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The Electronic Health Record – Making it Work for Us and Our Patients

By Tim M. Ridgway, MD, FACP
SDSMA President

The president of the American Medical Association (AMA), Steven J. Stack, MD, is an emergency medicine physician who has a special interest in technology and its uses in medicine. Each time I have heard him speak over the past year, he begins by describing his frustration working in the emergency room, being distracted by the demands of entering data in the electronic health record (EHR), and the fact these requirements interfere with what is most important to him—interaction with his patients. Sounds familiar, doesn’t it? One of the consistent complaints I hear from family members is the limited time they spend face to face with their physician, and that much of this time is spent with their physician’s eyes on the computer screen and not on them!

Congress enacted the HITECH act with the best of intentions and, in large part, physicians have achieved the law’s goals of EHR adoption. In 2001, only 18 percent of physicians used EHRs. Today, more than 80 percent do. However, as the regulatory framework of “meaningful use” has evolved, layer after layer of new requirements have been added—above the original intent of the law. This has led to a complex web of requirements that has had a significant impact on the physician-patient relationship as physicians must now spend much of the patient visit entering data into a computer—and much of this data entry is typically unrelated to the immediate needs of the patient.

Complicating matters is the fact that regulators and software vendors have largely ignored the areas of greatest need—building the infrastructure to ensure systems work together to seamlessly exchange information and providing flexibility so that systems can be designed to support health care decision making by physicians and patients. I do not think many of us would argue about the potential good which can come out of use of the EHR, but also believe most of us have been exceedingly frustrated how its use in its present form interferes with patient care.

The AMA has been calling for reform, and in January, the Centers for Medicare and Medicaid Services (CMS) Acting Administrator Andy Slavitt stated: “The meaningful use program as it has existed, will now be effectively over and replaced with something better.” Among the steps outlined by CMS are: moving the focus away from the use of specific technology and towards a focus on improved patient outcomes; ensuring that health technology is developed for individual practice needs, not the needs of the government; and concentrating on interoperability.

I personally believe one of the most important recommendations for improvement in meaningful use is achieving seamless interoperability and information exchange. In Sioux Falls, for example, there are three different EHR systems which do not communicate with each other. When a patient is seen by their primary physician, and referred to a physician in a different health care system with a different EHR, volumes of fax records are generated. In addition, much of this information is meaningless, and the physician must carefully sort through the volumes of records to determine what is pertinent. This is simply not good patient care. A good EHR must correctly match patients to their medical information. A provider directory should be established so physicians can find and direct patient information to each other online. In addition, clinician input should be used to standardize data vocabularies so information has the same meaning and same format. Interoperability and measures reliant on connecting to other data sources should reflect how data is transported to improve patient care, not simply the quantity of data exchanged. Finally, and importantly, technology limitations, e.g., the lack of concise summaries of care, must be resolved before physicians are held accountable for these actions.

Recently, your South Dakota State Medical Association delegation (Dr. Mary Carpenter, AMA delegate, Dr. Tom Herman, SDSMA president-elect, and I) met with Rep. Kristi Noem, Sen. Mike Rounds, and Sen. John Thune, urging them to support the reforms mentioned above. Examples were given on how the EHR, in its present form, effects the care our patients receive. I believe we made an impact. The bottom line is we need the EHR to work for physicians and their patients, not the opposite.

With hard work and diligence, we can achieve meaningful reform on use of the EHR—reform that will benefit South Dakota physicians and their patients in a very positive way. It is hoped these reforms will help to transform the meaningful use program from one that frustrates and distracts physicians to one that empowers the physicians to provide the highest quality care possible.
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Reflections: A CJD Diary

By Jerome Freeman, MD, FACP

Reflections can be riveting. Of course the word “reflection” can pertain to thoughtful cognitive activity. But the term can also suggest an image, as when we perceive ourselves mirrored in still water. Certainly our perception of ourselves may seem magnified and eerily distorted on the occasions of turmoil and tragedy we may encounter in clinical medicine.

Virtually every clinician experiences times when very bad news must be given to a patient or a family. In neurology, revealing a diagnosis of motor neuron disease, brain glioblastoma or even Alzheimer’s disease can be emotionally daunting for the clinician and tragic for the patient/family. Often these conditions are diagnosed relatively early and the clinical course can be anticipated and predicted. A particularly tragic condition is Creutzfeldt-Jakob disease (CJD). It causes a swift and violent assault on personhood.

Despite the ordinary and routine often encountered in medicine, there are times when a unique challenge arises. I am reminded of a 71-year-old woman who presented to me with subtle motor and behavioral changes. She had been healthy and active but had recently been noted to have difficulty adjusting her motorcycle helmet strap. Her depth perception seemed altered and her cursive handwriting was observed to deteriorate. Despite such symptoms, she was continuing to do clerical work for an employer. Her coworkers had noted no real deterioration in her functioning except that she seemed to work more slowly. She did have a longstanding history of anxiety. Her primary physician ordered an MRI that showed some rather striking changes – bright signal on diffusion weighted images (DWI) was seen throughout the cortex of both hemispheres. Such MRI changes can be strongly suggestive of CJD.

When I performed my initial exam, she was alert and well-oriented, providing a seemingly accurate history. Despite interacting well socially, her formal cognitive test showed mild impairment.

After reviewing her MRI, I visited with her and her husband about the ominous prognosis her MRI suggested. I actually used the term Creutzfeldt-Jakob disease and generally explained that this condition would be expected to progress and shorten her life. I wondered at the time if I was being too gentle and vague about the outlook. Ordinarily when I have seen people with Creutzfeldt-Jakob disease, there has been severe and rapidly progressive dementia. I do not recall a time when I have made this diagnosis in somebody who was still doing well socially and gainfully employed. Her continued high level of social functioning gave me pause as to the accuracy of my diagnosis and what exactly I should say to her and her husband.

Thereafter, I saw her on two more occasions at two-month intervals. At our first follow-up visit, she could no longer sign her name or use the curling iron. By four months after the initial diagnosis, she was clearly having much more difficulty. She could not distinguish right from left and was only able to eat with her fingers, not utensils. She had become more apathetic and needed assistance with dressing and bathing. She continued to inexorably worsen and died seven months after I initially met her. Her rapid decline was very consistent with CJD.

Amazingly, on the very day I met this woman, another new patient appeared in my clinic with the same diagnosis. This was a startling coincidence since the estimated incidence of CJD in the U.S. is one case per 1 million per year. This second patient was a 77-year-old man who was seen urgently because of major behavioral and cognitive decline. His MRI also showed DWI changes very suggestive of Creutzfeldt-Jakob disease. He demonstrated profound cognitive impairment. He had some expressive dysphasia and trouble following two step commands and drawing a clock. In his case, I was able to sadly but confidently tell him and his family that CJD seemed likely and that palliative care was the best option. His neurologic condition rapidly deteriorated thereafter and he died a month after I first met him. The family opted for an autopsy which confirmed prion disease consistent with CJD.

And so it goes. Imagine standing solemnly before our patients and their families as we cast shimmering reflections in a mirror across the room. As we strain to focus, we might perceive ourselves as being emblematic of a soothsayer, the bearer of stern tidings. We might liken ourselves to the mythological Cassandra, having to foretell doom that still appears distant and implausible.

Our clinical work deserves thoughtful reflection and I’ve pondered these two patients with CJD a lot. The first patient and her husband were stunned by my diagnosis. They had no inkling that her vague symptoms would prove to be a rapidly fatal disease. Her condition was diagnosed at an unusually early stage. But perhaps even more unlikely and amazing is the fact that these two patients with CJD appeared in my clinic on the very same day. Such coincidences prompt uneasiness and wonder. Perhaps they should serve as a reminder that much in medicine is veiled. Statistics don’t drive the individual realities we encounter – patients do. While we may be staggered by the improbable and ominous, our care for patients demands that we acknowledge our limitations, shake off disillusionment and commit to trudge onward.

REFERENCES


Dr. Lamfers practices hospital medicine at Sanford Healthcare.

Early in his career, he emerged as a leader in Quality Improvement.

He has been instrumental in teaching evidence-based medicine to housestaff.

His rigorous approach to Patient Safety has inspired students, residents, fellows, and faculty.

Recently, his efforts to standardize quality have led to his appointment as GME Quality Officer at the University of South Dakota Sanford School of Medicine.
Total Ankle Arthroplasty Using the Agility Stemmed Talar Revisional Component: Three to Eight Year Follow-Up

By Gregory F. Alvine, MD; and Franklin G. Alvine, MD

Abstract

Background: Ankle fusion has been the traditional treatment of choice for failed total ankle arthroplasties or arthritic conditions that preclude the use of primary implants. A custom stemmed agility talar component was designed to be used in these conditions.

Methods: The first 30 cases by a single surgeon were reviewed at two intervals. The study was a retrospective chart review with data including ankle diagnosis, deformity, bone loss and other factors that may have an impact on ankle arthroplasty. American Orthopedic Foot and Ankle Society (AOFAS) hindfoot clinical rating scale scores were recorded and this group of patients was reviewed post operatively at a mean of 19 months (6-52), and at a mean of 54 months (37-94). The design rational will be discussed, as well as a brief description of the surgical technique.

Results: Retention of the implant was 93 percent at a mean of 19 months and 88 percent at a mean of 54 months. AOFAS scores were improved from 55 to 71 at the latest review. Complications included two slow healing lateral incisions, one deep infection, one fractured stem, and one below knee amputation secondary to acute femoral artery occlusion.

Conclusion: Our experience with this custom implant has allowed salvage of many complex and difficult talar sided problems that otherwise would have required a fusion.

Introduction

Total ankle arthroplasty has been traditionally limited to those cases that present with suitable bone for bony ingrowth on both tibial and talar sides of the ankle joint. Fusion is the only option where there was extensive avascular necrosis (AVN), large bone loss, and/or large areas of cystic degeneration of the talus. Fusion also is the most common option for failed total ankles where talar subsidence was the main problem thereby precluding revision with primary components. A custom stemmed talar component was developed to address those difficult primary ankle arthroplasty cases and to allow revision of failed total ankles where talar subsidence was severe. This prosthesis was designed with a stem projecting from the body of the talar component to allow it to be inserted across the subtalar joint into the body of the calcaneus.

The body of this custom prosthesis can be built up anterior or posterior to allow its use in virtually all talar failures where there is insufficient bone stock. Use of this custom stemmed component can also be considered in advanced primary arthritic conditions including loss of the talar dome from erosion, talar cystic areas that will preclude use of primary ankle arthroplasty components and large areas of avascular necrosis which will hinder bony ingrowth. Total talar replacement has also been accomplished using this technique by utilizing stem fixation and replacing the talar body by obtaining measurements from the contra lateral side. The purpose of this study was to review the outcomes of the first 30 consecutive patients implanted with this custom component.

Materials and Methods

The first 30 patients that received a custom stemmed
agility talar component were reviewed. Twenty-six patients were performed for failed total ankles. The other patients had talus pathology that precluded primary ankle arthroplasty. These were performed by a single surgeon, Dr. Frank Alvine. The study included a standardized prospective evaluation form, which included American Orthopedic Foot and Ankle Society (AOFAS) scores along with radiographic and clinical assessment and this study qualified for exempt status under federal regulations as noted by the Avera McKennan Institutional Review Board and that all individuals were consented.

The AOFAS score is an outcome measure. It combines subjective scores of pain and function provided by the patient with objective scores from the physician’s physical exam. There are 100 points possible with a higher number reflecting a better score. Range of motion measurements were obtained by clinical exam by the authors with the use of a goniometer. Ankle range of motion between 30 and 50 degrees is thought to be “normal” with a gait cycle requiring 10 degrees of dorsiflexion and 20 degrees of plantarflexion. Indications for use of this implant were as per Table 1. Four patients had primary arthroplasties done with the use of the stemmed talus component for changes, osteolysis, and avascular necrosis.

