices. Oncology pharmacists and nurses at the National Oncology Alliance (NOA) have developed Web-based tools to assist with these processes.

How we do it Our clinical team produces nationally recognized, evidence-based treatment guidelines addressing cancer and supportive care treatments, including drug dosing and administration recommendations. Once the guidelines have been vetted by oncology thought leaders, we incorporate their content into Web-based tools that the practice can implement. These guidelines include a regimen analysis tool that provides side-by-side comparisons of efficacy and side effects, cost, and reimbursement; preprinted, customizable patient assessment and medication ordering forms; customizable patient education handouts; and patient treatment-based financial assessment and counseling checklists.

Impact on practice and patients Using Web-based guidelines, the regimen analysis tool, and assessment and order forms helps a practice establish standards of care, optimize therapy and resource utilization, increase efficiency, minimize medication errors, and contribute to quality measurement. Implementation of financial assessment tools enables the practice to proactively conduct financial counseling, helping patients anticipate costs and avoiding delayed or compromised completion of therapy. Treatment adherence and timely reporting of side effects are enhanced by use of patient education handouts, to which practice name and contact information can be added.

Looking ahead Future uses for our clinical content include integrating guideline recommendations into an electronic medical record system, creating treatment algorithms for selecting and monitoring oral chemotherapy, and establishing and reporting quality benchmarks.

Clinical trials management

Efficiencies of a centralized clinical trial network model

Leavell A. Wall, Jr., Daniel W. Davis, and Lee Scheible
Eli Lilly and Company, Indianapolis, IN

Background With escalating economic pressures, onerous regulatory requirements, and ever-increasing demands on clinicians in their practices, the "single-site" clinical research model for clinical trial participation has become increasingly inefficient for both sponsors and investigators.

How we do it In contrast, the Centralized Clinical Network Model (CCNM) offers community-based researchers an opportunity to contribute to cutting-edge clinical trial research without making a significant investment in the investigatory infrastructure. In addition, it avails their patients the benefit of potentially life-enhancing

therapy without the need to travel to a "research center."

Impact on practice and patients CCNMs provide a variety of centralized administrative services, such as clinical trial management and regulatory, safety, financial services, that ensure consistency in clinical trial progression for all of the sites enrolled and, at the same time, frees up investigators to focus on the needs of their patients.

Looking ahead The CCNM offers a winning combination for patients, investigators, and sponsors alike. CCNMs benefit patients by offering access to newer, innovative therapeutic modalities; researchers are afforded opportunities to participate and publish through their involvement in novel clinical trials; and sponsors benefit by closer scientific collaboration with external investigators, a more diverse patient population accruing to their clinical trials, more robust clinical trial designs, and more efficient and rapid trial initiation and completion timelines.

Extending oncology care

Partnering in practice: hospice social worker in a private physician practice

Kim Arrington
Consultants in Blood Disorders and Cancer, Louisville, KY

Background The presence of a hospice social worker in a private oncology practice has developed into an innovative model that provides unique psychosocial support to patients and families. A hospice partners with a physician oncology practice to provide a full-time social worker. This individual is a hospice employee for administrative, educational, and supervision purposes. The salary plus benefits is paid by the physician group to hospice.

How we do it Although oncology social workers often work with hospice, this particular model was not found in the literature. However, another hospice within the state has contracted for a social worker within a radiation oncology practice.

Impact on practice and patients For patients, this partnership means that the social worker, as an integral part of the practice, screens them at their first visit and is available to them at any point in their illness. Patients believe that the physicians and staff must truly care about them to have provided this service. They appreciate that someone is available on their time frame, when they are ready to discuss difficult issues. They also perceive being treated as a "whole" person, not just a "disease." For the social worker, the hospice background and perspective provide the unique skills necessary to assist patients and families deal with life-threatening illnesses. This assistance may include having family meetings for "difficult conversations"; providing counseling, education, and support related to living with cancer and management of their disease; clarifying perceptions of hospice and other services; and pointing out unique resources, referrals, and the like.

Looking ahead The physicians and staff have been supportive of this partnership. They find that they are able to better focus on the medical management of the patient. Specific patient questions or needs are not delayed but can be immediately addressed by the social worker, who is already a person familiar to the patient and family. The social worker is also a resource and support to the staff. Benefits to hospice include an improved relationship with the physician practice, a better understanding of hospice services within the community, and continuity of care for patients and families.

Community cancer genetic counseling services: a unique model

Eric Fowler
Baptist Centers for Cancer Care, Memphis, TN

Cancer genetic counseling services are being increasingly incorporated into the community oncology setting. Genetic counselors do not have licensure in most states, and reimbursement for the newly developed CPT code 96040, "Medical Genetics and Genetic Counseling Services," is variable and evolving. We have developed a model in which genetic counselors are hospital employees, and genetic counseling services are provided on a contractual basis with local oncology practices. The success of the program is measured by the consistent annual increases in patient referrals, the associated expenses for the clinics and hospital, and the numbers of patients identified with hereditary cancer risks.

Outpatient radiofrequency ablation: our experience at The West Clinic

Thomas D. Hodgkiss
The West Clinic, Memphis, TN

Background A total of 80 radiofrequency ablations have been performed in 63 patients at The West Clinic over the past 2 years. Radiofrequency ablation has been performed on lung metastases, lung primaries, hepatic metastases, and renal cell primaries and metastases, as well as lung metastases from melanomas. Palliative treatment has also been successfully performed on peritoneal ovarian metastases and bone metastases.

Impact on practice and patients Radiofrequency ablation has been done effectively and safely in the outpatient setting. The solitary major complication has been pneumothoraces requiring placement of a chest tube. The radiofrequency procedure was performed following chest tube placement. The patients were sent home with the chest tube and treated accordingly as outpatients. Follow-up has shown significant success in the appropriate lesions.

Looking ahead Radiofrequency ablation can be successfully and safely performed in the outpatient setting.