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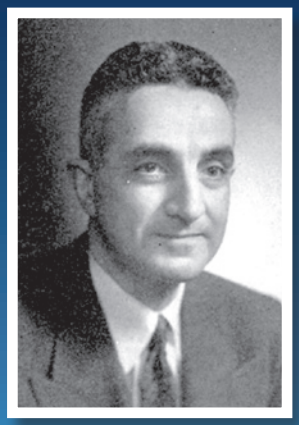

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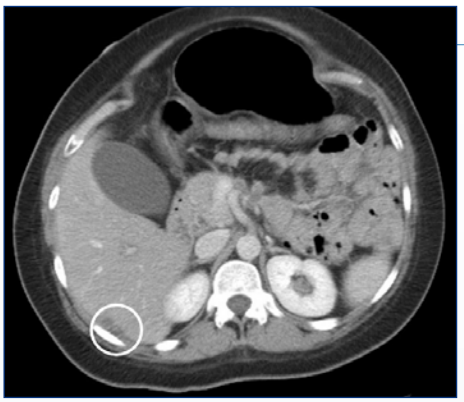

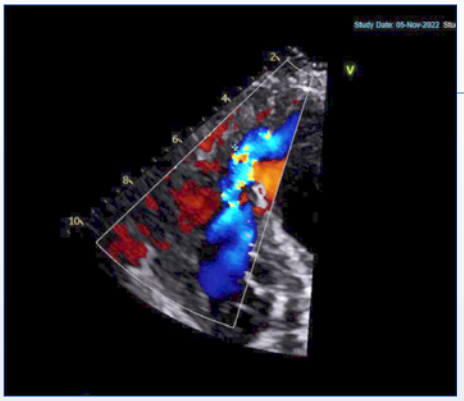

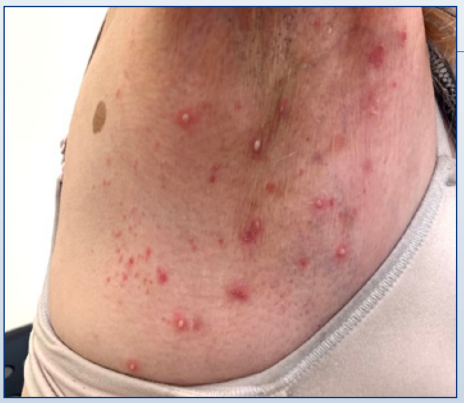

CASE REPORTS

IMAGES IN MEDICINE

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Spontaneous Hepatic Rupture in Pregnancy

ANASTASIA C. TILLMAN, MD; MARCELO L. PAIVA, MPP, MD; ANDREW BARTON, MD; NATALIE PASSARELLI, MD; TIMOTHY D. MURTHA, MD, MHS

ABSTRACT

Spontaneous hepatic rupture (SHR) is a rare and potentially fatal condition associated with both benign and malignant liver disease. Though rare, pregnant patients with HELLP (Hemolysis, Elevated Liver enzymes and Low Platelets) syndrome and preeclampsia are at elevated risk of SHR. Early identification and a high clinical index of suspicion for SHR in patients with preeclampsia and HELLP syndrome can reduce both maternal and fetal mortality. We review the existing literature and present the case of a 35-year-old woman with SHR. The patient was originally admitted for abdominal pain at 38 weeks' gestation and found to have preeclampsia with severe features. Cross-sectional imaging demonstrated a subcapsular hepatic hematoma on imaging. Following an uncomplicated Cesarean delivery, she became hemodynamically unstable. Imaging demonstrated bilateral hepatic rupture. She was successfully treated with angioembolization and operative control of the hepatic hemorrhage.

KEYWORDS: Spontaneous hepatic rupture; Preeclampsia; HELLP; Pregnancy

INTRODUCTION

Spontaneous hepatic rupture (SHR) in pregnant patients is a rare condition with high rates of morbidity and mortality. In a retrospective study of 391 patients with SHR, the maternal mortality rate was 22.1%.[1,2] Overall, the most common cause of SHR is hepatocellular carcinoma. In pregnant patients, SHR has been linked with trauma, but it is most commonly associated with preeclampsia with severe features (70.4%) and HELLP syndrome (Hemolysis, Elevated Liver enzymes, and Low Platelets, 83.3%).[2,3] SHR can also be caused by neoplasms or peliosis hepatis.[3,4] Disseminated intravascular coagulation (DIC), placental abruption, and acute renal failure are some of the more frequent complications associated with this condition. Treatment options include angioembolization, hepatic packing, arterial ligation, formal hepatectomy, and, less commonly, liver transplantation.[5]

In pregnancy, SHR can be fatal to both the pregnant patient and fetus. It commonly presents in patients with no history of hypertension or coagulopathy. SHR may be diagnosed intraoperatively during a cesarean section or in the postpartum period, with a median gestational age of 35 weeks at the time of diagnosis.[2] Presenting symptoms include severe abdominal pain, nausea, emesis, anemia, and sudden hemodynamic instability. Understanding the treatment pathways after diagnosis of hepatic rupture is crucial for safely managing patients. We present the case of a pregnant patient at full-term who had SHR requiring multiple surgical interventions and a protracted stay in the intensive care unit. This case emphasizes the importance of clinical awareness of SHR and highlights the advantage of multidisciplinary care in treating this condition.

CASE REPORT

A 35-year-old G3P0020 woman with a history of two spontaneous abortions presented at 38- weeks six-days gestation with severe right upper quadrant abdominal pain and emesis. Her prenatal course was complicated by urinary tract infection, resolved placenta previa, and large-for-gestational-age fetus on antenatal ultrasound. She was found to have a blood pressure of 152/100 on admission and elevated liver transaminases (ALT 548, AST 1480), leading to a diagnosis of preeclampsia with severe features. She was treated with labetalol and magnesium sulfate. She had no prior history of hypertension. Abdominal computed tomography (CT) demonstrated a 2.3 x 0.9 x 2.5 cm right hepatic lobe peripheral hypodensity suspicious for subcapsular liver hematoma without active extravasation [**Figure 1**]. She underwent a cesarean section for preeclampsia during which the estimated blood loss was 1 L, which is considered as the upper limit of normal expected blood loss in this operation. A surgical consult was obtained at the time of the cesarean section to evaluate the liver. The hepatic lesion was palpated, and the liver capsule was found to be intact. Her hemoglobin decreased from 13.1 to 9.0 within a few hours postoperatively.

Five hours later, the patient became somnolent, pale, and hypotensive to 68/41. On physical exam, her abdomen was distended and rigid to palpation with rebound tenderness. Extremities were cool and peripheral pulses were thready. An ultrasound revealed free fluid in the hepatorenal recess concerning for intraperitoneal hematoma. The massive transfusion protocol was initiated, and the patient received 8

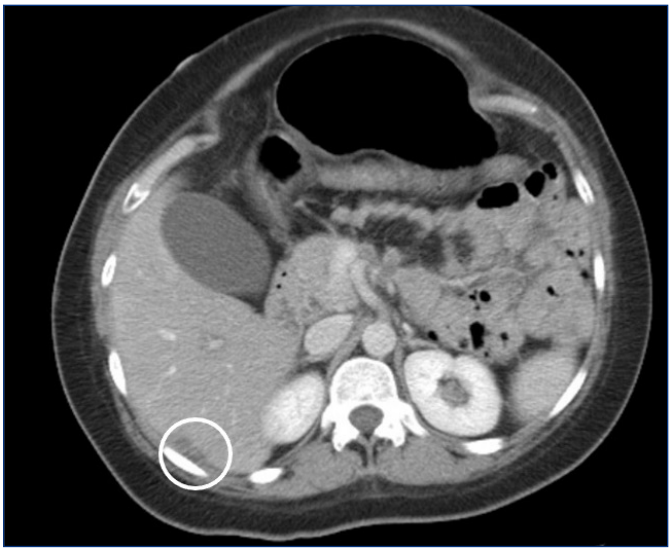

Figure 1. Initial CT on admission demonstrating a 2.3 x 0.9 x 2.5 cm right subcapsular hepatic hematoma (circle).

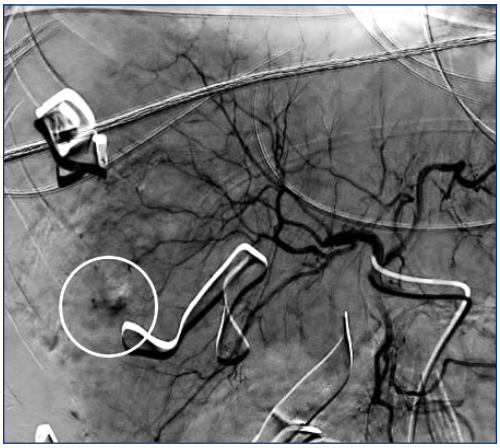

Figure 2A. Mesenteric angiography demonstrates diffuse vessel irregularity throughout the liver with some focal areas of contrast blush distally in the right hepatic lobe (circle).

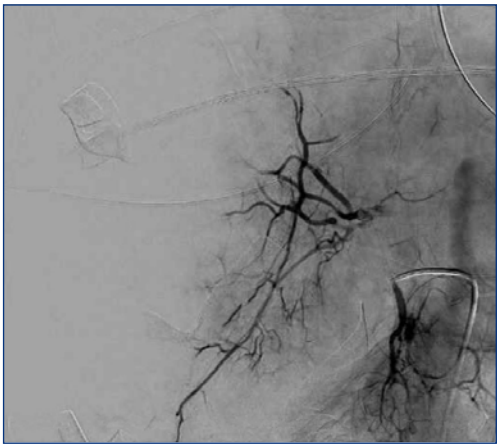

Figure 2B. Angiogram after Gel foam embolization of hepatic segments 6-8.

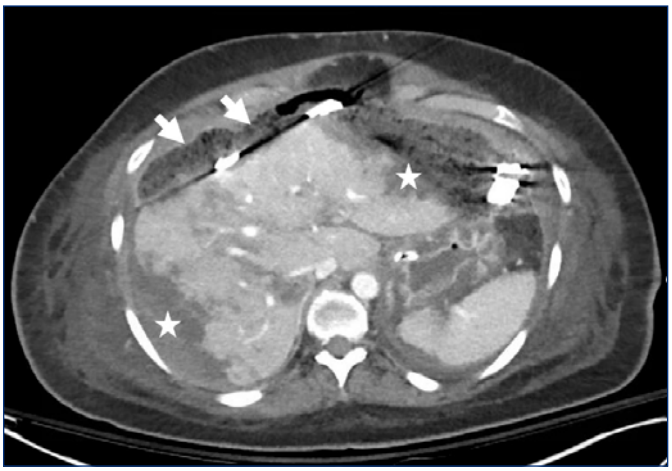

Figure 3. CT angiogram on post-operative day 5 demonstrating diffuse subscapular hematomas (stars) and packing material (arrows).

units (u) of packed red blood cells, 2 u of cryoprecipitate, 5 u of fresh frozen plasma, and 1 u of platelets. Arterial blood gas showed a pH of 7.1, lactate of 6.0 mmol/L, and low fibrinogen, concerning for DIC. An emergent exploratory laparotomy was performed during which the patient was found to have active hemorrhage from hepatic segments V and VI. The abdomen was packed and the patient was taken for catheter-directed embolization of hepatic segments VI-VIII [**Figures 2a,b**]. The Pfannenstiel and upper- midline incisions were left open, and a temporary abdominal closure device was placed.

The patient returned to the operating room on postoperative day 1. Although the initial right-lobe hemorrhage was hemostatic, the left liver capsule was found to be ruptured with considerably disrupted parenchyma. Bipolar cautery, topical hemostatic agents, and packing were used to control bleeding. In conjunction with the maternal fetal medicine service, the uterus was examined and was found to be unremarkable. On post-operative day 4, the patient was taken for operative washout of the abdomen and closure of the Pfannenstiel incision. A CT angiogram performed at that time demonstrated extensive hepatic damage, with liver heterogeneity and peripheral low-density hepatic/foci hemorrhage [**Figure 3**].

Her postoperative course was complicated by persistent respiratory failure and pneumonia requiring tracheostomy and thoracentesis. She also developed purpuric skin lesions consistent with a microvascular thrombotic process as seen in DIC on biopsy. She was eventually decannulated and discharged home after a 32-day hospital stay. After a few days in the neonatal intensive care unit for respiratory support, the newborn was deemed medically ready for discharge home.

DISCUSSION

Spontaneous hepatic rupture in pregnancy is a life-threatening emergency that can be successfully treated with prompt recognition and treatment. Multidisciplinary collaboration of obstetricians, surgeons, and radiologists is critical. The maternal and fetal mortality rates are 22.1% and 37.2%, respectively.[2] Most patients present in the late-second or third trimester. In a study of 391 patients with SHR, 250 (63.9%) were diagnosed during pregnancy (63.9%) and 141 (36.1%) were diagnosed in the postpartum period.[2] SHR is

strongly associated with hypertensive disorders of pregnancy, including preeclampsia or HELLP syndrome. In a prospective cohort study of 442 patients with HELLP syndrome, 0.9% developed SHR.[6] As a result of this association, prior literature has proposed that patients with preeclampsia or HELLP syndrome who have right upper-quadrant pain and hemodynamic instability warrant exclusion of SHR as the initial diagnosis.[2,7] However, not all hepatic rupture cases stem from HELLP and preeclampsia.[8,9] Augustin et al found that 81.4% of women with SHR had HELLP syndrome, 70.4% had preeclampsia, and 9.1% had eclampsia.[2] This association is often predicated on the assumption of universal prenatal care and early diagnosis of hypertensive disorders of pregnancy. Thus, clinical suspicion for SHR should exist for any third-trimester pregnant or postpartum patient with abdominal pain and unstable hemodynamics.

SHR is not evenly distributed in the liver. In the majority of cases, the right lobe is the origin of the hemorrhage (70.9%).[2,10] Rupture occurs bilaterally in (22.1%), and uncommonly in the left lobe alone (6.9%).[2,10] Management depends on patient stability, individual presentation, hospital resources, and physician expertise. While observation may be reasonable in a hemodynamically stable patient, active intervention is the best initial management option for acutely ill patients.[5,7] Interventions can include angioembolization, surgical packing, topical hemostatic agents, electrocautery, hepatic artery ligation, hepatectomy, and liver transplantation.[11] Surgical packing of the liver bed is the most common surgical intervention (56.4%).[2]

Some studies demonstrate a decrease in maternal mortality with liver transplantation and embolization; however, surgical packing is less morbid and should be considered initially with or without adjunct interventions like embolization.[2,5,12] Liver transplantation for HELLP is rare and reserved for severe hepatic failure. There were eight deceased donor liver transplants between 1987 and 2003 for HELLP syndrome of which six had long-term post-transplant survival.[13] As with the case presented above, damage-control laparotomy followed by additional operations for liver-directed therapy are appropriate in hemodynamically unstable patients. Hepatic embolization may also be suitable when both hepatic lobes are involved. Augustin et al found that while surgical packing was the most common treatment, it did not seem to influence survival.[2] In contrast, embolization was performed less frequently (n= 33 in comparison to n= 213 for liver packing) and was shown to have a significant survival benefit.[2] However, these therapies may be difficult to compare when using a retrospective approach. Persistent hemorrhage requires an individualized approach, so interval inspection and repacking can aid in the guidance of the treatment plan.

Interdisciplinary management has been shown to reduce the rates of maternal and fetal mortality and improves patient outcomes.[15] Furthermore, this multidisciplinary approach should continue after discharge from the hospital for continued optimization of both maternal and newborn outcomes. While there is a paucity of data regarding SHR recurrence in future pregnancies, the consequences of the resolved hepatic pathology, such as liver function, and interventions must be considered.[14] Close communication and continued interdisciplinary team follow-up can help identify potential physical and psychological complications after discharge.[15]

Special considerations are necessary in post-partum patients. Early consultation with lactation specialists and allowing women an opportunity to bond with their newborns is essential in optimizing the patient experience.

CONCLUSION

This case emphasizes the importance of clinical awareness in the rare but potentially fatal diagnosis of SHR in pregnant and post-partum patients. Individualized interventions, including endovascular and operative approaches, can be used to control the acute rupture. While the mortality rate in SHR is high, early identification and interdisciplinary management have the potential to optimize both maternal and fetal outcomes.

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Food Protein-Induced Enterocolitis Syndrome Masquerading as Sepsis in Early Infancy

TAYLOR PELS, MD; PRERANA BARANWAL, MD; EDWARD GILL, MD

ABSTRACT

Food protein-induced enterocolitis syndrome (FPIES) is a less common etiology of vomiting in an infant and can be challenging to diagnose. The absence of confirmatory laboratory testing or clear clinical criteria and signs/symptoms that overlap with other entities can lead to instances of misdiagnosis. We present a case of an exclusively breastfed infant who presented with emesis and dehydration. The infant was initially diagnosed with and treated for sepsis but was eventually diagnosed with FPIES. We discuss challenges in making a diagnosis of FPIES and potential factors that can distinguish it from sepsis.

KEYWORDS: food protein-induced enterocolitis syndrome (FPIES); neonatal sepsis; dehydration; vomiting; immunoglobulin E (IgE)

INTRODUCTION

The differential diagnosis for a vomiting, ill-appearing infant is broad and can prompt extensive work-up. More common infectious diagnoses are infectious gastroenteritis and bacterial sepsis. Anatomical causes can include pyloric stenosis, volvulus, and intussusception, among others. More rare presentations include Hirschsprung disease, necrotizing enterocolitis, metabolic disorders, and allergic disorders such as anaphylaxis, eosinophilic esophagitis, and food protein-induced enterocolitis syndrome (FPIES).[1,2] FPIES is a non-IgE-mediated food hypersensitivity reaction that ranges in severity of presentation, with 15–20% of cases leading to hypovolemic or distributive shock.[3,4] The pathophysiology is poorly understood. In 2017, diagnostic criteria for acute FPIES were published, but those for chronic FPIES remained quite broad—vomiting and/or diarrhea to varying clinical degrees after ingestion of an offending food.[3] Regardless of degree of presentation, symptoms should resolve after removing the offending food.[3] Given this fairly non-specific criteria, diagnosis is often delayed, and patients are often initially misdiagnosed with other conditions. We report a case of an exclusively breastfed infant who presented with dehydration and emesis. Based on initial laboratory studies and exam, she was initially thought to have, and was treated for, sepsis, but was ultimately diagnosed with FPIES.

CASE PRESENTATION

The patient is a 44-day-old female with sickle cell trait who presented to the emergency department with approximately one week of vomiting, dehydration, and weight loss.

Six days prior to presentation, the patient began spitting up with feeds, which was unusual for her. This gradually progressed to larger, more frequent non-bloody non-bilious emesis, vomiting two to three ounces of breastmilk after each feed. Parents also noted mild non-bloody diarrhea over the prior several days. Parents denied recent sick contacts, rhinorrhea, cough, or congestion.

The patient was born at 40 weeks gestation via cesarean section for fetal distress. Delivery was complicated by meconium-stained amniotic fluid and maternal fever during birth. The patient had no respiratory distress at birth, did not require sepsis rule-out, and did not require NICU admission. The patient's mother was diagnosed with postpartum endometritis requiring hospital stay and intravenous antibiotics. Sickle cell trait was identified on newborn screen, but the patient had otherwise been healthy.

She was exclusively breastfed and gained weight well in the first weeks of life. Her mother reportedly had a good breast milk supply. However, weight gain gradually slowed over the two weeks prior to presentation and weight eventually declined, with a notable weight loss of two ounces over the three days prior to presentation. She initially presented to her pediatrician, who ordered an abdominal ultrasound to rule out pyloric stenosis, which was normal. Continued weight loss, more frequent non-bloody non-bilious emesis, and the start of slightly watery stools prompted presentation to the emergency department.

In the emergency department, the patient was fussy but consolable with evidence of dehydration and delayed capillary refill on exam. Lungs were clear to auscultation, no rashes or vesicles noted, and abdomen was soft, non-tender, and nondistended without palpable masses. Given vomiting and poor growth, the pediatric gastroenterology team was consulted and recommended laboratory work-up. Initial labs were significant for leukocytosis with bandemia and elevated C-reactive protein of 46.67 mg/L. While in the emergency department, she gradually became more ill-appearing, with evidence of hypothermia and poor perfusion. Initial labs and worsening clinical status prompted a full septic work-up including blood, urine, and cerebrospinal fluid (CSF) studies.

Urinalysis was without pyuria but with evidence of dehydration. CSF studies were unremarkable. Respiratory and stool infectious panels were negative. Given concern for sepsis with hypothermia, tachycardia, and hypotension, leukocytosis with bandemia, and elevated inflammatory markers, the patient was started on ceftriaxone monotherapy at meningitic dosing and admitted for 48-hour sepsis rule out. Intravenous fluids were initiated for hydration in the setting of continued large-volume emesis after breastmilk feeds and worsening diarrhea.

Blood, urine, and CSF cultures remained negative at 48 hours, so antibiotics were discontinued. Speech Language Pathology was consulted given feeding concerns. Intake improved slightly with transition to different nipple and oral electrolyte solution. Given her negative infectious work-up and lack of improvement on antibiotics, suspicion increased for gastrointestinal concerns including milk protein allergy. An amino acid-based formula was started on hospital day four. On hospital day five, the patient continued to have feeding intolerance with worsening non-bloody diarrhea, and she became more ill-appearing and lethargic. She also became febrile, prompting repeat labs revealing significant electrolyte derangements (hypernatremia, hypokalemia, hyperchloremia), leading to transfer to the intensive care unit (ICU).

Given persistent vomiting and diarrhea, FPIES with possible bacterial translocation was high on the differential. The pediatric infectious disease team was consulted and recommended initiation of ceftriaxone and metronidazole. The pediatric gastroenterology team was consulted and recommended bowel rest and initiating parenteral nutrition.

In the ICU, she required continued electrolyte replacement. Stool output gradually slowed with bowel rest and parenteral nutrition. Repeat infectious studies were negative at 48 hours, so antibiotics were discontinued. Additional work-up revealed fecal calprotectin >3000 mg/kg, fecal elastase 68 ug/g. Clinical improvement with removal of trigger food (breastmilk, milk protein) suggested a diagnosis of FPIES.

After a period of bowel rest, the patient gradually tolerated Pedialyte and subsequently full enteral nutrition with an amino acid-based formula. She was ultimately discharged home with pediatric gastroenterology follow-up.

DISCUSSION

This case is an example of a particularly challenging diagnosis of FPIES in an exclusively breastfed infant who presented with clinical symptoms of sepsis.

