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An international honor, the Children’s Miracle Achievement Award, was bestowed this year on only one physician — Dr. Robert Gustafson, West Virginia’s esteemed pediatric heart surgeon. The award, presented by the Children’s Miracle Network, honors Dr. Gustafson for a career of achievement and service as the state’s only provider of heart surgery for children. Gustafson and an outstanding group of pediatric cardiologists have created a pediatric heart program at WVU Children’s Hospital whose excellence is recognized throughout the country. “He is a visionary whose leadership has had a positive impact on the state, national, and international levels,” noted the nomination for the award.

Gustafson, a native of Keyser, W.Va., joined WVU in 1984. He has provided surgical care to more than 4,000 young patients. “Helping children with heart problems is a way to leave a legacy for the future,” Gustafson says. “Helping these children thrive is the best gift I can give.”
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WHITE COAT DAY
Annual Business Meeting & Practice Management Conference
January 21-22
see pgs. 10 & 11

The West Virginia Medical Journal is the winner of the 2010 Association TRENDS™ All-Media Contest Gold prize in its category for Scholarly/Technical/Scientific Journals!
President’s Message

Stop the Presses!

Just as Angie was finalizing this issue of the Journal, a federal district judge in Virginia issued a ruling finding the individual mandate requirement under federal health care reform unconstitutional. This decision comes on the heels of two prior federal court rulings that upheld key provisions of the reform package, including the individual mandate. Court watchers and legal experts now say it is all but certain the United States Supreme Court will be forced, sooner rather than later, to resolve the constitutionality question of this and possibly other key provisions of the new federal health care law. ‘Sooner’ under even the most expeditious scenario, however, will likely be one to two years before our nation’s highest court issues its final ruling.

I cannot recall a time in all my years as a practicing physician of the level of uncertainty we physicians have faced on so many fronts. Thanks to a ninth… and tenth reprieve in the last eight years by congress, the specter of a twenty-five percent cut in Medicare reimbursement under the seriously flawed SGR formula was put off for another year. There has not been a December in the last eight years that physicians, faced with the possibility of a looming reimbursement cut, were forced to consider whether or not they would be able to continue to care for Medicare patients.

Possibly the most immediate concern for every West Virginia physician is the challenge to West Virginia’s cap on non-economic damages, the cornerstone provision of our hard fought medical liability reform. Despite the fact that the state supreme court has upheld previously (1991 and 2001) that the state legislature was within its constitutional authority to place a cap on non-economic damages, the Court has again accepted a case (MacDonald v. City Hospital) that puts our cap squarely in jeopardy.

Physicians remember all too well the access to care crisis our West Virginia patients faced a decade ago when many physicians were forced out of practice or out of state because of our broken medical liability system. The improved practice environment the medical liability reforms have brought are now at risk. National actuarial experts calculated that the anticipated increase in medical liability insurance premiums will be eighteen percent—thanks to a ruling in Illinois striking down that state’s non-economic damages cap. Higher insurance premiums, lower reimbursement, just more uncertainty for West Virginia physicians.

West Virginia physicians can have confidence in the advocacy efforts the West Virginia State Medical Association is making on their behalf. In my first few months as your president, I have visited a number of component societies around the state, participated in medical society meetings in our neighboring states and attended the Interim AMA meeting where the groundwork was laid for a strong push in 2011 for congressional action on legislation to allow physicians to directly contract with Medicare patients and not be hamstrung by the onerous ‘take it or leave it’ CMS provider participation requirements.

We have also been outspoken in the press and on public affairs programs about the importance of preserving our medical liability reform. We worked with a broad coalition of advocacy groups from the medical, business and insurance communities to submit Amicus briefs outlining our most persuasive legal and policy arguments to the state supreme court on why preserving the cap on non-economic damages is critical.

We pushed, prodded (and candidly, demanded) our congressional delegation for a permanent repeal to the SGR and coordinated a media outreach with AARP calling on congress to preserve access to care for the over 371,000 West Virginia seniors and our service men and women and their families who receive their health coverage under Tri-Care.

Our government relations committee is finalizing a pro-active agenda for the upcoming legislative session that begins January 12. The committee is making recommendations on several new items that will help improve the practice environment for all West Virginia physicians, including a measure to prohibit health insurance companies from creating silent PPO’s. Notably absent from this year’s agenda is our need to fight for the further phase out of the onerous provider tax. Every West Virginia physician has shared in our successful lobbying effort to repeal the provider tax. In case you missed it, as of July 1, 2010, the provider tax on physicians exists no longer thanks to the efforts of your WVSMA.

Yes, physicians are faced with many uncertainties but rest assured your professional society is fighting every day on your behalf. Now is not the time to be discouraged—rather let us unite in our efforts to preserve and protect the practice of medicine for the future of our beloved profession and our patients.

John H. Schmidt III, MD
WVSMA President
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I first encountered David Zaquill Morgan on a very foggy morning in late August of 1968. It was the first day and orientation for the 62 men and 6 women of the WVU medical school class of 1972. It was so foggy that one of my classmates became disoriented and instead of walking up the Med Center hill, found himself at the top of what is now the law school hill. He joined the rest of us in the pathology amphitheater about two hours later. Dr. Morgan was the master of ceremonies for the orientation and very adroitly set us all at ease. We quickly realized he was our advocate.

About six weeks later we had our first big exam in histology and about eighty percent of us failed. Most of the rest received a D, though there may have been one or two C's, but none better. I suspect that this was the first time many of us had tasted failure of any kind. Being students of the 60’s we did the obvious thing and staged a sit in outside of Dr. Morgan’s office door. Isabel Price (DZ’s long standing secretary who I believe knew the name and location of every 4-year school graduate and thought of us all as her personal charges) came out into the hall and assessed the situation. She quickly slipped back in her office and in short order DZ came out to talk with us. He patiently listened to our grievances, calmed us and assured us that this was a mere bump in the road – as indeed it was.

As we moved on through our clinical years we came to know him as a skilled and gifted teacher of the history and physical. He always had great empathy for his patients and communicated well with them.

I stayed at WVU for four years of residency followed by four years of faculty time. During those years I came to know DZ as a friend and colleague. Serving on committees together, I came to admire and respect his skill as an administrator.

A few years later I came to know DZ Morgan, political activist. In the fall of 1984, Harry Weeks, founder of WVMI, Steve Ward, my predecessor as Editor, DZ as WVSMA President, and I, a political neophyte, made congressional visits to Washington. It was quite an education for me to watch these skilled communicators in action advocating for physicians and their patients.

DZ did such a good job with the state legislature during the 1985 session that WVSMA asked him to come back as a lobbyist for the 1986 session. The 1986 session was very important as we were experiencing the first liability crisis of my career. WVU allowed DZ a leave of absence. He spent every day of that session walking the marble halls. He knew every legislator and they knew him. Our bill passed at the eleventh hour. Without DZ, it never would have happened.

For about the last 15 years, I have had the opportunity to know DZ as a member of the editorial staff of this Journal. His knowledge, critical eye and attention to detail made him a great editor. He reviewed more than his share of articles. His turnaround time was always quick and he was always available.

He was a great mentor, colleague, and friend and we will all miss him greatly.

F. Thomas Sporck, MD
Editor
How Many Deaths Due to Medical Errors? Maybe We Should Have a Recount

by Susan Baek, JD

In the September/October 2010 issue of the *West Virginia Medical Journal*, WVMSA President John Schmidt III, MD mentions the Institute of Medicine (IOM) report on the prevalence of medical errors in the United States, which has been used to demonstrate safety problems in our healthcare system. Dr. Schmidt notes that the data is incomplete because it fails to compare the safety of care in other countries. I would agree and add that the data in the IOM report is not only incomplete but potentially flawed. Further, some data from the studies the IOM used actually support the need for tort reform.

The 1999 IOM report, *To Err is Human: Building a Safer Health System*, reported that an estimated 44,000 to 98,000 deaths occur in this country each year as a result of medical errors. This data has been repeated in many publications and widely used to argue against tort reform, but its validity is not irrefutable. A closer look at the origins of the data reveals some significant problems.

*First, the data is old and inconclusive.* The IOM published its report in 1999, but the data dates back much further. The upper estimate of 98,000 was based on data from a random sample of just over 30,000 hospital records from 1984 in New York State, and the lower estimate was based on data from 15,000 hospital records from 1992 in Utah and Colorado. In both studies researchers determined the average number of adverse events (3.7 percent of hospitalizations in New York; 2.9 percent in Colorado/Utah) and the percentage of those adverse events that led to death (13.6 percent and 6.6 percent, respectively). They also calculated the percentage of adverse events caused by medical error (58 to 68 percent), and the percentage attributable to negligence (about 27 percent of adverse events in New York and Colorado; 32.6 percent in Utah).

The IOM figures represent an extrapolation of the data from the two studies to the 33.6 million admissions to U.S. hospitals in 1997. Note that the IOM report used medical error, not negligence, and the two are not interchangeable. Medical error is very broad. The IOM report explains, "Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Among the problems that commonly occur during the course of providing health care are adverse drug events and improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities."

Although the IOM classifies medical errors as preventable, not all medical errors represent a deviation from the standard of care, or negligence. For example, drug complications comprise the most common type of adverse event in both studies (about 20 percent), but drug complications only result from negligence if the patient has a known sensitivity to the drug. As noted above, less than half of the "medical errors" in the studies were actually attributable to negligence. If the IOM had extrapolated only the data on negligence, it would have reported 17,400 to 45,600 deaths per year. This number would be more meaningful since it would ostensibly represent errors that medical professionals could prevent by adhering to appropriate standards of care.

Even then, the extrapolation is suspect. The data relies on studies from two distinct and very different areas of the country, which may or may not be representative of the whole country, and were collected nearly a decade apart, a few decades ago. Even the more recent data is nearly 20 years old. Consider the advances in medicine since then. Further, there was a huge amount of variability among the hospitals within the studies. In New York, for example, adverse event rates among hospitals ranged from 0.2 to 7.9 percent, and those associated with negligence ranged from 1 to 60 percent. Taking this variability into account, that means that the average number of negligent hospital deaths per year in the United States could range anywhere from 91 to 216,599, a range far too wide to be meaningful.

*Second, the reliability of the research methods is debatable.* The IOM report applied data that had been based on retrospective reviews of medical records. The reviews were subjective, and the reviewers disagreed frequently. In the New York study, for example, the kappa statistic for judgments about the presence of adverse events was 0.61, and for judgments of negligence was only 0.24, although the agreement as to incidence of negligence was 93 percent. That is, different researchers did not find negligence in the same cases but estimated a similar overall

Continued on page 8
amount of negligence. In a separate study assessing the reliability of reviewer ratings of medical error, researchers found that even though their reviewers had a higher kappa statistic of 0.34, “If one reviewer rated a death as definitely or probably preventable, the probability that the next reviewer would rate that case as definitely not preventable (18 percent) was actually slightly higher than the probability that the second reviewer would agree with the first (16 percent). (The probability that the next reviewer would rate the death as possibly preventable was 18 percent.)”10 In other words, the reviewers were more likely to disagree than to agree.

Retrospective reviews also have questionable validity since they require judgments as to the cause of events based on limited information. For example, the New York study’s authors classified errors of omission as negligence, although they admitted they had no way of knowing whether patients or their families had requested limited care. Additionally, if a patient suffered an adverse event and then died, the researchers classified it as an adverse event leading to death, even though some terminal patients suffered an adverse event shortly before their imminent death. The methodology did not control for requested omissions or imminent deaths, and the researchers noted that adverse events occurred more often in elderly patients, so these issues may have significantly skewed the results.4

Third, the researchers could have drawn very different conclusions from the very same data. The New York researchers produced some interesting data on malpractice claims. They observed that 1.5 percent of patients who suffered negligence filed claims (a “weighted” calculation: 8 of 280 is actually 2.9 percent). They wrote, “Medical-malpractice litigation infrequently compensates patients injured by medical negligence and rarely identifies, and holds providers accountable for, substandard care.” 11

The researchers did not mention the other possible explanation for this seemingly low rate of claims: maybe the study over-identified negligence. The researchers also did not mention other, maybe even more obvious, conclusions from their data, such as that 43 of 51 (a whopping 84 percent, non-weighted) of the claims were apparently meritless. The researchers therefore could have concluded that medical-malpractice litigation frequently targets blameless health care providers, a finding that would argue for reforms to limit meritless claims. Furthermore, since the researchers observed that elderly patients in the study may have suffered more adverse events due to the likelihood that they had more complicated and serious procedures, this begs the questions of why elderly patients are subject to potentially dangerous interventions, especially at the end of their lives. The Colorado/Utah researchers set out to verify the New York findings, according to the background section of their report, and they replicated the methodology of the earlier study. They found, as noted above, a significantly lower percentage of adverse events among the records they reviewed, as well as a much lower percentage of adverse events leading to death, as compared with the New York study. Yet they simply concluded that their study confirmed the earlier research and that iatrogenic injury was a serious ongoing problem.5

The IOM committee, on which sat Lucien Leape, a principal investigator of the New York study, could have considered the numerous criticisms of the studies and published a balanced report of the pros and cons and other implications of the data. Alternatively, it could have noted the apparent improvements in safety that occurred from 1984 to 1992; that is, apparently national deaths due to medical negligence decreased by more than 60 percent during the time period (see above, from 45,600 to 17,400). At the very least, the IOM could have reported the number of deaths they identified as due to negligence rather than reporting all deaths they attributed to the broad and ambiguous term, “medical error,” but of course that would have meant reporting far fewer deaths, thus leading to less sensational headlines.

