

# focus on Patient Safety

A NEWSLETTER ON PATIENT SAFETY FROM THE NATIONAL PATIENT SAFETY FOUNDATION

## Alternative Therapies: Helping Patients Find Their Way

BY KIM BULLOCK, MD

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A SIGNIFICANT NUMBER of Americans today are turning to alternative therapies for both acute and chronic medical conditions, while increasing numbers of medical professionals are using and endorsing them. Indeed, several studies have set the prevalence rate for unconventional therapies at 40% of the American people.

The investment being made in these therapies is significant. Conservative estimates have placed the amount spent on alternative medicine at \$21.2 billion in 1997, some \$3.5 billion of that on herbal preparations alone, and the *Nutritional Business Journal* estimates that this figure will exceed \$5 billion by the year 2000. Although such top-selling herbs as echinacea, St. John's Wort, feverfew and ginseng are now commonplace in mainstream pharmacies and food stores, scientific research has uncovered only 10% of the available higher plants and their constituents for therapeutic effectiveness. Clearly, the market for over-the-counter herbal treatments will continue to grow, making it imperative that providers become more familiar with them.

Yet that may be more easily said than done. Botanicals or nutraceuticals—plant components with identified therapeutic properties—are classified by the US Food and Drug Administration as dietary supplements, 250 of which have been designated as GRAS, or “generally recognized as safe.” Under the 1994 Dietary Supplement Health and Education Act (DSHEA), the burden of providing safety evidence for these supplements rests with their manufacturers. In addition, DSHEA permits the manufacturers of medicinal herbs to list nutritional benefits of their products prior to FDA authorization. As a result, critics hold, these products can be marketed for up to 30 days with claims that may be unproven or false. Nor is scientific scrutiny or regulatory agency review required for FDA submission concerning manufacturing claims. Post-marketing surveillance for herbal adverse drug reactions also has been slow, although clinical information is now beginning to be recognized and published, including findings

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that, for example, the popular feverfew can produce GI problems and that St. John's Wort may interact with certain serotonin reuptake inhibitors.

One problem surrounding herbal remedies is that, because they are marketed as foods and are considered “natural,” they are also considered safe. However, herbals or nutraceuticals contain many different components and may interact differently, depending on how they are harvested, processed or packaged. Each herbal product consists of a variety of chemical components in varying concentrations, depending on such variables as plant genetics, plant parts and growing conditions. Contamination or adulteration also can occur at any point in the production process, leading to variations in the quality and quantity of the bioactive substance. Thus, it is critical that providers acquire some knowledge concerning the most commonly available plant constituents, their dosages and their effectiveness.

This information is becoming available from a variety of resources. Alternative medical therapeutics has been incorporated into the curriculum of 60% of medical schools, while prominent hospital centers throughout the country have opened centers and programs on holistic or complementary medicine. Governmental and

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private organizations have been established in both the US and Europe to assist providers in interpreting the growing body of information, such as the National Center for Complementary and Alternative Medicine. With a budget of \$50 million, the Center can now independently fund projects on alternative practices related to such diseases as asthma, cardiovascular and respiratory diseases, cancer, chronic pain syndrome and addiction disorders. The Center also has links to other august groups, such as the National Cancer Institute and the Agency for Health Care Policy and Research, for the purpose of reviewing published data and developing relevant projects.

Meanwhile, what guidelines can physicians follow when discussing issues related to alternative medicine with their patients?

- First, remember to always ask patients about their use of over-the-counter products, including so-called 'natural' remedies. Although studies have shown that well-educated patients from higher socio-economic backgrounds are more likely to integrate alternative treatments with orthodox medicine, all patients should be considered potential candidates for their use.
- Emphasize that "natural" and "safe" are not always equivalent terms. Be sure, too, to invest the time to develop individualized, patient-specific therapeutic plans. Doing so is likely to improve adherence and decrease misunderstanding concerning medication regimens. Many patients seek out alternative practitioners because they view them as more compatible with their own beliefs concerning illness and wellness. Alternative practitioners also are likely to spend more time listening to and talking with their patients than are mainstream physicians.
- Be aware that certain patients are more likely to use one or more alternative therapies. For example, from 50% to 70% of cancer patients or those with Acquired Immunodeficiency Syndrome use one or more herbal products.
- Remind patients that herbal products should not be used indefinitely, because there have been few long-term trials of their efficacy and safety. In addition, caution should be exercised when prescribing or agreeing

to the use of herbal therapies for pediatric and geriatric patients because the risk of toxicity and side effects is much higher among these populations. Physicians also should document in the medical record that side effect risks were discussed with the patient, and any adverse reactions should be recorded.