FPIES typically presents within the first year of life when a new formula or food is introduced that triggers a reaction. The severity depends upon the amount and frequency of intake of the trigger food.[3] FPIES in children can be acute or chronic. In 2017, the "International consensus guidelines for the diagnosis and management of [FPIES]" were published, detailing major and minor criteria for acute FPIES but only a categorical description of chronic FPIES.[3] Acute FPIES is more common, presenting with acute onset emesis within several hours of ingesting the trigger food with or without associated lethargy, pallor, and diarrhea. Chronic FPIES is characterized by gradually worsening emesis or diarrhea over days to weeks and typically occurs when the trigger food is ingested regularly. It can be associated with poor weight gain or growth faltering. The diagnosis of chronic FPIES is typically confirmed by a trial of reintroduction of the trigger food thought to be leading to acute onset vomiting and diarrhea. Without this trial, the diagnosis remains presumptive.[3,4]

Because FPIES is a clinical diagnosis with poorly understood pathophysiology and no known biomarker for confirmatory testing, the diagnosis is often delayed and patients are often misdiagnosed with other conditions.[2,3,5] The case presented is an example of a delayed diagnosis of FPIES in which the patient was initially diagnosed with sepsis, no bacterial source was confirmed, and she did not recover until replacement of breast milk with amino acid-based formula. FPIES and sepsis share many clinical and laboratory features. Both can present with weakness, lethargy, vomiting, tachycardia, and hypotension, and both can be associated with leukocytosis with neutrophilia, thrombocytosis and metabolic acidosis.[2,5]

Lee et al conducted a retrospective case study attempting to identify distinguishing factors between acute FPIES and common mimickers including bacterial sepsis and gastroenteritis.[5] They found clinical features to be most helpful in identifying the diagnosis. While vomiting is common in all three, they found lethargy and pallor to be more commonly associated with FPIES, whereas diarrhea is more common in bacterial sepsis and gastroenteritis. Fever and elevated CRP were more predictive of sepsis and gastroenteritis.[5] However, another study found fever and elevated CRP to be present in at least one third of patients with FPIES.[6] In any case where fever or hypothermia is present, it is important that sepsis is first ruled out before consideration of alternative diagnoses. In the absence of a confirmatory biomarker or laboratory test, FPIES will likely remain a challenging diagnosis to make. Of note, in the present case, stool calprotectin was notably high and fecal elastase was low. While these studies are not always obtained when suspecting FPIES, the values noted in this case are not unusual in a patient with profuse diarrhea, which can lead to intestinal inflammation (and thus elevated stool calprotectin) and low fecal elastase (due to dilutional effect).

Another unique element of this case that made diagnosis challenging is that the infant was exclusively breastfed at the time of presentation. Several studies have shown that only about 5% of infants diagnosed with FPIES were exclusively breastfed at the time of presentation.[7,8] Mild FPIES in

an exclusively breastfed infant can be managed with transition to an extensively hydrolyzed formula (and sometimes, mothers can implement an exclusion diet). However, in severe cases like the one presented here, an amino acid-based formula is generally the preferred management.[9]

CONCLUSION

When evaluating an ill-appearing infant presenting with emesis, the initial differential diagnosis is broad and includes several potentially serious conditions that require rapid diagnosis. It is important to consider FPIES as a potential cause of this presentation, especially in cases where a child has unexplained refractory hypovolemic shock despite appropriate empiric therapy. FPIES will likely remain a challenging diagnosis to make given the clinical nature of the diagnosis and the absence of confirmatory testing.

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Ventricular Septal Rupture Secondary to Late-Presenting Myocardial Infarction

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ABSTRACT

BACKGROUND

Over 800,000 acute myocardial infarction (AMI) events occur annually in the United States. Increased emphasis on primary prevention strategies has decreased the incidence of AMI.[1,2] Treatment of AMI includes reperfusion of the culprit coronary arteries, and expeditious intervention has led to a decrease in the rate of post-AMI complications.[3] However, these complications still occur in approximately 0.3% of patients presenting with AMI; this is estimated to be about 2,400 patients annually.[4,5]

Myocardial tissue necrosis secondary to AMI can lead to several different mechanical complications, including papillary muscle rupture, ventricular septal rupture (VSR), and free-wall rupture.[2,3,6] These complications usually occur within the first seven days after an AMI.[2,3] Mortality from one of these MCs is over 42%, with women and patients older than 75 years of age having an even higher mortality rate.[5] This makes prevention, recognition, and prompt treatment critically important. Here we present a case report of a patient with post-AMI VSR.

KEYWORDS: Ventricular Septal Rupture; Acute Myocardial Infarction; Mechanical Complication

CASE REPORT

An 86-year-old female with a past medical history of coronary artery disease, hypertension, diabetes mellitus, atrial fibrillation without anticoagulation, and previous cerebrovascular accident presented with two days of generalized weakness and nausea. Upon arrival, the patient's vital signs included: temperature 98.6°F; heart rate 137, respiratory rate 21; blood pressure 130/77; pulse oximetry 95% on room air. Physical exam revealed a harsh, holosystolic murmur, heard best along the mid-left sternal border. Electrocardiogram demonstrated anterolateral ST segment elevation without reciprocal depression, and initial laboratory evaluation revealed a high-sensitivity troponin I of 15,857 ng/L. Comprehensive echocardiography was not available at time of the patient's initial presentation; however, a previous echocardiogram from one year prior had shown no significant wall-motion or valvular abnormalities. Due to concern for acute ischemia, the patient was taken to the cardiac catheterization laboratory from the Emergency Department. Cardiac catheterization revealed a total occlusion of the left anterior descending (LAD) artery without evidence of collateralization. A ventriculogram during the cardiac catheterization was suggestive of a ventricular septal rupture with left-to-right shunting. Stenting of the LAD artery occlusion was deferred, a heparin infusion was initiated, and the patient was transferred to the Coronary Care Unit (CCU) for evaluation by cardiothoracic surgery. Placement of an intra-aortic balloon pump (IABP) was deferred prior to transfer, predominantly due to logistic reasons.

The patient had stable vital signs and did not require vasopressor medications. Follow-up laboratory studies revealed a significant increase in high-sensitivity troponin up to 64,876. A comprehensive echocardiogram identified an 8 mm apical septal defect with left-to-right shunting [**Figures 1,2**]. The apex was akinetic and aneurysmal with an estimated left ventricular ejection fracture of 45%.

Within a few hours, and while heart-team discussions were ongoing, the patient suddenly became hypoxic and bradycardic. Advanced cardiovascular life support was immediately initiated, and the patient was intubated. A bedside point-of-care echocardiogram was performed which demonstrated a new moderately-sized pericardial effusion with right ventricular collapse consistent with cardiac tamponade. The patient had a sudden arrest of cardiac activity and cardiopulmonary resuscitation was initiated. The patient was pronounced dead after the family requested termination of resuscitation efforts. The etiology of the patient's acute decompensation was suspected to be progression of the VSR to include free-wall rupture.

DISCUSSION

This case represents the development of a post-AMI VSR, likely further complicated by free-wall rupture. VSR is the most common AMI-related mechanical complication,[5] and it results in a left-to-right shunt which can be appreciated on physical exam by auscultation of a holosystolic murmur.[2,3,6] The left side of the heart will eventually develop volume overload, causing dyspnea and clinical signs of cardiogenic shock.[3] Cardiogenic shock is the most significant cause of mortality following AMI and can be due to either left, right, or biventricular dysfunction.[7,8]

Figure 1. Partial view of the apical four-chamber view defect in the apical portion of the ventricular septum.

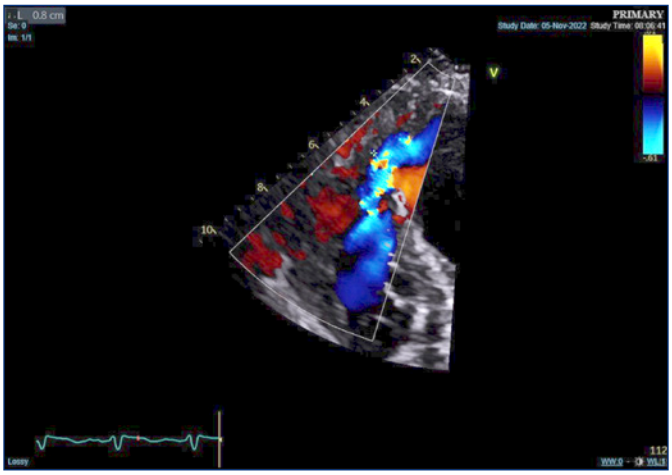
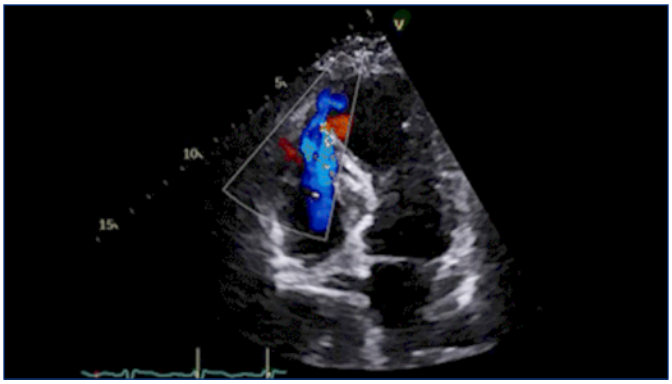


Figure 2. Clipped image of an apical four-chamber view showing a defect in the apical portion of the ventricular septum which shows left-to-right shunting.



Before the introduction of thrombolytic and percutaneous coronary intervention (PCI) therapies, VSR occurred in 1–3% of AMI cases. After these therapies were adopted, the incidence of VSR dropped to 0.2–0.5%.[7] The risk of developing a VSR after an AMI occurs in a bimodal fashion, with highest risk in the first 24 hours and again three to five days later.[9] The median time from AMI symptom onset to VSR has been reported to be between 16 hours and one day.[10,11] Longer time to PCI or thrombolytic administration increases the risk for development of a VSR.[12]

Diagnosing post-AMI mechanical complications require suspicion based on history and exam followed by emergent imaging, the latter including bedside echocardiography and ventriculography during cardiac catheterization. Mortality is related to management of cardiogenic shock prior to and after repair of the VSR, and thus immediate treatment of a post-AMI VSR involves management of cardiogenic shock. While ultimately closure of the defect, either with open or percutaneous surgical repair, is necessary, optimal timing of the repair is in question.[3,6,13] Based on case series and retrospective analyses, a delayed repair is associated with improved repair success and outcome.[14,15] The delay allows time for tissue remodeling, a reduced chance of defect progression, an opportunity to manage cardiogenic shock, and an opportunity to better define the defect and associated dysfunction with more advanced imaging.[14-17] Stabilization of patients awaiting surgical closure of a VSR often require vasopressors and inotropes, which may increase myocardial stress and oxygen consumption, potentially leading to increased defect progression.[14]

Alternatively, mechanical circulatory support (MCS) could be employed and has shown to reduce stress on the infarct and per-infarct zone while potentially limiting extent of cardiac injury.[5,17] Reduction of cardiac stress is crucial for reducing the risk for progression to free wall rupture or ventricular pseudoaneurysm.[18] An intra-aortic balloon pump reduces cardiac loading conditions and the VSR-induced left to right shunt; however, its role in increasing cardiac output is minimal.[17] Extracorporeal Membrane Oxygenation (ECMO) effectively increases systemic blood flow but, when placed peripherally, there may be an increase in afterload due to retrograde perfusion from the circuit, causing added strain on the left ventricle.[17] More recently, the role of temporary ventricular assist devices (tVAD) have been investigated in the management of cardiogenic shock in patients with a post-AMI VSR.[17] Clinical studies on tVAD are ongoing, and the available clinical data is still limited. Mortality was not found to be significantly improved with the use of IABP or ECMO. [5] In most studies, the placement of MCS in elderly patients typically refers to those over 65 or 70 years old. However, the use of MCS in octogenarians, including our patient, is less well documented and has been considered a relative contraindication.[19-21] Additionally, due to the logistical and procedural complexity of MCS, there are limitations on when and where it can be implemented, as was the case for our patient, who initially presented to a small hospital and required transfer for further care.

CONCLUSIONS

Our patient presented with a post-AMI VSR. Although the diagnosis was made in a timely manner, progression of the defect to include a free-wall rupture likely occurred, causing a fatal outcome. Immediate suspicion and emergency imaging are critical toward implementing immediate therapy, which is directed at preventing defect expansion and pression while managing cardiogenic shock. It is possible that immediate percutaneous revascularization and implementation of a MCS device might have reduced the likelihood of progression.

Despite available therapies, mortality associated with a VSR remains high. Current opinion supports a delay in definitive repair and early implementation of MCS to reduce cardiac load and stress, to permit time for per-infarct tissue

remodeling, to manage cardiogenic shock, and allow the opportunity to accurately define the defect with advanced imaging. Multidisciplinary teams involving emergency medicine physicians, cardiologists, interventional cardiologists, and intensivists play a vital role in optimizing outcomes for patients with a post-AMI VSR.

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A Vesiculopustular Skin Eruption

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KEYWORDS: Subcorneal pustular dermatosis; Sneddon-Wilkinson; vesiculopustular

CASE PRESENTATION

A 69-year-old female with no significant past medical history presented with tender, flaccid vesiculopustules and bullae located on the right lower and mid back, bilateral upper arms, and left thigh [**Figure 1**]. No new medications had been prescribed several months prior to presentation. She had no systemic symptoms and Nikolsky's sign was negative. She was prescribed clobetasol 0.05% ointment twice daily for two weeks. One month later, the lesions on her back had improved; however, new lesions had developed in the right axilla, bilateral medial thighs, right rib cage, and abdomen [**Figure 2**]. Punch biopsies of the right superior and inferior axillary vault were performed for Hematoxylin and Eosin and Direct Immunofluorescence. Pathology demonstrated subcorneal vesiculopapule with intraepidermal neutrophils and eosinophils consistent with subcorneal pustular dermatosis.

SPD, also known as Sneddon-Wilkinson disease, is a rare chronic vesiculopustular condition. It typically presents as sterile pustules in an annular pattern on the trunk, proximal extremities, and flexural regions while sparing the face, palms, and mucosa. It is most commonly seen in women over the age of 40 and has an unknown etiology.[1,2] Diagnosis is made through biopsy. Histopathologic examination shows subcorneal pustules filled with neutrophils and occasional eosinophils sitting atop the epidermis. In addition to neutrophils and occasional eosinophils, in older lesions, a rare acantholytic cell may be present as well. There are no mitotic features seen in the epidermis and within the underlying dermis, mixed superficial perivascular inflammatory cell infiltrate is present. Direct and indirect immunofluorescence are generally negative.[2]

When evaluating vesiculopustular eruptions on the trunk, upper arms, and legs, it is important to consider a broad differential diagnosis, as a variety of dermatologic conditions can present with similar morphologies. Common considerations include acne vulgaris, folliculitis, and generalized pustular psoriasis.

Figure 1. A woman with scattered vesicles and pustules on her bilateral upper abdomen.

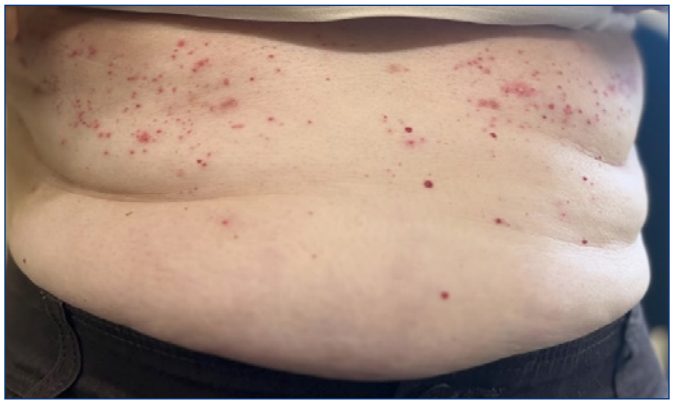
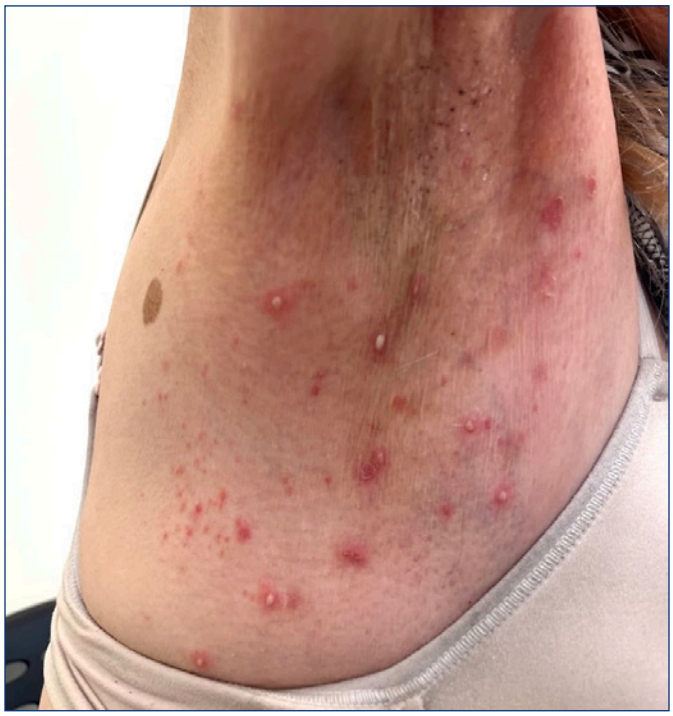


Figure 2. A woman with vesicles and pustules in her right axilla.



Acne Vulgaris is a chronic condition characterized by pustules and papules on the face, neck, and trunk. It is caused by inflammation of the pilosebaceous unit and involves many factors including hormones increasing sebum production,

hyperkeratinization of the follicle, and the presence of *Cutibacterium acnes*. Unlike SPD, acne is more common in adolescents and young adults. Histopathology shows a dilated follicle with keratin plug and can show signs of surrounding inflammation.[3]

Folliculitis is a common condition caused by the inflammation of hair follicles which can arise from infectious and noninfectious origins. It presents as inflamed pustules or papules anywhere there are hair follicles. These lesions differ from SPD in that they center around hair follicles. Noninfectious folliculitis is often due to friction while infectious folliculitis can be due to superficial or deep bacterial, fungal, or viral causes. Histologic evaluation shows lymphocytic inflammatory infiltrates near hair follicles.[4]

While both Generalized Pustular Psoriasis (GPP) and SPD can present with a widespread pustular eruption, GPP is also often accompanied by systemic symptoms, such as fever and malaise. GPP is also similarly predominantly diagnosed in women around 50 years of age. GPP is suspected in patients with a family history of psoriasis or physical exam findings consistent with psoriasis. The flares of GPP, commonly after a patient with psoriasis is given systemic steroids, can be life threatening if left untreated as it can lead to complications such as cardiovascular failure and sepsis.[5]

Given the broad range of potential diagnoses, careful clinical evaluation is essential when assessing vesiculopustular eruptions on the trunk and extremities. Recognizing subtle differences in lesion morphology, distribution, and associated symptoms can help narrow the differential and guide appropriate management. As primary care and urgent care/emergency room clinicians are typically the first to see these patients, we recommend increasing their level of suspicion when pustules in an annular pattern on found on the trunk, particularly in females above the age of 40.

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The Role of Therapeutic Plasma Exchange in Treatment of Autoimmune Glial Fibrillary Acidic Protein Astrocytopathy

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ABSTRACT

KEY IDEAS

- Autoimmune glial fibrillary acidic protein (GFAP) astrocytopathy is a recently identified inflammatory central nervous system (CNS) disorder marked by GFAP-IgG autoantibodies.
- Therapeutic plasma exchange (TPE) removes pathogenic autoantibodies, cytokines, and immune complexes, thereby targeting the disease's core immunopathology.
- TPE is a rational and potentially lifesaving therapy in autoimmune GFAP astrocytopathy, especially in refractory or life-threatening cases.

KEYWORDS: Autoimmune GFAP Astrocytopathy; Plasma Exchange; Plasmapheresis

INTRODUCTION

Autoimmune GFAP astrocytopathy is a rare, recently recognized autoimmune inflammatory disease of the central nervous system with presumably less than a thousand cases reported to date.[1] It is characterized by the presence of GFAP-IgG autoantibodies,[2,3] and it typically manifests as an antibody-mediated meningoencephalomyelitis, with patients often presenting with acute meningeal irritation and encephalitic symptoms such as fever, headache, ataxia, psychosis, dyskinesia, dementia, seizures and altered consciousness, and sometimes myelitis or optic neuritis.[4–6] Nevertheless, a subset of patients may only present with some or a few of the aforementioned symptoms, thereby eluding early detection.[6] Although the exact pathophysiology is unknown, autoimmune GFAP astrocytopathy appears driven by both T-cell and B-cell immune mechanisms as well as cytokines.[7,8] Pathological analyses have found abundant CD138+ plasma cells in CNS lesions with intrathecal antibody synthesis—GFAP-IgG titers are often higher in cerebrospinal fluid (CSF) than serum[9]—and elevated inflammatory mediators in the CSF. In particular, patients show significantly increased levels of proinflammatory cytokines (IL-1β, IL-6, IL-17) and activation of the NLR family pyrin domain containing 3 (NLRP3) inflammasome in CSF—involved in the release of IL-1β and IL-18 from the cells—correlating with disease severity and antibody titers.[10] These findings hypothesize that pathogenic autoantibodies and downstream neuroinflammatory cascades immune-cell recruitment with subsequent cytokine release and eventual astrocytic injury are central to autoimmune GFAP astrocytopathy's pathogenesis. Due to the rarity and only recent recognition of the disease, there is an absence of solid evidence such as controlled studies or randomized trials. The purpose of this brief review is to critically evaluate the emerging evidence supporting TPE in refractory autoimmune GFAP astrocytopathy, offering clinical insights and guidance for neurologists managing this condition.

UTILITY OF THERAPEUTIC PLASMA EXCHANGE IN AUTOIMMUNE GFAP ASTROCYTOPATHY

Given this immune-driven pathology, TPE has emerged as a logical acute treatment modality in severe autoimmune GFAP astrocytopathy. TPE can rapidly eliminate autoantibodies, cytokines, chemokines, immune complexes, and complement components that contribute to ongoing CNS injury.[5] By reducing this inflammatory burden and modulating immune-cell trafficking, plasma exchange directly addresses the disease's mechanism, attenuating the immune attack on astrocytes.[5] Clinically, high-dose corticosteroids remain first-line therapy as the majority (approximately 70–80%) of patients show a dramatic and rapid response to the treatment.[5] However, a significant subset experience relapses or inadequate response, especially those with high CSF antibody load or extensive CNS lesions.[9] In such refractory or fulminant cases, plasma exchange has been shown to improve outcomes.

