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## JOURNALS IN MEDICINE

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### American Journal of Medicine

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Volume 123, Number 11  
November 2010

#### Risk of Suicide after Long-Term Follow-Up from Bariatric Surgery

*H. A. Tindle et al.*

*Purpose:* Bariatric surgery is recognized as the treatment of choice for class III obesity (body mass index greater than or equal to forty) and has been increasingly recommended for obese patients. Prior research has suggested an excess of deaths due to suicide following bariatric surgery, but few large long-term follow-up studies exist. The authors examined postbariatric surgery suicides by time since operation, sex, age, and suicide death rates as compared with U.S. suicide rates. *Methods:* Medical data following bariatric operations performed on Pennsylvania residents between January 1, 1995, and December 31, 2004, were obtained from the Pennsylvania Health Care Cost and Containment Council. Matching mortality data from suicides between September 1, 1996, and December 28, 2006, were obtained from the Division of Vital Records, Pennsylvania State Department of Health. *Results:* There were thirty-one suicides (16,683 operations), for an overall rate of 6.6 per 10,000; 13.7 per 10,000 among men and 5.2 per 10,000 among women. About 30 percent of suicides occurred within the first two years following surgery, with almost 70 percent occurring within three years. For every age category except the youngest, suicide rates were higher among men than women. Age- and sex-matched suicide rates in the U.S. population (ages thirty-five to sixty-four

years) were 2.4 per 10,000 (men) and 0.7 per 10,000 (women). *Conclusions:* Compared with age and sex-matched suicide rates in the United States., there was a substantial excess of suicides among all patients who had bariatric surgery in Pennsylvania during a ten-year period. These data document a need to develop more comprehensive longer-term surveillance and follow-up methods in order to evaluate factors associated with postbariatric surgery suicide.

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### Annals of Internal Medicine

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Volume 153, Number 1  
July 6, 2010

#### Sexually Transmitted Diseases among Users of Erectile Dysfunction Drugs: Analysis of Claims Data

*A. B. Jena et al.*

*Background:* Pharmacologic treatments for erectile dysfunction (ED) have gained popularity among middle-aged and older men. Increased sexual activity among those who use these drugs raises concerns about sexually transmitted diseases (STDs). *Objectives:* To examine the rates of STDs in men who use and do not use ED drugs. *Design:* Retrospective cohort study. *Setting:* Database of claims from 1997 to 2006 for 1,410,806 men older than age for years with private, employer-based insurance from forty-four large companies. *Patients:* 33,968 men with at least one filled prescription for an ED drug and 1,376,838 patients with no prescription. *Measurements:* STD prevalence among users and nonusers of ED drugs. *Results:* Users of ED drugs had higher rates of STDs than nonusers the year before initiating ED drug therapy (214 versus 106 annually per 100,000 persons;  $P=0.003$ ) and the year after (105 versus 65;  $P=0.004$ ). After adjustment for age and other comorbid conditions, users of ED drugs had an odds ratio for an STD of 2.80 (95 percent confidence interval [CI], 2.10 to 3.75) in the year before initiating drug therapy; the odds ratio was 2.65 (CI, 1.84 to 3.81) in the year after. These differences were

largely due to infections with HIV. The odds ratio for HIV infection was 3.32 (CI, 2.38 to 4.36) in the year before and 3.19 (CI, 2.11 to 4.83) in the year after an ED drug prescription was filled. Significant changes in STD rates from the year before to the year after the first ED drug prescription was filled were not documented (adjusted odds ratio for STD for users before versus after the first ED drug prescription was filled, 0.96 [CI, 0.87 to 1.06]). *Limitation:* Selection bias precludes conclusions about whether use of ED treatments directly leads to increases in STDs. *Conclusion:* Men who use ED drugs have higher rates of STDs, particularly HIV infection, both in the year before and after use of these drugs. The observed association between ED drug use and STDs may have more to do with the types of patients using ED drugs rather than a direct effect of ED drug availability on STD rates. Counseling about safe sexual practices and screening for STDs should accompany the prescription of ED drugs.

