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I wish I had a dollar for every time I was told to “hold still” when I was a kid. I also wish I had a dollar for every time I’ve been asked if I was Dr. Rinderknecht’s son! I’d be retired if I got paid for either scenario! But you know, growing up is HARD! We had a lot to deal with...riding our bikes, climbing trees, playing basketball all day, playing tackle football in a friend’s front yard, and, of course, going to the pool. Atari 2600 was just coming to a house near you and there were no smart phones to occupy our time and thoughts.

But back to the words I heard over and over so many times... “Reed, HOLD STILL!”

I can’t help but smile when I think about running downstairs from my attic bedroom on a Saturday morning about 6 AM to crawl into my parent’s bed for a few minutes of cuddle time before turning on the cartoons and watching a little “Superfriends” or “Speed-Racer.” Being the parent of two amazing kids, I now understand how exhausted my own parents must have been from a long week of working and maintaining a busy household of three kids. I’m certain they were praying all of us would sleep in past 7 AM on Saturday morning. I loved getting that extra precious hour of sleep, but it didn’t happen very often!

For most investors, “holding still” is equally as difficult as it was for a six-year-old that jumped into his parent’s bed on a cold Saturday morning. Investors tend to want to wiggle...a lot! In my 21 years of being in the financial planning and investment management business, this is one of the biggest mistakes I’ve seen people make. Usually, investors want to “wiggle” the most when things get a little uncertain and crazy. The market has a way to discipline most of these wiggles that also isn’t very fun to endure. Jumping in or out or up and down usually only proves that no one can predict the future and we worried a lot about normal volatility. Markets go up roughly 70% of the time and down about 30% of the time... (Hint: that’s good, if you can resist wigging too much!) The best way for all of us to have a higher probability of long-term success is to do these five things:

1. Make sure you understand what your money needs to do for you to achieve your goals
2. Have a written Investment Policy Statement and consistently execute that strategy
3. Have a plan on what/how you’ll respond when (not if) things get crazy
4. Review your financial planning and investment policy regularly with your financial advisor
5. Don’t sweat the day-to-day craziness, and get out there and enjoy life!

*Source: Dimensional Fund Advisors – *Performance of the Premium*
Earlier this year I met an old friend at a Hand Society meeting in Denver. He practices Orthopedic surgery in Summit County, Colorado. He asked me if I had any retirement plans (he is a few years younger than me). I told him that I hadn’t thought much about it and that I still like taking care of patients. Peter told me that he also likes working but all “the other stuff” drives him crazy. We commiserated about our respective electronic medical records (EMR) and how the EMR is number 1 on his “the other stuff” list. (Sound familiar?) He is not alone. Several of my friends have retired recently for the same reason.

What is Burnout? Burnout is characterized by exhaustion, cynicism, and reduced effectiveness. It has been shown to influence patient care, patient safety, physician turnover, and patient satisfaction. Burnout also leads to broken relationships, alcohol use and suicidal ideation.1,2

Who is Affected? In a recent study from the Mayo Clinic and the American Medical Association, approximately 50 percent of physicians in the U.S. are suffering from some degree of burnout. This has increased approximately 10 percent from a previous survey done in 2010.3 All specialties are affected with the primary care specialties (family practice, internal medicine, pediatrics and emergency medicine) having the highest rates of burnout.4 In that same study, after adjusting for physician age, sex, specialty, practice setting and hours worked, physicians who used EMRs and computerized physician order entry (CPOE) were less satisfied with the amount of time spent on clerical tasks and were at higher risk for professional burnout.5 In that study, after adjusting for physician age, sex, specialty, practice setting and hours worked, physicians who used EMRs and computerized physician order entry (CPOE) were less satisfied with the amount of time spent on clerical tasks and were at higher risk for professional burnout.6,7 Burnout has also been reported in medical students, residents and residency program directors.8-6

What are the Causes? The reasons for burnout are variable and complex. Some physicians feel that the widespread use of EHR, electronic prescribing, electronic patient portals, and CPOE has led to information overload, interruption/distraction, and a dramatic change in the content of professional work.9 A 2015 study showed that high-stress environments (odds ratio, 13.7) and poor work control (odds ratio, 4.3) correlated with high burnout rates. The factors include chaotic clinical environments, insufficient time for documentation and use of EHR at home, short visits for complex patients, organizational ambivalence toward physician support and a need for work-life balance.9 Sinsky et al. reported on a time and motion study in four specialty practices (family medicine, internal medicine, cardiology and orthopedic surgery). During office hours, physicians spent 27 percent of their time in direct clinical face time with patients and 49.2 percent of their time on the EHR and desk work. With patients in the exam room, physicians spent 52.9 percent of their time on direct clinical face time and 37 percent on EHR and desk work. Twenty-one physicians completed an after-hours diary and reported an additional one to two hours of after-hours work each night, devoted mostly to EHR tasks.10

A recent article described a surge in “desktop” medicine (practicing medicine on your desktop computer). The authors studied physicians’ time spent with EHR transactions. Thirty-one million EHR transactions were recorded for 471 primary care physicians who were involved with 765,129 visits. The physicians logged an average of 3.08 hours on office visits and 3.17 hours on desktop medicine every day; 34 percent of the logged time was spent doing progress notes.11

A recent paper in Clinical Orthopedics and Related Research entitled “Clinical faceoff: physician burnout – fact, fantasy, or the fourth component of the triple aim” discusses physician burnout. One of the phrases used in the article is “the triple aim,” which suggests a redesign of the health care delivery system to do the following: improve patient outcomes, increase patient satisfaction, and decrease overall cost. The authors suggest adding a fourth component to the triple aim: provider well-being. The most crucial cog in transforming health care is the practitioner, without whom the delivery of care is impossible. With the dramatic changes in health care today, the effect on health care providers has been largely ignored. If the system is transforming for the better, why are we seeing an epidemic of early physician retirements, career changes, and burnout?2 There are many suggestions on what to do but these are not easy for physicians to accomplish. Because of the relationship between distress and the quality of care, we first need to promote physician well-being.2 We will discuss possible solutions in next month’s editorial.

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.

President’s Comments

Physician Burnout: How Are You Doing?

By Robert E. Van Demark, Jr., MD
SDSMA President

October 2017
INFORM YOUR PATIENTS

1 Before ONE Month of Age: Hearing Screening

3 Before THREE Months of Age: Hearing Evaluation

6 Before SIX Months of Age: Early Intervention

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For information contact Haifa A. Samra at Haifa.abousamra@usd.edu or Jessica Messersmith at Jessica.messersmith@usd.edu
The Impact of the Opioid Epidemic and Overcoming Addiction

By Malia Holbeck, LCSW, LAC

The opioid epidemic has recently been a popular topic which has led people to question how opioid use impacts people’s lives and how addiction can be overcome. Many individuals have used opioids with no negative consequence. However, because opioids are highly habit-forming, many have found themselves addicted to their medications. Not only has there been an increase in the number of people becoming addicted to opioids but also the number of overdoses continues to rise at an alarming rate. According to the Centers for Disease Control and Prevention (CDC), over 1,000 people are treated in emergency departments for misusing prescription opioids every day. The CDC reports that in 2015, the highest rates of opioid overdose was among people aged 25-54 years.1

Not everyone that takes an opioid will become addicted. Because no one person is the same, there is no specific amount of usage or a defining moment when someone will become addicted. However, there are many risk factors that will increase the possibly of becoming addicted. First, prolonged daily use and/or misuse of the drug places an individual at higher risk. Additional risk factors include having a family history of addiction, having started to use substances at an early age, growing up in an environment where substance abuse was present and being male.

There are many warning signs of addiction. With addiction, the individual will experience negative consequences that impact their life and even the lives of people around them. Their use will impact their relationships, employment, finances, legal involvement, health and emotional wellbeing. With addiction, an individual will find that they have been using for a longer period of time than intended and are unable to cut down/quit their use. Individuals may use to self-medicate or as a way to escape. They abandon important social and job commitments. They may be preoccupied with the drug are dishonest or defensive about their use or isolate themselves. Additionally, changes in mental health status including increased anxiety, depression, irritability and a lack of energy/motivation. Withdrawal is also a warning sign of addiction. Withdrawal from opioids can be rather uncomfortable and could require medical assistance. Often times, the individual will continue to use to avoid the misery of withdrawal which often fuels development of addiction. Once addicted to a drug, one can continue to experience cravings for months and even years after their last use. In addition, symptoms of anxiety and depression can continue during abstinence and challenge one’s recovery. Bottom line, addiction robs people of the things that are important to them and they may never get those things back.

Fortunately, there are a variety of options available for someone to successfully overcome the grasp of addiction. The first step is to complete a chemical dependency evaluation with a licensed addiction counselor. The chemical dependency evaluation will help the licensed addiction counselor to determine the severity of the problem and provide appropriate treatment recommendations. Treatment recommendations can include inpatient treatment, outpatient treatment or individual counseling. An additional option is to work with a physician that practices medicine assisted treatment (MAT). Medications used in MAT include buprenorphine, naloxone, naltrexone and methadone. Each of these medications works differently. Choosing the right medication can depend on the severity of the addiction, history of use and the long-term goal. Individuals can increase their success with an MAT approach in conjunction with supportive counseling or addiction treatment.

In most communities, recovery support groups and peer sponsorship is also available. Community support groups are a great option to utilize in addition to participation in a treatment program and also as on-going continued support. Some communities have programs that offer monitoring programs that include case management and drug screenings to assist individuals with maintaining sobriety through accountability and support.

Opioids not only have ruined people’s lives but also have taken the lives of many. Individuals using opioids can quickly develop an addiction resulting in many negative consequences. Fortunately, there is help available to successfully manage their addiction and live a fulfilling life. The opioid epidemic will challenge the health care field to develop safer approaches to treating pain. This offers a sense of hope for individuals and family members that are suffering because of opioids.

REFERENCES

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October 2017 437
OUR WORK IS SAVING LIVES BECAUSE OF PARTNERS LIKE YOU.

By telling your patients about the **All Women Count!** Program, more women are here today, and will be long into the future.

---

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Last year I lost my full-time job, when it came time for this year’s appointment, I felt the additional stress of having a huge medical bill and the chance of a cancer diagnosis. It was your program that helped me worry less and get the care I needed.

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Vicki

AWC! Participant

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Assessing HPV and Cervical Knowledge, Preference and HPV Status Among Urban American Indian Women

By Kristin R. Cina, BS; Adam A. Omidpanah, MS; and Daniel G. Peteriet, MD, FASSTRO

Abstract

Introduction: To evaluate whether or not an educational intervention would lead to a change in knowledge and attitudes about human papillomavirus (HPV), HPV vaccines, and cervical cancer. The HPV status was also investigated for interested participants.

Methods: We provided HPV and cervical cancer education to urban American Indian (AI) women 18 and older using a pre and post-knowledge exam to assess knowledge and attitudes. Women were also given the option to perform vaginal self-tests for high risk HPV (hrHPV) analysis immediately after the education.

Results: Ninety-six women participated in our educational sessions. Improvement in performance on a knowledge exam increased from 61.6 to 84.3 percent (p<0.001). Ninety-three women performed the vaginal self-test with 63.1 percent of women preferring vaginal self-testing over conventional screening methods. Thirty-five out of 91 women (38.5 percent) had hrHPV types with 12 of the 35 harboring multiple hrHPV types (13 percent overall).

Conclusion: HPV and cervical cancer education was beneficial for urban AI women with the majority of women preferring vaginal self-testing. HPV self-testing may be a strategy to improve screening rates for cervical cancer. Urban AI women had high rates of hrHPV compared to rural AI populations as reported in previous studies.

Introduction

Cervical cancer is relatively uncommon in the U.S. with an estimated incidence of 12,990 in 2016. The mortality rate ranges between 30-50 percent and is higher for underserved populations such as American Indians (AIs). One study reported cervical cancer mortality rates were highest among Northern Plains AI women compared to white women for all age groups. Cervical cancer is detectable by screening and potentially preventable with vaccination. Furthermore, advanced stages are still curable if appropriate radiation doses are delivered with a combination of chemotherapy, external beam radiation and brachytherapy.

Infection by human papillomavirus (HPV) – especially high risk strains 16, 18, 31, and 33 – causes cervical cancer with a typical latency period of 10 to 30 years. Most women clear the virus and do not develop cervical cancer. Primary prevention with vaccines may prevent the majority of HPV induced cancers involving the ano-genital and oropharyngeal regions.

Barriers to cervical cancer screening are well documented, and may partially be overcome through vaginal self-sampling. Previous studies indicate self-collected samples are as sensitive as clinician-collected samples for detecting HPV infections.

To address the lack of knowledge about cervical cancer and low rates of screening that were observed for AI women presenting with advanced cervical cancer in our region, we tested whether an educational intervention would improve knowledge about HPV, HPV vaccines, cervical cancer, and, potentially, influence attitudes...
towards HPV. Women were given the option to perform vaginal self-tests on site for high risk HPV (hrHPV) analysis and asked about their preference and satisfaction with self-testing.

Materials and Methods
Setting
The study was conducted in Rapid City, South Dakota, and was approved by our local institutional review board (IRB). A total of four educational workshops were conducted at various locations frequented by AI women including a community center and a church. Each workshop lasted an average of two hours and included informed consent, pre-knowledge assessment, educational presentation, the option to complete a vaginal self-swab onsite and a post-knowledge assessment. The participants were given an incentive of $25 for completing the knowledge assessments, and an additional $50 if they completed the vaginal self-swab.

Several informational tables were displayed for participants to visit before and after the workshop including information about HPV, cervical cancer screening and breast cancer screening and treatment.

Participants
Participants were eligible to take part if they were female, over 18 and self-identified as AI. Initial recruitment of women into this study was challenging. Flyers were displayed in various locations throughout the city. The first scheduled workshop was attended by only six women, all of whom are involved in community health education for the AI population in Rapid City. Recruiting these women was invaluable as they promoted the workshops among community members in their network. We recruited a large number of participants from a community center that offers resources, meals, and a post office box. Additional locations for recruitment were daycares, a local basketball tournament, dry cleaners, bingo hall, shelters for men and women, Indian Health Service (IHS) hospital, local library, churches, the Boys Club, thrift stores, the tribal college, community health, and non-IHS physician offices.

