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Prescription Drug Abuse is a Major Public Health Problem

By Bob E. Van Demark, Jr., MD
SDSMA Vice President

Last spring, the South Dakota State Medical Association formed a special committee to study the growing problem of prescription drug abuse and determine guidelines for opioid prescribing. I would like to thank Dr. Bob Van Demark, Jr., committee chair, and the rest of the committee, whose names are listed below. This group of physicians and other health professionals dedicated their time and expertise to this cause, and the result is a whitepaper on prescription opiate prescribing guidelines that can serve as an excellent resource for physician practices. I encourage you to visit www.sdsma.org to download the whitepaper.

Tim Ridgway, MD, FACP
SDSMA President

More than 16,500 people died after overdosing on prescription opioid pain relievers in the U.S. in 2010, and overdose deaths due to prescription opioid pain relievers have more than tripled in the past 20 years. For each death, there are an additional 10 treatment admissions, 32 emergency department visits, and 825 nonmedical users of these drugs. Enough painkillers were prescribed in 2010 to medicate each American adult every four hours for one month. And unfortunately, prescription drug abuse is a problem in which South Dakota is not isolated. In 2012, 40.5 million controlled substances were prescribed in South Dakota – approximately 55 per man, woman and child.

The problem of prescription drug abuse and its related health consequences is a significant public health problem, and the SDSMA is alarmed by these statistics as concerns about undertreated chronic pain and prescription opioid misuse (i.e., overdose, addiction and diversion) are present in our communities too. People often think that prescription drugs are safer than illicit drugs, but that’s only true when they are taken exactly as prescribed and for the purpose intended. Taken as prescribed, prescription opioids can be used to manage pain safely and effectively. Properly managed, short-term medical use of prescription opioids rarely causes addiction. But while opioids are an effective tool for managing chronic pain, when abused, they can be addictive and put abusers at risk for other adverse health effects, including overdose. Even one single large dose can cause severe respiratory issues and death.

The SDSMA is at the forefront on this issue by providing physicians with helpful, evidence-based guidelines for prescribing opiate analgesics to both effectively treat pain and minimize patient risk. Through a special committee on pain management and prescription drug abuse, the SDSMA has developed a whitepaper, Opiate Analgesics for Chronic Non-Cancer Pain, to serve as a resource for physicians and prescribers when treating patients for chronic, non-cancer pain. Over the past several months, our committee has researched evidence-based guidelines based on a review of the literature by a diverse group of highly trained health professionals. The whitepaper is available on the SDSMA website at www.sdsma.org.

When used for severe acute pain in time- and dose-limited ways, or for the relief of cancer and end-of-life pain, opiates can be uniquely valuable and the risk of addiction and abuse is low. By working with physicians, prescribers and other partners at the state and local levels to implement policies and programs such as these guidelines and education, the physicians of the SDSMA are leading efforts to not only effectively manage and care for their patients, but to reduce prescription drug abuse and improve public health.

By developing this whitepaper with guidelines to improve the way opioids are prescribed, we can better ensure our patients have access to safe, effective treatment while reducing the number of people who misuse, abuse or overdose from these powerful drugs.

<table>
<thead>
<tr>
<th>SDSMA Ad-Hoc Committee on Main Management and Prescription Drug Abuse</th>
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<tbody>
<tr>
<td>Benjamin Aaker, MD</td>
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<tr>
<td>Rob Allison, MD</td>
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<td>Daniel Blaney-Koen, JD</td>
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<td>James Brunz, MD</td>
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<td>Chris Dietrich, MD</td>
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<td>Brooke Eide, MD</td>
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<td>Jared Friedman, MD</td>
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<td>Barbara Goehring, RN</td>
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<td>Michelle Hagen, PA-C</td>
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My regular patients expect to see medical students. Indeed, with the new Longitudinal Integrated Curriculum and expanded Pillar 3 elective time, it is becoming unusual for a medical student not to be part of a patient’s office visit. Occasionally, when I don’t have a student with me, a patient and family will act surprised and somewhat disappointed. After witnessing such a response a number of times, it occurred to me that we physicians should not merely be asking our patients permission for students to participate. In addition, we should be emphasizing to patients why they should hope and expect to have medical trainees as part of their care. I recently advocated this mindset in a column I wrote for the regional Parkinson’s newsletter. The positive responses I received encouraged me to promote this perspective to a wider medical audience. My remarks, as reproduced below, were written for patients and families but can serve as an important reminder to clinicians as well:

South Dakota is fortunate to have a medical school. The University of South Dakota Sanford School of Medicine helps prepare medical students who, in many cases, will ultimately practice medicine in communities throughout the state. Our largest cities and small communities share a need for more physicians. The medical school is training the doctors who will be caring for many of us for years to come.

In effect, many of you play an important role in the enduring legacy of the medical school when you interact with the medical students who are working with the physicians who care for you. I believe most patients and families recognize this. In my experience, it is very rare for one of my patients to decline to have a medical student be part of an evaluation. Indeed, most patients seem to welcome “another set of eyes” and the attention they receive from students.

Students benefit from seeing a wide-range of patients. The experience of seeing persons with a chronic disease like Parkinson’s is particularly important. Book learning about features of Parkinson’s is not enough. Students need to understand how to identify such physical findings as cogwheel rigidity and typical gait changes. They also need to see, first-hand, the importance of listening carefully to patients and families as they describe the response to drug therapy and such features as freezing and the “on-off” phenomenon. Students must learn when shortening a dosage interval of a Parkinson’s medication is more effective than simply increasing the dose.

Each of you can help students by informing them of issues that affect your daily functioning and family life. Be frank about your questions and concerns. Let students know what you hope for and expect in a physician. Having a disease like Parkinson’s is a frustrating burden. But the opportunity to serve as an effective teacher is a gift to be treasured. Your interactions with medical students have the potential to positively impact lives of future patients and families you will never know. And, as your physician and student ponder with you the best treatment options, you may find your own medical care is enhanced as well.

Teaching opportunities should be celebrated. Patients and physicians throughout our state benefit from being involved in medical student education. All of us want and need superbly trained physicians for the future. Clinicians should seek opportunities to remind patients and families that interaction with medical students is relevant and rewarding.

REFERENCES

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State of South Dakota’s Child: 2015

By Ann L. Wilson, PhD; Tyler A. Hemmingson, BS; and Brad Randall, MD

I extend my warm greetings to you as we begin 2016 with our dedicated efforts to promote health in South Dakota.

This annual review of the state of South Dakota’s child demonstrates recent progress in decreasing infant mortality. Yet, racial disparities in survival in the first year of life remain apparent. These observations heighten our awareness of the complex dynamics affecting health and remind us of the important role communities must play to protect their youngest citizens. As physicians, parents, and citizens, this message is vital to the future of us all.

Mary D. Nettlemann, MD, MS, MACP
Dean, University of South Dakota Sanford School of Medicine
Vice President for Health Affairs
University of South Dakota

Abstract

In 2014 there was an increase in the number of births in the state with 24 percent representing minority populations. This year also brought a decrease from 2013 in deaths for infants, yielding an infant mortality rate of deaths per 1,000 live births (5.9) slightly below that of the most current national rate of 6.0 in 2013. Consistent with previous years, disparities persist in rates of death for white and minority infants with 45 percent of 2014 infant deaths (versus 24 percent of the births) represented by minorities. Between 2010 and 2014, 57 percent of white and 60 percent of minority post neonatal deaths in South Dakota were attributable to sudden unexpected infant death, accidents and homicide for both whites and minorities. The rates of infant deaths due to these causes, however, were significantly higher (p<.01) for minorities than for whites.

Natality

The year 2014 brought the fourth consecutive year of an increase in live births in South Dakota with 12,281 new babies becoming residents of the state.1 Shown on Figure 1 is how the dip observed following the economic recession year of 2008 has been reversed with increasing numbers of births paralleling to a lesser degree the most recent rising peak in births noted in the late 1970s. Figure 1 also likely reveals a longer interval between generations and smaller family size.

Over the past decade, increasing racial diversity has been noted in the state’s annual birth cohorts. The data in Figure 2 show that now 24 percent of the resident births between 2012 and 2014, with race noted on the birth certificate, represent minorities.1,2 This exceeds the percent of minority births (23 percent) observed nationally and reveals the growing cultural complexity of our state.3

A fundamental marker of perinatal outcome is birth weight. Most recent data (2010 to 2014) show that 6 to 7
percent of all newborns in South Dakota are low birth weight (less than 2,500 grams) compared to 8 percent of newborns nationwide. The relatively small population of South Dakota yields jagged peaks and valleys in line graphs when annual shifts in low birth weight data are plotted. Use of rolling five-year means helps to normalize data over time, as noted in the birth weight data for South Dakota and the U.S. presented in Figure 3. Data presented in this figure show that over time, both South Dakota’s white and minority populations typically deliver a lower percent of mid low birth weight (MLBW = 1,500 to 2,499 grams) newborns than the rest of the nation. A slightly different trend is apparent for very low birth weight (VLBW = less than 1,500 grams) newborns. While South Dakota’s white population delivers a smaller percent of newborns in this VLBW cohort than observed nationwide, the percent of its minority population newborns that are VLBW is similar to what is observed in the country’s total population. Data on gestational age of these cohorts of newborns would add another dimension important to assessing health status at birth.

Assessments of racial disparities in perinatal outcome add to an understanding of the dynamics impacting the health of the state. Figures 4 and 5 provide five-year rolling mean ratios of the percent of low birth weight white versus minority newborns for South Dakota and the U.S. The rolling mean indicates the good news that this ratio is lower for the state than the nation but that the state’s racial disparity in birth weight is greater for VLBW than for MLBW. In recent years, the difference in percent of MLBW newborns among minority and white births has been fairly consistent nationally and for the state, with the national five-year ratio of 1.6 minority to white MLBW newborns compared to an approximate 1.2 ratio for South Dakota. Similarly, Figure 5 shows that the national ratio of VLBW for minority to white newborns is higher (2.1) than that observed in South Dakota (1.4). These ratios are showing a slight trend of decreasing disparity for the VLBW newborns. Whether these differences are statistically significant is unclear.

**Infant Mortality**

In 2014, the South Dakota infant mortality rate (IMR), expressed as infant deaths per 1,000 live births, was 5.9, representing a decrease from the previous year’s rate (2013 IMR = 6.5). This provides further evidence that the spike in the 2012 IMR of
was indeed a spike that has not been sustained. The 73 infant deaths in 2014 (IMR 5.9) represent the lowest rate since 2000 when the rate was 5.5,\(^1\)\(^2\) Notable, as seen in Figure 6, for the first time since 2007, the state’s 2014 IMR was also slightly lower than that of the nation (6.0) in 2013,\(^3\) the most recent year for which national data are available.

