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Asthma - Getting to the Guidelines

Dennis Spangler, M.D.

For a CME/CEU version of this article please go to http://www.namcp.org/cmeonline.htm, and then click the activity title.

Summary

Asthma is a significant illness in terms of costs, morbidity, and mortality. Although clinical practice guidelines have been around for several years, numerous studies have shown that adoption of these guidelines is not optimal. An update of the National Asthma Education and Prevention Program (NAEPP) Guidelines for the Diagnosis and Management of Asthma was published in the summer of 2007. The major changes to the guidelines include breaking down recommendations into more age groups (0-4, 5-11, 12 and older), redefining how to assess disease control, and recommending allergy and specialist evaluation for many patients. Some changes to the medication recommendations were also made. Programs to help practitioners adopt the asthma management guidelines should help managed care save significant health care expenses.

Key Points

• The United States has the fourth highest prevalence of asthma in the world.
• Costs depend on the severity of disease, extent of exacerbations, and degree of disease control.
• There are approximately 5,000 possibly preventable deaths in the U.S. each year from asthma.
• Adoption of the asthma management guidelines has not been optimal.
• Achieving disease control is a major focus of the updated asthma management guidelines.
• Disease control is defined differently for each level of disease severity.
• For patients with moderate persistent asthma or worse, increasing the dose of inhaled corticosteroids is considered equivalent to adding a long acting beta agonist inhaler to the patient’s regimen.
• Specialist care and allergy testing are recommended for patients with moderate persistent asthma or worse.
• Wider implementation of the asthma management guidelines should help control the costs of asthma management by reducing the morbidity associated with uncontrolled disease.

Asthma involves people of all ages and in all countries. Since the ‘80s, there has been a doubling in the incidence of asthma in the general population. This has occurred specifically in developed countries, but even to a certain extent in underdeveloped countries. Asthma is a significant burden, not only in terms of health care costs but also of lost productivity (work and school) and reduced participation in family life.

The worldwide prevalence of asthma is more than 300 million cases. The affected population varies from 1 to 18 percent in different countries (Exhibit 1).1 Countries with the highest prevalence include Scotland (18.4 percent), New Zealand (15.1 percent), Canada (14.1 percent) and the United States (10.9 percent). The international patterns of asthma prevalence are not explained by the current knowledge of the causation of asthma. Research into the causation of asthma, and the efficacy of primary and secondary intervention strategies, represents key priority areas in the field of asthma research.

Developed nations have more problems with asthma than some of the undeveloped nations. The rate of asthma increases as communities adopt Western
lifestyles and become urbanized. Part of this is explained by the theories of hygiene, obesity, and pollution playing a role in the development of asthma. With the projected increase in the proportion of the world’s population that is urban — from 45 percent to 59 percent by 2025 — there is likely to be a marked increase in the number of asthmetics worldwide during the next two decades. It is estimated that an additional 100 million to 150 million persons are likely to have asthma by 2025.\(^1\)

Asthma-related fatality rates range from 0 to almost 40 fatalities per 100,000 asthmatics. Despite having an asthma prevalence at the lower end of the scale, countries such as China, Russia, and Mexico have fatality rates at the high end of the scale (36.7, 28.6, and 14.5 fatalities per 100,000 asthmatics, respectively).\(^1\)

The countries where controller therapies are not available have the highest asthma mortality rates. It is estimated that asthma accounts for about 1 in every 250 deaths worldwide. Approximately 5,000 people die from asthma annually in the U.S. The U.S. overall asthma-related death rate (Exhibit 2) has flattened out since the early 1980s.\(^2\) Despite this flattening, asthma deaths have increased in the past 20 years in poor minority groups with limited access to health care. The asthma related deaths are related to suboptimal long-term medical care and delay in obtaining help during the final attack and are thus preventable. There is significant room for improvement in the area of asthma related deaths as well as the day-to-day care of asthmatic patients.

Costs depend on the severity of disease, extent of exacerbations, and degree of disease control. Patients with uncontrolled asthma use a disproportionate share of resources.\(^3\) They are going to have the most exacerbations, hospitalizations, and need for medication. This is a group of patients who need the closest monitoring.

The annual cost of asthma in the U.S. is over $15 billion.\(^4\) Fifty percent of this is patient borne in the form of copays and loss from work, and 50 percent is for medical care. Of the medical costs, half are for rescue or emergency treatment and a third are for medications and regular treatments. During 2000, there were 1.8 million emergency room visits for asthma and nearly 500,000 hospitalizations.\(^5\) The aging of our population is having an impact on hospital admission rates for asthma.\(^6\) Older patients are likely to have some chronic obstructive pulmonary disease (COPD) component to their asthma, which may not be adequately treated. Reducing the number of emergency room visits and hospitalizations is an area for greatest improvements in care and reduction in costs.
Exhibit 3 illustrates one of the biggest problems in current management of asthma by non-specialists. This is the dependence on patient symptoms to determine medical care.

Symptoms are the peak of the iceberg. Waiting until the patient is physically symptomatic means their disease has been out of control for quite a long period of time. Asthma symptoms can be triggered by many exacerbating factors including allergens, exercise, irritants, viral infections, gastroesophageal reflux, and sinusitis. Many asthmatics will cough long before they will wheeze. This is especially true in pediatric patients, but in adults as well. Patients are already in moderate distress when they present with wheezing, difficulty breathing, and chest tightness. Once symptomatic, they have significant levels of air-flow obstruction, bronchial hyper-reactivity, and airway inflammation.

Patients with asthma develop a tolerance for their reduced lung function. They will tolerate 40 percent reductions in lung functions without complaints and will limit their exercise because they know it bothers them. They figure that is the way life will be. Relying on symptoms without associated pulmonary function testing allows patients to leave the physician’s office out of control. Any asthma trigger such as a viral infection or air pollution will prompt a major decline in function, and the patient will end up in the emergency room and possibly the hospital.

There is a neurological irritant respiratory link between the upper and lower airway. Patients’ asthma will not be controlled until their upper respiratory problems such as sinusitis are controlled. About 80 percent of asthmatic patients have significant upper airway disease, and 20 percent of allergic rhinitis patients have asthma.7,8

For office diagnosis of asthma, many people rely on peak flow. Asthma may be indicated if peak expiratory flow (PEF) increases >20 percent after a short acting bronchodilator. Unfortunately, peak flow only measures large airway function. It does not measure small airway function and small airway irritability and inflammation, which is a major contributor to asthma. Spirometry is recommended over peak flow meters for diagnostic purposes. Only through pulmonary function testing can a good assessment of the patient’s lung function be obtained. One of the premier points of guidelines is normalization of pulmonary functions. Pulmonary function testing needs to be incorporated in the care of asthmatic patients.

The National Asthma Education and Prevention Program (NAEPP) Guidelines for the Diagnosis and Management of Asthma were first released in 1997 and have been updated twice since. The most recent update was published in August of 2007.9 The initial asthma management guidelines recognized that most adverse outcomes result from poor diagnosis, inadequate prescribing, and less than optimal adherence to therapy.

Implementation of the asthma management guidelines has been poor, and adherence to guidelines has not achieved the hoped-for results.10, 11, 12 Problems with clinicians following the guidelines have occurred. Under-diagnosis has been a significant problem. Patients are treated as having less severe disease than they actually have. That leads to inadequate prescribing with low usage of inhaled corticosteroids, the gold standard for decreasing lung inflammation. Another problem has been inadequately educating the patients so there is poor buy-in from the patient and, therefore, poor adherence to therapy.

One group assessed tertiary care center physicians on their abilities to understand the asthma guidelines.10 When quizzed about the guidelines, the mean correct total score for all physicians was 60 ± 2 percent (mean ± SEM). Asthma specialists scored higher in total score and in pharmacology and prevention. However, no group performed well on estimating disease severity. There is some loss of transference of the guidelines into practice. Cabana and colleagues found similar problems with translation of the guidelines by pediatricians.11 Although most of the surveyed pediatricians were aware of the guidelines (88 percent) and reported having access to a copy of the guidelines (81 percent), they had self-reported rates of adherence between 39 percent and 53 percent for the guideline components.