- Finally, physicians must be willing to devote some time to the study of alternative medicine. With so many consumers interested in such alternatives as herbal medicine, vitamin therapy, homeopathy and macrobiotic diets, it is incumbent upon physicians who are concerned about patients' safety to take whatever steps they can to offer appropriate advice and counsel. **NPSF**

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**THE NATIONAL CENTER for Complementary and Alternative Medicine provides information on funded or conducted research in the area of alternative medical therapies. It can be reached by telephone at 888.644.6226. Its web site address is <http://altmed.od.nih.gov/nccam/>. Other resources include:**

**The World Health Organization, which in 1991 published Guidelines for the Assessment of Herbal Medicines.**

**The US Pharmacopeia and the US Pharmacopeia-National Formulary, whose database provides clinically relevant and scientifically-based drug information for health care providers and consumers; call 301.881.0666 for general information on this source.**

**The German Commission E, established by the German Federal Health Agency, an equivalent to the FDA. Although no longer active, it produced a series of monographs that are now available in English through the American Botanical Society; call 512.926.4900 for more information.**

**The European Scientific Cooperative of Phytotherapy, an organization similar to the Commission E in its research and publication efforts, which is located in the Netherlands.**

**The Herb Research Forum at 303.449.2265 and <http://www.herb.org>.**

**The US Office of Dietary Supplements at <http://odp.od.nih.gov/ods>.**

resources

# Physician Assistants and Medication Compliance

BY NANCY HUGHES

ACCORDING TO A nationwide survey of Americans age 50 and over, more than 40% of those who responded had chosen not to fully comply with medication regimes that had been prescribed for them. Twelve percent of the respondents had decided not to fill a prescription that had been written for them, while another 12% had decided not to take a prescription after it had been filled. The survey, which was conducted in 1996 on behalf of the American Association of Retired Persons, documents a significant threat to patient safety about which all health care professionals must be concerned.

Physician assistants (PAs) are among those who both share in this concern and can contribute to the solution of the problem illustrated by the survey results.

Approximately 34,000 physician assistants practice in the US today, the realization of a vision for a new type of health care professional that was shared more than 30 years ago by a group of physicians and educators. They believed that physicians could treat more patients, utilize their time and talents more wisely, and provide better patient care if they could work with someone trained in medicine who practiced with a physician's supervision.

Physician assistants provide comprehensive medical services that range from primary care to assisting in surgical subspecialties. Physician-PA teams make it possible for patients to be seen promptly. Patients have come to recognize that any illness or condition will be handled effectively and efficiently, and that the expertise of the physician is available if needed.

All states require a physician assistant to work with a supervising physician, although the physician is not necessarily required to be physically present when the PA is treating patients. To ensure a synergistic working relationship between the physician and the PA, physician assistant education closely parallels the education process for physicians, including course work in pharmacology, although PA programs require approximately two-thirds the time required by medical school. As a prerequisite for state licensure, after graduation PAs

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must pass a comprehensive national certification examination developed in cooperation with the National Board of Medical Examiners.

In 1998, physician assistants handled 140 million patient visits and prescribed 158 million medications. Forty-four states plus the District of Columbia now permit PAs to prescribe medications, including more than 30 that extend this authority to prescription of controlled substances.

As members of one of the fastest-growing health care professions in the country, physician assistants are in an excellent position to work with physicians, other members of the health care team, and patients to eliminate errors associated with prescriptions.

Physician assistants focus on patient education as an integral part of their responsibilities and practice. PAs have reported that they are responsible for all direct care in almost 70% of the cases presented to them, and research has documented high levels of patient satisfaction with the care provided by PAs, due in part, no doubt, to the time PAs devote to educating patients about their medications and treatment plans.

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## Medication Use: A Systems Approach to Reducing Errors

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### book review

*In Medication Use: A Systems Approach to Reducing Errors*, (1998, ISBN: 0-86688-522-6) the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has published a collection of analyses and comments on serious and ongoing problems within the health care industry related to adverse drug events (ADEs). The purpose of this publication is to assist health care providers in their efforts to decrease the incidence and improve the reporting of ADEs within the health care system. The approach considered to offer the most promise for improved outcomes is a systems approach that focuses on processes rather than on people.

