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Leaders Identify Top Health Care Innovations

Recently, 100 health care leaders were asked to identify the most important innovations that are transforming health care in the United States. The leaders included representatives from hospitals, physician groups, health care suppliers, and policy makers. Interestingly, there was a lot of agreement among the 100 leaders interviewed by telephone in May and June.

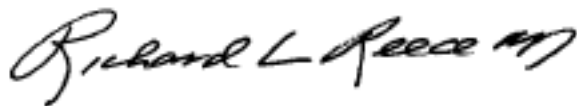
In particular, they agreed that pay-for-performance programs supported by patient outcomes data is one of the strongest trends operating in health care today. Given that data are impersonal and non-judgmental, using numbers to segregate the best physicians from other providers would seem to be a sensible way to address concerns about quality. But physicians are worried that the data being used to evaluate them may come from a sample size that is too small, or that the collection methods do not reflect the actual art and science involved in delivering health care to patients. Nevertheless, health care buyers are using data to pay more to those who show they deliver top-quality care.

The respondents to this admittedly unscientific telephone sampling of health care leaders also expressed deep faith in the ability of information systems to make data on the cost of care transparent to patients and to health care buyers. Patients are interested in the costs of care in part because of the growth of consumer-drive health plans (CDHPs). The survey respondents predicted that CDHPs will continue to attract patients and payers to this new model of care.

The use of information systems in health care also is a strong trend that will continue, respondents said. One example of information systems being used widely are electronic health records (EHRs) in medical offices and personal health records (PHRs), which patients use to store their medical information. The leaders who responded to the survey said they believe EHRs and PHRs are having a positive effect on how care is delivered and will have a more significant effect in the coming years.

Technology also is being used in disease management programs, the respondents said. Such technology allows disease management vendors to collect information from patients, to gather more information on the quality of care they deliver, and to deliver more educational materials to patients.

For physicians, the changes that are coming likely will have a significant effect on their practices. Therefore, the respondents said physicians should develop new business models so that they can take advantage of these trends. The new business models should allow physicians to invest in EHRs and information systems to let them compete more effectively in a changing health care environment.



Richard L. Reece, MD
Editor in chief

Phone: 860/395-1501

Fax: 860/395-1512

E-mail: Rreece@premierhealthcare.com

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Publisher

Premier Healthcare Resource, Inc.
150 Washington St.
Morristown, NJ 07960
888/457-8800; Fax: 973/682-9077
publisher@premierhealthcare.com

Editor

Joseph Burns
508/495-0246
editor@premierhealthcare.com

Neil Baum, MD
Urologist
New Orleans

Daniel Beckham
President
The Beckham Co.
Physician and Hospital Consultants
Whitefish Bay, Wis.

Harold B. Kaiser, MD
Allergy & Asthma Specialists, PA
Minneapolis

Nathan Kaufman
President
The Kaufman Group
Division of Superior Consultant Co. Inc.
Physician and Hospital Consultants
San Diego

Paul H. Keckley, PhD
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Evidence-based Medicine
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BAR Health Strategies
New Brunswick, N.J.

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Milliman Care Guidelines
Milliman USA
San Diego

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Chairman
Sokolov, Sokolov, Burgess
Scottsdale, Ariz.

Adolescent GERD Medicines: Safety of Active and Inactive Ingredients

By Sharon L. Cross, PhD

One of the mantras of the pediatrician is, “Children are not small adults.” This statement is particularly important when pediatricians are prescribing pharmaceutical agents, including medications for pediatric gastroesophageal reflux disease (GERD). Although the two major classes of GERD medications, proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs), are commonly used in both adults and children, there are important differences between the two populations.

Children who are treated with PPIs, for example, usually require a higher dose for each pound of body weight than adults due to differences in drug metabolism. Even within the pediatric population, the age of the child makes a difference. In one study, famotidine, an H2RA, was found to result in reversible agitation in more than 10% of children less than 1 year of age, but this effect has not been seen in older children or adults.

Reviewing Safety Profiles

In recognition of the differences in the responses of children and adults to pharmacological agents, two laws that encourage pediatric studies were enacted: the Food and Drug Administration Modernization Act of 1997 and the Best Pharmaceuticals for Children Act of 2002. These laws

provide an additional six months of marketing exclusivity for drugs (meaning no generic versions can be approved for sale in that time) if the sponsors provide requested pediatric information within a specified time.