The prosthesis was designed on a custom basis for each individual patient based on measurement films sent to the engineering department of Depuy Orthopaedics, Warsaw, Idaho. The prosthesis is made of cobalt chrome with the porous-coated surface being on the undersurface of the talus component and around the entire stem. Porous coating is 50 to 150 microns and the stem is angled 20 degrees in valgus off the body of the talus and 45 degrees posteriorly (see Figure 1). In some instances, the body of the talus component was built up anteriorly, posteriorly or both to replace bone loss secondary to talus subsidence, osteolysis, and or avascular necrosis.

### Surgical Technique

The author’s technique to revise a failed total ankle with the custom stemmed talar component was to expose the ankle joint and remove the talus component and polyethylene. The talus was re-cut to bleeding bone if possible and a separate lateral sinus tarsi incision was made to expose and decorticate the subtalar joint in preparation for a subtalar fusion. If the talus was found to be fractured, the subtalar joint can usually be visualized through the anterior incision and a second lateral incision for decorticating that joint can be avoided. The external fixator was applied after the components have been removed and the subtalar joint decorticated. The ankle was distracted to allow direct visualization of the remaining surface of the talus. The talus trial without the stem is positioned on the re-cut talus surface and the guide wire for the stem is inserted into the calcaneus. Radiographs are then taken to make certain that the guide pin is in the tuberosity of the calcaneus. After the diameter of the stem is measured at the tip and at its base, which would commonly range from 6 to 10 mm, reaming over the guidewire is performed. The guide wire and talus trial are removed, and the stemmed talus trial component are inserted. Once in place, a trial polyethylene could then be inserted to see if there is any tendency for varus or valgus deformity or ligament instability. A final polyethylene is snapped into place and the distractor removed. On occasion, heel cord lengthening is required, but if a posterior capsulectomy had been done thoroughly at the time of the debridement of the joint, this frequently was not necessary. Also on occasion where a talus fracture is encountered, a supplemental screw is used to stabilize the fragment, inserting this across the subtalar joint into the body of the calcaneus. In one post traumatic case where the body of the talus was completely missing, a total talus body prosthesis was manufactured and inserted without difficulty.

Postoperatively, the patients were immobilized in a
posterior plaster splint for two weeks, after which a removable cam walker was applied. Range of motion was started at that time and at six weeks, partial weight bearing was initiated and advanced to full weight bearing over the next four weeks. At 10 weeks they were transitioned to a supportive walking shoe. Pre-op and post-op X-rays are depicted in Figures 2, 3 and 4 which show an example of a failed total ankle arthroplasty secondary to a fractured talus.

Results
This study included the first 30 patients that received a custom stemmed agility talar prosthesis in the senior author’s practice. We first reviewed the patients at a mean follow-up of 19 months (range 6-52). A second review was done at a mean of 54 months (37-94 months)

In the first follow-up period, 27 of the 30 patients were available for the study. At that time, seven patients were over two years from surgery. There were 18 males and nine females. Three ankles were not included in the review for the following reasons: one patient could not be found initially during the first review (was later available for second study). A second patient required a below knee amputation secondary to an acute femoral artery occlusion one week following surgery. A third patient had implant removal secondary to an infection. Of the 27 ankles available for review in the first assessment, the mean pre-
op AOFAS score was 55, post-op was 74 (Figure 5). The mean range of motion was 33 degrees.

Radiographic analysis revealed 24 of 27 (88 percent) had evidence of bony ingrowth. Of the three without firm evidence of bony ingrowth, one patient was diabetic with peripheral neuropathy. The other two patients showed some radiographic lucency around a portion of the talar component. Twenty-four of the 27 ankles had 5 degrees or less of varus or valgus malalignment. One patient had greater than 10 degrees.

Complications included two patients with minor, slow-healing lateral incisions. Both eventually healed without surgical intervention. Another patient cracked the stem of the component one year post-op. This was treated with the insertion of a new stemmed component in a more vertical position.

Three patients had incomplete clinical follow-up secondary to distance. They were interviewed by phone and all were doing well. They all stated they had an improved quality of life. One was still wearing an ankle support.

Defining implant survival as retention of the implant, 28 of the 30, or 93 percent, of the implants were retained at a mean of 19 months.

In a second follow-up assessment, 23 of the original 30 ankles were available for study. Of the remaining seven patients, four were deceased with their implants. As previously mentioned, one had been amputated, one removed secondary to infection, and one removed for aseptic loosening. The mean follow-up was 53 months with a range of 37-94 months post-op. The mean pre-op AOFAS score was 55, post-op was 71 and the mean range of motion was 23 degrees.

Radiographically, one patient had notable subsidence and another had notable radiolucency circumferentially around the stemmed component. Eighteen of the 23 had six degrees or less of varus or valgus malalignment, with two patients having greater than 10 degrees. Excluding the four deceased patients, 23 of 26 patients (88 percent) retained the implant at a mean of 96 months post-op.

**Discussion**

The use of a custom stemmed talar component that bridges the subtalar joint gives the surgeon additional options in treating complex ankle conditions. Myerson et al. discussed and described the technique and its use in difficult primary and revision cases. Its use in the revision of total ankle arthroplasty talar failures, or other conditions involving the talus, i.e., AVN, large cystic lesions, or insufficient bone, seems to be a viable option in our early experience. Implant survivorship based on retention is encouraging at 88 percent at a mean of 54 months. The AOFAS outcomes score is not an ideal measurement tool since the subtalar joint is fused. However, the scores improved and clinically the patients are doing well. The learning curve for this procedure is not as steep as a primary total ankle arthroplasty, and recovery seems to be faster since the implant is typically very stable at time of implantation. Limitations of this study are low patient numbers, relatively short follow-up, lack of a control group, and ankle range of motion measurements were not based on radiographs. However, these early results of the agility custom stemmed talar component are encouraging for managing talar bone loss problems.
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The Asfora Bullet Cage System Shows Comparable Fusion Rate Success Versus Control Cage in Posterior Lumbar Interbody Fusion in a Randomized Clinical Trial

By Jeremy P. Morgan, MS; Ashley L. Miller, MPH; Paul A. Thompson, PhD; and Wilson T. Asfora, MD, FRCSC, FAAN, FACS

Abstract

Background: Low back pain and degeneration of the intervertebral disc are an integrated malady that affects millions of Americans. Cage devices used in association with posterior lumbar interbody fusion (PLIF) have been shown to be an effective approach in the treatment of a number of lower spine disorders attributed to degenerative disc disease (DDD).

Objective: This study was undertaken as part of a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study and compares the effectiveness of the Asfora Bullet Cage System (ABCS) to successfully fuse vertebra at one or two levels between L2 and S1 in patients with DDD to an FDA approved comparison device, the Medtronic-Sofamor Danek Inter Fix Threaded Fusion Device (MSDIFD).

Methods: A total of 257 randomized participants were implanted with either the ABCS device (n=132) or the MSDIFD device (n=125) through an open posterior approach using autogenous local bone graft without the use of pedicle screws. Patients were evaluated prior to surgery and at the 24 month (24-M) visit for fusion status, deep tendon reflex status, sensory function, motor function, straight leg raise status, pain, disability, and device safety. Radiological evaluation and statistical analysis were performed by independent professionals.

Results: Evaluation of device success was performed at 24-M visit. From the original group of 257 patients, 59 were lost to follow-up. Primary measures of success at the 24-M visit involved pain and function, fusion, neurological status, and device-related adverse events measures. Pain and function improved in both (MSDIFD: 75.7 percent; ABCS: 82.6 percent). Fusion success with all radiographic points at 24-M visits was 79.4 percent MSDIFD and 88.2 percent ABCS. Neurological improvement was seen in both (MSDIFD: 77.0 percent; ABCS: 87.8 percent). One device-related grade 1 adverse event was reported in the MSDIFD group. Disc height preservation was equivalent for single level fusions (MSDIFD: 16.1 percent; ABCS: 20.0 percent) and second level fusions (MSDIFD: 10.7 percent; ABCS: 14.3 percent). General health and well-being improvement was the same (MSDIFD: 37.0 percent; ABCS: 40.0 percent). Subsequent fusion, up to 10 years, was equivalent (MSDIFD: 83.8 percent; ABCS: 91.2). Results for both devices were considered to be satisfactory, with a slight non-significant superiority for the ABCS.

Conclusion: From the ABCS device FDA IDE sanctioned study and the review of the literature, we concluded that the Asfora Bullet Cage System is safe, effective and comparable to other interbody fusion devices which are used stand-alone or in conjunction with pedicle screws, rhBMP-2, or autogenous bone harvested from the iliac crest inserted through anterior, lateral or posterior approaches.
Introduction
Degeneration of the lumbar intervertebral disc is a common condition that has a number of causes and results in a variety of symptoms with varying treatment strategies. Surgical interventions are becoming an increasingly common option for the stabilization of the lumbar spine at one or two levels from L2 to S1. Existing therapeutic methods such as activity modification, medications, and physical therapy are not effective for an important subset of the population. As numerous surgical treatment options are available, each with specific advantages and disadvantages, patients must be carefully assessed to determine which procedure is most appropriate.

One available treatment option for degenerative disc disease (DDD) and its subsequent effects on the spine is posterior lumbar interbody fusion (PLIF). Though Cloward first described PLIF and his successes with it in detail in 1953, the use of this procedure was not widely adapted as a technique for interbody fusion until the last 25 years. Advances in interbody fusion devices and surgical procedures have led to the use of PLIF as a well-defined treatment option for DDD when more conservative measures fail. DDD is defined as back pain and/or radicular pain with degeneration of the disc as confirmed by history and radiographic studies, and with distinctive physical features (see Supplement 1 at www.sdsmoa.org for full definition). The onset of DDD is multifactorial with causative and cascading factors relating to genetics, activity level, environment, inflammation, among others.

The objective of this study was to compare the fusion rate, quality of life, and physiological improvements in a new device (the ABCS device) to an established one (the MSDIFD device). The MSDIFD device was chosen because it is comparable to the new device, as both are hollow, porous cylindrical devices, and composed of titanium alloy. The ABCS device cage differs in two ways. First, it has a tapered or bullet shape that facilitates positioning and insertion. Second, it has sharp, deep-angled self-tapping threads designed to hold the cage firmly between the vertebral bodies (Figure 1). The specific hypothesis we tested was that the ABCS device would provide equal or better resolution of pain, function, neurological abnormalities, device safety, and interbody fusion than that of the MSDIFD device at the 24-M visit.

Methods
Trial Design
This trial was designed as a prospective, randomized, single-surgeon IDE study approved by the FDA. Local Institutional Review Board approval was obtained from the participating institutions. Signed informed consent was obtained from all participating subjects. Subjects were randomly assigned to either the ABCS device or MSDIFD device. They remained masked as to the device used for treatment. Because the surgeon cannot be masked to the device, follow-up evaluations were performed by a team member masked to the condition.

Device Descriptions
The MSDIFD device cage was the Inter Fix cage (Medtronic Sofamor Danek, Memphis). The Inter Fix is a straight-sided threaded device that is constructed with the ability to be prepacked with autogenous and local bone grafts to promote fusion. The Asflora Bullet Cage system (Medical Designs, Sioux Falls) is a tapered device with a bullet shape which has sharp, deep-angled self-tapping threads designed to hold the cage firmly between the vertebral bodies to minimize the probability for migration and/or retropulsion.

Inclusion Criteria
1) Age 18 to 70 years; 2) failed conservative treatment measures; 3) DDD between L2 and S1, with specific pathology (see detailed inclusion criteria, Supplement 2, at www.sdsmoa.org).

Exclusion Criteria
1) Previous fusion attempts at index location; 2) spondylolisthesis greater than or equal to grade II; 3) DDD greater than or equal to three segments; 4) specific pre-existing physical or mental disease; or 5) were pregnant or interested in becoming so (see detailed exclusion criteria, Supplement 2, at www.sdsmoa.org).

Randomization
Randomization was done as a blocked sequence of assignments (with blocks of varying sizes). After signing the informed consent form, the patient was assigned by the coordinating center to one of the two arms. The Biostatistics Consulting Laboratory at the University of Minnesota designed the randomization scheme.