Between 2010 and 2014 in South Dakota, 63 percent of all mortality occurred during the first 28 days of life. Death occurring in this period of time per 1,000 live births is referred to as the neonatal mortality rate (NMR). In 2014, the total NMR for the state was 3.4.\(^1\) Figure 7 shows the NMR of South Dakota’s white and minority populations compared to those of the U.S. In recent years, the state’s NMR for whites, with the exception of 2012, has been quite similar to what is observed nationally. While Figure 7 shows variable rates for neonatal mortality for minorities, the average NMR is slightly higher than national rates for this population. A consistent and differing image emerges as data for post neonatal deaths (28 to 365 days of age) are examined. As noted in Figure 8, the post neonatal mortality rate (PNMR) again shows that for whites, the state’s rate resembles that of the nation but its rate for minorities consistently exceeds national rates. The 2014, the state’s PNMR was 2.5, with the white rate the lowest ever noted at 1.2 and the minority rate much higher at 7.0.\(^1\)

Figure 9 provides an additional analysis of the state’s infant mortality with a comparison of the most recent five-year (2010 to 2014) mean mortality rates for South Dakota with the national rates for 2012. Apparent in this figure is how the state’s neonatal rates for this period of time have been slightly higher than national rates for both the white and minority populations; however, these differences are not statistically significant. Also noted in Figure 9 are data showing that in the post neonatal period, the state’s white rate is comparable to national rates for whites. For minorities, the state rate for post neonatal deaths is twice as high as what is observed for this population nationwide, revealing a significant difference (chi square, p<.01) that is also seen in the PNMR for the state’s total population compared to that of the nation. Between 2010 and 2014, half of all post neonatal deaths were minority infants who comprise 24 percent of all births. In addition, nationally, approximately one-third of all white and minority infant deaths occur in the post neonatal period of time. For the state’s minority PNMR to equal what is observed nationally, its current

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**Figure 6. Infant Mortality Rates, South Dakota and United States, 1964-2014**

**Figure 7. Neonatal Mortality Rates, White and Minority Populations, South Dakota and United States, 1965-2014**

**Figure 8. Post Neonatal Mortality Rates, White and Minority Populations, South Dakota and United States, 1965-2014**

**Figure 9. Neonatal and Post Neonatal Mortality Rates, South Dakota and United States**

South Dakota data from South Dakota Department of Health; U.S. data from NCHS.
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five-year average of 15 minority post neonatal deaths per year would need to decrease by 47 percent to eight per year. If the national rate for this population occurred in the state in 2014, South Dakota’s overall infant mortality rate would have decreased from almost six to approximately five deaths per 1,000 live births.

Data presented in Figure 10 provide birth weight specific mortality data for infant deaths during the first year of life.

Vital to interpretation of these data is the need to temper observations with an awareness of the impact of small year to year changes in the numbers of deaths in the state. Further, such analyses by gestational age would be helpful to understanding perinatal outcomes. Nonetheless, these data show that in recent years, mortality for infants weighing between 500 and 999 grams is higher than the mean for 2005 to 2009.1,2 Data comparing recent mortality of VLBW and MLBW infants in South Dakota with those for those in the U.S. in 2013 show that mortality in these weight groups in the state is significantly higher than it is nationally.1 Between 2010 and 2014, in the state, 28 percent of VLBW infants died versus 21 percent observed nationwide in 2013 (chi square, p<.01). Over the same period of time, 1.8 percent of MLBW infants in the state died versus 1.3 percent nationally (chi square, p<.05).

The pie charts presented in Figure 11 present the distribution of neonatal and post neonatal deaths for the state’s white and minority populations. Consistent with 2010 to 2014 data showing that 81 percent of South Dakota infants who die during the first 27 days of life are LBW, the data in this figure show that the majority of neonatal deaths are due to “perinatal causes,” (primarily “extreme prematurity”) for both whites and minorities.

The second leading cause of neonatal death for both populations is congenital anomalies. These two causes of death comprise 95 to 96 percent of deaths that occur during the first 27 days of life. A different pattern emerges as causes of death are identified during the post neonatal period of time. The leading cause of infant death for both whites and minorities after the first month of life is sudden unexpected infant death (SUID) that comprises 39 percent of post neonatal deaths for both whites and minorities (SUID=causes of deaths certified as unknown, accidental suffocation and strangulation in bed, and sudden infant death syndrome).6,7 Accidents and homicides are the second leading cause of post neonatal death with 18 percent of white and 21 percent minority deaths between 27 and 365 days resulting from these tragedies. SUIDs, accidents and homicides together
cause 57 percent of white and 60 percent of minority infant deaths between 1 and 12 months of age.

Table 1 presents the causes of infant deaths by mean rates for South Dakota and the U.S. Unlike the data in Figure 11, which show similar distributions of deaths by their causes for the state’s white and minority populations, the rates of these deaths per 1,000 live births show significant racial disparities. With the exception of congenital abnormalities, chi square analyses show significantly (p<.01) higher rates of death for perinatal, SUID, and accidents/homicides and other causes for minorities than for whites. Further, the total IMR for minorities is significantly higher (p<.01) than it is for whites. Comparisons of rates of death by causes for all 2010 to 2014 South Dakota infants with those of the U.S. in 2012 are also presented in Table 1. These data show that the state’s rates of death for congenital abnormalities and accidents/homicides are significantly higher (chi square, p<.01) than that observed nationally. In addition, the state’s total rate of infant mortality for these years is significantly higher (chi square, p<.01) than that observed nationally.

Discussion
The state may be heartened by the decrease in infant deaths observed in the past two years. Yet, this observation must be seen in light of the fact that the 2014 rate of infant death is now comparable to what was observed 13 years prior to this time. Further, over the past decade, there have been a number of years when the state’s IMR has exceeded national rates. Data on birth weight show that the state’s rate of low birth weight newborns is lower than the national rate and that the state’s racial disparity between white and minority MLBW and VLBW newborns is less than observed nationally. Nonetheless, data also show that over the past decade, birth weight-specific mortality for LBW infants in the state currently is significantly higher than that observed nationally.

Over time, the glaring disparity between the state’s post-neonatal mortality rate for minority versus white infants persists. In the past five years (2010 to 2014), the state’s PNMR was twice as high for minority as for white infants. Social factors related to family income, patterns of life, and education are typically associated with post-neonatal mortality and are likely associated with South Dakota’s high rate of death for minority babies. Such observations beg the question of how they may be prevented. Data from reviews of infant deaths of residents of the 10 counties in southeastern South Dakota tell us that many of these deaths occur in unsafe sleep environments.8 9 Challenging is implementing effective approaches that assure safe sleep for babies cared for in populations having a high prevalence of mobility, poverty and variability in daily life. Nonetheless, determination must persist to achieve community based strategies that are culturally sensitive and unequivocal in their creation of expectations of safe care of infants that promote survival during the first year of life. With growth in the state’s minority population that includes recent immigrants, crucial are ongoing, determined efforts to reach all parents and families with education and support. Communities must be mindful that not until the fifth decade of life will the risk of death be greater than it is during its first 12 fragile months following birth.

The main points presented in this article are:
- The annual number of births in South Dakota has continued to increase since 2008 and the percent of minority births (24 percent) in the state is now comparable to what is observed nationally.
- The 2010 to 2014 state rate of 6 to 7 percent low birth weight (less than 2,500 grams) is lower than the 8 percent noted in the U.S.
- The 2012 spike in the state's infant mortality rate (8.7) has been reversed in 2013 and 2014 with a current IMR of 5.9 for South Dakota. Yet, the state mean 2010 to 2014 IMR is significantly higher than the nation's most recent 2013 rate.
- The state's 2010 to 2014 minority post neonatal mortality rate is almost twice that observed nationally.

Table 1. Causes of Infant Deaths

<table>
<thead>
<tr>
<th>Causes</th>
<th>South Dakota 2010-2014</th>
<th>Total Populations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>White</td>
<td>Minority</td>
</tr>
<tr>
<td>Perinatal Causes</td>
<td>2.3</td>
<td>4.9</td>
</tr>
<tr>
<td>Congenital Abnormalities</td>
<td>1.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Sudden Unexpected Infant Death (SUID)</td>
<td>0.7</td>
<td>2.3</td>
</tr>
<tr>
<td>Accidents and Homicides</td>
<td>0.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Other*</td>
<td>0.5</td>
<td>1.3</td>
</tr>
<tr>
<td>Total</td>
<td>5.3</td>
<td>12.1</td>
</tr>
</tbody>
</table>

(p<.01). Half of deaths during this period of time are minority infants that comprise 24 percent of the births.

- Reflecting an almost equal distribution of causes of post neonatal deaths in South Dakota between 2010 to 2014, 57 and 60 percent white and minority post neonatal deaths, respectively, were caused by SUID, accidents and homicides. Yet, the minority rate death for SUID is three to four times higher (p<.01) and for accidents and homicides is over four times higher than it is for whites (p<.01).

- Risks for infant deaths in South Dakota can be minimized with efforts to promote safe sleep.

REFERENCES


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Acknowledgement: The author expresses her gratitude to David Brechtelsbauer, MD for his assistance with this manuscript.
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Managing H*V in Pregnancy

By Mark K. Huntington, MD, PhD, FAAFP; and Charles W. Shafer, MD, AAHIVS

Abstract
A number of chronic viral infections require special attention during pregnancy in the prenatal, perinatal and postnatal periods. In many rural areas of South Dakota, these conditions are present, but readily-accessible subspecialty consultation is not. Fortunately, most aspects of management of these conditions in pregnancy are easily within the scope of practice of primary care physicians. This paper presents a review of the management of pregnancies complicated by HBV, HCV, HIV, HPV and HSV, offering a quick-reference guide for physicians who may infrequently encounter these patients as a part of their practices.

Introduction
Viral infections are common complications of pregnancy, some of which have quite significant consequences. Vertical transmission can occur, adversely affecting longevity and quality of life of the child. For some of the most significant viral infections, specific prophylactic interventions have been shown to diminish risk of mother to child transmission, and are routinely implemented in major medical centers. However, not all at-risk pregnancies occur in areas in which major medical centers are available. It is important for physicians in rural areas to be able to implement these potentially lifesaving interventions, yet the frequency with which these conditions are encountered may be low enough that specific management steps are not in the front of one’s mind. This paper is written – and its tables compiled – as a ready reference for physicians who may occasionally encounter pregnancies complicated by viral infections. Our goal is to aid rural physicians in identifying how to appropriately manage these pregnancies, and to determine who may be delivered locally, and who should be transferred to a referral center. Naturally, the resources offered here do not take the place of appropriate telephone consultations with specialists at referral centers.

The original research literature has been extensively reviewed in the preparation of this manuscript. However, rather than offering a bibliography that exhaustively references these works, specific citations in the text focus primarily on useful review articles that offer integrated summaries of the topics for those looking for additional clinically relevant reading on each subtopic.

HAV
Hepatitis A virus (HAV) is spread by the fecal-oral route. Though rare, vertical HAV transmission has been documented, both at the time of labor and delivery and earlier in utero. Acute HAV infection has been associated with maternal complications and preterm labor. No specific recommendations exist for the management of pregnancy, labor or the postpartum recovery in the context of HAV, other than identifying and addressing complications as they arise, with any pregnancy. Some authorities recommend immunoglobulin administration to infants born within two weeks of acute maternal HAV illness. Vaccination of at-risk individuals prior to pregnancy and delivery greatly reduces the risk of infection and thus vertical transmission.

HBV
Hepatitis B virus (HBV) is arguably the most prevalent blood-borne infection. Worldwide, HBV in pregnancy is a significant health problem: more than half of chronic HBV carriers acquired their infection perinatally. The most effective way to prevent perinatal HBV
infection is immunization of the population. This goal should be a priority for all health professionals. While early studies suggested reduced vertical transmission with the use of antenatal hepatitis B immunoglobulin (HBIG), subsequent controlled trials failed to demonstrate effectiveness, so this is not recommended. Antiviral treatment (telbivudine 600 mg daily) in late pregnancy (from 20 to 32 weeks through one month postpartum) is safe in pregnancy (Table 1) and has demonstrated decreased perinatal transmission in women with high circulating level of HBV. Lamivudine has shown some benefit, but subsequent studies indicate low potency and substantial risk of antiviral resistance selection. Tenofovir, a nucleotide analogue widely used in the treatment of HIV, is also quite effective against HBV and can be used in pregnant women. Though not yet recommended, the developing potential of antiviral therapy during pregnancy to decrease vertical transmission in select viremic women bears watching.

While a study in 2002 suggested no difference in transmission based on delivery method, a 2008 meta-analysis identified a significant reduction in vertical transmission with caesarean delivery, suggesting that elective caesarean section may be indicated in highly viremic mothers. Though not yet part of the American College of Obstetrics and Gynecology’s (ACOG) recommendations, this intervention may be worth considering.

