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**Wisconsin  
Medical**

# Journal

Official publication of the Wisconsin Medical Society



A look at neonatal care in Wisconsin





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# Wisconsin Medical Journal

Official publication of the Wisconsin Medical Society



## COVER THEME A look at neonatal care in Wisconsin

Improvements in neonatal care over the past 3 decades have increased the survival of infants at lower birth-weights and gestational ages. In this issues of the *Wisconsin Medical Journal*, researchers report that Wisconsin is doing well when compared to leading NICUs in the United States.

Cover design by Mary Kay Adams-Edgette.

## ORIGINAL CONTRIBUTIONS

A Comparison of Wisconsin Neonatal Intensive Care Units with National Data on Outcomes and Practices .....320  
*Erika W. Hagen, PhD; Mona Sadek-Badawi, MBBCh; Aggie Albanese, BS; Mari Palta, PhD*

Women's Knowledge of Commonly Used Contraceptive Methods .....327  
*Sarina Schrager, MD, MS; Sarah Hoffmann, BS*

## CASE REPORT

Patent Foramen Ovale with Right to Left Shunt as a Cause of Hypoxia .....331  
*Ravi K. Mareedu, MD; Juan E. Mesa, MD*

Calciphylaxis Responsive to Lanthanum Carbonate (FOSRENOL) Therapy .....335  
*Micah R Chan, MD, MPH; Alexander S Yevzlin, MD; Molly Hinshaw, MD; Jonathan B Jaffery, MD*

## YOUR SOCIETY

In Remembrance .....316

Resolutions due February 17, 2009, for Wisconsin Medical Society Annual Meeting .....317

New Web site aims to alleviate physician workforce shortage .....319  
*Susan L Turney, MD, MS, FACP, FACMPE*

The mission of the *Wisconsin Medical Journal* is to provide a vehicle for professional communication and continuing education of Wisconsin physicians.

## Volume 107 • Issue 7

### YOUR PROFESSION

Proceedings from the Wisconsin Research  
and Education Network's 2007 Research Forum.....339

#### *Dean's Corner*

Thoughts from the White Coat Ceremony.....343  
*Robert N. Golden, MD*

### YOUR PRACTICE

#### *From the Office of General Counsel*

Federal Appeals Court reverses lower Court ruling;  
reaffirms immunity for hospitals and physicians  
in peer review cases.....344  
*Michelle Leiker, JD*

#### *MetaStar Matters*

2008-2009 recommendations for use of  
influenza vaccine .....347  
*Jay A. Gold, MD, JD, MPH*

ProAssurance/PIC WISCONSIN offers preview of  
rate reductions and coverage enhancements.....349  
*W. Stancil Starnes, CEO, ProAssurance Corporation*

Statement of Ownership.....342

The *Wisconsin Medical Journal* (the *Journal*) (ISSN 1098-1861) is the official publication of the Wisconsin Medical Society and is devoted to the interests of the medical profession and health care in Wisconsin. The managing editor is responsible for overseeing the production, business operation and contents of the *Journal*. The editorial board, chaired by the medical editor, solicits and peer reviews all scientific articles; it does not screen public health, socioeconomic, or organizational articles. Although letters to the editor are reviewed by the medical editor, all signed expressions of opinion belong to the author(s) for which neither the *Journal* nor the Wisconsin Medical Society take responsibility. The *Journal* is indexed in Index Medicus, Hospital Literature Index, and Cambridge Scientific Abstracts.

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## In Remembrance

*Editors note: The following physicians passed away between March 2008 and September 2008.*

**Billy J. Bauman, MD**, 80, of Madison, Wis; Indiana University School of Medicine, Indianapolis, Ind; passed away July 14, 2008.

**Darren B. Bean, MD**, 37, of Middleton, Wis; University of Vermont College of Medicine, Burlington, Vt; passed away May 10, 2008.

**Wanda L. Bincer, MD**, 77, of Madison, Wis; Royal College of Surgeons in Dublin, Ireland; passed away June 26, 2008.

**Harold F. Hardman, MD, PhD**, 80, of Eden Prairie; University of Michigan Medical School, Ann Arbor, Mich; passed away July 14, 2008.

**Steven L. Lawrence, MD**, 64, of Muskego, Wis; University of Wisconsin Medical School, Madison; passed away June 23, 2008.

**Lloyd E. Baldwin, MD**, 82, of Tomah, Wis; University of Wisconsin Medical School, Madison; passed away May 8, 2008.

**Brad W. Mays, MD**, 44, of Thiensville, Wis; University of Louisville School of Medicine, Louisville, Ky; passed away July 22, 2008.

**Susan L. Sipes, MD**, 47, of Green Bay, Wis; Northwestern University Medical School, Chicago, Ill; passed away May 15, 2008.

**John R. Talbot, MD**, 94, of Lake Placid, Utah; University of Wisconsin Medical School, Madison; passed away March 22, 2008.

**William L. Treacy, MD**, 75, of Waukesha, Wis; Medical College of Wisconsin, Milwaukee, Wis; passed away June 28, 2008.

**Eugene J. Usow, MD**, 93, of Laguna Hills, Calif; Rush Medical College, Chicago, Ill; passed away August 1, 2008.

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**Deadline is January 15, 2009.**

# Wisconsin Medical Journal

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The *Wisconsin Medical Journal* is seeking reviewers to add to our list of highly qualified reviewers for manuscripts. We need contributions from reviewers who can be objective, insightful, and respond in a timely manner. Manuscript review is an important collegial act and is essential to the integrity of the *Journal*.

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# Resolutions due February 17, 2009, for Wisconsin Medical Society Annual Meeting

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**J**ust a reminder that members can submit issues/resolutions year around. For time sensitive issues, this may be a better avenue. Please use the Member Communication Form which is available on the Society Web site at [http://www.wisconsinmedicalsociety.org/members\\_only/member\\_communication\\_form](http://www.wisconsinmedicalsociety.org/members_only/member_communication_form).

Issues presented are referred to the Board, a specific Council, or the House for further study and recommendations. Also, if desired, assistance will be provided to develop a resolution that reflects a policy change you are possibly seeking.

The 2009 Annual Meeting of the Wisconsin Medical Society will convene Friday, April 17, 2009, at the Monona Terrace Convention Center in Madison.

The deadline for receipt of resolutions you wish submitted to the House of Delegates is Monday, February 17, 2009. Resolutions must be submitted, in proper form, to the CEO's office no later than 2 months prior to the opening session of the House of Delegates.

**Unanimous consent** of the House of Delegates shall be required for the introduction of **any late resolutions**, except those that are submitted by the Board, a Board member, or the Society's constitutional officers. The Board of Directors will submit recommendations regarding the acceptance of late resolutions to the House at its opening session.

When drafting resolutions for submission, please note the following:

- The title of the resolution should appropriately reflect the action for which it calls.
- Information contained in the resolution should be checked for accuracy.
- **The resolves should stand alone, since the House adopts only the resolves and the whereases do not appear in the proceedings.**
- It is strongly encouraged, but not required, that all resolutions submitted to the House of Delegates for its consideration contain a statement by the author as to existing Society policy on the topic, or that the Society does not have any current policy on the topic.
- Any resolution submitted to the House of Delegates for its consideration that requests that the resolution be taken forward to the American Medical Association (AMA) for its consideration should contain a statement by the author as to existing AMA policy on the topic, or that the AMA does not have any current policy on the topic.

Fiscal notes will be added to all resolutions whose implementation would require funds not normally included in the Society's budget. **For each resolution submitted, a sponsor should be in attendance at reference committee hearings to provide background information.**

Resolutions may be sent to Susan L. Turney, MD, Executive Vice President/CEO, Wisconsin Medical Society, PO Box 1109, Madison, WI 53701 or via e-mail to [noreen.krueger@wismed.org](mailto:noreen.krueger@wismed.org).

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Susan L. Turney, MD, MS, FACP, FACMPE

# New Web site aims to alleviate physician workforce shortage

Susan L. Turney, MD, MS, FACP, FACMPE

In 2004, the Wisconsin Medical Society and the Wisconsin Hospital Association released “Who Will Care for Our Patients,” a report documenting the current and projected physician workforce shortage. At that time, there was a shortage of primary care physicians in rural Wisconsin and inner city Milwaukee, and general surgeons and radiologists were “critically needed in rural areas.”<sup>1</sup> The report also predicted that by 2015, the demand for primary care physicians would increase by an additional 13.5%, while the physician supply would lag even further.

An updated version of “Who Will Care for our Patients” will be released in the coming weeks, but it’s clear we still face a growing problem. The good news, however, is that we’re working to do something about it, both as part of our own strategic initiatives, which the Society’s Board of Directors approved at its October 11 meeting, and as a member of the Wisconsin Council on Medical Education and Workforce (WCMEW).

In mid October, WCMEW launched an aggressive physician

recruitment campaign designed to attract physicians back to Wisconsin and retain those already practicing or studying here. WCMEW’s members include the Society, the Wisconsin Hospital Association, the University of Wisconsin School of Medicine and Public Health, the Medical College of Wisconsin, the Rural Wisconsin Health Cooperative, and the Wisconsin Academy of Physician Assistants.

The cornerstone of this initiative is a new Web site, WisconsinPhysicianCareers.org, which features exclusively physician career opportunities available in Wisconsin (Figure 1). There is no charge to the Wisconsin clinics, hospitals, and academic medical centers that are able to list physician openings, and in the few weeks since its launch, more than 600 positions across 61 specialties have been posted. Of those opportunities, nearly 300 are for primary care positions—a clear reminder of the need to keep the workforce shortage issue among our top priorities. You can learn more about this new site from recent issues of *Medigram* and on the Society’s Web site, [www.wisconsinmedicalsociety.org](http://www.wisconsinmedicalsociety.org), where you can also easily access a link to WisconsinPhysicianCareers.org.

We know Wisconsin is a great

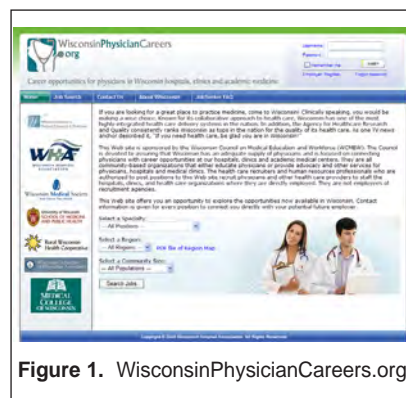


Figure 1. WisconsinPhysicianCareers.org

place to practice medicine, but because there is a limited pool of physicians nationwide, there’s a lot of competition to fill positions. That’s why it’s imperative that we do everything we can to ensure the physicians we train here stay here and that we make it easier for physicians with family or educational ties to consider coming back. I’m confident that this site will be a valuable tool in our arsenal and that as we work to implement our strategic plan, we can help ameliorate the physician workforce shortage to ensure that our patients have access to the care they need.

## Reference

1. Wisconsin Medical Society, Wisconsin Hospital Association. Who Will Care for Our Patients? <http://wha.org/physicianshortage3-04.pdf>. Accessed October 31, 2008.

Susan L. Turney, MD, MS, FACP, FACMPE, is the Chief Executive Officer and Executive Vice President of the Wisconsin Medical Society.

# A Comparison of Wisconsin Neonatal Intensive Care Units with National Data on Outcomes and Practices

Erika W. Hagen, PhD; Mona Sadek-Badawi, MBChB; Aggie Albanese, BS; Mari Palta, PhD

## ABSTRACT

**Context:** Improvements in neonatal care over the past 3 decades have increased survival of infants at lower birthweights and gestational ages. However, outcomes and practices vary considerably between hospitals.

**Objective:** To describe maternal and infant characteristics, neonatal intensive care units (NICU) practices, morbidity, and mortality in Wisconsin NICUs, and to compare outcomes in Wisconsin to the National Institute of Child Health and Human Development network of large academic medical center NICUs.

**Methods:** The Newborn Lung Project Statewide Cohort is a prospective observational study of all very low birthweight ( $\leq 1500$  grams) infants admitted during 2003 and 2004 to the 16 level III NICUs in Wisconsin. Anonymous data were collected for all admitted infants ( $N=1463$ ). Major neonatal morbidities, including bronchopulmonary dysplasia (BPD), intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), and retinopathy of prematurity (ROP) were evaluated.

**Results:** The overall incidence of BPD was 24% (8%-56% between NICUs); IVH incidence was 23% (9%-41%); the incidence of NEC was 7% (0%-21%); and the incidence of grade III or higher ROP was 10% (0%-35%).

**Conclusion:** The incidence rates of major neonatal morbidities in Wisconsin were similar to those of a national network of academic NICUs.

## INTRODUCTION

The Newborn Lung Project is a unique regional cohort of very low birthweight (VLBW),  $\leq 1500$  grams, chil-

dren based on births in Wisconsin. This study, started in 1987, has followed up on health, behavior, and academic outcomes of cohort children for almost 2 decades. The first cohort includes all VLBW children admitted to 6 Neonatal Intensive Care Units (NICU) between 1988 and 1991, covering a contiguous region of Wisconsin and Iowa.<sup>1-3</sup> The most recent Newborn Lung Project (Project) cohort covers the entire state of Wisconsin and includes all VLBW admissions during 2003 and 2004. Reflecting a trend toward decentralization of NICU care, there are now 16 level III NICUs in the state. This recent population-based cohort gives us the opportunity to compare VLBW infants in Wisconsin to infants born at centers that are part of a prominent national network of NICUs.

