Original Article

Surviving the Perfect Storm: An RVU-Based Model to Evaluate the Continuing Impact of MMA on the Practice of Oncology

David M. Dunning, MD, and Thomas A. Paivanas, MHSA, *Fairfax, Virginia*

Key Words

MMA, reimbursement, cost accounting, practice administration, RVU, financial protocol analysis, practice financial management

Abstract

The Resource-Based Relative Value Scale (RBRVS) system instituted by Centers for Medicare and Medicaid Services has lead to the implementation of a new financial analysis paradigm based on relative value units (RVUs). RVU-based financial tools have great potential to allow in-depth analysis of all components of the cancer care delivery system. Because all medical oncology practices must become conversant in RVU terminology and methodology, RVU-based financial tools will allow standardization and benchmarking for intra- and interpractice comparisons. Understanding this approach is essential for sound business management. The emotional and financial pressures facing the medical oncologist in private practice are enormous, with no real relief in sight. The complexity of managing the business of private practice oncology rivals that of managing the complexity of cancer care. With anticipated reductions in total net revenue per clinical treatment protocol per course of care, funds available for providers and their practices will be severely reduced. Only those practices with superlative RVU-based cost and revenue accounting systems will be able to prospectively and efficiently manage their businesses. Clearly, management of the Oncology Practice Econometric Model (OPEM) expense RVU or similar RVU-based data will be required for survival. The purpose of this article is to explore an RVU-based model to analyze the professional, infusion, and therapeutic components of contemporary cancer care. (*JNCCN* 2006;4:3–15)

From the DD-TAPA, Fairfax, Virginia.

Submitted August 8, 2005; accepted for publication October 14, 2005.

Neither author has received any financial consideration from any person or organization to support the preparation, analysis, results, or discussion of this article.

Correspondence: Thomas A. Paivanas, MHSA, DD-TAPA, 4440 Sleaford Road, Annandale, VA 22003. E-mail: paivanas@verizon.net

The increasing sophistication of treatment and the resulting costs of cancer care have rapidly increased the burden on public payers, private payers, and patients. An estimated 1.37 million people will be diagnosed with cancer in 2005, with approximately 570,280 succumbing to the disease.[1] The 5-year relative survival rate for all cancer diagnosed between 1995 and 2000 is 64%, up 50% from 1974 to1976.[1] The National Institutes of Health estimated overall costs for cancer in 2004 at $189.8 billion: $69.4 billion for direct medical costs (total of all health expenditures); $16.9 billion for indirect morbidity costs (cost of lost productivity because of illness); and $103.5 billion for indirect mortality costs (cost of lost productivity because of premature death).[2] Table 1 summarizes the drivers of change for oncology practices and areas of potential impact from those drivers.

In the United States, 80% of all cancer care occurs in the community setting, with more than 85% of all chemotherapy delivered in the private practice setting.[3] Since the 1970s, the number of therapeutic agents in the medical oncology armamentarium has increased dramatically, as evidenced by the steadily expanding number and complexity of drugs and biologics in *The NCCN Drugs and Biologics Compendium*.[4] Associated with this increase in therapeutic agents is a corresponding increase in the complexity of financial and clinical decision-making for the medical oncologist. The number and breadth of peer-reviewed journals devoted to treatment of the oncology patient reflect this clinical cognitive burden.

Unfortunately, the financial complexities of oncology care delivery have not been adequately recognized, quantified, or analyzed. The legislative and regulatory actions that led to the passage of the Medicare Prescription Drug, Improvement, and Modernization

Table 1 The Complexity of Oncology Practice is Approaching the Complexity of Managing the Oncology Patient

Drivers	Private Practice of Oncology
Federal and state legislation	Quality of care
Regulation and reimbursement →	Volume, productivity, relative market share
Managed care, carve outs disease management	Bottom line
Competition and consolidation	
New technologies, medicines and procedures	
Consumer, employer and provider activism	
Medical manpower	

Act of 2003 (MMA)[5] resulted in a disproportionate focus on limiting therapeutic-agent reimbursement without adequately addressing reimbursement for cognitive (professional and infusion) services. In most practices, 65% to 75% of revenue is derived from therapeutic-agent reimbursement and 50% to 60% of costs are related to their purchase.[6] This focus on therapeutic agents ignores the variation of costs and revenues for professional and infusion services within clinical treatment protocols for a course of care.

In this environment, oncologists are faced with increasing practice management demands, and the confluence of these fiscal pressures threatens the viability of oncology practices. In the current climate, oncologists must have more sophisticated financial tools that will allow them to assess their ability to deliver cancer care.

Traditionally, oncology practices have relied primarily on accounting-centric analyses to aid them. All components (professional, infusion, and therapeutic agents) of cancer care delivery must be analyzed to determine whether care can be delivered. As discussed and advocated at the Oncology Business Management Issues in the Changing Reimbursement Environment session at the Annual 2005 American Society for Clinical Oncology (ASCO) meeting,[7] all practices will need some methodology to allow them to more carefully and precisely manage their costs and revenue. The Resource-Based Relative Value Scales (RBRVS), also known as the Physician Payment Reform Provisions, were enacted by congress in 1989[8] as part of an effort to restructure Medicare part B payments for outpatient services. Effective January 1, 1992, this RBRVS system, based on relative value units (RVUs) and instituted by Centers for Medicare & Medicaid Services (CMS), has lead to the implementation of a new financial analysis paradigm. RVU-based financial tools have great potential to allow in-depth analysis of all components of cancer care delivery. Because all practices must become conversant in RVU terminology and methodology, RVU-based financial tools will allow standardization and benchmarking for intra- and interpractice comparisons. Understanding this approach is essential for sound business management.

The purpose of this article is to explore an RVU-based Oncology Practice Econometric Model (OPEM) to analyze the professional, infusion, and therapeutic components of contemporary cancer care. Although OPEM can be used to evaluate all payer environments, this discussion focuses on Medicare in the private practice setting.