Trial Visits
The baseline visit was used to establish eligibility for the study, assign the study condition, and obtain initial values.
Initial values for disc height were obtained at the six-week visit before the procedure. Follow-up visits occurred at six weeks, three, six, 12, and 24 months and annually until the last subject enrolled completed the 24-M visit. All measures were administered on all visits. The primary visits were the initial and 24-M visits.

Statistical Analysis
Data were collected in a Microsoft Access database. Prior to analysis, data were examined for problematic values. The primary outcome comparison was difference between the ABCS and MSDIFD arms on the difference between the initial and 24-M visit values. Continuous measures were evaluated using mixed effects repeated measures methods with PROC MIXED. Categorical measures were compared using generalized estimating equation methods using PROC GENMOD and PROC FREQ. Data analysis was performed using SAS 9.3.

Power Analysis
Sample size was determined by a power analysis for inferiority of the ABCS device, assuming a difference of 10 percent, power = 0.85, and a 30 percent attrition rate. The Biostatistics Consulting Laboratory, University of Minnesota, performed the power analysis.

Fusion Measures
Fusion was evaluated using plain film X-ray imaging and computed tomography scans, read by a single unmasked independent radiologist (reliability of assessment not available). Radiographic evaluations were made at consecutive follow-up visits up to and including the 24-M visit. Fusion success is defined as: 1) bridging trabecular bone between the involved vertebral endplates, facets, and spinous processes; 2) having translational motion less than 3 mm; 3) having angular motion less than 5 mm; and 4) an absence of radiolucent lines around greater than or equal to 50 percent of the assembly.

Pain and Function Measures
Pain was assessed using four visual analogue scale (VAS) questions (back and leg pain; current, past week). The current and past week pain scores were averaged. Success for the pain and function measures was defined by: 1) greater than or equal to 15 percent point improvement over initial at the 24-M visit in the ODI scale; and 2) greater than or equal to 20 percent improvement over initial at the 24-M visit in the VAS for the location of the presenting pain (back, leg) and maintenance or improvement for the secondary site.

Neurological Measures
The neurological assessment included measures of reflex, motor, sensory function, and straight leg raise. Reflex was assessed using independent bilateral Achilles reflex and quadriceps reflex measures, with success defined as a score at the 24-M visit exceeding or equaling the initial score. Motor and sensory function were measured using the Standard Neurological Classification of Spinal Injury assessment form and grading scale (American Spinal Injury Association, 2005), with success defined as a score at the 24-M visit exceeding or equaling the initial score. The straight leg raise assesses the degree (0 to 90 degrees, measured using a goniometer positioned at the subject’s greater trochanter) to which the patient can elevate the leg before the onset of pain in the leg or back, with success is defined as a non-painful straight leg raise with degree exceeding or equaling the Initial value. Overall success for neurological status at the 24-M visit is obtained if all components are successful, and no study-related neurological AEs occur.

Device Safety Measures
All subjects were evaluated for adverse events. Adverse events (AE) were classified as related to implant or surgical procedure. Device-related adverse events were compared between the ABCS device and the MSDIFD device. If a subject experienced an AE that was indirectly related to the implantation of the device or to their participation in the study that was not resolved prior to study conclusion, they were considered a study failure. Subjects who underwent subsequent surgical intervention or died as a result of the implantation of the device or as a result of their participation were also considered study failures. A Data Safety Monitoring Board was not convened for this study.

Disc Height Measures
Disc height was measured at each visit. Both anterior and posterior heights were considered in evaluation of this endpoint. Success was defined as a difference in disc height at the 24-M visits in comparison with the 6-weeks within +/-2mm, for each level fused.

General Health and Well-being Measures
General health and well-being was assessed using the SF-36 questionnaire, with success defined as a 15 point improvement in both the Mental Component Score (MCS) and Physical Component Score (PCS).

Surgical Procedure
Detailed description of the procedure is given in Supplement 4.
Results
Study Timeline
Conditional approval by the FDA for an investigational device exemption was granted on February 17, 2000. The date of the first implant was May 2000 with the final implant placed in November 2006. Final follow-up occurred in August 2008, with study closure on December 2008.

Participants
A total of 268 patients were enrolled (see Figure 1 – CONSORT diagram). A total of 11 patients were removed from the study and are not included in

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>MSDIFD</th>
<th>ABCS</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>n = 125</td>
<td>n = 132</td>
<td>n = 257</td>
<td></td>
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<td>50.24(11.89)</td>
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<td>Gender (SD)</td>
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<td>62(49.6)</td>
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<tr>
<td></td>
<td>Female</td>
<td>63(50.4)</td>
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<td>N=10 (7.6%)</td>
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<tr>
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<td>Married</td>
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<td>N=101 (76.5%)</td>
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<tr>
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<tr>
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<td>2</td>
</tr>
<tr>
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<td>Widowed</td>
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<td>11</td>
</tr>
<tr>
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<td>68.07(4.14)</td>
<td>67.95(4.03)</td>
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</tr>
<tr>
<td>Weight (lb), Mean (SD)</td>
<td>191.90(43.02)</td>
<td>193.01(41.37)</td>
<td>192.47(42.10)</td>
<td></td>
</tr>
<tr>
<td>BMI (SD) kg/m2</td>
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<td>29.34(4.88)</td>
<td>29.37(5.16)</td>
<td></td>
</tr>
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<td>N=29 (23.2%)</td>
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<tr>
<td></td>
<td>No</td>
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<td>N=99 (75.0%)</td>
<td>195</td>
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<td>Levels Fused</td>
<td>One-level</td>
<td>N=90 (72.6%)</td>
<td>N=90 (68.2%)</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>Two-level</td>
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<td>N=41 (31.1%)</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>Three-level</td>
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<td>N=1 (0.8%)</td>
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</tr>
<tr>
<td>Segments Affected Level 1</td>
<td>L2-L3</td>
<td>N=5 (4.0%)</td>
<td>N=5 (3.8%)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>L3-L4</td>
<td>N=16 (12.8%)</td>
<td>N=15 (11.4%)</td>
<td>31</td>
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<tr>
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<td>L4-L5</td>
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<td>N=59 (44.7%)</td>
<td>111</td>
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<tr>
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<td>L5-S1</td>
<td>N=52 (41.6%)</td>
<td>N=53 (40.2%)</td>
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</tr>
<tr>
<td>Segments Affected Level 2</td>
<td>L3-L4</td>
<td>N=2 (5.6%)</td>
<td>N=1 (2.4%)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>L4-L5</td>
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<td>N=8 (19.0%)</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>L5-S1</td>
<td>N=23 (63.9%)</td>
<td>N=33 (78.6%)</td>
<td>56</td>
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<td>SPP: None</td>
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<td>3</td>
<td>0</td>
<td></td>
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<td>SPP: One-level fusion</td>
<td>1 Single-level</td>
<td>86</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>SPP: Two-level fusion</td>
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<td></td>
</tr>
<tr>
<td>SPP: Two-level fusion</td>
<td>2 Single-level</td>
<td>3</td>
<td>0</td>
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</tr>
<tr>
<td>SPP: Two-level fusion</td>
<td>1 Two-level</td>
<td>36</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

SPP = Spinal Process Plates
subsequent analysis (eight prior to surgery, three prior to implant). A total of 257 patients were randomized for study treatment on the ABCS device (n=132) or the MSDIFD device (n=132; Table 1, Figure 2). Three subjects died during the study, two of natural causes (death certificates were not requested) and one of respiratory failure after suffering from metastatic transitional cell cancer of the bladder with large pleural effusions. A fourth died after completing all required study follow-up visits but prior to study closure. No deaths were attributed to the study devices. A total of 59 patients were lost to follow-up (ABCS device: 34; MSDIFD: 25).

Surgical Procedures and Deviations
Initial characteristics and procedure information. No large differences between groups were observed (Table 1, Rows 1-14, p-values not presented). Comparable frequencies of one-, two-, and three-level fusions were performed (Table

---

**Figure 2. CONSORT 2010 Flow Diagram MSDIFD Device**

**Enrollment**
- Assessed for eligibility (n=268)
- Excluded (n=11)
  - Not meeting inclusion criteria (n=3)
  - Declined to participate (n=8)

**Randomized (n=257)**
- Allocated to ABCS (n=132)
  - Received allocated intervention (n=123)
  - Did not receive allocated intervention (give reasons) (n=9)
    - Surgical Protocol deviations
- Allocated to MSDIFD (n=125)
  - Received allocated intervention (n=121)
  - Did not receive allocated intervention (give reasons) (n=4)
    - Surgical Protocol deviations

**Follow-Up**
- Lost to follow-up (give reasons) (n=34)
  - 24 month analysis not performed
  - Incomplete analysis at 24 month (n=4)
    - Missing chart forms or fusion status at 24 month follow-up
    - Discontinued intervention (give reasons) (n=0)
- Lost to follow-up (give reasons) (n=25)
  - 24 month analysis not performed
  - Incomplete analysis at 24 month (n=13)
    - Missing chart forms or fusion status at 24 month follow-up
    - Discontinued intervention (give reasons) (n=0)

**Analysis**
- Analysed – total (n=89)
  - Complete (n=85)
    - 132-9-34-4
  - Incomplete (n=4; see follow-up box)
  - Excluded from final analysis (give reasons) (n=43)
    - 24-M visit not performed
    - Surgical protocol deviations
- Analysed – total (n=96)
  - Complete (n=83)
    - 125-4-25-13
  - Incomplete (n=13; see follow-up box)
  - Excluded from complete analysis (give reasons) (n=29)
    - 24-M visit not performed
    - Surgical protocol deviations
1, Rows 15-17). Spinal process plates were used primarily in the ABCS device (Table 1, Rows 25-29). Most single-level fusions used single-level plates, while most two-level fusions used 2-level plates.

**Fusion Status**

At the 24-M visit, fusion was observed in most cases (Table 3, Line 1 – ABCS: 88.2 percent; MSDIFD: 79.4 percent, p=0.07), and at a slightly increased proportion overall (Table 3, Line 2 – ABCS: 91.2 percent; MSDIFD: 83.8 percent, p=0.08).

**Pain and Function**

Scores improved on the ODI, back pain, and leg pain measures (Table 2, Lines 3-5). Successful results were seen for a majority of patients on the ODI (Table 3, Line 3 – ABCS: 90.2 percent; MSDIFD: 89.5 percent, p=0.85), back pain (Table 3, Line 4 – ABCS: 92.2 percent; MSDIFD: 89.3 percent, p=0.47), and leg pain assessments (Table 3, Line 5 – ABCS: 89.5 percent; MSDIFD: 87.3 percent, p=0.61).

**Neurological Status**

Successful results were seen for a majority of patients on the reflex measure (Table 3, Line 6 – ABCS: 88.9 percent; MSDIFD: 82.0 percent, p=0.17), sensory function (Table 3, Line 7 – ABCS: 96.9 percent; MSDIFD: 95.0 percent, p=0.49), motor function (Table 3, Line 8 – ABCS: 99.0 percent; MSDIFD: 100.0 percent, p=0.32), and straight leg raise tests (Table 3, Line 9 – ABCS: 100.0 percent; MSDIFD: 100.0 percent, p=NS). Overall neurological success at 24-M visit was better for ABCS (Table 5, Line 3 – ABCS: 87.7 percent; MSDIFD: 77.0 percent; p=0.0473).

