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New frontier in ob/gyn
A modern approach to an ongoing need
Curtis Lowery, MD

Rural perspective on maternal care and mortality

SMFM COMMENTARY
Ventriculomegaly

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The neglected challenge: Saving America’s rural ob care

Often overlooked in the debate over health care reform are the growing disparities in health outcomes among America’s rural population. Overall mortality and age-adjusted annual death rates from heart disease, cancer, unintentional injury, chronic lower respiratory disease and stroke are all higher in rural compared with urban settings.1 Americans who live in rural counties are more likely to be obese, older, poorer, and addicted to opioids than their urban counterparts. However, reduced access to high-quality medical care is also a major contributor to adverse health outcomes in rural populations. At the heart of reduced rural access is a shortage in providers and hospitals. Rising health care fixed costs and declining reimbursement are exacerbating the problem. Indeed, it has been estimated that 673 of 2,161 rural hospitals (31.1%) may close over the next 5 years.2

Childbirth is the most common reason for hospitalization in the United States and 28 million women of reproductive age live in rural counties giving birth to 500,000 infants each year.3 Rural hospital obstetrical services are especially vulnerable financially due to their very high fixed costs, low patient volumes, and heavy dependence on often-meager Medicaid-based reimbursements. Thus, it shouldn’t come as a surprise that more than half of rural counties in the United States have no hospital obstetrical services, many remaining services are closing at a frightening pace, and maternal and perinatal mortality and/or morbidity are rising as a consequence.

Rural access to obstetrical services is declining
Hung and associates analyzed the availability of inpatient obstetrical services in rural US hospitals between 2004 and 2014 using multiple data sources including the Centers for Medicare and Medicaid Services (CMS), the American Hospital Association and the Census Bureau.3 They defined rural counties as micropolitan, if they had an urban core of 10,000 to 50,000 residents, and non-core, if no such “urban” core was present. The authors further analyzed their data based on whether the rural county was adjacent to an urban area or not. They found that in 2004, 45% (898) of rural counties had no hospital-based obstetrical services. These counties had significantly fewer family physicians per capita, a higher percentage of African-American women of reproductive age, lower median household incomes, a higher percentage of residents in poverty and their states had more stringent household income thresholds for pregnant women to be eligible for Medicaid – all risk factors for adverse pregnancy outcomes.

By 2014, a further 9% (179) of rural counties had lost their hospital-based obstetrical services. When compared with micropolitan counties, non-urban core counties were more likely not to have hospital-based obstetrical services (17.6% vs. 58.6%) and were more likely to have lost their inpatient obstetrical service (4.5% vs. 11.2%). Worst yet, 59% of noncore rural US counties not adjacent to an urban area, the most isolated of our population, had no hospital-based obstetrical services in 2004 and by 2014 that share had increased to 69%.

In contrast, rural counties with obstetrical services in 2004 who maintained them over the next decade had significantly more births, more obstetricians and certified nurse midwives per capita, higher median incomes and less stringent income-eligibility thresholds for Medicaid.
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thresholds for pregnant women to obtain Medicaid. In 2018, such thresholds varied from an appalling 138% of the federal poverty line in Idaho and South Dakota to a generous 380% in Iowa.4

Loss of hospital-based OB services adversely impact outcomes
Delivery in rural hospitals is associated with higher rates of postpartum hemorrhage.5 Moreover, infant mortality rates are 6% higher in rural compared with large urban counties. Among non-Hispanic black women, this geographic difference in infant mortality reaches 16%. However, loss of inpatient obstetrical services adds an additional pregnancy-related health threat. Kozhimannil and associates examined the impact of loss of hospital-based obstetrical services on birth outcomes between 2004 and 2014.7 For rural, non-urban adjacent and urban-adjacent counties, the out-of-hospital birth rates were 1.2% and 1.3%, respectively, the year before they lost their hospital-based obstetrical services. For non-urban and urban-adjacent areas, the rate of such deliveries increased 1.6% and 1.5%, respectively, the year following loss of services. Similarly, rates of delivery at hospitals without obstetrical services increased in rural, non-urban adjacent counties from 0.37% to 2.47% the year after service loss. In rural, urban-adjacent counties, loss of services increased deliveries at hospitals without obstetrical services from 0.01% to 1.88%.

Multivariate analysis suggested that even after controlling for potential confounders, rates of preterm birth increased in rural, non-urban adjacent areas by 0.67% (95%CI: 0.02-1.33) and patients receiving ≤ 10 prenatal care visits increased in such counties by 4.37% (95%CI: 2.33-6.41). Lesser and more transient effects were seen in rural, urban-adjacent counties that lost their inpatient obstetrical services.

Potential solutions
The solution to this rural obstetrical access problem is not straightforward. Even if state or federal government subsidies were provided to keep units open, it is not entirely clear there would be sufficient numbers of providers to staff them. More importantly, even if adequately staffed, facilities with very low volumes would likely be at risk for reduced quality since volume is an important determinant in maintaining quality outcomes. The current impasse in Washington over revising the Affordable Care Act and the failure of 27 states to undertake Medicaid expansion adds additional challenges, particularly as the latter states often have the most counties without obstetrical services.

To address the issue of maintaining quality in low-volume settings, each state should have in place a robust regional maternal/perinatal care program designed to minimize both perinatal and maternal mortality.

Such a program should include increased use of:
1) telemedicine, which has been used successfully to enhance outcomes in rural intensive care units;
2) safety drills and simulation;
3) maternal air transport;
4) induction of labor at 39 weeks.

The latter is associated with reduced perinatal morbidity and mortality, maternal morbidity, and cesarean delivery rates and helps mitigate the logistical issues imposed by geographic distance from providers.9

IT HAS BEEN ESTIMATED THAT 31.1% of rural hospitals may close over the next 5 years.2

Dr Lockwood, editor in chief, is Senior Vice President, USF Health, and Dean, Morsani College of Medicine, University of South Florida, Tampa. He can be reached at DrLockwood@ubm.com.

FOR REFERENCES VISIT contemporaryobgyn.net/RuralOBcare
Seven recommendations for mild fetal ventriculomegaly

A thorough investigation is crucial to making a prenatal diagnosis of ventriculomegaly and assessing prognosis.

by SOCIETY FOR MATERNAL–FETAL MEDICINE, GIANCARLO MARI, MD, MARY E. NORTON, MD, JOANE STONE, MD, VINCENZO BERGHELLA, MD, ANTHONY SCISCIONE, DO, DANIELLE TATE, MD, AND MAURO SCHENONE, MD

Ventriculomegaly, or dilation of the fetal cerebral ventricles, is a relatively common finding on prenatal ultrasound. This summary of SMFM Consult Series #45 reviews key points for diagnosis, evaluation, and management of mild fetal ventriculomegaly.

Q | How is ventriculomegaly defined?
Fetal cerebral ventriculomegaly is defined as an atrial diameter ≥ 10 mm on prenatal ultrasound. Ventriculomegaly is typically categorized in one of two ways: mild (10–15 mm) or severe (> 15 mm); or as mild (10–12 mm), moderate (13–15 mm), or severe (> 15 mm). Because the chance of an adverse outcome and potential for other abnormalities are higher when the ventricles measure 13–15 mm vs 10–12 mm, the latter classification method should be used for the purposes of patient counseling. The incidence of mild to moderate fetal ventriculomegaly is approximately 1%.

Q | What are the causes of ventriculomegaly?
The differential diagnosis of ventriculomegaly is extensive and includes a normal variant as well as disorders associated with severe impairment. A thorough evaluation is critical to make the correct diagnosis and to provide an accurate prognosis.

Normal variation
Fetuses with a ventricular atrial diameter of 10–12 mm are found to have a normal postnatal evaluation in > 90% of cases. The chance that mild ventriculomegaly represents a normal variant decreases with increasing degrees of dilation. Mild ventriculomegaly is likely to represent a normal variant if no other structural abnormalities are noted and if aneuploidy screening or diagnostic genetic testing results are normal. Because it is not possible to determine with certainty that mild ventriculomegaly is truly isolated during pregnancy, normal variation is a diagnosis of exclusion that cannot be made with certainty until after birth.

Structural abnormalities
Structural abnormalities that can lead to dilation or enlargement of the lateral ventricles include agenesis of the corpus callosum, Dandy-Walker malformation, neural tube defects, cortical defects, and migrational ab-
normalities or heterotopia. Some structural central nervous system (CNS) anomalies, such as holoprosencephaly, hydranencephaly, porencephaly, or schizencephaly, and cystic lesions, such as arachnoid cysts, result in abnormal fluid collections in the fetal brain that may be misdiagnosed as ventriculomegaly, although these anomalies do not truly represent dilation of the ventricular system. In rare cases, a tumor or choroid plexus papilloma may result in overproduction of cerebrospinal fluid with resultant ventriculomegaly. Large isolated choroid plexus cysts may transiently dilate the fetal cerebral ventricles.

The most common cause of severe ventriculomegaly is aqueductal stenosis, which results from narrowing of the cerebral aqueduct of Sylvius located between the third and fourth ventricle, leading to progressive dilatation of the lateral and third ventricles. Aqueductal stenosis can be genetic or can result from fibrosis secondary to fetal infection (e.g., cytomegalovirus [CMV], toxoplasmosis, or Zika virus) or bleeding (e.g., intraventricular hemorrhage). A mass or congenital tumor can also lead to compression of the aqueduct with resultant ventriculomegaly. In many cases, the cause of aqueductal stenosis is unknown.

**Infection**
Approximately 5% of cases of mild to moderate ventriculomegaly are reported to result from congenital fetal infections, including cytomegalovirus (CMV), toxoplasmosis, and Zika virus. Many cases of ventriculomegaly associated with congenital infection demonstrate other sonographic features, including fetal growth restriction; periventricular, hepatic, and other intra-abdominal calcifications; echogenic fetal bowel; hepatosplenomegaly; ascites; meconium peritonitis; polyhydramnios, and microcephaly. However, these features may not be evident until later in gestation, and not all infected fetuses will have other sonographic signs.

**Genetic disorders**
Approximately 5% of fetuses with apparently isolated mild to moderate ventriculomegaly have an abnormal karyotype, most commonly trisomy 21. Another 10% to 15% have abnormal findings on chromosomal microarray. Although hydrocephalus is a component of several congenital syndromes, there are relatively few genetic causes of isolated ventriculomegaly or hydrocephalus. Syndromes typically associated with more severe ventriculomegaly as well as additional abnormalities that may be identified sonographically or by fetal magnetic resonance imaging (MRI) include Walker-Warburg, Bardet-Biedl, Meckel, Joubert, and hydroethalalus syndromes.

