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Chairman & CEO
West Virginia Mutual Insurance Company

 

# WVSMA Publications Committee Associate Editors



 

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Harpers Ferry, WV as seen from Maryland Heights.

## Peer-Reviewed Articles



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## Features



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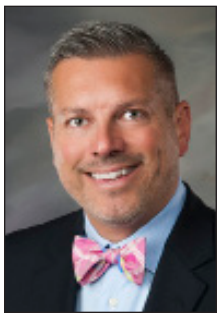
# President's Message



**Coy A. Flowers, MD, FACOG**
WVSMA President, 2018-2019

## WVSMA: diverse organization advocating for patients, public health, physicians

Several things strike me as I approach the end of my year as president of the West Virginia State Medical Association. We are a diverse organization. There hangs in the WVSMA headquarters in Charleston—a building of which we should all be proud—a photograph taken in 1887 at a West Virginia State Medical Association annual meeting. It is a bunch of old white men at The Greenbrier. We're still at The Greenbrier for our annual meeting—register now. Venue is where the similarity stops. We're an incredibly diverse organization of women and men of diverse nationalities and sexual orientations. Diversity empowers us to meet WVSMA's vision of serving as a unified voice for the practice of medicine and the premier authority for evidence-based health policy in West Virginia.

We're an **incredibly diverse organization** of women and men of diverse nationalities and sexual orientations.

Our 1887 colleagues were pillars in their communities who probably had the biggest houses in town and owned their local hospitals, as opposed to being hospital employees. At those hospitals, under the watchful eyes of physicians, were trained generations of registered nurses to provide patient care under the direction of physicians during routinely extended hospital stays.

While some of these gentlemen may have graduated from West Virginia University or other institutions of higher learning in the state, none of them finished medical school here. That training was unavailable. Students had to leave the state finish their medical educations. We are a state of 1.8 million people and now have three outstanding medical schools.

I'm in a unique position. I was born at St. Mary's in Huntington and grew up in the area. I went to medical school at West Virginia University and and serve as an adjunct professor at the West Virginia School of Osteopathic Medicine in Lewisburg. As an association, WVSMA has the unique opportunity to represent the needs of all West Virginia physicians. If you are currently a member—and you probably are if you're reading this column—take the time to discuss WVSMA membership advantages with a colleague. We continue to welcome our osteopathic colleagues. I'm proud Dr. Sherri Young, a graduate of the West Virginia School of Osteopathic Medicine, is succeeding me as WVSMA president.

While we represent the needs of physicians, it is also part of our mission to represent the needs of our patients and public health. We do this through our strong advocacy program. Physicians are warriors on the front lines of public health and witnesses to the effect of the government's actions on our patients' lives.

West Virginia State Medical Association is an everyday presence in state government. Few decisions regarding health care are made without our input. Lawmakers seek our counsel. We work closely with legislators and their staffs to achieve our goals.

West Virginians being protected from an international measles outbreak is a good example of achieving our advocacy goals. In Great Britain, where you would think the National Health Service would routinely ensure vaccinations, universities are being called upon to help give shots to hundreds of thousands of unvaccinated teenagers. Germany is fining parents who don't immunize their children $2,800.

New York, which is at the epicenter of the outbreak and still can't seem to get things under control even though Gov. Andrew Cuomo has said public health concerns should trump (no pun intended) religious exemptions, has routinely kept the unvaccinated out of school for two - three weeks at a time.

Oregon and Washington State are looking to eliminate non-medical exemptions.

All these states look to West Virginia when considering a successful program to require immunizations and provide medical exemptions when they are needed. West Virginia's strong immunization laws are intact because of the advocacy efforts of West Virginia State Medical Association and our partners.

Keeping intact our vaccination requirements is not easy. SB 459, which was introduced this year during the legislative session, saw no action. It was similar to SB 359, introduced the year before with a little more traction. The bills grant exemptions from mandatory or required vaccinations to school students, college and vocational students and employees of businesses requiring immunizations.

We must continue our vigilance to maintain our immunization laws. Physicians must stay involved! A study from the Pew Charitable Trusts points out little real interest exists in tightening vaccination requirements in states with vaccination laws much more lax than West Virginia's. Only through your support of WVSMA and our advocacy efforts can we continue our mission of protecting the public and our patients.

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And speaking of advocacy…

Advocacy is easier and more efficient with legislators sympathetic to our causes who have received WESPAC's endorsement. Elections are expensive. Your WESPAC contributions enable physicians to financially support candidates attuned to our needs. Contribute today.

Testify at the legislature. Physicians have extremely busy schedules, but take time to go to Charleston and testify about legislation where physicians have an interest. Take the time to meet with your delegates and senators. Legislators, many of whom don't care about all the issues presented to them, are always looking for experts. What better expert than their hometown physician?

***

Take time for yourself. I've been on my own self-care journey. I'm learning not to feel guilty when I say no. It's sometimes difficult. The day my son was born--14 years ago!--I doubled down working on issues greater than me and my everyday practice. I'm still working, to paraphrase Dr. Martin Luther King, to arc the moral universe to justice.

It's a long arc, and a difficult journey. As physicians and members of the West Virginia State Medical Association, we're everyday extending that arc making the state a healthier place to live and work.

While we represent the *needs of physicians*, it is also part of our mission to represent the *needs of our patients* and *public health*. We do this through our **strong advocacy program.** Physicians are **warriors on the front lines of public health** and **witnesses to the effect** of the government's actions on our patients' lives.

*R. Austin Wallace, MD*
*Chairman & CEO*
*West Virginia Mutual*
*Insurance Company*

# Peril in choosing a medical liability carrier based only on price

On several past occasions in these pages, I have stressed the peril of choosing a medical liability insurance carrier based only on price (i.e. lower premiums), almost to the point of seeming to be a broken record. We all know the history of medical malpractice insurance companies coming into our state and then becoming insolvent due to insufficient premiums (ICA and PIE, for example,) or beating feet out of here when the going got tough (St. Paul and CNA).

**We all know the history of medical malpractice insurance companies coming into our state.**

Indeed, because our hard-fought and hard-won medical liability civil justice reforms have worked well, competition has come into our state, which is certainly a healthy thing. However, some carriers have used a strategy of unsustainable low premiums in an effort to gain a foothold, and as I said on a number of occasions, if something is too good to be true, it probably is.

Indeed, my fears have come to fruition, as one such carrier, Capson, was been placed in rehabilitation earlier this year by the Texas Department of Insurance, its state of domicile. Unfortunately, some West Virginia physicians have been caught up in the chaos created by this action because they had previously decided to leave the Mutual and become insured by this company, sometimes even while knowing that the company's finances were in shambles.

As a former privately practicing Otolaryngologist, I certainly understand the desire to keep overhead as low as possible in our medical practices because of the increasing challenges in the business of medicine, but, as I have stated repeatedly, skimping on medical liability insurance is quite hazardous and has, indeed, proven to be quite detrimental to those affected in this case.

Now, previous Capson insureds are reportedly being encouraged to purchase medical liability insurance through an excess and surplus lines carrier. Again, **buyer beware**. Excess and surplus lines carriers are not admitted in the state of West Virginia, which means that these companies are not regulated by our state Insurance Commissioner and, therefore, are not subject to rate review. Furthermore, these companies' policyholders are not eligible to participate in the state guaranty fund, which protects an insured if the company becomes insolvent with a total of $300,000 of coverage. This is obviously significantly less coverage than the amount that would have been available in the policy had the company been able to continue in business, but it is certainly better than nothing (which is the case when insured by an excess and surplus line company.)

Furthermore, should a physician retire or move, most excess and surplus lines companies offer and charge for what turns out to be only limited tail coverage both in duration and amount, whereas admitted medical malpractice insurance carriers offer tails without time limits. Indeed, if a physician retires after having been insured by the Mutual for five years or longer, the tail coverage is without charge.

I obviously continue to believe that the West Virginia Mutual Insurance Company far and away offers the best option for your medical professional liability coverage in our state, even when our premiums may, by necessity, be a little bit higher than those of certain competitors, especially in view of what has happened as described above. Please be reassured that our rates are realistically and actuarially determined based on what is actually happening in our region, and if our experience is more beneficial than projected, as it was last year, then dividends will be given to our owners (you, our policyholders.) It should be great comfort to you that we have been and continue to be Physicians Insuring Physicians.

 

# WVU's Dr. Berry testifies before Senate Subcommittee

## Statement to the U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services and Education and Related Agencies Feb. 28, 2019

**James H. Berry, DO**
Director of Addictions,
West Virginia University

...My name is Dr. James H. Berry, and I am a physician from West Virginia University who specializes in treating addiction and mental illness. I have been invited by Sen. Shelley Moore Capito to share my experience and thoughts with you regarding our nation's addiction epidemic.

Having completed medical school in Michigan, I moved to West Virginia in 2002 to pursue residency training in psychiatry. At the time, I had no idea we were on the eve of an evolving opioid crisis and that West Virginia would prove to be the bellwether for the rest of the nation. Early in my tenure most of the patients seeking addiction treatment were doing so because of alcohol problems. Before long, patients began trickling in seeking help for addiction to opioid pain pills. In a relatively short amount of time, the trickle became a tsunami, and we became overwhelmed by the incredible demand to provide services for opioid use disorders. We quickly had to adapt and develop innovative strategies to expand access to and keep people in treatment.

Over the past decade and a half, we have treated thousands of these patients through our university-based treatment program and have learned much from them about the nature of addiction and the path forward. I would like to share with you a few observations.

First, and most importantly, addiction is a treatable condition. There are very few other areas of medicine where a health care provider can witness dramatic changes in a patient's health and well-being like that afforded in addiction treatment. The process can be slow and painful, but the rewards are unparalleled. People get their lives back. They become better parents. They finish school. They enter the workforce. They inspire others. Unfortunately, it is estimated that only 20 percent of the people who need addiction treatment ever receive it. We desperately need to expand access to evidence-based treatment.

Second, addiction is a multi-faceted problem that requires multi-faceted solutions. There is no silver bullet. Addiction has biologic, psychologic, social and spiritual manifestations. Genetics, environment and experience all play a part. Addiction is a mental disorder that is often present with other mental disorders such as anxiety and depression. There are incredibly high rates of traumatic experiences, such as sexual and physical abuse during childhood that lead to the development of addiction. None of this can be ignored, and the best treatment incorporates all elements. Medications proven to improve outcomes should be readily available, and barriers preventing widespread use should be removed. People should also have ready access to psychological therapies known to improve functioning and increase quality of life. We are creatures that thrive in community, and addiction is a very isolating condition. Supporting the use of peer support groups such as 12-step programs, are incredibly valuable in forming healthy connections that are reparative. In addition, we are creatures hungry for meaning and purpose. Involvement in faith-based and other purpose-driven community organizations foster healthy relationships in addition to supporting a drive to reach beyond one's illness.

Third, our addiction epidemic extends beyond opioids and is rapidly evolving.

The *trickle* became a **tsunami**, and we became **overwhelmed by the incredible demand** to provide services for opioid use disorders.

 

Opioids have captured our national attention and rightly so due to the staggering jolt of acute overdose deaths. However, please note that these deaths remain outpaced by the number of people who die every year from alcohol or tobacco-related causes. Furthermore, many of us in the addiction treatment and research community are preparing for a significant increase in cannabis-related health problems as states move to legalize and the public perception of harm diminishes. The epidemic continues to evolve as more and more people are using stimulants such as methamphetamines and incredibly lethal synthetic opioids such as fentanyl that account for the sharpest increase in overdose deaths over the past several years.