Education Intervention
The education curriculum used was a combination of the “You Are the Key to HPV Cancer Prevention” through the Centers for Disease Control and Prevention’s (CDC) clinician continuing education and Native American Research Corporation’s “Get on the Path to Cervix Health” validated curriculum. Because the CDC curriculum was developed to target clinicians, the materials were modified so they were culturally appropriate for the AI population. Slides specifically targeting providers were removed, and the curriculum was combined with the “Get on the Path to Cervix Health” curriculum that is culturally appropriate. Culturally tailored wording and graphics were also included in the modified presentation. In addition, if there was any material that would have been culturally inappropriate to discuss in a large group, it was removed.

We developed and modified our knowledge assessment survey based upon validated tools from the American Cancer Society, Partnerships for Native Health as well as other sources. A list of 36 questions was developed by our research staff in collaboration with Partnerships for Native Health staff. The survey questions include demographics such as age, level of education, HPV and cancer history, health care access and tribal enrollment. The knowledge section of the survey included questions assessing cervical cancer knowledge and attitudes about screening access/barriers, causes, symptoms, screening guidelines, and follow-up for abnormal results. Also included were questions assessing HPV knowledge and attitudes about vaccination, transmission, risk factors, symptoms, testing and treatment. All participants were consented and given the survey before the educational event using an audience response system. After the educational workshop, they were given a follow-up survey to assess an improvement in knowledge and any attitude changes. All answers were anonymous but were linked for each individual. Following the workshop, participants were given the option to perform a vaginal self-swab test on site to determine the presence of hrHPV, and to determine their preference for screening methods.

HPV Assays
Instructions were given during the educational workshop on how to administer the HPV vaginal self-swab test. The HerSwab kits were donated from Eve Medical. Samples were stored and batch-shipped to the Molecular Diagnostics Laboratory of the University of Washington’s Pathology Department to test the following 37 hrHPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 40, 42, 45, 51, 52, 53, 54, 55, 56, 58, 59, 61, 62, 64, 66, 67, 68, 69, 70, 71, 72, 73, 82, 83, 84, CP6108, IS39 as described elsewhere. Results were recorded as positive or negative for hrHPV DNA, or unsatisfactory if negative for the gene HPRT1 (hypoxanthine phosphoribosyltransferase 1). All samples were destroyed at the University of Washington upon
completion of testing.

Results from the vaginal self-swab tests were mailed to participants. The results explained whether the participant’s cervical sample was positive or negative for an hrHPV strain. For those with a positive hrHPV result, the letter also explained that a positive strain put them at higher risk of developing cervical cancer and they were encouraged to see their primary care provider for a pelvic examination and Pap test. The letter to participants who were negative for a hrHPV strain also encouraged completing regular pelvic exams and Pap tests. Patients were also given a phone number to call if they had questions about their results.

Statistics

Summaries were calculated for demographic characteristics. Knowledge tests were scored with each item counting as a correct or incorrect response. Multiple response items were only counted as correct if only correct levels were endorsed and incorrect levels were not. Multilevel logistic regression models were used to fit proportions of correct responses. Exploratory analysis and variance component testing using ANOVA was used to determine specification of random effects. Paired t-tests were used to test differences in vaccine attitudes between baseline and follow-up.

Results

Ninety-six women participated in four educational sessions. Sixty-two percent of participants were 44 years of age or younger. Twenty-six percent of participants lacked a high-school diploma, although 22 percent were students. Fifty-seven percent of participants were unemployed and 22 percent were married. Twenty-one percent were non-smokers, 29 percent were former smokers and 49 percent were current smokers.

Thirteen percent of women self-reported a positive HPV diagnosis. The majority of women had a Pap test within the past three years. Most women underwent Pap tests at the appropriate time, but frequently described barriers to screening such as difficulty with scheduling times and conflicts, not wanting a male provider, and being afraid of receiving a “bad” result. Seven percent of women reported a personal history of cervical cancer and 24 percent had received at least one HPV vaccination.

Participants were scored for correct answers to the 36 item knowledge assessment at baseline and then at follow-up after the educational session. Proportions of correct responses were calculated for each participant and for each item. The average participant-level proportion correct at baseline was 61.7 percent (SD = 14.7%). Item-level proportion correct had a much larger standard deviation of 23.2 percent. These results both suggest presence of participant-level and item-level effects. Paired differences of participant and item level proportions of correct responses were taken between follow-up and baseline. The standard deviation of participant level differences was 12.3 percent. The standard deviation of item level differences was 19.3. This suggests presence of heterogeneity in intervention effects which may be handled with random slopes. ANOVAs for nested models showed significant effects for random intercepts and slopes by participant and item.

The odds ratio for correct responses at follow-up compared to baseline was 4.98 (95 percent CI: 3.45, 8.60) suggesting a very strong effect for the educational intervention. Baseline item-level proportion correct was greater than 90 percent for the Pap test’s ability to screen for HPV and the asymptomatic “window” for cervical cancer. Proportion correct increased the most in: items on cervical cancer risk factors of parity, smoking, and long-term birth control usage; effectiveness of HPV vaccination prior to first intercourse; and time of initiation of routine Pap screening. At follow-up, item-level proportion correct remained under 70 percent for: procedures to follow-up abnormal pap-tests; ability of HPV vaccine to prevent genital warts; inability of antibiotics to cure HPV; and that cervical cancer can be prevented by a vaccine.

Seventy-two percent of participants agreed the HPV vaccine was important. The point-average of responses increased by 0.07 at follow-up was not statistically significant. A large difference was noted in frequencies of participants who perceived the possible risks of HPV vaccine outweighed possible benefits. At baseline, 24.2 percent of women disagreed or strongly disagreed with the notion that risks outweighed benefits. At follow-up, 57.3 percent of women disagreed or strongly disagreed with this. The point-average of responses decreased by 1.11 (95 percent CI: 0.65, 1.57) which was statistically significant at the 0.05 level. Interestingly, the proportion of respondents who strongly agreed that risks of HPV vaccines outweigh possible benefits did not change from baseline to follow-up. Of the 11 percent of women who said they would not vaccinate their eligible son or daughter for HPV at baseline, only 5 percent reported the same at follow-up.
Only six women refused the self-swab test. The reasons included pregnancy and feeling it was unnecessary due to their age, as well as the invasive nature of the test. Ninety-three women performed the vaginal self-swab test with 59.3 percent reporting the vaginal self-swab was easy to use, and 57.3 percent reporting it was comfortable. About 63 percent preferred self-testing over conventional screening methods.

There was adequate DNA to determine the HPV status in all but two participants. Thirty-five out of 91 women (38.5 percent) had hrHPV strains (16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). Twelve of the 35 women had multiple hrHPV types (13 percent overall).

**Discussion**

We successfully recruited 96 urban AI women to participate in our cervical cancer knowledge assessment with 93 performing the vaginal self-swab with 38.5 percent harboring hrHPV strains. Participants had greater knowledge about HPV following the education workshop. This is one of the first studies to investigate vaginal self-sampling for hrHPV in urban AI women. Our premise was that AI women would prefer self-testing compared to conventional testing for cervical cancer. As in other studies, the majority of patients prefer self-collected samples to clinician collected ones.

The Food and Drug Administration approved HPV for primary screening for cervical cancer in 2014, with a colposcopy or Pap test as a confirmatory examination if patients were HPV positive. Because self-collected samples are as sensitive as clinician-collected samples, this may be an excellent strategy to increase cervical screening rates in vulnerable and hard to reach populations such as the AI population or those with limited health care access.

About 38 percent of women in our sample had hrHPV strains with 13 percent harboring multiple hrHPV types. This compares to 30 percent from a study conducted on the Rosebud and Pine Ridge Indian Reservations in South Dakota. The prevalence of hrHPV was three times higher than the non-AI women. In another study about 22 percent of Hopi women in Arizona had hrHPV strains and 4.6 percent had more than one high risk strain. In the largest study in the U.S., 29 percent of 4,150 women screened between 2003 and 2006 were positive for any hrHPV strain.

The first vaccine introduced in the U.S. was the quadrivalent vaccine Gardasil (Merck) in 2007, which protects against HPV types 6, 11, 16, and 18. In 2009, a bivalent vaccine, Cervarix was introduced by GlaxoSmithKline which protects against HPV types 16 and 18, with prescription information citing a post hoc analysis that showed efficacy against HPV-31 related CIN 2+ lesions. A nine-valent vaccine, Gardasil (Merck), was approved in 2014 and also covers HPV types 31, 33, 45, 52, and 58, which together account for 15 percent of cervical cancers.

In our study, 24 percent of women received at least one HPV vaccination. It is unlikely anyone received the nine-valent vaccine as it has been available for only two years. Furthermore, since the median age of our population was 44 and the quadrivalent vaccine has been available for nearly 10 years, no one in our study would have received vaccinations at the current recommendations between 10 and 12 years of age. The HPV bi-valent and quadrivalent vaccines were available to our participants but only covered four hrHPV types – two of which are known to cause 70 percent of cervical cancers (16 and 18). Of the 35 women who were positive for hrHPV strains, 27 (77 percent) had a hrHPV type not covered by either the bi-valent or quadrivalent vaccine. Furthermore, 17 (48.5 percent) of these women had an hrHPV type not covered by the nine-valent vaccine. Therefore, vaccinating all of these women in our study at the appropriate age - even if the nine-valent vaccine had been available – would not have prevented the emergence of many oncogenic HPV types. Nonetheless, the nine-valent vaccine may offer some cross protection against these other types. Although the efficacy of these vaccines should not be underestimated, a clear need exists for ongoing cervical cancer screening at the appropriate times. Similar findings were also reported among the AI population by Winer et al. and Bell et al.

After our educational program, 95 percent of women indicated they would vaccinate their son or daughter – an increase of 6 percent. Inoculating these children is critical to lower the development of HPV induced cervical cancer, ano-genital cancers, as well as oropharyngeal cancers - which have been rapidly increasing in the U.S. In a study of head and neck cancers among the AI population in western, South Dakota, 67 percent were HPV positive. Educational efforts can be an important strategy to lower the incidence of these HPV induced malignancies.

Limitations of our study include a relatively small number of urban AI women, motivated participants who most
likely had had higher baseline knowledge, a self-selected group of women willing to self-sample for HPV testing and recruitment of women from health care facilities.

Our study suggests potential interventions to lower the cervical cancer mortality among AI women include increased community education, HPV vaccination and compliance with all three doses, early detection, and use of vaginal self-tests for women in remote areas who may not have ready access to health care.

**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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Quadrilateral Space Syndrome Treated with Ultrasound-Guided Corticosteroid Injection: A Case of Isolated Teres Minor Atrophy and Review of the Literature

By Peter S. Chang, MD; Nathan Jacobson, MSIV; and Kwang U. Chang, MD

Abstract
Quadrilateral space syndrome (QSS) is a rare orthopedic condition caused by compression, entrapment, or injury to the axillary nerve or posterior humeral circumflex artery as they arise from the quadrilateral space. QSS can present with point tenderness over the quadrilateral space and weakness and paresthesia in the axillary nerve distribution. It is commonly associated with repetitive overhead activities and is seen in athletes engaging in such activities. Here we report a case of QSS in a 42-year-old male weight lifter who presented with pain and soreness in the posterior aspect of his right shoulder radiating around his arm as well as slight weakness of his right shoulder of a few weeks duration. MRI results of his shoulder demonstrated moderate atrophy and fatty infiltration of the teres minor. His diagnosis of QSS was confirmed with electro diagnostic testing which showed axillary neuropathy. He was treated with ultrasound guided corticosteroid injections and gained relief from this treatment. His axillary neuropathy was shown to be resolving on repeat electro diagnostic testing at six-months follow-up. Here we report a case of QSS and provide a brief review of the literature.

Introduction
The quadrilateral space is an anatomical space comprised medially by the long head of the triceps, laterally by the medial edge of the surgical neck of the humerus, inferiorly by the tendon of the teres major and latissimus dorsi muscle, and superiorly by the teres minor muscle and scapulohumeral capsule.¹ The axillary nerve and posterior humeral circumflex artery travel together through the quadrilateral space.² Quadrilateral space syndrome (QSS) is due to compression, entrapment, or injury to the axillary nerve or posterior humeral circumflex artery as they arise from the quadrilateral space (QS).³ The axillary nerve carries nerve fibers from the ventral rami of C5 and C6 and arises from the posterior cord of the brachial plexus.⁴ It gives muscular branches to the teres minor and the deltoid.⁵ We present our experience and management of a 42-year-old male presenting with quadrilateral space syndrome who was treated with ultrasound guided injections into the quadrilateral space.

Case Description
A 42-year-old male presented with pain and soreness in the posterior aspect of his right shoulder radiating around his arm as well as slight weakness of his right shoulder of a few weeks’ duration. He was a frequent heavy weight lifter and had a history of rotator cuff tear in the contralateral arm. He also complained of numbness and tingling into his right hand, particularly in the median distribution. Physical examination demonstrated slight muscle atrophy in the back of the right scapula and 4+/5 strength with external rotation of his right shoulder. Otherwise, strength testing was intact. A T1-weighted MRI without fat saturation was performed with coronal, axial, and sagittal views displayed in Figures 1-3, respectively. MRI showed moderate atrophy and fatty infiltration of the teres minor muscle as well as mild hypertrophic acromioclavicular arthrosis with inferior osteophyte formation and atrophy. On electro diagnostic testing the right teres minor showed few denervation potential changes of +1 fibrillation, positive sharp waves, increased insertional activity with
mildly decreased recruitment of muscle units overall which was consistent with isolated right axillary neuropathy. The MRI and electro diagnostic testing results were diagnostic of quadrilateral space syndrome. He was treated with an ultrasound guided corticosteroid injection into the quadrilateral space. At two months follow-up he had near complete relief of his symptoms of pain and weakness. At six months follow-up electro diagnostic testing results showed improvement of his axillary neuropathy and he was re-injected at that time.