**Ultrasonography**
Incidence of additional CNS and non-CNS sonographic abnormalities identified in fetuses with mild or moderate ventriculomegaly ranges from 10% to 76% but appears to be < 50% in most studies. When ventriculomegaly is identified, a detailed ultrasound should be performed by a practitioner experienced in diagnosis of fetal anomalies. Careful attention should be given to intracranial anatomy including the lateral, third, and fourth ventricles; corpus callosum; thalami; germinal matrix region; cerebellum; and the cerebellar vermis. The fetal heart should be carefully examined, and fetal biometry should be assessed for evidence of growth restriction. Finally, a thorough inspection should be performed for signs of fetal infection, including intracranial or extracranial calcifications, hepatosplenomegaly, ascites, and fetal growth restriction.

**Testing for genetic disorders**
Diagnostic testing (amniocentesis) with chromosomal microarray should be offered when ventriculomegaly is detected. Cell-free DNA screening can be considered for women who decline diagnostic testing after counseling about the limitations of this approach. Women with prior normal screening test results, including cell-free DNA, should still be offered diagnostic testing.

**Q** How should a fetus with mild or moderate ventriculomegaly be evaluated?
When mild or moderate ventriculomegaly is detected, further evaluation is indicated. Such evaluation is focused on determining whether additional structural (CNS and non-CNS) anomalies, genetic abnormalities, or congenital infection are present.

**Women with prior normal screening test results should still be offered testing due to higher diagnostic yield.**
Telehealth: A new frontier in obstetrics and gynecology

Eight steps are key to success for launching virtual visits in low- and high-risk obstetrics and gynecology.

by CURTIS LOWERY, MD

Introduction
Telehealth is a modern-day solution to health problems both old and new. Though it presents benefits to a variety of patients, rural patients likely experience the richest benefits. As Health Resources & Services Administration (HRSA) notes, it can sometimes be difficult to determine whether an area is urban or rural. In fact, the term “rural” is not even defined by the Census Bureau—it is considered to encompass “all population, housing, and territory not included within an urban area.” Essentially, according to this definition, whatever is not urban is considered rural. There are two types of urban areas identified by the Census Bureau: 1) Urbanized Areas (UAs) of 50,000 or more people and 2) Urban Clusters (UCs) of at least 2,500 and less than 50,000 people. Generally, rural areas are characterized by low population and lack of access to critical resources such as medical care.

Rural individuals face many health disparities compared to urban individuals. Poverty and poor access to healthcare contribute greatly to these disparities. Overall, rural communities are in poorer health than others. According to the Centers for Disease Control and Prevention, rural Americans are at higher risk of death from five leading causes: heart disease, cancer, unintentional injuries, chronic lower respiratory disease, and stroke. In addition, rural areas have higher rates of preterm births and infant mortality.

Telehealth offers convenient and cost-effective access to specialty healthcare that may not be readily available locally.

Low-risk women who participate in telemedicine prenatal visits have shown similar outcomes to women who had traditional prenatal care, and improved outcomes are also noted in high-risk mothers who participate.

Telehealth has helped combat these rural disparities through the following four modalities:

1. Live video, which uses audiovisual telecommunications technology;
2. Store-and-forward, which involves transmission of health information such as x-rays and other images through a secure electronic communications system to a healthcare provider;
3. Remote patient monitoring, which involves electronic transmission

continued on page 15
Important Safety Information for Makena® (hydroxyprogesterone caproate injection)

• Do not use Makena in women with any of the following conditions:
  - Current or history of thrombosis or thromboembolic disorders
  - Known or suspected breast cancer, other hormone-sensitive cancer or history of these conditions
  - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
  - Cholestatic jaundice of pregnancy
  - Liver tumors, benign or malignant, or active liver disease
  - Uncontrolled hypertension
• Makena should be discontinued if thrombosis or thromboembolism occurs
• Allergic reactions, including urticaria, pruritus and angioedema, have been reported with use of Makena or with other products containing castor oil
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**EFFICIENT**
- Pre-filled auto-injector that is ready to use out of the box
- Administered in ~15 seconds

**DISCREET**
- Shorter, thinner, nonvisible needle
- Administered in the back of the upper arm—no need for patients to disrobe

**ADMINISTRATION FRIENDLY**
- Protective needle guard to help minimize accidental needle-sticks
- Appointment flexibility—no need for private exam rooms

Personalized patient support.
Healthcare professional resources.
More than Makena.

Women receiving Makena should be monitored if they:
- Are prediabetic or diabetic
- Have conditions that may be affected by fluid retention, such as preeclampsia, epilepsy, cardiac or renal dysfunction
- Have a history of clinical depression; Makena should be discontinued if depression recurs
- Develop jaundice; consider whether benefit of use warrants continuation
- Develop hypertension

Certain pregnancy-related fetal and maternal complications or events were numerically increased in Makena-treated subjects as compared to placebo subjects, including miscarriage (2.4% vs. 0%) and stillbirth (2% vs. 1.3%), admission for preterm labor (16% vs. 13.8%), preeclampsia or gestational hypertension (8.8% vs. 4.6%), gestational diabetes (5.6% vs. 4.6%), and oligohydramnios (3.6% vs. 1.3%)

In a study where the Makena intramuscular injection was compared with placebo, the most common adverse reactions reported with Makena intramuscular injection (reported incidence in ≥2% of subjects and higher than in the control group) were: injection site reactions (pain [35%], swelling [17%], pruritus [6%], nodule [5%]), urticaria (12%), pruritus (8%), nausea (6%), and diarrhea (2%)

In studies where the Makena subcutaneous injection using auto-injector was compared with Makena intramuscular injection, the most common adverse reaction reported with Makena Auto-Injector use (and higher than with Makena intramuscular injection) was injection site pain (10% in one study and 34% in another)

Please see brief summary of full Prescribing Information on the following page.

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered >37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

INDICATIONS AND USAGE
Makena is for use in women who are at 16 to 20 weeks of gestation and who have a singleton pregnancy with gestational age of <20 weeks by obstetric ultrasound. The majority of women are enrolled <20 weeks by obstetric ultrasound. In a controlled clinical trial, Makena was administered by auto-injector or intramuscular injection beginning at 16 to 20 weeks of gestation and continuing to 20 to 24 weeks of gestation. There were no significant differences between treatment groups using either route of administration in the primary endpoint of time to delivery. Therefore, the data from the clinical trials of another drug and may not reflect the rates of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Table 1 Selected Maternal Complications

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In the clinical trial using intramuscular injection, 2.2% of subjects receiving Makena who were reported as discontinuing therapy due to adverse reactions compared to 2.6% of control subjects. The most common adverse reactions that led to discontinuation in both groups were uterine and injection site pain/swelling (1% each). Pulmonary embolus in one subject and injection site cellulitis in another subject were reported as serious adverse reactions in Makena-treated subjects.

Two clinical studies were conducted in healthy post-menopausal women, comparing Makena administered via subcutaneous auto-injector to Makena administered as an intramuscular injection. In the first study, injection site pain occurred in 3/30 (10%) of subjects who used the subcutaneous auto-injector vs. 2/30 (7%) of subjects receiving intramuscular injection. In the second study, injection site pain occurred in 20/59 (34%) of subjects who used the subcutaneous auto-injector vs. 5/61 (8%) of subjects receiving intramuscular injection.

Postmarketing Experience
The following adverse reactions have been identified during postapproval use of Makena. See Warnings and Precautions.

Clinical Trials Experience
In vitro drug-drug interaction studies were conducted with Makena. Hydroxyprogesterone caproate has minimal potential for CYP1A2, CYP2A6, and CYP2B6 related drug-drug interactions at the clinically relevant concentrations. In vitro data indicated that the pharmacokinetic concentration of hydroxyprogesterone caproate is not likely to inhibit the activity of CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4. No in vivo drug-drug interaction studies were conducted with Makena.

USE IN SPECIFIC POPULATIONS

Pregnancy
Risk Summary: Low levels of progestins are present in human milk with the use of progestin-containing contraceptives. In nursing mothers, embryolethality was reported in rhesus monkeys administered hydroxyprogesterone caproate up to 2.4 and 24 times the human dose equivalent based on a 60-kg human was not associated with adverse developmental outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

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Data: Animal Data Reproduction studies of hydroxyprogesterone caproate administered to various animal species have been reported in the literature. In nonhuman primates, embryolethality was reported in rhesus monkeys administered hydroxyprogesterone caproate up to 2.4 and 24 times the human dose equivalent, but not in cynomolgus monkeys administered hydroxyprogesterone caproate at doses up to 2.4 times the human dose equivalent, every 7 days between days 20 and 146 of gestation. There were no teratogenic effects in either strain of monkey.

Reproduction studies have been performed in mice and rats at doses up to 35 and 5, respectively, times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to hydroxyprogesterone caproate.

Lactation
Risk Summary: Low levels of progestins are present in human milk with the use of progestin-containing contraceptives. In nursing mothers, embryolethality was reported in rhesus monkeys administered hydroxyprogesterone caproate up to 2.4 and 24 times the human dose equivalent, but not in cynomolgus monkeys administered hydroxyprogesterone caproate at doses up to 2.4 times the human dose equivalent, every 7 days between days 20 and 146 of gestation. There were no teratogenic effects in either strain of monkey.

Reproduction studies have been performed in mice and rats at doses up to 35 and 5, respectively, times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to hydroxyprogesterone caproate.

Pediatric Use
Makena is not indicated for use in children under 16 years of age. Safety and effectiveness in patients less than 16 years of age have not been established. A small number of children ages 4 to 16 years were included in the clinical studies. The safety and efficacy of Makena in patients <16 years of age are unknown.

Hepatic Impairment
No studies have been conducted to examine the pharmacokinetics of Makena in patients with hepatic impairment. Makena is extensively metabolized and hepatic impairment may reduce the elimination of Makena.

