

## Antenatal Corticosteroids Administration is Associated With Less Death and Disability in Infants Born Around the Limits of Viability



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Mortality and severe morbidities are common in infants born at the lowest gestational ages at which support is provided and have not been reduced during

the last decade.<sup>1</sup>,<sup>2</sup> Neonates as immature as 22 to 25 weeks' gestation frequently receive intensive care but do not always get the benefits of all effective perinatal therapies. There is wide variability in the United States in antenatal corticosteroid use at these early gestational ages because of limited data.

Meta-analyses demonstrate that antenatal corticosteroids improve outcomes at <26 weeks although this is in part due to the small number of extremely preterm mothers enrolled in the trials.<sup>3</sup> Investigators at the University of Alabama at Birmingham designed a national study to determine if antenatal corticosteroid exposure in infants born at gestational ages from 22 to 25 weeks is associated with improvement in important outcomes, including death or childhood neurodevelopmental impairment, using a large multicenter cohort of infants. Infants born at any of the 23 National Institute of Child Health and Human Development Neonatal Research Network perinatal centers between January 1, 1993 and December 31, 2009 were included if they were 22 to 25 weeks' gestation and had a birth weight of 401-1000 grams. The results of this study were recently published in the Journal of the American Medical Association (JAMA).4

### Results

A total of 10,541 infants were included in the study. Follow-up was accomplished until the infants were 18-22 months corrected age (past the due date). Overall, antenatal corticosteroid exposure was associated with a lower risk of hospital death (35% versus 56%, number needed to treat 5) and a lower risk for death/neurodevelopmental impairment at 18-22 months (64% versus 82%, number needed to treat 6). Death by hospital discharge (odds ratio 0.58, confidence interval 0.52-0.65), intraventricular hemorrhage grades 3-4/periventricular leukomalacia (0.67, 0.57-0.79), death by follow-up (0.59, 0.53-0.65), and neurodevelopmental impairment (0.83, 0.70-0.99) in addition many of the composite outcomes were significantly lower in the infants whose mothers had received antenatal corticosteroids. Psychomotor disabilities including moderate to severe cerebral palsy were also lower in the infants exposed to antenatal corticosteroids. Intact survival (no death or neurodevelopmental impairment by follow-up) at 18-22 months was higher in infants whose mothers

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## **Summary of MASA Governmental Affairs Conference**

February 5-7, 2012 Washington, D.C.

By: Darlene Traffanstedt, MD

On February 5th, 2012, members of your JCMS Executive Committee, including Dr. Darlene Traffanstedt, President, Dr. Stephen Steinmetz, President-Elect, and Dr. Michael Harrington, Immediate Past-President, traveled to Washington, DC for the MASA Governmental Affairs Conference. As part of this conference, the hundred-plus MASA physicians who attended heard from multiple speakers who discussed current legislative issues of interest to physicians and the practice of medicine. Mr. Richard Deem, Senior Vice-President for Advocacy for the AMA, outlined several major issues on which the AMA is working. The AMA supports repeal of the SGR. The AMA estimates that it will cost \$316 billion to repeal the SGR in 2012 and the cost will continue to rise if action is not taken. The AMA has produced two public service videos, which are available on YouTube, to encourage voters to demand an SGR fix. Both are producing significant interest on the part of the general public. The second issue is that of Private Contracting which has been strongly supported by MASA. There are respective House and Senate bills (H.R. 1700 and S. 1042) supporting the ability of physicians to privately contract to provide medical care outside of the health insurance system. Congressman Jo Bonner of Alabama is a supporter of the House bill. The AMA also strongly supports halting ICD-10 implementation. Mr. Deem also informed us that there are two bills with strong support to repeal the Independent Payment Advisory Board which was part of PPACA Health Care Reform. The respective bills are H.R. 252 and S. 668. The AMA is also supporting H.R. 5 which is a medical liability reform bill with a \$250,000 cap on non-economic damages. Lastly, the AMA is supporting H.R. 1409 which would exempt health professionals from Anti-Trust regulations.

We also heard from Mr. Fred Barnes of *The Weekly Standard* who spoke on the current political environment in Washington and the difficulty in pushing



legislation forward in an election year. The keynote speaker was Congressman Andy Harris, M.D. (R - Maryland) who discussed the importance of physician advocacy as well as his perception of the important issues affecting physicians today. Following the educational sessions, we traveled to The Hill to meet with our congressional delegation beginning with Senator Jeff Sessions, followed by meetings on February 6th with Congressman Spencer Bachus and Senator Richard Shelby. The group made them aware of the importance of repeal of SGR, halting of ICD-10, repeal of the IPAB and other issues such as medication shortages. The delegation was familiar with the issues we are facing and receptive to our concerns. The District 6 leadership made some key staff contacts during our meeting and will be providing some follow-up information to our Congressmen regarding drug shortages.