Discussion
This report provides one case of neurogenic QSS with axillary nerve compression and concomitant isolated teres minor atrophy. Based on a comprehensive review by Brown et al., QSS can be categorized into neurogenic and vascular on the basis of axillary nerve compression versus posterior circumflex humeral artery injury. The proposed cause of neurogenic QSS (nQSS) are fixed structural lesions in the QS from fibrous bands as a result of scarring from repetitive microtrauma to the connective tissue in the QS causing compression of the axillary nerve. We postulate that this patient's repetitive heavy weight lifting caused repetitive inflammation and microtrauma within the QS. Interestingly, this patient suffered from isolated teres minor involvement without evidence of any deltoid involvement. The motor branch of the axillary nerve to the teres minor is the most medial branch within the QS, with the motor branches to the deltoid branching laterally. It is possible that this patient had fibrous band formation or other space occupying inflammatory lesion medially in the QS leading to the isolated compression of the teres minor branch of the axillary nerve. In a cadaveric dissection study by McClelland et al. fibrous bands were found between the teres major and the long head of the triceps. Our patient was non-surgically managed with ultrasound guided injections into the QS, and at six-month follow-up had electro diagnostic evidence of improvement of his axillary neuropathy. Had no improvement been seen with injections, our patient would have been treated with surgical decompression of his QS. A review of the literature of QSS is also presented.

Epidemiology – The term QSS was originally introduced
in 1980, and repeated again in 1983 by Cahill, to describe patients experiencing axillary nerve compression. To date, there is a lack of literature regarding the prevalence of QSS, but as knowledge of the syndrome increases, prevalence may increase. Additionally, diagnosis of QSS remains difficult due to the vague presenting symptoms. Nonetheless, QSS is a rare cause of posterior shoulder pain. In a study by Hoskins et al., QSS was reported most commonly in athletes involved in repetitive throwing motions, tennis, and, volleyball. More recently, cases of QSS have continued to be diagnosed in individuals involved in volleyball, baseball, and swimming as well as window cleaning and yoga. Although further epidemiologic studies are needed for QSS, Brown et al. noted a male to female ratio of 7:1. Further studies are needed for average age of onset and other contributing factors to QSS.

**Etiology** – Fibrous bands, along with muscular hypertrophy, are most commonly cited in the literature as the causes of axillary nerve entrapment. McClelland et al. confirmed this finding when they found fibrous bands present in 14 of 16 cadaveric shoulders which limited the cross-sectional area of the quadrilateral space. The fibrous bands can occupy the quadrilateral space and compress the axillary nerve leading to neurogenic QSS (nQSS). Cases of nQSS reported in individuals not involved in repetitive overhead throwing motions have been attributed to acute shoulder trauma, atypical nerve course, glenoid labrum cyst, paralabral cyst, ganglion, spontaneous occurrence, bone spike, soft-tissue hematoma from a humerus fracture, and humeral osteochondroma. Another proposed etiology of QSS is vascular QSS (vQSS) seen primarily in athletes engaging in repetitive overhead physical activities, such as volleyball players, stemming from repetitive trauma to the posterior circumflex humeral artery (PCHA) leading to aneurysm formation and thrombosis. Embolic occlusion of the distal extremity can produce ischemic changes and worsen the symptoms.

**Clinical features** – QSS often presents vaguely and non-specifically. Clinical symptoms have been described as point tenderness over the QS and shoulder pain radiating down to the arm due to compression of the axillary nerve or damage to the PCHA. Signs and symptoms of QSS range from weakness and poorly localized posterior shoulder pain to point tenderness over the quadrilateral space. Additionally, paresthesia may affect the lateral shoulder and arm in a non-dermatomal pattern radiating into the forearm. Forced humeral abduction and external rotation of the arm have been reported to aggravate the symptoms. It appears that most cases of QSS have elements of pain, except for a recent case report in which two volleyball players exhibited no pain, but presented with worsening deltoid atrophy and reduced strength. Furthermore, in patients with vQSS, unique signs and symptoms included hand paresthesias, blue/purple discoloration of the digits, splinter hemorrhages, intermittent swelling of the digits, and pallor of the hand.

**Evaluation**: Due to the overlapping similarities involving axillary nerve compression including thoracic outlet syndrome, rotator cuff injuries, and C5 and C6 radiculopathies, among others, it is important for the physician to maintain a high degree of suspicion in evaluating for QSS to elicit a proper diagnosis. Unfortunately, there is not a diagnostic test that is considered the “gold standard” for QSS. Imaging modalities such as distal subtraction angiography (DSA), CTA, MRI, MRA, and ultrasonography have been used. A study by Mochizuki et al. concluded that MRA had no value in the diagnosis of QSS. A more recent study by Robinson et al. concluded that ultrasound could reliably locate the PCHA and be used in the evaluation of QSS. There are currently no studies evaluating the sensitivity or specificity of MRI or angiography in the evaluation of QSS. Chen et al. reported a novel case in 2015 in which they successfully diagnosed QSS using an ultrasound-guided block. Additionally, Chen et al. used electro diagnostic testing in conjunction with ultrasound to diagnose an overweight patient with QSS. However, although electromyography (EMG) and nerve conduction studies (NCS) can identify axillary nerve injury, these studies can also be completely normal in QSS. Therefore, the combination of patients’ presenting symptoms, physical exam, and interpretation of imaging modalities are needed to confirm the diagnosis of QSS. A repeat MRI was not necessary in this patient due to resolution of his symptoms as well as improvement of his axillary nerve neuropathy on electro diagnostic testing.

**Treatment** – There is only one reported spontaneous resolution of QSS reported in the literature where conservative treatment using pregabalin, oxycodone, and naproxen resolved the patient’s symptoms. Otherwise, there are a variety of treatment options available for patients diagnosed with QSS and treatment can depend on whether the patient has nQSS or vQSS. Initial treatment should be conservative and like other forms of axillary nerve injury, the shoulder should be rested until
the physician feels comfortable initiating a physical therapy program.23 Oral anti-inflammatory medications and analgesics are also indicated.1,5 If conservative measures do not help, surgery is the most definitive therapy for both nQSS and vQSS.1 For nQSS, surgery involves neurolysis and decompression of the quadrilateral space by removing fibrous tissue or other lesions.1,16 A study by McAdams et al. evaluated four patients with QSS who underwent surgical decompression with all four returning to full activity 12 weeks post-surgery.24 For vQSS, surgery is the most definitive therapy although thrombolysis has been used in acute exacerbations.1 The PCHA is ligated at the aneurysm and thrombectomy can be used if distal emboli are present.1 Finally, with the recent case report of ultrasound-guided injection for diagnosis, along with our case report of ultrasound-guided injection for treatment, this modality may be a less invasive treatment modality.1

Conclusion
QSS is a rare orthopedic condition in which compression of the QS can lead to axillary nerve entrapment and neuropathy. The treatment of QSS can range from conservative measures to injections and surgical decompression of the QS. QSS is especially debilitating for athletes participating in overhead activities and in the select patient population the clinician should be suspicious of QSS.

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REFERENCES

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Impact of the Hydrocodone Schedule Change on Opioid Prescription Patterns in South Dakota

By Lauren M. Kuschel; and Jane R. Mort, PharmD

Abstract

Introduction: Prescription opioid use is becoming increasingly common; consequently, opioid overdose deaths are increasing at an alarming rate. Hydrocodone, one of the most commonly abused opioids, was changed from a schedule III controlled substance to the more stringent schedule II to decrease abuse and diversion, effective Oct. 6, 2014. The objective of this study was to examine the impact of the hydrocodone schedule change on opioid prescribing in South Dakota.

Methods: Opioid prescription patterns were examined in the following six-month phases: the baseline phase before the change, the transition phase when existing hydrocodone prescriptions could still be refilled, and the final phase. The South Dakota Board of Pharmacy Prescription Drug Monitoring Program provided aggregate monthly data for South Dakota opioid prescriptions (i.e., total number of prescriptions and days supplied), including urban and rural stratification. T-tests were performed on the monthly values for each phase to determine the significance of differences in prescription features between phases.

Results: The number of hydrocodone prescriptions significantly decreased 14 percent from baseline to final phase, while the days supplied per prescription significantly increased 7.4 percent. These changes were greater in rural areas than in urban areas. Conversely, the number of other opioid prescriptions significantly increased by 6.5 percent over this timeframe.

Conclusions: The number of hydrocodone prescriptions decreased, while the days supplied per prescription increased. These changes were greater in rural areas than in urban areas. In addition, the number of other opioid prescriptions increased. These trends may reflect some unintended effects of the schedule change.
Department of Health and Human Services (HHS) in 2004 to research the request and provide a recommendation. Reclassifying HCPs as CIIIs would impose more stringent controls, including strict ordering, storage, and inventory requirements, as well as the prohibition of faxing, phoning in, transferring, or refilling of these prescriptions.

The meeting of the Public Drug Safety and Risk Management Advisory Committee and comments submitted from the public resulted in HHS drawing the following conclusions: people are consuming HCPs in amounts large enough to create hazard to their own health and the safety of others; significant HCP diversion is occurring; and people are taking HCPs on their own initiative rather than on the basis of medical advice.

Upon review of relevant data and recommendation from the Assistant Secretary for Health of the HHS Department, the DEA noted that HCPs met the following descriptors for CII controlled substances: high abuse potential, accepted medical use in the U.S., and potential for abuse leading to severe psychological or physical dependence.

Subsequently, the DEA rescheduled HCPs from CIII to CII controlled substances effective Oct. 6, 2014, with a two-phase implementation plan. During the transition phase, prescriptions written before Oct. 6, 2014, could still be refilled if allowed by state governing bodies. This phase ended April 8, 2015, followed by the final phase during which HCP prescriptions could no longer be refilled as dictated by CII requirements. The intent of the schedule change was to reduce HCP misuse and abuse.

The objective of this study was to examine the impact of the HCP schedule change on opioid prescribing in South Dakota, including stratification by urban and rural areas.

### Methods

**Data Source**

In an effort to minimize prescription drug abuse and diversion, the South Dakota Board of Pharmacy Prescription Drug Monitoring Program (PDMP) carries out two major tasks. First, the PDMP receives all information on controlled substance prescriptions filled in South Dakota. Pharmacies are required to submit data on all schedule II-IV prescriptions at least weekly to the PDMP. Information submitted includes the following: patient name, date of birth, and address; prescriber name and DEA number; the date the prescription was written and filled; the drug name and strength; the prescription quantity and days supplied; and the pharmacy name, address, and phone number. Optional information includes patient phone number, prescriber NPI, and payment type (i.e., cash or insurance). Second, the PDMP delivers information on a patient’s controlled prescription use history upon electronic query by a prescriber or pharmacist.

**Data Extraction**

The South Dakota Board of Pharmacy PDMP data vendor provided aggregate monthly data of all South Dakota opioid prescriptions (i.e., total number of prescriptions, doses, and days supplied for individual agents) for the 18-month study period. Data were also provided according to counties, which were stratified into urban and rural categories based on the following definitions from the U.S. Census Bureau: urbanized areas contain 50,000 people or more, urban clusters contain 2,500 to 50,000 people, and rural areas are all those not included in the previous definitions.

**Phase Analysis**

Opioid prescription patterns were examined in three phases. The baseline phase (April 2014 through September 2014)
was the six-month period before the HCP schedule change. The following six-month period (October 2014 through March 2015) was defined as the transition phase, during which HCP prescriptions written before the change could still be refilled in South Dakota. The final phase (April 2015 through September 2015) was the six-month period after the final effects of the schedule change in which HCP prescriptions could no longer be refilled.

Exclusions
Data from the Veteran Administration (VA) facilities in South Dakota (n=3) were excluded, as the VA did not begin reporting to the PDMP until December 2014. Tramadol was excluded from statistical analysis due to its unscheduled status until Aug. 18, 2014, leading to the lack of data throughout the baseline phase.

Data Analysis
All combination products containing a specific opioid (e.g., hydrocodone with acetaminophen and hydrocodone with ibuprofen) were combined into single values for the opioid. The average days supplied per prescription for each month was then calculated for each opioid. The percent change from baseline to transition phase and baseline to final phase was calculated for the total number of prescriptions and average days supplied per prescription for the six opioid agents with the highest number of prescriptions. T-tests were performed by comparing the six monthly values from each of the three phases (i.e., total number of prescriptions per month, monthly mean days supplied per prescription) to determine the significance of differences in prescription features from baseline to transition phase and baseline to final phase.

Institutional Review Board
The South Dakota State University Institutional Review Board deemed this study exempt, as it was a study of de-identified data.

Results
Number of Prescriptions
Table 2 shows the average number of prescriptions per month in each phase of the study period. Hydrocodone prescription numbers significantly decreased by 13.5 percent (p<0.01) from baseline to transition phase and 14 percent (p<0.0001) from baseline to final phase. This was accompanied by a significant increase in the total number of opioid prescriptions (excluding hydrocodone and tramadol) of 11.2 percent (p<0.05) from baseline to transition phase and 6.5 percent (p<0.01) from baseline to final phase. Specifically, the number of oxycodone prescriptions significantly increased by 5.9 percent (p<0.05) from baseline to final phase, and the number of codeine prescriptions significantly increased from baseline to transition phase by 43.7 percent (p<0.001).

Figure 1 illustrates these trends over time.

![Figure 1. Number of prescribers per month for total data](image-url)
Table 3 shows the average number of prescriptions per month in each phase of the study period stratified by rural and urban counties. Hydrocodone prescription numbers showed a significant decrease in both areas. However, the decrease was greater in rural versus urban areas by 5.9 percent from baseline to transition phase (reductions: 18.6 percent rural and 12.7 percent urban) and 5.1 percent from baseline to final phase (reductions: 18.5 percent rural and 13.3 percent urban).

Days Supplied per Prescription
Table 4 shows the average days supplied per prescription in each phase based on the monthly values. The days supplied per prescription for hydrocodone significantly increased by 7.8 percent from baseline to transition phase and 7.4 percent from baseline to final phase (p<0.0001). Figure 2 illustrates this trend.

Table 5 shows the average days supplied per prescription in each phase stratified by rural and urban counties based on monthly values. The days supplied per prescription for hydrocodone significantly increased in both areas; however, the increase was greater in rural versus urban areas by 2 percent from baseline to transition phase (reductions: 9.7 percent rural and 7.7 percent urban).