CLINICAL EVIDENCE FOR THERAPEUTIC PLASMA EXCHANGE IN AUTOIMMUNE GFAP ASTROCYTOPATHY

Case reports describe patients who failed to improve with steroids and IVIG yet had dramatic recovery after TPE. In a case reported by Du et al,[5] two patients with autoimmune GFAP astrocytopathy and life-threatening brainstem involvement with respiratory failure were successfully weaned off ventilatory support only after plasma exchange therapy was instituted.[5] Likewise, immunoadsorption, a selective form of

plasma exchange that specifically removes IgG, has reversed severe steroid-resistant autoimmune GFAP astrocytopathy in at least one case described by Qin et al,[3] underscoring the pivotal role of pathogenic antibodies in this disease. Ip et al[11] described a patient who developed autoimmune GFAP astrocytopathy-associated meningoencephalomyelitis, acute bilateral sensorineuronal deafness, tetraplegia, bulbar palsy and respiratory failure. The patient was treated with steroids and IVIG that resulted in partial recovery. Later, she had a course of TPE followed by rituximab and she showed marked recovery of her disease. Gklinos et al[12] reported a severe case that did not respond to steroid treatment and underwent five cycles of TPE that resulted in clinical improvement. Yang et al[13] presented a patient who failed to respond to steroids and IVIG but improved after TPE. Taken together, these insights suggest that timely TPE can be a critical therapeutic option in the management of autoimmune GFAP astrocytopathy—presumably by acutely removing the immune elements driving the astrocytic inflammation, TPE targets the presumed core pathophysiology and may improve neurologic outcomes when conventional immunotherapies are insufficient.

PRACTICAL CLINICAL CONSIDERATIONS AND LIMITATIONS

Despite recognition of TPE as a valuable intervention in autoimmune GFAP astrocytopathy, several challenges limit its widespread integration into clinical practice. Due to the rarity of the condition, current evidence is largely derived from isolated case reports, which, although informative, lack the power to guide definitive recommendations. Additionally, the optimal timing, number of exchange sessions, and integration of TPE with other immunotherapies (e.g., corticosteroids, IVIG, rituximab) remain uncertain. Moreover, the risks of procedure-related complications and cost effectiveness in this context have not been systematically evaluated. Although TPE is promising, clinicians must balance potential benefits against procedural risks, including infections, bleeding, vascular access complications, and resource demands. Early initiation may be most beneficial in rapidly progressive disease or severe clinical presentations with high antibody loads, although this hypothesis warrants validation.

FUTURE DIRECTIONS AND RESEARCH NEEDS

Future research should include prospective, multicenter studies to validate TPE efficacy systematically, identify reliable biomarkers of therapeutic response, and determine optimal protocols for integrating TPE with adjunctive immunotherapies.

CONCLUSION

Autoimmune GFAP astrocytopathy is a challenging neuroinflammatory disorder driven by autoantibodies and immune activation. While corticosteroids are the currently considered mainstay of therapy, a subset of patients with severe or refractory disease may benefit from TPE. By removing circulating autoantibodies and proinflammatory mediators, TPE directly addresses the immunopathological mechanisms underlying astrocytic injury. Accumulating case-based evidence supports its use in steroid-resistant or fulminant presentations, including life-threatening brainstem involvement. TPE should be considered in the treatment of autoimmune GFAP astrocytopathy, especially in refractory cases.

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The Unfinished Story: Analyzing Publication Rates in Diabetic Retinopathy and Diabetic Macular Edema Trials Before the COVID-19 Era (1972–2018)

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ABSTRACT

Clinical trials are essential to evidence-based ophthalmology, yet publication bias and discontinued studies threaten data transparency. For diabetic retinopathy (DR) and diabetic macular edema (DME), the extent of unpublished or terminated trials remains unclear. This study evaluates publication trends in DR and DME trials conducted prior to the COVID-19 pandemic. We performed a retrospective cross-sectional analysis of interventional DR and DME trials registered in ClinicalTrials.gov from 1972–2018. Collected variables included funding source, intervention type, trial phase, publication and discontinuation status, and sample size. Chi-square tests assessed associations between trial characteristics and publication outcomes using Stata/SE 18.0. Among 333 included trials, 284 were non-terminated. Of these, 70.1% (n=199) were unpublished, representing 26,251 participants, while 29.9% (n=85) were published, accounting for 45,747 participants. Trials with fewer than 50 participants were over three times more likely to remain unpublished (P <0.0001). Industry-funded trials comprised 48.6% of the cohort but were not significantly more likely to publish than academic-funded trials (P = 0.874). Phase 2 trials were the most common (31.2%), and 18.3% of trials lacked phase designation. This is the first study to comprehensively assess publication patterns in DR and DME trials. The high rate of non-publication, particularly among smaller trials, contributes to a substantial loss of participant data and raises ethical concerns. Greater accountability and complete dissemination of trial outcomes are necessary to uphold the integrity of ophthalmic research and ensure that patient contributions meaningfully inform clinical care.

KEYWORDS: publication bias; clinical trial; research ethics; diabetic retinopathy; macular edema.

INTRODUCTION

Clinical trials serve as the cornerstone of evidence-based medicine, guiding treatment decisions across all medical specialties, including ophthalmology. For diabetic retinopathy (DR) and diabetic macular edema (DME), clinicians rely on landmark trials to inform management strategies. However, the quality of available evidence is undermined by publication bias, trial discontinuation, and unpublished results. While the COVID-19 pandemic disrupted approximately 80% of clinical trials,[1] this study focuses on trials conducted from 1972 to 2018 to avoid confounding factors. Our aim is to identify and analyze publication patterns in DR and DME interventional trials, addressing a critical gap in the current literature.

METHODS

We conducted a retrospective, cross-sectional analysis of DR and DME trials registered in ClinicalTrials.gov from 1972 to 2018. Data collected included funding source, intervention type, publication status, trial phase, discontinuation status, and sample size. Chi-square tests explored associations between trial characteristics and publication outcomes, using Stata/SE 18.0.

RESULTS

As shown in **Table 1**, among the 333 analyzed trials, 78.7% investigated drug/biological interventions, 16.2% device/procedural, and 5.1% other types. Funding was evenly split between academic institutions (51.4%) and industry (48.6%). Most trials (93.4%) were conducted from 2003-2018, with 9.3% terminated and 5.4% withdrawn. Phase distribution varied considerably, with Phase 2 trials comprising 31.2% of all studies, followed by Phase 3 (26.4%) and Phase 4 (15.0%), while 18.3% did not specify their phase.

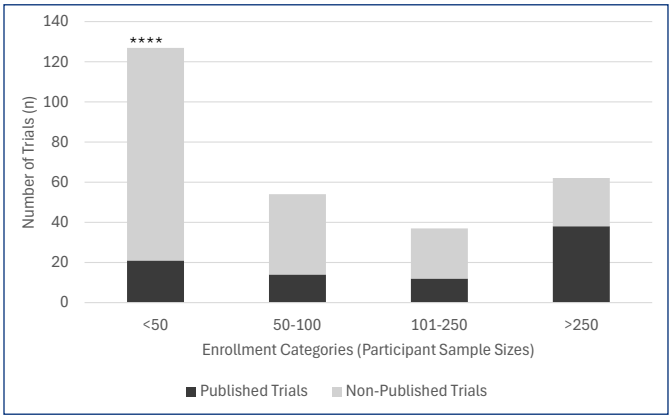
Of the 284 non-terminated trials, 70.1% (n=199) remain unpublished, representing 26,251 participants. In contrast, 29.9% (n=85) were published, contributing data from 45,747 participants. Among discontinued trials, 1.5% (n=5) were published and 7.8% (n=26) unpublished. As illustrated in **Figure 1**, non-terminated trials with fewer than 50 participants were over three times more likely to remain unpublished compared to larger trials (P <0.0001). Funding source did not significantly influence publication status (P = 0.874 for non-terminated trials; P = 0.56 for terminated trials).

Table 1. Characteristics of Diabetic Retinopathy and Diabetic Macular Edema Clinical Trials (1972–2018) by Trial Status and Outcome

	All Trials (n = 333)	Non-terminated Published Trials (n = 85)	Non-terminated Unpublished Trials (n = 199)	Terminated Published Trials (n = 5)	Terminated Unpublished Trials (n = 26)	Withdrawn Trials (n = 18)
Primary Funding Source [n (%)]						
Academic Institution	171 (51.4)	47 (55.9)	108 (54.3)	2 (40)	7 (26.9)	7 (38.9)
Industry	162 (48.6)	38 (44.7)	91 (45.7)	3 (60)	19 (73.1)	11 (61.1)
Study Date [n (%)]						
Before 2003	22 (6.6)	16 (18.8)	6 (3)	0	0	0
2003-2018	311 (93.4)	69 (81.2)	193 (97.0)	5 (100)	26 (100)	18 (100)
Intervention [n (%)]						
Drug/Biologic	262 (78.7.)	62 (72.9)	158 (79.4)	4 (80)	21 (80.8)	17 (94.4)
Device/Procedure	54 (16.2)	15 (17.6)	34 (17.1)	1 (20)	3 (11.5)	1 (5.6)
Other	17 (5.1)	8 (9.5)	7 (3.5)	0	2 (7.7)	0
Trial Phase* [n (%)]						
Phase 1	30 (9)	2 (2.4)	20 (10.1)	0	4 (15.4)	4 (22.2)
Phase 2	104 (31.2)	21 (24.7)	69 (34.7)	2 (40)	6 (23.1)	6 (33.3)
Phase 3	88 (26.4)	39 (45.9)	38 (19.1)	2 (40)	7 (26.9)	2 (11.1)
Phase 4	50 (15.0)	9 (10.6)	33 (16.6)	0	3 (11.5)	5 (27.8)
Unknown	61 (18.3)	14 (16.4)	39 (19.6)	1 (20)	6 (23.1)	1 (5.6)
Enrollment [n (%)]						
<50	163 (49.0)	21 (24.7)	106 (53.3)	2 (40)	16 (61.5)	18 (100)
50–100	55 (16.5)	14 (16.5)	40 (20.1)	0	1 (3.8)	0
101–250	45 (13.5)	12 (14.1)	25 (12.6)	3 (60)	5 (19.3)	0
>250	64 (19.2)	38 (44.7)	24 (12.0)	0	2 (7.7)	0
Unknown	6 (1.8)	0	4 (2)	0	2 (7.7)	0
Total Number of Participants [n]	74,252	45,747	26,251	606	1,648	N/A

* Trials described as Phase 1/2 (n = 16) were categorized as Phase 2 and trials described as Phase 2/3 (n = 6) were categorized as Phase 3.

Figure 1. Publication Status by Sample Size in Non-Terminated Diabetic Retinopathy and Diabetic Macular Edema Clinical Trials



Chi-square test was used to compare publication status by sample size. Trials with fewer than 50 participants were over three times as likely to remain unpublished ($p < 0.0001$). Statistical significance is indicated by four asterisks (****).

DISCUSSION

This study presents the first comprehensive analysis of publication patterns in DR and DME trials, revealing concerning trends. Non-publication threatens evidence-based medicine. Small sample sizes (n<50) were significantly associated with non-publication, potentially due to limited result generalizability. The lack of phase designation in 18.3% of trials complicates interpretation of progress and outcomes.[2] Consistent with previous research,[3] funding source did not impact publication likelihood. Notably, 36.5% of non-terminated trial participants did not contribute to the literature due to non-publication, representing not only a loss of valuable data but also a disservice to those who gave their time and effort to advance scientific knowledge.

While ClinicalTrials.gov may not include all trials and reported data are not always independently verified,[4] it captures at least 70% of globally registered trials,[5] and is supposed to capture 100% of American trials, thus providing a robust sample.

The high rate of non-publication in DR and DME trials results in a substantial loss of evidence and raises significant

ethical concerns regarding the appropriate use of participant data and the responsible conduct of research. Greater transparency and more consistent reporting of outcomes, regardless of findings, are needed to uphold the integrity of the scientific process and honor the contributions of study participants. Future research should explore factors contributing to non-publication and develop strategies to enhance the complete dissemination of trial results. Our findings highlight a similar theme that span clinical medical trials across various specialties. Clinical trial publication rates and individual study characteristics have been examined across neurology, oncology, rheumatology, and gynecology.[6-9] Addressing this critical issue is essential to advancing evidence-based medicine and improving patient care across healthcare.

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The authors report no conflicts of interest relevant to this work. The views expressed herein are those of the authors and do not necessarily reflect the views of their affiliated institutions. This study is based on a retrospective analysis of publicly available, de-identified data from ClinicalTrials.gov. As the data does not involve human subjects or require interaction with participants, the Brown University Institutional Review Board (IRB) Human Research Protection Program deemed this study exempt from IRB review.

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Trends from the Rhode Island Harm Reduction Surveillance System: 2021–2024

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ABSTRACT

Amid the increase in fatal overdoses in Rhode Island (RI) over the past decade, understanding substance use and harm reduction practices is critical for informing prevention strategies. This work aimed to evaluate trends in substance use behaviors, overdose experiences, and harm reduction practices among people who use non-prescribed substances in RI. In a convenience sample of 673 participants from the 2021–2024 Harm Reduction Surveillance System (HRSS), the most reported substances used in the past 30 days were: alcohol (73%), crack cocaine (72%), cannabis (69%), cocaine (42%), and fentanyl/heroin (39%). We observed a decrease in harm reduction practices in 2024, including always using fentanyl test strips and always using substances in the presence of others after an increase from 2021 to 2023. Notably, 86% of respondents reported having a disability. These findings emphasize the ongoing need for comprehensive harm reduction programs to engage high-risk individuals, tailored to those with disabilities.

KEYWORDS: harm reduction; overdose; substance use

INTRODUCTION

Over the last 10 years, deaths from accidental drug overdoses in Rhode Island (RI) increased by 68%, from 240 in 2015 to 404 in 2023.[1] To address the overdose epidemic, the Rhode Island Department of Health (RIDOH), in partnership with community organizations, promotes harm reduction strategies to improve the health of individuals who use substances.[2,3] To help inform these prevention strategies, RIDOH launched the Harm Reduction Surveillance System (HRSS) to understand how substance use, overdose experience, and harm reduction practices may have changed among individuals in RI who use non-prescribed substances.

METHODS

The HRSS was launched in January of 2021 by RIDOH in partnership with Preventing Overdose and Naloxone Intervention (PONI) based at The Miriam Hospital. The HRSS used a convenience sampling method to collect information from people who were actively using non-prescribed substances in RI, including capturing data on demographics, substance use behaviors, overdose experience, harm reduction practices, and access to health services and substance abuse treatment. In 2023, the survey added a question to collect self-reported diagnosed disability information on physical, sensory, developmental disability, mental health, traumatic brain injury, and post-traumatic stress disorder (PTSD). Participants were recruited via targeted canvassing and referrals at community outreach and needle exchange programs, encampments, and overdose hotspots in RI. Individuals who participated in this survey were given $25 compensation. Recruitment for the HRSS ended on December 31, 2024.

Survey participants were included in this analysis if they were a current RI resident, aged 18 or older, provided verbal consent, and self-reported use of non-prescribed substances in the past 30 days (excluding individuals who only used cannabis). We compared demographic characteristics, alcohol and non-prescribed substance use, overdose experience, and harm reduction practices stratified by year using chi-square or Fisher's exact tests when expected cell counts were less than or equal to five (p=0.05). This work is considered public health surveillance and was deemed exempt by the RIDOH Institutional Review Board (IRB) and approved by the Miriam Hospital IRB. All analyses were performed in SAS (Version 9.4).

RESULTS

From 2021 to 2024, 673 RI residents met inclusion criteria. Most participants were ages 25–54 (79%), male (66%), non-Hispanic White (40%), experienced housing instability (77%), and had health insurance (93%) [**Table 1**]. Since the disability module was added in 2023, 86% reported having a disability, and the most common disability types were mental health (73%), PTSD (58%), and developmental disabilities (42%). When looking at harm reduction practices by diagnosed disability types, significant differences were observed in currently carrying naloxone and use of fentanyl test strips between those who reported having diagnosed developmental disability compared to those who did not [**Table 2**].

Alcohol (73%), crack cocaine (72%), cannabis (69%), cocaine (42%), and fentanyl/heroin (39%) were the most

Table 1. Demographics of respondents by year, Rhode Island Harm Reduction Surveillance System, 2021–2024

	2021 N=200	2022 N=193	2023 N=111	2024 N=169	Total N=673
Age[a]					
18–24	9 (4.5)	10 (5.2)	5 (4.6)	10 (5.9)	34 (5.1)
25–34	54 (27.0)	57 (29.5)	26 (23.6)	28 (16.6)	165 (24.6)
35–44	50 (25.0)	65 (33.7)	41 (37.3)	58 (34.3)	214 (31.9)
45–54	54 (27.0)	37 (19.2)	28 (25.5)	36 (21.3)	155 (23.1)
55–64	26 (13.0)	21 (10.9)	9 (8.2)	34 (20.1)	90 (13.4)
65+	7 (3.5)	<5	<5	<5	14 (2.1)
Sex assigned at birth					
Male	129 (64.5)	127 (65.8)	74 (67.3)	116 (69.1)	446 (66.5)
Female	71 (35.5)	66 (34.2)	36 (32.7)	52 (31.0)	225 (33.5)
Race and ethnicity					
Hispanic (any race)	44 (22.0)	53 (27.5)	36 (32.4)	49 (29.0)	182 (27.0)
Non-Hispanic Black	35 (17.5)	38 (19.7)	16 (14.4)	34 (20.1)	123 (18.3)
Non-Hispanic White	93 (46.5)	69 (35.8)	46 (41.4)	61 (36.1)	269 (40.0)
Other	28 (14.0)	33 (17.1)	13 (11.7)	25 (14.8)	99 (14.7)
Housing status[a]					
Housing Stable	45 (23.0)	54 (28.4)	26 (24.1)	26 (15.5)	151 (22.8)
Housing Instable	151 (77.0)	136 (71.6)	82 (75.9)	142 (84.5)	511 (77.2)
Health insurance					
Yes	191 (95.5)	181 (93.8)	102 (91.9)	154 (91.1)	628 (93.3)
No	9 (4.5)	12 (6.2)	9 (8.1)	15 (8.9)	45 (6.7)
Diagnosed disabilities[b,c]					
Physical	—	—	35 (32.1)	60 (36.4)	95 (34.7)
Sensory[a]	—	—	17 (15.6)	47 (28.5)	64 (23.4)
Developmental	—	—	47 (43.5)	69 (41.6)	116 (42.3)
Mental Health	—	—	74 (68.5)	124 (75.2)	198 (72.5)
Traumatic Brain Injury	—	—	16 (14.8)	37 (22.3)	53 (19.3)
Post Traumatic Stress Disorder (PTSD)	—	—	54 (50.9)	102 (61.8)	156 (57.6)

Notes: Percentages may not add up to 100% due to rounding; Count may not add up to total due to missing/unknown responses.

Counts less than 5 are reported as <5.

[a] Statistically significant at p<0.05

[b] Diagnosed disabilities question was asked starting in 2023; Total percentages are based on 2023 and 2024 participants

[c] Physical category include conditions such as cerebral palsy, mobility impairment, and multiple sclerosis. Sensory category includes any problems with hearing or seeing. Developmental category includes autism, ADHD, and dyslexia. Mental health category includes conditions such as depression, bipolar, and anxiety.

reported non-prescribed substances used in the past 30 days [**Table 3**]. In all included years, at least 85% of respondents reported using more than one substance in the past 30 days. From 2021 to 2024, we observed decreases in the proportion of respondents who reported using benzodiazepines (30% to 7%), fentanyl/heroin (49% to 36%), and opioid pain medications (22% to 9%). About one-third of respondents reported consuming alcohol most days per week (4–7 times). The proportion of those who reported not using alcohol at all in the past 12 months, however, increased from 22% in 2021 to 27% in 2024.

Respondents experiencing an overdose in the last 12 months decreased from 41% in 2021 to 24% in 2024 [**Table 4**]. The percentage of respondents reporting they witnessed an overdose in the past 12 months, however, was similar between 2021 (64%) and 2024 (63%). When asked about the most recent overdose witnessed by the respondents, the two most frequent actions following the overdose were someone (not Emergency Medical Technician (EMT)/police) gave naloxone (69%) and someone called 911 (60%). Among those who witnessed an overdose in the past 12 months, 54% of respondents in 2024 said someone (excluding EMT or police) gave the individual who overdosed naloxone, which is a decrease compared to 2021 (68%). The percentage of those who witnessed an overdose where 911 was called remained similar from 2021 to 2024, at roughly 60%.

In 2024, 4% of respondents reported always using fentanyl test strips to test a new batch of drugs, 55% that they currently had naloxone, 47% reporting always using with others, and 20% always starting with a low dose [**Table 5**]. The proportion of respondents who always use fentanyl test strips decreased down to similar proportions to 2021 (5%), while the proportion of those who always use substances in the presence of others decreased down to proportions in 2022 (43%) [**Figure 1**]. The proportion of respondents who never used with others remained similar in all four years at around 10%.

Table 2. Harm reduction practices by diagnosed disability types, Rhode Island Harm Reduction Surveillance System 2023–2024

	Physical N=95	Sensory N=64	Developmental N=116	Mental Health N=198	Traumatic Brain Injury N=53	PTSD N=156
Currently have naloxone						
Yes	60 (63.2)	45 (70.3)	79 (68.1)*	120 (60.6)	30 (56.6)	99 (63.5)
No	35 (36.8)	19 (29.7)	37 (31.9)*	78 (39.4)	23 (43.4)	57 (36.5)
Had naloxone past 12 months						
Yes	74 (77.9)	54 (84.4)	96 (82.8)	155 (78.3)	42 (79.3)	126 (80.8)
No	21 (22.1)	10 (15.6)	20 (17.2)	43 (21.7)	11 (20.8)	30 (19.2)
Used fentanyl test strip						
Always	<5	<5	14 (12.4)*	15 (7.7)	<5	12 (7.8)
Most/sometimes	21 (22.3)	12 (19.4)	28 (24.8)*	42 (21.4)	12 (23.1)	36 (23.4)
Never	69 (73.4)	46 (74.2)	71 (62.8)*	139 (70.9)	39 (75.0)	106 (68.8)
Use with other people						
Always	49 (52.1)	28 (45.2)	59 (52.2)	108 (55.1)	29 (55.8)	82 (53.3)
Most/sometimes	37 (39.4)	26 (41.9)	44 (38.9)	72 (36.7)	18 (34.6)	61 (39.6)
Never	8 (8.5)	8 (12.9)	10 (8.9)	16 (8.2)	5 (9.6)	11 (7.1)
Start with low dose						
Always	24 (26.1)	18 (28.6)	22 (20.6)	47 (25.0)	8 (15.4)	41 (27.3)
Most/sometimes	31 (33.7)	24 (38.1)	38 (35.5)	59 (31.4)	18 (34.6)	49 (32.7)
Never	37 (40.2)	21 (33.3)	47 (43.9)	82 (43.6)	26 (50.0)	60 (40.0)
Share needles						
Always	<5	<5	<5	<5	<5	<5
Most/sometimes	<5	<5	6 (21.4)	5 (13.9)	<5	5 (16.1)
Never	17 (94.4)	14 (87.5)	22 (78.6)	31 (86.1)	10 (83.3)	26 (83.9)
Share a pipe						
Always	7 (9.5)	7 (13.2)	7 (8.1)	11 (7.1)	<5	11 (9.1)
Most/sometimes	35 (47.3)	24 (45.3)	41 (47.7)	77 (50.0)	19 (48.7)	62 (51.2)
Never	32 (43.2)	22 (41.5)	38 (44.2)	66 (42.9)	17 (43.6)	48 (39.7)

Notes: Percentages may not add up to 100% due to rounding
Count may not add up to total due to missing/unknown responses.
Counts less than 5 are reported as <5.
Diagnosed disability categories are not mutually exclusive.
* Statistically significant at p<0.05

DISCUSSION

Among this convenience sample of marginalized individuals who use non-prescribed substances in RI, many individuals had witnessed (66%) or experienced (30%) an overdose in the last 12 months, highlighting the continued need to provide harm reduction services to this population. It is concerning to see that in 2024, only 55% of respondents currently had naloxone, given that 63% of respondents witnessed and 24% of respondents experienced an overdose in the past 12 months. Additionally, the percentage of most recently witnessed overdose in which someone called 911 remained similar over all years (~60%), while the proportion of someone (not EMT or police) administering naloxone decreased from 84% in 2023 to 54% in 2024. These data together underscore the importance of sustaining low-barrier naloxone availability and distribution in RI through a variety of settings for high-risk individuals who use non-prescribed substances to prevent future fatal overdoses.

