Rhode Island Medical Journal

Spotlight

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Case Discussion on ‘Return-to-Play’ for the Athlete Following COVID-19 Infection

NATHANIEL MOULSON, MD; MEAGAN WASFY, MD, MPH

KEYWORDS: COVID-19, SARS-CoV-2, myocarditis, athletes, return-to-play

INTRODUCTION

Myocarditis, or inflammatory disease of the myocardium, is a well described etiology of sports-related sudden cardiac death.¹ Viral illness is amongst the most common causes for myocarditis.² Shortly after the emergence of coronavirus disease 2019 (COVID-19) as a global pandemic, reports of associated myocarditis led to concern regarding how to appropriately evaluate athletes who had COVID-19 prior to return to their sport. This concern arose given the potential risk of arrhythmia and cardiac arrest, potentiated by exercise, in those who have had recent myocarditis. Resultant expert consensus guidelines have addressed the clinical dilemma of athlete evaluation prior to returning to sport following COVID-19 infection and have evolved over the past year in order to address new data. Herein we describe an illustrative case of a young (<35 years of age) college athlete presenting for assessment prior to returning to competitive athletics after COVID-19 illness. A similar framework may be utilized for the assessment of pediatric and masters (>35 years of age) populations consisting of both competitive and recreational athletes as outlined by the American College of Cardiology’s (ACC) Sports and Exercise Cardiology Section guidelines.³

CASE PRESENTATION: Part 1

A 21-year-old Caucasian male college student contracted COVID-19 upon return to campus to resume in person classes and training. He is a member of his school’s lacrosse team and immediately self-quarantined upon diagnosis. He has no relevant medical history, is on no regular medications, and has not previously undergone cardiac screening or evaluation. His initial symptoms included profound fatigue, subjective fever, headache, loss of taste and smell, and shortness of breath occurring with minimal exertion. He did not require medical assessment or hospitalization. While many of his symptoms resolved over the course of 72 hours, the fatigue and shortness of breath persisted for the remainder of his 14-day quarantine period. He felt back to normal by the conclusion of his quarantine, though had not completed any exercise over this span. About 10 days after the conclusion of his quarantine, he attempted a short distance run. During this run, he experienced shortness of breath with minimal exertion forcing him to cease exercise. He was referred by his school for outpatient cardiology evaluation prior to being permitted to return to organized team training.

‘RETURN-TO-PLAY’ ASSESSMENT POST-COVID-19

Among patients hospitalized with severe COVID-19, a high prevalence of ‘cardiac injury,’ defined as a cardiac specific troponin level exceeding the 99th percentile, was observed early in the pandemic.⁴ In the critically ill population, this cardiac injury may be due to several different mechanisms, one of which is inflammatory heart disease (myocarditis, pericarditis) secondary to a systemic inflammatory response and/or direct viral invasion.⁵ The concern that COVID-19 viral myocarditis may occur in young athletes suffering from non-severe infection resulted in a series of clinical practice recommendations aimed at identifying those at risk prior to return to sport and exercise.⁶ The first set of U.S. recommendations were published in the spring of 2020, based largely on expert consensus. These recommendations were updated in the fall of 2020⁷ to account for limited athlete-specific research data and growing clinical experience. The guidelines recommend that all athletes should avoid exercise during the acute infectious period. After quarantine, the recommended approach to post-COVID-19 cardiac screening is symptom-driven and stepwise. On the basis of experience suggesting the risk of COVID-19 related inflammatory heart disease is very low in this group, athletes with asymptomatic or mildly symptomatic initial infection do not need to undergo cardiac investigations prior to return to sport. In those suffering from moderate or greater severity infection, or those who develop cardiopulmonary symptoms on return to sport, cardiac diagnostic testing is warranted as detailed further below. Moderate symptoms are defined as persistent fever, chills, myalgias, lethargy, or any cardiopulmonary symptoms, which include chest pain or tightness, dyspnea, syncope, or palpitations. The presence of a ‘multi-system inflammatory syndrome’ in pediatric populations should also be considered in those with moderate or greater disease severity. This symptom-driven stepwise approach is supported by recent large cohort studies of both collegiate and professional athletes.⁸,⁹
CASE PRESENTATION: PART 2
The patient’s initial symptom burden would most appropriately be classified as ‘moderate.’ Additionally, he experienced the cardiopulmonary symptom of dyspnea on attempted return to exercise after initial symptoms had resolved. The presence of both a moderate initial symptom burden and cardiopulmonary symptoms on return to exercise warranted further testing to both rule out cardiac involvement secondary to COVID-19 and assess for other clinically important causative etiologies. He underwent initial testing, with a 12-lead electrocardiogram (ECG), high-sensitivity cardiac troponin level, and a transthoracic echocardiogram, as recommended by the expert consensus statement. His high-sensitivity cardiac troponin-T level was found to be mildly elevated at 18 ng/L (0-14 ng/L) and his 12-lead electrocardiogram demonstrated abnormal T-wave inversions in the inferolateral leads (Figure 1). Notably, no exercise was performed within 24-hours of his blood draw and no prior 12-lead ECG existed. His echocardiogram demonstrated biventricular size at the upper limit of normal, and mild biventricular dilatation. His biventricular function was normal, and there was no evidence of wall motion abnormalities, pericardial effusion, or valvular disease.

INITIAL CARDIAC EVALUATION
In athletes for whom cardiac screening is warranted after COVID-19, ‘triad’ testing, which refers to the combination of a 12-lead ECG, cardiac troponin, and transthoracic echocardiogram, should be considered as the initial strategy to identify COVID-19 inflammatory heart disease. Cardiac magnetic resonance imaging (CMR) should be reserved for athletes who have abnormal triad testing results that are concerning for COVID-19 inflammatory heart disease and that are not otherwise readily explained. CMR may also be considered for patients where a high index of clinical suspicion remains for COVID-19 cardiac involvement on the basis of the clinical history despite normal triad testing. Contemporary CMR diagnostic criteria for myocarditis include the combination of myocardial edema, as determined by abnormal T2-weighted images or T2 parametric mapping, and a non-ischemic myocardial injury, as determined by abnormal T1 mapping or late gadolinium enhancement (LGE).

Several specific sports leagues have utilized screening algorithms that stipulate all athletes who have had COVID-19 should undergo a screening CMR regardless of presenting symptoms and triad testing results. This practice is driven by several small observational studies in both non-athletic and athletic populations with COVID-19 that demonstrated a high prevalence of CMR abnormalities. In non-athletes, cardiac abnormalities were seen in up to 78%, while abnormalities in athletes suggestive of either myocarditis or pericarditis ranged from 1.4–40%, often without abnormal triad testing results. These studies were limited by the absence of standardized disease definitions and lack of adequate control group comparators. Many of the athletes with CMR abnormalities lacked the other clinical features of inflammatory heart disease that would usually be paired with the CMR imaging findings to make the diagnosis, which makes the significance of these results unclear. Subsequent multi-center studies of both collegiate and professional athletes, utilizing the symptom-driven, stepwise approach described above, have demonstrated substantially lower prevalence of inflammatory heart disease after COVID-19 (0.5–3%), and importantly no adverse clinical events in short-term follow-up. This relatively low prevalence and favorable short-term outcomes support the symptom-guided and stepwise testing strategy.

Another important consideration in screening for COVID-19 cardiac involvement in athletes is the impact of exercise on the heart. Exercise is a well-established non-pathologic cause of low-level cardiac troponin elevation in otherwise healthy athletes. The timing of last intensive exercise bout in relation to blood draw should be sought for all abnormal results, and a repeat level drawn 24-48 hr. after last exercise should performed prior to considering an elevated troponin result abnormal. Testing is also impacted by exercise-induced cardiac remodeling, which consists of cardiac structural and functional adaptations to sustained and repeated bouts of vigorous activity results. Care must be taken not to mistake findings of physiologic adaptation on 12-lead ECG and cardiac imaging as evidence of cardiac involvement from SARS-CoV-2 or other cardiac pathology. Athlete specific criteria for 12-lead ECG and cardiac imaging interpretation should be followed, and pre-COVID-19 ECG and imaging results reviewed for comparison whenever available.

CASE REPORT/DISCUSSION

Figure 1. 12-lead Electrocardiogram
Sinus bradycardia with RSR’ pattern in V1 (QRS <100ms). Abnormal finding of T-wave inversion in the inferolateral leads.
Table 1. Normal or Non-specific Cardiac Testing Findings in Athletes* versus Abnormalities Possibly Related to COVID-19 Infection

<table>
<thead>
<tr>
<th>Cardiac Testing Modality</th>
<th>Normal or Non-specific findings in Athletes</th>
<th>Abnormalities Possibly Related to COVID-19 infection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiac Troponin</strong></td>
<td>1) Below the 99th percentile for specific assay (either conventional or high sensitivity)</td>
<td>1) Troponin elevation &gt;99th percentile with no other readily explainable cause</td>
</tr>
<tr>
<td></td>
<td>2) Isolated troponin elevation within 24–48 hr of moderate-to-vigorous exercise and resolved on repeat testing</td>
<td></td>
</tr>
<tr>
<td><strong>12-lead ECG</strong></td>
<td><em>Normal Athlete ECG findings</em></td>
<td>1) Abnormal TWI</td>
</tr>
</tbody>
</table>
| [Adapted from the International Criteria for Electrocardiographic Interpretation in Athletes^3] | 1) Increased QRS voltage for LVH or RVH   
2) Incomplete RBBB   
3) Early Repolarization   
4) ST elevation followed by TWI V1-V4 in black athletes   
5) TWI V1-V3 < age 16 years old   
6) Sinus bradycardia or arrhythmia   
7) 1st degree AV block   
8) Mobitz Type 1 2nd AV block | 2) Pathologic Q waves   
3) Abnormal ST-depressions   
4) ≥2 PVCs   
5) Complete LBBB   
6) QRS≥140ms   
7) 3rd degree AV block   
8) Atrial tachyarrhythmias   
9) Ventricular tachyarrhythmias   
10) Complete RBBB combined with axis deviation or atrial enlargement   
11) Diffuse ST elevations or PR depressions |
|                                   | *Borderline ECG findings^*                                                                                 |                                                                                           |
|                                   | 1) Left axis deviation   
2) Left atrial enlargement   
3) Right axis deviation   
4) Right atrial enlargement   
5) Complete RBBB           |                                                                                           |
| **Transthoracic Echocardiogram**  | 1) Mild symmetric increased LV wall thickness (<13mm; <15mm in black male athletes)                        | 1) LVEF <50%                                                                             |
| [Adapted from the 1) 2020 Recommendations on the Use of Multimodality Cardiovascular Imaging in Young Competitive Athletes;^16 and 2) Screening Potential Cardiac Involvement in Competitive Athletes Recovering from COVID-19: An Expert Consensus Statement^15] | 2) Regional wall motion abnormality   
3) Small or greater pericardial effusion   
4) Focal thickening suggestive of edema   
5) Intracavitary thrombi   
6) Diastolic dysfunction   
7) Global longitudinal strain<-15%   
8) Failure to augment low-normal LVEF with exercise |                                                                                           |
|                                   | 2) Symmetric biventricular enlargement at or mildly above ULN                                              |                                                                                           |
|                                   | 3) Mildly enlarged atrial size/volume                                                                       |                                                                                           |
|                                   | 4) Low normal biventricular systolic function                                                               |                                                                                           |
|                                   | 5) Supra-normal diastolic function                                                                         |                                                                                           |
|                                   | 6) Normal global longitudinal strain (-16–22%)                                                              |                                                                                           |
| **Cardiac Magnetic Resonance Imaging** | 1) Mild symmetric increased LV wall thickness (<13mm; <15mm in black male athletes)                        | 1) LVEF <50%                                                                             |
| [Adapted from the 1) 2020 Recommendations on the Use of Multimodality Cardiovascular Imaging in Young Competitive Athlete;^16 2) Updated Lake Louise Criteria for CMR imaging in Non-ischemic Myocardial Inflammation;^19 and 3) Screening Potential Cardiac Involvement in Competitive Athletes Recovering from COVID-19: An Expert Consensus Statement^15] | 2) Regional wall motion abnormality   
3) Focal thickening suggestive of edema   
4) Small or greater pericardial effusion   
5) Non-ischemic Myocardial Injury (Abnormal T1, ECV, or LGE)^ |
|                                   | 2) Symmetric biventricular enlargement at or mildly above ULN                                              | 6) Hyperemia, capillary leak or myocardial edema (T2-mapping or T2W imaging abnormality)^  |
|                                   | 3) Mildly enlarged atrial size/volume                                                                       | 7) Intracavitary thrombi                                                                 |
|                                   | 4) Normal/ low normal biventricular systolic function                                                       |                                                                                           |
|                                   | 5) Isolated LGE particularly if confined to the RV insertion points                                         |                                                                                           |
| **Transthoracic Echocardiogram**  | 1) Mild symmetric increased LV wall thickness (<13mm; <15mm in black male athletes)                        |                                                                                           |
| [Adapted from the 1) 2020 Recommendations on the Use of Multimodality Cardiovascular Imaging in Young Competitive Athlete;^16 and 2) Screening Potential Cardiac Involvement in Competitive Athletes Recovering from COVID-19: An Expert Consensus Statement^15] | 2) Regional wall motion abnormality   
3) Focal thickening suggestive of edema   
4) Small or greater pericardial effusion   
5) Non-ischemic Myocardial Injury (Abnormal T1, ECV, or LGE)^ |
|                                   | 2) Symmetric biventricular enlargement at or mildly above ULN                                              | 6) Hyperemia, capillary leak or myocardial edema (T2-mapping or T2W imaging abnormality)^  |
|                                   | 3) Mildly enlarged atrial size/volume                                                                       | 7) Intracavitary thrombi                                                                 |
|                                   | 4) Normal/ low normal biventricular systolic function                                                       |                                                                                           |
|                                   | 5) Isolated LGE particularly if confined to the RV insertion points                                         |                                                                                           |

*Findings should be considered within the context of sport type and volume

^Borderline ECG abnormalities in isolation require no further evaluation

TWI = T wave inversions; LVH = Left ventricular hypertrophy; RVH = right ventricular hypertrophy; RBBB = right bundle branch block; LBBB = left bundle branch block; AV = atrioventricular; ULN = Upper Limit of Normal; RV = Right Ventricle; LGE = late gadolinium enhancement; ECV = extracellular volume; T2W = T2 weighted
**CASE PRESENTATION: PART 3**

The combination of clinical symptoms, troponin elevation, and abnormal T-wave inversions in the inferolateral leads elevated the pre-test probability of COVID-19 related myocarditis, and a CMR was performed. The CMR demonstrated normal biventricular size and function with no evidence of wall motion abnormalities or pericardial effusion. There was late gadolinium enhancement (LGE) within the subepicardial to mid-wall involving multiple left ventricular segments, and increased native T2 in a small focal area of the basal inferolateral septum [Figure 2]. These imaging findings were consistent with a small area of myocardial edema [increased native T2] and corresponding injury (LGE) consistent with myocarditis.10 His high-sensitivity troponin-T was undetectable on repeat testing 10 days later. Given the clinical presentation and diagnostic testing consistent with a diagnosis of myocarditis secondary to COVID-19, the patient was provided with the recommendation to avoid moderate to vigorous intensity physical activity for at least a 3-month period.19 This recommendation is consistent with sports participation expert consensus guidelines for athletes with cardiovascular disease that pre-dated COVID-19 as discussed further below. In the absence of LV dysfunction or any high-risk arrhythmias on ambulatory ECG monitoring, no medical therapy was indicated.

**Figure 2. Cardiac MRI with Gadolinium Contrast**

Subepicardial to mid-wall late gadolinium enhancement involving the inferolateral wall of the left ventricular (Yellow arrow) with associated small area of increased native T2 (not shown).

**MANAGEMENT CONSIDERATIONS**

Patients with acute cardiac inflammation, either myocardial (myocarditis) or pericardial (pericarditis), should refrain from moderate-to-vigorous intensity physical activity until acute inflammation has resolved.19 This acute inflammatory period represents one of increased arrhythmic risk particularly if placed under the physiologic stress of intensive exercise. In pericarditis, although the inflammation does not involve the myocardium, there is potential for a small degree of disease overlap in the form of myopericarditis. As such, the diagnosis of pericarditis results in similar exercise restriction recommendations as for myocarditis but for a shorter duration.19 In pericarditis, if no evidence of myocardial inflammation is demonstrated and there is complete resolution of disease including symptoms, pericardial effusion, and serum markers of inflammation [i.e., CRP, ESR] with appropriate treatment, patients may resume exercise after two weeks. In contrast, the expert consensus recommendations for acute myocarditis suggest a period of 3–6 months of exercise avoidance to allow for resolution of myocardial inflammation19 with the exact duration to be determined by disease severity and trajectory. This timeframe is based on expert opinion rather than any prospective data examining the appropriate duration of sports restriction. Return to sport may occur after this timeframe assuming symptoms have resolved, left ventricular systolic function has remained/returned to the normal range, serum markers of myocardial injury and inflammation have normalized [i.e. troponin], and there is no evidence of clinically relevant arrhythmia on exercise and ambulatory ECG monitoring.

This case represents a relatively straightforward clinical scenario in that the criteria for a clinical diagnosis of myocarditis were fulfilled, including the presence of suggestive symptoms, and cardiac testing was performed based on appropriate pre-test probability of disease. The clinical scenario becomes more challenging when cardiac testing abnormalities are present but do not formally fulfill diagnostic criteria for inflammatory heart disease, or testing is abnormal but there are no clinical symptoms. Examples of these scenarios include: 1) isolated troponin elevation and/or ECG abnormalities with a normal CMR, 2) isolated abnormal CMR findings (LGE, T1 or T2 mapping) that do not fulfill CMR criteria for myocarditis, 3) small pericardial effusions in the absence of symptoms. Expert consultation with a clinician, such as a sports cardiologist, is recommended in these situations to balance the need to identify clinically relevant disease with the importance of avoiding over-diagnosis and unwarranted restriction from sport.

This case also serves to highlight the uncertainty of current return-to-play recommendations regarding duration of sports restriction for mild presentations of myocarditis (i.e., cases in which there is no ventricular dysfunction or arrhythmia and a relatively small area of involvement on CMR). In athletes for whom restriction has been recommended, but where return to sport may be more pressing, such as in professional or high-level amateur athletics, re-imaging with CMR at the 3-month mark or potentially earlier, may be considered pending resource availability. If complete resolution of acute inflammation is demonstrated by biomarkers and imaging, and other appropriate risk stratification measures including exercise and ambulatory ECG monitoring are normal, an earlier return-to-sport may be considered in consultation with an experienced clinician.
CONCLUSION

The use of cardiac diagnostic testing to screen for cardiac involvement in athletes following COVID-19 infection should be performed by a symptom-guided and stepwise strategy. The interpretation of testing abnormalities should be considered within the context of exercise-induced cardiac remodeling and the pre-test probability of disease. Expert referral should be considered for challenging cases.

References


Infected Endocarditis with Pseudoaneurysm of the Mitral-Aortic Intervalvular Fibrosa Presenting as Complete Heart Block

CULLEN SOARES, MD; PINAR ARIKAN, MD; MICHAEL GILSON, MD, MPH, FACC

ABSTRACT
A 79-year-old male with a history of ESRD and treated MRSA endocarditis was found to have a recurrence of MRSA bacteremia. He was treated with antibiotics. During his hospitalization, he suddenly developed complete heart block requiring transcutaneous pacing, and subsequently transvenous pacing wires were placed. Transesophageal echocardiography demonstrated pseudoaneurysm of the mitral-aortic intervalvular fibrosa as well as aortic valve thickening, and a mitral vegetation. Cardiothoracic surgery was consulted to obtain source control, but the patient was deemed to be a poor surgical candidate. While continuing medical therapy and transvenous pacing, the patient developed refractory hypotension, acidosis, and ultimately expired.

KEYWORDS: endocarditis, echocardiography, complete heart block, mitral-aortic intervalvular fibrosa pseudoaneurysm

CASE REPORT
A 79-year-old male was brought to the hospital by his family after collapsing at home due to weakness after missing a session of dialysis. There was no head strike or loss of consciousness. He denied lightheadedness, dizziness, vision changes, palpitations, fever, or chills. On presentation he was afibrile, pulse 76, blood pressure 140/61, respirations 18, saturating 94% on room air. He appeared thin, frail, and elderly, in no acute distress. Mouth was remarkable for poor dentition and moist mucosa. Lungs had mild bibasilar rales, heart had a regular rate and rhythm, abdomen was soft, and extremities had no cyanosis or edema. He had multiple excoriations on the scalp, arms, and legs. His dialysis tunneled catheter was clean, dry, and intact.

The patient had a past medical history of end-stage renal disease on hemodialysis, heart failure with preserved ejection fraction (LVEF 50%), paroxysmal atrial fibrillation (on warfarin), prior gastrointestinal bleeds, hypertension, and type 2 diabetes. He had a prior hospitalization for MRSA endocarditis 7 months earlier, diagnosed with positive blood cultures and a transthoracic echocardiogram (TTE) that demonstrated a 1.4 cm aortic valve vegetation and severe leaflet thickening. A transesophageal echocardiogram (TEE) was not performed at that time due to patient refusal. The patient was treated for 6 weeks with vancomycin followed by doxycycline suppression therapy due to concern for MRSA colonization of his nonfunctional fistula. His tunneled dialysis catheter was replaced at that time.

He was a former smoker with 27 pack-year-history and quit more than 20 years ago. Family history was remarkable for diabetes, hypertension, and hyperlipidemia in his mother. There was no family history of renal disease.

Admission EKG showed findings suggestive of left ventricular hypertrophy, similar to the EKG during his previous hospitalization (Figures 1 and 2). The basic metabolic panel was abnormal, but not significantly different compared to prior values for this patient over the last 6 months.

Blood cultures and dialysis catheter cultures grew MRSA, for which the patient was started on vancomycin. Blood cultures cleared on hospital day 5.

TEE showed thickening of the aortic valve, but no clear vegetation.

He was scheduled to have a new dialysis catheter placed, but while being transported for the procedure the patient developed bradycardia (pulse of 32) and hypotension [80/34]. He appeared listless and had cool extremities with a bradycardic pulse. An EKG was obtained showing the patient to be in complete heart block (Figure 3). His heart rate failed to respond to 2 doses of atropine 0.5mg, so transcutaneous pacing was initiated, followed by placement of transvenous pacing wires, and the patient was transferred to the Coronary Care Unit (CCU).

TEE revealed an aortic valve ring abscess, pseudo-aneurysm of the mitral-aortic intervalvular fibrosa, aortic valve thickening without an obvious vegetation, perforation of the left coronary leaflet resulting in mild to moderate aortic regurgitation and a mitral valve vegetation (Figure 4 and Video 1).

Despite pacemaker support and multiple intravenous pressors, he developed refractory hypotension and acidosis and died the following day.

DISCUSSION
Pseudoaneurysm of the mitral-aortic intervalvular fibrosa (MAIVF-P) and complete atrio-ventricular heart block are each rare complications of infective endocarditis. The incidence of infective endocarditis in the United States is approximately 15 cases per 100,000 of the total population, with rising rates of Streptococcal infection since guidelines for prevention were released in 2007. A prior review of the literature found approximately 89 cases of MAIVF-P.
Figure 1. EKG from first hospitalization with findings suggestive of left ventricular hypertrophy and secondary repolarization abnormalities.

Figure 2. EKG from second hospitalization with findings suggestive of left ventricular hypertrophy and secondary repolarization abnormalities.

Figure 3. EKG from second hospitalization showing new complete heart block with narrow QRS complex during episode of hemodynamic instability.

Figure 4. TEE image from second hospitalization demonstrating MAIVF-P.

Figure 5. Diagram of cardiac anatomy depicting the location of the MAIVF.

Video 1. Transesophageal echocardiogram demonstrating MAIVF-P. [0.03, https://vimeo.com/558106605]

Click to view video.
reported from 1966 to 2010.2 Complete heart block has previously been reported at 4% and 11% in 2 prior cohorts.3,4

The MAIVF refers to the inter-annular zone between the mitral and aortic valves, adjacent to the atrio-ventricular node [AVN]. Due to the relatively avascular nature of this cardiac structure, it is prone to infection and injury, and is susceptible to forming pseudoaneurysms as a complication of endocarditis or valve replacement.2 A pseudoaneurysm generally develops between the left coronary or non-coronary aortic cusp and the anterior leaflet of the mitral valve. Localized edema and extrinsic compression of the AVN by the expanding pseudoaneurysm may result in AVN dysfunction eventually progressing to complete heart block.

This patient presented with recurrent MRSA bacteremia and endocarditis. MRSA is a virulent organism that, once established on a valve surface, commonly invades the surrounding cardiac tissue resulting in formation of a valve ring abscess or fistula. According to the 2020 ACC Guidelines for the Management of Patients with Valvular Heart Disease, paravalvular cardiac abscesses occur in 30% to 40% of cases of MRSA endocarditis.5 Trans-thoracic echocardiography has poor sensitivity for identifying these complex infections.6,7 As such, the ACC Guidelines endorse a Class I indication for TEE in the setting of MRSA bacteremia if endocarditis is suspected. CHB, because it almost always signifies ring abscess formation4 and also represents a Class I indication for TEE.5 The AHA also supports similar guidelines.7 Furthermore, CHB also represents a Class I indication for early surgery, during the initial hospitalization and before completion of a course of IV antibiotics.5

The chronology of events in this patient’s cases suggests that he could have already developed an aortic valve ring abscess at the time of his initial presentation. Antibiotics may have suppressed the bacteremia but not completely sterilized the valve annulus, despite appropriate medical therapy. At his second presentation, the abscess could have progressed to cause a MAIVF-P. Examination of cardiac anatomy demonstrates that the MAIVF lies adjacent to the AV node at the AV junction. Extrinsic compression of the AV node by the expanding pseudoaneurysm as well as localized edema and inflammation associated with the infection likely resulted in the development of complete heart block (Figure 5). The ECG is consistent with this pathophysiology; the narrow QRS complex suggesting heart block at the level of the AV node, rather than below (Figure 3). From our literature search, MAIVF-P has been reported before in case reports and case series8-11, and of these only 1 report found an intermittent AV block.11 CHB has been reported previously as a presenting sign of infective endocarditis.12 However, we believe our patient is the first reported case of MAIVF-P presenting as complete heart block.

CONCLUSIONS

This case highlights two rare and late complications of infective endocarditis occurring concurrently: the pseudoaneurysm of the mitral-aortic intervalvular fibrosa and complete heart block. In cases of MRSA bacteremia, TEE is important to properly assess for endocarditis and to guide appropriate management.

References


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Disclaimer

This work does not represent the views of Brown University, Rhode Island Hospital, or Lifespan.

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Abdominal Pain Due to Renal Infarction: An Unexpected Presentation of COVID-19
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ABSTRACT
Although respiratory symptoms dominate the clinical presentation of COVID-19, atypical, misleading non-pulmonary complaints can occur. Here we present a case of an otherwise healthy 28-year-old cisgender woman whose initial presentation of COVID-19 was unexplained acute abdominal pain, which was later found to be due to renal infarction. She was treated with anti-coagulation and was discharged after a short hospital stay. This case demonstrates the heterogeneous presentations that are associated with COVID-19. Medical providers must be aware that this virus may mimic a diverse array of disorders, even in the absence of respiratory symptoms.

KEYWORDS: COVID-19, hypercoagulability, renal infarction

INTRODUCTION
Pulmonary symptoms dominate the clinical presentation of COVID-19. However, the virus can affect many other organ systems. For example, case reports of hypercoagulability linked to COVID-19 include pulmonary embolism, cerebral infarction, myocardial infarction, and mesenteric ischemic events. In addition, there have been an increasing number of cases in the literature of renal infarction in COVID-19 patients. Most patients in prior reports in the setting of COVID-19 initially presented with respiratory symptoms and suffered from serious co-morbidities. We present a case of an otherwise healthy cisgender woman with a history of well-controlled asthma whose initial presentation of COVID-19 was pain from renal infarction.

CASE PRESENTATION
A 28-year-old cisgender woman with a history of asthma and migraines presented to the emergency department with sharp, waxing and waning left lower quadrant pain for three days that acutely worsened on the night of admission. The pain was exacerbated by movement and was not responsive to over-the-counter analgesics. The patient denied fevers, chills, dysuria, hematuria, nausea, vomiting, diarrhea, cough, dyspnea, or chest pain. She was an active smoker (0.5 packs/day), but had no other drug use history, such as cannabis or cocaine. She denied personal or family history of blood clots, blood disorders, or rheumatologic disorders, such as lupus or vasculitis. She had three healthy children, a history of three planned abortions, and one miscarriage at five months of gestation. She was not taking hormonal contraceptives. Her medications consisted of albuterol and fluticasone-salmeterol inhalers.

On presentation, she was afebrile, tachycardic to 112 beats per minute, had a blood pressure of 111/82 mmHg, and her oxygen saturation was 96% on room air. Her physical exam was notable for tenderness to palpation in the left upper and lower quadrants, as well as left-sided costovertebral angle (CVA) tenderness. There were no signs of peritoneal irritation.

Laboratory findings on presentation were notable for a creatinine of 1.2 mg/dL (baseline approximately 0.9 mg/dL) and mild thrombocytopenia with a platelet count of 129 x 10^9 Units/L. Urinalysis showed 16 RBCs/HPF and 1+ blood, but was negative for nitrites and leukocytes esterase, with 1 WBC/HPF. A SARS-CoV-2 PCR test from a nasopharyngeal sample, sent for screening prior to inpatient admission per hospital guidelines, was positive. D-dimer was 303 ng/mL (normal range: 0–300 ng/mL), LDH was 117 IU/L (normal range: 100–220 IU/L) and CRP was mildly elevated at 15.72 mg/L (normal range: 0–10 mg/L). A pregnancy test and urine toxicology were negative. A pelvic ultrasound was negative. Abdominal and pelvic computed tomography (CT) with intravenous contrast showed a hypoattenuating area in the lower pole of the left kidney with additional possible wedge-shaped, hypoattenuating regions in both kidneys. Per the radiology read, these findings could reflect renal infarcts versus pyelonephritis. Infection was felt to be less likely given the absence of clinical or laboratory signs of acute urinary tract infection. Magnetic resonance angiography (MRA) of the abdomen with and without intravenous contrast to assess for possible vasculitis demonstrated normal renal and mesenteric vasculature. EKG exhibited normal sinus rhythm. Transthoracic echocardiogram (TTE) with bubble study did not show any evidence of thrombus or shunt.