Volume 153, Number 7  
October 5, 2010

### **Insufficient Sleep Undermines Dietary Efforts to Reduce Adiposity**

*A. V. Nedeltcheva et al.*

*Background:* Sleep loss can modify energy intake and expenditure. *Objective:* To determine whether sleep restriction attenuates the effect of a reduced-calorie diet on excess adiposity. *Design:* Randomized, two-period, two-condition crossover study. *Setting:* University clinical research center and sleep laboratory. *Patients:* Ten overweight nonsmoking adults (three women and seven men) with a mean age of forty-one years (SD, 5) and a mean body mass index of 27.4 kg/m<sup>2</sup> (SD, 2.0). *Intervention:* Fourteen days of moderate caloric restriction with 8.5 or 5.5 hours of nighttime sleep opportunity. *Measurements:* The primary measure was loss of fat and fat-free body mass. Secondary measures were changes in substrate utilization, energy expenditure, hunger, and twenty-four-hour metabolic hormone concentrations. *Results:* Sleep

curtailment decreased the proportion of weight lost as fat by 55 percent (1.4 versus 0.6 kg with 8.5 versus 5.5 hours of sleep opportunity, respectively;  $P=0.043$ ) and increased the loss of fat-free body mass by 60 percent (1.5 versus 2.4 kg;  $P=0.002$ ). This was accompanied by markers of enhanced neuroendocrine adaptation to caloric restriction, increased hunger, and a shift in relative substrate utilization toward oxidation of less fat. *Limitations:* The nature of the study limited its duration and sample size. *Conclusion:* The amount of human sleep contributes to the maintenance of fat-free body mass at times of decreased energy intake. Lack of sufficient sleep may compromise the efficacy of typical dietary interventions for weight loss and related metabolic risk reduction.

Volume, 153, Number 10  
November 16, 2010

### **Informing the Debate: Rates of Kidney Transplantation in Nations with Presumed Consent**

*L. D. Horvat et al.*

*Background:* The kidney is the most common transplanted organ, accounting for almost all living donor transplantations and most deceased donor organ transplantations. The organ shortage has caused policy makers in many nations to debate the merits of adopting presumed consent legislation as a way to increase donor organ donation from deceased donors. *Objective:* To compare characteristics and kidney transplantation rates for countries with presumed consent for deceased organ donation with countries with explicit consent. *Design:* A longitudinal study of international kidney transplantation from 1997 to 2007. *Setting:* Forty-four nations performing kidney transplantation. *Patients:* Recipients of deceased and living kidney donor transplants. *Measurements:* Rates of transplantation of kidneys from deceased and living donors. *Results:* National characteristics, such as population size, proportion of the population self-identified as Catholic, per capita gross domestic product, health expenditures, and physician density, varied widely for the twenty-two nations

with presumed consent and the twenty-two nations with explicit consent. Deceased donor kidney transplantation rates were higher in nations with presumed consent (median, 22.6 transplantations per million population [pmp]; interquartile range [IQR], 9.3 to 33.8) versus nations with explicit consent (median, 13.9 transplantations pmp; IQR, 3.6 to 23.1). Living donor kidney transplantation rates were lower in nations with presumed consent (median, 2.4 transplantations pmp; IQR, 1.7 to 4.3) versus nations with explicit consent (median, 5.9 transplantations pmp; IQR, 2.3 to 12.2). The findings were consistent when nations were classified according to per capita gross domestic product, health expenditures, and physician density. *Limitation:* As with any observational study, associations may not be causal. *Conclusion:* Nations with presumed consent have higher rates of deceased donor kidney transplantation than nations with explicit consent. Any nation deciding to adopt presumed consent should carefully consider and reduce any negative effect on rates of living donation.