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## **Letter From The President**



Thank you for the opportunity of serving as your president for 2012. I look forward to a year of great accomplishments for the Jefferson County Medical Society. I would like to share my vision for our Society for the next year. First, this medical society has traditionally been politically and socially active. I would like to expand our reach in the coming years to include scholarship and service. We are planning to begin the Jefferson County Medical Society Medical Student Scholarship Fund working closely with the Dean's office at the University of

Alabama School of Medicine. The Dean, Dr. Ray Watts, has agreed to partner with us and match any funds raised in 2012 dollar for dollar. As you all know, the cost of medical education has risen sharply and many students finish medical school with significant debt. It would be wonderful to relieve that burden from some of the best and brightest of our future colleagues. We anticipate compiling a Scholarship Committee and arranging a fund raising event in the Fall of 2012. We will also look for additional ways to partner with medical students and residents in Jefferson County, hoping to get them involved in organized medicine early in their career. One such way to partner with them will be our second major focus for 2012, service to the community. We are currently planning a Habitat for Humanity work day in 2012. This would be a great opportunity for the members, their families, and even their office staff to give back to the communities that we serve. We are exploring other service opportunities and are open to any suggestions. The third major focus for 2012 is growth of the Young Physician section of the JCMS. We will again sponsor our annual Night at the Barons on Sunday May 6th. We will continue recent work with our legislative delegation and inform them of important issues that affect our work. Lastly, and probably most importantly, we will continue to focus on growth of our membership. We will primarily focus on technology and outreach, including use of social media tools such as Facebook and Twitter to keep our members informed.

I would like to invite you to join me at the MASA Annual Session at The Wynfrey on April 12-15, 2012. Dr. Michael Harrington, our Immediate Past-President, will be inaugurated as President of MASA at this meeting and it is a great opportunity to meet your colleagues from around the state, get CME credit and learn more about the work your Medical Association is doing for you.

We have many opportunities this year and I am excited about the work ahead. Won't you join me? Get involved and help us make our Medical Society and our community better! Please feel free to call or email with any ideas or concerns.

Darlene Traffanstedt, MD 205-422-3390 darlene.traffanstedt@bhsala.com

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Gilder L. Wideman, M.D. November 23, 2011

William O. Romine, M.D. December 5, 2011

William A. Maddox, M.D. December 27, 2011

Karl E. Hofammann, Jr., M.D. January 15, 2012

# New Members

Jeffrey B. Albright, M.D.	Surgery	Beth Anne Malizia, M.D.	Infertility
Angus T. Baird, M.D.	Radiology	Robert C. Osburne, M.D.	Endocrinology
Kathleen Bowen, M.D., MBA	Emergency Medicine	Alexander M. Pisaturo, M.D.	Physical Med & Rehab
Yung Hsien Chiang, M.D.	Internal Medicine	Roy F. Roberts, Jr., M.D.	Surgery
Shannon B. Ellis, M.D.	Obstetrics/Gynecology	Anthony M. Roman, M.D.	Emergency Medicine
Caroline Feist, M.D.	Occupational Medicine	Bruce W. Romeo, M.D.	Occupational Medicine
Lyman W. Fritz, M.D.	Family Practice	John D. Shugrue, M.D.	Family Medicine
Robert S. Goodwin, M.D.	Radiology	Merle Kelley Snow, Jr., M.D.	Orthopedic Surgery
Lauren Graham, M.D.	Resident	Kelli H. Tapley, M.D.	Pediatrics
Alice M. Hardy, M.D.	Pediatrics	Julie Tullos Taylor, M.D.	Obstetrics/Gynecology
Lindy E. Harrell, M.D.	Neurology	Victor J. Thannickal, M.D.	Pulmonary/Allergy/CC
Clint Holladay, M.D.	Radiation Oncology	Robert Ty Thomas, M.D.	Physical Med & Rehab
Wesley W. King, M.D.	Neurology	Daniel W. Thompson, M.D.	Radiology
Joseph M. LeJeune, M.D.	Internal Medicine	Colleen Tobe-Donohue, D.O.	Family Medicine