Given the concern for acute thrombosis, she was started on enoxaparin 1 mg/kg twice daily. Repeat urinalysis and urine culture were negative. An extensive hypercoagulability
workup, including lupus anticoagulant, anti-cardiolipin antibody, protein C, protein S, antithrombin III, beta-2 glycoprotein antibody, factor V activity, and activated protein C resistance, was negative. Anti-neutrophilic cytoplasmic antibody, ANA and complement C3 and C4 to evaluate for a possible autoimmune process were all unremarkable.

On hospital day two, the patient reported new onset of loss of taste and alteration of smell, followed by a mild non-productive cough. She remained afebrile and without oxygen requirement throughout her hospital stay. Her creatinine decreased to 0.88 mg/dL, D-dimer down-trended to 204 ng/mL, and CRP decreased to 6.09 mg/L. Prior to discharge, her anti-coagulation regimen was switched to aspirin 81 mg PO daily and rivaroxaban 20 mg PO daily with a plan of at least three months of anti-coagulation and outpatient hematology follow-up.

**DISCUSSION**

While predominantly known as a respiratory disease, data indicate that patients suffering from COVID-19 have an increased risk of hypercoagulable complications, such as deep vein thrombosis, pulmonary emboli, and cerebral infarctions. However, renal infarction, as in this case, is an uncommon manifestation and an exceedingly rare presenting complaint of COVID-19. The pathogenesis of hypercoagulability with COVID-19 is still being examined, with suggested etiologies including massive cytokine release, anti-phospholipid antibody formation, and endothelial activation.

Renal infarction can arise from a variety of etiologies which can be divided into embolic, thrombophilic (or hypercoagulable), and renal artery lesions. In a single-center retrospective case series (N = 186 cases), the most common cause (>80% of cases) of renal infarct was a renal artery lesion, which includes causes such as atherosclerotic disease, dissection, and fibromuscular dysplasia. To our knowledge, this case is one of the first reports of an otherwise healthy young patient whose initial presenting symptom of COVID-19 was pain from abdominal pain, later found to be a renal infarct. Her hypercoagulability workup was negative, and she denied any family history of bleeding or clotting disorders, making a primary hypercoagulable pathology less likely. Her only hypercoagulable risk factor was active tobacco smoking; she denied any other drug use and at the time of presentation was not using hormonal contraceptives. A negative TTE suggested that a cardiac embolic event was less likely. In addition, a negative MRA excluded other etiologies such as fibromuscular dysplasia or vasculitis.

Our literature review revealed 13 articles with a total of 16 other cases of renal infarcts in the setting of COVID-19 (Table 1). Including the case presented here, 4/16 patients had female sex assigned at birth. Three of these patients were also the youngest among the case reports (28, 39, and 41 years) and included the only three patients whose presenting symptom was flank or abdominal pain. In contrast to this case, the other patients presenting with flank pain had other comorbidities such as poorly controlled hypertension, diabetes mellitus, and obesity. All other patients in this small sample size presented with fever and/or respiratory symptoms.
This case suggests that COVID-19 may present with potentially misleading non-pulmonary complaints that mimic a wide array of other diseases. Especially during the current pandemic, physicians need to be aware that COVID-19 should be considered in selected patients in the absence of pulmonary symptoms or systemic signs such as fever. Further research is necessary to evaluate the relationship between COVID-19 and hypercoagulable events. This is particularly important in the setting of recent pauses in vaccine roll-out due to vaccine-associated thrombotic complications.22,23

Table 1. Literature review of renal infarcts in the setting of COVID-19

<table>
<thead>
<tr>
<th>Article</th>
<th>Patient Age</th>
<th>Patient Sex</th>
<th>Past medical history</th>
<th>Presenting symptom(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mukherjee et al.7</td>
<td>71</td>
<td>Male</td>
<td>None</td>
<td>Fever, cough, dyspnea, chest discomfort</td>
</tr>
<tr>
<td>Xu et al.18</td>
<td>46</td>
<td>Male</td>
<td>Kidney and pancreas transplants</td>
<td>Dyspnea and cough</td>
</tr>
<tr>
<td>Post et al.3</td>
<td>62</td>
<td>Male</td>
<td>HTN, Henoch-Schönlein glomerulonephritis, kidney transplant</td>
<td>Dry cough, fever, dyspnea</td>
</tr>
<tr>
<td>Post et al.9</td>
<td>58</td>
<td>Male</td>
<td>Obstructive sleep apnea</td>
<td>Fever, cough, rhinorrhea, abdominal pain, increasing dyspnea</td>
</tr>
<tr>
<td>Tascón et al.10</td>
<td>56</td>
<td>Male</td>
<td>T2DM, mixed dyslipidemia, uncomplicated diverticulosis</td>
<td>Malaise, fever, cough, diarrhea</td>
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<tr>
<td>Imo et al.11</td>
<td>64</td>
<td>Male</td>
<td>Gastric and duodenal ulcers</td>
<td>Fever</td>
</tr>
<tr>
<td>Besutti et al.12</td>
<td>54</td>
<td>Male</td>
<td>Asthma, smoking history, ulcerative colitis</td>
<td>Syncope, dyspnea, fatigue, fever</td>
</tr>
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<td>Besutti et al.12</td>
<td>53</td>
<td>Male</td>
<td>HTN, mitral valve replacement</td>
<td>Fever, cough, sore throat</td>
</tr>
<tr>
<td>Ramanathan et al.9</td>
<td>54</td>
<td>Male</td>
<td>None</td>
<td>Dry cough, dyspnea, fever</td>
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<tr>
<td>Ammous et al.6</td>
<td>62</td>
<td>Male</td>
<td>HTN, Asthma</td>
<td>Dyspnea</td>
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<tr>
<td>Kundal et al.19</td>
<td>39</td>
<td>Female</td>
<td>Poorly controlled HTN, obesity, OCP use, patent foramen ovale</td>
<td>Right flank pain</td>
</tr>
<tr>
<td>Añazco et al.14</td>
<td>41</td>
<td>Female</td>
<td>Diabetes Mellitus, obesity</td>
<td>Low back pain, respiratory failure, DKA, shock</td>
</tr>
<tr>
<td>Webb et al.15</td>
<td>49</td>
<td>Male</td>
<td>CKD, Deceased donor kidney transplant</td>
<td>Cough, fever, dyspnea, and myalgia</td>
</tr>
<tr>
<td>Mantica &amp; De Rose16</td>
<td>67</td>
<td>Female</td>
<td>Lung adenocarcinoma</td>
<td>Nausea and abdominal pain</td>
</tr>
<tr>
<td>Lushina et al.17</td>
<td>84</td>
<td>Male</td>
<td>HTN</td>
<td>Respiratory distress</td>
</tr>
<tr>
<td>This case</td>
<td>28</td>
<td>Female</td>
<td>Asthma, Migraines</td>
<td>Left lower quadrant pain</td>
</tr>
</tbody>
</table>

Abbreviations: HTN: hypertension; T2DM: Type 2 Diabetes Mellitus; OCP: oral contraceptive; DKA: diabetic ketoacidosis

References

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INTRODUCTION

Omental thickening or “caking” is a radiologic sign that frequently indicates advanced peritoneal disease. It may be secondary to malignant, infectious, or inflammatory etiologies. Notably, the association between omental caking and ovarian cancer has been well established. We present a patient whose initial imaging finding of omental caking preceded a diagnosis of metastatic ovarian cancer.

CASE REPORT

A 59-year-old woman, G2P2, with no documented past medical history presented with 3 weeks of constipation. In the emergency department, she described new-onset bloating, intermittent lower back discomfort, and fatigue, and she denied fever, chills, weight loss, diarrhea, hematochezia, melena, change in stool quality, vaginal bleeding/discharge. Her family history was significant for multiple primary BRCA-associated malignancies. Vital signs were significant for tachycardia to 111 beats per minute sitting upright; otherwise the patient was afebrile and normotensive. Physical examination revealed a protuberant, soft abdomen with diffuse lower tenderness to palpation, no signs of peritoneal irritation, and normal bowel sounds.

On admission, electrolytes and renal function were within normal ranges, hemoglobin was normal, and platelets were elevated to 434,000 platelets/µL. Liver enzymes were significant for elevated Alkaline Phosphatase to 157 U/L; Serum calcium was 9.4 mg/dL and serum albumin was 3.3 g/dL. A CT Abdomen Pelvis with intravenous contrast showed a peritoneal mass of 12 x 4 cm, omental thickening, ascites and no bowel obstruction (Figure 1). CA-125 = 488.8 U/mL (normal: 0-35 U/mL) and CEA of <0.5 ng/mL (normal: <0.5 ng/mL). A diagnostic paracentesis to evaluate for malignancy showed cells consistent with metastatic adenocarcinoma with reproductive tract primary (Figure 2).

After tumor board review of relevant imaging and paracentesis results, the patient was diagnosed with FIGO stage IIIC ovarian cancer and was found to be BRCA2 positive. She underwent neoadjuvant chemotherapy and debulking surgery with good response.
DISCUSSION

Omental thickening refers to radiographic changes of the omentum that result from seeding and/or inflammation of normally translucent fat. Typically, the omentum is barely visible as a fatty band, but inflammation and displacement of bowel from the abdominal wall lead to an opacified appearance classically known as “omental caking.”

Omental caking on CT is most closely associated with ovarian cancer, but can be secondary to a variety of neoplastic, inflammatory, or infectious etiologies. Metastatic involvement is the most common cause of omental caking, with colonic, pancreatic, and gastric cancers also being frequent causes. Cases due to lymphoma are associated with extensive lymphadenopathy. Conditions that cause inflammation of the peritoneum such as cirrhosis, portal hypertension, hematoma, and infarction can lead to CT abnormalities that mimic caking. Infectious etiologies such as tuberculosis have also been shown to induce omental changes.

CT scan is a reliable diagnostic tool for evaluating omental thickening, but imaging methods such as PET/CT and diffusion-weighted MRI also show utility in staging and assessing treatment response. On CT, normal omentum appears as a band of fatty tissue with penetrating vessels. Pathologic features can range from localized fluid collections or infiltrating lesions, to amorphous haziness and generalized changes of the entire omentum. On our patient’s CT scan, significant omental thickening with a large peritoneal mass and numerous implants was observed in addition to extensive ascites without identifiable suspicious ovarian lesions.

CONCLUSION

Omental thickening is an important finding to indicate peritoneal pathology and should trigger alarm when present with no attributable primary cause. In this case, presence of omental thickening on CT led to workup, biopsy, and staging of metastatic ovarian cancer in a previously undiagnosed patient.

References


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Clinical Outcomes of Free, Public Skin Cancer Screening Events, Rhode Island, 2015–2019

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ABSTRACT

BACKGROUND: In Rhode Island, malignant melanoma of skin causes about 30 deaths a year. Early detection has been shown to reduce mortality risk.

METHODS: Dermatology volunteers and public health professionals convened 27 free skin cancer screenings at public beaches in 2015–2019 to raise skin cancer awareness and screen patients for malignancy. Participants with suspicious lesions were referred for follow-up and later telephoned to ascertain outcomes.

RESULTS: Of 2354 people screened, 597 (25%) were referred. 319 of 597 (53%) were later reached by telephone. 196 of 319 (61%) who had kept appointments by the time of the telephone call reported the following diagnoses: 7 malignant melanomas, 32 keratinocyte carcinomas, and 34 actinic keratoses, yielding 3.0 as number needed to biopsy [NNB], and 18.3 as number needed to screen [NNS].

CONCLUSIONS: Our results demonstrate the value of convenient skin cancer screening events, suggesting the desirability of additional interventions of this type.

KEYWORDS: skin cancer screening, melanoma, squamous cell carcinoma, basal cell carcinoma, skin cancer, NNB, NNS

BACKGROUND

The reduction of skin cancer morbidity and mortality has been a nationally recognized objective in the United States [U.S.] since at least 1991, with the publication of Healthy People 2000: National Health Promotion and Disease Prevention Objectives. Since then, the federal government has consistently promoted skin cancer prevention efforts, bolstered by support from other national organizations, state and local departments of public health, and ongoing expert reviews of the scientific literature.

Despite these efforts, morbidity from skin cancer has been difficult to control in the U.S. For example, even though the age-adjusted death rate from cutaneous malignant melanoma [MM] fell about 20% among white U.S. residents between 1990 and 2017 [inclusive], the age-adjusted incidence rate of MM for the same group approximately doubled in the same period. Furthermore, MM diagnosis and treatment is costly: about $3.3 billion annually.

Additionally, MM is not the only potentially lethal skin cancer, even though it is the only form of skin cancer tracked by the Surveillance, Epidemiology, and End Results [SEER] program of the National Cancer Institute and most state cancer registries in the U.S. Squamous cell carcinoma, a type of keratinocyte carcinoma [KC], has been estimated to cause a majority of skin cancer deaths in the U.S., and has been shown to cause a majority of skin cancer deaths globally.

Skin cancers of all varieties, including MM, are more successfully treated when detected early, before the opportunity for regional spread or metastases, but mass screening is not recommended by national authorities in the United States, for lack of sufficient evidence to justify its cost.

Nevertheless, the promotion of skin cancer risk awareness is strongly endorsed by all, and the benefits of selective vigilance for MM on the part of primary care physicians, e.g., among high-risk individuals, have been suggested in the literature.

THE SITUATION IN RI, ‘THE OCEAN STATE’

The Rhode Island Cancer Registry, like the vast majority of state cancer registries in the U.S., collects reports of MM while excluding other forms of skin cancer. The completeness of MM reporting was problematic until about 2000, when direct reporting from pathology labs became common. Since that time, Rhode Island’s age-adjusted MM incidence rates have declined only slightly from about 23.2 per 100,000 in 2002 to about 22.3 per 100,000 in 2017. Annually at present, the state records about 230 new MM cases and 30 MM deaths, and spends about $10 million on MM healthcare. Rhode Island, “The Ocean State,” has many occupational and recreational opportunities for ultraviolet light [UV] exposure. Thus MM has been a focus of the state’s cancer control efforts since the late 1980s.

OBJECTIVE

To raise awareness of risks and symptoms of skin cancer and to facilitate early detection and treatment of concerning skin lesions, a partnership of volunteers, including dermatologists,
Twenty-seven skin cancer screening events were held at Rhode Island beaches from 2015 through 2019 during peak UV flux hours (12:30 p.m. to 2:30 p.m.) in July or August. Screenings were publicized via earned (unpaid) broadcast media [WJAR Channel 10] and social media to assure capacity attendance. Promotional signage was also used at events. Screenings were performed in cabanas by dermatologists and dermatology residents, assisted by medical students, and supported by other volunteers. All screenings performed by residents and medical students were supervised by a board-certified dermatologist. Non-medical volunteers took responsibility for set-up and break-down, participant flow, and record keeping.

Using the American Academy of Dermatology “SPOTme” screening registration and report form, an encounter record was created for each participant, noting demographic information (gender, age, race, ethnicity), risk factors (sunscreen use, history of tanning and sunburns), examination findings, and referrals for dermatology appointments.

Participants who were referred were asked to volunteer contact information so that we might ascertain definitive diagnoses. Virtually all consented to follow-up telephone calls, though some could not be reached. (Up to three calls were attempted.) Most calls were made 1–2 months post screening, and a few up to 6 months post screening.

Recording, management, and analysis of screening data were done in Microsoft Excel. Confidential information was managed in a secure, hospital-based data system. Only authorized personnel had access to confidential information. A fully de-identified dataset was prepared for data analysis.

**RESULTS**

### Demographics and History of Subjects

2,354 members of the general public were screened. The number of subjects screened at events ranged from 41 to 127. More subjects presented for screening on “good beach days” and when screenings were better publicized. Almost two-thirds of the subjects (63%) had reached age 40. One-third (33%) had reached age 60. Only 8% were younger than 19. (Minors were screened in the company of parents.) Slightly more than half of the subjects (56%) were female. Most self-reported as white/non-Hispanics. (Table 1) Almost a tenth of the subjects (9%) reported personal history of skin cancer, and about one-fourth (23%) reported family history of skin cancer. About one-third (31%) reported indoor tanning, and slightly more than one-third (35 percent) reported four or more episodes of blistering sunburn. (Table 1) In short, subjects were predominantly fair-skinned adults who had reached middle age, many of whom reported personal or family histories of skin cancer or high-risk exposures to UV.

<table>
<thead>
<tr>
<th>Year of Screening</th>
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<td>Number screened</td>
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<td>432</td>
<td>515</td>
<td>379</td>
<td>513</td>
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<tr>
<td>&lt;19 years</td>
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<td>7%</td>
<td>4%</td>
<td>6%</td>
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<td>20–39 years</td>
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<td>29%</td>
<td>16%</td>
<td>12%</td>
<td>15%</td>
<td>18%</td>
</tr>
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<td>40–59 years</td>
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<td>30%</td>
<td>23%</td>
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<td>60–79 years</td>
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<td>39%</td>
<td>20%</td>
<td>39%</td>
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<td>80+ years</td>
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<td>White/Non-Hispanic</td>
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</tr>
<tr>
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<td>1%</td>
</tr>
<tr>
<td>Asian</td>
<td>1%</td>
<td>0%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Mixed Race/Ethnicity</td>
<td>2%</td>
<td>3%</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Family history of skin cancer</td>
<td>23%</td>
<td>41%</td>
<td>38%</td>
<td>27%</td>
<td>19%*</td>
<td>18%*</td>
</tr>
<tr>
<td>Personal History of skin cancer</td>
<td>9%</td>
<td>9%</td>
<td>11%</td>
<td>8%</td>
<td>8%</td>
<td>8%</td>
</tr>
<tr>
<td>Ever engaged in indoor tanning</td>
<td>31%</td>
<td>36%</td>
<td>27%</td>
<td>37%</td>
<td>24%</td>
<td>31%</td>
</tr>
<tr>
<td>Sunscreen use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td>39%</td>
<td>47%</td>
<td>37%</td>
<td>36%</td>
<td>40%</td>
<td>36%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>42%</td>
<td>43%</td>
<td>45%</td>
<td>45%</td>
<td>38%</td>
<td>40%</td>
</tr>
<tr>
<td>Rarely</td>
<td>8%</td>
<td>6%</td>
<td>10%</td>
<td>9%</td>
<td>7%</td>
<td>8%</td>
</tr>
<tr>
<td>Never</td>
<td>4%</td>
<td>2%</td>
<td>4%</td>
<td>5%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Unknown</td>
<td>7%</td>
<td>2%</td>
<td>4%</td>
<td>5%</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Estimated number of previous blistering sunburns</td>
<td>0–3</td>
<td>57%</td>
<td>62%</td>
<td>61%</td>
<td>52%</td>
<td>51%</td>
</tr>
<tr>
<td>4–6</td>
<td>19%</td>
<td>19%</td>
<td>18%</td>
<td>20%</td>
<td>22%</td>
<td>17%</td>
</tr>
<tr>
<td>7–10</td>
<td>7%</td>
<td>8%</td>
<td>7%</td>
<td>10%</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>10+</td>
<td>9%</td>
<td>8%</td>
<td>7%</td>
<td>10%</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Unknown</td>
<td>8%</td>
<td>3%</td>
<td>7%</td>
<td>8%</td>
<td>11%</td>
<td>10%</td>
</tr>
</tbody>
</table>

* In some 2018 screenings and in all 2019 screenings, a direct question about family history was not asked, but participants could indicate family history as one of the reasons for attending the screening.
Table 2. Results of screenings, by year of screening

<table>
<thead>
<tr>
<th>Year of Screening</th>
<th>5 Years</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number screened and referred to dermatologist</td>
<td>2,354</td>
<td>432</td>
<td>515</td>
<td>379</td>
<td>513</td>
<td>515</td>
</tr>
<tr>
<td>Number referred to dermatologist</td>
<td>597</td>
<td>73</td>
<td>134</td>
<td>126</td>
<td>118</td>
<td>146</td>
</tr>
<tr>
<td>% referred to dermatologist</td>
<td>25%</td>
<td>17%</td>
<td>26%</td>
<td>33%</td>
<td>23%</td>
<td>28%</td>
</tr>
</tbody>
</table>

Follow-up by persons screened

| Number of those referred reached by follow-up interview | 319 | 45 | 75 | 67 | 47 | 85 |
| % of those referred reached by follow-up interview | 53% | 62% | 56% | 53% | 40% | 58% |

| Number with a completed visit to a dermatologist confirmed | 196 | 29 | 53 | 44 | 26 | 44 |
| Number with a scheduled visit to a dermatologist confirmed | 24 | 2 | 3 | 1 | 2 | 16 |
| % with a completed visit, confirmed (of 597) | 33% | 40% | 40% | 35% | 22% | 30% |
| % with a completed or scheduled visit, confirmed (of 597) | 37% | 42% | 42% | 36% | 24% | 41% |

Initial observations at screening of all screened

| Observation: Actinic keratosis AK | 248 | 22 | 67 | 50 | 57 | 52 |
| Observation: Keratinocyte carcinoma KC | 126 | 16 | 38 | 21 | 24 | 27 |
| Observation: Melanoma MM | 8 | 0 | 2 | 1 | 4 |
| TOTAL of AK + KC + MM observations | 382 | 39 | 105 | 73 | 82 | 83 |
| TOTAL of KC + MM observations | 134 | 17 | 38 | 23 | 25 | 31 |
| Observation: Other | 762 | 89 | 183 | 105 | 204 | 181 |

Initial observations at screening of those with confirmed visits

| Observation: Actinic keratosis AK | 99 | 8 | 20 | 24 | 21 | 26 |
| Observation: Keratinocyte carcinoma KC | 89 | 10 | 14 | 11 | 12 | 42 |
| Observation: Melanoma MM | 9 | 1 | 0 | 1 | 0 |
| TOTAL of AK + KC + MM observations | 197 | 19 | 34 | 36 | 33 | 75 |
| TOTAL of KC + MM observations | 98 | 11 | 14 | 12 | 12 | 49 |
| Observation: Other | 98 | 8 | 20 | 11 | 11 | 48 |

Reported diagnoses

| Diagnosis: Actinic keratosis AK | 34 | 0 | 3 | 19 | 3 | 9 |
| Diagnosis: Keratinocyte carcinoma KC | 32 | 6 | 6 | 4 | 5 | 11 |
| Diagnosis: Melanoma MM | 7 | 3 | 3 | 1 | 0 | 0 |
| TOTAL of AK + KC + MM diagnoses | 73 | 9 | 12 | 24 | 8 | 20 |
| TOTAL of KC and MM diagnoses | 39 | 9 | 9 | 5 | 5 | 11 |

Initial Observations and Referrals

Of 2354 subjects screened, 597 [25%] were referred for dermatology appointments, 248 [42%] for suspicion of actinic keratosis [AK], 126 [21%] for suspicion of keratinocyte carcinoma [KC], nine [1%] for suspicion of melanoma of skin [MM], and 215 [36%] for suspicion of other conditions. (Table 2)

Follow-up Interviews

Of 597 subjects referred, 319 [53%] were subsequently reached by telephone and asked: “Did you make a dermatology appointment?” [If yes] “Did you keep it?” [If yes] “What was your diagnosis?”

Reported Diagnoses

The 196 subjects who had completed appointments reported 73 diagnoses of special note: 34 AK, 32 KC, and seven MM (Table 2), yielding [minimum] prevalence estimates among 2354 subjects of: 1444/100,000 [AK], 1359/100,000 [KC], and 297/100,000 [MM]. These prevalence minima may be compared very roughly with analogous estimates of prevalence [PRV as available, or incidence INC in the absence of prevalence estimates] for the United States as a whole: 11,000-25,000/100,000 [AK PRV].19 1,056/100,000 [KC INC].20 41/100,000 [MM INC].21

Screening Efficiency

Maximum and best estimates of two measures of screening efficiency, “number needed to screen” [NNS] and “number needed to biopsy” [NNB] were calculated for cancerous lesions [KC + MM] and for precancerous and cancerous lesions combined [AK + KC + MM]. NNS and NNB were defined as follows: NNS = number screened ÷ number diagnosed; NNB = number referred ÷ number diagnosed.

Maximum estimates were calculated from raw numbers of subjects screened, subjects referred, and confirmed diagnoses. Best estimates were calculated from raw numbers of subjects screened, subjects referred, and estimated numbers of confirmed diagnoses. The latter were constructed by assuming that the number and types of diagnoses were proportionately the same among referred subjects who had been seen by a dermatologist and those who had not been seen or could not be recontacted.

The resulting estimates provide a range between which “true” measures of NNS and NNB probably reside.
good yield of serious diagnoses and the relative efficiency of our screening efforts over five years of public screenings. Concerning yield, our screenings were highly publicized and conducted at beaches, where sun worshipers congregate. Concerning efficiency, our screenings were overseen by board-certified dermatologists. Indeed, the consistency of our findings suggests that we would continue to achieve strong yield and high efficiency were we to maintain these practices. Our study had two limitations. First, given the effort that went into promoting our screening events, it is quite likely that participants may have self-selected on the basis of existing concerns. Although this possibility is not a problem in itself, our yield of skin cancers should not be considered representative of what is discoverable in the general population or, for that matter, among beach goers. Second, we were able to recontact only 53 percent of the participants referred for dermatological care. Therefore, our yield of confirmed diagnoses almost certainly underestimates the true yield. Even though the latter may have biased our results conservatively, we will attempt to increase our “recontact rate” in future.

CONCLUSIONS

In our study, we conducted a screening program primarily at public beaches in the summer, and thus, our participants were “presumptively-at-high-risk” individuals, most of whom were sunbathing at the beach during peak UV index hours. Our yield of serious lesions was consistently strong.

Our approach has the following advantages: It is simple, it is accessible, it is inexpensive, and it facilitates non-invasive visual inspection, since most participants at the beach are wearing bathing suits when they decide to participate. Furthermore, we believe our approach is highly replicable. We held screenings on 27 separate occasions using different sets of volunteers, and found similar results across five years.

A potential risk of public screening events is low yield, which increases the cost-per-case-detected for staff and participants alike, and may lead to increased health care costs because of unnecessary dermatology appointments and biopsies. However, our “formula” has demonstrated consistent and efficient yields, and therefore, we propose to continue our efforts in Rhode Island.

In the future, we will continue to evaluate our efforts closely, broadening our focus from screening yield and

Subjects’ Satisfaction

Virtually all participants valued rated the screening experience either “excellent” or “very good.”

DISCUSSION

Over five summers, 27 skin cancer-screening events were conducted at Rhode Island beaches at very low cost because of volunteered space, labor, and publicity. Overall, 2354 subjects were screened, 597 of whom (25%) were referred for dermatological follow-up, including 134 for suspicion of KC or MM (cancer), 248 suspicion of AK (precancer), and 215 for other conditions. Of the 597 subjects referred, 319 subjects (53%) could be recontacted, and of these, 196 had kept appointments, allowing us to calculate minima for confirmed diagnoses and related maxima and best estimates for NNS and NNB.

Our best estimate of NNS for KC and MM combined [18.3] compares favorably with a range of NNS estimates observed in office-based practices over the past 29 years: 10.5–122.6.22,23,24,25,26

Similarly, our best estimate of NNB for KC and MM combined [3.0] compares favorably with estimates of NNB observed for office-based practices over the past 15 years: 1.5–6.6.27,26,29,30,31,32

Several factors may have contributed to the consistently

Table 3. Estimating number needed to screen (NNS) and number needed to biopsy (NNB), by year of screening

<table>
<thead>
<tr>
<th>Year of Screening:</th>
<th>5 Years</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number screened, referred, interviewed, diagnosed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number screened</td>
<td>2,354</td>
<td>432</td>
<td>515</td>
<td>379</td>
<td>513</td>
<td>515</td>
</tr>
<tr>
<td>Number referred for AK, KC, or MM</td>
<td>382</td>
<td>39</td>
<td>105</td>
<td>73</td>
<td>82</td>
<td>83</td>
</tr>
<tr>
<td>Number confirmed as seen for AK, KC, or MM</td>
<td>116</td>
<td>14</td>
<td>33</td>
<td>30</td>
<td>17</td>
<td>22</td>
</tr>
<tr>
<td>Number diagnosed with AK, KC, or MM</td>
<td>73</td>
<td>9</td>
<td>12</td>
<td>24</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Number diagnosed with KC or MM</td>
<td>39</td>
<td>9</td>
<td>9</td>
<td>5</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Number needed to screen for cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum:</td>
<td>A + E</td>
<td>60.4</td>
<td>48.0</td>
<td>57.2</td>
<td>75.8</td>
<td>102.6</td>
</tr>
<tr>
<td>Best Estimate:</td>
<td>A + [E x (B + C)]</td>
<td>18.3</td>
<td>17.2</td>
<td>18.0</td>
<td>31.2</td>
<td>21.3</td>
</tr>
<tr>
<td>Number needed to screen for cancer or precancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum:</td>
<td>A + D</td>
<td>32.2</td>
<td>48.0</td>
<td>42.9</td>
<td>15.8</td>
<td>64.1</td>
</tr>
<tr>
<td>Best Estimate:</td>
<td>A + [D x (B + C)]</td>
<td>9.8</td>
<td>17.2</td>
<td>13.5</td>
<td>6.5</td>
<td>13.3</td>
</tr>
<tr>
<td>Number needed to biopsy for cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum:</td>
<td>B + E</td>
<td>9.8</td>
<td>4.3</td>
<td>11.7</td>
<td>14.6</td>
<td>16.4</td>
</tr>
<tr>
<td>Best Estimate:</td>
<td>C + E</td>
<td>3.0</td>
<td>1.6</td>
<td>3.7</td>
<td>6.0</td>
<td>3.4</td>
</tr>
<tr>
<td>Number needed to biopsy for cancer or precancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum:</td>
<td>B + D</td>
<td>5.2</td>
<td>4.3</td>
<td>8.8</td>
<td>3.0</td>
<td>10.3</td>
</tr>
<tr>
<td>Best Estimate:</td>
<td>C + D</td>
<td>1.6</td>
<td>1.6</td>
<td>2.8</td>
<td>1.3</td>
<td>2.1</td>
</tr>
</tbody>
</table>

(Although it is possible that the true measures of NNS and NNB are lower than best estimates, we have no evidence to suggest this.) NNS appears to lie between 18 and 60 for cancerous lesions, and between 10 and 32 for cancerous and precancerous lesions together. NNB appears to lie between 3 and 10 for cancerous lesions, and between 2 and 5 for cancerous and precancerous lesions together. (Table 3)
participant satisfaction to include careful measurement of costs (including the dollar value of the time spent by our unpaid volunteers). We will also attempt to measure changes in the knowledge, attitudes, and practices of the Rhode Island general public in regard to skin cancer prevention and screening which may be attributable to the publicity generated by the public screenings we conduct.