Vertical transmission of hepatitis B is reduced by use of passive and active immunoprophylaxis. Administration of HBIG and the hepatitis B vaccination to neonates has been shown to be highly effective in preventing vertical transmission of HBV from women with high HBV viral loads. These should be initiated within 12 hours of birth, and the vaccination series should be completed with at least two more doses by 6 months of life. Hepatitis B serology (HBsAg, HBsAb) is checked at 9 months of age to identify those protected and those infected.

Infants who received HBIG may breastfeed without incurring any additional risk of transmission, though breastfeeding by mothers who are receiving antiviral therapy is not recommended.

HCV

Hepatitis C virus (HCV) has become the most common...
Table 2. Preferred and Alternative HIV Medications in Pregnancy

<table>
<thead>
<tr>
<th>Drug</th>
<th>Class</th>
<th>Prenatal Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir</td>
<td>NRTI</td>
<td>300 mg BID or 600 mg daily</td>
<td>Must do HLA-B*5701 allele screening and demonstrate a negative result prior to starting abacavir.</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>nRTI</td>
<td>600 mg daily; may be initiated after the first 8 weeks of pregnancy</td>
<td>Contraindicated during the first 6 weeks of pregnancy due to teratogenicity (neural tube defects) in human studies. If pregnancy is discovered, may be continued as any fetal effects will have already occurred by the time pregnancy diagnosis has been made.</td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>NRTI</td>
<td>200 mg daily</td>
<td></td>
</tr>
<tr>
<td>Lamivudine</td>
<td>NRTI</td>
<td>300 mg daily</td>
<td></td>
</tr>
<tr>
<td>Nevirapine</td>
<td>nNRTI</td>
<td>200 mg BID or 400 mg daily (ER form)</td>
<td>Can be used in ART-naive women if CD4 &lt; 250; can be continued in women receiving prior to pregnancy, regardless of CD4 count.</td>
</tr>
<tr>
<td>Raltegravir</td>
<td>II</td>
<td>400 mg BID</td>
<td>Limited data on raltegravir use in pregnancy, but may be considered when drug interactions with PI regimens are a concern. Twice daily dosing required.</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>NRTI</td>
<td>300 mg daily</td>
<td></td>
</tr>
<tr>
<td>Zidovudine</td>
<td>NRTI</td>
<td>300 mg BID</td>
<td>Zidovudine-containing regimens have the disadvantage of requiring twice daily dosing.</td>
</tr>
</tbody>
</table>

Medications routinely used in combination

| Atazanavir with ritonavir | PI        | 300 mg/100 mg daily     | Alternative dosing may be needed, depending on number of protease inhibitor resistance mutations. |
| Darunavir with ritonavir  | PI        | 800 mg /100 mg daily    |                                           |
| Saquinavir with ritonavir | PI        | 1000 mg/100 mg BID      | Baseline ECG is recommended before initiation because of potential PR and QT prolongation; contraindicated with pre-existing cardiac conduction system disease. Large pill burden. |

Single-pill combinations (Complete regimen formulated as one pill)

| Abacavir/lamivudine*      | NRTI      | 600 mg/300 mg daily    | See comments above on individual agents. |
| Efavirenz/emtricitabine/tenofovir | nNRTI/NRTI | 600mg/200mg/300mg | See comments above on individual agents. |
| Lopinavir/ritonavir        | PI        | 600mg/150 mg BID in 2nd and 3rd trimesters. | Twice daily dosing required. |
| Tenofovir/emtricitabine*  | NRTI      | 300 mg/200 mg daily    |                                           |
| Zidovudine/lamivudine*    | NRTI      | 300 mg /150 mg BID     | Zidovudine-containing regimens have the disadvantage of requiring twice daily dosing. |

Other HIV medications are occasionally used in pregnancy, but the agents in this table have the best data to support their use. Drug class abbreviations: II = integrase inhibitor, NRTI = nucleoside reverse transcriptase inhibitor, PI = protease inhibitor

*Bold indicates preferred agents. **Italics preferred, as an addition to the dual-NRTI preferred agents.

virus spread via blood-borne means in the U.S. An estimated 0.15 to 2.4 percent of pregnancies in the U.S. involve seropositive mothers; the prevalence approaches 9 percent of pregnant women in other areas. Although the vertical transmission rate is 3 to 5 percent, up to half of infants with congenitally-acquired HCV infection undergo spontaneous clearance. Risk factors for vertical transmission of HCV include high HCV viral load, HIV coinfection, history of maternal IV drug use and peripheral blood mononuclear cell infection. Although the medications traditionally used for HCV treatment are contraindicated in pregnancy (Table 1), the newer, direct-acting agents arriving on the HCV treatment scene are not. New HCV treatment options such as sofosbuvir, simeprevir and ledipasvir/sofosbuvir will require further study before they can be recommended as either suppressive or therapeutic interventions, but they appear to be safe in pregnancy and may hold some promise in this area. Neither elective cesarean delivery, abstinence from breastfeeding, nor any other intervention has been shown to decrease vertical transmission of HCV. Nonetheless, it may be wise to avoid prolonged rupture of membranes, invasive fetal monitoring, and operative vaginal delivery unless the benefit clearly outweighs the risk. Currently, the only effective means of preventing vertical transmission of HCV is to detect and treat infected women before they become pregnant, though this is not always practical.

HIV

Human immunodeficiency virus (HIV) is spread primarily by sexual contact, but is also blood-borne – albeit exponentially less efficiently than HBV. The risk of perinatal HIV infection in the absence of any preventative actions is approximately 25 percent.

Antiretroviral therapy (ART) has been shown to be the most effective intervention for decreasing vertical transmission of HIV. All HIV positive pregnant women should receive ART regardless of viral load. This is especially important for those women who seroconverted during pregnancy because that is the time maternal viral loads are at their highest. Reverse transcriptase inhibitors are the backbone of ART in pregnancy (Table 2). ART may be initiated as soon as possible in women not already on treatment, though waiting until 12 weeks EGA is typical. CD4 count, morning sickness, adverse gastrointestinal effects of antiretroviral drugs and patient readiness are variables which may influence the decision of precisely when to initiate ART.
For women on ART who become pregnant, maintaining their current regimen has been achieved. This includes efavirenz-containing regimens despite a known risk of neural tube defects with this medication (Table 2). Testing HIV RNA level is indicated every three months during the pregnancy, including once at 34 to 36 weeks gestation to help inform mode of delivery decisions. If any of these women has significant viremia, (currently defined by an HIV RNA level greater than 200 copies) antiretroviral resistance testing is indicated.12

ART should be continued regardless of planned mode of delivery. If viral load is greater than 1,000 (or unknown) at time of delivery, initiate zidovudine 2 mg/kg IV over the first hour, then 1 mg/kg/hr until cord clamp. Intrapartum zidovudine is not required if viral loads are consistently less than 1,000, the patient is on ART, and there are no concerns about adherence.13

If possible, obstetrical procedures that increase risk of transmission should be avoided, including amniocentesis, assisted rupture of membranes, intraterine pressure catheters, fetal scalp leads, vacuum- or forceps-assisted delivery. Of course, the obstetrical benefit of these interventions may outweigh the infectious risks in certain situations.

Scheduled caesarean delivery is indicated at 38 weeks if viral load is greater than 1,000 (or unknown); however, in women with viral loads less than 1,000, elective caesarean delivery does not appear to confer any additional benefit in decreasing risk of vertical transmission.13 Women scheduled for cesarean section whose viral load remains greater than 1,000 should receive intrapartum zidovudine whether they have been on ART or not. Spontaneous rupture of membranes has been shown to have up to a 2 percent per hour increase in risk of vertical transmission in viremic mothers;14 patients scheduled for caesarean delivery who experience spontaneous rupture of membranes prior to scheduled delivery time should be delivered expediently.

Patients of unknown HIV status who present in labor should be tested for HIV promptly. If the rapid test is positive – or in settings where rapid testing is not available – manage the delivery as if the patient is HIV-infected; do not wait for confirmatory test results. The infant should be treated as if the mother has HIV until confirmatory tests prove otherwise. Combination antigen/antibody rapid HIV tests have greatly reduced the rate of false positives.

A prophylactic six-week course of oral zidovudine is generally recommended for all HIV-exposed neonates, with gestational age-appropriate dosing initiated as soon as possible (preferably within six to 12 hours of birth). In addition, those born to mothers who were not on ART should also receive three doses of nevirapine: at birth, 48 hours after the first dose and 96 hours after the second dose.15 Breastfeeding by HIV-infected women in developed countries is not advised, but in settings such as sub-Saharan Africa breastfed infants of HIV-positive mothers have lower mortality than their bottle-fed counterparts.16

**HPV**

Human papilloma virus (HPV) is the most common sexually transmitted infection, and is the cause of cervical, anorectal, head and neck cancers. There is increasing evidence that vertical transmission of the virus may occur, in perhaps 6.5 percent of children born to HPV-infected mothers, though it is not clear whether this transmission occurs prenatally or perinatally.15 Transmission appears more common in vaginal than in caesarean deliveries.17,18 At present, there are no specific recommendations – either evidence-based or consensus – to manage pregnancy or delivery of expectant patients with HPV differently from those without the infection. HPV immunization has the potential to diminish risk of transmission, including in the setting of pregnancy and childbirth, and should be encouraged.

**HSV**

Approximately one in six Americans has genital herpes,
## Table 4. Summary of Pregnancy Management in the Context of H*V Infections

<table>
<thead>
<tr>
<th>Virus</th>
<th>Prenatal</th>
<th>Peripartum</th>
<th>Postpartum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical options</td>
<td>Surgical options</td>
<td></td>
</tr>
<tr>
<td>HAV</td>
<td>No specific recommendations.</td>
<td>Elective caesarean delivery not indicated. (SOR = C)</td>
<td>Breastfeeding not contraindicated. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Consider immunoglobulin for infant if born within 2 weeks of acute maternal HAV illness. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Newborns to HBV mothers receive HBIG and vaccine within 12 hours of birth. (SOR = B)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Breastfeeding not contraindicated in infants who have received HBIG. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Breastfeeding NOT recommended in mothers receiving antiviral therapy. (SOR = C)</td>
</tr>
<tr>
<td>HBV</td>
<td>Prophylactic hepatitis B vaccination recommended for entire population. (SOR = B)</td>
<td>Consider antiviral therapy as noted in prenatal column. (SOR = B)</td>
<td>Breastfeeding not contraindicated. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Newborns to HBV mothers receive HBIG and vaccine within 12 hours of birth. (SOR = B)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Breastfeeding not contraindicated in infants who have received HBIG. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Breastfeeding NOT recommended in mothers receiving antiviral therapy. (SOR = C)</td>
</tr>
<tr>
<td>HCV</td>
<td>Suppressive or therapeutic options NOT recommended. (SOR = C)</td>
<td>Elective caesarean delivery not indicated. (SOR = C)</td>
<td>Breastfeeding not contraindicated. (SOR = C)</td>
</tr>
<tr>
<td>HIV</td>
<td>ART for all patients. (SOR = B)</td>
<td>Scheduled caesarean delivery at 38 weeks if HIV RNA &gt; 1,000 (or unknown). Cae sarean delivery not recommended if HIV RNA &lt; 1,000. Patients scheduled for caesarean who experience spontaneous rupture membranes prior to scheduled delivery time should be delivered expeditiously. (SOR = C)</td>
<td>Chemoprophylaxis - see Table 5 (SOR = B)</td>
</tr>
<tr>
<td></td>
<td>RTI are first line agents for ART-naïve patients (SOR = C)</td>
<td>Avoid invasive monitoring and operative vaginal delivery if possible. (SOR = C)</td>
<td>Breastfeeding NOT recommended. (SOR = B)</td>
</tr>
<tr>
<td></td>
<td>Women on ART pre-pregnancy: maintain current regimen if effective. Test for viremia; if detectable, test for antiretroviral resistance. (SOR = C)</td>
<td></td>
<td>Infants born to mothers of unknown HIV status should be treated as if the mother has HIV until testing proves the mother is HIV negative. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td>Avoid amniocentesis if possible. (SOR = C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV</td>
<td>No suppressive or therapeutic options recommended.</td>
<td>Elective caesarean delivery not indicated. (SOR = C)</td>
<td>Breastfeeding not contraindicated. (SOR = C)</td>
</tr>
<tr>
<td>HSV</td>
<td>Suppressive therapy starting at 36 weeks for those with one or more HSV outbreaks during pregnancy. (SOR = B)</td>
<td>Elective caesarean delivery not indicated in the absence of active genital lesions or near-term PROM. (SOR = C)</td>
<td>Breastfeeding not contraindicated unless active lesions on breast. (SOR = C)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Strength of recommendation (SOR) taxonomy: A – strong patient-oriented evidence; B – moderate patient-oriented evidence; C – disease-oriented evidence, consensus/expert opinion.*
the result of herpes simplex virus (HSV) infection.\textsuperscript{19} It may be transmitted vertically, and neonatal infection is associated with severe morbidity and mortality. Overall, one in 3,200 live births is affected, with the highest risk being those infants born to women suffering from primary HSV infection at the time of delivery (20 to 50 percent rate, OR 33).\textsuperscript{19} Although this group is at highest risk, an estimated 70 percent of neonatal HSV cases are born to mothers with no lesions or known history of HSV.\textsuperscript{20}