Methods and Assumptions

The passage of the MMA prompted the development of OPEM, which evolved in scope and complexity in concert with the changing clinical and financial demands of oncology practice. OPEM was the result of a determined effort to embrace existing business tools and commonly collected practice data to develop a user-friendly physician-centric tool. OPEM provides a software modeling tool that allows clinicians to understand and address factors that affect a practice's financial viability and ability to deliver optimal patient care. The intent is to improve effective business decision making by integrating clinical, financial, and operational information around the core oncologist activity, which is employment of a treatment regimen or clinical treatment protocol.

The need to standardize the measurement of clinical activity was a challenge in developing OPEM. To meet this need, we used the RBRVS system employed by CMS. As delineated by CMS, each clinical activity is defined by current procedural terminology (CPT) codes[9] and is given a weight or relative value (RVU) on which Medicare reimbursement is then calculated. We have embraced this system and extended its use

to construct an OPEM Expense RVU that drives protocol-based econometric analyses.

Confidential data were collected from 13 private practices in geographically diverse areas, including the Middle Atlantic, West North Central, South Atlantic, West South Central, and Mountain regions as defined by the U.S. Census Bureau. All practice identities and data are held in strictest confidence with signed non-disclosure statements.

OPEM© Model Data Requirements

Several specific practice data elements are required for OPEM development, including:

- Practice productivity profile, volume by CPT code
- Practice expense profile, factoring out physician compensation and benefits
- Drug acquisition costs, not including rebates, and representing an average of the practices surveyed and third quarter 2005 data

OPEM uses the following information from CMS:

- RVUs assigned to each CPT code
- Geographic practice cost indices (GPCI)
- Physician conversion factor for Medicare payment
- Average sales price (ASP) to determine Medicare drug reimbursement

The construction of OPEM protocol-based output requires the development of 3 protocol components and an OPEM expense RVU. The 3 protocol components include:

1. *Infusion services:* chemotherapy administration services as defined by G codes
2. *Therapeutic agents:* chemotherapy, biologics, solutions, and supportive care drugs as defined by J and Q codes
3. *Professional and diagnostic services:* as defined by CPT codes; comprises essential cognitive activities and laboratory testing that occurs during and between therapeutic agent administration

The OPEM expense RVU measures the cost-efficiency and operational effectiveness of the practice and is used with the protocol components to determine financial viability.

The calculation of the OPEM expense RVU consists of:

- *OPEM productivity factor (OPF):* 12-month summary of inpatient and outpatient evaluation and management (E & M) volume and levels from all providers multiplied by their respective RVU to give the resultant total RVU production for the practice (GCPI modifier employed).
- *OPEM net expense factor (ONEF):* 12-month summary of all direct and indirect practice expenses (e.g., salaries, facilities, equipment, supplies, purchased services)
  - Minus therapeutic agent costs
  - Minus physician compensation and all direct and indirect benefits
  - Minus non-clinical revenue (e.g., research, investments, directorships)
  - Inclusive of mid-level provider costs and revenues
- OPEM expense RVU = ONEF/OPF = expense per RVU generated
  - Reflects cost-efficiency and operational effectiveness of the practice

Many factors can affect a practice's OPEM expense RVU. The OPEM expense RVU is not primarily a function of practice size, rather, it reflects fiscal leanness and operational efficiency. Thus, a solo practitioner can have the same OPEM expense RVU as a 5-physician/2-nurse practitioner practice. Major drivers of this metric include staffing costs (e.g., number, mix of salary levels), facility costs (e.g., number of practice venues, total rent/mortgage, cost of utilities), provider productivity (e.g., absolute volume and CPT level of activity), and severity of managed care (e.g., HMO penetration, payer mix, socioeconomic base). The OPEM expense RVU excludes any consideration of physician compensation and benefits. It does account for all the direct and indirect costs incurred in producing oncology care services, partially reflecting the practice style of providers.

Model Output

The overarching framework that integrates the coefficients of the OPEM is the clinical treatment protocol.

Two levels of model output exist:

- Single treatment encounter, which incorporates the specific and appropriate infusion services (i.e., CMS 2005 G codes) with the therapeutic agents (e.g., chemotherapy, biologics, anti-emetics) typically employed.
- Treatment course, which includes all treatment encounters or cycles over 3 to 6 months and all professional and diagnostic services that occur in association with treatment encounters over this same period. Typically professional services include CPT codes 99212 to 99215, and laboratory or

diagnostic services include complete blood counts, chemistries, and tumor markers.

OPEM employs the following clinical treatment protocol assumptions:

- All drug dose calculations are based on a body surface area of 1.7 m^2 or an area under the curve (AOC) of 5 (Calvert formula).
- Body mass is approximately 155 lb.
- There is normal renal function (serum creatinine = 1.0).
- Wastage for therapeutic agents obtained from multidose vials is minimized by rounding up dose to next billing unit.
- Therapeutic costs assume complete usage of single-dose vial when used.

Other important assumptions are as follows:

- An ideal reimbursement environment realizes 100% collection of required co-pays, co-insurance, and deductibles.
- Saline and antiemetics are included in all protocols.
- Diagnostic services include only commonly used laboratory tests.

We selected 10 protocols[10–19] to serve as a platform to illustrate the usefulness of OPEM analysis (Table 2; see also Table 3 for protocol dose summaries). These are clinical treatment protocols commonly used in treating breast, colon, and lung cancer and non-Hodgkin's lymphoma. The treatment course for all illustrative protocols is approximately 6 months, with the exception of Adriamycin Cytoxan, which is 3 months. As of July 2005, 54 treatment protocols that are commonly employed in community clinical oncology practices were constructed (Table 4).

Table 2 OPEM© Illustrative Protocols with Common Indicators

Protocol	Indication
Taxol carboplatin q3wk	Lung, breast
Taxol Herceptin q1wk	Breast
CHOP Rituxan Neulasta	Lymphoma
Gemzar cisplatin	Lung
Taxotere q1wk	Breast
Fludarabine Rituxan	Lymphoma
Adriamycin Cytoxan	Breast
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	CRC
Capecitabine + oxaliplatin	CRC
Abraxane q3wk	Breast

Abbreviations: CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; CRC, colorectal cancer; 5FU/LV, infusional 5-fluorouracil plus leucovorin.