Of the first 33 drugs to provide pediatric information under this program, significant new dosing or safety information was identified for 12 (36%) (Roberts et al. JAMA 1003;290:905-11). These findings suggest that specific pediatric information is necessary to fully evaluate medications used in children. The more information available, the more likely the drug is to be used correctly in the pediatric population, resulting in improved tolerability and better outcomes.

The GERD medications approved for use in adolescents (usually defined as 12 to 16 or 17 years of age, depending on the study) generally have excellent safety profiles, although precise safety data can be difficult to obtain. In some cases, safety information reviewed by the Food and Drug Administration (FDA) to determine pediatric indications is obtained from databases or studies whose reports may not be published. In other cases, pharmacodynamic or open-label studies provide the required information. Randomized, placebo-controlled trials of these agents in children are relatively rare.

Extensive Knowledge Base

“It’s much more difficult to enroll children in trials even when it’s a very well tolerated drug,” comments Marcia L. Buck, PharmD, clinical pharmacy specialist at the University of Virginia Children’s Hospital and professor of pediatrics at the University of Virginia Schools of Medicine and Nursing in Charlottesville, Va. “Compared with other medications commonly used in pediatrics, however, there is a fairly extensive knowledge base for pediatric GERD medications.

“We have learned a lot about these drugs from clinical experience, and in comparison to many drug classes used in the pediatric population, these drugs have more clinical trial data than most others,” Buck says.

Manufacturers list the most common adverse events for GERD medications in their prescribing information, the FDA indications for use in adolescents, and observations in pediatric populations (see sidebar). It is important to note that there are wide variations in how the data for medications are reported. Some of the reports on these medications focus on adverse events judged to be possibly or probably related to treatment and others list the most common adverse events regardless of causality. These differences can make it difficult to compare the adverse event profiles of the agents.

(Continued on page 4)

“It’s likely that puberty has a significant effect on response to many drugs; patients in that age group have not been very extensively studied,” says Marcia L. Buck, PharmD, of the University of Virginia Children’s Hospital in Charlottesville, Va.

(Continued from page 3)

Safety Findings for GERD Medications

The data below show the most common adverse events for GERD medications. The information was obtained from each product's approved prescribing information.

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The following findings are for GERD medications (histamine-2 receptor antagonists and proton pump inhibitors) that are approved for use in adolescents. For each medication, the adverse events (AEs) are listed, followed by the FDA indications for use in adolescents and observations in pediatric populations.

Histamine-2 receptor antagonists

Cimetidine. Most common AEs in adults: diarrhea, headaches, dizziness, and somnolence. Rare AEs include gynecomastia, confusional states, and hypersensitivity reactions. Pediatric observations: No specific information for pediatric patients; not recommended for children under 16 years of age.

Famotidine. Most common AEs in adults: headache (4.7%), dizziness (1.3%), constipation (1.2%), and diarrhea (1.7%). Rare AEs include arrhythmia, hypersensitivity reactions, musculoskeletal pain, psychic disturbances, and bronchospasm. Pediatric observations: Agitation that resolved upon discontinuation observed in 5 of 35 (14%) patients <1 year of age. No other specific pediatric safety information given.

Nizatidine. Most common AEs in adults: >5% of patients: headache, rhinitis, diarrhea; significantly more common in active group compared with placebo: anemia and urticaria; rare cases of reversible mental confusion. Pediatric observations: AEs occurring in >5% of pediatric patients: pyrexia, nasopharyngitis, diarrhea, vomiting, irritability, nasal congestion, and

cough. Mild elevations in serum transaminase levels (one to two times the upper limit of normal) noted in some patients. One patient had a seizure.

Ranitidine. Most common AEs in adults: headache (sometimes severe), constipation, diarrhea, nausea/vomiting. Rare AEs include reversible mental confusion, hepatitis, blood count changes, gynecomastia, and hypersensitivity reactions. Pediatric observations: No specific pediatric safety information provided.

Proton pump inhibitors

Esomeprazole. Most common possibly or probably treatment-related AEs in adults: diarrhea (4.3%), headache (3.8%), and abdominal pain (3.8%). Rare AEs include blurred vision, hepatitis, and hypersensitivity reactions. Pediatric observations: Most frequent treatment-related AEs: headache (8.1%), abdominal pain (2.7%), diarrhea (2%), and nausea (2%).

