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Choosing a Treatment

I am writing this before the New England Journal of Medicine has published letters responding to its editorial on two independent studies of vertebroplasty versus "sham" vertebroplasty. The articles, from different continents, concluded that vertebroplasty was no more effective than injecting lidocaine, which had lower morbidity and cost. The author made the bizarre statement that he didn’t know whether doctors should now advise vertebroplasty or not for compression fractures, and that the patient should simply be given the evidence, thus allowing them to make an informed decision. I am sure that there will be letters denouncing the editorial and still others pointing out the weaknesses in the vertebroplasty studies. While the evidence should point to a clear choice: a procedure with complications that costs a lot and doesn’t work, versus something cheap and low chance for bad outcome, the reality is that patients with friends who did well with vertebroplasty are likely to be more influenced by their friends’ results than the doctor’s ambivalent recommendation. But how can the doctor suggest a treatment that doesn’t work? Probably because it works in his hands.

No studies are free of weaknesses. All study designers make choices. What should be measured? When should it be measured? Which tests are the best for measuring these outcomes? How many subjects are required? Given multiple options for each question, one always can argue that a different choice would have been better, possibly producing a different outcome. What exclusionary and inclusion criteria were made “too lax” in order to not inhibit enrollment or too “strict” in order to narrow the focus? At what point does the “KISS” (Keep It Simple, Stupid) principle outweigh the tremendous desire to accrue as much data as possible?

It is one thing for a doctor to allow a patient to make an informed decision when there is no data and quite another to be offered the option of an expensive procedure with proven lack of benefit.

Many years ago, a procedure in which the external carotid and internal carotid were anastomosed, bypassing constricted carotids, was occasionally performed, with the goal of preventing stroke. It was intended to bypass completely blocked carotid arteries since the blocked vessels could not be re-opened. It was thought to be especially helpful when both carotids and the basilar were blocked, since this meant there was too little flow through the Circle of Willis to compensate for the carotid blockage. It seemed a match made in heaven. The operation was technically easy and impressively safe. There was virtually no risk of stroke associated with the operation. The external carotid was outside the skull, sitting almost directly on top of a distal, but moderate sized branch of the middle cerebral artery. Not only was the morbidity low but the anastomosis remained open in a very high percentage of cases. The only problem was that when the study was performed to prove efficacy, it was found not to help. Placebo-treated patients did just as well. What was most surprising to me was what happened next.

The surgeons who were the principal investigators at each site challenged the results by pointing out that the study was flawed by recruitment bias. They wrote that the “best” subjects, the ones most likely to improve with the procedure, were not offered entry into the study. They were operated on since it was common knowledge that the operation worked. Therefore the study really should have concluded that the procedure was not useful only in this selected group of patients who were poor candidates.

I am not sure what made those subjects worse than the patients who were kept from participating, but all studies have stringent inclusion and exclusion entry criteria, and there weren’t differences between the placebo and actively treated subjects. So one can only wonder how and why someone would undermine his own study by steering potential subjects away, and what sort of sophism would allow someone then to throw out all the results. Or why doctors would participate in a study that they thought was unethical to perform.

[Not to bad-mouth the surgeons, we should keep in mind that hormone replacement therapy trials were postponed for many years because most authorities in the field thought them unethical since it was “clear” that they reduced coronary artery disease and hip fractures. This proved, once again, the importance of evidence-based medicine.]

As far as I’m aware the external-internal carotid operation is no longer done, and, I can see by the NEJM editorial on vertebroplasty, that this may be because it isn’t paid for, not because it doesn’t work. Efficacy doesn’t seem to matter to everyone even in this alleged era of evidence-based medicine.

What are we physicians to do when evidence contradicts our everyday experience? We gave up blood-letting many years ago. We gave up operating on Bell’s palsy about 30 years ago; putting people with subarachnoid hemorrhages into a sedative-induced stupor and stimulus-reduced environment where they became psychotic while waiting for their vasospasm to resolve, about 20 years ago; using anticoagulants for stroke within the past few years, and so on. We sometimes learn from our mistakes especially when we “know” something to be true. It is not a new insight to say that we must be ever vigilant against our own prejudices, for we harm others as we fail to examine ourselves.

Evidence-based medicine is not the gospel, but it provides a surer footing than the old approach that we have all been guilty of, as distilled by a teacher of mine: "if you’ve seen one case you can say, ‘in my experience.’ If you’ve seen two cases you can talk about ‘my series.’ But
Racism and the Threat of Influenza

We humans have never lived in a bacterially sterile world, a world free of disease-causing germs. Nor dare we envision a future time when infectious disease will have retreated to history books lest we join those past civilizations that relied solely on fanciful illusions.