# UPCOMING EVENTS

April 13-15	MASA's Annual Session – Wynfrey Hotel in Birmingham	
April 16	Executive Committee Meeting – 5:30 p.m.	
April 17	The Wayne Finley 811 Breakfast Club Meeting - Glenn Cobbs, M.D., will speak on "The History of Infectious Disease Programs" at 8:30 a.m. in the JCMS Board Room	
	MASA's Resident Fellow Section Meeting at 6:00 p.m. in the JCMS Board Meeting	
Мау б	JCMS Annual Barrons Family Outing at 4:00 p.m. **Open to JCMS Members & Immediate Family Only	
May 15	The Wayne Finley 811 Breakfast Club Meeting – David Taunton, M.D., will speak at 8:30 a.m. in the JCMS Board Room	
May 21	Executive Committee Meeting – 5:30 p.m.	
	Board of Directors Meeting - 6:15 p.m.	
June 18	Foundation Trust Meeting – 5:30 p.m.	
	Executive Committee Meeting – 6:00 p.m.	
Aug. 25	JCMS/UAB SOM's Scholarship Fundraising Dinner – Speaker Gene Stallings	
Contact Juanita Pruitt at 933-8601 or jpruitt@jcmsalabama.org for more information regarding any of the above events.		

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received antenatal corticosteroids (36 versus 18% for the full cohort). Interaction analyses performed for both hospital and follow-up outcomes provided no evidence that the associations of antenatal corticosteroids with outcomes differed across the 22, 23, 24, and 25 week gestational age groups. However, many outcomes (including death and neurodevelopment) were not improved among infants born at 22 weeks gestation whose mothers received antenatal steroids compared to those who did not. Notably, the odds ratios for many of these outcomes at 22 weeks seemed favorable in the group receiving antenatal steroids, but were not statistically significant. There may be a number of explanations for this observation. Nevertheless, the study was not definitive regarding benefit among infants born at 22 weeks gestational age.

Further analyses indicated that antenatal corticosteroids groups were associated with lower hospital mortality, decreased mortality at 18-22 months, and decreased mortality/neurodevelopmental impairment at 18-22 months in singleton and multiple births, partial and full antenatal corticosteroids treatment groups, both betamethasone and dexamethasone treatment groups, maternal diabetes, all durations of rupture of membrane subgroups, antepartum hemorrhage, vaginal and cesarean section deliveries, all chronologic epochs, males and females, non-small for gestational age infants, and all racial/ethnic subgroups.

### DISCUSSION

This very large multicenter observational study documents that exposure to antenatal corticosteroids is associated with a lower mortality and lower neurodevelopmental impairment in infants born at 22 to 25 weeks after adjustment for multiple potential confounders. Further analyses provide no evidence that the associations with antenatal corticosteroids differed across the range from 22 to 25 weeks gestational age. Subgroup analyses of the combined 22 to 25 week cohort indicate that these associations are significant in all subgroups at this early gestational age range, except in the small for gestational age infants and in infants of mothers with hypertension or preeclampsia/eclampsia in whom there was no harm but the trends for benefits did not reach statistical significance.

In summary, antenatal corticosteroid therapy for mothers of infants born at 22 to 25 weeks is associated with large reductions in both mortality and important morbidities, including reduction of death/severe neurodevelopmental impairment at 18-22 months corrected age. These benefits were observed across subgroups without evidence that the effects differed across the ranges of gestational ages around the limits of viability. Despite their potential to improve outcomes and past increased use, the administration of antenatal corticosteroids is not increasing at gestational ages around the limits of viability,<sup>2</sup> and remain substantially lower than at later gestational ages when they appear to be as effective. Controlled trials could be performed to precisely determine the benefits of antenatal corticosteroids when administered this early, but such trials will be difficult to perform. Pending further recommendations by professional societies and other experts, antenatal corticosteroids may be considered before 24

weeks if the infant will be given intensive care, as they are associated with reduced mortality and morbidity in infants born around the limits of viability. Antenatal corticosteroids administration is a highly effective, low-cost intervention that should be considered for women in labor or with other indications for delivery. Harm was not observed in any of the subgroups of mothers studied.

#### REFERENCES

1) Stoll BJ, Hansen NI, Bell EF, et al: Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neonatal outcomes of extremely preterm infants from the NICHD Neonatal Research Network. Pediatrics 2010; 126 (3):443-56.

2) Hintz SR, Kendrick DE, Wilson-Costello DE, et al. Early-childhood neurodevelopmental outcomes are not improving for infants born <25 weeks' gestational age. Pediatrics 2011; 127 (1):62-70.

3) Roberts D, Dalziel S. Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth. Cochrane Database of Systematic Reviews 2006 Issue 3. Art. No: CD004454. DOI: 10.1002/14651858. CD004454.pub. 2.

