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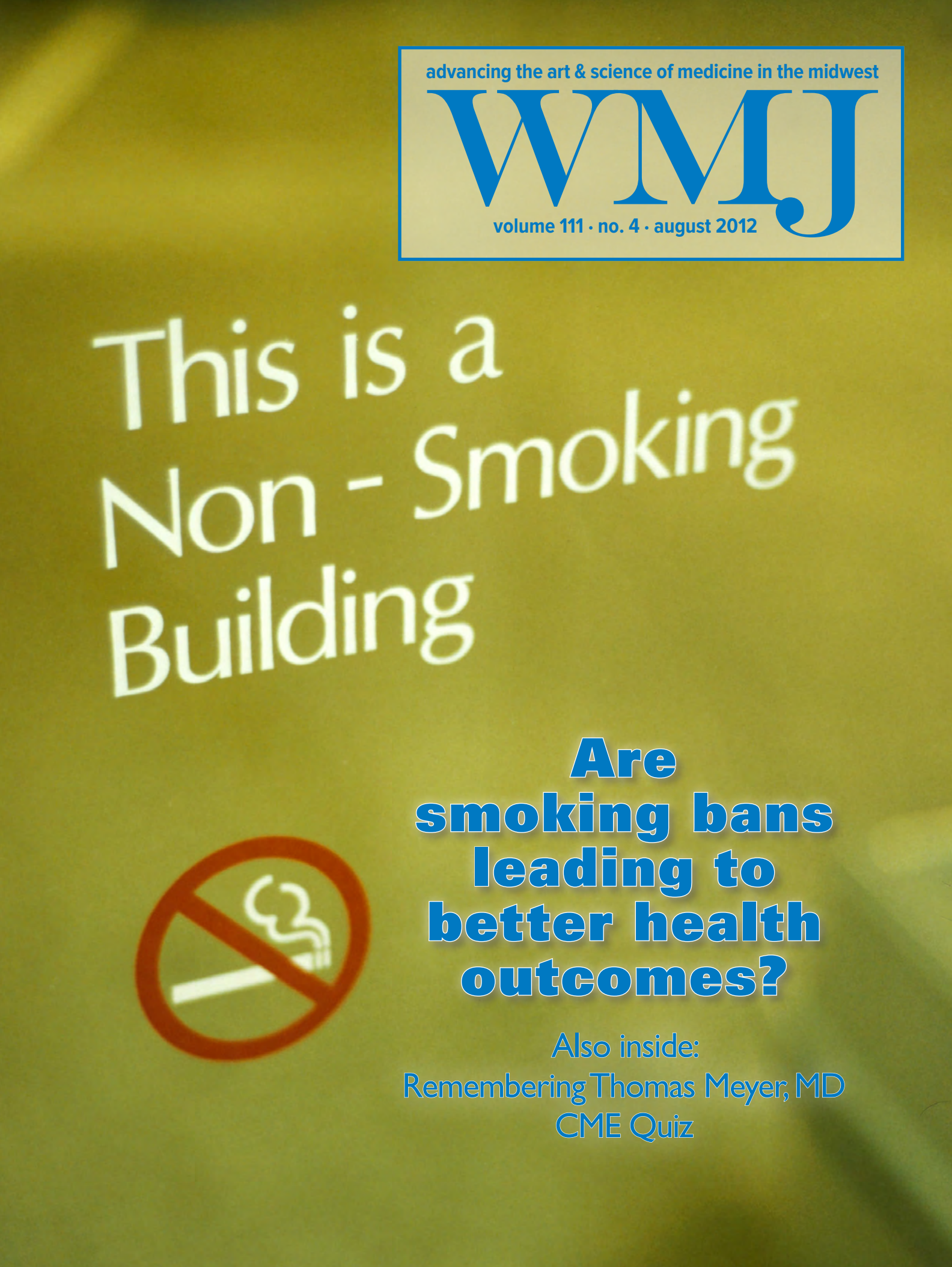

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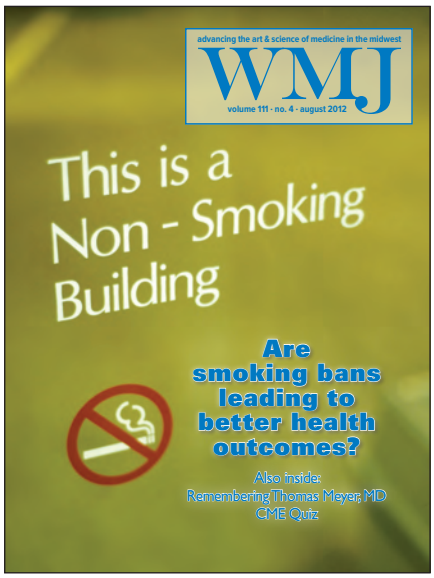

COVER THEME
Are smoking bans leading to better health outcomes?

Wisconsin's statewide tobacco ban is just one example of public policy's potential to make a lasting impact on public health. This issue of *WMJ* examines initial results of that smoking ban, along with prevention and the cost of technology—policies and issues that affect everyone.

Cover design by Mary Kay Adams-Edgette.

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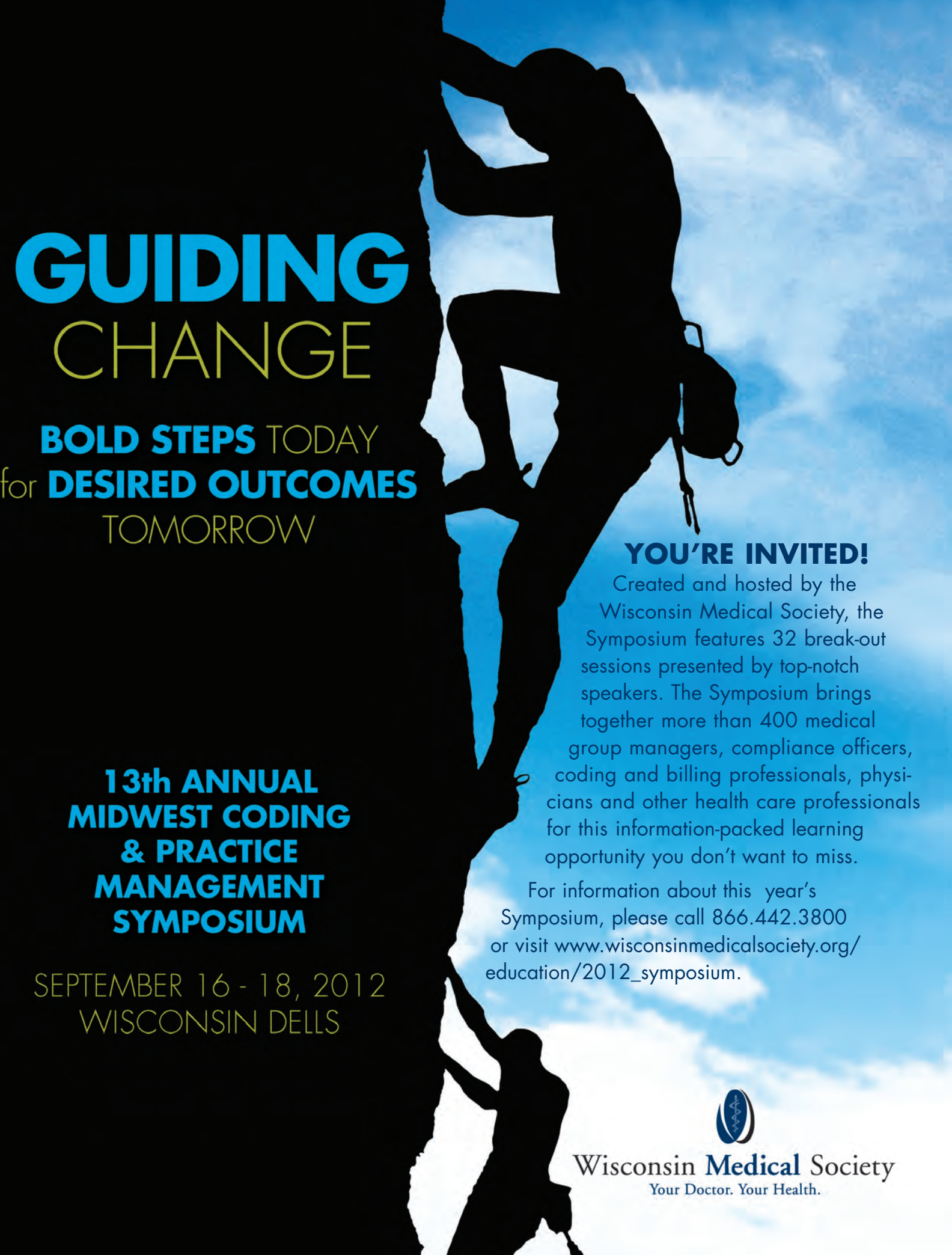

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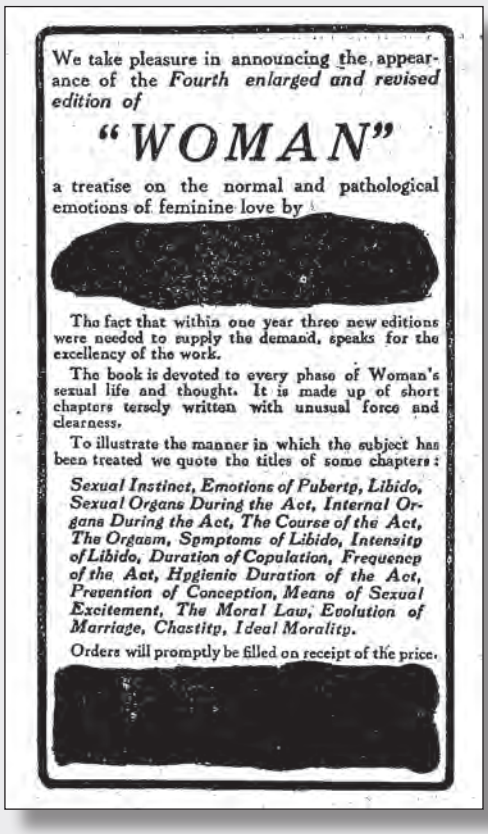
Sauce for the Gander

Arthur J. Patek, MD, Editor; Hoyt E. Dearholt, MD, Managing Editor

Editor's note: The following is from an editorial published in WMJ, *Volume 7 (No.9), February 1909, p. 536-538.*

Consistency must ever be the crowning jewel in the diadem of the anointed. And inasmuch as the *Journal of the American Medical Association* is the anointed power of the institution it represents, we must look there for a lavish display of consistent acts. Ever and anon the Association's *Journal,* now *sans peur, sans reproche,* ('twas not ever thus) takes a fall out of some thrifty, perhaps striving, journal because the latter does not find it consistent with its mode of thinking and its spirit of independent cogitation to conform in every particular to the rules that now govern the Association's *Journal*. Therefore it is but just that we ask the *Journal* to show the same critical sense of its advertising pages that it demands of others.


We take pleasure in announcing the appearance of the *Fourth enlarged and revised edition of*

"WOMAN"

a treatise on the normal and pathological emotions of feminine love by

[redacted]

The fact that within one year three new editions were needed to supply the demand, speaks for the excellency of the work.

The book is devoted to every phase of Woman's sexual life and thought. It is made up of short chapters tersely written with unusual force and clearness.

To illustrate the manner in which the subject has been treated we quote the titles of some chapters:

Sexual Instinct, Emotions of Puberty, Libido, Sexual Organs During the Act, Internal Organs During the Act, The Course of the Act, The Orgasm, Symptoms of Libido, Intensity of Libido, Duration of Copulation, Frequency of the Act, Hygienic Duration of the Act, Prevention of Conception, Means of Sexual Excitement, The Moral Law, Evolution of Marriage, Chastity, Ideal Morality.

Orders will promptly be filled on receipt of the price.

[redacted]

A recent issue of that *Journal* contains the advertisement of a book, now appearing in its fourth edition, which advertisement, because of its indecency and obscenity, outranks in relative harmfulness any dozen or more misrepresented preparations that formerly found a welcome home in the *Journal*'s advertising pages, and have now been numbered with the outcasts.

We are not concerned with the subject matter contained in this book; it matters little whether the book was begotten in virtue or in sin; whether it be a treatise scientific beyond reproach—giving forth much needed information on sexology to the un- and mis-informed profession, or a cleverly constructed medium through which, in the guise of science, to pander to the lowest instincts of the second, third and fourth edition readers. Our protest is directed to its foul advertisement as carried in the *Journal*. We here reproduce the announcement, omitting the name of the book and that of the publishers, because of our disinclination to further its sale by any form of publicity.

We would call attention to the further fact that the paragraph headings here reproduced are not those contained in the book in this form, but are selected from several chapters and published in the arrangement as here presented in order to stimulate the reader's "libido" for an acquaintance with the original. Though the facts may be otherwise, there is hardly a line in the advertisement to indicate that this book contains anything but the veriest filth.

This advertisement arouses our disgust.

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Remembering Tom Meyer

John J. Frey, III, MD, *WMJ* Medical Editor

I met Thomas Meyer, MD, shortly after I moved to Madison in 1993. He came to talk with me about a program he had developed through the office of continuing education at the University of Wisconsin that assessed and prescribed programs for remediation for physicians in trouble.

After participating in the program over 15 years, I came to realize that Tom was a national innovator who influenced many similar programs across the country. He was much too humble and self deprecating to take credit for the idea, but others recognized him and his work. He approached it as he did most interactions with colleagues—with thoughtfulness, generosity, compassion, and humor. He said we all were potential candidates for the program and my interaction with the doctors who I met during those assessments confirmed Tom's point of view. Physicians were sent to the 2-day assessment by their hospitals or insurance as a condition of continued practice, and Tom made what could have been a humiliating experience one of kindness and understanding. If physicians entered angry and defensive, it was because of the way that Tom and his colleagues treated them, they left feeling that they had had an opportunity to redeem themselves and that, whatever the overall recommendations, they were fairly treated. It is how everyone who ever interacted with Tom Meyer felt, in the end. The experience inspired me to reflect on my own struggles, faults, and need for redemption.[1]

I came to know Tom at our breakfast meetings at Mickies Dairy Bar and even though he was a trained cardiologist, I never felt that he looked with contempt at my usual bacon and eggs and potatoes. He would just offer me a statin with my coffee.

Thomas C. Meyer, MD, 1926-2012

His work on the *WMJ* and with the Wisconsin Medical Society was a continuation of his role as gentle teacher and guide for colleagues. His letters to authors were, in keeping with his nature, encouraging and positive while still letting the author know that a revision would require a great deal of work. His suggestions about my own letters were always funny but instructive. "He might respond a bit less angrily if you phrased this another way." And he was always right. He remained a wonderful teacher and colleague even though he struggled with chronic illnesses for a decade, making jokes about his "Swiss cheese brain" while continuing to be positive and exploring the world.

The most remarkable thing about Tom was his thoughtfulness. Because of a terrible tragedy that involved the death of a medical student and injuries to others and to a faculty member, I had to fly on less than 24 hours notice to Johannesburg, South Africa in the summer of 2000. I had no idea what to expect when I got there and was anxious and sleepless when I arrived. As I came through customs, I saw a tall man with a sign with my name. He introduced himself as Tom Meyer's brother, a GP in town, and said that Tom had called him and asked him to come meet me as I would probably need some help. I have no idea how Tom heard of the tragedy or how he knew I was traveling to South Africa but I will never forget his and his brother's kindness. Tom's first reaction to almost anything, it seems, was what could he do to help—whether a physician struggling with deficiencies, an author struggling with writing, or a colleague under pressure. Tom Meyer was a compassionate and humane physician who lived a full and remarkable life in the service of the profession and touched the lives of generations of doctors. We should all be so fortunate.