There was a decline in some harm reduction practices in 2024, including always using fentanyl test strips and always using substances in the presence of others, after yearly positive increases from 2021 to 2023. The proportion of those who never used with others remained similar across all years, suggesting the shift in proportions were within those who always and mostly or sometimes used with others. These behaviors are critical components of prevention efforts aimed to reduce the number of non-fatal and fatal overdoses, especially in the context of the high prevalence of polysubstance use.[4,5] The observed decrease in 2024 presents a meaningful trend and may be due to several underlying factors such as potential gaps in awareness or education, burnout from responding to overdose events, stigma towards using substances and harm reduction strategies that discourage users from adopting life-saving behaviors. It is also possible that the timing of data collection in 2024 may have coincided with periods of lower service engagement or during a temporal shift in offered services which may have impacted access to harm reduction supplies or programs. Therefore, we offer these factors as hypotheses to inform future research, rather than as definitive conclusions.

Nonetheless, these results highlight the need for continued efforts to promote harm reduction strategies and ensure individuals have access to necessary resources and programs for this population. As most fatal overdoses occur in private settings in the absence of a bystander, education on programs such as the Safe Spot or Never Use Alone hotline should be promoted to mitigate some of this risk for individuals who use alone.[6-8] Future analyses with mixed-methods approaches integrating HRSS data and participant perspectives should investigate specific factors such as demographics and

Table 3. Alcohol and non-prescribed substance use among survey respondents, Rhode Island Harm Reduction Surveillance System, 2021–2024

	2021 N=200	2022 N=193	2023 N=111	2024 N=169	Total N=673
Alcohol use					
4–7 times/week	70 (35.0)	60 (31.1)	35 (31.5)	56 (33.1)	221 (32.8)
1–3 times/week	41 (20.5)	48 (24.9)	25 (22.5)	34 (20.1)	148 (22.0)
2 or less per month	46 (23.0)	26 (13.5)	17 (15.3)	34 (20.1)	123 (18.3)
None in the past 12 months	43 (21.5)	59 (30.6)	34 (30.6)	45 (26.6)	181 (26.9)
Non-prescribed substances[a]					
Benzodiazepines[b]	59 (29.5)	46 (23.8)	12 (10.8)	11 (6.5)	128 (19.0)
Cannabis	133 (66.5)	138 (71.5)	86 (77.5)	109 (64.5)	466 (69.2)
Cocaine	85 (42.5)	88 (45.6)	48 (43.2)	63 (37.3)	284 (42.2)
Crack	150 (75.0)	130 (67.4)	77 (69.4)	126 (74.6)	483 (71.8)
Fentanyl/Heroin[b]	97 (48.5)	64 (33.2)	38 (34.2)	61 (36.1)	260 (38.6)
Methamphetamines	61 (30.5)	45 (23.3)	26 (23.4)	39 (23.1)	171 (25.4)
Opioid Pain Medications[b]	44 (22.0)	28 (14.5)	13 (11.7)	16 (9.5)	101 (15.0)
Other Stimulants[b]	26 (13.0)	27 (14.0)	17 (15.3)	8 (4.7)	78 (11.6)
Polysubstance use	179 (89.5)	170 (88.1)	101 (91.0)	144 (85.2)	594 (88.3)

Notes: Percentages may not add up to 100% due to rounding
Count may not add up to total due to missing/unknown responses.
a Categories are not mutually exclusive.
b Statistically significant at p<0.05

type of substances used that encourage these behaviors among people who use non-prescribed substances in RI.

The newly added disability measure shows that the prevalence of disabilities in this sample of adults who use non-prescribed substances in RI is higher than the national average. In 2022, the CDC estimated that 1 in 4 adults in the US had a disability, while 86% of 2023–2024 HRSS respondents reported having at least one type of disability (data not shown).[9,10] This is consistent with other current research that adults with disabilities are at increased risk for having a substance use disorder.[11-13] In addition, prior research has demonstrated that people with disabilities are at an increased risk for opioid overdose-related emergency department visits, and other quantitative and qualitative research has shown that people with disabilities experience barriers to receiving treatment.[14-16] The intersection of disability, substance use, and harm reduction can present significant challenges in public health, and this population should be considered more intentionally with prevention work and in clinical settings.[11] Treatment programs including modified residential settings and other tailored interventions that intentionally accommodate for the person's disability while providing integrated care have shown improved outcomes by addressing both substance use and disability as interconnected issues.[17,18] This highlights the importance of person-centered, accessible outreach, and tailored prevention and treatment efforts when serving this population.

This work also highlights the high prevalence of cannabis, cocaine, and alcohol use in this marginalized population and the continued need to develop harm reduction strategies, ways to reach, and ways to provide services to individuals who are not using opiods. While not representative of all individuals who use non-prescribed substances in RI, the data from this survey does align with recent fatal data from 2024 showing a decline in opioid, fentanyl, and benzodiazepines contributing to fatal overdoses in RI. While the number of fatal overdoses has declined from 2022 in RI, the number of stimulant-involved fatal overdoses has remained relatively stable from 2021–2024, highlighting the continued need of harm reduction for this population.[19]

Limitations for this data include the use of convenience sampling method to recruit from a high-risk population. While cost effective and easy to implement, this introduces biases that limit the generalizability of these results to just the studied population and not more broadly to all individuals who use drugs in RI, particularly those less connected to services. The use of convenience sampling may also skew the data if recruitment sites and/or outreach patterns change over time. Shift in recruitment from harm reduction centers to encampments and overdose hotspots, where harm reduction practices are harder to maintain, may result in lower levels of harm reduction practices.[20-22] This makes it difficult to attribute the observed trends in harm reduction practices to actual behavioral change among survey participants or simply due to sampling variation in sampling sites. Additionally, because the survey is primarily administered face-to-face by an interviewer, social desirability bias may be present.[23] Lastly, this study relied on bivariate analyses which does not account for potential confounding or effect modification. While this approach provides descriptive insights in factors associated with harm reduction practices, the findings should not be interpreted as causal. Future research with larger, probability-based samples may be able to explore adjusted associations.

Despite the decline in fatal overdoses in 2023 and 2024 compared to 2022, the results from this analysis revealed a notable reversal in several harm reduction practices. This trend highlights the importance of education, prevention, and policy efforts targeting high-risk individuals who use non-prescribed substances to reinforce harm reduction practices.

Table 4. Overdose experience among survey respondents, Rhode Island Harm Reduction Surveillance System 2021–2024

	2021 N=200	2022 N=193	2023 N=111	2024 N=169	Total N=673
Witness overdose in past 12 months					
Yes	128 (64.0)	137 (71.0)	74 (67.3)	105 (62.5)	444 (66.2)
No	72 (36.0)	56 (29.0)	36 (32.7)	63 (37.5)	227 (33.8)
What happened after overdose[a]					
Someone (not EMT or police) gave naloxone[b,c]	87 (68.0)	100 (73.0)	62 (83.8)	57 (54.3)	306 (68.9)
Someone called 911	77 (60.2)	77 (56.2)	48 (64.9)	64 (61.0)	266 (59.9)
Police administered naloxone[b]	13 (10.2)	7 (5.1)	9 (12.2)	<5	32 (7.2)
EMT administered naloxone	48 (37.5)	38 (27.7)	18 (24.3)	24 (22.9)	128 (28.8)
Someone gave rescue breaths	47 (36.7)	48 (35.0)	34 (46.0)	33 (31.4)	162 (36.5)
Someone administered chest compression[b]	51 (39.8)	52 (38.0)	39 (52.7)	32 (30.5)	174 (39.2)
Ambulance arrived[b]	64 (50.0)	58 (42.3)	31 (41.9)	29 (27.6)	182 (41.0)
Someone took them to the hospital	6 (4.7)	<5	<5	<5	9 (2.0)
Person came to their own	6 (4.7)	<5	<5	<5	13 (2.9)
Person died	10 (7.8)	6 (4.4)	8 (10.8)	<5	27 (6.1)
Witness left area before or when EMT/police arrived	8 (6.3)	13 (9.5)	<5	12 (11.4)	35 (7.9)
Experienced overdose in past 12 months[b]					
Yes	82 (41.2)	44 (23.3)	30 (27.3)	40 (24.0)	196 (29.5)
No	117 (58.8)	145 (76.7)	80 (72.7)	127 (76.1)	469 (70.5)

Notes: Percentages may not add up to 100% due to rounding
Count may not add up to total due to missing/unknown responses.
Counts less than 5 are reported as <5.
a Count and percentages are among respondents who witnessed an overdose in the past 12 months. Categories are not mutually exclusive.
b Statistically significant at p<0.05
c "Someone" includes anyone who may have administered naloxone excluding EMT or police.

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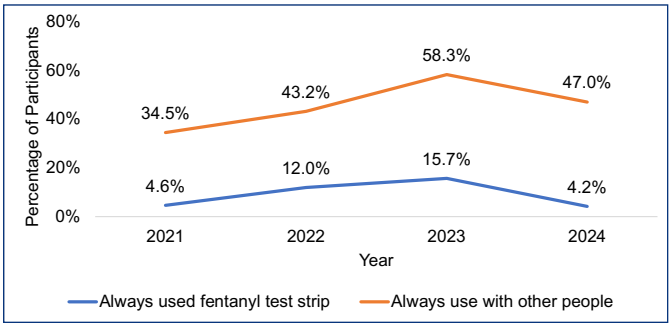
Table 5. Harm reduction practices among survey respondents, Rhode Island Harm Reduction Surveillance System 2021–2024

	2021 N=200	2022 N=193	2023 N=111	2024 N=169	Total N=693
Currently have naloxone					
Yes	130 (65.3)	108 (56.3)	74 (67.3)	93 (55.0)	405 (60.5)
No	69 (34.7)	84 (43.8)	36 (32.7)	76 (45.0)	265 (39.6)
Had naloxone past 12 months					
Yes	161 (80.5)	142 (73.6)	88 (79.3)	127 (75.2)	518 (77.0)
No	39 (19.5)	51(26.4)	23 (20.7)	42 (24.9)	155 (23.0)
Used fentanyl test strip[a]					
Always	9 (4.6)	23 (12.0)	17 (15.7)	7 (4.2)	56 (8.4)
Most/sometimes	41 (20.7)	51 (26.6)	17 (15.7)	35 (20.8)	144 (21.6)
Never	148 (74.8)	118 (61.5)	74 (68.5)	126 (75.0)	466 (70.0)
Use with other people[a]					
Always	68 (34.5)	82 (43.2)	6 (58.3)	79 (47.0)	292 (44.0)
Most/sometimes	110 (55.8)	86 (45.3)	33 (30.6)	71 (42.3)	300 (45.3)
Never	19 (9.6)	22 (11.6)	12 (11.1)	18 (10.7)	71 (10.7)
Start with low dose					
Always	48(24.5)	41 (21.9)	32 (32.0)	33 (19.8)	154 (23.7)
Most/sometimes	67 (34.2)	52 (27.8)	23 (23.0)	62 (37.1)	204 (31.4)
Never	81 (41.3)	94 (50.3)	45 (45.0)	72 (43.1)	292 (44.9)
Share needles					
Always	<5	<5	<5	<5	<5
Most/sometimes	19 (27.5)	5 (10.6)	<5	5 (16.1)	30 (17.8)
Never	49 (71.0)	41 (87.2)	21 (95.5)	26 (83.9)	137 (81.1)
Share a pipe					
Always	15 (9.2)	17 (11.6)	9 (11.3)	10 (7.3)	51 (9.7)
Most/sometimes	85(52.2)	57 (39.0)	30 (37.5)	70 (51.1)	242 (46.0)
Never	63 (38.7)	72 (49.3)	41 (51.3)	57 (41.6)	233 (44.3)

Notes: Percentages may not add up to 100% due to rounding
Count may not add up to total due to missing/unknown responses.
Counts less than 5 are reported as <5.
a Statistically significant at p<0.05

Figure 1. Trends in always using fentanyl test strip and using with other people among survey participants by year, Rhode Island Harm Reduction Surveillance System 2021–2024



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Expanding Abortion Training: Interest, Experience and Comfort in Abortion Care Among Family Medicine, Emergency Medicine, Internal Medicine and Pediatrics Residents

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ABSTRACT

BACKGROUND: Primary care and emergency medicine physicians may encounter patients who are seeking abortions, require miscarriage management or post-abortion care. Yet, little is known about their respective abortion training.

OBJECTIVE: We aimed to elucidate the interest and experience in abortion care among non-obstetrics/gynecology (OBGYN) residents.

METHODS: We conducted a cross-sectional survey of residents in family medicine, emergency medicine, internal medicine and pediatrics at a single academic institution in 2023–2024, evaluating interest and experience in abortion provision. Descriptive statistics were used for categorical variables, and comparisons were made via chi-square testing.

RESULTS: 104 out of 297 residents completed the survey (26 family medicine; 22 emergency medicine; 36 internal medicine; 20 pediatrics; 35% response rate). The majority (94%) thought abortion should be legal in all or most cases, and 90% were interested in learning more about abortion provision. A majority were interested in being trained to provide medication abortions (87%), counsel on pregnancy options (94%), manage abortion complications (95%) and learn more about abortion policies (92%). A majority thought their patients would be interested in accessing abortion care in their primary care offices (88%) or the emergency room (86%). Despite significant interest, experience in abortion care was minimal; the majority reported never prescribing medications (71%) or performing manual vacuum aspirations (88%) for abortion or miscarriage management.

CONCLUSIONS: While interest in abortion provision is high among residents in specialties beyond OBGYN, experience is limited. This represents an opportunity for expanded education and training in abortion care among these specialties.

KEYWORDS: abortion; medical education; primary care; emergency medicine; pregnancy

INTRODUCTION

The overturning of *Roe v. Wade* with the *Dobbs v. Jackson* decision changed the landscape of abortion provision overnight in the United States (US). It not only raised significant concerns about patient access to abortion and reproductive health care more generally, but also has significant implications on medical training. Concerns have arisen that trainees in the wake of *Dobbs* will lack experience in abortion provision and the surrounding services including comprehensive options counseling and referrals, evaluating complications related to abortion and helping care for people who have self-managed their abortions.[1]

While these changes impact trainees in obstetrics and gynecology (OBGYN), trainees in primary care fields such as family medicine, internal medicine and pediatrics, and emergency medicine are affected as well. These specialties also encounter patients seeking abortions, requiring miscarriage management or presenting for care after abortions.[1,2] In fact, early pregnancy loss accounts for an estimated 900,000 emergency room visits annually in the US,[3] and in most places, emergency medicine physicians evaluate all pregnancy complications under 20 weeks gestational age. Similarly, primary care physicians may be the first provider patients see in early pregnancy and many family medicine physicians provide reproductive and obstetrical care.

There are growing calls for providers outside of OBGYN to be trained in early pregnancy care and abortion to help facilitate appropriate care in the changing landscape post-*Roe*.[1,2] Since *Dobbs* was decided in June 2022, the American Academy of Family Physicians,[5] the American Academy of Pediatrics,[6] the American College of Emergency Physicians,[7] and the American College of Physicians[8] have all issued policy statements supporting the right to abortion as part of reproductive health care. Additionally, a growing number of scholarly articles have urged physicians in internal medicine, emergency medicine, family medicine and pediatrics to be involved in not only the advocacy efforts surrounding abortion access,[4] but also to incorporate abortion care and family planning services more broadly into their scope of practice.[9-16]

This will likely necessitate expanded training in abortion care among these specialties. Yet, little is known about the training that specialties outside of OBGYN receive in early pregnancy care and abortion, and how interested those

specialties are in caring for these patients. Given the lack of literature on this topic, we aimed to elucidate the interest, comfort level and experience in abortion care among non-OBGYN residents at one academic institution in the Northeast. We hypothesized that most respondents would have little experience in abortion care, but most would be interested in learning more about abortion provision.

METHODS

We conducted a cross-sectional survey of all Brown University affiliated residents in family medicine (FM), emergency medicine (EM), internal medicine (IM) and pediatrics (PEDS). This included seven respondents in a dual IM/PEDS residency, who were grouped with the IM residents for subgroup data analysis. Of note, the FM program is a RHEDI (Reproductive Health Education in Family Medicine) program which offers integrated abortion training to their residents.[17] Additionally, all FM and EM residents rotate through Women and Infants Hospital emergency room, which specializes in OBGYN care including exposure to management of spontaneous abortions and post-abortion care.

A survey was created based on assessing three domains within abortion and early pregnancy care—interest, experience and comfort level. Comfort level and interest were assessed using 4-point Likert scales, from very comfortable to very uncomfortable and from very interested to not at all interested. Experience was assessed by asking respondents to quantify the approximate number of times they had encountered various clinical situations. We also elicited perspectives on abortion care legality and access. The survey was face validity tested with five residents at other institutions in the aforementioned specialties before being deployed; these results were not included in the analysis.

Eligible residents were emailed three invitations to participate, from December 2023 to January 2024. This allowed all respondents to have completed at least five months of residency. This voluntary, anonymous survey was administered by REDCap and approved by the Care New England Institutional Review Board (#1990346). Descriptive statistics were used for categorical variables, and comparisons were made via chi-square testing with significance set at $p < 0.05$.

RESULTS

Response rate and sample characteristics

One hundred and four out of 297 residents emailed completed the survey (35% response rate). This included 26 FM, 22 EM, 36 IM and 20 PEDS residents with 54, 42, 31, 20% response rates respectively. Respondents were representative of all postgraduate years (PGY), with 25% PGY1s, 35% PGY2s, 34% PGY3s, 6% PGY4s (for applicable specialties) and 1% unspecified. The majority of residents thought abortion should be legal in all (74%) or most (20%) cases, with the minority selecting that abortion should be legal only in select cases (2%), illegal (1%) or preferring not to answer (3%) [**Table 1**].

Table 1. Demographic Characteristics of Respondents

Characteristics	Respondents (n = 104)
Specialty	
Family medicine (FM)	26 (25%)
Emergency Medicine (EM)	22 (21%)
Internal Medicine* (IM)	36 (35%)
Pediatrics (PEDS)	20 (19%)
Postgraduate Year (PGY)	
PGY1	26 (25%)
PGY2	36 (35%)
PGY3	35 (34%)
PGY4	6 (6%)
Unspecified	1 (1%)
Personal opinion on abortion:	
Abortion should be legal in…	
All cases	77 (74%)
Most cases	21 (20%)
Only select cases	2 (2%)
Illegal	1 (1%)
Prefer not to answer	3 (3%)

* Includes residents in combined medicine-pediatrics residency program
Study conducted at Brown University Affiliated residency programs (2023).

Interest in Abortion Care

The majority of all respondents (90%) were very or somewhat interested in learning more about abortion provision. Additionally, the majority of residents thought their patients would be very or somewhat interested in accessing abortion care in their primary care offices (96% for FM, 89% for IM, 79% for PEDS) or in the emergency room (86% for EM) [**Figure 1**]. There were no significant differences by specialty as to how interested respondents thought patients would be in accessing abortion care in their location of work.

Specifically, residents were most interested in learning more about pregnancy options counseling (very 74%,

Figure 1. Interest in abortion care among 104 residents in Family Medicine (FM), Emergency Medicine (EM), Internal Medicine (IM) and pediatrics (PEDS) at Brown University affiliated programs (2023).

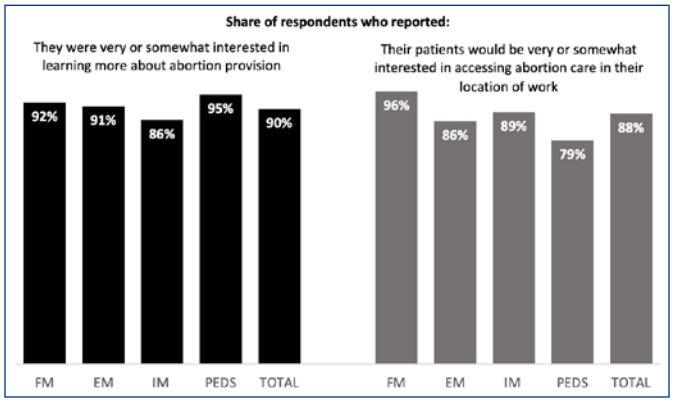

Table 2. Interest in abortion care among family medicine, emergency medicine, internal medicine and pediatrics residents

Respondents who were very or somewhat interested in learning more about:	Total n = 104	FM n = 26	EM n = 22	IM n = 36	PEDS n = 20	p-value
Abortion provision	**94 (90%)**	24 (92%)	20 (91%)	31 (86%)	19 (95%)	0.709
How to counsel patients on pregnancy options	**98 (94%)**	25 (96%)	22 (100%)	31 (86%)	20 (100%)	0.187
Becoming trained in prescribing medication abortions	**90 (87%)**	25 (96%)	21 (96%)	28 (78%)	16 (80%)	0.060
Becoming trained in manual vacuum aspiration	**51 (49%)**	22 (85%)	11 (50%)	14 (39%)	4 (20%)	<0.001
How to identify and manage complications arising from an abortion	**99 (95%)**	24 (92%)	22 (100%)	35 (97%)	18 (90%)	0.277
Self-managed abortions	**87 (93%)**	24 (92%)	21 (96%)	28 (78%)	14 (70%)	0.050
State and federal policies regarding abortion	**95 (91%)**	24 (92%)	20 (91%)	31 (86%)	20 (100%)	0.193

FM = family medicine. EM = emergency medicine. IM = internal medicine. PEDS = pediatrics.
Study conducted at Brown University Affiliated residency programs (2023).

somewhat 20%), how to identify and manage complications from an abortion (very 74%, somewhat 21%) and becoming trained in prescribing medication abortions (very 60%, somewhat 27%). There was also significant interest in learning more about self-managed abortions (very 51%, somewhat 33%) and state and federal policies regarding abortion (very 57%, somewhat 35%). Fewer residents (49%) were interested in being trained in performing manual vacuum aspirations, with the exception of FM where most residents were interested in this training (very 62%, somewhat 23%) [**Table 2**].