National vital statistics show that the percentage of births that are VLBW has increased from 1.3% to 1.5% since 1990.<sup>4</sup> In Wisconsin, the percentage of births that are VLBW has increased from 1.1% to 1.3% since 1995.<sup>5</sup> The Wisconsin infant mortality rate across all birthweights declined steadily until 2004, and has leveled off in recent years.<sup>6</sup> Exogenous surfactant and antenatal steroid therapy to enhance lung maturity of preterm infants are thought to be responsible for much of the increased survival.<sup>3,7</sup> Well-equipped, experienced NICUs also have contributed to the increasing survival of VLBW neonates.<sup>8-11</sup>

The decrease in mortality among VLBW infants was initially accompanied by an increase in early life morbidities such as intraventricular hemorrhage (IVH), bronchopulmonary dysplasia (BPD), and necrotizing enterocolitis (NEC).<sup>7,12-13</sup> The increases in these morbidities have leveled off in recent years.<sup>14</sup> Results from the first Project cohort showed a decreased mortality rate and an increased incidence of BPD among VLBW infants from the presurfactant to postsurfactant eras.<sup>3</sup> Recently, published work has reported a similar increase in the incidence of BPD.<sup>15</sup>

Characteristics of NICUs, such as annual volume and the presence of a pediatric residency program,

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**Table 1.** Very Low Birthweight Admissions to Level III Neonatal Intensive Care Units in Wisconsin, 2003-2004

| Neonatal Intensive Care Unit                             | All Admissions<br>N | Outborn Admissions<br>N (%) |
|--|---------------------|-----------------------------|
| St. Joseph's Hospital, Milwaukee                         | 256                 | 19 (7)                      |
| Aurora Sinai, Milwaukee                                  | 142                 | 8 (6)                       |
| St. Joseph's Hospital, Marshfield                        | 129                 | 30 (23)                     |
| Meriter Hospital, Madison                                | 115                 | 11 (10)                     |
| Children's Hospital of Wisconsin, Milwaukee              | 110                 | 30 (27)                     |
| St. Mary's Hospital, Madison                             | 109                 | 4 (4)                       |
| St. Vincent Hospital, Green Bay                          | 109                 | 31 (28)                     |
| Columbia-St. Mary's Hospital, Milwaukee                  | 108                 | 3 (3)                       |
| St. Luke's Hospital, Racine                              | 71                  | 6 (9)                       |
| Children's Hospital of Wisconsin—Fox Valley, Neenah      | 69                  | 12 (17)                     |
| Waukesha Memorial Hospital, Waukesha                     | 56                  | 5 (9)                       |
| Aurora Women's Pavilion, West Allis                      | 48                  | 3 (6)                       |
| Gunderson Lutheran Hospital, La Crosse                   | 47                  | 5 (11)                      |
| Aurora Bay Care, Green Bay                               | 37                  | 0 (0)                       |
| St. Elizabeth Hospital, Affinity Health System, Appleton | 34                  | 0 (0)                       |
| Franciscan Skemp Hospital, La Crosse                     | 23                  | 1 (4)                       |

have been investigated as contributing factors to neonatal outcomes. Higher annual NICU volume has been associated with lower risk for mortality<sup>10,16</sup> and severe IVH,<sup>17</sup> while no association was found between mortality and the presence of a residency program<sup>18</sup> in the 1 study that investigated this relationship.

The authors report on maternal and infant characteristics, NICU practices, and outcomes in the Project. The Project is a population-based cohort of all Wisconsin VLBW infants born during the current era of neonatal care and representing all NICUs. The data includes a range of volume and NICUs with and without residency programs. The objectives of this paper are to (1) describe maternal and infant characteristics, NICU practices, and the incidence of neonatal morbidities in the 16 NICUs in Wisconsin; (2) explore the association between NICU-level variables and the incidence of neonatal morbidities; and (3) compare outcomes in Wisconsin to outcomes of large academic neonatal centers in the National Institute of Child Health and Human Development Neonatal Research Network (Network).

## METHODS

The Project is a prospective study of all VLBW infants admitted from January 1, 2003, to December 31, 2004, to the 16 level III NICUs in Wisconsin (Table 1).

Twenty-five designated, trained neonatal nurses at participating centers abstracted deidentified data from

each infant's medical record onto standardized forms.<sup>19</sup> Data included pregnancy complications, multiple pregnancy, maternal antenatal steroid therapy to enhance fetal lung maturity, tocolytic therapy to halt premature labor, and outborn status (infant transfer from place of birth to level III NICU). Infant characteristics included birthweight, gestational age, race, sex, and Apgar score for health assessment of the newborn (higher score means better newborn health). Infants who had birthweights  $\leq 1000$  grams were classified as extremely low birthweight (ELBW). The Score for Neonatal Acute Physiology II was calculated, and used as an indicator of generic baseline physiologic status in the first 12 hours of life (higher scores indicate worse health).<sup>20</sup> We also collected data on NICU care, such as surfactant therapy, fraction of inspired oxygen at 24 hours of life, ventilation treatment, intubation, postnatal steroid therapy, and length of stay in hospital. The following infant diagnoses were also recorded: IVH, BPD, NEC, patent ductus arteriosus, and retinopathy of prematurity (ROP).

Two NICU-level structure variables were considered. The mean annual volume of infants admitted to the NICU was determined by taking the average of the 2003 and 2004 admissions.<sup>6</sup> The presence of a residency program was defined as having a pediatric residency or a neonatal fellowship program at the hospital.<sup>21</sup>

## Statistical Analysis

Statistical analyses were performed using SAS, version 9.1. Means, standard deviations, frequencies, and percentages were used to describe the Project cohort. Logistic regression was used to examine the association between NICU-level characteristics and neonatal outcomes, while adjusting for the following case mix variables: birthweight, gestational age, sex, 1-minute Apgar score, Score for Neonatal Acute Physiology II, and outborn status.

## RESULTS

During 2003 and 2004, 1463 VLBW infants were admitted to the 16 level III NICUs in Wisconsin. VLBW admissions to each NICU over this 2-year time period ranged from 23 to 256. The number of infants in the Project cohort was compared to the number of VLBW NICU admissions during 2003 and 2004 reported by the Wisconsin Interactive Statistics on Health.<sup>6</sup> The number of births to Wisconsin residents with birthweight  $< 1500$  grams in our cohort was 1385, a close match to the 1386 births reported by Wisconsin Interactive Statistics on Health (1 infant in our dataset had missing data for state of residence). Thus, our



**Table 2.** Maternal and Infant Characteristics for the Newborn Lung Project Statewide Cohort Study, 2003-2004

|  | Entire Cohort<br>N=1463 | Range<br>Between<br>NICUs |
|--|-------------------------|---------------------------|
| <b>Maternal characteristics</b>                      |                         |                           |
| Maternal age in years, mean (SD)                     | 28.0 (6.1)              | 24.8-31.5                 |
| <18 years  | 5                       | 0-9                       |
| Prenatal care  | 92                      | 84-100                    |
| Pregnancy induced hypertension                       | 28                      | 14-36                     |
| Premature rupture of membranes                       | 17                      | 9-35                      |
| Chorioamnionitis                                     | 8                       | 0-22                      |
| Antenatal steroids therapy                           | 69                      | 53-89                     |
| Tocolytic therapy <sup>a</sup>                       | 57                      | 51-83                     |
| Caesarean delivery <sup>a</sup>                      | 61                      | 54-84                     |
| <b>Infant characteristics</b>                        |                         |                           |
| Birth weight in grams, mean (SD)                     | 1049 (298)              | 960-1192                  |
| Gestational age in weeks, mean (SD)                  | 28 (3.0)                | 27-30                     |
| 1-minute Apgar score, mean (SD)                      | 5.1 (2.3)               | 4.2-6.3                   |
| SNAP-II <sup>c</sup> score, mean (SD)                | 17.4 (15.7)             | 12.9-27.1                 |
| FiO <sub>2</sub> <sup>d</sup> at 24 hours, mean (SD) | 0.27 (0.13)             | 0.23-0.30                 |
| Outborn <sup>b</sup>                                 | 12                      | 0-28                      |
| Multiple births                                      | 27                      | 9-35                      |
| Small for gestational age <sup>e</sup>               | 25                      | 15-33                     |
| Male   | 50                      | 39-65                     |
| White race   | 61                      | 18-94                     |

Note: Numbers shown are percentages, unless otherwise noted. SD=standard deviation.

<sup>a</sup> Available for 1034 infants (71% of cohort) with detailed medical records abstracting after informed consent

<sup>b</sup> Infant born at another hospital and transferred to a study NICU

<sup>c</sup> Score for Neonatal Acute Physiology II

<sup>d</sup> Fraction of inspired oxygen

<sup>e</sup> Weight <10th percentile

cohort contains all VLBW infants born during 2003 and 2004 who survived to admission to all level III NICUs in Wisconsin.

### Maternal Characteristics

The mean (standard deviation [SD]) maternal age was 28 (6.1) years, with 5% of mothers <18 years old. Ninety-two percent of mothers received prenatal care. Pregnancy-induced hypertension was diagnosed among 28% of mothers, prolonged rupture of membranes for >24 hours was diagnosed in 17% of mothers, and 8% of mothers were diagnosed with chorioamnionitis (infection of the placenta and amniotic fluid). Antenatal steroids were administered to 69% of mothers before delivery and 57% received tocolytics. Sixty-one percent of mothers had a Caesarean section delivery (Table 2). Maternal characteristics varied between the NICUs. For example, diagnosis of prolonged rupture of membranes ranged from 9% to 34% between NICUs, and diagnosis of chorioamnionitis ranged from 0% to

22%. There were also differences between NICUs in the percentage of mothers who received antenatal steroids (53%-89%) and tocolytic therapy (51%-83%). The rate of Cesarean section deliveries ranged from 54% to 84%.

### Infant Characteristics

Twelve percent of the infants were born at hospitals without level III NICUs and were transferred to participating centers after birth (outborn status). Twenty-seven percent of VLBW infants were multiple births and 25% were small for gestational age. The mean (SD) birthweight was 1049 (298) grams and the mean (SD) gestational age was 28 (3) weeks.

Several infant characteristics varied between study NICUs. The percentage of outborn infants ranged from 0% to 28%; the percentage of infants who were small for gestational age ranged from 15% to 33%; and the percentage of white infants ranged from 18% to 94% between NICUs. Mean birthweight ranged from 960 to 1192 grams and the mean for the Score for Neonatal Acute Physiology II ranged from 12.9 to 27.1, indicating that the illness severity level of the infants varied considerably between NICUs. Table 2 shows birth and early characteristics of the VLBW cohort and the range between NICUs.

### Practices and Outcomes in Wisconsin NICUs

Table 3 shows the variation in NICU practices and outcomes between participating centers. Seventy-seven percent of infants received surfactant, ranging from 41% to 91% between NICUs. Overall, 76% of infants were intubated, with a range of 48%-91% between NICUs. Postnatal steroids were administered to 18% of cohort infants, ranging from 4% to 45% between NICUs. There was a wide range in the median days on supplemental oxygen (medians ranged from 0 to 61 days) and the median days on ventilation (0 to 27 days). As expected, more ELBW infants received surfactant, were intubated, and received postnatal steroids than did VLBW infants. The group of ELBW infants also had a higher median number of days on supplemental oxygen and ventilation than the group of VLBW infants, and had a longer stay in the NICU (Table 3).

Table 3 also shows variation in neonatal diagnoses between the 16 NICUs. The overall incidence of any grade IVH was 23%, with a range of 9%-41% between NICUs. Grade III or higher IVH was diagnosed in 8% of the entire cohort, ranging from 0% to 18% between NICUs. Twenty-four percent of the VLBW cohort was diagnosed as having BPD, with a range of 8%-56% between the 16 NICUs. The incidence of NEC ranged

**Table 3.** Selected Neonatal Intensive Care Unit Practices and Outcomes of the Newborn Lung Project by Birthweight Category

|   | VLBW <sup>b</sup> Infants (N=1463) |                    | ELBW <sup>c</sup> Infants (N=626) |                    |
|---|------------------------------------|--------------------|-----------------------------------|--------------------|
|   | All VLBW                           | Range <sup>a</sup> | All ELBW                          | Range <sup>a</sup> |
| Received antenatal steroids             | 70                                 | 50-89              | 76                                | 56-94              |
| Received surfactant                     | 77                                 | 41-91              | 95                                | 79-100             |
| Intubated                               | 76                                 | 48-91              | 90                                | 75-96              |
| Received postnatal steroids             | 18                                 | 4-45               | 37                                | 6-71               |
| Survival                                | 88                                 | 80-96              | 76                                | 59-90              |
| Any grade intraventricular hemorrhage   | 23                                 | 9-41               | 33                                | 0-50               |
| ≥Grade III intraventricular hemorrhage  | 8                                  | 0-18               | 13                                | 0-27               |
| Bronchopulmonary dysplasia              | 24                                 | 8-56               | 42                                | 20-67              |
| Necrotizing enterocolitis               | 7                                  | 0-21               | 11                                | 0-22               |
| Patent ductus arteriosus                | 35                                 | 21-47              | 51                                | 29-71              |
| >Grade III retinopathy of prematurity   | 10                                 | 0-35               | 22                                | 0-61               |
| Discharged home/foster care             | 85                                 | 76-96              | 73                                | 58-90              |
| Median days on oxygen                   | 61                                 | 0-61               | 73                                | 56-85              |
| Median days on ventilation <sup>d</sup> | 4                                  | 0-27               | 29                                | 4-51               |
| Median days in hospital                 | 51                                 | 35-62              | 78                                | 59-95              |

Note: Numbers shown are percentages, unless otherwise noted.

<sup>a</sup> Range across 16 Wisconsin level III NICUs

<sup>b</sup> Very low birthweight, ≤1500 grams

<sup>c</sup> Extremely low birthweight, ≤1000 grams

<sup>d</sup> Available for 1034 infants (71% of cohort) with detailed medical records abstracting after informed consent

**Table 4.** Odds Ratios<sup>a</sup> and 95% Confidence Intervals for the Association Between NICU Structure Characteristics and Neonatal Outcomes

|                                   | ≥ Grade III IVH  | BPD              | NEC              | Death before Discharge |
|-----------------------------------|------------------|------------------|------------------|------------------------|
| Annual volume (per 10 admissions) | 0.94 (0.89, 1.0) | 0.98 (0.97, 1.0) | 0.99 (0.94, 1.1) | 0.97 (0.92, 1.0)       |
| Presence of residency program     | 0.82 (0.49, 1.4) | 2.0 (1.5, 2.5)   | 1.8 (1.1, 2.9)   | 1.3 (0.83, 2.2)        |

Note: IVH=intraventricular hemorrhage, BPD=bronchopulmonary dysplasia, NEC=necrotizing enterocolitis.