The IOM data has been repeatedly extensivly; less commonly reported are the substantive criticisms of the data and methodology.10,12 Notably, even Troyen Brennan, MD, JD, the lead author of the New York study and a coauthor of the Colorado/Utah study, criticized the IOM report.13 Trial attorneys love the IOM report because it indicates that there is a lot of room for growth in their field, but I think a closer look at the data reveals a serious need for better research and more careful analysis.

References
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Registration begins Friday morning at the Embassy Suites hotel in downtown Charleston followed by a policy issues briefing. We then move to the Statehouse for visits with legislators to discuss the importance of maintaining our medical liability reform and the 2011 WVSMA legislative policy agenda. Join us at the Embassy Suites Friday afternoon for the popular West Virginia State Medical Association’s Practice Management Conference, Evening Reception, Risk Management Seminar, and Saturday’s WVSMA Annual Business Meeting.

**Friday** January 21

**White Coat Day Activities**
Embassy Suites Hotel/State Capitol

- 7:30 a.m. Registration - Embassy Suites
- 8:00 a.m. Program and Policy Issues Briefing - Embassy Suites
- 8:45 a.m. Travel to WV State Capitol
- 9:00 - 11:00 a.m. Meetings with Legislators - State Capitol
- 11:00 a.m. House/Senate Floor Session - State Capitol
- 12:00 - 1:15 p.m. Additional Meetings with Legislators/Lunch on Your Own (Capitol Cafeteria)

**Practice Management Conference**
Embassy Suites Hotel

- 1:30 - 4:00 p.m. Practice Management Conference
  Program includes a broad range of topics critical to help prepare physicians and their medical practice for the future. Emerging payment models, insurance payor updates, healthcare reform implementation, and the latest information on the movement toward ACO’s (Accountable Care Organizations) will all be discussed.

**Risk Management Program and WVSMA Leadership Dinner Meeting**
Embassy Suites Hotel

- 5:00 - 6:30 p.m. Reception & Risk Management Seminar
  Hosted by WV Mutual Insurance Co. (Risk Management Credit Eligible - 1% for WV Mutual Insureds)
- 7:00 p.m. WVSMA Executive Committee/Council Dinner Meeting

**Saturday** January 22

**WVSMA Annual Business Meeting**
Embassy Suites Hotel

- 8:00 a.m. WVSMA House of Delegates Delegate Registration
- 8:30 a.m. WVSMA House of Delegates Opening Session

- 10:00 a.m. Resolutions Committee Open/Closed Sessions

- 12:00 p.m. Lunch

- 1:30-2:00 p.m. 2011-2012 WVSMA Officer Elections

- 2:00 p.m. WVSMA House of Delegates Second Session
“There they go again” — hCG and Weight Loss

Roger C. Toffle, MD
Department of Obstetrics and Gynecology, WVU, Morgantown

Introduction
Late night infomercials and the internet “inform” the public that there are treatments and cures that “they don’t want you to know about”. Included in these treatments is the use of human chorionic gonadotropin for the treatment of obesity. The basis for this proposed therapy is a 1954 article by Simeons who introduced the concept of a combination of a strictly restricted diet plus the daily administration of low doses of human chorionic gonadotropin (hCG) for the treatment of obesity.1 The controversies and scant scientific literature did not dissuade its early use and led to a Guest Editorial in the American Journal of Clinical Nutrition by Margaret Albrink in 1969 in which she felt that the subject should be considered in three parts: 1) Whether this treatment helps to bring about acute weight loss; 2) The usefulness in long-range treatment of obesity; and 3) The possible mechanism of action of hCG in obesity.2 Well designed studies to answer these questions were encouraged.

Thirty years have passed since she raised these questions. It is the purpose of this commentary to readdress this subject by updating information on hCG and hormones of pregnancy that were not available at that time, as well as to summarize the results of the controlled studies that Dr. Albrink recommended.

Review of hCG and hormones of pregnancy
Human chorionic gonadotropin is a glycopeptide secreted by the placenta. The glycopeptides Follicle Stimulating Hormone (FSH), Thyroid Stimulating Hormone (TSH), and Luteinizing Hormone (LH) are dimers made up of two glycosylated polypeptide chains called the alpha and beta subunits. They all share an identical alpha chain, but differ in their beta chain with hCG and LH being most closely related.3 The trophoblast of the placenta secretes hCG in increasing levels during the first trimester of pregnancy which is essential for the early rescue and maintenance of the corpus luteum and for stimulation of the fetal testes to allow normal sexual development in the male fetus. Levels of hCG begin to decrease during the second trimester when the fetal pituitary assumes control of the fetal gonad.4 Placental extracts of human chorionic gonadotropin were first marketed in 1931, purified urinary extracts of hCG were marketed in 1940, and the successful use of recombinant hCG to achieve pregnancy was reported in 1997.5 The hCG utilized in the Simeons protocol is derived from the urine of pregnant women.

Simeons development of the use of hCG in the treatment of obesity was based on his observations of the use of hCG in treating males with Frölich’s Syndrome and his observations about fat metabolism during pregnancy.3,7,8 Frölich’s Syndrome is a condition in males who have tumors of the hypothalamus and pituitary, obesity, and hypogonadism. The administration of hCG in these patients appeared to diminish and change body fat distribution. A similar change can be observed in female to male transgender patients who are undergoing androgen therapy.9 This would suggest that the changes that he observed in these patients was most likely due to hCG stimulation of the LH receptor in the testes leading to increased testosterone production and not a direct effect of hCG on obesity or fat distribution. The changes in glucose and fat metabolism that he observed during pregnancy are now known to be due to human placental lactogen and placental growth hormone and not due to hCG.4 Thus, the impetus to utilize hCG for the treatment of obesity was based on erroneous interpretations of clinical observations due to a paucity of available endocrinologic information.

High levels of hCG in early pregnancy can interact with the TSH receptor leading to transient hyperthyroidism.6 The Simeons protocol for administration of hCG is 125 I.U. of hCG for 6 days of every week. Such doses would result in serum levels much lower than occur during pregnancy so stimulation of thyroid function would not appear to be an explanation for any observed weight loss. The doses of hCG utilized for treatment of male hypogonadotropic hypogonadism are much higher than are used in the weight loss protocol so it is unlikely that significant androgen production is occurring; but there is no literature that describes hormonal levels during the Simeons protocol. It should be noted that low dose hCG when used alone during the late follicular phase during controlled ovarian hyperstimulation has been shown to stimulate the growth of...
larger follicles while inhibiting the growth of smaller follicles, but it is unlikely that this is an explanation for hCG associated weight loss.10

Proponents of the Simeons protocol also state that the administration of hCG leads to a sense of well-being, less fatigue, less hunger, and are thus more likely to stick to a strictly restricted diet.17,8

**Review of literature on effect of hCG in the treatment of obesity**

The available literature in 1969 suggested that the addition of hCG had no additional benefit in terms of weight loss than the restrictive diet alone.2 Subsequent designed studies gave mixed results,11,12 with proponents for each side of the debate challenging the validity of each other’s studies. Only 4 studies were published between 1977 and 1995. A rigorous meta-analysis of the available literature as of 1995 found that only one of 12 reasonably well-designed controlled studies showed an increased weight loss with the addition of hCG versus placebo. In addition, the overall findings also failed to demonstrate fat redistribution, reduction in hunger, or an improvement in well-being.13

There do not appear to be any published studies since that time.

**Summary**

Dr. Albrink’s review of information available in 1969 did not allow her to determine a physiologic basis for the use of hCG or any proof of immediate or long term benefit. Subsequent discoveries and clinical studies only support her impressions. Despite these facts, this form of therapy has achieved a resurgence in popularity. The difference today is that patients no longer have to rely on health care providers to prescribe their medications since internet sites allow them to obtain medications “on line”. This has potential adverse ramifications when we consider that the initial use of gonadotropins derived from the human pituitary was discontinued due to the iatrogenic transmission of Creutzfeldt-Jakob disease.3 It is thought that the disease is transmitted by an abnormal protein called prion protein. Subclinical forms of the disease exist and the prions could potentially be transmitted in urine.14

No cases or transmission via urine have been reported and reputable sources of hCG would appear to be safe, but products from countries with greater risk have the potential for contamination.4,15 The increased demand for hCG from reputable sources has led to shortages and increased expense for the legitimate uses of hCG in treatment of endocrine disorders and infertility.

Obesity and the adverse impact on health has become a priority in public health policies for the state of West Virginia and for our nation as a whole. The benefit of longevity in the practice of medicine is that one is given the opportunity to observe attempts to “reinvent the wheel” where medical practices that have been previously disproven are reintroduced. Fineberg and Hiatt state this more eloquently when they said:

> “What is unacceptable is to persist in demonstrably ineffective practices either because we fail to collect systematic information about the effects of our actions or because we establish and respond to inappropriate incentives.”16

Systematic information has been obtained and has shown lack of evidence for the benefit of this therapy. The alternative explanation for the persistence and promotion of this treatment is unacceptable.

**References**


Idiopathic Itch, Rash, and Urticaria/Angioedema Merit Serum Vitamin D Evaluation: A Descriptive Case Series

David W. Goetz, MD, PhD
Exemplar Allergy & Asthma, Morgantown, WV

Abstract

Background: Vitamin D insufficiency is epidemic. Rarely are cutaneous consequences attributed to low vitamin D. Methods: A retrospective case series of 63 patients describes an association of pruritus, rash, and urticaria/angioedema with low 25-hydroxyvitamin D (25[OH]D <32 ng/mL). The 90% (57/63) of patients with low vitamin D were treated with 8 to 12 weeks of vitamin D 50,000 IU weekly followed by daily supplementation. Concurrent diagnoses were treated routinely. Complete resolution of cutaneous symptoms defined response. Results: Patients were 3 to 80 years of age. The 90% (57/63) with low vitamin D (25[OH]D < 32 ng/mL) had a mean age of 47 (11 to 80) years old, 70% were atopic, and 77% were female. Median duration of idiopathic cutaneous symptoms was 18 months. Mean 25[OH]D was 18.0 ng/mL. With vitamin D treatment 70% (40/57) had complete resolution of symptoms. Mean 25[OH]D for vitamin D responsive patients (16.8 ng/mL) was significantly lower than for vitamin D non-responsive treated patients (20.9 ng/mL, P = 0.02 by unpaired t-Test). Resolution of cutaneous symptoms with vitamin D supplementation occurred in a mean of 4.2 weeks. Symptom recurrence was seen in subsequent months only if vitamin D insufficiency recurred. Conclusion: This retrospective case-series, with a 70% (40/57) vitamin D treatment success, suggests that vitamin D status should be assessed in patients with idiopathic cutaneous symptoms. If vitamin D is low, symptom resolution is often possible with oral supplementation of vitamin D. Controlled clinical studies are required to confirm these associations.

Introduction

Allergists/immunologists in clinical practice routinely see patients presenting with the primary complaints of itching, hives, angioedema, and non-pathognomonic rashes that have defied identification and cure during multiple previous encounters with their primary care practitioners, urgent care clinics, emergency rooms, and dermatologists. Systemic steroids have almost always been prescribed on multiple occasions and may or may not have temporarily suppressed these patients’ symptoms. Multiple H1 and H2 antihistamines have incompletely controlled the cutaneous symptoms. Arriving in the allergist’s office, such patients place their hopes for symptom relief in the allergist’s allergy and immunology diagnostic skills.

On some occasions a thorough history, physical examination, and skin testing or patch testing results in the identification of a drug, food, aeroallergen, contact allergen, or environmental exposure that accounts for the cutaneous symptoms. More often the allergist’s patient evaluation requires further investigation, including laboratory and imaging studies, in search of a cryptic etiology. The number and type of further studies considered reasonable and prudent is debated among allergists. This case series review suggests that one additional reasonable and useful laboratory study worth ordering for such patients is a 25-hydroxyvitamin D (25[OH]D) serum level. 25[OH]D is the major circulating form of vitamin D and reflects synthesis in sun-exposed skin as well as dietary intake. As described by Holick1, the standard measure of clinical vitamin D status is the serum level of 25[OH]D. Expected values for 25[OH]D are based on serum levels required for optimal health rather than on population norms. Serum 25[OH]D levels above 30 to 32 ng/mL are required for optimal health. Serum levels <10 ng/mL reflect severe vitamin D deficiency, levels 10-20 ng/mL are variously described as deficient or insufficient, and 25[OH]D levels of 20-30 ng/mL are defined as vitamin D insufficient.

Textbooks typically describe no skin lesions attributable to low vitamin D but acknowledge the use of vitamin D in some disease treatments. Sauer’s Manual of Skin Diseases (2006) lists hypovitaminosis D skin lesions as rare: “No skin lesions have been attributed to lack of this vitamin. Vitamin D and vitamin D2 (calciferol) have been used orally in the treatment of lupus vulgaris. Vitamin D3…is used topically for psoriasis.”2 Likewise no cutaneous consequences of low vitamin D are described in Holick’s extensive reviews of the health implications of vitamin D deficiency and inadequacy.1,3 In contrast, this case series reports significant skin lesions that resolved when vitamin D insufficiency was treated with oral supplementation of vitamin D. By extension it also suggests there are many fruitful opportunities for controlled clinical studies to research these associations.