During the last millennium there have been three lethal pandemics, killing millions of souls. The great bubonic plague commencing in 1346, sometimes called the Black Death, altered the economy of 14th Century Europe, presaging the end of its feudal economy and witnessing the hesitant beginnings of more diversified farming, and in cities, cottage industries. The plague killed perhaps one fourth of the European population.

The second communicable disease tragedy was the awesome influenza pandemic commencing in the summer of 1918 and killing in excess of 50 million people within 18 months. And we are in the midst of a third global pestilence, AIDS.

How, in general terms, do communicable disease threats, such as influenza, arise? Are they merely random phenomena, part of what mathematicians call chaos theory and hence unpredictable? Are they, perhaps, capricious happenings, proof of humanity’s maladaptive status in the overall scheme of things and therefore both tragedies and warnings that we repent? Are they, alternatively, manifestations of divine punishment, the predominant belief until the last century? Or, perhaps, are there underlying trends, secular patterns, etiological relationships in these various pestilences which, with more careful scrutiny, serve to clarify the dynamics and origins of pandemics?

And why, parenthetically, do these global perils always seem to take origin in distant, exotic places? We hear of Spanish flu, Asian flu, Hong Kong flu, Ebola fever, Lassa fever, tsutsugamushi, Siberian tick fever. But almost never do we hear of Jersey City influenza, Barrington encephalitis or Woonsocket fever.

And we who are privileged to give geographic names to newly encountered pestilences live under the naïve impression that we Americans prosper in an idyllic, pestilence-free community; and were it not for those alien pathogens from distant, unclean communities such as rain forests with strange names, we would thrive in a contagion-free society. Why, Oh why, said Henry Higgins, can’t the rest of the world be just like us?

Hyperbole perhaps, yet our American society truly contends that through clean living – and some marginal help from medical science – we have arrived at what the Pilgrims had called that shining city on the hill, essentially free of nasty pestilences.

Underlying this innocent perception of the contaminated and uncontaminated segments of the world, between the “them” (the teeming masses infested with communicable disease) and the “us”, essentially disease-free but now needlessly threatened by the unclean world beyond our borders, rests a subtle form of racism which simplistically divides the world by ethnicity and is prompted by the inchoate fear that the third world is intent on sending both its uneducated young and its threatening pathogens to seek shelter on our pristine shores. It is the 21st Century variant of Hearst’s 19th Century Yellow Peril.

It is an old tradition to assign blame before seeking constructive explanations. What person, tradition or institution can we blame for the unremitting threat of influenza? Epidemiologists, tracing the origins of new pandemics, tell us that China’s vast population of humans living in close proximity with two billion swine and ten billion domesticated poultry has generated many of the past influenza pandemics – and will likely do so again in the future. The biological crucible for mixing human, avian and swine influenza genes is there, and for reasons other than malice, China is therefore the likeliest location for a new and communicable influenza virus to be generated, emerging into the neighboring human population and then spreading to the other continents.

In truth, since 1974, this nation has been challenged by 29 new or resurgent human pathogens including HIV infection (AIDS), Lyme disease, legionnaire’s disease, cryptosporidiosis, SARS, avian flu, swine flu and more than a score of others; most, but not all, originating from less developed regions of the globe.

But it is well to recall, lest we think that the United States is a virologically privileged territory without its share of inciting world pandemics of influenza, that the tragic 1918 influenza pandemic, inaccurately called the Spanish flu and still the most lethal pestilence in human history, originated in the American prairies of Haskell County, Kansas.

– STANLEY M. ARONSON, MD

Stanley M. Aronson, MD is dean of medicine emeritus, Brown University.

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CORRESPONDENCE
e-mail: SMAMD@cox.net
Overview of the Providence VA Medical Center

Sharon Rounds, MD

The Veterans Health Administration is the largest health care system in the US and is part of the Department of Veterans Affairs. There are more than 23 million military veterans in the United States; approximately 10 million receive active medical treatment within the VA health system. The current health care reform debate has focused on the potential role of a single payer system. Thus, it seems particularly timely to feature the unique services that are possible because of the resources, culture, and environment of the VA system.

In 1930 President Herbert Hoover launched the Veterans Administration, which became the Department of Veterans Affairs in 1989. The first priority of the Department of Veterans Affairs has always been to provide outstanding healthcare for veterans. After World War II, General Omar N. Bradley became the head of the Veterans Administration. With thousands of veterans returning home, seeking healthcare, General Bradley decided that the best way to ensure high quality of care in VA hospitals was for these hospitals to be affiliated with medical schools. Currently 119 VA facilities offer graduate medical education or undergraduate medical education through affiliations with 107/130 medical schools and 15/35 osteopathic schools. In 2008 alone, over 30,000 residents and 20,000 medical students received some of their training in VA facilities. In the 1950s Congress approved funding of the VA research program that addresses the healthcare issues of US veterans.