Exhibit 4 shows the major changes in the newest revision of the asthma management guidelines. The guidelines are now broken down into more age groups (0–4, 5–11, 12 and older). Children need a slightly different approach than adults.

Understanding the variability of disease and focusing on control is the approach of the latest edition of the
Achieving good control is a matter of understanding what to do in a particular situation. The action plans provide specific instructions on what to take and when and when, to seek additional medical attention. Although asthma action plans have been recommended for some time, only 39 percent of children in one study had a plan. When patients do not have an action plan, they have the tendency to overuse short-acting inhalers before they even bother to call their doctor. By the time they seek medical attention, the exacerbation will have progressed to a point that it is more difficult to treat.

A major focus of the updated guidelines is evaluating how control is defined for various levels of disease in people over 12 years old. Achieving good control is a matter of being more aggressive on a day-to-day basis. If patients are under control, it takes a lot more to make them symptomatic and cause an emergency episode.

A key addition to the guidelines is the recommendation that a pulmonary or allergist consultation be obtained for patients with moderate or severe asthma. These patients are going to have the most exacerbations, need the most medications, and have the highest costs. They are also the ones who are doing the most, and will gain the most benefit from seeing a specialist if the specialist can find the triggers or causes of their exacerbations, there will be better success in getting the patients under good control.

Allergy evaluation is recommended for patients with moderate persistent and worse disease. An allergy evaluation can have value for children older than 4, even with mild disease. If they have significant allergies, these can be addressed to improve the patients' disease control.

Asthma action plans are recommended by the guidelines for all patients with asthma. These are specific instructions on how patients should use medications, both on a daily basis and when symptoms occur. Because the medication regimens can be complicated, patients may have difficulty remembering what they are to do in a particular situation. The action plans provide specific directions on what to take and when and when, to seek additional medical attention. Although asthma action plans have been recommended for some time, only 39 percent of children in one study had a plan. When patients do not have an action plan, they have the tendency to overuse their short-acting inhaler (e.g., albuterol) before they even bother to call their doctor.

Exhibit 4: Major Guideline Changes

- Asthma management broken into age groups 0 to 11, and 12 and older.
- Allergic evaluation for moderate persistent asthma up. Maybe all?
- Consultation with board certified specialists (allergists or pulmonologists) for moderate persistent asthma and up?
- Equal weighting to increasing ICS vs. adding a LABA in more severe asthmatics (moderate persistent and higher)

A tremendous number of medications have been introduced in the treatment of asthma. Many of these have been groundbreakers. Inhaled corticosteroids are the gold standard. They are the beginning therapy for most patients with persistent disease. About 60 percent of patients will do well on an inhaled corticosteroid daily with a short-acting beta-agonist for acute symptom relief. The other 40 percent will need some combination of daily therapy to achieve disease control. Stopping daily inhaled corticosteroids will result in declines in lung function to levels seen...
In many patients, long-acting beta-agonists are added to inhaled corticosteroids when the corticosteroid alone is not sufficient. There are subgroups of patients that are more susceptible to the side effects of long-acting beta-agonists. These long acting agents, such as salmeterol, should never ever be administered as monotherapy. They should always be given with an inhaled corticosteroid. Certain subgroups including African-Americans will get worse with long-acting beta-agonists. This is seen as a deterioration of lung function over time after the long acting beta-agonist is added. Unfortunately, which patients will have this reaction cannot be predicted.

Asthma is a whole lung disease process. Many of the treatments that have been available are large particle inhaler type drugs. They work well, but they only reach the large bronchi. In recent years, development of small particle inhaled corticosteroids that can reach into the smaller airways has occurred. In one study, the patients who were having difficulty with control had good function of their large airways but not small airways. Not addressing the closure of small airways resulted in these patients having increased costs, emergency room visits, and hospitalizations. Distal airway inflammation is associated with difficult to control asthma.

There are many things that are needed to improve asthma care during the next decade. We need better ways to disseminate and get “buy-in” for the NAEPP Guidelines. Patients must be educated on what is “good asthma care.” Physician behavior toward asthma needs to be changed. Pay for performance is one possible way to improve asthma care. We need to develop better asthma disease management programs. These programs need to move from disease control to disease modification to disease prevention (more allergy care, environment controls, etc.). There also

Exhibit 5: Assessing Asthma Control in Patients Greater Than 12 Years of Age

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<th>Component of Control</th>
<th>Classification of Asthma Control (≥ 12 years of age)</th>
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<tr>
<td></td>
<td>Well Controlled</td>
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<td>Impairment</td>
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<tr>
<td>Symptoms</td>
<td>≤ 2 days/week</td>
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<td>Nighttime awakenings</td>
<td>≤ 2x/month</td>
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<td>Interference with normal activity</td>
<td>None</td>
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<tr>
<td>Short-acting beta,-agonist use for symptom control (not prevention of EIB)</td>
<td>≤ 2 days/week</td>
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<tr>
<td>FEV&lt;sub&gt;1&lt;/sub&gt; or peak flow</td>
<td>&gt; 80% predicted/ personal best</td>
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<tr>
<td>Validated questionnaires</td>
<td>ATAQ</td>
</tr>
<tr>
<td></td>
<td>0</td>
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<tr>
<td></td>
<td>1-2</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
</tr>
<tr>
<td>Risk</td>
<td></td>
</tr>
<tr>
<td>Exacerbations requiring oral systemic corticosteroids</td>
<td>0-1/year</td>
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<tr>
<td>Progressive loss of lung function</td>
<td>Evaluation requires long-term follow-up care</td>
</tr>
<tr>
<td>Treatment-related adverse effects</td>
<td>Medication side effects can vary in intensity from none to very troublesome and worrisome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk.</td>
</tr>
</tbody>
</table>
needs to be a better understanding of the phenotypes of asthma and evaluation of small airways and their impact on disease severity and control.

Conclusion

Asthma is a disease of the entire respiratory tract and must be treated as an inflammatory disease. The key challenges for clinicians who manage patients with asthma include identifying and addressing patient needs; providing appropriate therapy and management for asthma; assessment of associated complications, sinusitis, reflux, small airway disease, smoking, etc; and examination of pulmonary functions. Poorly controlled asthmatics are expensive. Medications are essential for long-term control. But medications alone are not the entire solution to achieving control. Environment, allergies, other diseases, financial situation, asthma education, and many other factors also impact a patient’s disease control. Successful disease control requires looking at all aspects of the care of these patients. JMCM

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Health Economic Implications for Wound Care and Limb Preservation

Vickie R. Driver, DPM, MS, FACFAS, and Jean M. de Leon, MD
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Summary
Ulcers and the subsequent consequences are costly to the health care system. Prevention of ulcers is important in all diabetic patients. Once an ulcer occurs, it must be treated quickly and aggressively to prevent amputation. One option for limb preservation is the use of negative pressure wound therapy to promote faster healing, get patients out of the hospital faster, and reduce overall costs.

Key Points
• Every diabetic foot that becomes infected or requires amputation is a huge cost to the health care system.
• Early aggressive intervention of wounds is needed to prevent worsening of the wound and amputation.
• Amputation avoidance programs should include a risk stratification system allows quick access to care, aggressive management of ulcers and infections, a multidisciplinary care team, and a patient-centered education program for chronic patients.
• Calculating wound area reduction during the early weeks of therapy is a good benchmark for eventual wound healing.
• Compared with moist dressings, negative pressure wound therapy has been shown to heal wounds faster, reduce total length of hospitalization, and reduce total wound treatment costs.