Lansoprazole. Most common possibly or probably treatment-related AEs in adults: abdominal pain (2.1%), constipation (1.0%), diarrhea (3.8%), and nausea (1.3%). Rare AEs in adults include hypersensitivity reactions and severe dermatologic reactions. Pediatric observations: Most frequent treatment-related AEs in children 1 to 11 years of age: constipation (5%) and headache (3%). Most frequent treatment-related AEs in children 12 to 17 years of age: headache (7%), abdominal pain (5%), nausea (3%), and dizziness (3%).

Omeprazole. Most common AEs possibly or probably related to treatment in adults: headache (2.4%), diarrhea (1.9%), rash (1.1%), nausea (0.9%), and constipation (0.9%). Rare AEs include allergic reactions, chest pain or angina, muscle cramps, and psychic disturbances. Pediatric observations: Similar to AE profile in adults, except for these events described as "unique to the pediatric population:" adverse events of the respiratory system in both the 0- to 2-year (46.2%) and 2- to 16-year old (18.5%) age groups. Also, otitis media in the 0- to 2-year old age group (22.6%) and accidental injuries in the 1- to 16-year old age group (3.8%). —SLC

There are also important disparities in the extent of pediatric information provided. Some agents, such as cimetidine and ranitidine, provide no specific safety information for children. For cimetidine, the lack of safety information for children may be due to the fact that this agent is not FDA-approved for the treatment of children younger than 16 years of age.

Others, such as nizatidine, esomeprazole, and lansoprazole, provide more information on adverse events observed in children. Such information can be useful to prescribing physicians, particularly if the child being treated is suffering from side effects. For instance, information in the prescribing information suggests that children who experience

headaches during treatment with a proton pump inhibitor may find relief with an H2RA, while children who develop diarrhea while on an H2RA may fare better with a PPI.

The adolescent age group can pose particular challenges for safety observations due to the rapid physiologic changes that occur during this time. "It's likely that puberty has a signifi-

cant effect on response to many drugs,” Buck observes.

Inactive Ingredients

When developing formulations, pharmaceutical companies use the term “excipient” to describe the many different ingredients other than the active drug that is added to a pharmaceutical formulation. Excipients are added for a number of reasons, such as to improve drug solubility, stability, or palatability. Although more commonly referred to as “inactive ingredients” due to the fact that they do not affect the therapeutic benefit of the drug, excipients are not totally without physiologic effect. In fact, a severe problem with an excipient was one of the driving forces behind an expanded role for the FDA in the testing of drug safety.

In the 1930s, diethyleneglycol was used to solubilize an antibacterial agent, sulfanilamide, and to improve its taste in oral formulations. More than 100 children who took this medicine died of kidney failure due to the diethyleneglycol content of the formulation. In response to this tragedy, Congress passed the Federal Food, Drug and Cosmetic Act in 1938 to mandate safety testing before marketing (Osterberg and See, *Int J Toxicol* 2003;22:377-380).

Most inactive ingredients are well tolerated, but there is a substantial body of literature attesting to the fact that these substances can cause problems in children. One of the most authoritative documents on this issue is a report written by the American Academy of Pediatrics (AAP) Committee on Drugs (*Pediatrics* 1997;99:268-278). Cheston M.

Berlin Jr., MD, professor of pediatrics and pharmacology at Pennsylvania State University Milton S. Hershey Medical Center in Hershey, Pa., chaired the committee that authored this report. “Most of the substances used are probably inactive in the biological sense,” he says. “But as many substances as there are in some of those formulations, it’s probably a wonder we don’t see more problems.”

Gastrointestinal Effects

Problems may arise from some of the excipients found in pediatric GERD medications. “Traditionally, most adverse events related to inactive ingredients are gastrointestinal,” Berlin remarks. Often, however, the problem is inadvertently attributed to the active ingredient. Berlin explains, “For instance, one of the most common drug classes used in children is antibiotics, and gastrointestinal effects are a known complication of antibiotic use. If a child develops diarrhea in response to an antibiotic formulation, the doctor will probably think it is related to the active ingredient, rather than to other substances in the formulation.” Such thinking may be true when pediatric GERD medications are used, as gastrointestinal effects are frequently seen in both adults and children treated with these agents.

