

the Reporter



Organ donation overview

by Dana Leidig

Each year more than 25,000 Americans receive life-saving or life-enhancing organ transplants.¹ The United Network for Organ Sharing (UNOS) keeps a current, running statistic on their web site representing the number of U.S. patients waiting for a donated kidney, heart, liver, lung, pancreas, bone marrow, cornea, eye, bone, or skin. At press time, that number was more than 92,000.² By the end of 2005, 6,234 Texans were on the list . . . waiting. Of these, 4,120 had been waiting for more than a year. Waiting can be deadly for some patients. Nationwide, 17 patients die every day while waiting for donated organs. Last year, 285 Texans died while waiting.³

Clearly our system is overloaded with patients who need donated tissue and organs and the current supply of donors is inadequate. This article will provide an overview of the organ and tissue delivery system, current law concerning organ and tissue procurement, as well as the important role of informed consent.

NOTA and the organ donation network

The National Organ Transplant Act of 1984 (NOTA) created the Organ Procurement and Transplantation Network (OPTN), which is under contract with the U.S. Department of Health and Human Services. The OPTN rules govern the

“procurement, allocation and transplantation of organs and tissue. The organization brings together medical professionals, transplant recipients, and donor families to help develop organ transplant policy. NOTA makes it clear that donors will not be compensated for their donation of human organs. The Act prohibits the purchase or

sale of any human organ and, as amended in 1988, the sale of fetal organs. Buying or selling organs is a felony offense.⁴

The OPTN is a private, not-for-profit organization that provides a system of organ distribution by region through organ procurement organizations (OPOs). By law these OPOs have a monopoly in the geographic areas they cover. Texas has three OPOs: Texas Organ Sharing Alliance (TOSA) in San Antonio with branches in Austin and McAllen; LifeGift Organ Donation Center in Houston; and Southwest Transplant Alliance in Dallas, with offices in Corpus Christi, El Paso,

continued on page 2

continued from page 1

Galveston/Beaumont/Port Arthur, Midland/Odessa, Temple, and Tyler/Longview/Mt. Pleasant.

Since NOTA was enacted, there have been two sets of amendments with notable impact. Effective on July 1, 1998, the rules for OPTN included a “preemption provision” to protect policies that require organ sharing across state lines from state interference.⁵ In addition, rules concerning hospital notification of families of potential donors became effective August 21, 1998.⁶

Regulations provide for specified representation from various groups on the OPTN Board of Directors. Funding for OPTN is provided through the Health Resources and Services Administration’s (HRSA) Office of Special Programs. UNOS, based in Richmond, Virginia, administers the OPTN under contract with the U.S. Department of Health and Human Services (HHS).

The Centers for Medicare and Medicaid Services (CMS) is also indirectly responsible for enforcement of these rules, since the standard Medicare Conditions of Participation for hospitals require them to establish arrangements with their local OPO and notify the families of potential organ donors. Hospitals are expected to educate hospital staff about these issues. Failure to comply with these rules could put Medicare and Medicaid funding for hospitals that perform transplants at risk.⁷

Informed consent

In the United States, individuals or their families may consent to organ or tissue donation. Individuals may give “informed consent” by signing and carrying an organ donor card, by agreeing to donation on their driver’s license, by signing up with a state donor registry, by stating it in their living will or health care power of attorney, or by discussing their wishes with family. An individual who has signed up to be an organ donor may change his or her mind at any time, electing not to donate. Based on an established hierarchy, the highest-ranking family member may give consent for organ donation after the person has died, even without documentation that the person wanted to be a donor. Conversely, in Texas, a family member may override any existing documentation concerning that person’s intention to donate.

In 1968, the Uniform Anatomical Gift Act (UAGA) was adopted in 50 states. This act authorized individuals 18 years or older to make a gift donation of any part of their bodies at their death, stating that this gift could not be revoked by anyone without the consent of the donor. Amendments made in 1987 further clarified that “an anatomical gift that is not revoked by the donor before death is irrevocable and does not require the consent or concurrence of any person after the donor’s death.”⁸ A sample anatomical gift form is available at www.southwesttransplantalliance.com

Even with the UAGA in place, those who seek to donate their organs may be told that, unless they share their wishes with their families, their donation plans may not be implemented after their deaths. In fact, some OPOs may be more likely to honor the wishes of living families over those of deceased donors, possibly because they fear legal liability.

This fear of liability in the face of documentation of the donor’s wishes has no basis in law, but OPOs may prefer to avoid further stress for the family and any negative publicity that could come from forcing the issue. As it stands, even with the UAGA, families may override a person’s decision to be an organ donor. For further information on informed consent, please review “Model Elements of Informed Consent for Organ and Tissue Donation” available at <http://www.aatb.org/model.htm>.²

Presumed consent

More than 20 other countries operate under a “presumed consent” method of organ procurement. With presumed consent, every adult is a potential organ donor. Individuals not wishing to be donors must “opt out” by signing a statement that is registered with a public entity, like a motor vehicle registry or if implemented in the U.S., by a national registry that would be maintained by OPTN. The Presumed Consent Foundation’s web site states that, if presumed consent were the norm in the U.S., “it could have a dramatic impact on the number of organs available for transplant, significantly reducing the waiting list and the number of deaths on the waiting list, as well as relieving the pain and suffering of thousands.”⁹

First person consent

According to the Advisory Committee on Organ Transplantation (ACOT), “from a legal perspective, the decision to donate more appropriately fits under the context of a ‘gift’ rather than an ‘informed consent.’”⁷ ACOT uses the term “donor designation” to describe that any signed donor document is legal authorization to secure organs following death, and that no family member or other agent can legally refuse to honor the donor’s wishes. Currently 41 states plus the District of Columbia embrace first person consent. Texas does not have a first person consent law, leaving the family of the potential donor in charge of making the final decision.