Reference

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• • •

Doctor Meyer was medical editor of WMJ from 1995 to 2007. Before he retired, Dr Meyer was a professor of pediatrics at the University of Wisconsin Medical School, where he also served as associate dean. He was director of the medical school's Office of Continuing Medical Education and also served as medical director of St. Mary's Hospital/Medical Center in Madison.

Physician's Passion for Books Benefits Youngest Patients and Families

Kendi Parvin, *WMJ* Managing Editor

"I grew up with books; I read constantly. My relatives always said they never knew what I looked like because I always had a book stuck in front of my face," said Wendy Molaska, MD, a family physician who has made her passion for reading an integral part of her practice.

Since her residency, Dr Molaska has been a champion of Reach Out and Read (ROR), a program that promotes early literacy and school readiness by getting books in the hands of children beginning at 6 months of age.

During well-child visits, physicians give each child between 6 months and 5 years old a new book to take home that is age-, developmentally and culturally appropriate. They also discuss with parents the importance of reading aloud to their children each day, and for those parents who may feel uncomfortable or hesitant to read aloud to their kids, they offer encouragement and suggestions.

ROR data indicate that while "34% of American children entering kindergarten lack the basic language skills they will need to learn to read," the ROR model is an effective, low-cost intervention. "Parents involved with ROR are 4 times more likely to read with their children; parents for whom English is a second language are 10 times more likely to read with their children. Children participating in ROR score significantly higher on vocabulary tests and start kindergarten with a 6-month developmental edge."

"I got introduced to Reach Out and Read in residency and thought it was such a cool program," said Dr Molaska, who completed her residency at North Memorial Hospital in Minneapolis, Minnesota, where the diverse population included African American, Hispanic, Hmong and Somali patients.

Wendy Molaska, MD

"I saw how important Reach Out and Read was because it was a very underserved population and English was a second language for many patients," Dr Molaska said. "Many of the parents were illiterate, so we did a lot in terms of other literacy skills; we had referral sources to help them. Even without reading ability, parents can still point to pictures and work on language. It's time together—without TV."

Following her residency, Dr Molaska moved to Fort Morgan, Colorado, where she practiced in a federally funded community health center.

"The Fort Morgan clinic didn't have ROR but needed it," she said. "Its population was very underserved, mostly Spanish speaking, and many of the kids had no books at home. When it comes to buying food or buying books, people are going to buy food."

So Dr Molaska, who says she "can't imagine a life without books," worked with the Colorado Reach Out and Read Coalition as well as an Americorps volunteer at the clinic to establish a ROR program there. In addition to providing new books to children during their well-child visits, gently used books were placed in the exam rooms and waiting room for patients to take home. Families also were encouraged to visit their local library.

After 4 years in Colorado, Dr Molaska returned to her native Wisconsin in 2008, joining Dean Clinic-Platteville. And when she learned the clinic did not have a ROR program, she quickly went to work to establish one. Unlike Colorado, at the time Wisconsin did not have a ROR coalition to help establish the new program. (See sidebar.) But that didn't deter her.

"I feel that it's such a huge part of my practice in general that I couldn't give it up," Dr Molaska said. "I think everyone can benefit from the message of reading."

Dr Molaska completed the necessary paperwork and applied for grants to secure startup funding. Thanks in part to a $2000 grant from the Wisconsin Medical Society Foundation, the program was launched in May 2009.

For Dr Molaska's clinic, which has 700 to 800 well-child checks for patients in the

target age range, the program costs about $2000 per year. The only overhead is the cost of books, which are usually donated or purchased at a substantial discount through Scholastic and other book groups. Since July 2009 the clinic has distributed more than 2000 new books.

As the medical director for the clinic's ROR program, Dr Molaska completes and submits progress reports to the ROR National Center twice a year and continues to seek funding. In addition to grants from local businesses and larger corporations, she said the program has received support from the national ROR center (when available) as well as Dean Health System, which Molaska says "is recognizing the huge impact the program has." Community members, colleagues, local groups and others have donated both money and books as well. In fact, when she and her husband were married earlier this year, they asked that guests consider making a donation to the ROR program or one of their other favorite charities instead of buying gifts.

Obtaining funding for books hasn't been the only challenge Dr Molaska has faced, however. Initially, some of her colleagues expressed reservations about getting involved in the program.

"I think for a lot of physicians the initial reaction is we're already busy; we already do all this paperwork; it's just another thing we're adding on to our plates," she said. "That was the big drawback to providers initially. Everybody thinks it's going to add extra time, but it doesn't. It really doesn't."

"Your first minutes in the exam room are always trying to establish rapport with the child and being able to get into his or her space so that later you can do the exam," Dr Molaska said. "If I'm coming in with a book for them it's a much easier way to establish rapport." As she talks with parents about any concerns they have, she said she also is able to assess the child's gross motor skills, visual tracking, verbalization and other developmental milestones by watching how he or she interacts with the book.

"Kids come in for their well child checks and we give them shots and a sticker. Now we get to give them a book and we get to use the book for our own benefit. So it really doesn't add time," she continued.

Family physician Wendy Molaska, MD, shares books with 3-year-old Owen, 5-year-old Catie and their mom Amanda. The books are part of Reach Out and Read, an evidence-based program championed by Molaska that encourages parents to read aloud to their kids each day.

And despite some initial hesitation, today Dr Molaska's colleagues have embraced the program. "I now find my colleagues debating which book they want to give their patients and reminiscing about their favorite children's books."

In addition to her involvement with her own clinic's ROR program, Dr Molaska recently became a certified provider trainer for Reach Out and Read Wisconsin. As a trainer, she provides all-staff orientations for clinics applying to start a Reach Out and Read program.

"I am really excited about becoming more involved in such a great organization as Reach Out and Read," said Dr Molaska. "ROR is a great opportunity for any pediatrics department to help develop quality early childhood literacy for their patients."

"When you start doing the program, you see how grateful the parents are and how excited the kids are," Dr Molaska continued. "Now they come in and ask, 'Dr Wendy, where's my book?'"

For more information about Reach Out and Read, visit http://www.reachoutandread.org/.

Reach Out and Read at a Glance

At the national level, more than 4 million children and their families are served annually through ROR programs located in more than 4900 hospitals and health centers throughout the country, including Puerto Rico, the US Virgin Islands and 55 US military bases. Each year, children receive more than 6.5 million books.

Founded in 2010, Reach Out and Read Wisconsin is a statewide coalition that provides technical assistance, quality assurance and book support to participating ROR programs. There are currently about 60 programs in Wisconsin serving more than 44,300 children and families. An initiative of Children's Health Alliance of Wisconsin and a partnership with American Family Children's Hospital and Children's Hospital of Wisconsin, ROR Wisconsin distributes over 72,000 new books annually while working to expand the program. Dipesh Navsaria MD, MPH, MSLIS serves as the coalition's medical director; Karin Mahony, MEd, MSW, is project manager.

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Policy and Health

John J. Frey, III, MD, *WMJ* Medical Editor

One might read all of the articles in this issue of the *WMJ* as pertaining to health policy. While they have particular relevance to Wisconsin, other states and other readers might benefit from them as each state's policy makers consider the topics they address. Smoking, cost of technology, and prevention are everyone's issues.

The study by Guzman and colleagues[1] shows substantial changes in household and workplace policies about smoking after enactment of the 2009 Wisconsin public smoking ban. Taking data from the ongoing Study of the Health of Wisconsin (SHOW) project that collects data from a rigorous representative sample of state residents, their results suggest that both homes and workplaces have become healthier. Participants were less likely to be exposed to secondary smoke at work and in public spaces and less likely to be exposed to smoking in their homes. Individuals who smoked before and after the ban did not change their behavior. The argument against a statewide smoking ban tended to be framed as individual freedom to smoke or not. The data from Guzman's study show that smokers still smoke at the same rates—their freedom unimpaired, it seems —but that the rest of us are better off with the "freedom to smoke" folks literally out of our faces. A legislative policy change has had substantial positive effect on the general health of the public.

Colmenares argues persuasively that the state of Wisconsin and, by inference, other states that share problems of rising costs of care (which would be ALL other states) would benefit from having a statewide health technology assessment program to determine the value of any new technology over existing technology regarding outcomes and cost.[2] Even the *New York Times* is running a blog/discussion titled "Too Much Medical Care?", which highlights examples of technological overkill that have led to unsatisfactory or negative outcomes.[3] It is not just about cost, it is about quality; but it is also about getting the most tested and reliable care to a wider population of patients who need it. Colmenares's sobering historical perspective on the failure, despite legislation and national policy recommendations, to have evidence and science prevail over technological adventurism are worth reading – and remembering—in any efforts to bring a more disciplined and rational approach to standards of care. Further, his speculation about the benefits of using savings from unnecessary technology to expand care of the uninsured is supported by a recent study comparing mortality in states where Medicaid was expanded to single adults to states where there was no expansion; the results showed a significant decrease in all cause mortality and increased sense of well being in the states with expanded care.[4]

While getting care to patients who need emergency endoscopy does not at first appear to relate to policy, Haas and colleagues[5] illustrate the value of policies for processes of getting anesthesia and endoscopists where they are needed when they are needed. The fear about getting ill on a weekends is one that has a long history in reality; this study shows how the experience of a large community teaching hospital can prove those fears wrong. They outline 4 policies in their discussion that could, and should, apply to any urgent procedures.

> Smoking, cost of technology, and prevention are everyone's issues.

A simple policy that standardizes the process of taking blood pressures and gives rooming staff the responsibility to educate patients on the spot and arrange for individual staff follow-up showed a remarkable improvement in the control of blood pressure: 10% in 3 months.[6] The quality improvement process Gindlesberger led in one clinic, albeit a large one, if rolled out to the regional multispecialty clinic of which it is a part would have an enormous consequences for prevention and management of one of the least well-managed chronic health problems. Taking this policy to all primary care clinics

in the state would not require new technology, just persistence and people. A policy of consistency, teamwork, and communication works. But it takes leadership.

Finally, while persistent muscle aches may be among the most common reasons for seeing a physician, Policepatil and colleagues[7] report that screening for creatine kinase (CPK) might not be a bad choice to rule out common problems or, in this case of severe hypoparathyoidism, very uncommon problems. That the patient in question took 6 years to enter treatment after the initial elevated CPK says something about a need for all of us to aggressively follow up communication between primary care clinicians and specialty consultants. It is a problem we all share but a "follow up" box on our electronic health record and a staff designated to find folks might help the problem and help everyone, including clinicians, rest more easily at night.

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Comparison of Time to Endoscopy and Outcome Between Weekend/Weekday Hospital Admissions in Patients with Upper GI Hemorrhage

Jason M. Haas, DO; Jacob D. Gundrum, MS; Scott W. Rathgaber, MD

ABSTRACT

Objective: Recent findings suggest that time to endoscopy is prolonged in patients admitted on the weekend with upper gastrointestinal hemorrhage (UGIH), which may result in increased adverse outcomes. This study was designed to determine if these findings hold true for a community gastroenterology practice.

Methods: This retrospective study reviewed patients admitted to a community teaching hospital from January 1, 2008, through October 31, 2008 with the primary diagnosis of UGIH. UGIH was further defined as acute variceal hemorrhage (AVH) or non-variceal hemorrhage (NVUGIH). The primary groups were based on weekend vs weekday admission. Time to endoscopy, adverse outcomes, presenting symptom, and length of stay were analyzed.

Results: One hundred seventy-four patients were included (50 weekend; 124 weekday). Most patients (94.25%) received upper endoscopy within 24 hours of admission. Mean time to endoscopy was shorter for weekend admission compared to weekday (7.52 hours vs 10.82 hours; $P = 0.012$) for the entire group. No statistically significant difference was detected in AVH patients (6.37 hours vs 4.37 hours; $P = 0.09$), but a difference was observed in the NVUGIH group (7.65 hours vs 11.45 hours, $P = 0.015$). Adverse outcomes were not associated with weekend admission ($P = 0.583$). There was no difference in mean length of stay (3.08 days vs 3.85 days; $P = 0.131$) or mean units of blood transfused (2.44 units vs 2.07 units, $P = 0.417$) between admission groups.

Conclusions: Patients admitted to this community teaching hospital with UGIH on the weekend did not experience delayed endoscopy, increased adverse outcomes, or longer length of stay compared to those admitted on a weekday. The previously reported "weekend effect" was not observed. In fact, patients admitted with NVUGIH on the weekend received upper endoscopy earlier than patients admitted during the week.

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Corresponding Author: Jason M. Haas, DO; 1218 W Kilbourn Ave, Ste 404 Milwaukee, WI 53233; phone 414.219.4700; e-mail haas.jasonm@gmail.com.

INTRODUCTION

Upper gastrointestinal hemorrhage (UGIH) remains a common presenting problem to hospitals around the world, with an estimated annual incidence of 45 to 172 per 100,000 people.[1-4] The vast majority of these patients ultimately are hospitalized.[5] Timing of upper endoscopy in patients presenting with symptoms of UGIH has been well studied. It is now common practice to perform early endoscopy (within the first 24 hours). Early endoscopy has been proven to shorten length of stay (LOS), increase efficiency of care, lower rates of surgery and reduce the need for blood transfusions.[6-10]

Substantial evidence in the literature associates weekend admission with increased mortality and other adverse outcomes for a variety of medical conditions.[11-13] This so-called "weekend effect" recently has been shown to hold true for patients presenting with UGIH.[12-14] Time to endoscopy also has been shown to be prolonged in patients admitted on the weekend with UGIH.[12,13] As previous studies have shown, delayed endoscopy may result in increased adverse outcomes.[6-10]

This study was designed to determine if patients admitted to this community-based teaching institution on the weekend experienced the "weekend effect."

METHODS

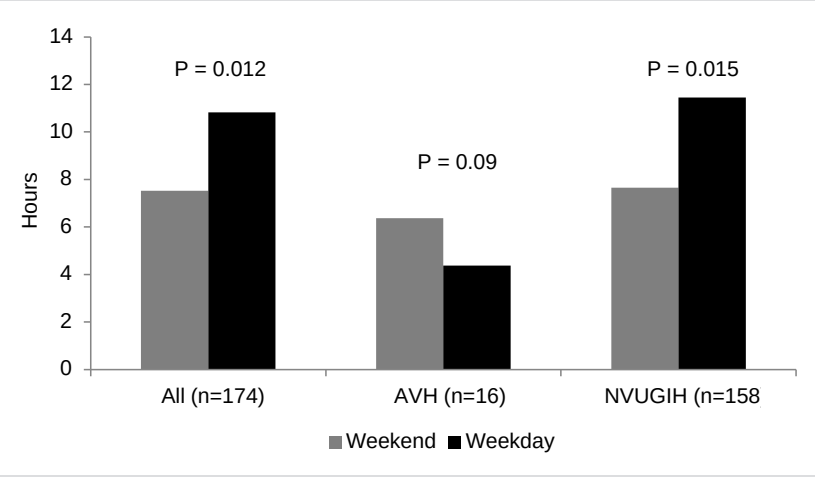
This study was a retrospective review of patients admitted to a community teaching hospital from January 1, 2008 through

Table 1. Study Cohort Demographics

	Weekend % (n = 50)	Weekday % (n = 124)	*P* value
Age (mean years± SD)	69.8 ± 15.5	70.4 ± 14.3	0.805
Men	60.0 (30)	61.29 (76)	0.875
AVH	10.0 (5)	8.87 (11)	0.779
Presenting vital signs/labs			
SBP (mean± SD)	121.7 ± 27.5	122.83 ± 25.3	0.788
Hgb (mean± SD)	9.5 ± 2.3	9.6 ± 2.5	0.809
HR (mean± SD)	85.1 ± 20.7	85.4 ± 16.8	0.933
Presenting symptom			0.464
ABLA	4.0 (2)	4.84 (6)	
Hematemesis	26.0 (13)	16.13 (20)	
Melena	58.0 (29)	68.55 (85)	
MH	12 (6)	10.48 (13)	
INR reversal	30.0 (15)	29.84 (37)	0.983

Abbreviations: SD, standard deviation; AVH, acute variceal hemorrhage; SPB, systolic blood pressure mmHg; Hgb, hemoglobin g/dl; HR, heart rate beats/min; ABLA, acute blood loss anemia; MH, melena and hematemesis.