**APPENDIX**

**SPOTime Registration Form**

**References**


18. See: SPOT me 2020 Program Guidelines. Rosemont, IL: American Academy of Dermatology, 2020, p. 5. https://assets.ctfassets.net/1nay4y9iyriqa/13ns00L1QbP0CPF1ehHdw4/819f5b9b0b8ca7b5bce321d093b9b9f/Member_Career_Volunteer_SPOT-screenings-resources_SPOT-Guideline_Book.pdf


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27. Waseh, Shayan; Bui, Michael; Hugo, Audra; Sherban, Alexander; and Jones, Elizabeth, “Total Body Skin Exams: Sensitivity, Specificity, and Number Needed to Screen” (2018). SKMC JeffMD Scholarly Inquiry, Phase 1, Project 1. https://jdc.jefferson.edu/cgi/viewcontent.cgi?article=1029&context=s_i_phr_2021_phase1

28. Waseh, Shayan; Bui, Michael; Hugo, Audra; Sherban, Alexander; and Jones, Elizabeth, “Total Body Skin Exams: Sensitivity, Specificity, and Number Needed to Screen” (2018). SKMC JeffMD Scholarly Inquiry, Phase 1, Project 1. https://jdc.jefferson.edu/cgi/viewcontent.cgi?article=1029&context=s_i_phr_2021_phase1
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Conflicts of Interest: None declared.

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Time to Head Computed Tomography Protocol in Traumatic Brain Injury: A Quality Improvement Metric

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ABSTRACT

BACKGROUND: Early identification of traumatic brain injury (TBI) with head CT HCT should expedite operative decision-making and improve outcome. We aimed to determine whether an early HCT protocol in TBI patients would improve outcome.

METHODS: A multidisciplinary protocol to obtain an HCT within 30 minutes from arrival for patients with GCS ≤ 13 was instituted on 1/1/2015. Our trauma registry was queried for patients evaluated between 3/2012 and 12/2015. Outcomes included compliance with protocol and in-hospital mortality.

RESULTS: 346 patients presented with GCS ≤ 13. Patients PRE- (n=264) and POST-protocol (n=82) were similar in demographic and physiologic characteristics. Time to HCT was lower (35 vs. 77 min; p<0.001). POST-protocol had lower odds of mortality (OR 0.65, 95% CI 0.43–0.99) adjusting for age, gender, ISS and GCS.

CONCLUSION: Implementing a protocol of early HCT for TBI optimized performance of the trauma team. Time to HCT could serve as a quality metric in TBI.

KEYWORDS: traumatic brain injury, head CT, time to CT, quality improvement

INTRODUCTION

Traumatic brain injury (TBI) is the leading cause of death in individuals younger than 45 years old and many survivors are left with significant, life-long disabilities.1,3 TBI accounts for nearly 1.4% of all emergency room visits, over 0.7% of U.S. hospitalizations, and contributes to over 30% of all injury-related deaths.3

Head computed tomography (HCT) is the preferred diagnostic imaging modality, and an expedited HCT should be a part of the initial workup in patients with suspected TBI.4,7 Early identification of TBI by means of HCT could expedite operative decision making, lead to earlier interventions, and subsequently improve outcome. Some authors have found significantly higher odds of survival in patients undergoing early neurosurgical interventions in severe TBI, recommending early HCT and neurosurgical consultation.8 To our knowledge there are no guidelines for time-sensitive HCT in patients with suspected TBI specifically, nor does data exist for its association with improved outcome. We hypothesized that the implementation of a protocol of early HCT in patients with moderate and severe TBI would be associated with improved outcomes.

METHODS

This is a retrospective cohort study of prospectively collected data following the initiation of a multidisciplinary quality improvement protocol at our level 1 trauma center. The protocol was initiated on January 1, 2015. It offered recommendations to transport patients to obtain HCT within 30 minutes of arrival to the emergency department (ED) for patients with suspected TBI and a Glasgow Coma Scale GCS of ≤ 13 (moderate and severe TBI). GCS was assessed at time of arrival to ED and re-assessed frequently. While GCS can be influenced by other factors, such as medical conditions or intoxication, patients with a traumatic mechanism and decreased GCS score were triaged as high-risk for traumatic brain injury.

Our ED is equipped with two CT scanners in close proximity to the trauma resuscitation rooms. The protocol included several educational sessions to ED staff and radiology technologists prior to and during the early phase of protocol implementation. Time to HCT was recorded in the registry in minutes from time of arrival to ED to time of first obtained image in CT. We elected to report time to first image of the CT scan to avoid variability among different scanning protocols. For patients with multiple injuries requiring more extensive CT imaging, the HCT was performed first and the start time of image capture was used to define time to HCT.

After constructing the study concept, we obtained an Institutional Review Board (IRB) approval prior to collecting the data. The trauma registry was queried for adult (≥18 years old) TBI patients with an Abbreviated Injury Scale (AIS) ≥ 3. AIS is coded by the trauma registrars based on severity of injury, from minor (AIS=1) to nonsurvivable (AIS=6), per the National Trauma Data Standards (NTDS) dictionary, [See Appendix]. The AIS cutoff was chosen to evaluate the impact on severe injuries that are more likely to require an intervention in order to detect maximal improvement
effect. Our exclusion criteria included those who had initial GCS>13, those with missing or incomplete data, and patients who were transferred from another facility. One patient was excluded because first head CT was obtained 24 hours after presentation due to new clinical findings suggestive of head injury. The time periods before [PRE] and after [POST] implementation of the protocol were compared. The PRE period included all patients captured in the trauma registry and extended from March 2012 until December 2014. The POST period extended from January 2015 until December 2015. Our primary outcome was compliance with protocol. Patients’ outcomes that were evaluated included in-hospital mortality, the need for discharge from the hospital to a facility vs. home, and time to surgical interventions – external drainage device placement (EVD), craniectomy, or craniotomy – for those who required such an intervention within the first hospitalization day. These outcomes were evaluated as surrogates of quality of care and not as a direct response to the reduced time to HCT.

Categorical data were analyzed using Chi-square and reported as frequencies and percentages. Nonparametric continuous data were analyzed using Wilcoxon-Rank Sum test and nonparametric equality-of-medians test. These are presented as medians or averages with interquartile range [IQR] or percent as appropriate. Multiple regression analysis was used for predicting the odd ratios of mortality as a primary outcome. All statistical analyses were computed using a commercial statistical software [Stata/SE 14, StataCorp 2015, College Station, TX, USA] and were conducted with a significance level of 0.05.

RESULTS

Between March 2012 and December 2015, 1873 patients with TBI and a head AIS ≥ 3 were evaluated. After excluding patients based on above-mentioned criteria, our analytic sample included 346 patients. Two hundred and sixty-four patients (76.3%) were evaluated before the protocol was initiated PRE and 82 patients (23.7%) after the protocol POST. [Figure 1] There was no statistically significant difference between PRE and POST groups with respect to demographics, mechanism of injury, injury severity, or physiology. The number of procedures performed in the ED was similar in each group [median=1, p=0.34]. [Table 1] Compared to the PRE group, the POST group was noted to have a significant difference in the percentage of patients who received HCT within 30 minutes [1.5% vs., 35.4%, p = <0.001], and the time to HCT [median: 77 minutes [58-95] PRE vs. 35 minutes [27-47] POST, p = <0.001, mean: 82 minutes PRE vs. 39 minutes POST]. [Figure 2]

Post-protocol, EVD was placed more frequently [13.3% PRE vs. 25.6% POST, p = 0.01] and more rapidly [307 minutes [142-542] PRE vs. 159 minutes [129-195] POST, p = 0.01]. Using multiple linear regression analysis to adjust for

**Table 1. Characteristics of patients in the PRE-protocol and POST-protocol groups.** Data are presented as mean, median with range, or total number with percentage.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>PRE-Protocol n=264</th>
<th>POST=Protocol n=82</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>52 (18–101)</td>
<td>48 (18–96)</td>
<td>0.21</td>
</tr>
<tr>
<td>Gender, male</td>
<td>180 (68.2%)</td>
<td>62 (75.6%)</td>
<td>0.20</td>
</tr>
<tr>
<td>Race, white</td>
<td>227 (86%)</td>
<td>69 (85.2%)</td>
<td>0.83</td>
</tr>
<tr>
<td>BMI</td>
<td>26 (13–44)</td>
<td>25.8 (15–40)</td>
<td>0.8</td>
</tr>
<tr>
<td>Mechanism, blunt</td>
<td>246 (93.2%)</td>
<td>77 (93.9%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Fall</td>
<td>109 (41.3%)</td>
<td>34 (41.5%)</td>
<td>0.98</td>
</tr>
<tr>
<td>Pre–hospital anticoagulation</td>
<td>28 (10.6%)</td>
<td>8 (9.7%)</td>
<td>0.84</td>
</tr>
<tr>
<td>Injury severity score (ISS)</td>
<td>24.4 (9–59)</td>
<td>26.1 (9–75)</td>
<td>0.18</td>
</tr>
<tr>
<td>Head AIS (median)</td>
<td>4 (3–5)</td>
<td>5 (3–5)</td>
<td>0.08</td>
</tr>
<tr>
<td>AIS=3</td>
<td>73 (27.9%)</td>
<td>21 (25.6%)</td>
<td>0.19</td>
</tr>
<tr>
<td>AIS=4</td>
<td>83 (31.7%)</td>
<td>19 (23.2%)</td>
<td></td>
</tr>
<tr>
<td>AIS=5</td>
<td>106 (40.5%)</td>
<td>42 (51.2%)</td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>18 (8.6%)</td>
<td>4 (6.4%)</td>
<td>0.57</td>
</tr>
<tr>
<td>Emergency department (ED)</td>
<td>35 (13.2%)</td>
<td>17 (21.2%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Number of ED procedures (median)</td>
<td>1 (0–6)</td>
<td>1 (0–3)</td>
<td>0.34</td>
</tr>
<tr>
<td>Tube thoracostomy</td>
<td>20 (7.6%)</td>
<td>3 (3.7%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Central lines</td>
<td>34 (12.9%)</td>
<td>9 (11%)</td>
<td>0.65</td>
</tr>
<tr>
<td>Fracture reduction</td>
<td>9 (3.4%)</td>
<td>3 (3.6%)</td>
<td>0.91</td>
</tr>
<tr>
<td>Intubation</td>
<td>158 (59.8%)</td>
<td>53 (64.6%)</td>
<td>0.44</td>
</tr>
</tbody>
</table>

BMI: Body mass index, ISS: Injury Severity Score, AIS: Abbreviated Injury Scale, ED: Emergency Department.

AIS: Abbreviated Injury Scale, HCT: Head Computed Tomography, GCS: Glasgow Coma Scale, OSH: Outside Hospital.

**Figure 1. Analytic sample selection process for traumatic brain injury patients who are evaluated in emergency department directly from the scene and who had GCS ≤13.**

**Figure 2.**

[Figure 2]
age, gender, head AIS, and GCS, there was still significantly less time to EVD placement in the POST group compared to the PRE group \(p=0.008\). While there was no difference in the percentage of patients requiring surgical decompression.

Figure 2. Boxplot showing the distribution of time to head computed tomography (31) in the PRE-protocol and POST-protocol groups. The horizontal line is a reference line that represents the goal of time to HCT in the protocol (30 minutes).

Table 2. Outcome differences between the PRE-protocol and the POST-protocol groups. Data presented as median with IQR or number of patients with percentage. Surgical decompression reflects number of craniectomy or craniotomy procedures performed on first hospital day (HD#1).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PRE-Protocol n=264</th>
<th>POST=Protocol n=82</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>101 (38.1)</td>
<td>27 (32.9)</td>
<td>0.4</td>
</tr>
<tr>
<td>Head CT scan within 30 minutes</td>
<td>4 (1.5)</td>
<td>29 (35.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time to head CT scan</td>
<td>77 (58-95)</td>
<td>35 (27-47)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ED length of stay, minutes</td>
<td>291 (199-460)</td>
<td>257 (154-413)</td>
<td>0.38</td>
</tr>
<tr>
<td>Hospital length of stay, days</td>
<td>6 (2-18)</td>
<td>9 (3-22)</td>
<td>0.3</td>
</tr>
<tr>
<td>EVD placed on HD#1</td>
<td>35 (13.3)</td>
<td>21 (25.6)</td>
<td>0.01</td>
</tr>
<tr>
<td>Time to EVD, minutes*</td>
<td>307 (142-542)</td>
<td>159 (129-195)</td>
<td>0.01</td>
</tr>
<tr>
<td>Surgical decompression†</td>
<td>37 (14)</td>
<td>7 (8.5)</td>
<td>0.26</td>
</tr>
<tr>
<td>Time to decompression, minutes</td>
<td>163 (112-280)</td>
<td>126 (112-131)</td>
<td>0.04</td>
</tr>
<tr>
<td>Discharged to Facility</td>
<td>120 (73.6)</td>
<td>43 (78.2)</td>
<td>0.52</td>
</tr>
</tbody>
</table>

CT: Computed Tomography, ED: Emergency Department, EVD: External Ventricular Drain.
* Time to EVD continued to be significantly less in the POST-protocol group when adjusted for age, gender, head AIS, and GCS in a multiple linear regression analysis \(p=0.008\)
† Rate of decompression if performed within 24 hours from admission.

Table 3. Multiple logistic regression analysis results showing crude and adjusted odds ratio (9) of mortality in POST-protocol group compared to PRE-protocol group adjusting to age, gender, ISS, and GCS. Results expressed as odds ratios and 95% confidence intervals.

<table>
<thead>
<tr>
<th></th>
<th>Crude OR (95%CI)</th>
<th>Adjusted OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>POST-Protocol</td>
<td>0.78 (0.57–1.07)</td>
<td>0.65 (0.43–0.99)</td>
</tr>
<tr>
<td>Age</td>
<td>1.00 (0.99–1.01)</td>
<td>1.05 (1.04–1.06)</td>
</tr>
<tr>
<td>Gender, male</td>
<td>1.51 (1.14–2.01)</td>
<td>1.62 (1.10–2.38)</td>
</tr>
<tr>
<td>ISS</td>
<td>1.16 (1.14–1.18)</td>
<td>1.12 (1.10–1.15)</td>
</tr>
<tr>
<td>GCS</td>
<td>0.75 (0.73–0.78)</td>
<td>0.74 (0.71–0.78)</td>
</tr>
</tbody>
</table>

DISCUSSION

Severely injured patients, specifically those with moderate to severe traumatic brain injuries have improved outcomes when treated at a Level 1 trauma center.\(^9\,12\) This is due to improved access to appropriate diagnostic modalities, management by highly trained care teams, and rapid intervention when indicated.\(^13\,15\) Computed tomography has contributed to improved outcomes in trauma,\(^16\) and many Level 1 trauma centers have implemented protocols that focus on expeditious image acquisition.\(^17\,19\) Delay in diagnosis of TBI is associated with increased mortality,\(^20\) and the implementation of a decision support intervention to obtain early head CT resulted in higher rate of identification of intracranial hemorrhage that would have otherwise been missed, resulting in improved mortality.\(^21\)

Ideal timing for first head CT in TBI patient is still unknown. Matsushima et al recommended faster times to CT scan in severe TBI patients in order to expedite neurosurgical interventions and subsequently to improve patients’ outcomes.\(^8\) In the aforementioned study of isolated severe trauma patients, the average time to HCT was 45 minutes. The Quality of Trauma in Adult Care (QTAC) program, based in the University of Calgary in Canada, uses time to HCT within 1 hour as a hospital quality indicator; however, the average time to HCT in one Canadian quality improvement study was 4 hours and 36 minutes.\(^22\)
time to HCT in a study by Easton and colleagues from the University of Newcastle in Australia was 66 minutes. A recent analysis of the Trauma Quality Improvement Program database showed that earlier head CT within 1 hour from presentation was associated with earlier neurosurgical interventions.

In an effort to improve the outcome of these patients, we implemented a quality improvement protocol in January 2015 to obtain head CT in moderate and severe TBI patients within 30 minutes from arrival. In our analysis immediately following the introducing the protocol, approximately one third of the patients POST-protocol met the desired goal time. Other investigators reported high compliance rates (>70%) after implementing similar CT protocols in acute stroke. The lower compliance rate we observed is likely multifactorial. Unlike stroke patients, moderate to severe TBI patients frequently present with an array of other injuries requiring immediate interventions during the initial resuscitation phase. Two thirds of the patients in our sample required intubation prior to obtaining diagnostic studies. These interventions, while unavoidable, cause significant delays in the workup of potential TBI. Future work is crucial to identify modifiable factors that could result in even further reduction in time to HCT. For example, in centers without immediate availability of CT scanners, the installation of these scanners in close proximity to trauma resuscitation rooms in the ED or the utilization of portable CT scanners has been shown to significantly reduce the time needed to obtain diagnostic imaging in trauma patients.

The time to critical neurosurgical intervention and in-hospital mortality are important quality metrics to consider when evaluating TBI-specific outcomes. After implementing our protocol, more patients underwent EVD placement and received this intervention more rapidly, halving the median time from 309 minutes to 159 minutes. The increase in EVD placement can be attributed to two potential factors. The early diagnosis likely helped in identifying eligible patients who would benefit from early neurosurgical interventions. The improved awareness that was generated around the time of the protocol could have been led to earlier and more aggressive management decisions regarding invasive monitoring. Similarly, for those who required surgical decompression – craniotomy or craniectomy – the time to the operating room was shorter in the POST group than the PRE group by 34 minutes. Ultimately, there were lower odds (OR 0.65) of mortality in moderate to severe TBI patients after implementing the protocol, controlling for age, gender, ISS and initial GCS. We believe the observed improvement in these outcomes to be a surrogate to quality of care after implementing the protocol and not due to direct effect of the time to HCT. We attribute these findings to the increased awareness of the importance of rapid diagnosis and treatment of traumatic brain injury. Similarly, Techar et al found an association between delay in head CT scan and in-patient mortality. They attributed this association to delay in neurosurgical interventions as a result of delay in diagnosis. However, while the analysis by Schellenberg et al did show that earlier head CT was associated with earlier placement of EVD and earlier surgical interventions when indicated, it did not find an association with reduced mortality. Both the use of intracranial pressure monitoring and the reduced time to surgical decompression have been suggested as interventions to improve outcomes in TBI patients.

LIMITATIONS
There are several limitations to this study. First, this is a retrospective cohort study, and therefore, we cannot prove causality, nor can we account for unknown biases. Moreover, there are likely unmeasured confounders that we could not control for in our regression analysis. Complete adjustment of all confounders could have resulted in a weaker association. We acknowledge that unrecognized and immeasurable changes in the practice patterns might have occurred. Our analysis was limited by observational bias due to data collection and entry. This study design might impact its generalizability. In this current analysis, we compared pre- and post-protocol implementation, similar to an intention-to-treat analysis, to reflect the protocol impact as a whole. Alternatively, we strongly consider, and encourage, analyzing time to head CT specifically as an independent factor influencing TBI-specific outcomes. To avoid the possible confounding of the time of protocol implementation, such an analysis would include patients in the post-protocol time period only and compare those who did and did not get a head CT within 30 minutes. Second, the reported time to HCT did not account for potential delays within the radiology suite after arrival. Third, we were unable to report neurological outcomes at the time of discharge. Traumatic brain injury patients often have significant short-term and long-term functional deficits. Functional outcome scales, like Glasgow Outcome Scale, are not routinely obtained for our TBI population. Finally, due to the limited length of the POST period we could not identify a transition period after which we could possibly observe even stronger improvement in outcomes. Future evaluation of long-term effects of the protocol on times to interventions and outcomes would likely clarify this relationship and evaluate sustainable results for a longer duration. Further prospective investigations would be needed to demonstrate a direct effect on our primary and secondary outcomes.

CONCLUSION
In our experience, the application of a novel protocol to obtain early HCT for severe TBI optimized performance of the multi-disciplinary trauma team and improved outcomes.
We believe that our study provides preliminary evidence that time to HCT could be recommended as a quality metric in patients with moderate to severe TBI. Future evaluations, as well as a larger prospective study, are warranted to further validate its value. While our protocol focused on triaging suspected TBI based on GCS, we encourage extending this protocol to those with suspected mild TBI and focal neurological signs as it is imperial to identify these suspected injuries early.

**References**


**Poster Presentation Acknowledgment**

The study was first presented as a poster at the 30th annual meeting of Eastern Association for the Surgery of Trauma, January 2017, Hollywood, Fla.

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**Disclosures**

None of the authors have any conflict of interest to report.

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Comparison of Resident and Faculty Screening for Social Determinants of Health in an Academic Pediatric Primary Care Practice

BRITTANY SILVA, MD; SHUBA KAMATH, MD; CIA PANICKER, MD; SRAVANTI PURANAM, MD; CAROL LEWIS, MD; ANARINA L. MURILLO, PhD; DELMA-JEAN WATTS, MD

ABSTRACT

BACKGROUND: Social determinants of health (SDH) have an important role in children’s health and development and should be investigated in pediatric well child care.

METHODS: A retrospective chart review of children aged 5-17 at well visits at an urban academic pediatric primary care practice was performed. Chi-square tests of independence and z-test for proportions were used to assess differences between residents and faculty SDH screening.

RESULTS: Faculty screened for SDH more frequently than residents (P<0.05). Residents screened less frequently for food insecurity (P<0.05) and financial insecurity (P<0.05). Financial insecurity was endorsed less frequently by resident families (P<0.05), while school absence was endorsed more frequently by resident families (P<0.05). Referrals to the clinic’s community resource desk did not differ between residents and faculty.

CONCLUSIONS: Differences exist in screening and need between clinician groups. Despite these differences, there was no difference in community resource desk referrals.

KEYWORDS: social determinants of health, screening, graduate medical education, community resources

INTRODUCTION

Graduate medical education is of paramount importance in teaching hospitals. Medical education includes training not only in the practice of medicine in inpatient hospital settings, but also in outpatient settings. Taking care of a patient in a primary care outpatient setting must include evaluation of socioeconomic factors that relate to the patients’ health. There are few studies in the literature that investigate resident training in regard to screening for social determinants of health. This study is an important evaluation of social determinants of health screening rates amongst trainee physicians and can be useful in shaping future medical education.

Sociodemographic factors including income, food security, and zip code play a significant role in childhood development, childhood mental health, and the long-term well-being of children. These are commonly referred to as social determinants of health (SDH). According to the 2013 US Census Bureau, approximately 20% of all children in the United States live in poverty, which puts them at greater risk of developmental and behavioral problems. This represents a large proportion of the pediatric population, making it important for clinicians who work with children to be familiar with the impact of poverty on health and be comfortable with addressing these issues. There are increased efforts by pediatricians to address SDH, as literature has shown that unmet social needs are associated with increased post-natal mortality, greater risk of injuries from accidents, higher percentages of asthma, and lower development scores.

When SDH screening is performed in pediatric primary care settings, high percentages of social needs are found. One study found that 82% of families of 0-6 year olds presenting for a well visit reported at least 1 health-related social problem. Despite research showing the high level of social needs in pediatric populations, relatively few pediatricians routinely screen for these issues. The American Academy of Pediatrics (AAP) recommends screening for SDH at routine visits as a new category of anticipatory guidance. Data from a survey of 600 AAP members who are active general pediatricians showed that although 61.6% of pediatricians reported that screening for these needs is important, only about half (52.6%) of the surveyed pediatricians reported they routinely screened for at least one social need. Most physicians realize the importance of screening, however, many reported that barriers such as lack of time during the visit, lack of standardization of screening methodologies, lack of screener training and orientation among staff, and lack of referral resources make the implementation of routine screening challenging in practice. Differences have been noted in adult clinics between faculty clinicians and residents in terms of patient panels, patient outcomes, and practice styles, but there are mixed results as to how these differences affect patient care.

There is a paucity of research on differences between faculty and resident patients with respect to SDH in pediatrics. The aim of this study was to determine if there are differences in SDH screening percentages and SDH needs between faculty and residents in an academic pediatric primary care practice.
METHODS
Setting
The study took place at Hasbro Children’s Hospital Pediatric Primary Care in Providence, Rhode Island, which is an urban, academic pediatric primary care setting. It is the teaching site for the Alpert Medical School of Brown University pediatric residents. Clinicians that see patients in this setting include faculty, residents, and medical students. Residents and students are supervised by faculty physicians. Approximately 10,000 patients are attributed to the practice. Over 90% of patients have Medicaid insurance and approximately 20% of parents have not graduated from high school or high school equivalent. On average, over a three-year period (2011–2014), there were approximately 23,000 visits per year.

Subjects
Subjects included 5–17 year old patients seen for a well visit during a three-month time period, January 1, 2019 to March 30, 2019. Only school-aged children [aged 5 years and older] were included because one of the SDH questions focuses on missed school days.

Data Extraction
A manual retrospective chart review was performed. There are four SDH screening questions for clinicians to ask built into the school-aged, well-child visit template in the electronic medical record (EPIC LifeChart). The questions were adapted from validated SDH screening tools that are recommended by the American Academy of Pediatrics (AAP).

The first SDH question, “In the past year have you worried about running out of food before you have money to buy more?” is adapted from the 2-question Hunger Vital Sign. The second SDH screening question “Do you worry about having enough money to pay your bills and rent?” is adapted from the housing and utility section of the IHE LLP social history screening tool, which is recommended by the AAP. The third SDH question “Has your child missed 2 or more days of school in the last month?” was created based on truancy literature that has shown that missed school is associated with poverty, homelessness, and adverse health outcomes. The final question in our four question SDH screen was “Would you like to be referred to Connect for Health?” Connect for Health is the community resource desk at the clinic that connects low-income families to community resources vital to their health, such as utility assistance, public benefits, furniture, and food. The Connect for Health program screens each referred family for various SDH needs, in addition to the clinician screening questions. They assist families with applications for federal and state welfare benefits, provide lists of food banks, assist families with utility assistance programs, in addition to many other services. There is an additional question at the end of the well visit template that asks the clinician to indicate if the patient was referred to Connect for Health.

The following data was extracted from the patient’s chart: were the above SDH questions asked, the answers to these questions [if asked], age of patient, and level of primary clinician who saw patients [faculty, PGY1, PGY2, PGY3, PGY4].

Data Analysis
Data was analyzed to determine overall percentages of screening, positive screens, clinician level, and referral to Connect for Health. Descriptive statistics performed included frequency [percentages] with 95% confidence intervals. Comparisons of screening percentages and patient populations were made between clinician groups using Chi-square tests of independence and a Z-test for proportions as appropriate. Statistical significance was accepted when $P < 0.05$ (two-tailed). All statistical analyses were performed using the statistical programming software, R, Version 3.6.1. Research protocol was reviewed and approved by the Lifespan Institutional Review Board.

RESULTS
890 charts were reviewed, 58.1% of patients were seen by residents and 41.9% by faculty [Table 1].

<table>
<thead>
<tr>
<th>Clinician Level</th>
<th>Total (n=890)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGY 1</td>
<td>141 (15.8%)</td>
</tr>
<tr>
<td>PGY 2</td>
<td>190 (21.4%)</td>
</tr>
<tr>
<td>PGY 3</td>
<td>164 (18.4%)</td>
</tr>
<tr>
<td>PGY 4</td>
<td>22 (2.4%)</td>
</tr>
<tr>
<td>Faculty</td>
<td>373 (41.9%)</td>
</tr>
</tbody>
</table>

Screening percentages
Overall screening percentage for at least one SDH need was 93% (829/890). When evaluating resident and faculty screening percentages, faculty screened for SDH more frequently than residents, defining screening as asking at least one SDH question. When analyzed using a chi-square test, an association was observed between clinician type and screening percentages ($P < 0.05$). Specifically, 91% of families seen by residents were screened for one or more SDH need [95% CI: 88.4% to 93.4%] as compared to 96% of faculty patients [95% CI: 94.3% to 98.2%].

Residents as a whole screened families significantly less frequently than faculty for food insecurity [79.3% vs. 92.5%, $P < 0.05$] and financial insecurity [79.9% vs. 93.6%, $P < 0.05$] [Table 2]. The percentage of residents and faculty that screened families for school absence were similar [83.9% and 86.1%, $P = 0.78$] [Table 2].
Positive screens
Food insecurity did not differ between resident and faculty families (7.8% and 6.1%, respectively, $P=0.4$) [Figure 1]. Financial insecurity was endorsed significantly less frequently by resident families than faculty families (10.7% vs. 16.6%, $P<0.05$) [Figure 1]. School absence was endorsed more frequently by resident families (17.7% vs 11.2%, $P<0.05$) [Figure 1]. Request for Connect for Health referral did not differ between residents and faculty (11.4% and 15.0%, respectively, $P=0.14$). Referrals to the clinic’s community resource desk did not differ for residents and faculty (12.4% and 13.4%, respectively, $P=0.7$).