4) Carlo WA, McDonald SA, Fanaroff AA, et al. Association of antenatal corticosteroids with mortality and neurodevelopmental outcomes among infants born at 22 to 25 weeks' gestation. JAMA 2011; 306 (21):2348-58.

## **Tobacco-Free Pharmacy: Eliminating Tobacco Products in Pharmacies**

By: R. Patrick Devereux, Pharm.D.

Your neighborhood drugstore has always been a place to turn to for your medicine, health advice, a gallon of milk, and a last minute birthday card. But in some of our neighborhood pharmacies there is something that is being sold there that is not in our best interest. This product is tobacco. We look to our pharmacies as a place that promotes our health and well-being and not as a place that sells an addictive and deadly substance, which is tobacco.

Tobacco kills more than 440,000 people annually which is more than HIV/AIDS, alcohol use, car accidents, illegal drugs, murders and suicides combined. Tobacco use is the leading cause of preventable death in the United States. Tobacco costs the U.S. more than \$193 billion in health care costs and lost productivity each year. While the United States has made major progress against tobacco use, one in five Americans still smoke, and about 4,000 kids try their first cigarette each day.

In Jefferson County there are over 30 pharmacies, independent and chain, that sell tobacco products. These pharmacies are sending mixed messages to their patrons who are visiting to purchase items that are intended to treat their ailments and diseases. The sale of tobacco products at the site of health care delivery or counseling undermines the efforts to educate patients about the hazards of tobacco smoke on their own lives and the lives of others. Virtually every other country in the world except the United States refrains from selling tobacco products in pharmacies. Different municipalities, such as the city of San Francisco and Boston, have taken the lead in eliminating tobacco products in pharmacies. The Jefferson County Board of Health has passed a resolution in support of the elimination of tobacco products in pharmacies and retail pharmacy chains. Refraining from the sale of tobacco in pharmacies is an important part of a public health strategy to reduce smoking. According to the U.S. Surgeon General, the only way to protect people from the dangers of secondhand smoke is to eliminate it entirely. There is no safe level of exposure to secondhand smoke. Even brief exposure can cause immediate harm.

Tobacco sales in pharmacies directly contradict the pharmacist's code of ethics, which states that "pharmacists must be committed to the welfare of their patients" and "must act with honesty and integrity in professional relationships", and "avoid actions that compromise dedication to the best interest of their patients". Pharmacists are community leaders that answer questions daily regarding a variety of health matters. They answer questions often that are related to conditions such as COPD, emphysema, chronic bronchitis, and heart disease. How can a patient take seriously the advice of a pharmacist working in a pharmacy that sells them their inhaler at one end of the store and gives the patient the option of purchasing tobacco at the other end of the store? Pharmacies have evolved over the years into retail destinations. In the old days of the traditional apothecary model, pharmacies simply sold prescriptions and over the counter products. The model was one of patient wellness. This model now sells everything from toys to phone cards. While there is nothing wrong with having a diverse front end that makes your store attractive to shop, tobacco products are one item that diminishes the image of a wellness destination that



many pharmacies hope to convey.

COPD and other smoking related diseases are nearly impossible to treat without patient cooperation. Pharmacists are uniquely positioned to assist patients with improved clinical outcomes through patient education on matters such as proper inhaler use, medication compliance, and other self care behaviors including smoking cessation. Pharmacists are the ones patients turn to first for advice on smoking cessation products. Oddly enough, in some retail pharmacies, smoking cessation products are stocked right next to the tobacco products! If the patient has to walk to the front of the store to purchase these and they are staring temptation right in the face, which do you think they will choose? The pharmacist's message will be long forgotten and the patient will have purchased his or her tobacco from that pharmacy. If you want other health providers assisting your patients with patient outcomes such as an improved FEV1 or O2 sats, those providers including pharmacists cannot sell tobacco. I know what you're thinking next; "Well, does that mean we need to remove other items that could be harming our patients such as candy and sweets for diabetic patients"? As someone who runs a comprehensive diabetes education program in our pharmacy, I've thought the same thing. However, a well informed diabetic patient can enjoy things in moderation with proper education and balancing of their other food choices. There is no such thing as enjoying tobacco in moderation. If pharmacies are going to sell tobacco products, then let the pharmacist sell them in the pharmacy department with the prescriptions as opposed to the front of the store. This doesn't happen because even management knows that would be a huge double standard. What is convenient and competitive is not always what is right.

Dr. Patrick Devereux is the Vice-President and Pharmacy Manager for FMS Pharmacy in Bessemer, Alabama. His pharmacy is a patient education centered pharmacy that offers services such as Medication Therapy Management and Patient Adherence Assistance, immunizations, and a comprehensive accredited diabetes education program for patients.

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