Figure 1. Comparison of Time to Endoscopy by Weekend or Weekday Admission and Type of Upper Gastrointestinal Hemorrhage



Abbreviations: AVH, acute variceal hemorrhage; NVUGIH, non-variceal upper gastrointestinal hemorrhage.

October 31, 2008 and was approved by the Institutional Review Board. The primary study sample was obtained using International Classification of Diseases 9th Version, Clinical Modification (ICD-9-CM) codes. Patients hospitalized with a primary diagnosis of acute blood loss anemia (ABLA; 285.1) secondary to UGIH, bleeding peptic ulcer (531.0, 531.4, 531.6, 535.01, 535.11, 531.41, 531.51, and 578.9) and/or symptoms of UGIH; hematemesis (578.0) or melena/blood in stool (578.1) were identified. Patients without UGIH as the primary indication for admission were excluded from the study. Since time to upper endoscopy was a study variable, patients who elected not to have upper endoscopy (n = 14) were excluded.

The primary study groups were based on day of admission (weekend vs weekday). Weekend admission was defined as from Friday at 17:00 through Sunday at midnight. For these two cohorts, the primary comparative measures were time to endoscopy and adverse outcomes, defined as inpatient death or death within 30 days of admission attributable to UGIH, need for emergent surgical intervention, need for blood transfusion, or need for repeat inpatient upper endoscopy. Time of upper endoscopy was defined as the time sedation medications were initiated.

Other factors compared between the study groups included LOS, presenting symptom, age, sex, time of admission, admitting vital signs, and hemoglobin concentration, as well as the need for INR reversal prior to upper endoscopy. Presenting symptom was defined as ABLA, hematemesis (H), and/or melena (M).

In addition, the study sample was divided into 2 categories based on etiology of UGIH, that is, acute variceal hemorrhage (AVH) and non-variceal upper gastrointestinal hemorrhage (NVUGIH) and the proportion of these were compared between the primary study groups. Subgroup analysis on the AVH and NVUGIH was done as well.

This institution is a community-based referral center that serves a 19-county area. On average, 13,400 patients are admitted annually. It is a teaching hospital, which is defined as having an AMA-approved residency program. This institution has internal medicine, transitional and general surgical residencies, but no gastroenterology fellowship. The gastroenterology department is a pure consultative service with 7 full-time practicing gastroenterologists and a fully trained support staff. All 7 endoscopists practice solely at this institution. Endoscopy is available around the clock, with 1 endoscopist covering the weekend. This institution follows the consensus recommendations for managing patients with NVUGIH as published in the *Annals of Internal Medicine* in 2003[15], including early risk stratification for bleeding and rebleeding; however, proto-

cols such as the Blatchford[16] or Rockall[17] risk scoring systems are not routinely used. Early risk stratification is determined clinically.

Statistical Analysis

Simple descriptive statistics, such as means, standard deviations, percentages, and frequencies were calculated. Categorical variables were compared with χ^2tests; if 25% or more of cells had expected values less than 5, the Fisher exact test was used. For comparing continuous variables between study groups, two-tailed *t* tests (choice dependent upon equality of variances) were used. *P* values < 0.05 were considered statistically significant. All analysis was performed using SAS software.[18]

RESULTS

One hundred seventy-four patients met the inclusion criteria for UGIH and underwent upper endoscopy during their admission. The mean age of the study population was 70 ± 14.6 years, with men outnumbering women 106 to 68. A large proportion (*n* = 158; 91%) of the sample was found to have NVUGIH as the etiology of their UGIH. During the week 124 (71%) patients were admitted and 50 (29%) were admitted over the weekend. Presenting symptom, hemoglobin, vital signs, sex, age, need for INR reversal, and proportion of AVH were not significantly different between the weekend and weekday groups (all *P* > 0.05) (Table 1).

The exact time of upper endoscopy was determined using individual procedure records. Of the study sample 164 (94.25%) received upper endoscopy within 24 hours of admission. When the time was extended to 30 hours, 173 (> 99%) of the sample received upper endoscopy. Of the 10 patients who did not receive upper endoscopy within the first 24 hours, 4 (40%) required INR reversal prior to procedure (data not shown). Compared with patients admitted on a weekday, patients admitted on the weekend received upper endoscopy earlier (7.52 ± 7.02 hours vs 10.82 ± 9.26 hours; *P* = 0.012). There was no significant difference in time to endoscopy for patients admitted with AVH on the weekend vs the weekday (6.37 ±4.01 hours vs 4.37 ± 6.23 hours; *P* = 0.09), although the sample size was small. A difference was detected in the NVUGIH group (7.65 ± 7.30 hours vs 11.45 ± 9.28 hours; *P* = 0.015) (Figure 1). Regardless of weekend or weekday admission, patients with AVH underwent upper endoscopy earlier than patients with NVUGIH (4.99 hours vs 10.36 hours; *P* = 0.002).

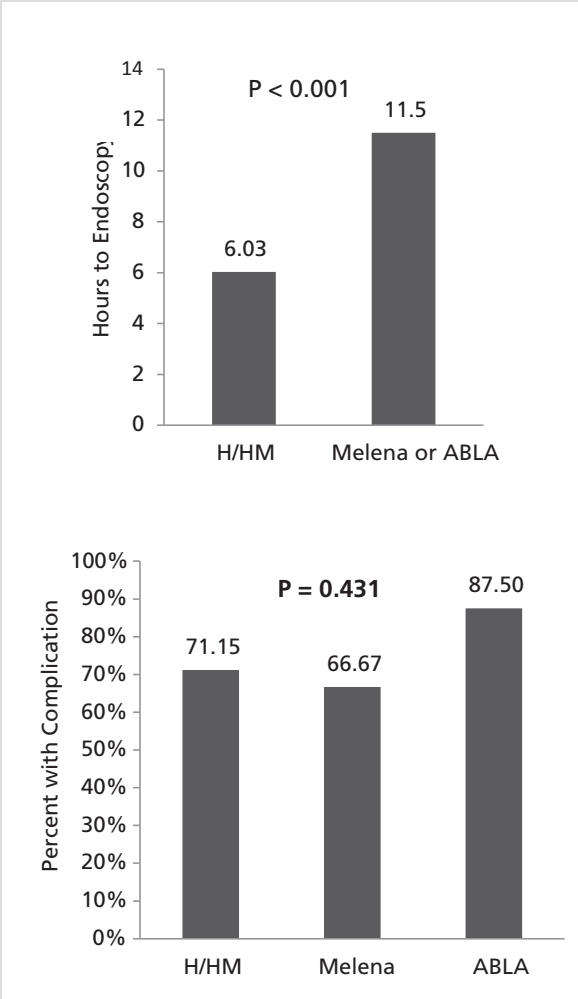
The overall rate of adverse outcomes was not associated with weekend admission (weekend: 36 of 50 [72%]; weekday: 84 of 124 [68%]; *P* = 0.583). The mortality rate in this sample was low (4 of 174, 2.3%), with 1 inpatient death and 3 deaths within 30 days of admission. All 4 patients who died were admitted on a weekday. Need for surgical intervention also was limited to 4 patients. No statistically significant difference in the rate of surgical interventions was noted for weekend vs weekday admissions (4.0% vs 1.61%; *P* = 0.325). There was no difference in mean LOS for weekend vs weekday

Table 2. Comparison of Adverse Outcomes, Weekend vs Weekday Admission

	Weekend % (n = 50)	Weekday % (n = 124)	*P* value
Adverse outcomes	72.0 (36)	67.7 (84)	0.583
Surgery	4.0 (2)	1.6 (2)	0.325
Repeat upper endoscopy	20.0 (10)	11.3 (14)	0.132
PRBC (mean ± SD)	2.4 ± 2.8	2.1 ± 2.3	0.417
Death	0 (0)	3.2 (4)	0.580
LOS (mean ± SD)	3.1 ± 2.2	3.9 ± 4.5	0.131

Abbreviations: SD, standard deviation; PRBC, packed red blood cells in units; LOS, length of stay in days.

Figure 2. Time to Endoscopy and Complications by Presenting Symptom



Abbreviations: H/HM, hematemesis alone or both hematemesis and melena; ABLA, acute blood loss anemia.

admissions (3.08 days vs 3.85 days, $P = 0.131$) or in the mean units of blood transfused per patient (2.44 units vs 2.07 units; $P = 0.417$). There was also no statistical difference in the need for repeat upper endoscopy if admitted on the weekend vs the weekday (20% vs 11.3%; $P = 0.132$) (Table 2).

Presenting symptom was not associated with adverse outcomes (H or HM = 7 of 52 [71%]; M = 76 of 114 [67%]; ABLA = 7 of 8 [87%]: $P = 0.431$); however, patients presenting with hematemesis averaged upper endoscopy earlier than patients presenting with melena or ABLA (6.03 hours vs 11.5 hours; $P < 0.001$) (Figure 2).

DISCUSSION

This study showed that patients admitted to this community teaching hospital with UGIH on the weekend received upper endoscopy earlier than patients admitted on a weekday. This study also showed that adverse outcomes and LOS were not associated with weekend admission. These results conflict with those of 2 larger US cohort studies published in 2009.[12,13] The previously reported "weekend effect" in those studies is not observed at this institution. In fact, this institution excelled on the weekend. There are several possible reasons for these findings. First, endoscopy is available 24 hours a day, 7 days a week. Second, the standard of practice employed by the gastroenterology department is the same regardless of the day of the week. Third, a competent support staff is available at all times. Fourth and probably most important is the ability of the emergency room physician, internist, and gastroenterologist to appropriately risk stratify patients early in their course, validating the consensus recommendations for managing patients presenting with NVUGIH. A number of European studies also have shown a lack of the "weekend effect" for patients with UGIH, including a recently published nationwide study from the United Kingdom.[19,20] This study from a US community teaching hospital suggests that consistent outcomes can be achieved by following published guidelines, independent of admission day.

It has been shown that outcomes, including mortality and LOS, are influenced by time to upper endoscopy.[6-10] It is now common practice to perform upper endoscopy within the first 24 hours of admission in patients with UGIH. A large US population-based study[7] found the prevalence of early endoscopy to be about 72% with similar Canadian[21] and Dutch[3] studies reporting a prevalence of 76% and 78% respectively. This institution far exceeded this average with >94% of patients receiving upper endoscopy within 24 hours. Of the patients not receiving upper endoscopy within 24 hours, almost half of them required INR reversal prior to the procedure. In accordance with other studies,[7-10] this institution had fewer adverse outcomes with early upper endoscopy.

Few studies have evaluated presenting symptom as a variable for time to upper endoscopy or adverse outcomes. A previous study[22] determined that the presence of hematemesis was a significant predictor of death. Our study showed that presenting symptom did not correlate with increased risk of adverse outcome; however, patients presenting with hematemesis received upper endoscopy earlier than patients presenting with melena or ABLA. At this institution, presenting symptoms are used for risk stratification. Hematemesis is considered to represent a more serious underlying pathology, such as a variceal bleeding, resulting in endoscopy being performed earlier. It is possible that this practice explains why presenting symptom is not associated with increased adverse outcomes.

Hospitals that are teaching institutions do not appear to have increased adverse outcomes on the weekend;[13] however, a higher mortality rate overall was reported in patients admitted to urban teaching hospitals (odds ratio, 1.16; 95% confidence interval, 1.06-1.26).[12] This institution is considered a medium-sized urban teaching hospital, which may have contributed to the lack of a weekend effect.

This study was limited by being a single-institution study, which could lead to a sampling bias. The population studied here may not reflect the general US population. The relatively low mortality rate may reflect the effect of early endoscopy, but it could also represent a lower acuity bleeding population. In addition, with 2 primary measures, the concern of multiple comparisons is a potential limitation; however, using a Bonferroni correction with family size of 2, the adjusted significance level of 0.025 does not change the interpretation of the conclusions on statistical significance. We also had a small sample size, which was acquired with timeliness in mind rather than formal power analysis. However, given the sample size we did have, we had about an 80% power to detect a 5-point difference on time to upper endoscopy and a 25 percentage-point difference in adverse event rates between the cohorts (assuming the Bonferroni correction stated above). The relatively low power for the proportional comparisons means there is a relatively high chance of concluding there is no difference between the cohorts when there really is one in the generalized target population. Finally, the retrospective design of this study allows for the potential of selection bias, but it does eliminate the potential for a Hawthorne effect, as well as accurately describing a genuine practice.

CONCLUSION

For patients admitted with UGIH, this community-based teaching institution performs at a highly efficient and safe manner regardless the day of the week, which does not lead to the so-called "weekend effect." Ninety-four percent of the study population received endoscopy within 24 hours of admission,

while a large US population-based study found the average to be only 74%. Early endoscopy may contribute to fewer deaths and other adverse outcomes, including need for blood transfusions, need for surgical intervention, and need for repeat upper endoscopy.

The weekend effect may be only a small part of the equation, leading to adverse outcomes in patients presenting with UGIH, but it remains a modifiable risk factor. The practice of this institution proves that the weekend effect can be avoided in patients presenting with UGIH. Efficient and safe care should be implemented regardless of the day of admission.

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Evaluating Effects of Statewide Smoking Regulations on Smoking Behaviors Among Participants in the Survey of the Health of Wisconsin

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ABSTRACT

Background: Studies have shown that laws banning smoking in public places reduce exposure to secondhand smoke, but the impact of such laws on exposure to smoke outside the home and on household smoking policies has not been well documented. The goal of this study was to evaluate the effects of 2009 Wisconsin Act 12, a statewide smoke-free law enacted in July 2010, among participants in the Survey of the Health of Wisconsin (SHOW).

Methods: Smoking history and demographic information was gathered from 1341 survey participants from 2008 to 2010. Smoking behaviors of independent samples of participants surveyed before and after the legislation was enacted were compared.

Results: The smoking ban was associated with a reduction of participants reporting exposure to smoke outside the home (from 55% to 32%; $P < 0.0001$) and at home (13% to 7%; $P = 0.002$). The new legislation was associated with an increased percentage of participants with no-smoking policies in their households (from 74% to 80%; $P = .04$). The results were stronger among participants who were older, wealthier, and more educated.

Conclusion: Smoke-free legislation appears to reduce secondhand smoke exposure and to increase no-smoking policies in households. Further research should be conducted to see if these effects are maintained.