When analyzed by clinician level, residents screened less frequently than faculty, 91% of families were screened by residents as compared to 96% by faculty. We defined screening as asking about at least one SDH need. An AAP survey of outpatient pediatricians suggests SDH screening in pediatric practices to be as low as 52%. Screening percentages may have been higher in this study due to perceived increased need, as there is a large underserved population of patients in the clinic. Additionally, the screening questions were built into the note templates, which prompts all clinicians to screen. It is unclear why the differences in screening of SDH between faculty and residents were found. Perhaps the relationships between faculty and their patients are longer and more trusting, leading to increased comfort of the physician with screening and increased likelihood of families to endorse insecurities. Adult medicine literature suggests that residents are more likely to have shorter relationships with their patients and patients are more likely to be less satisfied after their visits. Faculty may be more efficient at well child visits, allowing them time to perform screenings more often than residents. Residents are often just learning how to prioritize tasks during a visit and become more efficient and comfortable with these screening questions over time.

Compared to the literature, clinicians in our study seem to be under-referring for community support. The survey data for 600 AAP member pediatricians showed that 85% of these pediatricians referred families for at least one resource over a 1 year period. It is worth recognizing that in comparison to the AAP survey, our study looked at only one well visit per patient, and may not be as comparable to physician practices over a 1 year time period. In addition, the questions asked in this study were limited to only a few SDH categories. The percentage of referral to the community resource desk may increase if more questions regarding other SDH categories had been asked. Finally, this study only evaluated if referral to the community resource desk was made, rather than to what services the family received. Once referred to the community resource desk, the patient advocate screens for additional SDH needs and refers to appropriate services based on this second screen.

Resident patients endorsed less financial insecurity (10.7% vs. 16.6%) but no differences were found with food insecurity. However, resident patients endorsed more school absences (17.7% vs 11.2%). Despite differences in screening percentages and social needs between resident and faculty patients, there was no difference in the request for referral or the percentage of referrals to the community resource desk between clinician groups (12.4% vs. 13.4%). Perhaps
it is easier for a family to request a general referral without endorsing specific needs due to family concern for stigma or embarrassment. The academic clinic in this study cares for some of the most underserved families in the state of Rhode Island, but the percentage of food insecurity endorsed in our study (7.8% and 6.1%), is lower than state data (11% of all families) and national data (11.8% of all families).\textsuperscript{12,14,16} Additionally, the percentage of families in our study that endorsed financial insecurity (10.7% and 16.6%) is less than state data (18%) and national data (20%) for financial insecurity.\textsuperscript{2,14} The differences between national and regional food and financial insecurities and the food and financial insecurities noted in our study may be due to the shorter time period in our study, since only a single visit for each patient was evaluated. In addition, our method of screening could have contributed to the lower percentages of food and financial insecurities endorsed by families. Screening was performed verbally with yes-no questions, which could affect percentages of positive screens. Some studies suggest that yes-no screeners have lower sensitivity as compared to screeners that give “sometimes, never, always” as answer options.\textsuperscript{17} Further, questions were asked by the clinician rather than having the family complete a form on their own. This may have led to falsely low percentages of needs. There is literature that has documented that parents are more likely to disclose unmet social needs when screened via tablet than verbal screening.\textsuperscript{18} One study found a significant difference in food insecurity screening between written and verbal questionnaires.\textsuperscript{18} Interestingly, resident families did have more school absences endorsed than faculty families (17.7% vs. 11.2%). This was similar to state data (14-33% depending on age) and national data (13%).\textsuperscript{14,15} The resident patient percentages seem to be more similar to state and national data for students than faculty percentages. Research has shown that resident patients in academic clinics tend to be more complex, are more likely to be lower socioeconomic status with higher comorbidities, and may have a variety of other needs that should be addressed in a well visit.\textsuperscript{8,11} Residents having more patients with school absences could be a marker of medical complexity, which could support this. At our setting, however, patients are randomly distributed between faculty and residents and there is no division based on insurance type or other factors. Our clinic also has multiple specialized programs that provide care to children in foster care, children with complex medical needs and children in newly arrived refugee families. Most of the patients in these programs are seen by faculty clinicians rather than residents. This distribution of patients may limit the generalizability of our findings to other hospital-based academic practices.

The main limitation to this study is that it was a retrospective chart review. We relied on clinician documentation to determine if SDH screening was performed and how questions were answered. There could be mistakes in documentation as these are “fields” in the chart and are toggled through for selection. Another limitation, as mentioned above, is that our study only looked at one well-visit per child over a 3-month time frame in the school age period. There may be greater needs when children are younger, especially with costs of diapers and childcare. Overall further research is needed to determine differences amongst faculty and resident screening processes.

Further information about the characteristics of resident patient panels compared to faculty panels in this setting is needed. More research is also needed to determine the reason for referral to the community resource desk by each clinician. There are differences in screening percentages and endorsement in need between faculty and residents, which would be interesting to further investigate, perhaps with longitudinal studies.

CONCLUSION

Encouragingly, this study did show robust screening amongst all clinicians in the academic primary care clinic; however, the percentages of positive screens were lower than expected, perhaps suggesting there may be room to improve upon how screening is performed.

Overall, the information produced in this study is a valuable tool for resident training and also for resource allocation in residency continuity clinics.

References

Acknowledgments
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Prior Related Poster Publications
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The Lived Experiences of Adults with Multiple Sclerosis

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ABSTRACT

Multiple sclerosis (MS), a chronic, often disabling, nervous system disease, affects over 2.3 million people worldwide. This research examined the lived experiences of 46 community-dwelling adults with MS. We conducted five focus groups that covered topics such as diagnosis, decision-making regarding MS treatment, learning about and paying for assistance, and unmet needs. Focus group transcripts were qualitatively analyzed to identify overarching themes. Participants described how MS affects both current and future physical and financial security, how they often feel unheard or misunderstood by loved ones and healthcare providers, and how MS support organizations provide a vital collaborative and compassionate environment. Our findings reflect the importance of MS support organizations, and the incorporation of social workers in MS care teams, as they can foster communication and empathy between parties, provide psychosocial treatment, and link patients to needed services. 

KEYWORDS: qualitative research, multiple sclerosis (MS), lived experiences, social support, communication

BACKGROUND

Multiple sclerosis (MS) is a chronic, often disabling, neurological disease with an onset typically between ages 20 and 40. Although disease modifying therapies (DMTs) help prevent relapses, no cure is currently available. As a result, those who would ordinarily be in good health could find themselves physically impaired and dependent upon others. Symptoms such as unpredictable fatigue, reduced mobility, pain, cognitive dysfunction, incontinence, and depression limit employment, performing household chores, and completing activities of daily living. Research to capture the lived experiences of people with MS is imperative for greater understanding.

Existing research on the lived experiences of people with MS come from small qualitative samples with few male participants which reflect health care such as in Iran, Jordan, Sweden, Norway, and the United Kingdom and are not always current.

Our focus group research among individuals living with MS updates the current literature as it showcases a diversity of experiences and illuminates how MS impacts daily life. Our findings should be of particular interest to social workers, families, and other health care providers, highlighting how those with MS struggle with their unmet needs and require friend and family support. These findings will hopefully lead to enhanced communication to improve services.

METHODS

We conducted five focus groups with a total of 46 community-dwelling adults living with MS in Rhode Island between May and October 2017. We collaborated with a local MS support organization and described the study to members who then let us know if they wished to participate. To be eligible, individuals needed to be 18 or older and have an MS diagnosis.

During the focus groups, we asked how participants received their diagnosis, made decisions about MS treatments, learned about and paid for assistance, and identified their unmet needs. Focus groups lasted 60–90 minutes and were held in a private room at the MS support organization. The study was approved by the affiliated Institutional Review Board, and written informed consent was obtained from each participant. Participants received lunch and a $40 gift card.

Focus groups were audio recorded and professionally transcribed. Transcripts were analyzed by our team using established standards of qualitative research. Four team members individually coded each transcript. Meetings were held to reconcile codes, refine the coding scheme, and discuss preliminary themes. Team decisions were kept in an audit trail, which tracked the team’s developing analysis.

Our data were coded and organized via the qualitative software package NVivo. After identifying our themes, we returned to the community center and “member checked” our findings to ensure that data accurately reflected participants’ experiences and were complete.
RESULTS

Of the 46 who participated, 75.6% were female. Nineteen participants reported years since diagnosis, which ranged from 2 to 39 years, with an average of 17.2 years. A wide range of fluctuating disease severity was represented: one had difficulty with speaking, and two with writing. Only one reported maintaining full-time employment. Some participants required wheelchairs, some used canes, walkers, or other assistive devices, and some needed no mobile assistance. Participants described a range in assistance with daily living, including some who did not require services.

We elicited the following themes described below. Additional quotes representing these themes are found in Table 1, see appendix.

Theme 1. Participants described how MS symptoms complicate daily life by causing physical and financial insecurity.

MS symptoms were reported to cause hardship by making work and daily tasks progressively difficult. Although each participant described a unique set of symptoms, they emphasized that MS had decreased their energy level and mobility, negatively impacting their ability to care for themselves and family members. Low energy and mobility appeared especially pronounced during hot weather, accompanied by extreme fatigue that made it hard to move their limbs. Common struggles included dressing, meal preparation, and household chores that caused them to ask family or friends for assistance or pay others to carry out tasks. Participants also noted that MS caused secondary and sometimes unpredictable problems such as, depression, anxiety, gastroparesis, irritable bowel syndrome, further increasing burden and disability. While participants reported receiving subspeciality care for these issues, many voiced concerns around inter-departmental coordination and communication related to their medical care.

As their disease worsens, participants said they would rely more on health professionals, friends, and family for support. However, they said their health providers were not always adequately informed or attentively listening, as detailed below.

Theme 2. Individuals reported that health professionals need to be more active learners and listeners.

From participants’ perspectives, the heterogeneity of their symptoms baffled healthcare providers. Participants recounted initially receiving an incorrect diagnosis based on their symptoms. One shared, “For years, I kept being told that my urine problem was, ‘You’re overweight. Lose weight and you’ll be able to hold your bladder more.’” Participants said that diagnosing MS subtypes was guesswork. One man explained: “[The doctor] said, ‘worst case scenario is you have to try them all...I’ll tell you what might help and you can try that.’”

Participants suggested how health professionals could improve their care. One recommended MS-specific classes for general practitioners, while group members agreed with another who emphasized the importance of providing affirmative care: “If doctors understood that worry is one of the worst additives to the condition, and to help us to relax as we go through this, that would be good.”

Like health professionals, friends and family were also said to be perplexed about their struggles, as seen below.

Theme 3. Participants noted their relationships were strained due to lack of shared MS experience.

While participants said social networks helped alleviate burden, they also described strained relationships. A popular sentiment was, “You don’t really get it unless you have it.” Since symptoms fluctuate, are unpredictable and not always outwardly visible, participants said loved ones struggled to understand why they could no longer keep up. As a result, some loved ones reportedly refused to help when asked. One man described, “You don’t look like you have a problem. And they almost, like, they think you’re faking. [multiple participants agree].”

Unlike reports of feeling doubted and misunderstood, which were pervasive, only female participants reported feeling stigmatized and abandoned because of their diagnosis. However, individuals were not all explicitly asked to comment. One woman revealed: “I have lost my entire family, four years ago, when I was diagnosed, they flat out told me they don’t, uh, they do not believe me.” Another woman, agreed: “I’ve become a pariah to the majority of people that I knew before.”

Participants unanimously valued social engagement to cope with the disease. While health professionals and loved ones were said to not always offer support, individuals said they found assistance and friendship at MS support groups in contrast.

Theme 4. Individuals described collaboration and understanding as benefits to forming friendships within the MS community.

New ties within the MS community were described as highly beneficial. Participants reported liking the collaboration and support they received and appreciated learning tools for adapting to life with MS from each other. Their closeness was reflected by one man: “It’s a community, we’ve all become family, you know, I like to say that MS is the worst thing that’s ever happened to me because I’ve met the best people through coming here.” Another credited the group with saving her life through its support and resources.

Others noted improvements in their physical condition and social lives since attending the MS center. Despite these uplifting accounts, participants also confessed their fears for the future.
Theme 5. Anticipating increased disability over time, participants said they worried about future physical and financial insecurity.

Despite currently receiving treatment from neurologists and having health insurance, participants acknowledged the future would be difficult as symptoms increased. In valuing their independence, they worried that advancing disability would threaten it. Fears of reduced mobility included losing the ability to drive, traveling with loved ones, or walking children down the aisle.

Some were distressed that they did not have nearby relatives to help with their care. One woman commented: “In terms of dressing myself, cooking meals and things like that, I do that myself. My big concern is what happens when I can no longer do that because I don’t have family local.”

Anticipating worsening symptoms and inflating MS-related healthcare costs, they expressed fears about financial insecurity. Living with MS had already drained savings, as most lost the ability to hold full-time employment. One single mother shared: “While I was waiting to get on disability, it took a long time. So, what did my daughter and I live on, my savings. So, things have been depleted, bankruptcies have been filed, I mean, what is going to happen to me?”

Others considered more fortunate said they worried that challenges to employment and health insurance could lead to financial turmoil. Participants acknowledged that they could be fired, thereby losing insurance through their employers. They also feared periodic changes in coverage that may no longer cover their expensive treatments. Due to their young age, many participants failed to qualify for Medicare, which amplified these financial concerns. Those who could reported saving money: “Right now, I’m comfortable, but ...I got to keep saving, saving, saving, in anticipation of possibly needing help at home.”

The reports above illuminate just a few of the daily problems those with MS face.

DISCUSSION

We conducted focus groups to better understand the daily challenges faced by those with MS. The five resulting themes are largely consistent with previous research. Participants described the negative impact of MS on daily function,5,11 health providers’ shortcomings,5,11 altered relationships with friends and family,14,16 numerous benefits of attending an MS support organization [e.g., social support, learned coping skills, reduced anxiety, improved quality of life],16,28 and fear of an uncertain future as symptoms progress [e.g., psychosocial symptoms, social abandonment].4,5,9,10,16

However, our research differed from previous findings in nuanced ways. In our sample, males and females expressed equal frustration by their inability to perform housework and hold employment.11 There were fewer reports of disrespect and insensitive remarks by healthcare workers.5,11 Participants said they minimized their requests to avoid burdening loved ones and reported that they preferred accomplishing tasks themselves, as opposed to other research where individuals accentuated their disability to increase assistance.10

Our participants did not describe concealing MS status to avoid stigma,2,14 but this topic was not explicitly asked during our focus groups. Participants indicated they focused on obtaining needed services and were less concerned with avoiding wheelchairs and other supports that could reveal their illness to others, unlike prior research.2 Instead, participants freely discussed their use of mobility supports. Lastly, in addition to concerns around worsening disability, our participants were equally concerned that disease progression would divert their savings to healthcare and home services, leaving them with little for living expenses.

Participants’ accounts highlight the clinical importance of supportive social networks and informed healthcare providers. For instance, current efforts to link MS clients to needed healthcare and home services are considered inadequate. Therefore, social workers ought to be included in health care teams to help identify and match community and social services and resources with MS clients. Increasing involvement from friends or family members would likely foster increased understanding and empathy. More support organizations should be constructed that help social workers link clients to pertinent resources. Lastly, social workers should utilize cognitive behavioral therapy (CBT) to improve interpersonal communication with care team members,29 and mindfulness-based cognitive therapy (MBCT) to treat the psychosocial needs of those with MS.30,31

Strengths of this study include the robust sample size by qualitative research standards, the inclusion of men and a variety of MS subtypes, and the use of focus groups. By including various MS subtypes and males, who account for 26% of all cases and are usually diagnosed later in life with more severe symptoms than females,3,8,14,32 we were able to capture a wide range of disability and dependency. The focus group format allowed participants to relate to one another, and elicit varied viewpoints, opinions, and feelings, including estimating the amount of consensus and the range of opinion among them.

Certain limitations must also be noted. Results may not be generalizable to other MS populations. Since the focus groups took place at a support center, those with greater mobility impairment may have been excluded. Participants were linked to neurological (and other specialty) care and frequented the same MS support organization. Therefore, quality of health may have been overestimated and stress and burden may have been underestimated, as they were socially engaged and informed about MS services. Since participants knew each other, sharing may have been facilitated as well as inhibited. While group leaders perceived...
that participants expressed opinions candidly, participants may have felt disinclined to raise new or offer discrepant opinions from those of the group. Also, since focus groups took place in Rhode Island, findings reflect healthcare and support services that may not be generalizable to other locations. Since the focus groups took place prior to the COVID-19 pandemic (when video conferencing became ubiquitous), future research should examine how online support groups can advance camaraderie and assistance. 

Qualitative research such as this provides an essential look into individual frustration and loneliness of life with MS and the importance of social support. Our sample was unique in that everyone had access to an MS support center for resources and socialization. These facilities are out of reach for many with MS. Social workers and healthcare providers can keep these individuals from having to navigate painful symptoms and mounting bills by themselves. Stigmatizing those with chronic disease compounds their burden and discourages them from seeking needed treatment and services. Health professionals, friends, and family must, therefore, work together to create an encouraging environment by active listening to learn their specific needs and to ensure these needs are met.

**References**

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Disclosures
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Visits for Possible COVID-19 in a Pediatric Primary Care Practice Early in the Pandemic

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ABSTRACT

BACKGROUND: Children with COVID-19 usually present with mild symptoms. We characterize visits with respect to symptoms and testing in the outpatient setting.

METHODS: A retrospective chart review of sick visits in a pediatric academic primary care clinic April-August 2020. We included possible COVID-19 cases, or “persons under investigation” (PUIs), recording symptoms, positive contacts, and COVID-19 testing. Descriptive statistics and Chi-square or Fisher’s exact tests for comparisons were used.

RESULTS: 32% (476/1,474) of sick visits were PUIs; 20% were telehealth. Symptoms most commonly reported were fever, congestion/rhinorrhea and cough. 76% of PUIs were tested for COVID-19. Only presence of COVID-19 contacts and loss of taste/smell were significantly associated with positive tests (p<0.001).

CONCLUSION: Nearly a third of sick visits in an academic pediatric practice were seen for possible COVID-19 symptoms and most were tested. The majority with and without COVID-19 had fever, congestion and/or cough. Our findings suggest low thresholds for testing in children.

KEYWORDS: COVID-19, pediatric, outpatient

ABBREVIATIONS

COVID-19 = Coronavirus-19
PUI= person under investigation
IQR = Inter-quartile range
CDC = Centers for Disease Control
MIS-C = Multi-system inflammatory syndrome in children

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic has presented unique challenges to pediatric providers. COVID-19 affects children differently than adults, with a relatively mild course of illness with initial infection1,2, contributing to uncertainty in how outpatient pediatric providers should manage patients with viral symptoms. Moreover, the CDC-recognized list of COVID-19 symptoms strongly mimics a variety of other high prevalence viral illnesses in the pediatric population.

Though social distancing and lockdowns have thwarted much of the spread of common viral agents3,4, outpatient pediatric providers have had to adapt to frequent changes in clinical guidance while continuing to care for sick children and provide public health advice. Such clinical guidance has rarely been pediatric-focused. Additionally, outpatient healthcare providers of all specialties have had to quickly adapt to changes in practice to accommodate stay-at-home orders and recommendations to minimize exposure as much as possible.5 While pediatric providers have a great deal of experience with telephone triage6, telehealth sick visits have not been routinely performed.7 This, along with the many unknowns regarding how concerned to be regarding COVID-19 in various pediatric patients – from newborns to those with complex healthcare needs – presented unique challenges to outpatient pediatric practices across the country. While the current landscape of the pandemic has changed dramatically due to the rollout of vaccines, children under 12 years old remain at risk at this time. Additionally, the possibility of ongoing seasonal COVID-19 outbreaks emphasizes importance on discerning this infection from other common viruses in children.

Within one practice, we examined visits for possible COVID-19 over a five-month period early in the pandemic to characterize symptom and testing frequency and to evaluate factors associated with testing and positive versus negative test results in the pediatric outpatient setting.

METHODS

Study setting

We conducted a retrospective chart review of sick visits at a large urban academic pediatric primary care clinic located at Hasbro Children’s Hospital in Rhode Island from April 1 through Aug. 31, 2020. The clinic serves a population of about 10,000 patients from multi-ethnic backgrounds and families with low incomes. The clinic’s Urgent Care sees all same-day sick visits and is staffed by general pediatric faculty and residents.

We collected data during a period early in the pandemic when COVID-19 testing was available within the clinic and at drive-up sites. Additionally, on April 1, 2020, the Rhode Island Department of Health announced expansion of testing recommendations to include any symptomatic individual,
rather than high-risk populations only, and encouraged any-
one with symptoms to call their healthcare provider and
obtain testing. During the pandemic, only scheduled visits
[both in-person or telehealth] were available after discussion
with a phone triage registered nurse; however, an in-person
visit was never declined if that was desired by the parent/
guardian. Walk-in appointments were not offered. The study
was approved by the hospital Institutional Review Board.

Data Collection and Analysis
We included charts for all in-person and telehealth sick
visits for patients up to 18 years. Well-child or follow-up
visits were excluded, even if sick symptoms were reported.
We reviewed charts based on the CDC’s 12-symptom list 8
to identify possible COVID-19 cases, herein called “person
under investigation” (PUIs). Documentation of symptoms,
positive contacts, and COVID-19 testing status and result
were recorded. If a test had been obtained at an outside
site [emergency department or state site] during the same
episode of illness and reported in the visit encounter, this
was included.

All data was recorded in REDCap 9 and R version 4.0.3
was used for data analysis. We report descriptive statistics
and Chi-square, Fisher’s exact, and Wilcoxon rank sum tests
comparing variables for those tested versus those not tested
and positive versus negative results. We also compared vari-
ables for patients seen in-person versus telehealth using
these same analyses.

RESULTS
We reviewed 1,474 sick visits charts of which 32% [n=476]
of these were PUIs. Eighty-percent of PUI visits [n=383] were
conducted in-person, while 20% [n=93] were telehealth.
Among PUIs, the most common symptoms were: fever
[n=205, 43%], congestion/rhinorrhea [n=201, 42%], and
cough [n=177, 37%]. See Table 1 for patient characteristics.

Testing Decisions
The majority [n=362, 76%] of PUIs were tested for COVID-
19, ranging from 70% in April to 81% in July. See Figure 1.
The most prevalent symptoms for those tested were fever
[n=170, 47%] and congestion/rhinorrhea [n=170, 47%],
followed by cough [n=147, 41%]. Those not tested [n=114,
24%] presented with the same top symptoms: fever [n=35,
31%], congestion/rhinorrhea [n=31, 27%], and cough [n=30,
26%]. Greater median number of symptoms [p<0.001] and
reported COVID-19 close contact [p<0.001] were signifi-
cantly associated with COVID-19 testing. See Table 1.

Test Outcomes
Overall COVID-19 test positivity was 8%, ranging from 5%
in June to 15% in May. See Figure 2. The most prevalent
symptoms in COVID-19 positive patients [n=29] were con-
genosis/rhinorrhea [n=16, 55%], followed by cough [n=14,
48%] and fever [n=14, 48%]; these symptoms were similarly
found in COVID-19 negative patients. Only loss of taste or
smell was present significantly more in patients who tested
positive for COVID-19 [p<0.001]. See Figure 3. Number of
symptoms did not differ significantly for COVID-19 positive
and negative patients. The only patient variable significantly
associated with a positive test was reported COVID-19 close
contact [p<0.001]. See Table 1.

Table 1. Demographic and clinical characteristics for all PUIs, stratified by COVID-19 testing status and COVID-19 test result, n (%)

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>All PUIs n=476</th>
<th>Tested n=362, 76%</th>
<th>Not Tested n=114, 24%</th>
<th>p-value†</th>
<th>Positive n=29, 8%</th>
<th>Negative n=333, 92%</th>
<th>p-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, median (IQR)</td>
<td>5 (1–11)</td>
<td>5 (1–11)</td>
<td>5 (2–11)</td>
<td>0.954</td>
<td>9 (1–17)</td>
<td>5 (1–11)</td>
<td>0.112</td>
</tr>
<tr>
<td>Female gender</td>
<td>241 (48)</td>
<td>180 (50)</td>
<td>61 (54)</td>
<td>0.550</td>
<td>15 (52)</td>
<td>165 (50)</td>
<td>0.975</td>
</tr>
<tr>
<td>Medicaid</td>
<td>436 (92)</td>
<td>328 (91)</td>
<td>108 (95)</td>
<td>0.117</td>
<td>25 (86)</td>
<td>303 (91)</td>
<td>0.322</td>
</tr>
<tr>
<td>COVID-19 contacts</td>
<td>56 (12)</td>
<td>54 (15)</td>
<td>2 (2)</td>
<td>&lt;0.001</td>
<td>14 (48)</td>
<td>40 (12)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Presented ≥ 3 symptoms</td>
<td>162 (34)</td>
<td>149 (41)</td>
<td>13 (11)</td>
<td>&lt;0.001</td>
<td>15 (52)</td>
<td>134 (40)</td>
<td>0.313</td>
</tr>
<tr>
<td>Number of symptoms, median (IQR)</td>
<td>2 (1–3)</td>
<td>2 (1–3)</td>
<td>1 (1–2)</td>
<td>&lt;0.001</td>
<td>3 (2–4)</td>
<td>2 (1–3)</td>
<td>0.181</td>
</tr>
</tbody>
</table>

†Fisher’s exact test; chi-square test of independence; wilcoxon rank sum test comparing tested to not tested as well as positive to negative cohorts
PUI = person under investigation, IQR = inter-quartile range
Patients seen through telehealth visits were significantly older (p=0.014) and reported COVID-19 close contacts more frequently (p<0.001) than in-person visits, while number of symptoms did not differ. See Table 2. Fever, congestion, and cough were the top three symptoms reported for both in-person and telehealth visits, though fever was significantly less prevalent in telehealth than in-person visits (n=25, 27% vs. n=180, 47%, p<0.001). Thus, fever was the top symptom for in-person and third most common symptom for telehealth. Additionally, sore throat (n=113, 30% vs. n=14, 15%) and nausea/vomiting (n=76, 20% vs. n=10, 11%) were more prevalent for in-person than telehealth visits (p<0.001 for both). Tests were ordered on 63% (n=59) of telehealth visits, compared to 79% (n=303) for in-person (p=0.001), and the positivity rate was 14% (n=8) compared to 7% (n=21), respectively (p=0.086).

**DISCUSSION**

Nearly one third of all sick visits seen in an academic pediatric practice during the early months of the COVID-19 pandemic were PUIs. Of those, over three quarters were tested, with an overall COVID-19 positivity rate of 8% (ranging from 5–15%).

Although number of symptoms played a role in who was tested, no differences were found in number or type of symptoms in COVID-19 positive versus negative patients, other than loss of taste/smell. Loss of taste or smell was a relatively specific, though not sensitive, finding for COVID-19, supporting evidence for heightened suspicion if this symptom is discovered amidst other more common “viral” symptoms. Moreover, fever, congestion/rhinorrhea, and cough were the most common symptoms in those tested and not tested. The lack of difference in prevalence of these common symptoms shows how indistinguishable COVID-19 is in children from other viral respiratory illnesses and suggests providers should have a low threshold for testing children with viral symptoms, regardless of type or number of symptoms.

With loosening of social distancing and mask mandate restrictions, pediatricians will be assessing more children with fever, cough, and congestion. In fact, many viral illnesses have recently re-emerged and rates are rising quickly in the pediatric population.10-12 Pediatric emergency departments and primary care offices are returning to higher volumes. At this time, lower community prevalence,
natural immunity, and the vaccination of adults and children 12 years and up for whom the vaccine is now approved help provide some protection for younger children. However, full protection cannot be assumed.

Early studies had suggested children are less likely to spread COVID-19. However, as more adults and teens are vaccinated and newer research unfolds, it has become more evident that children, particularly those 10 years and up, do play a role in transmission, particularly within households. Indeed, children do seem to carry the same viral load in their upper respiratory tract as adults, even when mildly symptomatic or asymptomatic. Fortunately, children do not exhibit the same severe respiratory effects of this infection; however, important questions remain, and new questions arise daily. Multi-system inflammatory syndrome in children or “MIS-C,” while very rare, continues to be a concern. Additionally, children’s role in community spread is now more important than ever, as they remain the last group to be vaccine-eligible and make up a growing proportion of new infections. Transmission from children poses risk to unvaccinated adults and elderly or immune-compromised individuals, who likely do not gain the same protection from immunization. Prolonging community spread also poses risk of variant emergence, which has become more evident.

Our findings pose a number of questions for pediatric practices and public health policies going forward. The inability to discern COVID-19 from other common viral illnesses highlights the importance of testing. While point-of-care rapid antigen testing is not as sensitive as PCR, the ease of use, quick results and fairly good sensitivity in symptomatic individuals (if used early on in symptoms when viral load is highest) may induce widespread adoption of its use in pediatric offices handling large volume of sick visits. However, currently confirmatory testing with a PCR test for negative antigen tests is still recommended by the CDC; thus, while the antigen test may yield quick results, this extra step may not exactly lessen the impact on families. Additionally, while false negatives are often the concern most discussed regarding rapid antigen tests, when community prevalence is low enough, false positive rates near false negatives – both are problematic.

With the uptick in non-COVID-19 viral illnesses in the pediatric population expected during the fall and winter months, coinciding with relaxation of social distancing measures, it is paramount that improved guidelines for testing and quarantine become available to pediatric providers. In reality, some pediatric practices have still not re-instated sick visit availability while others have attempted to cohort sick and well to different locations or sessions. These measures are not only costly and revenue reducing, but have also had an impact on the availability and timing of well-child visits. Additionally many practices rely on private or state-run testing sites to augment telehealth visits and keep suspected COVID-19 cases out of the office. This was evident in our cohort, with the higher positivity for telehealth encounters. The ability to continue this practice will depend on the availability of an adequate testing infrastructure.