The development of liquid formulations for children can be particularly difficult, as taste and texture play a greater role in the acceptability of such products than they do in tablets or capsules swallowed quickly. Alcohol is sometimes used to enhance the solubility of active ingredients in liquid formulations.

The AAP Committee on Drugs recommends that over-the-counter liquid preparations be limited to a maximum of 5% volume/volume ethanol (*Pediatrics* 1984;73:405-407). However, prescription formulations are not subject to this voluntary limit. Of the two liquid pediatric GERD formulations, nizatidine oral solution is alcohol free, while ranitidine syrup contains 7.5% alcohol. “I don’t think most pediatricians are aware of that,” Berlin observes.

Buck concurs. “They probably wouldn’t use it if they were aware,” she says. “In general, we try to avoid the products containing alcohol. We have enough choices in the H2RA class that we don’t have to choose those products.” The presence of alcohol, however, should not be considered an absolute contraindication for pediatric patients, she says. “For most teens, this shouldn’t be a problem, since 7.5% is a rather small amount,” she adds. “We would be more concerned with use in infants.”

Although toxicity with chronic use is likely the major source of concern with formulations that contain alcohol, another possible problem is interactions with other medications or substances the patient is taking. “As with any patient, teens who are taking other drugs, herbals, or dietary supplements that might interact with alcohol should avoid those products,” Buck comments. “This is something their pharmacist can check for them.”

—Reported and written by Sharon L. Cross, PhD, in Mission Viejo, Calif. More information on physician practice strategies is available on our Web site (see page 8).

“As many substances as there are in some of those formulations, it’s probably a wonder we don’t see more problems,” says Cheston M. Berlin Jr., MD, Pennsylvania State University Milton S. Hershey Medical Center in Hershey, Pa.

Take Steps to Protect Financial Assets

By Christopher R. Jarvis, MBA, and Charles P. KinCannon, JD, LLM

Physicians and other high-income individuals should recognize that the financial planning steps outlined for most Americans may not apply to them. As professionals who earn more than the average worker, physicians must take unusual steps to protect their financial assets.

There are many ways that a physician can lose his or her personal and practice assets. One way is in a lawsuit against the physician, his or her partners, or employees. In addition to the malpractice risks of a medical practice (which may be covered in part by liability insurance), physicians have other business risks that would not be covered by a malpractice policy. These risks may result from being an employer, a leaseholder, or a landlord.

To protect assets in the event of a suit not covered by a malpractice policy, a physician can organize his or her medical practice as a corporation. A corporation could protect personal assets from both medical and non-medical legal actions of partners or employees. There will be costs associated with organizing a corporation and there could be filing fees of about \$1,000 to 2,000 per year. In addition, there could be state fees and tax preparation costs as well. While these costs will be higher than those associated with being a sole proprietor or

in a general partnership, a corporation provides protections that an individual physician does not have. Also, there are tax benefits that are possible through a corporation that a sole proprietor or general partnership cannot realize.

Reconsider Asset Ownership

Another way a physician can protect his or her assets is not to own any assets in his or her own name or jointly with a spouse. Owning assets in the physician's name or owning them jointly with a spouse is the most common ownership structure for real estate and bank accounts and is fine for most Americans. But physicians have potential lawsuit risks, probate fee liability, and estate tax risks that are much higher than that

to design an asset protection plan that will protect assets against lawsuits, probate fees, and estate tax liabilities.

Retirement Planning

One of the most important areas of consideration regarding financial planning involves the physician's retirement plan. And, once again, physicians should remember that they will likely need an atypical retirement plan. Typical retirement plans are fine for rank-and-file employees who are forced to put away funds for retirement. The money grows and then is available to them after age 59.5. When they pass away, there may be a modest amount remaining for their heirs.

If a physician has a number of employees covered under such a

While the costs of establishing a corporation will be higher than those associated with being a sole proprietor or in a general partnership, a corporation provides protections that an individual physician does not have. And there are tax benefits as well.

of the average American. Physicians seeking to protect their assets against lawsuits and who do not want to leave their children with unnecessary probate fees or estate tax liabilities, should consider alternative ownership structures.