Determining optimal prevention of perinatal HSV transmission has proven to be challenging. There has been shown no benefit to screening with polymerase-chain reaction (PCR) or other methods at time of labor.\textsuperscript{19} Suppressive therapy, beginning at 36 weeks gestation, of pregnant women with a history of HSV has demonstrated a decreased recurrence of lesions at time of delivery; however, it did not show a decrease in neonatal HSV infection.\textsuperscript{21} Nevertheless, ACOG recommends suppressive therapy starting at 36 weeks for those with one or more HSV outbreaks during pregnancy;\textsuperscript{19} others recommend it for all pregnant women with primary or recurrent HSV without regard to the timing of occurrence.\textsuperscript{20} Treatment and suppressive regimens are shown in Table 3.

Vaginal delivery is the ACOG-recommended route of birth if no genital lesions or prodromal symptoms are present at the time of labor; lesions that are fully crusted, and non-genital lesions are not indications for caesarean delivery, but non-genital lesions should be covered with an occlusive dressing during delivery.\textsuperscript{19} The British Royal College of Obstetricians and Gynaecologists recommend caesarean delivery for patients with primary HSV within six weeks of delivery.\textsuperscript{20} Although caesarean delivery is the current practice for recurrent HSV in the U.S., the data suggests that this may increase overall morbidity and mortality due to an excessive caesarean rate; in recurrent HSV, the number needed to treat (NNT) via caesarean is 1,580.\textsuperscript{19}

Invasive monitoring during labor, and operative vaginal deliveries, are best avoided whenever possible, especially in women with a history of HSV. These interventions – though considered almost routine in some facilities – increase the risk of transmission.\textsuperscript{19} Relative risk of transmission using scalp electrodes vs. external trans-abdominal monitoring is six-fold.

In the context of preterm premature rupture of membranes, ACOG advises expectant management. Antiviral therapy has not been shown to decrease risk of transmission in this setting.\textsuperscript{19} Some authors recommend caesarean delivery of women with premature rupture of membranes at term or near-term, in whom active lesions are present.\textsuperscript{20}

Breastfeeding is not contraindicated in women with HSV unless there are active lesions on the breast.

**Summary**

Appropriate and timely intervention in viral infection-complicated pregnancies can make a meaningful difference in mother to child transmission rates, significantly decreasing mortality and long-term morbidity. Many of these interventions are very time-sensitive and may be most effectively addressed at a pre-conception visit; therefore, it behooves physicians attending these deliveries to be aware of these management strategies and to implement them in a timely fashion (Table 4). In so doing, we increase the likelihood that the next generation starts life with a clean bill of health.
REFERENCES


Please note: Due to limited space, we are unable to list all references. You may contact South Dakota Medicine at 605.336.1965 for a complete listing.

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Both Dr. Huntington and Dr. Shafer are family physicians active in maternity care with experience globally in regions where some of these infections are far more prevalent than in South Dakota.

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Osteonecrosis of the Torus Palatinus in the Setting of Long-Term Oral Bisphosphonate Use – A Case Report

By Joshua L. Ryan, MD; and Eric Larson, MD, FACP

Abstract
Bisphosphonates are medications used orally and intravenously for a variety of conditions including cancer metastatic to bone, hypercalcemia of malignancy, Paget’s disease and osteoporosis. Osteonecrosis of the jaw has been related to bisphosphonate use. Osteonecrosis of the jaw most commonly occurs in the setting of intravenous bisphosphonate use and concomitant dental work or trauma. Oral bisphosphonates have much less risk of osteonecrosis of the jaw. We present an interesting case of a patient on an oral bisphosphonate for an extended period of time (nine years), with a torus palatinus, who burned her palate while eating a slice of pizza. Over six months later, she presented with an area of denuded bone and diagnosis consistent with osteonecrosis of the torus palatinus.

Introduction
Bisphosphonates (BPs) are a commonly used drug class for treatment of cancers metastatic to bone, hypercalcemia of malignancy, and osteoporosis. These agents are used to prevent bone resorption through the toxic death of osteoclasts. Parenteral (IV) BPs (pamidronate, zoledronate) are used primarily in malignancy (zoledronate is also used in osteoporosis), while oral BPs (risedronate, alendronate) are preferred agents for osteoporosis. One well known but rare adverse reaction to the use of BPs is bisphosphonate related osteonecrosis of the jaw (BRONJ), the first cases of which were reported to the literature in 2003 by Marx. Since 2003, there have been a large number of studies, protocols and guidelines published related to the diagnosis and definition of BRONJ. Parenteral BPs have been associated with higher incidence of osteonecrosis of the jaw, up to 8 to 10 percent when used in malignancy, compared to oral bisphosphonates, which only have a reported 0.01 to 0.1 percent incidence.

Originally, osteonecrosis of the jaw was defined by the American Association of Oral and Maxillofacial Surgery as exposed bone in the maxillofacial region for eight weeks, in the setting of bisphosphonate use, with no previous history of jaw radiation. Recently there has been debate on the definition and nomenclature of this disease process, with a recent cross sectional study showing 24 percent of patients with ONJ do not have exposed bone. Osteonecrosis of the jaw typically presents as a painful and infected area of denuded or necrotic bone in either the maxilla or mandible, with the incidence in the mandible around two times greater. While the maxilla and mandible are the commonly seen sites with this disease, there have been only a few case reports of osteonecrosis of maxillary exostosis, commonly known as torus palatinus.

Tori are exostosis that can occur on the maxilla (torus palatinus) or mandible (torus mandibularis). They are usually covered with a thin mucosa that generally has poor vasculature. The prevalence of tori is between 12 and 26 percent of a given population. They are most commonly found in middle age, with torus palatinus more prevalent in women.

One of the reported cases of torus palatinus osteonecrosis is a patient receiving parenteral zoledronic acid for breast cancer, the other reported case is a female on oral alendronate for six years prior to noticing a painful ulcerated area on her palate. This paper will present a case of osteonecrosis of the torus palatinus instigated by a burn in the setting of risedronate (Actonel) use.

Case
The patient is an 80-year-old woman with a medical history of hyperlipidemia, microscopic colitis and...
osteoporosis, for which she had taken risedronate 35 mg PO weekly for nine years. She also had a known torus palatinus present for many years. She is a non-smoker, and does not have any history of chronic steroid use or jaw radiation. She had no previous issues with her torus palatinus until she burned the roof of her mouth with a small bite of pizza that was given out as a grocery store sample. She was not initially concerned about this burn, but over the following months, she noticed that the roof of her mouth felt different. She stated that following the initial burn, she missed her appointment to see her dentist. However, seven months later, she saw her dentist due to increased concern for roughness and sensitivity on her palate. Her dentist noticed an area of concern and referred her to an oral/maxillofacial surgeon (OMS). He noted the exposed bone on the torus palatinus, which is seen in Figure 1. He obtained a cone beam CT scan, which was read as having evidence of abnormal resorptive pattern in the middle of the right lobe of the torus. Figures 2 and 3 show radiographic evidence of necrosis of the right lobe of the torus, with intact palatal bone above the area of relative lucency and decreased calcification and bone density.

The oral surgeon discussed the findings with the patient, and it was decided that the patient should discontinue her risedronate and undergo serum C-terminal telopeptide (CTX) testing to help guide decisions regarding the need for surgical debridement. Marx et al. published recommendations for risk stratification using CTX testing to help decide the need for surgical debridement in patients with osteonecrosis of the bone. CTX levels were observed to correlate with the length of bisphosphonate use. In general, the lower the CTX level, the greater length of bisphosphonate use. CTX levels less than 100 pg/ml constitute high-risk, levels between 100 and 150 pg/ml are moderate risk, and levels greater than 150 pg/ml are considered low risk. The lower the risk, the more likely the patient will have spontaneous healing of lesions and a more successful office debridement. In this case, the patient’s initial CTX level was 115 pg/ml in May 2013. A repeat CTX level done in September 2013 was 122 pg/ml. Both of these levels fell in the moderate risk zone (100 to 150 pg/ml). The patient noted that following discontinuation of the bisphosphonate, the area of denuded bone

![Figure 1. View of upper maxilla and torus palatinus.](image1)

![Figure 2. Cone beam CT scan: coronal and transverse plane showing areas of necrotic bone primarily in right lobe of torus palatinus.](image2)
began to regain mucosal coverage. It is not known if an area of bone spontaneously exfoliated, but on repeat exams, the patient did not have any exposed bone or pain with her torus. No surgical debridement was required for this patient. As of today, she is no longer taking bisphosphonates.

Given chronic use of bisphosphonates, an inciting injury with an area of exposed bone for greater than eight weeks, and no previous history of jaw radiation, this patient fits the classification of BRONJ, with the caveat of the osteonecrosis affecting her torus palatinus.3

Discussion
This case highlights an interesting mechanism of injury that initiated a severe reaction to a commonly prescribed medication. BPs are first line agents to combat fracture risk in postmenopausal, osteoporotic individuals.7 With the literature continuing to support the relationship between BPs and osteonecrosis, there has been a question of whether or not to use a drug holiday for patients taking oral BPs. A clinical review by Brown et al. states that although osteonecrosis of the jaw, and atypical femur fractures are related to BPs, drug holidays should only be considered in patients at low risk for fracture after three to five years of BP use. The fracture risk reduction benefits of the bisphosphonates generally out weigh the risk of these rare side effects.8 This recommendation is supported by the 2013 Clinician’s Guide to Prevention and Treatment of Osteoporosis.10 However, the guideline also states that the evidence for efficacy of BPs use beyond five years is limited, and that concerns for ONJ and atypical femur fractures are more common in longer term BP use.10

The patient had been on risedronate for nine years without a drug holiday. The presence of her torus palatinus put her at an increased risk for ONJ, as the overlying mucosa is thin and susceptible to injury.6 The inciting injury in this case was a burn on her torus palatinus from a hot slice of pizza. One article recommends that prior to starting IV BP therapy, physicians should refer patients to a dentist or oral/maxillofacial surgeon for evaluation.11 The same article also recommends that midline palatal tori with thin overlying mucosa be removed one month prior to initiation of bisphosphonate therapy.11 While this aggressive approach may be justified in IV BP use, there is currently no recommendation for patient pre-screening by a dental professional prior to prescribing oral BPs. It would be beneficial for providers to be aware of the patient’s dental history and monitor for ONJ and atypical femur fractures in their patients on BPs, particularly in patients who have been on oral BPs for longer than five years.