Discussion
The decrease in HCP prescription numbers of 13.5 percent from baseline to transition phase and 14 percent from baseline to final phase in South Dakota was comparable to the 22 percent decrease noted in the national data estimates from the IMS Health National Prescription Audit. Linear regression performed on the national data showed this reduction was substantially greater than would have been predicted without the schedule change. However, these reductions were much lower than results reported in several settings in Texas. Specifically, there was a 71 percent decrease in the number of hydrocodone prescriptions found in a Texas county safety net health system (Harris County) and 73 percent decrease in a large academic level one trauma center (Dallas County). When examining individual HCPs, a study of 14 retail pharmacies in central Texas found a 58 percent decrease in Norco 5/325 and a 34 percent decrease in Norco 10/325. In contrast to the notable decreases in HCP prescription numbers found in these studies, VA emergency department data showed a steady downward trend in hydrocodone/acetaminophen prescriptions since the peak in 2011 with a strong linear correlation to time, indicating that the rate of decreasing prescription numbers did not change after the schedule change in October 2014. Further details of these five studies are outlined in Table 6.

In contrast to the reduced number of hydrocodone prescriptions, the days supplied per HCP prescription increased 7.8 percent from baseline to transition phase and 7.4 percent from baseline to final phase in South Dakota. This data conflicts with the trends noted in a
study of VA emergency department hydrocodone/acetaminophen prescriptions from 2009 through June 2015. In the VA study, it was noted that the percent of prescriptions limited to a three-day supply (12 pills) increased from 22 percent in 2009 to 31 percent in 2015, prescriptions for five days (13 to 20 pills) increased from 31 to 41 percent, prescriptions for seven days (21 to 30 pills) decreased from 21 percent to 16 percent, and prescriptions for more than seven days (over 30 pills) decreased from 26 percent to 12 percent. However, the VA data represents primarily

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<th>Table 4. Average days supplied per prescription in each phase</th>
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<tr>
<td><strong>Location</strong></td>
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</tr>
<tr>
<td>Hydrocodone</td>
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<td>Tramadol</td>
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<td>Oxycodone</td>
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<td>Codeine</td>
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<td>Fentanyl</td>
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<td>Morphine</td>
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* Statistical significance not determined.

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<th>Table 5. Average days supplied per prescription in each phase for rural and urban data</th>
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<td><strong>Location</strong></td>
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<td>Morphine</td>
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* Statistical significance not determined.
acute prescriptions for hydrocodone/acetaminophen, while the data from the South Dakota study represents acute and long-term prescriptions, as well as all HCPs. This contrasting data may suggest that the increase in days supplied per prescription is primarily attributed to long-term prescriptions in the ambulatory setting, rather than acute prescriptions from an emergency department. In addition, this increase in days supplied per prescription accompanied by the decrease in HCP prescription numbers in South Dakota may indicate that prescribers compensated for the more stringent requirements by writing fewer HCP prescriptions with larger days supplies.

On the other hand, the number of prescriptions for other opioids (excluding tramadol and hydrocodone) increased 11.2 percent from baseline to transition phase and 6.5 percent from baseline to final phase in South Dakota. A similar trend was noted in the study of IMS Health National Prescription Audit data; non-HCP opioids increased 4.9 percent. The opposite trend was noted in other studies. There was a 9 percent reduction in the number of other opioid prescriptions in the study on Texas county safety net health system data, 13 percent decrease in the study of 14 retail pharmacies in central Texas (but only a 3 percent decrease in morphine milligram equivalents), and a 40 percent decrease in the study from a large academic level one trauma center in Texas. However, these values from comparator studies included HCPs, which could have confounded the increase in prescriptions for other opioids; included only select opioid products; and were carried out in Texas except for the IMS Health National Prescription Audit.

When looking at individual non-HCP opioid prescription numbers, the South Dakota study demonstrated an increase in oxycodone of 5.9 percent from baseline to final phase. Other studies did not examine the impact of the HCP schedule change on other CIIIs, such as oxycodone. The South Dakota study also demonstrated an increase in codeine of 43.7 percent from baseline to transition phase. The increases in codeine prescription numbers were much greater in other studies; TYLENOL #3 prescription numbers increased by 265 percent in the safety net health system study and 597 percent in the Texas retail pharmacy study. The Texas retail pharmacy study also showed a 1,056 percent increase in TYLENOL #4 prescription numbers. Overall, the study of the large academic level one trauma center data showed a 1,360 percent increase in codeine prescription numbers. While the South Dakota study did not examine statistical significance of tramadol prescription numbers due to the lack of baseline data, other studies showed an increase of 17 percent in the Texas retail pharmacies, 30 percent in the safety net health system study, and 54 percent in the large academic level one trauma center. This increase in other opioid prescription numbers along with the decrease in HCP prescription numbers perhaps represents an unintended compensatory response. This response may have been due to the loss of convenience in prescribing HCPs over more potent CIIIs or the selection of more convenient non-CII opioids.

A major strength of the South Dakota study in comparison to other studies was the time periods used for data comparison. This study separated the time period after the schedule change into the transition phase, during which refills were allowed, and the final phase. The study design of the three studies taking place in Texas was similar to the baseline to transition phase comparisons of the South Dakota study; therefore, they may have underestimated the decrease in HCP prescription numbers by using the transition phase to represent the final effect of the

<table>
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<tr>
<th>Study</th>
<th>Sample</th>
<th>Location</th>
<th>Comparative Timeframe</th>
<th>HCP Prescription Numbers</th>
<th>Days Supplied per HCP Prescription</th>
<th>Non-HCP Opioid Prescription Numbers</th>
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<td>Grasse MA, et al. (12)</td>
<td>VA emergency department visits</td>
<td>National</td>
<td>7.75 years</td>
<td>7 months</td>
<td>Steady downward trend with strong linear correlation to time</td>
<td>3 days supply: increased 5 days supply: increased 7 days supply: decreased</td>
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<tr>
<td>Jonas CM, et al. (8)</td>
<td>IMS Health National Prescription Audit</td>
<td>National</td>
<td>12 months</td>
<td>12 months</td>
<td>22% decrease</td>
<td>NA</td>
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<td>Schultz S, et al. (10)</td>
<td>Large academic level one trauma center</td>
<td>Texas</td>
<td>6 months</td>
<td>6 months</td>
<td>78% decrease</td>
<td>NA</td>
</tr>
<tr>
<td>Seage S, et al. (11)</td>
<td>Fourteen retail pharmacies</td>
<td>Central Texas</td>
<td>3 months</td>
<td>3 months</td>
<td>Norco 5/325: 58% decrease Norco 10/325: 44% decrease</td>
<td>NA</td>
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</table>

Table 6. Studies examining prescription patterns related to the HCP schedule
schedule change, when refills are no longer allowed.\textsuperscript{10-12} The effect of refills was demonstrated by the safety net health system data, which showed that refills accounted for 73.7 percent of the 71 percent decrease in HCP prescription numbers.\textsuperscript{10} The IMS Health National Prescription Audit study combined the transition and final phase of the South Dakota study, which would also underestimate the true decrease in HCP prescription numbers due to the presence of refills in the transition phase. The transition phase used in the South Dakota study provides a more accurate picture of the effect of the HCP schedule change on opioid prescribing patterns.

When stratified by rural and urban counties, the data showed a greater decrease in HCP prescription numbers in rural areas, with a relative difference of 5.9 percent from baseline to transition phase and 5.1 percent from baseline to final phase. Modest differences were noted in days supplied per prescription in rural versus urban counties. In addition, the average days supplied per HCP prescription was larger in the rural setting by 30 percent. These greater changes in prescription number and days supply found in rural areas of South Dakota may result from challenges in health care access in rural areas.

This study possesses three main limitations. First, data from the VA was excluded due to incomplete reporting throughout the study period. Second, lack of tramadol data limits analysis of the impact of the HCP schedule change on non-HCP opioids. Third, seasonal prescribing trends may have been a confounding variable.

Conclusion

As a result of this study examining the impact of the HCP schedule change on opioid prescribing in South Dakota, three major trends were identified. Most importantly, the number of hydrocodone prescriptions decreased, while the days supplied per prescription increased. Furthermore, these changes were greater in rural as compared to urban areas. Finally, the changes in HCP prescription trends were accompanied by an increased number of other opioid prescriptions. These trends may indicate some unintended effects of the HCP schedule change. The decrease in HCP prescription numbers and increase in other opioid prescriptions found in South Dakota were comparable to national data estimates. Further studies are needed to evaluate the effectiveness of this change on reducing HCP abuse and diversion.
Regional Infant and Child Mortality Review Committee – 2016 Final Report

By Ann L. Wilson, PhD; and Brad Randall, MD

Abstract

The Regional Infant and Child Mortality Review Committee serves 10 counties in southeastern South Dakota and aims to use its reviews to prevent future loss of life during childhood. In 2016, the Committee reviewed 25 deaths (compared to 32 cases in 2013, 25 in 2014, and 24 in 2015). In 2016, three deaths in the region were attributable to maltreatment. This is an outlier from previous years when typically one such tragedy occurs and reveals the fragility of young life in stressed and unstable home environments. In 2016, there was also an increase from recent years in accidental deaths that included three children who were not properly restrained as passengers or while driving. In 2016, five infants died during sleep compared to seven the previous year and four of these deaths occurred with risks present in the sleep environment. The Committee has not seen progress towards decreasing infant deaths during sleep in our region. In fact, their number may even be increasing. The report provides the Committee’s recommendations for community action that could prevent future deaths of infants and children.

The Regional Infant and Child Mortality Review Committee (RICMRC) was established in 1997 with the aim of examining deaths of infants and children to identify preventive strategies that may decrease the risk of loss of young life in Minnehaha County. The Committee’s mission is “to review infant and child deaths so that information can be transformed into action to protect young life.” Over time, it expanded its service area to also include Lincoln, Turner, McCook, Lake, Moody, Union, Hanson, Miner and Brookings counties.

The Committee in 2016 was chaired by the chief of the Sioux Falls Fire Rescue and is composed of professionals representing expertise in pediatrics, medico-legal death investigations, nursing, law enforcement, child protective services, emergency medical services, and mental health. Sheriff and police departments from the participating counties are invited to be present for the reviews of deaths of children occurring in their counties. Representatives of the South Dakota Department of Health also attend the meetings to help coordinate infant death investigation throughout the state. To operationalize its goal of prevention, these criteria are used for reviewing deaths of infants and children (under the age of 18):

- Residents of the RICMRC region whose deaths occurred subsequent to hospital discharge following delivery (or did not occur in a hospital) from causes sustained in the region; and
- Non-residents of RICMRC region whose deaths occurred in the region from causes sustained in the region.

Sixty-one percent of the total deaths of residents in the 10 county RICMRC review area in 2016 were residents of Minnehaha County. For illustrative purposes, the age distribution of these deaths is presented in Table 1. Important to recognize in these 2016 data is that 24 percent of the Minnehaha County resident deaths of those under the age of 18 occurred in the first 28 days of life (neonatal) and some of these occurred within hours of birth. Noted in Table 1 is how the population of Minnehaha County has grown by almost 33 percent between 1990 and 2015. Apparent over this span of time is year to year variation in the number of infant and child deaths in the county. However, a comparison of the mean
numbers of infant and child deaths for the intervals of 1991 to 2003 (mean=26.2) and 2004 to 2016 (mean=25.4) show a slight decrease. In light of the growth of the county's population, this is an encouraging finding. Caution must be exercised when examining data calculated with the small population base of the RICMRC area data. Nonetheless, for children (ages 1 to 17), the approximate 2011-2015 10 county regional rate of death (25 per 100,000 population) is lower than the state rate of 30, but higher than the national rate of 20 for these years. Further, the 2011-2015 rate of infant death (birth to age 1) in the RICMRC counties of southeast South Dakota is approximately 5.5 per 1,000 live births and is lower than the state rate of 6.9 during the same period. The national rate of infant mortality for these years was 5.

In 2016, 25 deaths met the Committee's criteria and all were reviewed (compared to 32 cases in 2013, 25 in 2014, and 24 in 2015). Of the 25 reviewed cases, 20 were residents of Minnehaha County, and five were from Lincoln, Turner, or McCook counties.

The reviewed deaths listed below are separated by their manner (natural, accidental, suicide, homicide and undetermined) with an additional section that addresses those attributed to sudden unexpected infant deaths (SUID). The number of deaths for 2016 in each manner category is indicated in bold adjacent to its heading. Numbers listed in parentheses represent the comparable number of deaths from 1997 through 2014. Care must be taken in comparing yearly data due to the addition of Lincoln County (1998), Turner County (1999), McCook County (2000), Lake and Moody counties (2001), Union County (2002), Hanson and Miner counties (2003), and Brookings County (2004) in years subsequent to the establishment of the review Committee's work in Minnehaha County in 1997. However, as 72 percent of the reviewed cases since 2005 have been residents of Minnehaha County, some meaningful comparison of data between years is justified.

### Natural Deaths

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### Accidental Deaths

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The number of childhood deaths (n=9) caused by accidents in 2016 is higher than the mean of 7.7 for the previous 10 years. Two of the three motor vehicle related accidental deaths were caused by car crashes that involved unbelted teen drivers while the third involved a child passenger not properly restrained. In addition, a tragedy involving a toddler's fall from a height and another from a

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Table 1. Minnehaha County resident deaths and population

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<th>Year</th>
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Mortality data for the 1991-1996 from the SD Department of Health.

Population data from US Census Bureau.
plane died in an unsafe sleep environment. In addition to this toddler, three of these nine accidental deaths included infants (less than one year of age) who died unexpectedly during sleep in an unsafe location. These deaths will be further discussed in the SUID section below.


There was one death due to suicide in 2016. As noted in the above annual data, typically, with the exception of 2013, there have been one or two such tragedies in the region. The one death in 2016 again confirms that the spike of five deaths observed in 2013 was indeed unusual.


In 2016, three homicidal deaths occurred in the region. Typically there is one such death per year due to fatal maltreatment. Complex family circumstances surrounded each of these deaths that included strained relationships and stressed care arrangements. Each of these deaths occurred when the child was in the care of a non-biological parent.


The manner of two of these deaths was identified as undetermined and involved sleeping infants and will be discussed below. The other included complex circumstances and its cause could not be determined.

