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On the cover: In patients with non-valvular atrial fibrillation (NVAF), most stroke-causing clots that come from the left atrium form in the left atrial appendage (LAA). The WATCHMAN implant device closes off the LAA, preventing blood clots from migrating out of it. See Drs. McCauley, Chu article in this issue.
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Malingering is often a difficult diagnosis to make. Like all neurologists, I see a significant percentage of patients with “functional” or non-physiological disorders. All clinicians do. In most cases it is clear that the patient is suffering and will often reject the notion that the problem is “all in my head,” and thus any hope of improvement, as doctor after doctor is consulted. Malingering is, of course, a different thing entirely. Malingers are consciously trying to fool the doctor, the health care system, the insurers, and whoever else needs to be fooled. The secondary gain for the conversion disorder patients, those who are unaware that their problem has an emotional basis, is often not identifiable, whereas the malingeringer always knows why he does what he does.

Many years ago a patient of mine was arrested for a robbery. Being not too bright, he had taken the purse off the arm of an old lady who knew him. On the day before he was to appear in court, he came to the office and had a convulsive fit, rolling on the floor for many minutes in the hope that I would diagnose epilepsy and get his appearance postponed for as long as possible. That did not happen.

Recently I saw a young man who claimed to be several years into a terrible, rare, inherited neurodegenerative disorder. I have some expertise in this disorder and it was very clear that he did not have it. The patient reported that he had seen several neurologists, and that a gene test confirmed the diagnosis. Unfortunately he could recall no doctors’ names or provide the gene test results. Unfortunately for him, there was only a single laboratory that did that gene test and it had no record that it was ever performed. Since this disease is a really terrible disorder, and the patient had a small child, who would have a 50% chance of having inherited the abnormal gene, and therefore a 50% chance of getting the disease, one might think the notion of raising hope that this all had been a bad dream, would be met with happy surprise. I could certainly understand a large degree of skepticism, if, in fact, several neurologists had confirmed the diagnosis. Why should I be correct and the others wrong? I could certainly understand that reaction, but, imagine, if you had an abnormal MRI and a doctor, or a few doctors, told you that you had a brain tumor and would die soon, and a presumed expert, who specialized in this problem, told you they were all wrong and that the problem was quite different and not life threatening, and possibly curable. One would think that this is a lot better than grasping at straws.

That was not the reception this information met. Anger, accusations of poor acumen and misplaced emphasis on psychiatric problems was how it was received. This later transformed into accusations of stated threats of removing disability, which had not, in fact, been discussed, although thought of immediately on my encountering the hostility of what should have been welcome news.

In diagnosing psychogenic disorders I generally don’t spend much time on figuring out secondary gain. In my experience, it is rarely a helpful pursuit. In older editions of the Diagnostic and Statistical Manual (DSM), the psychiatric manual for all diagnoses, a conversion disorder could only be diagnosed if the underlying psychiatric cause could be identified. That has been altered, as it was not helpful to non-psychiatrists and not always true. I have always shied away from making a diagnosis of malingering, as I thought that it usually reflected the doctor’s perception of the patient and not the actual clinical syndrome. If the doctor liked the patient it was a conversion disorder, and if the doctor did not like the patient, it was malingering.

In this case, as in many others with non-physiological neurological syndromes, the likelihood that this was a functional disorder was apparent as soon as I saw the patient stand up in
The waiting room. His odd manner of holding one arm, the ease of getting out of the chair and the idiosyncratic and irregular gait, suggested that things were not what they were billed as. The inconsistency of the movements as I took a history and then performed the neurological examination cemented the initial impression. In such cases, the history isn’t usually very important, although histories of unexplained memory lapses, peculiar spells and unexplained improvements add confirmatory support to the hypothesis. In this case, there were none of these, but the laboratory result that never existed was clearly a lie. It was not an exaggeration, a non-physiological occurrence. It was a knowingly told lie. Had he stated that he had been diagnosed based on clinical grounds, I would have easily accepted this as a mistake made by a well-intentioned but not very informed doctor, carried on by later doctors, to whom the clinical syndrome, quite rare, probably never seen by any of them before, made sense.

Diagnosing non-physiological disorders is often difficult, and studies have shown that experts often come to differing opinions about the same case. One must therefore be more humble than usual in making such a diagnosis. A diagnosis of malingering, however, is more than a diagnosis. It is an accusation. The “patient” is abusing the system for personal gain. It is, in fact, a crime. ✶

Author
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Providing non-emergency healthcare for undocumented immigrants raises issues

HERBERT RAKATANSKY, MD

There are at least 11.5 million undocumented immigrants (UI) currently in the US [about the same number as the total population of RI, CT, and MA]. Their health care is marginal, at best.

With three exceptions, these persons are barred from health coverage that utilizes federal funds. Medicaid will pay for true emergencies (criteria set by each state). But: “The potentially fatal consequence of discontinuing Medicaid coverage care even if such care is medically necessary, does not transform the condition into an emergency condition.” For example, chronic hemodialysis may not be covered, so some patients are treated for recurrent emergency crises every 7–10 days, a dangerous approach and expensive to boot.

Emergency care of UIs in RI is reimbursed by Medicaid only when it occurs in an in-patient setting or hospital emergency department. Active labor is deemed a medical emergency.

The law specifies that the treating physician must document that the medical condition meets the “definition of an emergency medical condition.” Doctors therefore, may be in a very uncomfortable position. Since the Medicaid coverage, once approved, can last 15 months there may be a conflict between the continuation of essential health care for one’s patient and denying payment for such care if the doctor declares the emergency to be over.

In some states, including RI, a pregnant woman may register her fetus [at any age] for care under the federal Children’s Health Care Program. This qualifies the mother for prenatal care, thus delivering care to the fetus. After birth the child is a citizen, but maternal care ceases 60 days after delivery. There are in excess of 500 such cases yearly in RI.

It is estimated that 8 million (70%) of the UIs have jobs, constituting 5% of the US labor force. These immigrants theoretically could get employer-based coverage but it is likely that most of them are working in the “cash business world.” To enter the standard job market they would need a social security number. It is a paradox that those immigrants who work using false social security numbers are paying taxes into a system from which they cannot benefit. From a strictly economic viewpoint, they are an asset to the health care system.

Doctors may not discriminate based on gender, race, ethnicity, sexual orientation and other factors, including immigrant status. Except for emergencies, however, doctors may choose to treat only those persons who can pay.

Patients may use false names because of fear [reality-based or not] of becoming known to “the authorities.” Interestingly, it is not against the law to use a name that is not one’s legal name. It is a crime, however, for the doctor to use a false name when billing a third party. Penalties for not identifying patients properly and not billing honestly can be severe, especially when federal or state funds are involved.

A patient using a false name may be at a medical disadvantage as well. Some medical records, including lab and imaging reports, might be under a different name and therefore not known to the treating doctor.

Doctors may not discriminate based on gender, race, ethnicity, sexual orientation and other factors, including immigrant status. Except for emergencies, however, doctors may choose to treat only those persons who can pay.
Even if doctors are willing to forgo payment for their services, modern diagnostics and therapeutics inevitably involve interventions that generally are not free.

The Supreme Court has affirmed that a state may require that persons stopped for any reason may be required to prove citizenship status. Such a statute (SB 1070) in Arizona has caused illegal immigrants to avoid medical care. They tend to not leave their immediate neighborhoods and they avoid health care facilities for fear that they might be “official.” There is documentation of fewer doctor visits. This happens despite current (this could change) regulations that designate medical care facilities as “safe zones.” Nutrition also suffers; the immigrants are afraid to visit markets outside their immediate neighborhood.

Lack of proficiency in English is widespread in the immigrant community and independently correlates with poor medical outcomes.

Our country has a long history of private philanthropy that includes medical care. Immigrants may utilize federally qualified community health clinics and “free clinics.” The RI Free Clinic (RIFC) provides continuous care to all RI residents who have no medical coverage and insufficient resources to access care. Since the RIFC does not bill anyone, UIs can be seen without legal consequences.

Immigrants in detention are another matter. The Immigration Control Enforcement (ICE) division is mandated to provide or pay for their medical care. In 2015 there were 26,500 persons in detention and 199,107 intake screenings, suggesting that about 13% of those detained are actually in detention at any time. There were 126,486 sick calls, 90,276 mental health interventions, 234,001 prescriptions filled and 19,483 emergency room or off-site referrals. Infectious diseases (HIV, TB, etc.) are treated and follow-up care is facilitated. Detainees are mostly held in “contract prisons” (e.g. Wyatt in Central Falls) where they are treated like convicted felons. The quality of medical care of prisoners is variable at best and there is no independent quality measure of ICE-provided care. Public advocacy groups (ACLU, etc.) and press reports have documented the poor quality of care provided by ICE.

Thus the current emphasis on increased deportation and detention adversely affects the health of those targeted in multiple ways. A small number of UIs are eligible for limited federally financed health care coverage (emergencies, prenatal care and in detention), but most UIs are outside the “system” and lack any care.

My conclusion: doctors, individually and collectively, should advocate for a national health care system in which we can fulfill our moral duty to care for all persons.

Author
Herbert Rakatansky, MD, FACP, FACG, is Clinical Professor of Medicine Emeritus, The Warren Alpert Medical School of Brown University.

Addendum
Subsequent to writing this article, the Trump administration rescinded federal health care standards for detained immigrants and now allows prisons to set their own standards.
Finally, some good news about insurance for medical professionals

We have partnered with the Rhode Island Medical Society to offer an exclusive Concierge Program designed specifically for medical professionals to save on their personal and business insurance.

Contact Robert A. Anderson, AAI at 401.272.1050 – randerson@rimsibc.com
SMITHFIELD, RHODE ISLAND
Nitin S. Damle, MD, MACP, takes a moment to check the Rhode Island Medical Journal while waiting for the academic procession to begin at Bryant University on March 25. Dr. Damle delivered the keynote address and received an honorary doctorate of humane letters as part of the inaugural commencement ceremonies of Bryant University’s Physician Assistant Program. The University awarded Master of Physician Assistant Studies degrees to 29 graduates that day, pictured below. Dr. Damle is the immediate past president of the American College of Physicians, managing partner of South County Internal Medicine in Wakefield, and a past president of the Rhode Island Medical Society.
We are read everywhere

MANAUS, BRAZIL
Dr. Tania Sanaiotti, (right) pesquisador, or research scientist, with Brazil’s Instituto Nacional de Pesquisas da Amazonia, and her niece, Tais Mauk, RISD grad and designer with Samsung in Mountain View, California, accessed the RIMJ archives from a 150-foot high observation platform overlooking the rain forest canopy in the Reserva Florestal Aldolpho Ducke, on the shore of the Amazon River (below.)

Wherever your travels take you, be sure to check the latest edition of RIMJ on your mobile device and send us a photo: mkorr@rimed.org.
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The Evolving Landscape of Thromboembolic Disease: Diagnostic and Management Strategies
KENNETH S. KORR, MD, FACC
GUEST EDITOR

This issue of the Rhode Island Medical Journal focuses on the broad topic of thromboembolic disease, its many and varied clinical presentations, their incidence, symptoms, diagnostic evaluation and, most importantly, their unique management and treatment strategies.

DRS. P. RILEY, A. MAAN and K.S. KORR open with an update on the current status of the Direct-Acting Oral Anticoagulants (DOACs), formerly referred to as new, novel or Non-Vitamin K oral anticoagulants (NOACs). In the brief span of 8 years since their approval, the DOACs are now prescribed more frequently than warfarin both in Europe and North America¹ and are expected to ultimately supplant warfarin due to their relative safety, improved efficacy and ease of use. Moving beyond the initial Randomized Control Trials (RCT) which established the DOACs as non-inferior to warfarin for the prevention of thromboembolism in patients with atrial fibrillation and deep-vein thrombosis, ongoing registry data and real-world experience continue to refine the role of these agents in distinct patient subsets, including those with chronic renal insufficiency, congestive heart failure, distinct ethnic groups and in the elderly.

DRS. B. MCCAULEY and A. CHU discuss the thromboembolic risks of atrial fibrillation, the role of the Left Atrial Appendage (LAA) and an overview of LAA closure devices and techniques as an alternative to anticoagulant therapy for the subset of patients with atrial fibrillation in whom oral anticoagulation is contra-indicated or high risk.

DRS. W. PRABHU and P. SOUKAS provide an update on the risk stratification and management strategies for patients with Pulmonary Embolism (PE) and the emerging role of multi-disciplinary pulmonary embolism response teams (PERT) for optimizing treatment opportunities in patients with intermediate and high-risk PE.

DRS. A. NOYES and J. DICKEY discuss the rising incidence and morbidity of Upper Extremity Deep-Vein Thrombosis (UEDVT) with the increasing prevalence of central venous catheters, PICCs, Ports, and implantable cardiac rhythm devices.

Finally, DRS. O. HYDER and P. SOUKAS present an overview of chronic venous insufficiency, venous ulcers, compression therapy and the role of endovenous ablation and other therapies.

These articles reflect the current state of medical practice in a rapidly changing therapeutic landscape which continues to evolve with the acquisition of real-world data and technologic advancements.


Guest Editor
Kenneth S. Korr, MD, FACC, is Associate Professor of Medicine Emeritus, The Alpert Medical School of Brown University.
Direct Oral Anticoagulants (DOACs): Current Status Among Distinct Patient Subgroups

PETER RILEY, MD; ABHISHEK MAAN, MD; KENNETH S. KORR, MD, FACC

ABSTRACT
The landscape of anticoagulant therapy for atrial fibrillation and deep-vein thrombosis has evolved considerably in the last decade with the advent of Novel or Direct-Acting Oral Anticoagulants (DOACs). The initial phase III randomized controlled trials established the individual DOACs as viable alternatives to warfarin for thromboprophylaxis but generalizations to the larger population were limited by the small number of protocol subjects with renal insufficiency, congestive heart failure, advanced age and other comorbidities. All the DOACs have some degree of renal excretion and while safe and effective in patients with mild to moderate renal insufficiency, dose adjustment is necessary based on creatinine clearance. Subsequent data registries and real-world experience with DOACs have continued to refine their role in these particular patient subgroups. Off-label use with both under- and overdosing is not uncommon in renal failure and carries increased risk. Their increasing use among the elderly, in patients with heart failure, hepatic and renal insufficiency and among the Asian population has been shown to be relatively safe and effective compared to warfarin. Gaps in our current understanding of this new class of anticoagulants will continue to narrow as additional data becomes available through ongoing registries and real-world experience.

KEYWORDS: DOACs, NOACs, thromboprophylaxis

INTRODUCTION
For almost six decades following its discovery and commercialization in the 1950s, warfarin has been the mainstay of anticoagulant therapy for the prevention of thromboembolic phenomena. Starting in 2009, a new group of potent oral anticoagulants called DOACs [Direct Oral Anti-Coagulants] or NOACs [Non-vitamin K antagonist Oral Anti-Coagulants née Novel Oral Anti-Coagulants] were approved as alternatives to warfarin. Warfarin’s anticoagulant effect is indirect; inhibition of Vitamin K oxide reductase results in decreased levels of pro-coagulant clotting factors in the direct, indirect, and common pathways. By contrast, the DOACs all act on the “Final Common Pathway” of the coagulation cascade. Since FDA approval,[1-8] prescribing has rapidly expanded as DOACs replace warfarin, occasionally beyond approved indications. Growing evidence from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation II (ORBIT-AF II) suggests that off-label use carries increased risk.[6] Current guidelines are limited by the paucity of real-world data with DOACs, and providers often fill gaps in trial data with therapeutic strategies derived from years of experience with warfarin. While meta-analysis of large randomized controlled trial data has shown consistently favorable results with DOACs, it must be applied with caution given the limited real-world data available.[6, 7]

DOACS IN RENAL IMPAIRMENT
Chronic Kidney Disease (CKD) is a frequent comorbidity in patients requiring anticoagulation.[8,9] CKD may potentiate renally cleared pharmaceuticals without appropriate dose adjustment, and all current DOACs undergo some renal excretion [See Table 1].[4,10-12] Concern about worsening renal function, lack of readily available anticoagulation reversal agents, and limited real-world experience with DOACs may lead to premature dose-reduction and inadequate thromboprophylaxis. Recent studies of real-world prescription practice suggest significant rates of under-dosing [10%] or over-dosing [3%].[6] Current safety data and renal dosing guidelines were derived from large RCTs that excluded patients with creatinine clearance (CrCl) of <25 mL/min or hemodialysis.[3,13,14] Recently, two large meta-analyses of data from patients with mild-moderate stable CKD suggested that all DOACS may provide a modest reduction of systemic embolization, stroke, and bleeding compared to warfarin, and furthermore, apixaban and edoxaban have significantly lower rates of major bleeding than dabigatran or rivaroxaban.[1-4,15,16] Anticoagulant use in subjects with declining renal function was evaluated in a sub-group of 3,000 patients in the ROCKET-AF trial who had a 20% reduction in CrCl from baseline. In this population, the risk of vascular death was significantly higher than in patients with stable renal function, and rivaroxaban significantly decreased embolization without increasing rates of major bleeding as compared to warfarin.[3,13]

Patients with end-stage renal disease (ESRD) were excluded from the Phase III trials for all current DOACs.[14] Apixaban was approved in ESRD-based on pharmacokinetic data;
but no RCT data exists to evaluate its safety, and all other DOACs are contraindicated in ESRD.[17, 18] Despite this, rivaroxaban and dabigatran were prescribed for 6% of patients in a large hemodialysis database, frequently without dose reduction. This was associated with increased rates of bleeding requiring hospitalization and fatal bleeding compared to warfarin.[14] Current guidelines recommend warfarin as first-line for thromboprophylaxis in ESRD patients; if warfarin is contraindicated, apixaban may be an acceptable alternative. Of note, edoxaban is contraindicated in patients with Cr Cl>95mL/min due to ineffective thromboprophylaxis.

Current DOAC maintenance dosing guidelines for thromboprophylaxis are summarized in Table 1. The maintenance dose for most DOACs is reduced in renal insufficiency to mitigate the effects of reduced excretion and half-life prolongation. Prolonged half-life requires earlier discontinuation of DOACs prior to procedures and current recommendations suggest discontinuation of DOACs 2–3 days prior to surgery and other invasive procedures.