of medical mistakes in the ambulatory care setting, including (1) overall experience with a medical mistake; type of mistake, such as a (2) diagnostic mistake or (3) treatment mistake, and its associated harm; and (4) effect of this mistake on changing physicians. *Results:* Of 1,697 participants, 265 (15.6 percent) responded that a physician had made a mistake, 227 (13.4 percent) reported a wrong diagnosis, 212 (12.5 percent) reported a wrong treatment, and 239 (14.1 percent) reported having changed physicians because of a mistake. Participants perceived mistakes and harm in both diagnostic care and medical treatment. Patients with chronic back pain, higher educational attainment, and poor physical health were at increased odds of perceiving mistakes, whereas African American patients were less likely to perceive mistakes. *Conclusions:* Patients perceived mistakes in their diagnostic and treatment care in the ambulatory setting. These perceptions had a concrete effect on the physician-patient relationship, often leading patients to seek another health care professional

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### Archives of Internal Medicine

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Volume 170, Number 16  
September 13, 2010

#### Patient Perceptions of Mistakes in Ambulatory Care

*C. E. Kistler et al.*

*Background:* Little information exists about current patient perceptions of medical mistakes in ambulatory care within a diverse population. The authors aimed to learn about the perceptions of medical mistakes, what factors were associated with perceived mistakes, and whether the participants changed physicians because of these perceived mistakes. *Methods:* The authors conducted a cross-sectional survey at seven primary care practices in North Carolina of English- or Spanish-speaking adults, aged eighteen years and older, who saw a health care professional during 2008. Main outcome measures were four questions about patient perceptions

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### British Medical Journal

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Volume 341, Number e2501  
September 30, 2010

#### The Effect of a Multifaceted Empowerment Strategy on Decision Making about the Number of Embryos Transferred in In Vitro Fertilisation: Randomised Controlled Trial

*A. van Peperstraten et al.*

*Objectives:* To evaluate the effects of a multifaceted empowerment strategy on the actual use of single embryo transfer after in vitro fertilization. *Design:* Randomized controlled trial. *Setting:* Five in vitro fertilization clinics in the Netherlands. *Participants:* Three hundred and eight couples (women aged over forty) on the waiting list for a first in vitro fertilization cycle. *Interventions:* The multifaceted strategy aimed to empower couples in deciding how many embryos should be transferred. The strategy consisted

of a decision aid, support of a nurse specializing in in vitro fertilization, and the offer of reimbursement by way of an extra treatment cycle. The control group received standard care for in vitro fertilization. *Main Outcome Measures:* Use of single embryo transfer in the first and second treatment cycles as well as decision making variables and costs of the empowerment strategy. *Results:* After the first treatment cycle, single embryo transfer was used by 43 percent (65 of 152) of couples in the intervention group and 32 percent (50 of 156) in the control group (difference 11 percent, 95 percent confidence interval 0 to 22 percent;  $P=0.05$ ). After the second treatment cycle, single embryo transfer was used by 26 percent (14 of 154) of couples in the intervention group compared with 16 percent (8 of 51) in the control group (difference 10 percent, -6 to 26 percent;  $P=0.20$ ). Compared with couples receiving standard care, those receiving the empowerment strategy had significantly higher empowerment and knowledge levels but no differences in anxiety levels. Mean total savings per couple in the intervention group were calculated to be €169.75 (£146.77; \$219.12). *Conclusions:* A multifaceted empowerment strategy encouraged use of single embryo transfer, increased patients' knowledge, reduced costs, and had no effect on levels of anxiety or depression. This strategy could therefore be an important tool to reduce the twin pregnancy rate after in vitro fertilization. This trial did not, however, demonstrate the anticipated 25 percent difference in use of single embryo transfer of the power calculation.

