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Number 5

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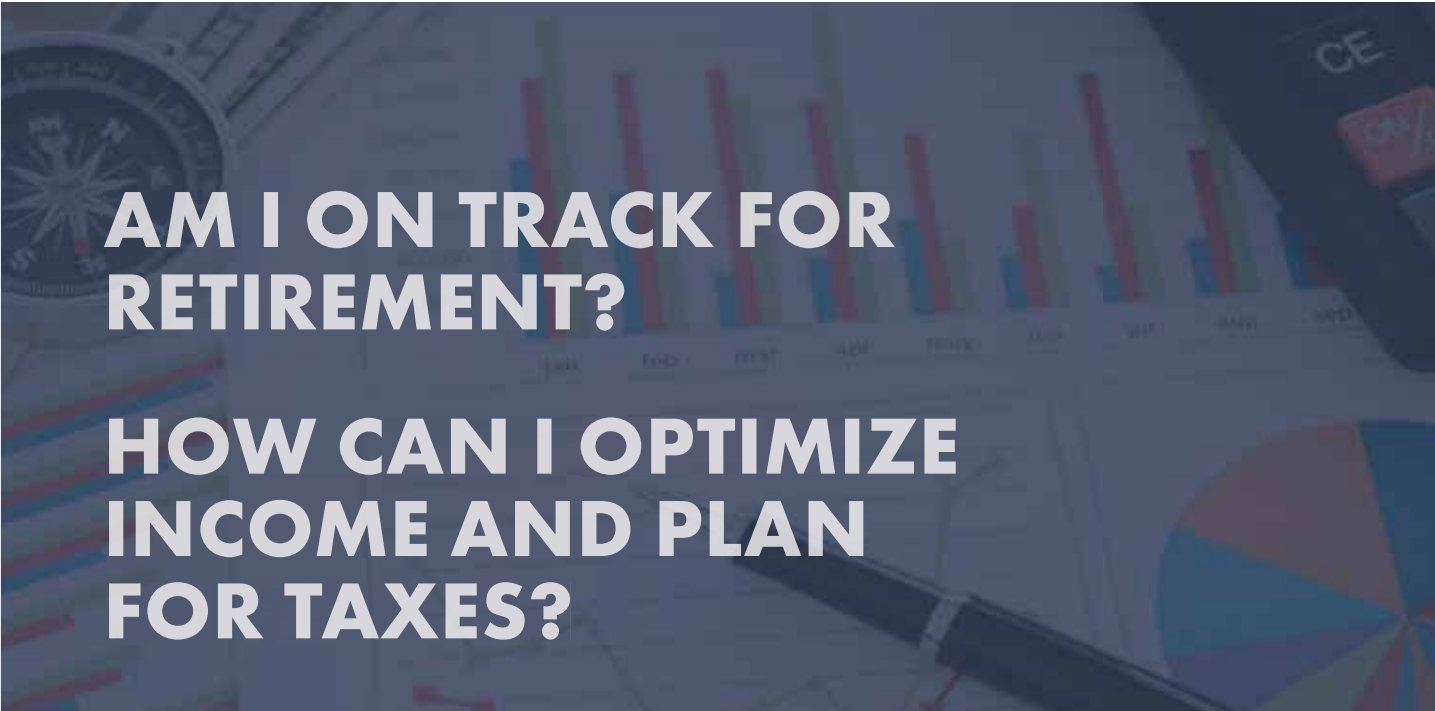
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SDSMA's Legislative Advocacy Efforts Made a Difference

Lucio N. Margallo II, MD
President, South Dakota State Medical Association

It has been an absolute honor and privilege to serve as the 141st president of the South Dakota State Medical Association. During my induction last June, I took an oath to work closely with the SDSMA staff, Board of Directors, Policy Council, and the entire membership. As my term ends, I am proud to provide an overview of legislative accomplishments.

The SDSMA advocates for issues that promote the art and science of medicine, protect and improve public health, and ensure access to and delivery of medical care. During the past year we were successful in doing so in many ways.

There were multiple attempts by legislators to create doubt regarding the efficacy of some vaccines and additional exceptions to their utilization. We provided evidence-based testimony regarding their value and demonstrating their impact as part of a coalition that ensured the bills' defeat.

There were numerous pieces of legislation aimed at curbing the opioid epidemic, which has accelerated in recent years. The SDSMA was an integral part of getting two important bills passed, one that exempted fentanyl testing strips from the definition of drug paraphernalia, and a second that provided for licensed health professionals to dispense or distribute opioid antagonists to employers.

We worked with the South Dakota Academy of Ophthalmology (SDAO) to convince legislators the evidence didn't support including a glaucoma diagnosis as a legitimate debilitating condition warranting certification for medical cannabis.

The SDSMA also teamed with the SDAO to defeat a proposed inappropriate scope of practice expansion by the optometry association. Optometrists were seeking the ability to perform injections and surgeries with insufficient education and training, and after a lengthy educational outreach that bill was defeated.

Finally, we once again defended the physician-led, team-based health care model from those that would like to see its demise. The model, which is overwhelmingly preferred by the majority of South Dakotans, was challenged by the physician assistants for the third year in a row. Watching our physician members participate directly in advocacy by calling and emailing their senators, attending legislative forums, and testifying in committee was a source of great pride. We must continue our vigilance with a constant focus on accessible, quality health care and patient safety.

As I reflect while I write my last monthly presidential column, I wish to thank you for your support. I continue to hope that what we've worked on together to protect the practice of medicine and enhance the delivery of high-quality medical care will endure.

Improving Health Outcomes Across South Dakota

Melissa Magstadt, Secretary of the South Dakota Department of Health



Editor's note: Below is an introduction from Melissa Magstadt, Secretary of the South Dakota Department of Health. Secretary Magstadt writes about promoting public health in South Dakota and discusses her ideas and what she has accomplished promoting health in the state. At this time in history it is important to have leaders who are advocates for data-driven decision-making in promoting health care.

Keith Hansen, MD, Editor

Over the last 100 + days of leading the South Dakota Department of Health, I have learned that this is one of the hardest working teams doing the people's work of public health. I am honored and humbled that Governor Noem appointed me to this position because the future is bright for what public health can do to help lead the way to positive change and improved health outcomes across our state.

South Dakota is at the forefront of supporting proactive quality of care for our residents and those who visit us. Our state has unique health challenges, which vary from our rural communities to our two largest urban cities. At the Department of Health, we tackle these challenges by focusing on an innovative, forward-looking approach to public health rather than simply reacting to difficulties. And through every challenge, we continue to respect the freedom of South Dakotans. Because in South Dakota, we know our friends, families, neighbors, and coworkers desire flexibility, affordable care, and freedom to make their own choices regarding practitioners, insurance, facilities, and treatment options. I am a firm believer that the government's role in healthcare is to empower, support, and partner – not mandate, control, and lock down. I am eager to show that it is possible to prioritize health and well-being while also maintaining one of our core values of freedom.

As a passionate advocate for data-driven decision-making, I will work with my staff and leadership team to achieve better and healthier outcomes by continuously using data to inform what we do next. We have wonderful opportunities ahead of us to work with our partners to collaborate in ways that allow us to maximize our capabilities through the sharing of data and resources, with the sole purpose of ensuring the well-being of all South Dakotans. Access to resources and quality information to make effective and timely decisions should not be a barrier for our citizens, nor for our health

care providers.

I take pride in sharing the success stories resulting from my team and our work. We just launched a social media series that will showcase firsthand who we are and what we do. Our public health workforce are the hearts of our South Dakota communities and celebrating them is a pleasure. From the community health nurses to the lab technicians and public preparedness and response professionals – they all are working proactively to prevent illness and injury, promote healthy behaviors, and foster environments that support our quality of life.

To say that I love healthcare and watching over those entrusted to me would be an understatement. I was born to do this work and have been doing so for more than 30 years. In addition to my role as cabinet secretary, I serve as an Advanced Practice Registered Nurse and co-owner of Quick Care SD. I was also a member of the South Dakota House of Representatives from 2011 to 2014 and served on the House Committee of Health and Human Services. I earned my Master's in Science from South Dakota State University with a focus as a family nurse practitioner. Go Jacks! And then I went on to pursue my Master's in Business Administration from Mount Marty University. I am a huge advocate of fostering professional development at any age and at any stage in one's career. I am a graduate of the Great Plains Public Health Leadership Institute at the University of Nebraska and am bringing this same opportunity to the table for some of my public health leaders, as an investment in the future of public health. Later this summer, I will graduate from the University of Arizona's Center for Integrated Medicine.

In my spare time, I enjoy spending time with my family, especially my two granddaughters. I also love reading, playing the piano, and listening to music.

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Retrospective Study of Long-term Surgical Outcomes in Patients Who had a Vaginal Hysterectomy in Conjunction with Pelvic Organ Prolapse Surgery

Sydney Bormann, MS IV; Tori Biach, MD; Adam DeLange, BS; and Matthew A. Barker, MD

Abstract

Introduction: Data on long-term outcomes and subjective patient symptom improvement following primary native tissue pelvic organ prolapse repair is limited. Our primary aim was to evaluate the long-term prolapse recurrence and retreatment rates of women who have undergone native tissue prolapse repair. Our secondary aim was to evaluate subjective patient improvement in pelvic floor symptoms and quality of life 7 to 10 years after surgery.

Methods: This retrospective cohort study included patients who had undergone primary prolapse repair surgery including a hysterectomy and native tissue repair by a single surgeon at a tertiary pelvic floor center from 2009 to 2013. The Pelvic Floor Distress Inventory was distributed to subjects before and 7 to 10 years after surgery and pre- and post-operative survey results were compared. Subjects were asked if they had symptom recurrence and if they required retreatment.

Results: One hundred twelve of the 204 distributed surveys were returned, yielding a 54.9% response rate. 8.57% of subjects reported prolapse symptom recurrence. 1.9% of subjects were retreated with a pessary. No subjects required additional prolapse repair surgery. 77.1% of subjects had improved PFDI-20 scores following surgery with an average improvement of 46.21 ($p < 0.001$) points. Statistically significant score improvements were also observed on PFDI-20 subsections.

Conclusions: Primary pelvic organ prolapse repair utilizing native tissue results in low recurrence and retreatment rates. Patients can expect long-term clinical improvement in pelvic floor disorders and quality of life following prolapse surgery. Definitions of surgical success should be based on subjective patient symptoms and quality of life measures.

Introduction

Pelvic organ prolapse (POP) is the descent of one or more female pelvic organs including the cervix, uterus, bladder, rectum, or small intestines down into or through the vagina.¹ This chronic condition is estimated to affect up to 50% of women, and a woman's lifetime risk for undergoing POP surgery is 12.6%.^{2,3} Common risk factors include increasing age, BMI, and parity.⁴ Prior hysterectomy and increased intra-abdominal pressure caused by chronic cough, constipation, and heavy lifting also increase a woman's risk of developing POP.⁴ Although many patients are asymptomatic, symptoms of pelvic organ prolapse can negatively impact quality of life. Symptoms commonly include vaginal pressure, bulging, or pain and the disruption of sexual, urinary tract, or bowel function.⁵ Patients who fail or decline conservative treatment

may undergo surgery to alleviate POP symptoms. There are approximately 300,000 POP repair surgeries each year in the U.S. and prolapse is the most common indication for hysterectomy in post-menopausal women.^{1,6}

Prolapse may reoccur after surgical repair, requiring additional treatment. The rate of reoperation ranges from 6-30%; however, data on long-term outcomes is limited.⁵ In an effort to decrease prolapse recurrence rates and subsequent repair surgeries, synthetic graft material for POP in place of native tissue repair has been developed.⁷ In 2005, the use of mesh to augment POP repair was introduced in the U.S. without clinical safety and efficacy data, and in recent years, the placement of transvaginal mesh has been controversial.⁸ The use of graft material may increase the risk of surgical complications.⁵ In 2016, the Food and Drug Administration



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changed its classification of mesh to class III, or high risk, and many companies have withdrawn their mesh products from the market.⁹

Reported rates of surgical success vary widely across the literature.^{2,10} Variation in surgical outcomes may be due to the use of multiple definitions of success and inconsistency in guidance from professional societies in defining surgical success standards.² Because POP often impacts quality of life, relief of patient symptoms should be considered when measuring surgical outcomes. Surgical success has been increasingly defined using retreatment rates and subjective measures such as the absence of vaginal bulge symptoms. These subjective and functional outcomes are best reported using valid, reliable, and responsive symptom questionnaires.⁵ Additionally, surgical success and failure are fluid states. In one study, approximately 1 in 4 patients who were initially considered surgical failures transitioned between success and failure during follow-up, suggesting that anatomic and subjective outcomes of POP surgery are dynamic and traditional approaches to determining surgical success may not be relevant.¹¹

The primary aim of this study was to evaluate long-term prolapse recurrence and retreatment rates of women who have undergone total vaginal hysterectomy in conjunction with prolapse repair using native tissue and no synthetic graft material for prolapse repair. The secondary aim was to evaluate subjective patient improvement in pelvic floor symptoms and quality of life 7 to 10 years after surgery.