In Texas, House Bill 120 was passed in 2005 establishing the Texas Donor Education, Awareness and Registry Program (DEAR). This is a computerized organ donation registry administered by the Texas Department of State Health Services and partially funded with a voluntary contribution of \$1 when an individual renews a Texas driver’s license or ID card or registers or renews registration for a vehicle.³ The registry is expected to be operational by September 2006.

Informed consent caveats

Because families are often in the position of making the decision to donate while dealing with the immediate loss of a loved one, it is vital that health care professionals are trained in obtaining consent from families when no donor designation exists and in making them feel secure about the process.

Disputes about informed consent that lead to claims or lawsuits may occur when there is no pre-existing donor document. Since nurses are often in the position to seek consent for organ donation, education and training in this area is paramount. Consent must be obtained without misrepresentation of what will happen to the deceased patient.

Acronyms

ACOT

Advisory Committee on Organ Transplantation (ACOT)

DEAR

Texas Donor Education, Awareness and Registry Program

NOTA

National Organ Transplant Act of 1984

OPOs

Organ procurement organizations

OPTN

Organ Procurement and Transplantation Network

UAGA

Uniform Anatomical Gift Act

UNOS

United Network for Organ Sharing (UNOS)

In a lawsuit in Kansas, a family agreed to donate the bone marrow and corneas of their deceased husband and father. The wife of the deceased signed the consent form after being reassured that these donations could be extracted without disfiguring her husband's body. However, the organ retrieval team did not use procedures that were in line with the nurse's representation to the family. They removed the long bones and both eyes, and the body suffered considerable disfigurement. The wife and adult children sued for breach of contract, negligence, conversion, and intentional infliction of emotional distress. Hospitals and other facilities should have policies and procedures for informed consent to donate in place. Nurses and other health care professionals who may be obtaining consent from families should follow these established guidelines.¹⁰

When working with a living donor, skill in communicating all aspects of the donation process is especially important. A living donor makes a voluntary organ donation. However, often a living donor will be donating an organ to a family member and may feel pressured to do so by a life or death situation that will affect their family. Encouraging discussion among family members and the health care professionals involved can ensure that the donor and family are fully informed and know what to expect. Additionally, the physician performing the surgery has a duty to make sure the donor understands all risks of the surgical procedure. Although UNOS has procedural recommendations for handling living organ donation, the federal government does not regulate it and does not require systematic follow-up studies.¹¹

Increasing organ donation in the U.S.

The need for organs and tissue is growing and current donations are not sufficient to meet the demand. Some organizations have expressed ideas that might help increase organ donation in the U.S. For example, the American Kidney Fund supports amending NOTA to allow for research studies that would evaluate the effect of financial incentive on cadaveric organ donation rates.¹² Adopting "presumed consent" could also help increase the number of organs available for transplant. While solutions to the problem of organ availability are being sought, physicians should encourage patients to take care of the organs they have.

References

1. Donate Life, the official U.S. Government web site for organ and tissue donation and transplantation. Available at www.organdonor.gov/creatingdonationfriendlyamer.htm. Accessed July 11, 2006.
2. Organ Procurement and Transplant Network. Available at www.optn.org. Accessed June 6, 2006.
3. New registry will help save lives, window on state government. *Fiscal Notes*. February 2006. Available at www.window.state.tx.us/comptrol/fnotes/fn0602/dear.html. Accessed June 6, 2006.
4. Conover CJ, Zeitler E. National Organ Transplant Act Working Paper No. F-8. Center for Health Policy, Law, and Management. May 2004. Available at <http://www.hpolicy.duke.edu/cyberexchange/Regulate/CHSR/HTMLs/F8-National%20Organ%20Transplant%20Act.htm>. Accessed June 6, 2006.
5. Organ Procurement and Transplantation Network; Final Rule. *Federal Register*. April 2, 1998;63:16296. Available at <http://www.gpoaccess.gov/fr/index.html>. Accessed June 6, 2006.
6. Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye

- Donors and Transplant Hospitals' Provision of Transplant-Related Data; Final Rule. *Federal Register*. June 22, 1998;63:33856. Available at <http://www.gpoaccess.gov/fr/index.html>. Accessed June 6, 2006.
7. U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation. Recommendations 19-28. Donate Life, the official U.S. government web site for organ and tissue donation and transplantation available at www.organdonor.gov/acotrecs2.html. Accessed July 11, 2006.
8. Texas Department of State Health Services. Organ Procurement Organizations. Available at www.dshs.state.tx.us/DEAR/ opos.shtm. Accessed July 11, 2006.
9. The Presumed Consent Foundation, Inc. Solutions. Available at <http://www.presumedconsent.org/solutions.htm>. Accessed July 11, 2006.
10. Tammelleo AD. When nurses obtain consent for organ donations. *Regan Rep Nurs Law*. 1995 Jan; 35(8):1.
11. Hensley MD, Samuel D. Informed Consent in Living Organ Donors. Available at www.cbhd.org/resources/bioethics/hensley_1005-06-16.htm. Accessed June 6, 2005.
12. American Kidney Fund. Position on methods to increase cadaveric organ donation. Available at www.kidneyfund.org/pl_cadaveric_organ.asp. Accessed July 6, 2006.

Dana Leidig can be reached at dana-leidig@tmlt.org.