<sup>a</sup> Adjusted for birthweight, gestational age, sex, 1-minute Apgar, outborn status, and Score for Neonatal Acute Physiology II

from 0% to 21%; patent ductus arteriosus incidence ranged from 21% to 47%, and grade III or higher ROP ranged from 0% to 35% between NICUs. As expected, the incidence of each of these morbidities was higher among the group of ELBW infants (Table 3).

The mean annual volume for 2003-2004 ranged from 13 VLBW admissions per year to 146 VLBW admissions per year. Three of the NICUs had a pediatric residency program or neonatal fellowship program. There was not a significant association between annual NICU volume and risk for any of the neonatal outcomes examined (Table 4). After adjusting for case mix, infants at NICUs with a residency program tended to have a lower risk for grade III or higher IVH. Infants who were cared for at NICUs with residency programs were at higher risk for BPD and NEC, and showed a trend toward being more likely to die before NICU discharge (Table 4).

## Comparison of NICU Practices and Outcomes in Wisconsin with National Data

Wisconsin infant characteristics and NICU practices

were compared to those in the Network for infants born between 1997 and 2002 (Table 5). The mean birthweight of infants in the Project was similar to the mean birthweight of infants in the Network (mean [SD], 1049 [298] and 1033 [289] grams, respectively). The percentage of infants from multiple-birth pregnancies was similar in the 2 cohorts, with 27% in the Project and 26% in the Network, while the percentage of infants who were small for gestational age was slightly higher in the Project (25%) than in the Network (21%).

NICU practices differed somewhat between the Project and the Network. Fewer mothers of infants in the Project received antenatal steroids than in the Network (69% versus 79%) and more infants in the Project received surfactant (77% versus 58%). There were slightly more Caesarean deliveries among infants in the Project than the Network (61% versus 58%). The administration of postnatal steroids was similar across the 2 cohorts (18% in the Project and 17% in the Network).

The incidence of major neonatal morbidities was

**Table 5.** Selected Patient Characteristics, Neonatal Intensive Care Unit Practices, and Outcomes of Wisconsin Very Low Birthweight Infants and the National Institute of Child Health and Human Development Neonatal Research Network

|   | Newborn Lung Project<br>N=1463 |                    | Neonatal Research Network<br>N=18,153 |                    |
|---|--------------------------------|--------------------|---------------------------------------|--------------------|
|   | Overall                        | Range <sup>a</sup> | Overall                               | Range <sup>b</sup> |
| Birth weight in grams, mean             | 1049                           | 960-1192           | 1033                                  | 998-1066           |
| Standard deviation                      | 298                            | 219-321            | 289                                   | 273-295            |
| Multiple births                         | 27                             | 9-57               | 26                                    | 18-40              |
| Small for gestational age <sup>c</sup>  | 25                             | 15-32              | 21                                    | 17-26              |
| Antenatal steroid therapy               | 69                             | 53-90              | 79                                    | 47-90              |
| Received surfactant                     | 77                             | 41-91              | 58                                    | 42-74              |
| Caesarean delivery <sup>d</sup>         | 61                             | 53-84              | 58                                    | 50-69              |
| Received postnatal steroids             | 18                             | 6-48               | 17                                    | 4-29               |
| Premature rupture of membranes          | 17                             | 9-35               | 24                                    | 16-28              |
| Bronchopulmonary dysplasia              | 24                             | 8-56               | 22                                    | 10-50              |
| Intraventricular hemorrhage > grade III | 8                              | 0-18               | 12                                    | 6-19               |
| Necrotizing enterocolitis               | 7                              | 0-21               | 7                                     | 4-11               |
| Survival                                | 88                             | 80-96              | 85                                    | 79-93              |

Note: Numbers shown are percentages, unless otherwise noted.

<sup>a</sup> Range across 16 Wisconsin level III NICUs

<sup>b</sup> Range across Neonatal Research Network centers

<sup>c</sup> Weight <10th percentile

<sup>d</sup> Available for 1034 Wisconsin infants with detailed medical records abstracting after informed consent

similar among the 2 cohorts. The incidence of BPD was slightly higher among Project infants than Network infants (24% versus 22%), while the incidence of grade III or higher IVH was somewhat lower among Project infants than Network infants (8% versus 12%). The incidence of NEC was 7% in each of the cohorts. Slightly more infants in the Project survived to discharge (88%) than in the Network (85%).

## DISCUSSION

This report summarizes infant and maternal characteristics, survival and the incidence of major neonatal morbidities, and NICU care practices for a Wisconsin cohort of VLBW infants born over 2 years and receiving recent neonatal care. We also compared characteristics, survival and morbidities, and NICU care among the 16 NICUs in Wisconsin and compared outcomes in Wisconsin to those in a cohort of infants cared for in major academic NICUs.

In the first cohort of the Project (1988-1991 births), we evaluated mortality and neonatal morbidities, as well as the receipt of perinatal therapies.<sup>3</sup> Survival was higher and the incidence of major morbidities, such as IVH and BPD, was lower for infants in the more recent cohort than for those in the first cohort. Additionally, the use of both surfactant and antenatal steroids has increased.

Results from the most recent Project show a rather wide variation in the survival rate of infants, the inci-

dence of major neonatal morbidities, and NICU care practices between the 16 level III NICUs in Wisconsin. In order to investigate whether NICU-level characteristics help explain some of the variation between NICUs, we investigated whether annual volume and the presence of a pediatric residency program were associated with neonatal outcomes, as these have been identified as important factors in the literature. Our results suggest that while annual volume seemed to have little association with neonatal outcomes, the presence of a residency program may be associated with higher risk for BPD and NEC, and lower risk for at least grade III IVH and for death before NICU discharge.

Results from other studies that have evaluated the effect of NICU volume have been mixed. A study of NICUs in California found that infants born at level III NICUs with low volume were at higher risk for death than infants born at level III NICUs with high volume.<sup>10</sup> Annual volume was not associated with neonatal mortality among infants born during 1992-1993 at NICUs participating in the Vermont Oxford Network,<sup>18</sup> but analysis of Vermont Oxford Network infants born between 1995 and 2000 found a threshold effect, such that higher volume was associated with lower mortality risk ≤50 admissions per year, and higher mortality >50 admissions per year.<sup>16</sup> Among infants in the Canadian Neonatal Network, larger NICU volume was associated with lower risk for severe IVH (grade III or higher).<sup>17</sup> To our knowledge, the relationship between



NICU volume and other neonatal morbidities has not been evaluated in other studies.

After adjusting for patient level characteristics, the presence of a pediatric residency program was not associated with neonatal mortality among infants in the Vermont Oxford Network.<sup>18</sup> Among infants in the Project, being cared for at a NICU with a residency program showed a trend toward being associated with increased mortality, and was significantly associated with higher risk for BPD and NEC, while it was associated with lower risk for grade III or higher IVH. Infants at 2 of the 3 NICUs in the Project that have residency programs were less healthy shortly after birth than infants at the NICUs without residency programs, with higher mean values on the Score for Neonatal Acute Physiology II. Each of these NICUs also had a rather high percentage of patients who were born elsewhere and transferred in for care. It could be that the NICUs with residency programs are serving different populations of infants than NICUs without residency programs, and that our adjustment for case mix to take into account baseline illness severity was not adequate to account for these differences. It is not clear what differentiates NICUs with and without residency programs, and further investigation is warranted to determine what is contributing to the poor outcomes with respect to mortality, some of the neonatal morbidities, and how outcomes may be improved.

The National Institute of Child Health and Human Development Neonatal Research Network is a network of NICUs at academic research hospitals that report on neonatal outcomes for infants weighing 500-1500 grams.<sup>7</sup> These centers generally represent cutting edge neonatal care in the United States. Their recent report of neonatal outcomes combines data from their 1997-1998, 1999-2000, and 2001-2002 data collection periods as there was very little difference in any of their parameters across these years.<sup>14</sup>

Compared to the national Network data, our Wisconsin cohort of VLBW infants had similar incidence rates for major neonatal morbidities, but NICU care practices were somewhat different in Wisconsin and the Network. For example, fewer Wisconsin mothers received antenatal steroids (69%) than mothers of infants in the Network (79%) and more Wisconsin infants received surfactant (77%) than those in the Network (58%). While variation in outcomes and NICU practices was more substantial between NICUs in the Project than the Network, there was quite a bit of variation in outcomes and practices between NICUs in the Network as well. Ranges in practices and outcomes

reported from the Canadian NICU Network, another population-based cohort of VLBW infants, were also quite large.<sup>22</sup> It is likely that the smaller amount of variation seen for Network NICUs is due to the much larger sample size for these NICUs arising from more years of follow-up.

The Project and Network cohorts differ in some significant ways. First, the Project is a population-based cohort that includes all VLBW admissions in Wisconsin. As the cohort includes infants born at all the level III NICUs in Wisconsin, NICUs with and without residency programs are included, and a wide range of annual admissions is represented among cohort NICUs. In contrast, each of the NICUs in the Network is at a large research university hospital and the cohort is not population-based. The Network evaluated outcomes for infants who weighed 500-1500 grams, while the Project included all VLBW NICU admissions ( $\leq 1500$  grams). However, birthweight was similar across the 2 cohorts, as only 40 infants (3%) had a birthweight  $< 500$  grams in the Project, and the mean [SD] birthweight in each cohort was very similar (1049 [298] grams for the Project and 1033 [289] grams in the Network).

Despite the differences between the Wisconsin and national cohorts, the groups of infants in each are rather similar, as the incidence rates of most major neonatal morbidities are quite comparable. The difference in care practices between the Project and the Network could be indicative of differences in physician habits in university and non-university settings.

## CONCLUSION

The incidence of mortality and neonatal morbidities, in addition to NICU care practices, vary widely between NICUs in Wisconsin. Neonatal care and outcomes in Wisconsin are similar to care and outcomes reported in the National Institute of Child Health and Human Development Neonatal Research Network. These similarities indicate that Wisconsin is doing well compared to some of the leading NICUs in the United States.

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## Appendix: Neonatal Diagnoses

**Bronchopulmonary dysplasia (BPD):** Chronic lung disease of prematurity. Defined as receiving supplemental oxygen at 36 weeks postmenstrual age (gestational age plus chronological age).<sup>23-24</sup>

**Intraventricular hemorrhage (IVH):** A bleeding inside or around the ventricles, the spaces in the brain containing cerebral spinal fluid. Graded on a scale of I-IV, with IV being the most severe.<sup>25</sup>

**Necrotizing enterocolitis (NEC):** Gastrointestinal disease that mostly affects premature infants.

**Patent ductus arteriosus (PDA):** A type of congenital heart defect in which a blood vessel that is supposed to be shut soon after birth remains open.

**Retinopathy of prematurity (ROP):** A disease that affects immature vasculature in the eyes of premature babies. Graded on a scale of I to IV, with IV being the worst.

# Women's Knowledge of Commonly Used Contraceptive Methods

*Sarina Schrager, MD, MS; Sarah Hoffmann, BS*

## ABSTRACT

**Introduction:** Despite the availability of reliable contraceptive methods in this country, half of all pregnancies are unintended. There is a scarcity of research in a primary care population that measures women's knowledge about commonly used contraceptive methods.

**Methods:** All women between 18 and 40 in the waiting room at 2 different family practice clinics were approached over a 2-week period. Women were asked to complete a short written questionnaire that included demographics, reproductive information, and 9 true/false questions about common contraceptive methods.

**Results:** Two hundred fifty-two surveys were completed. Half of all women believed that condoms are 99% effective and only 57% knew that condoms were not as effective as oral contraceptive pills. Close to half of all the women received their contraceptive information from the clinic. Only 42% of the women knew that oral contraceptive pills can reduce the incidence of some types of cancer. There was not correlation between number of questions answered correctly and number of children, type of contraceptive used, age, or race/ethnicity. Twenty-six percent of the respondents were not using any contraception.

**Discussion:** Overall, the women surveyed demonstrated fairly good knowledge of contraception methods. More women surveyed were aware that oral contraceptive pills can reduce the rate of uterine and ovarian cancer than in previous similar studies. Also, women in this survey were more likely to use intrauterine devices than the general population.

**Conclusion:** Health care professionals should develop more effective education about contraceptive methods.

## INTRODUCTION

Despite the availability of reliable contraceptive methods in this country, half of all pregnancies are unintended.<sup>1</sup> Half of all unintended pregnancies end in abortion.<sup>1</sup> Women who continue unplanned pregnancies are more likely to abuse drugs and alcohol during pregnancy, have later entrance to prenatal care, and to suffer from pregnancy complications.<sup>2-4</sup> Children who are born as a result of unplanned pregnancies are more likely to be victims of child abuse and to have lower educational attainment.<sup>4,5</sup> The estimated direct medical cost of unplanned pregnancy in 2002 in the United States was \$5 billion.<sup>6</sup> It is also estimated that the use of contraception afforded a savings of approximately \$19 billion in that same year.<sup>6</sup>

Many sexually active women start a contraceptive method and then stop without informing their health care providers. Many women who stop a particular method of contraception never restart another method and may be at risk for pregnancy. An analysis of 2002 data found that 23% of sexually active women of child bearing age had gaps in their contraceptive use during the previous year.<sup>7</sup>

Learning more about women's knowledge of contraceptive methods will help health care professionals address misconceptions, thereby improving consistent use of contraception. If providers could specifically address barriers to consistent use of contraception, they may be able to counsel women more effectively about specific methods. The aim of this study was to evaluate the knowledge of women in a primary care population.