References


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Introduction

The use of herbal and dietary supplements (HDSs) in developed nations has increased enormously despite awareness of their potential toxicities. Only one-third of HDS consumers reported their use of these products to a health care provider. In the U.S. in 2004, 18.9 percent of adults reported using these products. Of note, in 1998 an estimated $4 billion was spent on HDSs. There are currently no regulations to give the U.S. Food and Drug Administration (FDA) the authority to review and approve the safety of herbal products. The clinical presentation of HDS hepatotoxicity can range from mild hepatitis to acute hepatic failure requiring transplantation. Despite such ill effects, people continue to use these supplements widely.

Kombucha (or “mushroom”) tea, also known as Manchurian or Kargasok tea, is a misnomer. The “mushroom” is a symbiotic aggregate of several yeasts and bacteria held together by a thin, permeable membrane. Supposed benefits of consuming Kombucha tea have included the prevention of cancer, decreased blood pressure, boosting the immune system (especially in human immunodeficiency virus [HIV] patients), relief of arthritis pain, alleviation of constipation, treatment for insomnia, cleansing of the gall bladder, and hair regrowth. However, no scientific research has validated these claims. Several cases of acute hepatitis and lactic acidosis, in fact, were attributed to its use in the 1990s. Here, we present a case of cholestatic hepatitis related to the consumption of Kombucha tea that emphasizes the careful evaluation of these products by physicians and stringent scrutiny of their production by regulatory authorities.

Case Presentation

A 58-year-old non-obese female with a medical history significant for diabetes mellitus and hypothyroidism admitted to our institution with constant epigastric pain of five days’ duration associated with nausea. She had clay-colored stool three days prior, but stool had returned to its normal appearance when she presented. At that time, she also noted having dark-colored urine. Additionally, she noted having pruritus and jaundice for the previous three days. She denied experiencing vomiting, hematemesis, heartburn, dysphagia, odynophagia, diarrhea, constipation, melena, and greasy or fatty stools. The patient had been consuming a significant amount of Kombucha tea for one month prior to her admission.

Following the laboratory evaluation, she was noted as having a disproportionate elevation of alkaline phosphatase with respect to aminotransferases, along with direct bilirubinemia, which is suggestive of a cholestatic pattern (Table 1). Results of serological testing for hepatitis A, hepatitis B, hepatitis C, Epstein-Barr virus, cytomegalovirus, and herpes simplex virus were negative. The patient had normal ferritin, alpha-1-antitrypsin, ceruloplasmin, and coagulation panels. An autoimmune work-up showed normal anti-nuclear antibodies, anti mitochondrial antibodies, and anti-smooth muscle antibodies. Her hematological markers, electrolyte levels, metabolic profile, thyroid function tests, and lipase values were unremarkable. A right-upper-quadrant ultrasound showed no gallstones or bile duct dilation, and this was confirmed with magnetic resonance cholangiopancreatography.

The patient’s abdominal pain was resolved during the hospital course with conservative measures. She underwent a CT-guided liver biopsy that showed moderately active hepatitis with increased eosinophils and bile duct injury without any fibrosis, suggesting drug-induced liver
injury (Figure 1). She was discharged with ursodeoxycholic acid for the cholestatic pattern of liver injury and cholestyramine for itching. She was counseled not to take any herbal supplements and scheduled a follow-up clinic visit in two weeks with liver function tests (LFTs). Her liver biopsy slides were reviewed at the Mayo Clinic as well, and they concurred with the finding of acute drug-induced liver injury. At the patient’s two-week clinic follow-up, LFTs were significantly improved (Table 1). Her liver enzymes had normalized by the one-month follow-up visit, so ursodeoxycholic acid was discontinued. Her liver enzymes remained normal one month after discontinuing ursodeoxycholic acid (Table 1).

**Discussion**

In our patient, the use of Kombucha tea prior to the onset of symptoms and symptom resolution upon stopping tea consumption suggests a probable causal association with hepatotoxicity. The FDA has not found any pathogenic organisms or hygienic violations in the practices of the commercial manufacturers of this product. However, there is a clear possibility of contamination with spores from more pathogenic yeast or bacteria, because ingredients used for preparing Kombucha are passed from one user to another. The pH of tea becomes 1.8 in 24 hours in the brewing phase. For this reason, it should not be prepared or stored in ceramic or lead containers, as toxic constituents can permeate into the tea due to the acidity.

The mechanism underlying the potential toxicity and side effects of Kombucha tea consumption is not clear. More recently, hyperthermia, lactic acidosis, and acute renal failure were reported within 15 hours of Kombucha tea ingestion in a newly diagnosed, young HIV patient. In 2004, a case of anti-Jo1 antibody-positive myositis was noted as a consequence of Kombucha tea use. Elevated liver enzymes and the sub-acute onset of an erythematous papular rash were noted in a 53-year-old college professor after drinking a half-cup of Kombucha tea for two weeks. He was followed on an ambulatory basis. His symptoms and lab values were resolved over the next month. Two middle-aged women from Iowa presented with severe lactic acidosis and respiratory failure after consuming four ounces of home-fermented Kombucha tea for two months in 1995, and one of them died. However, at least 115 additional individuals in the town had brewed the tea from the same source as those two affected women and tolerated it well, without any ill effects. Also, a 55-year-old alcoholic female presented with jaundice and elevated hepatic enzymes and bilirubin after consuming two glasses of Kombucha tea for two months. After the cessation of tea consumption for the following seven weeks, her laboratory values were normalized.

This case serves to remind health professionals to be aware of potential hepatotoxic effects of this popular fermented tea.
care providers to question all patients regarding complementary and alternative therapies, along with prescription medications, and to caution patients against the consumption of any potentially hepatotoxic supplements. In most instances, even if harmful drug events are recognized, reporting rates are extremely low. Therefore, we advocate for the notification of any adverse health effects related to HDS use to the FDA through the MedWatch spontaneous reporting system at www.fda.gov/medwatch/ or by telephone at 800.332.1088 or 301.738.75537, with the goal of developing tighter regulations regarding HDS manufacturing practices and further research to analyze the chemical compositions and understand hepatotoxic mechanisms in HDSs. We encourage health care providers to search a comprehensive resource (www.livertox.nih.gov/) if there is any suspicion of an HDS causing drug-induced liver injury.

REFERENCES


Please note: Due to limited space, we are unable to list all references. You may contact South Dakota Medicine at 605.336.1965 for a complete listing.
Early Onset Sepsis

By Kyrsten Johnson, MD; and Stephen Messier, MD, FAAP

Abstract

Early onset sepsis (EOS) is a worrisome, life-threatening condition in newborns with onset during the first week of life. Evaluation can be challenging due to the dynamic nature of the condition as the infant transitions to life ex-utero. Symptoms/signs can be nonspecific, thus, a high index of suspicion is warranted for subtle changes in condition including poor feeding, respiratory distress, or decreased activity. Common risk factors include chorioamnionitis, maternal fever, group B strep (GBS) colonization and preterm delivery. Despite universal screening and intrapartum antibiotic prophylaxis (IAP), GBS remains the most frequent cause of EOS followed by Escherichia coli (E. coli). While the gold standard for diagnosis remains a positive blood culture, lab evaluation frequently involves complete blood count (CBC) with differential, c-reactive protein (CRP), and evaluation of spinal fluid if the infant is stable. Unfortunately, there is not a lab test that is rapidly diagnostic for sepsis, so treatment should be empirically started until it is clear that the infant is not infected. Treatment often includes ampicillin and gentamicin for coverage of the most frequent pathogens. There is much debate about timing of discontinuation of antibiotics. Frequently, antibiotics can be discontinued after 48 hours in well appearing, asymptomatic infants with negative blood cultures and either normal CBC analysis or normal CRP values.

Introduction

Welcoming a new baby is one of the great joys of being a provider who cares for children. The vast majority of the time, the infant transitions to its new surroundings without any complications; however, in 10 to 20 percent of cases, mothers may have risk factors or infants may show signs that allude to early onset sepsis (EOS). Infants who become infected during the perinatal timeframe can become severely ill to the point of death if the disease is allowed to persist untreated. EOS is one of the most worrisome and potentially damaging diagnoses that an infant can have in the first week of life. EOS can be difficult to rule out and even more challenging to explain to new parents. Just the initial workup and empiric management of these infants can cause their families emotional distress; however, decisions that are made in these first few hours can avoid devastating illness with potentially life long consequences.

Definition of Early Onset Sepsis

Despite the common nature of this clinical issue for newborns, a clear consensus definition of EOS remains elusive. The Centers for Disease Control and Prevention (CDC) defines EOS as a positive blood or CSF culture in an infant less than 7 days of age. The American Academy of Pediatrics Committee on the Fetus and Newborn (AAP COFN) definition, takes into account very low birth weight infants (VLBW) infants who have been instrumented in the neonatal ICU (NICU) and limits EOS to positive culture in the first 72 hours. The gold standard for diagnosis in both of these definitions is positive culture; however, up to 14 percent of cases of newborn sepsis documented at autopsy had negative pre mortem blood cultures. Clinical sepsis involves a systemic inflammatory response (SIRS) and the presence of known or suspected bacterial infection, however, there is a lack of consensus as to what parameters define SIRS in a neonate. The current pediatric consensus definition of sepsis determined in 2002 by the International Consensus Conference on Pediatric Sepsis and based on the adult definition takes
into account negative culture with clinical signs. However, some suggest that this does not adequately cover newborns, whose signs and symptoms of infection are less specific and supporting lab studies more equivocal. The lack of a clear, uniform definition significantly limits what can be learned from clinical research and meta-analysis of past studies.

**Incidence and Causes of EOS**

Recent estimates of the incidence of culture positive sepsis is three to seven cases per 1,000 births. This is an 80 percent decline in cases since the institution of maternal intrapartum antibiotic prophylaxis for GBS in the 1990s. With modern neonatal care including empiric antibiotic therapy, the mortality rate of those infected has dropped to about 10 percent. The incidence is tenfold higher in preterm infants than in term infants and the most recent CDC data suggests the risk of death or significant developmental delay, are about eight times higher in premature infants.

Despite current prevention strategies, the most common bacteria causing EOS in term gestation infants is group B Streptococcus (GBS) followed by Escherichia coli (E. coli). In preterm infants, this incidence is reversed, with E. coli more common than GBS. GBS is a gram positive diplococci which are beta hemolytic on blood agar plates. It is surrounded by a polysaccharide capsule which helps prevent opsonization by phagocytic cells in the immune system. Analysis of the polysaccharide capsule further distinguishes GBS into 10 distinct subtypes. Types Ia, Ib, II, III and V are the most common causes of disease in neonates in the U.S. Other regions of the world experience disease from other GBS serotypes. Surveillance cultures have found that 20 percent of women in the U.S. are transiently colonized with GBS. While GBS can affect patients across the entire age spectrum, newborns and elderly are at highest risk of disease. AAP, CDC and American College of Obstetrics and Gynecology (ACOG) guidelines recommend universal maternal screening at 35 to 37 weeks gestation and selective prophylaxis during labor based on maternal screening culture results.

E. coli are gram negative rods that are commonly found in the vaginal tract of women. The source of infection in neonates is typically vertical transmission from the vaginal tract or nosocomial infection from the hospital environment. While there are hundreds of subtypes of E. coli, 40 percent of those causing sepsis and 80 percent of those causing meningitis have a K1 polysaccharide capsule which increases its virulence in neonates. It is believed that the K1 antigen allows for easier penetration of the gastrointestinal epithelium. Predisposing factors to infection in these neonates include fetal hypoxia, acidosis, and other metabolic abnormalities. Frequent use of broad spectrum antibiotics is known to select out for resistant strains of these bacteria.