Table 3 Adverse Reactions Occurring in ≥2% of Makena-Treated Subjects and at a Higher Rate than Control Subjects

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Makena N=310</th>
<th>Control N=153</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>34.8</td>
<td>32.7</td>
</tr>
<tr>
<td>Injection site swelling</td>
<td>17.1</td>
<td>7.8</td>
</tr>
<tr>
<td>Urticaria</td>
<td>12.3</td>
<td>11.1</td>
</tr>
<tr>
<td>Pruritus</td>
<td>7.7</td>
<td>5.9</td>
</tr>
<tr>
<td>Injection site pruritus</td>
<td>5.8</td>
<td>3.3</td>
</tr>
<tr>
<td>Nausea</td>
<td>5.8</td>
<td>4.6</td>
</tr>
<tr>
<td>Injection site nodule</td>
<td>4.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Table 1 Selected Fetal Complications

<table>
<thead>
<tr>
<th>Pregnancy Complication</th>
<th>Makena n/N</th>
<th>Control n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miscarriage (&lt;20 weeks)</td>
<td>5/209</td>
<td>0/107</td>
</tr>
<tr>
<td>Stillbirth (&gt;20 weeks)</td>
<td>6/305</td>
<td>2/153</td>
</tr>
</tbody>
</table>

Table 2 Selected Maternal Complications

<table>
<thead>
<tr>
<th>Pregnancy Complication</th>
<th>Makena N=310</th>
<th>Control N=153</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission for preterm labor</td>
<td>16.0</td>
<td>13.8</td>
</tr>
<tr>
<td>Preeclampsia or gestational hypertension</td>
<td>8.8</td>
<td>4.6</td>
</tr>
<tr>
<td>Gestational diabetes</td>
<td>5.6</td>
<td>4.6</td>
</tr>
<tr>
<td>Oligohydramnios</td>
<td>3.6</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Other than delivery admission

Common Adverse Reactions
The most common adverse reaction with intramuscular injection was injection site pain, which was reported after at least one injection by 34.8% of the Makena group and 32.7% of the control group. Table 3 lists adverse reactions that occurred in ≥2% of subjects and at a higher rate in the Makena group than in the control group.
of health data from a patient in one location to a provider in another location; and

Mobile health (mHealth), which includes healthcare and education supported by mobile devices such as tablets and cell phones.

Although there are some barriers to successfully implementing telehealth, it is generally regarded as a convenient and cost-effective way to provide subspecialty healthcare that is not available locally. This is true in obstetrics and gynecology. In obstetrics, telehealth can be used for both low-risk and high-risk pregnancies, and in gynecology, it is used for both routine and specialty examinations.5-8

Telehealth benefits and considerations

Healthcare in America is becoming too expensive for companies, individuals, and taxpayers. Technology offers the potential to offer increased access to care at a better value. In utilizing telehealth, the overall healthcare system benefits from lower costs, less travel, improved health outcomes, and reduced emergency room utilization.9 Although there are numerous benefits to telehealth, there are also many things to consider when beginning or expanding a telehealth program or clinic, including for obstetrics and/or gynecology (see box below).10

Telehealth in low-risk obstetrics

Although the definition varies, low-risk pregnancies are generally defined as those that can be expected to proceed without major complications. Low-risk pregnant women can benefit from telehealth through routine, at-home appointments with their prenatal providers. Traditionally, even low-risk pregnant patients are seen for numerous in-person obstetrical visits to monitor progress. However, some clinics are offering integrated models of care for these women to save in-person appointments for situations that truly warrant this type of visit, such as for fetal anatomy ultrasounds. Women participating in these virtual visits are given supplies to use at home and are educated regarding how to use the supplies. A typical virtual visit includes the pregnant woman utilizing home monitoring supplies to track measures such as fetal heart rate, maternal blood pressure, and fundal height.11 Pregnancy outcomes have proven to be similar between women who have traditional prenatal care and women who have telemedicine prenatal visits.5 In addition, these virtual visits are associated with time savings and lower visit-related costs for patients,12 something that is a benefit especially to rural patients who must otherwise often travel long distances for obstetrical appointments.

Setting goals/timeline: Identify goals for implementation, identify a method to measure progress, and set a timeline.

Knowing the law: Be sure to know state-specific and federal laws regarding telemedicine reimbursement and other relevant issues, such as patient documentation requirements and related storage.

Starting small: Find those who are willing to be telemedicine champions through their support, and start by focusing on a small project, such as a single pilot telemedicine program.

Developing a business plan: Determine the services that will be provided and rates of reimbursement for them.

Determining the services specific to your needs: Work with providers to whom you are referring patients for specialty services and use telemedicine to keep your patients local.

Staying connected: Find resources within your state or region to help you stay up to date. Telehealth networks can supply useful tools and information.

Considering security: Compliance with the Healthcare Insurance Portability and Accountability Act, network encryption, and other security precautions are important factors to consider when developing and expanding a telemedicine program.

Choosing your technology partner: Importantly, you must ensure that the technology being used is acceptable to a pay source as being reimbursable. They should otherwise also meet your needs and provide 24/7 support for optimum telemedicine program operability.
Telehealth in high-risk obstetrics

A pregnant patient at high risk will have current or prior conditions—such as high blood pressure, venous thromboembolism, psychiatric disorder, substance abuse, or family history of a genetic disorder—that may threaten the health or life of the mother or infant. Telehealth has helped bring forth improved outcomes for high-risk obstetrics, offering a cost-effective solution to treating patients who are either difficult to transport or have inaccessibility to reliable transportation, a barrier many rural patients face. Within the telemedicine model, rural practitioners will oversee care for high-risk obstetrical patients while receiving direction from a specialist via telemedicine consultation. High-risk prenatal visits take place through videoconferencing between the rural practitioner, the patient, and the specialist, with the specialist at the hub (distant) site and the patient and rural practitioner at the spoke (originating) site. Specialists are able to view ultrasounds and other examinations through the available technology, often in real-time. Home monitoring is also possible for certain high-risk conditions, helping to reduce potentially dangerous travel, identify issues before they threaten the health of the pregnancy, and reduce hospital admissions, when appropriate.

Maternal-fetal medicine (MFM) specialists are crucial to monitoring high-risk pregnancies, as they pursue additional years of training specifically for high-risk pregnancy after completion of their obstetrics-gynecology residency; however, these specialists are often in short supply, especially in rural areas. The Medical University of South Carolina (MUSC) Center for Telehealth, a “National Telehealth Center of Excellence,” operates the MUSC Health Maternal Fetal Telemedicine program at six locations throughout South Carolina to address a shortage of MFM providers and high rates of pregnancy conditions such as diabetes and hypertension within many areas of the state. As of 2010, over one-third of the state resided in a rural community and thus had a higher likelihood of restricted access to specialty care. According to MUSC, “the Maternal Fetal Telemedicine program enables a partnership between MUSC Health’s Maternal Fetal specialists and local providers to co-manage the care and screening of patients with high risk pregnancies and support all the necessary steps to achieve the best possible outcome.”

Work with providers to whom you are referring patients for specialty services and use telemedicine to keep your patients local.

Telemedicine has many benefits for both patients and ob/gyns in rural areas. Read more about the challenges of rural care and its effects on maternal mortality on PAGE 21.
The program has been credited with helping to reduce premature birth rates and both neonatal and maternal mortality rates. As many as 50 to 60 MFM telemedicine consultations are performed by MUSC every week, and the program is on call 24/7. MUSC additionally uses telemedicine to treat pregnant women addicted to opioids, a devastating epidemic.

The University of Arkansas for Medical Sciences (UAMS) also offers a high-risk obstetrical telemedicine program—the Antenatal and Neonatal Guidelines, Education, and Learning System (ANGELS)—to help combat rural health disparities. Arkansas is a largely rural state with medically underserved areas. It has few MFM specialists practicing outside of UAMS, which is located in one of the few urban areas of the state. Utilizing one of the largest telehealth networks in the nation, ANGELS extends the expertise of Arkansas’ few board-certified MFM specialists into the hands of Arkansas’ community providers and patients through telemedicine. This allows UAMS providers to plan interventions through a system of co-management with rural providers. ANGELS is supported by a 24/7 nurse-staffed call center that provides triage to patients and facilitates maternal transport to ensure high-risk patients deliver at neonatal intensive care unit-equipped hospitals.

In 2005, the Agency for Healthcare Research and Quality selected ANGELS as one of five Medicaid programs in the United States to serve as models of how to develop patient care and outreach programs. Other organizations use the ANGELS model by working with insurers (like Medicaid and other payors) to develop telemedicine interventions that bring specialty care to those that need it most but have the poorest access. For the UAMS high-risk obstetrical telemedicine program, management of a telemedicine patient consult reflects best practices for patient care (see Table 1).

### Telehealth in gynecology

Patients may benefit from telehealth visits for follow ups to in-person well-woman exams. These virtual visits allow ob/gyns to discuss lab results and needed patient lifestyle changes. In addition, family planning and preconception care can be delivered via telehealth for the patient’s convenience.

Colposcopy is a specialty exam that is offered through some telemedicine programs to patients who need further testing after an abnormal pap smear. On average, rural areas have fewer practitioners who specialize in colposcopy than urban areas, and fewer ob/gyns in general, so these telehealth services especially benefit rural residents. Diagnostic outcomes were similar for tele-colposcopy when compared with in-person exams.

### Common barriers to telehealth

While telehealth has proven to be an effective method of increasing access to specialty care, there are myriad legal and regulatory issues complicating its expansion. These are issues that affect every clinical application of telemedicine, including obstetrics and gynecology.

### Licensing and credentialing

Licensing and credentialing are essential in healthcare but present an especially difficult problem for telehealth providers. Overall, licensing is state-specific for all telemedicine healthcare providers. Moreover, telehealth providers must follow the credentialing rules of the patient’s location, but hospitals can agree to credential by proxy for physicians across state lines.

### WE WANT TO HEAR FROM YOU

Do you use telemedicine in your practice? Share with your colleagues what has worked and what hasn’t. Do you have concerns about the use of telemedicine in your practice or in the specialty? Or do you see the role of telemedicine expanding in the future? Email us your thoughts at COGeditorial@ubm.com.
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**INDICATIONS AND USAGE**

Balcoltra is a progestin/estrogen combination oral contraceptive (COC) indicated for use by females of reproductive potential to prevent pregnancy.

**IMPORTANT SAFETY INFORMATION**

**WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS**

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.

**CONTRAINDICATIONS**

Balcoltra is contraindicated in women with a high risk of arterial or venous thrombotic diseases, liver tumors (benign or malignant) or liver disease, undiagnosed abnormal uterine bleeding, during pregnancy, with breast cancer or other estrogen- or progestin-sensitive cancer (now or in the past), hypersensitivity to any of the components, or in women who are currently taking Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir (with or without dasabuvir).

**WARNINGS AND PRECAUTIONS**

- Discontinue Balcoltra if an arterial thrombotic event or venous thromboembolic event (VTE) occurs, and at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during prolonged immobilization. Balcoltra should not be started any earlier than 4 weeks after delivery, in women who are not breastfeeding. The use of COCs increases the risk of VTE. The risk of VTE is highest during the first year of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions. Use COCs with caution in women with cardiovascular disease risk factors.
- If jaundice occurs, treatment should be discontinued.
- Balcoltra should not be prescribed for women with uncontrolled hypertension or hypertension with vascular disease. An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. If Balcoltra is used in women with well-controlled hypertension, monitor blood pressure and stop treatment if blood pressure rises significantly.
- Women who are prediabetic or diabetic should be monitored while using Balcoltra. Alternate contraceptive methods should be considered for women with uncontrolled dyslipidemia.
- Patients using Balcoltra who have a significant change in headaches or who develop new headaches that are recurrent, persistent, or severe should be evaluated, and Balcoltra should be discontinued if indicated.
- Irregular bleeding and spotting sometimes occurs in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles on Balcoltra, check for causes such as pregnancy or malignancy.
- This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Sensitivity to tartrazine is frequently seen in patients who have aspirin hypersensitivity.