Finally, the epidemic will require long-term solutions. There is no quick fix. We now have two generations that are severely impacted. Turning this epidemic around will require strategic investment in mental health treatment and prevention resources to meet today's adult generation and the ballooning child and adolescent population at risk. We are woefully short of such personnel nationally and even more so in rural areas hardest hit by the epidemic such as Appalachia. Investment in much needed addiction training programs and incentives to encourage laborers to work in areas of greatest need are paramount...

There are very few other areas of medicine where a health care provider can *witness dramatic changes* in a patient's health and well-being like that afforded in addiction treatment.

# Reducing Narcotic Use After Cesarean Delivery with Enhanced Recovery

**Kevin D White MD, MEd**
**Shirin Azadi BS**
**Nadim Bou Zghieb MD**
**Brenda Mitchell, MD**

*Study was conducted at Cabell-Huntington Hospital in Huntington, West Virginia, and the Joan C Edwards School of Medicine at Marshall University in Huntington,*

## Disclosure

The authors report no conflicts of interest. The paper has not been published or presented elsewhere. We have no funding sources to disclose. We have no financial relationship with Pacira Pharmaceuticals, Inc., the manufacturer of Exparel ® liposomal bupivacaine. Pacira Pharmaceuticals, Inc. had no role on the study design of this project or in the analysis of the data.

Furthermore, Marshall University and its affiliated hospital, Cabell Huntington Hospital, have no financial relationship with Pacira Pharmaceuticals, Inc.

There are no sources of funding to disclose. We have no financial disclosures and no conflicts of interest.

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## Abstract

**Background:** Prescription drug abuse presents a major problem to society and can impact postoperative pain management. A substantial number of patients struggling with addiction started while undergoing treatment of acute pain. We aimed to reduce opioid use and pain scores after cesarean delivery with enhanced recovery.

**Methods:** We implemented a protocol using liposomal bupivacaine injected at the time of cesarean delivery. Patients were then given 500mg acetaminophen every 4 hours, 800mg ibuprofen every 8 hours and 5mg oxycodone every 6 hours as needed. Fifty patients were prospectively recruited and then compared to a randomly-selected retrospective sample of fifty patients from a 1-year period.

**Results:** Patients in the treatment group utilized 66% less opioids ($p<0.001$) with 28% not using any opioids ($p<0.001$) and reported 27% lower pain scores ($p<0.001$). 64% achieved a mean pain score ≤3 ($p<0.001$). Patients in the treatment group were 19 times more likely to decline all opioids and 6 times more likely to have a mean pain score of 3 to 4 or less. Hospital charges were equivocal between the groups.

**Conclusion:** Our enhanced recovery protocol is an effective alternative to traditional pain control and is associated with a significant reduction in both opioid use and pain scores without any significant increase in hospital costs.

## Introduction

Prescription drug abuse continues to plague the nation and complicate postoperative pain management. Nationally 4.4% of pregnant women reported using illicit drugs with 1% using opioids for non-medical purposes and 0.1% reporting using heroin within the last 30 days[1]. 2.6% of all women have positive urine drug screens on routine labor and delivery admission[1,2]. Although the treatment of acute postoperative pain rarely leads to opioid addiction[3], diversion of medications remains a concern[3]. Studies suggest that 55% of those that abuse prescription medications obtained these drugs from relatives or friends[4]. Many of these received the prescriptions directly from a physician while undergoing treatment of acute pain[4,5]. West Virginia is a high-risk area with one of the highest drug overdose rates in the country at 52.0 per 100,000 and rising[6]. Recently one study found that the prevalence of substance use, opioids, and alcohol etc, among pregnant patients may be as high 19 percent in West Virginia[7]. In the setting of these statistics, it seems prudent to evaluate postoperative opioid use. As cesarean delivery is one of the most common operations on reproductive-aged women at a rate of 31% of deliveries[8], it is necessary to reexamine post-cesarean pain management protocols.

Enhanced recovery after surgery (ERAS) protocols are a set of guidelines that are designed to facilitate a more rapid recovery after surgery. While specific ERAS protocols vary, generally they include multimodal pain control, local anesthesia, early feeding, early ambulation, and early catheter removal[9-15]. ERAS protocols have been shown to both decrease opioid use, improve pain control, and improve patient satisfaction[9-15]. An ERAS protocol using liposomal bupivacaine in

 

patients undergoing laparotomy for gynecologic oncology indications reduced postoperative day 0 opioid by almost 50% and day 2 use by 25%[9] when compared to traditional methods of pain control. Recently, one study that utilized liposomal bupivacaine found that using a multimodal approach to pain along with other enhanced recovery methods had no increase in adverse events and decreased the length of stay after cesarean delivery[10]. Liposomal bupivacaine is a lipid encapsulated formulation of bupivacaine that extends the therapeutic benefit by several days[16] and is indicated for injection into the operative site for postsurgical pain[16].

There is a paucity of data evaluating the efficacy of the current standard of care for post-cesarean pain management, and data evaluating liposomal bupivacaine is limited to the aforementioned study. We hypothesize that implementation of an ERAS protocol that utilizes liposomal bupivacaine at the time of surgery will decrease overall opioid use without any concomitant increase in pain scores for patients undergoing a cesarean delivery.

## Materials, Methods

We first conducted a retrospective analysis of the standard of care currently utilized. Currently, at our institution, patients who are scheduled to undergo cesarean delivery receive spinal anesthesia consisting of 13mg bupivacaine, 10mcg of fentanyl and 0.2mg morphine. No local anesthesia is injected into the operative site. After surgery, patients are allowed regular diet 1 hour after surgery. Postoperative pain is controlled with 5mg IV morphine every 4 hours as needed for pain, 800mg ibuprofen 8 hours PO and acetaminophen-oxycodone 5/325 or 10/325 every 4 hours PO as needed for pain. The catheter is removed after 12 to 24 hours and patient is allowed to ambulate 12 hours after surgery. The retrospective analysis included patients within given time period that met inclusion criteria.

This was then followed by a prospective implementation of the ERAS protocol that is based on a published protocol in the gynecologic oncology literature[16]. The protocol involves the same spinal anesthesia described above. After cesarean delivery and at time of skin closure 266mg (20mL) diluted into an additional 20mL of normal saline, liposomal bupivacaine is injected subcutaneously along the length of the incision. Patients may resume regular diet 1 hour after surgery. Postoperative pain is controlled by an abdominal binder, scheduled PO acetaminophen 500mg every 4 hours, scheduled 800mg ibuprofen PO every 8 hours, and oxycodone 5mg PO every 6 hours as needed for breakthrough pain. IV morphine may be given for severe breakthrough pain. In addition, patients are ambulated after 4 hours, and the catheter is removed when the patient can safely ambulate.

We then compared the prospectively collected post-implementation data (prospective ERAS group) to the retrospective pre-implementation data (retrospective control group). Patients were included in the retrospective analysis if they had a non-emergent cesarean delivery over a 1-year period at gestational age 34 weeks or greater at Cabell Huntington Hospital and age ≥18. Patients were included in the prospective recruitment if they were posted for a non-emergent cesarean delivery at gestational age 34 weeks or greater at Cabell Huntington Hospital in Huntington, WV and age ≥18. Patients were excluded if they were under age 18, gestational age at delivery <34 weeks, posted with emergent status of cesarean delivery, or were on buprenorphine maintenance therapy for opioid addiction. Positive urine drug screens were not used as exclusion criteria beyond those positive for buprenorphine in patients undergoing medication-assisted therapy for opioid addiction. Based on our retrospective data, a Mann-Whitney test showed to have 80% power with an alpha of 0.05 to detect an opioid reduction of 30% was 39 patients per group. For the retrospective portion of the analysis we randomly selected 50 eligible patients from delivery records over a 1-year period from May 1, 2016 to April 31, 2017 using a random number generator. With informed consent we recruited 50 subjects and implemented the ERAS protocol. During the recruitment process, no guarantees were made that the medication would improve pain control. We stated that it may or may not improve postoperative pain. Due to the very low risk with the use of liposomal bupivacaine and chance it may help with pain plus the fact that the patients were free to receive traditional pain medications at their choosing, the vast majority of patients consented to the study. Only 2 patients elected not to participate, 1 due to allergy concern and the other due to the concern of the use of animal/human products.

Medical records were retrospectively evaluated for the following data points: demographics, medical comorbidities, postoperative pain score, gravidity, parity, postoperative complications, length of stay (LOS), charges for routine postoperative care, type and dose of opioid administered during hospitalization. Patient divulged or denial of personal history of illicit drug use was not included in the data collection due to concerns for inaccuracy. Urine drug screens were collected

as part of routine patient care. Postoperative drug administration started at the time the patient left the operative suite as documented by the circulating nurse. Standard opioid dose calculators were utilized to convert all opioid class medications to oral morphine equivalents[18,19]. Conversion from the given opioid to oral morphine used the follow ratios: IV morphine 1:3 and oxycodone 1:1.5.

The primary outcome was morphine total equivalents administered during their postoperative course. Secondary outcomes included median pain scores on day of surgery and postoperative days 1, 2 and 3. Pain scores were recorded by nurses for the documentation of routine postoperative care on a Likert scale of 0 to 10, using whole numbers, with 0 being no pain and 10 being severe pain. Whether or not the patient met the mean pain score of 3 or less, which is the goal at our institution, or 4 or less which may be used by some institutions. Other secondary outcomes included length of stay, pharmacy and hospital charges as well as nausea and vomiting requiring anti-emetics. Postoperative charges included any local anesthetic placed intraoperatively and all charges for postoperatively administered medications that were directly related to the treatment of postoperative pain, nausea and vomiting. Charges were used as a proxy for costs. This was done primarily because room and board costs are difficult, if not impossible, to quantify with any precision.

All participants were given a unique identifier with the master code kept on a secure password-protected computer. The Fisher Exact test and the Mann-Whitney U test was used to compare the retrospectively collected pre-implementation to the prospectively collected post-implementation non-opioid patients. All analyses were conducted using SPSS version 25. Due to the nature of the implemented ERAS protocol, patients, staff, and providers were not blinded. All data recorded were recorded as part of their routine postpartum documentation. Research staff did not interact with the patient after informed consent, beyond routine obstetric and postoperative care. The Institutional Review Board approved the study protocol and found it exempt from full review based on the low risk to the research subjects. Informed consent was waived for the retrospective arm. The authors have no financial disclosures.