Some significant differences were found between the various medical subspecialties. Respondents in family medicine were more likely than those in internal medicine and pediatrics to be very or somewhat interested in being trained in manual vacuum aspiration (FM 85%, EM 50%, IM 39%, PEDS 20%, p <0.001). However, there were no significant differences by specialty regarding how interested respondents were in learning more about abortion provision in general, being trained in medication abortion, options counseling, identifying and managing abortion complications and abortion policy [**Table 2**].

Experience and Comfort Level

Experience taking care of patients in early pregnancy was limited among the sampled residents. During medical training, the majority of respondents reported they had never prescribed medications for a termination of pregnancy or miscarriage management (71%), nor performed a manual vacuum aspiration for any indication (88%). Most had never cared for a patient who disclosed a self-managed abortion (77%), and the majority reported five or fewer experiences caring for patients seeking an abortion or unsure of how they wanted to proceed with their pregnancy (76%) or patients with potential complications after an abortion (91%).

Most reported receiving training in abortion care and miscarriage management through medical school didactics (69%), with fewer receiving any training in residency didactics (40%) or standard clinical rotations during residency (39%). Some (8%) reported no exposure to this training at all.

While all specialties had limited experience in abortion care, family medicine respondents were more likely than all other specialties to report having ever prescribed medications for abortion or miscarriage management (FM 77%, EM 18%, IM 14%, PEDS 5%, p <0.001). Respondents in family medicine were also significantly more likely than those in internal medicine and pediatrics to have ever performed a manual vacuum aspiration (FM 35%, EM 9%, IM 3%, PEDS 5%, p 0.002) or cared for a patient with potential complications from an abortion (FM 81%, EM 77%, IM 31%, PEDS 20%, p <0.001) [**Table 3**].

Assessment of subjective comfort level revealed that a

Table 3. Experience in abortion and early pregnancy care among family medicine, emergency medicine, internal medicine and pediatrics residents

Respondents who had *ever:*	Total n = 104	FM n = 26	EM n = 22	IM n = 36	PEDS n = 20	p-value
Cared for a patient seeking an abortion or unsure of how they want to proceed with their pregnancy	**76 (73%)**	25 (96%)	17 (77%)	21 (58%)	13 (65%)	0.003
Cared for a patient with potential complications after an abortion	**53 (51%)**	21 (81%)	17 (77%)	11 (31%)	4 (20%)	<0.001
Cared for a patient who disclosed a self-managed abortion	**24 (23%)**	11 (42%)	7 (32%)	6 (17%)	0 (0%)	n/a
Prescribed medications for an abortion (either for a miscarriage or termination)	**30 (29%)**	20 (77%)	4 (18%)	5 (14%)	1 (5%)	<0.001
Performed a manual vacuum aspiration	**13 (13%)**	9 (35%)	2 (9%)	1 (3%)	1 (5%)	0.002

FM = family medicine. EM = emergency medicine. IM = internal medicine. PEDS = pediatrics.
Study conducted at Brown University Affiliated residency programs (2023).
P-value not calculated if value was 0%

Table 4. Comfort level in abortion and early pregnancy care among family medicine, emergency medicine, internal medicine and pediatrics residents

Respondents who feel very or somewhat comfortable:	Total n = 104	FM n = 26	EM n = 22	IM n = 36	PEDS n = 20	p-value
Determining a patient's gestational age	**64 (62%)**	24 (92%)	17 (77%)	16 (44%)	7 (35%)	<0.001
Confirming an intrauterine pregnancy	**62 (60%)**	24 (92%)	19 (86%)	16 (44%)	3 (15%)	<0.001
Providing options counseling	**65 (63%)**	22 (85%)	13 (59%)	19 (53%)	11 (55%)	0.058
Performing a pelvic exam if clinically indicated	**67 (64%)**	23 (89%)	21 (96%)	14 (39%)	9 (45%)	<0.001
Knowing where to refer patients for an abortion	**56 (54%)**	19 (73%)	11 (50%)	15 (42%)	11 (55%)	0.104
Explaining the differences between medication and procedural abortions	**70 (67%)**	25 (96%)	15 (68%)	19 (53%)	11 (55%)	0.002
Explaining the risks of abortion versus the risks of continuing a pregnancy	**53 (51%)**	23 (89%)	9 (41%)	14 (39%)	7 (35%)	0.104
Prescribing medication for an abortion	**39 (38%)**	20 (77%)	4 (18%)	13 (36%)	2 (10%)	<0.001
Performing a manual vacuum aspiration	**0 (0%)**	0 (0%)	0 (0%)	0 (0%)	0 (0%)	n/a
Assessing for retained products of conception	**22 (21%)**	10 (39%)	12 (55%)	0 (0%)	0 (0%)	n/a
Assessing bleeding after an abortion	**28 (27%)**	16 (62%)	10 (46%)	2 (6%)	0 (0%)	<0.001
Assessing for signs of infection after an abortion	**60 (58%)**	21 (81%)	18 (82%)	15 (42%)	6 (30%)	<0.001
Caring for a patient who reports a self- managed abortion … from a clinical perspective	**25 (24%)**	11 (42%)	7 (33%)	7 (19%)	0 (0%)	n/a
… from a legal perspective	**54 (52%)**	15 (58%)	16 (76%)	16 (44%)	7 (35%)	0.038

Comparison group excluded if value was 0% and did not calculate p-value if more than one value was 0. Study conducted at Brown University Affiliated residency programs (2023).
FM = family medicine. EM = emergency medicine. IM = internal medicine. PEDS = pediatrics.

minority of respondents felt very comfortable with basic skills like performing a pelvic exam (33%), determining gestational age (22%), confirming an intrauterine pregnancy (21%), providing options counseling (24%), explaining the differences between medication and procedural abortions (23%) and knowing where to refer for an abortion (19%). Even fewer felt very comfortable assessing for complications after an abortion like retained products (7%), bleeding (7%) and infection (18%). Few respondents (12%) felt very comfortable prescribing medications for an abortion and no one (0%) felt very or somewhat comfortable performing manual vacuum aspirations.

Family medicine respondents were more likely than those in internal medicine and pediatrics to report they were very or somewhat comfortable with determining gestational age (FM 92%, EM 77%, IM 44%, PEDS 35%, p <0.001), confirming an intrauterine pregnancy (FM 92%, EM 86%, IM 44%, PEDS 15%, p <0.001), performing pelvic exams (FM 89%, EM 96%, IM 39%, PEDS 45%, p <0.001), assessing for bleeding (FM 62%, EM 46%, IM 6%, PEDS 0%, p <0.001) and assessing for infection after an abortion (FM 81%, EM 82%, IM 42%, PEDS 30%, p <0.001) [**Table 4**].

DISCUSSION

Our study reveals significant interest among residents in a variety of primary care specialties and emergency medicine in learning more about abortion care. The majority of respondents were very or somewhat interested in learning about abortion provision in general, and specifically interested in learning to provide medication abortions. To date, there are a few studies investigating interest in abortion care among primary care and emergency medicine specialties to compare our data. A survey of 30 residents and 22 attendings from the Albert Einstein Primary Care Social Medicine Program found that almost all respondents desired training in options counseling (100%) and medication abortion (96%), yet most felt uncomfortable with the basic skill of determining gestational age for patients (68%).[18] Another study by Wolgemuth et al surveyed 121 internal medicine attendings and trainees at a large academic center in Pennsylvania and found that 67% of trainees were interested in providing medication abortions in the future.[19]

In addition to personal interest in abortion provision, surveyed residents also reported high perceived interest among their patients for accessing abortion care in their respective locations of work, either in primary care offices or emergency rooms. Winsor et al reported that 100% of primary care residents and 96% of attendings surveyed thought patients would like access to medication abortion in their clinic.[18] Additionally, a patient facing study of 90 reproductive age women in the waiting room of an urban academic internal medicine clinic found that 68% of women thought the clinic should offer medication abortion; of those who reported they were open to having an abortion, 87% reported they would be interested in receiving this care from their

primary care doctor.[20] This suggests patients may be receptive to receiving abortion care from primary care providers, however the acceptability of receiving these services in primary care offices and emergency rooms is an understudied concept worth further exploration.

Despite significant personal and perceived patient interest in expanded training in abortion care, our study found that residents in the studied specialties had little experience in the field. This conclusion falls in line with existing research. Of all specialties surveyed, family medicine traditionally has had the most training in reproductive health, and yet a national survey of US family physicians found that just 3% provide terminations,[21] and a national survey of FM program directors and chief residents found abortion training was uncommon among FM residents.[22] Reproductive health training is even less standardized in internal medicine, pediatrics and emergency medicine. A national survey of 430 adolescent medicine providers found only 32% of respondents have what was deemed "very good" knowledge of medication abortions, meaning they understood the incidence, indications, safety, efficacy and rates of complications.[23]

Lack of training in reproductive health likely poses one of the biggest challenges to trainees in primary care and emergency medicine participating in abortion provision. Wolgemuth et al found 70% of internal medicine physicians cited limited training in residency as a barrier to medication abortion provision.[19] That said, a few studies have shown that support from OBGYN colleagues and tailored educational interventions can help support providers in these specialties in expanding scope of practice regarding early pregnancy care and abortion.[24,25] Other barriers to providing abortion care among these specialties include lack of administrative and community support, restrictive state and federal laws specifically aimed at limiting scope of practice and the Emergency Medical Treatment and Active Labor Act (EMTALA), ongoing abortion stigma in workplaces and insurance challenges.[1,11,24,26,27] Realistically, therefore, there remain several barriers to providing this care.

Our study has several limitations, namely generalizability. Our study is limited by its sample size, representing residents in just one hospital system, within a state with protective abortion policies. This limits our ability to generalize to other residency programs, particularly in states with more hostile abortion policies. Our comparative statistics are also reported with caution, as our sample size lends us to less confidence in the reproducibility of our results. While our study provides important information about the interest level in abortion care among residents in internal medicine, emergency medicine, family medicine and pediatrics at our institution, we still lack nationally representative data on this topic. We also acknowledge that response bias likely increased perceived interest in abortion care among this sample, as we presume those interested in abortion were more likely to respond to our survey. While our response rate is somewhat low, it is on par with most physician surveys and we believe still provides an adequate sample for our needs assessment.[28]

While our study is small, our study provides novel evidence that trainees in multiple specialties voice interest in learning more about abortion care. This has potential implications on medical training, at several levels of learning including medical school, residency and continuing medical education. While providers in these various specialties may not ultimately provide abortions themselves, having a workforce trained and competent in supporting people as they navigate early pregnancy is important, including offering thorough options counseling, appropriate referrals and being able to assess for complications should patients present to emergency rooms or primary care offices seeking this care.[29] At our institution, these survey results will serve as a needs assessment as we embark on expanding educational opportunities in abortion training for residents in these four specialties.

CONCLUSIONS

Many residents in specialties beyond OBGYN are interested in training in abortion care, and think their patients would be interested in accessing abortion care in their primary care offices and the emergency room. At present, however, comfort level and experience in abortion provision is limited. This represents an opportunity for expanded training in abortion care among these specialties.

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Bleeding Risk Following Total Shoulder Arthroplasty in Patients Using Selective Serotonin Reuptake Inhibitors

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ABSTRACT

BACKGROUND: The purpose of the current study is to evaluate the association between selective serotonin reuptake inhibitor (SSRI) use and the risk of perioperative bleeding and blood transfusion following total shoulder arthroplasty.

METHODS: The PearlDiver (PearlDiver Technologies, Colorado Springs, CO, USA) Mariner170 database was queried to conduct this retrospective cohort study. Patients were included if they were over 18 years, had anxiety or depression, and underwent primary TSA. Eligible patients were stratified by SSRI use and 1:1 case-control matched by age, gender, Charlson Comorbidity Index (CCI), and relevant comorbidities. Patient demographics and 30-day postoperative outcomes, including bleeding, transfusion, deep venous thrombosis, or pulmonary embolism, were extracted and compared across cohorts.

RESULTS: The SSRI and control groups each contained 3,346 patients who underwent anatomic or reverse TSA. For each group, the mean age was 67.45 ± 7.44 years with 2,410 (72.03%) males and a mean CCI of 1.04 ± 1.07. There were no significant differences ($p < 0.05$) in the risk of postoperative bleeding, transfusion, deep venous thrombosis, or pulmonary embolism between patients with anxiety and/or depression on SSRIs and those not using SSRIs.

CONCLUSION: The current study determined that there was no increased bleeding or thrombotic risk in patients with anxiety or depression on SSRIs undergoing TSA compared to those not using SSRIs. These findings do not provide support for the alteration of SSRI regimens in the TSA perioperative period due to bleeding or thrombotic risk. However, caution should still be used in patients on SSRIs undergoing TSA.

KEYWORDS: total shoulder arthroplasty; bleeding risk; SSRI; anxiety; depression

INTRODUCTION

Total shoulder arthroplasty (TSA), including both anatomic and reverse techniques, is a procedure that is being performed with increasing incidence across both older and younger populations.[1,2] While TSA is widely regarded as a safe and effective intervention for various shoulder pathologies, it carries the risk of bleeding-related complications.[3] Increased blood loss and the need for transfusions have been linked to longer hospital stays, dislocations, periprosthetic fractures, mechanical loosening, and periprosthetic joint infections.[4,5] Furthermore, blood transfusions following TSA have been associated with higher rates of sepsis, pneumonia, myocardial infarction, cerebrovascular accident, and venous thromboembolic events.[6] However, the studies also suggest that patients requiring transfusion often have a greater preoperative comorbidity burden, which may partly account for these associations.[6] Established risk factors for perioperative bleeding complications and transfusions in TSA include a higher Charlson-Deyo Comorbidity Index (CCI), low preoperative hemoglobin, coagulation disorders, and ischemic heart disease, among others.[7–9] Additionally, selective serotonin reuptake inhibitors (SSRIs) have been shown to increase the risk of transfusion in patients undergoing total hip (THA) or knee arthroplasty (TKA).[10-12] However, the hematologic effects of SSRIs in the setting of TSA remain poorly understood and underexplored in the existing literature.

SSRIs are among the most commonly prescribed medications nationally and represent the most frequently used class of antidepressants, with usage steadily increasing over the past 30 years.[13,14] While SSRIs are effective and widely used for a variety of psychiatric conditions, they are not without side effects—most notably, their impact on platelet function. SSRIs exert their antiplatelet effects by depleting serotonin levels within platelet dense granules, thereby impairing primary homeostasis and increasing the risk of bleeding.[15-17] In the orthopaedic setting, perioperative SSRI use has been linked to higher rates of both aseptic and all-cause revision following TSA.[18]

Despite SSRIs demonstrating an association with an increased risk of bleeding following both THA and TKA, the effect of SSRIs on the risk of perioperative transfusions and bleeds following TSA has not been previously investigated to our knowledge.[10–12] The purpose of the current study is to evaluate the association between SSRI use and the risk of perioperative bleeding and blood transfusion following TSA. We hypothesized that SSRI use during the perioperative period would be associated with an increased risk of bleeding and/or need for blood transfusion.

METHODS

Study Design

The PearlDiver (PearlDiver Technologies, Colorado Springs, CO, USA) Mariner170 dataset was queried as part of this retrospective cohort study. The Mariner170 dataset contains over 170 million United States (U.S.) patients receiving health coverage under commercial insurance, Medicare, Medicaid, government insurance, and self-pay between 2010 and 2023. Patient records were retrieved using procedural and diagnostic codes from the International Classification of Diseases Ninth (ICD-9) and Tenth (ICD-10) Revision, and Current Procedural Terminology (CPT). Institutional review board approval was waived since the dataset has been de-identified for public access.

Study Population

Adult patients over the age of 18 years with a history of anxiety or depression who underwent primary TSA (CPT-23472) and had 30-day postoperative outcomes data available were included. Patients with a history of coagulation or hemorrhagic disorder, thromboembolic disease, anemia, tumor or metastasis, trauma about the shoulder, or infection of the shoulder joint were excluded.

Data Extraction

Demographic variables included age, gender, Charlson Comorbidity Index (CCI), and history of diabetes, chronic kidney disease (CKD), obesity, hypertension (HTN), coronary artery disease (CAD), congestive heart failure (CHF), rheumatoid arthritis (RA), depression, alcohol use, tobacco use, anemia, coagulopathy, anticoagulant use, coagulation factor use, prothrombotic agent use, and SSRI use were extracted. Postoperative outcomes within the first 30 days of surgery included bleeding, transfusion needs, deep venous thrombosis (DVT), and pulmonary embolism (PE). Medication exposure was identified at the SSRI class level. Although individual agents can be identified within the database, overlapping treatment windows and transitions between antidepressants limit the accuracy of agent-specific classification.

Statistical Analysis

Eligible patients were stratified by SSRI use and case-control matched 1:1 by age, gender, CCI, and history of diabetes, CKD, obesity, HTN, CHF, RA, depression, alcohol use, tobacco use, anemia, coagulopathy, anticoagulant use, coagulation factor use, and prothrombotic agent use. Patient demographics and 30-day postoperative outcomes were compared across cohorts using student's t-tests for continuous variables and chi-square analyses for categorical variables. All analyses were conducted using the built-in R statistical software within PearlDiver, with p-value of <0.05 indicating statistical significance.

RESULTS

Demographics

After matching, a total of 3,340 patients undergoing TSA were included in the study, with 2,630 patients (78.60%) in both the SSRI and control group having a documented history of depression, with the remaining patients having anxiety [**Table 1**]. The mean age was 67.45 ± 7.44 years with 2,410 (72.03%) males and a mean CCI of 1.04 ± 1.07 were identical between SSRI and control group. [**Table 1**]

Outcomes

There were no statistically significant differences (p <0.05) in the risk of bleeding, transfusion, deep venous thrombosis, or pulmonary embolism 30 days following TSA between patients with anxiety and/or depression on SSRIs and those not on SSRIs [**Table 2**].

Table 1. Demographics of patients with anxiety/depression who underwent total shoulder arthroplasty

	SSRI n (%)	Control n (%)	p-value
Age (mean ± SD)	67.45 ± 7.44	67.45 ± 7.44	1
CCI (mean ± SD)	1.04 ± 1.07	1.04 ± 1.07	1
Gender	2,410 (72.03)	2,410 (72.03)	1
Diabetes	541 (16.17)	541 (16.17)	1
CKD	41 (1.23)	41 (1.23)	1
Obesity	967 (28.90)	967 (28.90)	1
HTN	2,542 (75.97)	2,542 (75.97)	1
CAD	328 (9.80)	328 (9.80)	1
CHF	16 (0.48)	16 (0.48)	1
RA	65 (1.94)	65 (1.94)	1
Depression	2,630 (78.60)	2,630 (78.60)	1
Alcohol Use	46 (1.37)	46 (1.37)	1
Tobacco Use	755 (22.56)	755 (22.56)	1
Anemia	26 (0.78)	26 (0.78)	1
Coagulopathy	0 (0)	0 (0)	1
Anticoagulation Use	41 (1.23)	41 (1.23)	1
Coagulation Factor	42 (1.23)	42 (1.23)	1
Prothrombotic	0 (0)	0 (0)	1

SSRI = selective serotonin reuptake inhibitor; SD = standard deviation;
SSRI = selective serotonin reuptake inhibitor; CCI = Charlson Comorbidity Index; CKD = chronic kidney disease; HTN = hypertension; CAD = coronary artery disease; CHF = congestive heart failure

Table 2. Bleeding and thrombotic risk in patients with anxiety or depression within 30 days following total shoulder arthroplasty

	SSRI n (%)	Control n (%)	p-value
Bleeding	7 (0.21)	10 (0.30)	0.627
Transfusion	10 (0.30)	14 (0.42)	0.539
DVT	7 (0.21)	3 (0.09)	0.342
PE	1 (0.03)	2 (0.06)	1

SSRI = selective serotonin reuptake inhibitor; DVT = deep vein thrombosis; PE = pulmonary embolism

DISCUSSION

The purpose of the present study was to evaluate the impact of SSRIs on the risk of perioperative bleeding and transfusions following TSA. Contrary to our initial hypothesis, the findings of this study did not demonstrate a significant increase in bleeding-related complications among patients with anxiety and/or depression on SSRIs undergoing TSA. Given the widespread and increasing use of SSRIs,[13,14] along with the rising incidence of TSA procedures,[1,2] it is important to understand the potential implications of SSRI use in the surgical context. The present findings contrast with prior studies that reported increasing bleeding risk associated with SSRIs in THA and TKA.[10-12] Thus, the current study does not provide support for the alteration of SSRI regimens in the TSA perioperative period due to bleeding or thrombotic risk. However, caution should still be used for patients undergoing TSA who are using SSRIs in the perioperative period.

Understanding whether SSRI use increases perioperative bleeding risk is important for guiding medication management in a growing surgical population with high rates of mental health comorbidity. SSRIs have been linked to impaired platelet aggregation by decreasing serotonin content in platelet dense granules,[15-17] which may account for increased bleeding risk reported in TKA and THA.[10-12] Bismuth-Evanzal et al demonstrated that in a clinical setting, SSRIs depleted platelet serotonin stores and reduced aggregation in response to ADT, collagen, and epinephrine.[15] Additionally, in-vitro studies have demonstrated that sertraline and its inactive metabolite, N-desmethylsertraline, inhibit platelet aggregation and down regulate surface markers of activation.[17] However, these effects did not translate into increased bleeding or transfusion requirements in our TSA cohort. These differences may reflect a gap between in-vitro models and differing clinical settings, where compensatory mechanisms and surgical factors influence outcomes. This discrepancy may also be due to anatomical and procedural differences between lower extremity arthroplasty and TSA. Additionally, although antiplatelet agents have been associated with increased blood loss in TSA,[19] this increase is not clinically significant and rarely necessitates transfusions.[19,20] It is possible that SSRIs exert a similar mild antiplatelet effect that does not result in significant clinical consequences in TSA.