Healthcare providers and insurers need to be concerned about wound care and limb preservation because every 30 seconds a limb is lost somewhere in the world to diabetes. More than 100,000 amputations happened in the U.S. last year secondary to diabetics alone. Forty to 70 percent of all lower extremity amputations are related to diabetes. The majority of amputations (85 percent) are preceded by foot ulcers. Fifteen percent of all patients with diabetes will develop an ulcer during their lifetime. Infected diabetic foot wounds account for up to 25 percent of all diabetes related hospital admissions.

The U.S. ranks number one in the incidence of amputations per 1000 patients with diabetes. One reason for this may be the availability of surgical expertise at virtually every hospital in the country. Unfortunately, wound care centers that aggressively treat wounds are not as widely available. Although the number of patients with diabetes is increasing, the amputation incidence decreased from 1999 to 2003 (Exhibit 1).

Exhibit 2 illustrates the causal factors leading to limb loss. The most common factors that initiate the downward spiral to amputation are microtrauma, ulceration, and faulty wound healing. The major final triggers for an amputation are infection and gangrene. Between 49 percent and 85 percent of all amputations can be prevented.

Preventing amputations is important because of the consequences of this procedure. The five-year mortality rate after a diabetes-related lower leg amputation is high. One series found that at five years, only 25 percent of patients with diabetes who had a lower extremity amputation were still alive.

Every diabetic foot that becomes infected or requires amputation is a huge cost to the health care system. An uncomplicated diabetic foot ulcer is estimated to cost $8,000 to treat. If the ulcer becomes infected, the costs increase to $17,000. If an amputation is required to resolve the ulcer, the costs soar to $45,000. Lower-extremity ulcers cost the...
Medicare system over $1.5 billion annually.\textsuperscript{11} Medicare expenditures for lower-extremity ulcer patients are on average 3 times higher than those for Medicare patients in general ($15,309 vs. $5,226).

With regard to the cost of chronic wound care, ulcer costs increase as wound severity increases.\textsuperscript{12} Deeper wounds require more resource intensive care. Additionally, infected wounds cost more to treat than non-infected wounds.\textsuperscript{13} Osteomyelitis is the most costly infectious event. Hospitalization accounts for the majority of healthcare costs in patients with lower extremity ulcers (70 percent to 80 percent).\textsuperscript{14} An analysis of Medicare data showed the major contributors to cost of lower extremity ulcers is hospitalization (74 percent), outpatient care (10.9 percent), home health care (11.4 percent), and hospice care (4 percent).\textsuperscript{11} Antibiotic costs are minor compared to care of infected wounds not properly treated initially. Treatment decisions should not be based upon antibiotic cost, but on the antimicrobial coverage and likely infecting organisms. Debridement, a cornerstone of wound care, is effective in preventing and managing infection, and improves wound closure.\textsuperscript{15} It does not add considerably to the cost of care ($7,104 vs. $6,278 average yearly cost in patient receiving debridement vs. no debridement).\textsuperscript{11} Early aggressive intervention of infected wounds with debridement and antibiotics will be most beneficial.

The goals in diabetic care are to prevent ulcers from developing and to heal wounds that do develop quickly while avoiding infections, deeper ulcers, and amputations. Any wound care intervention that could prevent even a small percentage of wounds from progressing to the stage at which inpatient care is required may have a favorable cost effect. An amputation avoidance program should include a stratification system for risk level that allows quick access to care, aggressive management of ulcers and infections, a multidisciplinary care team, and a patient-centered education program for chronic patients.

Several types of economic studies have been developed to assess costs of treatment. Cost-minimization, cost-effectiveness, cost-utility and cost-benefit studies
Exhibit 3: Probability of Healing Based on One-Week Wound Progression

Probability of healing by PWAR at one week

Percent Wound Area Reduction from Baseline (PWAR)

Exhibit 4: Probability of Healing Based on Four-Week Wound Progression

Probability of healing by PWAR at 4 weeks

Percent Wound Area Reduction from Baseline (PWAR)
all examine different aspects of disease or treatment costs. These types of studies are being used to demonstrate the benefits of various wound care regimens in achieving appropriate outcomes. Some of the outcomes being examined by these studies are time to healing, time to reoccurrence (i.e., reulceration), avoidance of infection, length of hospital stay, survival, death, and amputation. Minimizing total costs while preserve limbs is the ultimate goal in wound care. A study by Ortegon and colleagues is an example of a cost-effectiveness study in wound care. Guideline-based care (optimal foot care and good glycemic control) in patients with diabetes improved survival and quality-adjusted survival and decreased foot complications.

Negative pressure wound therapy (NPWT) is one of the wound treatments which has been examined in economic studies. A 16-week multi-center, randomized controlled trial in patients with partial foot amputation wounds compared NPWT (V.A.C.® Therapy™) or traditional moist dressing (alginites, hydrocolloids, foams, or hydrogels). Data were analyzed using a time-to-event strategy with Kaplan-Meier estimates. Seventy-seven percent of the patients achieved a 50 percent wound area reduction. Patients treated with V.A.C. therapy achieved 50 percent closure at twenty-nine days as compared to 42 days for traditional moist wound healing. The V.A.C. patients were almost one and a half times more likely to achieve wound closure during the 16-week treatment period.

Another 16-week randomized clinical trial of 162 patients compared outcomes associated with NPWT delivered through the V.A.C. Therapy System (n=77) versus standard moist wound therapy (n=85). These patients had a non-ischemic diabetic wound followed by a partial foot amputation. One and four-week regression models included 153 and 129 of the patients, respectively. This study found that early changes in percent wound area reduction were predictive of final healing at 16 weeks. Patients who achieved at least a 15 percent reduction of their wound area at one week or 60 percent by week four had a 68 percent or 78 percent probability, respectively, of achieving closure. If they did not achieve these percentage area reductions, the probability of closing was only 31 percent and 30 percent. Patients receiving V.A.C. therapy were two and one half times more likely to achieve a 15 percent reduction at one week and a 60 percent reduction at one month as compared to moist wound healing therapy. The results of this study suggest clinicians could calculate the percent reduction in an area as early as one week in order to predict the likelihood of wound closing.

A study by Sheehan in 2003 found similar results. This study found that reducing the area by four weeks was predictive of final wound healing. Another study found that a 10 to 15 percent reduction in wound area each week was a good benchmark for healing.

A plot of the one-week healing trajectories comparing V.A.C. therapy with moist dressings is shown in Exhibit 3. To have a 50 percent probability of healing by sixteen weeks, VAC patients have to achieve 7 percent closure at week one, while the moist wound healing patients have to achieve 37.5 percent at week...
one. At four weeks on the same healing trajectories, the V.A.C. patients would require a 45 percent area of reduction and the non-V.A.C. patients 68 percent, to have the same 60 percent probability of healing by sixteen weeks (Exhibit 4).

In a meta-analysis of studies, treatment with NPWT resulted in lower failure rates for primary closure, skin grafts, and surgical flaps than moist dressings (Exhibit 5). Comparing the levels of surgical intervention required to close wounds, the analysis showed that patients treated with moist dressing required more complex surgeries to close their wounds versus those that were treated with NPWT. Costs increase as complexity of the surgical procedures required to close the wound increase. Failure rates of the procedure also factor into the total cost.

Using Health Care Utilization Project (HCUP) operating room charges, converted to cost using CMS cost-to-charge ratio (45 percent), NPWT resulted in $4,323 in costs and moist dressing cost $5,225. There is a potential savings of $902 per patient with the use of NPWT. The biggest cost difference is in the length of stay. The average length of

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**Exhibit 6: Differences in Percent Wound Reduction Over Time with Early vs. Late Initiation of NPWT (V.A.C. Therapy®)**

<table>
<thead>
<tr>
<th>Week (Post-baseline)</th>
<th>V.A.C. Late</th>
<th>V.A.C. Early</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30%</td>
<td>19%</td>
<td></td>
</tr>
<tr>
<td>2*</td>
<td>39%</td>
<td>18%</td>
<td></td>
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<tr>
<td>3*</td>
<td>43%</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td>4*</td>
<td>18%</td>
<td>13%</td>
<td></td>
</tr>
</tbody>
</table>

* Indicates p<0.05 from a two-sample t-test. Please note that the sample sizes decrease over time due to patient’s healing, being discharged and missing data.

