



Nurse Advise-ERR™

Educating the healthcare community about safe medication practices

December 2003 ■ Volume 1 Issue 9

Herbal product safety and efficacy

Surveys suggest that one in three Americans use herbal products to self-manage the symptoms of illness and improve their health, often at a cost lower than traditional medications. But lack of strict regulations and solid clinical research regarding efficacy and safety limit our ability to know with certainty what these products can and can't do, and whether they could be harmful.

Safety. The Food and Drug Administration (FDA) requires pharmaceutical companies to demonstrate the safety of medications before they're approved. But herbal products are regulated as food supplements under the Dietary Supplement Health and Education Act (DSHEA) of 1994, which does not require safety testing.

Efficacy. While FDA requires all claims of efficacy to be demonstrated for conventional medications, the Act that governs herbal products has no such provision. As a result, efficacy claims may be misleading and without scientific basis. While efficacy claims are not allowed on product labels, the intended function of the product can be stated along with the following disclaimer: "This statement (about function of the product) has not been evaluated by the

FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

Manufacturing. The quality of conventional medications is guided by strict manufacturing standards, but similar standards do not exist for herbal products. Plant materials may be misrepresented or substituted, or the product may contain none of the plant listed on the label.

Clinical Trials. In 1998, the government established The National Center for Complementary and Alternative Medicine (NCCAM) to explore these products in the context of rigorous science (see <http://nccam.nih.gov/>).

The center believes that poorly defined products and dosing schedules could risk failure of premature efficacy studies. So it has initially focused its research on determining active ingredients, mechanisms of action, and optimal dosing schedules. These studies will then form the basis for larger clinical trials.

While NCCAM gives these promising treatment modalities scientific scrutiny, stay informed about the potential benefits and risks of using herbal products and counsel patients accordingly. See **Check it Out!** for ways to prevent adverse events with herbal products.

You can't fool Mother Nature.

check it out! ✓✓✓✓

To reduce the risk of adverse events with herbal products:

✓ **Hold inservices** on the most common herbs used (e.g., black cohosh, echinacea, garlic, ginkgo biloba, ginseng, kava, St. John's wort, cayenne, saw palmetto, valerian) to increase staff knowledge of the potential benefits and risks associated with using these products.

✓ **Keep a reliable text** on herbal products on each unit (or provide access to a reliable Internet site such as www.mskcc.org/aboutherbs).

✓ **Ask patients** which herbal products they use, record the information in the medical record, and communicate it to the pharmacy so that potential drug/herb interactions can be detected.

✓ **Ask surgical patients**, during the pre-admission process, whether they are taking herbal products. Some herbs can accelerate the heart rate (e.g., ephedra), inhibit blood clotting (e.g., ginkgo, garlic), alter the immune system (e.g., echinacea), and change the effects and duration of anesthesia (e.g., kava). See www.uchospitals.edu/news/2001/20010710-herbs.html for a chart to guide the discontinuation of herbal products before surgery.

✓ **Avoid sounding judgmental** when asking patients about their use of herbal products. They may fail to disclose this information, even when prompted, if they fear criticism.

✓ **Tell patients** about potential adverse effects related to herbal products and remind them to report any symptoms to their physician. Watch for signs of adverse effects when patients are under your care.

safetywire

⚡ **Do you have a "Safety Suggestion Box"** prominently located in patient care areas or near elevators? This is an easy way to tap into the insightful perspectives and creative solutions of patients, visitors, and staff. If you respond to the suggested improvements and show that the information has been used to enhance safety, you may find this to be a valuable resource. Perhaps you can advertise the suggestion box in the local news media and showcase how a suggestion (especially one from a patient or visitor) led to improved patient safety.

Readership Survey Results

✓ More than 400 nurses participated in our ISMP **Nurse Advise-ERR™** Readership Survey, which appeared in the September issue. Our thanks to all who responded! Your feedback will help us fine-tune **Nurse Advise-ERR™** so it can continue to meet your medication safety needs.