<table>
<thead>
<tr>
<th>CONTRA-INDICATIONS</th>
<th>DARIGATRAN</th>
<th>RIVAROXBAN</th>
<th>APIXABAN</th>
<th>ENDOXABAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>eGFR &lt;30 ml/min AND use of pGP inhibitor, ESRD-HD, CTP Class C</td>
<td>eGFR &lt;15 ml/min, ESRD-HD, CTP Class B, C</td>
<td>eGFR &lt;15 ml/min, CTP Class C</td>
<td>eGFR &gt;95 ml/min, eGFR&lt; 15 ml/min, ESRD-HD, CTP Class B,C</td>
<td></td>
</tr>
<tr>
<td>Cleared by Hemodialysis?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Minimally</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HALF-LIFE (HOURS) BASED ON RENAL FUNCTION</th>
<th>DARIGATRAN</th>
<th>RIVAROXBAN</th>
<th>APIXABAN</th>
<th>ENDOXABAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>CrCl &gt; 80mL/min</td>
<td>14-17</td>
<td>5-9</td>
<td>8-15</td>
<td>9-11</td>
</tr>
<tr>
<td>CrCl 50-79 mL/min</td>
<td>16.6 (12-18)</td>
<td>8.7</td>
<td>14.6</td>
<td>No data</td>
</tr>
<tr>
<td>CrCl 30-49 mL/min</td>
<td>18.7 (18-24)</td>
<td>9</td>
<td>17.6</td>
<td>No data</td>
</tr>
<tr>
<td>CrCl &lt;30 mL/min</td>
<td>27.5</td>
<td>9.5</td>
<td>17.3</td>
<td>No data</td>
</tr>
<tr>
<td>When to discontinue before surgery:</td>
<td>2-3 days; if CrCl &lt;50 mL/ min 2-4 days</td>
<td>2-3 days</td>
<td>2-3 days</td>
<td>2-3 days</td>
</tr>
</tbody>
</table>

**Table 1. Dosing Guidelines for DOACs**

**DOACS IN HEPATIC IMPAIRMENT**

Hepatic impairment and cirrhosis impose unique challenges in patients requiring anticoagulation. Standard laboratory assays for anticoagulant monitoring are rendered unreliable by altered production of pro- and anticoagulant factors, and variation in metabolic kinetics can lead to unpredictable serum drug levels.[20,21] DOACs are attractive candidates for patients with liver disease who require anticoagulation due to their independence from laboratory monitoring and lack of pro-coagulant effect seen with initiation of warfarin.[21-23] Initial DOAC phase III trials excluded chronic liver disease. Current use is guided by small trials and pharmacokinetic studies suggesting apixaban and dabigatran may be used in CTP class A or B, and rivaroxaban in CTP class A. All DOACs are contraindicated in patients with CTP Class C.[20,24] Small retrospective studies of anticoagulants in moderate hepatic impairment have shown DOACs to have non-inferior rates of embolization and reduced rates of bleeding compared to warfarin,[22,24] and surveillance data on DOAC

**eGFR – estimated glomerular filtration rate;**

**CrCl – creatinine clearance;**

**ESRD-HD end-stage renal disease- hemodialysis; bid-twice daily;**

**pGP- p Glycoprotein inhibitor (ketoconazole oral or dronedarone);**

**CTP- Child-Turcotte-Pugh Hepatic Impairment Class**
use for splanchnic vein thrombosis found no significant difference in adverse event rates in cirrhotic versus non-cirrhotic patients. Of note, early concerns of DOAC-induced hepatitis were evaluated in large prospective studies, which found that compared to warfarin, dabigatran, apixaban, or rivaroxaban did not increase risk of liver injury and dabigatran carried the lowest risk.

DOACS IN CONGESTIVE HEART FAILURE

Congestive heart failure (CHF) is a common comorbidity in the atrial fibrillation population, and significantly increases the risk of stroke in these patients. There is evidence that CHF constitutes a pro-thrombotic syndrome with low-flow states, biomarker evidence of endothelial dysfunction, and elevated pro-thrombotic biomarkers. Risk of thrombosis appears to increase correspondingly with clinical and echocardiographic worsening of CHF and can contribute to the development of left ventricular thrombi. Anticoagulation with warfarin has been traditionally used to treat apical thrombi, as well as cardiac structural abnormalities including noncompaction cardiomyopathy. The phase III trials evaluating DOACs in nonvalvular AF included many patients with CHF. Pooled analysis of data from CHF patients in these trials showed a significant reduction in intra-cranial hemorrhage (ICH) and major bleeding events with dabigatran and apixaban as compared to warfarin. Edoxaban was not included as detailed subgroup data from the ENGAGE-AF trial was not available. These findings may be driven by low time in therapeutic range for warfarin in CHF patients. There is evidence that CHF predisposes patients on warfarin to low time in therapeutic range as compared to other comorbidities, and CHF has been associated with higher rates of bleeding in subgroup analyses from large trials of AF patients. Together, these results suggest that DOACs are at least as efficacious as warfarin for thromboembolism in patients with nonvalvular AF and CHF, and may confer a reduction in bleeding as compared to warfarin.

There are no large RCT data available to guide the use of DOACs in treatment of left ventricular thrombi or in cardiomyopathies conferring additional thromboembolic risk; and current evidence is limited to case reports of ventricular thrombi treated successfully with apixaban or rivaroxaban. The pathophysiology conferring additional stroke risk in these conditions is mechanistically similar to that of atrial fibrillation and heart failure. There may be a similar role for DOACs in this patient population, however, further study is needed.

The role of prophylactic anticoagulation in CHF patients in sinus rhythm without known thrombus has been extensively studied in large trials. Data from these studies demonstrated a reduction in thromboembolic events with prophylactic anticoagulation with warfarin; however, no survival benefit was seen due to a concomitant increase in bleeding risk. Current guidelines do not recommend prophylactic anticoagulation in patients with heart failure without another primary indication. Emerging evidence supports an advantageous bleeding profile of DOACs as compared to warfarin in the CHF population, and CHF as a primary indication for anticoagulation is undergoing re-evaluation in the COMMANDER-HF trial designed to evaluate the efficacy and safety of rivaroxaban in reducing death, MI, or stroke in CHF patients with CAD.

DOACS IN THE ASIAN AND AFRICAN-AMERICAN POPULATIONS

There is growing evidence that optimal management of atrial fibrillation may differ in the Asian patient population compared to Western patients. Data from large global registries indicates that the incidence and mortality of stroke, especially hemorrhagic, is significantly greater in Asian countries as compared to the West, and is highest in patients of Japanese ancestry. The mechanisms behind this difference are unclear, but differential risk has been shown repeatedly in large international studies, including the phase III trials for dabigatran, apixaban and rivaroxaban. Subgroup analyses found that a composite clinical outcome of stroke, systemic embolism, pulmonary embolism, myocardial infarction, death, or major bleeding occurs at significantly higher rates in Asian patients on warfarin as compared to non-Asian patients, raising the question of whether anticoagulation with warfarin has a reduced net clinical benefit in the Asian population. Prescription practice analysis of large international registries suggests that warfarin is prescribed in Asian countries at approximately half the rate of Western countries, and antiplatelet therapy alone is more common for stroke prevention. Meta-analysis of the phase III RCTs for DOACs has demonstrated similar efficacy of embolic prevention in Asian patients treated with DOACs compared to warfarin, but with an overall mortality benefit largely driven by reduced rates of hemorrhagic stroke. Furthermore, a recent retrospective cohort study of Taiwanese patients anticoagulated with dabigatran, apixaban or rivaroxaban, or warfarin found a significant reduction in rates of embolism, ICH, and all-cause mortality in patients anticoagulated with a DOAC compared to warfarin.

African-Americans have a lower incidence of AF compared to Caucasians but a higher risk of stroke. This may be related to a higher prevalence of other stroke risk factors and limited access to health care among AAs. Warfarin is utilized less frequently among AAs who have a lower time in the therapeutic range and require higher warfarin dosage to maintain therapeutic INRs. Racial subgroups were under-represented in Phase III RCTs of DOACs and limited subgroup analyses have been published. However, the DOACs compared to warfarin were similar for outcomes of stroke, systemic embolization and bleeding and may be preferable agents in the AA population.
DOACS IN THE GERIATRIC POPULATION

Advanced age increases risk of stroke and also increases risk of ICH due to increased fragility of cerebral bridging veins, increased frailty and falls. Thus, the risk/benefit ratio of anticoagulation for thromboprophylaxis is less clear in the elderly population. Sub-group analysis of patients over age 75 in the Phase III RCTs suggested that DOACs were non-inferior to warfarin for thromboembolism prophylaxis. Rivaroxaban carried equivalent hemorrhagic risk compared to warfarin, and dabigatran, apixaban, and edoxaban were all found to have lower risk of ICH or major bleeding, despite an increased risk of GI bleed with dabigatran. \[59,60\] Emerging evidence from subsequent RCTs and real-world practice observational studies supports these findings. A sub-group analysis of approximately 2,000 patients over age 75 from a trial comparing aspirin to apixaban found significantly improved thromboprophylaxis with apixaban, without significant difference in bleeding rates.\[61\] A cohort study drawn from Medicare data of 118,000 patients over age 65, on dabigatran or rivaroxaban found that rivaroxaban usage had higher rates of ICH and major bleeding compared to dabigatran; however, renal function data was not available and dose-reduced regimens were not studied.\[62\]

CONCLUSIONS

The landscape of anticoagulation has evolved considerably in the last decade. The initial phase III RCTs established the DOACs as viable alternatives to warfarin. Subsequent data registries and real-world experience have shed light on potential differences in outcomes in certain subpopulations. In patients with renal impairment, there is mounting evidence that DOACs are safe, and may reduce ischemia and major bleeding in patients with stable mild-moderate CKD as compared to warfarin. Apixaban undergoes the least renal excretion of DOACs and may have lower bleeding risks than other DOACs in CKD. There is also limited evidence that apixaban may be useful in ESRD when warfarin is specifically contraindicated, while edoxaban, rivaroxaban, and dabigatran are contraindicated in ESRD, and may increase bleeding risk as compared to warfarin in this population. Current guidance for the use of DOACs in patients with hepatic impairment is driven by pharmacokinetic data and small studies suggesting that most DOACs are safe in mild-moderate hepatic impairment, though rivaroxaban should not be used in Class B impairment and all DOACs are contra-indicated in CTP Class C.

In patients with CHF, meta-analysis of pooled RCT data demonstrates that apixaban, dabigatran, and rivaroxaban are non-inferior to warfarin for thromboprophylaxis and may carry reduced risk of bleeding, therefore DOACs may be preferable first-line agents. Current guidelines do not recommend prophylactic anticoagulation for patients with heart failure; however, this concept is undergoing re-evaluation in the COMMANDER-HF trial. The Asian population is known to have elevated rates of stroke and hemorrhage with warfarin thromboprophylaxis and a growing body of evidence suggests that use of DOACs in place of warfarin carries reduced rates of hemorrhage and overall clinical benefit in this subgroup. Among the elderly, DOACs are non-inferior to warfarin for thromboprophylaxis, and dabigatran, apixaban, and edoxaban may confer reduced rates of major bleeding and ICH. Emerging evidence suggests rivaroxaban may carry a higher bleeding risk. However, until robust real-world outcomes data is available, caution must be exercised in extrapolating from RCTs, as even now available registry data suggests inappropriate dosing occurs at not-insignificant rates and is associated with adverse outcomes. Still, this emerging signal suggests an opportunity to improve outcomes in certain subpopulations and the picture will undoubtedly become clearer as data from ongoing registries and newer trials fill gaps in our knowledge.

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Minimally Invasive Closure of the Left Atrial Appendage: A Non-Pharmacologic Approach to Prevention of Stroke in Patients with Atrial Fibrillation

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ABSTRACT
Atrial Fibrillation’s (AF) role in the pathogenesis of thromboembolic stroke has been well established, with estimates from trials of approximately 15-20% of all strokes in the U.S. Research shows more than 90% of atrial thrombi originate from the left atrial appendage (LAA). Traditionally, oral anticoagulants (OACs) have been the keystone of management for AF in reducing the risk of thromboembolic stroke. However, OACs also pose a non-negligible risk of bleeding with between 30-50% of eligible patients not receiving OACs due to absolute contraindications or perceived increased bleeding risk. New technologies aimed at isolating the LAA through ligation, exclusion, or occlusion are attempting to mitigate the embolic risk posed by LAA thrombi while simultaneously reducing the bleeding risk associated with OAC. In this review, we discuss the safety, efficacy, and clinical utility of these technologies as alternatives to OACs.

KEYWORDS: Atrial fibrillation, Lariat, Left atrial appendage closure, stroke, Watchman

INTRODUCTION
Atrial Fibrillation’s (AF) role in the pathogenesis of thromboembolic stroke has been well established. Currently, in the United States, stroke ranks as the fifth leading cause of death. There are approximately 795,000 strokes annually with one occurring every 40 seconds [1]. Estimates from numerous trials, including the local Framingham trial, attribute approximately 15-20% of all strokes to AF [2-3]. The mere presence of AF carries with it a five-fold increased risk for embolic stroke [4]. Research has shown that more than 90% of atrial thrombi originate from the left atrial appendage (LAA). Strokes originating from the LAA tend to be more severe with a 70% chance of death or permanent disability [5]. Traditionally, oral anticoagulants (OACs) have been the keystone of management for AF and embolic strokes, with relative overall success. In fact, a meta-analysis in 2014, showed a 64% embolic stroke reduction with a 26% mortality reduction with OAC use [6,7]. While OACs have demonstrated an ability to reduce embolic stroke, they also are associated with a non-negligible risk of bleeding. Unfortunately, between 30-50% of eligible patients do not receive OACs due to absolute contraindications or perceived increased bleeding risk [8]. Bleeding risk takes several forms, from increased risk of spontaneous intraparenchymal hemorrhage to the complications of surgical procedures. Hence, current clinical guidelines for OAC balance the risk of stroke using risk assessment tools such as the CHA2DS2-VASc score against the patient’s native bleeding risk via HAS-BLED score. New technologies aimed at isolating the LAA through ligation, exclusion, or occlusion are attempting to mitigate the embolic risk posed by LAA thrombi while simultaneously reducing the bleeding risk associated with OAC. As with most percutaneous procedures in modern cardiology, these LAA occluder technologies have evolved from cardiothoracic surgical techniques traditionally used to isolate the LAA from the systemic circulation.

DEVICES FOR CLOSURE OF THE LAA
Broadly the devices used for closure of the LAA can be classified into two primary categories, epicardial and endocardial. The epicardial devices include the LARIAT suture delivery device (SentreHEART, Palo Alto, CA, USA) and the BELIEF trial. The LARIAT physically isolates the LAA by ligation, exclusion, or occlusion while attempting to mitigate the embolic risk posed by LAA thrombi while simultaneously reducing the bleeding risk associated with OAC. In this review, we discuss the safety, efficacy, and clinical utility of these technologies as alternatives to OACs.
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Therapy for the Prevention of Stroke in Patients with Atrial Fibrillation (PROTECT-AF) trial was a large, non-blinded, randomized trial utilizing the Watchman device in a non-inferiority comparison to standard warfarin therapy [11]. It was a multi-center, open-label trial involving 707 patients with non-valvular AF randomly assigned in a 2:1 ratio to either Watchman implantation or long-term warfarin (INR 2.0–3.0). Patients in the device group were given warfarin for 45 days to facilitate device endothelialization, a timeline chosen from canine experience. After 45 days, warfarin was discontinued and a follow-up transesophageal echocardiogram (TEE) showed either an acceptable residual per-device flow with a jet <5mm or complete LAAO. After discontinuation of warfarin, clopidogrel and aspirin were given for 6 months, followed by aspirin alone. The control arm received warfarin with a target INR between 2.0–3.0, which was only accomplished two-thirds of the time despite close INR monitoring. Implant success rate was 91%. Primary outcomes of stroke, systemic embolism, and cardiovascular death were measured at 18 months and the event rate was similar in both arms (3.0 vs. 4.9 events per 100 patient-years). The PROTECT-AF study successfully demonstrated non-inferiority of the Watchman device compared to standard warfarin therapy. Subsequently, several subset analyses were conducted, and while being constrained by the limitations inherent to subset analysis, some notable findings were discovered. One analysis of the PROTECT-AF trial assessed quality-of-life parameters in a subset of 547 patients [361 device and 186 control] [12]. This demonstrated that patients with AF at risk for stroke who underwent LAAO had favorable quality-of-life changes at 12 months compared to patient treated with warfarin. At face value this makes sense, warfarin patients require frequent blood-test monitoring, which places a burden on a patient’s time. A post-hoc analysis of the PROTECT-AF and its long-term monitoring registry, the Continuous Access Protocol, assessed the net clinical benefit (NCB) of LAAO. They looked for rates of thromboembolism, intracranial hemorrhage, major adverse events, and death while objectively comparing Watchman implantation to warfarin. This study showed that the NCB of LAAO was highest for those at highest risk for stroke, but also reported that this benefit increased over time. As with most device trials, the NCB favored the control arm in the initial 6-month period; however, by 6–9 months, the NCB changed favorably toward the intervention arm. In the early phase, those receiving the device had procedural-related complications to deal with such as cardiac tamponade or procedure-related stroke. Additionally, this study showed that operator experience might have some bearing on the procedural complication rate.

The ASA Plavix Feasibility Study with Watchman Left Atrial Appendage Closure Technology (ASAP) Registry demonstrated that all-cause stroke and systemic embolization risk was 2.3% per year. Also, the observed ischemic stroke rate was 77% lower than expected by the CHA2DS2-VASc predictive model [13]. In 2014, the long-term follow-up data from the PROTECT-AF trial were published [14]. With a mean follow-up of 3.8 years, the primary efficacy rate (combined end-point consisting of strokes, cardiovascular death or unexplained death, and systemic embolism) was lower in the Watchman group (2.3%) than in the control arm (3.8%), reflecting a 40% relative risk (RR) reduction, and a 96% probability of superiority. In 2016, the results from the Registry on WATCHMAN Outcomes in Real-Life Utilization (EWOLUTION) were released. In this large, prospective, multicenter registry a total of 1025 subjects from 47 centers in 13 countries were enrolled. Interestingly, their CHA2DS2-VASc risk scores were 4.5 +/- 1.6 with almost half the subjects having either a history of TIA (10.7%), ischemic stroke (19.7%), or hemorrhagic stroke (15.0%), classifying this population as high-risk. Additionally, 62% of patients were deemed unsuitable for OAC by their physician based...
on factors such as inability to adhere to OAC use, bleeding history, or high risk for bleeding as dictated by their elevated HAS-BLED score. The EWOLUTION (15) registry demonstrated high procedural success rate (98.5%) with a low 7-day serious adverse event rate (2.8%). An interesting feature of this trial was the inclusion of patients who would have been OAC candidates, in contrast to the PROTECT-AF and PREVAIL trials in the U.S., which restricted enrollment to patients deemed unsuitable for OAC administration. The flexibility regarding enrolling individuals who are OAC candidates was made possible by current European Society of Cardiology (ESC) guidelines for AF. Under current ESC guidelines, LAAO is given a Class IIb, Level of Evidence B recommendation (8).