**ADVERSE REACTIONS**

In a clinical trial with levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg, the most common adverse reactions (incidence ≥ 2%) were headache (14%), metrorrhagia (8%), dysmenorrhea (7%), nausea (7%), abdominal pain (4%), breast pain (4%), emotional lability (3%), acne (3%), depression (2%), amenorrhea (2%), and vaginal moniliasis (2%).

**DRUG INTERACTIONS**

Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the effectiveness of COCs or increase breakthrough bleeding.

Patients should be counseled that COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Please see full Prescribing Information, including BOXED WARNING, for Balcoltra.

Balcoltra™ (levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg tablets and ferrous bisglycinate 36.5 mg tablets) for oral administration

Brief Summary of Prescribing Information

For additional information, refer to the full Prescribing Information.

INDICATIONS AND USAGE
Balcoltra is indicated for use by female reproductive potential to prevent pregnancy.

DOSEAGE AND ADMINISTRATION
Patients should take one tablet by mouth at the same time every day in the order directed on the blister pack.

CONTRAINDICATIONS
Balcoltra is contraindicated in individuals with:
- A history of arterial or venous thrombolic diseases, including in women who:
  - Have had a stroke or pulmonary embolism, now or in the past
  - Have inherited or acquired hypercoagulapathies
  - Have had cerebrovascular disease
  - Have had a thrombotic or hemorrhagic stroke
  - Have had a thrombogenic valvular or rhythm diseases of the heart
  - Have had uncontrolled hypertension
  - Have had diabetes mellitus or a vessel disease
  - Have headaches with focal neurological symptoms or have migraine headaches with:
  - Women over age 35 with any migraine headaches
  - Liver tumors or liver disease
  - Undiagnosed abnormal uterine bleeding
  - Pregnancy
  - Breast cancer or other estrogen- or progesterin-sensitive cancer or history of these cancer
  - Hypersensitivity of any of the components
- Co-administration with Hepatic C drug combinations containing ombitasvir/paritaprevir/ritonavir, or with or without dasabuvir

WARNINGS AND PRECAUTIONS
Thrombosis Disorders and Other Vascular Problems
Stop Balcoltra if an arterial or venous thromboembolic (VTE) event occurs, or if unexplained visual loss, proptosis, diplopia, papilledema or retinal vascular lesions occur. If possible, stop at least 4 weeks before undergoing a major surgical procedure or before some minor procedures known to have an elevated risk of VTE as well as during the following prolonged immobilization. Start no earlier than 4 weeks after delivery, in women who are not breastfeeding.

The use of COCs increases the risk of VTE, however, pregnancy increases the risk of VTE as much or more than the use of COCs. The risk of VTE increases with the length of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. The risk of thromboembolic disease due to COCs gradually disappears after use is discontinued. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes). This risk increases with age, particularly in women over 35 years of age who smoke. Use COCs with caution in women with cardiovascular disease risk factors.

Liver Disease
Do not use Balcoltra in women with liver disease, as acute viral hepatitis or severe (decompensated) cirrhosis of liver. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COCA causation has been excluded. Discontinue Balcoltra if jaundice or cholestasis develops. Balcoltra is contraindicated in women with benign and malignant liver tumors. Hepatic adenomas are associated with COC use. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with the Hepatitis C combination drug regimen that contains ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, ALT elevations occurred in > 5 times the upper limit of normal (ULN), including some cases greater than 20 times the ULN, were significantly more frequent in women using ethinyl estradiol-containing medications, such as COCs. Discontinue Balcoltra prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. Balcoltra can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

High Blood Pressure
Balcoltra is contraindicated in women with uncontrolled hypertension or hypertension with uncontrolled risk factors. If used in women with well-controlled hypertension, monitor blood pressure and stop Balcoltra if blood pressure rises significantly. An increase in blood pressure has been reported in women taking COCs, and this is another reason to carefully observe women who are breast-feeding. If the increase is not controlled within 3-4 weeks of use of COCs, blood pressure should be re-evaluated in order to determine if the hypertension is due to the COCs or some other cause.

Hepatitis C Treatment
During clinical trials with the Hepatitis C combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, the drug interaction between the contraceptive and COCs has been decreased when the two drug products were given 4 hours apart.

- Co-administration of atorvastatin or rosuvastatin and certain COCs containing EE increase AUC values for EE by approximately 20-25%.
- Ascorbic acid and acetaminophen may increase plasma EE concentrations, possibly by inhibition of conjugation.
- COCA inhibitors, such as itraconazole, verapamil, clofibrate, grapefruit juice, or ketoconazole may increase plasma hormone concentrations.

Safety and efficacy of Balcoltra have been established in women of reproductive age, efficacy is expected to be the same in post-menopausal women and is not indicated in this population.

Hepatic Impairment
The pharmacokinetics of Balcoltra has not been studied in women with severe hepatic impairment. The metabolism of Balcoltra may be metabolized in patients with hepatic impairment. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COCA causation has been excluded.

OVERDOSAGE
There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdose may cause withdrawal bleeding in females and nausea.

The FDA-approved product labeling can be found at www.balcoltra.com, or call 1-888-612-8466.

Used by: Avion Pharmaceuticals, LLC
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1-888-81-AVION (1-888-612-8466)

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Avion Pharmaceuticals, LLC
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1-888-81-AVION (1-888-612-8466) Rev. 0002 AV-524
Maternal death in rural America
Focusing on risks and seeking solutions

Women who give birth in rural areas face unique challenges because of geography but state-based data collection hampers efforts to understand and address the factors that place them at particular risk for morbidity and mortality.

by SHARON T. PHELAN, MD, AND LINDA MARIE WETZEL
Nationally, rural health care availability is under attack with closure of hospitals and lack of medical personnel in communities, as described by Dr. Lockwood in this month’s editorial on page 6. ACOG reports that in 2010, 49% of the nation’s counties lacked an obstetrician-gynecologist, leaving over 10 million women—or 8% of those in our country—without that service. The challenge is even greater when one looks at hospital-based obstetrical services (or lack of) and birth outcomes in rural communities. Clearly, the impact of closing a maternity ward in a rural hospital where the nearest obstetrical unit is 100 miles away would be very different than in an urban community with another center of care less than 10 miles away.

It is possible that pregnancy-associated deaths, rather than pregnancy-related deaths, may provide a unique window into the socioeconomic and cultural challenges faced by rural communities. Teasing out the possible differences, however, is not possible with our current system of state-collected data. State and national statistics, therefore, are inevitably dominated by the cause of maternal deaths in population centers simply due to sample size. To begin to address this problem, policy makers need to look at aggregate rural-based data to see if the causes of mortality and morbidity there are similar to those in urban settings and determine if interventions for urban patients can be applied to those in rural settings.

For example, maternal deaths from motor vehicle accidents may be more common in remote rural settings due to the long distances at high speeds that rural women travel on a regular basis to obtain care. In that setting, seat belt education may be more important than it would be in a metropolitan area. Postpartum hemorrhage (PPH) deaths may be more preventable if tranexamic acid and cryoprecipitate were available as well as six to eight units of total blood products in the hospital blood bank, together with streamlined procedures for obtaining those products in emergency situations. Or interventions in a rural setting may focus on early recognition of risk of PPH or active blood loss, basic stabilization techniques and prompt transport rather than a detailed mass transfusion protocol.

Data collection and analysis challenges
In addressing any health care disparity, accurate data are critical to identifying specific problems and tailoring interventions to address actual issues rather than issues “perceived” by “outsiders.” Because the absolute numbers of maternal deaths are small in rural states given their overall lower populations and birth rates, it is impossible for a single state to have numbers sufficient to accurately interpret data without aggregation of five or more years of information. With current published state reports, it is also impossible to aggregate data across states because they use different definitions and presentations for their aggregate state data. Until recently, that has stood in the way of accurate data collection and management across the nation.

Working toward solutions: ACOG maternal mortality task force
In 2017, to help address these challenges and better identify sources of health care disparities in rural settings, ACOG District VIII launched a Maternal Mortality Task Force. District VIII

FEWER THAN HALF
of rural women live within a 30-minute drive to a hospital with perinatal services.

Over 10% have a drive of 100 miles or more.

MATERNAL MORTALITY REVIEW INFORMATION APPLICATION
In 2015, a project called “Building U.S. Capacity to Review and Prevent Maternal Deaths” worked with the CDC and the AMCHP to unite the efforts of the different MMRCs and collect data on maternal deaths in formats that are both consistent and comparable. This platform is also known as “Maria”. Learn more about this project and the MARIA platform at http://mmria.org/
is uniquely situated to collect data on rural maternity care and deaths. District VIII is made up of 12 states as well as Guam, American Samoa, Alberta, British Columbia, and Central America. Those states alone make up over 50% of the land mass of the United States but only about 15% of the US population resides in those areas. Much of the population in the 12 states is concentrated in one or two urban settings (e.g., Alaska with Anchorage and Juno). Using data standards developed by the Centers for Disease Control (CDC) and the Association of Maternal and Child Health Programs (AMCHP) and employed by the national Maternal Mortality Review Information Application (or MMRIA) database, it is possible to capture information about the distance from the woman’s home to where she delivered as well as the level of maternity care available where the delivery occurred. The data collected also include details of a patient’s circumstances, building an extensive narrative that covers all aspects of her experience of pregnancy and then presenting those facts in standardized format for examination and analysis.

The ACOG District VIII Task Force hopes to be able to aggregate the data over the 12 states using the structure of the MMRIA database. Without specifying state or county, data will be combined across the region, using references of distance from hospitals and levels of care as the standard. That, in turn, will produce samples sizes large enough to allow examination of rural vs urban causes of death on an annual or biannual basis. This larger data pool would also allow for quicker identification of unique evolving issues (Hantavirus, suicides or motor vehicle accidents) and evaluation of intervention strategies. Because the 12 states have some of the largest populations of indigenous people, a detailed data collection of this type may also be of great assistance in documenting data for increased maternal morbidity and mortality associated with this particular group and guiding interventions.

To accomplish this ambitious goal, the sections in District VIII are working with their respective departments of health to enact legislation as needed to support MMRCs and to encourage and empower individual departments of health to provide their data through MMRIA to the CDC. As more states enter data into the CDC database, the task force will look at the reports, identify issues to address, identify already established interventions a state may have that can be exported to other states in the region and continue to educate our district providers as to steps they can take to decrease our unacceptable national maternal mortality statistics and disparities.