OPEM© Simulation Results and Practice Implications

Table 5 summarizes core outputs and their derivations, practice implications, and potential responses arising from an OPEM analysis. Provided that valid and complete data have been supplied, the core outputs will drive discussions about potential practice responses. We have distilled those potential responses into 4 categories: therapeutic interchange, change of venue, contract negotiation, and cost restructuring. However, responses that are appropriate for one practice environment may not be applicable to another practice environment.

Tables 6 through 8 show our sample protocol analysis over differently stylized practice environments as reflected by 3 levels of OPEM expense RVU for a course of care. Again, we postulate that 80% to 90% of the oncology private practices in the United States have an OPEM expense RVU between $25 and $45. Based on practices within our client database, we believe that a greater sample set would show that the OPEM expense RVU median and mode for the oncology practice population would be closer to $45 rather than $25. Generally, practices in metropolitan areas are more likely to have a higher OPEM expense RVU because of the increased cost of doing business.

Review of the estimated total cost of goods sold (COGS) reveals that all oncology practices go at-risk for substantial amounts of resources to produce and deliver cancer care services over an entire course of therapy. For example, the estimated total COGS (professional, infusion, and therapeutic agents) for the Adriamycin Cytoxan protocol ranges from $1,946.15 to $2,988.35. More dramatically, the range for FOLFOX4 in combination with Avastin is $70,165.96 to $81,838.44. The OPEM protocol total COGS component analysis in Table 9 reveals some additional interesting findings regarding our sample set of protocols for our model practice with an expense RVU of $45, including:

- The cost of infusion services accounts for 7.3% to 63.8% of total protocol costs per course of care.
- The cost of therapeutic agents accounts for 21.5% to 91.7% of total protocol costs per course of care.

Table 3 OPEM© Protocols: Dose Summaries for Cited Treatment Regimens

Protocol	Indication	Cycle Length	Days per Single Treatment	Treatment per cycle	Cycles per Course	Chemotherapy Component	Chemotherapy Component	Chemotherapy Component	Chemotherapy Component
Taxol carboplatin q3wk	Lung, breast	3wk	1	1	8	Paclitaxel 200 mg/m^2 IV on day 1	Carboplatin AUC = 6		
Taxol Herceptin q1wk	Breast	q1wk	1	3	6	Paclitaxel 80 mg/m^2 on day 1	Trastuzumab 4 mg/kg on day 1		
CHOP Rituxan Neulasta	Lymphoma	q21d	1	1	8	Doxorubicin 50 mg/m^2 day 1; rituximab 375 mg/m^2 on day 1	Cyclophosphamide 750 mg/m^2 on day 1; vincristine 2 mg on day 1	Pegfilgrastim 6 mg SQ on day 2	
Gemzar cisplatin	Lung	21d	1	2	8	Gemcitabine 1000 mg/m^2 on days 1 and 8	Cisplatin 40 mg/m^2 IV on days 1 and 8		
Taxotere q1wk	Breast	q1wk	1	3	6	Docetaxel 25 mg/m^2 on day 1			
Fludarabine Rituxan	Lymphoma	28d	5	1	6	Fludarabine 25 mg/m^2 on days 1–5	Rituximab 375 mg/m^2 on day 1		
Adriamycin Cytoxan	Breast	q21d	1	1	4	Doxorubicin 60 mg/m^2 on day 1	Cyclophosphamide 600 mg/m^2 on day 1		
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	CRC	q2wk	1	2	6	Oxaliplatin 85 mg/m^2 on day 1	Leucovorin 200 mg/m^2 on days 1 and 2	5FU 400 mg/m^2 IV bolus and 600 mg/m^2 by CI X 22 h on days 1 and 2	Bevacizumab 5 mg/kg on day 3 after chemotherapy completed
Capecitabine + oxaliplatin	CRC	Repeat cycle q21d	1	1	8	Capecitabine: 1000 mg/m^2 po bid on days 1–14	Oxalplatin: 130 mg/m^2 IV on day 1		
Abraxane q3wk	Breast	q21d	1	1	8	Paclitaxel 260 mg/m^2 on day 1			

Abbreviations: CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; 5FU/LV, infusional 5-fluorouracil plus leucovorin; AUC, area under the curve; CI, confidence interval; IV, intravenously; SQ, subcutaneously.

- The cost of professional and diagnostic services accounts for 1.1% to 14.7% of total protocol costs per course of care.

Again, the total of the COGS is the practice's "at-risk" amount every time a course of care is provided for a patient. In other words, it is the total cost outlay in terms of professional services, infusion services, and therapeutic agents that a practice needs to expend to create the product/service mix that constitutes an entire course of care for a particular protocol. Because of the significant range of expenses ($2,988.35 to $81,838.44), management of cash flow for these narrow-margin, high-cost protocols becomes extremely important for overall practice viability.

CMS Demonstration Project Grant

The CMS Demonstration Project grant was an intervention by CMS to compensate for the excessive

Table 4 OPEM© Protocol Inventory

Abraxane q3wk
Abraxane q1wk
Adriamycin cytoxan
Aranesp q2wk
Aredia
Avastin
Camptosar
Camptosar cisplatin
Capecitabine + irnotecan (XELIRI)
Capecitabine + oxaliplatin (XELOX)
Carboplatin q1wk
Carboplatin VP-16
CHOP
CHOP Rituxan
CHOP Rituxan Neulasta
CMF
CPT11 5FU/LV
Doxil
Faslodex
5FU/LV Mayo Clinic Schedule
5FU/LV
Fludarabine
Fludarabine Rituxan
FOLFOX4 (oxalaplatin 5FU/LV)
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)
Gemzar
Gemzar carboplatin
Gemzar cisplatin
Herceptin q2wk

Table 4 Continued.