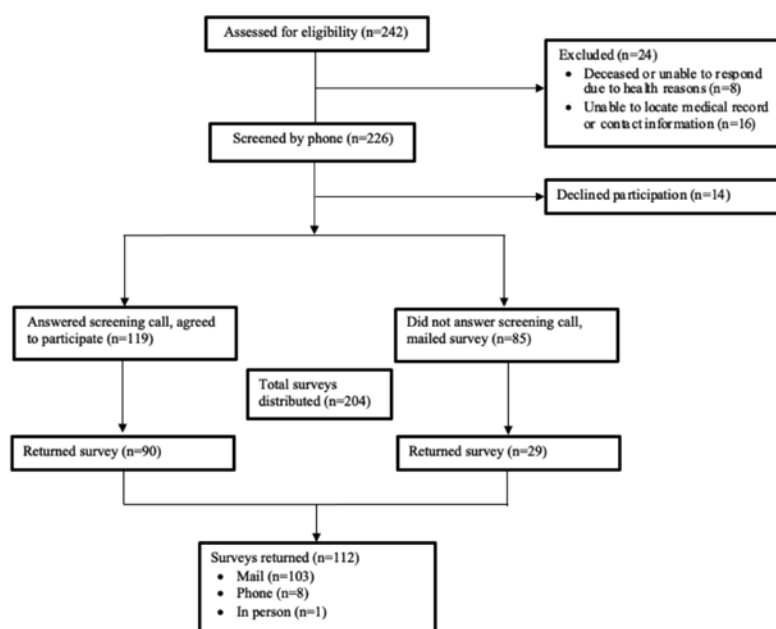
Materials and Methods

This retrospective cohort study was approved by the Avera Health institutional review board. This study assessed surgical outcomes of women with POP who had undergone total vaginal hysterectomy in conjunction with prolapse repair utilizing a transvaginal native tissue approach from September 2009 to December 2013. Women were evaluated by a female pelvic medicine and reconstructive surgery fellowship-trained surgeon, senior author (M.B.), and advanced practice providers at a tertiary medical center. Patients were identified from the medical center's surgical database. Each subject had a diagnosis of pelvic organ prolapse and underwent surgery by the senior author (M.B.).

Patients underwent surgery under general or regional anesthesia and all surgeries were performed by the senior author (M.B.). A vaginal hysterectomy was performed, and adnexal surgery was also performed if indicated. After the hysterectomy, a uterosacral ligament suspension was performed bilaterally with 2-0 polyglactin 910 (Ethicon, Raritan, New Jersey) sutures on each side placed in the intermediate uterosacral ligament, at or above the ischial spine, which were to be affixed to the vaginal apex, typically considered a "high" uterosacral suspension.¹²⁻¹⁵ The posterior cul de sac was oversewn and the more proximal uterosacral ligaments plicated with 2-4 2-0 monofilament polypropylene (Ethicon, Raritan, New Jersey) sutures. If indicated, an anterior colporrhaphy and/or suburethral sling procedure was then performed. The 4 uterosacral suspension sutures were then passed through the apex of the vagina and the cuff was then closed with delayed absorbable sutures. The now externalized suspension sutures were then elevated and tied in an interrupted fashion elevating the apex of the vagina. A posterior repair and or perineoplasty was then performed if indicated. Delayed absorbable sutures were used for the anterior and posterior repairs where indicated and either a transobturator or retropubic mesh suburethral sling was utilized if the patient had demonstrated stress urinary incontinence or occult incontinence pre-operatively.

The study design is shown in Figure 1. Inclusion criteria included proficiency in the English language and no

Figure 1. Flow diagram of study design.





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previous prolapse surgeries. Patients who had undergone previous POP repair surgeries were excluded. Chart review of patients was performed via electronic medical records. All subjects were recruited over the phone and were sent a consent form by mail. Subjects who consented to participate completed a paper survey in person, by mail, or by phone. Subjects were contacted for follow-up 4 weeks after the initial survey was sent. All surveys were completed within 6 weeks of distribution. The data from the paper surveys was then transferred to an electronic data collection form.

This study used a patient-centered approach by assessing subjective patient responses to determine surgical success. The primary outcome, assessing prolapse recurrence and retreatment, was measured by asking subjects, "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" Subjects were also asked if they had required retreatment in the form of surgery or a pessary. The secondary outcome, improvement in patient pelvic organ symptoms and quality of life, was defined using a validated quality-of-life questionnaire, the Pelvic Floor Distress Inventory (PFDI-20). The PFDI-20 assesses the degree of bother POP symptoms cause with a four-point Likert scale. The PFDI-20 consists of three subsections assessing prolapse (POPDI-6), colorectal-anal (CRAD-8), and urinary (UDI-6) symptoms. Higher scores indicate a greater perception of symptoms. Subjects had completed the PFDI-20 before undergoing POP repair surgery and 7 to 10 years after surgery. Overall subjective patient improvement was measured through changes in PFDI-20 summary and subsection scores. The collected data was summarized with mean and standard deviation (SD). A paired *t* test was

performed to compare pre- and post-operative survey results. Statistical significance was defined as $p \leq 0.05$. Some subjects failed to complete every survey question, and this analysis assumed that missing data were missing at random. Subjects who completed both the pre- and post-operative PFDI-20 were included in the summary score analysis. Subjects who failed to answer one or more question on a PFDI-20 subsection were excluded from that specific subsection analysis. Rates of retreatment, recurrence of symptoms, and changes in survey scores by subject age and BMI were determined.

Results

Between September 2009 and December 2013, 242 patients underwent total vaginal hysterectomy in conjunction with native tissue repair. Of these patients, 8 were deceased or unable to respond due to health reasons, 16 had medical records that could not be located, and 14 declined participation. Two hundred four surveys were distributed and 112 were returned, yielding a response rate of 54.9%. Subject demographics are presented in Table 1. The mean (SD) age for participants was 67.7 (10.3) years with a range of 38 to 91. All subjects self-identified as White Caucasian. The mean (SD) BMI for all participants was 28.7 (6.2) kg/m² with a range of 17.8 to 49.8. The largest proportion of subjects were in the age range of 70 to 79 years and were considered overweight (25 to 29.9 kg/m²) by BMI measurement.

One hundred five subjects responded to the portion of the survey assessing retreatment and prolapse symptom recurrence rates (Table 2). 1.9% of participants reported requiring retreatment in the form of a pessary. No subjects required additional POP repair surgery. Prolapse symptom

Table 1. Demographics.

	n = 112
Age, mean (SD)	67.7 (10.3)
Age, n (% total)	
<50	5 (4.5%)
50-59	18 (16.1%)
60-69	33 (29.5%)
70-79	45 (40.2%)
>80	11 (9.8%)
Ethnicity	
White	112 (100%)
BMI, mean (SD), kg/m ²	28.7 (6.2)
BMI, n, kg/m ² (% total)	
Underweight <18.5	1 (0.9%)
Normal 18.5-24.9	33 (29.5%)
Overweight 25-29.9	38 (33.9%)
Obese 30-34.9	27 (24.1%)
Severely obese ≥ 35	13 (11.6%)
Parity, median (range)	3 (0-11)
Years since surgery, mean (range)	7.4 (6.6-10.8)

Table 2. Rates of retreatment and prolapse recurrence.

	Retreatment required	Prolapse symptom recurrence
Overall, (%), n=105	2 (1.90%)	9 (8.57%)
Age, years, n, (%)		
<50 (n=4)	0 (0%)	1 (25%)
50-59 (n=18)	0 (0%)	0 (0%)
60-69 (n=29)	1 (3.45%)	4 (13.79%)
70-79 (43)	1 (2.32%)	4 (9.30%)
>80 (n=11)	0 (0%)	0 (0%)
BMI, kg/m ² , n		
Underweight <18.5 (n=1)	0 (0%)	0 (0%)
Normal 18.5-24.9 (n=30)	1 (3.33%)	0 (0%)
Overweight 25-29.9 (n=37)	0 (0%)	6 (16.22%)
Obese 30-34.9 (n=24)	1 (4.17%)	2 (8.33%)
Severely obese > 35 (n=13)	0 (0%)	1 (7.69%)

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HEALTH INSIGHTS SUITE OF TOOLS

POP ANALYZER: The Health Catalyst Pop Analyzer application is a visually-oriented application that allows SDHL to define populations quickly for members, without using sophisticated or customized SQL coding. Through rapid ad-hoc analysis capabilities, Pop Analyzer enables organizations to reduce analyst workload and increase analytics productivity. Analysts can leverage Pop Analyzer's reusable elements such as value sets and populations to improve data governance and consistency.

POP INSIGHTS: The Health Catalyst Pop Insights application is a self-service visualization and reporting tool that empowers users to discover and share data-driven insights without the help of advanced analysts or data scientists. No coding is needed to create and customize mobile-friendly dashboards from a semantic layer that maps data to common healthcare terms.

USE CASES

READMISSIONS: Customized dashboard to understand the all-cause 30-day readmissions for the data submitted to SDHL. Health Insight tools look at the index admissions and readmissions, calculates the readmission rate and trends it in a Statistical Process Control chart by breaking down the data by various dimensions (*age, gender, Medicare Severity Diagnosis Related Groups, days between admits, facilities, etc.*) to allow slicing and filtering of the data.

CHRONIC CONDITIONS: Customized dashboard to better understand the patient population that suffers from multiple chronic conditions. Health Insight tools calculate the prevalence rate of the chronic conditions, provides high level metrics, and breaks down the data by various dimensions (*age, gender, common combined conditions, etc.*) to allow slicing and filtering of the data.

Utilization: Customized dashboard shows insight into the utilization of emergency department (ED) and inpatient (IP) stays for the population in SDHL. Health Insight tools trend the ED and IP encounters over time and shows insight into frequent (heavy) utilizers. Allows members to better understand the patients that consistently utilize services, by breaking down the data by various dimensions (*age, gender, facilities, common diagnosis, and procedures, etc.*) to allow slicing and filtering of the data.

recurrence was reported by 8.57% of subjects. Subjects were asked to rate their vaginal bulge symptoms on a Likert scale from 0 to 4 before and after POP repair surgery, with a higher score indicating worse bulge symptoms. Subject vaginal bulge symptoms improved by -2.52 points ($p<0.001$) on average (Table 3) for the 89 subjects who responded to this question.

Of the 112 subjects that returned the post-surgery survey, 96 had also completed the PFDI-20 pre-surgery survey and were included in the data analysis (Table 4). Seventy-seven point one percent of subjects reported a score improvement after surgery, with an average improvement of -46.21 points ($p<0.001$). Of 74 subjects, 82.7% reported improved prolapse symptom scores with an average score change of -24.72 points ($p<0.001$). Of 67 subjects, 53.73% reported improvement in colorectal-anal symptoms with an average score change of -7.16 points ($p<0.001$). Of 70 subjects, 64.29% reported improvement in urinary symptoms with an average score change of -14.33 points ($p<0.001$).

Discussion

Our study determined that patients who underwent total vaginal hysterectomy in conjunction with native tissue repair had low retreatment rates and prolapse symptom recurrence 7 to 10 years after surgery. Subjects showed a significant decrease ($p<0.001$) in perceived impact of pelvic floor dysfunction on their quality of life. Subjective surgical cure rates were measured by the absence of retreatment and vaginal bulge symptoms and improved scores on standardized surveys assessing POP symptoms. In this study, 77.1% and 82.7% of subjects showed improvement in PFDI-20 and POPDI-6 scores. Karjalainen et al. determined that clinically

meaningful improvement requires a score reduction of 24 points on the PFDI-20 and 11 points on the POPDI-6.¹⁶ Based on these standards, 63.5% and 66.2% of our study's subjects had clinically meaningful improvement in PFDI-20 and POPDI-6 scores; however, 91.4% of subjects denied prolapse symptom recurrence and 98.1% denied requiring retreatment. Using anatomic criteria as an outcome measure, a systematic review determined that 36% of patients experience POP recurrence following repair surgery.¹⁷ Few studies have a follow-up period beyond 5 years. A study with a 10 to 12 year follow-up period reported a 46% subjective cure rate, defined as patient satisfied with the operation and no symptom recurrence and a 56% objective cure rate, defined as the absence of stage II-IV prolapse.¹⁸ Another study with a 10 year follow-up period reported a 25% recurrence rate, defined as anatomic prolapse recurrence. Eighty-one percent of the women in this study with recurrence described symptoms associated with their prolapse.¹⁹ One cohort study assessed women at 20 years follow-up and determined a reoperation rate of 11.5%.²⁰ Although it is thought that prolapse will worsen over time, it is difficult to predict the progression of asymptomatic prolapse. Longer term follow-up may demonstrate a higher recurrence of prolapse and need for retreatment.

The variation in POP repair surgery outcome reporting may be due to the absence of standardized definitions of success. Some studies define recurrence based on the need for reoperation while other studies utilize anatomic or subjective criteria, leading to a wide range in reported rates of prolapse recurrence. Many studies show that patient satisfaction is unrelated to anatomic measurements alone while other

Table 3. Change in vaginal bulge symptoms.