Methods

Retrospective Chart Review

Within a single allergist’s practice, patients presenting with a primary cutaneous complaint (itching, rash, urticaria, or angioedema) during the 6 months between December 2008 and May 2009 were identified for a retrospective case-series review. Patient charts were then excluded from further evaluation...
if complaints of itching, rash, urticaria, or angioedema had been explained by physician-confirmed diagnoses. Typical diagnoses for exclusion included: atopic dermatitis, contact dermatitis, seborrheic dermatitis, psoriasis, insect bites, drug allergy, and food allergy. After exclusions, 63 remaining patients who had presented with unexplained itch, rash, urticaria, or angioedema constituted the case series for review. Patients had been drawn from a geographic area including the northern half of West Virginia and adjacent Pennsylvania and Maryland counties.

Every patient had been evaluated at initial allergy/immunology consultation with history, physical examination, review of prior evaluations and treatments, appropriate testing, and laboratory studies. Skin testing and patch testing were performed on an individualized basis. Laboratory studies ordered were individualized with commonly ordered tests including: complete blood count and differential, erythrocyte sedimentation rate, comprehensive metabolic panel, antinuclear antibodies, rheumatoid factor, C-reactive protein, complement factor 4, thyroid stimulating hormone, free thyroxine, thyroid peroxidase, immunoglobulins, four Epstein-Barr virus titers, and 25(OH)D. Less frequently ordered tests included vitamin B12, folate, zinc, Lyme titers, Celiac panel, and latex specific-IgE. Laboratory tests were performed primarily at Laboratory Corp of America, but other laboratories were used when dictated by third-party payers or by employers.

Patient information was anonymously archived into a database for analysis. Collected patient information included: age, sex, referral status, cutaneous symptoms, symptom duration and corporal distribution, atopic status, relevant preexisting conditions, initial serum 25(OH)D, new diagnoses, treatments including vitamin D if prescribed, and response to treatments. Cutaneous symptoms segregated into three categories: 1) generalized itching without rash, 2) urticaria and angioedema, or 3) rashes of any other type with or without itching. All patients had symptomatic treatments continued, including antihistamines (H1 and H2) and topical preparations as needed. All other treatments prescribed were based on the diagnoses made after completion of initial consultation and laboratory investigations. Vitamin D replacement was prescribed for patients with serum levels of 25(OH)D below 32ng/mL, i.e. below the primary laboratory’s normal range (laboratories minimum normal values varied between 30 and 32ng/mL). Treatment for low vitamin D was usually provided as prescription vitamin D 50,000 IU, one capsule every week for 8...
to 12 weeks, followed by over-the-counter vitamin D 1000 IU daily. Two patients intolerant of Vitamin D 50,000 IU received daily over-the-counter vitamin D 1000 IU. Six patients preferred to self-limit their treatment to 400 IU to 1000 IU of Vitamin D per day. Patient follow-up appointments, repeat laboratory testing including vitamin D levels, and treatment of concurrent conditions were individualized over the following weeks.

**Definition of treatment response**

Response to treatment was recorded as either fully resolved or failed to resolve. For itching, a positive response required complete resolution of generalized itching. For urticaria and angioedema, a positive response required resolution of all urticaria and angioedema (historical dermographism was required to return to baseline). For rash, a positive response required the involved skin to return to its condition before the rash had developed. If urticaria or angioedema accompanied the rash, a positive response required their complete resolution as well. A positive response did not require patients to discontinue nonsedating antihistamines previously in regular use.

Treatment responses were classified into two categories: the “vitamin D responders” category included all patients with a positive response to vitamin D supplementation alone, and the “vitamin D non-responders” category included all patients who failed treatment with vitamin D. The statistical comparison employed the t-Test for unpaired samples.

**Illustrative Cases**

E.T. is a healthy 58 year old woman who presents with more than 5 years of episodic generalized itching 6 to 9 times a year. Each episode persists for several weeks and is poorly controlled by multiple antihistamines prescribed. Itching greatly interferes with sleep and social activities. She denies any new illnesses or prescription of new medications preceding the onset of itching episodes. Her medical history includes hypertension, hypothyroidism, cough variant asthma, nickel contact dermatitis, and hives with the ingestion of shrimp. She avoids shellfish and wears only gold jewelry. She has no history of fungal disease or autoimmune disease. Review of current medications identifies no potential causes for pruritus. Skin testing for foods demonstrates only shellfish hypersensitivity. Extensive laboratory evaluation was remarkable for a vitamin D serum level 19 ng/mL. On vitamin D 50,000 IU per week, itching resolved in 4 weeks and has not recurred in over 10 months of vitamin D 1000 IU daily. Follow-up vitamin D level was 37 ng/mL on daily supplementation.

C.C. is a 28 year old man who presents with a 7 month history of whole body, generalized urticaria and lip angioedema. Symptoms are episodic every one to two weeks, are partially relieved on daily antihistamines, and last for more than a week unless he is treated with systemic steroids. Episodes occur despite strict avoidance of the few food allergens that have caused hives in the past. He has been seen by three different dermatologists and had one skin biopsy that was consistent with the diagnosis of urticaria. Laboratory studies during allergy/immunology evaluation were normal, including alpha-1-antitrypsin, except for a 25[OH]D level of 11 ng/mL. Vitamin D supplementation of 50,000 IU per week for 12 weeks was initiated, and the rashes resolved completely in 2 to 4 weeks and have not recurred in the following 9 months on daily 1000 IU vitamin D supplementation. Follow-up vitamin D level was 42 ng/mL.

**RESULTS**

**Characteristics of patients with idiopathic itching, urticaria and angioedema, or rash**

The 63 patients with idiopathic generalized itching, urticaria and angioedema, or rash ranged in age from 3 to 80 years of age and were predominantly female (78%). Eighty-four percent had been referred to the allergist by another physician.
or health practitioner, and 57% had previously been evaluated by one or more dermatologists. Urticaria was the most common symptom for 62% of patients. Rash was present in 25% and itching alone without rash or urticaria in 21%. When present, angioedema always accompanied urticaria except in two patients in whom it accompanied a rash. Preceding duration of cutaneous symptoms was an average of 33 months with a median of 16 months. Mean vitamin D level was 20.0 ng/mL (range 5.0 to 44.6 ng/mL) and was low (<32 ng/mL) in 90% of patients. During the same six months, a total of 15 clinic patients with no cutaneous symptoms had vitamin D measured. This “control” group had a mean vitamin D level of 39.5 ng/mL with a low of 12.1 ng/mL and a high of 54.0 ng/mL.

There were no cases of vasculitis. Among the 16 patients presenting with rash, all rashes were macular or maculopapular and were usually pruritic. There were no nodular, vesicular, or plaque-like lesions. When they had been done by a dermatologist, previous biopsies of any rash or urticaria were non-diagnostic. Rashes themselves resolved without scarring. When residual excoriation and minor scarring persisted it was attributable to patient scratching.

Treatment responses to vitamin D supplementation

Table 1 lists further patient characteristics of the 90% (57/63) of patients with low vitamin D (25(OH)D < 32 ng/mL), each of whom was prescribed vitamin D supplementation. The 57 patients with low 25(OH)D were a mean age of 47 (11 to 80) years old, 70% were atopic, and 77% were female. Median duration of idiopathic cutaneous symptoms was 18 months. Mean 25(OH)D was 18.0 ng/mL.

With vitamin D treatment 70% (40/57) had complete resolution of symptoms. Mean 25(OH)D for vitamin D responsive patients (16.8 ng/mL) was significantly lower than for vitamin D non-responsive treated patients (20.9 ng/mL, P = 0.02, Figure 1). Resolution of cutaneous symptoms with vitamin D supplementation occurred in a mean of 4.2 weeks. Responders and non-responders were not distinguished by mean age (48 vs. 44 years), sex (73% vs. 88% female), atopy (68% vs. 76%), prior evaluations by dermatology (60% vs. 59%), or mean symptom duration (35.2 vs. 40.7 months).

The mean 25(OH)D was similar for atopic (17.0 ng/mL) and non-atopic patients (16.8 ng/mL). The time to resolution of cutaneous symptoms with vitamin D supplementation did not correlate with 25(OH)D level. Of the 8 patients receiving vitamin D supplementation consisting only
of daily 1000 IU or less, 7 were in the vitamin D responder category.

Other treatments for cutaneous symptoms

While 63% (40/63) of all patients had complete resolution of cutaneous symptoms with correction of low vitamin D, the remaining 23 patients (30%) required further investigation and treatment. They had presented with urticaria (74%), angioedema (39%), rash (13%) or itching alone (13%). One was lost to follow-up after the initial evaluation.

Of the 23 patients, 13 responded to a treatment other than vitamin D supplementation. Their mean age was 39 years (3 to 63 years old). The median symptom duration was 12 months. Half had seen a dermatologist and half were atopic. Mean vitamin D was 30.2 ng/mL (14.6 to 44.6 ng/mL). Their distribution of vitamin D values was skewed toward higher values. Several different treatments resulted in clinical resolution of cutaneous symptoms among the 13 patients: avoidance of newly diagnosed food allergen (black pepper, fish, shellfish) (2 patients), avoidance of newly diagnosed contact allergen (1), avoidance of NSAIDS (1), avoidance of newly diagnosed food allergens in a patient with a mast cell syndrome (1), levothyroxine for hypothyroidism (1), hydroxychloroquine for lupus or nonspecific autoimmune syndrome (2), valacyclovir for acute or reactivated mononucleosis (2), monthly B12 injections for newly diagnosed vitamin B12 deficiency (1), intravenous immunoglobulin for common variable immunodeficiency (1), and zinc supplements for low zinc serum levels (1).

Review by symptom

Table 2 describes patients with low vitamin D in their three symptom categories: A. Generalized itching without rash (13), B. Urticaria and angioedema (28), and C. Rash of any other type (16). The three types of presentation were not distinguished by duration of symptoms, age, or sex. Patients presenting with rash were more likely to be atopic (75%) and more likely to have seen a dermatologist previously (81%). The three symptom subgroups had mean presenting vitamin D levels between 16.3 and 20.3 ng/mL. Vitamin D supplementation resulted in clearance of symptoms in 61% (urticaria and angioedema) to 77% (itch alone) and 81% (rash) of patients, without a difference in time to resolution of symptoms (3.8 to 4.3 months).

Follow-up observations of patients responsive to vitamin D supplementation

Patient follow-ups usually were scheduled at 3 to 4 weeks and 6 to 8 weeks of treatment, and then again at individualized times every several months as required clinically. When symptoms improved with rising vitamin D levels, symptomatic treatments were tapered on an individual basis. Some patients became symptom free at less than optimal vitamin D levels. Patients asymptomatic after 3 to 4 months and with no reason for continued allergy/immunology follow-up were returned to their primary care provider with instruction to return if symptoms recurred. All 40 patients

Table 1. Treatment responses to Vitamin D supplementation.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Treatment Responders</th>
<th>Treatment Failures</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>29</td>
<td>15</td>
<td>44</td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Symptom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itch alone</td>
<td>25%</td>
<td>18%</td>
<td>23%</td>
</tr>
<tr>
<td>Rash*</td>
<td>33%</td>
<td>18%</td>
<td>28%</td>
</tr>
<tr>
<td>Urticaria</td>
<td>55%</td>
<td>65%</td>
<td>58%</td>
</tr>
<tr>
<td>Angioedema</td>
<td>22%</td>
<td>35%</td>
<td>26%</td>
</tr>
<tr>
<td>Symptom duration before treatment (mo)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Maximum</td>
<td>240</td>
<td>240</td>
<td>240</td>
</tr>
<tr>
<td>Mean</td>
<td>35.2</td>
<td>40.7</td>
<td>35.3</td>
</tr>
<tr>
<td>Median</td>
<td>16</td>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td>Vitamin D (ng/mL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td>5.0</td>
<td>7.5</td>
<td>5.0</td>
</tr>
<tr>
<td>Maximum</td>
<td>29.3</td>
<td>31.0</td>
<td>31.0</td>
</tr>
<tr>
<td>Mean</td>
<td>16.8</td>
<td>20.9</td>
<td>18.0</td>
</tr>
</tbody>
</table>

*Seven of 16 patients with rash had concurrent urticaria/angioedema: 4 urticaria, 2 angioedema, 1 both.
with successful responses to vitamin D alone remained symptom free as long as successful vitamin D supplementation was maintained. Less than 10% of responders had relapse of cutaneous symptom, and all relapses were associated with falling serum vitamin D levels due to either patient discontinuation of supplementation or due to a patient requirement for more than 1000 IU of oral vitamin D supplementation per day. Subsequent individualized treatments required 2000 IU or 3000 IU per day, and in a few cases required reinstitution of 50,000 IU of vitamin D weekly to maintain adequate serum levels and recapture control of cutaneous symptoms. Relapse in symptoms was not seen in patients unless vitamin D serum levels were allowed to fall to pretreatment levels.