**Disc Height**

For cases with one or more levels fused, the height for Disc 1 decreased by a comparable amount for both devices (Table 2, Line 1 – ABCS: 1.80 mm; MSDIFD: 1.71 mm; p=0.78). For fusions with a second level, change in height was non-significantly smaller for ABCS (Table 2, Line 1 – ABCS: 1.26 mm; MSDIFD: 1.64 mm; p=0.52). For Disc 1,

### Table 2. Statistics for Outcome Variables at Initial and 24-Month Assessments

<table>
<thead>
<tr>
<th>Category</th>
<th>Variable</th>
<th>MSDIFD</th>
<th>ABCS</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Mean</td>
<td>Diff</td>
<td>Diff</td>
</tr>
<tr>
<td></td>
<td>Base</td>
<td>24-M</td>
<td></td>
<td>Base</td>
</tr>
<tr>
<td>Disc Height (mm)</td>
<td>Disc 1 Height</td>
<td>6.66</td>
<td>4.95</td>
<td>1.71</td>
</tr>
<tr>
<td></td>
<td>Disc 2 Height</td>
<td>6.79</td>
<td>5.15</td>
<td>1.64</td>
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<tr>
<td>Pain &amp; Function</td>
<td>Back Pain</td>
<td>7.20</td>
<td>2.42</td>
<td>4.78</td>
</tr>
<tr>
<td></td>
<td>Leg Pain</td>
<td>6.88</td>
<td>2.21</td>
<td>4.67</td>
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<tr>
<td></td>
<td>Oswestry Scale</td>
<td>52.80</td>
<td>19.76</td>
<td>33.04</td>
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<tr>
<td>Gen Health</td>
<td>MCS</td>
<td>46.49</td>
<td>54.06</td>
<td>7.57</td>
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<tr>
<td></td>
<td>PCS</td>
<td>28.12</td>
<td>42.81</td>
<td>14.68</td>
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</table>

### Table 3. Success Indicators for Outcome Variables

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<th>Category</th>
<th>Variable</th>
<th>MSDIFD</th>
<th>ABCS</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusion</td>
<td>Confirmed-24m</td>
<td>93(97.5)/24(20.5)</td>
<td>105(88.2)/14(11.8)</td>
<td>0.07</td>
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<td></td>
<td>Confirmed-Overall</td>
<td>99(83.9)/19(16.1)</td>
<td>114(91.2)/11(8.8)</td>
<td>0.08</td>
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<tr>
<td>Pain &amp; Function</td>
<td>Oswestry Scale</td>
<td>93(90.3)/10(9.7)</td>
<td>94(88.5)/11(10.5)</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Back Pain</td>
<td>92(89.3)/11(10.7)</td>
<td>95(92.2)/8(7.8)</td>
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</tr>
<tr>
<td></td>
<td>Leg Pain</td>
<td>89(87.3)/13(12.7)</td>
<td>94(89.5)/11(10.5)</td>
<td>0.61</td>
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<tr>
<td>Neurological</td>
<td>Reflex</td>
<td>82(82.0)/18(18.0)</td>
<td>88(88.9)/11(11.1)</td>
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<td>Sensory Function</td>
<td>95(95.0)/5(5.0)</td>
<td>95(96.9)/3(3.1)</td>
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<td>Motor Function</td>
<td>100(100)/0(0.0)</td>
<td>98(99.0)/1(1.0)</td>
<td>0.31</td>
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<tr>
<td></td>
<td>Straight Leg Raise</td>
<td>100(100)/0(0.0)</td>
<td>99(100)/0(0.0)</td>
<td>NS</td>
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<tr>
<td>Disc Height</td>
<td>Disc 1 Height</td>
<td>49(52.7)/44(47.3)</td>
<td>50(55.6)/40(44.4)</td>
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<tr>
<td></td>
<td>Disc 2 Height</td>
<td>13(46.4)/15(53.6)</td>
<td>14(50.0)/14(50.0)</td>
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<tr>
<td>Gen Health</td>
<td>PCS</td>
<td>77(77.0)/23(23.0)</td>
<td>87(82.9)/18(17.1)</td>
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</tr>
<tr>
<td></td>
<td>MCS</td>
<td>47(47.0)/53(53.0)</td>
<td>51(48.6)/54(51.4)</td>
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<tr>
<td></td>
<td>Gen Health</td>
<td>37(37.0)/63(63.0)</td>
<td>42(40.0)/63(60.0)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

All cells represent N (%)  
PCS = Physical Component Score; MCS = Mental Component Score.
Figure 3. Plain film X-ray images of the MSDIFD implanted between L4-L5 and L5-S1. Top row images taken one day post-operatively and bottom row images taken approximately one year post-operatively.
Figure 4. Plain film X-ray images of the ABCS device implanted between L4-L5 and L5-S1. Top row images taken one day post-operatively and bottom row images taken approximately one year post-operatively.
success was seen in roughly half the cases (Table 3, Line 10 – ABCS: 55.6 percent; MSDIFD: 52.7 percent, p=0.70), Overall disc height success at 24-M visit was not different (Table 5, Line 4 – ABCS: 51.1 percent; MSDIFD: 46.2 percent; p=0.51).

General Health and Well-being
Measures increased for both MCS (Table 2, Line 6 – ABCS: 7.87; MSDIFD: 7.57; p=0.88) and PCS (Table 2, Line 6 – ABCS: 16.46; MSDIFD: 14.68; p=0.32). Overall success rate for general health and well-being was not different (Table 5, Line 4 – ABCS: 40.0 percent; MSDIFD: 37.0 percent; p=0.66).

Adverse Events
There were 1,068 AEs reported (Table 4; ABCS: 554; MSDIFD: 514 group). Of these, 92 were serious (grade 3 or 4), with three surgical or implant/surgical. During the study, four participants died, three from natural causes and one from respiratory failure related to metastatic transitional cell cancer of the bladder with large pleural effusion (this case was not considered early discontinuation as all follow-up visits were completed). For evaluation of adverse event frequency, a generalized linear model assuming a Poisson process for frequency of adverse events was examined. The difference between arms was nonsignificant (z=1.12, p=0.2637).

Overall Individual Subject Success
Table 5 shows success for pain and function, 24-M visit fusion, neurological, overall disc height, and general health and well-being. There is a significant difference for neurological (p=0.0473), but if cases missing at 24-M visit are counted as non-successes, the difference is no longer significant (p=0.5546). An individual subject was considered an overall success if, at the conclusion of the study, the outcomes for pain, function, intervertebral body fusion, and neurological status were successful and the subject did not experience a device related complication. Overall individual success is shown in Table 5. At the 24-M visit, there is an overall difference in success (ABCS: 63.8 percent; MSDIFD: 47.6 percent; p=0.0184). When all missing cases are considered non-successes, the difference is not significant (p=0.0628).

Discussion
The fusion rate, radiological evaluation, and clinical outcome were considered to be satisfactory for both devices with a slight superiority of the ABCS device in all categories. This did not, however, reach statistical significance. Figures 2 and 3 demonstrate typical AP and lateral X-rays seen in subjects immediately after surgery (Figures 3 and 4 top) and one year post-operatively (Figures 3 and 4 bottom). The cases reported are limited to patients enrolled in the ABCS device FDA IDE sanctioned study with a number of patients having been followed for up to 10 years. Fusion, in most patients, was confirmed with CT scan at two years. Our outcomes reported here are in line with those reported within the literature for lumbar interbody fusion.21-27

Features unique to the ABCS device include the bullet shape facilitating insertion and distraction of the disc space thus restoring disc space height and lordosis. This is feasible due to the disc space distractor, the fact that the disc space is drilled with a drill of a diameter smaller than the diameter of the cage, and the drill stops short of the anterior one-fourth of the vertebral body while the cage is advanced to the anterior edge. Although not expandable, the ABCS device will distract significantly more anteriorly thus re-establishing lordosis. At the edge of the vertebral body, the bone has a thicker

<table>
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<th>SDIFD</th>
<th>ABCS</th>
</tr>
</thead>
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<tr>
<td>Surgical</td>
<td>80/7/0</td>
<td>69/20/2/0</td>
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<tr>
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<td>0/0/0</td>
<td>1/0/1/0</td>
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<tr>
<td>Undetermined</td>
<td>185/90/13/0</td>
<td>183/105/9/0</td>
</tr>
<tr>
<td>Not related</td>
<td>60/43/35/1</td>
<td>80/53/30/0</td>
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Entries list # AEs categorized as level 1/2/3/4.

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<th>SDIFD</th>
<th>ABCS</th>
<th>p-val</th>
<th>Neurological</th>
<th>Overall Disc Hght</th>
<th>General Health</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain &amp; Function</td>
<td>14.2/52.6/33.1</td>
<td>17.7/58.7/23.7</td>
<td>0.2169</td>
<td>0.2169</td>
<td>0.6464</td>
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</tr>
<tr>
<td>24-M Visit Fusion</td>
<td>7.2/68.9/23.9</td>
<td>9.2/81.3/9.6</td>
<td>0.0675</td>
<td>0.0675</td>
<td>0.3269</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological</td>
<td>15.8/64.6/19.6</td>
<td>19.9/67.4/12.7</td>
<td>0.0473</td>
<td>0.0473</td>
<td>0.5546</td>
<td></td>
<td></td>
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<tr>
<td>Overall Disc Hght</td>
<td>22.8/31.3/45.9</td>
<td>25.9/39.9/34.2</td>
<td>0.5095</td>
<td>0.5095</td>
<td>0.9398</td>
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<td></td>
</tr>
<tr>
<td>General Health</td>
<td>18.1/22.9/59.0</td>
<td>16.1/30.8/53.1</td>
<td>0.6591</td>
<td>0.6591</td>
<td>0.7001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>14.6/33.1/52.2</td>
<td>16.0/44.8/39.2</td>
<td>0.0184</td>
<td>0.0184</td>
<td>0.0628</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table entries are percentages of missing, improved, and not improved cases.

Im = improved; NIm = not improved; NIm+Miss = combined not improved and missing cases.
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cortex which decreases the chance of subsidence or sinking into the body of the vertebrae. It is important to restore disc space height because weight bearing is then transferred to the vertebral body, thus relieving the facet joint stress and back pain.

The ABCS device also has large, sharp, self-taping threads which are angled posteriorly, which prevent cage migration and protrusion. For the surgeons’ convenience, the cage can be filled with bone before insertion. Since it has six equidistant vertical slits, it may be inserted in any position. These open slits allow increased contact of the bone graft contained in the cage with the vertebral body. The posterior cap is threaded and made of titanium. When it is inserted, it pushes the bone graft out of the cage for increased contact with the vertebral body. Once the cap is applied, it seals the posterior end of the cage. Thus, the epidural space may be irrigated without the risk of washing out cage contents. In addition, the base of the cage has no slits or openings, if rh-BMP2 is used, bone of washing out cage contents. In summary, the device for increased contact with the vertebral body. The epidural space may be irrigated without the risk of washing out cage contents. In addition, the base of the cage has no slits or openings, if rh-BMP2 is used, bone of washing out cage contents.

More recently, with the introduction of minimally invasive percutaneous pedicle screws, in conjunction with the ABCS device (or other fusion techniques) the burden on the patient has been reduced allowing continued highly satisfactory clinical results.

There is a recent trend to favor titanium over plastic/PEEK devices. The penetration of sharp titanium threads into the end plates of the vertebrae promotes fusion by increasing the fusion surface and creates a pathway for migration of osteoblasts into the cage. In combination with recent evidence suggesting that titanium increases and promotes osteoblast maturation and local BMP production, titanium devices are an ideal environment to successful fusion. Drilling of the disc space prior to insertion of titanium threaded devices creates a surface propitious for fusion.

In summary, this study presents the results of an FDA approved IDE path to market study showing the ABCS device is safe and effective. It has been used since May 1996 alone, as well as with spinous process plates as in this study or, more recently, in association with percutaneous pedicle screws where we continue to observe highly satisfactory results in the OR and clinic. It is currently FDA approved for anterior, posterior, and transforaminal lumbar interbody fusion.

Disclosure: Dr. Asfora is an investor and owner in Medical Designs, LLC.


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Takotsubo Cardiomyopathy (Broken-Heart Syndrome): A Short Review

By Kalyan Chakravarthy Potu, MD; Amol Raizada, MD; Maheedhar Gedela, MD; and Adam Stys, MD

Abstract

Takotsubo cardiomyopathy, also called “broken heart” syndrome or apical ballooning syndrome, is a reversible cardiomyopathy characterized by left ventricular dysfunction and ballooning of the left ventricular apex on imaging during systole. It predominantly occurs in post-menopausal women and is commonly associated with emotional or physical stress.