Although thrombotic events following TSA are uncommon, certain patients—such as those with prolonged operative times, elevated BMI, or older age—are at increased risk.[19,20] Therefore, individualized risk stratification for potential venous thromboembolism (VTE) prophylaxis remains critical.[21] Given the role of SSRIs in modulating platelet function, their potential effect on thrombotic risk also warrants consideration. Prior work by Bruun et al did not find a significant difference in the rate of VTE between SSRI and non-SSRI patients who underwent operative repair of hip fractures.[22] In alignment with these findings, the current results did not demonstrate a significant difference in VTE rates post-TSA between SSRI and non-SSRI users. This mirrors findings with other antiplatelet medications, such as aspirin and clopidogrel, which also do not increase VTE risk after TSA.[23]

Limitations

The most significant limiting factor of this study is that the data source was an administrative claims database. This introduces potential inaccuracies due to coding variability in ICD or CPT codes, upon which the analysis relied. In addition, the data source lacked clinical granularity and patient-level details. Prior studies have reported variability in bleeding risk among specific SSRIs.[24,25] However, specific SSRI, dosage, treatment duration, and overlap between agents were not assessed in the present study. Important perioperative variables such as operative times, known to influence bleeding and VTE risk,[20,21,26] could not be measured. Additionally, estimated blood loss was also unavailable, as were patient-specific risk factors such as prolonged immobility or bed confinement.[27] These limitations reduce the ability to control for potential confounders.

CONCLUSION

The current study determined that there was no increased bleeding or thrombotic risk in patients with anxiety or depression on SSRIs undergoing TSA compared to those not using SSRIs. These findings do not provide support for the alteration of SSRI regimens in the TSA perioperative period due to bleeding or thrombotic risk. However, caution should still be used in patients on SSRIs undergoing TSA.

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Evaluation of Naloxone Uptake Disparities Among Harm Reduction Clients in Rhode Island: A Deeper Dive Using Disaggregated Race and Ethnicity Data

ERIN BROWN, MPH; SARAH OGUNDARE, MPH; NYA REICHLEY, MPA; JENNIFER KOZIOL, MPH; THOMAS BERTRAND, MPH, MA; SUZANNE BORNSCHEIN, MD

ABSTRACT

INTRODUCTION: Although opioid overdose deaths decreased between 2022 to 2024, racial and ethnic disparities persisted during this time. The goal of this analysis was to explore disparities in naloxone uptake by racial and ethnic identity and harm reduction supply preference. This article builds upon prior work and disaggregates race and ethnicity categories that were previously aggregated due to small numbers.

METHODS: Clients were divided into three mutually exclusive groups based on the type of harm reduction supplies they requested: 1) those who requested injection supplies only, 2) those who requested smoking supplies only, and 3) those who requested both injection and smoking supplies. We calculated descriptive statistics and odds ratios to investigate racial and ethnic disparities in naloxone uptake.

RESULTS: Overall, Black and Hispanic clients were significantly less likely to receive naloxone compared to their White counterparts. Racial and ethnic disparities in naloxone uptake varied after accounting for supply preference. The clearest racial and ethnic disparities were observed among clients who requested smoking supplies.

CONCLUSION: It is important to consider multiple factors when designing harm reduction and overdose prevention interventions, including racial and ethnic identity, culture, preferred substance, and preferred route of administration. People with lived experience should continue to be included when designing interventions. Given the rapidly changing nature of the illicit drug supply and the emergence of novel substances, anyone who uses illicit substances is at risk of an opioid overdose. Harm reduction agencies should continue to educate stimulant users about their risk of opioid overdose and the benefits of naloxone.

KEYWORDS: harm reduction; overdose; naloxone; disparities

INTRODUCTION

Opioid overdose deaths are a leading public health concern in Rhode Island. Although opioid overdose deaths decreased between 2022 and 2024, racial and ethnic disparities persist. In 2023, non-Hispanic Black individuals experienced the highest rate of fatal overdoses in Rhode Island at 47.0 decedents per 100,000 person-years.[1] Nationwide in 2023, non-Hispanic Black individuals experienced a similar rate of fatal overdoses (48.9 per 100,000), which was second to that of Native American or Alaskan individuals (65.0 per 100,000).[2] Racial and ethnic analyses related to opioid overdoses in Rhode Island typically include Hispanic, non-Hispanic White, and non-Hispanic Black individuals. If additional racial identities are included, they are aggregated because of small population sizes. Therefore, the rate of fatal overdose among Native American or Alaskan individuals in Rhode Island is unknown. Although there is strong statistical justification for the suppression of counts and rates based on small numbers,[3] hidden disparities may exist among minority communities.

Naloxone, also known by the brand name Narcan®, is a life-saving medication that can reverse an opioid overdose. Distribution of naloxone, which is plentiful in Rhode Island following a settlement with drug manufacturers, is a key strategy to reduce opioid overdose deaths.[4] Anyone who uses illicit substances is at risk of an opioid overdose given the increased presence of synthetic opioids in the drug supply. People who use stimulants may not know that their drugs contain opioids. Even those who knowingly use opioids may encounter synthetic opioids that are much more potent than they are accustomed to.[5] This article builds upon prior work and disaggregates race and ethnicity categories that were previously aggregated due to small numbers.[6,7] The goal of this analysis was to explore disparities in naloxone uptake by racial and ethnic identity and harm reduction supply preference.

METHODS

AIDS Care Ocean State,[8] Community Care Alliance,[9] Project Weber/RENEW,[10] and Parent Support Network of Rhode Island (until September 2024),[11] with funding in part from the Rhode Island Department of Health, have provided life-saving harm reduction services since as early as 1986. These

Table 1. Unique Clients Requesting Injection Supplies, Smoking Supplies, and Naloxone by Race and Ethnicity (RI, January 1, 2022–June 30, 2025)

Race and Ethnicity	Unique Clients N (%)	Unique Clients who Requested Naloxone n (%)	Unique Clients who Requested Injection Supplies		Unique Clients who Requested Smoking Supplies		Unique Clients who Requested Injection and Smoking Supplies	
			Requested Injection Supplies n	Requested Injection Supplies and Naloxone n (%)	Requested Smoking Supplies n	Requested Smoking Supplies and Naloxone n (%)	Requested Injection Supplies and Smoking Supplies n	Requested Injection Supplies, Smoking Supplies, and Naloxone n (%)
White*	12,612 (61.3%)	6,573 (52.1%)	4,253	2,363 (55.6%)	5,322	2,384 (44.8%)	3,037	1,826 (60.1%)
Hispanic	4,137 (20.1%)	2,041 (49.3%)	1,272	720 (56.6%)	1,928	753 (39.1%)	937	568 (60.6%)
Black*	3,340 (16.2%)	1,572 (47.1%)	842	509 (60.5%)	1,830	623 (34.0%)	668	440 (65.9%)
More than one race*	281 (1.4%)	142 (50.5%)	81	46 (56.8%)	144	62 (43.1%)	56	34 (60.7%)
Native American or Alaskan*	135 (0.7%)	72 (53.3%)	35	24 (68.6%)	72	29 (40.3%)	28	19 (67.9%)
Asian*	48 (0.2%)	20 (41.7%)	15	8 (53.3%)	25	7 (28.0%)	8	5 (62.5%)
Native Hawaiian or Pacific Islander*	13 (0.1%)	9 (69.2%)	—	—	—	—	—	—
All Unique Clients	20,566 (100%)	10,429 (50.7%)	6,503	3,673 (56.5%)	9,326	3,862 (41.4%)	4,737	2,894 (61.1%)

Non-Hispanic

organizations provide harm reduction supplies, basic needs, case management, education, linkage to services, and more through various access points, such as mobile outreach, fixed sites, and home-delivered services. Clients' autonomy is always respected; they only receive supplies and services that they request. During client encounters, outreach workers at these organizations recorded clients' identification codes, demographic data, and supplies requested; this data is subsequently reported to the Rhode Island Department of Health.[12]

As in previous articles published on this topic,[6,7] clients were divided into three mutually exclusive groups based on the type of harm reduction supplies they requested between January 1, 2022 and June 30, 2025: 1) those who requested injection supplies only, 2) those who requested smoking supplies only, and 3) those who requested both injection and smoking supplies. Injection supplies included sterile needles, and smoking supplies included a variety of pipes intended for different substances. Intranasal naloxone was offered separately from injection and smoking supplies.

Client race and ethnicity data were occasionally discrepant or missing, as the provision of essential supplies and services was prioritized over demographic data collection when necessary. Demographic data were self-reported, and clients may have identified themselves as various races and ethnicities at different encounters. Demographic data reported at the clients' last encounter were used for this analysis. Race and ethnicity were combined to categorize clients into the following groups: non-Hispanic White (henceforth "White"), non-Hispanic Black (henceforth "Black"), Hispanic, non-Hispanic Native American or Alaskan (henceforth "Native American or Alaskan"), non-Hispanic Native Hawaiian or Pacific Islander (henceforth "Native Hawaiian or Pacific Islander"), non-Hispanic Asian (henceforth "Asian"), and non-Hispanic of more than one race (henceforth, "more than one race"). We calculated descriptive statistics [**Table 1**] and odds ratios [**Table 2**] to investigate racial and ethnic disparities in naloxone uptake.

RESULTS

Between January 1, 2022 and June 30, 2025, 20,566 unique clients requested injection supplies and/or smoking supplies [**Table 1**]. Of the clients who requested injection supplies only, 56.5% also requested naloxone. By comparison, 41.4% of people who requested smoking supplies only also requested naloxone, and 61.1% of the clients who requested both injection and smoking supplies also requested naloxone. Receipt of naloxone by race and ethnicity varied within the three groups. Of the clients who requested injection supplies only, Native American or Alaskan clients were most likely to receive naloxone (68.6%), followed by Black clients (60.5%), clients with more than one race (56.8%), Hispanic clients (56.6%), White clients (55.6%), and Asian clients (53.3%). Of the clients who requested smoking supplies only, White clients were most likely to receive

Table 2. Odds Ratios of Clients Requesting Naloxone by Race and Ethnicity for Clients who Requested Injection Supplies, Smoking Supplies, and both Injection Supplies and Smoking Supplies (RI, January 1, 2022–June 30, 2025)

Race and Ethnicity	All Clients	Unique Clients who Requested Injection Supplies: Odds Ratio (OR) of Requesting Naloxone (Lower, Upper 95% CI)	Unique Clients who Requested Smoking Supplies: OR of Requesting Naloxone (Lower, Upper 95% CI)	Unique Clients who Requested Injection and Smoking Supplies: OR of Receiving Naloxone (Lower, Upper 95% CI)
White*	1.00	1.00	1.00	1.00
Hispanic	0.89 (0.83, 0.96)	1.04 (0.92, 1.18)	0.79 (0.71, 0.88)	1.02 (0.88, 1.19)
Black*	0.82 (0.76, 0.88)	1.22 (1.05, 1.42)	0.64 (0.57, 0.71)	1.28 (1.07, 1.53)
More than one race*	0.94 (0.74, 1.19)	1.05 (0.67, 1.64)	0.93 (0.67, 1.30)	1.02 (0.60, 1.76)
Native American or Alaskan*	1.05 (0.75, 1.48)	1.75 (0.85, 3.57)	0.83 (0.52, 1.34)	1.40 (0.63, 3.10)
Asian*	0.66 (0.37, 1.17)	0.91 (0.33, 2.53)	0.48 (0.20, 1.15)	1.11 (0.26, 4.63)
Native Hawaiian or Pacific Islander*	2.07 (0.64, 6.72)	—	—	—

**Non-Hispanic*

naloxone (44.8%), followed by clients with more than one race (43.1%), Native American or Alaskan clients (40.3%), Hispanic clients (39.1%), Black clients (34.0%), and Asian clients (28.0%). Finally, of the clients who requested both injection and smoking supplies, Native American or Alaskan clients were most likely to receive naloxone (67.9%), followed by Black clients (65.9%), Asian clients (62.5%), clients with more than one race (60.7%), Hispanic clients (60.6%), and White clients (60.1%).

Further analyses were conducted to determine if there were racial and ethnic disparities in naloxone uptake based on type of supplies requested [**Table 2**]. Among clients who requested injection supplies only, only Black clients had statistically significant higher odds (Odds ratio (OR)=1.22; 95% Confidence Interval (CI): 1.05, 1.42) of receiving naloxone compared to their White counterparts. Hispanic clients (OR=1.04; 95% CI: 0.92, 1.18), clients with more than one race (OR=1.05; 95% CI: 0.67, 1.64), and Native American or Alaskan clients (OR=1.75; 95% CI: 0.85, 3.57) had higher odds of receiving naloxone compared to their White counterparts, but the findings were not statistically significant. Asian clients (OR=0.91; 95% CI: 0.33, 2.53) had lower odds of receiving naloxone compared to their White counterparts, but the findings were not statistically significant. Among clients who requested smoking supplies, Hispanic clients (OR=0.79; 95% CI: 0.71, 0.88) and Black clients (OR=0.64; 95% CI: 0.57, 0.71) had statistically significant lower odds of receiving naloxone compared to the White counterparts. Clients with more than one race (OR=0.93; 95% CI: 0.67, 1.30), Native American or Alaskan clients (OR=0.83; 95% CI: 0.52, 1.34), and Asian clients (OR=0.48; 95% CI: 0.20, 1.15) had lower odds of receiving naloxone compared to their White counterparts, but the findings were not statistically significant. Finally, among clients who requested both injection and smoking supplies, only Black clients had statistically significant higher odds (OR=1.28; 95% CI: 1.07, 1.53) of receiving naloxone compared to their White counterparts. Hispanic clients (OR=1.02; 95% CI: 0.88, 1.19), clients with more than one race (OR=1.02; 95% CI: 0.60, 1.76), Native American or Alaskan clients (OR=1.40; 95% CI: 0.63, 3.10), and Asian clients (OR=1.11; 95% CI: 0.26, 4.63) had higher odds of receiving naloxone compared to their White counterparts, but the findings were not statistically significant.

DISCUSSION

This analysis demonstrated the importance of including supply preference when investigating racial and ethnic disparities in naloxone uptake. Among all clients, Hispanic and Black clients were significantly less likely to receive naloxone than their White counterparts. Asian clients and those with more than one race were also less likely to receive naloxone, while Native American or Alaskan clients and Native Hawaiian or Pacific Islander clients were more likely. Unfortunately, Native Hawaiian or Pacific Islanders had to be excluded from further analyses because of small numbers. Among clients who requested injection supplies, Black clients were significantly more likely to receive naloxone than their White counterparts. Hispanic clients, clients with more than one race, and Native American or Alaskan clients were more likely to receive naloxone compared to their White counterparts, while Asian clients were less likely. The clearest racial and ethnic disparities were observed among clients who requested smoking supplies. Compared

to their White counterparts, all other racial and ethnic identities were less likely to receive naloxone, although the only significant findings were among Hispanic and Black clients. Finally, among clients who requested both types of supplies, all other racial and ethnic minorities were more likely to receive naloxone than their White counterparts, although the only significant findings were among Black clients.

There were some limitations to this analysis. First, the data in this analysis only represented the efforts of harm reduction agencies funded by the Rhode Island Department of Health. Although the vast majority of naloxone is distributed by these agencies, this analysis undercounts the number of individuals who requested naloxone because it is possible to access naloxone from other sources. Next, client counts were approximate because there may have been client code data entry errors and clients may have used various codes to preserve their anonymity. Finally, despite the 3.5-year study period, clients who identified with previously aggregated racial and ethnic categories (non-Hispanic and more than one race, Native American or Alaskan, Asian, and Native Hawaiian or Pacific Islander) represented only 2.3% of all clients. The small numbers in these categories contributed to wide confidence intervals.

In conclusion, racial and ethnic disparities in naloxone uptake vary based on supply preference. It is important to consider multiple factors when designing harm reduction and overdose prevention interventions, including racial and ethnic identity, culture, preferred substance, and preferred route of administration. Most importantly, people with lived experience should continue to be included when designing interventions. The clearest racial and ethnic disparities were observed among clients who requested smoking supplies. Clients who smoke substances are typically using stimulants and may not perceive themselves to be at risk of opioid overdose.[5] Given the rapidly changing nature of the illicit drug supply and the emergence of novel substances, anyone who uses illicit substances is at risk of an opioid overdose. Harm reduction agencies should continue to educate stimulant users about their risk of opioid overdose and the benefits of naloxone. Future research into overdose-related topics should attempt to disaggregate racial and ethnic identities as much as possible to uncover hidden disparities. In Rhode Island where small numbers are an evergreen issue, this can be most easily accomplished by looking at multiple years of data. Finally, access to evidence-based, life-saving harm reduction services must be maintained, including a comprehensive and culturally responsive array of supplies and services offered through various low-barrier access points.

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Rhode Island Monthly Vital Statistics Report
Provisional Occurrence Data from the Division of Vital Records

VITAL EVENTS	REPORTING PERIOD		
	MAY 2025	12 MONTHS ENDING WITH MAY 2025	
	Number	Number	Rates
Live Births	965	10,837	10.2*
Deaths	880	10,799	10.2*
Infant Deaths	4	43	4.0#
Neonatal Deaths	3	31	2.9#
Marriages	677	7,080	6.7*
Divorces	165	2,517	2.4*

* Rates per 1,000 estimated population
# Rates per 1,000 live births

Underlying Cause of Death Category	REPORTING PERIOD			
	NOVEMBER 2024	12 MONTHS ENDING WITH NOVEMBER 2024		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	174	2,376	216.5	3,025.0
Malignant Neoplasms	196	2,175	198.2	4,087.5
Cerebrovascular Disease	38	438	39.9	482.0
Injuries (Accident/Suicide/Homicide)	64	931	84.8	10,438.0
COPD	30	479	43.6	467.0

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.
(b) Rates per 100,000 estimated population of 1,097,379 for 2020 (www.census.gov)
(c) Years of Potential Life Lost (YPLL).

NOTE: Totals represent vital events, which occurred in Rhode Island for the reporting periods listed above.
Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

Why join RIMS?

The Rhode Island Medical Society is your voice at the State House and in the community. In 2025, we secured wins on prior authorization, clinician wellness, and primary care funding—but this work depends on physician support. Without membership, RIMS cannot continue to advocate, educate, and protect the profession. Join or renew today—and consider getting involved in one of our committees. Together, we are stronger. The Rhode Island Medical Society is the only organization dedicated solely to advocating for physicians and their patients in our state.

In 2025, RIMS members helped

- Eliminate prior auth for PCP-ordered services (3-year Medicaid pilot)
- Secure fair Medicaid rates—up to 100% of Medicare starting Oct. 2025
- Protect physician wellness with the Clinician Wellness & Support Act

We're not stopping here

RIMS is fighting for the future of telemedicine, tackling workforce shortages, and reducing administrative burdens.

Click to join

https://rhodeislandmedicalsociety.wildapricot.org/Join-us/

Wins for providers

RIMS worked to secure and support key budget investments.

Medicaid primary care rate increase

Up to 100% of medicare rates
Starting October 2025

Medicaid prior authorization pilot

Eliminates prior authorization for Medicaid for three years
Starting October 2025

Physician loan repayment funding

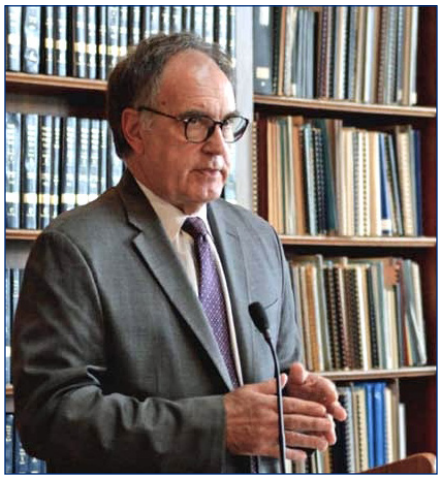
Includes $200,000 in funding to recruit and retain clinicians

Health center funding

Sustained investments in FQHCs and community health

Health services funding assessment

$30Mannually for primary care and other critical programs



Our priorities

RIMS focused on strengthening Rhode Island's healthcare system, protecting physicians' well-being, reducing administrative burdens, and improving access to care. Together with members, specialty societies, and partner organizations, we made significant progress on our top priorities.

The Rhode Island Prior Authorization Reform Act (SB 168/HB 5120)

Eliminates prior authorization for admissions, services, and procedures ordered by in-network primary care physicians in a three-year pilot.
Effective: October 1, 2025.
Status: Passed and signed
Sponsored by: Rep. Brandon Potter; Sen. Melissa Murray

The Rhode Island Clinician Wellness and Support Act (SB 695/HB 6036)

Recognizes RIMS' Physician Health Program in statute, strengthens confidentiality protections, and updates licensing language to encourage clinicians to seek care without fear.
Status: Passed and signed
Sponsored by: Rep. John "Jay" Edwards; Sen. Bridget Valverde

"I'm Sorry" Bill (H6210/S66)

Although not yet enacted, RIMS made significant progress this session on legislation to allow physicians to express sympathy or apologize after an adverse outcome without it being used as evidence of liability. We met twice with the Rhode Island Association for Justice (trial lawyers) and reviewed their suggested language—which we ultimately could not support—laying important groundwork for next session.
Sponsored by: Rep. Teresa Tanzi; Sen. Pamela Lauria

IT ALL STARTS HERE!
JOIN OR RENEW IN 2026
RHODE ISLAND MEDICAL SOCIETY

The Rhode Island Medical Society is the statewide home for physician advocacy, education, wellness, and leadership. This past year, RIMS vdelivered meaningful wins for Rhode Island physicians, including:

- **MAJOR PRIOR AUTHORIZATION REFORM**
- **STRONGER CLINICIAN WELLNESS PROTECTIONS**
- **MEDICAID RATES TO 100% OF MEDICARE**
- **12 SPECIALTY SOCIETIES SUPPORTED AND 35+ EDUCATION PROGRAMS**
- **CONFIDENTIAL SUPPORT THROUGH THE PHYSICIAN HEALTH PROGRAM**

Your membership strengthens our voice at the State House and supports the future of medicine in Rhode Island.

JOIN OR RENEW TODAY AT
rimedicalsociety.org/membership

Questions about individual or group membership?
EMAIL **membership@rimed.org**

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YOUR PROFESSION.

RIMS gratefully acknowledges the practices who participate in our discounted Group Membership Program

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For more information about group rates, please contact Ali Walz, RIMS Director of Member Services

Publication Bias

JOSEPH H. FRIEDMAN, MD

It is widely believed that there is a bias against publishing "negative" studies. Researchers think that editors are more likely to reject trials that do not show a positive effect of some intervention, or that a purported risk for a disorder, is, in fact, not a risk factor. Yet, research looking to support findings of clinical publications have often shown a failure to confirm the original report. The reasons for this unreliability are manifold. All clinical research on living specimens is biased by the sample chosen. Even large data "mining" operations, for example, looking at a Medicare database involving hundreds of thousands of people, obviously reflect only those who have Medicare insurance. In research, as in everything else, there are "the known knowns, the known unknowns and the unknown unknowns." Lack of publishing results is one of the unknown unknowns.