DR. PHelan is a member of the Contemporary OB/GYN editorial board. 
Linda Marie Wetzel is the executive editor for Contemporary OB/GYN magazine.

FOR REFERENCES VISIT contemporaryobgyn.net/RuralMothers

TO THIS YEAR’S INTERNS AND RESIDENTS... WELCOME TO CONTEMPORARY OB/GYN

As you begin your new year in women’s health we invite you to make Contemporary OB/GYN part of your regular reading. Taken from the pages of the Contemporary OB/GYN magazine, the newsletters offer ob/gyns at all stages of their careers:

- Peer-reviewed research on topics of interest in obstetrics and gynecology
- Commentary on ACOG practice bulletins
- Our “Legally Speaking” column that discusses recent cases and legal topics in detail
- Practice management information and guidelines
- Updates, information
- Links to editorials and commentary from Charles J Lockwood, MD, MHCM, editor-in-chief

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Subscribe to our online magazine at CONTEMPORARYOBGYN.NET/DIGITAL-EDITION
Title X: Raise your voice with women’s health organizations
Ob/gyns and other women’s health providers can help save Title X for their patients and their voices need to be heard on Capitol Hill. That was the clear message from speakers at a recent media event in Washington, DC.
Contemporaryobgyn.net/TitleX

How risky is extended tamoxifen?
While extended adjuvant tamoxifen therapy has been found to improve breast cancer-free survival rates in premenopausal women with estrogen-receptor positive breast cancer, new research suggests that may not be without risk.
Contemporaryobgyn.net/TamoxifenRisk

“Revealing the scope of rural OB unit closures”
This issue of Rural Horizons (published by the NRHA) examines the crisis in communities affected by the closure of rural maternal care facilities.
https://nrha.informz.net/informzdatasevice/onlineversion/ind/bWFpjbGluZ2luIzc3RhbmNlOQ9WQ9NzE5Ng3NSZzdWJzY3JpYmVyaQ9MTA4NTk4NA==

“Oxytocin may not be best for PPH prevention”
A meta-analysis from the Cochrane Collaboration shows that oxytocin may not be the best choice for prevention of postpartum hemorrhage, despite the current recommendation from the World Health Organization (WHO). Our Maternal Mortality Series Editor, Carolyn Zelop, provides commentary on the findings.
Contemporaryobgyn.net/oxytocin

To keep women from dying in childbirth, look to California
By bringing together key players — nurses, doctors, administrators and other officials — California has cut its rate of women dying in childbirth by more than half.

U.S. is the most dangerous place to give birth in the developed world.
According to the CDC, at least 700 women die every year from pregnancy or childbirth and 60% of childbirth-related deaths are preventable. NBC talks to a surviving spouse about his experience with his wife’s death.

Each month, Contemporary OB/GYN sorts through the enormous pile of published research, bulletins and releases to find the advances of most importance to clinicians.

BENCH TO BEDSIDE
YOUR MONTHLY MUST READS

JOURNAL ARTICLES AND REFERENCES
National Rural Health Association (NRHA)
The National Rural Health Association provides leadership on rural health issues through advocacy, communications, education and research.
https://www.ruralhealthweb.org/

UKOSS: UK Obstetric Surveillance System
UKOSS was created as a nationwide system to gather data on the epidemiology of uncommon pregnancy disorders. A PowerPoint introduction and a studies information collection example poster are included.
https://www.npeu.ox.ac.uk/ukoss
https://www.npeu.ox.ac.uk/downloads/files/ukoss/Introduction-to-UKOSS.ppt

The American Heart Association Get With the Guidelines
Guidelines from the AHA for treatment of stroke, heart failure and coronary artery disease. Includes guidelines and management tools, research links, and workshops and webinar info.
https://www.heart.org/en/professional/quality-improvement

MASS MEDIA UPDATES
Sale of controversial contraceptive implant to end
The manufacturer of a device for permanent birth control that reportedly causes serious adverse events has decided to cease selling it at the end of the year.
Contemporaryobgyn.net/ImplantSales

Are prenatal vitamin D levels tied to adverse pregnancy outcomes?
A recent study examining risk of gestational hypertension or preeclampsia in women with low levels of vitamin D produced findings which support the current World Health Organization (WHO) position on vitamin D.
Contemporaryobgyn.net/vitaminD

Oxytocin may not be best for PPH prevention
A meta-analysis from the Cochrane Collaboration shows that oxytocin may not be the best choice for prevention of postpartum hemorrhage, despite the current recommendation from the World Health Organization (WHO). Our Maternal Mortality Series Editor, Carolyn Zelop, provides commentary on the findings.
Contemporaryobgyn.net/oxytocin
How should states support pregnant teens?

A national poll suggests that most adults with children favor some type of state support for pregnant teens. But how strongly someone feels about that and whether the help comes with caveats may be influenced by the person’s gender.

The findings are from the C.S. Mott Children’s Hospital National Poll on Children’s Health. It was commissioned by the University of Michigan institution and conducted by GfK Custom Research, LLC.

For the research, a randomly selected, stratified group of 2,005 parents aged 18 and older were polled. The sample was from GfK’s web-enabled KnowledgePanel, which closely resembles the US population, and was weighted to reflect Census Bureau population figures. Administered in November 2017, the survey had a completion rate of 60% with a margin of error of ±2% to 4%.

Many of the poll respondents placed caveats on a pregnant teen’s receipt of state support. Requirements endorsed included attending prenatal visits (90%), taking parenting classes (85%), undergoing drug testing (85%), and finishing high school (78%). Seventy percent of adults felt that all four of those requirements should be met in order for a teen to receive the support.

When asked about the state providing medical care, 60% of adults said it should definitely be offered to pregnant teens and 69% said it should be offered to their babies. Women were more likely than men to believe the state should provide medical care, formula and baby supplies for pregnant teens. The authors of the survey report said that “this may reflect women’s empathy with their situation, or their recognition that in many cases, it is the teen mother – not the father - who pays the financial, emotional and social cost of having a baby.”

Regarding putting caveats around state support for pregnant teens, the researchers cautioned that “the consequence for non-compliance may have a negative impact on the health of the pregnant teen or her baby.” They urged a “thoughtful approach to implementing requirements.”

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Teen pregnancy, depression and the Internet

Internet addiction often is linked with depression but a new study suggests that there is a way to use the technology to help encourage teens with postpartum depression to get treatment. The findings were published in the *Archives of Women’s Mental Health*.

Supported by funding from the National Institute of Nursing Researcher, the study was led by a researcher from the University of Louisville. The aim was to determine whether an Internet-based depression intervention was effective in spurring adolescent mothers to get treatment for their depression.
The participants were a small group (n = 151) of adolescent mothers from Kentucky and data on their experiences were compared with outcomes in a control group (n = 138). All the women (97.1%) had given birth in the last year (average < 4 months prior) and were living with the infant. Eighty-nine percent were African American and 51.7% had less than a high school education; mean age was 18.2 years.

The intervention included vignettes, questions and answers, and resources. The video vignettes were of other adolescent mothers describing their experience with depression and how they successfully sought depression treatment. They were also shown a list of 10 questions commonly asked about postpartum depression and mental health treatment, including information about medication, counseling, and the range of feelings that teens may experience postpartum. Resources described were county and national resources for pregnant and parenting adolescent mothers including referrals for counseling services and suicide and child abuse prevention hotlines.

Before, immediately after, and two weeks after being exposed to the Internet intervention, the teens answered questions related to the theory of planned behavior (TPB) variables and depression treatment. (TPB predicts an individual’s intention to engage in a behavior at a specific time and place.) For the control group, data were collected in community organizations or home visits; those in the intervention group used a computer of their choice.

The authors found that those in the intervention group more often intended to seek treatment (P = 0.003) and actually receive treatment (P = 0.009) over time when compared with the control group. The intervention independently increased positive attitudes about treatment (B = 2.92, P = 0.018), beliefs of perceived control (B = 2.05, P = 0.021), intention to seek treatment (B = 4.19, P < 0.001), and actually receiving treatment (B = 5.02, P < 0.001). Being depressed (OR = 2.15, 95% CI 1.15-4.04, P = 0.005) and being exposed to the intervention (OR = 1.65, 95% CI 1.06-2.32, P = 0.012) increased the odds of seeking treatment. (Incidence of depression was 12.3% in the intervention group and 13.0% in the control group.) Unadjusted, a majority of those who intended to seek treatment (n = 26, 17.1%) actually did report receiving treatment (n = 22, 84.6%), which is strongly correlated (r = 0.86, P < 0.001).

Limitations of the study included use of self-report measures and unavailability of medical records to confirm participants’ reports of use of mental health services. Because the majority of the adolescent mothers found the Internet intervention acceptable, the authors said similar tools should be considered to promote the health of teens and their infants.

Research presented during the Pediatric Academic Society (PAS) 2018 Meeting suggests that when it comes to decision-making about hormone therapy (HT), transgender teens and their parents may have different views about preserving biologic fertility.

Included in the study, by researchers from Children’s Hospital of Philadelphia, were 66 youth and 52 parents who obtained medical care at a pediatric hospital-based clinic for transgender/gender non-conforming (T/GNC) between January 2017 and December 2017. Youth participants were mean age 16 and a majority (63%) of the participants were assigned female sex at birth. The mean age of the parents was 48. Both youth and parents completed an electronic 36-item survey with questions about their knowledge of fertility preservation (FP), desire to have biologic children, and other factors that might affect desire to pursue FP.

Only 20% of youth and 11.5% of parents found it important to have biologic offspring. For the youths, the importance of having biologic children was associated with perceiving it as something that was important to their parents (OR = 6.07; 9% CI, 1.28 – 28.7). Only 4.5% of youth agreed that they would be willing to delay HT; the importance of having biologic children was the most important predictor for these youth (OR = 6.76; 95% CI, 1.28 – 28.7).

For parents, the most important predictor for delaying HT was lack of information about whether that treatment definitely prevents biologic fertility (OR = 24.57, 95% CI, 3.9 – 154.15).
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Intrauterine devices (IUDs) are a highly effective form of long-acting reversible contraception and recommended by the American College of Obstetricians and Gynecologists but insertion can be associated with discomfort. In a new study, researchers from Pennsylvania sought to quantify the impact of the procedure on IUD satisfaction in younger women.

Patients in the study, which was published in *Obstetrics and Gynecology*, were aged 14 to 22. The results reflect data from three family planning clinics in Philadelphia.

For the multi-site, single-blind, sham-controlled randomized trial, the researchers sought women who had a levonorgestrel 13.5-mg IUD inserted between March 2015 and July 2016 at the clinics. Eligible participants were aged 14 to 22, nulliparous, not pregnant and English-speaking. Participants were randomly assigned through computer-generated allocation to block sizes of four to a 1% lidocaine paracervical or sham block. The patients were blinded about which treatment they received.