Volume 341, Number c5174  
October 5, 2010

**Reporting of Euthanasia in  
Medical Practice in Flanders, Belgium:  
Cross Sectional Analysis of  
Reported and Unreported Cases**

*T. Smets et al.*

*Objectives:* To estimate the rate of reporting of euthanasia cases to the Federal Control and Evaluation Committee and to compare the characteristics of reported and unreported cases of euthanasia. *Design:*

Cross sectional analysis. *Setting:* Flanders, Belgium. *Participants:* A stratified at random sample was drawn of people who died between June 1, 2007, and November 30, 2007. The certifying physician of each death was sent a questionnaire on end-of-life decision making in the death concerned. *Main Outcome Measures:* The rate of euthanasia cases reported to the Federal Control and Evaluation Committee; physicians' reasons for not reporting cases of euthanasia; the relation between reporting and non-reporting and the characteristics of the physician and patient; the time by which life was shortened according to the physician; the labeling of the end of life decision by the physician involved; and differences in characteristics of due care between reported and unreported euthanasia cases. *Results:* The survey response rate was 58.4 percent (3,623 of 6,202 eligible cases). The estimated total number of cases of euthanasia in Flanders in 2007 was 1,040 (95 percent confidence interval [CI], 970 to 1109); thus the incidence of euthanasia was estimated as 1.9 percent of all deaths (95 percent CI, 1.6 to 2.3 percent). Approximately half (549 of 1040; 52.8 percent; 95 percent CI, 43.9 to 60.5 percent) of all estimated cases of euthanasia were reported to the Federal Control and Evaluation Committee. Physicians who perceived their case as euthanasia reported it in 93.1 percent of cases (67 of 72). Cases of euthanasia were reported less often when the time by which life was shortened was less than one week compared with when the perceived life shortening was greater (37.3 versus 74.1 percent;  $P<0.001$ ). Unreported cases were generally dealt with less carefully than reported cases: a written request for euthanasia was more often absent (87.7 versus 17.6 percent verbal request only;  $P<0.001$ ), other physicians and caregivers specialized in palliative care were consulted less often (54.6 versus 97.5 percent; 33.0 versus 63.9 percent;  $P<0.001$  for both), the life-ending act was more often performed with opioids or sedatives (92.1 versus 4.4 percent;  $P<0.001$ ), and the drugs were more often administered by a nurse (41.3 versus 0.0 percent;  $P<0.001$ ). *Conclusion:* One of two euthanasia cases is

reported to the Federal Control and Evaluation Committee. Most non-reporting physicians do not perceive their act as euthanasia. Countries debating legalization of euthanasia should simultaneously consider developing a policy facilitating the due care and reporting obligations of physicians.

Volume 341, Number c5812  
November 11, 2010

**Association of Suicide Attempts with Acne and Treatment with Isotretinoin: Retrospective Swedish Cohort Study**

*A. Sundstrom et al.*

*Objective:* To assess the risk of attempted suicide before, during, and after treatment with isotretinoin for severe acne. *Design:* Retrospective cohort study linking a named patient register of isotretinoin users (1980 to 1989) to hospital discharge and cause of death registers (1980 to 2001). *Setting:* Sweden, 1980 to 2001. Population 5,756 patients aged fifteen to forty-nine years prescribed isotretinoin for severe acne observed for 17,197 person years before; 2,905 person years during; and 87,120 person years after treatment. *Main Outcome Measures:* Standardized incidence ratio (observed number divided by expected number of suicide attempts standardized by sex, age, and calendar year), calculated up to three years before, during, and up to fifteen years after end of treatment. *Results:* One hundred twenty-eight patients were admitted to hospital for attempted suicide. During the year before treatment, the standardized incidence ratio for attempted suicide was raised: 1.57 (95 percent confidence interval [CI], 0.86 to 2.63) for all (including repeat) attempts and 1.36 (0.65 to 2.50) counting only first attempts. The standardized incidence ratio during and up to six months after treatment was 1.78 (1.04 to 2.85) for all attempts and 1.93 (1.08 to 3.18) for first attempts. Three years after treatment stopped, the observed number of attempts was close to the expected number and remained so during the fifteen years of follow-up: standardized incidence ratio 1.04 (0.74 to 1.43) for all attempts and 0.97 (0.64 to