Clinical research publications follow a format, most of which is on a template formulated by the journal or recommended by some organization. In the discussion section, which follows the research data presentation, there is a summary of the important findings, both negative and positive and their implications. In the next to last paragraph the authors usually summarize the weaknesses of their study. They address the possible biases of their study, then explain why their results should be believed, albeit with certain cautions, and conclude with the final sentence noting that the results need to be confirmed. This is sound advice, but there is always the lurking problem of the unknown unknowns.

In this issue of RIMJ, Khatri et al[1] reviewed English language studies of two common eye disorders in diabetics. They found that only 20% were published. This was a surprise to me, having never thought of the problem and would have guessed that maybe 20% or less were not published. I learned that this is a common problem and similar rates of non-publication span the spectrum of medical studies. There are many potential reasons for not publishing. For example, I knew of a clinical study that tested a European antipsychotic drug in patients with psychotic symptoms associated with Parkinson's disease. A small open label trial was very suggestive of significant benefit so that a double blind placebo trial was sponsored by the drug company. I thought this was a great idea, but I was not directly involved in the study. The study was completed but with a negative result. The drug was ineffective. I waited for the publication and learned that there would be none. No one explained to me why this was to be the case. Most researchers like to see their names in print and these investigators were not bound to hide their results by virtue of being employees of the company. Presumably, and understandably, the drug company thought that negative results would reflect poorly on the drug. There was little to be gained by proving themselves good corporate citizens. I don't know why the investigators didn't publish. The results were readily available, however, in ClinicalTrials.Gov, so I got to publish in one of the easiest papers in history.[2] Of course, anyone could have looked up the results that way, but few people knew of the trial, and most papers are identified via topic searches in PubMed. Except for active researchers, few scan ClinicalTrials.Gov for study results.

Many clinical trials fail to meet their recruitment goals, which means that their careful planning for how many subjects they needed in order to obtain a statistically significant outcome was for nought and that the study was unable to obtain useable data. Since the estimate for how many subjects are needed is something of a guess, the study may have recruited too few to draw reliable conclusions. Some projects faltered because investigators did not adequately oversee their portion of the study, recruiting subjects who should not have meet inclusion criteria, or who dropped out prematurely, lacking sufficient commitment ("garbage in, garbage out"). A study may produce results that mystify the researchers, expecting one outcome, anticipating a possible failure, but not expecting a surprise that they cannot explain.

Studies are often abandoned mid-stream, possibly because of worrisome side effects or unwanted trends. Occasional studies are halted due to business decisions. A company purchases a new drug that will compete with the one being studied. And the acceptance rate for manuscripts submitted to many journals may be small.

A likely major contributor to non-publication is repeated rejections. Peer review requires independent experts in the field to read a paper, make suggestions for improvement and grade it. Most journals have two anonymous reviewers, but some may have four or five. The quality of the reviews vary, and since reviewers do not see the other reviewers' comments until after their own has been submitted, their opinions may vary enormously. In addition, one may wait

several months to get a review back, make suggested changes and have it then rejected. After five or six submissions, the authors may give up.

Most likely there are other reasons for failure to publish as well, but the implications of this failure are more difficult to assess. Non-publication does not mean the outcome was negative, although that would be the likely implication, but literature searches won't turn up studies that were not reported. We don't know what we don't know. Maybe a study I want to do has been done before? Maybe I think a treatment is a great and innovative idea, not knowing that it's failed in five different studies. Or the opposite: a treatment was successful in a small trial, which would bolster your chance of getting funded for a larger trial.

We owe it to our subjects to try to publish what we find. Institutional review boards (IRBs) will ask about publications when a study officially ends, but they may not require a justification for failure to publish. They should. ❖

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Vintage article by Seebert J. Goldowsky, MD, describes founders, physicians, funders of Miriam Hospital

Dr. Goldowsky, surgeon and prolific writer, was longtime RIMJ editor-in-chief

MARY KORR
RIMJ MANAGING EDITOR

On June 19, 2025, at a Miriam Hospital event in anticipation of its formal Centennial this year, a time capsule was opened that had been sealed in the cornerstone of its building 75 years ago. Among the papers inside were:

- The Program of Ceremonies at the laying of the cornerstone, dated May 20, 1951 [**Figure 1**)].
- Newspapers from 1925 to 1951, reporting on the history and opening of the Miriam Hospital, first on Parade Street [**Figure 2**] in Providence, and then on Summit Avenue.
- There was also a May 1951 issue of the *Rhode Island Medical Journal* (RIMJ) [**Figure 3**]. Inside the issue, there was a photo of the hospital [**Figure 4**] with the caption "New Miriam Hospital."

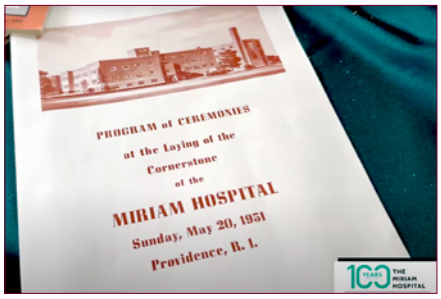

Figure 1. Program of Ceremonies at the laying of the cornerstone, dated May 20, 1951. [THE MIRIAM HOSPITAL/BROWN HEALTH]

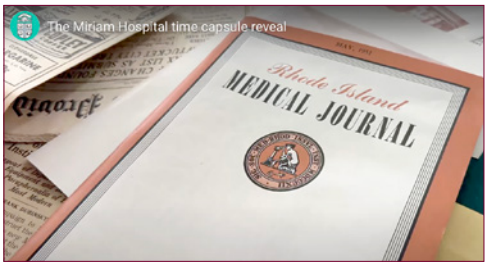

Figure 3. The May 1951 issue of the *Rhode Island Medical Journal* (RIMJ) was among the artifacts inside the recently opened time capsule of The Miriam Hospital. [THE MIRIAM HOSPITAL/BROWN HEALTH]

Figure 2. Photo of the Miriam Hospital, Parade Street, Providence, taken on its tenth anniversary. [PROVIDENCE DIGITAL LIBRARY]

Figure 5. Seebert J. Goldowsky, MD, (1907–1997), served as RIMJ's editor-in-chief from 1961–1989. A surgeon, as well as a prolific writer and historian, he wrote about the underpinnings of The Miriam's formation. [RIMJ, JAN. 2017]

Through the writings of **SEEBERT J. GOLDOWSKY, MD,** (1907–1997), longtime RIMJ editor-in-chief, from 1961–1989 [**Figure 5**], more of the Miriam's history is amplified. A Providence native and graduate of the Harvard Medical School, class of 1932, he was a general surgeon at Rhode Island and the Miriam hospitals for 37 years.

Dr. Goldowsky was also an active member of the Jewish community, civic organizations, a veteran of World War II, and a prolific writer with a historical bent.

An article he wrote in the *Notes of the Rhode Island Jewish Historical Society* in 1957[1] detailed facts on the formation of The Miriam Hospital. The women's organization, "Miriam Lodge, Number 13, Order of Brith Abraham was, in all probability, the precursor of later Miriam organizations and was the source of the name of the hospital."

He reported that in 1902 the group reorganized and was chartered by the State as the Miriam


NEW MIRIAM HOSPITAL

The cornerstone for the new Miriam Hospital was laid on Sunday, May 20, 1951. Among the documents deposited in the record box was a copy of the May issue of the R. I. Medical Journal.

Figure 4. Photo of the hospital inside the May 1951 issue of RIMJ with the caption "New Miriam Hospital." [RIMJ, MAY 1951]

Figure 6. Collection boxes were distributed throughout the Jewish community to raise money for the hospital.[1]

Society, Number One. Several years later, the organization was chartered as The Miriam Hospital Association of Providence "for the purpose of building, maintaining and operating a Hebrew Hospital in the State of Rhode."

In 1914, an individual was hired to distribute collection boxes to Jewish homes to raise money for the hospital [**Figure 6**]. After World War I, a quadruplex brick building with three rooming houses and a hospital on Parade Street became available for purchase. In 1921, a deposit was put down for $1,000. The eventual cost came to $27,000, Dr. Goldowsky wrote.

Jacobi Medical Club

In the article, he also reported the formation of the Jacobi Medical Club in 1923, "to satisfy a need for a fuller academic life and to foster social ties." The Club was named after **DR. ABRAHAM JACOBI**, considered a pioneer in pediatrics, who had given a Rhode Island Centennial oration in 1912 on "The Educational Value of Medical Societies and Libraries." **MAX B. GOMBERG, MD**, (1875–1934), was elected the group's first president.

Dr. Goldowsky wrote that the Jacobi Medical Club, anticipating the opening (late in 1925) of the new Miriam Hospital, assisted in its planning and staffing. Club physicians initiated a campaign "for the establishment of a Jewish-sponsored, non-sectarian hospital."

By 1924, the various campaigns raised approximately $80,000, and the hospital was chartered by the State on March 25,1926. At the time, the hospital on Parade Street had 63 beds and 14 bassinets. Photos of the Miriam Hospital medical staff and later, its Board of Trustees, depicted in the *Notes* article, add to the visual history [**Figures 7,8**].

Decades later, when the need to expand beyond a small neighborhood hospital became evident, a major building fund drive was initiated. The result was $1.3 million raised and the opening of the new 150-bed Miriam Hospital on 164 Summit Avenue in 1953—which brings us back to the aforementioned time capsule. A YouTube video of the unearthing event can be found at: https://www.brown-health.org/locations/miriam-hospital/celebrating-100-years.

As Centennial celebrations unfold this year, and The Miriam's expansion and additions launch, one hopes a time capsule will be ensconced in a cornerstone—a solid yet tangible lock box of legacies for future generations to unearth and discover. ❖

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Figure 7. Medical staff of The Miriam Hospital shown in this 1925 photo.[1]

Figure 8. First Board of Trustees shown in this 1932 photo.[1]

Ocean State Labs Opening to Accelerate a New Era of Life Science Innovation

MARK A. TURCO, MD; LILIA KIRTLEY HOLT, MBA; HAILEY BATHURST, MAIDP

PROVIDENCE — Rhode Island will open its very first life sciences incubator in Providence's 195 Innovation District this month—a milestone that highlights the state's position as an emerging biotech cluster. The launch of Ocean State Labs, powered by Portal Innovations, represents the first major infrastructure investment designed specifically to help early-stage scientific companies as they establish operations in Rhode Island to scale, mature, and translate research and technology development into clinical impact.

Mark A. Turco, MD, President & CEO of the Rhode Island Life Science Hub (RILSH), at the podium during a September event announcing the opening of the incubator.

Since its creation two years ago and under the leadership of President & CEO **MARK A. TURCO, MD**, the Rhode Island Life Science Hub (RILSH) has been rapidly building and serving as a catalyst to set the foundation needed to expand Rhode Island's Life Science capabilities. Dr. Turco, a cardiologist and former medical device innovation executive, guides RILSH with a clear vision: Connect Rhode Island's scientific breakthroughs and entrepreneurial community with the commercial, investment, and infrastructure required to advance breakthroughs from bench to bedside.

RILSH's mandate, backed by a significant state funding allocation approved several years ago, is to create an environment where biotech founders can grow their companies locally rather than leaving the region in search of lab space, talent, or capital. In addition, the organization is working to bring innovative companies from across the world to build and scale in Rhode Island. Once companies scale in the incubator, the hope is to have those companies graduate to labs, offices and manufacturing facilities within the State and utilizing a growing and active life science workforce in the region.

The opening of Ocean State Labs marks a major step toward that goal. Developed with support from Brown University, the 30,000-sq.-ft. incubator will provide fully equipped, move-in-ready labs and a built-in support structure through Portal Innovations, the operator of the lab space. By offering technical infrastructure, subsidized space, and business and investment support, RILSH and Portal aim to attract new companies to the state as and enable spinouts from Rhode Island's academic institutions and health systems to scale here at home in the Ocean State.

Ocean State Labs is a 30,000-sq.-ft. incubator that will provide fully equipped, move-in-ready labs and a built-in support structure through Portal Innovations, the operator of the lab space.

Ocean State Labs is expected to house 20–30 startups and a community of 150–180 scientists, entrepreneurs, and operators. Incubators like this accelerate scientific discovery and technology development by delivering entrepreneurial support, promoting inclusive growth with opportunities for diverse founders and teams, and fostering collaboration that drives innovation with real impact—prioritizing bold ideas that improve health outcomes and quality of life.

When the Ocean State Labs incubator opens this month, it will be home to six foundational tenants. Each company is advancing technologies rooted in areas where Rhode Island has scientific depth: neuroscience, aging, oncology, regenerative medicine, and RNA biology.

The first cohort at Ocean State Labs

MindImmune Therapeutics

MindImmune Therapeutics is a biopharmaceutical company focused on neuroinflammation and Alzheimer's disease. MindImmune is affiliated with the George and Anne Ryan Institute for Neuroscience at URI, where its co-founders have faculty appointments as Ryan Research Professors of Neuroscience.

The company's lead program, MITI-101, is a treatment being developed for patients with Alzheimer's disease and seeks to inhibit deleterious immune cell recruitment from the blood into the brain in response to pathology. This could represent a fundamental therapeutics breakthrough for the field.

MindImmune was recently awarded a grant to accelerate IND-enabling studies for MITI-101. The company has also raised $30 million in Series A financing. The company was launched by co-founders **STEVIN ZORN, PhD**, **FRANK MENNITI, PhD**, and **ROBERT NELSON, PhD**, who originally met as scientific collaborators in central nervous system (CNS) research at Pfizer. Biotech veteran **ISAAC STONER** is CEO.

OncoLux Inc.

OncoLux is a medtech company developing advanced optical imaging and AI technology to improve surgical procedures in the field of oncology. The company was founded to solve a recurrent challenge for surgical oncologists, who often cannot completely and definitively distinguish cancer from surrounding healthy tissue. It is led by **ALAN KERSEY**, a veteran of the optical instrumentation and biotech worlds.

The OncoLux technology uses enhanced theranostic tissue-imaging technology to learn the fingerprint of malignant tissue to highlight regions of potential positive margins intraoperatively and provide real-time imaging—and actionable data—during surgery to improve outcomes, preserve function, and reduce disease recurrence.

OncoLux is the recipient of non-dilutive funding from RILSH that enabled the company's relocation from Connecticut to Rhode Island.

p53-Therapeutics

p53-Therapeutics is pursuing a new class of small molecule therapeutics designed to overcome p53 tumor suppressor mutations in cancer. p53 is mutated in most human cancers and at an even higher frequency among difficult-to-treat cancers and in patients that fail first-line therapies. The company's two lead programs are currently in IND-enabling studies.

WAFIK S. EL-DEIRY, MD, PhD, FACP, the scientific founder and Board chair of p53, is the Associate Dean for

Renderings of the incubator depict the entrance, a large conference room, an open lab and office, as well as the Coffee Commons.
[PHOTOS COURTESY OF RHODE ISLAND LIFE SCIENCE HUB]

Oncologic Sciences at the Warren Alpert Medical School and Director of the Legorreta Cancer Center at Brown University.

PAX Therapeutics

PAX Therapeutics is advancing gene delivery technologies to optimize healing of tendon and ligament injuries. PAX-001, the company's lead program, is currently in development for the treatment of flexor tendon injuries of the hand. PAX has completed preclinical testing and is preparing to enter a human clinical trial of PAX-001.

PAX was spun out of the labs at Rhode Island Hospital of **PAUL LIU, MD**, who serves as Chair and Professor of Plastic Surgery at Brown University. PAX has received non-dilutive funding from RILSH for IND-enabling studies.

XM Therapeutics

XM Therapeutics is developing tissue repair and regeneration platforms for chronic disorders. By targeting the extracellular matrix (ECM), XM's technology is initially focused on repairing damaged cardiac tissue after heart attack, improving outcomes in heart failure, accelerating healing of chronic wounds, and preventing debilitating scarring in joints. The platform also enables future expansion to other organs and chronic conditions.

XM received non-dilutive funding from RILSH. The company was founded in 2022 in Providence and has close ties to Brown University, where co-founder **JEFFREY MORGAN, PhD**, is Professor of Pathology and Laboratory Medicine and Professor of Engineering, and co-founder **FRANK SELKE, MD**, is Chief of Cardiothoracic Surgery, Rhode Island Hospital and Professor of Medicine, Brown University.

Lilac Biosciences

Lilac Biosciences is developing next-generation tools that advance RNA research by enabling precise detection and quantification of RNA modifications in the body to detect early disease. Lilac's technology bypasses the need for expensive sequencing methods, addressing a major unmet need as RNA-based applications expand across the life sciences.

Lilac is building scalable, high-impact platforms that support innovation in diagnostics, therapeutics, and precision medicine. Through focused and quietly transformative R&D, the company is helping shape the next era of RNA-driven discovery.

Lilac has received non-dilutive funding from RILSH, and was co-founded by **SABRINA TOLPPI**, a Biomedical Engineering graduate of Brown University, and **ANUBHAV TRIPATHI, PhD**, who is Professor of Biomedical Engineering at Brown University.

A Growing Pipeline of Companies Supported by RILSH

The incubator is just one pillar of RILSH's broader mandate. Beyond Ocean State Labs, RILSH offers wraparound support to help companies move from innovative science into clinical impact. This support includes:

- Rigorously vetted funding for therapeutics, diagnostics, medtech, and platform companies
- Subsidized lab space and access to specialized scientific infrastructure
- Connections to capital, investors, and strategic partners
- Clinical validation pathways through Brown University, the University of Rhode Island (URI), and Brown Health
- Mentorship and commercialization support through partnerships such as Portal Innovations

About $25M has been allocated for non-dilutive grants over a two-year period. To date, RILSH has supported almost 40 companies and catalyzed $160M in private investment. Some of the recipients of RILSH funding include service organizations critical to the regional life science ecosystem. Many are Brown or URI spinouts that might otherwise have left the state due to lack of laboratory capacity or seed-stage resources.

The View from Providence

With Ocean State Labs opening, Rhode Island will have, for the first time, a dedicated space to support the earliest stages of biomedical innovation. This progress reflects the emergence of a cohesive translational ecosystem, where discovery at Brown, URI, Brown Health, and Care New England can be supported, funded, housed, validated, and ultimately developed into technologies to benefit patients.

Ocean State Labs will provide Rhode Island with the physical and strategic infrastructure to ensure that homegrown innovation can stay—and thrive—here. ❖

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School of Public Health Dean Ashish K. Jha, MD, departs Brown; Francesca L. Beaudoin, MD, to serve as interim

PROVIDENCE [BROWN UNIVERSITY] — **ASHISH K. JHA, MD**, dean of the Brown University School of Public Health, departed Brown at the end of December to lead an initiative that aims to bolster the nation's defenses against emerging pandemic and biological threats. The initiative builds on work he started at the White House while on leave from the University in 2022 and has further cultivated during his time at Brown.

Brown Provost Francis J. Doyle III said that while Jha's leadership will be missed at the School of Public Health, he is embarking on exciting work that will have an impact far beyond the University.

"As the U.S. and other nations have continued to witness the impact of avian flu, mpox, COVID-19 and other infectious diseases, Ashish's work can bring scientists, policymakers and organizations together to develop solutions to confront a new era of biological threats," Doyle said. "This work holds the potential to connect directly with the pioneering work in Brown's School of Public Health to advance pandemic preparedness and response."

Dr. Jha was appointed to lead the School of Public Health (SPH) in February 2020, weeks before COVID-19 grew to a major public health crisis for the United States. He began his tenure as dean in September 2020, and under his leadership, SPH has experienced a period of growth and expansion. In Fall 2023, SPH expanded into 155 South Main Street, which now houses the school's Mindfulness Center; Survey, Qualitative and Applied Data Research Core; and Hassenfeld Child Health Innovation Institute.

The school also opened an office in Washington, D.C., in 2024, contributing to the national impact of the Pandemic Center that launched in 2022. The new presence in the capital complements the work of other research units dedicated to driving policy changes as the school has continued to build upon its tradition of research excellence by tackling some of the most pressing public health issues facing society.

In addition to biosecurity and pandemic preparedness, the school has increased its influence in the areas of climate change and public health, health policy reform, and overdose prevention. Dr. Jha has recruited world-class faculty with expertise across many of these areas, in addition to building the school's work in global health and information disorders.

"Helping lead and build this school has been an extraordinary privilege, and I'm enormously proud of what we as a team have accomplished," Dr. Jha said.

Interim leadership

FRANCESCA L. BEAUDOIN, MD, academic dean of the School of Public Health and a professor of epidemiology and emergency medicine, will serve as interim dean of the school.

"For the past two years, Francesca has been part of an exceptional leadership team at the school and has been a key partner in SPH's growth and success," Doyle said. "Under her leadership, the school will continue to build its national influence in using data and analysis to inform recommendations for public health policy and concrete actions to improve population health."

Dr. Beaudoin will oversee the school's academic departments, research centers, doctoral and master's programs, and undergraduate concentrations. With more than 150 faculty and 800 undergraduate and graduate students, the school is home to 13 nationally renowned research centers and receives more than $90 million in external funding annually.

In addition to the national and global public health initiatives that will continue to engage faculty and student scholars across the school in the coming months and years, SPH will continue research and education initiatives to make a positive impact on local communities. This includes work on public health challenges like Rhode Island's overdose epidemic, efforts to address air and water pollution, and collaborating with scholars across disciplines to help families cope with Alzheimer's disease and dementia. ❖

Butler Hospital launches Express Care

PROVIDENCE — Butler Hospital recently announced the launch of Express Care, designed to provide timely, high-quality support for individuals seeking mental health care. Similar to the "urgent care" medical office model, Express Care will offer a shorter wait and a specialized patient experience, helping patients reach the right clinical care more quickly. The Express Care Clinic provides psychiatric evaluation with individualized treatment planning and level of care recommendations.

"This program was created to fill the gap between routine outpatient scheduling and the emergency department," said **GRETCHEN ANDERSON, LICSW, CCS, LCDP**, Sr. Clinical Director of Ambulatory & Outpatient Behavioral Health at Butler and CNEMG Behavioral Health Practices "Our goal is to provide rapid access to compassionate expert care for people who need timely support without the long wait times."

Butler Express Care is available Monday through Friday, 9:00 a.m. to 9:00 p.m., providing care to adolescents, adults, and older adults who may need:

- Medication refills
- Connection to a new therapist or psychiatrist
- Bridge care while transitioning into or out of a partial hospitalization program
- Support and resources to begin behavioral health, even for the first time
- Short-term stabilization and assessment
- Collaboration of care
- Individualized recommendations of care within our CNE network or to community behavioral health providers

This model strengthens access to behavioral health services by offering immediate connection to clinicians who understand the distinct needs of every life stage, supported in part by Butler's specialized adolescent and geriatric providers. This streamlined approach ensures that adolescents, young adults, college students, adults, and older adults can receive timely, personalized care for a wide range of concerns, including anxiety, depression, mood dysregulation, stress related to life transitions, and grief and loss.

"We recognize that navigating the mental health system can be overwhelming," said Anderson. "Express Care simplifies that journey. Whether someone needs support in managing symptoms with medication management, a therapy connection, or guidance on starting treatment, we're here to help them take the next step."