While Listeria monocytogenes is a relatively rare cause of EOS, it does have implications in an agricultural state like South Dakota. Listeria is a gram positive motile rod which is implicated in food borne disease from unpasteurized dairy products and deli meats. While disease is rare in immunocompetent hosts, bacteria can be transmitted transplacentaly, causing EOS. Mothers typically will have a “flu-like” illness prior to the onset of labor. The incidence of disease in pregnant women is difficult to determine since many cases result in spontaneous abortion and, thus, go undiagnosed. Of note, cephalosporins have no activity against Listeria and ampicillin is considered first line treatment with concomitant gentamicin given for synergy.

**Risk Factors for EOS**

By far, the greatest risk factor for EOS in a neonate is chorioamnionitis in the mother. Chorioamnionitis, diagnosed by maternal fever, uterine tenderness, foul smelling amniotic fluid, and/or tachycardia either in the mother or fetus increases the risk of EOS in the infant tenfold. Other risk factors for EOS are listed in Table 1. Of these factors, the ones that constitute the highest risks are maternal chorioamnionitis, preterm delivery and intra-partum fever.

<table>
<thead>
<tr>
<th>Table 1. Maternal Risk Factors For Neonatal EOS</th>
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<tr>
<td>Maternal chorioamnionitis</td>
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<td>GBS colonization at the time of delivery</td>
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<tr>
<td>GBS bacteruria at any time during pregnancy</td>
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<td>Prolonged rupture of membranes (&gt; 18 hours)</td>
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<td>Prior infant with EOS</td>
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<tr>
<td>Intrapartum fever</td>
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<td>Preterm delivery</td>
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**Clinical signs of EOS**

Symptoms of EOS can initially be very subtle. Tachypnea that persists past or worsens during the initial four-hour transitional period after birth can herald a life threatening bacterial infection in the newborn. Nonspecific findings
such as poor feeding or decreased activity can easily be overlooked by the clinician. Table 2 lists a more comprehensive list of symptoms. The most common symptoms in patients with culture positive sepsis include apnea, tachypnea, and hypotension. Infants infected before or during labor may have immediate onset of symptoms after birth and a higher disease burden. However, infants can be inoculated by passage through the birth canal, in which case symptom onset may be delayed for several hours. Once the inflammatory cascade is activated, significant physiologic events lead to SIRS ultimately resulting in respiratory failure, cardiovascular instability, or death in a matter of hours to days.

**Lab Studies for EOS**

With clinical signs of infection being so non-specific, clinicians have resorted to laboratory analysis to delineate those who are septic from those who are not. Sepsis is a dynamic process which evolves rapidly in a neonate who is concomitantly recovering from another dynamic process, that of birth. Current views of inflammatory markers with specific cutoff values attempt to apply static definitions to this very dynamic condition and thus limit the reliability of laboratory testing. Many studies relate the effectiveness of lab testing by its sensitivity and specificity. While these statistical parameters help describe the accuracy and precision of the test, when the disease state is in question the positive predictive value (PPV) and negative predictive values (NPV) are more useful as these predict how often a test result reflects true disease. A lab marker with sufficiently high NPV could reduce antibiotic use, hospital stays, and health care costs; however, no laboratory testing or clinical sign in isolation currently accurately identifies neonatal infection. The most common current lab tests that are performed in sepsis evaluations are blood cultures, complete blood counts, C-reactive proteins, and analysis of spinal fluid.

Blood culture has been considered the gold standard for diagnosis of EOS in the past. Most hospitals use a BACTEC system which has a high probability of detecting bacteria in 1 milliliter (ml) specimen sample. A minimum of 1 ml of sample per blood culture tube is necessary for accurate diagnosis. False negative blood culture can be caused by maternal antibiotic exposure during labor, low level bacteremia at birth, and inadequate blood volume sampling taken from neonates for culture. Only studies from the microbiological lab can identify a pathogen with its sensitivity to treatment and thus remains vital to the diagnosis and treatment of EOS. According to the AAP COFN guidelines, bacterial cultures from urine, skin, and gastric aspirate add little to the workup of EOS and should be avoided.

The CBC has traditionally been used to aid in the assessment of EOS. Parameters such as the white blood count (WBC), immature to total neutrophil ratio (I:T ratio) and platelet count are frequently assessed in patients whose clinical appearance or maternal risk factors place them at increased risk for EOS. Many of the parameters on the CBC can be abnormal in the newborn for reasons other than infection.
than sepsis, thus the positive predictive value (PPV) for abnormal CBC parameters is low. However, in a large multicenter retrospective cohort study of newborns evaluated for sepsis with CBC, low WBC, low absolute neutrophil count (ANC), elevated I:T ratio, and low platelets were most predictive of culture positive sepsis. Additionally, the values for these parameters can change over the first 12 to 24 hours of a brewing infection, so a single CBC is of limited value. A large, retrospective cohort study determined that when CBC parameters (WBC, I:T ratio, platelet count, and ANC) were normal and clinical signs of infection were transient or absent, the probability of culture positive sepsis dropped to 0.6 percent (negative predictive value [NPV] 99.4 percent), which is the baseline risk for sepsis for all newborn infants. This demonstrates the true value of serial CBCs in EOS evaluation lies in its NPV when coupled with a normal or improved clinical picture.

CRP is a non-specific acute phase reactant synthesized by hepatocytes under the regulation of interleukin (IL) -1 and IL-6. Synthesis of CRP by other tissue types has also been reported. The function of CRP is not known; however, it may play a role in first line host defense and lipid metabolism. It works well as a marker of inflammation in the newborn as maternal CRP does not cross the placenta; however, an elevated CRP does not differentiate between causes of inflammation in newborns. CRP values are generally higher with bacterial infection (especially gram negative infections), severe viral infections, vaginal birth and even higher in vacuum assisted births. CRP values can be lower in premature infants and low birthweight infants. CRP values start to elevate four to six hours after an insult and then peak at 48 hours. Since it can take up to 24 hours for the CRP to enter the abnormal range, it has little utility in determining when to start antibiotics in EOS. However, the NPV of serial normal CRPs in EOS is greater than 99.7 percent, so documentation of normal CRPs may be useful in deciding when it is appropriate to stop antibiotics.

Newborns have a poor ability to localize infections well, so infants with either culture positive sepsis or high suspicion for clinical sepsis should have a lumbar puncture (LP) performed at some point during their evaluation. While data suggests that well appearing infants, even with significant risk factors, are at low risk for development of early onset meningitis, ill-appearing bacteremic infants have an incidence of meningitis that can approach one in five. Ideally, LP should be performed prior to starting antibiotics; however, frequently septic neonates, have respiratory compromise or hemodynamic instability, making lumbar puncture difficult in the acute phase of illness. Deferral of LP until the neonate is stabilized is prudent, although this can affect the outcome of testing. In cases when the LP is performed after antibiotic administration, cell count parameters, glucose, and protein values are frequently the markers of choice when ruling in or out meningitis. It is important to determine if the patient has meningitis since infants with meningitis should be treated for a minimum of 14 days for gram positive organisms and 21 days (or 14 days after obtaining a negative culture) for patients with gram negative disease.

**Treatment Regimen for EOS**

Delay in treatment of neonatal sepsis can be devastating. Thus, while the workup is ongoing, the standard of care is to empirically treat with broad spectrum antibiotics until it is apparent that the infant is not infected. If the offending bacteria is identified, treatment can be tailored to the pathogen and site of infection. Ampicillin, a bactericidal semisynthetic penicillin, inhibits the production of bacterial cell walls leading to cell lysis. Ampicillin is particularly effective against GBS and *Listeria*. As an aminopenicillin, it has increased activity against gram negative organisms; however, resistance in gram negative bacteria (especially in *E. coli*) is generally secondary to TEM-1 betalactamase production. Gentamicin, an aminoglycoside, inhibits bacterial protein synthesis by binding to the 30S subunit of bacterial ribosomes. Some resistance to gentamicin occurs through ribosomal mutation and inactivation of the aminoglycoside molecule. Gentamicin has ototoxic and nephrotoxic side effects and thus serum trough drug levels must be monitored. The synergistic effects of ampicillin combined with gentamicin make it particularly effective against bacteria responsible for EOS. Recent testing in South Dakota determined that 99 percent of GBS isolates tested were sensitive to ampicillin. *E. coli* resistance to ampicillin is a known problem with only 60 percent of isolates tested sensitive to ampicillin. Ninety-four percent of *E. coli* isolates were sensitive to gentamicin in South Dakota.

Cefazolin, as a third generation cephalosporin, has been proposed as an alternative to gentamicin. Cefazolin has excellent gram negative coverage and better CNS penetration than gentamicin; however, it should be used judiciously. In a retrospective analysis of treatment of neonatal sepsis, use of third generation cephalosporins was associated with increased risk of fungal sepsis as well as...
increased risk of death. Resistance to cephalosporins can be induced and is not always apparent during in vitro lab testing.\textsuperscript{29,30} Ceftiraxone is not recommended for neonatal sepsis as it can displace bilirubin from albumin, increasing the possibility of kernicterus. Furthermore, there have been reports of calcium-ceftiraxone precipitate in patients who have had calcium and ceftiraxone administered within 48 hours of one another.\textsuperscript{25,31}

**Recommended Algorithm**

The CDC recommendations published in 2010 stress the importance of evaluation and empiric treatment of EOS; however, they do not comment on when it is appropriate to discontinue antibiotic therapy.\textsuperscript{11} The AAP COFN also published recommendations in 2012 which stated discontinuation of antibiotics “at 48 hours in clinical situations in which the probability of sepsis is low.”\textsuperscript{19,32} Some report that these recommendations have led to a large number of infants with little or no clinical signs of infection being treated with prolonged antibiotics based on abnormal inflammatory markers and CBC parameters. They argue that this treatment philosophy leads to over treatment of otherwise healthy neonates exposing them to known side effects of antibiotics as well as invasive procedures (central venous catheters, LPs, etc.). Kiser did a single center retrospective review of patients treated with prolonged antibiotics based solely on results of both CBCs and CRPs. This retrospective review found that 20 percent of infants undergoing a rule out sepsis work-up were treated with prolonged antibiotics and received lumbar puncture based only on abnormal laboratory values.\textsuperscript{33} This caused a revision of the COFN recommendations in 2014 which reiterate that “physical examination is as good or better than most laboratory tests in ‘ruling in or ruling out’ sepsis,” and “antibiotics may be discontinued in well appearing term newborn infants born to women with chorioamnionitis by 48 hours of life.”\textsuperscript{33}

The lack of a standard definition of EOS and the equivocal nature of lab tests in delineating who is and who is not at risk of disease makes formulation of a standard clinical practice in this area cumbersome. As recommended in the AAP policy statement in 2012, neonates who show clinical signs of sepsis and thus are not considered healthy and physiologically stable outside of the four-hour transitional period should be transported for evaluation and treatment with antibiotics to a level II (special care nursery) or level III (NICU).\textsuperscript{14}\textsuperscript{A} A review of the literature suggests a reasonable approach for when it is safe to discontinue antibiotics:

If clinical signs of infection are either transient or absent, and lab studies are drawn based on risk factors, either two normal CBCs or two normal CRPs in the first 48 hours with a negative blood culture can justify discontinuation of antibiotics after 48 to 72 hours of observation.

If clinical signs of infection are either transient or absent and lab studies drawn demonstrate both abnormal CBCs and abnormal CRPs which do not normalize, then a LP with prolonged antibiotic course may be warranted.

If clinical signs of infection persist for more than 24 hours, LP should be performed and antibiotic treatment should continue for at least seven days.

If findings on LP are suggestive of meningitis, a minimum of 14 days of antibiotic treatment is recommended.\textsuperscript{8}

Of course, clinical judgment of the physician when dealing with individual cases is most important when making treatment decisions for these vulnerable patients.