Our findings bring up questions about children in congregate settings, namely schools, particularly for this coming fall/winter. Even with vaccination, which certainly limits spread and disease severity, outbreaks can be expected. We now know that children are vectors of infection, even though spread within the school setting (particularly for elementary age children) has been low. Less controlled settings, like sports activities and social events are more likely associated with child-child transmission. Will schools continue with strict illness policies as they have now? These have major impact on parent/guardians’ work productivity and loss of in-person learning time for children. These policies have been feasible, again, because of significant infrastructure in place [e.g. prompt access to testing through K-12 sites, quick PCR turnaround, remote learning options for children awaiting test results or needing to quarantine for close contacts]. With all children presumably back to in-person school going forward, the return of the usual spread of viral respiratory illnesses in schools is expected – school officials may face even more challenging decisions regarding testing and illness policies as long as the lingering threat of COVID-19 remains.

Finally, this study highlights a sentiment felt by pediatricians throughout the pandemic – a drastic change in our guiding mantra: general reassurance to parents about run-of-the-mill viruses. The difficulty in distinguishing COVID-19 from the myriad of common viral infections has altered our way of practicing, and rerouted the automatic mental processing that we do all day. We fear this may impact parents’ understanding of supportive home care in the long run. In addition, this has led to feelings of exhaustion and burnout among our work force.

LIMITATIONS

As this study was conducted through retrospective data collection, we were limited to data available within the electronic medical record. Variation in both documentation and patient management likely existed between providers as well as over time throughout the pandemic, as more was understood about patient symptoms and community spread. Our research was confined to a single academic clinic site and practice behaviors may differ from other settings. Particularly, our clinic had early access to COVID-19 testing, which was not available at many community practices. In the time frame of our study, patients in Rhode Island were required to have a provider order to obtain a COVID-19 test; thus, most children in our practice who were tested for COVID-19 were likely captured by our study. However, though testing was
recommended for all ages during the study period in Rhode Island, drive-up testing at the state-run sites was lacking early on. The variety of location options and accessibility for pediatric patients improved significantly throughout the pandemic, such that currently both providers and parents/guardians are able to request a drive or walk-up testing appointment easily and promptly.

**CONCLUSION**

This study provides a look at the initial months of the pandemic through the lens of outpatient pediatric providers with early access to testing. Our findings suggest readily testing children with mild or few symptoms. In the face of the marked changes that the pandemic brought to outpatient pediatrics as we know it, providers were able to pivot and incorporate COVID-19 testing and telehealth to provide sick visit care early in the pandemic. Looking forward, increased vaccination has allowed lessened social distancing, and, as a result, the make-up of circulating respiratory illnesses is changing. Due to the difficulty discerning COVID-19 from the common cold in children, testing remains paramount.

**References**

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Can Older Adult Emergency Department Patients Successfully Use the Apple Watch to Monitor Health?
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ABSTRACT

OBJECTIVE: To determine usability of the Apple Watch in older adult emergency department (ED) patients after a fall.

METHODS: We recruited older adults who fell and visited two urban EDs. They participated in an Apple Watch orientation and interviews on their experiences using the watch to complete varied tasks for 30 days. Interviews were recorded, transcribed, coded, and analyzed using framework analyses.

RESULTS: Eight participants (mean age 77.6 years) enrolled from November 2019 to March 2020. Participants reported being able to apply and charge the watch but struggled with navigating screens, monitoring charging status, and responding with de novo text messages. Many cited difficulties with advanced tasks, such as the study’s app-based movement and memory activities. Experience with smartphones and caregiver assistance enhanced users’ ability to complete tasks.

CONCLUSIONS: Older adults successfully performed basic Apple Watch functions. Family and community members may be necessary to assist with complex tasks.

KEYWORDS: older adults, wearable technology, Apple Watch, emergency department

BACKGROUND

Each year, one in four older adults fall, leading to nearly 30,000 deaths1 and costing the United States (US) healthcare system $50 billion.2 Technological innovations, such as wearables using data collected from sensors such as accelerometers and gyroscopes, could help monitor falls, alert caregivers3 and medical personnel after a fall occurs, and predict falls. In particular, the Apple Watch, with its sophisticated sensors and fall-detection algorithm, has the potential to benefit individuals, if it is found to be useful in older adults at risk for falls.

Empirical research suggests that simple, wearable activity monitors are easy for many older adults to use, can improve awareness of physical activity levels, and may increase physical activity. However, older adults desire more than usability; they prefer comfortable and aesthetic wearables that are rich in features.3 The Apple Watch may meet these demands, as it includes fall detection, heart rate monitoring, and electrocardiogram features that could confer health benefits.4 One major drawback of the Apple devices is cost (prices range from $199 to $1,499), but some Medicare Advantage policies subsidize them.5

Existing research on the use of the Apple Watch in older adults has focused on validating the accuracy of its measurements, such as heart rate, energy expenditure,6 step count,7 and detection of atrial fibrillation.8 However, little published work examines the usability of the Apple Watch in older populations. The Unified Theory of Acceptance and Use of Technology (UTAUT) is a framework that has been applied previously to investigate the behavioral intention of older adults using e-Health applications,9 app-guided fall-risk self-assessments,10 and telehealth services,11 but no published studies have explored UTAUT in the context of Apple Watch usage in older adults.

Our objective was to examine the usability of Apple Watch in older adults most likely to benefit from the fall detection features — older ED patients with a recent fall — using the key constructs of UTAUT as our conceptual framework. We sought to explore barriers/facilitators of use, ability of older adult patients who presented to the ED after falling to initiate and continue use after a brief in-ED orientation, and need for assistance with basic and advanced tasks.

METHODS

Summary

We aimed to recruit 30 older adult ED patients who presented following a fall.14 After 30 days of continuous use — or earlier, if participants were unable to complete the study — we performed semi-structured interviews with participants and/or caregivers to assess the Apple Watch’s usability. This qualitative study was designed to understand older adults’ lived experience with the Apple Watch, uncover barriers to use, and inform use of the wearable in future studies.

Setting and Population

We recruited at two academic EDs in Providence, Rhode Island: Rhode Island Hospital and The Miriam Hospital. Research assistants screened patients 65 years and older...
who had sustained a fall, using the electronic health record. To be eligible, patients needed to meet the following inclusion criteria: English-speaking, community-dwelling, fall not due to syncope or external force or acute serious illness (e.g., acute stroke or myocardial infarction), and likely to be discharged to home/assisted living/rehabilitation at completion of ED visit. Patients with cognitive impairment were required to have a legally authorized representative present to give informed consent. We used the Six-Item Screener to screen for cognitive impairment (scores less than four out of six suggest impairment). We excluded patients with altered mental status, injuries that prevented mobilization, allergies to any device component, and those who were unable to wear the Apple Watch at home or had a diagnosis of advanced cancer or those in hospice care.

**Approach, Recruitment, and Training**

After written informed consent, participants were trained in device use and study procedures. Once they demonstrated understanding of the basic functionality of the Apple Watch and iPhone, research assistants guided them through movement and memory assessments using the study app: RI FitTest. Participants were instructed to wear the Apple Watch continuously at home except during charging, including in the shower. Participants were asked to complete daily fall surveys and weekly movement and memory tasks using the app. Research assistants called participants on the third day of participation to review study procedures. Research assistants were available to provide technological support by phone or in-person at any time. Staff scheduled an in-person semi-structured interview at 30 days or at the end of study participation, whichever came first.

**Theoretical Framework**

Our study was grounded in constructs of UTAUT, namely performance expectancy, effort expectancy, self-efficacy, and facilitating conditions. Performance expectancy refers to the degree to which participants believe they will be able to use the technology as it was intended. Effort expectancy refers to participants’ perceptions of the ease of use of the watch and RI FitTest app. Self-efficacy refers to participants’ beliefs in their ability to perform study tasks. Facilitating conditions refer to available resources participants can access to support their use of the Apple Watch and their participation in the study.

**Semi-Structured Interview Procedures**

We developed two interview guides – one for participants and another for caregivers of participants with dementia – using questions adapted from prior studies of older adults and further developed by the research team. The interview guides contained open-ended questions with probes specific to the study goals. These questions addressed the four domains of the UTAUT. (See Appendices)

A member of the research team conducted interviews with participants and their caregivers [if present] and completed a debrief listing new or emerging themes and observations that may not be obvious on review of the transcripts. All interviews were recorded, transcribed, and de-identified. For accuracy, the research team reviewed and corrected each transcript against the recordings.

**Analysis**

Data were analyzed using framework analysis, a qualitative analysis method that is systematic and rigorous and involves summarizing findings in charts.15,16 We (1) read each transcript to familiarize ourselves with the data, (2) developed a preliminary set of codes based on the interview guide and the theoretical framework, (3) coded the first transcript, (4) discussed coding differences to resolve inter-observer differences, (5) reviewed and coded subsequent transcripts, (6) generated additional codes to capture emergent constructs. Both inductive codes, which emerge from the research agenda, and deductive codes, derived from material participants volunteered unprompted, were used. (7) Each transcript was coded by two members of the team using NVivo 12 software. (8) We identified major themes and subthemes across interviews and selected representative quotes, and (9) reduced the content into understandable, brief summaries in charts. The chart headings and subheadings were themes and subthemes; each participant was represented in a row. We created an audit trail of all decisions regarding codes and themes.

**Ethics**

The study was approved by the hospital Institutional Review Board and registered at www.clinicaltrials.gov (NCT04304495).

**RESULTS**

**Participants and Demographics**

Due to constraints imposed by COVID-19 starting in March 2020, we stopped in-person recruitment early. As a result, 16 participants were recruited, of whom eight consented to participate in semi-structured interviews (Figure 1).
average participant age was 77.6 years (standard deviation 10.0 years), 2/8 were non-white, 7/8 had used a cellphone previously, and 3/8 had used a wearable device [e.g. Fitbit] previously (Table 1).

Summaries for each UTAUT construct, along with representative quotes from the participants can be found in Table 2. Key existing barriers and potential benefits of Apple Watch use in the older adult population are presented in Table 3.

### Table 1. Clinical and technology characteristics

<table>
<thead>
<tr>
<th>Participant #</th>
<th>Age Interval</th>
<th>Sex</th>
<th>Ethnicity</th>
<th>Comfort with technology (out of 100)a</th>
<th>Insurance</th>
<th>Living Statusb</th>
<th>Prior cellphone use</th>
<th>Prior wearable use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>65–69</td>
<td>F</td>
<td>NHUPI</td>
<td>50</td>
<td>Medicare</td>
<td>Lives with others</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>65–69</td>
<td>F</td>
<td>White</td>
<td>0</td>
<td>Medicare</td>
<td>Lives alone</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>75–79</td>
<td>F</td>
<td>White</td>
<td>80</td>
<td>Commercial insurance provided by employer or spouse’s employer</td>
<td>Lives alone</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>85–89</td>
<td>F</td>
<td>White</td>
<td>80</td>
<td>Medicare</td>
<td>Lives alone</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>95–99</td>
<td>M</td>
<td>Black</td>
<td>41</td>
<td>Medicare</td>
<td>Lives alone</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>75–79</td>
<td>F</td>
<td>White</td>
<td>30</td>
<td>Medicare</td>
<td>Lives alone</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>70–74</td>
<td>F</td>
<td>White</td>
<td>40</td>
<td>Medicare &amp; Commercial (bought privately)</td>
<td>Lives with others</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>75–79</td>
<td>M</td>
<td>White</td>
<td>93</td>
<td>Medicare</td>
<td>Lives alone</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*a The question “How comfortable are you with technology?” was asked during enrollment. Responses were indicated with a 0 to 100 Likert scale.

*b All our participants lived in the community and none lived in assisted living facilities.

### Performance Expectancy

Comfort levels with technology varied; some participants reported owning smartphones and using them daily, whereas others used them “for emergency use only.” Most participants had never used the Apple Watch; a few previously used wearable fall detection devices and other fitness trackers, such as the Fitbit. All participants described feeling able to complete the study tasks using the watch and app.

### Table 2. UTAUT concepts, data summaries, and representative quotes from interviews

<table>
<thead>
<tr>
<th>UTAUT Constructs</th>
<th>Summary of Data</th>
<th>Representative Quotes</th>
</tr>
</thead>
</table>
| Performance expectancy | Participants varied in their levels of experience with technology. | Q1: “I play games, I watch news, I catch up on Facebook, Instagram, what my family is doing.” (Participant 4)
Q2: “I’m not a technical person… I’d rather speak to somebody on the phone. I’d rather visit somebody.” (Participant 7) |
| Effort expectancy | Expectations differed on ease of use of the watch. | Q3: “I avoid technology… I can barely navigate a computer… I’m not skilled enough to develop a spreadsheet or anything of that nature, I knew… my abilities were limited. I didn’t anticipate that it would be a piece of cake.” (Participant 2)
Q4: “I just figured I’d put [the Apple Watch] on and that would be it.” (Participant 6) |
| Facilitating conditions | Often sought assistance from others, such as family or research staff. | Q5: “I consulted… my granddaughter who’s fairly tech savvy… she has an Apple Watch, I bought her one when she turned 13.” (Participant 2)
Q6: “You [interviewer] told me more than anyone ever told me… you know I’ve talked to [RA] and… all she did was call and things. She never explained anything to me.” (Participant 5) |
| Physical condition | Mixed opinions about initial orientation/technical support from research staff. | Q7: “I thought I would be able to do more… I didn’t know what my limitations were going to be after I fell, you know?… I was kind of disappointed that I wasn’t able to do more.” (Participant 6) |
| Self-efficacy | Participants found the watch to be comfortable. | Q8: “I didn’t even know it was on there. It was very comfortable. I forgot it was on.” (Participant 3) |
| Ability to use the watch | Participants were divided over their ability to use the watch on their own after the study. | Q9: “I never did figure out… how to navigate the screens. I would answer some text messages on it, if it was one of the options listed as a single word or two.” (Participant 2)
Q10: “I found this pretty seamless. I didn’t have any real difficulty.” (Participant 8) |
| Confidence in using the watch | Participants felt more confident using the watch if others helped them. | Q11: “It was kind of nice having family help.” (Participant 4) |
Table 3. Barriers to and benefits of Apple Watch use in older adults

<table>
<thead>
<tr>
<th>Existing Barriers</th>
<th>Potential Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affordability: The Apple Watch costs $199 or more, and users must own a compatible iPhone (iPhone 6S or later).</td>
<td>Payor support: Some insurance companies subsidize the cost of the Apple Watch to enhance mobility in their enrollees.</td>
</tr>
<tr>
<td>Health literacy: Older adults may not understand how to interpret and use the health data collected by the Apple Watch.</td>
<td>Data visualization: Users can access trends over time and graphs of their health measures on the watch.</td>
</tr>
<tr>
<td>Digital literacy: Older adults who already struggle with using computers and smartphones may face a potentially steep learning curve to use the Apple Watch. They may perceive that the watch is too complex for them.</td>
<td>Passive tracking: The Apple Watch is able to measure health data, such as heart rate, gait analysis, and oxygen saturation, passively without active involvement by the user, which could enhance ease of use.</td>
</tr>
<tr>
<td>Complete integration with healthcare: Although healthcare professionals can be given access to the health data collected by the Apple Watch, most individuals do not give it to their clinicians and Apple Watches are not yet integrated into routine clinical practice.</td>
<td>Data sharing features: The users’ Apple Watch data is stored in the Health app on the iPhone and can be shared with healthcare professionals. Some features are programmed to alert designated contacts without involvement by the user after the initial set-up, such as fall occurrences.</td>
</tr>
<tr>
<td>Quality-of-life improvement: It is unknown if wearables enhance users’ quality of life.</td>
<td>Sleep tracking: Older adults can wear the Apple Watch to sleep and receive basic data on their sleep quality. Step count: Older adults who walk more could benefit from more mobility and a longer lifespan.</td>
</tr>
</tbody>
</table>

**Effort Expectancy**

Some participants expected the Apple Watch would be difficult for them, while others felt they would “master [the watch] after a few times.” One participant expected that using the Apple Watch “would be easy...because the Apple Watch has a good reputation.” Participants held similar sentiments regarding the RI FitTest app. One participant expected that the app would be difficult to use, since “I don’t like to get into apps and I can’t get them off.” Another remarked that she did not expect any challenges “as long as it was downloaded” for her.

**Facilitating Conditions**

Most participants thought the initial orientation was adequate and prepared them for the study tasks. However, one participant expressed frustration with the protocol, “Actually, no one explained to me how it’s supposed to work...” (of note: multiple in-person and over the phone attempts by research staff were attempted to explain the study steps, but the participant was noted by the research team to have memory problems).

Many participants noted that their acute condition in the ED, or their health impaired their ability to understand instructions or perform study tasks [Table 2, Q7]. One participant explained, “Well, I thought that it would be very helpful, [but] I didn’t realize that when I got home, my recovery period would take as long as it has.”

All participants found the Apple Watch comfortable [Table 2, Q8]. One participant compared the Apple Watch to another wearable device she wore routinely, “I wear a Fitbit and it’s basically the same type of a bracelet, so it’s something that I’m accustomed to.”

**Self-Efficacy**

Several participants felt confident in their ability to use the Apple Watch and noted improvements in their ability as the study progressed. Others felt their ability was unchanged. One participant noted that she struggled with navigating various screens, while another expressed frustration at identifying whether the watch was fully charged. Many participants described assistance from family members as essential, and said written and verbal instructions were necessary to use the watch. One participant noted that she was open to try new technology, adding, “As long as I have the correct instructions, I think I’ll do fine with it.”

**DISCUSSION**

In this qualitative study of eight older ED patients, participants were successful with performing basic device functions, but experienced varying degrees of success with advanced device features. Those who already used smartphones had more positive experiences and were more able to explore its features, including using the watch to respond to messages and answer phone calls. Those who lacked prior smartphone experiences had more difficulty completing the study tasks on their own. Support from caregivers and/or research staff facilitated positive user experiences and use of advanced features. For the Apple Watch to be feasible for daily use in the older adult population, a high level of sustained and continued guidance and training is likely necessary, whether from technologically-adept family members, friends, or other caregivers, and/or from user-centered instructional tools offered by the device developers.

Future studies could circumvent the challenges we experienced by offering more hands-on training, pairing older adults with younger tech-savvy community members, or
encouraging caregiver participation. Alternative recruitment settings, such as primary care offices, adult day care centers, and assisted living facilities, can be explored to improve outreach to the general older adult population. Additionally, studies of more diverse participants, across ethno-racial groups, socioeconomic status, educational level, etc., are encouraged. We learned that varied training modalities and technological support should be offered, including in-person demonstrations, on-demand video tutorials, and pamphlets with written and pictorial step-by-step instructions. Apple’s official “Apple Watch Support” landing page (https://support.apple.com/en-euro/watch) and the Apple Support YouTube channel (https://www.youtube.com/c/AppleSupport) provide guidance in written and visual formats, respectively.

Although we initially aimed to recruit 30 participants, recruitment ended early because the study’s Data Safety Monitoring Board ruled that in-ED recruitment was unsafe during COVID-19. Additionally, remote recruitment, consent, and orientation was not successful. Other challenges encountered included eligible patients being unwilling to add another device to the myriad of health devices they were already using, not feeling comfortable with technology, not thinking their fall was a problem, or simply not being interested in participating in our research study. These recruitment challenges were anticipated, given that older adults often refuse participation due to health issues, mistrust, family members’ objections, etc.20 Yet, it is essential to continue to include older adults in research involving technology to address older adult underrepresentation in clinical research and to close the digital divide. Recent research indicates that some older adults are willing to use wearable technologies such as the Apple Watch as part of clinical research participation.21

Researchers and clinicians should be aware that many participants relied on the support of the research team to successfully engage with the Apple Watch, and more support is necessary when caregivers are not available to provide assistance. Older adults in the community setting would likely need additional support to use and especially troubleshoot the watch. Additionally, our participants were provided with the Apple Watch and an accompanying iPhone (if they did not own one already) for free, which is not representative of real-world circumstances. The iPhone and an Apple Watch may be too cost-prohibitive for older adults. As wearable technology becomes more prevalent, physicians may integrate more remote health monitoring into their practice, and insurers may expand their coverage of these devices which could facilitate uptake.

We believe these data provide valuable insights into how older adults can be supported to use novel wearable technology. Even if older adults are unable to engage with the advanced feature set of the Apple Watch, its remote monitoring capabilities, including heart rate monitoring, gait analysis, and fall detection – all of which are recorded passively without active engagement with the device – may still prove to be useful. For reluctant older adults, messaging regarding the Apple Watch can focus on the benefits of passive use, rather than its advanced features that require active participation.

CONCLUSIONS

Our results suggest that older adults who presented to the ED after falling are able to wear and charge the Apple Watch after a brief ED training. Their ability to engage with advanced features of the watch is dependent on various factors, including previous experience and comfort with technology and adequate support and instruction from others, such as family and community members. However, some older adults may be poor candidates for this technology. More widespread uptake of wearable technology such as the Apple Watch among older Americans can be expected if device manufacturers make them easier to navigate and if payors subsidize the cost.

References


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**Disclaimer**

The views expressed herein are those of the authors and do not necessarily reflect the views of Apple.

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Interactive Television as a Medium to Reduce Social Isolation in Older Adults During the COVID-19 Pandemic

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ABSTRACT

OBJECTIVE: To develop an interactive television program, Room with a View, to address social isolation in older adults residing Rhode Island (RI) and Southern Massachusetts (MA) during the COVID-19 pandemic.

METHODS: Using an Omaha System guideline for best practices in reducing social isolation and loneliness in older adults, the project team developed 25 evidence-based television episodes with the help of a production company. The program was aired on commercial, traditional (non-cable) television to allow for easy access.

RESULTS: Using a traditional consumer media in an interactive format allowed for rapid outreach to an older population in congregate care and community settings to engage them in activities that included physical, psychological, and social engagement.

CONCLUSION: Room with a View was a quick, but effective, interactive TV program that has successfully reached older adults at risk of loneliness and social isolation in RI and Southern MA, and it can serve as a model for future programs.

KEYWORDS: older adults, social isolation, loneliness, evidence-based interventions, COVID-19

BACKGROUND

Older adults residing in long-term care facilities (LTCFs) worldwide have been significantly impacted by the novel coronavirus (COVID-19). According to an August 2020 analysis by the Kaiser Family Foundation, people in LTCFs made up about 8% of COVID-19 cases, but 45% of all deaths in the United States (US).1 The social distancing requirements resulting from the pandemic have posed another challenge to institutionalized older adults: an increase in preexisting loneliness and isolation.

Before COVID-19, the prevalence of severe loneliness among older people living in long-term care was about two times that of those in community-dwelling populations: 22% to 42% for the resident population compared with 10% for the community population.2,3 Another study found that more than half of nursing home residents without cognitive impairment reported feeling lonely.4 Studies show that people who are socially isolated and lonely have a higher rate of early mortality,5 increased rate of all-cause mortality,6,7 more cardiovascular disease,8 and have poorer cognitive functioning.9 It has been found that loneliness has similar health effects on older adults as smoking 15 cigarettes a day.10 Recent data from the Centers for Disease Control and Prevention (CDC) showed that the deaths attributed to Alzheimer’s disease and dementia rose to more than 20% above normal over the past summer, with elevated isolation and stress during lockdown likely playing a key role in that increase.11

WHY A TELEVISION PROGRAM?

Many older adults have limited access to technology and even the Internet, especially in congregate settings. The most recent Pew Research Center findings recently reported that as of November 2019, 27% of adults ages 65 and older were completely offline, and 59% said they did not have home broadband services.12 Meanwhile, the proportion of older adults who said they owned smartphones was 53%.12 Further contributing to this digital divide are substantial differences in technology adoption within the older adult population based on factors such as age, income, disability status, and educational attainment. Older adults often experience difficulties while using technological devices because
METHODS

Target Population Reached
The target population for this TV program was any older adult residing in LTCFs, assisted living, senior housing, or in the community in RI and Southern MA. The show was available on both cable and antennalocal TV to increase accessibility to the program. Currently, the show is available on-demand.

Timeline/Methodology of Show Production
CareLink RI, a non-profit membership network of senior care post-acute and community-based care providers, developed the idea to create the interactive TV program Room with a View in April of 2020. Clinical leadership staff recognized the need for a rapid intervention to address the social isolation that older adults in congregate care settings were experiencing. The team leveraged their experience in congregate care settings to identify challenges that facility staff faced in delivering any interventions. The TV-based intervention was chosen because it required no specialized skills or training of staff, and could very easily be incorporated into existing care delivery.

As clinicians, the CareLink team understood the benefit of utilizing an evidence-based approach. As part of the initial development process, the team contacted a Doctor of Nursing Practice student at the University of Minnesota, whose research focused extensively on interventions to reduce social isolation in older adults, to collaborate, and to assist with ensuring content included was directly connected to the evidence. The researcher reviewed all content prior to airing, made edits, and served as part of the program’s advisory board.

In order to identify which evidence-based interventions should be included in the episodes, the team conducted a literature review using the Omaha System guideline entitled Decreasing Social Isolation in the Older Adult.16 The identified interventions were then considered for applicability to video content and current COVID-19 restrictions, and then applied to create 25 evidence-based episodes. Each episode was broken down into three segments addressing physical, psychological, and social health. The 25 episodes were 30 minutes each and the program spanned across a 10-week time frame. Over the 10-week period, one 30-minute episode played each Monday-Friday. All episodes Monday-Friday during the first five weeks were unique, while all episodes during the last five weeks were reruns. Additionally, two 30-minute episodes played each Sunday throughout the 10-week period, and these were all reruns. Therefore, across the 10-week timeframe, 70 total episodes were broadcasted.

Each segment was designed to utilize an evidence-based intervention to decrease social isolation and/or loneliness.

Table 1. A Sample of Evidence-Based Interventions Utilized in the Room with a View Episodes

<table>
<thead>
<tr>
<th>Target Health Outcome</th>
<th>Evidence-Based Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Health</td>
<td>Chair exercises</td>
</tr>
<tr>
<td></td>
<td>Tai chi</td>
</tr>
<tr>
<td></td>
<td>Chair/standing yoga</td>
</tr>
<tr>
<td></td>
<td>Body Mechanics for at-home injury prevention</td>
</tr>
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<td></td>
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<td>Animal webcams around the world</td>
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<td>Inside the J. Paul Getty Museum</td>
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*The evidence-based interventions listed in this table are just a sample of the many interventions included in all 25 Room with a View episodes. Each 30-minute episode included interventions from all three target health outcomes.
in the older adult. These interventions include reminiscence therapy, horticultural therapy, humor/laughter therapy\textsuperscript{17-20}, exercise,\textsuperscript{21-23} art therapy,\textsuperscript{21-23} pet therapy,\textsuperscript{17} and mindfulness, gratitude, meditation, and stress reduction activities.\textsuperscript{17,24,25} A segment with children was also added after receiving input from an expert in recreational therapy for older adults. Each 30-minute episode included evidence-based interventions targeted at physical, psychological, and social health. See Table 1 for a sample of the many evidence-based interventions included in the Room with a View episodes. The literature also stressed the importance of assessing and individualizing interventions,\textsuperscript{22} so a feedback telephone line and email were created to elicit feedback from all viewers. This enabled real-time modifications within the evidence-based framework based on stakeholder feedback.

After selecting the interventions for the episodes, it was necessary to identify a production company who could rapidly take content and produce a TV episode, a team of professionals to lead sessions, and a TV station willing to broadcast the program into the community at specific age-friendly times. When approached, WPRI TV-12 was enthusiastic about the idea, and agreed to air the program during some key times for older adults. CareLink Rehabilitation, which specializes in providing rehab and wellness services, as well as dedicated physical therapy, Tai Chi, yoga, and mindfulness for older adults, provided experts to tape show segments in those areas. (Images 1,2)

Initially, there were concerns about finding a producer to take on the project because the typical pilot to show lifecycle is over three months minimum and the team understood that a quicker turnaround time would maximize the impact for older adults. Fortunately, the research team reached out to a contact at a non-traditional TV format production company, Convention News Television (CNTV). This production company had expertise in creating content and news broadcasts rapidly for the convention industry. After sharing the vision, the research behind it, and the potential challenges, the staff at CNTV were able to develop a sample show in less than 48 hours. To create an episode, an iterative process was taken in which an outline was first developed by the research team and sent to writers at CNTV. The writers then sent it back to the team where more edits were made before it was sent back for filming. Finally, each episode was viewed by the research team and final changes were made before the completed version was sent to WPRI TV-12 for airing. This process occurred with each of the 25 episodes, and all 25 episodes were completed in about six to eight weeks. (Image 3)

The team then applied for and received funding through the Rhode Island Foundation COVID-19 Behavioral Health Fund Grant #57267. After securing funding, the TV show was broadcasted on June 1, 2020 for the first time. Room with a View was broadcasted Monday-Friday at 2pm on CW Providence. Additionally, it was played Sundays both on Fox Providence at 8 a.m. and MY RI at 9 a.m. It took a team of producers, rehabilitation and wellness specialists, and the feedback and review of the collaborating recreational therapists, and researchers to produce each episode. Viewers who had feedback for the show or wanted to request an activity for a future program were encouraged to call the feedback
line or send an email, both of which were shown during the episodes and listed on all distribution and marketing materials. Unfortunately, these were used minimally by viewers, so we did not receive as much feedback as we had hoped. One viewer did indicate that they appreciated the interactive nature of the program. Additionally, staff from a LTCF in RI let our team know that their residents enjoyed the segments with children and pets, so we intentionally included more of that content in the remaining weeks.

RESULTS
Ratings and Viewer Totals
Ratings were collected using the Nielsen rating system; these ratings are commonly utilized for understanding TV viewership within the US. The overall share of the market averaged 4%. The share is the percentage of the television sets in use who were tuned to specific programs, stations, or networks in a specific area at a specific time. In calculating the viewership in the first 10 weeks of the show’s initial run, the Actual Average was utilized. The Actual Average is the number of people who were using their television at the time the show aired who viewed the show during the 30-minute segment. In the first 10 weeks, the show totaled an actual average of 240,747; this translates to about 4,000 viewers per episode. Some episodes, however, had more viewers than others, with the highest viewership of one episode totaling 10,255 individuals. To put this in perspective, a highly rated, long-running food show on the same channel garners an average of 10 to 20 thousand viewers per episode. The show has been moved to free on-demand access through the CareLink RI website (https://carelinkri.org). As of February 2021, 1,170 individuals have viewed the show on playbacks.