	Pre-operative prolapse symptoms	Post-operative prolapse symptoms	Change in prolapse symptoms	P-value
Overall, (SD), n=89	2.74(1.29)	0.16(0.59)	-2.52(1.36)	<0.001
Age, years, n				
<50 (n=2)	2.25(1.48)	0.4(0.8)	-1.75(1.48)	0.13
50-59 (n=15)	2.56(1.06)	0.35(1.03)	-2.19(1.18)	<0.001
60-69 (n=23)	2.69(1.29)	0.09(0.38)	-2.57(1.29)	<0.001
70-79 (n=39)	2.97(1.38)	0.13(0.46)	-2.87(1.43)	<0.001
>80 (n=10)	2.56(0.96)	0(0)	-2.11(1.1)	<0.001
BMI, kg/m2, n				
Underweight <18.5 (n=1)	3(0)	2(0)	-1(0)	
Normal 18.5-24.9 (n=21)	2.27(1.18)	0.21(0.77)	-2.03(1.2)	<0.001
Overweight 25-29.9 (n=35)	3.03(1.26)	0.09(0.37)	-2.93(1.28)	<0.001
Obese 30-34.9 (n=20)	2.95(1.43)	0.09(0.42)	-2.94(1.51)	<0.001
Severely obese > 35 (n=12)	2.82(1.03)	0.17(0.55)	-2.27(1.14)	<0.001

Table 4. Change in PFDI-20 summary and subsection scores.

	Pre-operative PFDI-20	Post-operative PFDI-20	Change in PFDI- 20	P-value
Overall, (SD), n=96	95.32(52.42)	46.91(43.81)	-46.21(52.52)	0.00
Age, years, n				
<50 (n=3)	98.51(47.58)	32.71(17.6)	-70.65(60.98)	0.14
50-59 (n=15)	82.78(51.37)	53.4(54.55)	-28.77(45.47)	0.03
60-69 (n=27)	97.35(54.11)	44.68(35)	-49.28(55.04)	<0.001
70-79 (n=41)	107.09(49.24)	50.52(47.29)	-51.29(49.58)	<0.001
>80 (n=10)	65.86(46.04)	35.23(38.03)	-37.21(53.4)	0.07
BMI, kg/m², n				
Underweight <18.5 (n=1)	102.08(0)	41.67(0)	-60.42(0)	
Normal 18.5-24.9 (n=29)	85.98(52.95)	46.54(46.41)	-37.98(49.74)	<0.001
Overweight 25-29.9 (n=31)	108.14(50.71)	50.66(48.9)	-50.62(55.19)	<0.001
Obese 30-34.9 (n=23)	97.39(47.95)	46.16(35.35)	-50.4(50.56)	<0.001
Severely obese > 35 (n=12)	80.49(56.24)	38.78(36.35)	-46.9(54.79)	0.02
	Pre-operative POPDI-6	Post-operative POPDI-6	Change in POPDI-6	
Overall, (SD), n=74	34.71(20.69)	9.76(13.04)	-24.72(21.72)	0.00
Age, years, n				
<50 (n=2)	36.46(22.12)	5(4.08)	-32.29(23.08)	0.09
50-59 (n=13)	29.27(13.49)	10.05(11.53)	-19.64(13.71)	<0.001
60-69 (n=19)	34.63(19.49)	9.32(11.94)	-24.31(21.63)	<0.001
70-79 (n=31)	38.78(20.47)	11.22(15.58)	-27.21(21.47)	<0.001
>80 (n=9)	28.33(28.67)	6.82(7.38)	-22.08(29.29)	0.05
BMI, kg/m², n				
Underweight <18.5 (n=1)	54.17(0)	8.33(0)	-45.83(0)	
Normal 18.5-24.9 (n=21)	28.31(16.8)	8.69(9.61)	-19.58(18.21)	<0.001
Overweight 25-29.9 (n=25)	40.87(19.36)	12.39(17.51)	-26.42(22.6)	<0.001
Obese 30-34.9 (n=19)	34.54(19.78)	8.04(10.78)	-28.5(19.78)	<0.001
Severely obese > 35 (n=8)	32.99(28.18)	8.33(7.67)	-25(27.53)	0.01
	Pre-operative CRAD-8	Post-operative CRAD-8	Change in CRAD-8	
Overall, (SD), n=67	24.22(20.67)	15.64(17.98)	-7.16(20.16)	<0.001
Age, years, n				
<50 (n=2)	12.05(9.66)	14.38(10)	4.35(12.71)	0.59
50-59 (n=11)	17.07(19.44)	16.1(19.56)	-0.36(13.62)	0.92
60-69 (n=22)	26.52(20.37)	15.29(13.64)	-10.31(20.22)	0.01
70-79 (n=25)	28.12(22.42)	16.63(20.47)	-7.94(22.62)	0.05
>80 (n=7)	19.78(13.2)	12.5(18.37)	-10.71(17.36)	0.10
BMI, kg/m², n				
Underweight <18.5 (n=1)	6.25(0)	25(0)	18.75(0)	
Normal 18.5-24.9 (n=16)	19.91(19.45)	15.1(16.9)	-3.72(14.8)	0.19
Overweight 25-29.9 (n=24)	29.48(19.69)	15.97(17.33)	-11.59(20.7)	<0.001
Obese 30-34.9 (n=18)	23.27(23.6)	16.09(20.49)	-3.44(23.97)	0.54
Severely obese > 35 (n=8)	24.03(18.09)	14.42(17.53)	-12.31(19.53)	0.06
	Pre-operative UDI-6	Post-operative UDI-6	Change in UDI- 6	
Overall, (SD), n=70	36.39(25.38)	21.51(21.89)	-14.33(26.07)	<0.001
Age, years, n				
<50 (n=1)	50(34.74)	13.33(12.75)	-42.71(39.02)	0.15
50-59 (n=11)	36.43(26.59)	27.25(26.97)	-8.78(28.33)	0.25
60-69 (n=20)	36.21(28.22)	20.08(21.13)	-14.66(26.99)	0.01
70-79 (n=29)	40.19(20.58)	22.67(21.48)	-16.13(21.94)	0.00
>80 (n=9)	17.75(14.05)	15.91(16.93)	-4.42(15.41)	0.41
BMI, kg/m², n				
Underweight <18.5 (n=1)	41.67(0)	8.33(0)	-33.33(0)	
Normal 18.5-24.9 (n=24)	37.76(29.97)	22.75(24.46)	-14.68(32.22)	0.02
Overweight 25-29.9 (n=20)	37.79(24.32)	22.3(22.17)	-12.6(24.66)	0.01
Obese 30-34.9 (n=18)	39.58(19.96)	22.02(20.03)	-18.46(21.03)	<0.001
Severely obese > 35 (n=7)	23.47(20.39)	16.03(16.89)	-9.58(18.38)	0.11

studies report that symptoms are weakly correlated with objective measures of prolapse.² The incidence of surgical retreatment may not be a reliable indication of the true incidence of prolapse recurrence due to the variation in thresholds for surgical intervention. The presence of a palpable or observable vaginal bulge is consistently reported by patients with POP.^{10,21} Surgical outcomes that utilize definitions of success based on the absence of vaginal bulge symptoms have the strongest relationship with overall patient satisfaction.²¹ The majority of asymptomatic women in the population have some degree of weakened vaginal or uterine support and do not meet the criteria of optimal anatomic measures. Thus, current composite definitions of success that require both objective and subjective criteria may result in overestimation of surgical failure rates despite low retreatment rates.¹⁰ Definitions of surgical outcomes that do not account for patient symptoms may not be as accurate or clinically relevant.^{2,11,21} Methods that assess patient symptoms and quality of life are necessary to accurately assess surgical outcomes.

Age younger than 60 and obesity are risk factors for prolapse recurrence after surgery.^{1,5} A study with a 20-year follow-up found that women ages 18 to 49 at the time of primary surgery had a reoperation rate of 26.9% and women over age 50 had a reoperation rate of 10.1%.²⁰ In our study, subjects ages 60 to 79 years had the highest rate of retreatment and symptom recurrence. The rate of subjects under the age of 60 who developed prolapse recurrence was lower than that found in other studies. Subjects ages 60 to 79 years had the greatest significant improvement in PFDI-20 scores. Studies have shown that pelvic floor surgery in older women is safe and effective, and age should not be the only determining factor when deciding if a patient is a suitable surgical candidate.²² In our study, all patients reporting prolapse symptom recurrence were in the overweight, obese, or severely obese BMI categories. Subjects considered overweight or obese had greater score improvements in the PFDI-20 and POPDI-6 than patients in the normal BMI category.

All subjects in this study underwent POP repair using native tissue without the use of synthetic mesh placed vaginally or abdominally to correct prolapse in any compartment. A systematic review of randomized control trials, FDA publications, and gynecology society statements related to the safety and efficacy of transvaginal mesh for prolapse determined that more long-term studies are needed to provide information on the risks and benefits of mesh use.⁸ In a Cochrane review of 56 randomized control studies,

the use of mesh was shown to reduce the risk of anterior wall prolapse but evidence did not support the use of grafts for posterior vaginal repair.²³ Other systematic reviews determined that the use of graft material was not superior to native tissue repair.^{24,25} Success rates appear similar, and mesh did not reduce long-term reoperation rates. Outcomes including improved patient satisfaction, quality of life, and reduced risk of subsequent operations have not been demonstrated with mesh use.²³ At this time, the evidence does not support the use of transvaginal multicompartiment repair with mesh, and there is no consensus on the efficacy of its use in prolapse repair surgery to date.^{8,23} It remains unclear if there are subgroups that may benefit from the use of graft material or subgroups that may be at higher risk of adverse graft-associated outcomes.²⁴ Our study did not control for whether a mesh suburethral sling was utilized or not as it is utilized to treat urinary incontinence and not prolapse.

POP relapses often occur several years after initial surgical repair; thus, long-term follow-up is required to accurately assess surgical outcomes and reoperation rates. This study's long-term follow-up period accounts for complications and prolapse recurrence that may not have occurred during a shorter follow-up period. In this study, all procedures were performed by one fellowship-trained surgeon at a single institution, limiting confounding variables due to variation in surgical technique; however, this limits the generalizability of findings to other surgeons and regions. Our study focused on women undergoing a hysterectomy and this limited our method of apical suspension to uterosacral ligament fixation. We were also unable to account for subjects lost to follow-up. This study is not representative of all women due to all survey respondents identifying as white/Caucasian; however, results could likely be extrapolated to other ethnicities. It is also possible that there may be bias in patients who were dissatisfied with surgical outcomes declining to participate in the study. Additionally, this study did not collect anatomic measurements for comparison with subjective survey responses.

We conclude that native tissue repair for POP performed by a single surgeon at a tertiary pelvic floor center produces low recurrence and retreatment rates as well as clinically meaningful improvement in symptom control and quality of life. Based on these findings, high surgical success rates can be achieved using native tissue repair. Additionally, long-term follow-up is required to determine accurate POP recurrence. Surgeons performing POP repair should document long-term surgical outcomes to better counsel patients on expectations,

risks, and benefits of surgery. Future research considerations include the need for studies that compare anatomic outcomes to subjective symptoms as well as studies assessing long-term prolapse repair outcomes. Recommendations on defining

surgical success and failure should also be updated based on current literature that supports subjective patient symptoms and quality of life measures.

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COVID-19 Vaccine Hesitancy in Rural Midwestern Infertility Patients: A Cross-Sectional Survey

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Abstract

Background: Pregnant patients with COVID-19 experience higher rates of maternal mortality, pregnancy loss, and other severe comorbidities. Despite these well-characterized risks, this group displayed a high level of vaccine hesitancy that contributed to their slow acceptance of the COVID-19 vaccinations and greater maternal mortality during the pandemic. The rural Midwest was no exception to this unfortunate trend, so here we sought to determine attitudes, beliefs, and perceptions in these women and their partners associated with vaccine hesitancy to better address uncertainties and improve vaccination rates.

Methods: We used a cross-sectional survey of rural Midwestern infertility patients. Study population included both women and men, ranging from 21 to 53 years old. We evaluated vaccination status, hesitancy or refusal for COVID-19 vaccination, sociodemographic factors, sources and types of medical information, employer vaccination requirements, and specific attitudes, beliefs, and perceptions towards vaccines using questions guided by the Health Belief Model.

Results: We surveyed 390 Midwestern patients with pre-existing clinic appointments who were being evaluated for infertility and/or trying to conceive. Vaccine-hesitant patients held significant concerns of rushed vaccine development, safety, and benefits not outweighing potential risks. Patients were significantly more likely to obtain the vaccine if it was recommended by their physician. They were also more likely to receive the vaccine if they were given written resources or if required by their employer.

Conclusions: Survey results identified specific concerns and strategies that may be used to address vaccine hesitancy in this at-risk population. Addressing vaccine hesitancy may improve vaccination rates and in turn reduce maternal mortality and morbidity, particularly in rural populations.