The Providence VA Medical Center (PVAMC) was built at its present site at Davis Park in Providence in 1948. It is one of 8 hospitals in the VA New England Healthcare System, also known as Veterans Integrated Service Network (VISN)1. In fiscal year 2008, the PVAMC provided care for 30,306 veterans with 307,351 outpatient visits and 3169 hospital admissions. The clinical services are organized by service lines, including Mental Health, Specialty and Acute Care, and Primary Care. The focus of PVAMC is on outpatient care, with small inpatient services in psychiatry, internal medicine, and surgery. The Providence VAMC is categorized as a community teaching hospital in the VA system. Veterans who require services not available at Providence, such as neurosurgery or cardiac surgery, are referred to other VISN1 hospitals or to non-VA local hospitals, depending on the urgency of the referral.

In the 1990s the VA healthcare system underwent major changes under the leadership of Kenneth Kizer, MD. This reform was based on the principles that the VA would offer lifetime care to veterans as an integrated health care system dedicated to delivering “best value” care with “management of total costs; a focus on populations rather than individuals; and a data-driven, process-focused customer orientation.” A data management system, called VistA, a collection of VA-developed software programs that is uniform across the VA system, has undergirded the reform. VistA provides an outstanding electronic medical record with graphical user interface that has been in use at the PVAMC since 1998. Dr. Tanya Ali describes this electronic medical record and subsequent improvements in patient care. In addition, the VA was the first to adopt bar coding for medication administration on a national basis. Using VistA, physicians in Providence can view medical records, radiographs, and other clinical data of patients cared for at VA hospitals across the country—a particular advantage in caring for an elderly population in Rhode Island with “snowbirds” traveling to Florida annually. In addition, the electronic medical record has made feasible research on health care delivery; medication use, efficacy, and complications; and outcomes of care. Most importantly, VistA has enabled the VA to routinely monitor measures of quality and to facilitate corrective actions. Indeed, numerous measures of quality of patient care are assessed and compared between individual providers, hospitals, the VA nationally, and Medicare.

Thomas O’Toole, MD, describes the Primary Care Service Line activities in this issue. The PVAMC Primary Care Service is a site for medical resident and Brown medical student training in ambulatory internal medicine.

The full range of surgical specialties (except for neurosurgery and cardiac surgery) are represented at the Providence VAMC. The PVAMC is a site for general surgery resident and subspecialty resident training and for the surgical clerkship at Brown Medical School. The Providence VAMC is a site for VISN1 referral for lithotripsy. The surgical services of all VA hospitals participate in the American College of Surgery National Quality Improvement Program (ACS-NSQIP).

Michael Goldstein, MD, describes Mental Health Service activities in this issue. The PVAMC Mental Health Service is a site for psychiatry and psychology resident training, training for post-doctoral fellows and for Brown medical student training.

Both inpatient and outpatient services are offered in all medical specialties at the Providence VAMC. The PVAMC is a site for third and fourth year Brown medical student and resident training in inpatient internal medicine and in dermatology. In addition, the PVAMC is a site for post-doctoral training in the Cardiology, Endocrinology, Gastroenterology, Hematology/Oncology, Infectious Diseases, Pulmonary/Critical Care, and Rheumatology. The VA has pioneered with group clinics for clinical problems for which patient adherence to treatment regimens is difficult, but crucial. These group clinics and the VA telehealth and teledermatology programs are described in this issue.

The Providence VAMC clinical facilities are undergoing major infrastructure improvements. A new building housing the Operating Room and a Diagnostic Imaging suite are nearing completion, as is a new 3-tesla magnetic resonance imaging facility. New construction projects will house the Intensive Care Unit, Emergency Department, Specialty Clinics, and Pharmacy.

The Providence VA Medical Center is affiliated with the Warren Alpert Medical School of Brown University and with
Boston University School of Medicine. In addition, the PVAMC has educational programs in nursing, pharmacy, and dental care with affiliations with 56 educational institutions, including the University of Rhode Island, Rhode Island College, and others. In 2008 the PVAMC was the site of education of 506 students, residents, and MD and PhD post-doctoral fellows in various disciplines.

In 2008, the PVAMC was awarded a competitive VA Nursing Academy grant that established a nursing education affiliation between the Providence VAMC and Rhode Island College School of Nursing (RICSON). The VA Nursing Academy was established in 2007 to address the nationwide shortage of nurses and to ensure that veterans continue to receive the best services available. The PVAMC-RICSON Nursing Academy is a four-year program that has brought about both faculty and student expansion and innovative initiatives.

The Providence VAMC has grown in research funding and facilities. In 1997, the VA dedicated the Research Building (Building 35), providing 13,000 sq. ft. of newly constructed wet laboratory and clinical research space and investigator offices. Construction will soon begin on an 1860 sq. ft. addition to the Research Building. Animal care facilities at the Providence VA Medical Center have a total space of 12,761 sq. ft. The Research Service of the PVAMC is accredited by both AAALAC-I and AAHRPP.