INTRODUCTION

Laws banning smoking in public places, passed in parts of Canada and the United States as well as in several European countries, have been shown to reduce secondhand smoke exposure in public places and to improve overall air quality.[1-3] However, the evidence on the effects of smoke-free environment laws on exposure to secondhand smoke in the home[1,4] and on active smoking[1,5-7] is more limited. Continued study of the effects of smoking bans is therefore important in order to better understand the impact of these laws on reducing exposure to tobacco smoke and on changing smoking behaviors.

While the entire United States is not under a 100% smoke-free law, states such as Wisconsin and 22 others have seen the implementation of such laws in recent years. Like the rest of the United States, Wisconsin suffers the devastating effects of tobacco smoke with approximately 7700 deaths (or about 15% of all deaths) being associated with tobacco use each year.[8] In an attempt to minimize the effects of secondhand tobacco smoke, on July 5, 2010 the state government enacted 2009 Wisconsin Act 12, banning smoking in public places and places of employment across the entire state. A study conducted by the University of Wisconsin's Carbone Cancer Center already has demonstrated that this law improved air quality in Wisconsin bars and restaurants by reducing the mean particulate matter detected in the air by 92%.[9] The effects of the law on reducing secondhand smoke exposure and on changing smoking behaviors among Wisconsin residents, however, has not yet been studied.

We used data from the 2008-2010 waves of the Survey of the Health of Wisconsin (SHOW) to study the effects of 2009 Wisconsin Act 12 on smoking behaviors of Wisconsin residents. We hypothesized that those surveyed after the enactment of 2009 Wisconsin Act 12 on July 5, 2010 would have a lower smoking prevalence, lower exposure to smoke outside and inside the home, a higher desire to quit smoking, and

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CME available. See page 172 for more information.

increased no-smoking policies in their households than those surveyed prior to the enactment of the ban. If the effects of 2009 Wisconsin Act 12 are positive, such results could imply that legislative smoking bans could be key components in future attempts made to reduce the poor health outcomes associated with tobacco use and exposure to tobacco smoke.

Table 1. Selected Characteristics of Participants Exposed and Not Exposed to a Local Smoking Ban Before 2010, Survey of the Health of Wisconsin, 2008-2010.

	Exposed		Not Exposed		
	n	%	n	%	*P* value
Smoking status					
Never smokers	246	56.7	471	52.0	0.27
Former smokers	114	26.3	268	29.6	
Current smokers	74	17.1	167	18.4	
Exposed to smoke outside home	181	44.4	377	45.6	0.72
Exposed to smoke at work	37	9.1	92	10.8	0.41
Exposed to smoke at home	38	8.9	92	10.3	0.49
Had strict smoking policy in household	370	81.3	759	76.4	0.04
Age					
21–40-year-old age group	229	45.4	317	29.7	<0.0001
41-60-year-old age group	187	37.1	530	49.6	
61-74-year-old age group	88	17.5	221	20.7	
Family income					
< $30,000 per year	127	26.4	256	25.0	0.005
$30,000-$59,999 per year	122	25.4	336	32.8	
≥ $60,000 per year	232	48.2	431	42.1	
Education					
High school education or lower	104	20.7	344	32.2	<0.0001
Some college education or higher	398	79.3	723	67.8	

METHODS

Data Collection

SHOW is an annual survey of the health status of a randomly selected representative sample of Wisconsin residents and communities that began in June 2008. Study methods previously have been described.[10] In brief, a 2-stage cluster sampling method was used to randomly select households and recruit adult study participants (21-74 years old) each year from various communities across the state. To increase participation and awareness, a public relations campaign was launched 6 to 8 weeks before recruitment was scheduled to begin at a particular location. The participants were surveyed about their health, demographic, behavioral, lifestyle, and housing characteristics as well as their smoking behaviors and usual exposure to tobacco smoke. The smoking questionnaire included questions about the length and extent of tobacco use, exposure to secondhand smoke, as well as quit attempts and strategies used to stop smoking.

A smoking history was obtained from 1341 SHOW participants from 2008 to 2010. This information allowed evaluation of the effects of the statewide smoking ban (2009 Wisconsin Act 12) on smoking behaviors by comparing the behaviors of those surveyed before and those surveyed after the law's enactment on July 5, 2010.

To determine the effect of the law to its maximum potential, participants who lived in an area with a workplace or complete public smoking ban prior to the statewide ban were excluded from the analysis. A report by the Wisconsin Department of Health Services titled *Wisconsin Tobacco Facts 2009,*[11] listing which communities had smoke-free policies before 2010, was used to assign participants as being exposed or not exposed to a local smoking ban prior to 2009 Wisconsin Act 12. If a particular community within a Census Block Group had a local ban in place before 2010, then all of the communities within that Census Block Group were assigned as having a smoking ban prior to the enactment of the statewide ban. Survey participants' addresses were linked to the smoking ban status of their Census Block Group and 273 participants (20.4% of original 1341) with a ban prior to 2009 Wisconsin Act 12 were excluded from the analysis. The sample size after this exclusion was reduced to 1068 participants with 634 being surveyed before the enactment of 2009 Wisconsin Act 12 and 434 after.

Data Analysis

SAS software[12] was used to conduct the data analysis. For all analyses shown, a SHOW study enrollment date before or after July 5, 2010 was used to place participants into the before or after statewide ban groups. Chi-square tests were used to compare proportions and two-tailed *t* tests were used for comparison of means. Appropriate sample weighting was applied based on survey strata and cluster structure. Logistic regression models were used to estimate crude and adjusted odds ratios of exposure to smoking variables comparing SHOW participants recruited after and before the state smoking ban. The results were stratified by age, income, and educational level to determine whether the effects of the law varied depending on these factors.

RESULTS

Table 1 provides select characteristics of the SHOW participants exposed and not exposed to a smoking ban before 2010. It demonstrates that among those not exposed to a smoking

Table 2. Comparison of Smoking Behaviors and Exposure to Tobacco Smoke Before and After the Enactment of Wisconsin Act 12, Survey of the Health of Wisconsin, 2008-2010[a]

	Total (n)	Before Ban[b]	After Ban[b]	*P* Value
Smoking status				
Never smokers	906	52% (271)	52% (200)	0.8
Former smokers		30.1% (157)	28.8% (111)	
Current smokers		17.9% (93)	19.2% (74)	
Exposed to smoke outside home	826	55.5% (264)	32.3% (113)	<0.0001
Mean number of cigarettes smoked among current smokers	162	15.2 (93)	14.2 (69)	0.6
Exposed to smoke at work	849	12.2% (59)	9% (33)	0.1
Exposed to smoke at home	894	13% (67)	6.6% (25)	0.002
Current smokers who want to completely quit	160	87.5% (77)	83.3% (60)	0.5
Current smokers who Seriously considered quitting within next 6 months	151	80.7% (67)	77.9% (53)	0.7
Had strict smoking policy in household	993	74% (416)	79.6% (343)	0.04

[a]Participants that were exposed to a local smoking ban before 2010 were excluded.
[b]Numbers given in parenthesis correspond to the n values of each category.

Table 3. Unadjusted Odds Ratios Comparing Smoking Behaviors and Exposure to Tobacco Smoke After vs Before the Enactment of Wisconsin Act 12, Survey of the Health of Wisconsin, 2008-2010[a]

	Total (n)	Odds Ratio (95% CI)
Being current smoker	906	1.08 (0.76-1.55)
Participants being exposed to smoke outside home	826	0.31 (0.22-0.44)
Participants being exposed to smoke at work	849	0.60 (0.41-0.88)
Participants being exposed to smoke at home	894	0.41 (0.23-0.71)
Smokers who want to completely quit smoking	160	0.60 (0.25-1.46)
Smokers who considered quitting within next 6 months	151	1.20 (0.70-2.04)
Participants having a strict ban in the home	993	1.43 (0.96-2.13)

[a] Participants that were exposed to a local smoking ban before 2010 were excluded.
Abbreviation = CI, confidence interval.

ban before 2010, 52% were never smokers, 29.6% were former smokers, and 18.4% were current smokers. In the same group, 45.6% reported exposure to smoke outside the home, 10.8% at work, and 10.3% at home. On the other hand, among those who were exposed to a law prior to 2009 Wisconsin Act 12, 56.7% were never smokers, 26.3% were former smokers, and 17.1% were current smokers. In this group, 44.4% were exposed to smoke outside the home, 9.1% at work, and 8.9% at home. The *P* values for the comparison of exposed vs not exposed groups with regards to smoking status and exposure to secondhand smoke are shown.

Table 2 shows the comparison of smoking behaviors and exposure to tobacco smoke among participants surveyed before and after the enactment of 2009 Wisconsin Act 12. The proportion of survey participants who reported exposure to smoke outside the home decreased from 55% to 32% after the statewide ban ($P < 0.0001$). A similar reduction was observed for exposure to smoke at home (13% to 7%; $P = 0.002$). Smoke-free legislation in Wisconsin also was associated temporally with an increase in the percentage of participants with strict no-smoking policies in their households from 74% to 80% ($P = 0.04$). The prevalence of smoking in participants recruited after the ban was slightly higher than among SHOW participants before the ban, but the difference was not statistically significant.

Table 3 provides the unadjusted odds ratios comparing smoking behaviors and exposure to tobacco smoke after vs before the enactment of 2009 Wisconsin Act 12. It shows that participants were 0.31 times as likely of being exposed to smoke outside the home after vs before the legislation, 0.60 times as likely of being exposed to smoke at work, and 0.41 times as likely of being exposed to smoke at home. Analyses adjusted for potential confounders (age, sex, income and education) resulted in virtually identical results as those presented in Table 3 (not shown).

Table 4 shows results stratified according to age, family income, and education. Overall, participants who were older, wealthier, and more educated tended to have larger improvements in their smoking behaviors and exposure to tobacco smoke as a result of the statewide ban. 2009 Wisconsin Act 12 was associated with decreased exposure of participants to smoke outside the home equally among all age groups, but it was associated with reduced exposure to smoke at work and at home to a larger extent among participants who were older. Participant exposure to tobacco smoke outside the home improved among all income groups but it was decreased further in the highest income group (family income >$60,000 per year). The law also had varying effects among different educational groups, with a higher increase in the odds of having a no-smoking policy at home following the implementation of the smoking ban among those with some college education. When the results were stratified by rural vs non-rural place of residence, the effects of 2009 Wisconsin Act 12 were similar in both areas (not shown).

Table 4. Unadjusted Odds Ratios Comparing Smoking Behaviors and Exposure to Tobacco Smoke After vs Before the Enactment of Wisconsin Act 12 Stratified by Age, Family Income, and Educational Level, Survey of the Health of Wisconsin, 2008-2010.[a]

	21–40-Year-Old Age Group		41–60-Year-Old Age Group		61–74-Year-Old Age Group	
	Total n	Odds Ratio (95% CI)	Total n	Odds Ratio (95% CI)	Total n	Odds Ratio (95% CI)
Being current smoker	242	1.68 (0.82-3.43)	461	0.88 (0.54-1.42)	203	0.94 (0.34-2.59)
Participants being exposed to smoke outside home	224	0.30 (0.18-0.51)	419	0.34 (0.21-0.55)	183	0.26 (0.13-0.54)
Participants being exposed to smoke at work	230	0.89 (0.47-1.71)	432	0.54 (0.28-1.02)	187	0.26 (0.06-1.13)
Participants being exposed to smoke at home	240	0.84 (0.28-2.51)	455	0.33 (0.15-0.75)	199	0.18 (0.05-0.75)
Smokers who want to completely quit smoking	55	0.78 (0.34-1.79)	87	0.51 (0.16-1.61)	18	0.52 (0.10-2.58)
Smokers who considered quitting within next 6 months	52	4.38 (0.54-35.8)	82	1.15 (0.68-2.0)	17	0.20 (0.02-1.84)
Participants having a strict ban in the home	290	1.15 (0.54-2.44)	495	1.62 (1.06-2.47)	208	1.58 (0.80-3.15)
	Family Income <$30,000 Per Year		Family Income $30,000-$59,999 Per Year		Family Income ≥$60,000 Per Year	
	Total n	Odds Ratio (95% CI)	Total n	Odds Ratio (95% CI)	Total n	Odds Ratio (95% CI)
Being current smoker	200	1.03 (0.53-1.99)	287	1.35 (0.79-2.32)	385	1.03 (0.59-1.78)
Participants being exposed to smoke outside home	172	0.52 (0.30-0.88)	262	0.31 (0.17-0.58)	361	0.26 (0.17-0.39)
Participants being exposed to smoke at work	181	1.14 (0.64-2.01)	273	0.38 (0.17-0.82)	365	0.52 (0.26-1.04)
Participants being exposed to smoke at home	192	0.35 (0.10-1.18)	285	1.07 (0.52-2.19)	384	0.17 (0.07-0.45)
Smokers who want to completely quit smoking	54	0.58 (0.18-1.86)	51	0.48 (0.16-1.46)	47	0.76 (0.35-1.66)
Smokers who considered quitting within next 6 months	52	0.38 (0.09-1.56)	46	1.01 (0.50-2.02)	46	3.03 (1.14-8.05)
Participants having a strict ban in the home	238	1.77 (0.93-3.36)	313	0.79 (0.45-1.38)	405	1.77 (1.02-3.07)
	High School Education or Lower		Some College Education or Higher			
	Total n	Odds Ratio (95% CI)	Total n	Odds Ratio (95% CI)		
Being current smoker	272	0.90 (0.50-1.63)	633	1.19 (0.78-1.81)		
Participants being exposed to smoke outside home	232	0.29 (0.16-0.53)	593	0.32 (0.22-0.47)		
Participants being exposed to smoke at work	250	0.53 (0.27-1.04)	598	0.64 (0.36-1.13)		
Participants being exposed to smoke at home	259	0.52 (0.26-1.02)	634	0.32 (0.17-0.63)		
Smokers who want to completely quit smoking	75	0.31 (0.07-1.45)	85	1.10 (0.47-2.61)		
Smokers who considered quitting within next 6 months	72	0.51 (0.29-0.91)	79	3.78 (1.33-10.80)		
Participants having a strict ban in the home	317	1.11 (0.61-2.03)	676	1.63 (1.11-2.41)		

[a]Participants that were exposed to a local smoking ban before 2010 were excluded.
Abbreviation = CI, confidence interval.

DISCUSSION

The implementation of smoke-free legislation in Wisconsin was associated with a statistically significant decline in reported exposure to tobacco smoke outside the home, inside the home, and at work among SHOW participants. These results are consistent with those of previous studies on the effects of smoke-free legislation in parts of Europe, Canada, and the United States.[1] For example, a phone interview study conducted in Ontario, Canada that evaluated whether smoking bans affect rates of secondhand smoke exposure also found that smoke-free legislation was associated with decreased exposure in public places, the home, and in the workplaces of its survey participants.[13]

It is noteworthy that our results showed that smoke-free legislation in Wisconsin was associated with a decrease in secondhand smoke exposure not only in public places, but also in the home; it also was associated with an increase in prevalence of no-smoking policies in the households of Wisconsin residents. According to our results, only 20.4% of households in Wisconsin did not have a strict no-smoking policy after 2009 Wisconsin Act 12 went into effect. This number is much lower than the 1999 estimate provided by the Centers for Disease Control and Prevention, which showed that 55.3% of Wisconsin households in 1999 did not have smoking policies.[14] Most previous studies on the effects of smoke-free legislation on secondhand smoke exposure in the home did not find the association seen in our results. A study conducted in Hong Kong before and after the implementation of smoke-free legislation in 2007 found that such legislation increased smoke exposure in the home.[15] A review by Callinan et al

found that smoke-free legislation generally was not associated with a decrease in secondhand smoke exposure in the home.[1] Similar results to this review article also were found in a study conducted in Scotland in 2006.[16] A telephone interview study conducted in Ireland after implementation of its smoke-free legislation in 2004 found that 71% of Irish smokers reported that the legislation did not affect their smoking behaviors in the home, 22% reported that it had caused them to place stronger home smoking restrictions, and 6% reported smoking more in their homes.[17] In contrast, a study conducted in Scotland before and after the implementation of smoke-free legislation found that the legislation had increased home smoking restrictions.[4] Further research is needed to reconcile these different findings on the effects of smoke-free legislation on smoking behaviors in the household.