1.40) for first attempts. Twelve (38 percent) of thirty-two patients who made their first suicide attempt before treatment made a new attempt or committed suicide thereafter. In contrast, 10 (71 percent) of the fourteen who made their first suicide attempt within six months after treatment stopped made a new attempt or committed suicide during follow-up (two sample test of proportions,  $P=0.034$ ). The number needed to harm was 2,300 new six month treatments per year for one additional first suicide attempt to occur and 5,000 per year for one additional repeat attempt. *Conclusions:* An increased risk of attempted suicide was apparent up to six months after the end of treatment with isotretinoin, which motivates a close monitoring of patients for suicidal behavior for up to a year after treatment has ended. However, the risk of attempted suicide was already rising before treatment, so an additional risk due to the isotretinoin treatment cannot be established. As patients with a history of suicide attempts before treatment made new attempts to a lesser extent than did patients who started such behavior in connection with treatment, patients with severe acne should not automatically have isotretinoin treatment withheld because of a history of attempted suicide.

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**Journal of the American Medical Association**

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Volume 304, Number 11  
September 15, 2010

**Effect of Reminders of Personal Sacrifice and Suggested Rationalizations on Residents' Self-Reported Willingness to Accept Gifts: A Randomized Trial**

*S. Sah and G. Loewenstein*

*Context:* Despite expanding research on the prevalence and consequences of conflicts of interest in medicine, little attention has been given to the psychological processes

that enable physicians to rationalize the acceptance of gifts. *Objectives:* To determine whether reminding resident physicians of the sacrifices made to obtain training, as well as suggesting this as a potential rationalization, increases self-stated willingness to accept gifts from industry. *Design, Settings, and Participants:* Three hundred and one U.S. resident physicians from two sample populations (pediatrics and family medicine) who were recruited between March and July 2009 participated in a survey presented as evaluating quality of life and values. *Intervention:* Physicians were randomly assigned to receive one of three different online surveys. The sacrifice reminders survey (n=120) asked questions about sacrifices made in medical training, followed by questions regarding the acceptability of receiving gifts from industry. The suggested rationalization survey (n=121) presented the same sacrifice questions, followed by a suggested possible rationalization (based on sacrifices made in medical training) for acceptance of gifts, before the questions regarding the acceptability of gifts. The control survey (n=60) asked about the acceptability of gifts before asking questions about sacrifices or suggesting a rationalization. *Main Outcome Measures:* Physician self-stated acceptability of receiving gifts from industry. *Results:* Reminding physicians of sacrifices made in obtaining their education resulted in gifts being evaluated as more acceptable: 21.7 percent (13 of 60) in the control group versus 47.5 percent (57 of 120) in the sacrifice reminders group (odds ratio, 1.81; 95 percent confidence interval [CI], 1.27 to 2.58; P=0.001). Although most residents disagreed with the suggested rationalization, exposure to it further increased the perceived acceptability of gifts to 60.3 percent (73 of 121) in that group (odds ratio relative to sacrifice reminders group, 1.45; 95 percent CI, 1.22 to 1.72; P<0.001). *Conclusions:* Providing resident physicians with reminders of sacrifices increased the perceived acceptability of industry-sponsored gifts. Including a rationalization statement further increased gift acceptability.