PERCUTANEOUS LAA LIGATION AND LAA ABLATION

Percutaneous LAA ligation devices such as the LARIAT offer a method of LAA exclusion by ligation, utilizing a novel pericardial and transseptal process. See Figure 3. While less well-studied than the LAAO devices, the benefit of the LARIAT lies in the establishment of tissue-to-tissue exclusion of the LAA from the circulation and the lack of an implantable device with a risk of embolization. The downside of the LARIAT stems from its procedural complexity and the exclusion of individuals with a history of pericarditis, cardiothoracic surgery, recent myocardial infarction, or a prior embolic event within 30 days of the procedure. The first single-center trial of the LARIAT device was done in Poland. It included 89 patients, mean age 62 years and a mean CHA2DS2-VASc score of 2.8. Technical success was achieved in 96%, with 2 epicardial complications and 1 transseptal complication. Major post-operative adverse events included severe pericarditis in 2 patients, 1 late pericardial effusion, 2 unexplained sudden deaths, and 2 late strokes (9). While complete closure was verified by TEE one year later, only 65 of the 89 patients underwent follow-up TEE. In 2013, the results from the U.S. Transcatheter LAA Ligation Consortium, a multi-center retrospective analysis of 154 LARIAT procedures (16) were published. Their findings included a procedural time of 76.6 minutes, a technical success rate of 94%, and procedural success rate of 86%. Major adverse events included significant pericardial effusion requiring intervention in 10.64%, bleeding requiring transfusion 4.5%, and emergent cardiac surgery 2.0%. Their median follow-up was 112 days with TEE performed in 63 patients demonstrating residual leak in 20%, and presence of thrombus in 4.8%. The U.S. experience showed that technical success is possible, but not without concerning pericardial bleeding and effusion.

The application of radiofrequency energy to achieve electrical isolation of the LAA represents a departure from implantable device or surgical exclusion therapies. In the BELIEF Trial, a randomized trial of patients with long-standing persistent AF (LSPAF), patients underwent two different ablative strategies; an extended pulmonary vein (PV) antrum ablation plus non-PV trigger ablation (Group 1) versus standard ablation plus non-PV trigger ablation plus empiric LAA isolation (Group 2) (10). The primary endpoint of the study was freedom from atrial arrhythmia, defined as atrial fibrillation, atrial flutter, and atrial tachycardia lasting >30 seconds. The secondary endpoints assessed at a <12-month interval included stroke, death, and rehospitalization. Patients were followed at 12- and 24-month intervals with no patients lost to follow-up. If the patients had breakthrough arrhythmia at their 12-month evaluation, they were rescheduled for another ablation. Individuals in the BELIEF trial underwent an average of 1.3 procedures and all were followed out to 24 months. At 24 months, the cumulative success rates were 76% and 56% in Group 1 and Group 2 respectively. Four patients (4.5%) in Group 1 suffered a stroke but there were no strokes or TIAs among Group 2 patients at the 24 month follow-up. While the success rates for complete electrical isolation are relatively low, the lack of stroke or TIA in the electrically isolated LAA remains an interesting finding. Larger studies will need to be done to see if electrical isolation of the LAA remains a viable alternative to device-based or suture-mediated LAA exclusion.

CONCLUSION

Exclusion of the LAA as a nidus for thromboembolic stroke in patients with AF stands as a viable alternative therapy, especially in light of the risks posed by OAC. Leading the charge in excluding the LAA, the Watchman device is well studied, touting efficacy data from PROTECT-AF and further bolstered by

Figure 3. LARIAT (SentreHEART Inc.) Left Atrial Appendage Ligation Device showing transeptal and epicardial delivery catheters and ligature being deployed at the neck of the left atrial appendage.
long-term registries such as PREVAIL[17] and CAP. Currently, the Watchman device is FDA-approved for patients with non-valvular AF at increased risk for stroke, recommended for OACs, and have an appropriate reason for seeking an alternative to OACs. Emerging devices and technologies, such as the LARIAT and LAA isolation via ablative strategies clearly warrant further investigation and are currently only available through clinical trials and registries but are not currently approved alternatives to either OAC or the Watchman device.

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Pulmonary Embolism in 2017: Increasing Options for Increasing Incidence
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ABSTRACT
Scope of the problem – An increasing burden of disease
Acute pulmonary embolism (PE) is a problem encountered by a majority of medical and surgical specialties in their scope of practice. Acute PE is currently the 3rd leading cause of cardiovascular death in the United States, resulting in 100,000 deaths annually as estimated by the Centers for Disease Control (CDC) [1]. There is a paucity of data and a broad range of estimates for both incidence and morbidity due to acute PE. The mortality of all patients presenting with acute PE is estimated between 10-30% at 90 days utilizing current treatment regimens [2]. The incidence of acute symptomatic PE seems to be increasing from 3/100 to more than 6.5/100 in the past 15 years [2]. The increasing burden of disease has led to a period of intense investigation into new therapies and strategies to treat acute PE.

KEYWORDS: pulmonary embolism, pulmonary embolism response team, catheter-directed thrombolysis, RV to LV ratio, PESI

PULMONARY EMBOLISM - MORTALITY RISK
Pulmonary embolism has a wide morbidity range, from the asymptomatic and incidentally discovered where mortality is less than 1%, to massive acute PEs that often lead to progressive shock and death. The difficulty lies in stratifying patients into categories based on risk. Only recently has increased research begun to codify categories of acute PE based on risk. Acute PE in 2017 is currently divided into 3 categories of low, moderate and high risk. The mortality for low-risk patients is approximately 1% and this represents 40% of all presenting pulmonary embolism [4,5]. Another 5-15% of presenting pulmonary embolisms have shock and hemodynamic compromise representing a high-risk cohort. Even with systemic tPA thrombolysis the mortality for these patients exceeds 30%. The third category is the sub-massive or moderate-risk patient population, and makes up the remaining 40-45% of presenting PEs. These patients have a large central thrombus burden and signs of RV failure or compromise without frank shock. These intermediate-risk patients have a high risk of degeneration to shock and death. Depending on the exact definitions, the mortality in this subgroup of patients ranges from 5-20% [4].

STRATEGY FOR RISK STRATIFICATION AND THERAPY SELECTION
Given that PE requires expertise from pulmonology, radiology, non-invasive and interventional cardiology, and cardiothoracic surgery, a multi-disciplinary team approach has been adopted at many institutions to help better serve patients with acute PE. The success of multi-disciplinary teams in the arenas of complicated coronary disease and aortic stenosis have served as a model for PE. PE response teams or PERT are gaining traction at many large medical centers that offer advanced therapies available to patients with acute PE. Engaging specialists from different backgrounds using telemedicine allows timely and efficient discussion of treatment options and provides immediate advice and therapy for patients with massive and sub-massive PE.

Prognostic scoring systems incorporate clinical, laboratory and radiographic parameters. The original and simplified pulmonary embolism severity index (PESI) scores utilize clinical variables that predict mortality [Figure 1]. The modified Miller index uses the CTPA clot burden to predict prognosis. These scores have variable accuracy in predicting morbidity and mortality [6,7,8,9,10]. Laboratory markers of RV dysfunction include BNP or N-terminal-proBNP, which reflect the severity of hemodynamic compromise and RV dysfunction in PE and predict adverse outcome [8,12,13]. They may be an effective tool for triaging patients in the ED for admission to the ICU, step-down or floor units but they do not take into account RV parameters such as RV to LV ratio or RV size and systolic function that are important decision points when considering advances therapies and refining risk stratification.

THE RVS THE PROBLEM
Mortality in acute pulmonary embolism is caused by acute RV failure from acute pressure overload in the setting of a large volume of thrombus. Multiple registries have shown a strong association with RV dysfunction and subsequent death from acute PE [12, 13, 14, 15, 16]. The difficulty lies in which RV parameter seems to best correlate with poor outcomes. Current data suggests that an RV to LV ratio greater than 1 appears to be the best predictor of morbidity and mortality [15, 16]. The RV to LV ratio has been validated both on CT imaging, which is typically the modality through which acute PE is diagnosed, as well as via 2-D
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Transthoracic echocardiogram (Figure 2). Combining PE-related risk and patient’s clinical status and co-morbidities predicts early outcomes and may be used to guide treatment decision-making (Figure 4).

Emerging Therapies with a Paucity of Data

The standard therapy for acute pulmonary embolism remains parenteral anticoagulation with the addition of high dose (100 mg) bolus systemic thrombolysis for cases of shock (currently defined as a SBP less than 90 mmHg). These both have level 1 evidence supporting their use in acute PE but are based on decades-old data with small sample sizes. A meta-analysis of trials in patients with massive PE showed a reduction in the composite of recurrent PE and death in systemic lysis patients versus heparin [19]. The PEITHO trial demonstrated reduced composite endpoint of death and hemodynamic collapse in intermediate-risk patients (2.6% vs. 5.6%), but no mortality benefit and at the expense of a higher bleeding risk [17,18,19]. The MOPPET trial randomized moderate-risk patients to half-dose alteplase (50 mg over 2 hours) anticoagulation with lower pulmonary artery pressure at 28 months and no major bleeding [23]. These studies collectively demonstrate that systemic fibrinolysis in patients with massive and sub-massive PE leads to improved hemodynamic stabilization and possibly lower risk of recurrent PE and death but with a higher risk of severe bleeding and intracranial hemorrhage [ICH].

Catheter-based therapies to relieve obstruction quickly and restore pulmonary blood flow and improve RV dysfunction may improve cardiac output and stabilize hemodynamics. Delivery of fibrinolytics directly into the clot may allow for increased clot dissolution, shorter treatment

Figure 2. RV to LV ratio from Ultima trial
Instructions for study sites and core laboratory for measurement of sub-annular right ventricular to left ventricular (RV/LV) ratio from the echocardiographic apical 4-chamber view: (1) Obtain an end-diastolic image defined as last available image before onset of tricuspid valve closure. (2) Obtain center line through inter ventricular septum (gray vertical line). (3) Obtain tricuspid annular line (gray horizontal line) at septal insertion point of tricuspid valve (oblique arrow), perpendicular to interventricular septum line. (4) Obtain subannular line 1 cm above and parallel to annular line (vertical arrow). (5) Obtain RV and LV dimensions on subannular line with the use of endocardial borders (red arrows). (6) Calculate RV/LV ratio.
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Times and reduced risk of bleeding complications. Catheter-directed infusion of tPA plus ultrasound for clot separation is currently the only FDA-approved therapy for PE treatment. The smaller studies supporting EKOS catheter directed thrombolytic therapy include the randomized controlled ULTIMA trial which examined patients with intermediate or sub-massive PE vs traditional anticoagulation therapy or catheter-directed thrombolysis and the single arm Seattle II PE trial.

**ULTIMA AND SEATTLE II PE TRIALS (20, 21, 22)**

The Ultima trial showed rapid improvement of RV function and reduced pulmonary artery pressures within 24 hours when compared to standard anticoagulation in patients with sub-massive acute PE. This benefit was no longer statistically significant at 90 days of follow-up. Bleeding rates were no higher in the treatment arm and led to the approval of catheter-directed thrombolytic therapy for this moderate-risk population. The US based Seattle II PE trial, of which the Miriam Hospital was a site, was a prospective, single arm safety and efficacy trial that confirmed improvement in RV function using catheter directed thrombolytic therapy. (See case example of EKOS CDT, Figure 3.) It also confirmed no major bleeding events as a result of lower dose catheter-directed thrombolytic therapy, [like ULTIMA, a total of 24 mg of tPA]. Although proven safe and effective there has yet to be a randomized controlled trial showing benefit for clinical endpoints in acute pulmonary embolism using catheter-directed therapy (CDT). The pivotal trial for moderate risk PE patients, PE TRACT, hopes to recruit over 500 patients and randomize to anticoagulation with or without catheter-directed thrombolysis. Long-term clinical endpoints should answer this critical clinical equipoise question.

**Figure 3. Sub-massive pulmonary embolism angiogram**

Right and left pulmonary angiograms with sub-massive pulmonary embolism prior to EKOS catheter placement.
Figure 4. ESC 2014 guidelines

Clinical suspicion of PE

Shock / hypotension?

Yes

No

Diagnostic algorithm as in Figure 3

Diagnostic algorithm as in Figure 4

PE confirmed

Assess clinical risk (PESI or sPESI)

PE confirmed

Intermediate risk

Consider further risk stratification

RV function (echo or CT)

Laboratory testing

Both positive

High risk

Primary reperfusion

A/C; monitoring; consider rescue reperfusion

One positive or both negative

Intermediate–high risk

Intermediate–low risk

Low risk

Hospitalization; A/C

Consider early discharge and home treatment, if feasible

A/C = anticoagulation; CT = computed tomographic pulmonary angiography; PE = pulmonary embolism; PESI = pulmonary embolism severity index; RV = right ventricular; sPESI = simplified pulmonary embolism severity index.

1If echocardiography has already been performed during diagnostic work-up for PE and detected RV dysfunction, or if the CT already performed for diagnostic work-up has shown RV enlargement (RV/LV (left ventricular) ratio >0.9), a cardiac troponin test should be performed except for cases in which primary reperfusion is not a therapeutic option (e.g. due to severe comorbidity or limited life expectancy of the patient).

2Markers of myocardial injury (e.g. elevated cardiac troponin I or T concentrations in plasma), or of heart failure as a result of (right) ventricular dysfunction (elevated natriuretic peptide concentrations in plasma). If a laboratory test for a cardiac biomarker has already been performed during initial diagnostic work-up (e.g. in the chest pain unit) and was positive, then an echocardiogram should be considered to assess RV function, or RV size should be reassessed on CT.

3Patients in the PESI Class I-II, or with sPESI of 0, and elevated cardiac biomarkers or signs of RV dysfunction on imaging tests, are also to be classified into the intermediate–low risk category. This might apply to situations in which imaging or biomarker results become available after calculation of the clinical severity index. These patients are probably not candidates for home treatment.

4Thrombolysis, if (and as soon as) clinical signs of hemodynamic decompensation appear; surgical pulmonary embolectomy or percutaneous catheter-directed treatment may be considered as alternative options to systemic thrombolysis, particularly if the bleeding risk is high.

5Monitoring should be considered for patients with confirmed PE and a positive troponin test, even if there is no evidence of RV dysfunction on echocardiography or CT.

6The simplified version of the PESI has not been validated in prospective home treatment trials; inclusion criteria other than the PESI were used in two single-arm (non-randomized) management studies.
The AngioVac thrombectomy device utilizes a 22F venous catheter that can remove large volume thrombus using a centrifugal pump and venous reinfusion, and is designed to remove thrombus from iliac veins, IVC, RA and PA. The need for a 26F sheath and a perfusionist limits its use. The Inari FlowTriever device is a 22F venous sheath aspiration system that utilizes an aspiration guide catheter and a catheter composed of three self-expanding nitinol disks to entrain and remove thrombi. Limitations include the large access sheath and difficulty manipulating the guide catheter into the pulmonary artery. The Penumbra thrombectomy device provides 29 mmHg vacuum aspiration with an 8F device that uses a separator wire to clear the system of thrombus.

**OTHER PE THERAPIES**

In high-risk patients with shock from acute PE who fail or have a contraindication to systemic thrombolytic therapy, several options remain. Extracorporeal membrane oxygenation (ECMO) therapy can unload the RV and provide oxygenation to allow for recovery. It is being used more frequently for critically ill patients with high expected mortality but vascular complications from large bore sheaths remain the current limitation to this promising therapy. Data is only available through small registry and single-center data with regards to the efficacy of ECMO in the acute PE patient. Surgical embolectomy remains an important option for critically ill patients for whom high dose thrombolytics have failed or are contraindicated, and they must have proximal disease that is accessible through a median sternotomy. IVC filter use has fallen out of favor due to its high complication rate and low efficacy rate, and is only indicated in patients with an absolute contraindication to anticoagulation. Both the American and European guidelines do not recommend routine use of IVC filters in patients with PE.

Due to the complexities of assigning risk and choosing therapy for acute PE patients in a rapid manner, we’ve taken the burden of PE head-on in an effort to improve outcomes for patients. At Rhode Island and The Miriam Hospitals we offer advanced therapy for intermediate- and high-risk PE that include percutaneous catheter-directed thrombolysis, aspiration thrombectomy, surgical embolectomy and ECMO therapies. In order to rapidly triage patients to the appropriate therapy, we have created a pulmonary embolism response team to provide a multi-disciplinary approach to the management of acute PE. A call placed from the pulmonary fellow rapidly assembles a team including pulmonary critical care, interventional and non-invasive cardiology, interventional radiology and a cardiothoracic surgeon. The case is presented by the pulmonary critical care fellow, including access to all relevant imaging data and a discussion is held to determine the best care for the patient. We are currently collecting clinical data to compare our efforts pre- and post-initiation of the PERT team in a prospective trial dubbed Providence PE.

**MORE WORK TO BE DONE**

Definitive randomized controlled trials are currently in the early phases of approval so 3-5 years will lapse before any decisive data is available to guide treatment of acute PE patients. In the interim we are using guideline-based therapies and the PERT in an effort to maximize benefit for this common and highly morbid condition. Until appropriate studies fill knowledge gaps, we suggest utilization of multi-disciplinary PERTs and collection of data both locally and nationally through the PERT Consortium. (Figure 4. Suggested PE Treatment Algorithm, adapted from the ESC 2015 Guidelines)

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The Arm is Not the Leg: Pathophysiology, Diagnosis, and Management of upper Extremity Deep Vein Thrombosis

ADAM M. NOYES, MD; JOHN DICKEY, MD

ABSTRACT

Upper extremity deep venous thrombosis (UEDVT) involves thrombosis of the deep veins of the arm as they enter the thorax. They are increasing in frequency, largely due to the rising use of central venous catheters and implantable cardiac devices, and represent more than 10% of all DVT cases. Upper extremity deep venous thrombosis has been historically misunderstood when compared to lower extremity deep vein thrombosis (LEDVT). Their associated disease states may carry devastating complications, with mortality rates often higher than that of LEDVT. Thus, education on recognition, classification and management is critical to avoid long-term sequelae and mortality from UEDVT.