## METHODS

This survey was written at a Flesch-Kincaid reading grade level of 3.9. It included several demographic questions, information about current contraceptive use and reproductive history, and 9 true/false questions

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**Table 1.** Sample Demographics

| Age (N=248)                                      | No. (%)  |
|--|----------|
| 18-22  | 54 (22)  |
| 23-27  | 70 (28)  |
| 28-31  | 33 (13)  |
| 32-35  | 38 (16)  |
| 36-40  | 54 (21)  |
| Race/Ethnicity (N=252)                           | No. (%)  |
| White  | 131 (52) |
| African American                                 | 74 (29)  |
| Hispanic   | 21 (8)   |
| Asian  | 11 (4)   |
| Other  | 4 (2)    |
| Biracial   | 11 (4)   |
| Type of Birth Control Used (N=238 <sup>a</sup> ) | No. (%)  |
| None   | 62 (26)  |
| Condoms alone                                    | 25 (11)  |
| Oral contraceptives                              | 36 (15)  |
| Depoprovera                                      | 24 (10)  |
| Intrauterine device                              | 17 (7)   |
| Tubal ligation                                   | 26 (11)  |
| Vasectomy  | 7 (3)    |
| Patch or ring                                    | 11 (5)   |
| Condoms and another method                       | 19 (8)   |
| Other  | 11 (5)   |
| No. of Children (N=252)                          | No. (%)  |
| 0  | 80 (32)  |
| 1  | 63 (25)  |
| 2  | 43 (17)  |
| 3  | 28 (11)  |
| 4 or more  | 24 (10)  |
| Pregnant   | 14 (5%)  |

<sup>a</sup> Fourteen women were pregnant and were excluded

**Table 2.** Information Sources About Contraception

| Where Information Was Received | N=248     |
|--------------------------------|-----------|
| Clinic                         | 104 (42%) |
| Friends                        | 5 (2%)    |
| Family members                 | 6 (2%)    |
| TV or magazines                | 4 (2%)    |
| Internet                       | 4 (2%)    |
| 2 sources                      | 63 (25%)  |
| 3 sources                      | 28 (11%)  |
| >3 sources                     | 9 (4%)    |
| Other                          | 25 (10%)  |

about commonly used contraceptive methods. The questions came from commonly heard misconceptions in practice. The survey also asked women where they received information about contraception. The survey was given to 5 female medical students to determine if the questions were understandable. Questions were revised based on the responses. These results were not included in the final analysis.

Subjects were recruited on consecutive days over a 2-week period at each of 2 urban family practice residency teaching clinics in Madison, Wis. A medical student researcher sat in the waiting room of each clinic and approached every woman who entered the clinic who appeared to be between 18 and 40 years of age. Women who had appointments themselves, as well as women who were accompanying someone with an appointment, were asked to complete the surveys. Women were asked their ages to assure their eligibility for the study. The medical student researcher provided clarification of the questions if needed. If a woman declined to complete the survey, her age and ethnicity were asked.

Data was entered into a Microsoft Excel database. Chi square comparisons and Pearson correlation coefficients were performed using Excel.

## RESULTS

A total of 252 surveys were completed (124 at Clinic 1; 128 at Clinic 2). The respondents at the 2 clinics were compared on demographic measures, reproductive health measures, and number of questions answered correctly using the Chi square statistic (ie, age, ethnicity, number of children, birth control type, sources of information, and number of correct answers). There were no significant differences between the groups. Therefore data from the 2 clinics was analyzed together. Their ages and ethnic distribution were similar to the general sample. Only 5 women declined to answer the survey and stated many reasons for not participating in the survey that included being in a rush, being in pain, and being embarrassed about the topic. Twenty-five women needed clarification of certain questions, most commonly asking what an intrauterine device (IUD) was.

Participants' ages were distributed equally among the groups (Table 1). About half of the respondents were white and a third were African American. Over half of the sample had 0 or 1 child. Twenty-six percent of the respondents were not currently using any contraception and 11% were using condoms alone for contraception. Forty-two percent of the respondents received information about contraception from the clinic and many used information from several different sources (Table 2).

Twenty-four women answered all 9 questions correctly (10%), 116 (46%) answered 7 or 8 correctly, 88 (35%) answered 5 or 6 correctly, and 24 (10%) answered less than 5 correctly. For answers to specific questions, see Table 3.

Pearson correlation coefficients were calculated to determine possible associations between demographic

**Table 3.** Answers to Specific True/False Questions

|   | Correct Number | Incorrect Number | Answer |
|---|----------------|------------------|--------|
| Condoms are as effective as birth control pills. (N=248)                    | 144 (58%)      | 104 (42%)        | False  |
| IUDs are not safe. (N=232)  | 184 (79%)      | 48 (21%)         | False  |
| Birth control pills can cause blood clots. (N=238)                          | 200 (84%)      | 38 (16%)         | True   |
| Condoms are 99% effective in preventing pregnancy. (N=248)                  | 112 (49%)      | 116 (51%)        | False  |
| Spotting when you take birth control means it is not working. (N=238)       | 225 (95%)      | 13 (5%)          | False  |
| Birth control pills can decrease your risk of some types of cancer. (N=240) | 99 (41%)       | 141 (59%)        | True   |
| I only need to use condoms in the middle of the month. (N=246)              | 241 (98%)      | 5 (2%)           | False  |
| Birth control pills don't work unless you take them every day. (N=250)      | 237 (95%)      | 13 (5%)          | True   |
| You can't get pregnant if you have sex during your period. (N=248)          | 227 (92%)      | 21 (8%)          | False  |

IUD=intrauterine device.

and reproductive variables and contraceptive knowledge (ie, number of questions answered correctly). There were no significant associations between number of questions answered correctly and age ( $r=0.093$ ), race/ethnicity ( $r=0.279$ ), or number of children ( $r=-0.037$ ). There was not an association between number of correct answers and type of birth control used ( $r=-0.126$ ) or information sources for contraceptive information ( $r=-0.044$ ).

## DISCUSSION

Overall, the women in our study demonstrated fairly good knowledge of commonly used birth control methods. Two of the 3 questions answered most incorrectly relate to the effectiveness of condoms and birth control pills. A study of female college students found that over half of the respondents overestimated the effectiveness of condoms, though 90% correctly estimated the efficacy of oral contraceptive pills.<sup>8</sup> However, 42% of the women in this study thought that condoms are as effective as birth control pills for preventing pregnancy and that over half (51%) thought that condoms were 99% effective in preventing pregnancy. With perfect use, condoms may be 98% effective. With typical use, however, they are only 85% effective in preventing pregnancy.<sup>9</sup> This knowledge deficit may explain why many women use condoms and don't feel the need to use a more reliable form of contraception.

Only 41% of the women in our sample knew that oral contraceptive pills can reduce the rate of uterine and ovarian cancer. A similar survey administered in Oregon to women in the waiting rooms of 4 obstetric clinics found that less than 15% of the participants knew of the decreased risk of uterine cancer with oral contraceptive pills and 28% knew of the decreased risk of ovarian cancer.<sup>10</sup> A study from the Yale University Health Services of adult women found that between 80% and 95% of the women surveyed did not know that oral contraceptive pills decreased the risk of endo-

metrial and ovarian cancer.<sup>11</sup>

IUDs are a safe and effective form of contraception. It is heartening to note that only 21% of our sample thought that IUDs were not safe. A study of pregnant women in New York found that 71% of the 190 women surveyed did not know about the safety of IUDs.<sup>12</sup> Women in our sample had a higher rate of IUD use (7%) than the general population of women in the United States (2.1%),<sup>13</sup> which may explain the better knowledge about IUD safety. IUDs have suffered in popularity secondary to the side effects of the Dalkon Shield IUD in the 1970s. This type of IUD was on the market for 3 years and was linked to multiple cases of septic abortions. Subsequent types of IUDs are very safe, and have become a more attractive contraceptive option over the past 5-10 years.

A limitation of our study is the sample selection. This was a convenience sample of women attending a family medicine clinic (either as a patient or accompanying a patient) over a 2-week period during the summer. It was assumed that these 2 weeks were typical in the clinics. However, there is no way to know whether the women we studied were different in some way from the general population of women attending these same clinics. The fact that the populations of each of the 2 clinics were similar speaks to the idea that this was a typical period of time.

The survey itself was not validated. Each question was derived from clinical experience and then written in the most readable language. Even so, there were several reasons why women may have gotten questions wrong. Women may have misinterpreted questions, been in a hurry, or not understood the questions themselves. The questions focused on common clinical misconceptions and were therefore not comprehensive. Several commonly used contraceptive methods (ie, Depot Medroxyprogesterone Acetate [DMPA], the contraceptive patch and ring) were not covered in the survey due to space constraints. Future

research may examine women's knowledge of these kinds of contraception.

## CONCLUSION

Women in this study demonstrated some important gaps in their knowledge about commonly used contraceptive methods. Health care professionals need to develop more effective education about contraception. This study is unique in that it captures women in "real life" primary care clinics where presumably much education about contraception takes place. Future research should look at whether contraception education coming from physicians makes a difference in women's contraceptive behavior. Furthermore, educational materials about contraception need to be written at reading levels appropriate for all patients. Clearer educational materials and patient-centered counseling about pregnancy readiness, attitudes toward contraception, and all the contraceptive options need to be emphasized in primary care offices.

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# Patent Foramen Ovale with Right to Left Shunt as a Cause of Hypoxia

*Ravi K. Mareedu, MD; Juan E. Mesa, MD*

## ABSTRACT

Patent foramen ovale with right to left shunt as a cause of hypoxia without Eisenmengers physiology or with only moderately pulmonary artery pressures is an uncommon presentation. Initial diagnosis via transesophageal echocardiography requires detection of a shunt with either color Doppler or agitated saline contrast with or without Valsalva maneuver. This rare but diagnosable case presented was simply corrected with placement of a CardioSEAL device. Causes of right to left shunt without elevated pulmonary artery pressures are discussed.

## INTRODUCTION

Patent foramen ovale (PFO) is an anatomical variant occurring in the septum separating the atrial chambers. PFO provides communication between the atrial chambers of the heart through the ostium secundum with the septum primum acting as a 1-way valve that allows flow from the right to left atria, bypassing the lungs.<sup>1</sup> This septum normally remains patent before birth and closes with the first breath of air a baby takes because of increased left-sided pressures. Anatomical closure usually occurs by 2 years of age. However, it remains patent in a subset of the population. Autopsy studies have shown an overall prevalence of approximately 27% in the general population, decreasing with increasing age (35% and 20% in age groups <30 years and >80 years, respectively).<sup>2</sup> The average size is estimated at 4.9 mm with a majority being <10 mm in size.<sup>2</sup> The agitated saline contrast study with transesophageal echocardiography (TEE) and the Valsalva maneuver is the gold standard test for detection of PFOs. The

authors present a case report of a 58-year-old woman with an uncommon presentation of hypoxia secondary to right to left shunt (without Eisenmengers physiology and with only moderately elevated pulmonary artery pressures). A 23 mm CardioSEAL device was placed in the PFO with significant improvement in the patient's functional status at 1 month and continued stability at 6-month follow-up.

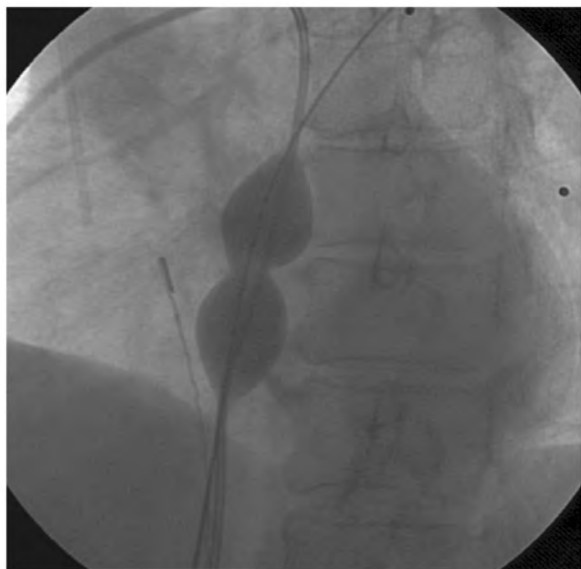
## CASE REPORT

A 58-year-old woman presented with a 9-month history of shortness of breath and a 1-month history of bilateral lower extremity pedal edema with baseline oxygen saturation in the 60s to 70s. She denied orthopnea or platypnea. Pulmonary history was significant for 41 pack years of smoking and prior diagnosis of chronic obstructive pulmonary disease. Past medical history was also significant for hypertension, cervical carcinoma (28 years ago), cecal adenocarcinoma (1 year ago) stage I, earliest stage (Tis), no lymph node involvement (N0), no distant spread (M0), status post-right hemicolectomy, anal cell carcinoma (1 year ago), status post-surgical resection, and chemotherapy. The patient had an unremarkable surgical course during her hemicolectomy 1 year ago. She did not have excessive bleeding and had a hemoglobin of 12.6 g/dL. She had no problems with hypoxia. Her medications included carvedilol, furosemide, aspirin, acetaminophen with codeine, and vitamin B<sub>12</sub>.

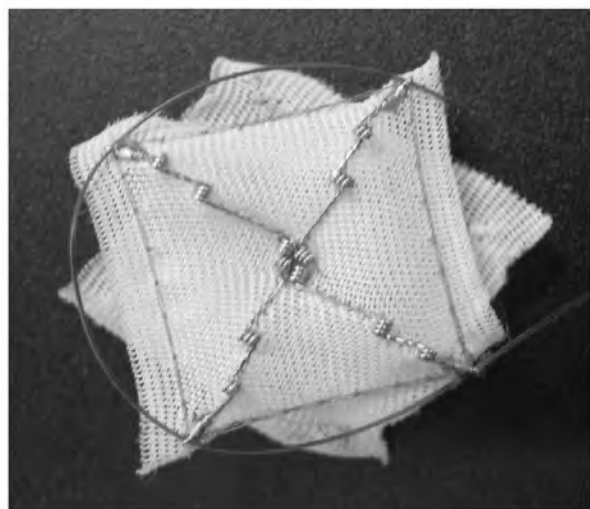
Physical examination showed the patient was afebrile with a blood pressure of 133/76 mm Hg, regular pulse of 75 beats/min and respirations at 17 beats/min. She exhibited central cyanosis and elevated jugular vein distension. Her lungs were clear to auscultation and heart sounds were regular with non-displaced apical impulse. Clinically hepatomegaly was not noted. Bilateral lower extremity pedal edema of 2-3+ was present. The remainder of the physical examination was within normal limits. The patient's oxygen (O<sub>2</sub>) saturation measured 66% on 2 liters of O<sub>2</sub> and increased to

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**Figure 1.** Sizing balloon showing the diameter of the PFO.