### Discussion

New appreciation for the silent epidemic of vitamin D insufficiency in the United States and throughout much of the industrialized world has driven ongoing research into the biological consequences of low vitamin D. Beyond the classic consequence of rickets, low vitamin D has been implicated in other bone, muscle, cardiovascular, neurological, endocrine, skin, and malignancy conditions. Ongoing investigation has identified vitamin D as a central mediator in immunological mechanisms underlying a wide-range of diseases, including asthma, other atopic diseases, and autoimmune diseases presenting to the allergist.\(^1\,\,^3\)

The current retrospective case-series review suggests that the long list of conditions possibly associated with vitamin D insufficiency should be extended further to include generalized pruritus, rashes, and urticaria and angioedema. Vitamin D has a multifaceted role in human body homeostasis. Vitamin D is well known for its major role in the intestinal, skeletal, kidney and parathyroid mechanisms for homeostasis of calcium and phosphorus.\(^1\) 25-hydroxyvitamin D is the major circulating form of vitamin D and reflects synthesis in sun-exposed skin as well as dietary intake. It is the standard serum marker for vitamin D status. Dietary sources of vitamin D include oily fish and egg yolks, as well as vitamin D fortified milk (and a few other fortified foods), but many individual’s diets may be lacking in these sources. Sun exposure and skin production of vitamin D is unlikely to rectify dietary shortfalls of vitamin D in modern societies where individuals are spending more time indoors and actively avoiding the sun. Vitamin D insufficiency is prominent in all age groups, with many studies reporting vitamin D insufficient in more than 50% of individuals.\(^1\)

The elderly are at increased risk of vitamin D insufficiency, as are patients with conditions that include fat malabsorption.

Skin is one of the many tissues with known vitamin D receptors. Vitamin D is a major factor in regulation of the innate immune system and production of cutaneous and mucocutaneous cathelicids, antimicrobial peptides whose dysregulation has been associated with inflammatory skin diseases. Along with a large and disparate group of other diseases,
Vitamin D deficiency has been proposed to be a risk factor for bacterial vaginosis in early pregnancy. Vitamin D deficiency has been described as a risk factor for bacterial vaginosis and systemic symptoms (DRESS) due to low body stores of vitamin D. Vitamin D deficiency has been scrutinized for their association with phystiologies are being closely scrutinized for their association with vitamin D. Vitamin D deficiency has recently been suggested as a risk factor or severity factor in drug rash with eosinophilia and systemic symptoms (DRESS). Vitamin D deficiency has been described as a risk factor for bacterial vaginosis and systemic symptoms (DRESS). Vitamin D deficiency has been described as a risk factor for bacterial vaginosis and systemic symptoms (DRESS)

Figure 1. Distributions of vitamin D levels for vitamin D treatment responders and non-responders.

<table>
<thead>
<tr>
<th>Vitamin D (ng/ml)</th>
<th>Responders</th>
<th>Non-responders</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-32</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P = 0.02

Atopic dermatitis and asthma pathophysiologies are being closely scrutinized for their association with vitamin D, Vitamin D deficiency has recently been suggested as a risk factor or severity factor in drug rash with eosinophilia and systemic symptoms (DRESS). Vitamin D deficiency has been described as a risk factor for bacterial vaginosis and systemic symptoms (DRESS). Vitamin D deficiency has been described as a risk factor for bacterial vaginosis and systemic symptoms (DRESS). Current Practice Parameters for the treatment of urticaria and angioedema do not address vitamin D. There are no current Practice Parameters for idiopathic rash or for isolated generalized itching. Representative available literature does not address vitamin D status. This dearth of available literature suggests that there are major opportunities waiting for research into cutaneous and mucocutaneous consequences of vitamin D deficiency (and perhaps into other cofactors necessary for the homeostasis of body tissues). Among specific questions that need to be answered is what if any association there is between vitamin D insufficiency and the autologous-serum positive skin tests in many patients with idiopathic chronic urticaria. Controlled studies are needed to address this question and the wider question of cutaneous syndromes associated with low vitamin D. While we wait for these questions to be answered more rigorously, this case series suggests that serological measurement of 25(OH)D in patients with idiopathic chronic urticaria, rash, or isolated itching can identify those patients with low vitamin D levels who may experience resolution of their cutaneous symptoms with vitamin D oral supplementation.

References

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Altitude Induced Migraine

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Introduction

Ascent to high altitude is associated with a variety of neurologic symptoms, most commonly headaches. High altitude is known to induce both migraine and non-migraine headaches, and is more common in those who previously suffered from headaches. No reports were found in the literature of first migraine or probable migraine triggered at high altitude. We report a case of new onset headaches at altitude that did not resolve on return to the patients normal altitude and subsequently progressed to probable migraine without aura.

Case Report

The patient is a 23 year old male college student and division one collegiate football player without a history of recent or remote head injury or personal history of headaches. His headache began after flying with his team to Colorado and staying at an altitude of approximately 1800m for less than 24 hours. He reported seeing spots in his vision and “tracers” moving across his visual field for about 20 minutes, followed by development of a global mild-moderate headache. Over the next few hours the pain localized to the right frontal and retro-orbital areas. He denied nausea, photophobia or phonophobia, and the pain was not made worse with activity. After his initial visual complaints he did not report any other neurologic symptoms with his headache. The headache began before the team practiced that day, and he was treated with anti-inflammatories with minimal relief. He was able to participate fully in practice and in the following day’s game despite the headache. On return to his home, the headache continued in a similar pattern for 10 days, then began to worsen, becoming more severe and developing a pulsatile quality, limiting his ability to practice due to worsening pain. He was treated by team physicians with tramadol, sumatriptan nasal spray, amitriptyline, and prednisone without any improvement.

He presented to the Headache Center after he had missed two full days of practice. He denied any use of supplements other than fish oil and protein shakes. His past history showed only some orthopedic injuries and surgical corrections. He did not smoke or use alcohol. He reported a history of migraines in his mother, but otherwise denied any significant family history. His review of systems revealed only mildly increased daytime sleepiness, with good sleep schedules and sleep hygiene.

His exam was unremarkable except for being 1.91 meters tall and weighing 134 kilograms. There was no papilledema, scalp tenderness, or neck range of motion limitations. MRI of the head (with and without contrast) was normal.

He was treated with 1mg of subcutaneous dihydroergotamine, 10mg of intramuscular metoclopramide, and increase in his prednisone dose from 40mg to 60mg with a rapid tapering schedule. By the following morning team trainers reported that his headache had resolved and he was symptom free. He was able to return to his normal practice schedule without incident, and has not had a recurrence of his headache. Due to the players graduation, long term follow-up is not available, but from personal communication with the team physician, the headache did not return while a student of the university.

Discussion

The International Classification of Headache Disorders-2 (ICHD-2) defines High-altitude Headache (10.1.1) under the category 10.1: Headache attributed to hypoxia and/or hypercapnia with the following diagnostic criteria:

A. Headache with at least two of the following characteristics and fulfilling criteria C and D:
   1. Bilateral
   2. Frontal or frontotemporal
   3. Dull or pressing quality
   4. Mild or moderate intensity
   5. Aggravated by exertion, movement, straining, coughing or bending

B. Ascent to altitude above 2500m
C. Headache develops within 24 hours after ascent
D. Headache resolves within 8 hours after descent

High altitude illness risk factors include younger age, rate of ascent, altitude obtained, and living at low altitude at baseline. Various etiologies have been proposed, including intracranial hypertension, declines in barometric pressure, hypoxia, and dehydration. Treatment options for altitude headache include non-steroidal anti-inflammatories, aspirin, acetaminophen, and oxygen, with acetazolamide and dexamethasone showing evidence for prevention. Typically, however, altitude headaches resolve with return to lower altitudes. Mack has reported a case of New Daily Persistent Headache in a child after high altitude camping, but we could not find other reports.
in the literature of continuous headaches triggered at altitude and not resolved with descent.

Our patient’s headache does not meet ICHD-2 criteria for HAH, but the presentation is suggestive that ascent to relatively high altitude can act as a trigger for the development of headache. The development of migraine headache with ascent to altitude is recognized in known migraine sufferers, but we could not find documentation of high altitude causing probable migraine in a patient without a previous history of migraine. Despite his lack of personal history of migraine, his family history suggests that he may be genetically predisposed toward migraine, with high altitude serving as a potent trigger for his first migraine headache.

Other possible explanations for our patient’s headache include travel, stress, and changes in time zones, but the previous travel experience of this fifth-year senior would suggest that the main difference in this case was an ascent to higher altitude. The trigger in this case is possibly low barometric pressure, rather than hypoxia or hypercapnia seen in true HAH, although our patient does carry multiple risk factors for HAH, including his young age, living at only 293m, and a rapid ascent via airplane, albeit to only 1900m. Low barometric pressure’s influence on migraine has not been satisfactorily evaluated, as conflicting results have been found in previous investigations, but has been theorized to cause depolarization of neurons within the trigeminovascular pain pathways.5

The triggering of migraine headache by ascent to high altitude in known migraine sufferers is well recognized, but this case suggests that high altitude induced headache (not High-Altitude Headache) may be the presenting headache in patients with no previous headache history and may lead to the progression to migrainous headache if left inadequately treated. A careful review of travel history should be included when patients present with new onset daily severe headaches of unclear etiology.

References
Isolated Bladder Vasculitis: A Rare Presentation of Wegener’s Granulomatosis

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Introduction

Wegener’s granulomatosis (WG) is a systemic necrotizing vasculitis mainly involving the lungs and kidney. Urological involvement of WG is mostly prostate and kidneys; it rarely involves the urinary bladder. Bladder involvement of WG can mimick bladder neoplasia and should be included in the differential diagnosis of hematuria. We present a case of WG initially presenting as isolated bladder vasculitis (IBV) which has never been reported to the best of our knowledge.

Case report

A seventy year old Caucasian female was admitted with hemoptysis, fatigue and worsening anemia. Her past medical history was significant for hypertension, hyperlipidemia, gout and anemia of chronic disease. Eight months prior she had been admitted with chest pain. Cardiac enzymes, electrocardiogram, and chest x-ray were normal. A normocytic, normochromic anemia of chronic disease was noted with a hemoglobin of 10 g/dL. Over the next two months, her hemoglobin declined to 8.3 g/dL. A urine analysis showed microhematuria. Due to persistent microhematuria, cystoscopy was performed and revealed very small papillary lesions in the bladder and biopsy showed focal vasculitis and perivasculitis of a small artery of the lamina with no evidence of malignancy (Figure 1). One month later she developed a cough with hemoptysis for two weeks. Hemoglobin was found to be 8.0 g/dL. Chest x-ray showed a faint area of consolidation at the right lung base. A CT scan showed the area of consolidation in the right lower lobe consistent with pneumonia and poorly defined areas of increased density in the right middle and left lower lobes.

Over the ensuing months her cough and hemoptysis never completely resolved. She felt increasingly fatigued and dyspneic. A chest CT scan was repeated during present hospitalization which showed progression of the densities in both lungs. She also underwent bronchoscopy, which showed a diffuse alveolar hemorrhage. Her

Figure 1.
Focal vasculitis and perivasculitis of a small artery (arrow) of the lamina propria with mixed inflammatory infiltrate including eosinophils, histiocytes and neutrophils.
erythrocyte sedimentation rate was 99. She was found to be positive for antineutrophil cytoplasmic antibodies (C-ANCA). Based on the above findings she was diagnosed with Wegener’s granulomatosis. She was started on corticosteroids and cyclophosphamide. She had an excellent recovery of her symptoms. Follow up CT scan of chest showed resolution of the previously described opacity.

Discussion

Wegener’s granulomatosis is a systemic disorder but it can present in a limited form. Involvement of the bladder in the systemic vasculitis has been rarely reported with only two cases reported so far which were initially diagnosed as bladder hamartoma. Both cases had multiple recurrences of ‘tumor like growth’ in the bladder with no systemic involvement without immunosuppressive therapy. On further review they were diagnosed with polyarteritis nodosa like vasculitis and small vessel vasculitis respectively with good therapeutic response on appropriate treatment. This underscores the importance of including bladder vasculitis in the differential diagnosis of neoplasia as it can present as hematuria, irritative voiding symptoms, urgency and incontinence along with constitutional symptoms such as fatigue, malaise, weight loss or intermittent sweats. WG may initially present with granulomas of the affected tissues and subsequently vasculitis develops as a complication of the granulomatosis. Recognizing isolated bladder involvement in WG is very important because its early treatment may help in the preservation of bladder function and reduce the need for surgical interventions.

Conclusion

WG initially presents with granulomas of the affected tissues, later complicated by systemic vasculitis. Early diagnosis and treatment is important because it involves less toxic regimens than systemic vasculitis which helps prevent many complications. Surgical treatment should reserved for severe impairment of bladder function.

References


“What fits your busy schedule better, exercising 30 minutes a day or being dead 24 hours a day?”
Rational Care or Rationing Care? Updates and Controversies in Women’s Prevention

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Abstract
Prevention has potential benefits, but the majority of people undergoing disease screening will not be benefitted and may actually be exposed to health risks. Public opinion is generally very favorable toward prevention. Eighty-seven percent of nationally surveyed adults believed cancer screening is almost always good and two thirds indicated that they would be tested even if nothing could be done for abnormal findings.1 Many women would continue Papanicolaou (Pap) testing to screen for cervical cancer even if their physician recommended against it.2 Women who have had a hysterectomy often continue to get Pap tests despite recommendations against doing so.3 Despite this apparent enthusiasm, many beneficial preventive services, such as breast and colorectal cancer screening, are under utilized.4 Experts evaluate several factors to balance potential benefits and harms before recommending a preventive service. USPSTF (United States Preventive Services Task Force) recommendations are considered by many to be the “gold standard” for prevention guidelines. The task force grades the strength of evidence for each service as A or B (recommended), C (recommended against using routinely), D (recommended against), or I (insufficient evidence to recommend for or against). Several guidelines have recently been updated to recommend doing less prevention in women than previously suggested. These recommendations have caused widespread confusion and, because of being revealed during a national health reform debate, have even been perceived as “rationing care.” This article reviews recent data and compares different organizations’ prevention guidelines for average risk women.