KEYWORDS: upper extremity deep vein thrombosis, catheter associated deep vein thrombosis, pacemaker associated deep vein thrombosis, thoracic outlet syndrome, Paget-von Schröetter syndrome

INTRODUCTION

Upper extremity deep venous thrombosis (UEDVT) accounts for more than 10% of all cases of deep venous thrombosis (DVT). UEDVT is about 1/5 as common as lower-extremity deep vein thrombosis (LEDVT) (0.19 vs 0.96 per 100,000 hospitalizations). The subclavian vein is most often affected, with the internal jugular, brachial, and basilic veins involved in approximately 4–30% of patients. Complications, such as pulmonary embolism (PE) as well as mortality are more frequent and more severe when UEDVT involves the axillary or more proximal veins than if thrombosis is confined to the brachial vein. As such, the term “UEDVT” is typically used only when referring to thrombosis involving axillary and more proximal veins. In addition, UEDVT has associated under-recognized and distinct disease states, which are often misunderstood when compared to LEDVTs. Prompt recognition and appropriate management of UEDVT is vital due to the significant risk of PE and observable long-term sequelae.

In this article, we review the pathogenesis, diagnosis, classification, and clinical characteristics of the different forms of UEDVT as well as treatment and management.

ANATOMY OF THE VEINS OF THE UPPER EXTREMITY

The superficial veins of the arm include the cephalic, basilic, and median cubital veins. These veins drain into the deep veins, which are the radial and ulnar veins in the forearm and the brachial, axillary, and subclavian veins in the upper arm and shoulder. The subclavian vein continues, joining with the internal jugular vein and eventually emptying into the superior vena cava (SVC).

CLASSIFICATION AND PATHOGENESIS

The mechanism of DVTs was first described by Rudolf Virchow as a triad of factors thought to contribute to thrombosis: hypercoagulability, hemodynamic stasis or turbulence, and endothelial dysfunction. From this, the mechanism of UEDVT can be further characterized as primary, or “spontaneous,” and secondary.

Primary Upper Extremity Deep Venous Thrombosis

A DVT of the arm veins without apparent predisposing factors in the patient’s history is classified as primary UEDVT and accounts for up to 33% of all thromboses involving the upper extremities. Classifying an UEDVT as primary requires thorough evaluation for predisposing anatomic and hematologic abnormalities. Primary UEDVT can be further classified into effort thrombosis, otherwise referred to by the eponym Paget-von Schröetter Syndrome (PSS), and idopathic thrombosis.

Paget-von Schröetter Syndrome is the most common form of primary UEDVT and typically occurs in young and otherwise healthy individuals with a male to female ratio of approximately 2:1. UEDVT occurs in the dominant arm after strenuous, repetitive or unusual physical activity, such as lifting weights, playing tennis, pitching a baseball, or performing repetitive overhead activities such as painting. Patients with PSS have an underlying anatomic abnormality involving the thoracic outlet. The repetitive physical activity leads to damage to the subclavian vein intima with subsequent fibrosis and activation of the coagulation cascade. This elicits effort-related thrombosis due to compression of the subclavian vein from anatomic abnormalities within the anterior portion of the thoracic outlet triangle leading to the formation of the venous thoracic outlet syndrome (VTOS).

The subset of primary UEDVT where there are no evident predisposing factors or underlying VTOS is identified as...
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idiopathic. However, occult malignancies in this subgroup of patients have been reported in up to 25% of cases, and the prevalence of coagulation abnormalities appears to be even higher in patients with idiopathic thrombosis than in those with PSS thrombosis or other forms of secondary thrombosis. Patients with PSS generally have good functional status with longer life expectancies than that of idiopathic UEDVT.

Secondary UEDVT

Secondary UEDVT accounts for up to 80% of UEDVT and is defined as any UEDVT related to a predisposing factor, such as central venous catheters (CVC), implantable cardiac rhythm devices, malignancy, or insertion of other prosthetic or foreign material. Compared to primary UEDVT, there is increased mortality in patients with secondary UEDVT, usually related to the underlying disease state. The incidence of secondary UEDVT is increasing due to growing use of medical devices, particularly use of central venous catheters, which have been reported in 25–50% of UEDVT. The internal jugular, subclavian or axillary veins can be involved, and the risk of thrombosis is equal, regardless of vascular access site. The risk of developing catheter-related thrombosis depends on an individual patient’s profile, and is as high as 66% in cancer patients with CVCs.

UEDVTs occurred in 23% of patients following implantation of a permanent pacemaker, while peripherally inserted central catheters were associated with UEDVT in 9% of patients. Other related risk factors include personal or family history of thrombosis and thrombophilia, surgery, trauma or immobilization of the arm, pregnancy and oral contraceptive use. Malignancy is an independent risk factor for secondary UEDVT and is present in approximately 33% of cases, particularly ovarian and lung adenocarcinoma. Catheter-related risk factors such as technically difficult or left-sided catheter placement, location of the catheter tip not at the atriocaval junction, prior CVC, and large-lumen catheters also pose increased risk.

Clinical Presentation and Diagnosis

The most common clinical features of UEDVT are unilateral arm erythema, edema and discomfort, and dilated superficial veins, dyspnea, low-grade fever and failure to withdraw blood from a catheter may also be present. In cases where there is central vein obstruction or occlusion, SVC syndrome may be seen. When PSS is present, venous distention was reported in all cases, with edema of the arm (93%), cyanosis (77%) and pain with exercise (66%) also occurring. Compression of the brachial plexus can lead to paresthesias and arm pain, which worsens with hyperabduction of the shoulder when VTOS is associated with PSS. The incidence of symptomatic and asymptomatic UEDVT following CVC placement is 2–6% and 11–19%, respectively.

Clinical probability scores have a sensitivity of 78% and specificity of 64% for diagnosing UEDVT. Furthermore, 13% of patients with low probability scores were later diagnosed with UEDVT, thus, scores alone should not be used to rule out the likelihood of UEDVT. In contrast to LEDVT, D-dimer testing has not been prospectively tested and cannot be used to exclude UEDVT with one study showing a specificity of 14.

The mainstay in diagnosis of UEDVT is imaging. Duplex ultrasonography (US) is commonly used as the initial study and should be considered the first-line diagnostic imaging procedure for UEDVT. It is readily available, portable, non-invasive, inexpensive, and without radiation exposure. Ultrasound has 97% sensitivity and 96%

Figure 1. Greyscale image (A) of subclavian vein (arrows) with intraluminal PICC line (arrowhead) surrounded by heterogeneous echodensity filling the vessel consistent with thrombus. Color Doppler (B) shows flow (blue) between the vessel wall and thrombus demonstrating near-occlusive thrombus.
specificity for the diagnosis of UEDVT. Applying pressure to compress the visualized vein should easily collapse the vessel under normal conditions, with lack of expected venous collapse indicating presence of a thrombus. This technique cannot be used for centrally located veins, such as the SVC, where manual compression is not possible. Echogenicities visualized within the vessel lumen may represent acute or age indeterminate thrombus. Pulsed wave- and color-flow Doppler US can further assess dynamics of venous blood flow. Absence of flow, or conversion of the normal biphasic flow pattern into a non-pulsatile, continuous flow signal suggests venous obstruction and the presence of a DVT.

Contrast venography has the ability to visualize the entire deep venous system and can define complex and difficult anatomy not otherwise visualized with US. It is utilized infrequently and is typically reserved for these situations or if there is a disparity between US and clinical findings. Contrast venography is invasive and exposes the patient to iodinated contrast and radiation. When contrast is injected into the venous system, a non-filling venous segment suggests thrombosis.

Additionally, contrast-enhanced computed tomography and magnetic resonance venography are potential diagnostic tests for UEDVT, though limited evidence exists to guide their use. Sensitivity of magnetic resonance venography has been reported at 71%, and the value of computed tomography venography has not been systematically evaluated. However, both computed tomography and magnetic resonance imaging are useful not only to confirm UEDVT but also to diagnose concomitant pathologies, including cancer, adenopathy, or anatomic abnormalities suggestive of VTOS and have largely supplanted contrast venography.

**TREATMENT AND PREVENTION**

Goals of therapy can be divided into the acute treatment phase, defined as the first three months following diagnosis, and the secondary prevention phase, which refers to therapy beyond three months. In the acute treatment phase, the optimal treatment duration and intensity has not been determined in randomized controlled trials. However, a small prospective cohort study has shown low rates of recurrent DVT, PE, and episodes of major bleeding when acute UEDVT is treated similarly to LEDVT. The 2012 consensus guidelines of the American College of Chest Physicians recommend anticoagulation therapy with low molecular weight heparin (LMWH), unfractionated heparin, or fondaparinux followed by 3 months of vitamin K antagonists for idiopathic UEDVT involving the axillary and more proximal veins. Anticoagulation for isolated brachial vein thrombosis is not well studied, but is recommended if the thrombus is symptomatic or involves a CVC. In contrast to idiopathic LEDVT, anticoagulation therapy beyond 3 months is generally not recommended after a first episode of idiopathic UEDVT.

In UEDVT associated with malignancy, treatment with LMWH monotherapy for 3-6 months is preferred over the administration of vitamin K antagonists and should continue as long as the cancer remains active and the event was not related to a CVC. In patients with catheter-associated UEDVT (with or without cancer), anticoagulation therapy can be discontinued after at least 3 months if the CVC is removed. If the catheter is not removed, anticoagulation therapy should be continued as long as the catheter remains. In most patients with CVC-associated UEDVT, it is recommended that the catheter not be removed if it is functional and there is an ongoing need for central access.
The use of direct thrombin inhibitors and Xa inhibitors over vitamin K antagonists or LMWH for the long-term treatment of UEDVT is not recommended as their use has not been studied.11

Criteria for placement of SVC filters are similar to those in LEDVT, and should only be considered in patients with contraindications to anticoagulant treatment and PE.11

In patients with UEDVT due to PSS, physical therapy may reduce symptoms. If symptoms persist with evidence of residual subclavian venous stenosis by positional venography, surgical decompression should be considered.13

**PROGNOSIS AND FOLLOW-UP**

Mortality rates are significantly higher with UEDVT compared to LEDVT [7.6% vs. 4.2%; p<0.001], and two- and 12-month mortality rates following diagnosis of UEDVT have been reported at 30 and 40%, respectively.14, 15 Pulmonary embolism is a dire complication and drives mortality in both UEDVT and LEDVT, although rates in one large retrospective study showed a lower incidence of PE in UEDVT compared to LEDVT [5.4% vs. 27.9% p<0.001]. Nonetheless, the prevalence of hemodynamically unstable PE was higher among patients with UEDVT than LEDVT [5.2% vs. 3.6%; p<0.001].16 Another analysis reported the rate of PE to be 6% in primary UEDVT, 13% in secondary UEDVT and 17% in catheter-related UEDVT.17

Post-thrombotic syndrome (PTS) of the arm, a condition characterized by persistent pain, edema, and functional limitation due to persistent obstruction and valvular insufficiency, has been reported in up to 20% of patients after treatment for UEDVT.11 In contrast to LEDVT, use of compression therapy to prevent PTS of the arms is not recommended due to lack of evidence of efficacy in this population and a difference in the suspected pathophysiology of PTS in the upper extremity.11 Additionally, there is no evidence or recommendations to support the practice of serial US imaging in UEDVT.11

**CONCLUSION**

The clinician’s understanding and recognition of UEDVT is essential in avoiding PE. Mortality is elevated in patients with UEDVT, and prompt identification of thrombosis and initiation of anticoagulation is essential. Specific differences exist between the various types of UEDVT and can alter approaches to treatment. Further research should focus on use of novel anticoagulants given the anticipated increase in UEDVT incidence due to increasing use of CVC.

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Chronic Venous Insufficiency: Novel Management Strategies for an Under-diagnosed Disease Process

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ABSTRACT
Chronic venous insufficiency is an often-missed diagnosis that results in a variety of clinical manifestations that may severely compromise quality of life. Prompt recognition is important to provide symptomatic relief and prevent disease progression. Most patients can be treated with a comprehensive plan of conservative measures. However, it is important for providers to recognize those patients who require referral to a vascular specialist for more invasive therapies. Over the past 2 decades, a variety of endovenous strategies have demonstrated effective and lasting results in treatment of severe symptomatic venous insufficiency.

KEYWORDS: Venous insufficiency, venous ulcer, radiofrequency ablation, endovenous laser therapy, phlebectomy

BACKGROUND
Chronic venous disease is often underdiagnosed and consequently undertreated in a variety of healthcare settings. An estimated 25 million Americans are affected by some degree of chronic venous insufficiency. Manifestations of chronic venous disease range from asymptomatic varicose veins in 30% of screened individuals, to more advanced disease in 10% of patients. Varicose veins have an estimated prevalence of 5-30% in adults with a female-to-male preponderance of 3:1. Non-healing and healed venous ulcers occur in approximately 1% of the US adult population. Risk factors associated with chronic venous disease including increasing age, female gender, family history of venous insufficiency, obesity, pregnancy and prior leg injury or surgery. Furthermore, occupations that require prolonged standing predispose individuals to development of chronic venous insufficiency. Disability secondary to severe venous ulcers results in 2 million workdays lost. Moreover, an estimated $1 billion are spent annually in the treatment of chronic venous ulcers.

The superficial venous system above the muscular fascial layer is composed of the great saphenous vein (GSV), the small saphenous vein (SSV) as well as several accessory veins. Along with the superficial venous system, the deep venous system and perforating veins serve as both a reservoir and conduit to return blood to the heart. Normal venous return depends on patency of the venous system as well as proper functioning of a series of 1-way bicuspid valves. In addition, lower extremity muscular function must be adequate in order to ensure central venous return. When the venous system is functioning correctly, every movement of the lower extremity moves blood inward and upward past competent valves that ensure that the hydrostatic pressure is near zero. In patients with venous insufficiency, incompetent valves remain in an open configuration, resulting in an unbroken column of blood from head to foot with a subsequent high hydrostatic pressure.

Failure of superficial venous valves occurs most commonly from weak vein walls that dilate under normal venous pressures, resulting in secondary valve failure. In addition, direct injury from superficial phlebitis, as well as congenital abnormalities, can result in primary valve failure. Finally, normal valves can be excessively distensible under the influence of hormones as in pregnancy. The common pathway of these states leads to an inability to prevent backflow and venous pooling.

The CEAP classification (Figure 1) is commonly utilized to reliably and reproducibly grade severity of venous insufficiency. Furthermore, therapy can be tailored to the severity of venous insufficiency.

Figure 1. CEAP classification

<table>
<thead>
<tr>
<th>Clinical</th>
<th>C₀ – No clinical signs</th>
<th>C₁ – Small varicose veins</th>
<th>C₂ – Large varicose veins</th>
<th>C₃ – Edema</th>
<th>C₄ – Skin changes without ulceration</th>
<th>C₅ – Skin changes with healed ulceration</th>
<th>C₆ – Skin changes with active ulceration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etiology</td>
<td>E₁ – Congenital</td>
<td>E₂ – Primary</td>
<td>E₃ – Secondary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anatomy</td>
<td>A₀ – Superficial</td>
<td>A₁ – Deep</td>
<td>A₂ – Perforating</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pathophysiology</td>
<td>Pᵣ – Reflux</td>
<td>Pₒ – Obstruction</td>
<td></td>
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PRESENTATION

Early clinical manifestations of chronic venous insufficiency include the reporting of subjective symptoms. The characteristic ache of venous insufficiency comes on after prolonged standing and is described as pain, pressure, burning, itching or heaviness in the affected limb. Importantly, episodic symptoms may occur temporally, related to hormonal changes during pregnancy. Symptoms are alleviated by walking and leg elevation unlike in peripheral arterial disease. As the disease process advances, damage to the capillary basement membrane results in leg edema. The characteristic appearance of lipodermatosclerosis results from the breakdown of red blood cells and the subsequent deposition of hemosiderin in the skin. In the most advanced cases, non-healing ulcers are noted around the medial malleolus where venous pressure is maximal. Unlike typical arterial ulcers, the wound of chronic venous insufficiency is shallow, superficial, irregular in shape and associated with painful edema.

DIAGNOSIS

Venous duplex imaging is the simplest and most commonly used technique for establishing the diagnosis of venous insufficiency. Furthermore, duplex imaging is usually sufficient enough to guide therapy and management. Presence of venous reflux is confirmed by determining direction of blood flow. This is evaluated by placing the patient in reverse Trendelenburg position, and assessing blood flow direction during a Valsalva maneuver or after augmenting blood flow with more proximal limb compression. An alternative method requires venous duplex interrogation following a rapid cuff inflation-deflation technique while the patient is standing. The presence of significant reflux is determined by the presence of reverse flow towards the feet for a significant amount of time: ≥ 0.5 seconds for superficial veins and ≥ 1.0 seconds for deep veins. A longer duration of reflux corresponds with more severe disease but not necessarily with clinical manifestations.

Venous duplex imaging is often more than sufficient in diagnosing and managing patients with venous insufficiency. Air plethysmography is utilized occasionally to determine the relative contribution of venous reflux, as opposed to venous obstruction or muscle pump dysfunction, to the clinical syndrome. Computed tomography (CT) and magnetic resonance (MR) are rarely utilized to evaluate venous disease. The utility of advanced imaging modalities is mainly to diagnose both intrinsic and extrinsic compression of the venous system by surrounding structures. Invasive contrast venography is very rarely utilized if surgical intervention is considered.

TREATMENT OF CHRONIC VENOUS INSUFFICIENCY

Compression therapy between 20–50 mmHg remains the cornerstone of any treatment plan for chronic venous insufficiency. Graded external compression to the leg opposes the hydrostatic pressure that results in venous hypertension. The presence of compression grades is essential as non-graded ACE wraps and stockings cause a touriquet effect that in turn exacerbates venous insufficiency. Compliance with 30-50 mmHg compression therapy is sufficient in the vast majority of patients to alleviate symptoms of chronic venous insufficiency as well as improve mobility. Even in more severe disease, compression therapy has been associated with complete venous ulcer healing at 5 months.

The most common compression stocking prescribed is for knee-high garments. A general rule of tension prescription that correlates with disease severity would be 20–30 mmHg for C2-C3 disease, 30-40 mmHg for C4-C6 and 40–50 mmHg for recurrent ulcers. Stockings should be worn daily and removed only at night for maximal benefit. Any compression garment should be replaced every 6 to 9 months.