**Figure 2.** CardioSEAL device.

73% on 5 liters of O<sub>2</sub>. Laboratory studies showed an elevated red blood cell count ( $5.83 \times 10^6/\mu\text{l}$ ), an elevated hematocrit (47.8%), an elevated D-Dimer (3.94  $\mu\text{g/ml}$ ), an elevated B-type natriuretic peptide (1180 pg/ml), and arterial blood gases demonstrating respiratory alkalosis (pH 7.46, pCO<sub>2</sub> 29 mm Hg, pO<sub>2</sub> 42 mm Hg, FiO<sub>2</sub> 10 liters). A computed tomography (CT) angiogram did not show any evidence of pulmonary embolus, and pulmonary function tests showed mild to moderate obstructive ventilatory defect. CT of the abdomen showed hepatomegaly at 17 cm.

Electrocardiogram showed sinus rhythm with T-wave abnormality in antero-inferior leads, long QT interval, and left posterior hemi-fascicular block. Echocardiogram

(ECHO) showed evidence of a severely enlarged right atrium and right ventricle, depressed right ventricular systolic function, normal left ventricular systolic function, and continuous flow to left atrium from an unknown source. A systolic pulmonary artery pressure was estimated to be at 40-45 mm Hg from a tricuspid regurgitation jet. A pulmonary regurgitation jet was not identified. TEE showed marked right heart enlargement and presence of a defect in atrial septum with the presence of a flap valve formed due to overlapping layers of foramen ovale with the blood flowing from the right atrium to the left atrium under this flap, consistent with a PFO.

Catheterization confirmed presence of low femoral artery saturation (82%) with normal saturation in the left upper pulmonary vein (100%). There was a 9 mm Hg pressure gradient across the interatrial septum with mean pressure in the right atrial of 20 mm Hg and mean pressure in the left atrial of 11 mm Hg. Pulmonary artery trunk pressure was moderately elevated at 40/20/28 mm Hg with normal capillary wedge pressure at 8 mm Hg. To evaluate for tolerance of right heart after closure, temporary occlusion of the PFO with the sizing balloon was attempted (Figure 1), and the femoral artery O<sub>2</sub> saturation increased from a value of 75% O<sub>2</sub> saturation to a value of 94% O<sub>2</sub> saturation at 10 minutes, and to a value of 95% O<sub>2</sub> saturation at 30 minutes. The size of the PFO was measured at 10 mm. Pulmonary artery trunk pressures (baseline 48/27/34 mm Hg, 37 minutes after occlusion 52/25/37 mm Hg) and aortic pressures (baseline 145/90 mm Hg, 37 minutes after occlusion 157/94 mm Hg) remained stable after temporary occlusion of PFO. A 23 mm CardioSEAL device (Figure 2) was subsequently placed in the PFO without complications. An ECHO obtained the next day documented successful PFO closure with minimal residual shunting. The patient's O<sub>2</sub> saturation ranged between 85%-93% on 5-6 liters of oxygen in the first 24 hours. At 1 month follow-up, the patient showed significant improvement in functional status with O<sub>2</sub> saturations of 82% on room air. She continued to be stable at 6 months post-procedure.

## DISCUSSION

Clinical manifestations of PFO include stroke, platypnoea-orthodeoxia, decompression sickness, right to left shunt, and migraine headaches. Hypoxia secondary to right to left shunt (without Eisenmengers physiology or significantly elevated pulmonary artery pressures) is an uncommon presentation. Initial diagnosis via TEE requires detection of a shunt with either color Doppler

or agitated saline contrast with or without Valsalva maneuver. The agitated saline contrast study with TEE and the Valsalva maneuver is the gold standard test for detection of PFOs.

### Pathophysiology

Right to left shunt via PFO is commonly seen secondary to chronically increased right side pressures including tetralogy of Fallot, pulmonary stenosis, right heart tumors, tricuspid atresia, tricuspid stenosis, ventricular septal defects, and atrial septal defects. There is another subset of patients wherein acute right to left shunting occurs secondary to increased right side pressures with recurrent pulmonary emboli, right ventricular infarction, pulmonary hypertension secondary to pneumonectomies or lobectomies, asthma, low atmospheric pressure, and pericardial tamponade.<sup>3-8</sup>

It is sometimes simple to find the trigger for right to left shunt, but in patients whose pulmonary artery trunk pressure was only moderately elevated, there is no easily identifiable single cause. Multiple theories have been postulated to explain severe shunting that can lead to hypoxia. One theory is the transient elevation of right atrial pressure in each cardiac cycle. The presence of sino-atrial node causes earlier depolarization of the right atrium leading to higher pressure in the right atrium compared to the left, thus leading to the right to left shunt.<sup>9</sup> This transient elevation of right-sided pressures is exacerbated in a variety of physiological conditions like respiratory cycles (inspiration), Valsalva maneuver, posture (underlying mechanism for platypnea-orthodeoxia syndrome), etc. A second theory that may explain this phenomenon is the flow of blood from the inferior vena cava preferentially toward the PFO (and inter-atrial septum), similar to the circulatory pattern in the fetus.<sup>10-11</sup> This flow is secondary to the anatomical remodeling of the right atrium, positioning the fossa ovalis in the direction of the blood flow from the inferior vena cava, with the Eustachean valve contributing significantly to the flow phenomenon into fossa ovalis.<sup>11</sup> A third theory proposes the decreased compliance of the right ventricle in comparison to the left ventricle as the mechanism of cause.<sup>12</sup>

### Diagnosis and Treatment

The gold standard for diagnosing PFO is TEE with agitated saline contrast and Valsalva maneuver. Typically initial screening is performed with TTE with agitated saline contrast.<sup>13</sup> Because of the preferential blood flow from the inferior vena cava toward the atrial septum, contrast administration from the femoral vein has shown higher sensitivity for detection of PFOs compared to

the ante-cubital vein approach.<sup>13-14</sup> Common respiratory conditions and thromboembolic events as a cause of hypoxia should be ruled out initially. Correction of hypoxia with temporary occlusion of the PFO during catheterization will provide clear evidence of PFO with right to left shunt as the etiology of hypoxia, as demonstrated in this patient.

Mechanical closure is clearly indicated in significantly hypoxic patients. In recent years, with advancement of percutaneous techniques, transcatheter closure of the PFO has yielded positive results without accompanying surgical morbidity and mortality.<sup>15</sup> Most studies regarding the effectiveness of closure devices in patients with PFOs were performed in patients with cryptogenic strokes.<sup>16-17</sup> Complications arising from percutaneous closure include thrombus formation on the closure device, pericardial effusion, or fracture of the device. One case series reported thrombus formation on the closure device in only 20 of 1000 patients who had device placement.<sup>18</sup>

In summary, this case illustrates the pathophysiological mechanisms underlying a left to right shunt across PFO with only moderately elevation of the pulmonary artery trunk pressures. This is a rare but identifiable cause of hypoxia, which can be simply corrected.

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# Calciophylaxis Responsive to Lanthanum Carbonate (FOSRENOL) Therapy

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Molly Hinshaw, MD; Jonathan B. Jaffery, MD

## ABSTRACT

Calciophylaxis is a rare and debilitating vasculopathy predominantly seen in patients with renal failure. The proposed mechanism of injury is active vascular calcification with associated elevated parathyroid hormone, hypercalcemia, or hyperphosphatemia. With improved pharmacologic agents including non-calcium containing phosphate binders, vitamin D analogues, calcimimetics, and bisphosphonates, targeted therapy on the mineralization process has been tried with varied success. We report a case of biopsy-proven calciophylaxis in a patient with acute kidney injury requiring dialysis that had persistently elevated calcium-phosphorus product refractory to treatment. The patient, however, responded rapidly to the initiation of lanthanum carbonate therapy and modified dialysis. This is the first known case reported in the literature utilizing this new non-calcium-based phosphate binder in the setting of calciophylaxis.

## INTRODUCTION

Calciophylaxis or calcific uremic arteriopathy was first described by Bryant and White in 1898 in a child with renal failure.<sup>1</sup> In 1962, Hans Selye coined the term calciophylaxis with his animal studies of soft tissue calcium deposition that were “sensitized” to vitamin D, parathyroid hormone (PTH), high calcium and phosphorus and then challenged with iron salts and egg albumin.<sup>2</sup> The entity is a rare and debilitating vasculopathy predominantly seen in patients with renal failure, however also seen in patients without end-stage renal disease.<sup>3</sup> Although all of these cases possessed a proposed etiologic mechanism of injury and vascular calcification in the form of elevated serum PTH, hypercalcemia, and hypercoagulable state, the pathophysiology remains

an elusive topic. The predominant theory is that it is a systemic syndrome that almost always affects the skin with characteristic calcification involving the media of small- to medium-sized arterioles. Much research and attention to date has focused on the internal milieu that causes the histologic findings of calcium-phosphate aggregation within blood vessels.

In order to treat calciophylaxis, multiple case series and cohorts have targeted the ectopic or dystrophic calcification of injured tissue and vessels. Elevated calcium-phosphorus product has been a major focus of experimental studies and the pharmacologic management utilizing non-calcium-containing phosphate binders and vitamin D analogues.<sup>4-5</sup> Low-calcium dialysate and dietary modification, especially in patients on total parenteral nutrition and enteral feeding, have also been studied.<sup>5-6</sup> Parathyroidectomy in the past had been a successful strategy for treating calciophylaxis, however not until recently have results been controversial.<sup>6-7</sup> The extremely high mortality associated with the procedure and recent improved medical management of secondary and tertiary hyperparathyroidism has significantly diminished its role as a treatment regimen. Other novel and evolving treatment modalities cited in the literature include intravenous sodium thiosulfate, calcimimetics, bisphosphonates, tissue plasminogen activator, and hyperbaric oxygen.<sup>8-9</sup>

We report a case of biopsy proven calciophylaxis in a patient with acute kidney injury requiring permanent hemodialysis that had persistently elevated calcium-phosphorus product recalcitrant to longer dialysis treatments and low-calcium dialysate. The patient interestingly responded rapidly to the initiation of lanthanum carbonate therapy and continued dialysis. This is the first case reported in the literature utilizing this new non-calcium-based phosphate binder in the setting of calciophylaxis.

## CASE REPORT

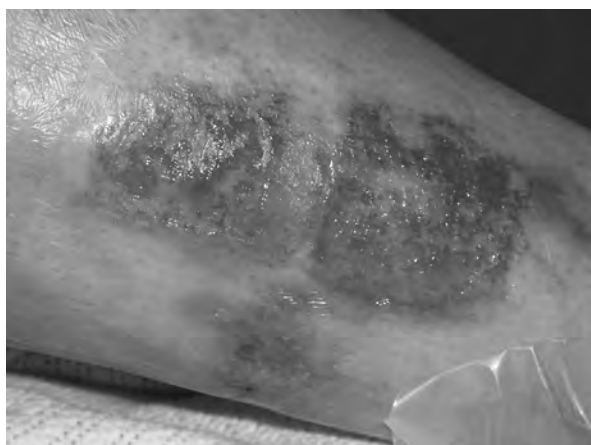
A 64-year-old man with a history of cryptogenic cirrhosis was transferred to the trauma and life support unit after worsening liver failure, hypotension, renal failure,

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**Figure 1.** Photograph of lower right leg showing violaceous necrotic skin lesions with black eschar.



**Figure 2.** After 2 months of combination treatment with lanthanum and dialysis, there was significant healing with only superficial ulceration.

and encephalopathy. Prior to transfer, the patient was started on empiric antibiotics for presumed spontaneous bacterial peritonitis and septic shock, given aggressive crystalloid and blood products for fluid resuscitation and correction of coagulopathy, and eventually started on vasopressors for hemodynamic instability. The patient was transferred for renal failure thought to be due to hepatorenal syndrome and evaluation for liver transplantation.

On examination, the patient was diffusely jaundiced and had a pruritic, erythematous papular eruption over his trunk, abdomen, and lower extremities thought to be a drug eruption secondary to cephalosporin therapy he was receiving. He had pitting edema to his sacrum and no pain or hyperaesthesia over his lower extremities.

Laboratory findings on admission included a blood urea nitrogen of 106mg/dL, creatinine 3.1mg/dL, total calcium 6.7mg/dL, phosphorus 4.8mg/dL, calcium-

phosphorus product of 32.2mg<sup>2</sup>/dL<sup>2</sup>, and an albumin of 1.3g/dL. The patient had numerous blood, urine, and peritoneal fluid cultures during his hospitalization that were negative. The patient was started on continuous venovenous hemofiltration (CVVHF) due to anuric renal failure, shock, and extreme volume overload that eventually necessitated intubation for hypoxemic respiratory failure due to pulmonary edema. Over the next several days, the patient continued on CVVHF with citrate regional anticoagulation secondary to a new internal capsule central nervous system bleed. Pre- and post-filter ionized calcium, as well as total calcium and phosphorus were managed without difficulty. The patient eventually was extubated, weaned off pressor agents, and tolerated intermittent hemodialysis 3 times weekly.

Due to severe malnutrition and failed swallow studies, he necessitated nasogastric (NG) tube feeds with low phosphorus Nepro™ enteral nutrition. It was noted on day 20 of his admission that his calcium (uncorrected) and phosphorus was 10.3mg/dL and 7.1mg/dL respectively with a calcium-phosphorus product of 73.1 mg<sup>2</sup>/dL<sup>2</sup>. A low dialysate calcium bath at 1.25meq/L was initiated from 2.5meq/L and dialysis time was increased from 3.5 hours to 4 hours and 4 times weekly. Despite these measures, over the next few days calcium and phosphorus levels did not show improvement. Calcium-phosphorus product rose to a maximum of 135.7mg<sup>2</sup>/dL<sup>2</sup>. An intact PTH was checked and normal at 26pg/mL. Calcium-based phosphate binders such as calcium carbonate or calcium acetate (Phoslo®) could not be used because of increasing calcium serum levels and calcium-phosphorus product. Sevelamer (Renagel®) could not be given due to the difficulty of crushing the tablets and the potential of obstructing the NG tube. Around this time, the patient developed extremely painful “tears” on the bilateral anterior lower legs. These lesions began as erythematous, indurated blisters/nodules that eventually ulcerated over approximately 2 weeks, resulting in necrotic eschar formation. Dermatology was then consulted (Figure 1) and a skin biopsy and cultures were performed.