## Results

Fifty patients' medical records were randomly selected for inclusion into the control group. 63 prospective patients were recruited for possible inclusion into the ERAS group. 11 of these were excluded due to their participation in an opioid addiction recovery program that utilizes buprenorphine. These 11 were instead included on a separate parallel study[20]. The other 2 declined participation for the aforementioned reasons. The remaining 50 patients were included into the ERAS group. Overall mean age was 27.4 years with a range of 18-43 years and a standard deviation of 5.6 years. Mean BMI was 35.3 kg/m2 with a range of 22-63 kg/m2 and a standard deviation of 8.1 kg/m2. BMI was similar in both groups. Medical comorbidities and surgical characteristics were similar between the groups as well. There was no significant difference in the distribution of intraoperative anesthetics. Two patients in the ERAS group had general anesthesia due to a medical contraindication to spinal anesthesia. 8% of patients in both groups had incidentally positive urine drug screens. Urine drug screens were positive for opioids in 2% of the control group and 4% of the ERAS group, however this was not statistically significant (p=0.34). The remaining 6% in the control group and 4% in the ERAS group were positive for other controlled substances, most commonly marijuana. There were more deliveries at less than 36 weeks in the ERAS group (18% versus 4%, p<0.05), which require NICU admission for prematurity at our institution and subsequently there were more NICU admissions in the ERAS group than the control group at 30% versus 10% (p<0.05).

As outlined in table 2, patients in the ERAS group used 64% less opioid on the day of surgery (6.3mg versus 17.4mg, p<0.0001), 65% less opioid on postoperative day 1 (14.7mg versus 42.2mg, p<0.0001) and 62% less on postoperative day 2 (15.1mg versus 38.9mg, p<0.0001). Since a majority of patients were discharged at the end of postoperative day 2, we analyzed postoperative day 2 opioid totals. Patients in the ERAS group used 63% less opioid (36.0mg versus 98.5mg, P<0.0001) by the end of postoperative day 2. For those that stayed for postoperative day 3, ERAS patients used 60% less opioid (11.1mg versus 27.5mg, p<0.0001). Overall, ERAS patients used 66% less opioid (39.6mg versus 115.2mg, p<0.0001). A greater proportion of ERAS subjects declined all postoperative opioids (28% versus 2%, p<0.001), despite their availability per protocol.

Overall reported median pain scores were 27% lower in the ERAS group at 3.3 versus 4.1 (p=0.001), as shown on table 3. 90% of those in the ERAS group versus 60% of those in the control group achieved the stated pain goal of a mean pain score of 4 or less (p<0.001). 64% of those in the ERAS group versus 22% of the control group achieved

 

our institution's goal of a mean pain score of 3 or less (p<0.0001). ERAS subjects were less likely to experience one or more days with ineffective pain control as defined as a median score greater than 5 (24% versus 50%, p<0.01). Patients were also less likely to report persistent ineffective pain control, as a lower proportion of ERAS subjects reported an overall median score of greater than 5 (2% versus 16%, p<0.05).

When considering all patients, including those with infants admitted to the NICU and the newborn nursery, there was no statistical difference in the day 2 discharge rate as shown on table 4. However, when considering those whose infants were in the newborn nursery and thus eligible for day 2 discharge, the day 2 discharge rate was higher in the ERAS group at 77% versus 51% (p<0.05). There was no difference in the amount of nausea and vomiting that required a breakthrough antiemetic. Pharmacy charges were increased by $714 (p<0.0001) in the ERAS group. However, when considering the savings from a higher discharge rate there was no difference in overall charges. Overall charges include room and board charges for both mother and infant (at newborn nursery rates) and pharmacy charges. When considering those with infants in the newborn nursery the savings was $206, however this did not reach statistical significance.

Table 5 outlines the outcome odds ratios as well as the number needed to treat for the statistically different measures outlined on tables 2 and 3. ERAS patients were 19.1 times more likely to decline all opioids with a number needed to treat of 3.8. ERAS patients were 6.3 and 6.0 times more likely to reach the pain goals of 4 or lower and 3 or lower, respectively. Patients who were in the ERAS group and had an infant in the newborn nursery were 3.2 times more likely to elect discharge on postoperative day 2.

None of the patients abandoned the protocol to return to traditional pain control methods. With regard to the liposomal bupivacaine, none of the patients reported allergy, wound infection, injection site reaction or any other complications. We did not have any adverse events such as urinary retention and no falls, despite early ambulation and early catheter removal. All patients completed the study as no patients withdrew consent.

## Discussion

Our data show that the use of liposomal bupivacaine with scheduled acetaminophen and oxycodone as needed was associated with a significant reduction in overall opioid use. Similar results have been shown in gynecologic oncology literature[12-14] and in the obstetric literature[9]. Our study is the first study to demonstrate 66% reduction in overall opioid use. Furthermore, patients in the ERAS group were 19 times more likely to not take any opioids. This protocol was also associated with a 27% reduction in overall pain scores. Therefore, patients enrolled in the study were about 6 times more likely to meet stated pain goals of pain scores 3 - 4 or lower. Patients were also less likely to report poorly controlled pain as defined as a score of 5 or greater. Given the cost of liposomal bupivacaine, it is not surprising that pharmacy charges were higher in the ERAS group, yet the protocol was not associated with an increase in total hospital charges. This is likely due to the fact that patients in the ERAS group were 3 times more likely to elect discharge on postoperative day 2.

This study has many strengths: a unique population that is obese (78-80 percent), high smoking (32-40 percent) and in an area highly addicted to opioids. 4 of the 50 included patients plus the 11 patients that were excluded from this study, but placed in a parallel study[20], had positive urine drug screens. Which means that 18 percent of the recruited patients had positive urine drug screen, which matches the 19 percent previously published prevalence of substance use among pregnant women in West Virginia[7]. This study is among the first that evaluates the safety of liposomal bupivacaine after cesarean delivery. This study was not designed to evaluate the efficacy of liposomal bupivacaine in and of itself, rather it evaluates the efficacy of an enhanced recovery after surgery protocol that utilizes it. While certainly differences in dosage of the oxycodone 10mg versus 5mg and differences in opioid dosage intervals (4 hours versus 6 hours) may artificially lower opioid utilization, it would not fully explain the 66% reduction observed and would not account for the 28% of patients who declined all opioids. Furthermore, if opioid use were artificially lowered to a substantial degree, we would expect to see a concomitant increase in pain scores, rather we observed a 27% reduction in pain scores as well as fewer patients reporting uncontrolled pain. A higher NICU admission rate was identified in the ERAS group of the non-opioid addicted patient. This is an artifact from non-randomization as there were higher mandatory NICU admissions for prematurity in the ERAS group and all interventions occurred after delivery of the neonate. This could have potentially confounded the results as patients may be visiting their child in the NICU thereby not being on the ward to take opioids or experiencing additional stress and thereby increase pain and opioids. If opioids were artificially lowered due to unavailability of the patient to the nursing due

to visitation of the newborn, we believe it to be minimal and certainly not account for results observed. In addition, if pain were poorly controlled due to patients not being present to receive opioids, we would expect an increase in pain scores as these were recorded as soon as patients were available. This however, was not observed. Although not statistically significant, more patients in the ERAS group received epidural or general anesthesia. Those that received general anesthesia did so because of a medical contraindication to spinal anesthesia. If this confounded the results in any way, we believe that it would have artificially increased pain scores and opioid use and increase the probability of type 2 error.

Our study design is an ambispective study containing both a retrospective, before intervention, and a prospective, after intervention, component. Given the nature of our interventions, blinding was not possible. To avoid artificially lowering pain scores in the study as it was designed, we were careful in our language when describing our study while obtaining informed consent. We specifically stated that the use of liposomal bupivacaine has not be studied after cesarean deliveries and it may or may not help with postoperative pain. Patients were also told that they may withdraw consent from the ERAS protocol and receive the traditional pain medications, however once the liposomal bupivacaine was injected that could not be undone. To further avoid bias, we did not interact with the patient on the postpartum ward beyond clinical indications. We acknowledge, however, that no amount of precaution could conclusively remove bias from the mere mentioning of opioid use and postoperative pain control discussed during the informed consent process. However, this possible confounding would not in and of itself account for a 66% reduction in opioid use. If this potential confounder artificially lowered opioid use, we would expect a concomitant increase in pain scores, rather we observed a 27% reduction in pain scores. Nurses recorded pain scores in the same manner done for all patients. To avoid artificially lowering opioid use, patients had similar quantities of opioids available to them.

Our population is vastly Caucasian, with insufficient minorities to draw any meaningful statistical conclusion regarding minorities. Our study was done with a relatively small sample (n=100) however this is consistent with the studies currently done in this area of reasearch[12-15]. This study was not designed to conduct cost-analysis of the protocol. Charges were analyzed in this study to highlight that the cost of liposomal bupivacaine could potentially be offset by savings in earlier discharge and reduced use of other medications. Patients who underwent surgery earlier in the day would logically have a longer postoperative day 0 and thus use more opioids; however, this discrepancy would have a limited impact as an additional few hours of postoperative time would not account for the significant difference seen between the groups.

## Conclusion

An ERAS protocol including liposomal bupivacaine with an abdominal binder, scheduled acetaminophen and ibuprofen along with oxycodone as needed for breakthrough pain is a safe alternative to traditional methods after non-emergent cesarean delivery after 34 weeks. Our protocol was associated with a 66 percent reduction in opioid use and significant reduction in pain scores. This study shows the promise of enhanced recovery protocols in reducing both opioid use and pain postoperatively.

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**Table 1. Demographic and Surgical Characteristics (n=100)**

| Characteristic | Control (n=50) | ERAS (n=50) | p Value |
|---|---|---|---|
| Demographic | | | |
| Age(y) | 27.1 (25.7-28.6) | 28.0 (26.3-29.7) | 0.88‡ |
| BMI (kg/m2) | 35.1 (32.8-37.4) | 36.1 (34.0-38.2) | 0.74‡ |
| Normal or overweight | 10 (20) | 11 (22) | 0.72§ |
| Class I and II obesity | 29 (58) | 25 (50) | |
| Morbid Obesity | 11 (22) | 14 (28) | |
| Smoking | | | 0.68§ |
| Never | 34 (68) | 30 (60) | |
| Former | 3 (6) | 4 (8) | |
| Current | 13 (26) | 16 (32) | |
| Comorbidities | | | |
| Hypertension | 11 (22) | 17 (34) | 0.35§ |
| GHTN, Preeclampsia | 5 (10) | 10 (20) | |
| CHTN | 6 (12) | 7 (14) | |
| Diabetes Mellitus | 6 (12) | 6 (12) | >0.99§ |
| Pre-pregnancy | 4 (8) | 3 (6) | |
| Gestational | 2 (4) | 3 (6) | |
| Surgical Characteristics | | | |
| EGA at time of delivery | 384/7 (382/7-390/7) | 376/7 (372/7-383/7) | 0.23‡ |
| Primary Cesarean Delivery | 13 (26) | 15 (30) | 0.83§ |
| Indication | | | 0.19§ |
| Repeat | 37 (74) | 35 (70) | |
| Malpresentation | 2 (4) | 1 (2) | |
| Obstructed Labor | 9 (18) | 6 (12) | |
| Fetal Intolerance | 2 (4) | 8 (16) | |

| | | | | |
|---|---|---|---|---|
| Anesthesia | | | 0.24§ | |
| Spinal | 47 (94) | 42 (84) | | |
| Epidural | 3 (6) | 6 (12) | | |
| General | 0 (0) | 2 (4) | | |
| Tubal Ligation | 16 (32) | 17 (34) | >0.99§ | Birth |
| Weight (g) | 3340 (3213-3467) | 3299 (3093-3506) | 0.63‡ | |
| EBL (mL) | 655 (615-695) | 656 (607-705) | 0.88‡ | |

Data are mean (95% CI) cohort or n (%)