Tipping the scales

The obesity epidemic

Objectives

At the conclusion of this educational activity, the reader will be able to:

1. Discuss the factors that play a role in the development of obesity.
2. Identify the challenges faced by physicians in the assessment and management of the obese patient.
3. Recognize the economic impact of obesity on the health care system.
4. Describe strategies to fight the obesity epidemic.
5. Develop an awareness of ways to create a positive practice environment for the obese patient.

Course author

Barbara Rose is a senior risk management representative at Texas Medical Liability Trust.

Disclosure

Barbara Rose 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. In order 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. 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 one hour to read this article and complete the questions.

Release/review date

This activity is released on August 1, 2006 and expires on August 1, 2008. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction

Obesity has been described as an epidemic in society today and its impact transcends age and ethnicity. Managing the health care of those who are obese affects all areas of physician practice and presents unique challenges. This article and CME activity will focus on identifying the scope and demographics relevant to obesity and the associated

medical problems and inherent challenges in the management of health care for these patients in your practice. A previous article in *the Reporter* (November/December 2004) reviewed weight loss surgery. This article will address societal influences and the subsequent personal choices that have led to the myriad of medical problems faced by those who are overweight.

Overview

There are a number of factors that play a role in obesity, making it a complex health issue to address. Multiple influences including genetics, behavior, and environment may be contributing factors in obesity. In 2001 the *U.S. Surgeon General’s Call to Action to Prevent and Decrease Overweight and Obesity* included the following statements.

- Overweight and obesity result from an energy imbalance caused by consuming too many calories and getting inadequate

physical activity.

- Body weight is influenced by genes, metabolism, behavior, environment, culture, and socioeconomic status.
- Behavior and environment play a large part in the causes of obesity. These are the areas for prevention and treatment plans. ¹

Terminology and definitions

The National Institutes of Health (NIH) uses Body Mass Index (BMI) to measure overweight and obesity in four categories. BMI is derived from the factor that weight in normal adults is proportional to height squared.

- BMI of 25-30 = overweight
- BMI of 30-40 = obese
- BMI of 40-50 = morbidly obese
- BMI > 50 = super obese

Overweight and obesity are labels for ranges of weight that are greater than what is generally considered healthy for a given

height. BMI is used because, for most individuals, it correlates with their amount of body fat. BMI is determined by dividing a person’s weight in kilograms by height in meters squared. The mathematical formula is BMI = weight (kg)/height squared (m²). For the math challenged, multiply weight in pounds by 704.5 and divide the result by height in inches. Divide that result by height in inches a second time. Or, even better, access the BMI calculator at <http://www.nhlbisupport.com/bmi>. The table below may be maintained for a quick reference. ²

Statistics and trends

Data compiled by the Centers for Disease Control and Prevention (CDC) in 2000 indicate that more than 64% of American adults qualify as overweight or obese; 15% of adolescents (age 12 to 19) are overweight; and 15% of children (age 6 to 11) are overweight. ¹ “Overweight and obesity are found world-

Body Mass Index Table																							
To use the table, find the appropriate height in the left column labeled Height. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.																							
BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	
Height (inches)																						Weight (pounds)	
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	
68	125	131	138	144	151	158	164	171	177	184	190	197	204	210	216	223	230	236	243	249	256	262	
69	128	135	142	149	155	162	169	176	182	189	196	203	210	216	223	230	236	243	250	257	263	270	
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	

wide, and the prevalence of these conditions in the United States ranks high along with other developed nations.”² Globally, there are more than 1 billion overweight adults, and at least 300 million are obese. The key causes are increased consumption of energy-dense foods high in saturated fats and sugars, and reduced physical activity.³

As the prevalence of overweight and obesity has increased in the U.S., so have related health care costs. Based on CDC estimates for the year 2000, \$117 billion dollars were spent in direct medical costs and indirect costs such as lost wages due to illness. These costs were related to more than 300,000 premature deaths.⁴

Health impact of obesity

With a known decrease in quality of life and increase in the risk of premature death, what are the identified medical co-morbidities of obesity that create such complex health management challenges? Overweight and obesity lead to adverse metabolic effects on blood pressure, cholesterol, triglycerides and insulin resistance. Debilitating health problems associated with obesity include respiratory difficulties, chronic musculoskeletal problems, skin problems, and infertility. The more life-threatening problems fall into four main areas: cardiovascular disease; conditions associated with insulin resistance such as type 2 diabetes; certain types of cancers, especially the hormonally related and large-bowel cancers; and gallbladder disease.³

Elevated BMI also increases the risk of developing cancer of the breast, colon, kidney, prostate, endometrium, and gallbladder. Chronic overweight and obesity contribute significantly to osteoarthritis, a major cause of disability in adults.³ Obesity is also associated with high blood cholesterol, menstrual irregularities, complications of pregnancy, hirsutism, stress incontinence, increased surgical risks, and psychological disorders such as depression.²

With the increase in childhood and adolescent obesity, this segment of the population has shown an alarming increase in the incidence of type 2 diabetes. Many obese children have high cholesterol and blood pressure, both risk factors for heart disease. A potential and severe problem for obese children is sleep apnea that, in some cases, may lead to difficulties with learning and memory. Obese children have a high incidence of liver disease, orthopedic problems, and asthma. Adolescents who are overweight have a 70% chance of becoming overweight or obese adults.⁵

In the June 2001 issue of *American Family Physician*, the article “Obesity: Assessment and Management in Primary Care” highlighted many of the challenges faced by physicians

in the assessment and management of obese patients. Of particular note is the acknowledgment that many health care plans may not cover treatment for these patients and the lack of meaningful data on the “long-term safety and efficacy of pharmacotherapeutic agents for obesity.”⁶

Guidelines for obesity management

There are many challenges inherent in caring for patients who are obese. Among them is the reality that they may delay seeking medical care. The obese patient may be less likely to consent to preventive services such as Pap smears, breast and pelvic examinations. Physicians and their staffs can implement measures to overcome barriers and ensure optimal medical care for patients who are obese. Begin with your own education and that of your staff to treat all patients with respect. The following list can serve as a guide in creating a positive practice environment for the obese patient.