As Lucian Leape, MD, writes in the foreword, "While medication errors have always been with us and have long been recognized as a major cause of patient injury, their control has eluded our best efforts." Leape reminds us that as many as 10% of patients admitted to tertiary hospitals are injured as a result of medication errors, one-third to one-half of which are considered preventable. As Leape points out, past efforts to reduce medication errors have focused primarily on rules and procedures for safe handling of drugs and training of personnel in consistent application of those rules and procedures. However, this is no longer enough, he believes. Health care providers are beginning to recognize that even the best-trained and most highly motivated people can make errors, Leape explains, urging that more be done to deal with this problem.

Each chapter of *Medication Use* looks at the problem from the perspective of various members of the health care team, illustrating the multi-layered challenges that must be met to improve outcomes. In the opening chapter, for example, Deborah Nadzam, RN, PhD, describes a medication use system that consists of five separate processes: (1) selection and procurement, (2) prescribing and selecting drugs for the patient, (3) preparation and dispensing, (4) administration, and (5) monitoring of the patient. Nadzam identifies the health care professional responsible for each process and offers examples of errors that may occur in various stages of the process. The "monitoring" component involves all health care professionals, as well as the patient and the patient's family members. The importance of educating the

patient or the patient's family about medication administration is emphasized. According to Nadzam, "the health care professional must be sure that the patient's quality of education is sufficient and that the patient has learned the critical information about medication administration and monitoring desired and adverse effects."

The objective of this systems approach is to move away from blaming the individual when an error occurs and move toward making an assessment of the process as a whole. As history has shown, placing blame on an individual decreases the voluntary reporting of errors, thus limiting the ability of researchers to study the problem. Seeking a more productive response, Nadzam explores a research technique called root-cause analysis, which looks beyond proximate causes of an error to the root of an event, specifically focusing on the big picture instead of zeroing in on one person or one phase of the total process. This approach identifies basic or causal factors that underlie variation in performance, including the occurrence or potential occurrence of a sentinel event, a reactive rather than a pro-active technique to probe the reasons for a problem that has already occurred. Means for improvement can then be analyzed to prevent recurrence.

To complete the chapter, Nadzam discusses various deterrents to reporting ADEs, including fear of retribution and the use of time-consuming report forms, and offers strategies for improving reporting rates, such as establishing clearly defined indicators and performance measures for the whole medication use system, as well as proactive strategies for analysis of such measures.

In Chapter II, Philip J. Schneider, RPh, MS, and Maja Gift, RPh, explain the techniques used to measure and monitor the performance of the medication use system. Their approach is a systematic one that includes establishing a measurement system that involves the use of staff members to monitor performance of the process through data analysis, obtaining organizational commitment to improving the medication use process, determination of data elements to track performance, selection of staff members to collect data, and, finally, analysis of the data collected.

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Also discussed in detail are the data collection process and methodology applicable under the system. This discussion provides a resource for use in both monitoring and measuring errors in all aspects of the medication use system, including prescribing, transcribing, dispensing, administering, and monitoring the effects of medications. The discussion also defines severity levels as potentially fatal or severe, potentially severe, or potentially significant. Categorizing errors by severity levels in this way, the authors believe, permits trends to be identified and then analyzed. Sampling techniques and forms are also reviewed. However, this discussion, while thorough and specific for those interested in data collection, may be more technical than the average practitioner will find useful.

In July 1995, the National Coordinating Council for Medication Error Reporting and Prevention, a group of representatives of some of the leading health care and consumer groups in the US, convened to address concerns related to medication error. In its deliberations, the Council defined medication error as “[A]ny preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.” Such events, it continued, “may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature compounding; dispensing; distribution; administration; education; monitoring; and use.” The Council’s definition includes both potential and actual medication errors.

Diane Cousins, RPh, cites the Council’s definition in Chapter III, a discussion of the complexity of the health care system. Noting that medication use is only one component of that complex system, Cousins observes

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that medication errors are “episodes in drug misadventuring that should be preventable through effective systems controls,” and proposes that systems controls must be improved before ADE rates can be improved.

Cousins lists examples of the kinds of errors made in medication management in a way that is pertinent and applicable to practitioners, identifying flaws and breaks in the system that could result from the actions of various members of the health care team, from errors in ordering to errors in preparation and administration. Errors are identified in broad categories, including product errors, process errors, and human errors. The reasons for human errors have been studied extensively by human factors specialists, Cousins notes, identifying two: complacency among providers that leads to decreased caution and vigilance, and a poor work environment that encourages practitioners to become careless or makes them error-prone as a result of work overload, inadequate workspace, poor lighting or distractions.