Introduction

Pregnant patients with COVID-19 are at increased risk of severe complications including miscarriage/stillbirth, hospitalization, and maternal mortality.¹⁻¹⁰ Despite mounting evidence supporting safety and efficacy of COVID-19 vaccinations during pregnancy and post-partum,¹¹⁻²³ as well as recommendations from the Centers for Disease Control and Prevention and American College of Obstetricians and Gynecologists that all pregnant and breastfeeding women be vaccinated,^{24,25} uptake has been slower among pregnant patients than for the general adult population. Although pregnant women are now vaccinated and boosted at a higher rate than the general U.S. public, when the SARS-CoV-2 Delta variant—the most severe strain for pregnant women⁵—was declared a “variant of concern” by the World Health Organization in May 2021 the vaccination rate of pregnant

women was 28.7%, behind the general adult population’s rate of 38.8%.²⁶⁻²⁸

The first step to addressing barriers to vaccination in people who are pregnant or trying to conceive is understanding the attitudes, beliefs, and perceptions associated with their vaccine hesitancy. This study intended to help fill this knowledge gap using questions on patient sociodemographic factors, sources and types of information, trust in medical providers, and specific feelings and concerns regarding COVID-19 infections and vaccines guided by the Health Belief Model (HBM).²⁹ The HBM was developed by the United States Public Health Service in the 1950s and provides a framework for identifying beliefs that dictate whether patients adopt health-related behaviors,^{30,31} in this case vaccinating against COVID-19. Questions were designed to address perceived



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susceptibility, perceived severity, perceived barriers, and perceived benefits of COVID-19 infections and vaccination.

Several studies since the start of the COVID-19 pandemic have evaluated factors associated with vaccine hesitancy in female patients trying to conceive, currently pregnant, or lactating.³²⁻³⁷ However, these studies did not evaluate the rural United States or women's partners. To fill this knowledge gap, we focused on a Midwestern population of infertility patients and their partners. We aimed to identify factors associated with vaccine hesitancy that may be emphasized to increase vaccination rates in this at-risk population, and we hypothesized that these patients would have concerns of vaccines being unsafe or affecting fertility.

Materials and Methods

This cross-sectional study surveyed patients of a single Midwestern reproductive endocrinology clinic who were being evaluated and treated for infertility from February 2022 to May 2022. Participants were at least 18 years old, had preexisting appointments (for consecutive sampling), and were trying to conceive or planning to conceive in the future. This study was developed with input and review by the Sanford Research Design and Biostatistics Core to ensure sound survey design and accurate statistical analysis and reporting of results. Full protocol was reviewed and approved by the Sanford Health Institutional Review Board. This manuscript was written following STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.³⁸ Full 20-question survey is available as Supplemental Figure 1 at sdsma.org.

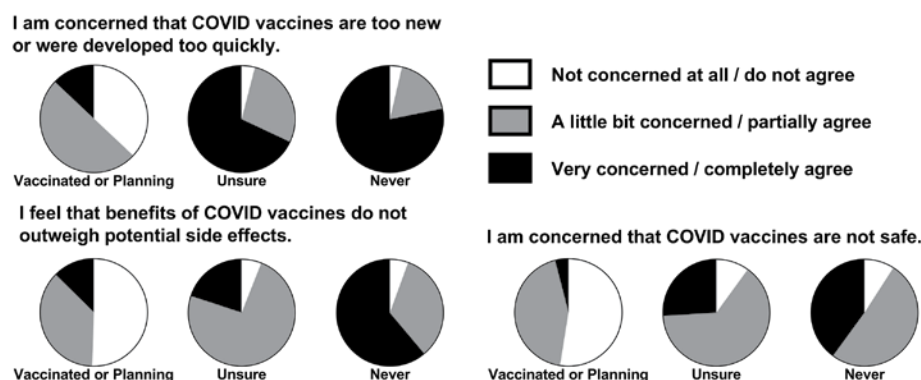
Power analysis was conducted by the methods of Price et al. 2005.³⁹ A total of 390 participants were compared by vaccination status: 1) vaccinated/planning to get vaccinated (N=284), 2) unsure about receiving COVID-19 vaccine (N=51), and 3) planning to never receive (N=55). In the first group, 274 of 284 participants were already vaccinated and the remaining 10 were planning to receive COVID-19 vaccination, almost all before conceiving.

Data were analyzed using Prism v9.4.1 (GraphPad Software, San Diego, CA). Normality was assessed by Shapiro-Wilk and Kolmogorov-Smirnov tests. Odds ratios with 95% confidence intervals were calculated for "vaccine-accepting" (group 1) vs "vaccine-hesitant" participants (combined groups 2 and 3). Multi-way variables were compared using multiple logistical regression to identify significant variables which were interrogated by chi-squared (χ^2) analyses. HBM questions/variables were confirmed by Fischer's exact test as some responses were selected by fewer than 10 participants in at least one group. Full data used to generate Tables 2 and 3 are shown in Supplemental Tables 1-22 at sdsma.org. Statistical significance was defined as $P < 0.05$ in all cases.

Results

Participant sociodemographic characteristics are shown in Table 1. Overall vaccine acceptance rate, i.e. participants vaccinated or planning to receive COVID-19 vaccine, was 72.8%; the rate in females was 77.8% (176/226) and in males was 65.6% (107/163). Mean age was 32 years, and participants ranged from 21 to 53 years old. 58% of participants were female, and nearly all (94.8%) were racially

Figure 1. COVID-19 vaccine hesitancy is associated most strongly with concerns for rushed vaccine development, potential side effects, and safety.



Graphs represent percentages of participant responses by group. Responses to each question differed significantly by group ($P < 0.0001$) by χ^2 analysis and Fischer's exact test. Nvaccinated/planning=100-101 participants; Nunsure=50; Nnever=54-55.



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white/ethnically non-Hispanic. Annual household income was similar across participants with approximately 75% of participants' household incomes falling in the inner quartiles, i.e., \$48,500 – \$145,500 per year. Eighty-eight percent of study participants had some college experience or a college-level degree (Table 1). Of the 387 participants who answered this question on pregnancy status, 367 participants were trying to conceive and 20 were not trying to conceive but considering it in the future. Significant relationships existed between vaccination status and gender and education level (Table 2).

Odds ratios were used to compare vaccine-accepting to vaccine-hesitant participants (Table 2). Vaccine-accepting participants were more likely to be female and more educated, but no significant associations were found with age, household income, first appointment with this provider, or whether the patient was trying to conceive or considering pregnancy. Vaccine-hesitant participants were more likely to have been offered the COVID vaccine by another provider and less likely to have received other vaccines. Unsurprisingly, vaccine hesitancy was associated with perceived religious/spiritual conflicts and having

received material from providers *against* COVID vaccination. Participants were more likely to be vaccine-accepting if healthcare providers were a main source of information, if they had been provided written materials by their providers, and if their employer had a vaccination requirement. Of note, the odds ratio of vaccine-accepting participants being more likely to receive COVID vaccination if recommended by their provider, compared to vaccine-hesitant participants, was nearly 16 (Table 2). For those who were vaccine-hesitant and never planning to receive the vaccine, none of them were more likely to receive the vaccine if recommended by their provider. However, a subset (14 “unsure” of 93 total vaccine-hesitant participants) answered “yes,” indicating they would be more likely to vaccinate if their provider recommended it. Of the 390 total participants, there were 163 couples. Of those, 21.5% minorly disagreed, i.e. both were vaccine-hesitant but one partner was unsure about getting vaccinated and the other was never going to vaccinate. Of those 163 couples, 12.9% of them majorly disagreed, i.e. one partner was vaccine-accepting and the other was vaccine-hesitant.

Survey questions guided by the HBM were used to identify attitudes, beliefs, and perceptions associated with vaccine

Table 1. Participant sociodemographic characteristics.

Characteristic	All participants	Already received or planning to receive COVID-19 vaccine	Unsure about COVID-19 vaccination	Never receiving COVID-19 vaccination
Vaccine acceptance, N (%)	284/390 (73)			
Age, years $\pm$ STDEV	32.1 $\pm$ 5.4	31.9 $\pm$ 5.0	31.6 $\pm$ 6.5	33.5 $\pm$ 6.2
¹ Gender, N (%)				
Female	226 (58)	176 (62)	27 (53)	23 (42)
Male	163 (42)	107 (38)	24 (47)	32 (58)
Race/ethnicity, N (%) white	364 (95)	260 (94)	50 (98)	54 (98)
² Annual household income, N (%)				
<\$48,500	23 (7)	13 (5)	5 (11)	5 (11)
\$48,500 – 97,000	135 (39)	95 (38)	20 (44)	20 (44)
\$97,000 – 145,500	132 (39)	103 (41)	15 (33)	14 (30)
>\$145,500	53 (15)	40 (16)	6 (13)	7 (15)
² Education level, N (%)				
Less than HS	7 (2)	4 (2)	1 (2)	2 (4)
HS diploma/GED	33 (10)	18 (7)	11 (25)	4 (8)
Some college	51 (15)	37 (15)	6 (14)	8 (17)
College degree	178 (53)	131 (54)	18 (41)	29 (60)
Graduate degree	68 (20)	55 (22)	8 (18)	5 (10)

¹one participant identified as non-binary and was excluded in this row; all other participants identified as cis-gendered male or female. ²sum of responses unequal to 390 due to participants skipping the question. STDEV, standard deviation; HS, high school; GED, general educational development test.



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Table 2. Factors associated with COVID-19 vaccine acceptance or hesitancy.

Characteristic/question	Vaccine-accepting vs vaccine-hesitant participants, OR (95% CI)	P value
*Gender: female vs male	1.84 (1.18 - 2.91)	0.008
Age: younger (≤ 32 years old) vs older (> 32)	0.78 (0.50 - 1.22)	0.271
Household income: less than vs greater than median (\$97,000/year)	1.11 (0.68 - 1.80)	0.664
*Education: No college degree vs college/grad degree	0.60 (0.36 - 0.99)	0.049
First appointment with this provider: yes or no	0.93 (0.58 - 1.45)	0.749
Considering pregnancy vs trying to conceive	1.14 (0.43 - 2.91)	0.806
*If provider seen, were you offered a COVID vaccine: yes or no	0.40 (0.21 - 0.78)	0.006
*Have you received other vaccines: yes or no	2.85 (1.58 - 5.15)	<0.001
Fear of vaccination affecting fertility, conception, or causing pregnancy complications or loss: yes or no	2.06 (0.93 - 4.37)	0.072
*Perceived religious/spiritual reasons against vaccination: yes or no	0.19 (0.06 - 0.63)	0.007
*Providers as a main source of information: yes or no	2.22 (1.15 - 4.32)	0.016
*Written materials provided by providers: yes or no	1.99 (1.26 - 3.13)	0.003
*Received materials from providers against COVID vaccination: yes or no	0.14 (0.05 - 0.41) Reciprocal: 7.20 (2.47 - 20.9)	<0.001
*If not vaccinated and your provider recommended it, would you be more likely to receive it: yes or no	15.97 (7.16 - 33.91) Reciprocal: 0.06 (0.03 - 0.14)	<0.0001
*Employer vaccination requirement: yes or no	4.59 (2.37 - 8.86)	<0.0001

Vaccine-accepting group composed of participants who had already received or were planning to receive COVID-19 vaccine; vaccine-hesitant group composed of patients unsure of receiving or planning to never receive COVID-19 vaccine. Statistically significant variables ($P < 0.050$) are indicated by asterisk (*) and bolded. OR, odds ratio; CI, confidence interval.

Table 3. Assessment of vaccine hesitancy using the Health Belief Model.

Question	HBM parameter	χ^2 statistic	P-value (χ^2)	P-value (Fischer's exact test)
I am concerned that pregnant women are at increased risk of severe COVID-19 infections.	Perceived susceptibility	6.6	0.157	0.173
I am concerned that COVID-19 infections during pregnancy increase risk of preterm birth, miscarriages, and stillbirths.	Perceived severity	8.5	0.076	0.065
* ^a I am concerned that COVID vaccines are too new or were developed too quickly.	Perceived barriers	82.5	5.26E-17	7.60E-19
* ^a I am concerned that COVID vaccines are not safe.	Perceived barriers	59.4	3.97E-12	4.00E-13
*I am concerned that COVID vaccinations will affect my fertility or increase my chances of miscarriage or stillbirth.	Perceived barriers	24.7	5.80E-5	3.20E-5
* ^a I feel that benefits of COVID vaccines do not outweigh potential side effects.	Perceived benefits	79.7	2.06E-16	3.40E-16
*I believe that vaccines are not effective in preventing the spread or severe symptoms of COVID.	Perceived benefits	55.4	2.65E-11	6.00E-11

Question responses ranged from: 'Not concerned at all'/'do not agree,' to 'a little bit concerned'/'partially agree,' to 'very concerned'/'completely agree.' $N=99$ -205 responses/question. Degrees of freedom=4. Fischer's exact test was used to confirm statistical significance as some categories had less than 10 responses by ≥ 1 group. Statistically significant variables ($P < 0.050$) are indicated by asterisk (*) and bolded. ^agraphic representation shown in Figure 1. HBM, Health Belief Model.