Since sevelamer could not be used, dialysis was continued and lanthanum carbonate therapy (1000mg) was started 3 times daily. He also continued on low phosphorus tube feeds and meticulous wound care. Over the next 8 weeks, the calcium and phosphorus levels were much more manageable, with a product averaging 35.5 mg<sup>2</sup>/dL<sup>2</sup>. His nutritional status improved with an albumin level of 3.8g/dL, and his intact PTH was still within normal limits at 27pg/mL. The patient’s skin lesions dramatically improved with these measures and the pain completely dissipated (Figure 2). The skin biopsy



revealed vascular calcification with intimal proliferation consistent with calciphylaxis (Figure 3).

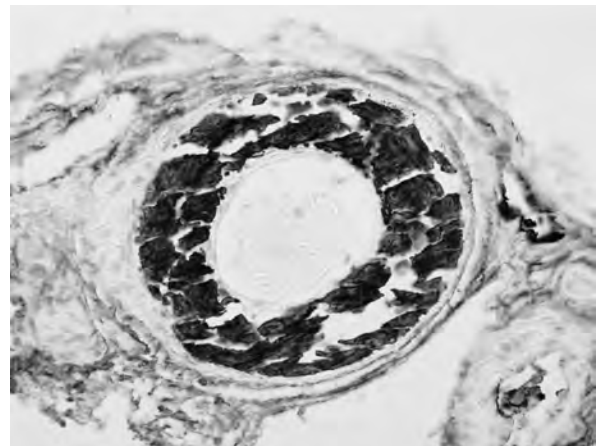
The patient's functional status has improved with physical therapy and receipt of a successful kidney and liver transplant. No side effects in this patient have been observed with continued therapy with lanthanum carbonate.

## DISCUSSION

Calciphylaxis has a prevalence rate of approximately 1%-4% in long-term hemodialysis patients, with 1-year survival of 45% and an 8-fold risk of death as compared to the general dialysis population.<sup>10</sup> Sepsis is the major cause of death in these patients.<sup>11</sup> Clinical suspicion and the evolvement of the classic skin lesion is the major clue to the diagnosis of this syndrome. Corresponding to the vascular nature of this disorder, patients typically present with a livedo reticularis pattern that progresses to exquisitely painful plaques. These plaques often have a stellate appearance, then ulcerate, and are covered in a black eschar. The lower extremities are the most common site of involvement.

Risk factors reported in the literature range from obesity and female gender to hypoalbuminemia and protein C or S deficiency (Table 1).<sup>3,7,12</sup> These risk factors, in conjunction with key laboratory parameters of hyperparathyroidism, hypercalcemia, or hyperphosphatemia, should raise clinical suspicion of calciphylaxis. Levin et al described a mathematical formulation using some of these lab values as a surrogate in determining high-risk patients.<sup>13</sup> Unfortunately, this has not been validated in subsequent studies. Skin biopsy is still the gold standard for diagnosis and shows calcification of the media of small cutaneous blood vessels with intimal hyperplasia, vascular thrombosis, cutaneous ulceration, and necrosis. Recently bone scintigraphy has emerged as a highly sensitive tool in diagnosing calciphylaxis and as an adjunct to track prognosis in treated individuals.<sup>14</sup>

Biomedical research has helped elucidate which cellular mechanisms are dysfunctional in patients with severe ectopic vascular calcification, ie, calciphylaxis. It has been shown that hyperparathyroidism is found in 82% of patients, hyperphosphatemia in 68%, hypercalcemia in 20%, and elevated calcium-phosphorus product in 33%.<sup>12</sup> What was once thought to be a passive deposition of calcium and phosphorus in blood vessels, now clearly points to an active and tightly regulated cell-mediated process.<sup>3,7</sup> Many groups have shown that a complex set of endogenous factors may induce the increased mineralization of vascular beds much like bone formation, whether by up-regulation of calcium or phosphorus



**Figure 3.** Von kossa stain showing calcium deposition of intima and media of vessel wall.

**Table 1.** Reported Risk Factors in Patients with Calciphylaxis

|  |
|--|
| Calcium carbonate and acetate                      |
| Caucasian race                                     |
| Cirrhosis  |
| Corticosteroids                                    |
| Crohn's disease                                    |
| Diabetes mellitus                                  |
| Elevated calcium-phosphorus product                |
| Female gender                                      |
| Human immunodeficiency virus                       |
| Hypercalcemia                                      |
| Hyperparathyroidism (primary, secondary, tertiary) |
| Hyperphosphatemia                                  |
| Hypoalbuminemia                                    |
| Hypotension  |
| Iron overload                                      |
| Malignancy   |
| Obesity  |
| Protein C or S deficiency                          |
| Renal transplantation                              |
| Trauma   |
| Vitamin D  |
| Warfarin   |

deposition or down-regulation of inhibitors.

Matrix G1a protein (MGP), which originally was thought to promote calcification, has now been shown to be a potent inhibitor. In the MGP deficient mouse model, aggressive and uncontrolled vascular calcification occurs.<sup>12</sup> It has also been shown to be constitutively expressed in vascular smooth muscle cells and macrophages responsive to intimal injury.<sup>5</sup> Experimental evidence also suggests that vascular smooth muscle may differentiate into a phenotype capable of inducing proteins of "osteoblastic" type activity. Both osteopontin and osteocalcin expression has been demonstrated to be up-regulated by a high phosphorus environment.<sup>5</sup> Ahmed et al demonstrated in a controlled study of calciphylaxis

patients that osteopontin expression by vascular smooth muscle was seen in the setting of high phosphorus and calcium-phosphorus product.<sup>7</sup> Moe et al further showed the importance of matrix Gla protein and  $\alpha$ 2-Heremans-Schmid glycoprotein as inhibitors of vascular calcification in chronic kidney disease.  $\alpha$ 2-Heremans-Schmid glycoprotein is an endogenous inhibitor of calcification that has been observed to be significantly lower in calciphylaxis patients.<sup>15</sup> Based on experimental studies, elevated phosphorus levels seem to be the putative ion involved in elevation of calcium-phosphorus product and calciphylaxis.<sup>7</sup> Lanthanum carbonate or FOSRENOL is a potent non-aluminum, non-calcium phosphate binder that was approved for use by the US Food and Drug Administration in October 2004. It is indicated to reduce serum phosphate levels in patients with end stage renal disease. It is not metabolized and is not a substrate or inhibitor of CYP450. It inhibits intestinal absorption of phosphate by forming highly insoluble complexes, thereby lowering serum phosphorus and calcium-phosphorus product. Well-designed studies have shown that doses of 375mg/day up to a maximum of 2250mg/day were effective in reducing phosphorus levels and calcium-phosphorus product as compared to placebo.<sup>16</sup> Adverse effects were predominantly gastrointestinal, including nausea, vomiting, and abdominal pain, but in a majority of cases these doses were well tolerated. Pre-clinical data has shown minimal systemic absorption and, furthermore, bone biopsies in open-label active-controlled studies did not show differences in mineralization.<sup>16</sup>

Our patient's calciphylaxis developed over the course of weeks with no history of previous chronic kidney disease. The patient's laboratory markers were not typical of classic calciphylaxis with elevated serum PTH, and therefore pharmacologic measures such as cinacalcet or bisphosphonates could not be tried due to risk of adynamic bone. The need to control his calcium and phosphorus levels were critical due to excruciating pain and high risk for secondary infection of his skin lesions. In contrast to conventional treatment, lanthanum carbonate in combination with low-calcium dialysate and longer duration/frequency of dialysis provided a brisk response. More study is needed to determine whether the lanthanum carbonate was effective by decreasing the phosphorus levels or an active inhibitor of the mineralization process. Also, future therapeutic trials should investigate if treating an acute rise in phosphorus may mitigate potential detrimental effects such as vascular calcification.

## CONCLUSION

In conclusion, our case report suggests an effective therapy for calciphylaxis in combination with modified hemodi-

alysis and meticulous wound care. The rapid response to treatment may hold promise for many patients suffering from this deadly and debilitating syndrome. Lanthanum therefore offers an exciting and new option for health care professionals, but more studies need to determine whether it can be used safely and efficiently in all forms of this enigmatic disease.

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# Proceedings from the Wisconsin Research and Education Network's 2007 Research Forum

## INTRODUCTION

The Wisconsin Research and Education Network (WREN) held its 2007 Research Forum November 1-2, 2007 in the Wisconsin Dells. During the Forum, the abstracts below were presented, representing current research relating to primary care. The Forum was held to facilitate interaction between primary care researchers of all levels in Wisconsin.

A sixth abstract, titled "Women's Knowledge of Commonly Used Contraceptive Methods," was also presented at the forum by author Sarah Hoffmann. The full manuscript was submitted to the *Journal*, and is published in its entirety on page 327.

### Evaluations of the Diagnosis and Treatment of Pneumonia in Outpatient Primary Care Practices

*Jennifer Everts, MS, Dennis Baumgardner, MD, Ann Regnery, BS, Indrani Banerjee, BS; Center for Urban Population Health, Department of Family Medicine, University of Wisconsin, Madison, Wis and Aurora UW Medical Group, Milwaukee, Wis*

**Context:** Many articles discuss the importance of ordering a chest X-ray to diagnose pneumonia based on prediction rules of signs and symptoms. It is unclear which signs and symptoms primary care clinicians use to diagnose pneumonia or prompt X-ray in comparison to bronchitis and upper respiratory infections (URIs).

**Methods:** Six hundred and four patients aged 18-80, diagnosed with pneumonia (n=200), acute bronchitis (205), or URIs (199).

**Results:** Race, gender, and chronic obstructive pulmonary disease were significant predictors of pneumonia in both univariate and multivariate analysis. Multiple signs and symptoms were significant individually. A

stepwise regression identified rales/rhonchi, temp >100°F, heart rate, rhinorrhea, cough, and chest pain to best explain the variation in the diagnosis of pneumonia compared to bronchitis and URI ( $R^2=44.11$ ). Thirty-five percent (n=59/175) of patients diagnosed with pneumonia had a negative chest X-ray. Rales/rhonchi, dyspnea, rhinorrhea, chills, chest pain, and temp >100°F best predicted ordering a chest X-ray ( $R^2=38.22$ ). The same variables remained significant as independent predictors of ordering a chest X-ray in binary logistic regression except chills and respiratory rate. Rales/rhonchi ( $P=0.000$ ), heart rate ( $P=0.009$ ), and dyspnea ( $P=0.003$ ) were significant predictors for prescribing antibiotics. These variables remained significant when removing patients with concurrent sinusitis ( $P\leq 0.004$ ). A significant number of bronchitis patients (95%) received antibiotics; removing those with sinusitis, 93% were still prescribed antibiotics. Overall, the most highly predictive symptoms of clinical diagnosis of pneumonia were rales/rhonchi or decreased breath sounds ( $P=0.000$ ).

**Conclusions:** No constellation of signs and symptoms was highly predictive of the clinical diagnosis of pneumonia, use of X-ray, or prescription of antibiotics compared to bronchitis and URI. Symptoms of rales/rhonchi or decreased breath sounds are the best predictors of pneumonia diagnosis.

### Geographic Distribution of Human Blastomycosis by Season in Northern Wisconsin

*Dennis J. Baumgardner, MD, Zachary J. Baeseman, Andrea Schreiber, MA; Center for Urban Population Health, Aurora UW Medical Group, Milwaukee, Wis and University of Wisconsin School of Medicine and Public Health, Madison, Wis*

**Background:** Blastomycosis is a potentially fatal systemic and cutaneous fungal infection that is contracted by inhalation of spores from an incompletely defined ecological niche. Previous studies have not conclusively demonstrated seasonality for blastomycosis. Seasonality might suggest certain environmental factors.

**Methods:** A retrospective analysis was performed to determine if there is a non-random distribution of blastomycosis, generally and geographically by season, and over time in a highly endemic area. Street addresses and demographic data from a registry of human cases in or near Vilas County, Wis from 1979 to 2006 were geocoded with Map Marker Plus and mapped using Arc-GIS. Controls were 200



randomly selected households from 2001 county tax records. A chi-squared test was used for categorical data, and Mood's Median Test was performed on the geographic distribution data. An individual/moving range control chart was constructed for county cases 1984-2006.

**Results:** The distribution of cases by season of symptom onset, winter (n=47), spring (n=42), summer (n=45), and fall (n=40), was not statistically significant ( $P=0.89$ ). The geographic distribution of cases was similar regardless of season or time period. Overall geographic distribution by season in Vilas County regarding proximity to waterways did not differ ( $P=0.338$ ): winter (n=40, median=172 m), spring (n=39, 247 m), summer (n=41, 138 m), and fall (n=38, 184 m); however summer cases were closer to water than spring cases ( $P=0.044$ ). Three time periods exceeded both control chart upper process/control limits in the past 23 years without change in average moving range.

**Conclusions:** The geographic distribution of blastomycosis cases has remained consistent over time and season, perhaps representing important relatively fixed environmental factors.

#### Mindfulness Meditation for Alcohol Relapse Prevention: A Feasibility Pilot Study

Aleksandra Zgierska, MD, PhD, Megan Zuelsdorff, BS, Michael Fleming, MD, MPH, Benjamin Craig, PhD, David Rabago, MD, Sahar Safavi; Department of Family Medicine, University of Wisconsin School of Medicine and Population Health, Madison, Wis

**Context:** Relapse prevention in alcohol dependence remains a challenge. Meditation is a promising but not well-studied treatment for alcohol dependence. This study evaluated methods feasibility and gathered pilot data on efficacy of meditation for alcohol relapse prevention.