1. Create an accessible and comfortable office environment.
 - Have sturdy, armless chairs and high, firm sofas in waiting rooms.
 - Provide a sturdy, wide examination table that is bolted to the floor to prevent tipping.
 - Have extra-large examination gowns available.
 - Install a split lavatory seat and provide a specimen collector with a handle.
2. Use medical equipment that can accurately assess patients who are obese.
 - Have large adult blood pressure cuffs or thigh cuffs for patients with an upper-arm circumference greater than 34 cm.
 - Have extra-long phlebotomy needles, tourniquets, and large vaginal speculums available.
 - Have a weight scale with a capacity greater than 350 pounds.
3. Reduce patient fears about weight.
 - Weigh obese patients only when medically appropriate and in a private area.
 - Record weight without comments.
 - Ask patients if they wish to discuss their weight or health.
 - Avoid verbally using the term obesity and substitute terms such as “being overweight” or “difficulties with weight.”
4. Monitor obesity-related medical conditions and risk factors.
 - Conduct appropriate tests to assess type 2 diabetes, dyslipidemia, hypertension, sleep apnea, ischemic heart disease, and nonalcoholic steatohepatitis.

- Evaluate for risk factors that may be overlooked such as lower extremity edema, thromboembolic disease, respiratory insufficiency (Pickwickian syndrome), skin ulcers, and foot infections.

5. Offer preventive care services.
 - Schedule adequate time during office visits for preventive care services.
 - Recommend and/or provide Pap smears, breast examinations, mammography, prostate examinations, and stool testing.
6. Commit to patient education and encourage healthy behaviors.
 - Discuss weight loss as a treatment for weight-related medical conditions.
 - Emphasize healthy behaviors to prevent further weight gain.
 - Encourage physical activity to improve cardiovascular health.
 - Seek out professional resources to assist your patients and provide referrals to registered dietitians, certified diabetes educators, exercise physiologists, weight management programs, and support groups as appropriate.
 - Promote self-acceptance and encourage patients to lead a full and active life.²

Strategies to fight the obesity epidemic

In August 2004, the NIH released a Strategic Plan for NIH Obesity Research, described as a “multi-dimensional research agenda to enhance both the development of new research in areas of greatest scientific opportunity and the coordination of obesity research across NIH.”⁵ This plan calls for “interdisciplinary research teams to bridge the study of behavioral and environmental causes of obesity with the study of genetic and biologic causes.”⁶ Increasing efforts along several fronts are recommended and include:

- modifying lifestyle to prevent or treat obesity with behavioral and environmental approaches;
- pharmacologic, surgical, and other medical approaches to effectively and safely prevent or treat obesity;
- breaking the link between obesity and diseases such as type 2 diabetes, heart disease, and certain cancers;
- increase in research on special populations at risk for obesity, including children, ethnic minorities, women, and older adults;
- translating basic science results into clinical research and then into community intervention studies; and
- disseminating research findings to health professionals and the public.⁵

NIH invested \$378.6 million for obesity research in fiscal year 2003, about \$400.1 mil-

lion in 2004, and was projected to support obesity research in 2005 with about \$440.3 million, an increase of 10 percent over 2004.⁷

Federal guidelines

In 2001, the first federal guidelines on the identification, evaluation, and treatment of overweight and obesity in adults were published. The National Heart, Lung, and Blood Institute (NHLBI) in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) released the clinical guidelines.⁸ They are designed to aid physicians in their care of this segment of the population by presenting a new approach for the assessment of overweight and obesity and establishing principles of safe and effective weight loss. Evaluation of three key elements is central to the guidelines — body mass index, waist circumference, and risk factors for diseases and conditions associated with obesity. The panel that developed the guidelines recommends that BMI be determined in all adults.

A National Health and Nutrition Examination Survey (NHANES III)⁹ and subsequent analysis revealed as BMI levels rise, average blood pressure and total cholesterol levels increase, and average HDL or good cholesterol levels decrease. “Men in the highest obesity category have more than twice the risk of hypertension, high blood cholesterol, or both, compared to men of normal weight. Women in the highest obesity category have four times the risk of either or both of these risk factors.”⁸

The federal guidelines recommend weight loss to lower high blood pressure, to lower high total cholesterol and to raise low levels of HDL, and to lower elevated blood glucose in overweight persons with two or more risk factors and in obese persons. Overweight patients without risk factors should prevent further weight gain. Physicians are advised to determine waist circumference, as it is strongly associated with abdominal fat. Excess abdominal fat is an independent predictor of disease risk. A waist measurement of more than 40 inches in men and more than 35 inches in women signifies increased risk in those with a BMI of 25 to 34.9.⁸

According to the guidelines, “the most successful strategies for weight loss include calorie reduction, increased physical activity, and behavior therapy designed to improve eating and physical activity habits.”⁸ Other recommendations include:

- moderate physical activity with progression to 30 minutes or more on most and preferably each day of the week;
- reducing dietary fat that aids in calorie reduction and is heart-healthy;
- setting an initial goal to reduce body

weight by about 10 percent from baseline;

- a reasonable timeline for a 10% reduction is six months with a weight loss of 1 to 2 pounds per week;
- encourage lifestyle therapy for at least six months before starting prescription drug therapy.