Breast cancer
Breast cancer is the most common non-skin malignancy in US women and the second leading cause of cancer deaths, after lung cancer. 1 in 8 women will get breast cancer in their lifetimes. Fortunately there is a 90% 5-year survival if it is localized at diagnosis, so early detection is important. However, mammography screening does not prevent a woman from getting cancer, and detecting it early does not necessarily mean a life is saved. Mammography screening has a sensitivity of 77-95% and a specificity of 94-97%. PPV (positive predictive value) varies by age, being lower in women in their 40’s compared to women in their 50’s and 60’s because of the lower prevalence. Evidence indicates reduced mortality with mammography screening. However, there is also potential for harms such as false positives, anxiety, unnecessary procedures, and overdiagnosis. DCIS (ductal carcinoma in situ), a non-invasive cancer, may be an example of overdiagnosis. It has low potential for progression to invasive cancer, with less than half of cases progressing. DCIS cases get treated with surgery and radiation because it is not possible to predict which will progress.5 Two recent publications led to changes in USPSTF breast cancer screening guidelines. The first was a meta-analysis of mammography screening trials which included data from 2 new studies since the last USPSTF meta-analysis. These two new studies both provided data on women ages 39-49. The
trials of women in their 40’s did not demonstrate significant breast cancer mortality reductions individually, but when pooled together, reductions were significant. Relative risks for breast cancer mortality were significantly lower for all age groups (Table 1). The relative risk reduction was largest for women in their 60’s (32%). Although the relative risk reduction was nearly identical for women in their 40’s (15%) and 50’s (14%), the higher incidence of breast cancer made the absolute risk reduction greater in the older women. The NNI (number needed to invite for screening to prevent 1 breast cancer death) was lower for the oldest group of women (in their 60’s) than for women in their 40’s and 50’s. False positives were higher with younger age and decreased with age.6

The second publication was a CISNET (Cancer Intervention and Surveillance Modeling Network) modeling study of screening strategies. Computer modeling is useful because the long follow-up and expense make conduction of randomized controlled screening trials challenging. Models can predict outcomes under different strategies, adjusting the intervals between screening and the starting/ stopping ages. This study compared 20 screening strategies, including 10 different screened age groups, each with annual and biennial testing.7

Most of the strategies that were found to be efficient (with efficient strategies having more health gains from fewer resources) utilized a biennial screening interval and initiated screening at age 50. A biennial screening interval was found to be beneficial in terms of both mortality and life-years gained. Harms were greater with annual compared to biennial screening, with more false positives, unnecessary biopsies, and overdiagnosis. Biennial screening was calculated to keep 81% of the mortality benefits of annual screening with about half the harms.7

Findings for optimal screening ages were not as clear as findings for interval. Screening initiation at age 50 was efficient for the outcome “mortality.” However, initiation at 40 was efficient for the outcome of “life-years gained” due to the additional years of life expectancy. In absolute terms, compared to screening a baseline group of women aged 50-69, it was estimated that adding 10 years of screening to those 70-79 would save 2 lives per 1000 women. If those 10 additional years of screening were instead added to those 40-49, 1 life per 1000 women would be saved (half as many). However, looking at a different outcome, life-years gained would be greater from starting earlier rather than stopping later (33 vs. 24 life-years per 1000 women screened). More harmful false positives and more biopsies would occur with

### Table 1. Meta-analysis of mammography screening trials, by age

<table>
<thead>
<tr>
<th>Age group</th>
<th>Number of trials</th>
<th>Pooled RR for mortality</th>
<th>95% CI</th>
<th>NNI</th>
<th>FP per 1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>40’s</td>
<td>8</td>
<td>0.85</td>
<td>0.75-0.96</td>
<td>1904</td>
<td>98</td>
</tr>
<tr>
<td>50’s</td>
<td>6</td>
<td>0.86</td>
<td>0.75-0.99</td>
<td>1339</td>
<td>87</td>
</tr>
<tr>
<td>60’s</td>
<td>2</td>
<td>0.68</td>
<td>0.54-0.87</td>
<td>337</td>
<td>79</td>
</tr>
</tbody>
</table>

N NI = Number needed to invite for screening
RR = Relative risk
CI = Confidence interval
FP = False positive


### Table 2. Mammography screening recommendations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Screening Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF</td>
<td>Routinely begin every 2 years at 50</td>
</tr>
<tr>
<td></td>
<td>Individualized decision in 40’s</td>
</tr>
<tr>
<td>ACP</td>
<td>Routinely begin at 50</td>
</tr>
<tr>
<td>ACS</td>
<td>Annual starting at 40 Continue as long as good health</td>
</tr>
<tr>
<td>ACOG</td>
<td>Every 1 to 2 years in 40’s Annual starting at 50</td>
</tr>
<tr>
<td>WHO</td>
<td>Every 1-2 years Ages 50-69</td>
</tr>
<tr>
<td>Canada</td>
<td>Every 2 years Ages 50-69</td>
</tr>
<tr>
<td>Britain</td>
<td>Every 3 years Ages 50-69</td>
</tr>
<tr>
<td>Italy</td>
<td>Every 2 years Ages 50-69</td>
</tr>
</tbody>
</table>

USPSTF = United States Preventive Services Task Force
ACP = American College of Physicians
ACS = American Cancer Society
ACOG = American College of Obstetrics and Gynecology
WHO = World Health Organization

Findings for optimal screening ages were not as clear as findings for interval. Screening initiation at age 50 was efficient for the outcome “mortality.” However, initiation at 40 was efficient for the outcome of “life-years gained” due to the additional years of life expectancy. In absolute terms, compared to screening a baseline group of women aged 50-69, it was estimated that adding 10 years of screening to those 70-79 would save 2 lives per 1000 women. If those 10 additional years of screening were instead added to those 40-49, 1 life per 1000 women would be saved (half as many). However, looking at a different outcome, life-years gained would be greater from starting earlier rather than stopping later (33 vs. 24 life-years per 1000 women screened). More harmful false positives and more biopsies would occur with
screening initiation at 40 compared to 50. However, overdiagnosis would be more of a problem if 10 years of screening were added by extending screening to age 79 rather than by starting screening at 40.\(^7\)

With the publication of these studies in November 2009, USPSTF updated their screening guidelines to recommend mammograms every 2 years starting at age 50 (B recommendation). The new recommendations call for individualized decision-making and consideration of benefits/harms before the age of 50 (C recommendation). The task force had previously recommended annual mammography starting at 40. These guideline changes created a significant amount of controversy, and many politicians, health care organizations, and US women disputed them. One criticism was that USPSTF did not emphasize the data on life-years gained as much as the data on mortality. Also, the CISNET study was limited, as are all computer modeling studies, by the fact that modeling requires assumptions. Many opponents disagreed with the value judgments of the task force, with some believing that additional false positives, anxiety, and cost are worthwhile if even a small number of lives are saved.

Other organizations’ screening recommendations vary, as shown in Table 2.\(^8-10\) ACP (American College of Physicians) guidelines, which preceded USPSTF, resemble the new task force recommendations, and were based on similar reasoning.\(^8\) Guidelines in many other countries such as Canada, Britain, and Italy, as well as the World Health Organization, target the age group of 50-69 for screening.\(^11\)

Cervical cancer

Cervical cancer is decreasing in incidence, but is still the 10th leading cause of cancer death in women. Pap tests are the mainstay of screening, HPV is known to be a necessary precursor and HPV testing can be done in conjunction with a Pap test. Most cervical cancer deaths occur in women who had not been screened in the last 5 years. Survival depends heavily on stage at diagnosis. Ninety-two percent will survive 5 years when cancer is localized but only 13% will survive distant disease. The sensitivity of a single Pap test is 60-80% for high-grade lesions. Observational evidence strongly suggests that Pap test screening programs reduce cervical cancer mortality by 75-80%. This was announced with their new mammogram recommendations, adding to the screening controversy.

Table 3. Breast Self Exam and Clinical Breast Exam Recommendations

<table>
<thead>
<tr>
<th>CBE</th>
<th>BSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF</td>
<td>Insufficient evidence to address CBE (I statement)</td>
</tr>
<tr>
<td>ACS</td>
<td>CBE yearly ≥40</td>
</tr>
<tr>
<td></td>
<td>Every 3 years in 20’s-30’s</td>
</tr>
<tr>
<td>ACOG</td>
<td>All women should have annual CBE</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CBE=Clinical breast exam  
BSE=Breast self exam  
USPSTF=United States Preventive Services Task Force  
ACS=American Cancer Society  
ACOG=American College of Obstetrics and Gynecology

Women showed no difference in breast cancer mortality with BSE, and only one showed increased detection. More biopsies were done in the intervention arm so it may do more harm than good.\(^12\) ACS and ACOG (American College of Obstetrics and Gynecology) recommend BSE with some reservations.\(^9,10\) However, USPSTF now recommends against teaching BSE (D recommendation), a change from their previous I statement.\(^5\) This was announced with their new mammogram recommendations, adding to the screening controversy.
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cancer incidence and mortality.\textsuperscript{5} Institution of these programs is considered to be one of the biggest cancer screening success stories. However, potential harms from screening exist. Surgical intervention such as LEEP (loop electrosurgical excision procedure) for cervical lesions has been associated with approximately twice the risk of preterm birth (RR 1.99, 95% CI 1.81-2.2), and some of the increase in US preterm births has been attributed to these interventions.\textsuperscript{13, 14} Cone biopsy procedures have also been associated with increased rates of low birth weight, PPROM (preterm premature rupture of membranes), and perinatal mortality.\textsuperscript{15}

USPSTF strongly recommends Pap tests (A recommendation) beginning within 3 years of sexual activity or 21 (whichever comes first).\textsuperscript{5} ACS generally agrees with the task force, but ACOG has recently suggested that Pap test screening before age 21 should be avoided, regardless of the age of starting sexual activity.\textsuperscript{9, 16} ACOG’s recommendations are based on the potential harms and a less than 1 in a million chance of cervical cancer in women under 21.\textsuperscript{17} The rationale is that most dysplastic lesions are low-grade and transient, and treating lesions that will regress spontaneously could lead to inappropriate interventions that may do more harm than good.

USPSTF and ACOG both recommend stopping screening around age 65 if the woman has had adequate recent normal Pap tests. Both organizations also recommend stopping after hysterectomy done for benign reasons. Because there is a long progression time of preinvasive lesions to invasive cancer (around 10 years), USPSTF guidelines recommend a Pap test screening interval of every 3 years. ACOG and ACS now agree that annual screening is too frequent unless there is a history of cervical cancer or dysplasia, with ACOG recommending Pap tests every two years before the age of 30. After the age of 30, ACOG guidelines state that screening can be done every 3 years if there have been 3 negatives. If HPV testing is done and is negative in women >30, they also recommend not screening more often than every 3 years.\textsuperscript{5, 9, 16}

These new ACOG cervical cancer screening guidelines were released in November 2009, just days after the release of the USPSTF mammogram guidelines. The concept of annual lifetime Pap testing had been widely embraced in the US despite the fact that USPSTF had been recommending longer cervical cancer screening intervals since 1996. The news of these ACOG recommendations to start Pap tests later and to do them less often seemed to some like a radical shift that would take care away from women.

**Ovarian cancer**

Ovarian cancer does not have a high prevalence, striking only 50 of 100,000 women. However, it is important in terms of mortality. It is the 5th leading cause of cancer death in US women. Treatment is more effective for presymptomatic disease, with an estimated 40% reduced mortality with early diagnosis. One reason for the high fatality rate of ovarian cancer is that >70% of women are diagnosed with advanced stage disease.

The CA-125 test is often elevated in ovarian cancer, a finding that led to considering use of the test for ovarian cancer screening. Despite the fact that ovarian cancer would be a good disease for a screening program, the CA-125 doesn’t have the test characteristics necessary for a screening test. It has a very low PPV because of the low prevalence of the disease,\textsuperscript{9} and abnormal CA-125 tests often require ultrasounds or even surgery to make a definitive diagnosis. There is currently no data showing a decreased mortality with testing, but the Prostate, Lung, Colorectal and Ovarian (PLCO) trial is an ongoing large randomized controlled trial looking at mortality. It involves screening women with both a CA-125 and a transvaginal ultrasound vs. usual care. Recently, data has been evaluated from women in the intervention arm after the first 4 rounds of screening. Only 6 invasive cancers were detected per 10,000 screens. The surgery to detected cancer ratio showed that 20 oophorectomies were done to find 1 case of invasive cancer. 72% of the detected cancers were stage III and above, so it did not find early cancers as had been hoped. The PPV was poor at around 1%.\textsuperscript{18} Women sometimes ask their providers to order CA-125 tests, but while final results are pending, there is no current evidence for screening with either CA-125 or transvaginal ultrasound.