‡ Mann-Whitney U Test

§ Fisher Exact

GHTN = Gestational hypertension

CHTN = Chronic hypertension or chronic hypertension with superimposed preeclampsia

As outlined in table 2, patients in the ERAS group used 64% less opioid on the day of surgery (6.3mg versus 17.4mg, p<0.0001), 65% less opioid on postoperative day 1 (14.7mg versus 42.2mg, p<0.0001) and 62% less on postoperative day 2 (15.1mg versus 38.9mg, p<0.0001). Since a majority of patients were discharged at the end of postoperative day 2, we analyzed postoperative day 2 opioid totals. Patients in the ERAS group used 63% less opioid (36.0mg versus 98.5mg, P<0.0001) by the end of postoperative day 2. For those that stayed for postoperative day 3, ERAS patients used 60% less opioid (11.1mg versus 27.5mg, p<0.0001). Overall, ERAS patients used

**Table 2. Primary Outcome - Opioid Use (n=100)**

| Characteristic | Control (n=50) | ERAS (n=50) | Change | p Value |
|---|---|---|---|---|
| Opioid Use | | | | |
| Opioid Use (mg PO Morphine) | | | | |
| Day 0 | 17.4 (13.4-21.4) | 6.3 (3.5-9.0) | - 64% | <0.0001‡ |
| Day 1 | 42.2 (36.2-48.2) | 14.7 (9.9-19.4) | - 65% | <0.0001‡ |
| Day 2 | 38.9 (32.4-45.4) | 15.1 (10.8-19.3) | - 62% | <0.0001‡ |
| Total by Day 2 | 98.5 (86.2-110.7) | 36.0 (25.6-46.4) | - 63% | <0.0001‡ |
| Day 3 | 27.5 (22.0-33.0) | 11.1 (9.1-13.1) | - 60% | <0.0001‡ |
| Total | 115.2 (100.4-130.6) | 39.6 (27.5-54.5) | - 66% | <0.0001‡ |
| Declined All Opioids | 1 (2) | 14 (28) | | 0.0002§ |

Data are mean (95% CI) or n (%)
‡ Mann-Whitney U Test
§ Fisher Exact

Overall reported median pain scores were 27% lower in the ERAS group at 3.3 versus 4.1 (p=0.001), as shown on table 3. 90% of those in the ERAS group versus 60% of those in the control group achieved the stated pain goal of a mean pain score of 4 or less (p<0.001). 64% of those in the ERAS group versus 22% of the control group achieved our institution's goal of a mean pain score of 3 or less (p<0.0001). ERAS subjects were less likely to experience one or more days with ineffective pain control as defined as a median score greater than 5 (24% versus 50%, p<0.01). Patients were also less likely to report persistent ineffective pain control, as a lower proportion of ERAS subjects reported an overall median score of greater than 5 (2% versus 16%, p<0.05).

 

**Table 3. Secondary Outcome – Pain Control(n=100)**

| Characteristic | Control (n=50) | ERAS (n=50) | p Value |
|---|---|---|---|
| Markers of Effective Pain Control | | | |
| Pain Score | | | |
| Day 0 | 4.0 (2.6 – 5.4) | 2.5 (0.2 – 4.8) | <0.001‡ |
| Day 1 | 3.8 (3.0 – 4.7) | 4.0 (3.4 – 4.6) | 0.035‡ |
| Day 2 | 4.1 (3.5 – 4.7) | 3.8 (3.1 – 4.4) | 0.011‡ |
| Day 3 | 4.8 (4.1 – 5.5) | 3.0 (2.1 – 3.9) | 0.023‡ |
| Overall | 4.1 (3.5 – 4.8) | 3.3 (2.6 – 4.0) | 0.001‡ |
| Achieved Pain Goal (≤3) | 11 (22) | 32 (64) | <0.0001§ |
| Achieved Pain Goal (≤4) | 30 (60) | 45 (90) | 0.0005§ |
| Markers of Ineffective Pain Control | | | |
| Patients who had one or more individual day(s) with a median pain score of: | | | |
| 5 or greater | 25 (50) | 12 (24) | 0.01§ |
| 6 or greater | 8 (16) | 2 (4) | 0.05§ |
| 7 or greater | 3 (6) | 0 (0) | 0.12§ |
| Patients reporting persistent pain with an overall median pain score of: | | | |
| 5 or greater | 8 (16) | 1 (2) | 0.03§ |
| 6 or greater | 3 (6) | 0 (0) | 0.24§ |
| 7 or greater | 1 (2) | 0 (0) | >0.99§ |

Data are median (Interquartile Range) or n (%)
‡ Mann-Whitney U Test
§ Fisher Exact

When considering all patients, including those with infants admitted to the NICU and the newborn nursery, there was no statistical difference in the day 2 discharge rate as shown on table 4. However, when considering those whose infants were in the newborn nursery and thus eligible for day 2 discharge, the day 2 discharge rate was higher in the ERAS group at 77% versus 51% ($p<0.05$). There was no difference in the amount of nausea and vomiting that required a breakthrough antiemetic. Pharmacy charges were increased by $714 ($p<0.0001$) in the ERAS group. However, when considering the savings from a higher discharge rate there was no difference in overall charges. Overall charges include room and board charges for both mother and infant (at newborn nursery rates) and pharmacy charges. When considering those with infants in the newborn nursery the savings was $206, however this did not reach statistical significance.

**Table 4. Other Secondary Outcomes (n=100)**

| Characteristic | Control (n=50) | ERAS (n=50) | Change | p Value |
|---|---|---|---|---|
| Day 2 Discharges | | | | |
| All | 23 (46) | 27 (54) | | 0.27§ |
| NBN* | 23 (51) | 27 (77) | | 0.02§ |
| Needed Breakthrough Antiemetic | 22 (44) | 17 (34) | | 0.41§ |
| Postpartum Charges ($) | | | | |
| Pharmacy Charges | 616 (462-770) | 1330 (1304-1357) | + $714 | <0.0001‡ |

| | | | | |
|---|---|---|---|---|
| R&B Charges All | 8342 (7896-8789) | 7890 (7405-8374) | - $452 | 0.18‡ |
| R&B Charges NBN | 8157 (7704-8610) | 7186 (6751-7620) | - $972 | 0.008‡ |
| Total Charges All | 8959 (8480-9438) | 9220 (8740-9699) | + $261 | 0.45‡ |
| Total Charges NBN | 8727 (8260-9195) | 8521 (8092-8949) | - $206 | 0.39‡ |

Data are mean (95% CI) or n (%)
‡ Mann-Whitney U Test
§ Fisher Exact
* For the control group n=45, for the ERAS group n=35
NBN = Those with patients admitted to the newborn nursery
All = Those with patients in the newborn nursery and NICU
R&B = Room and board charges for both mother and infant in the postpartum period

**Table 5** outlines the outcome odds ratios as well as the number needed to treat for the statistically different measures outlined on tables 2 and 3. ERAS patients were 19.1 times more likely to decline all opioids with a number needed to treat of 3.8. ERAS patients were 6.3 and 6.0 times more likely to reach the pain goals of 4 or lower and 3 or lower, respectively. Patients who were in the ERAS group and had an infant in the newborn nursery were 3.2 times more likely to elect discharge on postoperative day 2.

Table 5. Outcome Odds Ratios and the NNT of Those in ERAS Group

| Characteristic | Odds Ratio (95% CI) | NNT (95% CI) |
|---|---|---|
| Declining All Opioids | 19.1 (2.4-151.6) | 3.8 (2.6-7.7) |
| Achieving Pain Goal (≤3) | 6.3 (2.6-15.3) | 2.4 (2.1-7.0) |
| Achieving Pain Goal (≤4) | 6.0 (2.0-17.7) | 3.3 (1.5-2.9) |
| Day 2 Discharge (NBN) | 3.2 (1.2-8.6) | 3.8 (2.2-17.1) |

NBN = Those with patients admitted to the newborn nursery
NNT = Number needed to treat

None of the patients abandoned the protocol to return to traditional pain control methods. With regard to the liposomal bupivacaine, none of the patients reported allergy, wound infection, injection site reaction or any other complications. We did not have any adverse events such as urinary retention and no falls, despite early ambulation and early catheter removal. All patients completed the study as no patients withdrew consent.

# WVSMA continues strategic planning process.

The West Virginia State Medical Association continues its Strategic Planning process. Executive committee members met this spring for three three days with a facilitator from West Virginia University to expand upon the process started last year.

 

# Using the Patient Generated Index in Spine Surgery in an Appalachian Population

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## Abstract

In most health care fields, outcomes are becoming increasingly scrutinized and may play a role in "pay for performance;" therefore, selecting the most appropriate outcomes measures for the populations being studied or treated has evolved into a key aspect of outcomes monitoring. One way to assess patient goals is to administer a patient generated index (PGI). The philosophical underpinning of the PGI is that the person living the life is the best judge of the quality of that life. The PGI has been utilized in low back pain, as well as in adult spinal deformity surgery, however, it has not been previously utilized in an Appalachian population. The PGI was administered by means of self-report to 80 new patients with back pain who presented for assessment in the neurosurgery clinic. Participants completed an acceptability survey and provided written comments. Compliance was analyzed. Findings indicate that the PGI in its earliest form did not meet acceptable levels for use in this Appalachian sub-specialist clinic setting. This study contributes to the growing body of knowledge on patient-reported outcomes, and more specifically, the importance of utilizing patient-generated responses to map improvements in quality of life for patients over time.

Introduction

The World Health Organization defines quality of life (QOL) as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. [1]" Knowledge of a patient's goals and expectations for care is important in any medical interaction but especially if the patient's medical condition negatively impacts their QOL. One way to assess patient goals is to administer a patient generated index (PGI)[2]. The philosophical underpinning of the PGI is that the person living the life is the best judge of the quality of that life. This measure has been previously validated in a number of clinical settings[3]. A patient-generated measurement tool of quality of life may be particularly important in spine surgery, where patient treatment goals may not always align with surgeon goals of care.

Findings indicate that the PGI **in its earliest form did not meet acceptable levels**

The PGI is completed in three stages:

Stage 1: Patients are asked to list the five most important areas of their lives affected by their medical conditions.

Stage 2: The patient rates how much each of the five areas has been affected by his or her health condition using a scale of 1-100 where 0 is the worst imaginable and 100 is "exactly as you would like it to be."

Stage 3: Patients are asked to "spend" 60 tokens on the area they would like to see the most improvement. The 60 tokens are allocated according to the patient's priorities. A global index can be calculated by calculating the rating on stage 2 by the proportion of tokens allocated in stage 3, which are then summed to produce an index between 0 and 100.

A higher score indicates a higher quality of life. The index indicates how the patient's reality falls short of the goals and expectations for areas of their life they deem most important.[2]

Patient-reported outcome measures are increasingly popular and utilized for a variety of health conditions. One limitation of such surveys, which tend to be multiple choice for ease of assessment, is that patient-generated ideas or values are not assessed.

Unlike these surveys, the PGI presents a free-text design, coupled with a ranking of disability levels and importance, and has been utilized and validated in a variety of medical conditions.[4,5] For example, it has been utilized in low back pain [6] as well as in adult spinal deformity surgery.[7] However, it has not been previously utilized in an Appalachian population. Appalachia is a distinct cultural region and has been associated with an aging population, high poverty rates, and low educational levels.[8] The objective of this feasibility study is to assess the utility and acceptability of the PGI for Appalachian patients with back pain.