In addition to compression therapy, calf muscle exercises should be performed as part of any treatment plan. In very small studies, coumarins, flavonoids, saponosides and other plant extracts have demonstrated mild improvement in edema-related symptoms. However, currently, there are no pharmacological agents approved in the United States for treatment of chronic venous insufficiency. Although diuretics are commonly used to treat edema for short periods of time, it is important to understand that chronic venous insufficiency is not a state of volume overload. As a result, the benefit of temporary relief must be balanced with the metabolic and renal side effects of long-term diuretic usage.

Interventional therapy of chronic venous insufficiency includes both venous ablation as well as sclerotherapy. Endovenous ablation involves the application of thermal energy, either radiofrequency (RF) or laser (EVLT), to the vein wall which in turn leads to thrombosis followed by fibrosis of the treated segment. In the case of GSV ablation, both RF and EVLT procedures involve ultrasound-guided placement of a 7 Fr sheath in the GSV with subsequent passage of a catheter to the level of the saphenofemoral junction. Radiofrequency ablation of the greater saphenous vein has resulted in successful venous closure in 85% of patients with a 10% rate of recanalization at 2 years. A very rare complication (< 1%) of RF is deep-vein thrombosis and subsequent pulmonary embolism. Laser treatments have reported rates of closure as high as 95% at 2 years with no major complications. At present venous ablation, by either laser or RF, has a higher rate of success compared to sclerotherapy and lower rate of co-morbidity compared to traditional surgical ligation and stripping. Endovenous ablation is performed almost exclusively with local tumescent anesthesia which prevents skin burns and reduces any pain associated with the procedure. Although most commonly utilized in the treatment of GSV insufficiency, endovenous ablative techniques have also been utilized in treatment of perforator reflux in the case of non-healing ulcers.

A variety of sclerosing agents have been utilized to treat...
telangiectasias, varicose veins and smaller segments of venous reflux. In addition, sclerotherapy has been used to treat spider veins, bleeding varicosities and cavernous hemangiomas. Currently in the United States, the only approved sclerosing agents are detergents including sodium tetradecyl sulfate, polidocanol, glycerin and sodium morrhuate. Generally, all agents have to be diluted with air or saline in order to avoid tissue inflammation and necrosis. The most common complication of any sclerotherapy is skin hyperpigmentation of surrounding tissue from hemosiderin degradation.

Endovenous deep-system therapy has become an important part of restoring venous outflow from the lower extremities. In the case of deep venous insufficiency from obstruction, venous balloon angioplasty followed by stenting has evolved as an alternative to surgical bypass surgery which is now very infrequently performed. Primary patency rates of 80% at 6 years for non-thrombotic and 60% for thrombotic disease have been reported1. The success of iliac stenting for venous ulcers has proved to be effective with 90% of patients free from recurrent ulceration at 2 years12.

Surgical therapy is reserved for those individuals with venous insufficiency symptoms refractory to compression and endovenous therapy. High ligation at the level of the saphenofemoral junction followed by excision of the GSVs ameliorate symptoms and possibly improves ulcer healing13. Following vein stripping or endovenous ablation, symptomatic varicose veins can be removed with stab phlebectomy. Surgical intervention on incompetent perforator veins for non-healing ulcers has proved to be effective with 90% of patients free from recurrent ulceration at 2 years12.

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SUMMARY

Chronic venous insufficiency is a common medical problem. Adequate screening and recognition of its various manifestations are important to appropriately treat patients. Conservative measures including compression therapy, leg elevation and calf exercises are usually sufficient for most patients. In cases refractory to conservative therapy, interventional modalities including radiofrequency and laser ablation as well as sclerotherapy are effective at alleviating symptoms and venous ulcer healing. Rarely, surgical therapy may be required if ablation is ineffective.

References

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Disparities in Secondhand Smoke Exposure among Nonsmoking Adults in Rhode Island: Tobacco Control’s Pro-Equity Approach

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Secondhand smoke (SHS) is defined as smoke from burning tobacco products.¹ There is no risk-free level of exposure to SHS.² SHS exposure can cause heart disease and lung cancer, resulting in 41,000 deaths each year among nonsmokers.³ SHS exposure increases risk of sudden infant death syndrome and frequency and severity of child asthma attacks.¹ Non-smokers can be exposed to SHS in public places, worksites, homes, or vehicles. Eliminating SHS is one of four components of state-based tobacco control.⁴ SHS exposure among US nonsmokers declined from 88% in 1988-1991 to 25% in 2011-2012.¹ This is likely attributable to comprehensive smoke-free laws, declining cigarette smoking rates, increased voluntary smoke-free home rules, and changes in social norms. Despite progress, persistent disparities in SHS exposure suggest an unequal public health benefit. Among US nonsmokers, SHS exposure remains higher among children, non-Hispanic blacks, persons in poverty, and renters.¹

Rental status functions as a proxy for residence in multi-unit housing (MUH) [e.g., apartment, condo].⁵ Comprehensive smoke-free laws do not cover private settings like the home or multiunit buildings. MUH residents in buildings without smoke-free policies are uniquely susceptible to SHS due to smoke drift from nearby units. Among US multiunit residents with smoke-free home rules, 34% reported involuntary SHS exposure from smoke drifting into their unit.⁵ SHS exposure in subsidized MUH [e.g., Public Housing Authorities [PHAs], affordable housing] is of particular concern because many residents [i.e., disabled, adults with chronic disease, elderly, children] are more sensitive to SHS.⁶ Rhode Island’s Tobacco Control Program (RITCP) monitors self-reported SHS exposure to measure compliance to smoke-free laws and inform initiatives that advance tobacco control and health equity. We aimed to 1) examine SHS exposure by three sources among RI nonsmoker adults, 2) examine exposures over time, and 3) identify disparities in exposure.

METHODS

We combined five years (2011-2015) of weighted data from the RI Behavioral Risk Factor Surveillance System (BRFSS) and limited the analytic sample to adults who did not currently smoke cigarettes (n=25,746). BRFSS is conducted annually by the RI Department of Health with support from the Centers for Disease Control and Prevention (CDC). BRFSS uses a multistage cluster design based on random digit dialing of landline and cell phones to select a representative sample from each state’s non-institutionalized civilian population aged ≥18 years.

We determined the proportion of nonsmoking adults exposed to SHS by three sources: 1) their home [defined as someone else smoking tobacco in their home during the past 7 days], 2) smoke drift [defined as tobacco smoke drifting into their unit from a smoker in another unit or outside during the past 30 days], and 3) an indoor public place [defined as breathing in smoke from someone else in a public place [e.g., stores, restaurants, bars, casinos, clubs, sports arenas] during the past 7 days, not counting times at work]. Each exposure source was cross-tabulated by demographics and housing information. SHS variables were derived from state-added questions asked in varying years from 2011-2015. Smoke drift exposure was asked of adults who reported living in an apartment, condo/townhouse, or duplex. Respondents who reported living in a single-family home were coded as not exposed to smoke drift. Significant differences between groups were determined from non-overlapping confidence intervals [CIs]. Analyses were conducted in SAS Version 9.4.

RESULTS

Home exposure among nonsmokers decreased from 7.0% [95%CI=6.4-7.9] in 2011 to 3.1% [95%CI=2.8-3.4] in 2015 [Figure 1]. Smoke drift exposure among nonsmokers decreased from 4.8% in 2011 [95%CI=3.8-5.8] to 4.0% [95%CI=3.0-4.9] in 2015. Indoor public place exposure among nonsmokers decreased from 16.1% [95%CI=15.3-16.9] in 2011 to 12.0% [95%CI=10.9-13.2] in 2015. Decreases were not significant, but indoor public place exposure approached significance. Smoke drift was additionally examined using only nonsmoking MUH residents as the denominator (n=5,243). Prevalence of smoke drift [combined 2011-2015] among MUH residents was 19.9% [Figure 2].

Significant differences were found for exposure source by nonsmoker characteristics [Table 1]. Home exposure was higher among young adults (18-24), adults with less education [high school], low-income adults (<$25,000) than higher-income adults ($≥50,000), and renters versus owners. Smoke drift exposure was higher among young adults (18-24) than older adults (≥65), non-Hispanic blacks, Hispanics, and other non-Hispanic race groups compared to whites, low-income adults, adults with less education, and renters. Indoor public place exposure was higher among males, young adults (18-24) than older adults (≥45), Hispanic adults than white adults, adults with less education, and low-income adults ($≤25,000) than higher-income adults ($≥75,000).
RI has strong smoke-free laws and policies that protect non-smokers. In 2004, RI was the 7th state to pass a comprehensive smoke-free law banning smoking in indoor public places such as worksites, restaurants, and bars. Comprehensive smoke-free laws reduce heart attack and asthma hospitalizations among nonsmokers, and are one of the most effective tobacco control interventions because they synergistically reduce SHS exposure, change smoking norms, prevent initiation, and promote cessation.4,7 Most (23/25) RI PHAs voluntarily adopted smoke-free policies before the recent Housing and Urban Development (HUD) rule requiring PHAs to go smoke-free by July 2018.6 Adult smoking declined 23% from 2011–2015,8 and 79.4% of Rhode Islanders have voluntary smoke-free home rules.9 All of these protective factors contribute to the increasing majority of nonsmokers protected from SHS. From 2011–2015, 94.8% of nonsmokers reported no exposure in their home and 85.8% reported no exposure in an indoor public place.

Despite substantial success, this report shows that progress has not been the same for everyone. SHS exposure was higher among adults of low socioeconomic status, racial/ethnic minorities, young adults, and renters. SHS exposure occurred most frequently in an indoor public place, followed by the home, and then by smoke drift in MUH. While exposure from all sources declined from 2011–2015, declines were small and may indicate slowing progress as the remaining burden of SHS exposure becomes more concentrated among vulnerable populations. Of all exposure sources, smoke drift exposure showed the least change, highlighting the need for smoke-free policies (similar to PHAs) in the affordable MUH environment.

SHS exposure among nonsmokers underscores the disproportionate impact tobacco has on low-income persons and racial/ethnic minorities, regardless of whether one smokes or not. Across exposure sources, reported exposure was notably higher among nonsmokers earning ≤$25,000 than nonsmokers earning ≥$75,000. While Hispanics smoke less than whites,6 Hispanics were four times more likely to report smoke drift exposure than whites, and about two times more likely to report indoor public place exposure. Young adults (18–24) smoke less than older adults,8 but 20.1% of nonsmoking young adults reported exposure in an indoor public place and 11.6% reported exposure at home. Indoor public place exposure may be partially explained by poor compliance among certain businesses, or by visits to establishments exempt from the law (i.e., casinos, smoking bars). For example, qualifying hookah lounges are allowable under the smoking bar exemption, potentially exposing nonsmoking young adults. Further research (beyond single-item measures) is needed to better understand where and why certain nonsmokers are exposed more than others.

Findings are subject to at least four limitations. BRFSS is based on self-report and vulnerable to recall bias or measurement error. Missing data may have resulted in underestimation of SHS exposure. Exposure to secondhand aerosol from electronic nicotine delivery systems was not assessed. Small sample sizes limited reliability of estimates for non-Hispanic black nonsmokers.

About 20% of nonsmoking adults in MUH reported smoke drift exposure. Exposure was higher among renters and low-income adults. HUD’s recent smoke-free rule for PHAs does not extend to other affordable MUH. Smoke-free policies are legally permissible in these settings, but voluntary. Data from this report have policy and practice implications relevant to physicians, MUH staff, and tobacco control. Physicians should ask if a patient lives in MUH when evaluating risk for SHS exposure. Physicians can advise nonsmoking patients to avoid indoor areas where smoking occurs [including hookah lounges]. In addition to promoting quitting, physicians can influence protective social norms by advising smokers to adopt smoke-free rules in homes. MUH companies can protect nonsmokers by replicating RI PHA's policies.

**DISCUSSION**

RI has strong smoke-free laws and policies that protect non-smokers. In 2004, RI was the 7th state to pass a comprehensive smoke-free law banning smoking in indoor public places such as worksites, restaurants, and bars. Comprehensive smoke-free laws reduce heart attack and asthma hospitalizations among nonsmokers, and are one of the most effective tobacco control interventions because they synergistically reduce SHS exposure, change smoking norms, prevent initiation, and promote cessation.4,7 Most (23/25) RI PHAs voluntarily adopted smoke-free policies before the recent Housing and Urban Development (HUD) rule requiring PHAs to go smoke-free by July 2018.6 Adult smoking declined 23% from 2011–2015,8 and 79.4% of Rhode Islanders have voluntary smoke-free home rules.9 All of these protective factors contribute to the increasing majority of nonsmokers protected from SHS. From 2011–2015, 94.8% of nonsmokers reported no exposure in their home and 85.8% reported no exposure in an indoor public place.

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voluntarily adoption of smoke-free policies. RITCP's pro-equity approach to eliminate SHS exposure includes smoke-free policy technical assistance (TA) for PHAs and other affordable MUHs. RITCP launched “Live Smoke Free” in 2011 in response to smoke drift complaints from PHA and other MUH residents, and currently provides no-cost workshops and individual TA. Finally, RI tobacco control interventions can simultaneously reduce socioeconomic disparities in smoking and SHS exposure by extending smoke-free policies to affordable MUHs and strategically promoting cessation services to low-income residents through on-site services, referrals to the Quitline, and health systems changes that remove barriers to cessation coverage by public and private insurers.

References
1. CDC. Secondhand Smoke (SHS) Facts. Available at: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/general_facts/

Authors
Elsa Larson, PhD, MS, is the Program Evaluator for the Tobacco Control Program, Rhode Island Department of Health.
Benvinda Santos, MPA, is the Community Coordinator for the Tobacco Control Program, Rhode Island Department of Health.

Table 1. Secondhand Smoke Exposure among RI Nonsmoking Adults by Exposure Source, 2011-2015

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Home</th>
<th>Smoke Drift</th>
<th>Indoor Public Place</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>weighted % (95% CI)</td>
<td>weighted % (95% CI)</td>
<td>weighted % (95% CI)</td>
</tr>
<tr>
<td>Combined Year Prevalence (2011-2015)</td>
<td>5.2%</td>
<td>5.1%</td>
<td>14.2%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4.4 (3.6 - 5.3)</td>
<td>5.4 (4.8 - 6.1)</td>
<td>12.1 (10.8 - 13.5)</td>
</tr>
<tr>
<td>Male</td>
<td>6.0 (4.7 - 7.4)</td>
<td>4.6 (3.7 - 5.5)</td>
<td>16.7 (14.7 - 18.6)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>11.6 (7.4 - 15.7)</td>
<td>6.2 (4.2 - 8.2)</td>
<td>20.1 (14.9 - 25.5)</td>
</tr>
<tr>
<td>25-44</td>
<td>4.8 (3.3 - 6.2)</td>
<td>7.2 (5.8 - 8.5)</td>
<td>17.2 (14.8 - 19.7)</td>
</tr>
<tr>
<td>45-64</td>
<td>4.1 (3.4 - 4.7)</td>
<td>4.3 (3.7 - 4.9)</td>
<td>12.6 (11.2 - 14.0)</td>
</tr>
<tr>
<td>65+</td>
<td>3.6 (2.9 - 4.3)</td>
<td>2.8 (2.4 - 3.3)</td>
<td>9.2 (7.9 - 10.6)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>4.9 (4.0 - 5.7)</td>
<td>3.3 (2.9 - 3.7)</td>
<td>12.7 (11.5 - 14.0)</td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>5.6 (2.4 - 8.9)</td>
<td>14.1 (7.5 - 20.8)</td>
<td>19.9 (13.5 - 26.3)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4.8 (2.6 - 7.0)</td>
<td>12.9 (10.2 - 15.5)</td>
<td>21.9 (17.4 - 26.3)</td>
</tr>
<tr>
<td>Other Race, Non-Hispanic</td>
<td>9.7 (5.2 - 14.1)</td>
<td>8.1 (5.7 - 10.5)</td>
<td>16.1 (11.1 - 21.1)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ High School</td>
<td>6.6 (5.2 - 8.1)</td>
<td>7.1 (5.9 - 8.2)</td>
<td>17.8 (15.6 - 20.1)</td>
</tr>
<tr>
<td>≥ Some College</td>
<td>4.3 (3.4 - 5.1)</td>
<td>3.8 (3.3 - 4.3)</td>
<td>11.9 (10.7 - 13.1)</td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ $25,000</td>
<td>7.8 (5.8 - 9.8)</td>
<td>11.5 (9.8 - 13.3)</td>
<td>19.5 (16.6 - 22.4)</td>
</tr>
<tr>
<td>$25,000-$49,999</td>
<td>6.5 (4.4 - 8.6)</td>
<td>6.2 (4.7 - 7.7)</td>
<td>14.7 (12.2 - 17.1)</td>
</tr>
<tr>
<td>$50,000-$74,999</td>
<td>4.0 (2.7 - 5.3)</td>
<td>2.9 (2.1 - 3.7)</td>
<td>14.8 (11.8 - 17.7)</td>
</tr>
<tr>
<td>≥ $75,000</td>
<td>2.9 (2.1 - 3.8)</td>
<td>1.4 (0.9 - 1.9)</td>
<td>10.8 (9.1 - 12.5)</td>
</tr>
<tr>
<td>Rental Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rent</td>
<td>7.5 (5.9 - 9.1)</td>
<td>16.6 (14.7 - 18.4)</td>
<td>--</td>
</tr>
<tr>
<td>Own</td>
<td>3.8 (3.1 - 4.4)</td>
<td>1.4 (1.1 - 1.7)</td>
<td>--</td>
</tr>
<tr>
<td>Children in Home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4.6 (2.9 - 6.2)</td>
<td>5.0 (3.9 - 6.1)</td>
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</tr>
<tr>
<td>No</td>
<td>5.5 (4.7 - 6.3)</td>
<td>5.1 (4.5-5.7)</td>
<td>--</td>
</tr>
</tbody>
</table>

*estimates for groups are statistically unreliable (RSEs between 20-30%) and must be interpreted with caution. Data Source: 2011-2015 RI BRFSS
# Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data from the Division of Vital Records