Routine ovarian cancer screening has never been recommended by any organization, and USPSTF has recommended against it since 1996 (D recommendation).\textsuperscript{5}

Without a good screening test, diagnosing ovarian cancer early requires having a low threshold for working up symptoms such as pelvic pain, increased abdominal size, urinary urgency, and bloating. These symptoms are nonspecific and often seen in primary care patients without cancer. In cancer patients compared to primary care patients, symptoms were recently found to be significantly more frequent (20-30 times per month vs. 2-3 times per month). Symptoms were also of shorter duration in cancer patients (3-6 months) vs. primary care (12-24 months).\textsuperscript{19} An ovarian cancer symptom index is being tested in combination with CA-125 for screening.\textsuperscript{20} Until better ovarian cancer screening methods are found, if a woman presents
with these common symptoms, particularly if they are occurring almost daily (at least 12 days/month) or if they are new (starting in the last year), it is important to evaluate them for ovarian cancer.

**Cardiovascular disease**

Heart disease is the leading cause of death in women, and preventing it could have a large public health impact. The mainstay of prevention involves reducing modifiable risk factors such as hypertension, hyperlipidemia, and smoking. Women’s later development of CHD (coronary heart disease) compared to men seemed to be associated with loss of the protective effect of estrogen, which led to the use of hormone therapy at menopause for CHD prevention. That fell out of favor after the Women’s Health Initiative trial showed no benefit and possible harm. Aspirin and medications to reduce lipid levels are routinely used as CHD chemoprophylaxis in men, but recent studies have suggested that responses to these agents may vary by gender.

**Aspirin**

The Women’s Health Study was the largest trial of aspirin for primary prevention in women, following almost 40,000 health professionals for 10 years. For the primary end point of major cardiovascular events, there was a non-significant finding (RR 0.91, 95% CI 0.80-1.03). No effect was seen on risk of MI (myocardial infarction) or death from cardiovascular causes. Aspirin lowered women’s stroke risk (RR 0.83, 95% CI 0.69-0.99) with a number needed to treat of 444. The benefit of aspirin for stroke was offset by an increased risk of GI bleeding with a number needed to harm of 553 for GI bleeding requiring transfusion. Only in a subgroup analysis of women older than 65 was a reduced risk seen for MI and major cardiovascular events. This study’s findings were opposite to other studies’ findings of reduced risk for MI but not stroke in men using aspirin. Limitations included the low dose of aspirin of 100 mg every other day and the low risk characteristics of the study population, including a young mean age of 55.

USPSTF updated their guidelines for aspirin for primary prevention after this study was published, noting that aspirin does not decrease MIs in women. For stroke prevention, they recommend using aspirin in women when potential benefits outweigh potential for GI bleeding (A recommendation). A table available on the USPSTF website can help with this tricky risk-benefit analysis. If used, aspirin is not recommended until age 55, which is 10 years older than the recommended starting age for MI prevention in men.

**Lipids**

In a systematic review of lipid lowering for primary prevention...
in women, only one of four trials reported lower mortality in treated women. In the pooled analysis, there was no significant reduction in mortality, CHD mortality, nonfatal MI, CHD events, or revascularization. These results were limited by short follow-up, a young mean age of 60, and a low number of events.

Despite widespread agreement that further research with longer follow-up is needed, in 2008 USPSTF scaled back their recommendations for lipid screening in women. The task force had previously recommended routinely screening women at age 45 and screening anyone high risk at 20. The new recommendation is to screen women only if they have increased risk at any age (A recommendation for age 45 or greater, B recommendation for ages 20-45). They give no recommendation for or against screening women who are not at increased risk (C recommendation). Their rationale is that the known benefits of lipid treatment only outweigh the harms (which are admittedly small) when the CHD risk is substantial.

Conclusions

Many recent guidelines recommend doing less prevention in women than previously suggested. Some of the new guidelines are to wait until 50 for mammography screening, to screen only every other year, and to not teach SBEs, although not all organizations are in agreement. Pap tests for cervical cancer screening are recommended to be done less often (every 2-3 years) and to be started later than previously suggested (not before age 21). Screening for ovarian cancer is not recommended. Guidelines suggest avoiding hormone therapy for primary prevention of coronary heart disease, not giving aspirin to prevent MIs in women, and not screening women without risk factors for hyperlipidemia.

Some perceive these guidelines as “rationing care.” Others see them as “rational care,” because they encourage utilization of beneficial services while discouraging use of those that may lead to more harms than benefits. Development of prevention guidelines requires value judgments, so despite the use of evidence, these recommendations have not all achieved widespread support. Understanding the data behind the guidelines, health care providers can decide how to approach prevention in practice, taking into consideration individual patient risk factors and preferences.

References

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The completion of a death certificate by a physician serves several different functions for the patient’s family. The death certificate is crucial as legal proof of death. Without it, bank accounts cannot be accessed, utilities and creditors cannot be properly notified and paid, life insurance benefits cannot be distributed, and estates cannot be opened for probate.

From a genealogical viewpoint, the death certificate serves as an historical reference to an individual, recounting name, dates and places of birth and death, parents’ names, as well as other useful demographic information.

The death certificate, however, has another vital function – providing the synopsis of the cause and manner of death. It is in this scientific role that the physician has a responsibility to the general public’s health and advancement of medical science.

Unfortunately, the synopsis of the cause of death noted on many death certificates is often inadequate in denoting physical and, when significant, mental factors, that were the underlying cause of death or that otherwise contributed to the death.

How many women died from breast cancer in the United States in 2008? How many people died from Parkinson’s disease or Alzheimer’s disease? How many died from . . . . .? The answers to all of these questions are compiled by physicians who were responsible for the care of their patients in their final months, days, or hours.

The literal cause and manner of death written on a completed death certificate, collected by all states, is coded to national and World Health Organization standards (currently the International Classification of Diseases, 10th Revision [ICD-10]). This information is used by individual states and transmitted to the National Center for Health Statistics, a division of the Centers for Disease Control and Prevention. Once compiled, the information is widely disseminated and used as the basis of comparison of mortality by race, age, sex, educational attainment, and geographic boundary.

Recently, the accuracy of death certificate information has come into question – not just in West Virginia but nationwide. Although nearly all states have some legal provision for auditing the accuracy of death certificate information, the cause of death is rarely audited.

The reporting of a death and the certification of a cause of death is a legal mandate placed on physicians, however without accuracy compliance is incomplete. We are often asked, “To what degree of accuracy?” Simply put, the cause of death provided by the attending physician should be the physician’s best informed medical opinion based on their training and knowledge of the patient’s medical history, course of treatment, and the other circumstances surrounding the final illness that resulted in death. Some physicians fear that placing a cause of death on a death certificate that is not 100% accurate could be a liability issue. It is not reasonable, however, nor could it ever be held to be a physician’s responsibility, legal or otherwise, to render a cause of death with the measure of clinical accuracy that could only be obtained through a full autopsy of the decedent. A physician has no liability if a mistake is made when placing the cause of death on the certificate as long as the cause and manner are not willfully and knowingly misrepresented. This immunity was codified in West Virginia law in 2006. If a simple mistake or omission is made, it can be corrected. Nonetheless, there are baseline expectations for quality and timely completion.

Often, there is more than one way to complete the cause of death on a death certificate, and a fairly wide variation is acceptable. But just as there are many acceptable ways to certify the cause of death, there are also many wrong ways. There are basic tenets to be followed. From a technical viewpoint, the cause of death as written on a death certificate is to be a mini case history of those events that surrounded and ultimately led to the death. The underlying cause of death, i.e., “the disease or injury which initiated the train of morbid events leading directly to death or the circumstances of the accident or violence which produced the fatal injury,” must be stated. It is that underlying cause, along with any other relevant cause or factor and the immediate cause of death, that is important in terms of accurate collection, comparison, and analysis of data.
ALL deaths in West Virginia in which the underlying cause of death is an external cause (injury) MUST be reported to the local coroner or to the Office of the Chief Medical Examiner, no matter the time interval between the external event and the death. To do otherwise is a clear violation of law. It also causes delay in certificate filing since the medical examiner must be responsible for investigation and resolution.

"Cardiac arrest" and "respiratory arrest" are often incorrectly listed as underlying causes of death on certificates in West Virginia and nationally. Neither are legitimate underlying causes of death. The important piece of information sought on the certification of death is not “that” a heart stopped beating but “why” the heart stopped beating. Terms of that nature are often referred to as “mechanisms of death,” “modes of death,” “agonal events,” or “terminal events,” and only serve to further attest to the fact that the person is dead. They are void of information and should not be used unless the underlying cause of the terminal event is also specified.

The Vital Registration Office, as the governmental agency responsible for the filing of death certificates in West Virginia, must balance the timely filing of death certificates for legal purposes and the accurate certification of cause of death. In the past, the balance was weighted heavily toward more rapid filing for legal use. Also, the broad assumption was made that all physicians automatically knew how to complete a death certificate as an extension of their extensive training and experience. Indeed, many physicians do an excellent job, especially those in specialties in which death of patients is a more common event. However, it has become clear that additional training and feedback to physicians must receive higher priority, stressing the importance of this issue. As a “first wave,” we invite all physicians to examine the basic training materials available on our website: http://www.wvdhhr.org/bph/hsc/ and welcome comments and inquiries on this subject.

Gary L. Thompson
State Registrar of Vital Statistics,
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The final Spina Bifida Clinic was held at St. Mary’s Hospital, West Virginia, in October 2009. It had been held regularly for almost 30 years for the benefit of children with neural tube defects. It ended, not because of lack of interest by the attending physicians, but because of declining incidence of this severe affliction.

When I was a medical student and resident in the 1960s, children with neural tube defects were rarely seen. In the pre antibiotic and early antibiotic eras death usually occurred early from meningitis. However with the development of the Holter valve and of magnification techniques in neurosurgery it is now possible to close the defects during early infancy. By the 1970s and early 1980s, new cases suited for neurosurgical treatment were encountered about once each month. Following surgery they were referred for follow-up care by orthopaedic surgeons and urologists. Since the incidence of neural tube defects is about one of every 2,500 live births, it became apparent in the early 1980s that a multi-disciplinary approach was necessary for optimal management. Thus, the Department of Children with Special Health Needs established clinics in Morgantown, Charleston and Huntington. Each was staffed by a neurosurgeon, a urologist, an orthopaedist and sometimes a pediatrician. Orthotists and seating specialists also attended to add their expertise.

The clinics provided services for the past three decades. Most of the children had problems with bowel and bladder control and required periodic urological evaluation and treatment. Anesthetic tissues in the areas of the buttocks and feet were prone to develop decubiti; these problems could be controlled with the use of molded orthotic devices and molded seating. Orthopaedic procedures are sometimes required for the correction of scoliosis, dislocated hips and club feet.
Visual defects occurred in some, secondary to pressure in the area of the optic chiasm from associated hydrocephalus. In earlier years urological diversion procedures were used, but later self-catheterization became the treatment of choice. The clinics not only afforded better coordination of care, avoiding the need for multiple visits to individual specialists, but also acted as sources of support for family members and other caregivers. They facilitated interchange of knowledge between the various specialists.

In the late 1980s one of my partners, Dr. John Mullen, together with Ms. Sally Oxley (a physical therapist) and Ms. Sylvia Boggs (a social worker) established the first spina bifida summer camp, held each summer at Cedar Lakes, West Virginia. This provided recreational activities and opportunities for socializing for the children and, of equal importance, a period of respite for their families and caregivers. I am aware of the existence of only one other such camp in the United States.

In those years many of us were hard put to explain the high incidence of myelodysplasia or neural tube defects among our children, an incidence secondary only to that in Wales. Some felt that perhaps a common gene pool of Celtic or Anglo-Saxon heritage might account for the similarly high incidence. At about the same time Dr. Lawrence, a pediatric geneticist in South Wales, published a paper linking the relatively high incidence to a dietary deficiency of folic acid. He had become aware of a report in the 1950s about the use of aminopterin (a folic acid antagonist) to induce therapeutic abortion; this had resulted in a high incidence of neural tube defects and anencephaly in the aborted fetuses. Lawrence then studied women who had had prior delivery of a child with spina bifida and found a marked decrease in incidence following the use of folic acid. A subsequent study in the *Lancet* in 1991 confirmed the decreased incidence of neural tube defects in a series of women who had had dietary folic acid supplementation.

Adoption of a policy of prenatal dietary supplementation in this country was delayed by a classic clash of bureaucracy between the Centers for Disease Control, the Food and Drug Administration, and the Federation of American Societies for Experimental Biology and Medicine. Eventually, in the 1990s, folic acid supplementation was adopted as a policy for prenatal care. Since then the incidence of myelodysplasia and neural tube defects has fallen dramatically. Since I do not regularly read obstetrical journals I was unaware of this change in prenatal care until quite recently when we became aware of the decrease in the number of new cases of defects in the Spina Bifida Clinic.

The addition of dietary folic acid added to enriched breads has also contributed to the reduction of neural tube defects.

Although the number of children with myelodysplasia was markedly less than those affected in the poliomyelitis epidemics of the past, the decline in the incidence is equally gratifying. Loss of motor and sensory function in the lower limbs and loss of control of bladder and bowel function are devastating handicaps, and the resulting dependency imposes major demands on parents and caregivers. The development of polio vaccine and its widespread use was a dramatic chapter in the history of medicine. Control of the much less common neural tube defects might be considered a mere numerical footnote by some, but not by those of us who have been involved in the care of these unfortunate children!

Thomas F. Scott, MD

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**Drug or Alcohol Problem? Mental Illness?**

If you have a drug or alcohol problem, or are suffering from a mental illness you can get help by contacting the West Virginia Medical Professionals Health Program. Information about a practitioner’s participation in the program is confidential. Practitioners entering the program as self-referrals without a complaint filed against them are not reported to their licensing board.