DISCUSSION
Next Steps/Implications
Thus far, Room with a View has successfully reached a large segment of older adults at risk of social isolation and loneliness in RI and Southern MA. The population of older adults is expected to increase exponentially in the US, so program development to help with reducing social isolation in this population will become even more critical. Room with a View demonstrated that it is possible to reach a wide population of older adults through an interactive TV program while maximizing accessibility, even during a limited timeframe. Many researchers are now focusing on Information and Communication Technology (ICT)-based interventions that employ newer technology, rather than TV-only interventions. However, the use of traditional technology, such as television, applies a person-centered approach to intervention by using a medium that older adults engage with regularly, and can be an effective tool to rapidly engage older adults. It would be beneficial for a television component to be included to increase accessibility and older adult participation in future ICT-based interventions.

Currently, we do not have funding to develop new episodes of Room with a View, but there have been discussions of continuing show production if we can obtain another grant. However, all 25 Room with a View episodes can be found on-demand and online on the CareLink RI website. CareLink RI connects with LTCFs in RI every day, as well as with other statewide collaborations and workgroups, so we continue to encourage LTCFs to utilize this program with their residents. Moving forward, these episodes will be permanently available online and on-demand.

Limitations
Although we achieved our goal of getting this show out to older adults quickly to reduce the negative impact of the social distancing mandates, it was not possible to complete a pre-post measure of the impact of the show on our viewers. As the priority was to get the show out as soon as possible, we did not administer a baseline assessment prior to the distribution of the program. In the future, it would be valuable to implement this type of intervention with a pre-post design to actually quantify if there was a reduction in loneliness and perceived benefit of the program amongst viewers. Due to limited funding and a quick implementation period, we were unable to design the program in languages besides English. Opportunities for future programs can increase accessibility by adding programming across a broader number of channels, at more times, and in other languages. Additionally, although we implemented a feedback line and email for viewers to provide suggestions, these were accessed minimally. As a result, we primarily relied on evidence-based literature when developing the interactive episodes. Future programs should place a greater emphasis on soliciting viewer feedback and iteratively making updates to episode content as necessary. Despite these limitations, Room with a View has reached a wide number of older adults in RI and Southern MA, and continues to have an impact with the transition to availability on-demand and online.

CONCLUSIONS
The COVID-19 pandemic has highlighted the pressing need to facilitate social connection amongst the older adult population. Loneliness has been shown to negatively impact health in older adults, so prevention will be key as society continues to move throughout the rest of the pandemic and beyond. Room with a View was a quick, but effective, interactive TV program that has successfully reached older adults at risk of loneliness and social isolation in RI and Southern MA, and it can serve as a model for future programs. In challenging situations, such as a global pandemic, where researchers are pressed for time to come up with innovative solutions, an interactive TV program, similar to Room with a View, can reach a wide audience in a much shorter amount of time than is typically required for extensive intervention development.
References


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Disclaimer
The views expressed herein are those of the authors and do not necessarily reflect the views of the Rhode Island Foundation.

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Incidence and Mortality Changes of Screening Preventable and Detectable Cancers in Rhode Island, 1995–2018

JUNHIE OH, BDS, MPH; ERIC LAMY, BA; MATTHEW BOUDREAU, BA

Cancer is the 2nd leading cause of death among men and women in Rhode Island.1 Over the last few decades, advances in cancer screening, diagnosis and treatment have lowered cancer mortality.2 Screening for breast, cervical and colorectal cancers has become a public health priority as these are highly prevalent cancers whose health outcomes are greatly improved when they are identified at early or precancerous stages. In short, early detection for these cancers saves lives.3-5

The study examined incidence and mortality changes from 1995 through 2018 for breast, cervical and colorectal cancers, and discussed implications of screening efficacy.

METHODS

From the Rhode Island Cancer Registry (RICR) data, newly diagnosed malignant cancers* of the breast (female only), cervix, and colon/rectum were identified, using the International Classification of Diseases for Oncology 3rd revision (ICD-O-3) site/behavior coding: C500-C509/3 (breast), C530-539/3 (cervix uteri), and C180-C209, C260/3 (colon and rectum). Stage at cancer diagnosis was also extracted and analyzed, using the diagnosis year-specific “Summary Staging” systems (Summary Staging | SEER Training [cancer.gov]).

Cancer mortality data, 1995–2018, provided by the National Center for Health Statistics (NCHS) were accessed and summarized using SEER*Stat software v8.3.9 (SEER*Stat Software [cancer.gov]). Causes of death were classified by NCHS, according to the International Classification of Diseases (ICD-Classification of Diseases, Functioning, and Disability [cdc.gov]).

Cancer type-specific denominator populations were defined to approximate cancer screening starting ages: ≥40 years old for female breast cancer, ≥20 years old for cervical cancer, and ≥50 years old for colorectal cancer. U.S. Preventive Services Task Force (USPSTF) Recommendations have been regularly updated and changed, including cancer screening ages.3-5 Age cutoffs used in this study reflect the past and the current screening practices to demonstrate screening effects on cancer incidence and mortality throughout the study period.

Finally, incidence and mortality rates were age-adjusted based on the US 2000 Standard Population (19 age groups – Census P25-1130) and presented per 100,000 Rhode Island men and/or women. For the trend analyses during the studied period [1995–2018], annual percentage change (APC) of the rates was computed and statistical significance was evaluated (at p value <0.05).

RESULTS

Female breast cancer (Figure 1)

Among Rhode Island women ages 40 years and older, incidence of malignant breast cancer (including in-situ lesions) slightly increased from 1995 to 2018 by 0.5% annually. Parallel to overall incidence change, in-situ and localized cancer diagnoses increased by 2% and 1% per year, respectively. Incidence of regional and distant (metastatic) cancer remained stable during the years. Meanwhile, mortality rate (deaths caused by breast cancer) significantly declined by 3% per year, on average, from 1995 to 2018.

Figure 1. Changes of Breast Cancer Incidence and Mortality, Women Age ≥40 years, Rhode Island Cancer Registry, 1995–2008


“In-situ (carcinoma in situ)” is abnormal cells, confined to epithelium. “Localized” cancer is confined to the organ of origin without extension beyond the primary organ. “Regional” cancer has spread to adjacent organs or structures, or to regional lymph nodes. If the cancer has spread to parts of the body remote from the primary tumor, it is classified as “distant” stage.

Cervical cancer (Figure 2)

From 1995 to 2012, continuous and significant declines were observed in both incidence and mortality rates among Rhode Island women ages 20 years and older, and then these rates plateaued since 2012. Trendline of localized cancer
“Localized” cancer is confined to the organ of origin without extension beyond the primary tumor. “Regional” cancer has spread to adjacent organs or structures, or to regional lymph nodes. If the cancer has spread to parts of the body remote from the primary organ, it is classified as “distant” stage. “In-situ” lesions of the cervix were not collected by central cancer registry from 1996-2017, according to the Rhode Island State Regulation for the Cancer Registry.

Data Sources: Rhode Island Cancer Registry (incidence) & National Center for Health Statistics (mortality), summarized using SEER*Stat Software version 8.3.9


Since 1995, newly diagnosed colorectal cancers steadily declined among Rhode Island men and women ages 50 and older. This decrease over the past 24 years was remarkable, and cancer rates in recent years were half of what they were in the late 1990s. Cancer diagnoses at all stages, and colorectal cancer deaths significantly decreased over the past decades.

**DISCUSSION**

Population-level (statewide) cancer incidence and mortality reports may conceal crucial heterogeneity in the risk of cancer development and death by age at cancer diagnosis, latency period, tumor characteristics, treatment, underlying predisposing conditions, and other clinical and individual factors. Despite these limitations, cancer statistics derived from cancer registry and vital records [death certificates] provide valuable measures to assess screening efficacy in decreasing the screening detectable and preventable cancer burden and mortality.6,7 Mortality rates, in particular, can be a better indicator in evaluating screening outcomes than incidence, because they are less affected by biases resulting from changes in detection technologies and frequencies.8

Observing changes of cancer incidence for early-detected and advanced cancers associated with cancer screening implementations, increases in early-stage disease and decreases in late-stage tumors are not always seen. For instance, among breast cancer screening eligible women in Rhode Island, rising incidence and falling mortality imply a mixed effect on screening: true increases of the disease and overdiagnosis by screening.9 From 1995–2018, increasing breast cancer rates were mainly driven by increasing diagnoses in in-situ and localized cancers. Stabilized rates of advanced cancer diagnoses and fewer cancer deaths are combined effects of effective cancer screening and treatment.9,10

Reductions in cervical cancer diagnoses at localized cancer and mortality can be attributed to the effective screening [Papanicolaou testing] and successful treatment of precancerous lesions.4 However, stagnant improvement both in cancer prevention and deaths may reflect an increasing proportion of adenocarcinoma which is often undetected by conventional cytology and increasing prevalence of underlying HPV infections.11,12 These new trends underscore the importance of HPV vaccination uptake and HPV DNA co-testing [preferred screening method for women aged 30 to 65 years by current guideline].4

Colorectal cancer rates have steadily decreased among Rhode Islanders for the last two decades. This reduction can be attributed to increases in screening among at-risk populations.10 Screening for colorectal cancer can identify the presence of precancerous and cancerous cell growths, thereby preventing the cancer development and improving colorectal cancer treatment outcomes.4 Nationwide, colorectal cancer is rising among younger adults leading the USPSTF to recommend average-risk individuals to initiate screening at age 45 instead of 50.3,13 Studies suggest that modern dietary habits and obesity may correlate with colorectal cancer rate increases in younger generations, but further research is needed.14 This increase in colorectal cancer incidence among younger populations has yet to be observed in Rhode Island.

*RICR collects, processes and reports on primary cancers only. Recurrent or metastatic cancers are not reportable to RICR, according to the Rhode Island State Regulation for the Cancer Registry.*
References

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We thank all dedicated Rhode Island cancer registrars in the central and local hospital registries for their quality cancer surveillance and reporting.

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Disclosure
The authors declare no conflict of interest.

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

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

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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 1,059,361 for 2019 (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.
Rhode Island Monthly Vital Statistics Report
Provisional Occurrence Data from the Division of Vital Records

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

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‘How not to do things’
FDA approval of new Alzheimer’s drug triggers controversy
JOSEPH H. FRIEDMAN, MD

Background
In June 2021, the Food and Drug Administration (FDA) approved the first drug to treat Alzheimer’s disease. This decision brought about a great deal of discussion in the scientific community for the following reasons:

- The two pivotal trials, EMERGE and ENGAGE (which have not yet been published) had negative outcomes.
- The ENGAGE study was aborted early during a futility analysis. (A review of data by the study’s safety monitoring board found that the data accumulated at the review showed that if the study continued, the results were very unlikely to have a positive outcome, so that continuing the study was futile.)
- The FDA’s own internal reviewers recommended for approval based on a post-hoc analysis of subjects who had longer-term follow-up than had been available when the ENGAGE study was aborted, yet its own statisticians disagreed and reported that efficacy had not been established.
- The FDA’s selected external advisory board of national experts voted 11–0 that efficacy had not been established; three members of this board then publicly resigned following announcement of the approval.

I am not an Alzheimer’s disease expert, but have significant experience with clinical trials, dementia, and peer review of grants and medical journal submissions.

Charles Dickens’ novel, Little Dorrit, introduces the most important ministry in the British government, The Ministry of Circumlocution, whose mission is, “How Not To Do It.” Unlike the current Food and Drug Administration [FDA], the Ministry of Circumlocution’s goal is to not get things done. This stands in contrast to the FDA’s recent decision on aducanumab, an anti-amyloid drug for Alzheimer’s disease, in which, one could argue, they apparently had the result – if not the actual goal – in getting things done wrong.

Amyloid has been strongly implicated in Alzheimer’s disease, although there is also strong evidence that it is not the cause of the disorder. Amyloid protein accumulates in the disease in the form of “plaques,” but is not the sole pathological change. Neurofibrillary tangles also accumulate and a large number of brain cells die, possibly related to amyloid, possibly not. I have not reviewed the data on the drug from its pivotal clinical trials, but I have read critiques of the FDA’s decision by prominent Alzheimer experts who supported the FDA’s approval.

Mark Twain, in a famous lecture criticizing James Fenimore Cooper’s novel, The Last of the Mohicans, provided a list of rules that should never be violated in a novel. One was that a character who is dead should not reappear later in the book, alive. I believe an adaptation of this rule is that the FDA should not have requested another opinion if they didn’t want a different opinion. The danger in getting second opinions is that you may actually get one. Then, what to do? The FDA convened a panel of 11 experts in neurodegenerative disorders to review the data. There was 100% concordance that the results were not convincing of the drug’s efficacy. Ten of the 11 thought the results did not indicate efficacy and one thought the results were possibly indicative of efficacy, but not persuasive. Pronouncing a decision without arbitration and without confronting the opposing viewpoint is an example of “how not to do it.”

The conclusion of the FDA’s own statistical team was that the drug’s efficacy was not proven, another strike against the FDA’s own review team. Since efficacy of drugs (not necessarily devices) is based on both clinical and statistical interpretations, it is surely an example of “how not to do it” when you choose to ignore your own statistical advisors when making decisions based on statistical significance.

One of the cardinal rules in clinical trials is that you can’t go back again to re-interpret data that didn’t turn out the way you wanted. This isn’t to say that doing this is a bad thing, unless you then use the post-hoc analysis to re-interpret the study’s results, hence redesigning the trial after it’s been completed. It is acceptable to note that using different criteria would have resulted in different results, and then re-doing the study using a different methodology based on the first trial’s outcome. The aducanumab study that led to the drug’s FDA approval actually was aborted before recruitment goals had been achieved because of an absence of sufficiently positive data to possibly yield a positive outcome. To
then harvest new data is an excellent idea, but using it after the study ended is an approach that does not meet usual clinical trial standards.

It is not a good idea to help justify a decision by claiming that the results supported “proof of principle,” that disease progression was due to amyloid deposition and the measured benefit was in sync with the reduced amyloid, when older studies had shown that reducing amyloid did not produce improvement. Proof of principle is important, although why it should be related to a drug’s approval is not clear. In arguing that this is important, opposing arguments based on stronger data should be discussed, another example of “how not to do it.”

Stating that the approval is temporary, pending a confirmatory trial that needn’t be completed for nine years is akin to a wish, i.e., I hope you will provide more data to help justify our decision since we’re standing on very thin ice, but just to make sure we don’t fall through the ice, there’s no need to hurry.

I have no reason to think that the FDA decision was based on reviewers in the pocket of drug companies. I have no idea whether politics played a role in the FDA administration’s decision, but that’s the only rational explanation I can come up with. I have not reviewed the actual data, and hope to when it is published. I can recall a similar situation facing the FDA about 15 years ago, when rasagiline, a drug for Parkinson’s disease, my area of expertise, was reviewed by the FDA for treating symptoms as well as for slowing disease progression. The symptomatic treatment portion was clear-cut, but the progression part showed efficacy if only part of the data was reviewed. But, the whole picture was mixed, presenting a puzzling set of data, without a good explanation, presumably a statistical aberration. The FDA chose to believe that the argument for disease modification was not proven and approved the drug only for symptomatic use, which most authorities in the movement disorders’ world thought was a wise decision.

One major difference from the aducanumab study is that in the Alzheimer study there was no symptomatic benefit. There was slower progression, an important benefit, but one that cannot be measured in any particular patient. Patients will be taking a drug that experts disagree on whether or not it has benefit, has resulted in substantial side effects such as small brain hemorrhages and focal brain swelling in some patients, and costs $56,000 per year, plus expensive testing to qualify for the drug and expensive testing while on the drug, and no one will be able to tell if it is helpful. It is a remarkable decision that will hopefully not come back to haunt the FDA. Whether or not it was a good decision, it certainly was an example of “how not to do it.”

**References**


**Disclaimer**
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A few months ago, we received news of the death of our colleague Jack Ruddell, a fourth-year medical student at Brown University. Jack’s life ended tragically through suicide, and revelation of the event created immediate shock and devastation in our local medical community. The loss of Jack was deeply saddening and warranted taking a personal inventory of our relationship with him.

Jack was an exceptional classmate and a truehearted friend. We were blindsided by his passing; in a moment, the life of an ambitious young man with innumerable future accomplishments had been halted. As a young student eager to get involved in the Department of Orthopaedics, his quiet but confident demeanor and intense focus immediately separated him from his peers. He appeared wise beyond his years - truly a quick study with amazing natural potential. His meteoric rise with several high-impact publications in just two years of work impressed an array of senior faculty. When faculty encounter a rare student with potential as great as Jack’s, we in academic medicine dream of a future colleague, a future partner, a future educator and revolutionary thinker; we selfishly think how great it is for our careers to benefit from his presence and for our professional relationships so that we all may navigate times of trouble together. The bittersweet reflections on Jack’s life have lifted our heads and encouraged us to do the same for others.

One must marvel at the mountains Jack was conquering despite the special challenges of struggles with mental illness. Perhaps his shadows had lingered for some time. Jack knew to make much of his relationships with others, and the staying power of his friendship was a substantial force. Yet still hidden to us and many others was a constellation of emotions and thoughts within Jack that remained unroofed by others in his moment of crisis. This realization is the most saddening. It is impossible to say whether anyone could have reached that depth within him, but no one deserved the attempt more than Jack, who had given so much of himself to his friends and colleagues.

We are bound in the obligation of looking after each other. While we cannot try to control the decisions of others around us, we must cultivate a vigilant concern for their wellness and trajectory. Medical training imposes various challenges to our sense of self and wellbeing, including necessary pressures toward stoicism and perfection. These forces must be counterbalanced by coping skills, most notably leaning on our connection with others. To that end, we must build the bridges for others to walk toward us when they are in need. We may probe when we sense hurting or issue out the sense of our presence when silence is preferred. Ultimately, creating an approachable environment by whatever means is doing the work of protecting the lives of our colleagues, who are humans before they are healthcare workers.

Dismantling the stigma surrounding the conversation of physician suicide promises to yield immeasurable benefit to physicians, and their families and patients. The medical profession is unique in our daily management of life-and-death situations and life-altering tragedies; yet, we are not unique in our personal battles with mental health challenges. Together, we lament the loss of Jack’s potential influence on his future patients and his contributions to medical knowledge. But his example has reminded us of our ever-present duty as a reinforcement for others, to constantly build bridges to safety in our professional relationships so that we all may navigate times of trouble together. The bittersweet reflections on Jack’s life have lifted our heads and encouraged us to do the same for others. And we will continue to hear his voice, always singing.

The impact of losing a colleague to suicide carries a weight that is both permanent and deeply human. We present our perspectives on the premature death of our colleague as a peer and mentor to memorialize the incredible young man he was, but also to issue
to our community a call to action to establish deep roots with one another. The time is now to begin this difficult, even unfamiliar work together.

While we as colleagues stand as one of the primary layers of defense for each other, we urge physicians and medical students at risk or those who feel isolated to reach out and speak to someone. This may be informally, to a close confidante, friend, family member or colleague, or formally to a therapist, the anonymous National Suicide Prevention Lifeline (1-800-273-8255), or support group. A comprehensive list of local, state, and national resources for Rhode Island physicians and others at risk of suicide can be found on the National Alliance on Mental Illness Rhode Island Chapter website (https://namirhodeisland.org/resources/national-and-state/). Therapeutic modalities for depression and mental health issues including suicide have improved and diversified greatly in recent years. Help is available to all, even in a dark and most desperate hour. May we as a community strengthen our connections so that our lifelines with each other are never far away. From medical students at the earliest stages of training, to physicians and surgeons in long-standing group practices and academic departments, we all have a role to play. Creating a culture of caring, openness, and support is our collective duty; we are the ones to wield this responsibility to protect each other from the known occupational mental health dangers of working in our challenging but rewarding profession. We urge our community to build bridges in our professional relationships, so that a way out is always close at hand, and a kind ear is always ready, to disarm the threats of feeling isolated, abandoned, or distressed. We take great care of our patients everyday; we must also remember to take care of each other.

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Physician-patient relationships are influenced by surrounding legislative climates. Recent rulemaking by the Centers for Medicare and Medicaid Services (CMS), which went into effect on January 19, 2021 and intended to facilitate value-based treatment, has made significant changes to the regulations underlying the Ethics in Patient Referrals Act, also known as the Stark Law, and the Anti-Kickback Statute. [See Background]

The new rules, which modify and expand the regulatory exceptions of the Ethics in Patient Referrals Act and the Anti-Kickback Statute, are part of a larger concerted effort launched by the U.S. Department of Health and Human Services (HSS) to stimulate innovative, collaborative arrangements in the healthcare system. These modifications remove previously existing regulatory red tape and obstacles to the adoption of promoting value-based models in modern clinical care.

Patient referrals
Among other things, the changes in the rules modify and expand the regulatory exceptions that pertain to healthcare providers and institutions in connection with patient referrals. The anti-kickback rules applicable to patient referrals are of exceptional clinical significance because their prohibition on billing for patient referrals to related health services directly affects physicians’ ability to deliver quality, coordinated and efficient care. The new rules are intended to provide relief for value-based enterprises and the value-based arrangements between participants in a given value-based enterprise.  

When the Stark Law was first introduced, Medicare operated primarily on fee-for-service models, prior to value-based payment models, which are becoming more prevalent. In value-based arrangements, the self-referral incentive is dramatically reduced compared to fee-for-service models. However, even in fee-for-service models, these updated rules give greater autonomy to providers.

Value-based arrangements
The variables in qualification for safe harbors include the status of the payees as value-based enterprises, and whether, and to what extent, both the payee organization and the particular physician take on financial risk with respect to payment. Central to the new rules is the protection of payments among participants in a value-based arrangement, defined as arrangements with the purpose of:

**Background**

The Ethics in Patient Referrals Act/Stark Law and Anti-Kickback Statutes were adopted during the height of the fee-for-service model and were intended to address the practice of physicians prescribing and referring patients for additional therapies to providers in which the physician had a financial interest, or who paid the physician a referral fee.

In the years since the Stark Law was enacted and the CMS’ regulations for its enforcement were adopted, the practice of medicine has steadily migrated away from the fee-for-service model that motivated the Stark Law, evolving towards a value-based model in which patient outcomes, rather than procedures performed and tests administered, are the basis of compensation and reimbursement. However, the fee-for-service model still exists, particularly in procedural subspecialties, where it is generally compensated higher than in nonprocedural care.  

**Ethics in Patient Referrals Act**

The Ethics in Patient Referrals Act, with some narrow exceptions, prohibits a physician from knowingly referring patients to designated health services payable by Medicare or Medicaid, if a relationship exists between the physician and/or family member and the designated health service. Designated health services are those that perform inpatient and outpatient clinical services, physical or occupational therapies, prescription services, clinical laboratory testing, radiology services, medical equipment and supplies, parenteral and enteral resources, prosthetic and orthotics, or home-health services. The Stark Law also prohibits healthcare providers from charging Medicare or Medicaid for medical services performed on the basis of a prohibited referral. Violations of the Stark Law may result in denial of reimbursement claims, restitution of payments made and civil penalties.  

**Anti-Kickback Statute**

The Anti-Kickback Statute covers similar activity, but has a broader scope. It imposes criminal, and in connection with the False Claims Act (31 U.S.C. Sec. 3729-3733), civil sanctions on those who knowingly or willfully offer, solicit, receive or pay any remuneration in exchange for covered medical services and products underwritten by any federal healthcare program. It is applied to all government programs, whereas the Stark Law only applies to Medicare and Medicaid. Therefore, patients under Department of Labor programs would also be included in the Anti-Kickback Statute. Additionally, the Anti-Kickback Statute is not limited to physicians, as is the Stark Law. Any person who illegally refers patients in exchange for compensation is potentially culpable under the Anti-Kickback Statute. While the Stark Law only applies to designated health services, the Anti-Kickback Statute applies to all services and items if they are paid for by a government program.
• Coordinating care;
• Improving the quality of care;
• Reducing costs for payers (without negatively impacting care); or
• Transitioning the practice from a volume-based model to an outcome-based model for a target patient population.

Qualifying value-based enterprises must have a person or body responsible for overseeing the enterprise’s clinical and financial activities, and must create a document that evidences the way the member of the enterprise will meet the value-based objective.

**Modifications/Safe harbors**
The new rules create a number of exemptions and safe harbors to permit what would otherwise be prohibited physician referrals under the *Stark Law*, where the physician and the designated health service provider are part of a value-based enterprise. One major modification permits pharmaceutical manufacturers, distributors and wholesalers, pharmacy benefit managers, laboratories, and medical device manufacturers and suppliers to be considered participants in value-based enterprises.7

**Care-coordination arrangements**
The new rules also create a care-coordination arrangement safe harbor under the *Anti-Kickback Statute* for in-kind remunerations between value-based enterprise participants according to the terms outlined in a value-based arrangement.6-7 The safe harbor cannot be applied to administrative duties of the recipient or to benefit patients outside of the target patient population of the value-based arrangement, which must be defined. A qualifying value-based arrangement must also specify an evidence-based outcome that the arrangement will advance. The arrangement also requires the recipient to pay at least 15% of the cost to ensure they are motivated to benefit the target population.7-8 If the arrangement does not achieve its outcomes, it must be terminated within 60 days.7-8

**Downside financial-risk safe harbors**
The amendments also create downside financial-risk safe harbors. This allows for referral remuneration for participants in value-based arrangements who have specified amounts of downside financial risk due to the nature of their arrangements and would share in any loss incurred by the arrangement. This risk is determined by a participant who receives a partial payment or it shares in the payer’s losses.

The CMS also outlined a parallel rule for physicians under the purview of the *Stark Law*. A clinical example of such an arrangement that is permitted by the updated rules would be a hospital discharging patients to a skilled nursing facility. Under the new rules, the hospital could provide a nurse to follow patients discharged from the hospital to the nursing facility and the nursing facility could aid in transitioning care from the hospital to the nursing facility without concerns about violating the *Stark Law*, which helps control costs and maintain a higher degree of clinical care between the two institutions. Previously, this exchange of services would have to be monetized and discretized individually, leading to higher costs for patients.

**Patient engagement and support**
A new patient engagement and support safe harbor outlines an exception to the *Stark Law* that permits participants to provide patients in the target population with tools or supports that are specific to certain goals and must be recommended by a patient’s healthcare provider.7 This exception only extends to in-kind items, purposefully not extending to cash or cash equivalents, and is capped at $500 annually.7

**Services and management contracts**
Finally, the new rules extend an existing Anti-Kickback Statute safe harbor for services and management contracts, for which payments are dependent on outcomes, and requires the arrangement to specify the total size of payments.8 The rule removes the requirement of specifying the total size of payments as long as there is transparency in how the payment will be calculated. The sixth rule concerns the CMS-sponsored care delivery and a payment arrangement safe harbor, and removes the scrutiny on these programs by the Office of the Inspector General (OIG), since they are CMS-sponsored. A limitation of this exception is that it does not extend to arrangements or patient populations outside of the CMS ecosystem.

These modifications collectively remove regulatory oversight on healthcare providers and their referral channels, by providing them with increased autonomy for their respective practices.

**Examples of value-based arrangements**
With these changes, the opportunity exists for healthcare providers to enter into innovative value-based arrangements without a fear of *Stark Law* violations. For example, consider a primary care practice that wants to collaborate with a gastroenterology practice to lower costs and improve health outcomes of its patients. If the gastroenterology practice performs data analytics to analyze risk factors of the primary care’s patients, the previous *Stark Law* would prohibit the gastroenterology practice from sharing that data with the primary care practice unless the primary care practice paid the “market price” for the information. Despite the clinical utility of the information, the market price requirement actually discourages its use by increasing the cost to
the primary care provider, patient and payers.

Another inefficiency that the updated Stark Law addresses are arrangements between hospitals and physicians within the hospital’s electronic health records system, where the hospitals could not previously provide cybersecurity software at a reduced fee to physicians because of a potential Stark Law violation. With the updates, those concerns of violations no longer exist, and hospitals do not need to decide between accepting increased risk of security breach and restricting physician access to electronic health records.

**Conclusion**
The changes to the Stark Law and the Anti-Kickback Statue are complex and are not completely congruent with each other. Providers should consult with counsel regarding their specific arrangements, as compliance with the new rules requires close analysis. Hopefully, though, these changes will accelerate the implementation of innovative and more coordinated patient care practices by facilitating arrangements between physicians and designated health services.

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**Key Changes in the Anti-Kickback Statue and Stark Law**

<table>
<thead>
<tr>
<th>Key Change</th>
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<tr>
<td>Pharmaceutical manufacturers, distributors and wholesalers, pharmacy benefit managers, laboratories, and medical device manufacturers and suppliers are considered participants in value-based enterprises.</td>
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<tr>
<td>“Care-coordination arrangements” safe harbor for in-kind remunerations between value-based enterprise participants according to the terms outlined in a “value-based arrangement.”</td>
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<tr>
<td>“CMS sponsored-care delivery and payment arrangements” safe harbor removes the scrutiny on these programs by the OIG.</td>
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**References**
2. The Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn
4. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
7. Physician Self-Referral Law (Stark Law), 42 C.F.R. § 411.354(d)
8. Exceptions, 42 C.F.R. § 1001.952

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Independent Medical Evaluations and Depositions for Workers’ Compensation: A Physician’s Perspective

JOHN R. PARZIALE, MD

KEYWORDS: Disability Evaluation, Occupational/industrial medicine, Practice management, Workers’ compensation, Independent medical evaluation [IME]

INTRODUCTION
Workers’ compensation plays an important role in the protection of workers injured in the course of employment. Physicians, judges, attorneys and others each contribute to the modern system of assessment and compensation for injuries, whose earliest roots can be traced back to before the modern era. In ancient Sumeria (present day Iraq), for example, the loss of a thumb was equivalent to the loss of half of a finger. Similar systems of compensation were recorded in ancient Egypt, Greece, Rome and China. Modern systems of workers’ compensation were established in Prussia, evolved in Great Britain, and were introduced in the United States (US) in the early 1900s; each of the 48 states in the continental US had passed workers’ compensation laws by 1948. Social Security Disability Insurance was established in 1956, amending the Social Security Act of 1935 to include benefits for disabled persons. The Americans with Disabilities Act (ADA) became law in 1991 and required employers to make reasonable accommodations for injured workers.