**Methods:** A 16-week prospective case series in an intensive outpatient addiction treatment was conducted. Study participants were alcohol-dependent adults who attended 8-week meditation course (2-hour weekly sessions) and at-home meditation (30 minutes/day, 6 days/week), adjacent to "standard of care" therapy. Of 19 enrolled subjects, 15 completed the study.

**Results:** The average age of the participants (53% female) was 38.4 years old (standard deviation [SD] 8.6 years). At enrollment, they were abstinent for 30.9 (SD 22.2) days. Those who completed the study attended 82% of meditation course sessions. During the study, they were abstinent on 94.5% (SD 7.4) of days, with 47% reporting complete abstinence and 47% reporting  $\geq 1$  heavy drinking day. Subjects meditated on average 4.6 (SD 1.1) days/week; their severity of depression, anxiety, and stress—documented relapse triggers—decreased ( $P<0.01$ ). Craving severity showed a tendency to improve ( $P=0.08$ ), and degree of mindfulness increased ( $P<0.01$ ). On a Likert scale (10="very important/likely"), subjects rated the meditation course as very important in general (8.7, SD 1.8), useful as a relapse prevention tool (8.5, SD 2.1), and reported that they were very likely to continue meditation practice (9.0, SD 1.5). In qualitative responses, they listed "gaining skills to reduce stress," "coping with craving," and "good group support" as the most valuable aspects of the meditation training. At baseline, salivary cortisol and serum interleukin-6 (IL-6) concentrations were higher than normative values. At 16 weeks, IL-6 level decreased (n=12,  $P=0.05$ ); changes in cortisol level (n=11) were not significant. There have been no adverse events or side effects.

**Conclusions:** Results suggest study methods feasibility and the possibility of efficacy of meditation as an adjunctive therapy for relapse prevention in alcohol dependence.

#### Practitioner Empathy and the Duration of the Common Cold (The PEP Study)

David P. Rakel, MD, Theresa J. Hoelt, PhD, Bruce P. Barrett, MD, PhD, Betty A. Chewning, PhD, Benjamin M. Craig, PhD, Min Niu; University of Wisconsin-Madison, Madison, Wis

**Objective:** This study assesses the relationship of empathy in the medical consultation to subsequent cold outcomes.

**Methods:** The study included 351 subjects  $\geq 12$  years of age from southern Wisconsin who received either a standard physician visit or an enhanced patient-oriented visit as part of an ongoing randomized controlled trial. The patient-scored Consultation and Relational Empathy (CARE) scale questionnaire assesses several aspects of the doctor-patient interaction with a focus on measuring empathy. CARE scores range from 0 to 50, with 50 being a perfect score. Area-under-the-curve (AUC) cold severity is assessed from twice daily symptom reports using the Wisconsin Upper Respiratory Symptom Survey (WURSS-21) and cold duration is monitored. The cytokine IL-8 was also monitored at study intake and approximately 48 hours later.

**Results:** Eighty-four individuals reported perfect CARE scores. These individuals differed in some demographics, tending to be older and have less education, but reported similar health status, quality of life, and levels of optimism. Cold duration was shorter in the perfect score group (mean 7.05 days versus 7.99 days,  $P=0.026$ ) and the mean WURSS-21 AUC measure was lower among those with a perfect CARE score (mean AUC 237.7 versus 284.6,  $P=0.095$ ). After accounting for possible demographic and perceived stress differences, cold severity and duration were still milder in those reporting a perfect CARE score ( $P<0.05$ ). A perfect score also appears to

correlate with a higher IL-8 level 48 hours after initial consultation.

**Conclusions:** Patients who gave the clinician a perfect CARE score subsequently had milder and shorter colds. These differences remained after accounting for age, gender, race, education, optimism, perceived stress, and time from first symptom to enrollment.

### Sufficiently Important Difference for the Common Cold

*Bruce Barrett, MD, PhD; University of Wisconsin School of Medicine and Population Health, Department of Family Medicine, Madison, Wis*

**Context:** Sufficiently important difference (SID) has been defined as "the smallest amount of patient-valued benefit that an intervention would require in order to justify associated costs, risks, and other harms." This study aims to estimate SID for common cold, both in terms of reduction


in length of illness (duration SID), and in terms of reduction of overall global severity (severity SID).

**Methods:** Benefit harm trade-off (BHTO) interviews assessed duration SID among 311 people with common cold, using scenarios based on evidence regarding vitamin C, echinacea, zinc, and pleconaril (an unlicensed antiviral). A second cohort of 253 people with colds participated in BHTO interviews eliciting severity SID.

**Results:** Overall mean duration SID was reduced 52.6 hours in a 7-day cold. Duration SID was 26.1 hours for vitamin C, 36.8 hours for echinacea, 64.8 hours for zinc, and 82.6 hours for the antiviral. Similar patterns emerged for severity SID, where on average respondents wanted a 25% overall severity reduction for vitamin C, 32% for echinacea, 47% for zinc, and 57% for the antiviral. While treatment type and potential side effects did influence response patterns, other factors such

as age, gender, education, income, and severity of illness at time of interview did not. These group averages tell only part of the story, however, as variability among persons was very high, with tri-modal response patterns evident in both studies. Some people would take treatments with benefits at or near 0, and some would not want the treatment even when benefits were large. However, the majority did indicate a SID benefit threshold, below which they deemed benefits too small to justify costs, possible side effects, or inconvenience. Distribution of threshold SIDs across samples resembled a normal curve.

**Conclusions:** People want duration benefits of 26-65 hours reduction in illness duration, or severity benefits in the range 25%-47% reduction in overall severity, in order to justify costs and risks of existing cold treatments. Prescription antiviral cold treatments would require larger benefits.



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Robert N. Golden, MD

## Thoughts from the White Coat Ceremony

*Robert N. Golden, MD, Dean, University of Wisconsin School of Medicine and Public Health, Vice Chancellor for Medical Affairs, University of Wisconsin-Madison*

In September, I had the great honor and pleasure to preside over the White Coat Ceremony for the Class of 2012. Each year, both the Medical College of Wisconsin and University of Wisconsin School of Medicine and Public Health hold this formal investiture ceremony in which we welcome our new medical students and their families. But more importantly, this is our first opportunity to formally emphasize the commitment to service that is such an integral part of the medical tradition.

As I looked out at the audience—which included so many enthusiastic and idealistic, if not somewhat anxious, first-year medical students and their incredibly proud families—I wondered about their future. I personally believe that despite the evolving stresses and strains surrounding the practice of medicine in this country, the time has never been better to join the profession. The future is brighter than ever in terms of our increasing potential to make a real difference in health, not only for our patients and their families, but for our communities as well.

At the same time, we must recognize and confront the challenges that are facing our medical students—and the rest of us who practice medicine. Health care reform is an issue of utmost national importance. It is disappointing that the dialogue on this complex issue that we heard at the earliest phases of the presiden-

tial campaign season has suddenly taken a back seat to discussions on the current economic crisis. This is understandable. As people lose their jobs and as families struggle to put food on the table, other vital concerns can fade from their immediate attention.

We must push the public to take a broader look at these inter-related issues. We should explain to our legislators and our neighbors that there is a strong link between the current acute economic crisis and the ongoing chronic issues of health care reform. It is impossible to compete in a global marketplace if we do not have a healthy workforce. It is also very difficult to compete in the global marketplace if the cost to business owners of providing health care insurance places them in a non-competitive position compared to factories that might be located or relocated in other parts of the world. At the same time, we should point out that the health care industry, including biomedical and health technology companies, can revitalize the economies in parts of our state and country that are struggling with the transition from older economic models to newer, more globally oriented economic strategies.

When one steps back to take a rational look at addressing our economic and health care challenges, it becomes clear that we are not facing an “either-or” situation. The two

are intricately entwined. Attention to health care and health care reform will help us out of our economic doldrums. And if we ignore the health of the public, we will not be able to compete successfully.

There are no easy answers to the dilemmas confronting the health of the American public. If there were, we would have discovered them by now. But we must keep pushing to provide equal access to health care for all. Our health care delivery systems must be effective and efficient. We must quickly address the growing crisis in the health care workforce, including not only physicians, but also nurses, pharmacists, dentists, and allied health technologists. This workforce issue should be identified as a critical component of the health care public policy debate. Otherwise, if we address health care finance and access to care but not workforce development, we will be shifting from one set of road blocks to another.

I wish that all of you could have seen the bright, eager faces of our soon-to-be new colleagues at the White Coat Ceremony. Over time, as they complete their passages through medical school and residency training, they will emerge as a vital new infusion of additional talent and dedication. Please join me in a pledge to do all that we can to create the best possible systems and environment for them as they enter the practice of medicine.

# Federal Appeals Court reverses lower Court ruling; reaffirms immunity for hospitals and physicians in peer review cases

Michelle Leiker, JD

On July 23, 2008, the US Court of Appeals for the Fifth Circuit Court (Appeals Court) overturned a \$33 million judgment awarded to Lawrence Poliner, MD, and found in favor of Texas Health Systems (Hospital), concluding that the peer review activities of the Hospital and its physicians were entitled to immunity under the Health Care Quality Improvement Act (HCQIA).<sup>1</sup> The ruling resulted in a sigh of relief from hospitals and physicians involved in peer review activities.

The medical and legal communities have watched the *Poliner* case closely since 2004 when a jury awarded a physician, Dr Poliner, \$366 million in damages against a hospital and members of its medical staff. The medical and legal communities were shocked by the amount of the jury award and amazed by the physician's ability to defeat the claims of immunity by the hospital and the physicians involved in the peer review process. The huge jury award also had a chilling effect, as physicians became more reluctant to serve on peer review committees or as leaders of hospital departments.

## Brief Case History

The case involved Dr Poliner, a

cardiologist, who was asked by the internal medicine department chair to hold his cardiac catheterization lab (cath lab) privileges in abeyance for a short time while an investigation occurred. The event that triggered the abeyance request was Dr Poliner's failure to diagnose and treat a blocked artery during a catheterization. When Dr Poliner asked what his options were, he was told that the alternative was suspension of his privileges.

The abeyance was extended once, as allowed by the medical staff bylaws, and on the 23rd day of the abeyance, the peer review committee met with Dr Poliner to discuss its investigation and concerns. The peer review committee recommended a temporary suspension of Dr Poliner's cath lab and echocardiogram privileges pending a full investigation. Approximately 5 months later, the full investigation resulted in a full reinstatement of Dr Poliner's privileges with a temporary mandatory consultation requirement. Doctor Poliner appealed, and the Hospital's Board of Trustees upheld the decision.

In May 2000, almost 2 years later, Dr Poliner filed suit against the Hospital, the physicians involved in the initial decision to hold his cath lab privileges in abeyance, and 7 other physicians involved in his medical peer review for anti-trust claims, violation of the Texas Deceptive Trade Practices Act,

breach of contract, business disparagement, libel, slander, tortious interference, intentional infliction of mental anguish, and emotional distress. Doctor Poliner claimed damages from the initial limited restriction on his privileges, the extension of those restrictions, and the suspension of his privileges. He alleged that competitors acting in bad faith motivated the suspension. The defendants moved for summary judgment based on immunity under HCQIA and other grounds.

On September 30, 2003, the District Court issued its decision. It extended HCQIA immunity to all defendants on the summary suspension itself and granted all defendants' summary judgment motion on that basis. However, the district court also held that a jury needed to decide whether the abeyance and its subsequent extension were proper. Consequently, the District Court allowed the case to proceed to a jury trial on only the alleged damages from the limited restrictions on Dr Poliner's privileges during the initial abeyance and the subsequent extension.

The jury found that the professional review related to the abeyance did not meet the standards for immunity under HCQIA or Texas law, and in favor of Dr Poliner on all of his claims. It awarded Dr Poliner \$366 million in damages, largely based on the fact that it believed that the defendants had acted mali-

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ciously and without privilege or justification. The defendants moved for a new trial or a reduction in the amount of damages.

In 2006, approximately 2 years later, the District Court denied the defendants' request for a new trial and reduced the overall damage award against the defendants to \$33 million. The defendants appealed the ruling, and in July 2008, the Appeals Court reversed the District Court's decision and ruled that the defendants should have been entitled to immunity under HCQIA. The Appeals Court held that Dr Poliner failed to rebut the presumption that the peer review action complied with HCQIA and further that the evidence independently established in the action complied with the statute.

This recent ruling should relieve many of the concerns felt by physicians and hospitals after the initial verdict. At the same time, it serves as a reminder that HCQIA immunity is not automatic and requires strict adherence to the terms of the Act.

#### What is HCQIA?

HCQIA, passed in 1986, grants peer review participants qualified immunity from damage liability, provided they demonstrate compliance with certain standards. HCQIA establishes a presumption that peer review actions are reasonable in a suit brought by a physician.<sup>2</sup> HCQIA allows states to enact even greater protections for medical peer review activities.

To protect and encourage peer review, Congress immunized from damages any peer review actions that meet certain objective standards of reasonableness. When it passed HCQIA, Congress created a National Practitioner Data Bank (NPDB), to which hospitals are required to report certain information, such as a hospital's revocation

of privileges for more than 30 days. Congress wanted to address the issue of physicians moving from state to state to escape knowledge of their prior practice. Congress understood that the lawsuits by those subject to peer review actions threatened the feasibility of the hospital peer review and that the NPDB would only encourage more lawsuits against peer reviewers.

To balance the interests of the physicians subject to peer review with the interests of those engaged in peer review, Congress immunized peer reviewers and their hospitals from individual damage suits if their actions satisfied certain standards of objective reasonableness. Congress did not restrict the physician's right to seek declaratory or injunctive relief to enforce the physician's procedural or other state law rights that might protect a physician during the peer review process. The immunity from damages provides those who grant and monitor physician privileges the ability to err on the side of patient safety and makes patient safety the top priority.

The 4 requirements for immunity under HCQIA are

1. The action must have been taken with the reasonable belief that it furthered quality health care.
2. There was a reasonable effort to obtain the facts.
3. There was adequate notice and hearing procedures afforded to the affected physician.
4. There was a reasonable belief that the adverse action was warranted by the facts known.

The Court of Appeals ruling in the Poliner case provided the following additional insight regarding the application of immunity under HCQIA.