Hybrid protocol no linked worksheet
IFL Douillard
IFL FOLFIRI
Lupron
Navel/Gem
Navelbine
Neulasta
Novantrone
Oxaliplatinn+ irotecan (IROX)
Procrit
Rituxan maintenance
RPCI 5-fluorouracil + leucovorin
Sandostatin
Taxol carboplatin q3wk
Taxol CIS
Taxol Herceptin q1wk
Taxol q1wk
Taxol q3wk
Taxol x 4 cycles
Taxotere q1wk
Taxotere q3wk
Topotecan
VP-16 carboplatin
Zoladex
Zometa
Abraxane q3wk

Abbreviations: CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; Nav/Gem, Navelbine Gemzar; 5FU/LV, infusional 5-fluorouracil plus leucovorin.

impact of MMA in adjusting reimbursement for infusion services, therapeutic agents, and other professional services.[20,21] The application of this compensatory grant is a function of the number of provider–patient therapeutic agent encounters experienced over a course of care. For more complex protocols (e.g., fludarabine Rituxan) with multiple sequential days of treatment or for more numerous treatments per course of care (e.g., Taxol Herceptin administered weekly) this allowance can provide critical financial relief. For our model practice with an OPEM expense RVU of $45 (Table 8), 2 of the 10 protocols experienced negative total net revenue without the relief garnered from the CMS demonstration project grant. Ignoring scheduled elimination of the remaining 3% temporary adjustment in infusion services reimbursement, OPEM analysis suggests that without the CMS Demonstration Project grant in 2006, many practices will not be able to deliver cancer care to Medicare patients.

Competitive Acquisition Program Considerations

The Competitive Acquisition Program (CAP) is intended to relieve the oncologist's burden of having to purchase, inventory, prepare, and bill and collect for therapeutic agents used to provide office-based therapy. At this paper's initial draft, many aspects and details of the CAP program had yet to be resolved. Despite these uncertainties, we have used OPEM to model net total revenue for practices that choose to

Table 5 OPEM© Core Outputs, Practice Implications, and Potential Practice Responses

OPEM Protocol-Based Core Outputs	Source or Calculation	Practice Implications	Potential Responses
OPEM expense RVU	Practice expenses/total provider productivity (see text)	Does provider productivity cover current cost structure?	Therapeutic Interchange (equivalent protocol or drug), change of venue (office, hospital other), contract negotiation (commercial payors), cost restructuring (facility, staffing, drugs, other operating expenses)
Net therapeutic agent costs	Discounted acquisition cost (does not include rebates)	Are supply sources, negotiated discount, and rebate optimal?	
Net therapeutic agent revenues	ASP or % AWP (new agents) minus net therapeutic agent costs	Participate in ASP or CAP?	
Net infusion services cost	Calculated OPEM expense RVU for infusion G codes	Can specific components in OPEM expense RVU be reduced or eliminated?	
Net infusion services revenue (includes demo project)	(Demo G codes + infusion G codes) minus net Infusion services cost	Are billing and coding practices optimal?	
Net professional and Dx costs	(OPEM expense RVU) × E&M RVUs	Can specific components in OPEM expense RVU be reduced or eliminated?	
Net professional and Dx revenues	Revenue for E&M codes minus net professional & Dx costs	Are billing and coding practices optimal?	
Total cost of goods sold (COGS)	Net therapeutic agent costs + net infusion services costs + net professional & Dx services costs	What is the practice's risk tolerance for providing a course of treatment?	
Total net revenue by payor	Net therapeutic agent revenue + net infusion services revenues + net professional & Dx services revenues	Can protocol be delivered in financial viable manner? Are there sufficient funds available for distribution (practice recapitalization, staff revenue sharing, physician compensation)?	

Abbreviations: ASP, average sales price; AWP, average wholesale price; CAP, Competitive Acquisition Program; Dx, diagnostic services; E&M, evaluation and management; OPEM, Oncology Practice Econometric Model; RVU, relative value.

participate by assuming that therapeutic agent acquisition costs equal therapeutic agent revenue (i.e., net therapeutic agent revenue equals zero).

A practice with an OPEM expense RVU of $45 would clearly fail if it elected to participate in CAP (Tables 6-8). Virtually all protocols in our sample set would experience negative total net revenue per course of treatment. The percentage decrease in net revenue in our protocol sample set ranges from –324.09% for CHOP (cyclophosphamide, doxorubicin, oncovin, and prednisone) plus Rituxan Neulasta to –100.85% for FOLFOX4 in combination with Avastin. In a model practice with an OPEM expense RVU of $35, all the protocols appear to generate positive, albeit small, total net revenue per protocol per course of care. The percentage decrease in total net revenue at this RVU level ranges in our sample set from –45.89% for FOLFOX+4 to –90.41% for Abraxane 3 times weekly. A model practice with a lower OPEM expense RVU of $25, although impacted the least, would still experience a significant financial strain. The percentage decrease in total net revenue in this setting for FOLFOX4 is –29.70%, whereas Abraxane drops 76.82%.

Thus, in conducting a CAP reimbursement sensitivity analysis, the impact on total net revenue for Medicare is a function not only of therapeutic agent costs and revenues but also of a practice's OPEM expense RVU. We believe that CMS will have to offer a substantial inducement in the guise of another grant (similar to the CMS Demonstration Project grant) or create additional G codes for broader therapy management. Clearly, many operational considerations for this new program will not be resolved until at least a year's worth of experience has been gained and analyzed. We believe only those practices with highly sophisticated financial management systems, relatively

Table 6 OPEM© Protocol Analysis with Expense RVU set at $25

OPEM Expense RVU = $25 Protocol	Total Net Revenue per Course (2005 Medicare, with CMS Demonstration Project Grant, 4th qtr ASP+6%)	Estimated Total Cost of Goods Sold per Course	Total Net Revenue per Course (2005 Medicare Without CMS Demonstration Project, 4th qtr ASP+6%)	Total Net Revenue per Course (2005 Medicare, Under Theoretical CAP Scenario)
Taxol carboplatin q3wk	$5,310.50	($6,216.50)	$4,270.50	$1,957.06
Taxol Herceptin q1wk	$7,170.98	($33,975.70)	$4,767.98	$3,504.02
CHOP Rituxan Neulasta	$3,402.19	($47,328.47)	$2,362.19	$2,369.23
Gemzar cisplatin	$6,764.35	($23,513.71)	$4,684.35	$3,033.31
Taxtere q1wk	$6,191.22	($20,281.37)	$3,851.22	$2,839.98
Fludarabine Rituxan	$8,835.16	($31,752.75)	$4,936.16	$3,474.82
Adriamycin Cytoxan	$1,270.82	($1,946.15)	$750.82	$797.10
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	$16,097.71	($70,135.96)	$14,537.71	$11,315.95
Capecitabine + oxaliplatin	$4,559.26	($35,069.19)	$3,519.26	$1,480.14
Abraxane q3wk	$4,932.41	($39,943.08)	$3,892.41	$1,143.13

