

the **Reporter**

TEXAS MEDICAL LIABILITY TRUST
March-April 2008

Small things considered



by Laura Brockway, ELS

Case study

In April 2001, a nine-month-old girl died in a Washington D.C. hospital after a nurse administered an overdose of morphine. Instead of two 0.5 milligram doses of morphine, the patient was given two doses of 5 milligrams each. The doses were given two hours apart as the patient was recovering from surgery.

An investigation later found that the mistake was caused by a misplaced decimal point. According to the hospital, the surgeon wrote the postoperative order for ".5 milligrams" of morphine, as needed. This was the appropriate dosage, but the order did not follow hospital procedures requiring such dosages to be written with a zero before the decimal point so that it would have read "0.5 milligrams." The unit clerk transcribed the order as "5 milligrams": his handwritten note on a temporary medication administration record did not include a zero or the decimal point. An experienced nurse on the medical-surgical floor followed the order and injected the morphine into the patient's IV.¹ Another 5 mg dose was given two hours later. About four hours after the second dose, the baby stopped breathing and suffered a cardiac arrest.²

The hospital's chief medical officer told the *Washington Post* "We have gone back and checked our

preventing errors by eliminating dangerous abbreviations

policies and procedures and find they are in place and should have prevented this. But in this situation, because of human error, all the checks and balances did not work."¹

Introduction

As illustrated in the case study, the use of abbreviations, acronyms, and symbols in prescribing and transcribing medication orders can result in the misinterpretation of the order's intent. Physicians often use these shortcuts to indicate drug names, dosages, the patient's condition, and route of administration. The result can be omission errors, extra or improper doses, administering the wrong drug, or giving a drug in the wrong manner. In addition to the potential for patient harm, these mistakes can also delay therapy, increase the cost of health care, and waste time spent in clarification.³

Common abbreviation errors include the abbreviation "U" for units which can be mistaken for a zero, a number four, or cc (i.e. cubic centimeter); the abbreviation "IU" for international units which can be misread as IV or the number 10; and the term "QD" for every day which can be erroneously read as "QOD" for every other day; "QOD" can also be mistaken for "QID" (four times daily). Other problems are caused when prescribers abbreviate drug names on prescription orders, such as "MS" which can mean morphine sulfate or magnesium sulfate or "CPZ" for Compazine which can be mistaken for chlorpromazine.³

A list of error-prone abbreviations, symbols, and dose designations frequently associated with misinterpretation and patient harm (as reported to the U.S. Pharmacopeia-Institute for Safe Medication Practices Medication Errors Reporting Program) can be found on page 3.

continued on page 2

Statistics

According to the Institute of Medicine report *Preventing Medication Errors*, at least 1.5 million preventable adverse drug events (ADEs) occur in the United States each year. These errors are common at every step of the medication process, from prescription and administration of a drug to monitoring the patient's response. However, errors occur most frequently during the prescribing and administering stages. "When all types of errors are taken into account, a hospital patient can expect on average to be subjected to more than one medication error each day. However, substantial variations in error rates are found across facilities."⁴

The IOM report cited studies that indicate 400,000 preventable drug-related injuries occur each year in hospitals; 800,000 occur in long-term care settings; and roughly 350,000 occur among Medicare recipients in outpatient clinics.⁵

"A number of studies have cited prescribing as a principal source of overall medication errors . . . even if the correct decisions are made in determining the medication regimen, poor communication of prescription orders in any format (written, oral, electronic) can lead to serious drug events."⁵ A common source of these prescribing errors — the use of ambiguous medical notations.

Efforts to reduce errors

The Institute for Safe Medication Practices (ISMP), U.S. Pharmacopoeia, and the Joint Commission have long warned of the dangers of using ambiguous abbreviations in writing and transcribing prescriptions. These organizations have led efforts to eliminate the use of error-prone abbreviations, symbols, and dose designations; however, this has been difficult to accomplish, mainly because it is difficult to break long-standing practices.

"We physicians seem to have a fascination with reducing words and phrases to their absolute minimum (a problem admittedly not restricted to our profession). But in the interest of convenience and reduction of the amount of legendarily illegible writing we produce, we leave ourselves open to danger and our patients to harm. Abbreviations have an inherent potential for misinterpretation and misunderstanding with resultant clinical errors. Caution in their use is mandatory."⁶

In 2006, the U.S. Food and Drug Administration (FDA) and the ISMP launched a national education campaign to help eliminate the most common ambiguous medical abbreviations. The campaign focused on eliminating the use of such abbreviations by health care professionals and students, medical communications and publishing professionals, the pharmaceutical industry, and FDA staff.⁷

The Joint Commission has established an official list of "Do Not Use" abbreviations that is part of the organization's National Patient Safety Goal 2B (Standardize a list of abbreviations, acronyms, and symbols that are not to be used throughout the organization). This "Do Not Use" list applies to all orders and all medication-related documentation that is handwritten, including free-text computer entry or on pre-printed forms. "This requirement does not currently apply to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems), but remains under consideration for the future."⁸

The Joint Commission reported that during its 2006 surveys, approximately 22% of accredited organizations were found to be out of compliance with the abbreviations requirement.⁸

In addition to their official "Do Not Use" list, the Joint Commission has developed another list of abbreviations, acronyms, and symbols that will be reviewed annually for possible inclusion in the official list.⁸ The Joint Commission's Official "Do Not Use" List and the additional list are included in the ISMP list found on page 3.

Other patient safety organizations have joined the ISMP in their efforts to reduce the use of unclear medical notations. "Several healthcare standards organizations have eliminated these abbreviations

from their style manuals or, in the case of USP, from its official compendium. The FDA will not permit their use with drug package labeling."⁹

Electronic prescribing

Computerized prescriber order entry (CPOE) or electronic prescribing systems have been offered as a way to reduce medication errors, and studies have found that these systems can reduce prescribing errors, potential ADEs, and actual ADEs.¹⁰ While CPOE systems have the potential to reduce errors associated with poorly handwritten prescriptions, "errors can still occur in the interaction between the clinician and the technology as a result of issues in such areas as usability, readability, training, and suboptimal system safeguards."⁵ A 2005 study found that a leading CPOE system facilitated 22 different types of errors. "As CPOE systems are implemented, clinicians and hospitals must attend to errors that these systems cause in addition to errors that they prevent."¹¹

According to the ISMP, many computer systems display drug doses without a zero in front of the decimal point or with trailing zeros. Others still use abbreviations such as "QD" and "U." "Thus, misinterpretation of an order is still a very real possibility with CPOE when these dangerous forms of communication are used."²

Risk management considerations

The following guidelines may help reduce the likelihood of medication errors related to abbreviations.

- Become familiar with the ISMP's list of error-prone abbreviations, symbols, and dose designations. Pay particular attention to drug name abbreviations for medications most commonly associated with your specialty.
- Because distraction can lead to errors, take a "prescribing moment" within each patient encounter and dedicate your attention to writing the prescription. "Temporarily delay the patient's additional comments via verbal or nonverbal clues. For example, say 'Let me complete your prescription, and then I'll answer your question.'"¹²
- Prescription drug orders should be legible. Prescribers with poor handwriting should type or print prescriptions.
- If you currently use a CPOE system or are considering implementing one, be aware of any system limitations related to abbreviations and dose designations. "For example, even if a practitioner can clearly read MTX on a screen, can you guarantee that it will be interpreted as methotrexate, as intended? Why not mitoxantrone? In print and electronic formats, some fonts, type color, and spacing make it difficult to differentiate between 100U and 1000, or between 1.0 and 10."¹³
- When prescribing drugs orally, speak slowly, clearly and articulately to avoid confusion. Develop a specific policy for phone-in prescriptions and oral orders. For example, insist that staff spell the full drug name and have the pharmacist spell the full name back.
- Educate patients about the medication(s) you are prescribing. Provide patients with written information about their medications, including the full brand and generic names. Document that this information was given to the patient.
- Patient safety organizations studying medication errors (U.S. Pharmacopoeia, the Joint Commission, the FDA, the ISMP) recommend that physicians specify the indication on the prescription. "By noting the purpose, you confirm to the pharmacist the appropriate medication."¹²
- Help others avoid mistakes. Report abbreviation issues to U.S. Pharmacopoeia's medication error reporting programs. For information, visit <http://www.usp.org/hqi/patientSafety/mer/> or call 800-23-ERROR. Reports can also be made to the FDA's MedWatch by calling 800-FDA-1088 or online at <http://www.fda.gov/medwatch/report/hcp.htm>.