Evaluation and treatment of adults

In 2005, the American College of Physicians (ACP) issued guidelines for the pharmacologic and surgical management of obesity and published these guidelines in the April 5, 2005 issue of the *Annals of Internal Medicine*.¹⁰ The ACP wanted to complement the 2003 recommendations of the U.S. Preventive Services Task Force on screening for obesity. The ACP recommendations are:

“1. Clinicians should counsel all obese patients on lifestyle and behavioral modifications such as appropriate diet and exercise, and goals for weight loss should be individually determined.

2. Pharmacologic therapy can be offered to obese patients who have failed to achieve their weight loss goals through diet and exercise alone. However, *there needs to be a doctor-patient discussion of the drugs’ side effects, the lack of long-term safety data, and the temporary nature of the weight loss achieved with medications before initiating therapy.* [italicized for emphasis by the author]

3. For obese patients who choose to use adjunctive drug therapy, the choice of agent will depend on the side-effects profile of each drug and the patient’s tolerance of those side effects.

4. Surgery may be considered as a treatment option for patients with a BMI of 40 or greater who instituted but failed an adequate exercise and diet program (with or without adjunctive drug therapy) and who present with obesity-related co-morbid conditions. *A doctor-patient discussion of surgical options should include the long-term side effects, such as possible need for re-operation, gallbladder disease, and malabsorption.* [italicized for emphasis by the author]

5. Patients should be referred to high-volume centers with surgeons experienced in bariatric surgery.”¹⁰

In August of 2005, the American College of Obstetricians and Gynecologists (ACOG) released its first committee opinion on obesity during pregnancy. The opinion is published in the September 2005 issue of *Obstetrics & Gynecology*. Gary D. V. Hankins, MD stated “everything we do in obstetrics is made more difficult and more complex by obesity — from using monitors to performing surgery.”¹¹ According to ACOG, some studies show that obesity is an independent risk factor for mis-

carriage among women who have fertility treatments. Data link obesity to miscarriage in women who conceived naturally. Obesity has also been linked to an increased risk of gestational hypertension, pre-eclampsia, and gestational diabetes. Furthermore, the higher BMI a woman has, there is an increased chance she will need a cesarean section.

Obese women may have more complications during and after a cesarean section including excessive blood loss, operating time greater than two hours, and wound infection. Anesthetic challenges may also be encountered, among them difficult epidural placement and respiratory problems from a difficult intubation. Increased risks to the babies of obese women include stillbirth, prematurity, macrosomia, neural tube defects, and higher rates of childhood obesity.¹¹

ACOG makes the following recommendations for ob-gyns who care for obese patients:

1. Explain the Institute of Medicine (IOM) guidelines for prenatal weight gain: 25-35 pounds for women of normal weight; 15-25 pounds for overweight women; and 15 pounds for obese women.

2. Record height and weight for all patients at the first prenatal visit to determine BMI.

3. Offer nutrition consultation and encourage an exercise program. These programs should be continued after delivery and before attempting another pregnancy.

4. Consider screening for gestational diabetes during the first trimester and repeating the test later if the initial test is negative.

5. Discuss potential pregnancy complications such as difficulty estimating fetal weight and obtaining fetal heart rate.

6. Suggest a consultation with an anesthesiologist before delivery, or at the very least, early in labor as obese patients are at high risk for emergency cesarean sections.¹⁰

Assessment of children and adolescents

A measurement called percentile of BMI is used to identify overweight and obesity in children and adolescents. The CDC in its role as the supplier of national growth charts and prevalence data, avoids using the word “obesity” for children and adolescents. They suggest two levels of overweight: 1) the 85th percentile, an “at risk” level, and 2) the 95th percentile as a more severe level. The 95th percentile is recommended as a marker for an in-depth medical assessment. It identifies children who are likely to have obesity in adulthood and functions as criteria for more aggressive treatment as well as clinical research trials of childhood obesity.¹²

Future generations — reversing the trend

In an article in *Pediatrics* on evaluation and treatment of obesity, a committee of pediatric

obesity experts recommended intervention that “begins early, involves the family, and institutes permanent changes in a stepwise manner.”¹³ This committee identified parenting skills as the “foundation for successful intervention that puts in place gradual, targeted increases in activity and targeted reductions in high-fat, high-calorie foods. Methodic, gradual, long-term changes will be more successful than multiple, frequent changes.”¹² This article is lengthy and cannot be summarized here. Those who provide health care services for children and adolescents can read the article on the web at <http://pediatrics.aapublications.org/cgi/content/full/102/3/e29>.

The 2001 publication *U.S. Surgeon General’s Call to Action to Prevent and Decrease Overweight and Obesity* identified action steps for several locations that may help prevent and decrease obesity and overweight. The table to the right provides some examples of these steps.¹⁴

Risk management considerations

Earlier in this article a list of suggestions to create a positive practice environment for the obese patient was included. Other aspects impacting the care of obese adults, children and adolescents that physicians may consider include their own attitudes and perceptions. Physicians who lack the time and patience to assess, implement, and monitor these patients may wish to refer them elsewhere. Such an attitude will likely have an adverse effect on the patient and family. Much of our societal attitudes place great value on appearance and a “belief that obesity results from laziness or lack of willpower.”¹³ These patients should be treated with compassion and sensitivity, and “a conviction that obesity is an important, chronic medical problem that can be treated.”¹³ Create an alliance with the patient. Teach and require your staff to do the same.

Comprehensive documentation in the medical record is always expected. Remember to clearly document patient/parent education regarding treatment options, the benefits and risks of each, and the patient’s informed choice. Have informed consents signed if relevant, particularly for weight-loss medications. Document treatment compliance or noncompliance as applicable.