Volume 304, Number 19  
November 17, 2010

### **Automated External Defibrillators and Survival after In-Hospital Cardiac Arrest**

*P. S. Chan et al.*

*Context:* Automated external defibrillators (AEDs) improve survival from out-of-hospital cardiac arrests, but data on their effectiveness in hospitalized patients are limited. *Objective:* To evaluate the association between AED use and survival for in-hospital cardiac arrest. *Design, Setting, and Patients:* Cohort study of 11,695 hospitalized patients with cardiac arrests between January 1, 2000, and August 26, 2008, at 204 U.S. hospitals following the introduction of AEDs on general hospital wards. *Main Outcome Measure:* Survival to hospital discharge by AED use, using multivariable hierarchical regression analyses to adjust for patient factors and hospital site. *Results:* Of 11,695 patients, 9,616 (82.2 percent) had non-shockable rhythms (asystole and pulseless electrical activity) and 2079 (17.8 percent) had shockable rhythms (ventricular fibrillation and pulseless ventricular tachycardia). AEDs were used in 4,515 patients (38.6 percent). Overall, 2,117 patients (18.1 percent) survived to hospital discharge. Within the entire study population, AED use was associated with a lower rate of survival after in-hospital cardiac arrest compared with no AED use (16.3 versus 19.3 percent; adjusted rate ratio, 0.85; 95 percent confidence interval [CI], 0.78 to 0.92; P<0.001). Among cardiac arrests due to nonshockable rhythms, AED use was associated with lower survival (10.4 versus 15.4 percent; adjusted rate ratio, 0.74; 95 percent CI, 0.65 to 0.83; P<0.001). In contrast, for cardiac arrests due to shockable rhythms, AED use was not associated with survival (38.4 versus 39.8 percent; adjusted rate ratio, 1.00; 95 percent CI, 0.88 to 1.13; P=0.99). These patterns were consistently observed in both monitored and non-monitored hospital units where AEDs were used, after matching patients to the individual units in each hospital where the cardiac ar-

rest occurred and with a propensity score analysis. *Conclusion:* Among hospitalized patients with cardiac arrest, use of AEDs was not associated with improved survival.

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## Journal of General Internal Medicine

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Volume 25, Number 9  
September 2010

### Leaving against Medical Advice (AMA): Risk of 30-day Mortality and Hospital Readmission

*J.M. Glasgow,  
M. Vaughn-Sarrazin, and P.J. Kaboli*

*Background:* With 1 to 2 percent of patients leaving the hospital against medical advice (AMA), the potential for these patients to suffer adverse health outcomes is of major concern. *Objective:* To examine thirty-day hospital readmission and mortality rates for medical patients who left the hospital AMA and identify independent risk factors associated with these outcomes. *Design:* A five-year retrospective cohort of all patients discharged from a Veterans Administration hospital. *Subjects:* The final study sample included 1,930,947 medical admissions to 129 Veterans Administration hospitals from 2004 to 2008; 32,819 patients (1.70 percent) were discharged AMA. *Measurements:* Primary outcomes of interest were thirty-day mortality and thirty-day all-cause hospital readmission. *Results:* Compared to discharges home, AMA patients were more likely to be black, have low income, and have co-morbid alcohol abuse (for all,  $\chi^2$   $df=1$ ,  $p<0.001$ ). AMA patients had a higher thirty-day readmission rate (17.7 percent versus 11.0 percent,  $p<0.001$ ) and higher thirty-day mortality rate (0.75 percent versus 0.61 percent,  $p=0.001$ ). In Cox proportional hazard modeling controlling for demographics and comorbidity, the largest hazard for patients having a thirty-day readmission is leaving AMA (HR=1.35, 95 percent CI, 1.32 to 1.39). Similar modeling for thirty-day mortality reveals a nearly significant increased hazard

rate for patients discharged AMA (HR=1.10, 95 percent CI, 0.98 to 1.24). *Conclusions:* Due to the higher risk of adverse outcomes, hospitals should target AMA patients for post-discharge interventions, such as phone follow-up, home visits, or mental health counseling to improve outcomes.

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## Journal of Health Economics

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Published online  
December 23, 2010

### The Impact of Emergency Birth Control on Teen Pregnancy and STIs

*S. Girma and D. Paton*

*Abstract* We use panel data from local authorities in England between 1998 and 2004 to examine the differential impact of increased access for teenagers to emergency birth control (EBC) at pharmacies on teenage pregnancies and sexually transmitted infections (STIs). We estimate both difference-in-difference (DD) and the more robust difference-in-difference-in-differences (DDD) models. The DD estimates provide some evidence that pharmacy EBC schemes are associated with higher teenage conception rates, but this result is not upheld in the DDD models. In contrast both the DD and DDD models provide consistent evidence that pharmacy EBC schemes are associated with higher teenage STI rates.