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# request for proposals

THE NATIONAL PATIENT Safety Foundation (NPSF) is requesting Letters of Intent (LOI) to submit research proposals for projects that enhance patient safety in the United States. The LOI will be no longer than five pages and must be submitted with the required content and format as described in the Request for Research Proposals (RFP), which is available by contacting the NPSF at the address below. The maximum award will be a total of \$100,000 for projects up to two years duration. The indirect cost rate is limited to 15% of total direct costs, excluding equipment. The deadline is March 29, 1999. Contact NPSF at the AMA, 515 N. State St., 8th Floor, Chicago, IL 60610; npsf@ama-assn.org; or 312.464.4848. The RFP is available at <http://www.npsf.org>. **NPSF**

## book review

Although the main emphasis relating to human errors is on health care providers, Cousins includes patients and their family members as having an important role in the final “safety check” of medication administration.

Many errors could be intercepted before a patient is harmed if a team approach were implemented, Cousins believes. In conclusion, she takes the encouraging position that voluntary reporting of potential ADEs has great potential to improve patient care and outcomes.

As these early chapters demonstrate, medication errors can occur at any stage of the medication use system. In Chapter IV, David Bates, MD, MSc, discusses their prevention. “In order to prevent medication errors, it is necessary to know what errors are occurring where and how the system should operate,” he writes. Focusing attention and blame solely on the individual who commits an error is counterproductive and may only serve to encourage staff to hide mistakes or sabotage data collection, he says. To prevent recurrences of medication errors, Bates proposes that problem areas be identified so that a proactive stance can be initiated.

**“Many errors could be intercepted before a patient is harmed if a team approach were implemented.”**

Bates goes on to identify five key prevention strategies to reduce the likelihood of medication errors. These are to (1) minimize reliance on memory, (2) improve access to reliable drug information, (3) develop systems that eliminate the possibility of error, (4) pursue standardization within organizations, and (5) provide training in the systems involved. Examples of specific safeguards are then discussed in detail, including unit dose dispensing, expanded pharmacist roles, education, computerized order entry, standardization of equipment, bar coding, and computerized medication records.

Some potential tools for use in reducing medication errors are provided in Chapter V, whose authors—Linda S. Hanold, MHSA, Bruce E. Vinson, PharmD, and Annette Rubino, MBA, CPht—designate steps for use in evaluating and improving a medication use system. Essentially a

workbook, this chapter offers a variety of tools and forms for use in data collection and analysis. The information contained in this chapter should provide useful assistance to any hospital or department that either wants to improve its current system or implement a new systems approach to decreasing medication error.

In a final chapter, P. Mardi Atkins, RN, MPA, and Louis D. Barone of the Cleveland Clinic Foundation (CCF) offer a case study on measuring and improving a medication use system. In it, they describe how CCF developed a system as the result of the work of a steering group comprised of various health care professionals within the institution.

To begin, the group set goals and priorities to improve the system that had been in place. A liaison group of members of the departments of pharmacy and nursing was formed, which evaluated methods used to order medications, transcribe medication orders, and prepare, dispense, and administer medications. Plans for improvement were then developed and implemented. Next, CCF conducted a pilot study of medication errors focused on drugs that alter the central nervous system (CNS), the objective being “to determine whether the system decreased the potential for adverse medication events while increasing efficiency and decreasing costs.” The study found a significant decrease in the rate of medication errors involving CNS drugs when major systems changes were made in their storage and control. CCF then implemented, on a pilot basis, an automated dispensing system, which was found to provide nurses with easier access to controlled substances and the pharmacy with better inventory control.

As the authors who contributed to this publication so well establish, reduction of medication errors must be at the forefront of efforts to improve care provided to patients within the health care system. To accomplish this goal, these experts agree that there must be a systems approach to the problem that permits practitioners at all levels to report potential and actual adverse events without fear of being blamed. Their work provides the basis for various health care professionals involved in medication management to become better educated in methods useful in initiating such a systems-based approach to management of medication errors. It should be a valuable tool for all those seeking direction in managing adverse drug events. **NPSF**

# Patient Safety: A Growing Community

BY LORRI A. ZIPPERER, MA

IN NOVEMBER 1998, 600 persons from throughout the world gathered in Rancho Mirage, CA, at the second in a series of conferences on patient safety. They came to learn, to share, and to become partners in the quest for safer health care.