ISMP's list of error-prone abbreviations, symbols, and dose designations

The abbreviations, symbols, and dose designations found in this table have been reported to the Institute for Safe Medication Practices (ISMP) through the USP-ISMP Medication Error Reporting Program as being frequently misinterpreted and involved in harmful medication errors. Avoid these terms when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

The Joint Commission has established a National Patient Safety Goal that specifies that certain abbreviations must appear on an accredited organization's do-not-use list; these items are highlighted with an asterisk (*). However, the ISMP encourages health care professionals to consider those beyond the minimum Joint Commission requirements. "By using and promoting safe practices and by educating one another about hazards, we can better protect our patients," says the ISMP.

Abbreviations	Intended meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" or "discontinue"
Ij	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS	Half-strength	Mistaken as bedtime	Use "half strength" or "bedtime"
hs	At bedtime, hours of sleep	Mistaken as half-strength	
IU*	International unit	Mistaken as "IV" (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter) leading to oral liquid medications administered in the eye	Use "daily"
Oj	Orange juice	Mistaken as "OD" or "OS" (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use "orange juice"
Per os	By mouth, orally	The "os" can be mistaken for "left eye" (OS-oculus sinister)	Use "PO," "by mouth," or "orally"
q.d. or QD*	Every day	Mistaken as "q.i.d." especially if the period after the "q" or the tail of the "q" is misunderstood as an "i"	Use "daily"
qhs	Nightly at bedtime	Mistaken as "qhr" or every hour	Use "nightly"
qn	Nightly or at bedtime	Mistaken as "qh" (every hour)	Use "nightly" or "at bedtime"
q.o.d. or QOD*	Every other day	Mistaken as "q.d." (daily) or "q.i.d." (four times daily if the "o" is poorly written)	Use "every other day"
q1d	Daily	Mistaken as "q.i.d." (four times daily)	Use "daily"
q6PM, etc.	Every evening at 6 p.m.	Mistaken as every 6 hours	Use "6 PM nightly" or "6 PM daily"
SC, SQ, sub q	Subcutaneous	SC mistaken as "SL" (sublingual); SQ mistaken as "5 every"; the "q" in "sub q" has been mistaken as "every" (e.g., a heparin dose ordered "sub q 2 hours before surgery" misunderstood as every 2 hours before surgery)	Use "subcut" or "subcutaneously"
ss	Sliding scale (insulin) or 1/2 (apothecary)	Mistaken as "55"	Spell out "sliding scale"; use "one-half" or "1/2"
SSRI	Sliding scale regular insulin	Mistaken as selective-serotonin reuptake inhibitor	Spell out "sliding scale (insulin)"
SSI	Sliding scale insulin	Mistaken as Strong Solution of Iodine (Lugol's)	
i/d	One daily	Mistaken as "tid"	Use "1 daily"
TIV or tiw	3 times a week	Mistaken as "3 times a day" or "twice in a week"	Use "3 times weekly"
U or u*	Unit	Mistaken as the number 0 or 4, causing a 10-fold overdose or greater (e.g., "4U" seen as "40" or "4u" seen as "44"); mistaken as "cc" so dose given in volume instead of units (e.g., "4u" seen as "4cc")	Use "unit"
Dose designations, other information	Intended meaning	Misinterpretation	Correction
Trailing zero after decimal point (e.g., 1.0 mg)*	1 mg	Mistaken as "10 mg" if the decimal point is not seen	Do not use trailing zeros for doses expressed in whole numbers
"Naked" decimal point (e.g., .5 mg)*	0.5 mg	Mistaken as "5 mg" if the decimal point is not seen	Use zero before a decimal point when dose is less than a whole unit

ISMP's list of error-prone abbreviations, symbols, and dose designations (continued)

Dose designations, other information	Intended meaning	Misinterpretation	Correction
Drug name and dose run together (causes problems for drug names that end in "l" such as Inderal40 mg; Tegretol300 mg)	Inderal 40 mg	Mistaken as "Inderal l40 mg"	Place adequate space between the drug name, dose, and unit of measure
	Tegretol 300 mg	Mistaken as "Tegretol l300 mg"	
Numerical dose and unit of measurement run together (e.g., 10mg, 100mL)	10 mg 100 mL	The "m" is sometimes mistaken as a zero or two zeros, risking a 10- to 100-fold overdose	Place adequate space between the dose and unit of measure
Placing a period at the end of abbreviations mg. or mL.	mg mL	The period is unnecessary and could be mistaken as the number 1 if written poorly	Use mg, mL, etc. without a terminal period
Large doses without properly placed commas (e.g. 100000 units; 1000000 units)	100,000 units 1,000,000 units	100000 has been mistaken for 10,000 or 1,000,000; 1000000 has been mistaken for 100,000	Use commas for dosing units at or above 1,000 or use "100 thousand" or "1 million" to improve readability
Drug name abbreviations	Intended meaning	Misinterpretation	Correction
ARA A	vidarabine	Mistaken as cytarabine (ARA C)	Use complete drug name
AZT	zidovudine (Retrovir)	Mistaken as azathioprine or aztreonam	Use complete drug name
CPZ	Compazine (prochlorperazine)	Mistaken as chlorpromazine	Use complete drug name
DPT	Demerol-Phenergan-Thorazine	Mistaken as diphtheria-pertussis-tetanus (vaccine)	Use complete drug name
DTO	Diluted tincture of opium, or deodorized tincture of opium (Paregoric)	Mistaken as tincture of opium	Use complete drug name
HCl	hydrochloric acid or hydrochloride	Mistaken as potassium chloride (The "H" is misinterpreted as "K")	Use complete drug name unless expressed as a salt of a drug
HCT	hydrocortisone	Mistaken as hydrochlorothiazide	Use complete drug name
HCTZ	hydrochlorothiazide	Mistaken as hydrocortisone (seen as HCT250 mg)	Use complete drug name
MgSO ₄ *	magnesium sulfate	Mistaken as morphine sulfate	Use complete drug name
MS, MSO ₄ *	morphine sulfate	Mistaken as magnesium sulfate	Use complete drug name
MTX	methotrexate	Mistaken as mitoxantrone	Use complete drug name
PCA	procainamide	Mistaken as patient controlled analgesia	Use complete drug name
PTU	propylthiouracil	Mistaken as mercaptopurine	Use complete drug name
T3	Tylenol with codeine No. 3	Mistaken as liothyronine	Use complete drug name
TAC	triamcinolone	Mistaken as tetracaine, Adrenalin, cocaine	Use complete drug name
TNK	TNKase	Mistaken as "TPA"	Use complete drug name
ZnSO ₄	zinc sulfate	Mistaken as morphine sulfate	Use complete drug name
Stemmed drug names	Intended meaning	Misinterpretation	Correction
"Nitro" drip	nitroglycerin infusion	Mistaken as sodium nitroprusside infusion	Use complete drug name
"Norflox"	norfloxacin	Mistaken as Norflex	Use complete drug name
"IV Vanc"	intravenous vancomycin	Mistaken as Invanz	Use complete drug name
Symbols	Intended meaning	Misinterpretation	Correction
℥	Dram	Symbol for dram mistaken as "3"	Use the metric system
℥	Minim	Symbol for minim mistaken as "mL"	Use the metric system
x3d	For three days	Mistaken as "3 doses"	Use "for three days"
> and <	Greater than and less than	Mistaken as opposite of intended; mistakenly use incorrect symbol; "<10" mistaken as "40"	Use "greater than" or "less than"
/ (slash mark)	Separates two doses or indicates per	Mistaken as the number 1 (e.g., "25 units/10 units") misread as "25 units and 110 units")	Use "per" rather than a slash mark to separate doses
@	At	Mistaken as "2"	Use "at"
&	And	Mistaken as "2"	Use "and"
+	Plus or and	Mistaken as "4"	Use "and"
°	Hour	Mistaken as a zero (e.g., q2° seen as q 20)	Use "hr," "h," or "hour"

Unless reported, reports were received through the USP-ISMP Medication Errors Reporting Program (MERP). Report actual and potential medication errors to the MERP via the web at www.ismp.org or by calling 800-FAIL-SAF(E). ISMP guarantees confidentiality of information received and respects reporters' wishes as to the level of detail included in publications.

Claims, communications, and talking to the attorney

by Matthew B.E. Hughes, R. Gregg Byrd, and Melissa Astala

When faced with an attorney's request for a patient's medical record relative to litigation or when asked by an attorney to discuss the care of a patient, physicians have rights, responsibilities, as well as options. This article answers basic questions about communicating with attorneys. For further clarification or for questions about specific situations, please contact the TMLT Claim Department.