With regard to changing the smoking behaviors of Wisconsin residents, in the short time since its implementation, 2009 Wisconsin Act 12 did not appear to be associated with a reduction in smoking prevalence or in the number of current smokers who wanted to completely quit or were considering quitting. Furthermore, we only found a slight, non-statistically significant reduction in the mean number of cigarettes smoked among current smokers in our study sample. Previous studies reporting on these outcomes have not been entirely consistent. For example, a study conducted in the town of Bury, England in 2007 found that England's smoke-free legislation did not affect smoking prevalence but did decrease the number of cigarettes smoked among current smokers.[18] Other studies conducted in Canada, Italy, and the United States found that smoke-free legislation significantly decreased smoking prevalence by as little as 1.9% and as much as 14.4%.[2,5-7,19] It is important to note that some of these studies had much larger sample sizes. The number of current smokers in the SHOW data so far was only 167, a number that limits the statistical power of the study when it comes to analyzing the effects of the law on smoking prevalence and on the behaviors of current smokers. It is also possible that more time is required for this kind of legislation to have an effect on active smoking behaviors. As the sample size of the SHOW data and the time since the new legislation increases over the coming years it will be possible to analyze the effects of 2009 Wisconsin Act 12 on smoking behaviors with greater statistical power.

Our results also demonstrate that 2009 Wisconsin Act 12 generally had a larger impact on exposure to smoke among Wisconsin residents who were older, wealthier, and more educated. When it comes to exposure to smoke outside the home, at work, and at home, the 61–74-year-old age group had the largest reduction after the implementation of 2009 Wisconsin Act 12. Participants with a family income greater than $60,000 per year also reported the largest reduction in exposure to smoke outside and inside the home, while the middle income group ($30,000-$59,999 per year) reported the largest reduction in exposure to smoke at work. The reduction in exposure to smoke outside the home and at work was about the same in both education groups but a larger reduction was seen in exposure to smoke at home in the group with a college education or higher. Those in the higher education group were also more likely to have a strict no-smoking ban in the home. A study conducted in the United States, Canada, the United Kingdom, and Australia regarding socioeconomic and country variations in smokers' knowledge found that higher education and income were associated with higher awareness of the negative effects of smoking.[19] The authors of this study explained this association by suggesting that such differences might exist because those who are wealthier and more educated have a wider knowledge of and access to sources of information. This can therefore make these groups more capable of reaping the benefits of laws such as 2009 Wisconsin Act 12 earlier and may explain the variation seen in our results among different income and educational groups. However, further research is needed to understand why differences based on socioeconomic variation were found in the current study.

CONCLUSION

The main findings of this study are that smoke-free legislation in Wisconsin increased the number of participants who reported having strict no-smoking policies in their households and decreased reported exposure to tobacco smoke outside the home, inside the home, and at work. If such results are maintained in the future, it is likely that smoke-free legislation can play a significant role in reducing the incidence of tobacco-related illnesses and in improving overall health outcomes.

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CME

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Quiz: Evaluating Effects of Statewide Smoking Regulations on Smoking Behaviors Among Participants in the Survey of the Health of Wisconsin

EDUCATIONAL OBJECTIVES

1. Understand the impact of Wisconsin Act 12 on the exposure to tobacco products for Wisconsin residents.
2. Understand the demographic differences in the outcomes to this legislation.
3. Understand the similarities and differences in outcomes of smoke-free legislation in different geographic areas.

PUBLICATION DATE: August 15, 2012

EXPIRATION DATE: August 15, 2013

QUESTIONS

1. Which of the following statements are true?

❑ A. Tobacco use accounts for about 25% of all deaths each year in Wisconsin.

❑ B. Wisconsin Act 12 was enacted on July 5, 2010 and banned smoking in public places and places of employment across the entire state.

❑ C. Following the enactment of Wisconsin Act 12, there has been a 92% reduction in the mean particulate matter in the air in Wisconsin bars and restaurants.

❑ D. B and C only

❑ E. A, B, and C

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You may earn CME credit by reading the designated article in this issue and successfully completing the quiz (75% correct). Return completed quiz to *WMJ* CME, 330 E Lakeside St, Madison, WI 53715 or fax to 608.442.3802. You must include your name, address, telephone number, and e-mail address.

The Wisconsin Medical Society (Society) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The Wisconsin Medical Society designates this journal-based CME activity for a maximum of 1.0 *AMA PRA Category 1 Credit*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

2. This study utilized the Survey of the Health of Wisconsin (SHOW) which is an ongoing annual survey of the health status of a randomly-selected representative sample of Wisconsin residents and communities.

❑ True

❑ False

3. Changes in smoking exposures and behaviors after as compared to before enactment of Wisconsin Act 12 include the following:

❑ A. A significant decrease in exposure to smoke outside the home.

❑ B. A significant decrease in exposure to smoke at home.

❑ C. A significant decrease in the number of smokers.

❑ D. A and B only

❑ E. A, B, and C

4. Which of the following statements are true:

❑ A. In 1999 more than half of Wisconsin households did not have a smoking policy whereas after Wisconsin Act 12 went into effect, only one-fifth of households did not have a strict no-smoking policy.

❑ B. When the data is stratified according to age, family income, and education, participants who were older, wealthier, and more educated tended to have larger improvements in their smoking behaviors and exposure to tobacco smoke as a result of the statewide ban.

❑ C. A and B

❑ D. None of the above

Hypocalcemic Myopathy Secondary to Hypoparathyroidism

Seema M. Policepatil, MBBS; Robert H. Caplan, MD; Michael Dolan, MD, FACP

ABSTRACT

Myopathy is a rare manifestation of idiopathic hypoparathyroidism. We report a 48-year-old man with a 6-year history of muscle pain and elevated creatine kinase levels. Laboratory analysis revealed low serum calcium, inappropriately low-normal parathyroid hormone, elevated phosphorus, and normal 25-hydroxy vitamin D levels. The patient was diagnosed with idiopathic hypoparathyroidism and treated with calcium and calcitriol. He demonstrated an excellent clinical response and creatine kinase values returned to normal. This case illustrates the subtle nature of hypoparathyroid myopathy and highlights the importance of measuring serum calcium in patients with unexplained myalgia and/or muscle weakness.

INTRODUCTION

Hypocalcemia may be associated with an array of seemingly unconnected symptoms and signs. Symptoms are often determined by the degree of hypocalcemia and how quickly the calcium level drops. Tetany, muscle cramps, carpopedal spasm, seizures, and laryngospasm are associated with acute hypocalcemia. Patients with chronic hypocalcemia frequently have nonspecific symptoms including fatigue, irritability, and anxiety. Other symptoms include dementia, papilledema, cataract formation, and ectopic calcification of the basal ganglia. Myopathy is a rare manifestation of hypoparathyroidism. The following case illustrates the uncommon nature of this diagnosis.

CASE REPORT

A 48-year-old man with muscle aches was seen in the internal medicine clinic. He denied severe muscle weakness but noted a slight loss of strength over the last few years that did not interfere with his job or activities of daily living. His past medical history was significant for hypertriglyceridemia and gout. He did not have any surgeries in the past. He drank between 6 and 12 beers per week. Family history was negative for hypocalcemia, hypoparathyroidism, connective tissue diseases, or myositis. His only medication was 300 mg of allopurinol daily for gout, which he was not taking regularly. Review of systems was negative for skin rash, photosensitivity, alopecia, mouth sores, sicca symptoms, Raynaud's phenomenon, pleurisy, prolonged morning stiffness, joint swelling, swallowing problems, or shortness of breath.

His physical exam was unremarkable and Chvostek's and Trousseau's signs were negative. Laboratory studies revealed a creatine kinase (CK) level of 461 IU/L (Normal value, 0-233 IU/L). The patient was referred to the rheumatology clinic for further evaluation.

Laboratory evaluation revealed a normal white blood cell count, hemoglobin, alanine transaminase, aspartate transaminase, Lyme titer, sedimentation rate, antinuclear antibody (ANA) screen, rheumatoid factor, C-reactive protein (CRP), serum protein electrophoresis (SPEP), aldolase and thyrotropin levels. His rheumatologist felt that the elevated CK level was related to physical exertion and perhaps alcohol use. He was recommended to have a repeat CK measurement after a week of abstinence from physical activity and alcohol. The patient, however, did not return for the study.

Four years later, the patient was referred again to the rheumatology clinic because of fatigue and elevated CK levels. He denied muscle pain but reported some morning stiffness that lasted for 5 to 10 minutes and resolved after a hot shower. Again, his blood tests were normal except for a CK level of 725 IU/L. Electromyography was recommended, but he did not follow through with this recommendation.

Two years later he was admitted to our hospital, with a subcapital femur fracture following a low impact injury sustained

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Table 1. Creatine Kinase and Calcium Levels Before and After Treatment of Hypoparathyroidism[a]

	Creatine Kinase	Calcium
	(0-233 IU/L)	(8.4-10.5 mg/dL)
August 29, 2002	365	
October 21, 2002	357	
November 21, 2002	461	
February 27, 2004	636	
April 3, 2006	635	
June 18, 2007	725	
September 4, 2007	415	
November 21, 2008	469	
March 5, 2009	734	
July 13, 2009	704	
September 10, 2009		6.1
October 5, 2009[b]	166	8.2
October 6, 2011[b]	139	8.6

[a]Normal values in parentheses.
[b]After treatment with calcium carbonate and calcitriol.

when he tipped over his motorcycle while stationary. His CK was noted to be high at 714 IU/L. A muscle biopsy done during the hip surgery was normal and did not display inflammatory infiltrates. He had undergone bilateral cataract extraction 2 months before this admission to the hospital.

At his follow-up appointment in the orthopedics clinic, a bone mineral density study showed lumbar spine density of 1.240 g/cm^2 at L1-L4, , consistent with a T-score of 0.2. The density of proximal left femur was 0.916 g/cm^2, consistent with a T-score of -1.3. The T-score of the left femoral neck was -1.9. He was diagnosed with osteopenia based on the World Health Organization classification.

The patient subsequently was referred to the endocrinology clinic, where serum calcium and parathyroid hormone measurements were obtained. They were inappropriately low at 6.1 mg/dL and 22 pg/ml respectively. His magnesium, albumin, TSH, and 25-hydroxy vitamin D levels were normal. Despite the absence of signs and symptoms of hypocalcemia, a diagnosis of hypoparathyroidism was made.

He was treated with 600 mg calcium carbonate twice daily and 0.75 mcg of calcitriol daily. He continued to complain of joint stiffness and occasional pain, but the muscle aching and pain improved and his CK levels returned to a normal level (Table 1). At a follow-up visit, his serum calcium level was 8.1 mg/dL and CK level was 166 IU/L.

DISCUSSION

Hypoparathyroidism is associated with a variety of symptoms that are due to hypocalcemia. Decreased parathyroid hormone secretion may be due to surgical destruction or removal of the parathyroid glands, autoimmune disease, irradiation of the neck, infiltrative diseases, or altered function of the parathyroid glands. Hypocalcemia is classically associated with hyperexcitability at the neuromuscular junction, which may result in tetany, muscle cramping, carpopedal spasm, laryngospasm, and seizures. Clinical problems seen with chronic hypocalcemia include cataract formation, papilledema, emotional instability, anxiety, depression, dry coarse skin, and brittle nails with transverse grooves, basal ganglia calcification, dementia, and extrapyramidal movement disorders. Myopathy with elevated CK enzyme levels is a rare manifestation of hypoparathyroidism.

Hypocalcemic myopathy due to hypoparathyroidism was first reported in 1972.[1] Since then, there have been only a small number of reports highlighting this association.[2-14] A summary of serum calcium levels, CK values, and presenting symptoms in published case reports can be found in Table 2.

Our patient did not experience or display symptoms or signs of acute hypocalcemia. He had bilateral cataract development and removal before the age of 55. It is well known that chronic hypocalcemia, especially associated with hypoparathyroidism, causes cataracts. The initial presentation of our patient's illness, elevated CK levels and myalgias, occurred 6 years prior to diagnosis. Some authors believe that the elevation in CK is the result of repetitive tetany or muscle spasm, resulting in leakage of CK from damaged muscle cells. Our patient denied muscle cramping, tetany, or carpopedal spasm. A muscle biopsy was not performed until the time of his hip surgery, and this showed no evidence of inflammation or structural alteration.

In a case describing the histological findings of a 65-year-old woman with hypocalcemic myopathy due to hypoparathyroidism, light microscopy and electron microscopy revealed type 2 fiber atrophy, perinuclear accumulation of mitochondria, and focal myofibrillar degeneration.[7] In addition, atrophic muscle fibers were negative for myoglobin staining, and normal fibers stained positive for myoglobin. The authors postulated that hypocalcemia resulted in the leakage of myoglobin from muscle cells, resulting in the elevated serum CK levels.

It has been postulated that patients with idiopathic hypoparathyroidism who develop myopathy with elevated CK probably remain minimally symptomatic due to the slow development of the hypocalcemia and the remarkable ability of the body to adapt to chronically low serum calcium levels.[2] A recent study retrospectively analyzed the clinical data of 9 patients with idiopathic hypoparathyroidism during the years 2006-2010 and found that there is an inverse relationship between serum calcium and CK.[15] Mild to moderate muscle cell degeneration was present in almost all patients. The degree of muscle change was related to the duration, but not the degree of hypocalcemia.

Table 2. Creatine Kinase, Calcium Values, and Presenting Symptoms from Case Reports

Authors	Year	Age	Sex	Duration of symptoms	Symptoms	Creatine Kinase[a]	Calcium[a]	Cataracts[b]
Wolf et al[1]	1972	53	M	5 years	Hand and feet cramps	1580 IU/L(5-50)	5.1mg% (9-11)	no
Barber et al[2]	2001	71	M	1 year	Anorexia, lethargy, stiffness	1600 U/L (<175)	1.13 mmol/L	no
Ishikawa et al[3]	1990	15	M	6 years	Seizures, mental retardation	315 IU/L (10-200)	6.2mg/dL (8.5-10.5)	no
Nora et al[4]	2004	30	M	10 years	Mild weakness, muscle pain	1361 U/L (0-190)	3.9mg/dL (9-10.8)	yes
Syriou et al[5]	2005	47	M	8 months	Myopathy, skin rash	3281 U/L (20-180)	1.1mmol/L (2.02-2.62)	no
Zambelis et al[6]	2009	62	M	1 year	Muscle weakness, paresthesias	1.29 U/L (26-174)	5.4mg/dL (8.1-10.4)	yes
Yamaguchi et al[7]	1987	65	F	20 years	Carpopedal spasm	756 IU/L (<110)	5.0mg/dL	yes
Roca et al[8]	1995	61	M	30 years, 2 years	Seizures, dementia	2220 U/L	5.5mg/dL	no
Kruse et al[9]	1982	13	F	2 years	Myopathy, waddling gait	268 U/L (<50)	0.98 mmol/L (2.2-2.6)	no
Van Offel et al[10]	2000	36	F	1 year	Fatigue, myalgia, muscle weakness	189 U/L(10-50)	5.1mmol/L (8.8-10.2)	no
Hower et al[11]	1974	8	F	7 years	Seizures	946 mU/mL (<50)	4.4 mg%	no
Walters[12]	1979	12	M	2 years	Muscle spasms, tingling	13.0 µmol/mL/hr (0.25 -3.6)	1.37 mmol/l	no
Wray et al[13]	1987	30	F	15 years	Muscle spasms ataxia	836 U/L	6.9 mg/dL	no
Akmal[14]	1993	45	F	5 days	Rhabdomyolysis	26080 U/L	4.1 mg/dL	no

[a]Normal values in parentheses.
[b]When cataracts were not mentioned in the published case report, it was assumed that there was no history of premature cataracts.