There are many different types of ownership structures, and the best guidance would depend on each physician's individual situation and desires for protection. Therefore, physicians should seek the advice of a qualified financial professional who works with high-income individuals

retirement plan, then the physician is responsible for making those contributions into the plan for each employee. If the physician has a large number of employees, these payments can be significant. As the one responsible for funding the plan, the physician would be liable if employees do not get the proper allocations or contributions from the practice.

If the physician's plan administrator makes a mistake that results in under funding the plan or if the employees are not treated fairly under the plan, the federal Department of

Christopher R. Jarvis, MBA, is a lecturer and author of Wealth Protection, MD: the Ultimate Financial Guide for 21st Century Physicians. (Guardian Publishing, LLC, 2004). He also is a co-founder of The Wealth Protection Alliance (WPA), a nationwide network of financial advisers (at 800-554-7233). Charles P. KinCannon, JD, LLM, is a certified wealth consultant with the Heritage Institute, in West Linn, Ore.

Labor may require the physician to make up the difference in funding. Therefore, physicians should ensure that the plan is properly funded each year, perhaps by having an outside auditor review the plan's filings and contributions annually.

In addition, physicians may want to consider what level of funding they will need after retirement. A hypothetical \$40,000 per year of pension contributions from ages 35 through 60 that grows at 7% will be worth \$2 million at a retirement age of 60. This amount would yield a lifetime income of \$12,000 to \$15,000 pre tax per month. By including the effects of inflation, this amount may be worth only \$6,000 to \$8,000 monthly in today's dollars. It's difficult to predict how much one will need upon retirement, but some doctors may want more income per month and so would need supplemental planning to reach a higher level of retirement income.

The Double-Tax Bind

Another problem to address when planning for retirement is the effect of income and estate taxes. Many physicians accumulate non-pension assets to support them in retirement, and it is not unusual for a physician to accumulate \$1 million or more of retirement plan assets that he or she will not spend before death. When the physician dies, these plan assets can be taxed at income tax and estate tax rates, and it is possible, in some states, for this double tax to take 70% to 80% of the total assets held. In other words, if the physician's family doesn't use these assets, it could lose most of the total. To protect their families against such high taxes, physicians should rely on the services of a qualified financial

professional who works with high-income individuals to structure a financial and tax planning strategy to protect such assets.

One way a physician can increase how much he puts away for retirement each year and avoid the double-tax bind is to consider non-traditional retirement planning. Non-traditional, non-qualified planning strategies allow higher income physicians to put away more money each year than physicians who use traditional planning strategies. Non-traditional, non-qualified plans are not subject to the same rules about discrimination that traditional plans must meet, allowing physicians to put more money into these plans without matching how much they put into retirement plans for employees.

An executive benefit plan may allow a physician to put away \$100,000 to \$1.2 million annually and deduct the full amount as a retirement plan contribution. Another advantage of such plans is that the physician could access the funds before age 59.5 and would not be forced to take withdrawals at age 70.5. And, finally, these plans are not taxed at rates up to 70% or 80% when the plan holder dies.

Non-traditional, non-qualified plans vary significantly in design, scope, and applicability. Some plans are ideal for small practices with one or two partners. Others work best for mid-size practices of three to 20 partners. Still others may work best for larger practices.

One last step physicians can take regarding asset protection is to consider the value of permanent life insurance versus term life insurance. Some financial advisers suggest it is a smart investment to buy term insur-

ance, which is usually less expensive than a permanent policy, and invest the difference. The advantages of a permanent life policy include the ability to borrow and to invest. A term life policy does not have these features and so costs less. If a physician took the money saved and invested that amount he might get a higher return on the investment than would be possible with a permanent life policy. According to some experts, this strategy makes term insurance (and a corresponding investment) the best buy.

Asset Considerations

This advice is excellent for the average American family with income of \$42,000 per year and paying 12% in federal income taxes. This family has no liability or estate tax risk and pays little tax on investment income. It is possible that the family's tax on investment gains ranges from 10% to 15%. The average family is not likely to have its assets taken in a lawsuit. Since a high-income physician has many more assets to consider, it may be better to buy cash value life insurance as a supplemental investment tool that will offer permanent life insurance protection as well.

As with any financial advice, physicians should consider all of these strategies carefully and it would be best to do so with a qualified financial professional who works with high-income individuals. Clearly, the financial situation of a high-earning physician is much different than that of the average American and so will require a more sophisticated adviser.

—More information on physician practice strategies is available on our website (see page 8).

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