For more information about the express care behavioral health service, including hours, location, and referral guidelines, visit www.butler.org/express-care. ❖

AMA welcomes CMS model targeting chronic conditions with tech tools

CHICAGO — The American Medical Association (AMA) endorsed the Centers for Medicare & Medicaid Services (CMS) for launching a voluntary initiative to test technology-supported care for the millions of patients with chronic conditions in Original Medicare.

The model aims to overcome Medicare's barriers to technological advancements that have proved beneficial in helping patients manage their chronic diseases. The voluntary model focuses on common conditions, such as high blood pressure, diabetes, chronic musculoskeletal pain, depression, and other conditions affecting millions of Americans. CMS announced the novel approach, known as ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model, this week.

"ACCESS is an important step toward bringing new, effective digital health tools into everyday care for Medicare patients. We applaud CMS and, in particular, Director Abe Sutton's team at the Center for Medicare and Medicaid Innovation, for this new approach," said AMA CEO **JOHN WHYTE, MD, MPH**. "For too long, outdated payment barriers have made it difficult for physicians to use new tools that can improve care for common chronic conditions. This new model has the potential to give clinicians more flexibility, strengthen care teams, and—most importantly—help patients live healthier lives. The AMA looks forward to supporting physicians as they adopt technology-enabled care models in ways that enhance the patient-physician relationship."

The ACCESS Model aligns payments with measurable improvements in patients' chronic conditions based on each person's starting point and tailored to patients' needs for care rather than the individual services provided. By enabling the use of telehealth, wearable monitoring devices, digital coaching tools, and other innovative technologies, the model will help modernize chronic disease management and expand access for patients who have traditionally faced barriers to technology-enabled care. ❖

Reed and Whitehouse co-sponsor legislation to prevent dangerous gun sales

WASHINGTON, DC — When it comes to the sale of firearms, Senators **JACK REED** and **SHELDON WHITEHOUSE** say the rule should be simple: 'no background check, no sale' for all firearm transfers and purchases.

In an effort to keep dangerous weapons out of the hands of people the law already says should not own them, Reed and Whitehouse joined Senator Richard Blumenthal (D-CT) and 23 of their Senate colleagues on December 12 in introducing the Background Check Completion Act (S.3458). This legislation would end an exemption—known as "default to proceed"—that allows a sale to go forward if the background check process takes more than 72 hours.

When a criminal background check indicates that a firearm purchaser may have a criminal record, the Federal Bureau of Investigation (FBI) tries to determine whether the purchaser can legally buy a gun. If this process takes longer than 72 hours for those 21 years of age or older, or 10 days for those under 21, gun dealers can complete the sale even though there is a heightened risk that the purchaser is legally disqualified from purchasing a gun.

The gap in existing law has allowed thousands of gun sales to prohibited buyers, including the sale of the firearm used by the shooter in the deadly attack at Charleston's Emanuel AME Church. In that case, the church shooter was able to buy a .45 caliber handgun, even though he admitted to a disqualifying drug crime. But due to a bureaucratic processing error, the FBI was unable to confirm the admission, and the mandatory 72 hours elapsed, so the gun purchase went forward.

Companion legislation in the U.S. House of Representatives is led by Representative James E. Clyburn (D-SC).

According to Everytown for Gun Safety, background checks stop gun sales to criminals every day. Since 1994, these laws have blocked more than 5 million gun sales to people who could not legally own guns.

"Background checks are effective, but only if they are allowed to be complete. Closing the Charleston loophole is a commonsense, overdue step to save lives and prevent guns from ending up in the hands of dangerous individuals who are ineligible to own them," said Senator Reed. "Someone who is ineligible to own a gun shouldn't be able to obtain one just because of an error or a three day shot clock running out. Congress should close this dangerous loophole and invest in modernizing the FBI background check interface to enhance public safety and keep guns out of the hands of dangerous individuals."

"America faces constant tragic reminders of how devastating gun violence can be. We need to do everything we can to keep guns out of the wrong hands, including making sure no one can purchase a gun without a background check," said Senator Whitehouse, who serves on the Senate Judiciary Committee. "This commonsense measure to finally close a background check loophole is long overdue and will help save lives."

The Background Check Completion Act would require a completed background check for every gun buyer who purchases a gun from a federally-licensed gun dealer.

The legislation has been endorsed by Everytown for Gun Safety, Giffords, Brady, Sandy Hook Promise and Newtown Action Alliance. ❖

LETTER TO THE EDITOR

United effort by physicians is part of strategy to address shootings

Gun violence to school-children incidence has increased over the last few decades. Whatever Americans have done so far to curb this terrible trend has not worked too well; we need a different approach. So, now is the time for action, not just nice words.

Open dialogue is one way hopefully to start combating this problem. Voice your opinions federal and state legislators. Talk to your governor, mayor, and city government people. Doctors are respected and thus have the power to speak and be heard. Facilitate discussions at local groups, at political sessions, and maybe with a letter to the newspaper. This topic is appropriate for a medical meeting agenda discussion, perhaps with a noted speaker. Maybe write about this topic to professional journals. Seek impact wherever you are comfortable. More united effort by physicians might diminish shootings and help us all, especially our kids.

Steven Lippmann, MD
Emeritus Professor
University of Louisville School of Medicine
Louisville, Kentucky

Reported use of most drugs remains low among US teens

BETHESDA, MD — For the fifth year in a row, use of most substances among teenagers in the United States has continued to hover around the low-water mark reached in 2021. The findings come from the latest report of the Monitoring the Future Survey, an annual survey of drug use behaviors and attitudes among eighth, 10th, and 12th graders that has been supported by the National Institutes of Health (NIH) for 51 years.

Researchers, based at the University of Michigan, Ann Arbor, detected a sharp decline in reported use of most drugs from 2020 to 2021. This substantial falloff was largely attributed to disruptions in drug availability and in the social lives of teens during the pandemic, when many were isolated at home with parents or other caregivers and spending less time with friends. The researchers also found that the percentage of teens currently abstaining from alcohol, tobacco, and nicotine use held steady at historically high levels.

"We are encouraged that adolescent drug use remains relatively low and that so many teens choose not to use drugs at all," said **NORA D. VOLKOW, MD**, director of NIH's National Institute on Drug Abuse (NIDA). "It is critical to continue to monitor these trends closely to understand how we can continue to support teens in making healthy choices and target interventions where and when they are needed."

For the survey, eighth, 10th, and 12th graders self-report their substance-use behaviors over various time periods, including past 30 days, past 12 months, and their lifetime. The survey also documents students' perceptions of harm, disapproval of use, and perceived availability of drugs.

The data indicates that, compared to 2024, reported use of most drugs in most grades held steady in 2025. These are some of the key findings:

- Abstaining from, or not using, marijuana, alcohol, and nicotine remained stable for all grades, with 91% of eighth graders 82% of 10th graders, and 66% of 12th graders reporting abstaining in the past 30 days.
- Alcohol use remained stable among all three grade levels, with 11% of eighth graders, 24% of 10th graders, and 41% of 12th graders reporting use in the past 12 months.
- Cannabis use remained stable among all grades, with 8% of eighth graders, 16% of 10th graders, and 26% of 12th graders reporting use in the past 12 months. Of note, 2% of 8th graders, 6% of 10th graders, and 9% of 12th graders reported use of cannabis products made from hemp, which include intoxicating products such as delta-8-tetrahydrocannabinol, in the past 12 months.
- Nicotine vaping remained stable among all grades, with 9% of eighth graders, 14% of 10th graders, and 20% of 12th graders reporting use in the past 12 months.
- Nicotine pouch use remained stable among all grades, with 1% of eighth graders, 3% of 10th graders, and 7% of 12th graders reporting use in the past 12 months.
- Heroin use among all three grades remains low, though values increased significantly from 2024, with 0.5% of eighth graders (compared to 0.2% in 2024), 0.5% of 10th graders (compared to 0.1% in 2024), and 0.9% of 12th graders (compared to 0.2% in 2024) reporting use in the past 12 months.
- Cocaine use also remained low and stable for 10th graders, with 0.7% reporting use in the past 12 months; though values increased significantly among the other grades surveyed, with 0.6% of eighth graders (compared to 0.2% in 2024) and 1.4% of 12th graders (compared to 0.9% in 2024) reporting use in the past 12 months.

"The slight but significant increase we see in heroin and cocaine use warrants close monitoring. However, to put these current levels of use in context, they are leagues below what they were decades ago," said **RICHARD A. MIECH, PhD**, team lead of the Monitoring the Future survey at the University of Michigan.

The results were gathered from a nationally representative sample, and the data were statistically weighted to provide national numbers. The investigators collected 23,726 surveys from students enrolled across 270 public and private schools nationwide from February through June 2025. Students took the in-school survey via the web—either on tablets or on a computer.

The 2025 survey results are available online from the University of Michigan. ❖

Appointments

Brown University Health names Corey Ventetuolo, MD, Director, Pulmonary, Critical Care and Sleep Medicine

PROVIDENCE — Brown University Health has appointed **COREY VENTETUOLO, MD, MS, ATSF, FAHA**, to serve as Director of the Division of Pulmonary, Critical Care and Sleep Medicine at Brown University Health and the Warren Alpert Medical School of Brown University after a national search.

Dr. Ventetuolo leads a research program dedicated to advancing care for patients with pulmonary hypertension and right heart failure. Her groundbreaking studies on sexual dimorphism in pulmonary vascular disease introduced hormonal modulation as a therapeutic strategy and were supported by NHLBI-funded clinical trials. She and her collaborators developed a first-in-field pulmonary artery cell biopsy technique using routine right heart catheter balloons, enabling point-of-care endotyping and precision medicine approaches.

She is nationally recognized for her work in the area, serving as Chair of the Pulmonary Circulation Assembly for the American Thoracic Society and holds leadership positions with the American Heart Association and the Pulmonary Hypertension Association. Her work has been continuously funded by the NIH and the American Heart Association since fellowship, with more than 140 peer-reviewed publications in high-impact journals including The New England Journal of Medicine, Circulation, Lancet Respiratory Medicine, and The American Journal of Respiratory and Critical Care Medicine.

Most recently, Dr. Ventetuolo oversaw the creation of the Center for Advanced Lung Care (CALC) at Brown University Health, which opened its doors in August, 2024.

"A dedicated mentor and educator, Dr. Ventetuolo has been recognized with multiple teaching honors from the Warren Alpert Medical School and the Department of Medicine and has become a model for what can be achieved through strong academic–clinical partnership and aligned institutional vision. A deeply engaged clinician with RI roots, Dr. Ventetuolo is driven to enhance patient care through innovation, collaboration, and academic excellence," said **LOUIS RICE, MD**, Chief, Department of Medicine, Brown University Health and Chair, Department of Medicine, Warren Alpert Medical School of Brown University.

Dr. Ventetuolo completed her residency and chief residency at Brown University before pursuing fellowship training and an early faculty appointment at Columbia University, where she earned a master of science degree in patient-oriented research. ❖

Ashish Misri, MD, named Chief Medical Officer at Saint Anne's Hospital

FALL RIVER, MA — Saint Anne's Hospital has announced the appointment of **ASHISH MISRI, MD**, as Chief Medical Officer (CMO), effective January 4, 2026. Dr. Misri will lead all aspects of quality, safety, and clinical operations at Saint Anne's Hospital, providing strategic clinical leadership to support exceptional patient care.

In addition to being CMO for Saint Anne's Hospital, Dr. Misri will continue to serve as associate director of hospital medicine and as a practicing hospitalist at Rhode Island Hospital. His dual presence will strengthen clinical alignment and further enhance the delivery of coordinated high-quality care within the Brown University Health system.

Dr. Misri brings a proven track record of advancing quality, safety, and operational excellence. During his tenure at Rhode Island Hospital, he has played a central leadership role in initiatives that increased patient safety, improved experience, and elevated systemwide performance.

Dr. Misri earned his medical degree from St. Johns Medical College in Bangalore, India, and completed his internal medicine residency at The Warren Alpert Medical School of Brown University and Memorial Hospital. v

Appointments

Methodius G. Tuuli, MD, MPH, MBA, to serve as the Interim President of Women & Infants Hospital

PROVIDENCE — Care New England recently announced that **METHODIUS G. TUULI, MD, MPH, MBA**, will serve as the Interim President of Women & Infants Hospital. Dr. Tuuli will assume this role during a search for a successor for Shannon R. Sullivan, who has accepted a new opportunity as CEO of Connecticut Children's health system in Hartford, CT.

Dr. Tuuli is a familiar face at Women & Infants. He has served as Chief of Obstetrics and Gynecology at Women & Infants and Executive Chief of Obstetrics and Gynecology for Care New England Health System since 2021.

"Method is an exceptional leader, not just at Women & Infants, but in our community. He consistently demonstrates vision, integrity, and unwavering commitment to our patients and staff," said **MICHAEL WAGNER, MD**, President and CEO of Care New England. "By appointing him to this role, we know he will continue to guide our hospital into its next chapter of excellence."

Dr. Tuuli earned his medical degree from the University of Ghana Medical School in 2001. He attended the University of California at Berkeley, earning a Master of Public Health degree in 2003 with a concentration in maternal and child health. He completed residency training in Obstetrics & Gynecology at Emory University in 2008 and fellowship training in Maternal-Fetal Medicine at Washington University in 2011. Dr. Tuuli completed the Business of Medicine Physician MBA program at the Kelley School of Business at Indiana University in 2020.

A board-certified Maternal-Fetal Medicine physician, his research is focused on the prediction and prevention of adverse obstetric outcomes. He currently leads four NIH-funded multicenter trials on intravenous versus oral iron for the treatment of anemia in pregnancy in the U.S., the use of a novel intrauterine negative pressure device for the management of postpartum hemorrhage and optimizing glycemic control in overweight and obese patients with gestational diabetes, and testing a chatbot for prenatal genetic counseling.

In addition, he leads a Department of Health and Human Services Office of Minority Health grant integrating community-based maternal support services into perinatal care to address care coordination and social determinants of health to promote perinatal health equity. He has over 250 publications in high-impact journals, including the NEJM, JAMA, JAMA Pediatrics, and the Lancet.

In his role as Chief of Obstetrics & Gynecology at Women & Infants Hospital, Dr. Tuuli has been focused on improving quality and eliminating disparities in perinatal outcomes. He also leads the Department of Obstetrics and Gynecology at The Warren Alpert Medical School as the Chace-Joukowsky Professor and Chair. He was elected to the distinguished National Academy of Medicine in 2023. ❖

Care New England names Thomas Ricci Interim Chief Operating Officer of Women & Infants Hospital

PROVIDENCE — **THOMAS RICCI, MPA**, will be assuming the role of Interim Chief Operating Officer (COO) of Women & Infants Hospital, which became effective December 26th.

Currently Vice President of Finance, he has been with Women & Infants since 2017, serving first as Finance Manager, then being successively promoted to Finance Director and his current VP role.

Before joining Women & Infants, he held financial roles at CVS Health and Citizens Financial Group, and holds both a bachelor's and master's degree in accounting from Rhode Island College. ❖

Recognition

Advance RI-CTR recognizes Chathuraka Jayasuriya, PhD, with inaugural research excellence award

PROVIDENCE [BROWN UNIVERSITY] — Advance RI-CTR has recognized **CHATHURAKA JAYASURIYA, PhD**, with its inaugural Award for Clinical and Translational Research Excellence.

"Dr. Jayasuriya is the embodiment of what Advance RI-CTR was designed to achieve—taking an idea from the lab bench and accelerating it toward patient care," says **SHARON ROUNDS, MD**, program director of Advance RI-CTR. "His journey, which began with one of our earliest Pilot Project awards, validates a decade of strategic investment in Rhode Island's brightest minds."

"I'm really honored to receive it," Dr. Jayasuriya, an associate professor of orthopaedics, says of the $10,000 prize, which will support his efforts to develop a stem cell-based therapy for meniscus tears, a common knee injury. "I don't think we would be where we are without Advance RI-CTR," he adds.

Advance RI-CTR was formed in 2016 with a grant from the National Institute of General Medical Sciences. It provides resources and services to clinical and translational scientists at the University of Rhode Island, Care New England and Brown University Health hospitals, and the Providence VA Healthcare System, as well as Brown, where the group is based.

The goal of the current study, Jayasuriya says, is to obtain safety and efficacy data required by the FDA to greenlight clinical trials in human participants. But, with venture capitalists already showing interest in investing in the technology, he and his former postdoc, **JAY TRIVEDI, PhD**, now an assistant professor of orthopaedics (research) at Brown, cofounded a start-up, EnkaBio Inc., this fall. Just weeks later, they received a $35,000 grant from the Rhode Island Life Science Hub to build out the company.

None of this would have been possible, he adds, without that early boost from Advance RI-CTR. Dr. Jayasuriya notes that only with federal funding can researchers translate basic discoveries in the lab into therapies or technologies that improve patient care. ❖

Codac CEO Linda Hurley with Neighborhood CEO Peter Marino.

Neighborhood presents CODAC with ACAP Supporting the Safety Net Award Honorable Mention

PROVIDENCE — Neighborhood Health Plan of Rhode Island (Neighborhood) celebrated CODAC Behavioral Health Care for earning an Honorable Mention in the Association for Community Affiliated Plans' (ACAP) Supporting the Safety Net Award. Neighborhood, an ACAP member, nominated CODAC for an award for all its work removing barriers to care.

The Supporting the Safety Net award recognizes a community-based organization or individual whose work goes beyond the norm by developing and applying innovative practices to address the medical, behavioral, or social needs of high-risk populations in their service area. The services provided by award recipients are recognized as best practices that serve as models for replication within the safety net environment.

Neighborhood President and CEO **PETER MARINO** presented a plaque to CODAC President and CEO **LINDA HURLEY** at Neighborhood's Smithfield headquarters. "Neighborhood is fortunate to have CODAC as a partner," said Marino. "The organization and its staff set a high standard for health care delivery and serve as a model for others." He added, "The work the agency does to support behavioral health and medical needs is commendable."

When accepting the award at Neighborhood's headquarters, Hurley thanked the organization for its ongoing support of CODAC's mission.

"Recognition from health insurers and their national affiliated organizations goes a long way in reducing the stigma associated with opioid treatment and other behavioral health issues," Hurley said. "We are fortunate in Rhode Island to have a partner in Neighborhood that is equally committed to taking care of the most vulnerable individuals in our state."

"Neighborhood's track record of extraordinary achievement and success wouldn't be what it is without the partnerships they have nurtured with allied organizations in and around Rhode Island," said ACAP CEO **MARGARET A. MURRAY**. "We're delighted to recognize CODAC today for their efforts and for their support of Neighborhood." ❖

Places

Newport Hospital celebrates ribbon cutting for adolescent behavioral health unit

NEWPORT — Newport Hospital proudly celebrated its new **James P. Nolan, MD and Peggy Nolan Adolescent Behavioral Health Unit** with a ribbon-cutting event on December 15, 2025. This milestone marks the culmination of planning and fundraising to address the urgent need for youth mental health services in Newport County.

The eight-bed specialized unit, developed in partnership with Bradley Hospital, will provide short-term stabilization, assessment, and treatment for adolescents ages 12 to 18 experiencing serious mental health challenges. The unit will begin treating patients in the first quarter of 2026.

"This unit represents hope for families in our community," said **TENNY THOMAS, MD**, President and Chief Medical Officer of Newport Hospital. "We know the mental health crisis for this age group is real and urgent. With this dedicated space, we can now offer specialized care close to home, ensuring that young people receive the support they need during their most vulnerable moments."

Plans to create the unit were announced in the summer of 2023 to address the critical need for pediatric mental and behavioral health services in Rhode Island. Construction began earlier than anticipated thanks to the generosity of donors who contributed more than $5 million to make this project possible.

The James P. Nolan, MD and Peggy Nolan Adolescent Behavioral Health Unit is the first of its kind in Newport County, where there are no local acute care options for struggling youth and their families.

The unit features modern group therapy spaces, activity rooms, and an enclosed outdoor area. It is expected to serve more than 240 adolescents and their families annually. ❖

Now open in Newport: South County Health's Center for Women's Health comprehensive OB-GYN care

NEWPORT — South County Health recently announced the expansion of its award-winning Center for Women's Health into Newport. Conveniently located at 38 Powel Avenue, the new office extends South County Health's trusted women's health services to families across Aquidneck Island and surrounding communities.

At the Center for Women's Health – Newport, patients have access to the same expert, compassionate care that has earned South County Health statewide recognition for excellence in obstetrics and gynecology. Services include comprehensive OB-GYN care, prenatal and postpartum support, and wellness visits designed to meet women's needs at every stage of life.

"We're thrilled to bring our team's experience and support to Newport," said **MARTHA MOE, MD**, director of the Center for Women's Health. "Our goal is to make high-quality, personalized women's health care accessible to more families—close to where they live, work, and raise their children."

To further support parents-to-be, South County Health is also offering free childbirth education classes and events at the Newport YMCA. These classes are open to all expecting families and designed to build confidence, connection, and knowledge before delivery. ❖

Obituary

PHILIP R. B. McMASTER, MD, 95, of Providence, Rhode Island, passed away peacefully and surrounded by immediate family on December 11. A devoted husband and father, he was an insatiably curious scientist, medical researcher and psychiatrist, an inveterate sailor and an indefatigable painter.

Phil was born on February 19, 1930, in Cambridge, Massachusetts, and graduated from South Kent School, Princeton University and Johns Hopkins University School of Medicine. As an intern at New York Hospital, he met Elizabeth (Betsy) Wilkins, a social worker, and the two were married in 1958. Following Phil's training in immunology, he and Betsy lived for two wonderful years in Paris while he worked at the Pasteur Institute.

Returning to the United States, Phil pursued his passion for laboratory research for decades at the National Institutes of Health in Bethesda, Maryland, where he also completed a residency in clinical pathology, the Centers for Disease Control in Atlanta and Rhode Island Hospital/Brown University in Providence. Always eager to master new subjects, he later did another residency in psychiatry at Brown and spent the remainder of his career in practice at area clinics. Working with patients in these settings gave him great satisfaction and proved a perfect match for his scientific mind, quietly outgoing nature, and ability to see the world in unconventional ways.

Predeceased by his beloved wife Betsy, he is survived by his son Charley and his wife Debbie of Pepperell, Massachusetts; his son Joseph and his wife Gretchen Sinnett of Melrose, Massachusetts; and his grandchildren Caroline (Callie), Benjamin and Iain, his sister Gail Alling of York, Maine, and dozens of relatives.

A memorial service will be held at St. Martin's Church at 50 Orchard Avenue in Providence on February 21 at 11:00 am with a reception to follow in the Great Hall. In lieu of flowers, the family suggests contributions can be made to St. Martin's in Phil's memory. Condolences may be left at monahandrabblesherman.com. ❖