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**Exhibit 7: Early vs. Late Initiation of NPWT (V.A.C.* Therapy)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>V.A.C. Late Mean Values</th>
<th>V.A.C. Early Mean Values</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent wound area change (3 weeks)</td>
<td>16.2%</td>
<td>38.8%</td>
<td>0.04</td>
</tr>
<tr>
<td>Days until 50% reduction in wound area</td>
<td>34.2</td>
<td>22.0</td>
<td>0.002</td>
</tr>
<tr>
<td>Total length of treatment (days)</td>
<td>31.6</td>
<td>25.1</td>
<td>0.116</td>
</tr>
<tr>
<td>Total length of stay (days)</td>
<td>56.4</td>
<td>35.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total wound care treatment costs</td>
<td>$4,182.13</td>
<td>$3,194.36</td>
<td>0.08</td>
</tr>
</tbody>
</table>
stay for the moist group was 15.8 days. For the NPWT group, it was 11.3 days. Saving 4.5 days of hospital stay is estimated to save $6,000.

Frykberg and colleagues used retrospective amputation claims data to compare NPWT versus traditional wound therapies in reducing the incidence of lower extremity amputations in patients with diabetic foot ulcers. Amputation incidences with NPWT versus traditional therapy were 35 percent lower in the Medicare sample (10.8 percent versus 16.6 percent, p=.0077) and 34 percent lower in the commercial payer sample (14.1 percent versus 21.4 percent, p=.0951). In the traditional treatment groups, more severe wounds had a higher incidence of amputation. The same increasing trend was not seen in the NPWT groups. The authors concluded that patients with diabetic wounds treated with V.A.C. therapy had a lower incidence of amputation than those undergoing traditional wound therapy.

In an unpublished retrospective analysis from a long term acute care setting, records of 241 patients treated with NPWT (V.A.C. Therapy®) were examined to identify if timing of therapy initiation made a difference in outcomes and costs. The majority of these patients had diabetes. The patient records were divided into those who had early therapy (within first 14 days of admission) and late therapy. A significant difference in percent wound reduction was seen at weeks two, three, and four post-baseline with early NPWT (Exhibit 6). A multiple regression model, controlling for severity of the wound as well as the initial size, showed that starting V.A.C. within the first 14 days was associated with a reduction of 22 days in total length of stay. In a long-term acute care hospital, a decrease in length of stay of 22 days would result in enormous cost savings. Starting patients on NPWT (V.A.C.® Therapy) within 14 days of admission was associated with significant differences in percent area change at 3 weeks, fewer days until 50 percent reduction in wound area (35 percent reduction), reduction in total length of stay (38 percent reduction), and reduced total wound treatment costs ($987.77) (Exhibit 7).

Conclusion
Cost drivers in wound care are ulceration, infection, hospitalization, and amputation. Prevention is important and cost-effective. Once wounds occur, quick aggressive treatment makes a difference in outcomes. It is clinically and economically beneficial to prevent and aggressively treat ulceration and infection. This keeps patients from needing hospitalization and amputation. Using negative pressure wound therapy is one way to cost effectively manage wounds.

References
2. Reiber GE, Vileikyte L, Boyko EJ, et al. Causal pathways for incident lower-
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THURSDAY, MAY 1

Keynote

The Future of Healthcare Delivery
Peter Kongstvedt, MD, Senior Partner, Health & Life Sciences, Accenture

Business Track

Matching Your Managed Care Strategy to Your Market
Douglas Wilson, Chief Executive Officer, University Health Link

Bridging the Gap: Using Predictive Analytics to Connect Payors, Physicians and Hospitals
Jim Lederer, MD, Medical Director, Novant Health

Clinically Integrate to Ensure FTC Compliance
Phil Kamp, President and Chief Executive Officer, Valence Health

How Payor/Provider Data Can Affect Your Bottom Line
Jonathan Pearce, Director, DGA Partners

A Provider-Owned Health Plan’s Journey Toward Becoming Value Based
Robert Kritzler, MD, Deputy Chief Medical Officer, and Martha Sylvia, RN, MSN, MBA, Director Outcomes & Evaluation, John Hopkins Healthcare

Preparing and Handling a Contract Termination of a Large Payer
Debi Hueter, Vice President Managed Care, Piedmont Hospital

FRIDAY, MAY 2

Keynote

10 Steps to Implementing an Effective Pay for Performance Program: Challenges and Opportunities for Managed Care
Howard Beckman, MD, Clinical Professor of Medicine, University of Rochester, Medical Director, Rochester IPA

Business Track

Collecting and Managing Data for Clinical Integration
Elizabeth Simpkin, President, The Lowell Group, Inc.

Reducing Managed Care Organization Denials
Mark Rosenberg, MD, Medical Director, Behavioral Health Management

Clinical Track

The Role of Prevention in Managed Care

Diabetes: When Behavior Modification is Not Enough

The Impact of Hepatitis B on Managed Care

The Physical and Fiscal Impact of the Obesity Epidemic - The Impact of Comorbid Conditions on Patients and Payers

Identification and Management of Pulmonary Arterial Hypertension

Migraine Prevention

Pain Management Issues

Clinical Track

Fibromyalgia: Prevalence and Management in Managed Care

Managing Atherosclerosis

The Role of Tech Assessments

Using Diagnostic Information to Make Formulary Decisions

Integrated Approaches to Dose Compliance with Biologic Therapies

Evidence-based Approach to Genetic Testing Evaluations

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<tr>
<th>Physician/Nurse</th>
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<td>□Non-Member Rate $695</td>
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Concurrent Track Sessions, Thursday, May 1
9:30 am - 10:30 am
- Matching Your Managed Care Strategy to Your Market
- The Role of Prevention in Managed Care

12:30 pm - 1:30 pm
- Clinically Integrate to Ensure FTC Compliance
- The Impact of Hepatitis B on Managed Care

3:00 pm - 4:00 pm
- A Provider-Owned Health Plan’s Journey
- Identification and Management of PAH

Concurrent Track Sessions, Friday, May 2
9:30 am - 10:30 am
- Collecting and Managing Data
- Fibromyalgia: Prevalence and Management

12:30 pm - 1:30 pm
- Pain Management Issues
- The Role of Tech Assessments

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THERE IS AN EMERGING CONSENSUS that poor quality in the health care system contributes to adverse patient outcomes, and leads to increases in overall costs. This has been brought to national attention through reports on the rate of adverse medication events and medical errors. Employers and the government are escalating their demands for quality benchmarks, outcomes reporting, and the development of a link between quality, performance, and reimbursement. Employers are educating their employees to seek care from providers who deliver high quality care at reasonable costs. Large American companies are collaborating to lead a number of initiatives, including the Leapfrog Group and the National Business Group on Health. More than 70 organizations and 40 private managed care organizations are focused on quality initiatives in health care. Additionally, multiple national quality programs exist, including National Diabetes Quality Improvement Alliance (NDQIA), American Board of Internal Medicine (ABIM), and National Committee for Quality Assurance (NCQA).

In 1999, the Institute of Medicine (IOM) published the report “To Err is Human: Building a Safer Health Care System.” This report, which is available for purchase at www.iom.edu, focuses on patient safety, medical errors, and adverse outcomes. The report quotes that “as many as 44,000 to 98,000 people die in hospitals each year as a result of medical errors.” The IOM report estimates that preventable medical errors cost the U.S. approximately $17 billion per year. Although there were disagreements about the content of this report, it did put the national spotlight on patient safety, medical errors, and adverse outcomes. The IOM report issued a call to action to improve quality and safety of U.S. healthcare with specific recommendations, including quality measurement and reporting, public transparency, and incentives for quality improvement (i.e., pay for performance).