## Methods

After institutional review board approval, the PGI, along with Ruta's previously validated instruction sheet [4] (Appendix A) was administered by means of self-report to 80 new patients with back pain who presented for assessment in the neurosurgery clinic. This procedure mimicked the previous administration of the PGI in an earlier published pilot of PGI in a spinal deformity referral center [7]. Inclusion criteria included patient's > 18 years of age, first visit to the clinic, and currently experiencing back pain. The patients were identified by the research nurse and asked if they would consider participating. Those who agreed gave written informed consent. Participants were given a copy of the PGI, written instructions to complete the PGI, acceptability questionnaire (Figure1) as well as a copy of the informed consent. In addition, the patients were given brief verbal instructions, an overview of the PGI, and given the opportunity to ask questions prior to completing the PGI and acceptability survey. The completed surveys were collected at the end of the patient's visit. The PGIs were assessed for compliance with instructions, including general content of stage 1 areas of impact, and compliance with numbering instructions for stages 2 and 3. Compliance data, any written comments, as well as the results of the acceptability survey were entered into a REDCap (Research Electronic Data Capture) secure web application for analysis.[9] "Acceptability" was defined pre-hoc as a favorable response (6-10 on Likert scale) on 80% of survey questions.[10] Compliance with instructions across all three stages was similarly assessed, and free-text comments were transcribed and analyzed using NVivo software.[11]

## Results

The acceptability survey was analyzed with "acceptable' being defined as favorable responses (6-10 on a 10-point Likert scale) on 80% of survey questions (Table 1). None of our questions et the 80% goal of a 6-10 response for acceptability from our participants.

Completion rates for each stage were also assessed. Stage 1 was completed correctly 93.7% of the time, but Stage 2 had only a 58.2% completion rate and similarly a completion rate of only 63.3% for Stage 3.

Written comments included positive comments such as "I think this is good for patients and staff to have and share this type of info," and "This form was easy to fill out and gave me a little comfort knowing you care." Other feedback from the free text data included suggestions and some negative comments such as "makes me want to go back to school," "Stage 1 needs more explanation of what you are looking for." "Stage 2 needs to total 100-best to worst to understand what is bad," and "The 60-point system seems a bit abstract. Trying to pick a top priority is a little vague because positions of the lower ones would change if the higher ones were addressed." Other comments included specific suggestions for improvement, and complaints over the amount of paperwork, or unrelated comments such as patient names, suggesting lack of comprehension.

## Discussion

The completion rates and acceptability results for the PGI did not meet acceptable levels for use in this Appalachian sub-specialist clinic setting. Other researchers have found similar difficulties with patients self-completing the PGI in its original form. For example, Ruta et al.[4], found that patients who lived in public housing, were less educated, or who were retired, seemed to have the most difficulty understanding and completing the PGI.

There were limitations with our study in that administration was during a previously scheduled patient visit in a fast-paced clinic. Although 76% of participants indicated they had enough time to complete the survey, compliance could be improved with more time spent on teaching the participant on how to properly complete the form. This was also a one-time administration. It is expected that compliance would also improve over multiple administrations, which in turn would yield more useful information in terms of change in health expectations for the patient. Other limitations may include using paper and pen to administer the PGI, although this method has been the most frequently utilized in previous studies. Using a tablet or other electronic device might be easier as some participants suggested. This could allow the stages to be on separate pages and appear less confusing to the participant.

This study contributes to the growing body of knowledge on patient reported outcomes and, more specifically, the importance of utilizing patient-generated responses to map improvements in QOL for patients over time. The original PGI was well-received by our patient population, which is mostly comprised

 

## PGI Acceptability Survey (Figure 1)

**Please answer the following questions on a scale of 1-10 where 10 indicates the most acceptable and 1 indicates the least acceptable.**

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| The instructions were easy to follow. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| I had enough time to complete the form. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| I felt comfortable answering all the questions honestly. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stage 3 assignment was easy to complete and understand. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stage 3 assignment was easy to complete and understand. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

of Appalachian residents. Only one person declined to participate. Overall, the participants appreciated feeling "heard" and appreciated that the clinic staff were interested in their personal stories and how back pain has impacted their QOL. Despite the positive comments, compliance was not acceptable and revisions are indicated prior to effective use in this clinical setting. It may be possible that in other clinical settings this tool may be utilized more successfully with a similar patient population. Next steps should include a focus group with Appalachian residents and health care providers to gain feedback on the PGI in order to increase compliance. This feedback will contribute to a revised PGI that would then be administered to a larger sample and validated against current QOL measures.

As outcomes are becoming more closely scrutinized and may play a role in "pay for performance" in the health care fields, selecting the most appropriate outcomes measures for the populations being studied or treated has evolved into a key aspect of outcomes monitoring. While the PGI has been validated across many medical conditions and health care settings, it does not, in its current form, reflect adequate acceptability and compliance for this Appalachian sub-specialist patient population.

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*'I think this is* **good for patients and staff** *to* **have and share** *this type of info.'*

## Appendix A

PGI Instructions

This section of the questionnaire is presented in three stages. Your answers should be entered on the answer sheet, which is marked "stage 1," "stage 2," and "stage 3." The instructions on how to fill it in also are divided into three stages. You might find it easiest to read through the instructions for stage one, then go to the answer sheet and fill in stage one, and then do the same for stages two and three.

When you are filling in each stage, we could like you to think about when you were at your worst with your back pain in the last month. If you are at your worst now, then think about how you feel now.

Stage 1

At this stage, we would like you to think of the different areas in your life, or activities in your life that have been affected by your back pain in the last month. When you think of areas or activities, you might think of some small area of activity that may be quite personal and special to you such as "I can't play with my kids."

We want you to write the five most important areas or activities of your life that are affected by your back pain in the boxes provided in stage one on the answer sheet. Put one area or activity in each box.

You may be able to think of more than five areas, but you can only write down the five most important ones. If you can't think of five areas or activities, there is a list of areas and activities that have been mentioned by other people suffering from back pain. You might want to use these areas or activities to fill in the boxes if you feel they apply to you.

You don't have to write down five areas of your life if you don't feel that five areas of your life have been affected. If you have less than five, you can write "none" in the empty box and move on to stage two.

If you feel that your life is not affected by your back pain at all, then just write "none" in each box. In this case, you don't need to go on to stages two and three.

Once you have written down the most important areas of activities that have been affected by your back pain, you can move on to stage two

# Table 1. Results of Acceptability Survey

| PGI Acceptability Question | Number of Favorable Responses 6 and over | % of Survey Questions |
|---|---|---|
| The instructions were easy to follow | 48 | 60% |
| I had enough time to complete this form | 61 | 76% |
| I felt comfortable answering all questions honestly | 56 | 70% |
| Stage 2 point assignment was easy to complete and understand | 48 | 60% |
| Stage 3 point assignment was easy to complete and understand | 51 | 64% |

Stage 2

Looking at the next page, you will see a scale from 0-100 in multiples of 10. The scale is supposed to show you how badly affected you are for each of the areas of activities you have mentioned. A score of 0 would mean that when you were at your worst in the last month, you felt that this was really the worst you could imagine for yourself. The score of 100 is meant to represent exactly how you would like to be in the area or activity of your life (even if it is impossible for you to reach).

For each area or activity that you have mentioned, write down a score out of 100 that you would give to reflect how you were affected when you were at your worst in the last month.

You will notice that we have filled in "all other aspects of your life" as the final "area or activity ." This is meant to include all the other aspects of your life affected by your back pain, but are not important enough to go in the top five boxes. It will also include areas in your life that might be totally unaffected, such as the size of your house.

You might suffer from another illness as well as your back pain, and any other areas that are affected by this illness would be included in this box.

Please give a score out of 100 to the "all other areas of your life" box in the same way that you scored the other "areas and activities." Even if you leave the other boxes empty, you must fill in this box.

Stage 3

For the final stage, we would like you to imagine that we can grant you a wish to improve any area of your life, including the areas that have nothing to do with back pain.

Imagine that you are given 60 points to improve your score in any of the areas you have mentioned. You cannot have more than 60 points in total, but you can spend them any way you like. For example, you could give 10 points to each area, or you might give 60 points to one area. The choice is yours to split the points up any way you like, but you cannot have more than 60 points in total.

If you don't give any points to an area of your life, you must try and imagine that this area will stay exactly as it is.

Go through the boxes in stage three and distribute your points to those areas or activities in which you would most like to improve. You can keep changing your mind until you feel that you have reached the best distribution of points. Remember that the total across all areas must add up to 60.

You have finished this section. It will tell us how your back pain has affected your life and also which aspects of your life you would most like to see improved.

**Next steps** should include a focus group **with Appalachian residents and health care providers** to gain feedback on the PGI in order to **increase compliance.**

 

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# Sofosbuvir and Ledipasvir (Harvoni) treatment for hepatitis C in children.

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## Abstract

**Objective:** Direct Acting Antiviral (DAA) drugs have been recently approved by the Food and Drug Administraation for children with HCV infection (FDA news release, April 7, 2017). We describe the first two HCV- infected children from Kentucky treated successfully with DAA drugs from a research protocol.

**Methods**: The charts of two children with HCV infections were reviewed. Once adolescent age was achieved (12 years), both children (one naïve and one experienced) were treated for eight weeks with Sofosbuvir and Ledipasvir (Harvoni) and were monitored. Their aminotransferases and HCV-RNA levels were followed before and after treatment.

**Results:** Both children were followed for their HCV infections since infancy. Both children achieved SVR at the end of therapy, one achieved SVR 12 weeks post therapy. The second patient is still on follow up post treatment.

**Conclusion:** This is the first report of children treated with DAA drugs not under a research protocol. We suggest the eight-week treatment may be sufficient to achieve SVR in children. Patient advocacy groups and government agencies should pressure the insurance companies to approve DAA therapy for HCV-infected children.

## Introduction

Hepatitis C virus (HCV) is a viral disease that causes inflammation of the liver and can lead to liver failure, cirrhosis, and hepatocellular carcinoma.[1] The Centers for Disease Control and Prevention has estimated that 2.7 - 3.9 million people in the United States have chronic hepatitis C, and 23,000 - 46,000 children are infected.

This is the **first report** of children treated with DAA drugs not under a research protocol.

We suggest the eight-week treatment may be sufficient to achieve SVR in children.

We suggest that patient advocacy groups and government agencies should pressure the insurance companies to **approve DAA therapy** for HCV- infected children.

The CDC has reported that HCV infection has almost tripled between 2010 - 2015, and it is related to the increased drug abuse in pregnant women. Kentucky and West Virginia were among the seven states that had double the national average rate of HCV infection. (CDC report May, 2017)

Until recently, the standard therapy for HCV-infected children included IFN–alpha with or without ribavirin. Unfortunately, this mode of therapy was unacceptable for its low rate of virus eradication (Sustained virologic response (SVR) - average 50% for genotype 1a); its long period of therapy (approximately one year); significant side effects, and others [1]. Those deficiencies limited the clinical use of this treatment in children.

Until recently, the standard therapy for HCV-infected children included IFN–alpha with or without ribavirin. Unfortunately, this mode of therapy was unacceptable for its low rate of virus eradication (Sustained virologic response (SVR) - average 50% for genotype 1a); its long period of therapy (approximately one year); significant side effects, and others [1]. Those deficiencies limited the clinical use of this treatment in children.