Sudden Unexpected Infant Deaths 5 (7-2015, 5-2014, 5-2013, 4-2012, 2-2011, 3-2010, 3-2009, 8-2008, 4-2007, 5-2006, 4-2005, 0-2004, 3-2003, 4-2002, 4-2001, 4-2000, 7-1999, 6-1998, 1-1997) (Note: these deaths are included by their manner in the above sections of this report)

In 2015 and 2016 slightly less than a quarter of the cases reviewed by the Committee were attributed to SUID. The term SUID, which began to be used on a Center for Disease Control and Prevention (CDC) investigation form issued in 1996, now describes deaths attributed to three different coded causes classified as also having three different “manners.” These are: sudden infant death syndrome (SIDS) (a “natural” manner), strangulation and suffocation – to include overlaying – in bed (usually an “accidental” manner), and other unknown causes (an “undetermined” manner). The most recent 2015 data show that the rate of death for SUID observed nationally is 0.93 per 1000 live births. For the RICMRC region, the 2016 SUID rate is approximately 1.0. Over time, nationally and locally, there has been a decline in the rate of deaths coded as SIDS, a code that only may be used as a cause for an infant death when it cannot be explained by a complete autopsy, a thorough examination of the death scene, and review of the clinical history. With increasing use of more complete death scene investigations, to include the Sudden Unexplained Infant Death Investigation Reporting Form and doll reenactments, potential hazards have commonly been identified in the sleep environment that could represent possible causes for many sudden unexpected infant deaths. As a definitive cause of these hazard-associated deaths usually cannot be exactly stated, their manner is frequently coded as accidental or unknown. It is quite likely that in previous RICMRC annual reports, the deaths listed in this report as SUID would have been listed as SIDS. Figure 1 shows that in the RICMRC region, between 2010 and 2015, there has not been a death coded as SIDS, while there have been between two and seven SUID deaths in subsequent years.

Among the five 2016 SUID deaths in the RICMRC region, two of these deaths were coded as “undetermined” and three as “accidents.” For the first time since 2010, one of these SUID deaths, whose manner was coded as “undetermined,” was identified as caused by SIDS. The death scene investigation of the sleep environment in which it occurred, the autopsy, and history did not identify a risk factor associated with this death. (Note: SIDS deaths are usually designated as natural in manner).
The other four SUID deaths occurred in unsafe environments that included adult beds, sofas or car seats.

Figure 2 presents the total SUID deaths for the RICMRC area with a trend line indicating that the number of these deaths is not decreasing. The statistical significance of this trend is not determined.

Figure 3 allows a comparison of data on the rates of SUID for the region, South Dakota and the U.S. Notably, the region’s rate of SUID decreased in 2016 from what it was in 2015 and is more consistent with its rates in 2012-2014. Nonetheless, it has remained higher than the national rate. As noted throughout this report, small numbers require caution as they are reviewed, but persistent trends warrant attention.

**Advocacy Issues**

Data from the reviews of the 2016 deaths highlight actions that health care professionals, community leaders, and citizens may take to prevent future loss of life of infants and children. Issues that are listed with an asterisk note those that have been discussed in previous reports and require ongoing attention.

1.* Unexpected infant deaths during sleep occur in unsafe sleep environments.

The “Back to Sleep” campaign that was initiated in the U.S. in 1994 led to a widespread educational efforts that communicated the message that babies should sleep on their backs to prevent SIDS. This campaign was accompanied by a decrease in the number of SIDS deaths.

With greater awareness of the risks associated with sleep environments, in 2012 this campaign shifted its message to “Safe to Sleep.” This message advocates more than positioning a baby on his or her back when put to bed and demands attention to the entire setting where a baby sleeps. Not surprisingly, the complexity of what this campaign requires has not been accompanied by the immedicacy of declining rates in deaths that was observed with the “Back to Sleep” campaign. Nonetheless, rigorous efforts must ensue to assure that babies sleep in places that do not create risks to their survival. Similar to previous calls for action by the Committee’s reports is this repeated plea for caregiving compliance with measures that assure safe sleep for all infants.

With rare exceptions, unexpected infant deaths in the region have occurred in environments that imposed hazards to the safety of the babies who died. Though there was a decrease in 2016 from 2015 in the number of deaths due to unsafe sleep in the 10 county region of southeastern South Dakota, striking was the spike noted in the number of these deaths that occurred statewide in 2015. Public education and expectations of infant care are not confined to geographical boundaries and efforts must be thought of as having ripple effects generated by concerned parents, professionals and citizens. Vigilance in promoting safe sleep must persist.

In 2016, the American Academy of Pediatrics issued updated recommendations for a safe infant sleeping environment that include the following:

- Place a baby on his or her back on a firm sleep surface with a tight fitting sheet;
- Avoid use of soft bedding (bumper pads, blankets, pillows or soft toys) – a crib should be bare;
- Have the baby share a bedroom with parents – but not the same sleeping surface; and
- Avoid the baby’s exposure to smoke, alcohol or illicit drugs.

Each of these recommendations requires promotion for public and professional attention to its message.

Analyses of regional SUID deaths provide data that also emphasize the importance of safe sleep in out-of-home settings where infants receive care. Education for parents must include their need to visualize where their babies will sleep when cared for in these settings. If the baby will sleep in a portable play pen, is it in good condition with a firm flat mattress and unbroken external structure? Will the baby be taken out of a car seat or other similar device when put to sleep in a safe crib? Will the baby not be
placed on an adult bed with pillows used as a barrier around the baby! The Committee in recent years has had the unfortunate experience of reviewing the deaths of babies that occurred on unsafe surfaces such as worn portable cribs, car seats, and adult beds that have been used for infant sleep in child care settings. If a safe place is not assured for a baby receiving out-of-home care, parents are encouraged to provide their child care provider with a safe play yard for their baby’s sleep.

All those who see where babies are sleeping are encouraged to assure the safety of these environments. Reticence to critique others’ baby care practices is a social norm, yet when a baby’s survival is at risk, such hesitance must be overcome. Further, the impact of gentle comments accompanied by practical suggestions can extend to care provided to infants other than the one whose perilous sleep is observed.

The Committee repeats its call for public awareness of how it can play a vital role in promoting safe sleep for babies. We describe again how narratives surrounding the events that have occurred just prior to a SUID death not uncommonly include a rushed decision to do what is easiest at a stressed moment. Exhausted parents or harried child care providers, even those who usually place their infants in safe sleeping environments, are prone to justifying placing a baby in an unsafe position “just this one time” and the “one time” can become fatal. Further, babies are known to die as house guests where proper places for them to sleep are not used in unfamiliar settings. Care in using a horizontal flat firm protected surface for the baby’s sleep is needed is such situations. Bed sharing or sleep in infant carrier devices pose hazards for sleeping infants.

2.* Proper seatbelt use is vital to survival.

The 2016 deaths of two teenagers in the region were likely preventable had seat belts been used. The common adolescent belief in personal immortality and immunity from harm from hazardous behavior creates challenges to efforts that promote driving safety. However, habits established early and social norms that expect seat belt use may resist teenage testing of safety education. News events that describe adults killed in auto crashes typically reveal the drivers’ failure to use seat belts. To promote safe teen driving, efforts must also target the adults children observe when they are passengers. Of course, when children grow up observing adult drivers buckle up and insist that all passengers are properly seat belted prior to starting a car, this behavior is more likely to become a habit when they become drivers.

In addition to the two teenagers who died in auto crashes, a young child also was killed in an auto crash. This child was incompletely strapped into a car seat at the time of the crash. Local efforts to provide instruction, support, and guidance on the proper use of car seats are applauded and encouraged. Compliance with this instruction is essential.

3. Child maltreatment and homicide are realities that demand vigilance.

The three homicidal deaths in 2016 reflected a spike in this cause of childhood death. Each of these deaths occurred outside of the care of a biological parent. One case involved a young child in the custody of the state. The other two cases involved fatal assault by an alleged perpetrator known to the families. Assessment of the personal resources and stability of those who are entrusted with the care of children emerges as an issue in each of these cases. Unstable relationships and limited resources create risks for potential harm to children and are harbingers of these tragedies. Parental judgment of when an adult’s capacity for child care is insufficient and how alternate arrangements can be sought is a theme apparent in these cases that may yield community attempts to provide education that protects children.

The Committee applauds the state’s creation of a new Center for the Prevention of Child Maltreatment. This center will provide focused attention on strategies, programs and policies that promote protective practices for the care of children.

4. Parents with limited intellectual capacity require intensive surveillance.

In 2015 and 2016, deaths of infants occurred in the care of parents with limited intellectual capacity. In these cases, extensive support and multi-disciplinary services were provided yet the lives of the infants were not sufficiently protected. Such cases arouse the need for judgments that require the complexity of balancing privacy and protection. While prevention is never easily provided in such situations, support is needed for those who make decisions about the best interests of children.

5.* Infants and young children place objects in their mouths upon which they may choke.

6.* The Big Sioux River creates safety hazards for the region.

7.* Adolescence is a time of vulnerability to social pressures and emotional volatility.

The volatility of adolescence creates risks for self-harm.
Assessing and responding to this risk is challenging and can defy valiant efforts to prevent this loss of life. Nonetheless, efforts to identify risks and provide supports are vital. The Committee applauds the work of the local Help Line Center that offers direct care to those distressed and offers its services to those who have survived personal loss caused by suicide.

8.* The sleeping environments for all children and adults should be protected by working smoke detectors.

9.* Maternal use of tobacco, alcohol and illicit drugs is a known risk factor for SUID.

10.* Care must be taken to assure that all infants and children have periodic physical examinations to detect potentially preventable and treatable illness and immunizations.

11.* Follow up activities from the 2011 State Task Force on Infant Mortality convened by First Lady Linda Daugaard include coordination between the South Dakota State Department of Health, RICMRC and the similar committee that reviews infant deaths in the Rapid City area. State support enables these committees’ reviews of an expanded cohort of infant deaths and analyses of the data generated from these reviews may enable the targeting of prevention efforts.

Report submitted by the 2016 Regional Infant and Child Mortality Review Committee:

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Ann Wilson PhD, Vice Chair, University of South Dakota
Jerry Blake, MD, Sanford Health
Kara Bruning, MD, Avera Health
Vicki Burger, BSW, South Dakota Department of Social Services
Carol Cressman, BSN, Sanford Health
Courtney Ehlers, RN, Avera Health
Nancy Free, DO, Child’s Voice, Sanford Health
Janet Kittams-Lalley, MA, LPC, Help Line Center
Lt. Mike Colwill, Sioux Falls Police Department
Jeff Luther, MD, Regional Emergency Services Authority
Brad Randall, MD, South Dakota Department of Health
Kenneth Snell, MD, Minnehaha County Coroner

REFERENCES

6. https://pediatrics.aappublications.org/content/138/5/e20162938.

About the Authors:
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Brad Randall, MD, Professor of Pathology, University of South Dakota Sanford School of Medicine.
Introduction

Many factors go into the selection of medications for patients: efficacy, safety, availability, cost, route of administration, insurance coverage, previous medications tried, drug/drug interactions, drug/disease interactions, familiarity of medications and other factors. An additional consideration to make, in some circumstances, includes the impact of genetic variation. As seen in earlier articles in this series, some pharmacogenetic testing can help guide medication choice based on either safety or efficacy or both.

Allopurinol is a medication commonly used to prevent exacerbations of gouty arthritis, and it is also used for patients undergoing chemotherapy to prevent tumor lysis syndrome. Allopurinol works by blocking uric acid production. Hyperuricemia can be asymptomatic and symptomatic. Symptomatic hyperuricemia could be in the form of acute or chronic gout (painful joint inflammation and tophi formation) or urate nephropathy (urate crystals causing kidney damage and failure) as in the case of tumor lysis syndrome (TLS). The incidence of hyperuricemia is increasing within the general community due in part to increased prevalence of obesity, chronic kidney disease and increased use of diuretics.

While the frequency of gout exacerbations is decreasing due to effective treatments like allopurinol, this disease still has a large impact on society. Gout is estimated to affect eight million Americans. Gout patients tend to miss nearly five days more of work compared to workers who do not have gout. The economic burden on the U.S. due to gout is estimated to be tens of billions of dollars.

Management of Gout

Acute episodes of gout are typically managed by using abortive anti-inflammatory medications (NSAIDs) like indomethacin, or steroids like prednisone. NSAID use needs to be closely monitored in patients with decreased renal function. If gout attacks are recurrent, providers typically add an agent to reduce uric acid production, such as allopurinol starting dose of 100 mg by mouth once daily (up to 800 mg maximum daily dose) or febuxostat starting at 40 mg by mouth once daily (up to 120 mg daily as clinically indicated). Allopurinol dosing should also be closely monitored in patients with decreased renal function. For example, renal dosing of no more than 200 mg by mouth per day is recommended for patients with creatinine clearance of 10-20 ml/minute. Most people with mild to moderate gout need around 300 mg daily of allopurinol or 40 mg daily of febuxostat. Moderate to severe gout patients need 400-800 mg daily of allopurinol or approximately 80 mg daily of febuxostat to maintain the uric acid levels at goal which is less than 6 mg/dL (see Box 1).

Allopurinol is the most commonly used agent for gout. The most common side effects reported with allopurinol are skin rash, nausea, diarrhea, increased hepatic enzymes and alkaline phosphatase. Allopurinol is also associated with a spectrum of side effects called allopurinol hypersensitivity syndrome (AHS) which can be classified as part of severe cutaneous adverse reactions (SCAR). This includes severe cutaneous manifestations like Steven Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), dress reaction with eosinophilia and systemic symptoms (DRESS). These complications can be devastating. The overall mortality rate among patients with SJS/TEN is approximately 30 percent, ranging from approximately 10 percent for SJS to more than 30 percent for TEN. Mortality continues to increase up to one year after disease onset. While the risk for AHS is small (0.1-0.4 percent), it is the greatest safety concern associated with allopurinol. The risk of SCAR is increased by four times in those with decreased renal function. Other uric acid lowering agents like febuxostat are not associated with SCAR.