References


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Acknowledgement: The authors would like to thank Dr. Larry Wellman for mentoring this project.
How Low Can You Go? What Can We Take From the SPRINT Trial

By William Hayes, PharmD, BCACP; and James Clem, PharmD

Blood pressure targets have been debated for a long time and will likely continue to be for the foreseeable future. Observational data indicates a progressive increase in cardiovascular risk as systolic blood pressure rises above 115 mm Hg, but randomized, controlled trial data is lacking in the general population and for targets this low. Randomized, controlled trials have found benefits in achieving a blood pressure goal of less than 150 mm Hg, but data is limited concerning lower blood pressure targets and some trials indicate potential adverse effects. Benefits of treating hypertension include lowering the risk of cardiovascular disease outcomes, including stroke (35 to 40 percent), myocardial infarction (15 to 25 percent) and heart failure (64 percent). Data is limited on the potential benefits or risks of blood pressure targets of 110/70 mm Hg or lower. The J-shaped curve hypothesis would suggest potential risks of aggressively lowering blood pressure beyond 110/70 mm Hg, thus determining the optimal target for systolic blood pressure lowering has remained elusive. Blood pressure targets in patients with comorbid conditions, such as type 2 diabetes mellitus or history of a stroke have been reported in the literature, but data is limited in those without these comorbid conditions. This article will summarize the findings of the Systolic Blood Pressure Intervention Trial (SPRINT) and identify implications for our patients.

Recent evidence from the SPRINT trial has provided additional clinical evidence of blood pressure target goals in an at risk patient population. The SPRINT trial focused on patients with hypertension who were at a high risk of developing cardiovascular events. However, it is important to note that this trial excluded diabetic patients. Based on recently published guidelines, the target systolic blood pressure goal for this patient population is less than 150 mm Hg. Subjects in the SPRINT trial were randomized to a systolic blood pressure goal of less than 140 mm Hg (standard treatment) or less than 120 mm Hg (intensive treatment). The trial was open label and any standard antihypertensive medication could be utilized to reach the appropriate systolic blood pressure goal. Subjects’ systolic blood pressure was assessed monthly for three months, then every three months for the duration of the trial. The primary outcome was the development of a composite cardiovascular outcome consisting of myocardial infarction, acute coronary syndrome without myocardial infarction, acute heart failure, stroke, or cardiovascular death. A major secondary outcomes included death from any cause.

The SPRINT trial was stopped early due to the significant differences in trial outcomes noted in the early evaluation by the data and safety monitoring board. The primary outcome event rate (cardiovascular events) with the standard treatment group was 2.19 percent compared to a lower event rate of 1.65 percent with the intensive treatment group, which was statistically different (p-value < 0.001). Differences were also seen in mortality outcomes. There were 210 deaths in the standard treatment group after two years of treatment compared to 155 deaths in the intensive treatment group, which was statistically significant (p-value = 0.003).

Although significant benefits were demonstrated with intensive treatment compared to standard treatment, there were some statistically significant differences with adverse events. Not surprisingly, hypotension and syncope were significantly higher in the intensive treatment group compared to the standard treatment groups. However, this did not lead to any differences between the two treatment groups when it came to injurious falls which the trial defined as a fall requiring medical treatment. Electrolyte abnormalities (hazard ratio 1.38, p-value = 0.006) and acute kidney injury or kidney failure (hazard ratio 1.71, p-value < 0.001) were also statistically significantly higher in the intensive treatment group compared to the standard treatment group.

Based on the results of the SPRINT trial, it is apparent that the lower systolic blood pressure goal of less than 120 mm Hg had a positive impact on cardiovascular outcomes in those at risk for cardiovascular events. Implementation of a more intensive treatment approach for elevated systolic blood pressure in patients at high risk for cardiovascular events will require a more extensive monitoring plan for potential adverse effects to achieve an optimal outcome. The optimal blood pressure goal in hypertension management remains unknown, and will likely continue to be modified based on trial results.

REFERENCES

Please note: Due to limited space, we are unable to list all references. You may contact South Dakota Medicine at 605.336.1965 for a complete listing.

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On average, smokers with serious mental illness will die 25 years sooner than people in the general public.

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Remember...
Ask. Advise. Refer.
Dear DAKOTACARE Provider,

I am sure you are aware of the advancements in genetic testing over the past few years. We have certainly noticed an upswing in the type and volume of genomic-based tests being ordered for DAKOTACARE members. This is an exciting time in medicine; however it is also fraught with confusion for patients, physicians, and payers as we work to determine which tests have true clinical applicability and provide meaningful information for patients.

As a way to help us provide the best value for DAKOTACARE members, we have made the decision to require genetic counseling prior to the ordering of BRCA 1 and 2 testing effective Jan. 1, 2016. The primary intent of this mandate is to insure that all of our members are fully counseled as to their specific risk of breast and/or ovarian cancer before any testing is initiated. We also want to make sure members are aware of the various testing options available and their costs. We do not cover this test in certain situations (our coverage policy follows NCCN guidelines), and unfortunately this has resulted in some members being burdened with the financial responsibility for tests that are noncovered because the ordering provider was not aware of current national guidelines.

Our coverage policies have historically included a strong recommendation of genetic counseling prior to ordering select genetic tests; the only change is we are now requiring this additional step. We understand there are not genetic counselors located in many parts of the DAKOTACARE network. Because of this challenge, we have been working in Sioux Falls with both Avera and Sanford genetic counselors and have received assurances both institutions have the capacity to handle the increased volume from our members (either face-to-face or via telemedicine capabilities).

We are planning to expand required genetic counseling in the future for other genetic tests available to you and our members; we will inform you further when that occurs. If you have questions regarding this new requirement, or any genetic coverage policy, please contact one of us at 605.334.4000.

Respectfully,

E. Paul Amundson, M.D.  
Chief Medical Officer

Scott Jamison  
Senior Director, Provider Relations

“DAKOTACARE Update” is a monthly feature sponsored by DAKOTACARE. For more information about DAKOTACARE, visit www.dakotacare.com
A 92-year-old retired college professor patient of mine, who seems significantly younger than his stated age, walks a mile and half every day. He said to me on his own one time, "When you exercise every day, you feel so much better. Why don't people do it?"

I think part of the problem is that getting started hurts a little, but maybe it is also because our motives are misplaced.

In a recent study of more than 10,000 middle aged-to-older men over a 12-year period of time, researchers discovered that weight training helped reduce abdominal fat while aerobic exercise did best with overall weight control. Their conclusion: a combination of weight training and aerobic exercise makes a person look best.

What I did not like about that research was, once again, a study seemed to speak to appearance, how the person looks in the mirror, rather than quality of life.

In this colder, darker, wintertime, after-holiday season, as the New Year begins, we find ourselves reassessing the errors of the past and making resolutions to change. After a year of inactivity and a month of holiday treats and celebration, too many of us resolve, "I have to lose weight."

And during this season, almost every magazine advertises methods to lose weight and "look better" with a pill or a supplement, or an easy trick. Not only are these profit-driven dishonest scams playing on our desires to be something we are not, the real truth is they don’t work. Even legitimate plans for eating correctly and exercising reasonably are destined to cause sustained weight loss in only a very few (less than 10 percent over one year, less than 1 percent over five.) Indeed if it is your intent simply to lose weight, you are destined to be disappointed.

Of course it is important to eat a balanced diet, avoiding excessive quantities, especially empty carbohydrates. But our goal should be to feel better and be healthier, rather than simply to look thinner, and I think the key to this treasure is with exercise.

To that end, all of us should make a New Year’s resolution to get started. Every day should not end without about 30 minutes of exercise of some kind. Start with a walk.

Dr. Rick Holm wrote this Prairie Doc Perspective for “On Call,” a weekly program where medical professionals discuss health concerns for the general public. “On Call” is produced by the Healing Words Foundation in association with the South Dakota State University Journalism Department. “On Call” airs Thursdays on South Dakota Public Broadcasting Television at 7 p.m. Central, 6 p.m. Mountain. Visit us at OnCallTelevision.com.

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- Protects the health and welfare of the state’s citizens by ensuring that qualified medical health care professionals are licensed to practice in South Dakota

- Licenses and regulates over 9,000 licenses within fourteen different medical categories

- Co-regulates medical professions with the Board of Nursing

- Establishes regulations by proposing legislation and adopting administrative rules

- Supports and promotes the Health Professionals Assistance Program that monitors the recovery and/or rehabilitation of impaired healthcare providers

Deborah K. Bowman
Mary S. Carpenter, MD
David K. Erickson, MD
Laurie B. Landeen, MD
David E. Lust, JD
Jeffrey A. Murray, MD

Board News is a monthly feature sponsored by the South Dakota Board of Medical and Osteopathic Examiners. For more information, contact the Board at SDBMEOE@state.sd.us or write to SDBMEOE, 101 N. Main Avenue, Suite 301, Sioux Falls, SD 57104.
The passage of the Medicare Access and CHIP Reauthorization Act (MACRA) earlier this year permanently repealed the sustainable growth formula (SGR) and received considerable acknowledgement for ending a long standing battle over this threat to physician Medicare Part B reimbursement. Though not widely discussed at that time, there were significant changes to future fee for service (FFS) payments for physicians contained in that bill. Beginning in 2019, physicians will have the option of participating in a modified FFS program known as the Merit Based Incentive Payment System (MIPS). Another choice would be to switch to an alternative payment model (APM) based on some degree of financial risk. Entities such as accountable care organizations or bundled payment systems would be in this category.

In the meantime, there remains a rather complex and complicated Medicare quality reporting system that has evolved over time and affected reimbursement. The Physician Quality Reporting System (PQRS) and the Value Based Payment Modifier (VBPM) in addition to the Meaningful Use (MU) program have placed a huge burden on physician practices to stay abreast of Centers for Medicare and Medicaid Services (CMS) reimbursement requirements in order to avoid a decrease in FFS payment. What was once a potential bonus is now often required to prevent financial penalty. To further confuse the issue, there are numerous models of physician billing status such as provider based clinics, rural health clinics, and federally qualified health centers that are reimbursed at different rates with variable requirements for quality reporting. Add in other factors such as the requirements of assorted private payers, ICD-10 and electronic health record (EHR) interoperability and the process becomes even more confounding.

Though the MACRA legislation does not eliminate fee-for-service, those practices who remain in that system will face flat reimbursement rates beginning in 2019. In addition the PQRS, VBPM and MU will all be combined to a single entity noted above as MIPS and it will be based on such factors as measurable quality, EHR and resource use as well as quality improvement activity. Another area to be aware of is the increasing public transparency of physician information. The Physician Compare website continues to evolve as a source of publically available data. The Quality Utilization and Resource Report is a confidential data source that can provide a form of a “report card” to compare the quality and costs of care that physicians provide to Medicare patients in comparison with other physicians. The information from this source will be used to calculate a practice’s VBPM in 2016 in groups with more than 10 physicians thereby affecting payment.

CMS has set goals for FFS and has challenged private sector payers to match or exceed them:

- **Goal 1:** 30 percent of Medicare payments tied to quality or value through alternative payment models by the end of 2016, and 50 percent by the end of 2018.
- **Goal 2:** 85 percent of all Medicare FFS payments are tied to quality or value by the end of 2016 and 90 percent by the end of 2018.

How this will transpire in our state remains to be determined given our rural status and limited number of providers, but given the national emphasis, it will sooner or later affect a significant number of South Dakota physicians.