In the last four years, a new type of therapy, direct-acting antiviral (DAA) drugs, has emerged. These drugs were directed towards the life cycle stages of the virus within the Hepatocyte, such as: NS5B polymerase inhibitor, NS5A inhibitors, and NS3/4A protease inhibitors. The benefits of these drugs were their oral intake, very high rate of SVR (>95%), short therapy period (8-12 weeks), no virus-dependent factors, minimal side effects, and high efficacy in patients who failed previous treatment (non-naïve), or patients with different degrees of liver

 

fibrosis (F1 - no fibrosis to F4 - cirrhosis) [2]. The high success rate of these medications suggest that we have come to a new era where hepatitis C can be eradicated. Unfortunately, the enthusiasm was hindered by the very high cost of treatment, approximating $1000 a day. [3,4]

Currently, there are only two published research-based clinical studies investigating the efficacy of two different DAA protocols in adolescent children [5,6]. Following those studies, the FDA approved Sofosbuvir, and Harvoni (Sofosbuvir and Ledipasvir) and Sofosbuvir with ribavirin protocols for children older than 12 years of age [1,7]. Accordingly, we present our experience with two cases of children with HCV treated with Sofosbuvir and Ledipasvir (Harvoni).

Table 1: Harvoni treatment in HCV patients

| Case 1 | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Age (Y) | 4 | 5 | 6 | 7 | 10 | 12 | 13 | 13,2mo | 13,5mo | |
| ALT/AST | 44/54 | 49/52 | 55/57 | 57/55 | 156/78 | 63/48 | 58/41 | 43/25 | | |
| HCV-RNA | $10^{5.6}$ | $10^{5.3}$ | $10^{5.4}$ | $10^{5.7}$ | $10^{5.4}$ | $10^{6.1}$ | $10^{5.8}$ | ND | ND | |
| Harvoni | | | | | | | 8 wks | | | |
| Case 2 | | | | | | | | | | |
| Age (Y) | 5.5 | 7 | 8 | 9 | 10 | 10.5 | 11.5 | 12,3mo | 12,5mo | 12,9mo |
| ALT/AST | 47/56 | 41/49 | 58/70 | 41/46 | 59/49 | 48/28 | 38/30 | | | 17/13 |
| HCV-RNA | $10^{5.5}$ | $10^{5.4}$ | $10^{6.6}$ | $10^{5.7}$ | $10^{6.0}$ | $10^{5.8}$ | $10^{5.8}$ | | ND | ND |
| Harvoni | | | | | | | | 8wks | | |

**Case 1:** MW is a 13 year-old female who has been known to our clinic since the age 14 months. The child was referred to our clinic with a history of hepatitis C. She was infected vertically by her drug-addicted, HCV- positive mother. The child was adopted by her new family at infancy. Upon arrival, the baby was asymptomatic, and the initial examination was normal. Laboratory data showed mild elevation of aminotransferase (<2X ULN), with positive hepatitis C antibody and HCV-RNA titer of 720K. At age 23 months, the child was sent to a tertiary hospital for a second opinion. Blood examination showed normal aminotransferases and HCV genotype 1a. Liver biopsy was performed and showed minimal inflammation and no fibrosis. Treatment was not recommended at that age. The child continued her follow-up in our clinic. Her aminotransferases were never higher than 2X ULN, and her HCV-RNA had slightly increased throughout the years (Table 1). Repeated liver biopsies performed at four years of age showed no change from initial biopsy at age two years (inflammation activity grade 1, fibrosis grade 0.) The option of IFN-alpha treatment was offered to the child, but due to the low efficacy of that regimen in genotype 1a, the mother denied the treatment and continued an annual follow up. At 13 years old, DAA protocol (Harvoni for eight weeks) was offered to the patient. After long discussion with the insurance company, the treatment was approved. The patient finished eight weeks of therapy and her HCV-RNA titer was undetectable at end of therapy and at three months post therapy.

**Case 2:** BK is a 12.5 year old female who was referred to our clinic at age six years. The child was born with HCV, vertically infected by her drug addicted HCV-positive mother. The child was adopted by a new family. The child was followed by a tertiary center since the age of one year, and at the age of four years she was treated with IFN-alpha plus ribavirin for six months. Prior to therapy, the child's IL28B genotype was CT, HCV genotype 1a, and her liver biopsy was normal. After six months of therapy the child's HCV-RNA levels dropped by 50%, and treatment was stopped. The patient was then followed by our clinic and yearly HCV-RNA levels were examined (Table 1). The child was totally asymptomatic, and annual blood examinations including aminotransferases and CBC were normal. Once patient was 12 years of age, the option of DAA protocol was offered. The approval by the insurance company was delayed, but after pressure, the treatment was authorized. The child started her therapy with Harvoni for eight weeks and HCV-RNA at the end of therapy was undetectable with normal aminotransferases (Table 1). HCV-RNA level at 3.5 months post therapy was negative with normal LFTs. The child is asymptomatic and continues her follow up in our clinic annually.

## Discussion

HCV in children is a chronic disease presented with minor symptoms and slow development [1]. In most cases infection is vertically transmitted from HCV-positive mothers. HCV infection has tripled between 2010 and 2015 related to the increased drug addiction among woman giving birth (CDC May, 2017). The CDC acknowledged that HCV rates in children are under-reported and recommended screening babies of any positive HCV pregnant women.

Until recently, the standard therapy for HCV-infected children included IFN-alpha with, or without, ribavirin. This treatment protocol is difficult for children and not efficacious (SVR average 50% for genotype 1a) thus, the clinical use in the pediatric population is limited.

The Centers for Disease Control and Prevention has estimated that 2.7 - 3.9 million people in the United States have chronic hepatitis C, and 23,000 - 46,000 children are infected.

In the last four years a new type of medications, Direct Acting Antiviral (DAA) drugs, have emerged. The benefit of these medications, usually used in combinations, are their oral intake, short therapy period (8-12 weeks), high rate of SVR (>95%), efficacy for all HCV-types, minimal side effects, and achieved high efficacy rates in difficult patients including those who failed previous IFN- based treatment, or patients with different degrees of liver fibrosis (F1- F4). The high success rate of DAA protocols in adults suggested that we may come to an era of possible complete eradication of HCV infection [8]. Unfortunately, that optimism was hindered by the very high cost of therapy [3,4].

As it often occurs, evaluations of DAA in children started much later than in adults. The first multicenter clinical trial was conducted in 2016. In this study, 100 HCV infected adolescents (naïve and previously treated) were treated with Harvoni (Sofosbuvir + Ledipasvir) for 12 weeks. SVR and side effects were followed at two, four, eight and 12 weeks of therapy and four and 12 weeks post therapy. Clinical and laboratory data of the naïve children included the following: LFTs were < 10ULN, the mean HCV-RNA levels were low (1.8 log10 IU/ml), no patient had liver fibrosis (F1), and most patients were infected prenatally. Results showed SVR of 100% at eight weeks and 12 weeks of therapy and SVR of 98% at 12 weeks post therapy, and minimal side effects, which included nausea, fatigue, diarrhea, vomiting and cough (all side effects were below 15% of the treated patients, which was similar to placebo) [5]. The SVR rate of that study was similar to the SVR reported in adult patients [8]. In the same year, a second multicenter clinical trial was published by Wirth et al. using a different DAA protocol [6]. In that study, the combination of Sofosbuvir (Sovaldi) with ribavirin was given to 52 HCV-infected adolescents with HCV type 2 or 3 for 12 weeks. SVR at 12 weeks post therapy was 100% and 98%, respectively. Another, yet unpublished study by Murry KF et al, will report the results in 90 children aged 6-11 years treated with Sofosbuvir + Ledipasvir with or without ribavirin. In that study SVR at four weeks post treatment was 99% [9]. We did not find any pediatric report using DAA treatment out of the confines of research protocols. In this report we present two children with HCV infection who were treated with DAA. Both children were vertically infected by their drug addicted, HCV-positive mothers and were followed since infancy. Their LFTs levels follow < 10 ULN, and liver biopsies showed no fibrosis (F1). The average HCV-RNA was higher than reported by Balistreri et al (5.0 log 10 vs. 1.85 log 10 IU/ml, respectively). In the first case, the mother refused IFN-based therapy and opted for ƒDAA based therapy once the patient reached the appropriate age (naïve patient). In the second patient, IFN-alpha plus ribavirin was tried and failed due to unfavorable IL28B genotype and HCV-genotype 1a (treatment experienced patient). Similar to the study of Balistreri et al. [5]. In both of our patients, HCV-RNA was undetected at the end of therapy (eight weeks) and three-four months after treatment (SVR-100%). In both children, no side effects were reported. Our results suggest that eight weeks of treatment may be sufficient to eradicate the virus, thus saving a significant cost.

The high cost of almost any DAA protocol has been a significant limitation for the treatment of children and adults alike. Although studies ultimately showed that DAA treatment is cost effective and cost saving, [1,10,11] insurance companies continue to deny their patients the treatment. In spite of the FDA approval of DAA in children that indicated no clinical or laboratory limitations, insurance companies continue to

 

refuse children DAA treatment unless their pre-requisite conditions are met. One of the major hurdles is the existence of a high grade of liver fibrosis (F3, F4) [12]. The clinical course and liver histology in childhood are mild thus, liver histology of F3-F4 is almost not existent [13]. The lack of published pediatric HCV cases treated with DAA protocol outside of clinical research trials is a testament to the difficulties physicians are encountering when trying to prescribe DAA medications to their HCV positive children. This reality is unacceptable, and a significant pressure on insurance companies and on the government by the patient advocacy groups will be needed to change this policy. The medical community has won this fight before, i.e.: the fight for AIDS medications. We must do it again for the sake of our children.

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# New Drinko Fellow named on silver anniversary of academy

James B. Becker, MD, vice dean for government relations, health care policy and external affairs for the Marshall University Joan C. Edwards School of Medicine and an associate professor in the department of family and community health, has been named the 25th Distinguished John Deaver Drinko Academy Fellow at Marshall University.

The announcement of his appointment was made at the annual Drinko dinner and symposium by executive director Montserrat Miller, PhD.

"Dr. Becker is the first Drinko Fellow to be named from our school of medicine and his appointment couldn't be more timely," Miller said. "His dedication to the study of population health, addiction medicine and rural health—all very important topics to our state, region and nation right now—is commendable. We are looking forward to great things during his term."

Distinguished Drinko Fellows receive a stipend, re-assigned time from teaching, and other financial and clerical support for two academic years to undertake research, special projects, or other scholarly pursuits.

In addition to his teaching and administrative responsibilities at the school of medicine, Becker is a family physician who maintains a clinical practice at Marshall Health. Named as the West Virginia Family Physician of the Year in 2013, Becker has received several other clinical awards and is noted for his tireless devotion to improving the quality of life for his patients. He is a widely sought consultant who has addressed audiences at more than 50 professional meetings and made nearly 20 grand rounds presentations.

A highly regarded physician executive whose work in health care and government relations has been recognized at the state and national level, Becker's service extends to state government as the medical director for the West Virginia State Bureau for Medical Services.

# Marshall opens new medical student wellness center


Marshall University Joan C. Edwards School of Medicine dedicated the Linda S. Holmes Student Wellness Center as a new study, relaxation and meeting space for medical students.