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hesitancy. The strongest associations with vaccine hesitancy were concerns of COVID vaccines being too new or developed too quickly ($\chi^2=82.5$, d.f.=4, $P=5.26E-17$), feeling that the benefits of COVID vaccination do not outweigh potential side effects ($\chi^2=79.7$, d.f.=4, $P=3.40E-16$), and concerns that COVID vaccines are not safe ($\chi^2=59.4$, d.f.=4, $P=4.00E-13$) (Table 3). Graphical representations of these strongest associations are shown in Figure 1. Of note, 13% vaccine-accepting participants were concerned that COVID vaccines are too new or were developed too quickly, but this number profoundly increased to 68% of participants unsure of vaccinations and 78% of those planning to never vaccinate. When participants were asked if the benefits of vaccination do not outweigh potential risks, 13% of vaccine-accepting patients completely agreed, but this number was 20% in patients of unsure of vaccinations and 61% in patients planning to never vaccinate. Similarly, only 4% of vaccine-accepting patients were very concerned that COVID vaccines are not safe, but this response was 28% of unsure participants and 40% of patients planning to never vaccinate (Figure 1).

Discussion

The purpose of this study was to determine attitudes, beliefs, and perceptions in the rural Midwest associated with vaccine hesitancy to better address patient uncertainties and ultimately improve vaccination rates in patients trying to conceive. Considering the maternal and fetal risks of COVID-19 infection during pregnancy,¹⁻¹⁰ it is paramount that factors associated with vaccine hesitancy be delineated and better addressed. The vaccine acceptance rate, i.e. participants already vaccinated or planning to receive the COVID-19 vaccine, of our study population was 72.8% (284 of 390 participants); this fell just below the 74% of our state's population who had received at least one dose in the same time period.⁴⁰ Although the level needed for herd immunity would have been lower with earlier variants, it has been estimated that immunization levels for current variants need to reach at least 90% of the population.^{41,42} That said, knowing the underlying causes of vaccine hesitancy allows clinicians to better address patient concerns, ideally reducing hesitancy and optimizing responses to future outbreaks or pandemics.

Since the start of the COVID-19 pandemic in March 2020, several surveys or questionnaires have investigated vaccine hesitancy in women who were pregnant, lactating, or trying to conceive.³²⁻³⁷ At the time of this survey, these studies had collected data from August 2020³³ to April 2021³⁶ and

demonstrated slowly rising vaccine acceptance rates in the United States. In a survey spanning Utah, Alabama, and New York from August to December 2020, Battarbee et al. found a 41% vaccine acceptance rate in pregnant women less than 28 weeks gestation,³³ and in California from December 2020 to January 2021, Simmons et al. found a 43% vaccine acceptance rate.³⁷ In Michigan in February 2021, Townsel et al. reported vaccine acceptance rates of 66% and 73% in female medical center employees who were pregnant or trying to conceive, respectively.³⁵ In contrast, our survey was in the rural Midwest from February to May 2022, at a point with extensive data demonstrating vaccine safety and efficacy for women and their offspring.¹²⁻²⁰ In our study, 77.8% of the females were vaccine-accepting, which hopefully indicates a societal trend towards increasing confidence in vaccination, at least in this at-risk population and their future offspring.

Our study echoed the concerns observed by several others. Tao et al. surveyed approximately 1400 pregnant women in China and found that hesitancy was associated with low concern for contracting SARS-CoV-2 infection, low recognition of maternal and fetal benefits, and high concern for vaccine side effects.³² Similarly, Battarbee et al. reported the most frequent concern in vaccine-hesitant adult women was potential effects of the vaccine on their pregnancy,³³ and Townsel et al. reported the most common concerns of pregnant participants were "safety and effectiveness" followed by "speed and development".³⁵ We found the factors most strongly associated with vaccine hesitancy to be perceived barriers and perceived benefits (or lack thereof). Specifically, vaccine-hesitant participants believed that COVID vaccines were too new or too quickly developed, the benefits do not outweigh potential risks, and they are not safe.

With these perceived barriers in mind, several strategies may be employed to address patients' concerns and increase vaccine acceptance. We found that patients need reassurance of the safety of COVID vaccinations and the now-extensive information available.¹¹⁻²³ Our findings suggest sharing this information in written format has a greater effect than spoken word. Many national organizations have printed materials available for patient distribution or electronic access that may be useful,^{43,44} including a recent, extensive review by Nunes and Madhi.⁴⁵ Interestingly, vaccine-hesitant participants were more likely to have been offered vaccines in the past, and when asked if they would be more likely to get vaccinated per a provider's recommendation, the odds ratio of vaccine-hesitant participants compared to vaccine-accepting participants was 0.06 (95% CI 0.03 - 0.14). Further, all 49



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participants planning to never receive a COVID vaccine who answered this question responded “no”, i.e. the only “yes” answers to this question in the vaccine-hesitant group were from the ‘unsure’ subgroup. Individuals in couples may not agree; indeed, we found that over 10% of couples disagreed on whether to receive a COVID vaccination. Even if one partner is vaccine-hesitant, their partner may not be, and ensuring vaccination of one protects them both. Collectively, our findings suggest that repeatedly offering vaccines may not make the difference, but providers may have more success reaching patients by the format and quality of information they provide.

Strengths

Strengths of this study include surveying both men and women in a rural, understudied region of the U.S. We recorded participants who were in couples, which demonstrated different stances on vaccination within partnerships. Although our study did not provide enough disagreeing couples to interrogate intra-couple differences adequately statistically by vaccination status, this should be addressed in future studies. The ability to stratify participants by level of vaccine hesitancy (‘unsure about receiving vaccine’ or ‘never planning to receive’) provided important conclusions on counseling these patients. To our knowledge, our survey is the most recently conducted cross-sectional study on concerns of COVID-19 infections and vaccines, but this study only allowed evaluation at one point in time. It would be of great interest to survey the same participants across the pandemic to determine changes in attitude over time.

Limitations

Our study had several limitations. We did not ask patients about vaccine formulations or booster doses; boosters were recommended at the time of this study and may have affected participant views. Although male and female genders were well-represented, our population was not racially/ethnically diverse which may have limited generalizability to minority populations. While investigators intended to limit sampling bias through assessing sociodemographic factors and consecutive sampling, there exists higher potential for response bias. Patients with stronger views may have participated to a greater extent than more disinterested patients. On the contrary, our vaccination rate (72.8%) may have been higher than the general population if the patients who agreed to fill out the survey were disproportionately vaccine-accepting and not reflecting a true regional or societal trend.

Conclusions

We believe most women who refuse the COVID-19 vaccination while trying to conceive are doing so because they believe they are doing the best thing for the outcome of their pregnancy. However, vaccine hesitancy leads to decreased vaccination rates, increased disease prevalence, and more severe infections with higher maternal mortality. To reduce vaccination hesitancy, we must understand patients’ concerns, build trust, and effectively counsel patients. The participants of this study were most concerned with vaccine development speed and safety; while the former is more challenging to address, there are now extensive data showing broad safety, specifically in pregnant patients and those trying to conceive, as well as benefits for the newborn infants. Interestingly, patients in this study were significantly more likely to receive the vaccine if it was recommended by their physician. In addition, they were more likely to be vaccinated if they received written information or the vaccine was mandated by their employer. In a recent commentary by Shook et al.,⁴⁶ the authors recommended adding a fourth “C,” “compassion,” to the “3 Cs” of factors affecting hesitancy (confidence, complacency, and convenience).⁴⁷ Based on the findings of our study, we believe vaccination rates in people who are trying to conceive may be improved through this compassionate approach with specific attention to the perceived barriers.

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A Persistent Umbilical Cord Anomaly

Laurie Richards, MD

A term newborn was noted to have an umbilical cord anomaly at birth. The pregnancy was uncomplicated. At delivery, the physician noted an abnormality of the cord and clamped distal to the defect. The umbilical cord was of normal caliber with a small segment of moist, pink tissue protruding laterally through the cord (Figure 1). There was no orifice and no drainage noted. Abdominal x-ray demonstrated a normal bowel gas pattern. In the NICU, the infant fed without difficulty and had normal urine and stool output. There was no drainage from the lesion. The prolapsed tissue did not dry or involute. Without drainage, the lesion was thought not to be a bowel or bladder fistula. The tissue persisted despite treatment with silver nitrate prompting umbilical exploration at 4 weeks of age. The lesion was found to be a tiny loop of small intestine protruding through a fascial defect (Figure 2). The base of the lesion was transected and the enterotomy closed. Pathology revealed a 1.7 cm x 0.8 cm blind pouch of small intestine with gastric and intestinal mucosa, consistent with a Meckel diverticulum.

Meckel diverticulum is a remnant of the omphalomesenteric duct (OMD), an embryonic structure traversing the umbilical cord, connecting the developing midgut to the yolk sac. The OMD typically involutes by the end of the seventh week gestation followed by return of bowel from the umbilicus to the abdomen by the 12th week gestation.¹ With incomplete obliteration of the OMD, several abnormalities can result. The most common is a Meckel diverticulum (90%), with fistula, sinus tract, polyp, cyst, or fibrous band comprising the rest.¹ Meckel diverticula typically originate from the antimesenteric border of the distal ileum as an intra-abdominal blind ending loop of bowel.¹ In this case, the diverticulum was retained in the base of the umbilical cord. It is speculated the diverticulum adhered to the umbilical cord instead of returning to the abdomen with the rest of the bowel.^{2,3} The adherent tissue resulted in localized rupture of the umbilicus and prolapse through the wall of the umbilical cord.⁴ This case was unusual in that the Meckel diverticulum ruptured through the umbilical cord. Meckel diverticula retained in the cord, but not prolapsed through the wall, have been reported.⁵⁻⁸ OMD remnants in continuity with the umbilical cord surface are typically cysts, sinuses or umbilical-enteric fistulas.⁶

Figure 1. Umbilical cord at 15 minutes of age.



Figure 2. Intraoperative photo of the Meckel diverticulum.



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Cryptorchidism Review for the Primary Care Provider

Brian M. Bishop, MS IV; and Kathryn M. Anderson, MD

Abstract

Cryptorchidism, or undescended testes, is the most common disorder of the genitals seen at birth. Due to its high prevalence and short- and long-term sequelae, it is crucial that primary care providers are familiar with the appropriate management of cryptorchidism. This paper serves to review the embryology, diagnosis, management, and treatment of cryptorchidism with the goal of serving as a valuable reference for providers managing pediatric and neonatal urological issues in the primary care setting, using the American Urological Association's most recent guidelines on the subject. Importantly, it also serves as a review of the long-term consequences of cryptorchidism (even after repair) and reinforces the need for continued surveillance for complications throughout a patient's life.

Introduction

There are many urologic disorders encountered in neonates and pediatric patients. It is important for the primary care provider to know the basics of diagnosis and management for common pediatric urological conditions. One such urological condition is cryptorchidism, or undescended testes (UDT). In fact, congenital cryptorchidism is the most common disorder of the genitals seen at birth, affecting between 1.8-8.4% of full-term male newborns and 15-30% of premature male newborns, and it is one of the most common disorders of the male endocrine glands overall.^{1,2} With this high prevalence, it is crucial that primary care providers are familiar with the appropriate management of cryptorchidism. This paper serves to review the embryology, diagnosis, and management of cryptorchidism with the goal of serving as a valuable reference for providers managing pediatric and neonatal urological issues in the primary care setting. The paper will also briefly summarize the treatment of cryptorchidism.

Cryptorchidism is the failure of the testicle to descend fully into the scrotum in males. It can be either congenital, which is noted at birth, or acquired, where the testicle was located in the scrotum at birth but later traveled to a position outside of the scrotum. Cryptorchidism can cause many long-term sequelae such as diminished fertility or infertility, testicular cancer, inguinal hernias, and testicular torsion. The purpose of diagnosing and treating cryptorchidism is driven mainly by the goal of reducing these risks in the future.³ The standard of care today is orchidopexy, or surgical permanent fixation of the testicle into the scrotum. While the success rate of this procedure is very high, orchidopexy reduces but does not

eliminate the risks of the long-term sequelae listed above.⁴

Embryology

Reviewing the embryology of testicular descent allows for better understanding of the pathophysiology of cryptorchidism. Testicular descent consists of two phases. The first phase, or transabdominal phase, takes place between the 8th and 15th week of gestation and is responsible for the descent of the testes from their original position located medially to the kidneys, down to the internal inguinal ring. This phase does not depend on androgen, but on Leydig insulin-like hormone (INSL3), which is a member of the relaxin family of proteins.² The gubernaculum, or scrotal ligament, is a fibrous structure that anchors the fetal testes to the bottom of the scrotum. INSL3 causes the gubernaculum to shorten and enlarge caudally to eventually form a gubernacular bulb. At the same time, the cranial suspensory ligament (CSL), which anchors the testes to the posterior abdominal wall, regresses, further permitting testicular descent. It is this regression of the CSL and the failure of the gubernaculum to elongate with the rest of the fetal structures during development that provide the traction necessary for the testicles to descend.²

The second phase of testicular descent, or the inguinoscrotal phase, begins by the 26th week of gestation and is androgen-dependent, unlike the earlier transabdominal phase. During this phase, the testicles travel from the internal inguinal ring down into the scrotum. Prior to this testicular descent, the gubernacular bulb extends caudally, herniating the inferior abdominal wall and forming the Processus vaginalis. That herniation then leads to the development of the inguinal canal, which is dilated by the passage of the gubernacular bulb, which precedes the testicles. As the gubernaculum shortens,



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the testicle is brought through the dilated inguinal canal with the help of increasing abdominal pressure. After the testicles have migrated into the scrotum, the gubernaculum regresses, leaving a vestige behind that continues to attach the testicles to the inferior aspect of the scrotum.²

A failure of any of the processes above can cause the failure of the testicles to descend into the scrotum. Although the exact cause of cryptorchidism is not known at this time, a combination of genetic, maternal, and environmental factors is thought to play a role. However, factors that are thought to increase the risk of cryptorchidism include low birth weight, prematurity, family history of UDT, and maternal alcohol use or exposure to cigarette smoke during pregnancy. Exposure to some pesticides has also been proposed as a risk factor as these chemicals can have estrogenic or antiandrogenic effects, potentially affecting the androgen-dependent inguinoscrotal phase of testicular descent, although study results have not shown a clear association.⁵

Guidelines

The following are several of the most up-to-date guidelines issued by the American Urological Association (AUA) regarding cryptorchidism diagnosis (summarized in figure 1, image adapted with permission from AUA publication in 2018) and treatment.¹ The rationale and clinical pearls associated with each section are discussed to enhance the primary care provider's knowledge on this topic. In this paper, some of the guidelines are grouped when related and/or presented in a different order than the AUA publication to improve the understanding of the principles presented. The AUA guidelines were published in 2014 based on a rigorous literature review of papers published from 1980-2013, with the first (and only) revision in 2018. Each guideline is designated as a "standard, recommendation, or option" and assigned a strength rating of A (high), B (moderate) or C (low) based on the evaluation of the evidence. Some of the guidelines are provided as "clinical principles" or "expert opinions" when there was limited evidence.¹

Figure 1. Evaluation of cryptorchidism.