CONCLUSION

The association of hypoparathyroidism with myopathy and elevated CK levels is an important one to consider when evaluating patients with myalgias and muscle weakness. When this is recognized, treatment with calcium and calcitriol relieves symptoms and CK levels return to normal.

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Proposal for a State Health Technology Assessment Program

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ABSTRACT

Evidence suggests that a significant number of medical technologies are of little or no benefit to patients. Under current budgetary pressures, state health care programs cannot afford continued spending on unnecessary medical care without further cuts in enrollment. Limiting coverage of high-tech care only to indications supported by good clinical evidence would help save state health care dollars. However, there is currently no public process to formally evaluate new medical interventions in Wisconsin. In fact, new therapies often are introduced into clinical practice, and covered by state health insurance programs, even when there is weak or questionable evidence of clinical effectiveness. This article proposes the creation of a state Health Technology Assessment program in Wisconsin to systematically evaluate new tests or treatments, and to promote evidence-based coverage decisions. Such a program would help limit wasteful spending on unnecessary technologies, reinforce good clinical practice, and protect patients from the risks of interventions that have not been proven effective.

Defining what does and does not work in medicine is a professional responsibility of the highest order, one that physicians have resisted assuming.[1]

INTRODUCTION

The 2011-2013 Wisconsin state budget calls for more than $550 million in reduced Medicaid spending. A significant portion of the spending reductions will be in the form of enrollment and benefit cuts. The state budget includes numerous efficiency proposals, but its projected savings are far more modest. Missing from the list of efficiency proposals is the establishment of a State Health Technology Assessment (HTA) program. The omission is striking since a program of this sort, created by the state of Washington, was projected to save $31.8 million in 2011.[2] This figure vastly exceeds any of the projected savings expected from any of the Wisconsin Medicaid efficiency proposals, and does not involve cuts to enrollment or evidence-based care.

Researchers have identified significant variations in the use of high-tech interventions. Studies of physician behavior have shown that a variety of incentives, unrelated to the evidence, drive the use of technology: a subjective bias in favor of technology, financial incentives, anxiety regarding patient expectations, fear of lawsuits, clinical decision-making based on anecdotal experience, and an erroneous underestimation of the risks of high-tech interventions.[3] According to Deyo, "[v]ested interests, marketing, politics, and media hype often have more influence on how new medical advances get used than the best scientific evidence."[4] All of these factors have contributed to the inappropriate use of medical technologies and help explain why experts have found that 30% of medical care—including high-tech care—is of little or no clinical benefit.[5]

The challenge for health care policymakers is to have a reliable process for identifying unproven interventions and thus avoid premature or overly permissive coverage decisions. Three consequences of the current approach include (1) higher health care costs without proven benefit, (2) too much influence of marketing over coverage policy, and (3) an increased risk to patients, including the adoption of a more aggressive clinical approach.

All of these consequences are well illustrated by the rapid adoption of robotic-assisted laparoscopic prostatectomy (RALP) into clinical practice over the past decade.

Weak Coverage Policy and the Case of Robotic Prostatectomy

The US Food and Drug Administration (FDA) approved RALP (da Vinci Surgical System; Intuitive Surgical Inc, Sunnyvale, California) for radical prostatectomy in 2001. Since then, RALP has become the dominant approach to prostatectomy, increasing costs significantly. The robot used to perform RALP

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now costs over $2 million, plus more than $150,000 per year in maintenance fees. It adds more than $2000 to the cost of each surgery. But the widespread adoption of RALP occurred despite a lack of clear evidence that the use of robotic technology in prostate surgery produced better clinical outcomes.

Marketing of the device has been particularly aggressive. According to Turner, the early adoption of RALP by hospitals and urologists was driven more by "[c]ompetitive market pressures and our enduring hope that somehow the latest, greatest and best will help us beat the odds."[6] Some of the marketing used by hospitals to promote RALP was reviewed in a study of 400 hospital websites. The study found that 86% of websites declared that RALP was clinically superior, and 32% claimed that it resulted in improved cancer control.[7] But there was no conclusive evidence of clinical superiority or improved cancer control at the time. In fact, Andriole concluded that "in this particular instance, with this particular robot, there hasn't been a quantum leap in anything."[8]

When the widespread adoption of a new medical technology precedes adequate vetting, there can be increased risks to patients. For instance, some early studies found that RALP was associated with higher rates of the 2 most feared complications of prostatectomy—impotence and incontinence.[9,10] These higher rates likely were due, in part, to the long learning curve required to achieve consistently low complication rates. Some studies found that surgeons needed to perform at least 250 RALP procedures to achieve consistently low rates of impotence and incontinence, but others have found that 1000 to 1500 surgeries are needed to assure consistently low complication rates.[11] The minimum number of procedures necessary to assure an optimal level of expertise has not yet been established or validated. Interestingly, more than 70% of RALP surgeries are performed by urologists who do fewer than 100 cases per year.

An additional risk to patients is that the technological imperative associated with new techniques can itself lead to increased rates of aggressive intervention. A study of 52 Wisconsin hospitals found that, between 2002 and 2008, 23% of the hospitals studied purchased robotic technology for prostate surgery. In hospitals that did not acquire robotic technology, prostatectomies decreased, consistent with the general trend in Wisconsin and across the country of decreasing prostate cancer rates. But, despite a decreased incidence of prostate cancer, prostatectomies increased by 25.6% in hospitals that acquired robotic equipment.[12] These findings suggest that purchase of the robotic technology seems to have incentivized Wisconsin urologists to perform more surgeries than they would have performed had they not been using RALP. In other words, the availability of the new technology, rather than any specific clinical factor, appears to have contributed to increased rates of aggressive surgery.

The lack of convincing evidence of clinical benefit at the start of the robotic era should have led policymakers to classify the procedure as essentially investigational. Instead, most public and private carriers—including Medicare—chose a more passive approach. They chose to cover robotic prostatectomies, but without additional reimbursement for use of robotic assistance. However, when no additional reimbursement is offered for new interventions, hospitals will routinely shift costs to other areas. In addition, surgeons will tend to increase the volume of procedures performed, as reflected by the increased rates of prostatectomies in Wisconsin hospitals that acquired robotic technology. All of these strategies increase health care costs for everyone, and allow unproven technologies to prematurely diffuse into clinical practice before they have been adequately evaluated.

BACKGROUND

Other developed countries have established national technology assessment programs. England's National Health Service (NHS), for example, established the National Institute of Clinical Excellence (NICE) in 1999 to set standards for the use of medical technologies and procedures.[13,14] Since 2002, NHS has been required to pay for technologies recommended by NICE. Those therapies not recommended by NICE are not usually covered. NICE also prepares public health policy recommendations and produces clinical guidelines. There is a strict conflict of interest policy which does not allow employees, NICE directors, or the chairs of advisory committees to have financial relationships with industry.[15] This is in sharp contrast to the United States, where up to 90% of clinical guideline authors have financial conflicts of interest.[16]

US Attempts to Establish a National HTA Program

Attempts to establish a national technology assessment program in the United States have been fragmented and frequently undermined by manufacturers and the medical profession.[17] The Office of Technology Assessment (OTA), established in 1972, acted as an advisory board to Congress on a broad range of health care issues, but was abolished by Congress in 1994. Nevertheless, the OTA became the model used by countries such as Denmark, Germany, the United Kingdom, the Netherlands, and Sweden to establish their national HTA programs.[18]

In 1978, the National Center for Health Care Technology was given a mandate to oversee research on health care technology. The center conducted a number of evaluations of surgical procedures, and issued about 75 recommendations to the Medicare program. The agency was abolished 3 years later due

to funding cutbacks by the Reagan administration and pressure from the American Medical Association and the Health Industry Manufacturers Association.[19]

Another US government initiative was the Agency for Health Care Policy and Research (AHCPR). The AHCPR was established in 1989 to enhance the quality, appropriateness, and effectiveness of health care services. In 1994, it published an evidence-based back pain clinical guideline demonstrating poor or insufficient evidence to support many back surgeries. In response to pressure from orthopedists, neurosurgeons, and the medical device industry, unhappy with the findings of the clinical guideline, Congress nearly abolished the agency. The agency survived, but Congress redirected its focus away from evaluative research and changed its name to the Agency for Health Care Research and Quality (AHRQ).[20]

AHRQ technology assessments are sometimes used by the Centers for Medicare and Medicaid Services (CMS) to guide coverage decisions. Based in part on AHRQ technology assessments, the CMS Coverage and Analysis Group (CMS-CAG) issues 10 to 15 National Coverage Determinations (NCDs) each year. CMS-CAG also has the option of requesting advice from the Medicare Evidence Development and Coverage Advisory Committee (MedCAC). MedCAC is an independent committee that includes 15 members with knowledge specific to the topic in question. Based on a systematic review of the evidence, MedCAC makes coverage recommendations to CMS-CAG. However, recent decisions suggest that the separation of MedCAC's advisory role from CMS-CAG's coverage policymaking authority has made it easier for special interests to derail evidence-based coverage decisions.

For example, in 2005, CMS-CAG requested that MedCAC review the evidence for the use of cardiac computed tomography angiography (CCTA) and provide coverage recommendations to CMS-CAG. After an exhaustive review of the evidence, in May 2006 MedCAC recommended that CMS-CAG issue an NCD for CCTA. The recommendation was based on the finding by the committee that "the relevant data were limited to small, single-center studies of selected populations and did not demonstrate a benefit with regard to outcomes."[21] However, pressure from cardiologists, radiologists, and industry representatives led CMS-CAG to essentially ignore the MedCAC recommendation.[22] CMS-CAG issued no NCD, resulting in widespread coverage of CCTA by Medicare. Three years after that CMS decision, the National Institutes of Health (NIH) agreed to fund a multimillion dollar randomized control trial (RCT) of 10,000 patients to help determine the proper clinical role for CCTA. Paradoxically, the relevant clinical effectiveness research is being performed after, instead of before, widespread coverage of the test.

Comparative Effectiveness Research (CER)

Despite setbacks, there is evidence that CMS is tightening its evidentiary requirements for new technologies.[23] In addition, the Patient Protection and Affordable Care Act (PPACA) of 2010 established an independent, trust-endowed, not-for-profit corporation named the Patient-Centered Outcomes Research Institute (PCORI) to support the production of well-validated scientific evidence, particularly comparative effectiveness research (CER). CER probably will account for an increasing portion of the US research enterprise, and will provide the high quality evidence necessary for future technology assessments and evidence-based coverage decisions.

PCORI will create and manage a national CER agenda, giving preference to the Agency of Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH). It is not yet clear how CER results will be used to make coverage decisions at the state or national level. In fact, the PPACA legislation explicitly states that CER findings by themselves cannot be considered sufficient to determine coverage policy. CMS-CAG (or a state HTA program) would need to include CER findings in its assessments, and make independent decisions based on all of the evidence.

State HTA Programs must Complement Federal Efforts

It remains to be seen whether the establishment of PCORI will be accompanied by an increased number of CMS technology assessments and NCDs. An average of 10 to 15 NCDs per year is insufficient to adequately address the large volume of new technologies entering the market every year. But it will take time for the federal HTA process to evolve and expand. In the meantime, increasing budgetary pressures at the state level are forcing states to find ways to address these issues sooner.

States are well-positioned to establish effective HTA programs.[24,25] Even if the United States ultimately adopts a more robust federal HTA effort, it will not eliminate the need for state or regional HTA programs. There are important differences between the Medicare and Medicaid populations. CMS tends to focus more on technologies that have the greatest impact on elderly populations, but state budgets are equally affected by technologies that impact their younger Medicaid patients. In addition, state HTA programs will be crucial in translating future CER findings into coverage decisions that take into account local health care needs and structures.[26]

CURRENT APPROACH TO STATE COVERAGE POLICY

In the absence of a formal state HTA program, most state coverage policy decisions rely on an ad hoc process, based as much on what others are doing as on a systematic review of the evidence. State health policymakers typically start by assuring

that new technologies have been cleared by the Food and Drug Administration (FDA). Yet, recent FDA failures have demonstrated that FDA review is sometimes an inadequate indicator of safety. The next step for policymakers usually is to establish whether a new intervention is considered to be the standard of care. But there is no accepted clinical measure for determining the standard of care. In practice, state policymakers frequently base their coverage decisions on a review of other public and private insurer policies rather than conducting their own formal technology assessment.

Limits of FDA Regulation

In 1976, Congress mandated that the FDA begin regulating medical devices.[27] The law created 2 pathways to FDA approval. The premarket approval (PMA) pathway was designed especially for high-risk medical devices and required the review of at least some trial data. A quicker pathway for approval, called the 510(k) provision or exemption, was designed for lower risk devices, such as tongue depressors and crutches. It required only that manufacturers claim that a device be substantially equivalent (SE) to a previously approved device.

The 510(k) provision was never intended for high-risk devices, but over 98% of all new medical devices are now cleared using the 510(k) provision, including many high-risk devices. The most frequent recalls for high-risk devices are for cardiovascular devices. It would seem prudent to require that high-risk cardiac devices undergo review through the PMA pathway, but a striking two-thirds are cleared using the 510(k) exemption. Furthermore, a review of FDA medical device recalls for life-threatening or very serious hazard found that 81% had been approved through the 510(k) provision.[28] These and other findings have led the Institute of Medicine to recommend eliminating the 510(k) exemption altogether.[29]

There is evidence that even the PMA review process is inadequate to assure the safety of high-risk devices. A study of high-risk cardiac devices undergoing PMA review found that less than one-third had been studied in a randomized control trial (RCT), and only 5% had been evaluated by 2 or more RCTs.[30] However, even if FDA reforms improve the safety review process, policymakers ultimately are interested in knowing which interventions are clinically effective. In the absence of clear guidance regarding clinical effectiveness, policymakers often base coverage decisions on the standard of care. But the standard of care is difficult to define and it is not always a reliable indicator of clinical effectiveness.

Limits of Relying on Standard of Care

The factors that lead physicians to adopt new technologies have been a frequent subject of social science research. Published findings from the University of Wisconsin show that science is often overshadowed by the strong influence of local consensus, and that "[t]he scientific literature fails for a number of reasons to speak persuasively to the practitioner."[31] Since the 1980s, evidence-based medicine (EBM) has focused more attention on some aspects of clinical practice, but it has had remarkably little effect in changing the way physicians adopt new technologies. In addition, the skills required to perform technology assessments go well beyond basic EBM principles.[32] As mentioned earlier, factors such as reimbursement incentives, biases in favor of technology, fear of lawsuits, and anxiety over patient expectations still play a significant role in physicians' use of technologies.