Patients commonly present with chest pain and electrocardiographic evidence of ST segment elevation or T-wave-mimicking acute coronary syndrome, but with an absence of angiographic evidence of obstructive coronary disease. The exact cause is unknown, but potential contributors include catecholamine excess and sympathetic nervous system hyperactivity.

There is no consensus on pharmacological treatment of takotsubo cardiomyopathy. Based on the suspected pathophysiology of the disease, adrenergic blockade using beta-blocker therapy is employed. Near complete resolution of left ventricular wall motion dyskinesis occurs in the majority of takotsubo cardiomyopathy patients within a month. Although the prognosis is generally favorable, there are reports of complications during the acute phase, including cardiogenic shock, pulmonary edema, ventricular tachycardia, apical thrombus formation, and death. This review article will briefly discuss the epidemiology, etiology, clinical features, diagnostic evaluation, and treatment of this condition.

Background

Takotsubo cardiomyopathy (TC) is described as an acute, reversible disorder of the heart characterized by left ventricular dysfunction and ballooning of the left ventricular apex during the contraction phase.¹ The disorder gets its name from the takotsubo, a Japanese ceramic pot used to trap octopuses that has a shape closely resembling that of the apical ballooning of the left ventricular apex as noted on a left ventriculogram.²

Epidemiology

The mean age for onset of takotsubo cardiomyopathy is greater than 60 years,¹ with 90 percent of cases occurring in postmenopausal women.⁴ TC is commonly mistaken for ST segment elevation myocardial infarction (STEMI). In a cohort of 2,648 patients in the HORIZONS-AMI trial,
2.1 percent of female patients (0.5 percent of all patients) with suspected ST-elevation myocardial infarction were diagnosed with apical ballooning syndrome.5

Etiology
TC is also called stress cardiomyopathy or broken heart syndrome due to its association with severe emotional or physical stress.4 The exact cause is unknown, but potential contributors include catecholamine excess and sympathetic nervous system hyperactivity.4 Catecholamine concentrations (such as epinephrine and norepinephrine levels) have been noted to be high in patients with TC.6 The high prevalence of takotsubo cardiomyopathy in post-menopausal women may suggest a role of estrogen activity deficiency in pathogenesis and the evidence of estrogen supplementation attenuating TC in an animal model.7

Clinical Features
The clinical features of takotsubo cardiomyopathy are important to recognize, as they resemble that of acute coronary syndrome. Symptoms include chest pain (70 percent) and dyspnea (20 percent), along with electrocardiographic changes, like ST segment elevation (30 to 50 percent) and T-wave inversions. Echocardiography reveals apical ballooning during systole, which does not correlate with a specific coronary artery distribution in addition to a decrease in ejection fraction.8,9 An atypical variant or apical sparing variant also exists in a minority of patients where the transient left ventricular hypokinesis is restricted to the midventricular segments without any involvement of the apical region.10 Cardiogenic shock and ventricular arrhythmias can also be presenting features of TC.11

Evaluation
The Mayo Clinic’s criteria are used most commonly and internationally for the diagnosis of takotsubo cardiomyopathy. The four criteria for diagnosis are as follows:12
1.Transient hypokinesis, akinesis, or dyskinesis in the left ventricular mid-segments with or without apical involvement. Regional wall motion abnormalities that extend beyond a single epicardial vascular distribution are frequently, but not always, a stressful trigger.
2. The absence of obstructive coronary disease or angiographic evidence of acute plaque rupture.
3. New EKG (electrocardiogram) abnormalities (ST segment elevation and/or T-wave inversion) or a modest elevation in cardiac troponin.
4. The absence of pheochromocytoma and myocarditis.

Treatment
Most patients with takotsubo cardiomyopathy are initially treated for STEMI, due to the initial similarities in clinical and EKG presentation. An early establishment of the diagnosis by the demonstration of nonobstructed coronary arteries is crucial in order to prevent unnecessary antithrombotic therapy.13 Although early echocardiography revealing apical ballooning may heighten the suspicion of
TC, acute coronary syndrome must be ruled out by coronary angiography.

There is no consensus on pharmacological treatment for TC. Based on the pathophysiology of the disease, adrenergic blockade is employed. A few studies have demonstrated the benefits of beta-blocker use, in the presence of dynamic left ventricular outflow tract obstruction.\textsuperscript{14,15}

Takotsubo cardiomyopathy can lead to significant complications like cardiogenic shock (15 to 20 percent), pulmonary edema (20 percent), ventricular tachycardia (4 percent), apical thrombus formation (4 percent), and death (1 percent). Immediate support is vital in the treatment of the aforementioned complications.\textsuperscript{16,17}

In patients with cardiogenic shock, intravenous fluids and mechanical support with an intra-aortic balloon pump may be required. Intravenous inotropic agents are not preferred because of potential deleterious effects, given the potential role of catecholamine excess in TC pathophysiology.\textsuperscript{18} Syed et al. and Dib et al. have suggested that beta-blockade could be of benefit in preventing arrhythmias.\textsuperscript{19,20} Apical thrombus formation is an uncommon complication (4 percent), but because of its potentially detrimental effects, anticoagulation with low molecular weight heparin should be considered if severe dyskinesis is present.\textsuperscript{17}

**Natural History**

Near complete resolution of left ventricular wall motion dyskinesis occurs in the majority of TC patients within a month.\textsuperscript{21} According to one publication, the recurrence rate is about 10 percent.\textsuperscript{22}

**Concluding Summary**

Takotsubo cardiomyopathy, characterized by apical ballooning of the left ventricle, predominantly occurs in post-menopausal women and is commonly associated with emotional or physical stress. Most commonly, patients present with chest pain and electrocardiographic evidence of ST segment elevation or T-wave-mimicking acute coronary syndrome, but with an absence of angiographic evidence of obstructive coronary disease. There is no consensus on the pharmacological treatment of TC. Based on the pathophysiology of the disease, adrenergic blockade using beta-blocker therapy is employed. Near complete resolution of left ventricular wall motion dyskinesis occurs in the majority of TC patients within a month.

\begin{itemize}
\end{itemize}
**Introduction**

Advances in medical research occur when the discoveries of bench and clinical scientists are presented to the scientific community and the public. Findings are typically disseminated through articles in research and clinical journals that present the research topic, the experiments performed, and a description of how the results presented advance the field. This enhances the existing scientific and clinical knowledge base, which is then accessible to researchers and clinicians around the world. While the primary goal of research publications is to disseminate the findings resulting from a study, drafting these manuscripts requires more than simply collecting data and reporting results. The process requires attention to what is already known and unknown, and suggests future directions within the field of study. Preparing a cogent, well-written manuscript can greatly improve its potential for acceptance for publication in a journal. This article has been written to provide guidance on the organization and preparation process, and it delineates key points to guide the writing process and improve publication success.

**Review of the Literature – Does Your Idea Have The Potential To Contribute?**

Before beginning the process of writing a manuscript, authors should consider some key points:

1. Has this been done before?
2. Will the article add to the current literature?
3. Will the data advance the field?
4. Will the data tell a meaningful story?

When considering the answer to these questions, authors may want to ponder the novelty of their story, even if the approach and/or findings are not necessarily novel. Some repetition within the medical literature can be expected, and is even encouraged as it demonstrates both the reliability of prior findings, and their potential to be replicated in a different setting. However, authors should attempt to advance at least one aspect of the topic being studied as they work toward telling their story.

**Preparation of the Manuscript**

**Format the Manuscript Based on Criteria Provided by the Journal**

All journals provide a guideline for authors that are preparing manuscripts for submission. One of the first things provided in this document is a description of the journal’s target audience, which can help authors decide whether the journal is appropriate for their work. This document will also inform the authors of the journal policies for formatting manuscript sections, including both style and word limits. This is also where authors can
learn the journal’s preference for citing previous work, including any limits the journal may have on the number of citations allowed. Finally, these guidelines typically include a description of the criteria required for data presentation, including the number, size, and format of figures to be submitted. During preparation, authors may want to view their figures at publication size, as defined by the journal, to ensure that figures remain legible. In addition to reviewing the instructions for authors provided by the journal, it is good practice to read articles published in the journal. This will allow the authors to view examples of work the journal publishes, which again assists in the process of selecting an appropriate journal. Reviewing these articles will also provide authors examples of the style of papers, which can help in the drafting process.

Determine the Type of Manuscript to Submit
The types of manuscripts published by journals varies, and they are described in the journal’s “Information for Authors.” The most common types of manuscripts written by bench scientists and clinical researchers performing hypothesis-driven studies fall into the category of original research. However, other manuscript types include: case reports, clinical reviews, systematic reviews, meta-analyses, essays, letters to the editor, and editorials. Authors should review the description of these types of articles within the published journal guidelines, and determine the type of article they want to prepare. Since most articles fall into the original research category, the rest of this manuscript will focus largely on preparing this type of manuscript for submission. Much of what follows, however, can help guide authors regardless of the kind of manuscript.

Steps in Writing
The first step in the writing process is to identify references that are pertinent to the topic being presented. Is the literature already replete with articles on the subject? Will the experiments proposed, and results obtained, advance the field? It is important to remember that the data does not always have to represent a completely novel finding. However, it should provide some insight that has not been published before, even if part of the story is corroborating results published by others. As you move toward preparing the manuscript, make sure to re-read the “Information for Authors,” especially as it relates to article format as this differs significantly based on the journal. Specifically, the required sections and their order will be detailed within these instructions, as well as descriptions of word limits.

An Abstract precedes the main text of the manuscript, and consists of a brief summary of the study. In some cases it may be unstructured (no headings), but in a typical research paper it is structured and includes the Introduction or Background, Methods (or Methods and Materials), Results, and Conclusions. Most authors find it easiest to write the abstract last. It is a key component of the paper and one should bear in mind that it may determine whether the reader (including the editor) continues to read on.

Within the Introduction section, authors are tasked with introducing the story, using past literature to indicate what is already known and not known, and how the results of this project fit into the current knowledge of the field. Within this section, authors should clearly state the hypothesis and goals or objectives for the study, and perhaps a very brief synopsis of the findings, which can help to establish the story being presented.

Within the Methods and Materials section, authors should provide the study design with enough information to repeat the experiments, while limiting unnecessary instruction. This can be accomplished by citing previous work, especially if the author has already described a particular method in a previous manuscript. However, it is important to provide information on any critical deviation and/or modification from the accepted technique so that future readers can perform the experiments with similar success. Methods used for statistical analyses, including software utilized, should be described. Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approval and patient consent (when applicable) should be documented in this section.

The results of a study are best presented in a manner that matches the tables, figures, and figure legends with the Results section, while minimizing redundancy. To accomplish this, results may be presented in narrative form, as tables, as figures, or as any combination of these. In fact, authors will often use all formats for data presentation within a given article. Depending upon the information conveyed, one of these means may be preferable for purposes of clarity, and it is the responsibility of the author to select the best way to present their data. Ideally, the tables and figures (along with corresponding figure legends) will be self-explanatory, so that the text within the Results section can be used to provide a narrative detailing the data presented. To complement this narrative description, figure legends should not repeat the results.
presented. Rather, they should describe experimental details, including both the number of samples and repeats being presented within the groups in the figure, as well as the statistical assay used to define significant differences between the groups. All outcomes of testing described in the Methods section should be included within the Results section. As a rule, do not be redundant by presenting the same information in more than one format. Within the Results section, authors should draw conclusions only when necessary for transition to further narrative or the next figure and/or table, as broad descriptions of the analysis and implications of these findings are subjects for the Discussion section.