## Reporting Period

**November 2016**

<table>
<thead>
<tr>
<th>VITAL EVENTS</th>
<th>Number</th>
<th>Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live Births</td>
<td>940</td>
<td></td>
</tr>
<tr>
<td>Deaths</td>
<td>810</td>
<td></td>
</tr>
<tr>
<td>Infant Deaths</td>
<td>5</td>
<td>4.8#</td>
</tr>
<tr>
<td>Neonatal Deaths</td>
<td>5</td>
<td>3.9#</td>
</tr>
<tr>
<td>Marriages</td>
<td>444</td>
<td>6.7*</td>
</tr>
<tr>
<td>Divorces</td>
<td>232</td>
<td>2.9*</td>
</tr>
<tr>
<td>Induced Termination</td>
<td>161</td>
<td>190.8#</td>
</tr>
<tr>
<td>Spontaneous Fetal Deaths</td>
<td>53</td>
<td>45.8#</td>
</tr>
<tr>
<td>Under 20 weeks gestation</td>
<td>46</td>
<td>39.6#</td>
</tr>
<tr>
<td>20+ weeks gestation</td>
<td>7</td>
<td>6.2#</td>
</tr>
</tbody>
</table>

**12 Months Ending With November 2016**

<table>
<thead>
<tr>
<th>VITAL EVENTS</th>
<th>Number</th>
<th>Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live Births</td>
<td>11,625</td>
<td></td>
</tr>
<tr>
<td>Deaths</td>
<td>9,931</td>
<td></td>
</tr>
<tr>
<td>Infant Deaths</td>
<td>56</td>
<td>4.8#</td>
</tr>
<tr>
<td>Neonatal Deaths</td>
<td>45</td>
<td>3.9#</td>
</tr>
<tr>
<td>Marriages</td>
<td>7,070</td>
<td>6.7*</td>
</tr>
<tr>
<td>Divorces</td>
<td>3,049</td>
<td>2.9*</td>
</tr>
<tr>
<td>Induced Termination</td>
<td>2,218</td>
<td>190.8#</td>
</tr>
<tr>
<td>Spontaneous Fetal Deaths</td>
<td>532</td>
<td>45.8#</td>
</tr>
<tr>
<td>Under 20 weeks gestation</td>
<td>460</td>
<td>39.6#</td>
</tr>
<tr>
<td>20+ weeks gestation</td>
<td>72</td>
<td>6.2#</td>
</tr>
</tbody>
</table>

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

## Underlying Cause of Death Category

**May 2016**

<table>
<thead>
<tr>
<th>Underlying Cause of Death Category</th>
<th>Number (a)</th>
<th>Number (a)</th>
<th>Rates (b)</th>
<th>YPLL (c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diseases of the Heart</td>
<td>190</td>
<td>2,382</td>
<td>225.5</td>
<td>3,916.0</td>
</tr>
<tr>
<td>Malignant Neoplasms</td>
<td>59</td>
<td>2,253</td>
<td>213.3</td>
<td>5,454.5</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>35</td>
<td>434</td>
<td>41.1</td>
<td>500.0</td>
</tr>
<tr>
<td>Injuries (Accident/Suicide/Homicide)</td>
<td>82</td>
<td>864</td>
<td>81.8</td>
<td>12,399.0</td>
</tr>
<tr>
<td>COPD</td>
<td>45</td>
<td>469</td>
<td>44.4</td>
<td>427.5</td>
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</table>

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<td></td>
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<td>427.5</td>
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(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 1,056,298 (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.
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Contact Sarah if you’ve missed an issue, sstevens@rimed.org.
Working for You: RIMS advocacy activities

April 3, Monday
Meeting with Department of Health regarding Diabetes Prevention Programs/RIMS grant
RIMS Council meeting:
Sarah J. Fessler, MD, President

April 4, Tuesday
RIMS Physician Health Committee:
Herbert Rakatansky, MD, Chair
Meeting with Department of Health regarding opioid regulations
RIMS Weight + Wellness Planning Committee wrap-up meeting
Legislative hearings

April 5, Wednesday
Workers Compensation Advisory Council Legislative Hearings

April 6, Thursday
Meeting of the End of Life Task Force
Legislative Hearings
Chairman Jacquard

April 7, Friday
Telephone interview with researchers from Boston Medical Center regarding Governor’s Opioid Task Force
Meeting with House of Representatives policy staff regarding RIMS’ Legislative Agenda: Michael E. Migliori, MD, Public Laws Chair

April 11, Tuesday
Presentation by American Academy of Physician Assistants to Massachusetts/Rhode Island MGMA
Meeting of the RI Department of Health Physician Assistant Licensing Board
Town Hall Meeting, RI Academy of PAs
Legislative hearings: Michael E. Migliori, MD, Public Laws Chair

April 12, Wednesday
Board of Medical Licensure and Discipline
Meeting of the Governor’s Opioid Overdose Prevention Task Force:
Sarah J. Fessler, MD, President;
Gary Bubly, MD, Past President
Meeting of Department of Labor and Training’s Workers Compensation Fee Task Force: Sidney Migliori, MD, President RI Orthopedic Society; RIMS staff
Meeting of RIMS Foundation Strategic Planning
Legislative hearings

April 13, Thursday
Legislative hearings
SIM Grant Steering Committee:
Peter A. Hollmann, MD, Vice President
RIMS Mix and Mingle

April 19–22, Wednesday–Saturday
Federation of State Physician Health Plans, Fort Worth, Texas: RIMS staff

April 19, Wednesday
RI Department of Health’s Primary Care Physician Advisory Committee
Meeting with Healthcentric Advisors regarding CMS Physician Quality Payment Program
RIMS’ Diabetes Physician Grant
Physician Advisory Committee: Roberto Ortiz, MD, and Sarah J. Fessler, MD, co-chairs

April 20, Thursday
Meeting with Senate policy staff regarding proposed amendments to current legislation

April 22, Saturday
RIMS annual CME event: Building Practitioner Resilience in Challenging Times; Russell E. Settipane, MD, Membership Committee CME Task Force Chair

April 24, Monday
Meeting with Blue Cross Blue Shield medical directors: Sarah J. Fessler, MD, President, Bradley J. Collins, MD, President-elect, and RIMS staff

April 25, Tuesday
Finance Committee:
Jose R. Polanco, MD, Chair
Legislative hearings

April 26, Wednesday
Workers Compensation Advisory Council Legislative Hearings
Meeting of RIMS Foundation Strategic Planning
Representative Corvese Fundraiser

April 27, Thursday
Legislative Hearings
YMCA Heroes
Meeting with Director, RI Department of Health regarding new opioid prescribing regulations
Chairman Keable Fundraiser

April 28, Friday
Department of Health Bridging Health Equity Across Communities reception at the State House

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Meeting with Senate policy staff regarding proposed amendments to current legislation

April 22, Saturday
RIMS annual CME event: Building Practitioner Resilience in Challenging Times; Russell E. Settipane, MD, Membership Committee CME Task Force Chair

April 24, Monday
Meeting with Blue Cross Blue Shield medical directors: Sarah J. Fessler, MD, President, Bradley J. Collins, MD, President-elect, and RIMS staff

April 25, Tuesday
Finance Committee:
Jose R. Polanco, MD, Chair
Legislative hearings

April 26, Wednesday
Workers Compensation Advisory Council Legislative Hearings
Meeting of RIMS Foundation Strategic Planning
Representative Corvese Fundraiser

April 27, Thursday
Legislative Hearings
YMCA Heroes
Meeting with Director, RI Department of Health regarding new opioid prescribing regulations
Chairman Keable Fundraiser

April 28, Friday
Department of Health Bridging Health Equity Across Communities reception at the State House
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The Rhode Island Medical Society continues to drive forward into the future with the implementation of various new programs. As such, RIMS is expanded its Affinity Program to allow for more of our colleagues in healthcare and related business to work with our membership. RIMS thanks these participants for their support of our membership.

Contact Marc Bialek for more information: 401-331-3207 or mbialek@rimed.org
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Contact Mark Bialek, Director of Membership

A Rhode Island Academy of Physician Assistants (RIAPA) town hall meeting was held April 11 at Kent Hospital on PA practice in the state. Representatives from the state and national PA organizations and the Rhode Island Department of Health and the Rhode Island Medical Society participated in a series of meetings and updates on recertification and looking at the future of PA practice in the state.

A RIMS Mix and Mingle event was held at the Chapel Grille restaurant in Cranston on April 11.
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Care New England announces layoffs at W&I, Kent, Butler, VNA

Care New England (CNE) Health System announced on April 26 that as a result of ongoing financial challenges, additional staff restructuring has been implemented. Notifications were made this week affecting a wide array of staff across the system, including clinical and non-clinical, union and non-union employees. The vast majority of the FTE reductions took place at Women & Infants Hospital; however, there was some impact at Kent and Butler hospitals, as well as the VNA of Care New England.

This action follows extensive efforts to improve the cost structure across Care New England over recent years, including improvements to the system’s revenue cycle, growth of volume where possible in key service lines, and expense management. Despite these efforts, Care New England continues to face significant financial challenges.

“Today’s announcement marks a difficult yet necessary step in what has been a challenging period for CNE,” said Jim Beardsworth, system director of communications. “We continue to make significant progress in our efforts to right our ship but that comes with careful and painful decisions affecting dedicated and hard-working people. It is important to note that these actions are not related to recent partnership announcements; these decisions are the result of an ongoing and exhaustive review of our operations. CNE management has determined that reducing the workforce is a fundamental necessity given our current environment and unwavering delivery of our mission to our patients through our valued and highly regarded hospitals, services and community-based programs.”

Specific to Women & Infants Hospital

“At Women & Infants and across Care New England, we have undertaken extensive measures to improve our financial stability while trying to minimize the impact on labor. Unfortunately, it has not been enough, as we have continued to experience reduced volumes due to changing demographics, reduced inpatient neonatal care, a declining birth rate, and a decrease in reimbursements,” said MARK R. MARCATANTO, president and chief operating officer at Women & Infants Hospital. “We must adapt to significant changes in health care delivery and payment, such as decreased population and births, and advances that change the way we provide care. Our payer mix is worsening, and the volume in the NICU is likely not going to recover to the levels that we previously experienced, which presents new challenges as this is a trend being seen elsewhere across the country. The irony, of course, is that this trend is good news from a public health perspective that there are fewer sick and premature infants. Unfortunately, that good news does have a significant impact on our financial health under our current payment systems.”

Butler, Kent hospitals and VNA

While also experiencing some changes associated with today’s announcement, DR. LAWRENCE PRICE, president, Butler Hospital and DR. MICHAEL DACEY, president, Kent Hospital, and KATHLEEN PEIRCE, vice president of operations, executive director and chief nursing officer, VNA of Care New England, issued this statement, expressing optimism in the face of these immediate changes. “We are in the midst of enormous change in health care in Rhode Island and across the nation. Although extremely painful, these actions are intended to improve our ability to serve our patients well into the future as we react to the continuing shift in the landscape of health care.”

Rhode Island Medical Journal Submissions

The Rhode Island Medical Journal is a peer-reviewed, electronic, monthly publication, owned and published by the Rhode Island Medical Society for more than a century. It is indexed in PubMed within 48 hours of publication. The authors or articles must be Rhode Island-based. Editors welcome submissions in the following categories:

CONTRIBUTIONS

Contributions report on an issue of interest to clinicians in Rhode Island. Topics include original research, treatment options, literature reviews, collaborative studies and case reports. Maximum length: 2000 words and 20 references. PDFs or Jpegs (300 dpi) of photographs, charts and figures may accompany the case, and must be submitted in a separate document from the text. Color images preferred.

POINT OF VIEW

The writer shares a perspective on any issue facing clinicians (eg, ethics, health care policy, patient issues, or personal perspectives). Maximum length: 600 words.

IMAGES IN MEDICINE

Authors submit an interesting image or series of images (up to 4), with an explanation of no more than 400 words.

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Care New England, Partners HealthCare explore merger

PROVIDENCE – Care New England Health System (CNE) announced on April 19th it has signed a Letter of Intent (LOI) to affiliate with Partners HealthCare of Massachusetts, and to negotiate exclusively with Partners.

The LOI sets forth a process to negotiate a transaction pursuant to which CNE will become part of Partners. Both organizations will continue to work together as the process moves into the next phase – developing and signing a definitive agreement. Following this phase, it is expected the organizations would move forward with the needed state and federal regulatory approvals.

The CNE Board of Directors selected Partners after an expedited review of more than 12 state, regional and national health care organizations, including for-profit and not-for-profit entities.

Care New England has maintained a close working relationship with Partners HealthCare since 2009 through a clinical affiliation with Brigham and Women’s Hospital (one of the founding members of Partners) in cardiology, and vascular, thoracic and colorectal surgery.

In addition, there has been a longstanding collaborative and collegial relationship between McLean Hospital (a Partners hospital) and Care New England’s Butler Hospital.

The LOI includes Kent Hospital, Women & Infants Hospital, the VNA of Care New England, Butler Hospital and The Providence Center in several Rhode Island locations. Under the proposal, the strong educational and research relationship that CNE has fostered with Brown University will continue to play a critical role.

“Today’s announcement represents the positive results of an extremely careful and deliberate process intended to ensure the best clinical, financial, and strategic direction forward for CNE,” said Board Chair CHARLES R. REPPUCCI.

Said CNE President and CEO DENNIS KEEFE, “This is a tremendous opportunity for both organizations to further advance their commitment to high-quality health care, access to leading-edge clinical treatment, world-class academics, and most importantly, enhanced opportunities for patients.”

In a media conference call following the announcement, Keefe said he hopes the two sides can reach an agreement within a three-month time span, which would then be followed by the regulatory review process.

“As health reform here and across the nation evolves, providers are developing more regional strategies and this affiliation between Partners and Care New England is a natural step in that evolution,” said Partners HealthCare President and CEO DAVID TORCHIANA, MD. “Today’s announcement is the beginning of a process that will better meet the needs of this region’s patients by improving access to specialized care while working to create new efficiencies in the delivery of that care.”

About Partners

Partners HealthCare is an integrated health system founded by Brigham and Women’s Hospital and Massachusetts General Hospital. In addition to its two academic medical centers, the Partners system includes community and specialty hospitals, community health centers, a physician network, a managed care organization, home health and long-term care services, and other health-related entities. Partners is one of the nation’s leading biomedical research organizations and a principal teaching affiliate of Harvard Medical School. Partners HealthCare is a non-profit organization.

About CNE

CNE was founded in 1996, and today it is the parent organization of Butler Hospital, Kent Hospital, Memorial Hospital of Rhode Island, Women & Infants Hospital of Rhode Island, the VNA of Care New England, The Providence Center, and Integra, a certified accountable care organization (ACO) created in collaboration with the Rhode Island Primary Care Physicians Corporation. Care New England includes 970 licensed beds and 216 infant bassinets. Through Butler, Memorial and Women & Infants, Care New England has a teaching and research affiliation with The Warren Alpert Medical School of Brown University. Kent is a teaching affiliate of the University of New England College of Osteopathic Medicine, located in Maine.
OffICE SPACE AVAIlABlE

The Rhode Island Medical Society has 442 square feet of newly renovated office space (3 contiguous offices of 200 sq ft, 121 sq ft and 121 sq ft), complete with convenient sheltered parking and the opportunity for tenants to share three well-equipped meeting spaces, break room, office machinery, etc. on the western edge of downtown Providence. Suitable for a small non-profit organization, boutique law firm, CPA firm or other office-based small business.

Inquiries to Newell Warde, nwarde@rimed.org

Care New England, Prime Healthcare Foundation sign letter of intent for Memorial Hospital sale

PROVIDENCE – Care New England Health System (CNE), announced on April 19 it has selected Prime Healthcare Foundation to pursue an acquisition of Memorial Hospital in Pawtucket, RI. The CNE Board has voted unanimously to sign a Letter of Intent (LOI) with the non-profit Prime Healthcare Foundation, a 501(c)3 public charity.

Prime Healthcare Foundation’s 14 hospitals are affiliated with Prime Healthcare, based in Ontario, California with 44 hospitals in 14 states.

With the LOI in place, both parties will now negotiate with the purpose of developing a definitive agreement and moving forward with needed approvals, including state and federal regulatory processes. The proposed transaction is expected to culminate in Prime Healthcare Foundation assuming control of Memorial Hospital, taking over operations of the hospital, and providing significant investment in Memorial post-closing.

CNE Board Chair CHARLES R. REPPUCCI said, “The path to today’s selection of Prime Healthcare Foundation by CNE has long been about ensuring that the important needs of the community and the employees continue to be met. Not only does this proposal ensure the continuity of acute care services for this community, but it also maintains a local hospital board, commitment to existing services, the medical residency program, and continued opportunity for the staff of Memorial Hospital.”

“It is certainly no secret that we have had significant financial challenges here,” said CNE President and CEO DENNIS KEEFE. “But at the same time it has been clear there is an important obligation to maintain the care and services offered to those in and around Pawtucket. The only way for this to continue is through the partnership we announce today with Prime Healthcare Foundation. It represents an extremely positive outcome with tremendous opportunity ahead.”

Prime Healthcare is a national, for-profit hospital system with 44 acute-care hospitals providing nearly 43,500 jobs in 14 states. The potential acquisition of Memorial Hospital will complement the Prime Healthcare’s existing presence in Rhode Island with Landmark Medical Center and The Rehabilitation Hospital of Rhode Island, located in Woonsocket and North Smithfield.

“Prime Healthcare’s motto is saving hospitals, saving jobs and saving lives, and we are confident Memorial Hospital will grow stronger under our management,” said PREM REDDY, MD, chairman, president and CEO of Prime Healthcare. “We look forward to working with the Memorial Hospital employees, nurses and physicians, and ensuring that the community and patients continue receiving exceptional care and service.”

Memorial Hospital of Rhode Island is a 294-bed community teaching hospital that has served northern Rhode Island and southeastern Massachusetts since 1901. A teaching affiliate of The Warren Alpert Medical School of Brown University, Memorial is the main site for the medical school’s residency programs.

In 2013, Memorial joined Care New England Health System to expand the scope of services available to its patients and provide a strong primary care focus within the system.

SOLIC Capital Advisors, LLC serves as financial advisor to Care New England, and McDermott Will & Emery provides external legal counsel.

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CMS Selects Care New England for 5-year $3.9M ACO agreement

Care New England (CNE) has been selected by the Centers for Medicare & Medicaid Services (CMS) as the recipient of one of 32 national Accountable Health Communities model grants, awarding an anticipated $3.9 million for the five-year initiative focused on ensuring high-risk Medicare & Medicaid patients have access to high-quality health care services while also achieving cost savings.