Abbreviations: ASP, average sales price; CAP, Competitive Acquisition Program; CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; CMS, Centers for Medicare and Medicaid Services; OPEM, Oncology Practice Econometric Model; 5FU/LV, infusional 5-fluorouracil plus leucovorin.

modest Medicare patient exposure, and high tolerance for risk should contemplate participating in this program in 2006.

Some additional important observations arise from the OPEM protocol total net revenues component analysis of our model practice (expense RVU = $45) as shown in Table 10 and Figure 1.

- In 10 of 10 protocols, none of the infusion services contributed positively to the viability of the protocol.

Table 7 OPEM© Protocol Analysis with Expense RVU set at $35

OPEM Expense RVU = $35 Protocol	Total Net Revenue per Course (2005 Medicare, with CMS Demonstration Project Grant, 4th qtr ASP+6%)	Estimated Total Cost of Goods Sold per Course	Total Net Revenue per Course (2005 Medicare Without CMS Demonstration Project, 4th qtr ASP+6%)	Total Net Revenue per Course (2005 Medicare, Under Theoretical CAP Scenario)
Taxol carboplatin q3wk	$4,062.45	($7,517.24)	$3,022.45	$709.01
Taxol Herceptin q1wk	$4,779.93	($36,382.79)	$2,439.93	$1,175.97
CHOP Rituxan Neulasta	$1,860.46	($48,922.90)	$820.46	$827.50
Gemzar cisplatin	$4,749.42	($25,581.33)	$2,669.42	$1,018.38
Taxotere q1wk	$4,336.32	($22,215.31)	$1,996.32	$985.08
Fludarabine Rituxan	$6,527.88	($34,218.12)	$2,627.88	$1,167.54
Adriamycin Cytoxan	$776.07	($2,467.25)	$256.07	$302.35
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	$10,419.56	($76,002.20)	$8,859.56	$5,637.80
Capecitabine + oxaliplatin	$3,651.04	($36,030.11)	$2,611.04	$571.92
Abraxane q3wk	$4,191.09	($40,710.74)	$3,151.09	$401.81

Abbreviations: ASP, average sales price; CAP, Competitive Acquisition Program; CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; CMS, Centers for Medicare and Medicaid Services; OPEM, Oncology Practice Econometric Model; 5FU/LV, infusional 5-fluorouracil plus leucovorin.

Table 8 Protocol Analysis with Expense RVU set at $45

OPEM Expense RVU = $45 Protocol	Total Net Revenue per Course (2005 Medicare, with CMS Demonstration Project Grant, 4th qtr ASP+6%)	Estimated Total Cost of Goods Sold per Course	Total Net Revenue per Course (2005 Medicare Without CMS Demonstration Project, 4th qtr ASP+6%)	Total Net Revenue per Course (2005 Medicare, Under Theoretical CAP Scenario)
Taxol carboplatin q3wk	$2,814.41	($8,817.98)	$1,774.41	($539.03)
Taxol Herceptin q1wk	$2,451.88	($38,789.89)	$111.88	($1,152.08)
CHOP Rituxan Neulasta	$318.73	($50,517.33)	($721.27)	($714.23)
Gemzar cisplatin	$2,734.49	($27,648.96)	$654.49	($996.55)
TAXOTERE q1wk	$2,481.42	($24,149.26)	$141.42	($869.82)
Fludarabine Rituxan	$4,220.61	($36,683.48)	$320.61	($1,139.73)
Adriamycin Cytoxan	$281.32	($2,988.35)	($238.68)	($192.40)
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	$4,741.41	($81,838.44)	$3,181.41	($40.35)
Capecitabine + oxaliplatin	$2,742.81	($36,991.03)	$1,702.81	($336.31)
Abraxane q3wk	$3,449.78	($41,478.40)	$2,409.78	($339.50)

Abbreviations: ASP, average sales price; CAP, Competitive Acquisition Program; CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; CMS, Centers for Medicare and Medicaid Services; OPEM, Oncology Practice Econometric Model; 5FU/LV, infusional 5-fluorouracil plus leucovorin.

- In 8 of 10 protocols, therapeutic agents accounted for more than 100% of the total net revenue without inclusion of revenue from the CMS Demonstration Project grant. In the Adriamycin Cytoxan and the CHOP Rituxan Neulasta protocols, therapeutic agent reimbursement was insufficient to cover unrebated drug acquisition costs.
- In all protocols, professional and diagnostic services were marginally positive, providing little net revenue per course.
- When the Demonstration Project grant is included in the total net revenue, 7 protocols generate less than approximately $2,800, 2 of which generate less than $500 per course of care. The remaining 3 protocols have total net revenues less than $4,800 per course of care. Abraxane administered 3 times weekly under third-quarter ASP + 6% had a total net revenue of $10,695.38 because of the temporary pass-through provision (% average wholesale price = reimbursement) for a new therapeutic agent. Under fourth quarter ASP, this drops 67.7% to $3,449.78 because under MMA provisions drug reimbursements can be adjusted quarterly.

Again, this model assumes that 100% of all co-payment, co-insurance, and deductibles will be collected.