In general, survey respondents felt that the newsletter raised their awareness of safe medication practices, and that the recommendations for error prevention were practical and helpful. In fact, 75% of supervisors and 80% of staff nurses told us that the information in the newsletter prompted them to make changes in their individual practice. A few examples include:

- ✓ increased reporting of drugs with similar names and labels
- ✓ decreased the use of dangerous abbreviations
- ✓ eliminated the numbering of orders and the use of checkmarks during transcription, and
- ✓ asked physicians to read their orders to staff before leaving the unit.

Also, about 40% of staff nurses, 69% of supervisors, and 85% of nurse executives reported making system-wide changes in response to the newsletter. A few examples follow:

- ✓ removed TB syringes with orange color-coded 25 gauge needles from patient care units

- ✓ sequestered neuromuscular blocking agents that are stored on units
- ✓ changed the concentrations of drugs stored in pediatric code carts to match those listed on the Broselow tape
- ✓ included newsletter information in new staff orientation and other education programs, and
- ✓ used the information to support computerized prescriber order entry (CPOE) systems.

Almost half of respondents (47%) have visited the ISMP website for information (most often quality/risk management staff [80%], least often staff nurses [25%]). Approximately 6% of survey respondents have reported an error to ISMP.



Most importantly, respondents provided us with a wide variety of topics they would like to see covered in future newsletters. The most frequent suggestions were associated with high-alert medications (e.g., insulin, chemotherapy, electrolytes, narcotics); high-risk patients (e.g., pediatrics, elderly); error-prone processes (e.g., transfer orders, antibiotic dosing times, legibility of handwritten orders); specialty areas (e.g., behavioral health, home care, obstetrics); and technology (e.g., bar-coding, CPOE). We thank you for your suggestions and hope to include many of these topics in 2004. See full survey results at www.ismp.org/NursSurvey200309Results.asp.

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To report medication errors to ISMP, please call 1-800-FAIL-SAF(E).

► NURSES In the News

In November 2003, the Institute of Medicine (IOM) released a report concluding that the environment in which nurses work cultivates error, not safety.

According to the report, *Keeping Patients Safe: Transforming the Work Environment of Nurses (2004)*, research is now beginning to document what we have long known: how well patients are cared for by nurses affects their health and safety. One example cited in the report found that nearly half of all prescribing errors and one third of transcription and dispensing errors were intercepted, largely by nurses, before they reached the patient.¹ Another study showed that greater numbers of patient deaths are associated with fewer nurses to provide care.² Recognizing the key role nurses play in safety, the Department of Health and Human Services commissioned this study to focus on issues such as mandatory overtime, unsafe workload, poorly designed care processes, failure to use technology to prevent errors, and barriers to communication.

The committee found serious threats to patient safety in four basic areas: failure to follow management practices necessary for safety (e.g., poorly balancing productivity and safety); unsafe workforce deployment (e.g., inadequate staffing and orientation of new staff); unsafe work and workspace design (e.g., long hours, lack of technology, inefficiencies from non-nursing duties); and a punitive culture that hinders reporting and prevention of errors.

Among many recommendations, the committee urged state regulators to prohibit nurses from working more than 12 hours per day and 60 hours per week. At the same time, it called for staffing level standards for nurses and nursing assistants. Other recommendations, especially those related to medication safety, will be highlighted in a subsequent issue of this newsletter in 2004. Read the full report at www.iom.edu/report.asp?id=16173.

References: (1) Leape L, Bates D, Cullen D, et al. Systems analysis of adverse drug events. *JAMA* 1995; 274:35-43. (2) Aiken L, Clarke S, Sloane D, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job satisfaction. *JAMA* 2002; 288:1987-1993.

Special Recognition...

Our 2003 Nurse Advise-ERR™ clinical advisory board

Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented clinical advisory board. As 2003 nears an end, we want to thank each of the following members of the advisory board for their dedication to making this newsletter a valuable medication safety resource for clinicians.

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