Conclusion

“Being overweight or obese is directly linked to development of chronic disease and it is second only to smoking as a preventable cause of death.”¹⁵ No physician specialty is exempt from challenges relevant to the assessment and care of patients who are obese. Our family, societal, and educational influences have an impact that may not be in our best interest, i.e. too many calories and too little activity. The U. S. has earned its unflattering

Location	Steps to help prevent and decrease overweight and obesity
Home	<ul style="list-style-type: none"> • Reduce time spent watching television and in other sedentary behaviors. • Build physical activity into regular routines.
Schools	<ul style="list-style-type: none"> • Ensure that the school breakfast and lunch programs meet nutrition standards. • Provide food options that are low in fat, calories, and added sugars. • Provide all children, from pre-kindergarten through grade 12, with quality daily physical education.
Work	<ul style="list-style-type: none"> • Create more opportunities for physical activity at work sites.
Community	<ul style="list-style-type: none"> • Promote healthier choices including at least 5 servings of fruits and vegetables a day, and reasonable portion sizes. • Encourage the food industry to provide reasonable food and beverage portion sizes. • Encourage food outlets to increase the availability of low-calorie, nutritious food items. • Create opportunities for physical activity in communities.

status as the “fast food nation” and a commitment by government, schools, the food and restaurant industries, physicians and patients for the prevention of obesity may be the best treatment. It will take a generation or even longer to reverse this trend and that timid prediction is based on an optimistic anticipation of success.

References

1. Centers for Disease Control and Prevention. Prevalence of overweight and obesity among adults: United States, 1999-2000. Available at www.cdc.gov/nchs/fastats/overwt.htm. Accessed March 3, 2006.
2. Weight-control Information Network. An information service of the National Institute of Diabetes and Digestive and Kidney Diseases. Statistics related to overweight and obesity. Available at <http://win.niddk.nih.gov/statistics/index.htm>. Accessed April 12, 2006.
3. World Health Organization. Obesity and overweight. Available at <http://www.who.int/dietphysicalactivity/publications/facts/obesity/en/print.html>. Accessed March 23, 2006.
4. Centers for Disease Control and Prevention. Overweight and obesity health consequences. Available at <http://www.cdc.gov/nccdphp/dnpa/obesity/index.htm>. Accessed March 3, 2006.
5. Torgan C. Childhood obesity on the rise. The NIH Word on Health. June 2002. Available at www.nih.gov/news/wordonhealth/jun2002/childhoodobesity.htm. Accessed May 15, 2006.
6. Lyznicki J, et al. Obesity: Assessment and Management in Primary Care. *Am Fam Physician*. 2001; June. Available at www.aafp.org/afp/20010601/2185.html. Accessed May 30, 2006.
7. NIH Obesity Research Task Force. Strategic Plan for NIH Obesity Research. Available at obesityresearch.nih.gov. Accessed March 23, 2006.

8. National Heart, Lung, and Blood Institute. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in Adults. Available at www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm. Accessed March 24, 2006.
9. National Center for Health Statistics. National Health and Nutrition Examination Survey III. Available at <http://www.cdc.gov/nchs/nhanes.htm>. Accessed June 15, 2006.
10. Snow V, et al. Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2005;142:525-531. Available at <http://www.annals.org/cgi/content/full/142/7/525>. Accessed May 30, 2006.
11. American College of Obstetricians and Gynecologists. ACOG Committee Opinion #315: obesity in pregnancy. *Obstet Gynecol*. 2005; 106: 671-675. Available at <http://www.greenjournal.org/content/vol106/issue3/>. Accessed June 15, 2006.
12. American Obesity Association. Childhood obesity: prevalence and identification. Available at <http://www.obesity.org/subs/childhood/prevalence.shtml>. Accessed May 15, 2006.
13. Barlow SE, Dietz WH. Obesity evaluation and treatment: expert committee recommendations. *Pediatrics*. 1998;102:497-570. Available at <http://pediatrics.aappublications.org/cgi/content/full/102/3/e29>. Accessed May 15, 2006.
14. Centers for Disease Control and Prevention. Overweight and obesity: contributing factors. Available at http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm. Accessed June 5, 2006.
15. Stokes DM. The impact of obesity on healthcare delivery. *For the record*. 16;2. Available at www.fortherecord.com/archives/ftr_012604p34.shtml. Accessed March 23, 2006.

Barbara Rose can be reached at barbara-rose@tmlt.org.

closed claim studies

Failure to timely perform surgery

by Barbara Rose and Anna Tauzin

The following 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.

Presentation

A 45-year-old woman was brought to the emergency department after being struck by an automobile while walking her dog. EMS noted left knee and left back injuries. Evaluation at the ED revealed a closed head injury, distended abdomen, dislocated left patella, and gross hematuria.

An emergency medicine physician reduced the dislocated left patella and also ordered an ultrasound that showed free fluid in the abdomen. The patient received two units of packed red blood cells due to declining blood pressure.

Physician action

A general surgeon took the patient to the OR for exploratory laparotomy. After confirmation of a ruptured spleen, splenectomy was performed. The surgeon also discovered a retroperitoneal hematoma in the left kidney area, believed to be the root of the patient's back pain and presence of blood in the urine. The hematoma was determined to be stable and not expanding, so it was left in place to be observed.

After surgery, the surgeon consulted with a urologist to review the patient's CT scans and kidney injury. The urologist noted a renal injury in the CT scan, but judged by the contrast in the ureter that the kidney was functioning properly. The patient's Foley bag was also found to be draining bloody urine. The hematoma was not expanding,

and conservative monitoring continued.

The patient continued to complain of severe pain in the left scapular area during the night and into the morning. She was restless and tachycardic. The nurse's notes showed that the patient's blood pressure dropped from 110/78 to 70/45 mm Hg in one hour. At that time, her pulse was ranging from 150-175 bpm.