OPEM Protocol At-Risk Revenue Analysis

The collection of co-payments, co-insurances, and deductibles has taken on new importance if not urgency given the impact of MMA. As shown by the analysis of our OPEM protocol sample set in Table 11, the oncology practice is "at risk" for a substantial portion of the total net revenue if these funds are not collected. These out-of-pocket payments expected of the patient can be significant over an entire course of therapy. In 4 of 10 protocols, the co-pay requirement to the patient is in excess of $8,000; in 2 of these, it exceeds $10,000, revealing a burden that will be especially onerous for patients who do not have effective secondary insurance. Assuming collection of all other co-pays and secondary insurances, failure to collect co-pays associated with the CMS Demonstration Project will lead to a total net revenue that approaches zero in the CHOP Rituxan Neulasta and Adriamycin Cytoxan protocols. In 6 of 10 of our OPEM protocol sample sets (OPEM expense RVU of $45), the total net revenue is clearly negative with the failure to collect even a portion of the co-pays. This results in a situation in which the oncology practice essentially "pays" for providing a course of care.

Sectipon Summary

OPEM RVU-based analyses clearly show that most practices will not be able to participate in CAP as

Table 9 OPEM© Protocol: Cost of Goods Sold Component Analysis

OPEM Protocol Cost of Goods Sold Component Analysis per Course

OPEM Expense RVU = $45	Infusion Services		Therapeutic Agents		Professional and Dx Services		Total Cost of Goods Sold per Course
Protocol	Cost	% of Total Cost	Cost	% of Total Cost	Cost	% of Total Cost	Cost
Taxol carboplatin q3wk	$4,973.89	56.4%	$2,964.64	33.6%	$879.45	10.0%	($8,817.98)
Taxol Herceptin q1wk	$9,974.68	25.7%	$27,957.96	72.1%	$857.25	2.2%	($38,789.89)
CHOP Rituxan Neulasta	$6,295.48	12.5%	$43,342.40	85.8%	$879.45	1.7%	($50,517.33)
Gemzar cisplatin	$8,424.87	30.5%	$18,344.64	66.3%	$879.45	3.2%	($27,648.96)
Taxotere q1wk	$7,845.49	32.5%	$15,446.52	64.0%	$857.25	3.5%	($24,149.26)
Fludarabine Rituxan	$9,881.19	26.9%	$25,589.34	69.8%	$1,212.95	3.3%	($36,683.48)
Adriamycin Cytoxan	$1,905.22	63.8%	$643.40	21.5%	$439.73	14.7%	($2,988.35)
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	$24,667.43	30.1%	$55,575.36	67.9%	$1,595.65	1.9%	($81,838.44)
Capecitabine + oxaliplatin	$3,444.70	9.3%	$32,666.88	88.3%	$879.45	2.4%	($36,991.03)
Abraxane q3wk	$3,014.76	7.3%	$38,023.92	91.7%	$439.73	1.1%	($41,478.40)

Abbreviations: CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; OPEM, Oncology Practice Econometric Model; 5FU/LV, infusional 5-fluorouracil plus leucovorin; DX, diagnostic services.

currently outlined when this article was accepted for publication. Without a small amount of net revenue from therapeutic agents, most practices will not be able to deliver many clinical treatment protocols in a financially viable manner. The way ASP is calculated means that the margin between acquisition costs and ASP + 6% reimbursement will become narrower for many therapeutic agents, placing greater financial burden on practices. The promise that infusion and professional services reimbursement would be increased to offset decreases in therapeutic agent reimbursement has not materialized. The completion of the 3-year schedule of declining reimbursement for infusion services (a net decrease of 3% in payment for infusion services) will occur in 2006. The financial consequences of the planned decrease in infusion services reimbursement for 2006 will potentially be compounded by any decrease in the CMS conversion factor for physician's services[22] and elimination of the CMS Demonstration Project grant. A demonstration grant or upward payment adjustment for infusion and professional services must be implemented

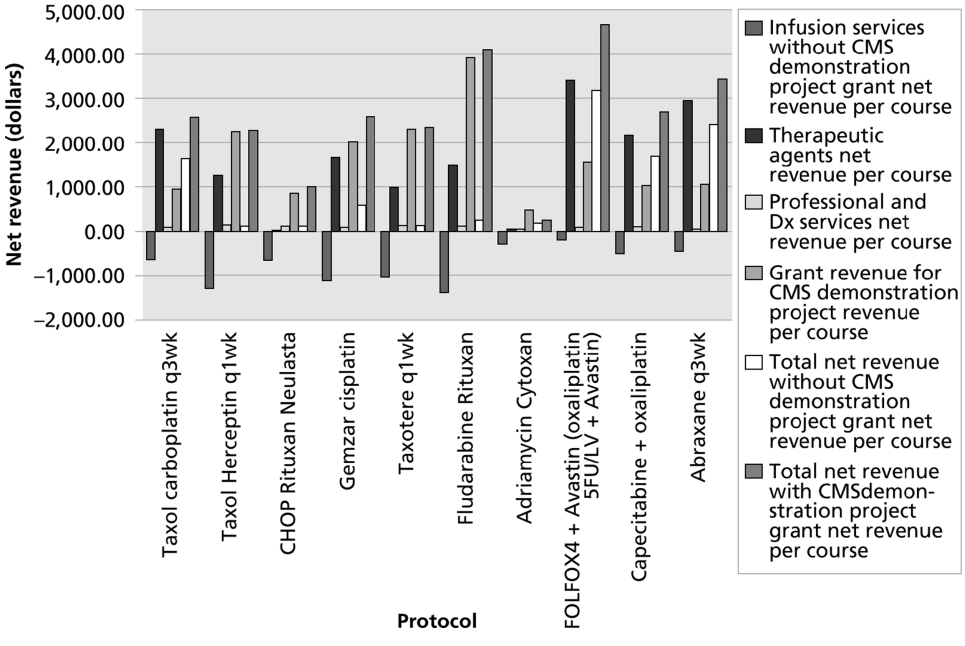

Figure 1 OPEM analysis: 2005 net revenue per course.