Physicians play a complex role in workers’ compensation and may be employed by the injured worker’s employer, an insurance company, an attorney representing the worker, or the Court. One aspect of patient evaluation is the Independent Medical Evaluation (IME), defined as the medical evaluation of a person not previously treated by the clinician. This examination may be performed by a physician for patients (subjects) with work-related complaints and/or injuries. The subject of the IME – the injured worker – often has little input or choice in the selection of the physician examiner.

While the terms independent medical evaluation and impartial medical examination are often used interchangeably, this is not accurate. The Commonwealth of Massachusetts notes that an Independent Medical Evaluation is paid for by a 3rd party, often the insurer, while an Impartial medical examiner has no allegiance to either the subject or their insurer and is considered a “judge’s expert”.

THE INDEPENDENT MEDICAL EXAMINATION: RESPONSIBILITIES TO THE INJURED WORKER AND THE 3RD PARTY

Prior to the independent medical examination, the physician thoroughly reviews a file that includes medical reports pertaining to the claim. Upon greeting the subject, the examiner should disclose that he/she has been asked to evaluate the injured worker as it pertains to the claim of injury, and that this interaction is not considered a physician-patient relationship. After the examination, a report is completed that includes the review of the medical file, the history taken on the date of the examination and the findings of the physical examination. This report concludes with medical opinions regarding whether an impairment or injury did or does exist, whether the impairment(s) is causally related to the subject’s employment, the extent of any residual disability or handicap, and whether the subject has reached a point of maximum medical improvement. In some cases, a permanent impairment rating may be rendered.

Once the IME report is filed with the Workers’ Compensation Court, attorneys for the injured worker and his/her employer (or the employer’s insurance carrier) may request further testimony from the physician via a legal deposition. If the IME is requested [and paid for] by the employer or its insurance carrier, the injured worker may question whether the conclusions rendered in the report are biased in favor of the entity paying for the IME. This can result in an uncomfortable, if not adversarial, interaction between the IME examiner and the injured worker.

The American Medical Association (AMA) “Work-related IME/Code of Medical Ethics Opinion 1.2.6” states that the IME physician must:

a) Disclose the nature of the relationship before gathering information from the patient [subject]: that the physician [examiner] is an agent of the insurer or 3rd party.

b) Explain the physician’s role as an objective assessor of the patient’s [subject’s] health and or disability, noting the difference between the usual patient-physician interaction.

c) Protect the patient’s [subject’s] personal health information in keeping with professional standards of confidentiality.
d) Inform the patient (subject) of incidental findings during the examination. When appropriate, suggest and/or provide assistance in securing follow-up care.

This last item (d) blurs the role of the “independent evaluator” and indicates that the IME physician actually has responsibility in securing medical care for the injured worker. For example, if an IME physician examined a subject for a work-related low-back injury and noted incidental findings of peripheral vascular disease and possible skin cancer, per AMA doctrine the IME physician should notify the subject of these incidental findings and assist in securing follow-up care as needed. Providing “assistance in securing follow-up care” might be considered establishing a physician-patient relationship, in contrast to section [b] of these guidelines.

RESPONSIBILITIES OF THE IME EXAMINER TO THE COURT

In addition to a review of medical records, interview and physical examination within the scope of one’s medical specialty and the timely production of a legible report, the IME physician must be available for medical deposition if required. Some IME examiners feel that their role ceases after the first three items and may not wish to be involved in a deposition, viewing it as tantamount to navigating a legal minefield. This perception may be due to a fundamental difference between the “medical model” and the “legal model” as it pertains to the deposition. Physicians are trained in the medical model, where an opinion is based on scientific fact and practitioners work in a collaborative arrangement with other clinicians. The physician is often viewed as a “Solomonic authority”, where his/her opinion is unquestioned. In contrast, the legal model is an adversarial system where, “Truth is best ascertained by witnessing the combat of minds. Each side will attack the other’s position” to find the truth. When an attorney questions or challenges a physician’s competence, expertise or authority as part of the legal model, it may place the IME physician in an uncomfortable position.

The IME physician is an expert witness. An expert witness opinion is admissible in court if based upon whether the science [a] has been tested, [b] has been subjected to peer review and publication, [c] has potential for error, with determination of the error rate, [d] has a standard controlling its operation, and [e] has widespread acceptance within the medical community.

PREPARING FOR A DEPOSITION

The IME physician should review all records prior to the deposition. The chart or notes should be organized for easy retrieval during the deposition and the IME physician must be familiar with the subject’s history and exam findings. If a jurisdiction has established treatment protocols, the physician should note whether these protocols have been followed.

Pertinent medical literature should be reviewed. As a medical expert within his/her field, the IME physician should be familiar with terminology, validity of exam or test results, and new or alternative treatment options.

The AMA Guides to the Evaluation of Permanent Impairment were established in 1971 as a means of assessing a permanent impairment with a relative value system, an evolution of the ancient Sumerian system. An impairment rating should only be assigned if the injured worker has reached a point of Maximum Medical Improvement (MMI). The IME physician should be able to cite training that he/she has received in the use of the Guides.

An attorney may challenge or contest the IME report based upon a) an item of medical history or physical examination, b) a laboratory finding that was reported (or not documented) in the IME report, c) the IME physician’s credentials as an expert witness, and/or d) information discovered since the IME was performed that may alter its conclusions.

IME depositions in the Workers’ Compensation system can often be arranged at a time and location that is suitable to the IME examiner. Individuals present at a deposition include the IME physician, a court reporter, and attorneys representing two parties, generally the injured worker and the Workers’ Compensation insurance carrier. No judge or jury is present at a deposition. At the initiation of the deposition, the court reporter will ask the physician to pledge an oath that the testimony given is complete and truthful.

During the deposition, attorneys have the right to review materials used by the IME physician, including notes, medical records, laboratory reports and imaging studies. The IME physician is permitted to meet with the attorney for the requesting party prior to deposition.

DO S AND DON’T S FOR A DEPOSITION

- Do remain calm and thoughtful. If a question is ambiguous, ask that it be repeated (or read back by the court reporter), or that a multi-part question be broken down to its individual components.
- Be truthful: if you don’t know an answer or you can’t remember a detail of the exam, say so. If an opinion is requested that is outside of your specialty or area of expertise, say so.
Do restrict your answer to the question that was asked. Don’t go off on a tangent or offer an opinion if it was not requested. Avoid giving opinions on medical conditions or impairments that are outside of your specialty or area of expertise.

Don’t interrupt the attorney[s]’ objections. A question may be withdrawn or phrased differently after the objection is raised, and that might affect your answer.

STAYING COOL IN THE HOT SEAT

Attorneys have many techniques to throw the IME physician off his/her game, analogous to the tactics used [crowd noise, waving signs, etc.] to distract a basketball player attempting a free throw in a crowded arena. The IME physician may be asked how often he or she has worked for a particular attorney or insurance company, how many IME examinations they have performed, or what percentage of their practice includes performing IMEs, all in an effort to discredit the IME examiner and/or suggest that his/her medical opinion and integrity are “for hire”. Physicians may consider these techniques as a personal affront to their professional abilities and stature.

The IME physician might consider that for some litigators, a deposition is an extension of their experience on a high school debate team. A talented lawyer can effectively argue either side of a case. Even if an attorney is aggressive with the line of questioning, the doctor should not take the lawyer’s actions personally.

CONCLUSIONS

Be prepared. Review all medical records and perform a thorough history and physical examination before producing your report.

If a deposition is required, keep calm and be professional. Avoid being argumentative.

Don’t regard an aggressive line of questioning by an attorney as a personal attack.

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4. www.mass.gov/service-details/impartial-medical-exam-v-independent-medical-exam#

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We are read everywhere

In 2021, approximately 30,000 unique viewers from 105 countries have read articles in the Rhode Island Medical Journal (RIMJ) or researched topics in its archives.

**Top 10 countries:**
1. US
2. Canada
3. UK
4. Australia
5. India
6. China
7. Germany
8. Italy
9. Netherlands
10. Brazil

**SAUSALITO, CALIFORNIA**
Rhode Island cardiologist Dr. Harry Schwartz, left, with his friend Dr. Ken Korr on a recent visit to the Issaquah Dock on Richardson Bay, Sausalito, CA. Each floating home is unique and this particular dock is often referred to as the Garden Dock, with plants, such as the digitalis purpurea or Foxglove, and succulents, flowers and orchard trees lining the boardwalk. The dock was immortalized in the song “Sittin’ on the Dock of the Bay,” composed by Otis Redding and guitarist Steve Cropper and released in 1967.

Wherever you may be, or wherever your travels may take you, check the Journal on your mobile device, and send us a photo: mkorr@rimed.org.
PETALUMA, CALIFORNIA

Sue Cooper, a social worker who volunteers at the Giant Steps equine therapy center in Sonoma County, CA, views a recent article on therapy animals in RIMJ. Gazing down with interest is little Miss Ellie in the barn. Scarlet (the boss mare!) is in the arena.

According to the Giant Steps website, http://www.giantstepsriding.org, the Center, accredited by the Professional Association of Therapeutic Horsemanship International (PATH), harnesses the therapeutic power of horses and works with a wide range of people with disabilities and conditions. It offers various programs including adaptive riding, and unmounted equine facilitated learning, to promote physical, cognitive, social and emotional benefits.

Wherever you may be, or wherever your travels may take you, check the Journal on your mobile device, and send us a photo: mkorr@rimed.org.
Adventures

Aetna® is proud to support the members of the Rhode Island Medical Society.
Vaccination

Preventive medicine was given a great impetus when inoculation with pus taken from a smallpox pustule was introduced beneath the epidermis, as a protection against infection of smallpox.

The work of Edward Jenner, MD, of England, in 1798, first made known and showed the value of vaccination and from that time on vaccination was extensively used in all countries. He was at first ridiculed, but later allowed to practice in a hospital.

In a few years France and America recognized the value of this prevention from infection and adopted its use.

The old form of the vaccination was the “arm-to-arm” kind; the scab resulting from a vaccine vesicle of a healthy child was used. This could be readily procured and kept a long time. The humanized lymph is preferred by some. The lymph is taken from a true vesicle from the fifth to the seventh day of its development. Both above methods have their drawbacks inasmuch as infection of the vaccine and at times the source being from diseased persons.

The method of securing vaccine virus now is from farms where cows are kept in a healthy state, all precautions against disease being taken and the inoculation of smallpox into them, with resulting vaccinia or cow-pox and lymph from typical vesicles put into sterile glass tubes or ivory points are dipped and dried. This virus must be kept cold and as fresh as possible and used within a few weeks.

All vaccination should be done under aseptic conditions. If the arm is the site chosen, it should be dressed by bandaging lightly so as to be easily removed for inspection and cleansing with a mild antiseptic solution or dry powder.

Vaccination can be done on infants a few weeks old, but unless smallpox is prevalent, better wait two to three years. Children of school age should be inoculated before going to school. Revaccination should be performed at puberty or at any time if smallpox is liable or has become epidemic.

Complications are rare and not serious as a rule. Some skin infections should cause one to defer vaccination until cured or improved.

No one should refuse if they understand the immunity given by vaccination.

It is common that certain parents of school children refuse vaccination, which, if they were permitted, and large numbers were not vaccinated, we would in time of epidemic find whole families wiped out of existence by this dreadful disease. Centuries ago China had its deadly experience of smallpox epidemics. Vaccination was its prevention.

A partial extract of our general laws, Chapter 65, Section 14: “No person shall be permitted to attend public school in this State without furnishing a certificate from some practicing physicians of being properly vaccinated as a protection from smallpox. The teacher to keep a record.

“Section 15. Fine of fifty dollars or imprisonment not exceeding thirty days for violation of this chapter.”

(Top of page) The hand Dr. Jenner used as a source for his vaccine from a book illustration of Jenner’s as part of an inquiry into the causes and effects of the variolae vaccinae in 1798. [NATIONAL LIBRARY OF MEDICINE]
Working for You: RIMS advocacy activities

June 1, Tuesday
RIMS Physician Health Committee [PHC]: Herbert Rakatansky, MD, Chair (via teleconference)
RI Health and Privacy Alliance (RIHPA) regarding legislation
Legislative hearings

June 2, Wednesday
Meeting with Neighborhood Health Plan of RI [NHPRI] regarding Physician Burnout Summit
Legislative hearings

June 7, Monday
RIMS Council meeting: Catherine A. Cummings, MD, President. Guest: Patrick Tigue, RI Health Insurance Commissioner

June 8, Tuesday
Legislative hearings

June 9, Wednesday
RI Department of Health [RIDOH] Board of Medical Licensure and Discipline
Governor’s Overdose Intervention and Prevention Task Force: Sarah Fessler, MD, RIMS Past President
Legislative hearings
Political Fundraiser

June 10, Thursday
Meeting with RI Academy of Physician Assistants
Legislative hearings
Political Fundraiser

June 11–16, Friday–Wednesday
American Medical Association (AMA) House of Delegates annual meeting, Peter Hollmann, MD, Senior Delegate; Alyn Adrain, MD, Delegate; Sarah Fessler, MD, Alternate Delegate; Catherine A. Cummings, MD, President, Alternate Delegate; RIMS staff

June 11, Friday
RI Health and Privacy Alliance (RIHPA) regarding legislation
Meeting with American Civil Liberties Union of RI (ACLU-RI) regarding Open Meetings Act
Legislative hearings

June 14, Monday
Legislative hearings
Political Fundraiser
Intersex and Medicine: Policy and Legislation info Session/Webinar

June 15, Tuesday
Virtual summit addresses physician burnout, advises steps to restore health: Kathleen Boyd, MSW, LICSW, Physician Health Program Director at the RIMS Office of the Health Insurance Commissioner (OHIC) Health Insurance Advisory Council (HIAC): Catherine A. Cummings, MD, RIMS President
Legislative hearings
Political Fundraiser

June 16, Wednesday
RIDOH Primary Care Physician Advisory Committee [PCPAC]: Elizabeth Lange, MD, RIMS President-elect
Legislative hearings
Political Fundraiser

June 17, Thursday
Legislative hearings
Political Fundraiser

June 18, Friday
RIDOH Health Professional Loan Repayment Board, Steve DeToy, RIMS Staff, Board Member
Legislative hearings
Political Fundraiser

June 21, Monday
Meeting with RI Public Health Institute regarding legislation
State House Update: Michael Migliori, MD, Chair, Public Laws Committee
Legislative hearings
Political Fundraiser: Peter Karczmar, MD, RIMPAC Chair

June 22, Tuesday
RI Health and Privacy Alliance (RIHPA) regarding legislation
Legislative hearings
Political Fundraiser

June 23, Wednesday
OHIC measure alignment meeting, Peter Hollmann, MD, Past President
State House Press Conference regarding drug related legislation
Legislative hearings
Political Fundraiser

June 24, Thursday
Governor’s Overdose Task Force Racial Equity Work Group
Legislative hearings
Political Fundraiser

June 25, Friday
Childhood Overweight and Obesity: Updated Data and Three-Year Trends for Rhode Island
Legislative hearings

June 28, Monday
Legislative hearings
Political Fundraiser
June 29, Tuesday
RI Health and Privacy Alliance (RIHPA) regarding legislation
Legislative hearings
Political Fundraiser

June 30, Wednesday
Executive Office Health and Human Services’ Transitions of Care Workgroup
Legislative hearings
Political Fundraiser

July 1, Thursday
General Assembly adjourned for 2021 session

July 6, Tuesday
RIMS Physician Health Committee (PHC): Herbert Rakatansky, MD, Chair

July 7, Wednesday
Office of the Health Insurance Commissioner (OHIC) measure alignment meeting, Peter Hollmann, MD, Past President

July 8, Thursday
RIMS Zoom meeting with Harm Reduction Center Advocacy Coalition

July 12, Monday
Call with the RI Department of Health (RIDOH) regarding legislation
RIMS Board of Directors meeting: Catherine A. Cummings, MD, President

July 14, Wednesday
RIDOH Board of Licensure and Discipline
Governor’s Overdose Intervention and Prevention Task Force: Sarah Fessler, MD, RIMS Past President
Diabetes Prevention Programs (DPP) Stakeholder’s call

July 15, Thursday
The Use of Medicines in the US: Spending and Usage Trends webinar
RIMS Zoom meeting with Harm Reduction Center Advocacy Coalition

July 19, Monday
Final State House Update: Legislative wrap-up, Michael Migliori, MD, Chair, Public Laws Committee

July 20, Tuesday
Senator Sheldon Whitehouse sub-committee hearing on drugs

July 21, Wednesday
American Medical Association (AMA) webinar: Harm Reduction Strategies to Save Lives: Steve DeToy, RIMS Staff, Presenter

July 28, Wednesday
Meeting with Congressman David Cicilline’s staff regarding legislation on biosimilars pharmaceuticals

July 29, Thursday
Governor’s Overdose Task Force Racial Equity Work Group
OHIC measure alignment meeting, Peter Hollmann, MD, Past President

July 30, Friday
Harm Reduction Center legislation briefing and discussion with US Senator Sheldon Whitehouse, RI Senator Joshua Miller, Brandon Marshall, PhD, Brown School of Public Health, and RIMS’ staff

Convivium
SAVE THE DATE
THURSDAY, SEPTEMBER 23, 2021
RIMS ANNUAL MEMBERSHIP CONVIVIUM and AWARDS DINNER
Reception at 6:00 pm, Dinner at 7:00 pm
The Squantum Association, East Providence

Please join us for good food, good music, and good company as we honor outgoing Presidents Christine Brousseau, MD, (2019–2020), and Catherine Cummings, MD, (2020–2021), inaugurate our new leadership team, and celebrate 210 years of organized medicine in Rhode Island.

Watch for your invitation soon.
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 health-care 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

Neighborhood Health Plan of Rhode Island is a non-profit HMO founded in 1993 in partnership with Rhode Island’s Community Health Centers. Serving over 185,000 members, Neighborhood has doubled in membership, revenue and staff since November 2013. In January 2014, Neighborhood extended its service, benefits and value through the HealthSource RI health insurance exchange, serving 49% the RI exchange market. Neighborhood has been rated by National Committee for Quality Assurance (NCQA) as one of the Top 10 Medicaid health plans in America, every year since ratings began twelve years ago.

RIPCPC is an independent practice association (IPA) of primary care physicians located throughout the state of Rhode Island. The IPA, originally formed in 1994, represent 150 physicians from Family Practice, Internal Medicine and Pediatrics. RIPCPC also has an affiliation with over 200 specialty-care member physicians. Our PCP’s act as primary care providers for over 340,000 patients throughout the state of Rhode Island. The IPA was formed to provide a venue for the smaller independent practices to work together with the ultimate goal of improving quality of care for our patients.
RIMS gratefully acknowledges the practices who participate in our discounted Group Membership Program

For more information about group rates, please contact Marc Bialek, RIMS Director of Member Services
Leading Alzheimer’s experts release appropriate use recommendations for new Alzheimer’s drug, Aduhelm

LAS VEGAS – JULY 27, 2021 – A group of six leading Alzheimer’s experts has presented the first recommendations for the appropriate use of aducanumab [Aduhelm, Biogen/Eisai], a newly approved treatment for early Alzheimer’s disease (AD). The recommendations will help provide clinicians with greater clarity and more specific use of the new treatment, which was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in June.

The recommendations were presented last week at the annual Alzheimer’s Association International Conference (AAIC) and were simultaneously published in a special article of The Journal of Prevention of Alzheimer’s Disease (JPAD) and in Alzheimer’s & Dementia©: The Journal of The Alzheimer’s Association.

stepheN salloW ay, MD, Ms, director of Neurology and the Memory and Aging Program at Butler Hospital, the Martin M. Zucker professor of Psychiatry and Human Behavior and professor of Neurology at the Warren Alpert Medical School of Brown University, and associate director of Brown University’s Center for Alzheimer’s Research, was among the panel of experts and co-authored the JPAD article.

University of Nevada, Las Vegas neuroscientist DR. JEFFREY CUMMINGS co-chaired the expert panel presentation at AAIC along with Alzheimer’s Association Chief Science Officer MARIA C. CARRILLO, PhD, and co-authored the JPAD article along with Dr. Salloway.

“One of the goals of the clinical use of this new agent are not in the FDA’s prescribing information,” Cummings said. “These recommendations fill the gap between the prescribing information and the real-world implementation of this treatment.”

“The recommendations made by this expert panel today and in the JPAD article mirror the guidelines used during the clinical trial of aducanumab,” Dr. Salloway said. “Our goal is to guide clinicians on the selection of patients most likely to benefit from treatment with recommendations on how to carefully monitor for safety. The evidence we have is that patients with early Alzheimer’s disease, mild cognitive impairment and mild dementia, are most likely to benefit and we will need close collaboration between primary care and specialty providers to identify these patients.”

The appropriate use recommendations made by the panel include a list of 11 factors that they say should be satisfied for a patient to be considered eligible for treatment with Aduhelm. Those factors include, in part: a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild stage AD dementia after a comprehensive evaluation; the presence of amyloid plaques in the brain as demonstrated on PET imaging or by AD signature pattern on cerebrospinal fluid (CSF) testing; the attainment of certain specific cognitive assessment scores; stable psychiatric and medical conditions including stable cardiovascular and cardiopulmonary health, no organ failure or active cancer, no evidence of neurological disorders other than AD, and a baseline MRI with no evidence of acute or subacute hemorrhage, among other factors. The article containing the complete list of appropriate use criteria is available on the JPAD website at jpreventionalzheimer.com. The summary article from Alzheimer’s & Dementia© is also available at alz-journals.onlinelibrary.wiley.com.

In addition to Drs. Cummings and Salloway, the expert panel included: PAUL AISEN, MD, Alzheimer’s Treatment Research Institute, University of Southern California, San Diego, CA; LIANA APOSTOLOVA, MD, FAAN, Departments of Neurology, Radiology, Medical and Molecular Genetics, Indiana University School of Medicine, Indianapolis, IN; ALIREZA ATRI, MD, PhD, Banner Sun Health Research Institute, Banner Health, Sun City, AZ; Center for Brain/Mind Medicine, Harvard Medical School, Boston, MA; and MICHAEL WEINER, MD, Departments of Radiology and Biomedical Imaging, Medicine, Psychiatry and Neurology, University of California San Francisco, San Francisco, CA. ❖
CDC summary of recent changes in COVID-19 recommendations

The following updates were released by the Centers for Diseases Control (CDC) on July 27th for fully vaccinated people given new evidence on the B.1.617.2 (Delta) variant currently circulating in the United States:

- Added a recommendation for fully vaccinated people to wear a mask in public indoor settings in areas of substantial or high transmission.
- Added information that fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID-19, or if they have someone in their household who is immunocompromised, at increased risk of severe disease or not fully vaccinated.
- Added a recommendation for fully vaccinated people who have a known exposure to someone with suspected or confirmed COVID-19 to be tested 3–5 days after exposure, and to wear a mask in public indoor settings for 14 days or until they receive a negative test result.
- CDC recommends universal indoor masking for all teachers, staff, students, and visitors to schools, regardless of vaccination status.

View all guidelines and charts of areas of high transmission at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html


Legionnaire’s Disease cases on the upswing

The Rhode Island Department of Health (RIDOH) has observed an increase in the number of reported cases of Legionnaires’ disease (LD). Between 2014 and 2020, there was an average of 10 cases during the months of June and July each year, ranging from 0–11 cases in a single month. From June 2, 2021 to July 26, 2021 there have been 30 cases of Legionnaire’s disease, 29 of which have illness onset dates between June 17 and July 21. Twenty-eight of the 30 people have been hospitalized. No common source of exposure has been identified, although an investigation is ongoing.

“This is another example that underscores the value of RIDOH’s routine monitoring for communicable diseases,” said Director of Health NICOLE ALEXANDER-SCOTT, MD, MPH.

“We know that Legionella bacteria grow best in complex water systems that are not well maintained. When this water becomes aerosolized in small droplets, such as in a cooling tower, shower, or decorative fountain, people can accidentally breathe in the contaminated water. This is of particular concern now as some buildings’ water systems have been offline for a prolonged period due to the COVID-19 pandemic and are just now returning to service.”

Legionella is especially a concern in buildings that primarily house people older than 65, buildings with multiple housing units and a centralized hot water system (like hotels or high-rise apartment complexes), and buildings higher than 10 stories.
CNE, Lifespan to require COVID-19 vaccination for employees

PROVIDENCE – Care New England announced on July 27th that they are moving toward a mandatory vaccination program for all staff across all operating units. CNE has required COVID-19 vaccination of students, volunteers, and new hires since July 1st, 2021. The next step is to require all managers to begin the vaccination series prior to Labor Day.

“It is our responsibility to keep our patients, and our staff, safe. This program will be based on the best evidence that we have to date about preventing transmission of COVID-19,” said JAMES E. FANALE, MD, President and CEO, Care New England.

Complete details of the program, and its implementation for all staff across the system, will be released in the next 7-10 days.

Shortly after Care New England’s statement, Lifespan said it will require all employees to be vaccinated. It said the requirement would go into effect September 1 and that “our goal is for all employees to show proof of immunization within 60 days.”

The organization cited the transmission rates and contagiousness of the Delta variant, recommendations from leading healthcare organizations, and the well-being of its patients as reasons for the mandate.

“This change is being made only after extensive and thoughtful review, and with our employees and patients’ safety as our top priority. We value and appreciate every member of our Lifespan team who contributes to our mission to deliver health with care,” the statement read.

HHS, DOJ issue guidance on ‘Long COVID’ and disability rights under the ADA

WASHINGTON, D.C. – At the recent commemoration of the 31st anniversary of the Americans with Disabilities Act (ADA), the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) jointly published guidance on how “long COVID” can be a disability under the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the Affordable Care Act. The guidance is on the HHS website at https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html and on the DOJ web-site at https://www.ada.gov/long_covid_joint_guidance.pdf.

“It’s critical that we ensure people who have disabilities as a result of long COVID are aware of their rights under federal nondiscrimination laws,” said ALISON BARKOF, Acting Administrator and Assistant Secretary for Aging at the Administration for Community Living at HHS.

“It also is crucial that they know how to connect to services and supports available if they now need assistance to live in their own homes, go to school or work, or participate in their communities.”

The ACL directory of resources for those with long COVID may be found at https://acl.gov/sites/default/files/COVID19/ACL_LongCOVID.pdf.

In February HHS launched a new initiative to study long COVID. Led by NIH, the goal of the initiative is to learn more about how COVID-19 may lead to widespread and lasting symptoms, and to develop ways to treat or prevent these symptoms.

VA mandates COVID-19 vaccines among its medical employees, including VHA facilities staff

WASHINGTON – On July 26, the Department of Veterans Affairs Secretary DENIS MCDONOUGH announced he will make COVID-19 vaccines mandatory for Title 38 VA health care personnel – including physicians, dentists, podiatrists, optometrists, registered nurses, physician assistants, expanded-function dental auxiliaries and chiropractors – who work in Veterans Health Administration facilities, visit VHA facilities or provide direct care to those VA serves.

VA is taking this necessary step to keep the Veterans it serves safe.

Each employee will have eight weeks to be fully vaccinated.

“We’re mandating vaccines for Title 38 employees because it’s the best way to keep Veterans safe, especially as the Delta variant spreads across the country,” McDonough said. “Whenever a Veteran or VA employee sets foot in a VA facility, they deserve to know that we have done everything in our power to protect them from COVID-19. With this mandate, we can once again make – and keep – that fundamental promise.”

The department’s decision is supported by numerous medical organizations including the American Hospital Association, America’s Essential Hospitals and a Multisociety group of the leading Infectious Disease Societies. The American Medical Association, American Nurses Association, American College of Physicians, American Academy of Pediatrics, Association of American Medical Colleges, and National Association for Home Care and Hospice also endorsed mandating COVID-19 vaccination for health care workers.

In recent weeks, VA has lost four employees to COVID-19 – all of whom were unvaccinated. At least three of those employees died because of the increasingly prevalent Delta variant. There has also been an outbreak among unvaccinated employees and trainees at a VA Law Enforcement Training Center, the third such outbreak during the pandemic.
RI first in nation to pilot harm reduction centers to prevent drug ODs

PROVIDENCE – Gov. DAN MCKEE signed legislation in July that authorizes a two-year pilot program to prevent drug overdoses through the establishment of harm reduction centers, a community-based resource for health screening, disease prevention and recovery assistance where persons may safely consume pre-obtained substances.

The law (2021-H 5245A, 2021-S 0016B), effective March 1, 2022, authorizes facilities where people may safely consume those substances under the supervision of health care professionals. It requires the approval of the city or Town Council of any municipality where the center would operate.

While 10 countries sanction the operation of harm reduction centers, this legislation makes Rhode Island the first in the United States to authorize such a pilot program.

Advisory committee

The law also creates an advisory committee to make recommendations to the Department of Health on ways to maximize the potential public health and safety benefits of harm reduction centers, as well as the proper disposal of hypodermic needles and syringes, the recovery of people utilizing the center, and ways to adhere to federal, state and local laws impacting the creation and operation of the centers.

“Rhode Island’s teamwork and trust in evidence-based medical decision making and strong public health policy led the nation in tackling COVID-19, and with that same spirit we are expanding our fight against substance use disorders and drug overdose deaths,” said CATHERINE CUMMINGS, MD, Rhode Island Medical Society President.

Studies of supervised injection facilities in other countries have demonstrated that they reduce overdose deaths and transmission rates for infectious disease, and increase the number of individuals who seek addiction treatment, without increasing drug trafficking or crime in the areas where they are located, according the American Medical Association.

“By enacting the nation’s first law in support of a pilot harm reduction center, Rhode Island is taking an important step to save lives from drug-related overdose and death,” said AMA Opioid Task Force Chair BOBBY MUKKAMALA, MD. “The AMA strongly supports the development and implementation of harm reduction centers in the United States. These facilities are designed, monitored, and evaluated to generate data to inform policymakers on the feasibility, effectiveness, and legal aspects of reducing harms and health care costs related to injection drug use.”