Tumor Lysis Syndrome

For some patients with large tumor burden, those highly proliferating tumors, or those who are highly sensitive to oncology treatment, the start of treatment can cause tumor cells to rapidly lyse. This lysis of cells releases large amounts of intracellular components into the body including electrolytes, and nucleic acids that are rapidly converted into uric acid. The resulting uric acid gets fil-
Uric acid crystallizes in our body if the serum concentration is greater than 6.8 mg/dL. Crystallization of uric acid (monosodium urate) in the joints causes activation of the neutrophils causing symptoms of acute gout characterized by severe inflammation of joints causing joint pain, redness and swelling. If the Uric acid concentration in the filtered urine is high, urate crystals can crystallize in the kidneys and cause urate stones and kidney damage leading to kidney failure. The 2012 American College of Rheumatology guidelines for management of gout recommends targeting a uric acid level of less than 6 mg/dL.10

In most mammals, urate (uric acid) is converted to a harmless substance called allantoin by an enzyme called urate oxidase. Humans do not have this enzyme. Therefore, the end product of purine metabolism is uric acid. Uric acid is filtered in the glomerulus but then reabsorbed again. Further down the nephron it is secreted into the tubule. Most people with hyperuricemia have an issue with the process of secretion of the uric acid and are therefore are called “hyposecretors.” The best interventions to help with hyposecretion are medications that help optimize the secretion of uric acid, such as probenecid. Although probenecid is clinically efficacious, adherence is often poor because it is dosed multiple times a day. Alternate medications include allopurinol which attenuates the production of uric acid. Allopurinol reduces uric acid production by inhibiting xanthine oxidase, an enzyme that converts purines like xanthine and hypoxanthine to uric acid. By inhibiting this enzyme competitively, allopurinol through its active metabolite oxypurinol decreases uric acid production and thus helps prevent recurrent episodes of gout and tumor lysis syndrome. Allopurinol is affordable and easy to use, due to once daily dosing.

Febuxostat is another medication which helps decrease uric acid production by inhibiting xanthine oxidase. Febuxostat is metabolized in the liver and it is therefore available for use in patients with decreased renal function. It tends to be well tolerated in those unable to tolerate allopurinol.5

Neower medications like pegloticase and rasburicase are available in the form of infusions. Rather than decreasing uric acid production, these medications decrease uric acid levels by increasing the conversion of uric acid to allantoin. Thus, both pegloticase and rasburicase function as urate oxidases.

Impact of HLA Genotype

Severe cutaneous adverse reactions (SCAR) due to allopurinol use have been found to occur more frequently in some ethnic populations within Southeast Asia. This is partly due to the presence of a gene variant named HLA-B*58:01, present more frequently in some Asian populations. It is important to note that the correlation between the presence of genotype HLA-B *58:01 and SCAR due to allopurinol is not 1:1. Most – but not all – people with SCAR due to allopurinol have the genotype HLA-B*58:01. However, only a minority/subset of the population with the positive HLA-B*58:01 genotype who take allopurinol develop SCAR. It is not entirely clear why only a small subset of population with HLA-B*58:01 are at an increased risk for SCAR due to allopurinol. The strength of this association may be driven by subtle changes in renal function. While, it is not clear if the incidence of SCAR is dose-dependent, it is often assumed that higher levels of allopurinol/oxypurinol in patients with renal impairment may place them at a higher risk for SCAR. Oxypurinol directly interacts with the immune receptors encoded by the HLA-B*58:01 gene variant resulting in a dose-dependent activation of T cells. Even after stopping allopurinol in patients with SCAR and renal impairment, oxypurinol concentrations continue to be elevated and have been associated with higher mortality. Given the morbidity/mortality of SCAR in patients who are positive for HLA-B*58:01, avoiding allopurinol in this population may be wise.6–9

The Clinical Pharmacogenomics Implementation Consortium (CPIC) publishes guidelines to help clinicians use genetic information in routine practice. CPIC provides gene-based prescribing guidance for allopurinol. If HLA-B genotype is available, CPIC recommends whether or not to use allopurinol based on the absence or presence of the HLA-B*58:01 allele.10 While not an absolute contraindication, the American College of Rheumatology (ACR) suggests avoiding the use of allopurinol in patients with
the HLA-B*58:01 genotype due to the increased risk of AHS/SCAR. The ACR guidelines suggest HLA-B*58:01 screening in patients who are at a high risk for allopurinol associated SCAR; this includes patients of Korean descent who have stage 3 or worse chronic kidney disease, as well as patients of Han Chinese or Thai descent regardless of kidney function. Asians have the highest frequency of the HLA-B*58:01 allele (approximately 6 percent) followed by Black or African Americans (approximately 4 percent), Middle Eastern (approximately 4 percent) patients, Hispanic or Latino patients, and patients of European descent (approximately 1 percent). In the U.S. current drug labeling for allopurinol does not include recommendations based on HLA-B*58:01 status. However, in Taiwan, drug labeling for allopurinol recommends that testing for HLA-B*58:01 be performed prior to initiating allopurinol. In Japan, the label recommends caution based on HLA-B genotype. Note that all recommendations focus on toxicity risk; testing for HLA-B*58:01 does not predict allopurinol efficacy.

Implementation and Challenges
The potential benefits of gene-based allopurinol dosing are huge. A study in Taiwan involving nearly 3,000 people of Han Chinese descent focused on a population who had never taken allopurinol before but had indications for its use. In patients with Han Chinese descent, screening for the HLA-B*58:01 allele prior to use of allopurinol greatly lowered the number of SCAR events. As noted above, there is also an association between HLA-B*58:01 and allopurinol induced SCAR in a variety of other populations, including some with European background. Even if the allele frequency of HLA-B*58:01 is low, it may be worth considering genetic testing for “high risk” patients such as those with compromised kidney function, rather than for all patients with symptomatic hyperuricemia. Given the rapid pace of globalization and relative ease of travel between countries, HLA genotyping may become common and more necessary going forward.

A number of potential obstacles remain. The cost of genotype testing may not be covered by insurance for the HLA gene locus. As these tests are fairly new and not widely used, they tend to be expensive but costs are decreasing as genotyping becomes more readily available. In patients found to have an abnormal HLA-B allele, additional costs can be incurred by switching to an alternate medication. In a local head to head comparison for cost, febuxostat is much more expensive than allopurinol. Even with insurance coverage, febuxostat still tends to be more expensive. It is not clear at this time if insurance would cover a medication like febuxostat instead of a cheaper generic version of allopurinol based on HLA-B*58:01 genotyping result. Medications like pegloticase and rasburicase are infusions and tend to be prohibitively expensive. Insurance coverage for these newer medications can be an issue as well.

Overall, we agree with the ACR recommendations. If a patient already had genetic testing done, it would be wise to review the patient’s HLA-B*58:01 status prior to initiating allopurinol. Beyond this, ACR recommends that only patients with specific ancestry, and those who are at the highest risk for SCAR (mentioned above), be genotyped at the time of prescribing. Guidelines for tumor lysis syndrome do not provide recommendations regarding genotyping cancer patients prior to use of allopurinol. CPIC guidelines are available to assist clinicians in applying the genetic test results, but do not focus on when genetic tests should or should not be ordered. For gout, HLA-B*58:01 genotyping appears to be cost-effective for patients of Asian and African descent, but cost-effectiveness is less clear for Hispanic patients and patients of European descent. For tumor lysis syndrome, the utility of genotyping may be more universal. Genotyping for HLA-B*58:01 prior to chemotherapy is not routinely done in our region; however St. Jude’s Children’s Research Hospital routinely tests its pediatric cancer patients for HLA-B*58:01 status prior to initiating allopurinol. Beyond this application, HLA-B*58:01 genotype is not utilized frequently by primary care providers in the U.S. It does nevertheless give providers another piece of data to guide therapy in patients at risk of toxicity (those with altered renal function).

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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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E-cigarettes. Talk to your young patients.

As a healthcare provider, your discussions with your patients – especially younger patients – will go a long way toward educating and could even prevent a dangerous habit from starting.

Patient: There are fewer risks with E-cigarettes.

Unfortunately, there are many risks to using E-cigarettes: many contain nicotine which is addictive, can disrupt brain development, can complicate pregnancy, and is a known cause of SIDS; E-liquids containing nicotine are often concentrated enough to cause poisoning if ingested or absorbed through the skin; E-cigarette batteries can explode and cause burns or other injuries.

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Patient: E-cigarettes don’t have nicotine in them.

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The Opioid Epidemic in 2017: Are We Making Progress?

By David Woodard, MS IV; and Robert E. Van Demark, Jr., MD

Abstract

With the emphasis on pain control (i.e., pain as the fifth vital sign) starting in the late 1990s and the increased prescribing of opioids, the opioid epidemic began. With the expanding misuse of opioids a new emphasis has been given for more responsible management of opioid prescribing by health care providers in all specialties. Since the pain experienced by patients with chronic musculoskeletal pain and acute postoperative pain can be severe, specific attention must be given to these patients who may be at increased risk for opioid abuse. We review the opioid epidemic and the impact of the epidemic on physicians and patients. As a result of this epidemic, several intraoperative techniques have been developed to decrease the need for postoperative pain medication. In addition, we identify several key features of a patient's background and their behavior that can indicate a potential for opioid abuse or misuse. Treatment strategies for providers including opioid prescribing guidelines are also discussed.

Introduction

In 1995, the American Pain Society in conjunction with the American Society of Anesthesiologists, began a national campaign to address the perceived under treatment of pain in the inpatient setting. The rise in prescription use of opioids continued in 1998 when the "pain as the fifth vital sign" initiative emerged from the Department of Veterans Affairs, followed in 2001 by implantation of new pain management standards by the Joint Commission. Concerns soon arose over the unknown consequences of under treatment of patient pain. Use of prescription opioids increased in the acute setting as well as treatment of chronic musculoskeletal pain of spine and extremities. The relaxation of laws governing prescribing opioids for treatment of chronic noncancer pain, marketing by the pharmaceutical industry, and promotion of opioids by numerous physicians have contributed to the rise in opioid prescriptions.

The Opioid Epidemic

Pain management is a priority in patient care, especially following surgery and traumatic injuries. However, in the ambulatory setting, the prevalence of patient-reported pain has not changed in the U.S. during the past decade while there has been a large increase in opioid prescriptions for pain. This increase in opioid prescriptions was not accompanied by similar increases in prescriptions for nonopioid analgesics.

Using opioids to manage pain has led to unanticipated consequences for individuals and society. For the individual, use of opioids can lead to tolerance and worse treatment outcomes. Issues in society such as addiction and drug overdoses are observed when opioids are used inappropriately. Nontherapeutic use has become an epidemic in recent years. In the U.S. the drug overdose deaths rose every year between 1999 and 2012. The prevalence of opioid abuse and dependence increased from 0.095 percent in 2002 to 0.24 percent in 2011, an increase of 152 percent. The rate of overdose deaths from prescription opioid pain relievers in the U.S. increased every year between 1999 and 2012, quadrupling between 1999 and 2008. Since 2008, the opioid overdose epidemic has continued to grow. Unintentional drug overdose is now the leading cause of accidental death in the U.S., killing more Americans that motor vehicle crashes or firearms. Opioid-related deaths are more frequent than deaths from suicide. In 2015, drug overdose deaths in the U.S.
exceeded 50,000; in one year more deaths were caused by opioid overdoses than at the peak of the HIV/AIDS epidemic in 1996.12

Increases in prescription drug overdoses are largely responsible for the alarming rise in unintentional overdose death in the U.S.13 Prescription opioids represent the fastest growing type of drug abuse, the most common cause of unintentional overdose, and lead to more deaths annually than all illicit drugs combined.14,15 For every opioid overdose death in Massachusetts, there were twice as many hospitalizations and four times as many emergency department visits for nonfatal opioid overdose.16 In Massachusetts, opioid overdoses have caused over 16,000 deaths per year and $55 billion of increased costs.15,17

The medical community has responded to the startling epidemic. Even though during 2007-2012 the opioid-prescribing rate increased by 3.7 percent, the growth in opioid prescribing stabilized in 2010, and both opioid prescriptions per capita and opioid-prescribing rates remained level during 2010-2012. All specialties except pain medicine, physical medicine/rehabilitation, and internal medicine reduced their prescribing rates since 2010. Surgery, dentistry, and emergency medicine showed declines in opioid prescription both before and after 2010. Historically the three primary care specialty groups (family practice, internal medicine, general practice) accounted for nearly half (44.5 percent) of all dispensed opioid prescriptions.14 Only one-fifth of prescription drug abusers receive their prescription opioids from a single physician-prescriber, and a growing percentage obtain them by seeking multiple providers for prescriptions.19

The U.S. makes up approximately 5 percent of the world’s population, yet consumes 80 percent of the world’s opioid supply.20 A recent study comparing the differences in opioid prescription following operative treatment of hip and ankle fractures found significant discrepancies between patients in the U.S. and the Netherlands. American patients were prescribed significantly more inpatient and outpatient narcotic pain medications after surgery for hip and ankle fractures than Dutch patients. Nonopioid pain medications (i.e., ibuprofen and Tylenol) offered sufficient pain relief for the majority of Dutch patients. The study concluded that accepted standards for pain control among physicians and patients seem to have significant influence on prescribing practices. Both physician and patient factors contributed according to the study. Physician factors included differences in training and attitude toward pain. Patient factors included attitude toward pain, attitude toward narcotics, medication tolerance, perceived and expressed pain, social acceptance of pain, coping skill and other psychosocial factors as well as secondary gain.21

Impact on Orthopedic Surgeons and Patients

The musculoskeletal pain experienced by patients can vary greatly depending on the severity of the trauma, the chronicity of the symptoms, and the type of procedure endured. Many patients will require opioid prescriptions for relief of pain. Orthopedic surgeons are the third highest prescribers (7.7 percent of prescriptions in the U.S.) of opioid prescriptions among physicians.22 The importance of adequate pain control has been emphasized as it has been linked to better clinical outcomes, including better wound healing and improved immune function.23

The importance of opioid use and their detrimental effects on clinical outcomes is important for patients and orthopedic surgeons to understand. Opioid use has been associated with worse clinical outcomes in musculoskeletal disorders,4 total knee replacement,3 reverse shoulder arthroplasty,14 and spine surgery.25 Many physicians have long suspected that orthopedic trauma patients may be at risk for longer duration of postoperative opioid use if the patient used opioids prior to the injury and a recent study confirms this.26 In a study by Chapman, et al. orthopedic surgery patients with a history of chronic opioid use were compared with orthopedic surgery patients without a history of chronic opioid use. It was found that patients who reported chronic opioid dependency experienced greater severity of acute pain and slower pain resolution despite adjustments made for additional opioid administration.27 Preoperative opioid abuse or dependence has also been associated with increased inpatient mortality (odds ratio 3.7; 95 percent CI 2.7-5.1) and aggregate morbidity (OR 2.3; 95 percent CI 2.2-2.4). An increase in morbidity included increased ratio of induced mental disorder, respiratory failure, surgical site infection, mechanical ventilation, pneumonia, myocardial infarction, postoperative ileus or other gastrointestinal events. Abuse and dependence were also associated with an increased risk for hospital length of stay.4