New interventions are often promoted on the basis of clinical efficacy trials, which are typically industry sponsored. Physician proceduralists, the medical device industry, and other technology enthusiasts often argue that it is unethical to wait for more evidence when initial trials demonstrate potential benefit. In the previously discussed case of CCTA, these groups even argued that using Medicare's Coverage with Evidence Development (CED) policy would have been unethical because it would have denied access of the new imaging modality to patients not enrolled in a clinical trial. Proponents of new technologies often argue that rigorous evidentiary requirements such as those preferred in HTA evaluations are too onerous and hamper innovation.

All of these arguments were used in the late 1980s and 1990s when, based on small clinical trials, oncologists, industry representatives, and hospitals promoted the use of autologous bone marrow transplantation (ABMT) for the treatment of late stage breast cancer. Although there had been no RCT to demonstrate its effectiveness, by 1989, almost 80% of oncologists considered it a recommended treatment for advanced breast cancer.[4] At the time, the cost of the procedure was about $150,000 and increased to $500,000 if there were complications, which were common. Use of the procedure grew exponentially throughout the 1990s. Finally, by the end of the decade, 4 RCTs had shown that ABMT was an ineffective therapy for advanced breast cancer, associated with more toxic effects and deaths than standard treatment.[33] Approximately 42,680 women were subjected to unnecessary ABMT procedures, and at least $1.7 billion in excess costs were incurred.[34]

The ABMT episode is just one of many examples of technology overuse and misuse in the United States. Other examples include the ongoing inappropriate use of pulmonary artery catheters, spinal fusion surgery, vertebroplasty, drug eluting stents, percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) surgery, and arthroscopic knee surgery for osteoarthritis. In comparison to other developed coun-

tries, the United States performs on average 1.9 times the rate of PCIs, 1.4 times the rate of cardiac catheterizations, and 1.9 times the rate of knee replacements.[35] But the ABMT example is especially useful to illustrate what happens when there is no formal HTA program in place to systematically evaluate the evidence for new technologies. It also highlights the risks of relying too heavily on the advice of influential specialists or idea champions who may err on the side of promoting treatments that have not been adequately proven.[31] The point is not that expert opinion should be ignored, but that it is inadequate in the absence of a formal HTA framework to evaluate and characterize the level of evidence for clinical effectiveness.

COVERAGE POLICY BASED ON HTA PRINCIPLES

Part of the problem is that the medical profession lacks a consensus definition for clinical effectiveness. As a result, experts often refer to evidence that speaks to safety or efficacy, but not to clinical effectiveness. One of the primary benefits of establishing a formal technology assessment program is that it compels physicians to use an explicit methodology for establishing clinical effectiveness. Clinical or comparative effectiveness studies are the most useful in conducting technology assessments. They measure hard clinical outcomes, make comparisons with standard therapies, evaluate real-world settings, and involve long-term follow-up. Hard clinical outcomes include death, functional status, or quality of life, and provide the most direct evidence of clinical effectiveness.

Most of the industry-sponsored studies used to promote the early adoption of unproven technologies are clinical efficacy trials. Clinical efficacy studies are much weaker than effectiveness trials, but easier to perform. They often use surrogate outcomes, comparisons with placebo, investigational settings, and short-term follow-up. Surrogate outcomes are clinical indicators or biomarkers such as blood pressure, lipid levels, glucose levels, or prostate specific antigen levels. Surrogate outcomes are attractive because they are easier to measure than clinical outcomes, but they often have not been well validated.[36] Furthermore, some experts warn that our over-reliance on surrogate outcomes has led to poor clinical practices and has helped promote false innovations that are often later proven ineffective or harmful.[37]

The Institute of Medicine has identified HTA as the best approach to evaluate new treatments.[38] HTA is defined by the International Network of Agencies for Health Technology Assessment (INAHTA) as "a multidisciplinary field of policy analysis, studying the medical, economic, social, and ethical implications of development, diffusion, and use of health technology."[39] International experts in the field have identified 15 key principles of HTA that can be divided into 6 broad categories: (1) organization and structure, (2) level of transparency, (3) stakeholder involvement, (4) topic nomination and selection, (5) evidence synthesis, and (6) use of HTA in decision making.[40]

States that establish HTA programs will be better positioned to adopt evidence-based coverage policies and save health care dollars by eliminating wasteful spending on ineffective technologies. Three states—Minnesota, Oregon, and Washington—have established HTA programs. But the Minnesota and Oregon HTA programs are limited to an advisory role. The Washington HTA program is the only program that combines technology assessment responsibilities and coverage decision-making authority within the same committee. As we have seen in the case of MedCAC and CMS-CAG, separating the advisory role from policymaking authority can lead to weaker coverage decisions that are poorly aligned with the evidence. Because the Washington HTA program provides a stronger framework for implementing evidence-based coverage policy, it merits closer consideration.

WA-HTA PROGRAM MODEL

The WA-HTA program was established in 2006 with strong bipartisan support. The nearly unanimous vote in the state legislature was backed by statewide medical groups, including the Washington State Medical Association. The mission of the WA-HTA is to assure that "formal methods are used to conduct critical appraisals of surgical devices and procedures, medical equipment, and diagnostic tests and to translate the results of those evaluations into coverage determinations."[41] The WA-HTA review board, composed of 6 physicians and 5 other practicing health care professionals, reviews all pertinent research prepared as an HTA report prior to voting on coverage decisions. It makes coverage decisions affecting about 763,000 people in state-purchased fee-for-service health care programs including Medicaid, the workers' compensation program, the state government employee benefit plan, and the corrections department. Any coverage decision reached by the WA-HTA committee must be followed by all state payers.

The WA-HTA program maintains a web-based portal that allows the public to make comments about ongoing assessments and view final health technology reports and decisions. At present, the website has more than 30 completed technology assessments.[42] About half of the completed assessments include decisions to stop coverage of specific tests or interventions including arthroscopic knee surgery for osteoarthritis, calcium scoring, spinal cord stimulators, therapeutic medial branch nerve block injections, intradiscal injections and facet injections. Other reports, for example those regarding the use of ultrasound in pregnancy and hip resurfacing, outline specific evidence-based coverage criteria.

Not surprising, some of the coverage determinations have been criticized, especially by industry representatives and physicians adversely affected by the decisions. However, this is a normal component of the HTA process, and it is why 2 of the 6 broad categories for any HTA include stakeholder involvement and level of transparency. The WA-HTA program also provides the opportunity for public comment on: topic nomination; submission of evidence for consideration; draft reports; coverage decision meetings; and draft coverage decisions. The coverage determinations are made in a public forum, and the committee members are independent of state agency payers and industry stakeholders. The WA-HTA program represents a model that other states should strongly consider.[24]

CONCLUSION

One estimate from the nonpartisan Wisconsin Legislature Fiscal Bureau calculates that up to 65,000 people, including 29,000 children may lose BadgerCare coverage due to budget cuts. Before further enrollment cuts are made, it would seem appropriate to establish a state HTA program in Wisconsin that can help identify and eliminate wasteful spending on unproven or ineffective medical technologies. Such a program would also improve the state's ability to align coverage policy with the findings of what will be a growing body of comparative effectiveness research to be published in the coming years.

Wisconsin could integrate a formal state HTA program with other state initiatives such as the Wisconsin Network for Health Research (WiNHR). A Wisconsin HTA program also could provide guidance to new Accountable Care Organizations (ACOs) in their attempts to bend the cost curve. It could help the Wisconsin Collaborative for Healthcare Quality (WCHQ) develop metrics for inappropriate medical technology utilization. The expertise gained through a state HTA program could be used to develop global capitation and other payment models that offer higher reimbursement schemes for the most clinically effective interventions and to stop rewarding volume over value in health care.[43] Finally, a Wisconsin state HTA program could work collaboratively with other federal and state HTA programs to avoid duplicating efforts when possible.

Albert Einstein once said, "[n]o problem can be solved from the same level of consciousness that created it." The consciousness that created our current problem is one that has failed to take a more scientific approach toward determining what works and does not work in health care. It is also a consciousness that has allowed interests other than science to have far too much influence in shaping clinical practice and has failed to emphasize physicians' professional responsibility for the stewardship of scarce health care resources.[44,45] A Wisconsin HTA program would represent a different consciousness with regard to coverage policy, one that is more evidence-based and sorely needed to address the problem of health care technology misuse and overuse.

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Office-Based Nursing Staff Management of Hypertension in Primary Care

Danielle R. Gindlesberger, MD

ABSTRACT

A family medicine practice in a large multi-specialty clinic undertook a quality improvement initiative focusing on blood pressure control. Current rooming procedures were reviewed, including obtaining accurate and reliable blood pressures. All rooming staff were instructed how to take an accurate blood pressure and were observed at random over a 3-month period to ensure continued accuracy. Rooming staff (medical assistants and licensed practical nurses) were engaged to give patient education and to arrange a standard 2-week follow-up with a rooming staff team member (nurse visit) if the patient's blood pressure was elevated. Clinicians were educated briefly about the importance of managing hypertension regardless of reason for visit. Blood pressure control (<140/90) in patients age 18-85 without diabetes improved from 68.4% to 75.8% in 3 months.

BACKGROUND

Dean Health Systems is a multi-specialty health care delivery system based in Madison, Wisconsin. The Sun Prairie, Wisconsin, clinic is predominantly a primary care clinic, with 11 family medicine providers. The system has provided primary care physicians with dashboard reports on Wisconsin Collaborative for Healthcare Quality (WCHQ) measurements. These reports were unblinded, so physicians and clinics were able to see areas for improvement when compared to their colleagues. Because of the need to improve hypertension control, the Sun Prairie clinic's Family Medicine department developed a hypertension improvement project using Lean methodology.

METHODS

Administrators, clinicians, roomers, and triage staff all provided insight into the workflow of a patient presenting to our primary care clinic. We mapped out our perception of the process a patient goes through when presenting to the clinic, and then observed the actual process through multiple patient interactions. This process allowed us to find the discrepancies between what ought to be done and what was actually happening in the clinic. With the input of the same group of people, we developed a more efficient work flow. To ensure accurate blood pressures, all nursing staff were educated on the appropriate technique for obtaining blood pressures and were observed randomly over 3 months to ensure maintenance of the appropriate technique.

Clinician inertia was often related to the number of problems to be addressed at any given visit. An elevated blood pressure (BP) often was pushed to the bottom of a list of concerns and sometimes was overlooked.[1] A process of alerts in the electronic medical record were built to alert roomers to the elevated blood pressure, prompt them to obtain a repeat blood pressure measurement after 5 minutes (the recommended timing of sitting at rest from the American Heart Association), hand out patient education material, and schedule a 2-week follow-up nurse visit for BP recheck. A 2-week follow-up was chosen because most antihypertensive medications have reached their full effect by 2 weeks.

An alert for the clinician also was designed, with interactive tools of most recent BPs and a reminder to update the patient's problem list. The problem list was enhanced so that all BP-related labs and medications would display in 1 place in the problem list to make medication adjustments easier. Since patients were aware that their BP was elevated and would be addressed at their appointment, more clinicians were taking the extra few minutes to change medication in addition to addressing the other concerns that patients had that day. When patients returned at 2 weeks for BP checks with nursing staff (medical assistants), patients were told their BP. If it was elevated they were told the clinician would be in contact with them to adjust their medication. A telephone encounter in the electronic medical record (EMR) then was generated and sent to the clinician with the patient's most recent blood pressures

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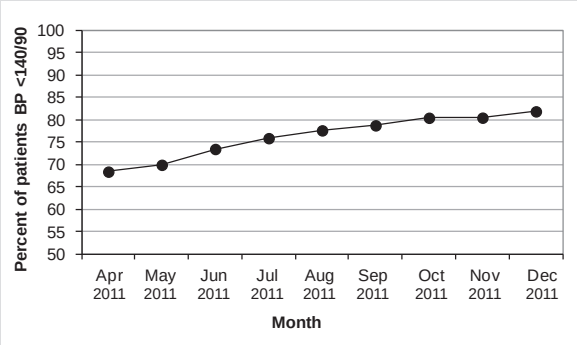
Table 1. Uncomplicated Essential HTN Blood Pressure Control, Dean Clinic—Sun Prairie, Wisconsin, Family Medicine

Month Ending	# of Patients BP <140/90	# of Patients HTN Population	% BP <140/90
April 2011	974	1425	68.4%
May 2011	1016	1454	69.9%
June 2011	1063	1448	73.4%
July 2011	1095	1444	75.8%
August 2011	1124	1449	77.6%
September 2011	1152	1464	78.7%
October 2011	1176	1463	80.4%
November 2011	1182	1470	80.4%
December 2011	1197	1463	81.8%

Abbreviations: BP, blood pressure; HTN, hypertensive

Figure 2. Uncomplicated HTN Blood Pressure Control



Dean Clinic - Deerfield and Dean Clinic - Sun Prairie Family Medicine

so that medication changes could be made. Again, a standard 2-week follow-up for a blood pressure check with nursing staff was implemented until the patient's blood pressure was under 140/90.

A "float room" that was previously used for walk-in patient triage was used to take blood pressures for these blood pressure-only visits. This process utilized the clinic's current space and did not require addition of any extra personnel.

RESULTS

At the start of this quality improvement project, BP control (BP <140/90 in nondiabetic patients age 18-75) was only 68.4%. By 3 months it had improved to 75.8% (Table 1, Figure 1). We continue to track progress.

Engagement of nursing staff was important in the improvement process, and hypertension control numbers were displayed each month in each nursing station along with the previous dashboard reports.

DISCUSSION

While the original focus on numbers was with the clinic's non-diabetic population, we are utilizing this same process for diabetic patients with a goal BP of < 130/80. We have seen improvement in these numbers as well, but with a slower change—as would be expected given the lower goal. We currently are extrapolating the lessons learned at our clinic and implementing them across other system sites. As a multi-specialty health system, we now are focusing on ways to incorporate what we have learned in a primary care setting and trying to implement changes in specialty departments in which the clinicians do not treat hypertension. The need for ease of follow-up for patients is key. Given rising health care costs and increases in patients' deductibles and co-pays, providing an easy-to-use nursing system that requires no payment from the patient increases patient willingness to return to the clinic at frequent intervals, which in turn results in quicker blood pressure improvement. Use of nursing intervention to help with blood pressure control is not a new model of care, but it is a new model of care for our clinic. We have utilized nursing staff to manage diabetes through diabetes nurse educators for many years, but this had not been expanded to blood pressure management before now.

CONCLUSION

A 2010 Cochrane review showed that family medicine and community-based clinics need an organized system to follow up and review their patients with hypertension.[2] How best to do this is yet to be determined, but a model of care allowing each person on the health care team to function to the highest level of their degree will provide quality, efficient, and low-cost health care. We have found that using nursing staff to provide this service allows for ease of patient use, improved follow-up, and in the end, lower blood pressures. Future plans include implementing protocols to allow rooming staff to increase blood pressure medications.

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Supreme Court Upholds Affordable Care Act, Questions Remain

John Rather, JD

The US Supreme Court (Court) issued its decision in *National Federation of Independent Business v. Sebelius,* the highly anticipated case regarding challenges to the Affordable Care Act (ACA), on June 28, 2012. In a 5-4 decision, the Court upheld the constitutionality of the ACA, including the requirement that most individuals obtain health insurance or pay a tax (commonly known as the "individual mandate"), as well as the ACA's expansion of Medicaid. However, the Court struck down the federal government's ability to withhold all Medicaid funding from states that do not expand Medicaid eligibility. While the Court's decision provides clarity on the current status of the law, there remains as many questions as answers about whether and how the ACA will affect states and physicians.