**ALL CALLS ARE CONFIDENTIAL**

West Virginia Medical Professionals Health Program
PO Box 40027
Charleston, WV 25364
(304) 414-0400 | www.wvmphp.org
Medicare Payments Stabilized Through 2011

On December 9, 2010, Congress passed a one year delay of the Medicare physician payment cut. On December 15, President Obama signed into law H.R. 4994, the “Medicare and Medicaid Extenders Act of 2010,” which stabilizes Medicare physician payments through the end of 2011. The legislation also includes funds to enable Medicare contractors to reprocess claims for physician services affected by provisions of the Patient Protection and Affordable Care Act with a retroactive effective date of January 1, 2010. AMA President Cecil Wilson, MD, and Board of Trustees Chair Ardis Hoven, MD, attended the ceremony, along with representatives of the AARP and the Military Officers Association of America, Senators John Barrasso, MD (R-WY) and Max Baucus (D-MT), and Representatives Pete Stark (D-CA), and Henry Waxman (D-CA).

In a statement made when this legislation cleared the Senate, President Obama noted: “It’s time for a permanent solution that seniors and their doctors can depend on and I look forward to working with Congress to address this matter once and for all in the coming year.” The WVSMA, along with the AMA, is committed to working to develop a long-term solution to the flawed Medicare physician payment formula that will achieve bipartisan support in Congress and by the Administration.

Red Flag Rule Update

On Tuesday, December 7, 2010, the U.S. House of Representatives passed S. 3987, the Red Flag Program Clarification Act of 2010. This legislation, which passed the Senate on November 30, was originally introduced by Senators John Thune (R-SD) and Mark Begich (D-AK) to limit the type of “creditor” that must comply with the Red Flags Rule.

The Red Flags Rule requires creditors to develop identity theft prevention and detection programs in their practices. As a result of continued discussions with FTC’s Chairman Jon Leibowitz and an aggressive congressional advocacy campaign, AMA efforts prompted the agency to delay the November 1, 2008 compliance deadline on several occasions, up through the end of 2010.

S. 3987 defines creditors as those who regularly and in the ordinary course of business: (1) obtain or use consumer reports, directly or indirectly, in connection with a credit transaction; (2) furnish information to certain consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, based on the person’s obligation to repay the funds or on repayment from specific property pledged by them or on their behalf. The legislation explicitly excludes those who advance funds on behalf of a person for expenses incidental to a service that is provided. Under this definition, the bill’s sponsors have stated that physicians, dentists, and other professionals would not generally meet the definition of a “creditor,” and so they are exempt from the rule’s requirements. However, the bill does leave open the possibility that the FTC may revisit the issue in the future through the process.

The legislation will now be sent to the White House where President Obama is expected to sign it into law before the January 1, 2011, compliance deadline.
Medicare News

If you are a Medicare Fee-For-Service physician, provider, or supplier submitting claims to Medicare for payment, this is very important information you need to know. Effective immediately, any Medicare Fee-For-Service claim with a date of service on or after Jan 1, 2010, must be received by your Medicare contractor no later than one calendar year (12 months) from the claim’s date of service – or Medicare will deny the claim.

If you have Medicare Fee-For-Service claims with a service dates from Oct 1, 2009, through Dec 31, 2009, those claims MUST be received by Dec 31, 2010, or Medicare will deny them. Claims with services dates from Jan 1, 2009, to Oct 1, 2009, keep their original Dec 31, 2010, deadline for filing.

When claims for services require reporting a line item date of service, the line item date will be used to determine the date of service. CR 7080, issued on July 30, 2010, clarified that for institutional claims containing claim level span dates of service (ie. a “From” and “Through” date span on the claim), the “Through” date on the claim shall be used to determine the date of service for claims filing timeliness. Conversely, professional claims containing claim level span dates of service (ie. a “From” and “Through” date span on the claim), the “From” date on the claim shall be used to determine the date of service for claims filing timeliness.
**WVU’s Dr. Hassan Ramadan honored by national group**

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) recently presented Hassan Ramadan, M.D., professor and vice chair of the West Virginia University Department of Otolaryngology, with its Distinguished Service Award.

Dr. Ramadan received the award in recognition of his exceptional services in the scientific programs, exhibits, continuing education courses and instructional courses of the society. He became a member of the society in the early 1990s. Since that time, he has participated in every annual meeting of the AAO-HNS with a scientific course, poster or presentation.

“I like to go to the meetings both to teach and to learn. It’s an opportunity to connect with colleagues in the field and exchange ideas, like new research and techniques, with them,” Ramadan said. “It’s great not only to learn but to share and teach. It’s very rewarding and satisfying.”

The AAO-HNS presented Ramadan with the award at its 2010 Annual Meeting and OTO EXPO, which was held Sept. 26-29 in Boston. The meeting is the largest gathering of otolaryngologists in the world with more than 165 scientific research sessions, 200 posters and more than 300 instruction course hours for attendees.

For more information on the AAO-HNS see [www.entnet.org](http://www.entnet.org).

For more information on the WVU Department of Otolaryngology see [http://wvuhealthcare.com/services/otolaryngology/index.aspx](http://wvuhealthcare.com/services/otolaryngology/index.aspx).

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**Dr. Robert Gustafson honored by Children’s Miracle Network**

Robert Gustafson, M.D., who’s known as “Dr. Gus” to his young patients at West Virginia University Children’s Hospital, has helped to save the lives of thousands of West Virginia children. Now he’s being honored with an international award for his work as the state’s sole provider of pediatric heart surgery.

The Children’s Miracle Network (CMN) recently presented the Children’s Miracle Achievement Award to Dr. Gustafson, surgeon-in-chief at WVU Children’s Hospital and chief of pediatric cardiothoracic surgery. He is one of three medical professionals to receive the award this year. It is given in recognition of “commitment to children’s health and the notable work they’ve made in their respective fields.”

A native of Keyser, W.Va., Dr. Gustafson completed his medical education, internship and residency at WVU. Following a pediatric cardiac surgery fellowship at Children’s Hospital Medical Center in Boston, he joined the faculty at WVU in 1984.

“Helping these children thrive is the best gift I can give.”

In nominating him for the award, Cheryl Jones, R.N., director of WVU Children’s Hospital, said, “Dr. Gus is the cornerstone and essence of our mission to serve the children of West Virginia. Through his efforts, increasing numbers of children are able to stay in West Virginia for care. He is a visionary, whose leadership has had a positive impact on children on the state, national, and international level. In his career, he has had more than 4,200 patient discharges, including those from Africa, where he gives of his time and talent to repair the broken hearts of children.”

Giovanni Piedimonte, M.D., chair of the WVU Department of Pediatrics and physician-in-chief at WVU Children’s Hospital, also wrote a letter of support for Dr. Gustafson. “His reputation is built on more than just clinical skill. He is a friend, advisor and confidante of young parents in their time of crisis,” Dr. Piedimonte wrote. “He creates lasting relationships with his patients as they grow and heal. He is a leader among our faculty, and is respected and admired by our nurses and staff.”

WVU Children’s Hospital provides maternal, infant and pediatric care for West Virginia and the surrounding region, giving care to high-risk mothers, premature infants and children with life-threatening conditions through adolescence to adulthood. It is the only Children’s Miracle Network hospital in the state. For information on WVU Children’s Hospital, see [www.wvukids.com](http://www.wvukids.com).

The CMN was created by the Osmond Foundation in 1983, and includes 170 hospitals throughout the United States, Canada and Mexico. For information on Children’s Miracle Network, see [www.childrensmiraclenetwork.org](http://www.childrensmiraclenetwork.org).
Researchers get more than $780,000 for breast cancer studies

Two Marshall researchers have been awarded federal funds totaling more than $780,000 to assess the effects of omega-3 fatty acids on breast cancer development.

The U.S. Department of Defense Breast Cancer Research Program awarded Dr. Elaine Hardman of the Department of Biochemistry and Microbiology and Dr. Philippe Georgel of the Department of Biological Sciences competitive grants of $460,249 and $320,750. The grants were among only 18 awarded nationwide through the program.

Over the next two years, Hardman and Georgel will use the funds to confirm earlier observations that consumption of canola oil, as a source of omega-3 fatty acid in the maternal diet of mice, could reduce risk for breast cancer in the offspring. They also will identify the genetic changes associated with a maternal diet that contains omega-3 fatty acid. They hope to find out how canola oil is altering the expression of genes, with the goal of developing a panel of biomarkers to assess risk for breast cancer development in humans.

According to Hardman, the studies highlight the importance of diet in altering — either reducing or increasing — cancer risk, and the importance of maternal diet in cancer risk of the offspring.

“Clinically, this is exciting,” she said. “We know that maternal diet is important for the immediate health of the baby but are just beginning to learn of the importance for long-term health. If a woman can be very careful of her diet for the time of gestation and lactation, the baby may have reduced risk for not only cancer but also heart disease and diabetes.”

Hardman said she found in an earlier study that the maternal diet containing a small amount of omega-3 fatty acids from canola oil was reducing breast cancer risk in the female offspring, even those weaned to a usual diet.

“This had to be an epigenetic influence — changes in gene expression not due to a mutation but due to markers placed on the chromatin,” she said. She and Georgel, an expert in changes in chromatin structure, collaborated on preliminary studies, which demonstrated a change in chromatin structure associated with changed gene expression that could reduce risk for breast cancer. That paved the way for the new DOD grants.

Georgel said the team’s work highlights the importance of studies of epigenetic events, or events that alter the activity of genes without changing their sequence.

“The generation of disease-specific epigenome maps will provide complementary and crucial information to the already well-established genome map,” he said.

Hardman said the grants will serve as a good foundation for the new Marshall University Nutrition and Cancer Center, which will support multiple researchers.

Once the current studies are complete, Hardman said, she and Georgel may explore whether or not diet changes later in life will also reduce cancer risk by the same or different mechanisms.

Human Research Protection Program awarded reaccreditation

Marshall University’s Human Research Protection Program has been awarded a five-year reaccreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The designation means Marshall’s program continues to meet or exceed all federal regulations regarding human subject research.

AAHRPP is an independent, non-profit accrediting body that works to protect the rights and welfare of research participants and promotes scientifically meritorious and ethically sound research.

Accreditation means that Marshall University is part of an elite group of institutions internationally renowned as promoting exceptional ethical and professional standards in the conduct of human subject research.

Marshall has two Institutional Review Boards, led by Dr. Henry Driscoll and Dr. Stephen Cooper.
WVSOM Students Take Second Place at Research Competition

Student researchers from the West Virginia School of Osteopathic Medicine (WVSOM) recently placed second in a national research poster competition. WVSOM second-year students Amanda Whaley, Maryna Popp and Joshua Smith won second place during the competition at the American Osteopathic Association’s 115th Annual Medical Conference and Exposition held in San Francisco on October 24-28. The students were competing with students from 26 other osteopathic medical colleges across the country.

“I am very proud of our students for their interest and dedication to research,” stated Michael Adelman, D.O., J.D., Acting President. “They represented WVSOM and our state very well on a national level.”

Student researcher Popp commented, “It’s great to see that meaningful research is being done at our school and that our passion, efforts and teamwork were recognized by the American Osteopathic Association.”

The winning poster title is “The Efficacy of Using a Small Molecule Inhibitor of Bcl-2 in the Treatment of Breast Cancer.” Additional authors are WVSOM Clinical Laboratory Instructor Bethany Hampton and Brian Griffith, Ph.D., assistant professor of Biochemistry.

“Amanda, Maryna and Joshua’s AOA research poster award is a great achievement for our students and for WVSOM,” said Dr. Griffith, explaining the students’ research focuses on finding new treatments for breast cancer, specifically the efficacy of the drug MNB.

“We were honored to represent WVSOM at the AOA conference and thrilled by the opportunity to share our investigations with our colleagues in San Francisco. Our hope is that the spotlight shown on our school helps to increase the desire to conduct research at WVSOM and to find better curative treatments for all cancers,” explained Whaley.

WVSOM Hosts Greenbrier East HOSA Students

The West Virginia School of Osteopathic Medicine (WVSOM) hosted 150 students from the Greenbrier East High School chapter of the Health Occupation Students of America (HOSA) club on November 9. The goal of the visit was to introduce the HOSA students to a variety of health science career options. Students not only learned what it means to be an osteopathic physician, but also about careers in nursing, pharmacy, public health, social work, physical therapy and emergency response.

Students toured the WVSOM campus, visiting the Science Building for a Human Gross Anatomy presentation. Students also visited the Clinical Evaluation Center and observed a demonstration of the Human Patient Simulators.

Haylee Heinsberg, Executive Director of the Southeastern Area Health Education Centers, says the WVSOM program and others like it help plant a seed for the future. “Programs like we offered today help to spark the interest of high school age students in the areas of science and health care,” Heinsberg said.

“There’s a shortage of health care professionals in rural areas of West Virginia and across the country. We hope that by offering educational pipeline programs, students will consider pursuing a health professions degree in college and eventually practice in areas that traditionally suffer from a lack of health care providers,” Heinsberg explained.

Kelly Shreve, MS, CHES, Threat Preparedness Coordinator for Monroe County, said WVSOM is a wonderful resource for area high school students to learn about medicine and science. “Having WVSOM in our backyard presents us with a wonderful opportunity to introduce local students to career possibilities in the health sciences,” she said. Shreve said they would like to widen the scope of future events to include HOSA students from other local area high schools as well.