A history of substance abuse is also the single greatest predictor of postoperative opioid overdose (OR 14.8; 95 percent CI: 12.7-17.2). A history of substance abuse could lead to inpatient opioid overdose due to an increased tolerance to opioids among these patients leading to dangerously narrow therapeutic to toxicity index, worse
pain tolerance in these individuals, or abuse of the medications in the inpatient setting. 28

In light of the complications and poor outcomes that preoperative opioid use had caused, one study calls for further development of multidisciplinary approaches to effectively reduce opioid prescribing and associated adverse consequences in the orthopedic surgery setting. Wide screening for opioid misuse preoperatively has also been suggested along with encouraging patients who are using opioids inappropriately to discontinue them. Physicians may be forced to postpone performing elective surgery in patients who are currently misusing opioids, and should closely monitor postoperative patients with a history of opioid abuse.4

Methods for Perioperative Pain Control

Overuse of opioids has increased interest in non-opioid treatments for perioperative pain. Multimodal therapy approach has been proposed and has shown clinical benefit. The principle behind multimodal therapy is to use interventions that target several different steps of the pain pathway, allowing more effective pain control with fewer side effects. 29 Several protocols for a variety of techniques have been developed including neuraxial, peripheral nerve 30 and local infiltration blocks 31 with and without catheters have been described. Novel intravenous, oral and local additive drugs and delivery systems have also contributed to the variety of treatment strategies. 32-34

Treatment Strategies

A strategy for determining a patient’s risk of preoperative opioid use includes obtaining a patient’s history, recognition of aberrant behaviors, drug testing, use of prescription drug-monitoring programs, and using opioid risk-assessment screening when necessary. Awareness of these objective measures can be useful adjuncts to clinical experience and judgment when dealing with challenging patient scenarios.

Identifying the At-risk Patient

Screening patients at risk for nontherapeutic opioid use is difficult to do because pain is a subjective symptom, and patients may have unknown motives or secondary gain issues when reporting pain. A physician’s intuition and suspicion are more commonly used than objective data when screening for nontherapeutic use but are not always reliable. Objective measures to help screen for nontherapeutic opioid use include elements of patient’s history, aberrant behaviors, drug testing, prescription drug monitoring programs, and opioid risk assessment tools. Specific characteristics in the patient’s history that may suggest a patient is at risk for opioid abuse include personal or family history of substance abuse other than nonprescription opioids, age less than 45, depression and other psychiatric diagnoses. 35 Two recent studies indicate that a lower level of education 36 and a history of preoperative opioid abuse 36,37 are significant predictors of postoperative doctor shopping in the orthopedic trauma population. Determination of these risk factors should be a part of the initial history and screening process. Obtaining an appropriate prescription drug history is recommended but unfortunately self-reported opioid use is often unreliable.7

Recognition of aberrant behavior is an important component of the screening process. Alarm behaviors include early refill requests, treatment noncompliance, or reports of “lost” or “stolen” prescription should be documented. Unfortunately monitoring for aberrant behavior alone may be inadequate, but when coupled with urine drug testing, the pair has been recognized as a valuable treatment strategy. 7

Several opioid risk-assessment screening tools have been applied to chronic pain patients and may better stratify patient risk factors for nontherapeutic opioid use. Among several validated screening tools for opioid risk assessment are the Pain Medications Questionnaire and the Screener and Opioid Assessment for Patients with Pain-Revised. 7 Another tool called The Opioid Risk Tool is a five-question instrument that can reliably differentiate between high and low risk patients for opioid misuse.38

State prescription drug monitoring programs (PDMP) are electronic databases that collect data on controlled substance prescriptions to deter nontherapeutic opioid use and doctor shopping. These programs are designed and maintained at the individual state level, so there is limited ability for data exchange between states. Although nearly every state has a PDMP, few states mandate providers to look up each patient in the online state database before prescribing opioid medications.

Setting Patient Expectations

Pain is an important determinant of patient satisfaction, and physicians should work with the patient to manage pain while avoiding overprescribing opioids. Most patients are honest about the level of pain they are experiencing, but a small percentage of patients use opioids nontherapeutically and doctor shop for additional opioids, making this delicate balance even more difficult. As physicians, we need to have a preoperative discussion
with our patients to optimize their coping mechanisms and provide a reasonable pain management program for their postoperative treatment.\textsuperscript{39}

Several strategies exist to help physicians establish patient expectations and set boundaries for pain management. Counseling patients to help establish reasonable expectations for pain management should be considered at the initial treatment plan discussion as well as each follow up visit. Preoperative visits with patients provide opportunities for patients to ask questions about the procedures and address their concerns regarding postoperative pain control. Physicians need to understand the fear-avoidance model theory of chronic pain development. This cognitive behavioral model proposes two extreme responses to pain: the adaptive response (i.e., confrontation) and the nonadaptive response (i.e., avoidance).\textsuperscript{39} The latter response can result in disability caused by persistent avoidance behaviors motivated by fear of causing themselves pain. This can lead to fear of movement and physical disuse. Associated with pain disability is pain catastrophizing – an exaggerated negative psychological response to the anticipation of pain – which can intensify the pain experienced following orthopedic surgery.\textsuperscript{40}

A standard pain protocol for specific surgical and nonsurgical treatment plans with an opioid taper can be helpful, such as transitioning a patient from an opioid to a nonsteroidal anti-inflammatory drug (NSAID) on a certain day postoperatively. Communicating pain goals for the perioperative period is important as many patients are under the assumption that the goal of the health care provider is complete elimination of pain with analgesics. The goal of postoperative pain relief should be 30-55 percent improvement, not a “0” perioperatively.\textsuperscript{39} For the most part, patients undergoing the same surgery have similar nociception based on similar tissue disruption and inflammation. However, the emotional, cognitive, behavioral response to nociception is highly variable and greatly impacted by psychosocial factors. The best pain reliever is self-efficacy – a belief that a person can achieve one’s goals.\textsuperscript{39}

Structured plans help physicians and other office members recognize when a patient is requiring a longer duration, or higher dose of opioid or is otherwise exhibiting aberrant behavior. Deviations from a standard pain protocol can help physicians identify when consultation from a pain management specialist is warranted. During the preoperative period affirming a patient’s commitment to opioid independence should be reinforced. An opioid contract may helpful to both patients and providers, as a formal and explicit written agreement that delineates key aspects of opioid therapy.\textsuperscript{38}

Prescribing Habits

The “opioid-centric habits” of surgeons has played a role in fueling the opioid epidemic. Surgeons need to change their approach to perioperative pain management: this will require a cultural change in our prescribing habits.\textsuperscript{12,38} Surgeons need to have a preoperative discussion with our patients to discuss pain management including the use of nonopioid medications (NSAID and Tylenol) along with the use of coping mechanisms for pain control. In addition, the role of nonpharmacologic methods (exercise, relaxation techniques, biofeedback, massage therapy, and physical therapy) can play an important role in postoperative pain management.\textsuperscript{38}

In general, surgeons should prescribe narcotics only for severe pain. Mild pain should be treated with a trial of nonopioid medication. If opioids are needed for pain control, the lowest effective dose should be used and for a limited time period. The need for prescribing narcotics for more than seven days should be documented.\textsuperscript{38}

In addition, we can implement new prescribing practices. Hill and Haythem have recommended the following guidelines:\textsuperscript{41}

1. Counseling patients preoperatively regarding adequate pain control to function (i.e., sleep, eat, ambulate) but not to achieve zero pain. (Function is a better indicator than pain level).
2. Using nonopioid alternatives for patients undergoing procedures with only minor pain.
3. Checking the state PDMP to confirm patients are not receiving opioids from another provider.
4. Providing clear instructions for methods of disposal for unused medication.
5. Prescribing the “minimum quantity necessary.”

Many times, opioids are over prescribed for patient and physician convenience (to avoid phone calls for a prescription renewal). Electronic prescribing will make it easier to prescribe a smaller number of pills and allow physicians to remotely order a prescription renewal electronically. In 2010, the DEA issued regulations allowing to prescribe controlled substances electronically. Although 90 percent of physicians have electronic medical records and 81 percent of pharmacies can receive computerized prescriptions, only 8 percent of physicians
use computerized prescriptions for controlled substances.12

Summary
Nontherapeutic opioid use is becoming more prevalent across all medical and surgical specialties, including orthopedics, and carries a risk of potentially serious consequences.13,22 Surgeons must continue to treat their patient’s pain while also establishing strategies based on objective measures and patient communication to help battle the opioid epidemic at both the individual and societal level.

With the current opioid epidemic, physicians need to improve our systems and practices for prescribing narcotics. We can’t wait for the state or federal government to legislate guidelines for prescribing medications. We can change our prescribing habits and temper our patient’s expectations regarding perioperative pain control.12

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Bacterial meningitis is a potentially life-threatening medical emergency. In just hours, death can occur. In the U.S., bacterial meningitis is most often caused by Streptococcus pneumoniae, group B Streptococcus, Neisseria meningitides, Haemophilus influenzae, and Listeria monocytogenes. Even with treatment, 10-15 percent of infected people will die from meningococcal disease and about 10-20 percent of survivors will experience disabilities, including nervous system problems, brain damage, hearing loss, and loss of limbs. Therefore, prevention is key. Immunization against various types of bacterial meningitis is the most effective way to protect against meningococcal disease.

Neisseria meningitides serogroups A, B, C, W, and Y are accountable for a large majority of meningococcal disease in children and young adults, with serogroups B, C and Y being most prevalent. There are two meningococcal vaccines that protect against serogroups A, C, W, and Y and two vaccines that specifically protect against serogroup B. The two Food and Drug Administration (FDA) approved vaccines available for serogroup B meningococcal disease are MenB-4C (Bexsero) and MenB-FHbp (Trumenba). Both are approved for individuals 10 through 25 years of age. MenB-4C (Bexsero) is a 2-dose series. MenB-FHbp (Trumenba) is a 3-dose series with a newly approved 2-dose series as of March 2017. Of note, MenB-4C (Bexsero) and MenB-FHbp (Trumenba) are not interchangeable. The two vaccines use unique protein antigens. Once the series has been started, the same product must be used for the entirety of the series.

Previously, the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) recommended the use of either 3-dose MenB-FHbp (Trumenba) or 2-dose MenB-4C (Bexsero), for people 10 years and older with increased risk of serogroup B meningococcal disease. Risk factors include anatomic or functional asplenia, having persistent complement component deficiency, microbiologists exposed to Neisseria meningitidis, patients receiving eculizumab (Soliris), and people found to be at increased risk because of an outbreak of serogroup B meningococcal disease. While not routinely recommended, healthy persons aged 16 to 23 years may consider vaccination for short-term protection using either 3-dose MenB-FHbp (Trumenba) or 2-dose MenB-4C (Bexsero).

Updated recommendations from ACIP now include 2-dose MenB-FHbp (Trumenba). The recommendations state persons at increased risk for meningococcal disease, as previously described, should receive the 3-dose MenB-FHbp (Trumenba) at 0, 1-2, and 6 month intervals. Healthy individuals that do not have an increased risk of meningococcal disease should receive the 2-dose MenB-FHbp (Trumenba) at a 0 and 6 month interval. Recommendations for MenB-4C (Bexsero) remain unchanged.

This recommendation comes in part from results of a clinical trial that assessed the immunogenicity of 3-dose versus 2-dose MenB-FHbp (Trumenba). The study included healthy persons between 11 and 18 years of age. Participants were randomly assigned to one of five different 2- or 3-dose vaccination regimens. The 5 regimens included 2 3-dose and 3 2-dose strategies. The 3-dose regimens administered vaccinations at 0, 1, and 6 month, or 0, 2, and 6 month intervals; the 2-dose regimens administered vaccinations at 0 and 6 month, 0 and 2 month, or 0 and 4 month intervals. The serum bactericidal assays using human compliment (hSBA) were assessed one month after the final vaccine dose as the primary endpoint. A titer of 1:8 or greater, a conservative measure, was chosen to correlate with a protective serorespance. The 3-dose regimens produced higher levels of hSBA antibodies, but all five regimens provided immunogenicity. Between the tested 3-dose regimens, there was no significant difference in response whether the second dose was at one or two months. While immunogenic responses generally increased when there was a longer...
interval between vaccine administrations in the 2-dose regimens, it is valuable to notice the study found immunogenic responses after just two doses only one month apart. This may be beneficial information in the case of an outbreak requiring rapid immunization.

When administered as either a 2- or 3-dose series, MenB-FHbp (Trumenba) is immunogenic and well-tolerated. The 3-dose series did produce more substantial hSBA response rates against Neisseria meningitides serogroup B. Therefore, ACIP has updated recommendations for MenB-FHbp (Trumenba) to include the 3-dose regimen for patients 10 years or older at increased risk of meningococcal disease or during an outbreak. ACIP now recommends MenB-FHbp (Trumenba) as a 2-dose series for healthy individuals between 16-23 years of age who are not at increased risk for meningococcal disease. ACIP does not recommend one MenB vaccine over the other.

REFERENCES


About the Authors:
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Through my years of caring for people, many seem caught in deep-down joy-starving depression. I have seen the devastation from that awful diagnosis involve not only those sad and melancholy, but greatly affect those around them. For those 18-45 years of age, depression is the number one cause for disability, resulting in an estimated $200-plus billion of lost earnings per year. I have looked on with aghast when depression caused such helplessness that the patient chose to escape life with suicide. There are about 40,000 deaths per year to suicide, which accounts for about the same number of deaths to breast cancer. Despite a similar death rate, the money invested in depression research is about 1 percent of that spent studying breast cancer.

Science has not yet defined why depression occurs, but theoretical causes for this malady, include a genetic tendency, a learned process, a troubled childhood and adolescence, a stressful environment, sad or traumatic situations, addiction, or even not enough sun. Most of us periodically have what is called “situational depression,” such as the appropriate sadness that follows severe loss or death of a loved one. What is more typical of harmful depression is when there is no “situation,” no reason for it to happen, no sad story to explain why one is filled with sadness. When the patient says, “there is no reason for my being so sad,” the clinician knows there is a problem.