Q: An attorney representing one of your patients contacts you and requests medical records. What is the law?

A: In Texas, state law provides for the exchange of relevant medical information between treating physicians and attorneys representing parties named in a claim or lawsuit through a specific authorization for the release of that information. The patient's authorization must name the physician(s) who have information relevant to the health care liability claim and must state that the named physician(s) are obligated to supply both verbal and written health information. The patient authorization also allows plaintiffs to specifically exclude physicians whose care is not relevant to the claim being made.

In most situations, the requesting attorney should provide you with a copy of the patient's authorization; however, state law includes an exception to the general physician-patient privilege in cases where a patient sues his or her physician. If the patient's health care information is relevant to the patient's claim or to the physician's defense, the attorneys may legitimately request and receive this information without a patient's authorization.¹ If you are uncertain, you should contact TMLT for assistance.

What about HIPAA? Under federal law, HIPAA allows a covered entity, such as a physician, to disclose otherwise protected health information based on the patient's signed authorization as long as the information to be disclosed is described in a specific and meaningful fashion. In Texas, the patient authorization required under Section 74.051 of HB 4 is consistent with the HIPAA rule. It identifies the information to be disclosed, the patient, the persons to whom the information may be disclosed, the expiration date, and the patient's signature. Please note that not all exceptions to state and federal law (HIPAA) regarding the release of health care information are addressed here.

Q: If an attorney calls and wants to meet to discuss the care of a patient, will I need my own attorney?

A: Possibly. If you receive such a request, before agreeing to meet with any attorneys, contact TMLT. Also, contact TMLT if you are concerned about another party or physician claiming that you have some responsibility for a patient's injuries. If you treated the patient — before or after the incident — then you may be a potential defendant in the case, even if a suit has already been filed without naming you.

It is important to understand the impact timeframes have on lawsuits. The Medical Liability Act limits the time in which a patient can file a lawsuit. Adult patients generally have 2 years plus 75 days after the alleged negligent act(s) to bring a medical liability claim. Minors have a longer time period within which to file a cause of action. A defendant physician can name non-defendant physicians as responsible parties, often based on opinion or testimony

of other physicians. This allows the plaintiff's attorney to bring them into the case as parties even after the normal statute of limitations has expired.²

Q: If I agree to meet with the attorney, then do the attorneys for both sides need to be present and am I obligated to meet with both sides?

A: The law does not require you to meet with either side or with both sides. If you agree to meet with either attorney, you may choose to limit the information you provide to the following:

- to that involving your care of the patient;
- to a specific timeframe; and
- to the specific condition for which you saw the patient.

If you do not have adequate information about the patient's current condition, medical history, or the care given by the defendant and/or other physicians, you may ask the attorney requesting the meeting to provide you with that information. Avoid offering opinions unless you have access to all of the important and relevant facts and medical records. Be careful about relying on representations not supported by the records.

Most parties to a lawsuit are willing to pay treating physicians reasonable fees for their time spent in reviewing records and in meeting with attorneys.

Q: How can any information I may provide help the parties to a lawsuit?

A: Investigating the facts of the case and understanding the medical issues are probably the most challenging tasks for an attorney in a medical liability lawsuit. The medical reasoning and thought processes contributing to the health care decisions can be very complex. For example, the relationship between the physicians in the case and who was managing various aspects of care can be difficult to piece together. Sometimes assistance is needed in deciphering handwritten medical records. Meeting with the treating physicians who have first hand knowledge of some of the events in the case, in addition to their medical training and expertise, helps attorneys more clearly understand the issues in the case. Your potential testimony not only assists attorneys in better representing their clients, but also may be very important in helping the jury to understand the issues.

Meeting with the attorney(s) to answer questions may be all that is needed from you; however, your willingness or refusal to meet with the attorney(s) is not a predictor of whether or not your testimony will be required in the case.

Q: Why should I choose to get involved by talking with the attorney(s)?

A: The unfortunate odds are that many Texas physicians will be sued at least once during their careers. Unless physicians agree to meet with attorneys so that they can discover the facts and investigate the merits of a claim, it is difficult to properly evaluate these cases. Both the physician and the patient deserve an accurate and objective evaluation of the claim being made. If information is provided informally, the costs of filing subpoenas, retaining court reporters, and

continued on page 13

Complementary and alternative medicine

studies indicate wider use of alternative therapies among patients



Objectives

At the conclusion of this educational activity, the physician should be able to:

1. describe five herbal medicines commonly used by patients;
2. recognize the possible risks and interactions of popular complementary and alternative medicine therapies; and
3. identify reliable sources for information on complementary and alternative medicine.

Course author

Tanya Babitch is a risk management representative at TMLT.

Disclosure

Tanya Babitch has no commercial affiliations/interests to disclose related to this activity.

Target audience

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement

Texas Medical Liability Trust is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. TMLT designates this educational activity for a maximum of 1 AMA PRA Category 1 Credits.[™] Physicians should only claim credit commensurate with the extent of their participation in the activity.

Ethics statement

This course has been designated by TMLT for 1 hour of education in medical ethics and/or professional responsibility.

Directions

Please read the entire article and answer the CME test questions. To receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Please allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

Estimated time to complete activity

It should take approximately 1 hour to read this article and complete the questions.

Release/review date

This activity is released on April 1, 2008 and expires on April 1, 2010. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction

“Doctor, I’ve been taking XXXX, and I hadn’t mentioned it to you before because I didn’t think it was important . . . I thought you would be angry, or think I didn’t trust your recommendations . . . I was embarrassed.”

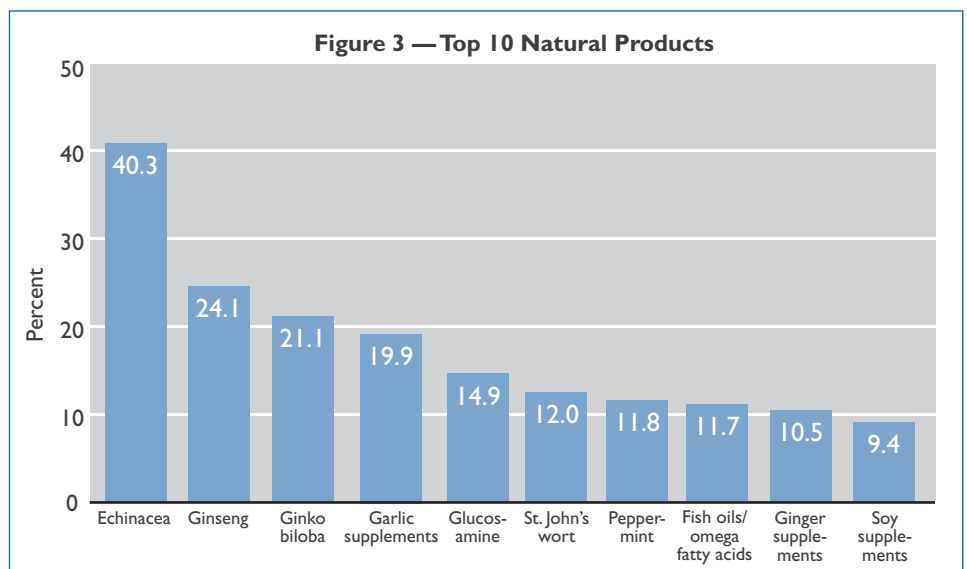
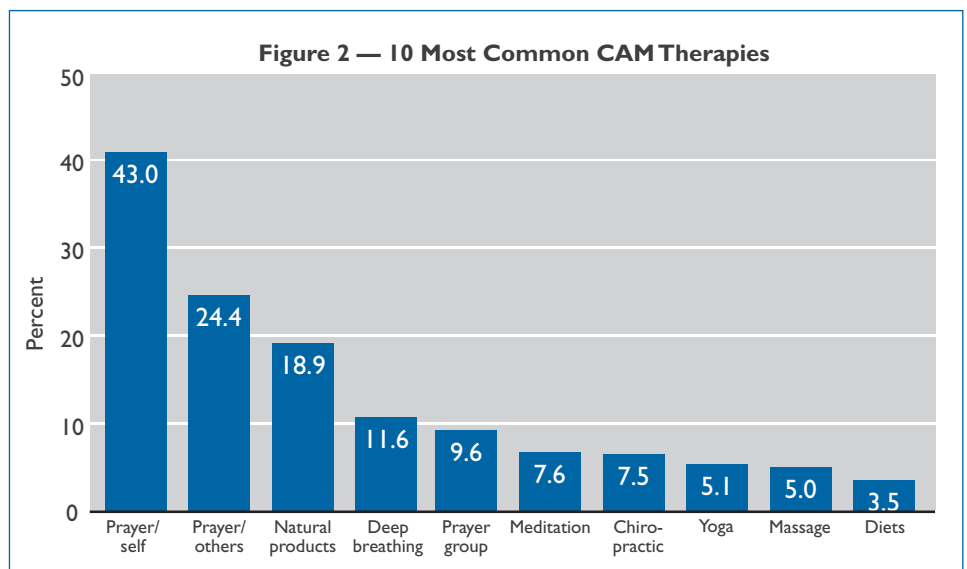
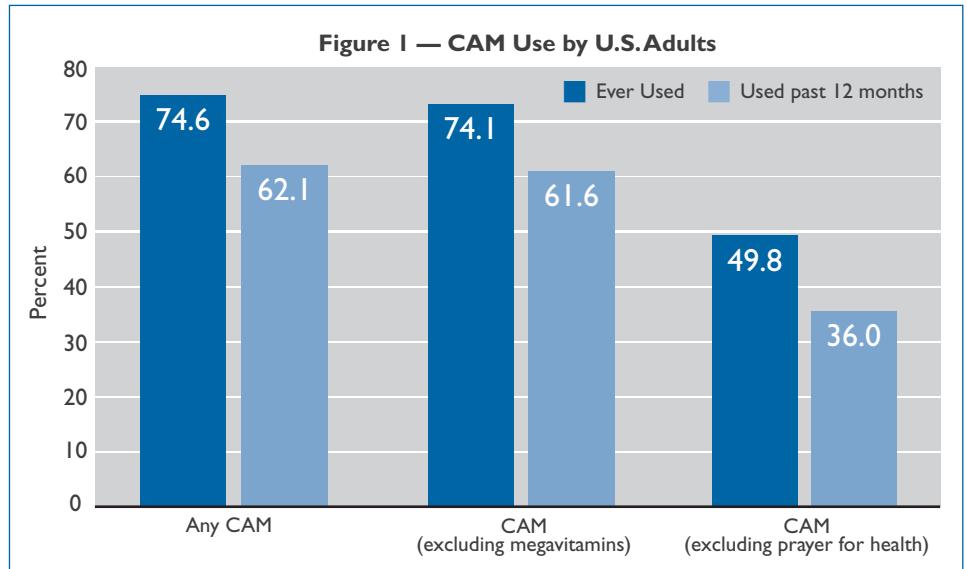
Physicians may hear many of these statements when they discover that their patients have been taking supplements, herbs, or other alternative therapies. Although complementary and alternative medicine (CAM) has always generated patient interest, studies show that CAM is becoming more widely used by Americans. The federally-funded National Center for Complementary and Alternative Medicine (NCCAM), a branch of the National Institutes of Health, is devoted to researching these therapies and distributing information to health professionals and the public.