The Integra Community Care Network, an accountable care organization comprised of CNE, Rhode Island Primary Care Physicians Corporation and South County Health, will serve as the bridge organization for the Integra Accountable Health Communities (AHC) Partnership in collaboration with and a broad, statewide network of clinical providers, community service organizations, academic institutions and governmental partners. Clinical sites will include Memorial Hospital, Women & Infants Hospital, Butler Hospital, South County Health, The Providence Center, CODAC Behavioral Health and CCAP Health Center.

Through the cooperative agreement, qualifying patients will be screened for specific health-related social needs at each clinical site. Participants will be screened for needs in the following core areas: housing, food insecurity, transportation, interpersonal violence, and utility needs. Additionally, participants will be screened for needs in the supplemental areas of substance use/addiction and independent living/caregiver support.

The overarching goal of the initiative is to impact the cost of health care and reduce avoidable health care utilization.

“Rhode Island is an ideal location to undertake this initiative because of our deep commitment to population health and to reaching beyond the traditional medical context to address health-related social needs,” said Dennis Keefe, president and CEO of Care New England. “Care New England, Integra and all of the partners provide a strong platform upon which to build and test the AHC program in cooperation with CMS.”

In addition to screening and navigation, the initiative will seek to increase Rhode Island Medicare and Medicaid beneficiaries’ awareness of community resources available to address unmet health-related social needs and improve statewide capacity to address health-related social needs through quality improvement, data collection and alignment of community-based resources.

“By addressing critical drivers of poor health and high health care costs, the model aims to reduce avoidable health care utilization, impact the cost of health care, and improve health and quality of care for Medicare and Medicaid beneficiaries,” said James Fanale, MD, executive vice president and chief clinical officer for Care New England and chief clinical officer for Integra. “The key to the success of this initiative is that everyone remains focused on ensuring that the necessary services and supports are available and responsive to the beneficiaries’ needs.”

This initiative will be overseen by an Advisory Board with representation from all members of the Integra AHC consortium. Alignment and integration of community resources will be led by a Community Services Council of major statewide organizations representing the core social determinant areas, including Rhode Island Coalition for the Homeless, Childhood Lead Action Project, RI Community Food Bank, Rhode Island Public Transit Authority, RI Coalition Against Domestic Violence, Rhode Island Community Action Coalition, among others.

RI receives $2.1 million in federal funds to stem opioid crisis

Funding will increase access to treatment, expand prevention efforts

PROVIDENCE – U.S. Senators Sheldon Whitehouse and Jack Reed and Congressmen Jim Langevin and David Cicilline recently announced $2,167,000 in federal funding for Rhode Island’s Department of Behavioral Healthcare, Developmental Disabilities and Hospitals (BHDDH) to stem the opioid epidemic. The federal funding is the result of $485 million in grants nationwide that was authorized by Congress last year in the 21st Century Cures Act.

The federal funding will increase access to lifesaving treatment and expand addiction prevention efforts, with the goal of reducing the growing number of prescription drug and opioid overdose-related deaths in Rhode Island. There were over 326 drug overdose deaths in the state last year and 290 deaths in 2015, according to the Rhode Island Department of Health.

“This vital funding is going to help ensure that tools and resources that are critical to fighting the drug overdose epidemic, such as naloxone, prevention education, and medication-assisted treatment, get to where they are needed most in Rhode Island. The funding that Senator Whitehouse fought for is also going to bring crucial support to our work to prevent fentanyl-related overdoses,” said Nicole Alexander-Scott, MD, Director of the Rhode Island Department of Health. “We have lost more than 1,200 lives to drug overdoses in the last five years. Every single one of those deaths was preventable. Addiction is a disease, but recovery is absolutely possible.”

In July, President Obama signed into law Whitehouse’s Comprehensive Addiction and Recovery Act (CARA), which established a range of policies to prevent and treat addiction to opioid drugs, including programs to increase education on drug use, to expand medication-assisted treatment, to improve prescription drug monitoring programs, to support those in recovery, and to promote comprehensive state responses to the opioid crisis.
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Updated opioid use regulations take effect in Rhode Island

Regulations aim to prevent overdoses through education and dosage limits for acute pain

Updated regulations intended to make the prescribing of opioids more judicious and safe in Rhode Island are now in effect, marking the implementation of a major component of the Strategic Plan developed by Governor Gina M. Raimondo’s Overdose Prevention and Intervention Task Force. “These updated pain management regulations focus on dosing limitations to help reshape how we as healthcare providers had been taught how to approach opioid therapy, and to make sure that we’re only prescribing what’s actually needed for the treatment of acute pain,” said NICOLE ALEXANDER-SCOTT, MD, MPH, director of the Rhode Island Department of Health (RIDOH). “While we work to minimize unnecessary prescribing of opioids for acute pain, it is essential that patients’ chronic pain needs are appropriately and compassionately treated. Although opioid prescribing in Rhode Island decreased by 16% between 2013 and 2015, which was the largest drop in the nation, the regulations were updated to ensure that acute pain and chronic pain are treated differently.”

These updates do not affect the long-term treatment being received by patients with chronic pain. Examples of patients receiving chronic pain treatment include patients with cancer-associated pain diagnoses and patients in palliative/ nursing home care. Just as a patient with diabetes would not be abruptly removed from diabetes medication, a patient receiving opioids for chronic pain should not be removed too abruptly from pain medication, but transitioned in a way that is safe for the patient to an acceptable alternative over time. Acute pain is pain that comes on quickly and usually does not last longer than a few days, weeks, or months. Examples of causes of acute pain include dental work, a broken bone, and certain back injuries.

Highlights of the updated pain management regulations focusing on acute pain include:

- Requiring that initial prescriptions for acute pain be limited to 20 doses and no more than 30 morphine milligram equivalents per day;
- Prohibiting long-acting or extended-release opioids for initial prescriptions for acute pain;
- Documenting the results of a thorough medical history, developing a treatment plan, and accessing the Rhode Island Prescription Drug Monitoring Program (PDMP) for relevant prescription monitoring information, all prior to issuing an initial prescription for acute pain; and
- Requiring continuing education training for prescribers on topics such as appropriate prescribing for pain, pharmacology, potential for dependence, and alternatives to opioids for pain management.

RIDOH’s original pain management regulations were developed in 2015. The work of updating these regulations falls within the prevention strategy of the Governor’s Overdose Prevention and Intervention Task Force’s Strategic Plan. The other three focus areas of the plan are treatment, rescue, and recovery. The goal of the Strategic Plan is to reduce the number of overdose deaths in Rhode Island by one-third within three years.

RIDOH began work on updating the state’s pain management regulations after the Rhode Island General Assembly passed a law requiring tighter regulations on opioid prescribing.

To support the implementation of these updated regulations, RIDOH and Brown University’s Warren Alpert Medical School will offer education sessions in May. Providers will learn more about how to appropriately prescribe opioids and consider interdisciplinary approaches to treating patients with pain.

Substance-use disorder should be treated as a life-long disease, and substance-use disorder related to opioid use is no different. A greater level of compassion and understanding are called for when patients with opioid-use disorder transition from pain management medication to alternative treatment. Rhode Island offers alternative treatment options for opioid use disorder, including outpatient programs through the Rhode Island Centers of Excellence. The six Centers throughout the state provide Medication-Assisted Treatment (MAT), counseling, peer support, and vocational counseling. A local recovery hotline is also available to connect individuals in crisis with treatment and recovery support. People can call 401-942-STOP (7867) to receive treatment and recovery support 24 hours a day, seven days a week. English and Spanish-speaking counselors who are licensed in chemical-dependency are available.

More information:

- Rhode Island’s updated pain management regulations
- General information on safe opioid prescribing
- Dr. Alexander-Scott’s letter to prescribers
- Drug overdose death data
- Additional data: http://preventoverdoseri.org/
The documentary, “Warning: This Drug May Kill You,” which airs on HBO tonight, May 1, addresses the opioid crisis through the experiences of four families who have lost loved ones through addiction to heroin and/or prescription painkillers. Brown alum PERRI A. PELTZ, MPH, ’82, directed the film, which premiered in April at a Brown University School of Public Health event on population health.

In an opening segment, the film traces the roots of the opioid epidemic to the late 1990s, and illustrates this with a video of a physician speaking for Purdue Pharma (which first marketed OxyContin in 1996). He extols the efficacy and safety of the product for long-term use. Nine years later, the company pleaded guilty to misbranding and deceptive marketing practices and settled for $600 million in fines.

The “black-box warning” title of the documentary is fitting; at times it is excruciatingly painful to watch as you enter the homes and lives of the victims, whose stories are told through family members; in one segment, a young girl reviews how to administer Narcan, kept in the kitchen cabinet, in case her mom, Stephany, overdoses.

In the film, Stephany, who has just finished rehab, relates how she was prescribed Dilaudid, OxyContin and Vicodin for pain while being treated for kidney stones at the age of 16. She ended up sharing the pills with her sister, Ashley, and when they could no longer get prescriptions, they turned to the streets and heroin. It is a grim family story. Ashley fatally overdosed. Stephany eventually entered “A Way Out,” a 30-day state-sponsored rehab program involving local police departments.

Another segment of the documentary tells the story of Wynne, a mother of three, whose addiction to opioids began after a C-section. “Doctors were just throwing pills at her and she became a totally different person, like a Jekyll and Hyde. I had no idea what was going on,” her ex-husband Britt says.

After checking in and out of multiple rehab facilities, and millions of dollars spent in the recovery effort, Wynne seemed to be doing better, until she was hospitalized with kidney stones. She was discharged with pain meds and relapsed. Her two teenage sons found her the next morning, unresponsive. Their panicked efforts to revive her failed.

In the panel discussion after the film, Peltz said, “These are good people who are becoming addicted. It is a chronic brain disease. We need to remove the stigma of addiction; this is happening to 91 people a day. It could be any one of us.”

DR. JODY RICH, medical adviser to the statewide Overdose Prevention and Intervention Task Force, said that 90 percent of those addicted to drugs who enter rehab programs relapse, and that Medication Assisted Treatment (MAT) is one of the best tools currently available to address this. Treatment drugs include methadone, Suboxone (buprenorphine), and Vivitrol (naltrexone).

In Rhode Island, six centers throughout the state provide Medication-Assisted Treatment (MAT), peer-based recovery coaches and vocational counseling.

Following the film, a panel discussion included filmmaker Perry A. Peltz; Rebecca Boss, acting director of the Department of Behavioral Healthcare, Developmental Disabilities and Hospitals; Jody Rich, MD, professor of medicine and epidemiology, and Nicole Alexander-Scott, MD, MPH, director of the Rhode Island Department of Health. At right is the dean of the Brown School of Public Health Terrie “Fox” Wetle, who moderated the event.
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New fund to accelerate medical technologies toward market

Brown’s new Biomedical Innovation Fund has made two grants to accelerate the commercialization of technologies – one for diagnosing drug dependence in newborns and a second for discovering anti-ALS medicines.

PROVIDENCE – Often what’s needed to turn biomedical advances in the lab into innovations that reach patients through the marketplace is a proof-of-concept stage of funding that allows researchers to explore, develop and can realize their full potential,” Elias said. “Moreover, this targeted program creates an environment that fosters faculty enterprise and provides real-life scientific and entrepreneurial experience to our students.”

The new fund is supported by gifts from two donor couples: Brown parents WES AND LYNN EDENS, and alumni and parents DR. MARK AND RECIA KOTT BLUMENKRANZ.

Earlier this year, the University called for faculty members to apply for the first Biomedical Innovation Fund grants of up to $100,000 each. A committee reviewed the proposals and decided upon the two winning projects. The members of the review panel are venture capitalists Amir Nashat of Polaris, David Donabedian of the Longwood Fund, Gaye Bok of Excel Venture Management, Rich Horan of Slater Technology Partners and Gregory D. Jay, professor of emergency medicine and engineering.

Two technologies

One technology could help doctors diagnose a tragic and increasingly common condition among newborns: Neonatal Abstinence Syndrome (NAS), or the withdrawal symptoms that accompany some babies born to a mother with an opioid addiction, such as to prescription pain medications. Babies with NAS have a characteristic cry but measuring it has been, until now, a subjective task. Developed by psychiatry and human behavior and pediatric faculty members Barry Lester and Stephen Sheinkopf and Professor of Engineering Harry Silverman, a computer algorithm that analyzes baby cries could make diagnosis more systematic and reliable.

“This proof-of-concept project will enable us to collect data that would attract potential investors in the development of an automated, hand held ‘iPhone-like’ device,” they wrote in their application.

The other technology is a fruit fly, or Drosophila, model of the devastating neurodegenerative disease amyloid lateral sclerosis. The lab of Robert Reenan, professor of biology, has engineered ALS-causing genetic mutations in the flies and used that to discover further mutations in a “suppressor gene” that mitigates the harmful effects of the disease. The team will use that information to guide a search for “small molecule” compounds that can pharmacologically achieve similarly beneficial effects in the ALS flies.

“These suppressor mutations identify a class of conserved human gene counterparts as potential drug targets of relevance in neurodegenerative disorders such as ALS and dementia,” Reenan wrote. “In this grant, we will engineer Drosophila expressing proteins from these human gene counterparts and using a powerful ‘humanized’ model approach, we will interrogate the system using existing small molecules to identify ‘hits’.”

Katherine Gordon, managing director of Brown’s Technology Ventures Office, said the fund will help these projects and future ones overcome a gap that could otherwise leave them unready for licensing or commercialization.

Robert Reenan, in the lab with colleague Kristi Wharton, studies ALS using fruit flies engineered to genetically model the human disease.
AMA launches effort to increase and improve EHR training in medical schools

CHICAGO – With the majority of today’s physicians graduating from medical school without comprehensive training using electronic health records (EHR), the American Medical Association (AMA) and the Regenstrief Institute are collaborating to ensure more medical students and medical trainees gain real-world experience using EHRs during their training. Developed by Indiana University School of Medicine (IU) and the Regenstrief Institute as part of the AMA’s initiative to create the medical school of the future, the Regenstrief EHR Clinical Learning Platform will be disseminated by the AMA and Regenstrief to medical schools across the country.

The first-of-its kind platform uses real, de- and mis-identified patient data to safely allow students to virtually care for patients with multiple, complex health conditions by navigating records, documenting encounters, and placing orders within an application that is similar to the EHRs used in practice. It also provides an immersive and cutting-edge way for educators to teach students how EHRs can be used to address important issues pertaining to population health, quality improvement, patient safety and social determinants of health. The platform uniquely offers tools for educators to create customized content that is specific to their curriculum goals and also tools to evaluate students.

Providing medical students with the ability to use EHRs during their training is one of the innovations identified by the AMA’s 32-school Accelerating Change in Medical Education Consortium as necessary to the medical school of the future. As one of the founding Consortium schools, IU School of Medicine received a $1 million AMA grant to work with the Regenstrief Institute to develop a way to incorporate EHR training into its curriculum so it could be implemented by other medical schools. After more than a year of use by, and feedback from, IU medical students, the newly enhanced Regenstrief EHR Clinical Learning Platform – which uses real de- and mis-identified patient data from Eskenazi Health, one of the nation’s largest essential health care systems – is now available for widespread adoption. With support from the AMA, the Regenstrief Institute is actively working to engage medical educators from across the country to implement the EHR clinical learning platform into their medical schools’ curricula.
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RIMWA to honor Dr. Dennehy at annual meeting May 24

Penelope H. Dennehy, MD, will be honored by the Rhode Island Medical Women’s Association (RIMWA) as Woman Physician of the Year 2017 at the organization’s annual meeting. The event will take place on Wednesday, May 24, at the Providence Marriott Hotel. Reception will begin at 6 p.m., followed by the program and dinner beginning at 7 p.m. RSVP by May 5 to mbialek@rimed.org.

Dr. Dennehy is a professor of pediatrics at the Alpert Medical School and vice chair of pediatrics, division of pediatric infectious diseases at Rhode Island Hospital.

Sarah M. Davis, MD, named to Brown/W&I scholar program

Sarah M. Davis, MD, was recently named the seventh scholar in the Brown University/Women & Infants Hospital Women’s Reproductive Health Research (WRHR) Career Development Program. Dr. Davis has been a member of the Recognition Division of Maternal-Fetal Medicine at Women & Infants since 2015. She was selected as a WRHR scholar to support her research to study causes of preterm birth, specifically on a study entitled “Mechanisms underlying obstetric pathobiology: The study of cell-free fetal DNA, TLR9 mediated inflammation, IL-10 and parturition using human in vitro modeling.”

Dr. Deborah Myers honored by Society of Gynecologic Surgeons

Deborah L. Myers, MD, FACOG, director of the Division of Urogynecology and Reconstructive Pelvic Surgery at Women & Infants Hospital and professor of obstetrics and gynecology at The Warren Alpert Medical School has recently received the Distinguished Surgeon Award at the 43rd Annual Scientific Meeting of the Society of Gynecologic Surgeons (SGS).

Dr. Myers is vice chair of the Department of Obstetrics and Gynecology and director of Continuing Medical Education at Women & Infants and chair of the promotions committee of the Department of Ob/Gyn at the Warren Alpert Medical School. She is past president of the national American Urogynecologic Society.

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South County Hospital earns A's for hospital quality, patient safety

For the fifth consecutive year, South County Hospital in Wakefield, RI, part of South County Health, earned straight A’s for hospital quality and patient safety. The Leapfrog Group, the nation’s leading nonprofit watchdog on hospital quality and safety, made the announcement after completing a review of 30 measures of publicly available hospital safety data. The performance measures produce a single score representing a hospital’s overall performance in keeping patients safe from preventable harm and medical errors. South County Hospital is one of only 63 hospitals nationwide to attain the straight A rating and the only hospital in Rhode Island to earn straight A’s for five consecutive years.

“The fact that we’re one of the few hospitals in the country to earn straight A’s in patient safety speaks to the efforts we make every day to ensure that patient care is our number one priority,” said Lou Giancola, president and CEO of South County Health.

Southcoast hospitals receive ‘A’ grades for patient safety

Southcoast Health has been awarded an “A” grade in the Spring 2017 Hospital Safety Grades, which rates how well hospitals protect patients from preventable medical errors, injuries and infections within the hospital. Southcoast Health’s three hospitals – St. Luke’s Hospital in New Bedford, Charlton Memorial Hospital in Fall River and Tobey Hospital in Wareham – were each recognized with the top rating.

The Leapfrog Hospital Safety Grades assign A, B, C, D and F letter grades to hospitals nationwide. St. Luke’s, Charlton Memorial and Tobey were three of 823 hospitals to receive an “A” for its commitment to reducing errors, infections, and accidents that can harm patients.