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## Mayo Clinic Proceedings

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Volume 85, Number 9  
September 2010

### Ethical Analysis of Withdrawing Ventricular Assist Device Support

*P.S. Mueller et al.*

*Objective:* To describe a series of patients with heart failure supported with a ventricular assist device (VAD) who requested (or whose surrogates requested) withdrawal of

VAD support and the legal and ethical aspects pertaining to these requests. *Patients and Methods:* The authors retrospectively reviewed the medical records of patients at the Mayo Clinic in Rochester, Minnesota, from March 1, 2003, through January 31, 2009, who requested (or whose surrogates requested) withdrawal of VAD support and for whom the requests were fulfilled. The authors then explored the legal and ethical permissibility of carrying out such requests. *Results:* The median age of the fourteen patients identified (thirteen men, one woman) was fifty-seven years. Requests were made by two patients and twelve surrogates. None of the patients' available advance directives mentioned the VAD. For eleven patients, multidisciplinary care conferences were held before withdrawal of VAD support. Only one patient had an ethics consultation. All fourteen patients died within one day of withdrawal of VAD support. *Conclusion:* Patients have the right to refuse or request the withdrawal of any unwanted treatment, and the authors argue that this right extends to VAD support. The authors also argue that the cause of death in these cases is the underlying heart disease, not assisted suicide or euthanasia. Therefore, patients with heart failure supported with VADs or their surrogates may request withdrawal of this treatment. In the authors' view, carrying out such requests is permissible in accordance with the principles that apply to withdrawing other life-sustaining treatments.

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**New England  
Journal of Medicine**

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Volume 363, Number 8  
August 19, 2010

**Early Palliative Care for  
Patients with Metastatic  
Non-small-cell Lung Cancer**

*J.S. Temel et al.*

*Background:* Patients with metastatic non-small-cell lung cancer have a substantial symptom burden and may receive aggressive

care at the end of life. The authors examined the effect of introducing palliative care early after diagnosis on patient-reported outcomes and end-of-life care among ambulatory patients with newly diagnosed disease. *Methods:* The authors randomly assigned patients with newly diagnosed metastatic non-small-cell lung cancer to receive either early palliative care integrated with standard oncologic care or standard oncologic care alone. Quality of life and mood were assessed at baseline and at twelve weeks with the use of the Functional Assessment of Cancer Therapy-Lung (FACT-L) scale and the Hospital Anxiety and Depression Scale, respectively. The primary outcome was the change in the quality of life at twelve weeks. Data on end-of-life care were collected from electronic medical records. *Results:* Of the 151 patients who underwent randomization, twenty-seven died by twelve weeks and 107 (86 percent of the remaining patients) completed assessments. Patients assigned to early palliative care had a better quality of life than did patients assigned to standard care (mean score on the FACT-L scale [in which scores range from 0 to 136, with higher scores indicating better quality of life], 98.0 versus 91.5;  $P=0.03$ ). In addition, fewer patients in the palliative care group than in the standard care group had depressive symptoms (16 percent versus 38 percent,  $P=0.01$ ). Despite the fact that fewer patients in the early palliative care group than in the standard care group received aggressive end-of-life care (33 percent versus 54 percent,  $P=0.05$ ), median survival was longer among patients receiving early palliative care (11.6 months versus 8.9 months,  $P=0.02$ ). *Conclusions:* Among patients with metastatic non-small-cell lung cancer, early palliative care led to significant improvements in both quality of life and mood. As compared with patients receiving standard care, patients receiving early palliative care had less aggressive care at the end of life but longer survival. (Funded by an American Society of Clinical Oncology Career Development Award and philanthropic gifts; ClinicalTrials.gov number, NCT01038271.)