Use of complementary and alternative medicine

A 2002 NCCAM study (published in 2004) estimated that at least 36% of adults in the U.S. were using some form of CAM, and this number jumped to 62% if multivitamin therapy and prayer were added to the list of therapies. (See Figures 1-3.) Almost one-fifth of people surveyed were using natural products (non-vitamin or mineral), such as echinacea, ginseng, ginko biloba, and St. John’s wort. In 2002, it was estimated that more than 2 million adults used acupuncture each year.¹

Many patients experiment with CAM therapies, but may not discuss them with their physician. One study found that only half of the patients using alternative therapies were informing their family physician,² which can put patients and physicians at risk. Although the risks of some commonly used herbal medications are known, new products enter the marketplace daily. Long-term effects of many herbal products are not yet known. As interest in alternative therapies has grown, the need for thorough and well-documented research in these areas has become critical.

Hospital systems are also becoming more interested in complementary and al-



ternative medicine. The Mayo Clinic, the University of California at San Francisco, and Duke University Medical Center all offer a variety of CAM therapies. An estimated 27% of hospitals offered CAM in 2005, and it is likely that this number has increased since then. Federal funding from NCCAM for research has changed the view of alternative and complementary medicine, and increased the medical community's interest. Hospitals are increasingly willing to take a chance on CAM therapies, especially those that come with little risk to the patient. Many hospitals offer more benign therapies such as yoga, acupuncture, meditation, and types of massage.³

Texas Medical Board guidelines

The Texas Medical Board addresses complementary and alternative medicine practiced by physicians as "Those health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods."⁴

The Board's expectation is that physicians will offer alternative therapies that have no greater safety risk for the patient than conventional treatment. Prior to offering complementary or alternative therapies, the physician should perform an appropriate assessment that includes history and physical examination, discussion of conventional medical treatment options, discussion of risks, benefits, and expected outcomes of the proposed treatment, and description of the basis for the proposed treatment. The treatment offered should "have a favorable risk/benefit ratio compared to other treatments for the same condition; be based upon a reasonable expectation that it will result in a favorable patient outcome, including preventive practices; and be based upon the expectation that a greater benefit for the same condition will be achieved than what can be expected with no treatment."⁴

The Board also states "All physicians must be able to demonstrate the medical, scientific, or other theoretical principles connected with any healthcare method offered and provided to patients."⁴ The Board has specific guidelines addressing patient assessment, discussion, documentation, and treatment of patients with alternative therapies, and their rules should be carefully

reviewed by any physician considering offering or recommending complementary or alternative therapies.

Commonly used complementary and alternative medicine therapies

Acupuncture

Acupuncture has been practiced for thousands of years in Asian countries, and is offered as a remedy for a multitude of ailments. Acupuncture most commonly involves stimulation of points on the body using metal needles manipulated by the practitioner, but may also use electrical current or simple pressure (acupressure). Acupuncture has been used in the U.S. for about 200 years, but it has grown in popularity since the 1970s, when a *New York Times* reporter wrote about acupuncture used after his own knee surgery.⁵

Summarizing acupuncture research has been particularly challenging for reviewers as studies have been plentiful but inconsistent in design and research methodology. The level of success documented by studies seems to be at least partially dependent on the nationality of the researchers. In Asian countries, where acupuncture is widely accepted, research is overwhelmingly positive, while in the U.S., Canada, Australia, and New Zealand, results are less encouraging.³ A 2004 Phase III clinical trial funded by NCCAM and the National Institute of Arthritis and Musculoskeletal and Skin Diseases studied acupuncture for relief of osteoarthritis of the knee, and showed that overall, "those who received acupuncture had a 40 percent decrease in pain and a nearly 40 percent improvement in function compared to baseline assessments."⁶

The National Cancer Institute summarizes clinical acupuncture studies done on cancer patients on their web site, stating that "in clinical studies, acupuncture reduced the amount of pain in some cancer patients" but that "studies using strict scientific methods are needed to prove how acupuncture affects pain." They also state that "the strongest evidence of the effect of acupuncture has come from clinical trials on the use of acupuncture to relieve nausea and vomiting. Several types of clinical trials using acupuncture methods showed acupuncture reduced nausea and vomiting caused by chemotherapy, surgery, and morning sickness. It appears to be more effective in preventing vomiting than in reducing nausea."⁷

A 2003 statement from the U.S. Department of Health and Human Services on

acupuncture for the treatment of fibromyalgia concluded that although "evidence supported the use of acupuncture as adjunctive or second line treatment for fibromyalgia," there was "insufficient evidence to conclude that acupuncture has efficacy for the treatment of fibromyalgia."⁸ More recent studies on acupuncture for fibromyalgia have revealed conflicting conclusions, with results ranging from "no advantage" in a study reported in the *Annals of Internal Medicine*, to "significantly improves fibromyalgia symptoms" in a 2005 Mayo Clinic study.⁹

A review of international research done on acupuncture for back pain reveals that "there is insufficient evidence to make any recommendations about acupuncture or dry-needling for acute low-back pain. For chronic low-back pain, results show that acupuncture is more effective for pain relief than no treatment or sham treatment, in measurements taken up to three months. The results also show that for chronic low-back pain, acupuncture is more effective for improving function than no treatment, in the short-term. Acupuncture is not more effective than other conventional and 'alternative' treatments. When acupuncture is added to other conventional therapies, it relieves pain and improves function better than the conventional therapies alone. However, effects are only small."¹⁰

Because much of the previous acupuncture research has been limited by poor methodology and small study size, more research is needed. Ongoing clinical trials in acupuncture should reveal much more about the treatment's effects on a wide range of conditions including depression, headache, and in-vitro fertilization. NCCAM is currently sponsoring several research studies in these areas, and will continue to gather evidence-based information for physicians and the public.