Subsequently, in 2001, the second report by the IOM, “Crossing the Quality Chasm: A New Health Care System for the 21st Century,” was published. This report again raised national attention about quality concerns. This report suggests that a fundamental innovation and redesign of the health care system is necessary. The IOM Committee on Quality in Health Care in America developed six aims that health care systems should model (Exhibit 1). They also developed 10 rules to follow for health care design. Health care should be based on continuous
healing relationships with customized care according to the patient needs and values. Control of care should be by the patient with information and knowledge being shared freely. Health care decisions should be based on evidence, principles, and measurements. Safety should be a system priority. Additionally, the system should be transparent to the patient and should anticipate patient needs. Health care systems should continuously look at ways to decrease waste, and, very importantly, prioritize cooperation among clinicians.

The IOM reports were two of the catalysts that brought the quality concern, which most people involved in health care were aware of, to the national level. Soon after these reports, initiatives were being disseminated, and then programs started to develop. Additionally, during this time, the federal government, through the Ways and Means and the Energy and Commerce committees, gave a clear message to the Alliance of Specialty Medicine. These committees said physicians needed to develop indicators, measures, or other methods of assessment that could be used in pay-for-performance programs.

Exhibit 2 illustrates how the number of pay-for-performance programs has grown. In 2007, 148 pay-for-performance programs existed in the U.S. with over 55 million patients involved in those programs. The Centers for Medicare and Medicaid Services (CMS) have launched multiple pay-for-performance demonstration projects. The American Medical Association (AMA), Joint Commission on Accreditation of Health Care Organizations (JACHO), American Association of Family Physicians (AAFP), and many other organizations set the principles and standards for pay for performance.

The goal of a well designed pay-for-performance program is to create a compelling set of incentives that will drive breakthrough quality improvement and patient experience through a common set of measures, a score card, and some payment system based upon performance measurements. The standard measures selected should be aligned with national measures, if possible. They should be clinically relevant, affect a significant number of people, be scientifically sound, and be evidence based. The measures should be feasible to collect using electronic data, a very important concept in any pay-for-performance program. Physician groups should impact the measures and health plans. The measures should be capable of showing improvement over time and, very importantly, be important to consumers. The 2007 CMS clinical measures are given in Exhibit 3. The patient experience measures that are incorporated into many pay-for-performance programs include effective communication, ratings of care, care coordination, specialty care and timely access to care.

Efficiency measures are missing in almost all of the current pay-for-performance programs. Approximately five percent of the programs have one or more efficiency measure in place. Even with missing efficiency measures, these programs do, however, focus on quality and quality information. They do solidify a mechanism for aggregating physician group data from several
Most of the time, particularly in 2006, the AGA Institute included a need for rules on contracting, incorporating information and data. Physicians are comfortable having higher administrative HEDIS rates and more valid data. Stakeholder needs must be balanced in developing and evolving a pay-for-performance program. Purchasers want more measures to provide meaningful information to consumers. Physician groups want more money to support quality improvement efforts and want to focus on a few measures at a time. Health plans cannot justify paying significantly more for basically the same measures year after year. There is a dichotomy or misalignment in many of the pay-for-performance programs that need a realignment of incentives.

Physicians have provided feedback on pay-for-performance programs. Most of the time, particularly in the mature programs, the reporting is favorable. Physicians have a strong motivation to perform when the data are publicly reported. Pay for performance has inspired many physicians to collect relevant information and data. Physicians are comfortable being held accountable if they have been involved with a measure development. In the markets where pay-for-performance programs are not mature, there is significant physician pushback initially.

Health plan feedback on these programs has included a need for rules on contracting, incorporating the cost with quality to create a business case, and more or better outcomes measures. Lastly, the plans want to address overuse and misuse.

Purchasers, on the other hand, aggressively want new measures added. They want to add efficiency domains that incorporate the total cost of caring for a population. They also want to rapidly increase the portion of the plan payments that go to performance-based groups.

The CMS Physician Quality Reporting Initiative (PQRI) began in July of 2007. Because the commercial market tends to follow CMS’s lead, managed care players need to be aware of this program. There were 66 quality measures posted on the CMS website in December 2006. Eight additional measures were added and the final list of 74 quality measures is available on the web site (www.cms.hhs.gov/PQRI). Currently, this is a measurement program, but it will eventually become a performance-improvement program. Eligible health care professionals who successfully report may earn up to a 1.5 percent bonus. The bonus is calculated based on the total amount of charges. Unfortunately, 1.5 percent is probably not enough to change behavior in today’s marketplace.

The 2008 PQRI measures have been published, but are dependent upon adoption or endorsement by consensus organizations, such as the National Quality Forum or the AQA Alliance. Physicians have been involved in the consensus-based process for development. In 2008 and beyond, the program will include structural measures, such as the use of electronic health records or electronic prescribing technology. The 2007 measures came out too early to insist upon electronic health records as being a determination for participation. Standardized specifications for centralized reporting could reduce the reporting burden for participants and CMS. CMS has a comprehensive education and outreach resource for physicians and others, including tools to support successful reporting.

Gastroenterologists, like many other specialists, are concerned that the shift to pay for performance will decimate their income unless the profession responds by developing consensus around quality measures. In 2004, the American Gastroenterological Association (AGA) convened a Quality in Practice Task Force. The Task Force was given two charters: to develop evidence-based quality measures in gastroenterology practice and programs to educate physicians on pay-for-performance practice implications. The task force came out with six evidence-based parameters recommendations (polyp surveillance, performance of colonoscopy, Hepatitis C management, H Pylori management, Crohn’s management, and gastroesophageal reflux disease). In 2006, the AGA Institute began working with the AMA Physician Consortium for Performance Improvement, the Agency for Healthcare Research and Quality (AHRQ), NCQA, JCAHO, and CMS to develop performance measures for GERD. As a result of this collaboration, four measures of the 74 CMS measures are GERD related. These measures are also under consideration at this point for endorsement by the National Quality Forum.

The GERD measures are based upon four simple principles. They are evidence-based, are aimed at

<table>
<thead>
<tr>
<th>Exhibit 3: 2007 Clinical Measures</th>
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<tbody>
<tr>
<td><strong>Preventive Care</strong></td>
</tr>
<tr>
<td>• Breast Cancer Screening</td>
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<tr>
<td>• Cervical Cancer Screening</td>
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<td>• Childhood Immunizations</td>
</tr>
<tr>
<td>• Chlamydia Screening</td>
</tr>
<tr>
<td>• Colorectal Cancer Screening</td>
</tr>
<tr>
<td><strong>Acute Care</strong></td>
</tr>
<tr>
<td>• Treatment for Children with</td>
</tr>
<tr>
<td>Upper Respiratory Infection</td>
</tr>
<tr>
<td><strong>Chronic Disease Care</strong></td>
</tr>
<tr>
<td>• Appropriate Meds for Persons with Asthma</td>
</tr>
<tr>
<td>• Diabetes: HbA1c Testing &amp; Poor Control</td>
</tr>
<tr>
<td>• Cholesterol Management: LDL Screening &amp; Control (&lt;130 and &lt;100)</td>
</tr>
<tr>
<td>• Nephropathy Monitoring for Diabetes</td>
</tr>
</tbody>
</table>

...
quality improvement, are something that can be used in practice, and have received a broad consensus among physicians. These measures are assessment for alarm symptoms, upper endoscopy for patients with alarm symptoms, biopsy in those patients suspected to have Barrett’s esophagus, and inappropriate use of barium swallow in assessing gastroesophageal reflux disease. The clinical performance measures for each of these is given in Exhibit 4.6

CMS in collaboration with the AMA, Mathematica Policy Research, and the NCQA, has developed participation tools for PQRI. These tools are designed to:

• aid in the selection of measures by physicians and other eligible professionals wishing to participate in the program,
• link to background information on the quality measures, and
• aid in required data collection.

These tools are easily accessible on the CMS website.