Volume 363, Number 22  
November 25, 2010

### Temporal Trends in Rates of Patient Harm Resulting from Medical Care

C. P. Landrigan *et al.*

*Background:* In the ten years since publication of the Institute of Medicine's report *To Err Is Human*, extensive efforts have been undertaken to improve patient safety. The success of these efforts remains unclear. *Methods:* The authors conducted a retrospective study of a stratified random sample of ten hospitals in North Carolina. A total of one hundred admissions per quarter from January 2002 through December 2007 were reviewed in random order by teams of nurse reviewers both within the hospitals (internal reviewers) and outside the hospitals (external reviewers) with the use of the Institute for Healthcare Improvement's Global Trigger Tool for Measuring Adverse Events. Suspected harms that were identified on initial review were evaluated by two independent physician reviewers. The authors evaluated changes in the rates of harm, using a random-effects Poisson regression model with adjustment for hospital-level clustering, demographic characteristics of patients, hospital service, and high-risk conditions. *Results:* Among 2,341 admissions, internal reviewers identified 588 harms (25.1 harms per 100 admissions; 95 percent confidence interval [CI], 23.1 to 27.2). Multivariate analyses of harms identified by internal reviewers showed no significant changes in the overall rate of harms per one thousand patient-days (reduction factor, 0.99 per year; 95 percent CI, 0.94 to 1.04;  $P=0.61$ ) or the rate of preventable harms. There was a reduction in preventable harms identified by external reviewers that did not reach statistical significance (reduction factor, 0.92; 95 percent CI, 0.85 to 1.00;  $P=0.06$ ), with no significant change in the overall rate of harms (reduction factor, 0.98; 95 percent CI, 0.93 to 1.04;  $P=0.47$ ). *Conclusions:* In a study of ten North Carolina hospitals, the authors found that harms remain common, with little evidence of widespread improvement. Further efforts are needed to translate effective safety interventions into

routine practice and to monitor health care safety over time.

Volume 363, Number 23  
December 2, 2010

### Body-Mass Index and Mortality among 1.46 Million White Adults

A. Berrington de Gonzalez *et al.*

*Background:* A high body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) is associated with increased mortality from cardiovascular disease and certain cancers, but the precise relationship between BMI and all-cause mortality remains uncertain. *Methods:* The authors used Cox regression to estimate hazard ratios and 95 percent confidence intervals (95% CIs) for an association between BMI and all-cause mortality, adjusting for age, study, physical activity, alcohol consumption, education, and marital status in pooled data from nineteen prospective studies encompassing 1.46 million white adults, nineteen to eighty-four years of age (median, fifty-eight). *Results:* The median baseline BMI was 26.2. During a median follow-up period of ten years (range, five to twenty-eight), 160,087 deaths were identified. Among healthy participants who never smoked, there was a J-shaped relationship between BMI and all-cause mortality. With a BMI of 22.5 to 24.9 as the reference category, hazard ratios among women were 1.47 (95 percent CI, 1.33 to 1.62) for a BMI of 15.0 to 18.4; 1.14 (95 percent CI, 1.07 to 1.22) for a BMI of 18.5 to 19.9; 1.00 (95 percent CI, 0.96 to 1.04) for a BMI of 20.0 to 22.4; 1.13 (95 percent CI, 1.09 to 1.17) for a BMI of 25.0 to 29.9; 1.44 (95 percent CI, 1.38 to 1.50) for a BMI of 30.0 to 34.9; 1.88 (95 percent CI, 1.77 to 2.00) for a BMI of 35.0 to 39.9; and 2.51 (95 percent CI, 2.30 to 2.73) for a BMI of 40.0 to 49.9. In general, the hazard ratios for the men were similar. Hazard ratios for a BMI below 20.0 were attenuated with longer-term follow-up. *Conclusions:* In white adults, overweight and obesity (and possibly underweight) are associated with increased all-cause mortality. All-cause mortality is generally lowest with a BMI of 20.0 to 24.9.