Acupuncture risks appear to be few. Although there are some potential risks of infection and punctured organs, relatively few complications have been reported to the Food and Drug Administration (FDA). The FDA regulates acupuncture needles, and requires that they be sterile and labeled as single-use.⁵ The Texas State Board of Acupuncture Examiners maintains standards in the practice of acupuncture and oversees the licensing of acupuncture practitioners in Texas. Information on the Board and their current rules can be accessed at <http://www.tmb.state.tx.us/boards/acubd.php>. Acupuncture practitioners should be well researched, just as any health care practitioner would be. Information about Texas acu-

puncturists is available at the Texas Medical Board's web site.

Compounded menopause hormone therapy drugs

Public interest in natural products, including "bio-identical hormones" has swelled since the publication of the 2002 Women's Health Initiative (WHI) study report warning against the long-term use of hormone replacement therapy in healthy postmenopausal women. The WHI study did not include bio-identical or "natural" progesterone in their research, and advocates of these products propose that there are critical differences between synthetic and natural hormones. Bio-identical hormones are custom-mixed for each patient and meant to mimic the hormones that are made by the body. Proponents also believe that estriol, a weak form of estrogen, is safer than FDA-approved estrogen replacement.

"According to the North American Menopause Society (NAMS), custom compounds may provide certain benefits, such as individualized doses and mixtures of products and forms that aren't available commercially. However, they may also pose risks to consumers. These compounds haven't been approved by the Food and Drug Administration (FDA) and as a result haven't been tested for purity, potency, efficacy or safety. These products may even contain unknown contaminants. For this reason, NAMS does not recommend these custom-mixed products over well-tested, government-approved commercial products for the majority of women."¹¹

On January 9, 2008, the FDA released a statement saying that they have sent warning letters to seven leading pharmacy operations compounding bio-identical hormone replacement therapy. The FDA reports that the pharmacy operations have made unsupported claims about the safety and effectiveness of their products, and that the use of the term "bio-identical hormone replacement therapy" is an inappropriate marketing tool that implies the drugs are identical to hormones produced by the body.

Because compounded hormones are not reviewed by the FDA, patients are encouraged to exercise caution. Patients who want to use compounded hormone therapy drugs are encouraged to discuss their options with their provider, and are reminded that the claims that compounded hormones can prevent and treat serious diseases are unsubstantiated. The FDA's guide for consumers, "Bio-Identicals: Sorting Myths from Facts," can be accessed at <http://www.fda.gov/consumer/updates/bioidenticals010908.html>.

Herbal medicines

Patients' use of herbal medicine can present a multitude of challenges for physicians. It can be difficult to stay informed of possible side effects and complications of herbal remedies, including interactions with conventional medicines. Unfortunately, the composition of herbal medicine compounds varies widely, which can affect both their usefulness and their potential safety. Most herbal medicines in the U.S. are considered dietary supplements and regulated as such; not subject to the same manufacturing standards or safety testing as conventional medicines. However, the FDA does issue warnings about supplements that could pose risks to consumers.

Supplements that have carried FDA warnings include kava, certain "dieter's teas," L-tryptophan, comfrey, St. John's wort, gamma hydroxybutyric acid (GHB), and certain sexual enhancement products, marketed as "natural" Viagra, among others.¹² Information about the FDA's regulation of dietary supplements can be accessed at <http://www.cfsan.fda.gov/~dms/supplmnt.html>.

If patients wish to use herbal medications, physicians should encourage them to research the quality of the manufacturer and the potential side effects of the product.

Certain patients should be discouraged from using herbal products or encouraged to use extreme caution. "A special note of caution is sounded concerning pregnant or lactating women and children. The risk of using poorly studied drug products in these groups may outweigh benefits unless documented otherwise. Few data are available on the effects of herbals during gestation, let alone on specific weeks or trimesters of pregnancy, as transfer across the placenta is poorly studied. Neonatal heart failure attributed to maternal use of blue cohosh was described recently. As a general guideline, in the absence of safety data it is best to avoid herbal products during pregnancy and lactation, as well as in infancy or childhood."¹³

Because herbal products or supplements can come with risks (both known and unknown), physicians should be diligent in discussing these issues with patients.

As the use of herbal medicines becomes more common, interest has increased in organizations promoting the safe use of herbal products. The American Botanical Council, a non-profit organization located

in Austin, Texas, strives to help "people live healthier lives through the responsible use of herbs and medicinal plants." The group's mission is to "provide education using science-based and traditional information to promote responsible use of herbal medicine — serving the public, researchers, educators, healthcare professionals, industry and media."¹⁴ The American Botanical Council was established in 1988, and distributes a wide range of publications addressing the efficacy and safety of herbal medicine.

Commonly Used Herbs

Echinacea is purported to strengthen the body's immune system, and is largely used as a preventative or treatment for cold and flu. It is generally taken orally for immune stimulation against infection, but is sometimes used externally on wounds or other skin problems. Studies have shown that echinacea does not appear to prevent or shorten the course of cold or flu, but NC-CAM continues to study its use in the treatment of upper respiratory infections.¹⁵

Echinacea is not known to have a high incidence of side-effects, but physicians and patients are warned that, "Allergic reactions can occur and are usually mild, but individuals with a history of asthma, atopy, or allergic rhinitis may experience severe allergic reactions that include dyspnea and anaphylaxis. Other adverse effects are mild and transient tiredness, somnolence, dizziness, headache, gastrointestinal disturbance, and eczema, not significantly different from those with placebo . . . there is little information on interactions with other drugs or nutrients. Echinacea may worsen metabolic control in some diabetic patients and is not recommended in individuals with altered immune function (tuberculosis, human immunodeficiency viral infection, multiple sclerosis, autoimmune diseases) because of altered immunomodulation. Use usually is restricted to 2 weeks for an acute episode and should not exceed 8 weeks as it may lead to immunosuppression. Echinacea should be avoided by patients receiving immunosuppressive therapy."¹³

Black cohosh is most commonly used to alleviate menopausal symptoms and menstrual irregularities, and can be taken orally in solid or liquid form. (Black cohosh is not to be confused with blue cohosh.) Studies on the effectiveness of black cohosh for the treatment of menopausal symptoms have been mixed, and long-term safety data are not available.

The NIH's Office of Dietary Supplements (ODS) states, "Although preliminary evidence is encouraging, the currently available data are not sufficient to support a recommendation on the use of black cohosh for menopausal symptoms. NCCAM is funding a rigorous scientific study to determine whether treatment with black cohosh reduces the frequency and intensity of hot flashes, and other menopausal symptoms. In 2001, the American College of Obstetricians and Gynecologists stated, primarily on the basis of consensus and expert opinion, that black cohosh may be helpful in the short term (6 months or less) for women with vasomotor symptoms of menopause."¹⁶

Side effects of black cohosh may include headache, stomach discomfort, gastric complaints, and heaviness in the legs. Black cohosh is not recommended for pregnant women or women with breast cancer. "If black cohosh is estrogenic, long-term use may adversely affect uterine or breast tissue. No studies have been published on long-term safety in humans, particularly regarding abnormal stimulation of cells in the endometrium or breast." A few instances of liver damage have been reported in users of black cohosh, but studies have not scientifically proven a link between the medication and the adverse events. No interactions have been reported between black cohosh and prescription medications.¹⁶

St. John's wort, taken in the form of a tea or a tablet, is most commonly used today to treat depression, anxiety, and sleep disorders. Studies suggest that St. John's wort may be beneficial in the treatment of mild forms of depression, but is of little benefit in treating major depression of moderate severity. Because it is not a proven therapy for all depression, patients should be evaluated by a health care professional before self-diagnosing and treating. Physicians should watch patients closely for signs of depression that exceed mild severity.