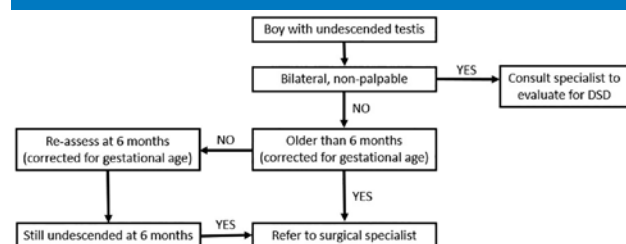


Image adapted and used with permission from AUA publication "Evaluation and Treatment of Cryptorchidism" which was published in 2014, reviewed and validity confirmed in 2018. DSD (disorder of sexual development).

Diagnosis of Cryptorchidism

Providers must immediately consult an appropriate specialist for all phenotypic male newborns with bilateral, nonpalpable testes for evaluation of a possible disorder of sex development (DSD). (Standard; Evidence Strength: Grade A). Providers should assess the possibility of a DSD when there is increasing severity of hypospadias with cryptorchidism. (Recommendation; Evidence Strength: Grade C). In boys with bilateral, nonpalpable testes who do not have CAH, providers should measure Müllerian Inhibiting Substance (MIS or Anti- Müllerian Hormone [AMH]) and consider additional hormone testing to evaluate for anorchia. (Option; Evidence Strength: Grade C). DSDs consist of a group of congenital conditions associated with abnormal development of the newborn's genitalia, both internal and external.⁶ CAH is the most common cause of DSD. CAH has an incidence of 1 in 15,000, and can result in the appearance of male external genitalia (but no testicles) in a child with a 46, XX karyotype.⁷ The AUA states that any newborn infant with a male phallus and bilateral nonpalpable gonads should be treated as potentially a genetic female (46 XX) with CAH until proven otherwise.¹ It is crucial that a diagnosis of CAH is not missed as patients with CAH can be extremely ill (presenting with hypotension, hyponatremia, and hyperkalemia) if not managed appropriately.⁷ As stated in the guideline above, increasing severity of hypospadias in the setting of cryptorchidism should also prompt evaluation for DSD. Furthermore, in patients with bilateral cryptorchidism in whom CAH has been ruled out, providers should obtain additional hormonal testing to help guide management. The authors of this paper felt this guideline should be listed first as missing CAH could have significant negative consequences for the patient, and should always be considered in a phenotypic male infant with bilateral nonpalpable testes.

Providers should obtain gestational history at initial evaluation of boys with suspected cryptorchidism (Standard; Evidence Strength: Grade B). As the process of testicular descent can take until the 33rd week of gestation, cryptorchidism can be up to 10 times as prevalent in premature male infants (up to 45%) as compared to those delivered at full term (1-4%).⁸ Therefore, it is important to obtain the corrected gestational age (CGA), or the age the child would be if the pregnancy had actually gone to term, as cryptorchidism can be common in premature boys in the first few months after birth, but the testicles may still descend normally during this time period. By obtaining the CGA, a child can be appropriately referred to a pediatric urologist



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or other specialist for further evaluation after the CGA of 6 months.

Primary care providers should palpate testes for quality and position at each recommended well-child visit (Standard; Evidence Strength: Grade B). Due to the possibility of change in testicular location throughout childhood that may require intervention (e.g. acquired cryptorchidism), it is recommended by the American Academy of Pediatrics that careful examination of the location of the testicles should be performed at each well-child visit.

Providers should refer infants with a history of cryptorchidism (detected at birth) who do not have spontaneous testicular descent by six months (corrected for gestational age) to an appropriate surgical specialist for timely evaluation. (Standard; Evidence Strength: Grade B) The current recommended age range for undergoing an orchidopexy, the standard of care for cryptorchidism, is between 6 to 18 months CGA. Timely surgical correction is done to help preserve the spermatogonia, the undifferentiated male germ cells that later undergo spermatogenesis. Even with treatment by 6-12 months CGA, there is an increased risk of impaired fertility of up to 33% and 66% in unilateral and bilateral cases, respectively.⁴ The risk for testicular cancer over the patient's lifetime is also increased by 5 to 10 times, and orchidopexy helps to allow for surveillance of the testicles by physical examination for early detection of cancer.⁹ Therefore, referral to a surgical specialist at 6 months CGA is important in order to treat and prevent continued damage to the testicle(s).

Providers should refer boys with the possibility of newly diagnosed (acquired) cryptorchidism after six months (corrected for gestational age) to an appropriate surgical specialist. (Standard; Evidence Strength: Grade B) As cryptorchidism can be acquired in addition to congenital, it is important for the patient's primary care provider to check for the position of the testes at each well-child visit. In acquired cryptorchidism, the testicles spontaneously ascend out of the scrotum without the ability to be brought back down. Surprisingly, acquired cryptorchidism peaks at the age of 8 and has a prevalence of up to 7% in the population. A history of retractile testicles or a history of proximal hypospadias both increase the risk for acquired cryptorchidism.¹⁰

Providers should not perform ultrasound or other imaging modalities in the evaluation of boys with cryptorchidism prior to referral as these studies rarely assist in decision making. (Standard; Evidence Strength: Grade B)

Undescended testicles can be palpated by experienced providers over 70% of the time.¹ It is vital to verify the presence or absence of the testicle in the event it is not able to be palpated. However, no imaging studies have shown to be 100% effective in determining a testicle's presence or absence. Ultrasound is the most commonly used imaging method, but it cannot be relied upon to locate a nonpalpable testicle as it has an estimated sensitivity and specificity of 45% and 78%, respectively.¹¹ Surgical exploration via diagnostic laparoscopy is extremely sensitive and specific for locating nonpalpable testicles and has the added benefit of allowing for subsequent surgical correction.

In boys with retractile testes, providers should assess the position of the testes at least annually to monitor for secondary ascent. (Standard; Evidence Strength: Grade B) A retractile testicle is a testicle that can be moved back and forth between the scrotum and the groin. They are normally descended testes, but can be pulled back into the groin by the cremasteric reflex. Retractable testes do not require any intervention. However, if there is difficulty differentiating between a retractile and undescended teste, that patient should be referred to a urologist for further evaluation.⁸

Treatment of Cryptorchidism

As this paper is directed at the primary care provider with focus on diagnosis and management of cryptorchidism, the treatment recommendations are summarized below and can be found in greater detail in the American Urological Association's Evaluation and Treatment of Cryptorchidism Guidelines published in 2018. Of note, these authors feel the final treatment recommendation deserves to be highlighted. It states, "providers should counsel boys with a history of cryptorchidism and/or monorchidism and their parents regarding potential long-term risks and provide education on infertility and cancer risk. (Clinical Principle)."¹ The burden of this recommendation can be shared by both the urologist and the primary care provider. It speaks to the importance of continued vigilance to a patient's past medical history. The primary care provider will likely follow a patient with a history of cryptorchidism long after they no longer require sub-specialty care. As such, it is imperative primary care providers are vigilant of the long-term risks (such as cancer and infertility) to ensure patients continue to be mindful of these risks for the remainder of their life.

Treatment Recommendations

- Providers should not use hormonal therapy to induce testicular descent as evidence shows low response rates and

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lack of evidence for long-term efficacy. (Standard; Evidence Strength: Grade B)

- In the absence of spontaneous testicular descent by six months (corrected for gestational age), specialists should perform surgery within the next year. (Standard; Evidence Strength: Grade B)
- In prepubertal boys with palpable, cryptorchid testes, surgical specialists should perform scrotal or inguinal orchidopexy. (Standard; Evidence Strength: Grade B)
- In prepubertal boys with nonpalpable testes, surgical specialists should perform examination under anesthesia to reassess for palpability of testes. If nonpalpable, surgical exploration and, if indicated, abdominal orchidopexy should be performed. (Standard; Evidence Strength: Grade B)
- At the time of exploration for a nonpalpable testis in boys, surgical specialists should identify the status of the testicular vessels to help determine the next course of action. (Clinical Principle)
- In boys with a normal contralateral testis, surgical specialists may perform an orchiectomy (removal of the undescended testis) if a boy has a normal contralateral testis and either very short testicular vessels and vas deferens, dysmorphic or very hypoplastic testis, or post-pubertal age. (Clinical Principle)
- Providers should counsel boys with a history of cryptorchidism and/or monorchidism and their parents regarding potential long-term risks and provide education on infertility and cancer risk. (Clinical Principle)

Conclusion

This paper is a review of the AUA's most recent guidelines for the evaluation and treatment of cryptorchidism. It can serve as a valuable reference for primary care providers who will likely encounter these patients initially and must make the timely decision to refer to a sub-specialist, when needed. Importantly, it also serves as a review of the long-term consequences of cryptorchidism (even after repair) and reinforces the need for continued surveillance for complications throughout a patient's life.

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Evaluation and Management of Attention-Deficit/Hyperactivity Disorder (ADHD) in Children and Adolescents

Shawn Van Gerpen, MD; Timothy Soundy, MD; Tamara Vik, MD; and Brendan Brodersen, DO

Abstract

Attention-deficit/hyperactivity disorder (ADHD) is the most common neurodevelopmental disorder in childhood. Children and adolescents with ADHD are at increased risk for behavioral issues, academic issues, substance abuse issues, and legal problems. Approximately 50% of cases of childhood ADHD will persist into adulthood where it can impact employment, organizational skills, and frustration tolerance. Use of amphetamine and methylphenidate stimulant medications have shown to have the best outcomes, and are considered first line treatments. It is important to monitor stimulant use closely in individuals with substance abuse concerns, however, studies in adolescents with both substance abuse histories and ADHD tend to support their use and benefits. It is important to identify other co-morbid conditions that a patient with ADHD may be struggling with and treat those accordingly. Providers should re-evaluate the symptoms and clinical presentation of patients that show minimal or no improvement with treatment to ensure a proper diagnosis has been made.

Introduction

Neurodevelopmental disorders typically arise during the early years of childhood development. According to DSM-5, these disorders “are characterized by developmental deficits that produce impairments of personal, social, academic, or occupational functioning.”¹ In this group, Attention-Deficit/hyperactivity disorder (ADHD) ranks as the most common of these disorders in childhood.² Although estimates of prevalence vary, ADHD is reported to occur “in most cultures in about 5% of children and about 2.5% of adults.”¹ According to the U.S. Centers for Disease Control and Prevention (CDC), between 2003 and 2011 for children ages 2-17 years of age, around 8-11% of children in the U.S. had been diagnosed with ADHD.³ The prevalence of ADHD is greater in males than in females by a factor of 2-3:1, however, females tend to be missed more frequently due to presenting with more inattentive symptoms of ADHD, whereas hyperactivity and impulsivity are more frequently noted in males.

Etiology

The development of ADHD is believed to constitute a multifactorial etiology, with genetic and environmental etiologies playing a significant role. Research utilizing twin studies estimates “the heritability of ADHD to be 76%”.² This genetic contributor to ADHD is believed to be due to the impact on the dopamine, norepinephrine, and serotonin

systems.² Environmental factors during the perinatal and early developmental years also have an impact in the development of ADHD. Neurotoxins such as lead, maternal cigarette smoking, malnutrition, alcohol, illicit drugs, and perinatal trauma have been noted contributors, as have premature birth and low birth weight.^{2,5} Other contributors include psychosocial conditions such as low socioeconomic status and poor access to prenatal healthcare.² It is estimated that ADHD continues into adulthood in about 50% of cases and according to the Multimodal Treatment of ADHD (MTA) study “just 10% of children completely outgrow it.”⁶

Evaluation and Diagnosis

ADHD should only be diagnosed after a thorough parent and child interview, and a quality clinical examination, have been completed. Collateral data from outside resources, such as the child’s school teacher, should also be obtained. Providers should utilize DSM-5 criteria when looking to make an ADHD diagnosis.