Most authors find the Discussion section the most difficult to write. In the first paragraph authors should briefly summarize results prior to providing a more in-depth description of what the results mean to the field of study. The subsequent text should indicate if the findings corroborate or contradict previous studies and support or deny the stated hypotheses. In cases where the study does not support previous researchers’ findings or the stated hypotheses, authors should offer possible explanations as to why. In this section authors discuss how their results move the field forward, draw conclusions from these results, and apply these conclusions to the big picture. This is also the section where potential future directions for the research are discussed, based on the results presented. This section should include a number of citations of previous work to provide context for the results, discussion, and the impact of the study within the field. Finally, strengths and limitations of the study should be described. Sometimes the Results and Discussion will be combined into a single section, based on the journal requirements. In this situation, presentation of the results will include a more detailed discussion of the impact of the findings, with citations that describe how these findings help to advance the field.

It is important to include acknowledgments within the manuscript to credit the assistance of non-authors in the study, specific funding sources, and key collaborators. The non-authors and key collaborators may include individuals that performed specific tasks within the project, without adding scientific insight, as well as individuals that provided reagents and expertise that were used within the experiments performed. When considering between work that should receive authorship, as opposed to work that should receive an acknowledgment, authors should identify the impact of the contribution to the overall success of the study. Since authorship is a highly debated and disputed field, authors should make sure that they discuss this issue with their collaborators as early in the study as possible.

Within the References section, authors should pay close attention to the journal criteria for citing previous results within the text. Specifically, most journals will detail the format for these citations. It is important to make sure that the literature cited includes both review papers and primary papers that reflect the key points of statements made within the text. Citing primary papers allows the original author of a particular finding to receive credit for making the discovery, while review articles should be used to demonstrate how the overall findings from their studies fit within a larger field. It is very important to check the references closely to ensure that you are using the correct ones to make your point, and to properly assign credit to the previous authors that made the original observations. The style for presenting these references should be included in the “Information for Authors,” but if this is not the case the Uniform Requirements for Manuscripts Submitted to Biomedical Journals or the AMA style can be used.

Outline the Manuscript

An important first step in the writing process is to produce an outline that covers all of the relevant sections of the manuscript. This allows authors to organize their thoughts, and to separate information into the appropriate sections. For example, when the sections are outlined in a couple of pages, it can be easier to determine which pieces of information belong in the Introduction and which points should be included in the Discussion. This approach also allows authors to collect references that support key statements within the outline, and to organize the data so that the story is presented as clearly as possible. Once a detailed outline is created, authors can expand it using their own words to transition between separate thoughts and sections of the manuscript. This practice will not only improve the organization of the manuscript, it can also reduce the potential for plagiarism.

Grammatical Considerations

Authors typically have freedom in drafting the body of the text within a manuscript. It is the responsibility of the author to make sure that the points included are clear, and that the reviewers can understand the story presented. In general, in the scientific literature an active voice is preferred over a passive voice, because it presents the story
using stronger words. With regard to tense, it is standard practice to use the present tense when referring to studies that currently exist in the literature, while the past tense is used to describe the results of the study presented in the manuscript. It is important that authors give attention to grammar and punctuation. These issues should not be viewed as minor aspects that can be corrected during the editorial process, as a manuscript with poor grammar may cause an otherwise scientifically strong manuscript to be viewed poorly by reviewers.

In addition to grammatical issues, one area that writers can struggle with is “writer’s block,” as it can be a difficult to get things down on paper. To overcome this, one piece of advice is to write something down – anything, in any format – as it will help move the writing process forward. For example, a simple word or phrase may help trigger development of a thoughtful paragraph. Further, preparing an outline as a first step in the process can help minimize the effects of “writer’s block.” It provides structure to the text that is being generated and aids in the process of transitioning from initial ideas to a comprehensive, cogent text.

Finally, it is recommended to always have a colleague review the manuscript prior to submission. This will help assure that the story is clear and the appropriate conclusions are being drawn. Assistance from colleagues at this stage can typically be cited within the acknowledgments section, as described above.

Summary

This article presents some key points for consideration by future, as well as, established authors related to manuscripts submitted to journals in the field of medicine. The goal of this part has been to present some tips that will improve the likelihood of successful publication, but it should be noted that following these guidelines will not guarantee this outcome. Each manuscript will follow a different process from collection through publication of data, and this process characteristically meets with some difficulty along the way. However, the successful publication of an article ensures that your results will be added to the knowledge of the field, and preserved for future scientists to access and use to make future advances. Putting in the extra work needed to develop a well-written article can improve publication success, which will make the effort very rewarding.
Introduction

Stress-related mucosal disease is estimated to affect more than 75 percent of critically ill patients that are admitted to the intensive care unit (ICU). These stress ulcers can lead to clinically significant bleeding in about 3 to 4 percent of patients who have stress-related mucosal damage if the proper prophylactic measures are not taken. Antisecretory agents such as proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs) are often used in these instances as gastrointestinal (GI) prophylaxis against stress-related mucosal bleeding.1

Guidelines regarding the appropriate use of stress ulcer prophylaxis (SUP) were published by the American Society of Health-System Pharmacists (ASHP) in 1999 and pertain to certain critically ill patients in the ICU (Table 1).2 The 2013 Surviving Sepsis Campaign treatment guidelines have also made recommendations.3 Both guidelines encourage SUP for patients with certain conditions identified to be at higher risk for stress ulcers and discourage the use of prophylaxis in patients that do not meet criteria. This article will focus on proper risk assessment and treatment of adult patients.

Indications for prophylaxis

GI prophylaxis should be reserved for patients with a risk for clinically significant bleeding. Unfortunately, it is often used inappropriately.4,5 SUP is not recommended for patients in the non-ICU setting and should only be recommended for those with risk factors in the ICU.2,3 GI prophylaxis is indicated in patients who have a coagulopathy defined as International Normalized Ratio (INR) greater than 1.5, a platelet count less than 50,000, or a Partial Thromboplastin Time (PTT) greater than two times the control value; who are mechanically ventilated for more than 48 hours; or who have a history of GI bleeding or ulceration within the last 12 months. The ASHP guidelines also state SUP is indicated when any of the two following minor criteria are met: sepsis, an ICU stay greater than seven days, occult bleeding greater than or equal to 6 days, or glucocorticoid therapy equivalent to 250 mg of hydrocortisone per day. In addition to the above criteria, special ICU populations may be considered for SUP such as a Glasgow Coma score less than or equal to 10 or an inability to follow simple commands, thermal injuries covering greater than 35 percent of body surface area, partial hepatectomy, multiple trauma with an Injury Severity Scale greater than or equal to 16, perioperatively in transplant patients, hepatic failure, or spinal cord injuries. Risk factors should be reevaluated daily and prophylaxis should be discontinued once risk factors have resolved and/or the patient has been transferred out of the ICU.2

Agents of Choice

The ASHP guidelines did not make a preference over class of agent to be used among H2RA, antacids, and sucralfate. At the time the ASHP guidelines were published the authors felt the data on PPIs was insufficient to include them in the recommendations.2 Based on more recent data, the Surviving Sepsis campaign guidelines recommend the use of a PPI over a H2RA but do not mention sucralfate or antacids.3 The strength of evidence for this recommendation is D rated,1 and other studies are conflicting on whether PPIs or H2RA are more efficacious.6

The selection of agent is often based on factors such as route of administration, adverse effect profile, drug

### Table 1. Indications for GI Prophylaxis in Adult ICU Patients

<table>
<thead>
<tr>
<th>Indication</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulopathy</td>
<td>[level of evidence-C]</td>
</tr>
<tr>
<td>Mechanical ventilation for &gt; 48 hours</td>
<td>[level of evidence-C]</td>
</tr>
<tr>
<td>GI ulcer or bleeding within past year</td>
<td>[level of evidence-D]</td>
</tr>
<tr>
<td>≥ 2 of the following risk factors:</td>
<td>[level of evidence-D]</td>
</tr>
<tr>
<td>- Sepsis</td>
<td></td>
</tr>
<tr>
<td>- ICU stay of &gt; 1 week</td>
<td></td>
</tr>
<tr>
<td>- Occult bleeding lasting ≥ 6 days</td>
<td></td>
</tr>
<tr>
<td>High-dose corticosteroids</td>
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<tr>
<td>Glasgow Coma score ≤ 10</td>
<td>[level of evidence-B]</td>
</tr>
<tr>
<td>Thermal injury to &gt; 35% of BSA</td>
<td>[level of evidence-B]</td>
</tr>
<tr>
<td>Partial hepatectomy</td>
<td>[level of evidence-C]</td>
</tr>
<tr>
<td>Multiple trauma</td>
<td>[level of evidence-D]</td>
</tr>
<tr>
<td>Transplantation perioperatively in the ICU</td>
<td>[level of evidence-D]</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>[level of evidence-D]</td>
</tr>
<tr>
<td>Hepatic failure</td>
<td>[level of evidence-D]</td>
</tr>
</tbody>
</table>

Reference 2.
interactions, and cost. Table 2 includes commonly used agents for SUP.2,9-12

### Potential Adverse Outcomes

Stress ulcer prophylaxis is often provided to non-critically ill patients despite a low risk of clinically significant bleeding.4,11 Other than the issue of unnecessary expense, increased risk for adverse outcomes such as *Clostridium difficile* and nosocomial pneumonia have been associated with acid suppressive therapy in the hospital. A higher incidence of these adverse effects have been observed with PPIs than with H2RAs.4,5,7 At hospital discharge, many patients are inadvertently continued on acid suppressive therapy.4,5 Prolonged use of PPIs may put patients at higher risk for developing osteoporosis and bone fracture, although randomized controlled trials are lacking.11 A number of other adverse effects have been reported to have a possible association with PPI therapy, including dementia, gastrointestinal cancer, and chronic kidney disease.13-15

### Conclusions

Treatment decisions often come down to weighing the risk versus the benefit for the individual patient. With recent studies bringing to light the risk of adverse effects with inappropriate use of acid suppressive therapies, it is imperative that GI prophylaxis be used only in high risk patients.2 Current guidelines can help health care providers identify those for which the benefits outweigh the risks.2,3 Updated guidelines by ASHP are expected to be published in the spring of 2016 and will provide recommendations based on the most current literature.16

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose in Normal Renal</th>
<th>Dose in Reduced Renal Function</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proton Pump Inhibitors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>20 mg IV/PO/NG q24hrs</td>
<td>None</td>
<td>Injection, DR capsule, powder for suspension</td>
</tr>
<tr>
<td>Lansoprazole</td>
<td>30 mg PO/NG q24hrs</td>
<td>None</td>
<td>DR capsule, DR O D tablet, powder for suspension</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>20 mg PO/NG q24hrs</td>
<td>None</td>
<td>DR capsule, DR tablet, DR granules for suspension</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>40 mg IV/PO/NG q24hrs</td>
<td>None</td>
<td>Injection, EC tablet, granules for suspension</td>
</tr>
<tr>
<td><strong>H2 Receptor Antagonists</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Famotidine</td>
<td>20 mg IV/PO/NG q12hrs; 1.7 mg/hr by continuous IV infusion</td>
<td>CrCl &lt;30 ml/min: 20 mg q24hrs PO/NG/IV; 0.85 mg/hr continuous IV infusion</td>
<td>Injection, tablet, powder for suspension</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>50 mg IV q 8 hrs or 150 mg PO/NG q12hrs; 6.25 mg/hr by continuous IV infusion</td>
<td>CrCl &lt;50 ml/min: 150 mg q24hrs PO or NG; 50 mg q12-24hrs IV; 2-4 mg by continuous IV infusion</td>
<td>Solution for infusion, tablet, syrup</td>
</tr>
</tbody>
</table>

*None of the listed medications are FDA approved for stress ulcer prophylaxis

DR= delayed release; EC=enteric coated; hrs=hours; IV=intravenously; NG=nasogastric; PO=orally; OD=orally disintegrating; q=every

**References:** [9-12]

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**About the Authors:**
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Sarah Ahrndt, PharmD, Sioux Falls VA Health Care System, PGY1 Pharmacy Resident.
Tarryn Jansen, PharmD, Assistant Professor of Pharmacy Practice South Dakota State University.

**April 2016**
Positioned for the Future, Focused on Partnership

Empowering Consumers with Choice

DAKOTACARE’s exceptional distinction is its broad provider network. Patients can stay with their doctor, choose their hospital and go to the pharmacy of their choice.