Side effects may include sensitivity to sunlight, dizziness, nausea, diarrhea, dry mouth, and fatigue. NCCAM also reports, "Research shows that St. John's wort interacts with some drugs. The herb affects the way the body processes or breaks down many drugs; in some cases, it may speed or slow a drug's breakdown. Drugs that can be affected include: Indinavir and possibly other drugs used to control HIV infection, Irinotecan and possibly other drugs used to treat cancer, Cyclosporine, which prevents the body from rejecting transplanted

organs, Digoxin, which strengthens heart muscle contractions, Warfarin and related anticoagulants, birth control pills, antidepressants," and "when combined with certain antidepressants, St. John's wort may increase side effects such as nausea, anxiety, headache, and confusion."¹⁷

Garlic is taken orally, either raw or in the form of tablets, for heart disease, high blood pressure, and high cholesterol. "Some evidence indicates that taking garlic can slightly lower blood cholesterol levels; studies have shown positive effects for short-term (1 to 3 months) use. However, an NCCAM-funded study on the safety and effectiveness of three garlic preparations (fresh garlic, dried powdered garlic tablets, and aged garlic extract tablets) for lowering blood cholesterol levels found no effect. Preliminary research suggests that taking garlic may slow the development of atherosclerosis (hardening of the arteries), a condition that can lead to heart disease or stroke. Evidence is mixed on whether taking garlic can slightly lower blood pressure."¹⁸

Garlic is generally considered safe for adults, but can thin the blood. Garlic should be used with caution or avoided if patients have a bleeding disorder, or are planning surgery. Raw garlic can cause upset stomach, heartburn, and possible allergic reaction. "Garlic has been found to interfere with the effectiveness of saquinavir, a drug used to treat HIV infection. Its effect on other drugs has not been well studied."¹⁸

Ginkgo biloba in the form of tablets, capsules, or tea, is commonly used to improve memory loss, poor circulation, and other conditions associated with aging. "Numerous studies of ginkgo have been done for a variety of conditions. Some promising results have been seen for Alzheimer's disease/dementia, intermittent claudication, and tinnitus among others, but larger, well-designed research studies are needed. Some smaller studies for memory enhancement have had promising results, but a trial sponsored by the National Institute on Aging of more than 200 healthy adults over age 60 found that ginkgo taken for 6 weeks did not improve memory."¹⁹

NCCAM is supporting clinical trials of ginkgo for dementia, Alzheimer's, asthma, symptoms of multiple sclerosis, vascular function, sexual dysfunction due to other medications, and insulin resistance.

Ginkgo is considered relatively safe, but side effects can include headache, nausea,

GI upset, or skin reactions. Some data suggest that ginkgo can alter bleeding times, so patients using anticoagulant drugs should discuss this with their health care professional before using ginkgo. "It also is advisable for patients with known risk factors for intracranial hemorrhage, such as those with systemic hypertension, diabetes, and amyloid senile plaques, to avoid ginkgo-containing products. An indirect safety issue revolves around replacing a physician's evaluation for serious conditions, such as advanced dementia or stroke, with self-medication with an herbal such as ginkgo."¹³

Ginseng is generally taken orally, and said to increase vitality, energy, and stamina. It is also used to treat some menopausal symptoms, erectile dysfunction, hepatitis C, to lower blood glucose, and to control blood pressure. Research has shown that ginseng may have some possible benefit in lowering blood glucose and improving immune function. Most studies on ginseng have been methodologically flawed or small in size, thus do not prove the herb's other health claims.

Ginseng is generally well tolerated, but can cause side effects such as headache, GI problems, and sleep disturbance. "There have been reports of breast tenderness, menstrual irregularities, and high blood pressure associated with ginseng products, but these products' components were not analyzed, so effects may have been due to another herb or drug in the product. Ginseng may lower levels of blood sugar; this effect may be seen more in people with diabetes. Therefore, people with diabetes should use extra caution with Asian ginseng, especially if they are using medicines to lower blood sugar or taking other herbs, such as bitter melon and fenugreek, that are also thought to lower blood sugar."²⁰

Hawthorn extract has been used for heart failure and other heart conditions since the first century. Recent research shows some evidence that hawthorn leaf and flower extracts are effective for mild forms of heart failure. "Hawthorn extract (made from the dried leaves, flowers and fruits of the hawthorn bush) may be used as an oral treatment option for chronic heart failure. In this review, 14 double-blind, placebo controlled randomised clinical trials (RCTs) were found. They did not all measure the same outcomes and several did not explain what other heart failure treatments patients were receiving. Those trials that could be included in a meta-analysis showed improvements

in heart failure symptoms and in the function of the heart. The results, therefore, are suggestive of a benefit from hawthorn extract used in addition to conventional treatments for chronic heart failure.”²¹

“Hawthorn is considered safe for most adults when used for short periods of time. Side effects are usually mild and can include upset stomach, headache, and dizziness. Drug interactions with hawthorn have not been thoroughly studied. It was once thought that hawthorn interacted with the heart medicine digoxin. However, a very small study in people without heart conditions found no interaction, but evidence is limited.”²²

Valerian root is commonly used for sleep disorders and anxiety, and less commonly for headaches, depression, irregular heartbeat, and trembling. Although well-designed studies are scarce, there is some evidence that it may be helpful for insomnia. NCCAM is currently studying valerian’s effects on sleep. There is not yet enough evidence to determine valerian’s effectiveness for any other conditions.

“Studies suggest that valerian is generally safe to use for short periods of time (for example, 4 to 6 weeks). No information is available about the long-term safety of valerian. Valerian can cause mild side effects, such as headaches, dizziness, upset stomach, and tiredness the morning after its use.”²³

Herbs for weight loss are of great interest to the general public. Often, patients may be taking weight loss “supplements” that they are reluctant to discuss with their physician. Two commonly used supplements for weight loss are hoodia and green tea.

Hoodia is a cactus-like plant native to southern Africa. Anecdotally, African bushmen have long used hoodia to reduce appetite on extended hunting trips, but no reliable scientific studies of the herb’s use in human trials have been published. Thus, the safety and potential risks are unknown. The use of hoodia for appetite suppression has been patented, and the patent-holding company is currently conducting clinical trials to measure the herb’s effectiveness. Other companies have marketed hoodia products, but the amount of hoodia found in available supplements varies widely, and there is often none or almost none of the plant in the finished product.²⁴

Green tea is promoted as having a variety of benefits, including cancer preven-

tion and treatment, lowering cholesterol levels, and weight loss. It is both brewed and drunk as a tea and taken orally as an extract. NCCAM continues to study green tea for the treatment of cancer, diabetes, and heart disease, but reports that “there are not enough reliable data to determine whether green tea can aid in weight loss, lower blood cholesterol levels, or protect the skin from sun damage.” Green tea appears to be safe for adults, but has the potential for side effects caused by caffeine. It also “contains small amounts of vitamin K, which can make anticoagulant drugs, such as warfarin, less effective.”²⁵

Homeopathy

Homeopathy is a controversial form of alternative health care that involves treating illness by giving small doses of substances or “remedies” that would produce symptoms of illness in healthy people when given in larger doses. Theoretically, by stimulating the body’s defense mechanisms through the use of highly diluted substances derived from plants, minerals, and animals, homeopathy prevents or treats illness.

Homeopathy was conceived by a German physician in the late 1700s, has long been popular in Europe, and has grown more popular in the U.S. since the 1960s. Because of the relative lack of scientific explanation of benefits from homeopathy, it generates quite a bit of controversy.

The results of previous research on homeopathy have been inconsistent. NCCAM summarizes that “systematic reviews have not found homeopathy to be a definitively proven treatment for any medical condition. Two groups of authors . . . found some positive evidence in the groups of studies they examined . . .,” but “a common theme in the reviews of homeopathy trials is that . . . it is difficult or impossible to draw firm conclusions about whether homeopathy is effective for any single clinical condition.”²⁶

Homeopathic treatments do not seem to be particularly harmful or to cause interactions with conventional medicines, but it is recommended that patients discuss any homeopathic remedies with their health care professional.

Chelation therapy

Chelation therapy involves the injection of ethylenediamine tetraacetic acid (EDTA) into the blood, and has long been used as

treatment for heavy metal poisoning. Some health care professionals believe it may be beneficial in the treatment of coronary artery disease. Chelation therapy is not approved by the FDA for treatment of coronary artery disease. The NIH and American College of Cardiology agree that reviews of previous studies have found no evidence of benefit. Because these studies have been poorly designed and inadequately controlled, NCCAM is currently conducting comprehensive trials in 100 research sites in the U.S., and expects to conclude their study of chelation therapy in 2010.²⁷

According to NCCAM, “The safety of EDTA for treating heart disease has not been established. The most common side effect is a burning sensation at the site where the EDTA is delivered into the vein. Rare side effects can include fever, headache, nausea, and vomiting. Even more rare are serious side effects that can include a sudden drop in blood pressure, abnormally low calcium levels in the blood, permanent kidney damage, and bone marrow depression. Reversible injury to the kidneys, although infrequent, has been reported with EDTA chelation therapy. Other serious side effects can occur if EDTA is not administered by a trained health professional.”²⁸

Chelation therapy has also been used to treat autism spectrum disorders, although there is no good research to show benefits.²⁹ The NIH is currently conducting studies “to address the widespread but unproven theory that autism may be treated successfully by chelation therapy, which seeks to remove heavy metals from the blood. Chelation is more commonly used to treat lead toxicity, but currently, many families seek the treatment to try to remove mercury and other metals from their autistic children’s blood. This practice is based on the belief that many cases of autism were caused by exposure to thimerosal, a mercury-based preservative previously used in childhood vaccines.”²⁹ Since 2001, childhood vaccines have contained no more than trace amounts of thimerosal, with the exception of some inactivated flu vaccine. “Regardless, many families continue to turn to chelation as a therapy for autism.”²⁹

Naturopathic medicine

Naturopathy is a health care system made popular in Europe in the 19th century, which has evolved into a whole-body approach that emphasizes maintaining good health instead of treating disease. Today, naturopathy combines ideas from many

traditions, including Eastern medicine. The central principle is that the body has the power to maintain a state of health and to heal itself if maintained properly. Naturopathic treatment may include an extensive interview, examination, and recommendations such as dietary changes, supplements and herbs, lifestyle changes, mind-body therapy, hydrotherapy (including colonic irrigation), and homeopathy.