That afternoon the surgeon noted clots in the bladder caused by the bleeding left kidney. Unable to find the consulting urologist, the surgeon took the patient back to the OR without the urologist. He performed a left nephrectomy.

The patient went into cardiac arrest at the end of surgery and attempts to resuscitate, including a thoracotomy and open heart massage, were unsuccessful.

Allegations

Lawsuits were filed against the surgeon and the urologist. Allegations against the surgeon included:

- failure to recognize symptoms of internal bleeding which caused the patient to go into hypovolemic shock;
- failure to timely perform surgery to stop the bleeding of the patient's kidney; and
- failure to accurately interpret the CT that showed active arterial bleeding.

Allegations against the urologist included:

- failure to properly interpret the CT scan of the patient's kidney;
- failure to timely examine the patient;
- not being present when the nephrectomy was scheduled.

Legal implications

Although there was solid support for the surgeon's actions, many expert reviewers felt the surgeon made no attempt to evaluate the kidney during the first surgery by performing an intraoperative IVP or other study. There were also no preoperative studies of the kidney before the first surgery.

The patient continued to be hemodynamically unstable after the first surgery and was still bleeding quite severely, which led the plaintiff's experts to conjecture that the surgeon's examination of the kidney during the first surgery was not extensive enough.

Additionally, no preoperative blood gas was drawn before the second surgery, which was later determined to be at an abnormal pH of 7.1, indicating severe acidosis. Though blame for this was originally placed on the anesthesiologist, the plaintiffs argued that it was also the surgeon's responsibility, since the patient was supposed to be under his supervision for the previous 12 hours. During that time the patient's labs and vital signs revealed the development of acidosis and hypovolemia.

Several experts also pointed out that had the patient been monitored more closely, she would have been brought in for surgery earlier and possibly survived.

Disposition

The case against the surgeon was settled before trial. The case against the urologist was dropped.

Risk management considerations

Negligence, when used with respect to the conduct of a physician, means failure to use ordinary care or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances or doing that which a physician of ordinary prudence would not have done under the same or similar circumstances. Whether the actions and choices of the defendant surgeon did or did not constitute negligence was argued by many physician consultants and experts for the plaintiff and defendant. In a retrospective review where the outcome is known, it is unlikely that a common consensus will be reached.

Barbara Rose can be reached at barbara-rose@tmlt.org. Anna Tauzin can be reached at anna-tauzin@tmlt.org.

Failure to re-excise a suspicious lesion

by Barbara Rose and Laura Brockway

Presentation

On September 3, a 36-year-old woman came to a plastic surgeon's office regarding a "progressively enlarging mole on her right foot." She reported that she had a positive family history for melanoma. Specifically, her grandmother died at age 45 from metastatic melanoma.

Physician action

The plastic surgeon examined the patient and noted that she had blond hair with fair skin. With the exception of the foot lesion, no other skin abnormalities were found. He described the foot lesion as "suspicious" and performed a 3 mm punch biopsy under local anesthetic.

The specimen was sent to a pathology lab. In his report, the pathologist described the tissue as having abnormal cell growth and thickening with proliferation of slightly atypical melanocytes within the epidermal area. The cells were atypical in that there was a visible, but not prominent nucleus. The pathologist believed that the dermis was fibrotic, but did not manifest fibroplasias of the dysplastic nevus. The lateral margins of the specimen were involved, and conservative re-excision with 0.5 cm margins was recommended. The pathologist also noted that the specimen had a more than expected degree of cytoarchitectural atypia. The final diagnosis was acral compound melanocytic nevus, moderate cytoarchitectural atypia, and nevus at peripheral, not deep edges. A second pathologist at the lab reviewed this specimen and concurred with the pathologist's opinion.

The surgeon saw the patient again on September 11. He concluded that the lesion was melanocytic nevus and that there was no need for removal. The plastic surgeon recommended biannual follow up for re-examination of the lesion.

The patient returned one year later on September 9 because the lesion on her foot had become infected. She wanted to discuss removal of the lesion. She complained that the lesion was rubbed by her shoe and was tender to touch. The plastic surgeon noticed some irritation in the area, but felt it was from the shoe. He recommended excision in light of the pathology report, irritation and recent infection. On September 30, the plastic surgeon saw the patient for a preoperative evaluation. The lesion was "not getting any better" and caused the patient pain with walking. The plastic surgeon obtained a full history and informed consent for the procedure.

On October 1, the plastic surgeon performed an excisional biopsy of this area as planned. The pathologist reported that the lesion represented an invasive malignant melanoma. He described it as Clarks Level III with Breslow thickness of 2.1 mm. The margins were free from lesional tissue, meaning the biopsy had theoretically removed the entire lesion.

The surgeon informed the patient of the results at a follow-up visit. He told her that the specimen would be reviewed for a second opinion, but indicated that she would be referred to a surgical oncologist for treatment. A dermatopathologist who reviewed the slides of the specimen agreed with the diagnosis of malignant melanoma.

The patient saw a surgical oncologist who performed a wide excision and lymph node biopsy. The pathology report revealed micrometastatic melanoma of the lymph node. The patient was referred to an oncologist and underwent adjuvant chemotherapy with interferon. The patient did well until widespread metastasis was revealed nine months later. Due to the metastasis, the only treatment given was palliative care. She died three months later at the age of 38.

Allegations

A lawsuit was filed against the plastic surgeon alleging negligence in performing only a punch biopsy on a suspicious lesion and for failing to re-excise the lesion after the pathology report recommended re-excision.