To measure satisfaction, participants were asked to respond to three items: overall satisfaction with the procedure, if they would recommend the IUD to a friend, and whether the associated discomfort with the IUD was worth it. Pain at IUD insertion was recorded using a 100-mm visual analog scale.

The study enrolled 95 women and 93 (97.9%) were included in the analysis. Of the participants, 45 (47.4%) were white and 34 (36.0%) were black. Sixty-four (67.4%) were privately insured and 75 (79%) had used contraception previously.

The majority (73 [76.8%]) reported high satisfaction with the procedure, 67 (67.4%) would recommend the device to a friend, and 79 (83.2%) perceived the IUD to be worth the discomfort. The median pain score reported immediately after insertion was 63.5 (IQR = ±53) though the lidocaine paracervical block group reported lower scores (less pain) compared to the sham block group (30.0±52 vs. 71.5±23.5, P<0.001). Higher pain scores were negatively correlated with the odds of recommending the device to a friend and perceiving the IUD as being worth the discomfort. However, there was no significant difference in likelihood of recommending IUD insertion to a friend between the lidocaine block group and the sham block group (91.5% vs 85.4%, P=0.45).

High overall satisfaction with the device had higher odds among young adults compared to adolescents (OR = 0.07, 95% CI, 0.008-0.68); those who had a gynecologic exam compared to those who had never had one (OR = 0.26, 95% CI, 0.07-0.99). Satisfaction scores were also inversely linked to pain scores and decreased as pain scores increased (OR = 0.96, 95% CI, 0.94-0.99). There were no differences between the lidocaine block group and the sham block group in terms of satisfaction (91.5% vs 91.7%, P=0.30).

While the study results show that most young women are satisfied with IUD insertion, the inverse relationship between that sentiment and young age, the authors said, suggests that delaying IUD insertion until patients are older may be beneficial.
Solosec™ (secnidazole) is the first and only bacterial vaginosis (BV) treatment designed to deliver a complete course of therapy in just one oral dose.1,2

To learn how Solosec may make it easy for patients to complete treatment, visit solosechcp.com/journal.

One Packet. One Dose. One Time.

INDICATION
SOLOSEC™ (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women.

SELECT IMPORTANT SAFETY INFORMATION
• SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.
• Vulvo-vaginal candidiasis may develop with SOLOSEC and require treatment with an antifungal agent.
• Potential risk of carcinogenicity in patients taking single-dose of SOLOSEC to treat bacterial vaginosis is unclear. Chronic use should be avoided.
• SOLOSEC is a single-dose therapy for oral use. The entire contents of SOLOSEC packet should be sprinkled onto applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules. SOLOSEC is not intended to be dissolved in any liquid.
• In clinical studies, the most common adverse events occurring in (≥2%) of patients receiving SOLOSEC 2g oral granules were vulvovaginal candidiasis (9.6%), headache (3.6%), nausea (3.6%), dysgeusia (3.4%), vomiting (2.5%), diarrhea (2.5%), abdominal pain (2.0%), and vulvovaginal pruritus (2.0%).

Please see Brief Summary of Prescribing Information on adjacent page.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.


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PP-SOL-0096
BRIEF SUMMARY OF PRESCRIBING INFORMATION

Rx Only

This Brief Summary does not include all the information needed to use SOLOSEC™ safely and effectively. See full Prescribing Information for SOLOSEC.

SOLOSEC (secnidazole) 2g oral granules

Single oral dose

Initial U.S. approval: 2017

INDICATIONS AND USAGE

SOLOSEC is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in adult women.

DOSED AND ADMINISTRATION

Administer a single 2-gm packet of granules once orally, without regard to the timing of meals. Sprinkle entire contents of packet onto yogurt, applesauce, or pudding and consume all of the mixture within 30 minutes without chewing or crunching the granules. A glass of water may be taken after the administration of SOLOSEC to aid in swallowing. SOLOSEC is not intended to be dissolved in any liquid.

CONTRAINdications

Hypersensitivity. SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.

WARNINGS AND PRECAUTIONS

Vulvovaginal Candidiasis. The use of SOLOSEC may result in vulvovaginal candidiasis and may require treatment with an antifungal agent.

Potential Risk for Carcinogenicity. Carcinogenicity has been seen in mice and rats treated chronically with nitroimidazole derivatives, which are structurally related to secnidazole. It is unclear if the positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of SOLOSEC to treat bacterial vaginosis. Avoid chronic use of SOLOSEC.

Drug Resistance. Prescribing SOLOSEC in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

Clinical Trials Experience. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates under widely varying conditions, adverse reaction rates observed in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described below reflect exposure to 589 patients, of whom 518 received a 2g dose of SOLOSEC. SOLOSEC was evaluated in 3 clinical trials of patients diagnosed with bacterial vaginosis: 2 placebo-controlled trials (Trial 1 n=215, Trial 2 n=189) and 1 uncontrolled safety trial (Trial 3 n=321). All patients received a single oral dose of study medication or placebo. Trial 1 evaluated a 1g (this dose is not approved) dose (n=71) and a 2g dose (n=72) of SOLOSEC. Trial 2 evaluated a 2g dose (n=125). The population was female, aged 15 to 54 years. Patients in the placebo-controlled trials were primarily Black or African American (54%) or Caucasian (41%). There were no deaths in the trials. Two patients in Trial 3 discontinued due to vulvovaginal candidiasis in the SOLOSEC-treated arm.

Most Common Adverse Reactions

Among 197 patients treated with a single 2g dose of SOLOSEC in the 2 placebo-controlled trials, Trial 1 and 2, adverse reactions were reported by approximately 29% of patients. Table 1 displays the most common adverse reactions (≥2% in SOLOSEC-treated patients) in these 2 trials.

Table 1: Adverse Reactions Occurring (≥2% SOLOSEC-Treated Patients) in the Pooled Placebo-Controlled Trials 1 and 2 in Adult Women with Bacterial Vaginosis

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>SOLOSEC N=197</th>
<th>Placebo N=136</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Vulvovaginal candidiasis</td>
<td>19 (9.6)</td>
<td>4 (2.9)</td>
</tr>
<tr>
<td>Headache</td>
<td>7 (3.6)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Nausea</td>
<td>7 (3.6)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5 (2.5)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>4 (2.0)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Vulvovaginal pruritus</td>
<td>4 (2.0)</td>
<td>2 (1.5)</td>
</tr>
</tbody>
</table>

Among the 321 patients in an uncontrolled trial, Trial 3, adverse reactions were reported in 30% of patients. Vulvovaginal candidiasis (8.4%), nausea (5.3%), vomiting (2.5%) and dysgeusia (3.4%) were the most common adverse reactions reported in this trial.

Postmarketing Experience. The following adverse reactions have been reported during use of other formulations of secnidazole 2g outside of the United States. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Reported adverse reactions were nausea, dysgeusia, abdominal pain, headache, and vomiting.

DRUG INTERACTIONS

Oral Contraceptives. There was no clinically significant drug interaction between secnidazole and the combination oral contraceptive, ethinyl estradiol plus norethindrone. SOLOSEC can be co-administered with combination oral contraceptives (eg, ethinyl estradiol plus norethindrone).

USE IN SPECIFIC POPULATIONS

Pregnancy. Limited available data with SOLOSEC use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. In animal reproduction studies, there were no adverse developmental outcomes when secnidazole was administered orally to pregnant rats and rabbits during organogenesis at doses up to 4 times the clinical dose.

Lactation. Breastfeeding is not recommended. Discontinue breastfeeding for 96 hours after administration of SOLOSEC.

Pediatric Use. The safety and effectiveness of SOLOSEC in pediatric patients below the age of 18 years have not been established.

Geriatric Use. Clinical studies with secnidazole did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Nitroimidazoles, which have similar chemical structures to secnidazole, have been associated with tumors affecting the liver, lungs, mammary, and lymphatic tissues in animals after lifetime exposures. It is unclear if these positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of secnidazole to treat bacterial vaginosis.

Secnidazole was positive in the bacterial reverse mutation assay, but was negative for the rat micronucleus test and mouse lymphoma test.

In a rat fertility study, females were dosed for 2 weeks prior to mating until Day 7 of gestation with males that were dosed for a minimum of 28 days before cohabitation. No parental toxicity or adverse effects on mating performance, estrous cycles, fertility or conception was observed at doses of up to the maximum tolerated dose (300 mg/kg/day, approximately 1.4 times the recommended dose based on AUC comparisons).

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

Manufactured for and Distributed by: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202

Based on 7179660 Issued 10/2017

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NP-SOL-0004
nagnostic testing due to the higher diagnostic yield.

**Testing for fetal infectious etiologies**
The woman’s history should be reviewed for symptoms suggestive of CMV infection, and exposure to potential sources of toxoplasmosis (e.g., outdoor cats, gardening, consumption of undercooked meat) and Zika virus should be assessed. A detailed travel history should be included in the evaluation. For women with a history of travel to any Zika-endemic area, testing according to the Centers for Disease Control and Prevention guidelines is recommended. Testing for CMV and toxoplasmosis is recommended when ventriculomegaly is detected, regardless of known exposure or symptoms. Testing can include maternal serology or polymerase chain reaction (PCR) on amniotic fluid. For women who decline amniocentesis, serum testing for CMV includes IgG and IgM, as does screening for toxoplasmosis.

**What is the role of fetal MRI?**
Fetal MRI can be useful in evaluation of ventriculomegaly because this modality can identify significant abnormalities not easily detected by ultrasound, such as cortical malformations and migrational abnormalities. The most common abnormality detected on MRI but missed on fetal ultrasound is agenesis of the corpus colossum. MRI may also be of benefit in assessing the extent of destructive injury in fetuses with known infection, hemorrhage, or ischemia, and when other

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**SUMMARY OF RECOMMENDATIONS**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>GRADE</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>We suggest that ventriculomegaly be characterized as mild (10–12 mm), moderate (13–15 mm), or severe (&gt; 15 mm) for the purposes of patient counseling, given that the chance of an adverse outcome and potential for other abnormalities are higher when the ventricles measure 13–15 mm vs 10–12 mm.</td>
</tr>
<tr>
<td>2</td>
<td>We recommend offering diagnostic testing (amniocentesis) with chromosomal microarray when mild ventriculomegaly is detected.</td>
</tr>
<tr>
<td>3</td>
<td>We recommend testing for CMV and toxoplasmosis when ventriculomegaly is detected, regardless of known exposure or symptoms.</td>
</tr>
<tr>
<td>4</td>
<td>We suggest that MRI be considered in cases of mild or moderate fetal ventriculomegaly when this modality and expert radiologic interpretation are available; MRI is likely to be of less value if the patient has had a detailed ultrasound performed by an individual with specific experience and expertise in sonographic imaging of the fetal brain.</td>
</tr>
<tr>
<td>5</td>
<td>We recommend that timing and mode of delivery be based on standard obstetric indications.</td>
</tr>
<tr>
<td>6</td>
<td>We recommend that with isolated mild ventriculomegaly of 10–12 mm, after a complete evaluation, women be counseled that the outcome is favorable, and the infant is likely to be normal.</td>
</tr>
<tr>
<td>7</td>
<td>We recommend that with isolated moderate ventriculomegaly of 13–15 mm, after a complete evaluation, women be counseled that the outcome is likely to be favorable but that there is an increased risk of neurodevelopmental disabilities.</td>
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</table>
sonographically evident CNS malformations, such as agenesis of the corpus callosum or Dandy-Walker malformation, are present.