Naturopathy's effectiveness has been difficult to study, and there is no rigorous research to evaluate. NCCAM is currently supporting research in naturopathy for low back pain, type 2 diabetes, and TMJ. "Naturopathy is not a complete substitute for conventional medical care. Some therapies used in naturopathy have the potential to be harmful if not used properly or under the direction of a trained practitioner. For example, herbs can cause side effects on their own and interact with prescription or over-the-counter medicines. Restrictive or other unconventional diets can be unsafe for some people. Some practitioners of naturopathy do not recommend using all or some of the childhood vaccinations that are standard practice in conventional medicine."³⁰

Mind-body treatments

Treatments such as yoga, massage, and meditation are at the benign end of the spectrum of alternative treatments, and have few detractors. Although there is debate about how much help a patient will receive from these treatments, most physicians agree that they cause little harm. Patients report benefits such as relaxation, stress reduction, muscle strengthening, increased flexibility, and pain relief. One issue in studying the effectiveness of these treatments has been the relative impossibility of doing placebo-controlled studies. In the absence of much risk, however, many physicians have found it beneficial to recommend these treatments to their patients. Although some are critical of CAM therapies, insisting that "placebo effect" has much to do with patients' satisfaction, proponents point out that if the patient sees improvement, little harm is done.

Conclusion

Only a few of the multitude of alternative and complementary therapies available to patients have been presented in this article. New products are advertised to the public almost daily, and patient interest does not appear to be waning. Patients without health insurance may also be more likely to

use "alternative" therapies because they are sometimes less expensive than traditional medicine. Physicians are reminded to ask their patients not only what medicines they are taking, but specifically if they are taking any herbal, "natural," or other "remedies," and to document their responses in the medical record.

Since many products can interact with conventional medications, physicians may need to research herbs and other alternative therapies as they hear about them. Finding trustworthy sources for information on CAM therapies can be challenging; sources for physicians and the public are available via the NCCAM web site and other sources listed below. Patients should be encouraged to discuss any potential therapies with physicians so that potential risks can be determined and discussed. Physicians may often need to explain that many complementary and not necessarily a substitute for traditional treatment.

Resources

Texas Medical Board rules regarding complementary and alternative medicine

<http://www.tmb.state.tx.us/rules/rules/bdrules.php> (See Chapter 200.)

Texas State Board of Acupuncture Examiners online verification of acupuncture practitioners

http://reg.tmb.state.tx.us/OnLineVerif/Phys_NoticeVerif.asp

National Center for Complementary and Alternative Medicine (NCCAM)

National Institutes of Health
<http://nccam.nih.gov/health/888-644-6226>

Office of Dietary Supplements

National Institutes of Health
<http://ods.od.nih.gov>
E-mail: ods@nih.gov

Center for Food Safety and Applied Nutrition — dietary supplements

U.S. Food and Drug Administration
<http://www.cfsan.fda.gov/~dms/supplmnt.html>

American Botanical Council

www.herbalgram.org
512-926-4900

The Cochrane Collaboration

www.cochrane.org

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talking to the attorney . . . continued from page 5

taking depositions may be avoided. Keeping costs down is a goal that serves everyone. As mentioned previously, you are advised to contact TMLT before scheduling a meeting to protect yourself from potentially being added as a defendant to the case.

Q: Do I have an alternative to meeting with the attorney(s) in person, such as writing a report?

A: There is generally no adequate way to address the information needs of the parties other than via dialogue. In addition, written statements by fact witnesses are not privileged and will generally be made available to both sides of the case.³ Therefore, merely writing a report is discouraged. This kind of written communication is unilateral and does not allow for an exchange of information. Often there is specific information you may need that may not be available to you absent a conversation. Conversations can trigger other questions and/or responses resulting in a more complete exchange of information.

There is an alternative to meeting with the attorney, however. It is time consuming and less effective than a personal meeting, but it does allow for some back and forth exchange of information. The attorney requesting information from you can provide information indirectly to you *through your attorney* regarding the issues in the case. Your attorney will act as intermediary. Oral statements to your attorney are not witness statements and are generally considered to be protected by the attorney-client privilege.⁴

Q: Am I required to respond to records requests? If so, how do I determine what records to copy?

A: Yes, you must respond to records requests. Texas law allows parties in a lawsuit to subpoena records from non-parties, such as treating physicians.⁵ Non-parties failing to comply with the subpoena can be held in contempt of court, fined up to \$500, and jailed for up to 6 months.⁶

Every document in your file should be copied. This includes obvious documents such as patient histories and physician notes, but also less obvious documents such as lab results, records from other physicians, phone messages, and self-stick notes. You might be surprised by the documents, such as copies of medical insurance cards, which could be important in a lawsuit. Producing these documents in a timely fashion also avoids embarrassing questions in a subsequent deposition about why you refused to comply with the law, or why you selected only certain portions of your file to produce. If you have to testify in a malpractice case, your credibility is your biggest asset.

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CME test questions

Instructions: Using black ink, read each question, select the answer, and then clearly mark your selection. Fax the completed test and evaluation forms to the Risk Management Department, attention Rebecca Henson 512-425-5996. You can also mail the test and evaluation forms to the TMLT Risk Management Department, attention Rebecca Henson, P.O. Box 160140, Austin, Texas 78716-0140. A certificate of completion will be mailed to the address you provide on the CME evaluation form.

1. Green tea is currently being studied by NCCAM for the following:
 - a. diabetes
 - b. eczema
 - c. cancer
 - d. a & c
 - e. menopausal symptoms

2. A 2002 NCCAM survey of Americans estimated that _____ of those surveyed were using "natural" products (non-vitamin or mineral).
 - a. almost one eighth
 - b. almost one quarter
 - c. almost one half
 - d. almost one fifth

3. Research on acupuncture for relief of osteoarthritis of the knee funded by NCCAM and the National Institute of Arthritis and Musculoskeletal and Skin Diseases showed that "those who received acupuncture had a _____ decrease in pain."
 - a. 10%
 - b. 40%
 - c. 60%
 - d. 20%

4. _____ is not recommended in individuals with altered immune function because it can cause altered immunomodulation and may lead to immunosuppression.
 - a. echinacea
 - b. ginkgo biloba
 - c. hawthorn
 - d. ginseng

5. Dietary supplements that have carried FDA warnings include:
 - a. St. John's wort
 - b. kava
 - c. saw palmetto
 - d. b & c
 - e. a & b

Statement of completion

I attest to having spent _____ hours in this CME activity.

Physician signature _____ Date _____

Complementary and alternative medicine

EXPIRED CME

CME evaluation form

Please complete the following regarding the article, "Complementary and Alternative Medicine."
Please fax the completed evaluation with the CME test questions.

1. The objectives for this CME were met. Yes No

2. The material will be useful in my practice. Yes No

3. Did you perceive any evidence of bias for or against any commercial products? If yes, please explain.
 Yes No

4. How long did it take you to complete this learning activity?
 .5 hr .75 hr 1 hr 1.25 hrs 1.5 hrs

5. On a scale of 1 to 5, with 5 being the highest, how do you rank the effectiveness of this activity as it pertains to your practice?
 1 2 3 4 5

6. What will you do differently in your medical practice after reading this article?

7. Suggestions for course improvement are:

8. Suggestions for future topics include:

Contact information

Name _____

Address _____

Phone _____

TMLT policyholder? Yes No

Medication error

by Barbara Rose and Laura Brockway

Presentation and physician action

An 86-year-old woman had been under the continued care of a family physician for five years. Her medical history included a CVA, coronary artery disease, right fractured hip, hypertension, interstitial pulmonary fibrosis, pericardial effusion, dementia, bradycardia, arthritis, hyperlipidemia, mild congestive heart failure, and renal insufficiency. The patient used a wheelchair and was unable to talk.