The 4,200-square-foot center, located just across Hal Greer Boulevard from the Marshall University Medical Center and Cabell Huntington Hospital, features five study rooms, group meeting space and a large gathering room. The center also houses the school's student affairs and financial aid offices. The center is designed to provide a safe, convenient relaxation space for medical students when they need to take a break from studying to relax and decompress.

The opening of the new Student Wellness Center is part of many strategic initiatives at the School of Medicine aimed at promoting the mental and physical wellness of its students, including teaching students healthy ways to manage stress and promote resiliency. In recent years, well-being in academic medicine has become a priority for national organizations like the Association of American Medical Colleges, Liaison Committee for Medical Education and medical schools across the county.

Through a generous gift from alumnus and retina specialist R. Mark Hatfield, MD, OD., and his wife, Monica J.W. Hatfield, the center was named in honor of the school's long-time developmenta nd alumni affairs director, Linda S. Holmes.

# Dean awarded Mastership in American College of Physicians

Joseph I. Shapiro, MD, dean of the Marshall University Joan C. Edwards School of Medicine and a practicing nephrologist, has been awarded Mastership in the American College of Physicians, the national organization of internists.

Election to Mastership recognizes outstanding and extraordinary career accomplishments. Masters must have made a notable contribution to medicine. This includes, but is not limited to, teaching, outstanding work in clinical medicine (research or practice), contributions to preventive medicine, improvements in the delivery of health care and/or contributions to the medical literature.

Shapiro is a practicing nephrologist with nearly 40 years of clinical, teaching and research experience. He was nominated for Mastership by Maurice A. Mufson, MD, professor emeritus, cardiologist and researcher at the Marshall University Joan C. Edwards School of Medicine. Of the ACP's 154,000 members across the globe, only 1% have been awarded Mastership. Shapiro is one of only eight West Virginia physicians, including Mufson, to receive the honor.

ACP honored new Masters at the annual Convocation ceremony during its Internal Medicine Meeting 2019, ACP's annual scientific conference, held April 11-13 in Philadelphia.

 

# School of Medicine marks 39th graduation

Marshall University awarded 60 Doctor of Medicine degrees and six Doctor of Philosophy in Biomedical Research degrees during the School of Medicine's 39th annual graduation and investiture ceremony  The School of Medicine also recognized Gary G. White as its honorary alumnus. Charles H. McKown Jr., vice president of health sciences advancement, radiologist and former dean of the Marshall's medical school, delivered the keynote address to the Class of 2019.

# Study reveals role of fat storage cells

New research from a team at the Marshall University Joan C. Edwards School of Medicine establishes a role of adipocyte Na/K-ATPase signaling in worsening obesity and its companion diseases, including neurodegeneration and non-alcoholic steatohepatitis (NASH), that was enhanced by specific targeting of NaKtide, an antagonist of Na/K-ATPase signaling, to the adipocyte.

The findings are published in the May 28, 2019, edition of Scientific Reports, an online journal from the publishers of Nature.

The results from this study at Marshall University demonstrate that the Na/K-ATPase oxidant amplification loop in adipocytes, or cells specialized for fat storage, when impaired, could cause adipocyte dysfunction, worsening obesity and potentially increasing the severity of related diseases. The basis of the research examined more closely the role of the adipocyte in obesity, including how it impacts oxidative stress, inflammation, neurodegeneration and NASH. The researchers were able to successfully demonstrate through decreased adiposity and an improved metabolic profile the therapeutic potential of targeting NaKtide to the adipocytes.

"Our data clearly suggests that obesity and the Na/K-ATPase oxidant amplification loop plays a role in neurodegeneration," said first author Rebecca Pratt, a PhD candidate in the department of biomedical research at Marshall University. "Even targeting NaKtide to adipocytes alone still showed a whole-body effect, which highlights the much larger role that adipocytes play in obesity and whole body homeostasis."

# Dedication held for WVU Rockefeller Neuroscience Institute Innovation Center

The West Virginia University Rockefeller Neuroscience Institute recently unveiled its new Innovation Center.

RNI's new 78,000-square-foot Innovation Center is a dedicated building featuring the latest technology for rapid applied human research. This unique facility has unparalleled capabilities in Human Performance and Recovery, Neuromodulation, Virtual Realty, Imaging, and Neuroscience Predictive Data Analytics – all under one roof.

The Center is working with national and international experts in a variety of public-private partnerships designed to accelerate discoveries and translate them into real-life applications.

The WVU RNI also convened its inaugural Summit, "Breaking Barriers," at the Morgantown Marriott at Waterfront Place. It gathered leading experts from across to world to explore the latest breakthroughs in neuroscience with a focus on combating public health challenges and optimizing brain health, performance, and wellness.

"The establishment of the RNI and the new Innovation Center reflects the vision of Sen. Jay Rockefeller to create a world-class facility in West Virginia to help tackle some of our biggest public health challenges, such as Alzheimer's and addiction," a WVU official said. "We are excited to showcase our partnership efforts with academic, military, and sports science and industry leaders working together at RNI."

# WVU research suggests conflicting drug laws may keep contaminated needles in circulation, contribute to hepatitis C infections

Acute hepatitis C infections rose 98 percent between 2010 and 2015 nationwide, largely because more people were injecting drugs. Using a new needle for every injection can slow the spread of hepatitis C, but getting those new needles isn't always as simple as buying glucose-meter lancets at the pharmacy. Safely disposing of old needles presents a whole other set of problems.

A team of West Virginia University researchers wanted to pinpoint what makes obtaining clean needles—and responsibly getting rid of used ones—difficult. To find out, they surveyed 100 people who attend needle exchange programs. Respondents cited one obstacle more than any other: fear of arrest.

"I believe the biggest barrier to needle exchange is paraphernalia laws and policing behaviors," said Steve Davis, an associate professor in the School of Public Health, who led the study. The team's findings, which appear in Harm Reduction Journal, bear that out. Nearly three-fourths of the study's participants (72 percent) said they "agreed" or "strongly agreed" that they could "get in trouble from the police" for carrying needles around. (continued on next page.)

 

"When I talked to people attending needle exchange programs, what I heard was, they don't want to discard needles," Davis said. "In fact, they would get upset at other attendees who perhaps would do that. They would say, 'If I had a child, I wouldn't want them to get stuck with a dirty needle.' But they also don't want to go to prison. So what do they do? Use them real quick and get rid of them—or share them."

As the Centers for Disease Control and Prevention reports, sharing needles is the number one reason people get hepatitis C today. The problem is pernicious in rural Appalachia. Davis' research project is the first to quantify the barriers to using new needles obtained from needle exchange programs in Appalachian locations. The survey respondents were selected from two programs in West Virginia: one in Cabell County and one in Monongalia County. Previous studies focused on large metropolitan populations.

West Virginia is one of few states that doesn't outlaw the purchase or possession of drug paraphernalia, including syringes and hypodermic needles. "But some local laws are being passed that criminalize possession of a new syringe unless a person has a prescription," Davis said, "and some of the people who inject drugs that I interviewed mentioned being cited for possession of new needles. It is my belief that this confusion over conflicting state and local laws contributes to fear of possessing new needles."

Davis suggested that unambiguously decriminalizing syringes and hypodermic needles could make needle exchange easier and curtail hepatitis C infections. He also recommended reframing needle exchange as a method to keep police officers and their families healthy, rather than as a means of enabling addiction or condoning illegal activity.

If a police officer were to accidentally get stuck with a needle while searching a suspect, Davis reasoned, he or she might be less likely to contract hepatitis C if a needle exchange program were flourishing in the community. More opportunities for needle exchange could mean fewer contaminated needles out in the world.

"In talking to law enforcement, we saw this real struggle with, 'If something is illegal, how am I supposed to let that go?'" he said. "But if you can conceptualize needle exchange as being protective, then you can—perhaps—get law enforcement buy-in. One of the police officers I talked to mentioned this."

Needle exchange programs are associated with a reduction in new hepatitis C cases across Europe, Davis explained, but in North America, this association doesn't hold. "The hypothesis," he said, "is that there's this criminal approach—paraphernalia laws and policing behaviors—that doesn't match up with needle exchange, a public health approach."

# WVU debuts new neuroscience 'Brain Camp' for high schoolers

Eleventh and 12th-graders looking for a unique, immersive science-based camp experience should consider Brain Camp, a new week-long educational program taking place on West Virginia University's Morgantown Campus in July.

The camp, run by the WVU School of Medicine's Department of Neuroscience, in association with the Rockefeller Neuroscience Institute, runs July 14 - 20 and is limited to 30 students.

Campers will participate in hands-on demonstrations with WVU faculty and graduate students in areas like neuroanatomy, studying the effects of light at night, impacts of stroke, and motion capture computer simulations of the body.

"A passion for science and a sense of curiosity are the only prerequisites needed to attend this camp," Randy Nelson, Ph.D., chair of the neuroscience department, said. "Campers will walk away from this experience having gained insight to the breadth of academic and career possibilities available to those interested in the brain and its functions. They will also learn that WVU is a great place to study neuroscience."

Campers will participate in **hands-on demonstrations** with WVU faculty and graduate students in areas like neuroanatomy, studying the effects of light at night, impacts of stroke, and motion capture computer simulations of the body.

While attending the camp, campers will stay in WVU's Oakland Hall under the supervision of WVU employees. Housing, meals, transportation, evening programs, and outings are all included in the $700 per camper costs. Limited financial assistance may be available for those who qualify.

A tentative schedule is available online at medicine.hsc.wvu.edu/neuroscience. Click on the "Brain Camp" button for more information and to register.

# WVSOM offers new clinical nutrition and culinary medicine elective to students

Students at the West Virginia School of Osteopathic Medicine won't be using their hands just for osteopathic manipulative treatment; they'll be using them to cook healthy meals.

The school offers a new elective for students that addresses clinical nutrition and culinary medicine. Five third- and fourth-year students took part in the two-week course that included not only a culinary lab where they received hands-on kitchen experience making plant-based dishes, but classes that explained mindful meditation exercises through yoga, clinical visits with diabetic patients, exercise physiology information from a sports trainer at The Greenbrier, and nature hikes to identify edible mushrooms.

While nutrition is addressed in the school's curriculum, the elective is the first time WVSOM has offered in-depth information about culinary medicine.

"This elective helps students look at the cause of a disease instead of just putting pills in a patient's body," said Robert Foster, DO, WVSOM's associate dean for osteopathic medical education. "We are training students to become physicians who can change a patient's lifestyle and reverse degenerative diseases. The body can repair itself, and that is a very osteopathic way of thinking."

Foster and other WVSOM faculty, including Brian Griffith, PhD., and Dina Schaper, DO, act as advisers in the course.

In the first culinary lab, students Carrie Fox, Hayden Moore, Victor Rendon, Brittany Ross and Jeff Spindel put on aprons and tested their chopping skills to make cucumber salad, black-eyed pea salad and wheat spaghetti with lentils. The students were under the guidance of WVSOM O'Cafe chefs Adam Sydenstricker and Paul Ciciora.

"People tend to eat with their eyes first, so food needs to look good or else people won't be inclined to taste it," Ciciora told the students during the lab. "We want to try to cook with all the senses."