Not unlike the group that participated in the first conference in the series, held two years earlier, those who participated in the second event seemed open to viewing the issues that affect patient safety in a new light. Simple failures of health care professionals, they learned, are rarely the cause of patient injury. More often, they discovered, it is the system in which those professionals work that plays a major role in permitting injury to occur.

Although the systems theory, as applied to health care, was not a new idea in 1996 to those regarded as leaders in thought about the quality of health care, many practitioners, patient advocates and administrators had not yet been galvanized to view patient safety in that way. The environment seemed to have changed by the second meeting, which brought together the novice and the expert, the nurse and the doctor, the risk manager and the trial attorney, among others, to further medicine's quest for safer care. Grizzled elder statesmen and eccentric practitioners alike talked about a "new look" and captivated audiences. One would think that the battle had been won.

But it has not been, as evidenced by chilling tales of grief, sadness and loss shared both among individuals and in the group, by arguments and disputes about responsibilities and goals, and by the recollections of personal harm and professional misfortune. The candor was sobering. The range of opinion expressed openly about many essential issues, such as the relationship between quality and safety, illustrated a lack of consensus.

Yet equally apparent was a collective desire to constructively come to consensus in order to progress. The sharing of successes at both the statewide and institutional level, the blending of human factors study and medicine, the application of technological advances to the practice of medicine, and the use of color to code patients and reduce their susceptibility to medication error—together, these efforts and others provided a

richly detailed map charting where patient safety stands today. It was apparent that everyone present wanted to make a difference by sharing what they had learned to bring about the sea change needed if the health care system is to become a safer place for patients.

**“...a community for patient safety can only be fully realized if patients are effectively involved.”**

Of course, patients also have a part to play in enhancing the safety of medicine. The role of the patient and how patients can take part most effectively in this change was of paramount concern to the group. It was suggested that one way to provide the patient voice was for those in attendance to see themselves as patients, as they all are more than likely to someday be. When that day comes, they too will be vulnerable to the potential for harm that exists with all the care provided by the health care system. Taking this approach to the discussion was essential, it was agreed, because a community for patient safety can only be fully realized if patients are effectively involved.

What better way to make a measurable difference, after all, than to try to capitalize on the strengths and knowledge of individuals as a community? And creating a community is what these conferences are accomplishing. At each, people have come together and introductions have been made that will serve as the building blocks for this multi-disciplinary community. No one can yet know what tangible results will grow out of these newly formed relationships, but the fact remains that, as evidenced by the attendance and atmosphere of the 1998 event, a community is beginning to form and that it will have an impact on both the safety of patients and the system that cares for them. **NPSF**

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**Focus on Patient Safety**

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*The opinions expressed in this publication are not necessarily those of the National Patient Safety Foundation or of its board of directors.*

*To submit articles to, or publications for possible review in, Focus, please direct materials to: Lorri Zipperer, Managing Editor, Focus on Patient Safety, National Patient Safety Foundation at the AMA, 515 N. State Street, Chicago, Illinois 60610. Materials, inquiries and subscription requests for the publication will be accepted electronically at [npsf@ama-assn.org](mailto:npsf@ama-assn.org) or via fax at 312-464-4154.*

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The physician assistant profession has played an active role over the years in addressing problems associated with prescription medications.

The American Academy of Physician Assistants (AAPA) is a founding organization of the National Council on Patient Information and Education (NCPPIE), a nonprofit coalition committed to improving communication between health care professionals and patients about prescription medicines.

NCPPIE was founded in 1982 and is headquartered in Washington, DC. It serves the public and health professionals through educational and advocacy programs that encourage the appropriate use of medicines and the development of patient education resources. In late 1996, as a member of a federally-appointed steering committee, NCPPIE helped establish targets for the receipt of written medication information in the new decade. The target to be achieved by the year 2006 is for 95% of consumers to receive useful written information with each new prescription.

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Greg Thomas, PA-C, AAPA vice president, clinical and scientific affairs, and a member of the NCPPIE Board of Directors, points out, "The PA profession is involved because patient understanding of medications and their compliance with treatment plans are basic to quality medical care. PAs seek to go beyond what we learn in the classroom. We're committed to life-long learning and to good communication—with both the patient and the physician—to ensure excellent outcomes."

That commitment, coupled with the unique interaction possible between patients and physician assistants, hold out the promise of a significant contribution to resolving the medication regime compliance problem.

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