MRI is most useful at > 22–24 weeks’ gestation, as milestones of CNS development become more evident with advancing gestation. The added value of MRI depends in part on the degree of ventricular dilation, as well as on the quality of the original ultrasound and whether a detailed neurosonography examination was performed by a provider with specific expertise. MRI can be considered in cases of mild or moderate fetal ventriculomegaly when this modality and expert radiologic interpretation are available. It is likely to be of less value if the patient had a detailed ultrasound exam performed by an individual with specific experience and expertise in sonographic imaging of the fetal brain.

Q What is the appropriate antenatal management of a pregnancy after mild to moderate ventriculomegaly is detected? Follow-up ultrasound after initial detection of fetal ventriculomegaly is helpful to assess progression, stability, or resolution. The optimal timing and frequency of follow-up ultrasound examinations in the setting of mild to moderate ventriculomegaly is dependent on the initial gestational age at diagnosis as well as other clinical factors.

Women should receive counseling from a health care provider with specific expertise in prenatal diagnosis and prognosis of fetal ventriculomegaly. They should be informed that the prognosis varies widely based on the exact findings of the complete prenatal and postnatal evaluation. If ventriculomegaly is progressive, consultation with a pediatric neurosurgeon may be useful, as some neonates may require postnatal surgical intervention, such as ventriculoperitoneal shunting. Overall, the likelihood of mild to moderate ventriculomegaly requiring surgical intervention after birth is low.

Q What is the optimal timing and mode of delivery for fetuses with ventriculomegaly? There is no evidence that preterm or cesarean delivery improves maternal or neonatal outcomes in the setting of mild to moderate ventriculomegaly. Timing and mode of delivery should therefore be based on standard obstetric indications. Given the potential for mild to moderate ventriculomegaly to be associated with long-term adverse neurodevelopmental outcomes, the primary pediatrician should be made aware of this prenatal finding.

Q What is the prognosis for infants with mild ventriculomegaly? The prognosis for infants with mild to moderate ventriculomegaly is widely variable and depends on presence or absence of structural or genetic abnormalities, fetal infection, and severity of ventricular dilation. After a complete evaluation, if the ventriculomegaly is mild and isolated, the outcome is most commonly normal. With isolated moderate ventriculomegaly of 13–15 mm, after a complete evaluation, the outcome is likely to be favorable, but there is an increased risk of neurodevelopmental disabilities. In the setting of mild to moderate ventriculomegaly with associated abnormalities, the prognosis primarily depends on the specific abnormality rather than the degree of ventricular dilation.

Progression is also a factor in outcomes. In cases in which ventriculomegaly progresses, the rate of adverse outcomes is reported to be as high as 44%, while outcomes are normal in > 90% of cases in which ventriculomegaly improves. In most cases, risk of recurrence of isolated ventriculomegaly in future pregnancies is low. In cases with an underlying cause, such as a chromosomal or genetic condition, risk of recurrence will depend on the specific diagnosis.

Agenesis of the corpus colossum is the most common abnormality diagnosed on MRI but missed on fetal ultrasound.

Antepartum fetal testing is not likely to be beneficial in the setting of mild to moderate ventriculomegaly, as this abnormality is not typically associated with placental insufficiency, unless other abnormalities such as fetal growth restriction or amniotic fluid abnormalities are present.
How do I approach working locum tenens?
How can I find the best assignment for me?
Who will pay for my malpractice?
Who can guide me through the process?
Who provides the best support?

The answer:
Weatherby Healthcare.

weatherbyhealthcare.com
Eight steps for successful telehealth **CONTINUED FROM PAGE 18**

### TABLE 1 UAMS obstetric telemedicine consult procedure for high-risk patients

<table>
<thead>
<tr>
<th>Communication</th>
<th>Teaching</th>
<th>Documentation</th>
<th>Follow-up appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Contact the MFM or ob/gyn that is conducting clinic to report that clinic is now starting.</td>
<td>• Discuss reason for consult.</td>
<td>• Complete a summary of the outside records prior to the consultation.</td>
<td>• Follow-up appointments should be obtained through the ANGELS appointment center.</td>
</tr>
<tr>
<td>• Inform the patient of what events will take place.</td>
<td>• Discuss significant history as it relates to pregnancy and recommendations as indicated.</td>
<td>• Review all available records, labs, ultrasound reports, pathology reports and request additional information if needed prior to the visit. Send the completed worksheet to team members as needed.</td>
<td>• Ensure that the patient is aware of follow-up visit appointment date, time and location.</td>
</tr>
<tr>
<td>• Communicate pertinent information and findings to covering physician.</td>
<td>• Discuss the management plan for pregnancy such as consultation as needed, co-management or transfer of care as indicated by the primary obstetric provider. i.e. We are seeing you today for a consultation due to chronic hypertension during pregnancy. Please keep your scheduled visit with your primary OB provider and we will provide recommendations for management to your provider.</td>
<td>• Document preliminary ultrasound findings and summary of visit in electronic medical record.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Upon completion of the consultation, ask the patient if she has any questions about the information she has received today. Discuss follow-up appointments and recommendations for the referring provider. In the event of a new or acute problem, call the referring provider and send a written summary of the consult.</td>
<td>• Route notes through electronic medical record to MFM or ob/gyn for review and updates for additional recommendations.</td>
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<tr>
<td></td>
<td>• Be prepared to give the MFM or ob/gyn a concise report on the patient such as reason for referral, age, Gravida and Para, estimated gestational age (EGA) by last menstrual period (LMP) and early ultrasound, medical and surgical history.</td>
<td>• Billing for visit is completed in electronic medical record under level of service.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inform the patient of her follow-up appointment. Emphasize the importance of follow-up and keeping the scheduled appointment.</td>
<td>• Inform referring provider of abnormal results or urgent recommendations and document appropriately with a telephone note in the electronic medical record.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Continually assess the patient’s behavioral response to the information provided and reiterate as necessary.</td>
<td>• Fax or email securely a summary of consultation through the electronic medical record to the referring provider.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Create a documentation note or letter in the electronic medical record to document patients that did not keep their scheduled appointment. Fax letters to referring providers through routing system.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Follow-up appointment should be obtained through the ANGELS appointment center.</td>
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</tbody>
</table>
health providers must follow the credentialing rules of the patient’s location. These issues act as barriers to practicing telehealth across state lines. However, hospitals can agree to credential and privilege by proxy for telemedicine services, which allows “the hospital receiving services to accept the distant site (where the telehealth provider is located) hospital’s credentialing and privileging decisions.”19 This would be done in a streamlined and simplified process in comparison to traditional credentialing and licensure, making it easier for providers to offer services across state lines.

**Malpractice insurer.** Before choosing a malpractice insurer, telemedicine providers should request proof in writing that the malpractice insurance policies cover telemedicine malpractice and that the coverage extends to other states in which the providers are practicing. Telemedicine providers also should check with malpractice insurers to see if there are limitations to telehealth services under the policy. Essentially, providers of telehealth must have total clarification from their insurance company concerning the nuances of telehealth to avoid complications.

**Reimbursement and billing.** Reimbursement and billing, too, pose a problem for many telehealth providers. In some states, such as Arkansas, telemedicine parity allows for many of these services to be reimbursed on the same basis as in-person services.20 But parity is not available in every state. Even if telemedicine parity laws are active within a state, telemedicine care can be complicated by reimbursement requirements that state rules such as the patient-physician relationship must first be established in person with a face-to-face visit before telemedicine treatment can begin.21 There are some restrictions to payment for services through telemedicine, as well: for example, Arkansas Medicaid will reimburse for up to two live video healthcare visits per patient yearly.20 There are also often limitations to services that can be provided through telemedicine, such as prescribing controlled substances. It is therefore important to be aware of state-specific telemedicine laws, especially as they change over time.

**Conclusion**

Despite telehealth’s barriers, it is an effective healthcare solution for many patients, especially those who are rural. Telehealth programs offer a cost-effective and convenient means to address for women’s obstetrical and gynecological health concerns, leading to improvements such as greater access to care and improved clinical outcomes such as reduced infant and maternal morbidity and mortality. By using best practices and applying lessons learned from telemedicine programs such as those at MUSC and UAMS, other medical institutions can implement successful obstetrical and gynecological telemedicine programs throughout the nation and world.

**DISCLOSURES**

The author reports no potential conflicts of interest with regard to this article.

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**TELEMEDICINE RESOURCES**

- Ob/gyns who are interested in starting a telemedicine practice or growing a practice through technical support, visit https://www.telehealthresourcecenter.org
- Academicians and innovators who want to learn more about how they can advance the field of telemedicine research, visit https://searchsociety.org
- Ob/gyns looking for information about telehealth reimbursement by state, visit http://ctel.org/expertise/reimbursement/
plaints of diffuse abdominal pain, tenderness, decreased bowel sounds, and guarding. On admission, her hemoglobin was 10, hematocrit was 29.9, platelets were 200, and white blood cell count was 11.2. An abdominal computed tomography (CT) scan was performed and the findings were compatible with intra peritoneal rupture of the uterus with free air and a hemoperitoneum seen. Following the CT, the plaintiff was seen by Dr. A at which time there was a discussion about the CT findings and the options of conservative management versus surgical intervention. Dr. A noted that she would proceed with a diagnostic laparoscopy and possible laparotomy. The risks of surgery were discussed.

Intraoperatively, a clot in the uterine fundus was removed, and a defect, approximately 2-3 cm in the uterine fundus and right side of the uterus, was identified. It was then decided to perform a laparotomy. The uterus was exteriorized and repaired. A 5- x 3-cm right ovarian cyst was also identified, and a cystectomy was done without any complications. The next day, Dr. A discussed with the patient that the perforation likely happened at the time her IUD was removed, the procedure extended it, and the area clotted, providing a tamponade. The risks of surgery were discussed.

The patient was informed that the perforation likely happened at the time her IUD was removed.

The patient was noted to be feeling and looking much better, and her abdomen was much less distended, soft, and non-tender, with positive bowel sounds.