Anchor Recovery Community Center makes naloxone boxes accessible on Block Island

PROVIDENCE – The Providence Center’s Anchor Recovery Community Center, along with local businesses, their employees, and residents of Block Island, recently partnered to make life-saving resources for people with substance use issues available on the island.

During their recent trip, certified peer recovery specialists provided Ballard’s Beach Resort and New Shoreham’s Island Free Library with Naloxboxes, 2 dozen naloxone kits, as well as opioid overdose prevention and rescue training. The effort is part of the Governor’s Overdose Prevention and Intervention Task Force, which launched Rhode Island’s 10,000 Chances Project, an initiative to reduce overdose deaths and save lives.

“We are very excited that the Anchor MORE [Mobile Outreach Recovery Efforts] team has been able to expand its outreach across the state. We are also grateful to have been awarded funding through the RI DOH’s Drug Overdose Prevention Program, the 10K chances grant. This funding has allowed us to expand our services to include meeting with local businesses to provide them with education, training and naloxone kits which can be used to save the lives of patrons in crisis. The response from the local community leaders has been quite remarkable, and we are thankful,” said HOLLY FITTING, VP of Addiction, Recovery, Residential Services, and Grants Administration, Anchor Recovery Community Center.

New suicide prevention law requires training/awareness for school personnel

STATE HOUSE – A new law signed in July will require all public school districts to adopt suicide prevention policies and train all personnel in suicide awareness and prevention annually.

The Nathan Bruno and Jason Flatt Act (2021-H 5353, 2021-S 0031) will require all school personnel – including teachers, administration, custodians, lunch personnel, substitutes, nurses, coaches, and coaching staff, even if volunteers – to be trained in suicide prevention and awareness. The state Department of Education would establish the guidelines for the training curriculum.

The bill is named for Nathan Bruno, a 15-year-old Portsmouth High School student who took his life in 2018. Part of the bill is modeled after a state law passed in Tennessee and 19 other states, which was named after Jason Flatt, a 16-year-old from Nashville who died by suicide.

According to the Department of Health, suicide is the second leading cause of death for Rhode Islanders between the ages of 15 and 34. In 2017, 15.9% of surveyed Rhode Island high school students they had considered suicide and 10.5% said they had attempted suicide. One in nine middle school students surveyed in Rhode Island that year reported having made a suicide plan.
AMA adopts policy to address increases in youth suicide

CHICAGO – With an alarming increase in suicide and suicide risk in youth and young adults across the US, the American Medical Association (AMA) adopted policy during the Special Meeting of its House of Delegates aimed at preventing suicide in young people.

The adopted policy report outlines risk factors for youth suicide, including the role of mental health, substance use disorder, adverse childhood experiences, increased use of digital devices, bullying and cyberbullying, and the impact of the COVID-19 pandemic. The report also identifies evidence-based interventions, protective factors, as well as resources to enhance resiliency aimed at mitigating youth suicide risk.

According to a recent Centers for Disease Control and Prevention (CDC) study, there was a 31% increase in the proportion of mental health–related emergency department visits for youth aged 12–17 years during 2020 as compared to 2019. Particularly concerning, CDC data also showed increased rates of suicide ideation and suicide attempts in 2020 during the COVID-19 pandemic as compared with 2019 rates.

“We were deeply concerned by the dramatic increases we were seeing in youth suicide and suicide risk even before the mitigation measures and disruptions caused by the COVID-19 pandemic. As a nation we must do everything we can to prioritize children’s mental, emotional and behavioral health and step up our efforts to prevent suicide and mitigate suicide risk among our nation’s youth,” said AMA Board Member WILLIE UNDERWOOD III, MD, MSc, MPH. “Physicians play a vital role and we must ensure that all physicians who see youth patients, not solely pediatric psychiatrists and addiction medicine physicians, have the ability, capacity, and access to the tools needed to identify when a young person is experiencing a period of imminent risk and help prevent suicide attempts.”

Under the new policy, the AMA will:

- Encourage the development and dissemination of educational resources and tools for physicians, especially those more likely to encounter youth or young adult patients, that address effective suicide prevention. This includes screening tools, methods to identify risk factors and acuity, safety planning, and appropriate follow-up care – including treatment and linkages to appropriate counseling resources;
- Support collaboration with federal agencies, relevant state and specialty medical societies, schools, public health agencies, community organizations, and other stakeholders to enhance awareness of the increase in youth and young adult suicide and to promote protective factors, raise awareness of risk factors, support evidence-based prevention strategies and interventions, encourage awareness of community mental health resources, and improve care for youth and young adults at risk of suicide;
- Encourage efforts to provide youth and young adults better and more equitable access to treatment and care for depression, substance use disorder, and other disorders that contribute to suicide risk;
- Encourage continued research to better understand suicide risk and effective prevention efforts in youth and young adults, especially in higher risk sub-populations such as Black, LGBTQ+, Hispanic/Latinx, and Indigenous/Native Alaskan youth and young adult populations, and among youth and young adults with disabilities;
- Support the development of novel technologies and therapeutics, along with improved utilization of existing medications to address acute suicidality and underlying risk factors in youth and young adults;
- Support research to identify evidence-based universal and targeted suicide prevention programs for implementation in middle schools and high schools;
- Advocate at the state and national level for policies to prioritize children’s mental, emotional and behavioral health;
- Advocate for a comprehensive system of care including prevention, management and crisis care to address mental and behavioral health needs for infants, children and adolescents;
- Support increased screening for Adverse Childhood Experiences (ACEs) in medical settings, in recognition of the intersectionality of ACEs with significant increased risk of suicide, negative substance-use related outcomes including overdose, and a multitude of downstream negative health outcomes;
- Support the inclusion of ACEs and trauma-informed care into undergraduate and graduate medical education curricula. ✴
Applications for BCBSRI’s LGBTQ Safe Zone Program due August 16th

PROVIDENCE – Blue Cross & Blue Shield of Rhode Island (BCBSRI) is accepting applications from Rhode Island-based healthcare providers – including all practices, facilities and services - for its latest round of LGBTQ Safe Zone practice certification. This new cohort will join more than 30 sites statewide that are providing safe, affirming and inclusive care to the LGBTQ community. Applications are due Aug. 16, 2021.

“Health equity is a top priority for our company,” said MATTHEW COLLINS, MD, MBA, BCBSRI executive vice president and chief medical officer. “Everyone deserves the right to culturally competent, inclusive and affirming healthcare. This can be a challenge for members of the LGBTQ community who, like other underserved groups, are often alienated due to experiencing discrimination when seeking care.”

Certification requirements for BCBSRI LGBTQ Safe Zones include staff training specific to the care of LGBTQ patients, protection for patients and staff from discrimination based on gender identity or expression, gender neutral bathrooms, inclusive forms and procedures, and a public commitment to connecting with, and serving, the LGBTQ community.

BCBSRI launched its LGBTQ Safe Zone program in 2016. The program has now certified more than 30 Safe Zone providers in towns and cities across Rhode Island representing a number of specialties, including dental and mental health practices, substance abuse and sexual trauma centers, and even assisted living facilities for older adults. View the full list of providers at bchsri.com/safezones.

To qualify as an LGBTQ Safe Zone, providers must meet certification requirements. Upon certification, practices are provided with a window cling and plaque so that patients visiting the practice site will recognize it as a place where safe and affirming care is offered to the LGBTQ community. Learn more and apply online at bchsri.com/providers/safezone-program. Applications are due by 5 p.m. on August 16, 2021 and those who have been approved for certification will be notified in October 2021.

High screen time linked to cognitive, behavioral problems in children born extreme preterm, NIH-funded study finds

PROVIDENCE – BETTY R. VOHR, MD, Medical Director of the Follow-up Clinic Program, Department of Pediatrics at Women & Infants Hospital, is the lead author of a manuscript published in JAMA Pediatrics titled: “Association of High Screen-Time Use With School-age Cognitive, Executive Function, and Behavior Outcomes in Extremely Preterm Children.”

According to Dr. Vohr’s research, among 6- and 7-year-olds who were born extremely preterm – before the 28th week of pregnancy– those who had more than two hours of screen time a day were more likely to have deficits in overall I.Q., executive functioning [problem solving skills], difficulty with impulse control and difficulty paying attention, according to a National Institutes of Health funded study. Similarly, those who had a television or computer in their bedroom were more likely to have problems with impulse control and paying attention. The findings suggest that high amounts of screen time may exacerbate the cognitive deficits and behavioral problems common to children born extremely preterm.

The researchers analyzed data from a follow-up study of children born at 28 weeks or earlier. Of 414 children, 238 had more than two hours of screen time per day and 266 had a television or computer in their bedroom. Compared to children with less screen time per day, in adjusted analyses, those with high screen time scored an average of nearly 8 points higher on global executive function percentile scores, roughly .8 points lower on impulse control [inhibition] and more than 3 points higher on inattention, all reflecting increased risk of greater deficits. Children with a television or computer in their bedroom also had increased risk of inhibition, hyperactivity, and impulsivity problems.

The authors concluded that the findings support the need for physicians to discuss the potential effects of screen time with families of children born extremely preterm.

ELISABETH MCGOWAN, MD, is a coauthor, and other healthcare experts at Women & Infants Hospital contributed. Funding for the study was provided by NIH’s Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Heart, Lung, and Blood Institute and National Center for Research Resources [now part of the National Center for Advancing Translational Sciences].
Hasbro to participate in Accelerating Child Health Care Transformation

PROVIDENCE – Hasbro Children’s Hospital was competitively selected to participate in Accelerating Child Health Care Transformation, a national initiative funded by the Robert Wood Johnson Foundation to transform child health care delivery. Hasbro Children’s Hospital is one of 12 leading pediatric practices across the country that will work with the Center for Health Care Strategies (CHCS) to develop strategies for making child health care more equitable and family focused.

“Hasbro Children’s Hospital plays an essential role in our community. Hasbro Children’s exists to serve our neighbors and community, including and especially the most vulnerable among us. Being selected to work together in this partnership will allow us to continue to fulfill that commitment to the individuals and the communities we serve,” said SAUL N. WEINGART, MD, president of Rhode Island Hospital and its Hasbro Children’s Hospital.

“As an academic medical center, we have opportunities to be at the cutting edge of medicine for children through research and through some of our collaborations, such as the Accelerating Child Health Care Transformation. These important partnerships enable us to do what’s best for kids, which means not only treating the child, but advocating for the child,” said PHYLLIS DENNERY, MD, pediatrician-in-chief and medical director of Hasbro Children’s Hospital.

Over nine months, the learning community participants will collaborate on three key goals: (1) adopting anti-racist practices to advance health equity; (2) co-creating equitable partnerships with families and providers; and (3) identifying family strengths and health-related social needs to promote resilience. OLUOTOSIN OJUGBELE, MD, led Hasbro Children’s application process for the joint initiative.

“Our team is extremely proud to have been chosen to participate in this important effort. The health and well-being of children is our top priority, and working collaboratively with other select organizations on this initiative will only strengthen our efforts to provide a high-quality family- and patient-centered medical home for children and youth,” said CAROL LEWIS, MD, medical director, Hasbro Children’s Hospital Pediatric Primary Care and director, Refugee Health Program.

New law protects hospital employees from violence, harassment on the job

STATE HOUSE – A new law passed by General Assembly will help protect hospital staff from violence and harassment at work.

The legislation (2021-S 0055A, 2021-H 6018A), which was passed by the Assembly July 1 and was recently signed into law by the governor, establishes procedures for hospital employees to file complaints with the hospital or the Department of Health for any assaultive behavior or other violation of law occurring on hospital grounds, and requires hospitals to develop plans to protect and respond to violence and employee safety issues and institute safety training for employees.

The new law, which takes effect January 15, 2022, will require that every hospital in Rhode Island create a workplace safety committee that shall conduct periodic security and safety assessments to identify existing or potential hazards for assaults committed against employees. It directs hospitals to develop and implement an assault prevention and protection program for employees, and provide assault prevention and protection training on a regular basis for employees.

It also ensures that any hospital employee may report any violation of law or safety or health violation to either their hospital or the Department of Health, may maintain anonymity if they want, and shall be protected from retaliation. The bill lays out the procedures for how such complaints should be investigated and addressed.

During testimony for the bill the United Nurses and Allied Professionals (UNAP), which represents nurses, technologists, therapists, pharmacists, mental health workers and support staff, reported that there has been a dramatic increase of instances in which frontline health workers are on the receiving end of violent and often traumatic instances of physical and mental abuse from patients, their families and visitors, and that more often than not, it goes unreported and undocumented.

A UNAP survey of its members working in hospitals found that 42% said their unit had experienced a violent or near miss violent episode requiring intervention by the local police; 67.8% said they had personally experienced workplace violence on the job; and 63.7% said they have at times felt unsafe working in their unit.
RIH study shows smartphone photos can screen for anemia

PROVIDENCE – A picture of a person’s inner eyelid taken with a standard smartphone camera can be used to screen for anemia, according to a new study published recently in PLOS ONE by authors, including SELIM SUNER, MD, JAMES RAYNER, MD, MEng, and GREGORY JAY, MD, PhD, all emergency physicians at Rhode Island Hospital and The Miriam Hospital, and faculty at The Warren Alpert Medical School of Brown University.

In the new study, researchers obtained smartphone images of the palpebral conjunctiva from 142 patients with a wide range of hemoglobin levels. They zoomed into a small region of the conjunctiva in each photo and developed a new algorithm optimizing color resolution as well as a prediction model linking conjunctiva color, compared to the surrounding skin and whites of the eyes, to hemoglobin levels. Then, the team tested the new algorithms on photos collected from 202 new patients.

When analyzing the new set of photographs, the model was 72.6% accurate (CI 71.4–73.8), 72.8% sensitive (71–74.6), and 72.5% specific (70.8–74.1) at predicting anemia. Accuracy for transfusion thresholds was higher, at 94.4% accurate (93.7–95.0) for a low transfusion threshold and 86% accurate (85.0–86.9) for a higher threshold. Skin tone did not change results, but image quality had some effect. The results suggest that a smartphone app could be used to screen for anemia in a telehealth or remote setting where the infrastructure for blood tests is not available.

“Others have used photos of the creases in the palms, fingernail beds, and other parts to devise algorithms to predict anemia,” said Dr. Suner. “Because those areas can be affected more readily by temperature changes or other conditions affecting blood flow, the eyelid gives us a more reliable way to make this prediction.”

Dr. Suner added that the next iteration of an app designed for this purpose will allow novice users to take the photo with sufficient quality for accuracy, honing focus and lighting to minimize error. That app will be validated with a new cohort of patients.

RIDOH announces new Health Equity Zones

PROVIDENCE – The Rhode Island Department of Health (RIDOH) announced that it is expanding support and funding to establish four new Health Equity Zones (HEZs). Warwick, Warren, Blackstone Valley (including Cumberland, North Smithfield, and Lincoln), and the 02905 ZIP code (including lower South Providence and nearby neighborhoods) were chosen through a competitive process that drew applicants from communities across the State.

The ongoing expansion of RIDOH’s HEZ initiative has been made possible in part through support from a pilot investment in place-based transformation in Rhode Island by Blue Meridian Partners and in partnership with ONE Neighborhood Builders (ONE|NB). Blue Meridian Partners is a national philanthropic organization that finds and funds scalable solutions to the problems that limit economic mobility and trap America’s young people and families in poverty. ONE|NB is the backbone, or convening entity, of the pilot initiative, known as Central Providence Opportunities.

The goal of Central Providence Opportunities is to improve economic opportunity in the 02908 and 02909 ZIP codes of Providence through affordable housing development, wage growth, local business development, and early education supports. The aim is to scale this pilot effort to other communities in Rhode Island by working with residents, community partners, and State agencies.

The investment to expand Rhode Island’s HEZ initiative will be managed by the Rhode Island Foundation in partnership with the Rhode Island Executive Office of Health and Human Services (EOHHS) and RIDOH, and the funding will be leveraged to expand the impact of the HEZ model into additional communities.

Like the 11 existing HEZs, the four new HEZs will annually receive $150,000 in core funding and support to ensure that these communities ground their work in public health principles and best practices, so that measurable outcomes are reached and evaluated.
Abbas El-Sayed Abbas, MD, to lead Brown Surgical Associates’ Thoracic Surgery Division; named Chief of Thoracic Surgery at Lifespan

PROVIDENCE – Brown Surgical Associates recently announced ABBAS EL-SAYED ABBAS, MD, has joined the practice as Chief of Thoracic Surgery. He will also serve as Chief of Thoracic Surgery at all Lifespan hospitals in addition to Chief of Thoracic Oncology at the Lifespan Cancer Institute and at the Alpert Medical School of Brown University.

Dr. Abbas specializes in robotic thoracic surgery for lung, mediastinal and esophageal diseases, including robotic lobectomy and totally endoscopic robotic esophagectomy. His expertise also extends to advanced thoracic endoscopy and minimally invasive management of foregut disease such as esophageal motility disorders and complex antireflux procedures.

He comes to Rhode Island from Temple University Health System in Philadelphia where he held the title of System Thoracic Surgeon-in-Chief and System Director of the Foregut Disease Thoracic Oncology Programs where he served as Chief of Thoracic Surgery at Fox Chase Comprehensive Cancer Center.

Dr. Abbas’ other areas of specialization include endoscopic procedures for gastroesophageal reflux disease (GERD), esophageal and bronchial stents, robotic surgery for myasthenia gravis and thymic tumors, airway surgery, laser endoscopy, and cryoendoscopy. His past and current research interests include gene therapy for esophageal and lung cancer, outcome-based research in robotic surgery, esophageal cancer and lung cancer, the role of tumor-initiating cells in the microenvironment of esophageal cancer and transplant immunology.

Dr. Abbas earned his medical degree with honors at the Ain-Shams University School of Medicine in Cairo, Egypt, where he also earned a Master of Science with honors. He went on to complete general surgery internship and residency at the University of Pennsylvania after which he completed a three-year fellowship in cardiothoracic surgery at the Mayo Clinic in Rochester, Minnesota. Dr. Abbas also completed postdoctoral research fellowships in mechanical cardiac support at Penn State University in the laboratory of Professor William Pierce and gene therapy for thoracic malignancies at the University of Pennsylvania in the laboratory of Professor Larry Kaiser.

Patricia Ryan Recupero, MD, JD, named to NIH Mental Health Council

PROVIDENCE – PATRICIA RYAN RECUPERO, MD, JD, Senior Vice President of Education and Training, Care New England, Butler Hospital, has been appointed to serve on the National Advisory Mental Health Council of the National Institutes of Health. Dr. Recupero’s term will begin immediately and end on September 30, 2024. The National Advisory Mental Health Council is governed by the provisions of the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services [Secretary] and the Director, National Institute of Mental Health [NTMH, also referred to as Institute] on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

Tammi-Marie Phillip, MD, has been appointed Chief of Adolescent and Young Adult Services at Butler

PROVIDENCE – TAMMI-MARIE PHILLIP, MD, has been appointed Chief of Adolescent and Young Adult Services at Butler Hospital. In this role, Dr. Phillip will oversee the clinical programs in the Inpatient, Partial, and Intensive Outpatient Programs. She will continue her work as Unit Chief of the Adolescent Unit.

Dr. Phillip completed her undergraduate studies at the Johns Hopkins University, received her medical degree from Yale University, followed by a fellowship in Child and Adolescent Psychiatry at Yale.

Urologic surgeon, Melinda Knight, MD, joins South County Medical Group

WAKEFIELD – MELINDA KNIGHT, MD, has joined South County Medical Group.

Dr. Knight specializes in the surgical treatment of urologic cancers using minimally invasive techniques, including the da Vinci XI surgical robotic system.

She received her medical degree from Johns Hopkins School of Medicine, Baltimore, MD, and completed a urological surgery residency at Mayo Graduate School of Medicine, Rochester, MN. She completed her general surgery residency and general surgery internship at the Medical College of Georgia.

During her career, Dr. Knight has been instrumental in starting multiple robotic surgery programs in Wisconsin, and most recently was Director of Robotic Surgery at Southwell Medical in Tifton, Georgia.
**Appointments**

**Stephanie Graff, MD, named Lifespan’s Director of Breast Oncology**

PROVIDENCE – Lifespan has appointed STEPHANIE GRAFF, MD, FACP, to serve as Director of Breast Oncology at the Lifespan Cancer Institute.

Dr. Graff is board-certified in medical oncology, hematology, and internal medicine. She obtained a medical degree at University of Missouri-Kansas City School of Medicine where she also completed a residency in internal medicine and later served as chief medicine resident with its partner, St. Luke’s Hospital. She completed a fellowship in hematology/medical oncology and sub-fellowship in breast oncology at the University of Kansas.

Dr. Graff is the medical director of the Dr. Susan Love Foundation for Breast Cancer Research. She is also active in the American Society of Clinical Oncology and a graduate of its 2019-20 leadership development program.

Dr. Graff comes to Lifespan from the Sarah Cannon Cancer Center of HCA Healthcare, where she was director of the breast program for HCA Midwest in Kansas City and both the National Breast Lead and Associate Director of Breast Cancer Research for the entire Sarah Cannon network.

**Lifespan appoints David Kirshner Exec. VP, CFO**

PROVIDENCE – DAVID KIRSHNER has been appointed executive vice president and chief financial officer for Lifespan, where he will oversee the budget for the health system and serve as senior finance executive for all Lifespan hospitals and affiliates.

Kirshner will develop operational, budgetary, and balance sheet goals that ensure Lifespan’s long- and short-term financial and operational stability. He will provide counsel to the CEO and board of directors on matters of financial management.

“I began my career trajectory working for and inside hospitals, and I was compelled to return when the COVID-19 pandemic made salient the need for a strong health care delivery infrastructure at the local level,” said Kirshner.

Kirshner has more than 30 years of experience in public accounting, hospital financial management, and chief financial officer positions in academic medicine. Over his career, he has led the financial turnarounds of several hospitals in Massachusetts, most notably for Boston Children’s Hospital, where in his 15 years as senior vice president, treasurer and CFO, he engineered an improvement plan that transformed a $50 million operating loss in FY ’97 to an operating surplus of $62 million in FY ’05.

Kirshner joins Lifespan from Ernst & Young in Boston, where he was senior executive advisor for healthcare.

He holds a bachelor of arts from University of Pittsburgh, and a master of business administration in health care administration and management from Boston University. He is a certified public accountant.

Kirshner replaces Mamie Wakefield, who is retiring after nearly 24 years at Lifespan.
Hospital Corpsman 1st Class Erica Reiter, right, from North Smithfield, RI, receives the Navy and Marine Corps Commendation Medal from Cmdr. Joseph Burgon, from Cottonwood, CA., aboard Independence-variant littoral combat ship USS Charleston (LCS 18), July 19. Charleston, part of Destroyer Squadron Seven, is on a rotational deployment, operating in the U.S. 7th fleet area of operations in the Philippine Sea to enhance interoperability with partners and serve as a ready-response force in support of a free and open Indo-Pacific region.

[U.S. NAVY PHOTO BY MASS COMMUNICATION SPECIALIST 2ND CLASS ADAM BUTLER]

Miriam named top hospital in RI in 2021–22

**U.S. News & World Report**

The hospital receives “high performing” honors for 12 specialties and conditions

PROVIDENCE – The Miriam Hospital has been named by U.S. News & World Report as the top hospital in Rhode Island and in the greater metropolitan area and was designated as “high performing” in a dozen specialties and conditions.

“Our number one priority through the pandemic has been to maintain excellent care for our patients and their families,” said MARIA DUCHARME, DNP, RN, NEA-BC, president of The Miriam Hospital. “It’s a testament to the work of The Miriam Hospital’s amazing team that, under such incredibly challenging circumstances, not only do we continue to be ranked No. 1 in the state and the metro region, we also were classified as ‘high performing’ in a remarkable number of specialties – 12, the most in the recent memory.”

U.S. News ranked The Miriam Hospital a Best Regional hospital – No. 1 among all Rhode Island hospitals as well as the top hospital in the Providence metro area (which includes Providence, Pawtucket, Fall River and New Bedford). The Miriam Hospital received “high-performing” honors for the following 12 specialties and conditions:

- Knee replacement
- Hip replacement
- Stroke
- Kidney failure
- Heart failure
- Heart attack
- Diabetes
- Colon cancer surgery
- Chronic obstructive pulmonary disease (COPD)
- Urology
- Orthopedics
- Neurology and neurosurgery

For the 2021–22 ratings, U.S. News evaluated more than 4,750 medical centers nationwide in 17 procedures and conditions. Fewer than a third of all hospitals received any high-performing rating.

The annual Procedures & Conditions ratings are designed to assist patients and their doctors in making informed decisions about where to receive care for common conditions and elective procedures. These ratings extend the beyond the Best Hospitals rankings, which are geared toward complex specialty care. “High Performing” recognizes care that was significantly better than the national average, as measured by factors such as patient outcomes.

- Recognition

**JH Communications wins three national awards for Brown Physicians campaign**

PROVIDENCE – JH Communications has received three Aster Awards for excellence in healthcare marketing for a series of video campaigns it produced for Brown Physicians, Inc.

JH Communications is a Gold Winner for recruitment videos for the Brown Emergency Medicine Residency and Fellowship program; a Gold Winner for videos for Brown Emergency Medicine’s telecare program; and a Silver Winner for a patient education video for the Brown Medicine’s Endoscopy Center.

“We are excited and proud of our video production and marketing team, who worked tirelessly to develop a series of videos to meet the marketing and communication needs of the Brown Physicians during the COVID-19 crisis. These awards are a testament to their hard work and expertise and the power of video as an effective marketing tool,” said JOHN HOULE, President, CEO, and founder of JH Communications. “We look forward to similar partnerships in the future.”

The Aster Awards is one of the largest and most respected national and international competitions of its kind. This elite program has recognized outstanding healthcare professionals for excellence in their advertising and marketing efforts for over 20 years.

JH Communications’ award-winning videos can be viewed by clicking the below links:

- https://vimeo.com/showcase/8663671
- https://vimeo.com/showcase/7346800
- https://vimeo.com/showcase/8663719
FRANCIS “FRANK” R. DIETZ, 81, of Seekonk, MA and Hobe Sound, FL, died peacefully on July 23, 2021.

Serving as President and CEO of Memorial Hospital of Rhode Island for 47 years, he led the transformation of the Hospital’s scope of medical services and facilities over four decades. His vision for advancing medical research and academic teaching led to Memorial Hospital becoming the area’s leader in primary care, serving as the home for the Brown University Warren Alpert Medical School’s Family Medicine program, and leading nationally-renowned research initiatives the Pawtucket Heart Health Program and the Women’s Health Initiative.

His industry and community volunteer service included the Pawtucket Rotary Club and the Pawtucket Boys and Girls Club, while also serving on the governing boards of the Hospital Association of Rhode Island and the Pawtucket Foundation.

In recognition of his years of leadership, service and dedication to the health care industry and the City of Pawtucket, he was honored annually by the Hospital Association of Rhode Island through the Francis R. Dietz Award for Public Service, received the Pawtucket Foundation Heritage Award in 2007, and was inducted into the City of Pawtucket Hall of Fame in 1992.

He is survived by his son, F. Richard Dietz, Jr. and his wife Elizabeth N. Dietz; his daughter Beth-Ann F. Dietz Norko and husband John, all of North Attleboro, MA; his brother John Dietz and his wife Carol Dietz of Greenwich, CT; and his grandchildren, nieces and nephews.

Donations in his memory may be made to Hope Health Hospice, 1085 N. Main Street, Providence, RI, 02904.

RONALD R. RICCO MD, of Pawtucket passed away on July 8, 2021.

He was the husband of Joanna T. [Hunt] Ricco.

Dr. Ricco was a United States Navy Veteran. After his tour of duty he was employed as the Chief of Obstetrics at the former Memorial Hospital in Pawtucket for over 40 years.

Besides his wife, Dr. Ricco is survived by his children; Michael H. Ricco and his wife Susan, Julie Ricco and Stephen Ricco. He also leaves a sister, Estherlene Pardini and three grandchildren, Colin, Brayden, and Logan.

ROBERT P. SARNI, MD, 90, of East Greenwich, passed away peacefully on July 21. He was a graduate of Classical High School in 1949 and the University of Rhode Island in 1953. Upon graduating, he enlisted in the United States Army. He served in Germany and rose to the rank of 1st Lieutenant at the time of his honorable discharge in 1955. He was admitted to the University of Maryland School of Medicine graduating in 1960. Upon completion of his internship at RI Hospital and residency at St. Joseph Hospital, he went into private family practice and Industrial Medicine in 1962 in Cranston, RI.

During his 55 years practicing he was staff president at St. Joseph Hospital, a member of the Hospital Board of Trustees, and Director of the Department of Family Medicine. From 1987–1993, he was appointed to the RI Board of Medical Licensure and Discipline. He was awarded the Distinguished Service Award from Our Lady of Fatima Hospital. He was a member of numerous professional societies, including The American Board of Family Practice, Industrial Medical Association, American Academy of Family Physicians, RI Medical Society, New England Occupational Medical Society (Past President), and RI Academy of Family Practice (Past President). He was also a fellow of the American Academy of Family Physicians and Industrial Medical Association.

An avid golfer, Dr. Sarni was a member of the Pt. Judith Country Club. He was also a member of the University Club, Dunes Club, and Aurora Civic Association. Besides his wife Janice [Lepore] Sarni, he is survived by his son Gregory Sarni of Lake Worth, FL, and his stepsons, Anthony T. Marotti, Jr., and Michael Marotti and his wife Christine Marotti of North Providence, RI. He is also survived by his beloved grandchildren Taylor Sarni, Cameron Sarni, Michael Marotti, and Isabella Marotti. He was the brother of Vincent Sarni and the late Lawrence Sarni.

Described by colleagues and friends as dedicated, compassionate, timeless, forthright and honest, Dr. Sarni was highly respected in the community and he will be missed. Donations in his memory can be made to the Sarni Family Endowment Scholarship [URI]. Please share memories and condolences at www.WoodlawnGattone.com.

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