The diagnosis is not always that easy. We suspect depression when people experience chronic pain, find it hard to concentrate, are without energy, have flares of temper, sleep too much or too little, have a loss of appetite or have over-eating binges, have unexplained crying spells, or become filled with anxiety for minimal reasons. People often make things worse by covering up depression with alcohol, sleeping pills, anti-anxiety medications, or substance abuse, and these meds all make the diagnosis even more difficult.

Although two-thirds of people with depression do not seek or receive help; when the one-third that do get help follow-through with treatment, 80 percent are better in four to six weeks. There is help and hope for those with this miserable condition, but people need to be open to the possibility of such a problem, (and men are usually the worst deniers.) Treatment includes a half-hour of exercise or walking daily, someone to talk to, and often a medication with minimal side effects.

If you are possibly struggling with depression, please get help. At least do it for those around you.
The serious condition of sepsis affects more than a million patients a year in the U.S., making it a costly disease with significant morbidity and mortality. It is defined as life-threatening organ dysfunction due to a dysregulated host response to infection. Updated criteria for defining sepsis and septic shock were released by an international task force in early 2016. The Surviving Sepsis Campaign (SSC) released International Guidelines for the Management of Sepsis and Septic Shock which was published online by JAMA on Jan. 19, 2017.

The SSC was launched in 2002 and is a world-wide effort to decrease sepsis mortality. Its agenda includes building disease awareness, increasing sepsis recognition, and implementing performance improvement. Mortality has improved over this time but sepsis remains a constant challenge. The guidelines published in January include updates in initial resuscitation recommendations and antibiotic therapy choices. These areas have noticeable changes and advances from earlier guidelines. Fluid resuscitation protocols have also evolved to become more patient-centered and responsive to status changes.

Timely and appropriate administration of antibiotic agents is essential for treatment and antibiotic stewardship must also be considered. In the case of suspected sepsis, new guidelines recommend antibiotics should be given within one hour. Multiple studies have shown delay was associated with increased mortality. Contrary to the emphasis on overuse of these agents, this condition requires rapid assessment and treatment with appropriate antibiotic therapy. It is advised to assess patients daily for de-escalation of antimicrobials and to direct the therapy based on cultures and/or clinical improvement.

The Centers for Disease Control and Prevention has launched “Get Ahead of Sepsis,” an educational initiative to emphasize the importance of early detection and timely treatment as well as the importance of preventing infections that could lead to sepsis. The initiative aims to educate providers as well as patients and family members.

There is hope to develop more reliable ways to measure the impact of interventions such as vaccination programs, chronic disease management and appropriate antibiotic use. The goal is to give resources to patients and providers to help stop this medical emergency in its early stages.

The public response to sepsis has been the incentive for certain states to pass regulatory protocols regarding sepsis treatment with public reporting of results. There has been discussion of legislation requiring all states to eventually follow these protocols. Some experts caution that regulating sepsis care, though well-intentioned, may have unintended consequences in over diagnosis and overuse of treatments. There still exists a fair amount of uncertainty around sepsis and its appropriate diagnosis, including coding and documentation. Protocols that mandate physician orders may pose a risk of promoting unnecessary testing, antibiotic overuse, intensive care unit capacity challenges and delayed diagnoses of other conditions.

Sepsis remains a challenge. The Centers for Medicaid & Medicare Services (CMS) is putting forth multiple efforts to increase sepsis detection and appropriate level of care. The Great Plains Quality Innovation Network continues to support these efforts and was awarded a special innovation project by CMS titled, “Reduce Diagnostic Error through Early Recognition of Sepsis.” The project will involve a collaborative effort with multiple stakeholders including emergency medical systems, home care, long-term care, patients, providers and hospitals to increase awareness of this disease.

To paraphrase a centuries-old quote about this disease: In the beginning of this malady, it is easy to cure but difficult to detect. In the course of time, it becomes easy to detect but difficult to cure. Please contact me at Stephan.Schroeder@area-a.hcquis.org with questions or comments.

SOURCES
1. JAMA. 2016 315(8) 762-774
What is a confidential monitoring program?
When an applicant or a licensee has been determined by an evaluation to be impaired in a manner where the individual demonstrates the inability to practice in their health-related profession with reasonable skill and safety due to mental health issues, physical issues, or substance use related disorders (alcohol or drug abuse, dependency, or addiction), the applicant or licensee is enrolled in a confidential monitoring program. The confidential monitoring program is an agreement between the participant (applicant or licensee) and the BMOE staff review panel to defer any recommendation for discipline on a license as long as the participant can be monitored to ensure their ability to safely practice. See the flowchart graphic for the process.

What is the purpose of the BMOE staff review panel?
The review panel administers the program for the individual. The participant’s case stays at the staff level and does not go to the full BMOE unless the participant is unable to comply with the MBMP. The review panel consists of the BMOE executive director and one BMOE board member who will, in effect, “be considered one of the staff” in order to make the recommendation as to whether the individual is eligible for the MBMP.

What are the eligibility requirements for the MBMP?
The MBMP monitors impaired healthcare providers. The potential participant will have undergone an evaluation that demonstrates their inability to practice in one’s health-related profession with reasonable skill and safety due to mental health issues, physical issues, or substance use related disorders (alcohol or drug abuse, dependency, or addiction).

Do I need to enroll in the MBMP if I already participate in a monitoring program administered by my employment or other entity?
You can continue in your current monitoring program without enrolling in the MBMP. However, you must report your participation in any and all monitoring/wellness programs, other than the MBMP, on or before you submit your annual license renewal application. You also need to be aware that the MBMP is the only state BMEO approved confidentially protected program for South Dakota licensees.

I am licensed in another state and am enrolled in that state’s monitoring program. Now I am also licensed in South Dakota where I currently practice. Do I have to enroll in the MBMP, and how do I keep my previous monitoring program informed that I am in compliance?
Yes, you do need enroll in the MBMP as it is the only state BMEO approved monitoring program. The MBMP will then contact your previous monitoring program and send reports regarding your compliance.

Do the BMEO members know who is in the MBMP?
The MBMP participation list is only known to designated BMEO staff and the BMEO investigative review panel. The BMEO members do not know who is in the MBMP except for the one board member who is assigned to the BMEO.
investigative review panel. All monitoring will remain confidential to the BMOE board members as long as the participant is compliant and doing well in the monitoring program.

Does the public know who is in the MBMP?
An individual’s participation in the MBMP is confidential to the public as long as the participant is in compliance with program requirements. The public does not have access to information that would identify participants in the program, except in rare cases where the BMOE staff files formal disciplinary charges against a participant which may include noncompliance with an MBMP contract.

Who administers the MBMP?
The MBMP is administered by BMOE staff and the established review panel pursuant to authority granted by administrative rules promulgated by the BMOE.

What happens when a licensee or applicant self-reports?
The MBMP monitors participants struggling with impairment issues related to substance abuse, mental health issues, or physical disability, and is not a disciplinary program. The MBMP considers a licensee’s or applicant’s self-report to be a positive first step toward bringing a potentially harmful situation under control before their professional reputation is damaged.

The MBMP will gather information and make referrals for evaluation as needed. The MBMP then works with the licensee or applicant to put the required supports in place to ensure the participant is able to continue to practice safely. The majority of individuals participating in the program are actively practicing.

Who evaluates the potential participants?
Potential participants are evaluated depending upon the case history of each individual. Some individuals may self-report or apply to the MBMP after having been involved in the judicial system; for example, a DUI or other incident where evaluations are already available. In other cases, there may be questions as to whether a diagnosis indicative of impairment exists. That individual would be referred to the appropriate evaluator or evaluation team prior to entering the confidential MBMP.

Who treats the participants?
Once a determination of impairment is made and the participant enters the MBMP, the participant chooses a medical and support team. The MBMP participant is an active participant with their medical and support team. As determined by the previously mentioned evaluation recommendations, this team is comprised of a monitoring physician or other healthcare provider; a monitoring therapist, psychologist, or counselor; a work-site monitor, and an aftercare monitor. The medical and support team will be approved by the MBMP.

Is it a good idea to have the licensing board administer the program?
The BMOE has a legal obligation and mission to ensure safe medical practice for the protection of the public who seek professional medical services within the State. The BMOE has promulgated administrative rules that provide a transparent process for the investigation and regulation of medical practice while providing due process rights to applicants and licensees. While the process is transparent, participation remains confidential. Healthcare facilities have immunity when reporting employees to the BMOE staff.

Who is the contact person?
For the convenience of the licensee or applicant, one person on the BMOE staff is designated for contact purposes. Separate and dedicated phones, both mobile and land-line with a toll-free phone number option, are available. A separate and dedicated email is also accessible. A separate and dedicated website is being developed.

Please contact:
- Randi Sterling
  Medical Board Monitoring Program (MBMP)
  Phone: 605-367-7700 | Toll free: 888-340-4371 |
  Cell: 605-400-4542
  Email: mbmp@state.sd.us

Who answers general questions?
Any general questions should be directed to the BMOE executive director, Margaret Hansen.

Summary
The BMOE has a long history of monitoring its licensees. The BMOE has agreements in place with the monitoring companies, Affinity eHealth and Soberlink to serve the MBMP. The BMOE is continuing to research other regional and national monitoring programs including protocols, processes, budgets, and program services, to identify best practices.
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SDSMA Membership Services works hard to ensure that you have the programs and services you want and need, as well as marketing the association to potential new members. We want to hear from you if you have questions, concerns or ideas on how we can serve you better, or if you know of a potential new member. It’s your association and we’ll work with you to make it the best it can be.

“For Your Benefit” is the SDSMA’s monthly update on programs and services available to members.

SDSMA Receives Grant to Provide Opioid Prescriber Education

In partnership with the South Dakota Department of Health, the SDSMA will conduct a 12-month prescriber educational campaign aimed at reducing prescription drug diversion and abuse by holding educational events for prescribers.

The nonmedical use and abuse of prescription drugs is a serious health problem in this country, and although most people take prescription medications responsibly, an estimated 52 million people – 20 percent of those 12 and older – have used prescription drugs for nonmedical reasons at least once in their lifetimes. While South Dakota had the lowest number of opiate deaths in 2015 when compared to any other state, prescription drug abuse is a problem to which South Dakota is not immune. The desired results of this project are to enhance prescriber knowledge, decrease the overall number of opioids prescribed in South Dakota, and increase prescriber registration, utilization and incorporation of PDMP data into daily practice.

Watch your email and South Dakota Medicine for future announcements regarding forthcoming programming and events.

Sign Up to be Doctor of the Day at the State Capitol!

The SDSMA’s Doctor of the Day program is a huge success every legislative session.

During session, the SDSMA commits to providing a physician member to serve as Doctor of the Day for the State Legislature in Pierre. This volunteer commitment involves one day of service at the State Capitol by providing basic medical assistance to legislators and staff as needed.

As Doctor of the Day, you’ll have the unique opportunity to interact with legislators on the House and Senate floors and get a firsthand look at the legislative process and how it affects the practice of medicine. Your presence at the Capitol shows legislators not only your expertise but also your concern for the health of South Dakotans.

The SDSMA is in need of volunteers willing to spend a day to serve as Doctor of the Day. Each year we receive requests from physician assistants and advanced practice nurse practitioners who wish to participate in the program. It is critical that volunteer physicians are serving each day of session.

For more information and to see a listing of available dates, visit www.sdsm.org. If you are interested in volunteering or have questions, please contact Mark East at 605.336.1965 or meast@sdsm.org.
Keep Your Information Up-to-Date: Log on Today

In order for the SDSMA office to provide members with timely information, it is important that members regularly review their contact information on file with the SDSMA. Have you changed practice locations? Is your email correct? Is your mail going to the right place?

All SDSMA members have an existing online profile. Visit www.sdsmo.org and log into your secure online account. Next, access your profile by clicking the “Update my Profile” link at the top of the page.

Please take a few minutes to review your profile and make any necessary updates. Updating your secure account keeps your information up to date and notifies the SDSMA of any changes so you are accurately listed in the member directory and ensures that your membership materials, emails and renewal notices are sent to the appropriate mailing and email addresses.

Do you have a new photo? Updated photos can be uploaded to your user account or emailed to membership@sdsmo.org.

SDSMA President Visits Medical Districts

SDSMA President Dr. Robert E. Van Demark Jr’s Presidential District Visits are underway. Dr. Van Demark and physicians attending these meetings have discussed issues facing physician practices, the challenges faced in health care in South Dakota and nationwide, and the ways physicians can work together toward common goals.

Members have the opportunity to provide input on the following topics and more:
• Prescription drug abuse – Safe prescribing practices and ending the opioid epidemic
• Telemedicine – Practice and regulation
• Tobacco – Purchase-age increase to prevent addiction
• Physician-assisted suicide – possible ballot measure in the 2018 General Election
• Marijuana – two proposed 2018 General Election measures to legalize

So far, Dr. Van Demark has been hosted by District 2 medical society in Watertown, District 3 in Flandreau and District 8 in Vermillion.

Please consider attending your district’s meeting. Dr. Van Demark and SDSMA staff want to hear your concerns about challenges that affect care for patients and to gather ideas on how to work together to represent physicians both at the state and federal levels.

Legal Brief Highlight: Commitment of People Who Are Mentally Ill

The procedures for the commitment of people who are mentally ill are complex and include provisions intended to protect the rights of the patient. While statutes are complex, they are required to ensure every person is secure in their right to due process before being detained. Because of the potential for unintentional violations of personal rights in the involuntary commitment of adults and minors, whether for treatment of mental illnesses or chemical dependency, the physician is strongly encouraged to review the applicable statutes and consult with legal counsel. It is important to remember the laws attempt to balance the patient’s rights with the need for commitment and treatment, even if the person cannot recognize their need or consent to treatment.

More information is available in the SDSMA legal brief Commitment of the Mentally Ill at www.sdsmo.org. Through the SDSMA Center for Physician Resources, the SDSMA has developed more than 50 legal briefs that are available to members. In addition, the Center develops and delivers programs for members in the areas of practice management, leadership and health and wellness.
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