The patient remained at Defendant Hospital three more days. Discharge instructions included a follow-up appointment with Dr. A on September 1, but the plaintiff never returned.

In November 2009, the plaintiff presented to Hospital B’s ED. She complained of vaginal bleeding for the past one year and then only delivering via cesarean. That evening, the patient complained of dizziness and difficulty passing gas, her abdomen was distended, and there was a tympanic note on percussion. The following morning, August 13, the patient’s abdomen was noted to be distended, tympanic, had mild bowel sounds, and there was no pain on pressure and neither guarding nor rebound. One unit of packed red blood cells was administered for symptomatic anemia. The next day a repeat abdominal/pelvic CT was performed which evidenced repair of the uterus, an ileus, and residual hemoperitoneum. There were no signs of perforation. By the morn-
Tobiotics for 14 days were prescribed. By January 19, she felt better but still complained of abdominal pain. She was informed that a hysterectomy would be the last alternative for management of her pain.

Ten days later, the plaintiff presented to the ED on referral from the gynecology clinic with complaints of abdominal pain 7/10 and vaginal bleeding. She described intermittent heavy vaginal bleeding and severe abdominal pain since the IUD removal in August 2009. She was admitted for pelvic inflammatory disease (PID) and IV antibiotics were started. She was given acetaminophen/oxycodone for the pain. She started. She was given acetaminophen/oxycodone for the pain. She expressed a desire for a hysterectomy, but the physicians recommended conservative treatment with antibiotics.

On February 2, the plaintiff plateaued on the antibiotics. She signed a consent form for a diagnostic laparoscopy, diagnostic hysteroscopy, possible lysis of adhesions, possible lysis of synchiae and other indicated surgical procedures. Risks of the procedures were explained.

The following day, laparoscopy revealed bowel and omental adhesions to the anterior mid-abdomen between the umbilicus and the pelvis. There were also adhesions of the bowel and omentum to the left lateral abdominal wall. The uterus was noted to be within normal limits with mild filmy adhesions to the adnexa. During enterolysis in the area of the left lateral abdominal wall, an incision was made into the peritoneum secondary to dense adhesions of peritoneum to the bowel. During the enterolysis, brisk bleeding was noted, suspected to be from the left epigastric artery. Due to poor visualization the decision was made to convert the procedure to an exploratory laparotomy. The plaintiff was discharged on February 6.

In April, the plaintiff presented to the ED with lower abdominal pain/cramping. She stated that the pain was similar to the pain she experienced in January but stronger. Despite her complaint of vaginal bleeding since March 25, she stated that the bleeding had now resolved. A CT scan of the abdomen and pelvis showed a small hiatal hernia; a tiny right hepatic dome hypodensity that most likely represented a cyst; and an up to 1.9-cm left ovarian cystic structure that most likely represented a physiologic cyst. The diagnosis was abdominal pain possibly related to recurrence of adhesions. The woman was discharged later that day.

On April 28, the plaintiff returned to the ED for complaints of vaginal bleeding for one day. She indicated that her last menstrual period (LMP) was on April 5, 2010. She was discharged with a diagnosis of vaginal bleeding.

Later that year, on December 14, the plaintiff complained of vaginal bleeding since December 3 and pelvic pain. Extended-cycle levonorgestrel and ethinyl estradiol tablets had been prescribed for chronic pelvic pain, but she had stopped taking the medication in November. The assessment was possible PID and chronic pelvic pain with no specific etiology of findings except for adhesions. Ceftriaxone and azithromycin were given. An extensive risk, alternative and benefit conversation was had with the plaintiff regarding a hysterectomy. She was to obtain a second opinion.

One week later, the woman complained of chronic pelvic pain and the physician noted that the “patient strangely desires [a] hysterectomy.” She was advised against a hysterectomy. She was treated for PID, but it was noted that PID was unlikely the cause of the chronic pain.

On January 4, 2011, the plaintiff still complained of pain and stated that the bleeding improved. She was admitted for IV antibiotics and again said she desired a hysterectomy. Pelvic ultrasound noted a right adnexal cystic lesion. The woman underwent a laparoscopic hysterectomy, left salpingectomy, and lysis of adhesions on January 10, 2011.

In July 2011, the plaintiff presented to the ER with complaints of right-sided abdominal pain with nausea and dysuria. The pain was 8/10 and morphine was given. She later reported abdominal pain in the right lower quadrant for the past three days, on and off, which became constant the night before. A CT scan of the abdomen and pelvis showed a 4.7-cm right ovarian cystic structure. Pelvic ultrasound showed a 4.1-cm hemorrhagic right ovarian cyst with a small amount of associated hemoperitoneum. The patient was discharged home with pain medication.

**Discovery**

The plaintiff alleged a failure to recognize the evidence of uterine perforation at the conclusion of the August 2009 procedure; that Dr. A failed to perform an ultrasound at the conclusion of the August
2009 procedure after the 900-mL fluid deficit was noted; that Dr. A discharged the plaintiff on August 10, 2009, without repairing the uterus; that Dr. A failed to timely repair the plaintiff’s uterus; that there was a failure to timely prescribe/administer antibiotics; a failure to timely perform surgery when the plaintiff was found to have a hemoperitoneum and blood in the abdomen; and that the failure to timely repair the plaintiff’s uterus resulted in the plaintiff having to undergo several surgeries including a hysterectomy. In particular, plaintiff asserted that her multiple surgeries, perforation, and hematoma bleeds resulted in massive adhesion formation, which contributed to her chronic, unremitting abdominal pain and discomfort.

The expert on behalf of the hospital felt that the attempt to remove the IUD in office was correct, however, when the attempt was unsuccessful, surgical removal was appropriate. She felt that the perforation was timely suspected/recognized due to the noted fluid deficit. Post-IUD removal, the defendants properly monitored vital signs for indication of a bleed and given that the plaintiff was clinically stable, it was appropriate for her to be discharged with instructions to return to the hospital if she experienced any pain or bleeding. Further, the expert felt that the plaintiff had a non-bleeding perforation that became symptomatic after discharge.

Trial
Plaintiff’s counsel argued that Dr. A discharged the plaintiff despite a suspicion of a perforation and that the discharge resulted in the plaintiff developing adhesions, which were the source of her continuing abdominal pain. Dr. A acknowledged that she suspected a perforation post-IUD removal, however, the monitoring post-procedure assured Dr. A that plaintiff was stable and could be discharged. The doctor also acknowledged that blood in the peritoneum could be an irritant and could result in formation of adhesions. Dr. A maintained that it was appropriate to monitor post-IUD removal even in light of a suspected perforation, given that the plaintiff was stable at discharge. In addition, the co-defendant reported that the patient had a number of conditions and procedures unrelated to the IUD removal that could have caused her adhesions.

Plaintiff’s expert testified on direct examination that Dr. A departed from accepted standards of care by discharging with a suspected perforation without further investigating the status of the perforation. The expert explained that the hysteroscope used for the IUD removal could have been reinserted and then used to repair the perforation. Had Dr. A taken those steps, per plaintiff’s expert, the plaintiff would not have suffered a continuous bleed resulting in a hemoperitoneum and formation of peritoneal adhesions. On cross, he was confronted with prior testimony from a case where he was a defendant and had suspected a uterine perforation and did not use a hysteroscope to investigate or repair a patient’s uterus. The doctor also acknowledged that prior abdominal surgery, a cesarean with a vertical scar, PID, Gardnerella vaginalis, and adenomyosis could all cause adhesions and that this plaintiff had all of those conditions. He acknowledged that one cannot distinguish between which adhesions cause pain and which will not.

The patient essentially testified that since her IUD removal, she had and continued to have abdominal pain. On cross, she acknowledged that over the past six to seven years despite presenting to Hospital B numerous additional times, she never complained of abdominal pain, did not seek treatment for her abdominal pain, did not request medication for her abdominal pain, and never saw a gastroenterologist or surgeon about her abdominal pain.

Verdict
Plaintiff’s counsel asked that the jury return an award of $2.6 million for past pain and suffering and $1.8 million for future pain and suffering. After two days of deliberations, the jury returned a unanimous verdict on behalf of the defendants.
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Was this uterine perforation properly managed?

Complications following IUD removal were the focus of this lawsuit.

Facts
In October 2007, the patient presented to a women’s health center, at which time an intrauterine device (IUD) was placed. In July 2009, the patient returned, requesting that the IUD be removed. On exam, the IUD thread was not seen and, as such, the removal could not be accomplished. Later that month, transvaginal ultrasonography (TVUS) showed that the device was in the uterine cavity, but part of the device appeared to have penetrated the myometrium posteriorly.

The plaintiff presented to Defendant Hospital emergency department (ED) in August 2009, with complaints of abdominal pain with foul-smelling discharge, vaginal spotting, and fever for three days. TVUS was performed and the IUD was again noted to have the distal end within the posterior myometrium. The IUD had not changed position since the patient’s prior TVUS in July. She was discharged from the ED with one dose of azithromycin and acetaminophen/oxycodeone and was scheduled for an appointment at the women’s health center the next morning.

The plaintiff presented to the women’s health center as scheduled and was seen by co-defendant, Dr. A. An IUD removal was scheduled for the following day.

On August 10, 2009, the patient returned to Defendant Hospital. Per the operative report, two attempts were made to remove the IUD with forceps and an IUD hook, but they were unsuccessful. Subsequently, a hysteroscope was introduced into the uterine cavity and normal saline was used to inflate it. The IUD strings were identified, and the device was removed. Of note, there was a 900-mL normal saline deficit noted at the end of the procedure and the operative report specifically indicates “suspicion for perforation given the deficit.”

Postoperatively, positive abdominal distention was noted, the abdomen was non-tender, and there was no vaginal bleeding. After transfer, the patient’s abdomen was still distended, semi-firm, and there was some vaginal bleeding. At 6 PM, the plaintiff’s hematocrit was 36.5 and her hemoglobin was 12.5. At 6:36 PM the woman was resting in bed and denied pain, shortness of breath, nausea or vomiting. Her abdomen was soft, non-tender, and there were positive bowel sounds. Dr. B noted that the plan was to discharge the patient home on ibuprofen and ciprofloxacin. At 7 PM, there was no vaginal bleeding, the plaintiff had not voided, her pain was 2/10, her oxygen was discontinued, and she was out of bed to a wheelchair. At 7:45 PM, she was discharged with instructions for activity as tolerated. Dr. B instructed the plaintiff to return to the hospital if she experienced fever, chills, abdominal pain, or weakness. An appointment was scheduled for later in August.

The following day the plaintiff returned to Defendant Hospital with com-

Andrew I Kaplan, Esq is a partner at Aaronson, Rappaport, Feinstein & Deutsch, LLP in New York City, specializing in medical malpractice defense and healthcare litigation. This case was handled by one of his partners.