Miriam’s Center for Bariatric Surgery reaccredited

The Center for Bariatric Surgery at The Miriam Hospital has been reaccredited by the national board that evaluates medical centers specializing in surgery for severe obesity.

Siva Vithiananthan, MD, chief of minimally invasive and bariatric surgery for the center, a program of The Miriam and Rhode Island Hospitals, announced that it had secured reaccreditation as a Comprehensive Center with Adolescent Qualifications by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP®) a joint program of the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMB).

To gain dual accreditation for adults and adolescents, the center demonstrated that it meets standards that ensure that bariatric surgical patients receive a multidisciplinary program that improves patient outcomes and long-term success through preoperative and postoperative care designed specifically for patients.

While the demand for bariatric surgery is not necessarily on the rise nationally, according to Vithiananthan, he said the center based at The Miriam Hospital continues to see its numbers grow steadily, with the number of procedures increasing about 15 to 20 percent a year. The center, established in 2012, is on pace to perform nearly 400 in 2017.

Obituaries

DR. KHALIL BIDADI passed away peacefully on April 12, 2017 at the age of 71. He is survived by his beloved wife Nahideh Nina Bidadi, son Ben Bidadi and wife Sheila and grandson Louis, son Brian Bidadi and wife Daria, and precious daughter Natasha Bidadi.

He was a doctor in his native country of Iran, and he immigrated to America in search of freedom and a better life for his family. Dr. Bidadi trained as a psychiatrist at Butler Hospital, and worked as a psychiatrist at the ACI and Wyatt Detention Facility.

In lieu of flowers, donations in his memory to honor the excellent care he received from Dr. Tony Mega, Dr. Fred Schifffman, and their team can be made to the Miriam Hospital Foundation at P.O. Box H, Providence, RI 02901.

ABBY LEE MAIZEL, MD, PhD, 71, died peacefully on April 7, 2017. He was the husband of Gail [Raiken] Maizel.

Dr. Maizel was a graduate of the University of Pennsylvania, School of Medicine. He was the chief of pathology at Roger Williams Hospital, the principal owner of University Pathologists, a professor of pathology at Brown University and Boston University Medical Schools and a pioneer in genetic research including trailblazing research in immunotherapy.

His passions began with his wife, children and grandchildren, and included growing Bonsai trees, antiques, photography, boating and his pets. He was a generous philanthropist to numerous charities.

Besides his wife, he is survived by his children Jennie Maizel-McKiernan and her husband Bill of East Greenwich and Rebecca Maizel of East Greenwich, his sisters Naomi Berne and her husband Bruce of Irvington, NY and Amy Maizel-Seeherman and her husband Les Brody of Newton, MA, his grandchildren Jonah and Ellie, and his nieces and nephews.

In lieu of flowers, contributions in his memory may be made to the Wildlife Rehabilitators Association, 240 Shermantown Rd., Saunderstown, RI 02874 or your own local animal shelter.
ROBERT “BOB” FORTIN, MD, 89, of Rumford and West Palm Beach, died March 14 after a brief illness. He is survived by his beloved wife of 65 years, Virginia [Bessette] Fortin, and their 8 children and spouses: Diane Jessop, Marc Fortin [Gretchen], Kevin Fortin [Lynda], Andrea Fortin [Walter Barrett, Fiance], Roberta Donaldson [Jonathan], Melanie Paradis [Richard], Robert Fortin Jr. [Jane], Alison Bianco [William], and 13 grandchildren.

Dr. Fortin attended high school at St. Raphael Academy, started Providence College, was interrupted by a two-year stint in the U.S. Army, returned and graduated from PC, then attended medical school at Université Laval, Quebec, Canada, where he graduated cum laude in 1955, and returned to RI.

He was the physician for the Pawtucket School Department from 1958–1995, and head of staff from 1990–1995. In private practice as a family practitioner from 1955–1995, he was often a surgical assistant for his patients and delivered children from 1955–1965. He was certified by the Board of Family Practice in 1967 and was a past member of Pawtucket Medical Society (past president), American Medical Association, and American Academy of Family Practice. From 1996-2002 he worked as a physician for the insurance industry. He was a longtime company doctor for Moore Fabrics and he also co-founded the Notre Dame Ambulatory Care Center in 1969, later transferred to Notre Dame Hospital.

Dr. Fortin was renowned for his uplifting spirit, sense of humor, compassion, and kindness. In lieu of flowers, donations may be made to the RI Community Food Bank. [www.rifoodbank.org]

RICHARD O. RECCHIA, MD, 82, of Johnston, passed away on April 17, 2017 at his home. He was the beloved husband of Paula [Rossignoli] Recchia for 56 years. He graduated from Harvard University and the University of Bologna Medical School. He interned at RI Hospital and did his residency at Providence Ly ing-In Hospital. Dr. Recchia was an obstetrician and gynecologist for over 30 years.

He was a Fellow of the ACOG, member of the RI Medical Society and the University of Bologna Medical Alumni Association, and a former member of the Alpine Country Club. He also served in the United States Army RI National Guard. He was an avid member of the Cranston Fish and Game Club. Dr. Recchia was truly a Renaissance man. In addition to being a surgeon, he was a wine/champagne maker, connoisseur, chef, fisherman, hunter, pianist, poet, artist, friend, and was loved and respected by all.

Besides his wife, he is survived by his three loving daughters, Lisa Dimitri and her husband William of Johnston, Mariesa Lane of Cranston and Donna Smith and her husband Steven of Providence. He was the cherished grandfather of Alicia and Nicholas Lane, Andrew and Angelica Dimitri and brother of Mary Lou Paolino and her husband Edward of Seekonk. Donations in his memory may be made to Hope Hospice and Palliative Care of Rhode Island, 1085 North Main Street, Providence, RI 02904.

DR. ARISTIDO V. SANTOPIETRO died on March 21, 2017. He was the husband of June M. (Altieri) Santopietro.

Dr. Santopietro was a graduate of the University of Maryland and Georgetown University, where he received his dental and orthodontic training. Dr. Santopietro had a private practice in Cranston for 30 years, retiring due to illness in 1995. He served as chief orthodontist at RI Hospital, Joseph Samuels Dental Clinic and held various positions in the Cranston and RI Dental Societies.

Dr. Santopietro served in the United States Army during the Korean War and was honorably discharged as a staff sergeant in 1955.

Besides his wife, he leaves three daughters, Lori Fitzsimmons and her husband John of Cranston, Linda Santopietro and her husband Steven of Providence, and Roberta Donaldson and her husband Jonathan of Johnston. He was the cherished grandfather of Alicia and Nicholas Lane, Andrew and Angelica Dimitri and brother of Mary Lou Paolino and her husband Edward of Seekonk. Donations in his memory may be made to Hope Hospice and Palliative Care of Rhode Island, 1085 North Main Street, Providence, RI 02904.
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Farmers, fishermen, domestic employees, professional people, small business men—are among those who may now join. The age limit is 65 years and the usual Blue Cross health statement is required. The waiting period for maternity cases will remain at 9 months.

Prospective applicants may obtain full information and enrollment blanks by applying to Blue Cross headquarters. You will help this greater Blue Cross plan to complete success by requesting and using descriptive folders for your outgoing mail and a small display cut-out in color for your waiting room.

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Prayer versus Atropine

The following letter was recently received by a physician in Providence.

Dear Doctor:

I write to inform you that I will not call at your office for any further treatment for my eyes. Of course you will wish to know the reason. I do not know how much you believe in the Bible or God’s word, or in prayer, and what I say may surprise you. In the fifth chapter of James, beginning at the 14th verse, it says: "Is there any sick among you? Let him call for the elders of the church and they will pray over him, anointing him with oil in the name of the Lord; and the prayer of faith shall save the sick, and the Lord shall rise him up and if he have committed sins they shall be forgiven him."

There are many other passages of Scripture which I could give you, but it is not necessary. I obeyed this scriptural injunction, had my district superintendent and my congregation join me in the prayer of faith, asking God to heal me, and I believe he has done it in the name of the Christ and through the merit of the shed blood of Christ.

I wish to say, however, that I have perfect confidence in you and feel that I can safely recommend you to anyone as a competent oculist.

Yours respectfully...

We can admire his faith, while disagreeing with him in the literal meaning of the passage quoted, and it is not an evidence of disbelief in the teachings of God’s word if we question his judgment in the matter. The case in question is trachoma of long-standing, with thickened and roughened lids and well-marked pannus, complicated by ulceration of the cornea. Without treatment for some weeks the inevitable occurred: pain, photophobia, and impaired vision. The use of cupric sulfate lessened the trachoma condition very markedly and the instillation of atropine caused an immediate improvement in the ulcerative process, and it was at this stage, when the ulcer had healed and there was only the resulting cycloplegia, that he decided to rely on the efficacy of prayer. Prayer continued for several days will relieve cycloplegia, so will several days without prayer, and the veriest sinner will recover as quickly as any saint from the cycloplegic effect of atropine. It is fortunate that he did not begin this treatment of the ulcer before the beneficial effect of the atropine was secured, and it seems strange, and is the reason for comment, that an intelligent and reasoning man can fail to appreciate the physical and material logic of such a case.

### The Workmen’s Compensation Act

On the last day of the present legislative session, the General Assembly of the state passed an amended Workmen’s Compensation Act which will serve to correct most of the flagrant abuses of the act hitherto in force. The new act permits the injured employee to select his own physician, extends the time in which the employer becomes responsible for medical treatment from 2 to 4 weeks, and gives the physician standing in a court of law, so that he may sue in his own name for the recovery of a disputed claim. The most important of the amendments for which we fought have been granted. The medical profession may justly feel that a notable victory has been achieved, and that the fairness of our contention that the former act worked a great hardship on the profession has been recognized by the law-makers.

This is also a significant victory for the workingman. The inalienable rights of every man, at time of injury or illness, to be able to summon a physician in whom he has confidence, is restored to the injured employee by this act. This legislation is preeminent in pointing the way to other democratic laws regarding the inherent rights of the workingman, which may be expected.

The committee of the Rhode Island Medical Society which has done such splendid and arduous work in pushing through this act is deserving of the congratulations and gratitude of every medical man in the state.
Hospitals/Organizations

Cure for alcohol, drugs in as little as 30 minutes
Advertisements for a cure for alcoholism and drug addiction appeared in Providence and Massachusetts publications and magazines 100 years ago. The Medical Institute, the ‘cure’ company, had offices in Providence and Worcester, Mass.

As the advertisements indicate, The Restaurare Institute in Worcester claimed to offer a cure in as little as 30 minutes. According to an article in The Worcester Magazine in 1915, the “Institute Company specializes in the cure of alcoholism and drug addiction with specific internal medicines and had all the handicaps and obstructions created by quack medical companies to overcome before it secured a standing as a reputable concern...It is a product of scientific investigation, knowledge and experience of master minds in chemistry and medicine.”

Harvard alumnus 1897, Robert W. Guiler, MD, served as medical superintendent.

St. Joseph’s Hospital
Clinic on the operative treatment of Pott’s disease
Dr. Fred H. Albee of New York held a clinic on the operative treatment of Pott’s disease of the spine at the hospital on April 4, 1917. About 50 physicians from various parts of the state were present. Dr. Albee demonstrated his method of treating Pott’s disease by inserting a bone graft, removed from the crest of the tibia, into the spinous processes at the level of the disease. The use of the motor saw and the fashioning of bone grafts, modeled after the methods of the Joiner and Orchard man, was of great interest to the audience. The patient has so far made an uneventful convalescence with no postoperative rise of temperature.

Rhode Island Hospital
‘The institution as a free horse is being ridden to death’
The Rhode Island Hospital has appealed to the towns for aid. It is facing a deficit of $45,000 for the past year and unless the towns come forward with appropriations, their poor patients will have to be turned away. Seven hundred and forty-three free patients in the state outside the city were given 17,350 days treatment at the hospital in the last fiscal year at a cost of $38,170, for which the communities from which they came paid nothing. The institution as a free horse is being ridden to death. Either the towns come across or they must make provision at home for their poor sick.

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US Navy hospital to use Binney mansion
The Italianate-style brick William Binney house (1859), 72 Prospect Street in Providence, is accepted by the Navy Department for a convalescent hospital. Alpheus C. Morse, Providence architect, designed the three-story mansion. He was the architect for Rhode Island Hospital and Sayles Hall at Brown University.

The William Binney house on Prospect Street in Providence.

A ward at the Rhode Island Hospital circa 1917.
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Meetings

Meeting of Alienists and Neurologists
The annual meeting of Alienists and Neurologists will be held Monday, July 9 to Thursday, July 12, 1917 in the Red Room of the LaSalle Hotel, Chicago, under the auspices of the Chicago Medical Society. Dr. George A. Zeller will act as chairman.

The topics for the meeting include: hospitals for cure, research, and prevention; colonies for the productive insane; therapeutic employment and reeducation; general paralysis of the insane; depressive insanity and the minor psychoses, delirium tremens and traumatic mental disturbances; legal aspects of insanity; dementia precox; epilepsy and the feeble-minded.

The program will be mailed June 28 with abstracts of each paper. Contributors to the program are solicited. This is a society without a membership fee. Address: Secretary A and N, room 1218, 30 N. Michigan Ave., Chicago.

Chiropractors to visit Providence
National Association to hold convention August 6; free clinics for the poor
Delegates to the convention of the National Association of Chiropractors from all parts of the United States will gather in Providence on August 6 to counsel over “the understandings of the people.” The convention takes on an unusual interest this year on account of the importance given chiropody by the war.

The first office in America for the practice of scientific chiropody is stated was opened in Boston in 1841. The second in this country was in Providence. The free clinic for the poor will be conducted in connection with the convention. The headquarters will be at the Narragansett Hotel and the clinics will be held mornings and afternoons.

Medical Research Club, April 4, 1917
Lantern slides, moving pictures shown of war surgery
Dr. Fred H. Albee of New York entertained the club and invited guests at the Medical Library with a very interesting address on surgical experiences in France. The talk was informal and was illustrated by lantern slides and moving pictures showing surgical conditions and the actual technique of several operations. Among many noteworthy films were several showing extensive injuries to the jaw with great loss of substance, which had been restored by bone grafts into the mandible.

Appointments

DR. JOHN W. MITCHELL was reelected president of the Providence Lying-In Hospital.

DR. JOHN CHAMPLIN of Westerly was elected president of the Rhode Island Medical Society.

Necrology

DR. DAN O. KING of Auburn died April 8, 1917. He was born in Stillwater, Rhode Island, on December 15, 1850, a member of an old Rhode Island family, many of whom had followed the medical profession. He graduated from Bowdoin College in 1875 and began the practice of medicine in Pontiac, Rhode Island. All of his practice had been in Cranston and Warwick, serving as medical examiner and superintendent of health in Warwick, and was a member of the House of Representatives from that town in 1878, and a member of the Town Council and County physician in the town of Cranston.

Dr. King was something of a traveler, having visited Mexico, Alaska and Europe. He was one of the first men of Rhode Island to go to the Klondike, making the trip for the mere pleasure and adventure of it, and not in search for gold.

In medical matters he was a great student. He made a study of the disease of rabies and administered the first Pasteur treatment to the first person to receive it in the city.
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When **Dr. Angelo D’Agostino**, a Jesuit priest, founded a children’s home in Kenya in 1992 for three orphans who tested HIV-positive, he called it Nyumbani – home in Swahili. The orphans called him “Faza.”

For Dr. D’Agostino, there was no place like home, whether in his native Rhode Island or his adopted homeland of Kenya. When he died of a cardiac arrest in a Nairobi hospital in 2006, he was 80 years young. His brother, Dr. Joseph D’Agostino of Fairfax, Va., later shared memories of their childhood to *The Washington Post*.

Their parents, Luigi and Julia D’Agostino, were Italian immigrants. Luigi was a construction worker who rebuilt an Atwell’s Avenue barn in the Mount Pleasant section of Providence into a cottage for his six children. Angelo, who suffered from severe asthma, liked to build model airplanes and grow vegetables and flowers in the backyard.

His only regret about his adopted homeland of Kenya was that “he couldn’t grow good tomatoes over there. Being a good Italian, that was important to him,” his brother recalled in the *Post*.

Angelo graduated from La Salle Academy, St. Michael’s College in Vermont, and Tufts University School of Medicine, class of 1949. He then interned for a year at Rhode Island Hospital, and completed a urology residency in Boston.

During the Korean conflict, Dr. D’Agostino joined the Air Force and served as chief of urology at Bolling Air Force Base in Washington, DC. After completing his service in 1955, he attended a Jesuit retreat, and found his second calling. He joined the Society of Jesus and was ordained a priest 11 years later, in 1966.

During this time, he switched his subspecialty, and studied psychiatry. For several years, he taught psychiatry at the George Washington University Hospital, and served as chief of its inpatient service.

His overseas pastoral work began in 1978, when the Jesuit order sent him to Thailand to set up refugee camps, and then later to coordinate the Jesuit Refugee Service Center in Africa based in Nairobi in 1981 for the thousands of refugees displaced from sub-Saharan Africa.

This visit to Kenya resonated with him and in his early 60s, he decided to make Kenya his home. Dr. D’Agostino opened a private practice in psychiatry and psychoanalysis in Nairobi in 1987, and saw patients 20 hours a week.

He also served on the board of an orphanage, and when the board did not take him up on his suggestion to open a separate facility for the throngs of children who tested HIV-positive, he did it himself. At that time, there were more than a million orphans in Nairobi, whose parents had died of AIDS.

Since its founding in 1992, Nyumbani has grown into a non-profit organization which supports the children’s home, an advanced diagnostic laboratory, a community outreach program providing services to more than 2,000 HIV-positive children and their families, and a self-sustaining village where 1,000 orphans and elders form blended families.

In 2001, Nyumbani became the first place in Africa to import deeply discounted AIDS drugs under an Indian pharmaceutical company’s program to make such drugs more affordable.

“I am sick and tired of doing funerals,” Dr. D’Agostino told the *Post*, explaining why he was willing to defy national regulations and patent rules to buy cheaper generics. He also sued the Kenyan government for its policy of banning HIV-positive children from public schools and eventually won that suit in 2004.

He received numerous humanitarian awards during his lifetime and in 2009 was inducted into the R.I. Heritage Hall of Fame.

A thousand people, including the president of Kenya and a Vatican representative, attended his funeral in Kenya. At the burial, the Nyumbani orphans dropped fistfuls of dirt on his coffin – as they had done with him at the funerals of so many children who had died of AIDS – in a final farewell to their “Faza.”