Recent survey results about pay for performance from 75 purchasers, government agencies, and health plans, revealed several important findings.1 Improving clinical outcomes remains the top reason for implementing pay-for-performance programs. At least 50 percent of the programs have shown significantly improved clinical performance. These programs demonstrate savings in more than 33 percent of the programs. Expanding the scope or number of performance measures have occurred in more than 70 percent of the programs. Posting public information of provider performance in the provider directories has occurred in more than 30 percent but that is still a challenge. Development of tools to measure improvements in outcomes and eligibility for rewards directly from medical records is occurring in the advanced pay-for-performance programs. In the advanced programs, they are using electronic distribution from health records, and they are more successful than those who do not have electronic means.

Pay-for-performance programs have to evolve over time. They cannot remain stationary or stagnant. They have to change to meet changing needs. In general, pay-for-performance is viewed as a necessary component of a quality driven health care system but certainly not the only or the final solution. It certainly is not going to repair the gaps that we have in our health care systems and the fact that reimbursement is based on sick care instead of well care. Secondly, health plans unfortunately have to tailor pay-for-performance scorecards and measures for specific needs leading to a cornucopia of metrics in the market. In the commercial sector, physician pay-for-performance programs have evolved more fully than hospital plans.

There are still a large number of challenges. There are at least 60 measures in pay-for-performance programs that are used by the 148 programs that exist today. There is not one measure that is used by

GERD Physician Performance Measurement Set

60. Assessment for alarm symptoms
Clinical Performance Measure: Percentage of patients 18 years or older with the diagnosis of GERD, seen for an initial evaluation, who were assessed for the presence of the following alarm symptoms: involuntary weight loss, dysphagia, and GI bleeding.
The physician should assess and document whether or not the patient has alarm symptoms.

61. Upper endoscopy for patients with alarm symptoms
Clinical Performance Measure: Percentage of patients 18 years or older seen for an initial evaluation of GERD with at least one alarm symptom who were either referred for endoscopy or who had one performed.
Patients with alarm symptoms should have additional assessment and treatment.

62. Biopsy for Barrett’s esophagus
Clinical Performance Measure: Percentage of patients 18 years or older with a diagnosis of GERD or heartburn whose endoscopy report indicates a suspicion of Barrett’s esophagus who had a forceps esophageal biopsy performed.
If Barrett’s esophagus is suspected at endoscopy, a biopsy should be performed and sent to pathology for diagnosis.

63. Barium swallow – inappropriate use
Clinical Performance Measure: Percentage of patients 18 years or older seen for an initial evaluation of GERD who did not have a barium swallow test ordered.
Barium radiology has limited usefulness in the diagnosis of GERD and thus is not recommended.
all of the programs. Transparency of physician performance is still in its infancy. There is still reluctance to do this. Reimbursements are too low to significantly change provider behavior. Results from pay for performance are sometimes spotty and few plans have set up tracking records. The impact of these programs is muted by the wide variation in program structures, performance metrics, and rewards structures. Pay for performance will have a significant impact on how care is delivered only if we can agree on one universal set of quality measures that providers need to reach in exchange for substantial rewards. This is a large challenge.

Conclusion

As pay-for-performance programs have grown, the results appear positive. There are still many challenges with these programs. Pay for performance can succeed if there is an all payer approach, wherein providers face the same metrics and incentives for all of their patients, regardless of their insurance coverage. Regardless of the deficiencies in pay-for-performance programs today, there is a lot of attention focused on these. JMCM

Kevin Roache, MD is the vice president of medical affairs at People’s Health, a Medicare administration company in Metairie, La. Dr. Roache also serves as chair of the Center for Continuity of Care within NAMCP’s Health Management Institute.

References

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AMERICAN ASSOCIATION OF MANAGED CARE NURSES

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Targeted Therapy In Cancer
Edward H. Lin, MD

Summary
Targeted cancer therapy is evolving rapidly, and is changing the choice of regimen in many cancers from an empiric guess to a predictive choice. Although many agents are currently available, many more are in the development pipeline. Each of these agents targets one or more of the hallmarks that drive cancer growth. Although they may be somewhat less toxic than traditional chemotherapy, these agents are not without adverse effects.

Key Points
• The goals of today’s targeted therapies are to selectively destroy cancer cells and produce less toxicity than traditional chemotherapy agents.
• Six hallmarks that drive cancer growth are self-sufficiency in growth signals, insensitivity of antigrowth signals, limitless replicative potential, evading cell death (or apoptosis), sustained tumor blood vessel formation, and tumor invasion and metastasis.
• Differences in response to these various targeted agents can be seen across different patient populations.
• Targeted cancer therapies do have adverse effects, some of which are significant.

TARGETED THERAPY FOR CANCER IN yesterday’s terms included such items as 5-flouracil (5-FU), which targets thymidylate synthase in many cancers, and tamoxifen for estrogen receptor positive breast cancer. These agents, even though they are toxic agents, do have targets.

The aim of current research is to find therapies that selectively destroy cancer cells, and leave normal cells alone, while producing less toxicity than traditional chemotherapy agents. Traditional chemotherapy agents do kill cancer cells but they also typically kill other cells such as those of the gastrointestinal tract and hair follicles. These new selective killing agents are referred to as targeted therapies.

In today’s terms, targeted therapies for cancer are agents that target one of the six hallmarks of cancer. These hallmarks are what drive cancer growth: self-sufficiency in growth signals, insensitivity of antigrowth signals, limitless replicative potential, evading cell death (or apoptosis), sustained tumor blood vessel formation, and tumor invasion and metastasis. Each one of these hallmark represents an area where an oncology drug has been designed. Some of the specific targets in each area are shown in Exhibit 1. An additional area besides the six hallmarks that is being targeted is the immune system. There are FDA-approved medications targeting tumor angiogenesis, growth signal transduction, and cell cycle apoptosis, in addition to others. Many different agents are also in various stages of clinical development.

The various ways to deliver one of these agents to cancer cells are outlined in Exhibit 2. For example, ibritumomab (Zevalin®) and tositumomab (BEXXAR®) deliver radioisotopes to lymphoma cells. Rituximab (Rituxan®) and alemtuzumab (Campath®) are monoclonal antibodies that induce cell lysis by activation of the host’s immune system. Bevacizumab (Avastin®), cetuximab (Erbitux®), and trastuzumab (Herceptin®) are other monoclonal antibodies that bind to the extracellular domains of receptors involved in cell growth. Gemtuzumab (Mylotarg®), a combination monoclonal antibody and cytotoxic molecule, is used to deliver the cytotoxic molecule in acute myelogenous leukemia (AML). Bortezomib (Velcade®), gefitinib (Iressa®), imatinib (Gleevec®), sunitinib (Sutent®) are all small molecule drugs which target specific proteins within cancer cells and stop the cancer cells from growing. Ribozymes block protein synthesis.

The target therapies that have been approved for use in the U.S. thus far are not without adverse effects. For example, agents which target the epidermal growth factor receptor such as cetuximab, panitumumab (Vectibix®), and erlotinib (Tarceva®) cause rash in a large percentage of recipients. The agents that target vascular endothelial growth factor (VEGF) or vascular endothelial growth factor receptor (VEGFR inhibitors) in various
tumors include bevacizumab, sunitinib, imatinib, and sorafenib (Nexavar®). Because these agents target the vascular system, the adverse effects include hypertension and, rarely, heart attack and heart failure.

For several cancers, studies of these targeted agents are showing an increase in overall survival. For example, in head and neck cancer, adding cetuximab with radiation or with cisplatin and radiation gives a significant survival benefit of about 10 months improvement in median overall survival. Historically with gastrointestinal stromal tumor (GIST), people would live about 20 months. With imatinib, treated median overall survival is 70 months, which is a revolutionary improvement.

Complete responses do not necessarily mean cure. For example, about 74 percent of liver cancer sites that had evidence of recurrence within one year. In general, the absolute complete responses are about 4 percent.