~ E. Paul Amundson, MD, Chief Medical Officer for DAKOTACARE

Committed to Participating Providers

DAKOTACARE and the South Dakota State Medical Association have enjoyed a long history of cooperation and mutual trust over the years, with direct involvement of South Dakota Physicians. This is what sets DAKOTACARE apart.

~ Michael W. Pekas, MD, Associate Medical Director for DAKOTACARE

Focused on Quality Care and Outcomes

DAKOTACARE works in a collaborative, non-adversarial way with network physicians, placing a top priority upon helping providers make quality-based decisions in the best interest of their patients.

~ James A. Engelbrecht, MD, Associate Medical Director for DAKOTACARE

2600 W. 49th Street ~ Sioux Falls, SD
605.334.4000
www.dakotacare.com
The health care insurance industry has had its fair share of ups and downs since the implementation of the Affordable Care Act. Health insurance companies that sell through the federal or state exchanges have suffered losses for providing insurance to higher cost customers. DAKOTACARE and other South Dakota plans suffered significant losses in 2015 and, since we are a smaller company, we approached potential partners to provide a source of equity to weather the losses.

With new financial strength and a decision to no longer participate in offering health insurance for individuals in the Health Insurance Exchange Marketplace, DAKOTACARE entered 2016 positioned for the future and focused on the same high quality products and services our customers have come to expect from us.

Empowering consumers with a broad provider network, the DAKOTACARE network includes 100 percent of South Dakota hospitals, and 98 percent of physicians and pharmacies. We cover 1,075 employer groups with 93,000 members, from every county in this great state. In addition, offices in Sioux Falls, Rapid City and Webster truly give us a statewide presence.

As has been previously mentioned in this section earlier this year, under its recent change in ownership DAKOTACARE continues to operate as a separate entity. We bring value to our participating physicians in a number of ways and are committed to delivering the service and support you have come to expect:

- DAKOTACARE remains the health plan of the South Dakota State Medical Association (SDSMA);
- Our provider network, contracts and fee schedules remain in place;
- Physicians experience a broad network for referrals with access to local Provider Relations support; and
- Medical Management and provider reimbursement decisions are made by a South Dakota-based company, by individuals you can contact and speak to directly.

Network providers will continue to have access to patients covered by DAKOTACARE, with no disruptions in care of current patients, or in referrals from other DAKOTACARE physicians. DAKOTACARE has developed proven wellness, preventive and medication management programs to keep costs under control. We pride ourselves in working in a collaborative, educational, and non-adversarial fashion with network physicians, placing a top priority on helping providers make evidence-based decisions which are in the best interest of their patients.

DAKOTACARE and the SDSMA have enjoyed a long history of cooperation and mutual trust over the years, with direct involvement of South Dakota physicians. The two organizations are returning to their earlier leadership model of a shared Chief Executive Officer. Barb Smith and I, along with other Provider Relations staff, will be traveling around the state and attending district and other meetings to share DAKOTACARE’s story and discuss our evolving partnership with physicians. We look forward to seeing you at one of these meetings!

In next month’s issue of South Dakota Medicine I plan to feature DAKOTACARE’s strategic business initiatives as well as more details about our health services, wellness, and quality improvement activities.

Happy Spring to all!
Quality Focus:

Nursing Home Composite Measure Score: A Tool for Improvement

By Stephan D. Schroeder, MD, Medical Director, SDFMC; Jane Mort, PharmD; and Lori Hintz, RN, Great Plains QIN/SDFMC Project Manager

The National Nursing Home Quality Care Collaborative (NNHQCC) has created a composite measure score to serve the purpose of timely performance evaluation. This composite measure score contains results from 13 long-stay, National Quality Forum (NQF) approved quality measures. The table below contains a list of the measures and their inclusion in Nursing Home Compare (all 13 measures) and the Five-Star Rating (8 measures).

<table>
<thead>
<tr>
<th>Composite Score Quality Measure Items (long-stay only – no short stay measures are included)</th>
<th>Quality Measures in Nursing Home Compare</th>
<th>Items Used in Calculating Five-Star Rating in Nursing Home Compare</th>
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<tbody>
<tr>
<td>1. Percent of residents with one or more falls with major injury</td>
<td>X</td>
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<tr>
<td>2. Percent of residents with a urinary tract infection (UTI)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>3. Percent of residents who self-report moderate to severe pain</td>
<td>X</td>
<td>X</td>
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<tr>
<td>4. Percent of high-risk residents with pressure ulcer</td>
<td>X</td>
<td>X</td>
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<tr>
<td>5. Percent of low-risk residents with loss of bowels or bladder</td>
<td>X</td>
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<tr>
<td>6. Percent of residents with catheter inserted or left in bladder</td>
<td>X</td>
<td>X</td>
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<tr>
<td>7. Percent of residents physically restrained</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>8. Percent of residents whose need for help with activities of daily living (AFDL) has increased</td>
<td>X</td>
<td>X</td>
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<tr>
<td>9. Percent of residents who lose too much weight</td>
<td>X</td>
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</tr>
<tr>
<td>10. Percent of residents who have depressive symptoms</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>11. Percent of residents who received antipsychotic medications</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>12. Percent of residents assessed and appropriately given the seasonal influenza vaccine*</td>
<td>X</td>
<td></td>
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</table>

*This measure must be converted to those not receiving the vaccine before being used in the score calculation.

A facility’s composite score is calculated by adding the number of residents in the numerator (those who meet each measure) and dividing by the number of residents who are included in the denominator (qualify for inclusion in the measure). Eleven of the 13 measures report results from a negative outcome perspective (e.g., residents in pain, residents having a pressure ulcer). Two measures are in the affirmative (influenza and pneumococcal vaccination) and therefore, the numerator used in the calculation is the difference between the numerator and denominators (i.e., denominator minus numerator equals the numerator for the calculation).

The composite score can be calculated or estimated using data that is available through two data sources—the National Coordinating Center (NCC) or the CASPER Quality Measure Facility Report. The NCC provides data to the Quality Innovation Networks that covers all thirteen measures, includes a rolling six month period, and has a two month delay. Alternatively, a nursing home can estimate their composite score by using data from the
CASP E R source and calculating the value; however, CASP E R does not contain vaccination data which would need to be obtained from other sources (e.g., QIN, nursing home records).

The Great Plains QIN has a Composite Predictor Calculator tool available at http://greatplainsqin.org/initiatives/hac-nh/ that will perform an estimated calculation by simply entering data from the CASP E R report and entering the vaccination data. This tool also allows facilities to project what their score would be if they changed the numerator in one of the individual measures. For example, if the facility reduced the number of residents receiving an antipsychotic by one or two residents, they will see the impact this has on their overall score. Alternatively, the QIN provides our South Dakota Great Plains Nursing Home Quality Care Collaborative teams with a quarterly dashboard containing the trend of the facility’s monthly scores and individual measures. The goal for the composite score is 6.0 or less.

The composite measure score is a useful tool for a facility’s quality improvement program. This score allows facilities to compare performance to a national standard, obtain timely information on performance, identify opportunities for improvement, project the potential impact of change on the composite score, and evaluate the true impact of change in a timely manner based on the data source selected.

For more information, please contact Great Plains QIN/ South Dakota Foundation for Medical Care at 605.336.3505 or email me at stephan.schroeder@area-a.hcqis.org.

REFERENCES
1. Oklahoma Foundation for Medical Quality and Stratis Health, the National Coordinating Center (NCC) for Improving Individual Patient Care (IPPC) Aim, IPPC National Coordinating Center for Discussion with QIOs. Frequently asked questions about the quality measure composite score used in the National Nursing Home Quality Care Collaborative (NNHQC), April 2015. Retrieved from www.alliantquality.org/sites/default/files/Composite%20Score%20FAQs%202015_4.pdf.
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Board News is a monthly feature sponsored by the South Dakota Board of Medical and Osteopathic Examiners. For more information, contact the Board at SDBMOE@state.sd.us or write to SDBMOE, 101 N. Main Avenue, Suite 301, Sioux Falls, SD 57104.
It is a cruel world out there. Consider how some people are so angry they are cutting heads off and burning people alive in front of video recorders likely for the very purpose to bring us to hate. Anger, bigotry, hate crime against those different, and even I dare say polarizing-politics can be found everywhere.

The old adage rings true: "To destroy your enemy, make them hate."

About the destructive power of hate, Buddha said, "Holding on to anger is like grasping a hot coal with the intent of throwing it at someone else; you are the one who gets burned." Another philosopher said, "While seeking revenge, dig two graves – one for yourself."

But it can go both ways. A research study not only showed when the study director treated the subject poorly he or she would then treat a stranger negatively; it also showed when the study director treated the subject kindly, he or she would then treat a stranger positively. But do we really need a study to prove the simple truth that we all find it easier to be a good person when we are treated well, and be mean when we ourselves are abused?

The rub comes with the difficulty getting into the habit of treating others with kindness. Confucius said, "It is easy to hate and it is difficult to love. All good things are difficult to achieve; and bad things are very easy to get."

A group of premed students recently asked me about how much volunteerism is enough to help get them into medical school. One student stated, "It is hard to be altruistic when I don't really feel the love in my heart. I don't want to be a hypocrite."

It made me remember a sermon given by a favorite minister a while back suggesting that if we don't feel the milk of human kindness, we should go through the motions and act like we do. The more we practice, the more it turns real.

I believe this is true but it's difficult and takes time. My lifetime job in the medical field as a physician has required very active listening, and I have noted that kindness, even if it is not completely heartfelt, is the most powerful and curative medicine, my favorite and most helpful treatment for almost every illness. Over the years with all that practice, the caring has only turned more genuine and thus more rewarding.

I am not suggesting tolerance to injustice, but in this world where there remains hate, cruelty, radicalization, and polarity, we should realize our best weapon might just come with patient kindness.

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

The Patient Education Page is a monthly feature sponsored by the Healing Words Foundation. For more information, visit www.prairiedoc.com.
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<td>SURG-PRE</td>
<td>University of Florida College of Medicine, Gainesville, Florida</td>
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<td>Joseph Anderson</td>
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<td>Rebecka Bogue</td>
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<td>Loyola University Medical Center, Maywood, Illinois</td>
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- Thomas Murphy

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- Kenneth J. Knudtson, MD
- Alan A. Lawrence, MD
- Scott A. Lockwood, MD
- Thomas L. Luzier, MD
- James B. MacDonald, MD
- Mary J. Milroy, MD
- Mark J. Oppenheimer, MD
- Tim M. Ridgway, MD
- William O. Rossing, MD
- Ronald R. Tesch, MD
- Thavam C. Thambi-Pillai, MD
- Eric R. Thomas, MD
- Gary L. Timmerman, MD
- Kynan Trail, MD
- Victoria L. Walker, MD
- Thomas C. White, MD
- Jason W. Wickersham, MD

### Student Member

- George A. Ceremuga

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Your SDSMA PAC membership is very important in order to elect political candidates who understand the practice of organized medicine in South Dakota. To donate to SDSMA PAC, please visit [www.sdsm.org](http://www.sdsm.org).
Legal Brief Highlight: Medical Malpractice

Physicians are held to certain standards of care in their treatment of patients, and when their treatment of a patient falls below this standard of care, they may be held responsible for damages for medical malpractice. A physician is not necessarily negligent if he or she makes an error in judgment or if treatment proves unsuccessful. Negligence only occurs if the error in judgment or lack of success is due to a failure to perform any of the duties associated with the care and skill ordinarily exercised under similar circumstances by similarly situated physicians.

South Dakota law imposes certain limitations on damages that may be awarded in a malpractice action. However, there is no limitation on the amount of special damages which may be awarded. “General damages” are damages for things like pain and suffering, loss of consortium, and loss of enjoyment of life. “Special damages” are more specifically-quantifiable items, such as past and future medical expenses, prostheses, and wheel chairs. The law also requires both physicians and their malpractice insurers to make reports on malpractice claims.