- HCQIA's reasonableness standard was intended to create an objective standard of performance rather than a subjective

good faith standard.

- The review of reasonableness must be based on the information known at the time, not what might be later shown to be true by experts or otherwise.
- HCQIA requires that the findings of the peer review body are objectively reasonable, not that they are correct.
- Allegations of anti competitive motives or evil intent do not affect the immunity offered by HCQIA if the actions are objectively reasonable.
- Immunity from money damages under HCQIA does not require compliance with the hospital's medical staff bylaws, as long as the requirements for immunity have been met.

#### Wisconsin Peer Review Immunity Statute

The Wisconsin peer review immunity statute, Wis. Stat. § 146.37, protects those engaged in peer review of health care services from liability by providing immunity, conditioned on good faith, from lawsuits based on their participation in peer review activities. Good faith is presumed under the statute. Wisconsin case law recognizes that the language in the statute is purposefully broad and that the statute provides protection for a wide scope of peer review activities performed by various actors (eg, external peer review groups).

#### Summary

Peer review committees in Wisconsin should keep in mind both the Wisconsin peer review immunity statute and HCQIA when structuring their peer review processes. Documenting that actions were taken in good faith is critical. While this is not a consideration under HCQIA, it is under Wisconsin law. Temporary restrictions on a physician's privileges can



be appropriate when patient safety requires it; in these circumstances, hospitals should make sure to keep the issue raised by HCQIA's emergency exception.

By and large, courts have sided with hospitals in peer review disputes. The physician challenging the peer review action bears the burden of showing by a preponderance of the evidence that no reasonable belief supported the action. While the initial rulings in the Poliner case raised concerns, these rulings were not typical and were ultimately reversed.

The recent ruling by the Appeals Court affirms that HCQIA stands on solid ground, provides reassurance to hospitals and physicians engaged in peer review, and advances the goals of Congress by allowing peer review committees to take actions that are in the best interest of patients. At the same time, physicians subject to review retain the right to seek

remedies other than money damages and to hold a hospital and its medical staff to a reasonable standard conduct that they can reasonably implement.

#### References

1. *Poliner v Texas Health Systems*, 537 F3d 368 (5th Cir 2008). Available at <http://www.ca5.uscourts.gov/opinions/pub/06/06-11235-CV0.wpd.pdf>. Accessed on October 8, 2008.
2. 42 USC § 11112(a), App. 1

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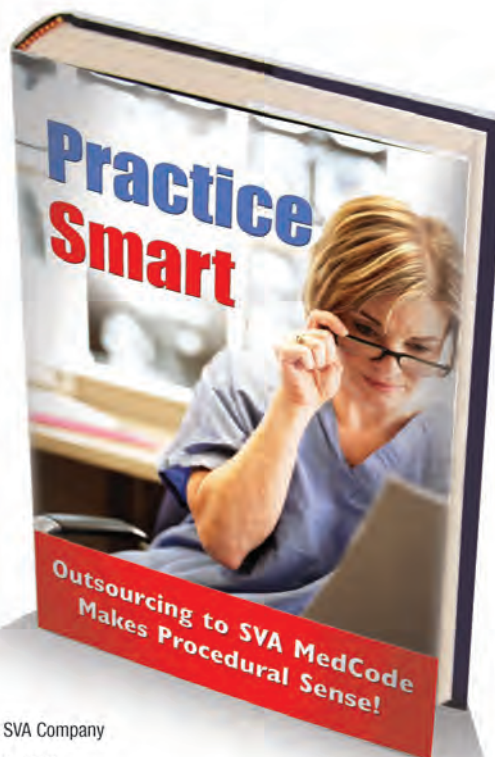
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# 2008-2009 recommendations for use of influenza vaccine

*Jay A. Gold, MD, JD, MPH*

The Wisconsin Department of Health Services (DHS) issued a memo September 12, 2008, regarding the recommendations for influenza immunization for the upcoming flu season to Wisconsin physicians and others. The memo, which is reprinted here, was signed by Jeffrey P. Davis, MD, DHS's chief medical officer and state epidemiologist for communicable diseases; Jonathan L. Temte, MD, PhD, chair of the Wisconsin Council on Immunization Practices; and this author, on behalf of the Wisconsin Adult Immunization Coalition.

• • •

## 2008-2009

### Recommendations for use of Influenza Vaccine

The 2008 Advisory Committee on Immunization Practices (ACIP) recommendations for the Prevention and Control of Influenza was issued on August 8, 2008, and includes a listing of the groups recommended to be immunized this year. This document can be downloaded from the MMWR Web site at [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr). Updated ACIP information on the vaccine supply and timing of distribution of influenza vaccine that affect the target groups will be posted on the Centers for Disease Control and Prevention (CDC) Web site at [www.cdc.gov/flu](http://www.cdc.gov/flu) as needed.

Doctor Gold is Senior Vice President and Chief Medical Officer of MetaStar, Inc. This material was prepared by MetaStar, Inc., the Quality Improvement Organization for Wisconsin, under a contract with the Centers for Medicare & Medicaid Services (CMS). The contents do not necessarily reflect CMS policy.

The 2008-2009 Vaccine Information Statements (VIS) for Influenza are available at [www.cdc.gov/vaccines/pubs/vis/default.htm](http://www.cdc.gov/vaccines/pubs/vis/default.htm).

Currently we do not expect vaccine-related delays or shortages, but because of the fragile nature of influenza vaccine production and distribution, we recommend that you do not schedule your influenza clinics until you have received your supply of vaccine. In the event of a shortfall in production or a delay in the delivery of adequate supplies of vaccine, you will be in a better position to communicate with providers in your area to assure appropriate coverage starting with the high-risk groups. If such an event should occur, a Prioritization Plan will be distributed. If needed, this Plan will provide a sequence of priority groups for you to follow to assure that high-risk individuals receive influenza vaccine first. Because the annual supply and timing of distribution of influenza vaccine cannot be guaranteed, we continue to stress the importance of local partnerships. The recent history of vaccine delivery delays and shortages underscores the need for these local coalitions to help coordinate redistribution and use of influenza vaccine.

It is important that you are aware of the current recommendations and periodically visit the CDC Web site for additional information and updates. Access to updated or supplemental information is often necessary throughout the influenza season and the months leading up to it. CDC and other public health agencies will assess

the vaccine supply on a continuing basis throughout the manufacturing period and will inform both providers and the general public in the event of substantial delays or inadequate supply.

During the 2007-2008 influenza season, 113 million doses of influenza vaccine were distributed in the United States. It is anticipated that >130 million doses will be produced for the 2008-2009 influenza season. The 4 companies that will produce trivalent inactivated influenza vaccine (TIV) and the name of the vaccine they produce are: sanofi pasteur (FluZone®), Novartis Vaccine, formerly Chiron (Fluvirin™), GlaxoSmithKline (Fluarix™ and FluLuval™) and CSL Biotherapies (Afluria®). One company, MedImmune, Inc., will manufacture the live, attenuated influenza vaccine (LAIV) FluMist™ for the US market.

FluZone® (manufactured by sanofi pasteur) is approved for use in persons ≥6 months old including those with high-risk conditions. Fluvirin™ (manufactured by Novartis) is labeled in the United States for use in persons ≥4 years old, Fluarix™ and FluLuval™ (both manufactured by GlaxoSmithKline) and Afluria® (manufactured by CLS Biotherapies) are labeled for use in persons ≥18 years old including those with high-risk conditions. FluMist™ (manufactured by MedImmune, Inc.) is approved for use among healthy, nonpregnant persons 2-49 years old.

The 2008-2009 ACIP recommendations include the following changes and

points of reemphasis

1. Beginning with the 2008-2009 influenza season, all children aged 6 months-18 years should be vaccinated against influenza annually. The expansion of vaccination should begin in 2008 if feasible, but should be implemented by no later than the 2009-2010 influenza season.
2. Annual vaccination of all children aged 6 months through 4 years (59 months) continues to be a priority as these children are at higher risk for influenza complications.
3. A new recommendation that either TIV or LAIV be used when vaccinating healthy persons aged 2 through 49 years.
4. Reemphasis of the importance of administering 2 doses of influenza vaccine to all children aged 6 months-8 years if they have not been vaccinated previously at any time with either LAIV or TIV.
5. Children 6 months-8 years who received only 1 dose in their first year of vaccination should receive 2 doses the following year.
6. Reemphasis of the need for providers to continue to offer influenza vaccine throughout the influenza season and schedule immunization clinics throughout the influenza season to include December and later.
7. The composition of the 2008-2009 trivalent vaccine includes the following 3 virus strains: A/Brisbane/59/2007 (H1N1)-like, N/Brisbane/10/2007 (H3N2)-like and B/Florida/4/2006-like antigens. The TIV and LAIV vaccines will contain these 3 antigens.
8. FluMist™ is now shipped to the end user at a temperature of 35°F-46°F (2°C-8°C). FluMist™ should be stored at 35°F-46°F (2°C-8°C) upon receipt and should remain at that temperature until the expiration date is reached. Do not freeze FluMist™. The dose of FluMist™ is 0.2 mL, divided equally between each nostril.

9. Health care administrators should consider the level of vaccination coverage among health care personnel (HCP) to be one measure of a patient safety quality program and should consider obtaining signed declinations from personnel who decline influenza vaccination for reasons other than medical contraindications.

### Childhood Influenza Vaccination Issues and Recommendations

In July 2004, influenza vaccine was added to the routine childhood immunization schedule. Recommendations now include influenza vaccination of all healthy children aged 6-59 months because children aged 6-23 months are at high risk for influenza-related hospitalizations and children aged 24-59 months are at increased risk for influenza-related clinic and emergency department visits.

When immunizing children, several factors must be considered or reemphasized:

- Either TIV or LAIV can be used when vaccinating healthy persons aged 2-49 years. Children aged 6 months-8 years who have not received vaccination against influenza previously should receive 2 doses of influenza vaccine (doses separated by  $\geq 4$  weeks) the first year they are vaccinated. Administer 2 doses (separated by at least 4 weeks) to children younger than 9 years old who are receiving influenza vaccine for the first time or were vaccinated for the first time during the previous influenza season but only received 1 dose.
- Vaccination of children younger than 9 years old who are receiving influenza vaccine for the first time can begin as soon as vaccine becomes available. This practice increases the opportunity for both doses to be administered in the same influenza vaccination season

and before the onset of influenza activity.

- Children aged 6-35 months should only receive a 0.25 mL dose of a split-virus vaccine formulation. Currently only Sanofi Pasteur provides this vaccine.
- Fluvirin™ (Novartis) is approved only for persons aged  $\geq 4$  years and Fluarix™ and FluLaval™ (GlaxoSmithKline) and Afluria® (CSL Biotherapies) are labeled for use in persons aged  $\geq 18$  years. FluMist™ (MedImmune Inc.) is approved for healthy individuals between the ages of 2-49 years old.
- Influenza vaccine without thimerosal used as a preservative will be available in limited supply for the 2008-2009 influenza season. The supply of this vaccine will be increased as manufacturing capabilities are expanded. Elimination of thimerosal in other vaccines has already been achieved and has resulted in substantially lowered cumulative exposure to thimerosal. The ACIP states that persons for whom inactivated vaccine is recommended may receive any age and risk factor appropriate vaccine preparation, depending on availability.
- The first and second doses of vaccine do not have to match; TIV or LAIV can be used to complete the 2 dose requirement. Doses should be separated by at least 4 weeks.

If you have any questions please call the Regional Immunization Program Advisor in your area listed below.

Immunization Program Advisors:  
Jim Zanto, Eau Claire Regional  
Office, 715.836.2499

Susan Nelson, Green Bay Regional  
Office, 920.448.5231

Wilmot Valhmu, Madison Central  
Office, 608.266.0008

Cathy Edwards, Milwaukee

Regional Office, 414.227.3995

Jane Dunbar, Rhinelander Regional  
Office, 715.365.2709





W. Stancil Starnes

## ProAssurance/PIC WISCONSIN offers preview of rate reductions and coverage enhancements

W. Stancil Starnes, CEO, ProAssurance Corporation

*Editor's Note: The Wisconsin Medical Society helped form PIC WISCONSIN in 1986 to ensure the availability of medical professional liability insurance for Wisconsin physicians. Today, the Wisconsin Medical Society continues to endorse PIC WISCONSIN/ProAssurance to provide professional liability insurance coverage with unmatched success in claims defense. For more information, contact Wisconsin Medical Society Insurance & Financial Services, Inc., at 866.442.3810.*

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Stan Starnes is the CEO of ProAssurance, the parent company of PIC WISCONSIN. ProAssurance Corporation is the nation's fifth largest writer of medical professional liability insurance through principal subsidiaries The Medical Assurance Company, Inc., ProNational Insurance Company, NCRIC, Inc., PIC WISCONSIN, and Red Mountain Casualty Insurance Company, Inc.

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### **Index to Advertisers**

|  |     |
|--|-----|
| Adair Floors and More.....   | 352 |
| Alexandria Clinic.....   | 350 |
| Allina.....  | 342 |
| Altru.....   | 351 |
| American Medical Association.....                                  | IBC |
| Aspirus.....   | 351 |
| Aurora Health Care.....  | 352 |
| Fairview Health Services.....                                      | 351 |
| Infinity HealthCare.....   | 351 |
| Jesser, Steven—Attorney.....                                       | 352 |
| Madison Emergency Associates.....                                  | 352 |
| Medical College of Wisconsin.....                                  | 352 |
| PROAssurance.....  | BC  |
| Remedy Medical Services.....                                       | 342 |
| Robert Corris, SC.....   | 346 |
| SVA Medcode Specialists, LLC.....                                  | 346 |
| SVA Wealth Management.....   | 350 |
| Society Insurance.....   | IFC |
| Sacred Heart Hospital.....   | 313 |
| Sensia Healthcare.....   | 352 |
| St. Joseph's/Brainerd.....   | 350 |
| Wapiti Medical Group.....  | 352 |
| Wisconsin Medical Society Financial & Insurance Services, Inc..... | 273 |
| Wisconsin Medical Society Financial & Insurance Services, Inc..... | IBC |
| WPS.....   | 318 |

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