Numerous rating scales exist to assist in screening a child or adolescent for ADHD. Common scales include the Conners form, the Achenbach Child Behavioral Checklist, and the NICHQ Vanderbilt Assessment Scale. Popular in school assessments is the Behavior Assessment Screening for Children (BASC). When reviewing screening forms, it may be beneficial for older children and adolescents to fill out a



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self-report version of these rating scales, but it is imperative that the provider attempt to get screening forms completed from the patient's parents and the patient's school teachers. It is important when reviewing screenings to look for discrepancies in behaviors that may exist in different settings, which may trigger the provider to evaluate for other factors that may be contributing to the patient's symptoms. ADHD symptoms should be present in all locations such as home, school, and church. Although a child or teenager may be able to keep their symptoms in check for brief periods of time, ADHD symptoms should present themselves in multiple aspects of the patient's life. When symptoms are noted at home, but not in the school setting, the provider should explore other potential reasons for the patient's symptoms. Some ADHD rating scales may identify other diagnosis for consideration that could account for the child or adolescent's symptoms. If a patient's symptoms consist of mostly poor attention and an inability to focus, rating scales may help differentiate a child suffering from inattentive ADHD versus another disorder such as anxiety.

Treatment

The treatment of ADHD may consist of both behavioral interventions and medications. According to the CDC, a national parent survey from 2016 on children ages 2-17 with a current diagnosis of ADHD revealed that 77% were receiving treatment, 30% were on medication alone, 15% received behavioral therapy alone, 32% were receiving both medication and behavioral treatment, and 23% were not receiving medication or behavioral treatment.³ It is important to establish early on what patient and family members' expectations and comfort levels are with regards to ADHD treatment, and specifically the use of medication. It is also important to educate the family about the disorder, the treatment options that exist, and the impact that the disorder may have on the patient's academic and social well-being. A 1999 report by Jadad et al. "consistently supported the superiority of stimulant over nondrug treatment."⁷ Treatment options for ADHD were looked at in the Multimodal Treatment Study of Children (MTA) study. This study reinforced "that a pharmacological intervention for ADHD is more effective than a behavioral treatment alone."⁷ Although the MTA study did support the use of medication either alone or in combination with intensive behavioral therapy, "longer-term analysis suggests that behavioral treatment provides additional benefits beyond medication alone, particularly regarding treatment satisfaction for parents and teachers and in children with lower socioeconomic status."⁸ For children under age 6 with

ADHD symptoms, it is recommended that treatment begin with behavioral therapy.⁸ For those who do not respond to therapy and who struggle with significant ADHD symptoms, medications may be utilized to assist in improving treatment response.⁸ In the Preschool ADHD Treatment Study (PATS), "the results show that preschoolers may benefit from low doses of medication when it is closely monitored, but the positive effects are less evident and side-effects are somewhat greater than previous reports in older children".⁹ Currently, only immediate-release dextroamphetamine is FDA approved for children 3-6 years of age; however, "the approval of immediate-release dextroamphetamine was made during a time of less stringent approval processes..."¹⁰ Currently, although off label, "methylphenidate is the only ADHD medication recommended for use in children as young as 4 years by AAP (American Academy of Pediatrics) guidelines."¹⁰ For children 6 years of age and older, therapy, especially to help address co-occurring disorders such as Oppositional Defiant Disorder or Conduct Disorder may be a beneficial adjunct to medication treatment, however, medication remains the treatment of choice in these populations.

First line treatment for ADHD typically involves the use of stimulant medications. Stimulant medications for ADHD can be highly effective, with some studies showing a 65%-75% response rate to a trial of one class of stimulants and up to an 85% response rate if both classes of stimulant medication are tried.⁷ Stimulant medications can be divided into two major classes: amphetamine based and methylphenidate based. Within these two groups of medications exist a number of individual medications with varying degrees of length of effectiveness of the medication, as well as varying routes of administration. Overall, the two different classes of stimulants have been found to be equally effective, as have the immediate release and extended release preparations, however, extended release preparations do offer benefits of more consistent blood levels throughout the day, more consistency in taking the medication, less substance abuse potential, and frequently only once a day dosing. Although long acting preparations of stimulants are most frequently recommended, medication costs, insurance preferences, or use in young children may dictate the need for use of short acting stimulant versions.

Weight based dosing formulas do exist for many of the stimulant medications, however, dosing is typically based on response and side effects. Titration of stimulants can occur quickly, with dosing increases occurring as soon as every 7 days. Going forward, the provider may wish to utilize ADHD

rating scales to help measure the effectiveness of the selected ADHD medication and its current dose. Once again, it is important that the information gathered be obtained from multiple sources, typically the parents and school teachers.

Certain stimulants offer unique characteristics that may help in the selection of the correct medication. For children who cannot swallow pills, a number of other medication delivery options exist to include: liquid, chewable, a patch, or mixing the content in water and drank. Other preparations utilize beads or sprinkles that may be put in food such as apple sauce or pudding and then eaten. For patients who struggle significantly with early morning ADHD symptoms, providers may wish to consider a trial of Jornay PM (Ironshore Pharmaceuticals Inc, Durham, North Carolina). This medication is taken at night, and its activation delayed until morning. This allows the stimulant medication to be in the system when the child wakes up in the morning, rather than having to wait for the medication to begin working after the child has woken up and taken their AM dose of medication.

For individuals with substance abuse issues and ADHD, it is important to weigh the risks and benefits of using stimulant medications. Due to their potential for abuse, use of stimulant medications must be monitored closely by the provider. Studies of adolescents with substance use (ASU) indicate that comorbidity with ADHD “range from 25% to 66%.”¹¹ Although more studies are needed, several studies “have found that ADHD medication helps prevent ASU.”¹¹ Other studies indicate that the use of medication in the treatment of ADHD “neither increases nor decreases ASU risk.”¹¹ In adolescents, “ADHD medications have proven safe and well-tolerated among active substance users in the context of controlled research settings.”¹¹ In addressing ADHD in patients with substance use disorder, the utilization of long acting stimulant medications may help to reduce the potential risk of abuse. Certain extended release formulations, such as Concerta (which utilizes the osmotic-release oral system [OROS]) (Janssen Pharmaceuticals, Raritan, New Jersey) or Vyvanse (which requires the removal of l-lysine in the gut before the release of dextroamphetamine can occur) (Takeda Pharmaceuticals, U.S.A., Inc., Lexington, Massachusetts), may both help to reduce the abuse potential of these medications due to their unique delivery mechanisms. Use of non-stimulant ADHD medications can also reduce abuse potential in this patient population.

Side effects of stimulant medications tend to be fairly consistent between the two classes of stimulant medications. Appetite suppression and weight loss tend to be the most

common side effects noted. Other side effects may include headaches, gastrointestinal issues, sleep disturbance, moodiness or irritability, tics, blood pressure elevation, pulse elevation, and psychosis. The MTA study reported “diminished growth velocity ... during the first 3 years of treatment, leading to a loss of 1 to 2 cm of growth”, however, more recent studies have failed to demonstrate any effect on overall growth or height.¹² Substance abuse issues can occur with the use of stimulant medications and cases of priapism have been associated with methylphenidate and amphetamine products. Cardiac issues, such as elevated blood pressure, elevated pulse, arrhythmia, and sudden cardiac death, related to the use of stimulants, especially when used with alpha agonists, has been studied in the past. It is important that the prescriber ask about any history of structural heart defects or arrhythmias in the patient, or any history of sudden death in family members from cardiac related events.¹² Also, any noted cardiac symptoms such as shortness of breath, chest pain, or heart palpitations should prompt a thorough cardiac evaluation, which may include an electrocardiogram (ECG) or referral to a pediatric cardiologist, before starting a stimulant medication. Although routine ECGs prior to starting stimulants is not recommended in healthy patients with no cardiac history or risk factors, obtaining an ECG prior to starting a stimulant may be discussed with the patient and their parents and may provide another level of comfort for those concerned about the potential cardiac risks involved.

Non-stimulant medications may also be of benefit for patients with ADHD. While the effects of stimulant medications on ADHD are due to its effect on dopamine, atomoxetine’s effects are derived from its inhibition of the reuptake of norepinephrine. Because of this, atomoxetine has been found to be effective in patients with both symptoms of ADHD and anxiety, and its effects seem to be greater for those patients struggling with inattention rather than symptoms of hyperactivity/impulsivity. Atomoxetine is also a non-stimulant medication, and thus does not carry the same risk for abuse that stimulants can carry. Although the overall effectiveness of atomoxetine is lower than stimulants, the benefits that it provides for patients make it a valuable option as either a stand-alone medication for individuals who do not respond to stimulants or who may not tolerate stimulant medications, or as an adjunctive treatment for stimulant responders who have maximized their stimulant dose, but who continue to struggle with significant ADHD symptoms. Atomoxetine also provides 24 hour coverage, which is important for those who require help throughout

the day and evening with their ADHD symptoms, or for those who need an additional medication to fill in the gaps in time where their stimulant medication is no longer effective.

Unlike stimulants, the effects of atomoxetine take several weeks to demonstrate effectiveness. It is important to titrate atomoxetine to its maximum weight based dose in order to see benefits. Dosing recommendations for atomoxetine for those weighing less than 70 kg is 0.5 mg/kg po per day for at least 3 days with a max dose of 1.2-1.4 mg/kg po per day. For those weighing over 70 kg, the medication should be started at 40 mg/day for at least 3 days and then increased to 80 mg/day. This medication may be taken either once daily or divided into twice daily dosing, but the medication must be swallowed whole and should not be crushed or chewed. Although rapid titration can occur, a slower titration schedule may help to reduce side effects. Atomoxetine is primarily metabolized by CYP2D6, while some Selective Serotonin Reuptake Inhibitors (SSRIs) such as paroxetine and fluoxetine inhibit CYP2D6 activity, which can result in increased levels of atomoxetine when the two medications are taken together.¹³ Subsequently, caution should be taken when combining these medications. When adding atomoxetine to a CYP2D6 inhibiting SSRI in children under 70 kg, atomoxetine should be started at the 0.5 mg/kg/day dose and only increased to the usual target dose of 1.2 mg/kg/day if symptoms do not improve after 4 weeks and the dose is tolerated. For those weighing over 70 kg, atomoxetine should be started at 40 mg/day and only increased to the 80 mg/day dose if symptoms do not improve after 4 weeks and the dose is tolerated.¹³ For those already on an established dose of atomoxetine for whom an inhibiting CYP2D6 SSRI is being added, it is important to reduce the atomoxetine dose by half before starting the SSRI.

Atomoxetine carries a black box warning similar to that for anti-depressants for increased suicidal ideation in children and adolescents. It is important to monitor patients on atomoxetine for mood changes and suicidal thoughts. There have also been reported cases of priapism, hepatotoxicity, hepatic enzyme elevation, and cardiac risks related to atomoxetine use, to include abnormal heart rate, abnormal blood pressure, and cardiac arrhythmias.

Another class of medications often used either alone or in combination with other ADHD medications are the alpha-agonists. Although traditionally used as add on medications in conjunction with stimulants, these medications may be used alone, especially in those individuals who may not tolerate stimulants or atomoxetine. Newer, long acting alpha-

agonists may reduce the need for multiple daily dosing and provide more consistent blood levels throughout the day. Alpha-agonists can be effective in reducing aggression in children, and short acting versions such as clonidine may be beneficial in helping with sleep issues. Alpha-agonists may also be helpful in patients with motor or vocal tics, or for those individuals who may notice exacerbation of their tics when taking stimulant medications.

It is important to monitor patients taking alpha-agonists for hypotension and bradycardia related to the medication. Other side effects can include dizziness, syncope, cardiac arrhythmias, and rebound hypertension. Prior to starting an alpha-agonist, especially if combining it with a stimulant, although not required, providers may wish to speak with the patient and their parents about obtaining an ECG prior to starting the medication. One other side effect of these medications can be sedation. Typically, clonidine has been noted to be more sedating than guanfacine. Subsequently, if alpha-agonists are being utilized to assist with sleep, clonidine may be the preferred medication. However, if being used to assist with daytime behaviors or aggression, the less sedating guanfacine may be a more tolerated option.

Monitoring of patients being treated for ADHD will be dependent on the patient's response to the effectiveness of the medication regimen being utilized. After initiation of a medication, follow up within a month may allow the provider the opportunity to evaluate the effectiveness of the treatment and help determine the need for adjustments to the medication regimen. Once symptoms stabilize, follow up visits may be extended to every 3-4 months. It is important at the clinical visits to monitor blood pressure, pulse, height, weight, and BMI. Utilization of rating scales may allow the provider an opportunity to measure the effectiveness of the current treatment. For patients who have not responded to multiple treatment trials, the provider should re-evaluate the patient's symptoms. This may include obtaining updated rating scales on the patient. Many different mental health disorders present with similar symptoms to those of ADHD. One of the most commonly missed diagnoses is anxiety in a child or adolescent who struggles with inattention issues. Other commonly missed diagnoses may include depression, oppositional defiant disorder, conduct disorder, and disruptive mood dysregulation disorder. For those whose diagnosis appears correct, but for whom satisfactory improvement in symptoms has not been achieved, a referral to a Child and Adolescent Psychiatrist for further evaluation and treatment recommendations may be warranted.