For more information, download the SDSMA legal brief Medical Malpractice or access the risk mitigation resources at www.sdsm.a.org. Through the SDSMA Center for Physician Resources, the SDSMA has developed more than 40 legal briefs that are available to members. In addition, the Center develops and delivers and programs for members in the area of practice management, leadership and health and wellness.

Source: SDSMA staff

Register Today for the 2016 SDSMA Annual Leadership Conference

The 2016 SDSMA Annual Leadership Conference – with a new schedule and new opportunities – heads back to the Hilton Garden Inn, Downtown Sioux Falls on Friday, June 3. With presentations, discussions, networking opportunities and social events, the Annual Leadership Conference is a great time to share ideas and learn from fellow members. Check out the new schedule and new events! Do you have an issue you’d like to bring to the SDSMA’s attention? Schedule a time to address the Council by contacting the SDSMA office at 605.336.1965 or visit www.sdsm.a.org. The Annual Leadership Conference is a benefit of your membership. For the latest details about exciting events taking place during the 2016 SDSMA Annual Leadership Conference, visit www.sdsm.a.org. Buy your tickets for the banquet and SDSMA PAC lunch online by May 20.

New Schedule & Events! Register at sdsm.a.org

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:30 a.m.</td>
<td>Membership Meeting with presentations from AMA President Dr. Steven Stack and SSOM Dean Dr. Mary Nettleman</td>
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<tr>
<td>9:30 a.m.</td>
<td>Medical Marijuana Panel Discussion</td>
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<tr>
<td>11 a.m.</td>
<td>Open Forum</td>
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<tr>
<td>12 p.m.</td>
<td>SDSMA PAC Lunch: Working Together to Combat Human Trafficking in South Dakota – Kevin Koliner, U.S. Attorney Sioux Falls</td>
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<tr>
<td>1:30 p.m.</td>
<td>Council Meeting</td>
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<tr>
<td>6 p.m.</td>
<td>Membership Mixer</td>
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<tr>
<td>7 p.m.</td>
<td>Awards Banquet &amp; Scholarship Recognition</td>
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Source: SDSMA staff
The president of the American Medical Association (AMA) has issued a “call to action” to the nation’s physicians to help prevent opioid misuse.

The AMA has released the findings of a national physician survey that shows strong support for key policies and recommendations to end the nation’s opioid epidemic, including ways to improve prescription drug monitoring programs, enhancing physician education as well as removing barriers to care. The survey shows that 87 percent of physicians agree that prescription drug monitoring programs (PDMPs) help physicians become more informed about a patient’s prescription history. The survey also found that to further enhance this as a resource, physicians said PDMPs need improvement to integrate with electronic health records, provide real-time data and other key features that would make them even more useful.

In light of the findings, AMA President Steven J. Stack, MD, issued a “call to action” to the nation’s physicians and physicians-in-training, encouraging physicians to increase their efforts in the fight against opioid misuse.

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

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

2016 SDSMA Legislative Accomplishments

Overview
South Dakota’s 2016 Legislative Session opened Jan. 12 and continued through March 11, with the 38th legislative day being held on March 29. Legislators brought forward 419 pieces of legislation – 58 had the potential to impact health care delivery in South Dakota. The SDSMA worked on a wide range of issues to protect the practice of medicine and to enhance the delivery of medical care.

Promoting the art and science of medicine
HB 1029, an act to make an appropriation to the SDDOH to fund the rural residency program and to declare an emergency, will appropriate $205,000 or the amount necessary, to the SDDOH to support a rural family medicine residency track for six medical students. HB 1029 was passed by the legislature and signed into law by Gov. Dennis Daugaard. The SDSMA supported this legislation.

Protecting and improving public health
HB 1110 will require the creation of a separate health assistance program under Title XXI of the federal Social Security Act to provide for the medical care of unborn children whose mothers are ineligible for coverage based on citizenship. Gov. Daugaard signed this legislation into law. The SDSMA supported this legislation.

Because lay midwives lack the necessary clinical training and skills to handle problematic births in non-clinical settings, the SDSMA strongly opposed HB 1162, an act to provide for the practice and regulation of midwives, and SB 117, an act to permit the practice of midwifery by certain persons. HB 1162 passed the House but died in the Senate; SB 117 was killed in committee.

SB 28, an act to require meningococcal immunization for school entry, was introduced into the Senate Health and Human Services committee on behalf of the SDDOH. As passed, any child entering school or an early childhood program will be required to have the following immunizations prior to admission: poliomylitis, diphtheria, pertussis, rubella, rubella, mumps, tetanus, meningitis, and varicella. Gov. Daugaard signed SB 28 into law. The SDSMA supported this legislation.
Improving access to and delivery of quality medical care

The SDSMA supported Gov. Daugaard’s plan to expand Medicaid, which would provide access to care and expand coverage for an estimated 50,000 South Dakotans, including 15,000 American Indians. For more than a decade, South Dakota has advocated for the Centers for Medicare and Medicaid Services (CMS) to fulfill its federal responsibility related to Indian Health Services (IHS) funding and Medicaid. While slowed negotiations with CMS prevented the introduction of legislation to expand Medicaid during the 2016 legislative session, a coalition established by the governor will continue its efforts to develop ways to expand coverage and services to those currently without.

As proposed, HB 1067 would have deemed health plans as being in compliance with IM 17 provided the insurer offers at least one health plan which is open to all health care providers. The House Commerce and Energy Committee voted to defer this legislation to the 41st legislative day, killing the bill. The SDSMA is opposed to this legislation.

Recruitment and retention of rural health care providers continues to be a challenge. HB 1170, an act to make an appropriation to reimburse certain eligible health care professionals, and SB 120, an act to make an appropriation to reimburse certain family physicians, dentists, physician assistants, and nurse practitioners who have complied with the requirements of the recruitment assistance program, will fund reimbursement to those who have complied with requirements of the state’s recruitment assistance program and will provide assistance for rural communities to recruit health care providers. Both bills were signed by the governor. The SDSMA supported both pieces of legislation.

Other legislative issues

HB 1079, an act to permit the prescription and possession of an opioid antagonist in certain instances, was signed by Gov. Daugaard. As proposed, a person who is a family member, friend, or other close third party to a person at risk for an opioid-related drug overdose, may be prescribed, possess, distribute, or administer an opioid antagonist that is prescribed, dispensed, or distributed by a licensed health care professional directly or by standing order. This was the third of a package of three bills introduced on behalf of the SDSMA. The SDSMA strongly supported this legislation.

SB 171, an act to authorize limited use of certain types of medical marijuana, was passed by the Senate but died in the House. If passed, a physician could have prescribed the use of cannabidiol in liquid, oil, or pill form for treatment of intractable epilepsy. In addition, a patient in possession of a valid cannabidiol prescription would not have been subject to prosecution nor would have physicians, pharmacists and other medical professionals properly prescribing it. Additionally proposed, a primary caregiver or a custodial parent of the patient could have assisted in the administering of the prescribed cannabidiol to the patient while not being subject to prosecution. While we share the interest of the sponsor(s) of this bill with regard to giving physicians options for the treatment and caring of patients, the SDSMA opposed it based on the fact that cannabidiol oil has yet to be approved by the FDA and it is possible that other solutions being researched may be more fitting for the concerns discussed thus far. An SDSMA task force has been formed to review this issue.

Outcome of other priorities

As proposed, HB 1077, an act grant limited immunity from arrest and prosecution, proposed that any person who experiences a drug-related overdose and is in need of medical assistance could not be arrested, charged, or prosecuted for any misdemeanor or felony offense of possession, inhalation, ingestion, or otherwise talking into the body any controlled drug or substance if that person contacted law enforcement or emergency medical services and reported that he or she is in need of medical assistance as the result of a drug-related overdose. HB 1077 was deferred to the 41st legislative day in committee. The SDSMA strongly supported this legislation.

Similar to HB 1077, HB 1078 was introduced on behalf of the SDSMA, and was a part of a package of three bills relating to the acts of good Samaritans. HB 1078, an act to grant limited immunity from arrest and prosecution for certain alcohol related offenses to persons who assist a person in need of emergency assistance or who are themselves in need of emergency assistance, was passed by the legislature and signed by the governor.

HB 1122, an act to establish procedures for payment of insurance claims by credit card or electronic funds transfer to health care professionals, was deferred to the 41st legislative day in committee. This act would have required insurers who utilize virtual credit card payments to notify the provider, in advance, of fees, to offer an alternative payment method that does not impose fees, and have an agreement to accept payment. The SDSMA strongly supported this legislation.

HB 1124 sought to prohibit the use of tanning devices by minors. Frequent exposure to ultraviolet rays for individuals under 35 increases the risk of developing melanoma — the most aggressive and deadliest form of skin cancer — by 75 percent, and melanoma is currently the second most common cancer after thyroid cancer among women in their 20s. While the SDSMA strongly supported this legislation, HB 1124 did not have sufficient support to pass the Senate.

SB 79, an act to expand the list of professionals authorized to perform certain examinations required for a plea of guilty but mentally ill, was signed into law by Gov. Daugaard. This legislation was based upon the thought that a licensed psychologist, as a mental health professional, is equivalent to a licensed psychiatrist in the training and experience of evaluation and treatment of persons experiencing severe psychiatric illness. The SDSMA strongly opposed this legislation. Going forward, we believe that by allowing psychologists to declare guilty but mentally ill, we will actually see greater delays in the judicial process as well as increased costs for the counties and state through an increased number of appeals, additional evaluations and retrials — the very opposite of the proposed reason for its introduction.
CME Events

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

April 2016

April 6
Internal Medicine Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

Surgery Grand Rounds: Role of Robotics in Bariatric Surgery
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 6
VA Tumor Conference
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 7
Pediatric Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 13
Internal Medicine Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 2016

April 14
Avera eEmergency Airway Management Program Powered by the Difficult Airway Course
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 20
Internal Medicine Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 20
VA Tumor Conference
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 21
Pediatric Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 2016

April 27
Internal Medicine Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 28
Pediatric Grand Rounds
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

April 28
Surgery Education Series – Best Practices for Mentoring Residents in Academic Medicine
AMA PRA Category 1 Credit(s)™ available
Register online: usdssom.learningexpressce.com

Do you have a CME event coming up? Would you like to have it listed here?

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

Don’t forget to send in your favorite scenic photo for South Dakota Medicine front cover consideration.
Send photos to ereiss@sdsma.org.
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Shannon Gabriel-Griggs, MD
Heather Peck, MD
Jenny Starks, PA
Kirsten Whalen, PA
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Edith Sanford Breast Center Symposium

Friday, April 29, 2016

Symposium Agenda:

7:15 a.m. Continental Breakfast and Registration
8 a.m. Welcome and Opening Remarks
8:15 a.m. Keynote: BRCA1 and 53BP1: Regulating DNA Repair Choice and Chemosensitivity  Shnidar Banesan, MD, PhD
9:15 a.m. The Role of Physical Activity and Energy Balance in Breast Cancer Prevention and Survivorship  Lisa Cadmus-Bertram, PhD
10:15 a.m. Break
10:30 a.m. Addressing the Needs of Patients with Metastatic Breast Cancer  Lillie Shackney, RN, BS, MAS
11:30 a.m. Case Studies in Breast Cancer Survivorship: Making the "new normal" better  Shelby Terstreip, MD
12:15 p.m. Lunch
1 p.m. Less is More: Current Trends in Breast Surgery  Michael Bouton, MD
1:45 p.m. State of the Art in Breast Surgery: Breast Reconstruction After Cancer  Heather Karu, MD & Jesse Dirksen, MD
2:30 p.m. Break
2:45 p.m. Breast Cancer Imaging Equipment and Why It Matters  Thomas Cink, MD
3:30 p.m. Hereditary Breast Cancer: What do I need to know?  Lauryn LaPoint, MS, CGC

Pre-registration is required:
Go to sanfordhealth.org and search keyword: Edith Symposium 2016.

Cost:
General Registration $50.00
Sanford Employees/Physicians, Students $25.00

For more information, please email Jessica Aguilar at jessica.aguilar@sanfordhealth.org.