The following is an outline of the visits prior to the incident leading to this claim.

April 2000 — the patient saw the family physician for urinary tract complaints and cough for one week. The family physician prescribed Bactrim and diagnosed seasonal allergies.

August 2001 — the patient was seen for follow up of a “rash to the diaper area.” The family physician diagnosed a urinary tract infection and prescribed Bactrim.

May 2003 — the patient was seen with complaints of abdominal pain, dark and malodorous urine. The family physician diagnosed a UTI and prescribed Bactrim.

June 2003 — the patient returned and complained of a recent rash due to the Bactrim. She was feeling better, and the diagnosis was allergic reaction — resolving. The family physician added sulfa to the drug allergies section at the top of the record.

August 2004 — the patient was seen again for urinary symptoms. The family physician noted a possible UTI. He noted in the medical record “UTI — tx empirically as unable to give same.”

The patient returned in December 2005 for monitoring of her medications. The family physician noted that she was recently discharged from the nursing home and was now at home. He noted a possible UTI and to treat with Bactrim DS b.i.d. He crossed this out and then wrote it again under the first entry. At the top of the record — under drug allergies — Paxil and sulfa were listed. The family physician marked through the sulfa and noted “per family has taken.”

Shortly after this visit, the patient developed skin lesions and went to a local emergency department (ED). Over the next few days, the lesions became worse, and she was transferred to a regional hospital. The patient began

to desquamate more layers of skin, and was transferred to a burn unit. The family physician’s assessment was that the patient had an acute drug reaction to the Bactrim and developed Stevens-Johnson syndrome. During her hospital stay, she sustained severe pain from the burns. Her condition deteriorated, and she died 18 days after her admission to the hospital.

Allegations

A lawsuit was filed against the family physician. The allegations included failure to properly treat by prescribing Bactrim to a patient with a known allergy to sulfa drugs.

Legal implications

Physicians who reviewed this case for the defense stated that the family physician deviated from the standard of care by prescribing sulfa to a patient with a known allergy to sulfa that was listed in the medical chart. The reviewers also believed that it was possible that he missed his prior notation regarding the sulfa allergy, later reviewed the chart, and altered the record by indicating that the family had reported that she had previously taken it. It was also noted that there were many other antibiotics available to treat a UTI, and it was poor judgment to prescribe Bactrim.

Although the defendant indicated that the family had advised him that the patient had previously taken Bactrim without a problem and that he believed the pharmacy should have called him, he acknowledged that he should not have prescribed the Bactrim.

Disposition

This case was settled on behalf of the family physician.

Risk management considerations

Medication errors continue to occur and could potentially be avoided in health care today with strict checks and balances in place that are consistently followed. Those who provide care must assure the accuracy of allergy documentation. It is wise to review and update this information at every encounter and document allergies boldly and visibly in the record in a designated place for physician and staff to see.

If a patient reports no allergies, it is relevant to document that as well. Leaving allergy information blank may not be a reliable indicator that the patient has no allergies. Documenting no known allergies when applicable will prevent an assumption that the patient has no allergy(s) if the designated area is mistakenly left blank. Exercise caution when prescribing. If a patient and/or family member report an allergy history inconsistently, prescribe an alternate medication.

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These closed claim studies are based on actual malpractice claims from Texas Medical Liability Trust. These cases illustrate how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physicians’ defensibility. The ultimate goal in presenting these cases is to help physicians practice safe medicine. An attempt has been made to make the material more difficult to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Failure to diagnose meningitis

by Barbara Rose and Laura Brockway

Presentation

A 21-year-old woman came to the emergency department (ED) on February 4. Her chief complaint was headache for three days with nausea and vomiting for two days. She had associated photophobia and rated her headache pain as 10 on a scale of 1 to 10. The triage nurse noted the headache was described as “pain in back of head, sharp, constant throbbing pain.” The patient’s temperature was 99.8 degrees.

Physician action

An emergency medicine physician saw the patient at 12:41 p.m. The physical exam indicated the patient’s head and neck were essentially normal, with the neck reported as being supple. The patient was given IV fluids, Phenergan, and Toradol.

After approximately 2 hours, the patient reported her headache pain was “1 out of 10.” She was released from the ED at 2:32 p.m. It was noted that she verbalized understanding of the discharge instructions. She walked out of the ED with a steady gait and no apparent distress was noted. The discharge diagnosis was “headache of Viral Cephalgia with nausea, vomiting and myalgias.”

The patient returned to the ED at approximately 7:53 p.m. She reported to the triage nurse, but immediately became unresponsive and was rushed to the treatment room. Within one to two minutes of her arrival, she was in respiratory arrest. Her Glasgow Coma Scale was 3.

Resuscitative therapy was initiated, and the patient was intubated. A central line was started and lab work and blood cultures were ordered. A head CT and a lumbar puncture were performed. The fluid was reported as cloudy and showing pleocytosis along with elevated protein and very low sugar, consistent with bacterial meningitis. The gram stain and culture came back negative for bacterial growth.

The immediate diagnosis was acute meningitis. The patient was given Rocephin, Vancomycin, and Decadron. She was admitted to the hospital at 11:40 p.m. The diagnosis was acute bacterial meningitis and sepsis.

The patient remained in a coma and was unresponsive. On February 5, the results from an electroencephalogram were interpreted as indicating brain death. The patient was continued on treatment and observation over the next 24 hours. She was pronounced dead on February 6.

Allegations

A lawsuit was filed against the emergency medicine physician, alleging that a more thorough work up should have been performed. If this had been completed, the patient’s meningitis would have been diagnosed and treated.

Legal implications

In reviewing this case, the plaintiff’s expert stated that the defendant violated the standard of care and should have ordered a CBC, CT of the head, and a lumbar puncture. Further, the defendant “failed to diagnose and treat acute bacterial meningitis after the patient presented with

symptoms of headache for three days, photophobia, and fever. Had a lumbar puncture been performed either in the morning or early afternoon of February 4, the diagnosis of bacterial meningitis would have been established and antibiotics started much earlier.”

Defense emergency medicine experts were not supportive of the defendant’s actions. One physician stated that considering the patient’s symptoms of a headache for 3 days, neck ache, nausea, vomiting, and a low-grade fever, a more thorough evaluation — including a CBC — was indicated. One expert stated the patient’s symptoms were “certainly suspicious” for meningitis, and that meningitis should have been considered in the differential diagnosis. Another expert stated that most ED physicians would not have performed a lumbar puncture on this patient, but the defendant missed signs of other possible causes for the headache.

The defendant testified that he ruled out the possibility of meningitis while the patient was in the ED. The patient was not in acute distress during the examination, and the neck examination gave no indication of suspicion for meningitis. The patient’s temperature was below 100.4 degrees. Further, the patient improved after treatment with Phenergan, Toradol, and IV fluids. The defendant stated that this confirmed his suspicion that the patient had a viral illness. If the patient had not improved, the defendant would have re-examined her and considered other options and possibly more tests.

An infectious disease specialist testified that it was not clear whether bacterial meningitis actually caused the patient’s death. The CSF fluid was consistent with this diagnosis, but the cultures did not show a causative organism. According to this expert, nonbacterial causes of meningitis can also cause a neutrophilic pleocytosis in the spinal fluid. Because it was uncertain whether the patient had bacterial meningitis, no one could be certain that an earlier lumbar puncture or initiation of antibiotics would have changed the patient’s outcome.

Disposition

This case was settled on behalf of the defendant.

Risk management considerations

This physician was criticized for not including meningitis as a possible diagnosis at the first ED visit and proceeding with tests to confirm or rule it out. Emergency medicine physicians risk criticism for under treating and over treating. When bad outcomes occur and are reviewed in hindsight, other treatment decisions become evident and failure to diagnose and treat is the alleged violation of the standard of care. The patient did not have fever and the headache improved while in the ED. These were supportive signs, but the photophobia, nausea, vomiting, and low-grade fever were problems and should have been considered more significant to the potential diagnosis.

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abbreviations . . . continued from page 2

Conclusion

Eliminating ambiguous abbreviations will require a change in practice for many physicians, but adopting these recommendations can contribute significantly to reducing medication errors. As stated by the ISMP, every physician is at risk of making an error when confusing or easily misinterpreted medical notations are used. “We have always advocated that it’s time to stop thinking ‘it hasn’t happened here so why should I change?’ What would make anyone think it won’t happen again, to one of their patients, when our newsletter has for years chronicled random repeated deaths and injuries at various hospitals from a handful of bad abbreviations.”¹⁴

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