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THE LOWDOWN ON TELEHEALTH

Telehealth is here to stay.

NOT JUST A FAD

Payment gateways are the first step in the online payment process, and they have been crucial in helping companies more easily accept online transactions. Healthcare organizations that had never before, or only occasionally, offered virtual care began to see it as a lifeline. It offered both a way to reserve in-person care for the patients that needed it most, as well as a way for others to seek care from the safety of their homes.



PRICING TRANSPARENCY

A demand for greater predictability and transparency around prices and billing is long overdue. America's system of paying for healthcare has long remained complex and opaque. Amidst this complexity, providers and patients bear the burden and risk. Providers want and deserve clarity around payment for health services they have performed.



REAL-TIME PAYMENTS

Technologies that streamline and modernize payment infrastructures have made a major impact within banking and financial services to shore up back-end operations, digitize analog processes and provide better customer experiences. The healthcare industry is primed for this exact transformation, and expects to see an immense shift in how providers get paid.



IMPROVED LONG-TERM CARE

Moving back to only in-person visits might hurt a practice's long-term outlook. Patients across all generations have found that telehealth is very convenient and that they still are very connected to their doctor.



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Member News

Visit www.sdsma.org for the latest news and information.



2023 Annual Leadership Conference is June 2!

Don't forget to register and book your room for the 2023 SDSMA Annual Leadership Conference! The conference is Friday, June 2. The conference is a benefit of your membership. There is no registration fee for SDSMA members (tickets required for some events/meals).

Opioids and substance use is the focus of this year's conference. Presentations will address the facts of opioid use, what can be done to reverse this crisis, safe prescribing, substance use disorders, and more.

Opioid prescribing continues downward while overdose and death related to illicitly manufactured fentanyl, methamphetamine, and cocaine increase -- further amplified by underlying social needs. Reversing the use and impact of illicit drugs requires physician leadership, an emphasis on overdose prevention/treatment, and coordinating efforts and best practices.

Lodging

The deadline for the block of rooms being held at a special rate at the Hilton Garden Inn Downtown is quickly approaching. The hotel is offering the room block until 5 pm CT Friday, May 5. After this date, reservations are subject to prevailing rates and availability. Call the hotel at 605.444.4705 from 8 am-5 pm Monday-Friday or find a link at sdsma.org to reserve your room under the South Dakota Medical Association block rate.

Presentations

Don't miss the lineup of presentations and speakers (please visit sdsma.org for the full schedule with times as updates are confirmed):

- **American Medical Association Update**
Bobby Mukkamala, MD – Immediate Past Chair, American Medical Association
- **Public Health Hot Topics – Rising Up to Current Challenges of Public Health and Health Care Sustainability in a Rural State**
Melissa Magstadt – Secretary, South Dakota Department of Health
- **Update from the South Dakota Department of Social Services**
Matt Althoff – Secretary, South Dakota Department of Social Services
- **Panel Discussion: Opioids and Substance Use**
Melissa Magstadt – Secretary, South Dakota Department of Health; Matt Althoff – Secretary, South Dakota Department of Social Services; Bobby Mukkamala, MD – Immediate Past Chair, American Medical Association; Moderator: Benjamin Aaker, MD – SDSMA Past President and Emergency Medicine Physician
- **SDSMA PAC Lunch: Legislative Efforts Related to Opioids and Substance Use Disorder**
Daniel Blaney-Koen – Senior Legislative Attorney, American Medical Association
- **Update from the University of South Dakota Sanford School of Medicine**
Tim Ridgway, MD – Dean and Vice President for Health Affairs, USD SSOM
- **Medical Student Poster Session**

SDSMA PAC Lunch to Feature AMA Attorney

American Medical Association Senior Legislative Attorney Daniel Blaney-Koen will be the speaker during the 2023 SDSMA PAC Lunch held in conjunction with the 2023 Annual Leadership Conference at the Hilton Garden Inn Downtown Sioux Falls.

The lunch is at noon on June 2 in the Revir Ballroom and will be presented via Zoom. Daniel will discuss state legislative efforts related to opioids and substance use disorder.

Tickets for the lunch are \$40 and are available at sdsma.org. It's not too late to register for all of the exciting activities taking place during the Annual Conference – find more information at sdsma.org.



Legal Brief Highlight: Advance Directives

South Dakota law allows patients to give advance directives for health care via either a durable power of attorney for health care or a living will, or a medical order for scope of treatment (MOST). A patient may also give a specific advance directive concerning cardiopulmonary resuscitation.

In the absence of the attorney-in-fact designated by the patient's durable power of attorney or other valid advance directive, health care decisions for an incapacitated patient may be made by certain members of the patient's family or in the last resort, by a close friend.

Physicians have an obligation to relieve pain and suffering and to promote

the dignity and autonomy of dying patients in their care. Where the performance of one duty conflicts with the other, the preferences of the patient should prevail; the principle of patient autonomy requires that physicians respect the decision to forego life-sustaining treatment of a patient who possesses decision-making capacity.

More information is available in the SDSMA legal brief *Advance Directives* at sdsma.org. The SDSMA provides legal briefs for member physicians on a variety of rules and regulations that apply to the medical profession.

Medical Student Poster Session to be Held During SDSMA Annual Leadership Conference June 2

During the 2023 SDSMA Annual Leadership Conference, medical students will present posters featuring their work. Please take a few minutes to stop, visit with the presenters, and view their projects!

USD SSOM Medical Student Poster Session

1:45-2:30 pm

Friday, June 2

Hilton Garden Inn Downtown Sioux Falls Pre-function area
outside the Revir Ballroom

2:30 pm

Revir Ballroom

#1 Scientific Presentation winner Mykayla Vollmer will speak about her work, "Influencing Children Through the Art of Storytelling Using Medically-Informed Children's Books"



Medicaid Postpartum Coverage Extension

The South Dakota Department of Social Services has opened a comment period regarding the adoption of administrative rules related to Medicaid. The proposed rule changes include extending the eligibility for postpartum coverage from 60 days to 12 months. Groups or individuals who wish to provide comments may:

- Email DSSAdminRules@state.sd.us
- Appear in person at a May 19 hearing at 10 a.m. CT at the DSS

building at 811 E 10th St in Sioux Falls

- Call 605-679-7263, conference code 385 249 439 on May 19
- Mail to Teresa Schulte, DSS Administrative Rules, 811 E 10th St., Sioux Falls, SD 57105

The deadline to submit written comments for consideration by DSS is May 29.

SD HOSA Golf Tournament

South Dakota HOSA – Future Health Professionals is hosting a golf tournament on Thursday, June 1 at Bakker Crossing Golf Course in Sioux Falls. The tournament will benefit students in HOSA programs who wish to become

future health care workers and have a financial need. For more information, contact Brock Rops, SD HOSA executive director, at Brock.Rops@usd.edu or visit sdhosa.org.

For Your Benefit:

Membership Services from SDSMA

SDSMA Membership Services works hard to ensure that you have the programs and services you want and need, as well as marketing the association to potential new members. We want to hear from you if you have questions, concerns or ideas on how we can serve you better, or if you know of a potential new member. It's your association and we'll work with you to make it the best it can be. Check out all the benefits of your membership at sdsma.org!

"For Your Benefit" is the SDSMA's monthly update on programs and services available to physicians through their affiliation with the SDSMA.

Don't Miss the Awards Banquet and Scholarship Recognition

Enjoy a fun-filled evening of celebration Friday, June 2 during the 2023 SDSMA Annual Leadership Conference at the Hilton Garden Inn in Downtown Sioux Falls.

Start the evening with the mixer at 6:30 pm and continue the celebration at the Awards Banquet & Scholarship Recognition, where Denise Hanisch, MD, will be sworn in as SDSMA president, awards will be announced, outgoing and incoming officers will be celebrated and welcomed, and medical student scholarship recipients will be recognized. Tickets required – for tickets, please visit sdsma.org.

Networking Opportunities at the Membership Mixer!

SDSMA members are invited to the social/mixer at 6 p.m. Friday, June 2 at the Hilton Garden Inn Downtown Sioux Falls during the 2023 SDSMA Annual Leadership Conference.

Enjoy a fun opportunity to meet SDSMA leaders and network with your peers. This event is sure to be an all-around great time! Spouses or a guest are welcome to attend.

Immediately following the mixer is the Awards Banquet & Scholarship Recognition at 7 pm (tickets required). For tickets, please visit sdsma.org.

Resources to Help Physicians Meet DEA Training Requirement

The American Medical Association is offering a resource on its Ed Hub at edhub.ama-assn.org to help physicians complete the new, one-time eight-hour training requirement issued by the Drug Enforcement Administration (DEA) on treating and managing patients with opioid or other substance use disorders. The training offers DEA-registered physicians and practitioners required continuing medical education (CME) and meets the requirements of the Medication Access and Training Expansion (MATE) Act that was passed as part of the Consolidated Appropriations Act of 2023.

By completing the CME, starting on June 27, 2023, physicians will be able to check a box on their DEA registration application or renewal form indicating that they have satisfied this training requirement. The free courses offered on the AMA Ed Hub page can be taken in any combination to fulfill the eight-hour requirement. The training does not have to occur in one session. Past trainings on the treatment and management of patients with opioid or other substance use disorders can count towards this requirement.

The deadline for satisfying this new training requirement is the date of a practitioner's next scheduled DEA registration submission—regardless of whether it is an initial registration or a renewal registration—on or after June 27, 2023.

The courses feature education from the AMA and other trusted sources including the American Society of Addiction Medicine (ASAM).

The AMA Ed Hub has multiple offerings on the treatment and management of patients with opioid or other substance use disorders, which are included in the Opioid Therapy and Pain Management CME course.

**New DEA
Training Requirement
edhub.ama-assn.org**

The Issue Is...

Congress Urged to Pass Annual Inflation-Based Medicare Payment Update

The SDSMA has joined the American Medical Association and 133 other health organizations – representing 900,000 patients and tens of millions of Medicare patients – to urge Congress to pass legislation providing for an annual inflation-based payment update. The current Medicare physician payment system is inadequate and efforts must be made to reform Medicare to make it more rational and serve patients better.

Medicare payments failed to respond adequately in the face of inflation, the COVID-19 pandemic, and growing costs. Additionally, physicians saw a 2% Medicare payment reduction for 2023.

The Medicare Payment Advisory Commission (MedPAC) has recognized that physician pay has not kept up with the cost of practicing medicine,

acknowledging that Congress should adopt a 2024 Medicare payment update that recognizes the full inflationary growth in health care costs.

When adjusted for inflation, Medicare physician payment has effectively declined 26% from 2001 to 2023. These increasingly thin or negative operating margins disproportionately affect small, independent, and rural physician practices, as well as those treating low-income or other underserved patient communities. According to MedPAC, nationwide, among those looking for a new primary care physician, half of Medicare patients had difficulty in finding one. And among Medicare patients looking for a new specialist, one-third struggled to find one.

COPIC – SDSMA's Endorsed Medical Liability Insurance Provider



COPIC is the South Dakota State Medical Association's endorsed medical liability insurance provider. Their dedication to improving health care in South Dakota extends beyond just offering trusted coverage. That's why we are proud to share the COPIC 2022 Annual Report with SDSMA members – watch your email for information and a link to download the report. It highlights a company that is driven by a mission to "improve medicine in the communities it serves."

While there are many reasons why we endorse COPIC, a few key examples stand out:

- A leadership team and board of directors led by physicians.
- Direct access to experts that includes physicians, attorneys, claims

staff, and other medical professionals, as well as a 24/7 risk management hotline staffed by physicians.

- Through its 3Rs Program, they've helped physicians maintain communication with patients and work toward a resolution when an unexpected medical outcome occurs.
- Eligible SDSMA members can receive a 10% discount with COPIC.

Please take the time to review this annual report and learn more about COPIC. Their commitment to build strong relationships with SDSMA members demonstrates why we partner with them and how they support improved health care across the state.

COPIC Tips: Informed Refusal

COPIC encourages shared decision-making with patients surrounding their care and treatment, but what do you do when a patient declines a care plan that you believe is important? Utilize an informed refusal form to document their decision. Watch your email for the article, Informed Refusal: An Underutilized Patient Safety and Risk Management Tool. A case study is examined in which the use of an informed refusal form might have protected the physician from allegations of negligent care and prevented a lawsuit.

COPIC Tips offers physicians, health care professionals, and medical facilities valuable insight on relevant health care topics. Concise and informative, these "tips" are based on COPIC's 25+ years of experience in providing unparalleled protection and guidance to the health care community.



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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.



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COPIC is proud to be the endorsed carrier of the South Dakota State Medical Association. SDSMA members may be eligible for a 10% premium discount.

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