Sponsors included Southeastern AHEC, Greenbrier Valley Medical Reserve Corps and Greenbrier County Emergency Management Agency.

The Greenbrier HOSA Chapter is part of West Virginia HOSA, a student organization of over 1,600 high school students across the state. Over 80 percent of student members ultimately pursue further education in health and medical careers.
Electronic Patient Care Records Implemented for West Virginia Emergency Medical Services

Quality is defined by the Institute of Medicine (IOM) as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Lohr, 1990). The IOM stated in their publication, Crossing the Quality Chasm (2005), that if there is to be a substantial improvement in health care quality in the coming decade, information technology must play a central role in the redesign of the healthcare system. In 1991, the IOM issued a strong call for nationwide implementation of computer-based patient records to support evidence-based practice (Institute of Medicine, 1991).

Healthcare researchers have determined the use of information technology can increase accountability for performance and improve coordination among health care providers (Blumenthal, 1997; National Committee for Quality Assurance, 2000), reduce errors and harm from errors (Bates et al., 1998; Raschke et al., 1998), support research (Blumenthal, 1997), make up-to-date evidence and decision support systems available at the point of patient care (Berner et al., 1999; Classen, 1998; Evans et al., 1998; Hunt et al., 1998), and help make quality measurement timely and accurate (Schneider et al., 1999).

The West Virginia Office of Emergency Medical Services (OEMS), under the direction of Jerry Kyle, BS, EMT-P, has implemented a statewide electronic patient care reporting system for pre-hospital providers and EMS agencies in West Virginia that are certified or licensed through OEMS. Beginning July 1, 2010, for the first time ever in West Virginia, all EMS agencies licensed to practice in the state, are submitting all patient care records electronically to the Pre-hospital Management Information System (PreMIS). Through a contract with the North Carolina based EMS Performance Improvement Center located at University of North Carolina, Chapel Hill, West Virginia OEMS has been able to collect data that will improve the quality of pre-hospital care for West Virginia citizens.

During the recent statewide EMS Conference, Dr. Greg Mears presented preliminary WV PreMIS data looking at a range of data elements from patient demographics to pre-hospital treatment provided and procedures performed. The graphs below provide a look at EMS personnel certified statewide, including those participating in the medical direction system.

It is an exciting time in pre-hospital care in West Virginia. The focus for the future is on performance measurement, in particular, increased quality in service delivery, professionals and patient care. In addition, performance improvement measures are being developed to complement the existing protocols. We are now able to identify opportunities that improve patient safety, including treatment, triage, and transportation to the most appropriate facility. In addition, there are opportunities to improve the education of EMS/Hospital personnel as well as patients and their families.

Drema Mace, PhD
Director, State Trauma and Emergency Medical System (STEMS)
Department of Health and Human Resources

Greg Mears, MD
EMS Performance Improvement Center

Robert Dozier, MA
STEMS Data Analyst
Risk Management: Can Medical Professional Liability Underwriting Be of Assistance in Physician Recruitment?

by Steve Brown, Agency Manager

Our agency is frequently asked if we can provide insurance coverage for a recently recruited physician that will join an existing practice in the next 30 days. This often alarms us as agents because we believe the underwriting process can be of benefit to the recruiting process.

We have seen some very negative results regarding physician recruits who were hired and expected to become partners in a few years only for things to just not workout between the parties.

While this article is not intended to help with personality issues, medical professional liability underwriting can be utilized as a resource in the recruitment process to avoid practice-type issues that could surface in the future.

Because risk is being transferred to the insurer, underwriters need to know the nature and severity of the hazards they are accepting and generally prefer less hazards to more. In the case of medical professional liability insurance, the underwriting hazard is generally the person to be insured; therefore, the underwriting process is focused upon people and the subsequent ability of the insurer to successfully defend the actions or failures to act by their insureds.

We recommend that any physician that is being offered a contract by another solo practitioner or a group be required to obtain insurance from the insurance carrier that insures the practice currently as a condition of acceptance of that offer.

While this may appear to be a meaningless requirement, it does provide another source of confirmation of the character, qualifications and experiences of the recruit.

What does the underwriter look at when evaluating a new risk for coverage? Of course the company’s application is a starting place and it includes the standard items of educational background and previous work experiences. On the surface these appear to be pretty much “given” information, but a closer inspection of these matters may uncover meaningful time gaps in the various phases of training, difficulties in achieving board certification, a pattern of “short” stays or frequent relocations; all of which may be easily explained, but any one of which could ultimately be detrimental to the practice.

In addition, the underwriter will review the applicant’s previous claims history; evaluating not only the results, but the actual medicine performed in open and closed claims. Board of Medicine complaints are also a source of information that will be evaluated. While the Board’s actions are important, the information in the complaint and the applicant’s response are probably more informative about the applicant.

Other application questions pertaining to hospital privileges, medical and narcotic licenses, physical injury or illness and violations of law all serve to secure information about an applicant to determine insurability as well as defendability. These items may all be red flags when looking for partners in your practice.

Red flags are important for evaluation purposes and if enough exist, an insurance carrier’s rejection of a risk may serve as a legitimate way to terminate a relationship without legal difficulties if the contractual requirement of acceptance (by the current carrier) is included in the offer.

In the case of building contractors, sureties are utilized to provide guarantees of a fulfillment of a promise by the contractor, while insurance companies accept the risk of the insured. But in both cases, the surety and the insurance company are obligated to scrutinize a risk and decide on the eligibility for coverage.

As a risk management tool, in this case “problem identification,” we recommend that the physician community take advantage of the underwriting responsibilities of their own insurers. This assistance benefits all parties in the long term.

While we are discussing new physician recruitment and contractual offers of employment, etc., this is a good opportunity to also discuss the handling of tail issues.

Since new relationships do not always work out, addressing the
handling of tail coverage in the initial contract offer will serve to address issues before they occur. For example, if a new recruit accepts the offer to practice with a group, but ultimately is only with the group one or two years, an issue can develop over who is responsible for the purchase of tail coverage. If this matter is addressed in the initial contract it has essentially been resolved.

We suggest that a time period be determined that will satisfy the group, creating comfort for the group to accept responsibility for the recruit’s tail coverage. Generally two years will be enough time for the entire group to make a determination about the long term status of their recruit and vice versa. Therefore, if the recruit leaves within the first two year period, the recruit can be responsible for the tail coverage, but after two years, the group will accept the responsibility. Regardless of the time period, the initial contract offer should address responsibility for tail coverage if or when the recruit leaves the practice.

New Physician Insurance Orientation Program

As a way to involve newly recruited physicians or physicians coming out of residency and joining an existing practice or starting solo, the West Virginia Medical Insurance Agency has developed an insurance orientation program for new practitioners to become more aware of the insurance issues related to a West Virginia practice.

This one-day insurance orientation program focuses on medical professional liability insurance, but also includes presentations on business owners insurance, workers’ compensation, individual health, life, and disability as well as group health, life, disability, vision and dental insurances.

Call Steve Brown, Agency Manager, West Virginia Medical Insurance Agency to schedule a New Physician Insurance Orientation Program designed specifically for your needs.
2010 WESPAC Contributors

The WVSMA would like to thank the following physicians, residents, medical students and Alliance members for their contributions to WESPAC. These contributions were received as of December 14, 2010:

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**Donor**
- Pedro F. Lo, MD
The West Virginia State Medical Association’s recently held conference was a tremendous success! The conference, “Prescribing in a World of Drug Diversion and Substance Abuse: Dealing with Key Issues Affecting Your Patients” was well attended by physicians, dentists, practice administrators, and many others, including government and health plan officials.

The conference focused on key issues relating to prescription fraud and abuse, including the appropriate use of prescription drug monitoring tools; new developments in safe pain management; critical issues in patient confidentiality; ethical and legal ramifications of treating or not treating pain; managing both the acute and chronic pain patients; and updates on drug treatment policies, guidelines and legislation.

According to the Substance Abuse and Mental Health Services Administration, West Virginia has one of the highest drug overdose death rates in the nation, due in part to the nonmedical use of prescription drugs. The National Institute on Drug Abuse reports that West Virginia also leads the nation with the most written prescriptions per patient at 18.4 per person compared to the national average of 11.6 per person annually.

The keynote speakers at the conference included Mary E. Johnson-Rochee, Diversion Program Manager, DEA, Washington Division, and J. David Haddock, MD, DDS, Vice President, Health Policy of Perdue Pharma, L.P. Other speakers included Sgt. Mike Lafauci and Sgt. Mike Smith of the West Virginia State Police Drug Task Force, Michael O’Neil, PharmD, J.K. Lilly, MD, Carol Foster, MD, Khalid Hasan, MD, Brittain McJunkin, MD, and Mary Lou Lewis, MD.

Attendees had great praise for the conference and suggested that much more education is needed on the topic of prescription drug abuse. The WVSMA is planning more activities on this topic and will keep our membership informed of new developments on this important issue.
Paul Francke Jr., MD

Paul Francke Jr., 88, died at home on October 21, 2010.

He was born September 7, 1922, in Middletown, NY, and was educated in public schools in Highland Park, NJ, Toledo, Ohio, and Chicago, Ill. After graduating from the University of Toledo, he obtained his medical degree from the University of Chicago and did a radiology residency at Presbyterian Hospital in Chicago. Dr. Francke served in the Army Medical Corps from 1943-1945, followed by two years of service for the U.S. Public Health Service in Greenwood, MS. There he met Ardath Stanton, and the two were married July 1, 1949. In 1952, they moved to Charleston, where he practiced radiology for the next 44 years.

During those years he was an active member of the Kanawha Valley Medical Society and various state and national radiologic societies. Dr. Francke enjoyed teaching as a professor of radiology at both the Charleston Division of WVU School of Medicine and, in later years at Marshall University School of Medicine.

He was a member of the First Presbyterian Church, Charleston, since 1952, where he enjoyed exploring the interface of science and religion. An avid athlete, he ran track in high school and college. Tennis was his passion, but he also enjoyed table tennis, skiing, horseback riding and golf.

Dr. Francke was preceded in death by his parents, Paul Francke Sr. and Sophie Lavater Francke; sister, Anita; and brother, Walter.

He is survived by his wife, Ardath; daughters Beth Lynn (John), Ann McWhorter (Dick), Wendy, Paula (Bob); son, Rick (Georgie); 13 grandchildren and two great-grandchildren.

Memorial contributions can be made to the First Presbyterian Church, 16 Leon Sullivan Way, Charleston, WV 25301.

You may send your condolences to the family at www.barlowbonsall.com.

David Z. Morgan, MD

Dr. David Zackquill Morgan died at home on November 5, 2010, after a brief illness. He was born in Fairmont on March 27, 1925, and was the son of Myrtle Marie Knotts Morgan and John Odgen Morgan.

Dr. Morgan was a graduate of the old Kingwood High School and entered into the U.S. Navy V-5 program, allowing him to receive college credits at Hampden Sydney College and Emory and Henry College in Virginia. He finished his military career as a LTJG Captain of a landing craft tank in the Philippines.

After the war, Dr. Morgan return to Morgantown to pursue his lifelong dream of becoming a physician and graduated from the two-year medical school at West Virginia University. He completed his MD degree at the Medical College of Virginia in Richmond, VA as part of an agreement between the state of West Virginia and MCV. Dr. Morgan then completed an internship at the Ohio Valley General Hospital in Wheeling.

Dr. Morgan worked as a general practitioner in Morgantown throughout the 1950s. He was a dedicated physician who always took pride in putting his patients first. In 1960, with the advent of the new WVU 4-year medical school, he completed a residency in Internal Medicine and ultimately became a faculty member in the department of internal medicine. His 30-year academic career was highlighted by his time as a dedicated clinician and his time as associate dean for student affairs. His academic career also led to hundreds of long-term career relationships with medical school graduates. In his later years, he became the director of the first geriatric program at WVU. He was also an advocate for medical legislative issues in the state of
West Virginia and served as the president of the West Virginia State Medical Association.

Despite being active as a physician, Dr. Morgan believed in service to the state with a special interest in Morgantown and the University. He served on committees that helped to rewrite Morgantown’s charter and future planning projects. With the help of many others, through CLIC, Dr. Morgan helped to establish the Village at Heritage Point, which was the tangible result of his foresight and planning.

Dr. Morgan is survived by his loving wife and partner of 17 years, Mary Jane Morgan; his son, David M. Morgan and wife Claudia Goodwin Morgan of Morgantown; daughter, Susan K. Morgan and husband Richard C. Brooks of Morgantown; granddaughter, Lauren Morgan Swager and husband Charles M. Swager of Morgantown; grandson, Evan Z. Morgan and wife Rebekah L. Aranda of Durham, NC; and great-grandson, William H. Swager. He is also survived by his stepson, Gerald Postlethwaite and wife Stacey Postlethwaite of Pittsburgh, PA; stepdaughter, Sara Postlethwaite and husband Richard Winebole of Aaronsburg, PA; stepdaughter, Bethany Connors and husband John Connors of Hopwood, PA; step-granddaughters, Iris and Selene Whitworth and Bailey Neville; and step-grandsons, Daniel and Eric Postlethwaite.

He was preceded in death by his parents; and four siblings, Jane, Betty, Rose, and John. He was also preceded in death by his first wife of 42 years, L. June Nixon Morgan.

Gifts of remembrance may be sent to the West Virginia University Alumni Association Loyalty Permanent Endowment at PO Box 4269, Morgantown, WV 26504.
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