In the second culinary lab, students prepared chickpea shawarma with millet, pinto sloppy Joes and rainbow cabbage slaw.

People tend to e**at with their eyes first**, so food needs to look good or else people won't be inclined to taste it.

Fourth-year student Moore said it is important for students to take time to learn valuable cooking techniques that could be shared with patients, especially since many students have so little time to prepare healthy meals themselves.

"It's such a critical part of health. The reason we have such a problem with diabetes is because we've lost control of healthy eating," Moore said. "What I want to get out of this elective is how to use this information as a tool. I'm doing a residency in surgery, and I'm going to need to know what kind of food will keep patients healthy after surgery."

Ross, a third-year student, said she is glad to see more schools incorporating nutrition into their curriculums.

"This is an aspect of medicine that makes a huge impact. We learn a lot about the 'micro' aspects of everything, but it doesn't easily translate to patients, so this is a better way of conveying information," she said.

Ross said she also appreciates a new learning environment outside the classroom or clinic.

"When you try new things, and try to improve yourself, you become more relatable to patients," she said. "I never want to stop learning, so when I have an opportunity to do so I'm going to take it."

The reason we have **such a problem with diabetes** is because we've **lost control of healthy eating**.

 

# Alumnus delivers keynote speech at WVSOM graduation

WVSOM 2019 Graduating Class

Along with the pomp and circumstance, the green and black regalia, the gold tassels hanging from caps and the exuberance and pride of family members and friends, graduates in the Class of 2019 waited in anticipation of the moment that they would walk across the stage and receive their Doctor of Osteopathic Medicine degrees from the West Virginia School of Osteopathic Medicine.

This year's graduating class was the largest in WVSOM's history, with 199 medical students participating in the school's 42nd annual commencement ceremony on May 25.

Christopher "Dino" Beckett, D.O., Class of 2000, delivered the keynote speech. He discussed his journey practicing family medicine for more than 16 years in southern West Virginia. After completing his residency and returning to his hometown of Williamson, W.Va., Beckett opened a family practice and offered a monthly free clinic for patients who had little or no insurance. This led to the transition of his practice to a Federally Qualified Health Center called the Williamson Health & Wellness Center. His work for his community eventually led to a farmer's market, community garden and mobile produce truck.

> His advice to graduates was to **be bold** and to **not be afraid to make mistakes**, because they are opportunities to learn.

"I'm here today not just to tell you about the things that I've done, but how my education at the West Virginia School of Osteopathic Medicine has been essential to the success that I've experienced," he said. "The foundation of osteopathic principles and passion for community have been a part of the very fabric of my story. When you leave here you will have the skills and tools to be a successful physician. It is up to you how to use them."

His advice to graduates was to be bold and to not be afraid to make mistakes, because they are opportunities to learn.

Class of 2019 President Nicholas Rawson reflected on the past four years during the class address, noting the perseverance and compassion of his classmates.

"Survival is exactly what medical school entails. The curriculum is demanding; the expectation for extracurriculars is high, and there is always the

looming specter of a board exam and residency any time you close your eyes," he said. "It takes blood, sweat and tears."

He said that the world doesn't stop turning while students are in medical school, but that the Class of 2019 still managed to shine in times of crisis.

"Whether it was a signed card, kind words or hanging a banner so that a woman who we never met, several hundred miles away, would know that we were rooting for her," he said, "We pulled together any way we could. This is what makes this class stand out. This is what makes me proud to be counted in our number. This is our class personality, if there is such a thing. Our compassion for one another and our patients is one of our greatest assets."

This was the first commencement ceremony as WVSOM's president for James W. Nemitz, PhD. He said he was honored to confer the graduates' degrees in his new institutional role. He also shared the four characteristics he thinks define a physician.

"Quality, excellence, commitment and caring — that's what makes an excellent osteopathic physician, and we expect no less from each of you," he said to the graduates. "You will have patients' lives in your hands. That is an awesome responsibility, and I know you are well prepared for that role."

The ceremony concluded with graduates reciting the osteopathic oath, which officially acknowledges their transition from student to physician.

# *... Third in nation for producing primary care physicians*

The West Virginia School of Osteopathic Medicine was listed third in the nation by U.S. News & World Report for producing the most primary care residents.

The 2020 edition of the publication's "America's Best Graduate Schools" recognized WVSOM for the 21st consecutive year.

The report shows that 70.2 percent of WVSOM graduates from 2016 to 2018 entered primary care residencies upon their completion of medical school. This is a slight increase from last year's 69.2 percent.

**WVSOM President James Nemitz confers with WVSMA President-Elect Sherri Young**

This distinction solidifies WVSOM's reputation among allopathic and osteopathic medical schools nationwide. Eight of the top 10 spots in the listing were osteopathic medical schools.

"This placement demonstrates that WVSOM is meeting our mission to provide support for graduate medical education that will allow our graduates to secure residency spots, specifically emphasizing primary care in rural areas. The fact that we continue to be recognized for producing primary care residents is great evidence that we are fulfilling our mission each year with a new set of graduates," said President James W. Nemitz, PhD.

Upon successful completion of medical school, graduates enter a residency program to further expand their knowledge in specific fields of study. While primary care, which encompasses family medicine, rural medicine and pediatrics, is the leading field at WVSOM, graduates also enter into a variety of specialties such as surgery, urology, pulmonology and dermatology.

"We are extremely proud of our graduates and the work they accomplish," said Craig Boisvert, DO, WVSOM's vice president for academic affairs and dean. "Our focus educates students to be well-rounded physicians. While WVSOM does place an emphasis on educating students who want to enter primary care residencies, they are not limited to those alone. Our students are prepared for any specialty when they complete medical school"

 

WEST VIRGINIA Department of Health & Human Resources BUREAU FOR PUBLIC HEALTH

# Alzheimer's and Other Dementias: A Community Health Issue

**Catherine C. Slemp, MD, MPH**
Commissioner and State Health Officer
West Virginia Department of Health and Human Resources
Bureau for Public Health

Alzheimer's disease has traditionally been seen as an individual aging issue, but the West Virginia Department of Health and Human Resources, Bureau for Public Health, also recognizes this and other dementias as a critical public health concern. The burden to society is large, the impact is major, and there are ways to intervene throughout the lifespan.

Over 38,000 individuals with Alzheimer's disease reside in West Virginia. There are likely many more due to the lack of early detection and underreporting of this disease. Only 45% of people with diagnosed Alzheimer's or their caregivers are aware of the diagnosis. Data from the Cognitive Module of the West Virginia 2015 Behavioral Risk Factor Surveillance System (BRFSS) found 10% of respondents aged 45 and older in West Virginia reported increased confusion or memory loss (i.e., subjective cognitive decline), and 38% said that it interfered with their work/social activities. Despite the known benefits of early detection, 52.4% of individuals with increased memory problems reported they had not discussed their symptoms with a healthcare provider.

The Bureau for Public Health strongly urges healthcare personnel to recognize the importance of early detection and the need to disclose dementia diagnoses to their patients. The numerous benefits of early detection and diagnosis disclosure include:

**Increased treatment options for patients and families**

*Access to information, services and support*

**Better management of co-occurring conditions**

*Enhanced care coordination across treatment teams*

**Better overall health outcomes**

*Opportunity to plan for medical, housing and financial desires*

**Discussions to address driving and safety concerns**

*Option to participate in clinical trials*

**Reduced healthcare costs**

The Alzheimer's Association has released recommendations to help clinicians detect cognitive impairment during annual Medicare Wellness Visits. The recommendations provide comprehensive guidance on how to assess for cognitive issues in primary care settings during a time-limited office visit. Detecting possible cognitive impairment is the first step in determining if a patient needs further evaluation. For more information about the comprehensive guidance on how to assess cognition in primary care settings, visit www.alz.org/professionals.

Cognitive decline, including Alzheimer's disease and other dementias, can be difficult and time consuming to discuss with patients. Although in-depth care planning is beneficial for all, this type of service has not been covered under Medicare — until recently. CPT® code 99483 provides reimbursement for a clinical visit that results in a comprehensive care plan, allowing providers to deliver services that can contribute to a higher quality of life for patients. Clinicians who can be reimbursed under the code include physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives.

The detailed care plan, including referrals to community resources, provides the essential foundation for care coordination and management. The Alzheimer's Association's Cognitive Impairment Care Planning Toolkit www.alz.org/professionals/healthcare-professionals/care-planning can help providers deliver person-centered care planning to those who have been diagnosed with Alzheimer's, other dementias, or mild cognitive impairment. It also includes those individuals without a clinical diagnosis who, in the judgment of the clinician, are cognitively impaired. Individuals with suspected or diagnosed Alzheimer's disease or another dementia should be referred to local support resources in their area.

The Bureau for Public Health continues to work with local and national organizations to promote awareness of Alzheimer's disease and other dementias and to make strides toward finding a prevention or cure while providing support for the many individuals and families affected by this disease. Becoming well-informed about the disease is the first step towards a long-term strategy.

# Manuscript Submission Guidelines

**ORIGINALITY:** Articles submitted for publication become the sole property of the West Virginia Medical Journal. Prior publication is unacceptable. The Publications Committee reserves the right to edit any material submitted. Scientific articles are to be prepared in accordance with the "Uniform Requirements for Submission of Manuscripts to Biomedical Journals." Please go to www.icmje.org for complete details.

**AUTHORS:** A cover letter from the corresponding author, complete with physical mailing address and email address, should be submitted with the manuscript. Persons listed as authors should have participated sufficiently in the work to take public responsibility for the concept. No more than six authors will be listed. Please include titles and affiliations for each author (i.e., MD, DO, WVU Dept. of Surgery, etc.). A corresponding author, complete with title, mailing address and email address must be identified. Other contributors may be recognized in an acknowledgement.

**FORMAT:** Submit articles in Microsoft Word and as a PDF. Both files should include all elements of the article, in position. This includes authors with titles and affiliations, abstract, main article, figures with legends, tables with titles and references. Additionally, all figures must be attached as separate .jpg files.

**JOURNAL PLATFORMS:** The WVSMA publishes a printed, quarterly WVMJ. We also publish case reports online in an Open Access platform—Scholastica. The purpose of publishing two journals is to enable publication of a larger volume of peer-reviewed case reports, review articles and original research.

The criteria for specific article types, i.e., case reports, review articles, and original research, please check the full manuscript guidelines on our website at www.wvsma.org.

**STYLE:** Manuscript word count is limited to 3200 words and approximate the style adopted by the American Medical Association as illustrated in JAMA and detailed in the AMA's Manual of Style. An abstract of 200 words or less should accompany each manuscript, stating the exact question considered, the key points of methodology, key findings, and the conclusion directly supported by the findings.

**Please submit articles to**

**wvmj.scholasticahq.com**

**There is a one-time $10 fee.**

**VISUALS:** No more than 5 visuals (tables and figures combined).

**REFERENCES:** References should be prepared in accordance to the American Medical Association Manual of Style. These instructions for authors are available online at www.jama.com. References are to be in superscript and appear AFTER punctuation.

**PHOTOGRAPHS/FIGURES:** Submit digital files, which are at least large enough to fill a 2-3/8 inch space at 100% at 300 dots per inch (dpi). Use arrows to point to areas of interest.

**RESUBMISSIONS:** Authors are required to submit a Response to Reviewers document in addition to the revised manuscript.

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