Resources for supporting providers through this process will expand over the coming years. Projects such as the Transformation for Clinical Practice Initiative will assist a number of practices in our state in dealing with change. Increasing access, decreasing costs, and improving outcomes are common goals. Concepts such as care transition, patient safety, and data reporting will require a significant collaborative effort to adapt to these physician payment changes.
### UNITED STATES SENATORS

**MIKE ROUND**S (R)
- **Office:** 502 Hart Senate Office Building
- **Washington, DC:** 20510
- **Phone:** (202) 224-5842
- **Website:** rounds.senate.gov

**JOHN THUNE** (R)
- **Office:** 511 Dirksen Senate Office Building
- **Washington, DC:** 20510
- **Phone:** (202) 224-2321
- **Website:** thune.senate.gov

### UNITED STATES REPRESENTATIVE

**KRISTI NOEM** (R)
- **Office:** 2422 Rayburn House Office Building
- **Washington, DC:** 20515
- **Phone:** (202) 225-2801
- **Website:** noem.house.gov

### SOUTH DAKOTA GOVERNOR

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- **Office:** State Capitol; 500 E. Capitol Avenue; Pierre, SD 57501
- **Phone:** (605) 773-3212
- **Website:** sd.gov/governor

### SOUTH DAKOTA LIEUTENANT GOVERNOR

**MATT MICHELS**
- **Office:** State Capitol; 500 E. Capitol Avenue; Pierre, SD 57501
- **Phone:** (605) 773-3661 • Fax: (605) 773-4711

### SOUTH DAKOTA SENATE

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  - **Majority Leader**
    - Sen. Cory Brown (R)
  - **Asst. Majority Leader**
    - Sen. Jim White (R)
  - **Majority Whips**
    - Sen. Alan Solano (R)
    - Sen. Ernie Otten (R)
    - Sen. Deb Soholt (R)
  - **Minority Leader**
    - Sen. Billie Sutton (D)
  - **Asst. Minority Leader**
    - Sen. Troy Heinert (D)
  - **Minority Whips**
    - Sen. Jim Peterson (D)
    - Sen. Scott Parsley (D)

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- Rep. Dean Wink (R)

**Speaker Pro Tempore**
- Rep. Mark Mickelson (R)

**Majority Leader**
- Rep. Brian Gosch (R)

All senators can be reached during the Legislative Session by calling the senate lobby at 605-773-3821. Email forms can be found at legis.sd.gov.

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<td>23, 28A, 28B</td>
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<tr>
<td>12</td>
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</tr>
</tbody>
</table>
In Memoriam 2015

Honoring physician members of the SDSMA who passed away in 2015

Dale A. Bergeron, MD
Donald W. Humphreys, MD
Bryce J. Iwerks, MD
Richard A. Kovarik, MD

Jeffrey M. Kowitz, MD
Karl A. Lustig, MD
Russell T. Orr, MD

Michael J. Schlosser, MD
Larry Sittner, MD
Karlis Zvejnieks, MD
For Your Benefit:

SDSM A Is Your Legislative Advocate

SDSM A’s legislative staff is your eyes, ears and voice in Pierre and Washington. We track hundreds of pieces of legislation that affect you, as well as coordinate opportunities for you to get involved in the process.

Do you want to be the Doctor of the Day during the South Dakota legislative session? How about a Physician Lobbyist? You can, and we can make it possible. Visit www.sdsm a.org.

There are more SDSM A benefits to tell you about, and you’ll hear about them in the months to come. In the meantime, if you’d like more information about our legislative services and advocacy programs, give us a call at 605.336.1965 or visit the SDSM A website at www.sdsm a.org.

Thank you for your membership in SDSM A.

*For Your Benefit “ is the SDSM A’s monthly update on programs and services available to physicians through their affiliation with the SDSM A.

SDSM A Center for Physician Resources

Practice Education Series on Risk Mitigation – March 8

The SDSM A Center for Physician Resources brings you its Practice Education Series on Risk Mitigation at 7 p.m. CT Tuesday, March 8 with the webinar “Apology and Communication in Medicine,” the third of five webinars in the series. To register for the webinar, find a link on the homepage calendar at www.sdsm a.org. The remaining programs in this series include the following:

- 7 p.m. CT March 8, 2016 - Apology and Communication in Medicine
- 7 p.m. CT June 14, 2016 - Anatomy of a Medical Malpractice Lawsuit
- 7 p.m. CT Sept. 13, 2016 - Physician Resiliency: Healing the Healer

This series will also provide key advice on the litigation process and how to get through a malpractice claim both personally and financially.

The USDSSOM designates this activity for a maximum of 1 AMA PRA Category 1 Credit(s). Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Source: SDSM A staff

Nominations Now Open for SDSM A Awards

Nominations for the 2016 SDSM A Awards are now being accepted. Each year the SDSM A recognizes physician members and supporters for their work to improve the practice of medicine in South Dakota by presenting four distinguished awards at the SDSM A Annual Meeting.

Please consider nominating a colleague or supporter who is deserving of recognition for his or her work. They may work right alongside of you, or serve on a committee with you, or volunteer in your organization or community, or maybe they are your mentor. Through these awards, the SDSM A strives to encourage and recognize the highest standards of service, and give recognition to the accomplishments and dedication of our members and supporters of the medical profession and citizens of South Dakota.

The SDSM A is seeking award nominations for the following awards: Distinguished Service Award, Community Service Award, Young at Heart Award, Outstanding Young Physician Award, and Media Award. The nominations deadline is Feb. 1.

Visit www.sdsm a.org review the awards nomination information, award categories, and to complete an awards nomination form.

Those with questions about the nomination or awards process may contact Laura Olson at 605.336.1965 or lolson@sdsm a.org.

Source: SDSM A staff
Noem Signs on as Sponsor of Meaningful Use Hardship Relief Act

Rep. Kristi Noem has signed on to legislation that would grant relief to physicians and providers from the 2015 Meaningful Use program. The Meaningful Use Hardship Relief Act of 2015, or H.R. 3940, would grant the Centers for Medicare and Medicaid Services (CMS) the authority to grant blanket hardship exceptions to physicians, hospitals and other affected providers for 2015. The SDSMA strongly supports this legislation.

In order to avoid a penalty under the Meaningful Use program, eligible professionals must attest that they met the requirements for Meaningful Use Stage 2 for a period of 90 consecutive days during calendar year 2015. However, CMS did not publish the modifications rule for Stage 2 of Meaningful Use until Oct. 16, 2015 – meaning that by the time eligible professionals were informed of the requirements, fewer than the 90 required days for reporting remained in the calendar year, allowing no time to upgrade systems and change workflows to meet the new program measures in 2015.

CMS has acknowledged this and has said that eligible entities may apply for a hardship exemption if they are unable to attest due to the lateness of the rule. They have also announced that they will broadly grant these exceptions for 2015. However, the statute requires that hardship exemptions be granted on a case-by-case basis only. This means that hundreds of thousands of eligible professionals will be required to apply for exemptions and that CMS will be required to act on each application individually. H.R. 3940 would allow for an expedited hardship exemption process for participants for the year 2015 and grant CMS the authority to grant blanket hardship exceptions to physicians, hospitals and other affected providers for 2015.

Source: AMA

“The Issue Is” is the SDSMA’s monthly update on key policy issues of importance to physicians.

Legal Brief Highlight: Corporate Practice of Medicine

Physicians may form corporations or limited liability companies to own and operate their practices or clinics. Corporations, limited liability companies (LLC), and similar entities – the officers, directors, and shareholders of which are not physicians – may not engage in the practice of medicine. They may, however, contract with physicians to provide medical services under certain circumstances.

Corporations and limited liability companies that aren’t owned by physicians cannot practice medicine. It is not considered the unauthorized practice of medicine, however, if a non-physician owned corporation enters into employment contracts with physicians that don’t interfere with the physician’s professional judgment. A non-physician owned corporation or LLC may enter into employment contracts with physicians that do not: 1) affect the physician’s independent judgment concerning the diagnosis and treatment of patients; 2) result in profit to the corporation from the practice of medicine itself, such as charging a greater fee than the physician could reasonably charge; and 3) have a term longer than three years (after which they may be renewed annually by mutual consent). A physician-owned medical corporation or LLC must be registered with the Board of Medical and Osteopathic Examiners.

For more information, download the SDSMA legal brief Corporate Practice of Medicine at www.sdsma.org. Through the SDSMA Center for Physician Resources, the SDSMA has developed more than 40 legal briefs that are available to members. In addition, the Center develops and delivers programs for members in the area of practice management, leadership and health and wellness.

Source: SDSMA staff
AMA Delegate Report: Interim Meeting 2015

Members of the South Dakota State Medical Association (SDSMA) and the SDSMA Medical Student Section attended the American Medical Association (AMA) Interim Meeting in Atlanta Nov. 14-17 with hundreds of others from across the country. The gathering was filled with activities and policy debate that will help shape the future of health care.

Some highlights include the following:

**EHRs**

The burden of meaningful use regulations and the associated problems with electronic health record (EHR) technology has plagued physicians for far too long. Physicians took action with the goal of removing these hindrances to physicians’ ability to provide quality care to patients. For example, policy was adopted concerning shortcomings in EHR interoperability. The meaningful use program offers powerful financial incentives and disincentives for physicians but does not do so for EHR vendors.

**Fairness in Drug Prices and Availability**

In response to increasing drug costs impacting patient access to needed medications, physicians voted to convene a task force and launch an advocacy campaign to drive solutions and help make prescription drugs more affordable.

**Solutions to Antibiotic Resistance**

The Centers for Disease Control and Prevention (CDC) estimates that 2 million U.S. illnesses and 23,000 deaths each year are caused by antibiotic-resistant infections, and these result in an estimated $20 billion in excess health care costs. A major factor in the growing problem of antibiotic-resistant infections is overuse of antibiotics. Three CDC experts spoke to physicians about this global health crisis and solutions to address it.

**Physicians in Training – Stopping Burnout**

As burnout and suicide continue to plague the medical profession at much higher rates than the general population, the physician community took action with new policy aimed at ensuring physicians in training have access to mental health services.

**Leadership Skill Sets**

Physicians have a strong history of leadership within their communities. When health concerns arise, the public turns to their doctors for answers. The AMA’s new Leadership Skills Series provides practical training for practicing physicians. Physicians who get involved improve their ability to lead. In addition, the SDSMA will begin offering leadership training in 2016 through the SDSMA Center for Physician Resources Health Leadership Institute.

Respectfully submitted by SDSMA delegates to the AMA Mary S. Carpenter, MD, and Herbert A. Saloum, MD
## CME Events

Continuing Medical Education events which are being held throughout the United States (Category 1 CME credit available as listed)

### January 2016

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>AMA PRA Category 1 Credit(s)™ available</th>
<th>Register online:</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 5</td>
<td>SDSMA Center for Physician Resources Practice Education Series on Physician Employment – Understanding an Employment Contract – Overview</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 6</td>
<td>Internal Medicine Grand Rounds – What you Need to Know About Cancer Immunotherapy</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 6</td>
<td>Surgery Grand Rounds – Updates on Vascular Surgery</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 7</td>
<td>Pediatric Grand Rounds – Liver Cases for the Primary Care Provider</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 12</td>
<td>VA Medical Center CME Activity – Acute CVA</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 13</td>
<td>Dermatopathology Conference</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 13</td>
<td>Internal Medicine Grand Rounds – New Technologies in Cardiology</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 20</td>
<td>Internal Medicine Grand Rounds – ICD-10</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
<tr>
<td>January 21</td>
<td>Pediatric Grand Rounds – ECMO: Past, President, and Future</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
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<tr>
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<tr>
<td>January 28</td>
<td>Pediatric Grand Rounds</td>
<td>available</td>
<td>usdssom.learningexpressce.com</td>
</tr>
</tbody>
</table>

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**DO YOU HAVE A CME EVENT COMING UP? WOULD YOU LIKE TO HAVE IT LISTED HERE?**

Contact: Elizabeth Reiss, South Dakota Medicine, 2600 W. 49th Street, Suite 200, Sioux Falls, SD 57105
Phone: 605.336.1965
Fax: 605.274.3274
Email: ereiss@sdsma.org

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Heather Peck, MD
Jenny Starks, PA
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The American Medical Association Economic Impact Study, completed in conjunction with the South Dakota State Medical Association, shows how much physicians add to the economic health of South Dakota.

Check the effect physicians have on the U.S. economy by viewing the national report from the AMA, as well as highlights from the South Dakota study, at ama-assn.org/go/eis.
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