Legal implications

The plaintiffs were able to locate experts supportive of their allegations. They claimed that if the lesion had been re-excised as recommended by the pathologist, in all reasonable medical probability, the patient would have been cured.

The biggest hurdle for the defense was the fact that the pathologist recommended re-excision but the plastic surgeon did not re-excise the lesion. It was clear from the medical records that the plastic surgeon did not read the entire pathology report. He specifically wrote in his notes that there was no reason to re-excise the lesion. In the pathology report, the recommendation to re-excise the lesion was placed in the "Microscopic Description" section instead of the "Diagnosis" section.

Defense consultants were divided on whether or not the plastic surgeon breached the standard of care. One consultant stated that the plastic surgeon's failure to read the entire pathology report was a breach in the

standard of care. Further, even if he did not read the comment on re-excision, certain "red flags" in the report could indicate the need for re-excision. These "red flags" included the fact that the patient had fair skin and a family history of melanoma; that the lesion extended to the margin; and the lesion had moderate atypia. Other consultants supported the surgeon's decision not to re-excise and stated that follow-up would have been the appropriate way to handle the lesion.

Several defense consultants did criticize the format of the pathology report. The recommendation to re-excise the lesion was "buried" at the end of a long paragraph in the "Microscopic Description" section. One consultant stated that when physicians review pathology reports they generally will not read the microscopic section of a report, but instead focus on the "top line" diagnosis.

Disposition

Due to the lack of strong expert support, this case was settled on behalf of the plastic surgeon.

Risk management considerations

Two aspects of this closed claim are worthy of note, and have relevance for prudent risk management. When physicians review reports generated by their orders — lab and imaging studies or, in this case, a tissue specimen sent to pathology — they will be held accountable for reviewing the content of the report and acting on the information in a timely manner. This case serves as an affirmation that the complete report be reviewed and that there be no assumptions regarding the anticipated "style" of a report.

Secondly, after the patient's follow up appointment to review the findings of the report, it was recommended that she return for biannual (twice a year) re-examination of the lesion. It is incumbent on all physician practices to have a recall/reminder system when patients leave without a scheduled return appointment. With this patient's family history of melanoma, a reminder system is a high priority.

Barbara Rose can be reached at barbara-rose@tmlt.org. Laura Brockway can be reached at laura-brockway@tmlt.org

the Reporter



TEXAS MEDICAL LIABILITY TRUST

P.O. Box 160140
Austin, TX 78716-0140
800-580-8658 or 512-425-5800
E-mail: laura-brockway@tmlt.org
www.tmlt.org

Editorial committee

Tom Cotten, President and CEO
Bob Fields, Executive Vice President, Claim Operations
Don Chow, Senior Vice President, Marketing
Jane Holeman, Vice President, Risk Management
Dana Leidig, Vice President, Communications & Advertising

Editor

Laura Brockway, ELS

Contributing editor

Barbara Rose

Staff

Dana Leidig, Anna Tausin

The Reporter is published six times a year by Texas Medical Liability Trust as an information and educational service to TMLT policyholders. All articles and any forms, checklists, guidelines and materials are for general information only, and should not be used or referred to as primary legal sources or construed as establishing medical standards of care. They are intended as resources to be selectively used and always adapted — with the advice of the organization's attorney — to meet state, local, individual organizations and department needs or requirements. The Reporter is distributed with the understanding that Texas Medical Liability Trust is not engaged in rendering legal services. © 2006 TMLT

Pre-sorted Standard
U.S. Postage
PAID
Permit No. 90
Austin, Texas

Patient safety news

Campaign against hospital errors says 122,300 lives saved

In June, the Institute for Healthcare Improvement (IHI) announced that hospitals enrolled in the 100,000 Lives Campaign have collectively prevented an estimated 122,300 avoidable deaths.

Begun by the IHI in December 2004, the campaign enrolled 3,100 hospitals in an 18-month effort to prevent 100,000 unnecessary deaths. The IHI initiative called on hospitals to institute six evidence-based interventions that have been proven to prevent avoidable deaths: deploy rapid response teams at the first sign of patient decline; deliver reliable, evidence-based care for acute myocardial infarction to prevent deaths; prevent adverse drug events by implementing medication reconciliation; prevent central line infections by implementing a series of steps called the "Central Line Bundle"; prevent surgical site infections by reliably delivering the correct perioperative care; and prevent ventilator-

associated pneumonia by implementing a series of steps called the "Ventilator Bundle."

Of the 3,100 participating hospitals, one-third implemented all six interventions and more than half committed to at least three measures. Eighty-six percent of the hospitals reported to the IHI the numbers of admissions and deaths during the campaign period and in 2004. Researchers examined the 2004 data to determine how many people were expected to die during the 18-month campaign. They then checked the count of actual deaths and adjusted for severity of illness and volume of cases.

According to an article in the *Wall Street Journal*, IHI staff say the campaign's effect will not be fully understood until they can compare their data with data from hospitals that did not participate. The IHI plans to gather those numbers in the next six months and include them in a paper to be submitted to a peer-reviewed journal.

Washington State law bans prescriptions written in cursive

As the result of a Washington State medical malpractice compromise bill passed earlier this year, pharmacists in the state can no longer accept handwritten prescriptions — unless they are hand-printed, not in cursive.

The new law defines a "legible prescription" as hand-printed, typewritten or electronically generated. Prescriptions written in cursive are to be treated as illegible and not accepted.

According to an article in the *Seattle Times*, many pharmacists were surprised and irritated at the new requirement that they say places pharmacists in the position of "enforcer."

While the Washington State Medical Quality Assurance Commission says it will not make "doctors who write" a top priority, it could take disciplinary action against serious and repeated violations.