There are several emerging areas in targeted oncology that may lead to significant changes in the landscape. One area is counting circulating tumor cells in the drug largely based upon the one-year survival difference. Canada and Europe both approved, studies with gefitinib have shown very little difference in survival. Canada and Europe both denied approval of this agent, but the FDA approved the drug largely based upon the one-year survival differences of about 7 percent in pancreatic carcinoma.

Many of these targeted therapies are producing significant complete responses, which means that cancer growth cannot be detected by current methods. Complete responses do not necessarily mean cure. For example, about 74 percent of liver cancer sites that had complete responses to first line chemotherapy showed evidence of recurrence within one year. In general, the absolute complete responses are about 4 percent.

There are several emerging areas in targeted oncology that may lead to significant changes in the landscape. One area is counting circulating tumor cells in colon cancer. The number of circulating tumor cells appears to be a stronger predictor of progression free and overall survival than age, performance status, or number of previous treatment regimens.

Another area of significant work is cancer stem cells. These are the cells that generally will not be eliminated by chemotherapy and subsequently these cells will give rise to other cells and tumor regrowth. The new cancer growth will no longer respond to treatments. Measurement of stem cell markers is being used to predict cancer recurrence. Presence of cancer stem cells may lead to longer duration of chemotherapy or use of suppressive agents like tamoxifen is used in breast cancer.

Another area of much research is modifying the immune system. Immunotherapeutic agents such as vaccines or immuno-stimulants are going to emerge as the next phase of revolution in oncology treatments.

**Conclusion**

Numerous targeted therapy agents are currently available and many more are in various stages of development. Many of these agents will be coming to market in the next few years. The paradigm of cancer treatment is clearly changing from a palliative to a curative, at least in some cancers, approach. If care is palliative, the emphasis on therapy is maintaining quality of life. The introduction of oral targeted therapies, rather than injectable agents, is very important in improving patient’s quality of life. Oncology is also changing from empiric therapy to predictive therapy. Predicting the patients most at risk of recurrence or most likely to respond to a particular agent is going to become the norm.

Edward H. Lin, MD is an associate member of the Fred Hutchinson Cancer Research Center, a part of the Seattle Cancer Care Alliance. Dr. Lin also is an associate professor in the oncology division at the University of Washington.

**References**

OBESITY IS A CHRONIC DISEASE OF multiple etiologies characterized by the presence of excess adipose tissue. The National Institutes of Health and the World Health Organization consider obesity a discrete medical condition that independently affects health. Defining obesity as a disease resulted in insurance coverage for obesity treatments, and expedites approval of new medications as well. Considering obesity a disease can help destigmatize the condition, similar to defining alcoholism as a disease. It can also remove some key economic and regulatory hurdles to prevention and treatment. Since 2002, the IRS has allowed an itemized income tax deduction for expenses related to treatment of a disease, such as obesity. Body mass index (BMI) is used to identify those people who are obese. BMI is a measure of an individual’s weight (kilograms) in relation to height (meters squared). A normal BMI is under 25 kg/m². BMIs between 25 kg/m² and 30 kg/m² are considered overweight. Obesity is defined as a BMI greater than 30 kg/m².

There is an epidemic of obesity in the U.S. About 127 million adults, or 1/3 third of our country, are overweight. Up to 60 million adults are obese. According to the American Society of Bariatric Surgery, the latest data show that about 11 million are morbidly obese and are candidates for bariatric surgery. The prevalence of obesity has more than doubled in 46 years from 13.3 percent to 30.9 percent. The prevalence of morbid obesity has nearly doubled in 12 years (2.9 percent to 4.7 percent).

Obesity results in $100 billion in annual medical costs. The overall costs of obesity are illustrated in Exhibit 1. Six percent of total adult medical expenditures are attributed to obesity. Seven percent of total Medicare expenditures and 11 percent of total adult Medicaid expenditures are a result of obesity. Twenty-seven percent of overall increases in medical spending between 1987 and 2001 were attributable to obesity. Per patient medical costs are higher for obese patients (Exhibit 2).

Obesity is a major contributing factor to high-cost, high-prevalence disease states—type 2 diabetes, hypertension, heart disease, osteoarthritis, gallbladder disease, and cancer. Approximately 10 percent of all the U.S. healthcare dollars are spent on some type of obesity-related condition. Exhibit 3 shows the percentage of certain disease costs that are attributable to obesity.

Societal Interventions
To begin to combat the obesity epidemic, the U.S. Preventative Services Task Force recommends that clinicians should screen all adult patients for obesity...
and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. Another example of a societal intervention is the FDA campaign called Calories Count.

Under this campaign, food nutrition labels have been revised to include larger type size, percentage of daily caloric intake, and total caloric count of packaged food eaten all at one time (candy bar, single serve chips, etc). This campaign has also defined the terms “low”, “reduced”, and “free” of carbohydrates. Other aspects of this campaign are the convening of an Advisory Board to review guidelines for diet drugs, encouraging development of new weight loss drugs, encouraging restaurants to provide more nutrition information on menus, and encouraging food manufacturers to use dietary guidance statements. The FDA has also strengthened the coordination of obesity research and development of healthier foods with other national agencies. A final component of the FDA plan is focused consumer education on influenc-
ing behavior, promoting healthier eating choices, and working with private and public sector partners to give consumers a better understanding of food labels.

**Obesity Treatments**

The major categories of treatments for obesity are lifestyle changes (dietary and physical activity), medications, and surgery. With dietary changes and exercise, patients lose five to 10 percent of their starting weight on average.\(^{10-12}\) This degree of weight loss can help reduce many of cardiovascular risk factors as shown in Exhibit 4. The decrease in blood pressure and glucose comes from weight loss and is irrespective of being on appropriate medical treatments for those comorbid diseases themselves. Unfortunately, once the patient stops a weight loss program, weight gain typically occurs (Exhibit 5).\(^{13}\) Commercial weight loss programs such as TOPS and Weight Watchers can produce weight loss. Regrettably, there is a high attrition rate from these programs (Exhibit 6).\(^{14}\)

The two anti-obesity medications currently approved for long term use are orlistat (Xenical\(^{®}\)) and sibutramine (Meridia\(^{®}\)). Short-term use of these agents alone is not much better than diet and exercise. For weight loss medications to be most effective, the patient must also make dietary and physical activity changes. The combination of dietary changes, increased physical activity, and weight loss medications will help lower BMI in many patients by 10 to 15 percent. Combination therapy may not get them under 25 kg/m\(^2\) but it can get them under 30 kg/m\(^2\).

---

**Exhibit 3: Percent of Disease Costs Attributable to Obesity**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cost Attributable to Obesity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 Diabetes</td>
<td>61%</td>
</tr>
<tr>
<td>Gallbladder Disease</td>
<td>30%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>17%</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>17%</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>24%</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>11%</td>
</tr>
<tr>
<td>Endometrial Cancer</td>
<td>34%</td>
</tr>
<tr>
<td>Colon Cancer</td>
<td>11%</td>
</tr>
</tbody>
</table>

**Exhibit 4: Impact of Weight Loss on Risk Factors**

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>~5% Weight Loss</th>
<th>5%-10% Weight Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Sugar</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>↑</td>
<td>↑</td>
</tr>
</tbody>
</table>

\(^*\) Diet restricted

---

**Exhibit 5: Nonsurgical Weight-Loss Therapy Has Not Been Shown to Result in Long-Term Weight Loss**

![Change in Weight (kg)](chart)

- **Diet alone**
- **Behavior therapy**
- **Combined therapy**

---

**Exhibit 6: Nonsurgical Weight-Loss Therapy Has Not Been Shown to Result in Long-Term Weight Loss**

![Graph showing weight change over time](chart)
Additionally, weight regain typically occurs once medication is stopped. Adverse effects with these medications may limit adherence. Adherence is both persistence—continuing to take medication and compliance—taking the medication correctly as prescribed on a regular basis.