Background

The ACA, which was signed into law by President Barack Obama in March 2010, represents the largest change to national health care law since the creation of Medicare and Medicaid. The ACA is comprised of the Patient Protection and Affordable Care Act (PPACA) and Health Care and Education Reconciliation Act (HCERA). The goals of the ACA are to expand health care access, improve health care quality, and implement cost-containment and financial reform strategies. The ACA increases the number of Americans with access to health care, expands health insurance market requirements, creates health insurance exchanges to provide individuals and small employers with access to insurance, reforms payments under Medicare and Medicaid, and establishes numerous programs, pilots, and incentives to control rising health care costs. The ACA calls for staggered implementation of various provisions. Some provisions went into effect immediately, others took effect in subsequent years, and still others will take effect between now and 2018.[1]

Multiple challenges to the ACA were filed almost immediately after its passage. Wisconsin joined a lawsuit with 25 other states, including Nebraska and North Dakota, in which the US Court of Appeals for the Eleventh Circuit affirmed a Florida district court's decision striking down the "individual mandate" as unconstitutional but upholding the remainder of the law. That decision was appealed to the US Supreme Court, which heard an unprecedented 3 days of oral argument in March 2012.

The Supreme Court Decision

The challenges focused on 2 provisions of the ACA: the "shared responsibility payment" (individual mandate) and the expansion of Medicaid eligibility. Under the individual mandate, most Americans will be required to obtain health insurance (personally or through an employer) or pay a tax starting in 2014. Under the Medicaid expansion, states would be required to expand Medicaid coverage to include any non-Medicare eligible individual without health insurance whose income is below 133% of the federal poverty line (FPL).

The Supreme Court upheld the individual mandate, not under the Commerce Clause of the Constitution as many anticipated, but as a valid exercise of Congress's power to impose taxes. The majority opinion, written by Chief Justice John Roberts, noted that taxes often are used to incentivize or deincentivize conduct and the ACA does not make going without health insurance illegal because an individual can fully comply with the law by paying the tax instead of purchasing insurance. Therefore, the Court found the individual mandate to be a valid exercise of Congress's power to impose taxes.

The Court did, however, strike down a provision in the ACA giving the federal government the power to withhold all Medicaid funding from states that do not expand eligibility. The Court held that while the federal government can provide financial encouragement to states to implement the desired Medicaid expansion, it cannot withhold existing funds in order to coerce states into compliance. Medicaid funding accounts for approximately 10% of most states' budgets. Withholding all Medicaid funding from states, according to the majority opinion, is not "relatively mild encouragement—it is a gun to the head." By striking down the

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federal government's ability to condition all Medicaid funding on a state's compliance with the expansion, the Court effectively made the expansion of Medicaid optional for states. However, all other provisions of the ACA remain in effect.

What the Supreme Court's Decision Means for Physicians

The ACA's goals of increased access to health care and cost control mean that physicians can expect increased patient demand and an emphasis on accountability and efficiency. The Congressional Budget Office estimates that 30 million to 32 million additional Americans will have access to health care as a result of the ACA.[2] While the fact that the Medicaid expansion was made optional by the Court undoubtedly will affect this estimate, there will still be millions of new patients looking for physicians. Primary care physicians are expected to see the greatest increase in demand. An unknown percentage of those new patients may be covered by Medicaid, increasing administrative and financial strains on certain providers. Physicians will have to ensure that increased demand does not result in decreased quality and will have to find efficient ways to handle the increased demand and associated administrative burdens.

Perhaps an even larger long-term effect of the ACA on physicians is the move toward new payment methodologies. The ACA begins a potential move away from the fee-for-service model that some contend incentivizes excess treatment and toward a more accountable, efficient, and coordinated system. These new methods stress coordination across provider networks and disciplines in order to reduce duplicate efforts and to control costs. These methods also stress accountability by incentivizing providers to cut down on unnecessary tests and by reducing payments under Medicare for readmissions and hospital-related infections. Some providers may find these new methods advantageous while others may find them cumbersome or even arbitrary. Regardless, these new methods will put physicians and other health care professionals at the forefront of cost containment and stress efficiency, coordination, and accountability for quality.

What the Supreme Court's Decision Means for Wisconsin

While the Supreme Court's decision confirms the current status of the law, it is not clear how this will affect Wisconsin. The same day the Court released its decision, Governor Scott Walker stated that Wisconsin will not take additional steps to comply with ACA until after the November elections, which he hopes will result in a federal government that repeals the ACA.[3] Wisconsin Attorney General J.B. Van Hollen has stated that Governor Walker is obligated to follow the ACA, but also noted that "…there are a number of parts of this law that give options to the states and give time frames that allow wiggle room."[4]

Wisconsin's strong record on health care will likely shape its implementation of the ACA. For example, the Medicaid expansion would provide coverage to anyone with income below 133% of the FPL. However, Wisconsin's BadgerCare Plus and Core Plan provide coverage to individuals with income below 200% of the FPL, including individuals without dependents. Thus, the now-optional Medicaid expansion may not have as dramatic of an impact in Wisconsin as it would in other states because Wisconsin has one of the lowest rates of uninsured people in the nation.[5]

Further, some states that currently cover more than the required minimum under Medicaid, like Wisconsin, have suggested that they could cut eligibility back to the federal minimum in order to save money. The ACA requires states to maintain their Medicaid eligibility to those at the time the ACA was enacted, but some states, such as Maine, contend that this too was struck down by the Supreme Court.[6] It is not clear yet whether Wisconsin will participate in the expansion, maintain current eligibility standards, or reduce eligibility as implementation of the ACA continues.

The ACA also requires states to set up health insurance exchanges, which are designed to foster competition among insurers, standardize plans, and allow consumers and employers to compare and purchase coverage. If a state does not set up an exchange, the federal government may set one up for the state instead. Wisconsin began work on a Wisconsin-specific exchange in 2010, but that work was halted soon after Wisconsin joined the legal challenges to ACA. It is not clear whether Wisconsin will resume work on a health insurance exchange, whether the federal government will be forced to set one up, or whether Wisconsin will establish a hybrid system shared between the state and HHS.

Additional Resources

- Wisconsin Medical Society FAQs: http://www.wisconsinmedicalsociety.org/_WMS/publications/medigram/_files/07262012/ACA_FAQ_july12.pdf
- Full text of the US Supreme Court's decision: http://www.supremecourt.gov/opinions/11pdf/11-393c3a2.pdf
- Full consolidated text of ACA: http://housedocs.house.gov/energycommerce/ACAcon.pdf

Conclusion

The US Supreme Court's historic decision upholding the majority of the ACA provides clarity in that we know that the ACA, with the exception that expansion of Medicaid eligibility is now optional for states, is the law. This allows physicians, other health care professionals, organizations, and states to continue to plan for and comply with the ACA.

However, many questions remain. The

Court's decision has pushed the debate over the ACA back into the political arena, with some groups calling for the law's total repeal. It is unclear whether states will implement optional features of the ACA, such as the health insurance exchanges or Medicaid expansion, or how these choices will affect physicians. The ACA also requires new federal regulations to be written that interpret the ACA, only some of which have been written to date. Thus, while the Supreme Court's decision clarified what the law is, questions remain about the implementation and future of that law.

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Eileen M. Smith

Robert N. Golden, MD

The Wisconsin Partnership Program: Investing in a Healthier State

Robert N. Golden, MD, and Eileen M. Smith

Nearly 9 years ago, the University of Wisconsin (UW) School of Medicine and Public Health and the Medical College of Wisconsin received funds resulting from the conversion of Blue Cross/Blue Shield United of Wisconsin Inc. to a for-profit entity. The schools were charged broadly with making Wisconsin a healthier state. At the UW School of Medicine and Public Health, these funds created the Wisconsin Partnership Program (WPP), which is beginning its ninth year. The WPP has implemented a funding model that allows for an array of investments in health improvement: from building community-academic partnerships to training new public health-oriented clinicians to exploring the full range of factors determining health and disease. Some of these investments have been featured previously in the Dean's Corner, but their connection to the WPP may not have been apparent.

Since its first funding cycle, the WPP has awarded 264 grants worth more than $106 million to community organizations, local governmental entities, and university faculty. The awards are enabling public health leaders, educators, policy makers, scientists, and clinicians to address serious health and public health challenges in ways that were impossible in the past.

In the process, the WPP has catalyzed and energized the School's commitment to the Wisconsin Idea, which extends the University's reach to every corner of the state, by finding creative ways to improve health and reduce health disparities. The WPP also meshes perfectly with the School's transformation into an integrated school of medicine and public health, in which public health principles and practices are incorporated into all its missions.

Through its two governing bodies—the Oversight and Advisory Committee, which includes public members, and the Partnership Education and Research Committee, which includes faculty, school leadership, and a public member—the WPP ensures effective stewardship of the funds and transparency of its grant-making processes.

Below are examples of some of the many ways the WPP is making a difference.

Community Partnerships: The Community-Academic Partnership Program is the cornerstone of the WPP—pairing the knowledge and skills of representatives of community organizations with faculty and staff expertise to produce health interventions that are highly beneficial. Focusing predominantly on interventions that use collaborative partnerships for community health improvement, the awards address alcohol and other drug use, healthy growth and development, physical activity, and access to high-quality health services. Community groups have been remarkably successful in leveraging the awards into additional funding—more than $35 million—to sustain and grow their projects. The additional funding is directly attributable to the WPP's initial investment.

The most comprehensive community-academic partnership has been an initiative to promote community-wide improvements

> From its inception, the Wisconsin Partnership Program's vision has been to foster innovative approaches for building healthier communities, preventing disease, and informing public health policy.

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Doctor Golden is Dean, University of Wisconsin School of Medicine and Public Health; Ms Smith is Director, Wisconsin Partnership Program.

in maternal and child health that address the state's persistent racial disparities in birth outcomes, which have reached unconscionable levels over 3 decades. The WPP partners with coalitions in Milwaukee, Racine, Beloit, and Kenosha through the Lifecourse Initiative for Healthy Families (LIHF). The initiative seeks to tackle the problem by improving health care for African-American women, strengthening African-American families and communities, and addressing social and economic inequities. Through an extensive 2-year planning period, coalitions of agency leaders, local officials, public health practitioners, and members of the African-American community have developed community action plans that provide a roadmap to respond to this challenge. The WPP has committed up to $10 million to the LIHF initiative.

Education: The WPP is deeply engaged in educational reform. It has given substantial grants to support the development of the School's Wisconsin Academy for Rural Medicine, the Master of Public Health Program, and the Transforming Medical Education Program. These programs help ensure that Wisconsin's future workforce needs are met by physicians trained to practice in rural, underserved areas of the state, and that future physicians and public health practitioners are equipped to implement policy and public health interventions throughout the state. Other service-learning programs support population health fellows who provide technical assistance and analysis to community and public health agencies, and train community teams that focus on priority health concerns in their communities. Each of the WPP-funded educational programs emphasizes changing traditional ways of educating students to embrace a more encompassing view of the health status of the population.

Research: As with its education initiatives, the WPP funds research programs that can be translated easily to community practice. The programs, which include the Institute for Clinical and Translational Research, the Health Innovation Program, and the Survey of the Health of Wisconsin, have been successful in attracting significant federal grant funds to Wisconsin and in strengthening the research mission of the School as it joins communities in addressing local health issues. These programs have broken down walls that traditionally have separated research from practice, evidence from policy development, and specific populations from health resources. The WPP also supports individual projects along a continuum of basic, clinical, translational, and applied public health research, ranging from personalizing therapy for women with polyploid breast cancers; to early identification of Alzheimer's disease; to barriers to physical activity, fitness, and health in Hispanic children in Wisconsin.

Looking ahead, the WPP soon will develop a comprehensive program to attack the increasing rates of obesity in Wisconsin, which is one of the state's most complex health problems. The goal is to find the right combination of research, education, and interventions to effectively address a health issue that is reaching epidemic proportions.

From its inception, the Wisconsin Partnership Program's vision has been to foster innovative approaches for building healthier communities, preventing disease, and informing public health policy. This vision is guiding the transformation of the School's missions of education, research, patient care, and community engagement in ways that serve the people of Wisconsin now and in the future. For more information, visit http://med.wisc.edu/wpp.

The Cardiac Population Health Learning and Action Network: An Invitation

Jay A. Gold, MD, JD, MPH; Carrie Finley, RN, BSN

MetaStar is pleased to announce that as part of the Centers for Medicare and Medicaid Services' national quality improvement program, we are partnering with WHITEC, the Wisconsin Health Information Technology Extension Center, to support a Cardiac Population Health Learning and Action Network (Cardiac LAN). Network activities support the national "Million Hearts" initiative. We are inviting primary care practices in Wisconsin to join us in this initiative.

In order to reduce the prevalence of cardiovascular risk factors, the federal Department of Health and Human Services, in conjunction with nonprofit and private organizations, is launching Million Hearts, a multifaceted combination of evidence-based interventions designed to prevent 1 million heart attacks and strokes over the next 5 years.

The Cardiac LAN is engaged in a 3-year collaborative initiative to standardize, sustain, and spread improvements in the delivery of cardiovascular health services. Participating practices benefit from free assistance on measures they can take to prevent heart disease and stroke in their patients, and at the same time fulfill the public health requirement for the EHR Meaningful Use incentive. We also provide targeted assistance to medical practices in using their EHRs to track and report cardiac measure data.

While the concept is not new, Learning and Action Networks are a way to foster, study, adapt, and spread large-scale improvement around a given aim. Such a network creates opportunities for in-depth learning and problem solving; it accepts all offers of support seeking to catalyze interested parties; it is transparent, flexible, interchangeable, and purposeful.

Goals of the Cardiac LAN are ambitious. We currently are working to bring together primary care practices, cardiologists, and local and national stakeholders as a sustainable network aimed at improving health in populations at risk for ischemic vascular disease and other vascular diseases. We have been doing this through monthly webinars, e-newsletters, and face-to-face meetings. Our overarching goal is to connect stakeholders and physician offices to implement evidence-based interventions aimed at reducing risk factors and addressing disparities that contribute to heart disease and stroke. In addition, we support physician offices in implementing and measuring interventions to improve delivery of evidence-based care to patients at risk and to draw on experiences of cardiac patients to keep the "patient" at the center of care improvement.

Participation Benefits

Benefits for participating practices include the following:

- Assistance with qualifying for Physicians Quality Reporting System (PQRS) incentive payments
- Free consulting services, technical assistance, continuing medical education, tools, resources, and support
- Assistance with using EHRs for care coordination, monitoring, patient engagement, spread of best practices, and identification in disparities of care
- Quality of care improvement with emphasis on cardiovascular disease
- Participation in a collaborative, statewide LAN
- Exposure to state and national clinical experts
- Opportunities to provide mentoring to other Wisconsin practices

In addition to convening a sustainable Learning and Action Network, MetaStar is working to assist practices that have reached Stage I Meaningful Use to provide a forum for health care professionals, community stakeholders, and patients to come together to address the common goal of improving more general preventive care for adult patients. The Network focuses on specific clinical topics—flu and pneumococcal vaccinations, mammograms, colorectal cancer screening, hypertension, and tobacco counseling — and educates clinicians on integrating health information technology into their everyday practice.

If you are interested in learning more about these activities, contact Carrie Finley, RN, BSN, at cfinley@metastar.com.

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Doctor Gold is Senior Vice President and Chief Medical Officer, MetaStar; Ms Finley is a Quality Consultant at MetaStar. This material was prepared by MetaStar, the Medicare Quality Improvement Organization for Wisconsin, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the US Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. 10SOW-WI-MISC-12-07

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