Table 10 OPEM© Protocol: Total Net Revenue Component Analysis

			OPEM analysis - 2005 Net Revenue per Course			
OPEM Expense RVU = $45	Infusion Services Without CMS Demonstration Project grant	Therapeutic Agents	Professional and Dx Services	Grant Revenue for CMS Demonstration Project	Total Net Revenue Without CMS Demonstration Project Grant	Total Net Revenue With Demonstration Project Grant
Protocol	Net Revenue per course	Net Revenue per course	Net Revenue per course	Revenue per course	Net Revenue per course	Net Revenue per course
Taxol carboplatin q3wk	($659.41)	$2,313.44	$120.38	$1,040.00	$1,774.41	$2,814.41
Taxol Herceptin q1wk	($1,322.40)	$1,263.96	$170.32	$2,340.00	$111.88	$2,451.88
CHOP Rituxan Neulasta	($834.61)	($7.04)	$120.38	$1,040.00	($721.27)	$318.73
Gemzar cisplatin	($1,116.94)	$1,651.04	$120.38	$2,080.00	$654.49	$2,734.49
Taxotere q1wk	($1,040.14)	$1,011.24	$170.32	$2,340.00	$141.42	$2,481.42
Fludarabine Rituxan	($1,310.05)	$1,460.34	$170.32	$3,900.00	$320.61	$4,220.61
Adriamycin Cytoxan	($252.59)	($46.28)	$60.19	$520.00	($238.68)	$281.32
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	($150.26)	$3,221.76	$109.92	$1,560.00	$3,181.41	$4,741.41
Capecitabine + oxaliplatin	($456.69)	$2,039.12	$120.38	$1,040.00	$1,702.81	$2,742.81
Abraxane q3wk	($399.69)	$2,749.28	$60.19	$1,040.00	$2,409.78	$3,449.78

Abbreviations: CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; OPEM, Oncology Practice Econometric Model; 5FU/LV, infusional 5-fluorouracil plus leucovorin; Dx, diagnostic services.

in 2006 to maintain the ability of practices to care for Medicare patients.

Discussion

Access to sophisticated tools and models that provide physicians with actionable, current information are essential in today's rapidly changing reimbursement environment. In our experience, an accounting-based decision-making system best supports a reactive or an adaptive approach to addressing opportunities and threats, whereas an RVU-based system better supports a real-time decision-making financial model. We propose that employing an integrated clinical-financial model will allow clinicians to prospectively address opportunities and threats. We further maintain that providing contemporary oncologists with financial tools and models that bridge their clinical and financial environment is the best way to empower them.

Historically, oncologists have been forced to place much emphasis on net therapeutic agent revenue in the absence of sufficient net infusion and professional services revenue. Legislation, regulation, and practice financial analyses have therefore primarily focused on net therapeutic agent revenue. OPEM protocol-based core outputs allow practitioners to account for any and all changes that may affect the financial viability of a treatment regimen for a particular patient. Practice cost restructuring will affect the viability of all clinical treatment protocols.

All the aspects of a "perfect storm" for the practice of medical oncology are accumulating, including:

- Costs of care are increasing because of the increasing chronicity of oncologic care, intensity of interventions, and plethora of new technologies, therapeutic agents, and procedures.

Table 11 OPEM© At Risk Analysis of Protocols and Deductibles

OPEM Expense RVU = $45	Total Reimbursement per Course (2005 Medicare, with CMS Demonstration Project Grant, 4th qtr ASP)	Total Net Revenue per Course with 100% Collection of All Co-pays, Secondary Insurance and Deductibles	Medicare Mandated 20% Out-of-Pocket Expense to Patient	Net Total Revenue per Course Without Collection of 20% Co-pay
Taxol carboplatin q3wk	$11,395.25	$2,814.41	$2,279.05	$535.36
Taxol Herceptin q1wk	$40,866.06	$2,451.88	$8,177.21	($5,725.33)
CHOP Rituxan Neulasta	$50,598.92	$318.73	$10,119.78	($9,801.06)
Gemzar cisplatin	$30,146.31	$2,734.49	$6,029.26	($3,294.78)
Taxotere q1wk	$26,274.98	$2,481.42	$5,255.00	($2,773.57)
Fludarabine Rituxan	$40,192.68	$4,220.61	$8,037.54	($3,817.93)
Adriamycin Cytoxan	$3,151.10	$281.32	$630.22	($348.90)
FOLFOX4 + Avastin (oxaliplatin 5FU/LV + Avastin)	$85,868.45	$4,741.41	$17,173.69	($12,432.28)
Capecitabine + oxaliplatin	$39,496.71	$2,742.81	$7,899.34	($5,156.53)
Abraxane q3wk	$44,809.61	$3,449.78	$8,961.92	($5,512.14)

Abbreviations: ASP, average sales price; CHOP, cyclophosphamide, doxorubicin, oncovin, and prednisone; OPEM, Oncology Practice Econometric Model; 5FU/LV, infusional 5-fluorouracil plus leucovorin.

- Both the relative and absolute numbers of practicing oncologists are decreasing.
- Funding of the entire oncology delivery care system is undergoing fundamental if fragmented changes. For office-based cancer care, changing reimbursement for therapeutic agents, professional and diagnostic services, and infusion services is at best disjointed.
- The number of patients is increasing because of demographics and successful cancer treatments. The growing number of baby boomers portends that Medicare will become a proportionately larger provider of cancer benefits and reimbursement.

Shifting costs to support patients who cannot afford to pay for increasingly complex and multifaceted care is no longer possible. No one clinical treatment protocol can be delivered as loss leader. Most medical oncology practices in the United States are composed of 7 members or fewer[23] and have no ancillary services. OPEM RVU-based analysis shows that without significant positive reimbursement changes for infusion and professional services and therapeutic agents, some supplements (e.g., the CMS Demonstration Project) will need to be provided to avoid even a partial deconstruction of the U.S. cancer care delivery system. Our experience shows that practices with limited ability to significantly impact fixed and variable costs will be at greatest risk for failure. Unless the "perfect storm" elements are addressed, most oncology practices will probably not be able to treat Medicare patients in a financially viable fashion. When practices realize zero or negative total net revenue for a course of care, that care cannot be given because funds are simply not available for practice reinvestment or physician compensation.