Bariatric surgery is more effective over time than the other two approaches. Patients can lose as much as 50 percent of their excess weight loss compared to five percent to 15 percent. This weight loss can be sustained for up to 10 years. Weight loss surgeries involve reducing the capacity of the stomach, bypassing parts of the stomach and intestines to prevent nutrient absorption, or a combination. Examples of surgical weight loss procedures include the jejunooileal bypass and vertical band gastroplasty. Each year, 120,000 bariatric procedures are done in the United States.

The available data suggest that surgery may be superior to medical treatments for morbidly obese patients. Surgical treatment for obesity in severely obese individuals (BMI 40 kg/m²) results in greater weight loss than does medical treatment.16 Severely

---

Exhibit 6: High Attrition Rates Limit the Effectiveness of Commercial Nonsurgical Weight-Loss Programs

<table>
<thead>
<tr>
<th>Commercial Weight-Loss Programs</th>
<th>Attrition Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOPS® (n = 234)</td>
<td>67% †</td>
</tr>
<tr>
<td>eDiets® (n = 46)</td>
<td>34% †</td>
</tr>
<tr>
<td>Optifast® (n = 517)</td>
<td>5% ‡</td>
</tr>
<tr>
<td>Health Management Resources™ (n = 85)</td>
<td>26% §</td>
</tr>
<tr>
<td>Weight Watchers® (n = 423)</td>
<td>18% †</td>
</tr>
</tbody>
</table>

*Usual TOPS program
† 1 year
‡ 1.5 years
§ 2 years
¶ 13 weeks

Exhibit 7: Laparoscopic Gastric Banding Results in Long-Term Weight Loss*

- Significant improvement in percent of excess weight loss vs. baseline was achieved at 12 months (34.5%), 24 months (37.8%), and 36 months (36.2%).
- Based on a chart review of 1,014 consecutive cases of patients undergoing laparoscopic banding system surgeries. Follow-up data were available for relatively few patients at 36 months (68 of 77) and at 48 months (12 of 14).
Obese patients lose 20 to 30 kg of weight that is maintained for 10 years and possibly longer, and is accompanied by significant improvements in several comorbid conditions. For patients with BMIs between 35 and 39 kg/m², data strongly support the superiority of surgical therapy however these data cannot be considered conclusive in the absence of a study with a concurrent comparison group. For people between 30 and 40, surgery may or may not be necessary to achieve an acceptable weight. Many health care insurers have developed policies to identify which patients would likely benefit the most from bariatric surgery.

The various bariatric surgery procedures have been compared with each other. The laparoscopic adjustable gastric banding (LAGB) procedure appears to be as efficacious as gastric bypass up to 60 months of follow-up. Long-term weight loss with LAGB is seen with a 62.0 percent (± 19 percent) mean excess weight loss three years after surgery (Exhibit 7). The complication rates of gastric bypass are higher than those with LAGB. This includes total complications (23 percent vs. 9 percent), major complications (2.1 percent vs. 0.2 percent), and short term postsurgical death (0.5 percent vs. 0.05 percent). Laparoscopic surgery has some other benefits compared with open gastric bypass including a shorter hospital length of stay, reduced recovery time, reduced incidence of wound complications (infections, hernias, dehiscence), and higher member satisfaction.

Both gastric bypass and LAGB procedures result in sustainable weight loss, which is an important outcome. Another important outcome of weight loss surgery is the reduction in comorbidities. As shown in Exhibit 8, LAGB can result in a significant resolution or improvement in asthma, hypertension, type 2 diabetes, sleep apnea, and gastroesophageal reflux. Reduction of comorbidities is an important outcome in terms of medical costs. Although bariatric surgery is costly, the reduction in comorbidities should reduce costs. Claims data cost analyses of bariatric surgery are being done but are not yet published. This information that can help managed care make better decisions about the use of these weight loss procedures.

Several professional organizations have produced favorable consensus statements recently on bariatric surgery. This includes the National Institutes of Health (NIH) Consensus Development Conference (2004), American Society for Bariatric Surgery (ASBS) Consensus Conference (2004), Blue Cross® Blue Shield® Association Technology Evaluation Center Assessment (2007), and ECRI Institute (2004).

The key finding of the NIH consensus statement is that bariatric surgery can be considered for appro-
appropriate patients (BMI ≥ 40 kg/m² or BMI between 35 and 39.9 with high-risk comorbidities).21 The risk-benefit assessment before surgery should include weight-loss potential, likelihood of improvement in comorbidity measures, psychological effects, and likelihood of perioperative/long-term complications or mortality. A multidisciplinary team evaluation including medical, surgical, psychiatric, and nutritional expertise is needed. This statement recommends that patients seeking surgical therapy be considered for treatment in a non-surgical program with integrated components of a dietary regimen, appropriate exercise, behavioral modification and support before surgery. This consensus statement also notes that patients who undergo weight loss surgery require lifelong medical surveillance.

The key findings in the ASBS consensus statement are:

• bariatric surgery is the most effective therapy available for morbid obesity;
• bariatric surgery can result in improvement or complete resolution of obesity-related comorbidities;
• it can be cost-effective before the fourth year of follow-up; and
• candidates should not be required to have completed formal non-operative obesity therapy as a pre-condition for the operation.2

Contrary to this surgeon point of view, non-operative therapy is probably appropriate for most patients in terms of an initial treatment step. Like the NIH statement, this group noted a multidisciplinary team should evaluate patients for appropriateness of surgery.

The key finding of the Blue Cross/Blue Shield Tech Assessment that was done at the beginning of 2007 is that LAGB surgery results in substantial weight loss of approximately 40 percent excess weight loss at one year with a substantial reduction in comorbidities.25 As previously discussed, this assessment also noted that LAGB surgery is less risky than gastric bypass. Greater short-term weight loss with gastric bypass may be outweighed by operative risks.

The ECRI Institute assessment noted that three years after adjustable gastric banding, patients lose a clinically significant amount of weight.26 In some patients, adjustable gastric banding results in the improvement or resolution of type 2 diabetes, hypertension, and sleep apnea. This assessment also stated that patients experience large improvements in quality of life when assessed up to four years after adjustable gastric banding.

For the morbidly obese patient, surgery may be a first option instead of wasting time and money trying other avenues. To achieve a significant weight loss and reduce comorbidity risks and costs in patients with BMIs over 40, they need a surgical procedure to an appropriate weight.

Because major lifestyle changes are required after weight loss surgery, patients require a pre-operative psychiatric consultation. The patient has to be ready to not only manage themselves post-operatively but also for the long term. The multidisciplinary team carrying for the obese patient should include nutrition counselor, exercise counselor, and psychologist or psychiatrist. Patients should also be offered support group meetings.

Managed Care Coverage

Across the county managed care plan coverage and criteria for bariatric surgery is variable. Overall 180 million lives in the U.S. are now covered under some type of managed care medical policy making them eligible, if they meet the clinical criteria, for the LAGB. Fifteen commercial payers added LAGB policies covering 22 million lives in 2007. The Centers for Medicare & Medicaid Services (CMS) made a national coverage decision in 2006.

To approve a bariatric procedure, most plans are going to require documentation of previous medically supervised weight loss attempts, absence of correctable causes of weight gain such as thyroid disease, comorbidities, current weight, and current medications. Most of the plans require that the patient be at least 100 pounds over their ideal body weight or have the BMI over 40 kg/m². If the BMI is between 35 and 40, there have to be documented comorbidities. Some plans require the patient have functional impairment related to his/her weight. Some also have a duration requirement (i.e., obesity has been present for five years).

Conclusion

The United States has an obesity epidemic. Although lifestyle changes and anti-obesity medications can provide modest weight loss, many severely overweight patients will need bariatric surgery to achieve an acceptable weight. For people with a BMI over 40 kg/m², surgery is probably the treatment of choice. Successful, sustained weight loss requires a multidisciplinary approach by health care professionals and major lifestyle changes by the individual. JMCM

Ross M. Miller, MD, MPH serves as physician advisor, Medicaid pharmacy operations, for the California Department of Health Services.

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2. Buchwald H. Consensus conference statement bariatric surgery for morbid

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