Summary

The emotional and financial pressures facing the medical oncologist in private practice are enormous, with no real relief in sight. The complexity of managing private practice oncology rivals that of managing cancer care. With anticipated reductions in total net revenue per clinical treatment protocol per course of care, funds available for providers and their practices will be severely reduced. Only practices with superlative RVU-based cost and revenue accounting systems will be able to prospectively and efficiently manage their businesses. Therefore, OPEM expense RVU or similar RVU-based data will be required for survival.

Thus, we posit the following questions: Will the planned changes in Medicare reimbursement,

exacerbated by the loss of operationally inefficient medical oncology practices, lead to irreparable changes in the oncology delivery system (e.g., access, availability, continuity, and quality)? What is the physical and emotional capacity of oncologists (e.g., quality of physicians' life) to accept increases in the number of patients seen to offset declining reimbursement? Will increasing practice burdens accelerate the exodus of physicians from this specialty? Will regulation and reimbursement become the primary determinants for practice standards of care? Will the United States abrogate its leadership in clinical cancer care and research and default to a specialty of algorithm followers rather than algorithm creators? Are the unintended systemic consequences of changes in regulation and reimbursement fully appreciated? And lastly and most importantly, what are the risks to the cancer patient resulting from the heuristic approach promulgated by regulators and legislators?

References

1. American Cancer Society. Facts and Figures, 2005. Atlanta: ACS; 2005:2.
2. American Cancer Society. Facts and Figures, 2005. Atlanta: ACS; 2005:3.
3. Status of the medical oncology workforce. The American Society of Clinical Oncology. J Clin Oncol 1996;14:2612–2621.
4. NCCN Drug Compendium. Available at: http://www.nccn.org/professionals/drug_compendium/Content/contents.asp?button=I+Agree. Accessed November 2005.
5. H.R. 1, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173. Enacted December 8, 2003. Available at: http://www.cms.hhs.gov/mmu/HR1/PL108-173summary.asp. Accessed November 2005.
6. Dunning D, Paivanas TA. Proprietary client database. Accessed July 1, 2005.
7. Oncology Business Management issues in the Changing Reimbursement Environment. 2005 American Society of Clinical Oncology (ASCO) meeting. Available at: http://www.asco.org/ac/1,1003,_12-002673-00_18-0034-00_19-00921-00_29-00E,00.asp.
8. Omnibus Budget Reconciliation Act (OBRA) of 1989 added section 1848(c)(2)(B)(1) to the Social Security Act. Requires that CMS reviews all work relative value units (RVUs) – physician work, practice expense and malpractice insurance- for services in Medicare's Resource Based Relative Value Scale (RBRVS) physician fee schedule (MFS) no less often than every five years.
9. American Medical Association. Current Procedural Terminology (CPT®). Available at: http://www.ama-assn.org/ama/pub/category/3113.html. Accessed November 2005.
10. Langer CJ, Leighton JC, Comis RL, et al. Paclitaxel and carboplatin in combination in the treatment of advanced non-small cell lung cancer: a phase II toxicity, response, and survival analysis. J Clin Oncol 1995;13:1860–1870.
11. Goldenberg MM. Trastuzumab, a recombinant DNA-derived humanized monoclonal antibody, a novel agent for the treatment of metastatic breast cancer. Clin Ther 1999;21:309–318.
12. Coiffier B, Lepage E, Briere J, et al. CHOP chemotherapy plus rituximab compared with CHOP alone in elderly patients with diffuse large B-cell lymphoma. N Engl J Med 2002;346:235–242.
13. Abratt RP, Bezwoda WR, Goedhals L, Hacking DJ. Weekly gemcitabine with monthly cisplatin: effective chemotherapy for advanced non-small cell lung cancer. J Clin Oncol 1997;15:744–749.
14. Baselga J, Tabernero JM. Weekly docetaxel in breast cancer: applying clinical data to patient therapy. Oncologist 2001;6(suppl 3):26–29.
15. Czuczman MS, Koryzna A, Mohr A, et al. Rituximab in combination with fludarabine chemotherapy in low-grade or follicular lymphoma. J Clin Oncol 2005;23:694–704.
16. Fisher B, Brown AM, Dimitrov, NV, et al. Two months of doxorubicin-cyclophosphamide with and without interval reinduction therapy compared with 6 months of cyclophosphamide, methotrexate, and fluorouracil in positive-node breast cancer patients with tamoxifen-nonresponsive tumors: results from the National Surgical Adjuvant Breast and Bowel Project B-15. J Clin Oncol 1990;8:1483–1496.
17. De Gramont A, Banzi M, Navarro M, et al. Oxaliplatin/5-FU/LV in adjuvant colon cancer: results of the international randomized mosaic trial [abstract]. Proc Am Soc Clin Oncol 2003;22:253. Abstract 1015.
18. Tabernero J, Butts C, Cassidy J, et al. Capecitabine and oxaliplatin in combination (Xelox) as first-line therapy for patients with metastatic colorectal cancer (MCRC): results of an international multicenter phase II trial [abstract]. Proc Am Soc Clin Oncol 2002;21:133a. Abstract 531.
19. Blum JL, Savin MA, Edelman G, et al. Abraxane Q3W- Long term disease control in taxane-refractory metastatic breast cancer treated with nab paclitaxel [abstract]. Pro Am Soc Clin Oncol 2004;22(suppl 14). Abstract 543.
20. Physician fee schedule final rule published in the Federal Register on November 15,2004 (page 66308) announcing one-year demonstration project associated with caring for cancer patients receiving chemotherapy services in an office-based practice for calendar year (CY 2005).
21. ASCO Lawyer Review's CMS's New Interim G-Codes. Oncol News Int 2005;14;75–76.
22. Section 1848(d)(1)(E) of the Social Security Act requires the Secretary to make an estimate of the Sustainable Growth Rate (SGR) and conversion factor applicable to Medicare Payments for physician services, published in the 11/1/2005 Federal Register and effective 1/1/2006.
23. Centers for Medicaid and Medicare Services. Recommendations Regarding Supplemental Practice Expense Data Submitted for 2003. Evaluation of Survey Data for: Physical Therapy, Oncology, Cardiology, Pediatrics. Available at: fhttp://www.cms.hhs.gov/physicians/pfs/PErecommendations2003.pdf. Accessed November 2005.