The PVAMC is the site of the Research Enhancement Award Program (REAP), led by Peter Friedmann, MD, Professor of Medicine. The REAP is funded by the VA Health Services Research & Development program to train junior investigators and to foster research collaboration in health services and outcomes. The REAP provides an ideal clinical collaborative research and training environment, with computing infrastructure, methodology expertise, and biostatistical support. Research training for junior investigators is facilitated in bi-weekly conferences that provide interactive learning in research design, methods and data analysis. The REAP is located in Building 32, which houses clinical and health outcomes research in 2500 square feet.

The PVAMC is also the site of the recently re-funded VA/Brown Center for Restorative and Regenerative Medicine, led by Roy Aaron, MD, Professor of Orthopaedics. The goal of the Center is to create bio-hybrid limbs and other unique tools to restore function. There is a particular need for this research in that veterans wounded in the conflicts in Iraq and Afghanistan have returned with devastating limb injuries. Because of improvements in body armor, soldiers are surviving after injuries that would have proven fatal in the past. The Center for Restorative and Regenerative Medicine is a collaborative multidisciplinary research effort between the PVAMC, Brown University, and the Massachusetts Institute of Technology. Research projects include: the development of powered lower leg prosthesis a project directed by Hugh Herr, PhD, at MIT; the first clinical trial of a robotic arm and hand, directed by Linda Resnik, PhD, PT, Associate Professor of Community Health at Brown; and a clinical trial of the “Braingate” device in patients with Amyotrophic Lateral Sclerosis, directed by John Donoghue, PhD, and Leigh Hochberg, MD, PhD, of the Departments of Neuroscience and Bioengineering at Brown. The VA is building a 23,500 sq. ft. new, state-of-the-art research space for this VA/Brown Center, an investment of $6 million by the VA to the Brown University research enterprise. The new facility will be dedicated in January 2010.

Another area of research excellence is the VA and NIH-funded Vascular Research Laboratory (www.brown.edu/Research/Vascular_Research_Laboratory/), consisting of investigators from Pulmonary/Critical Care and Cardiology sections of the Brown Department of Medicine. Alcohol and Addiction research is led by Robert Swift, PhD, MD, Professor of Psychiatry and Human Behavior and Associate Chief of Staff for Research at the VA, and two VA Career Scientists, Peter Monti, PhD, Professor of Community Health and Damaris Rohsenow, PhD, Professor of Community Health. Martin Weinstock, PhD, MD, Professor and Chief of Dermatology at the VA, leads VA and NIH-funded multi-center clinical trials in skin cancer epidemiology and treatment. Dr. Weinstock also leads the VISN1 Teledermatology Program, described in another article in this series. Albert Lo, PhD, MD, Assistant Professor of Neurology, leads VA-funded multi-center trials in the use of robotics in rehabilitation of patients with strokes and in multiple sclerosis. His work is described in another article in this series. Tracie Shea, PhD, and William Unger, Ph. have a research program in Post-traumatic Stress Disorder (PTSD), which afflicts a high percentage of veterans returning from Iraq and Afghanistan.

Thus, the Providence VA Medical Center provides a unique set of services for veteran patients and a practice environment that focuses on quality of care, with resources for education and research.

Sharon Rounds, MD, is Chief, Medical Service, Providence VA Medical Center, and Professor of Medicine and of Pathology and Laboratory Medicine, The Warren Alpert Medical School of Brown University.

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CORRESPONDENCE

Sharon Rounds, MD
Providence VA Medical Center
830 Chalkstone Ave
Providence, RI 02908
Phone: (401) 457-3020
e-mail: Sharon_Rounds@brown.edu
Innovative Approaches to Healthcare Delivery at the Providence VA Medical Center

Sharon Rounds, MD

The major goal of the VA system is cost-effective, high quality healthcare. Because VA physicians are salaried, there is no entrepreneurial incentive to bill for fee-for-service. Thus, VA healthcare providers are more likely to use physician extenders or other means of expanding outreach and have therefore developed innovative methods of delivering care to selected populations of patients. Examples of innovative modalities of care are described below.

Enhancing Patient Adherence to Prescribed Therapy

Obstructive sleep apnea (OSA) is estimated to be present in 9-14% of males and 2-7% of females in the US.1 OSA is associated with hypertension, coronary artery disease, and stroke,2 as well as motor vehicle accidents resulting from excessive daytime somnolence.3 Accumulating evidence indicates that treatment of OSA with continuous positive airway pressure (CPAP) decreases the prevalence of cardiovascular complications.2 However, although CPAP therapy is effective in reversing sleep apnea, there is a high rate of non-compliance. An estimated 29-83% of patients with OSA are non-adherent with CPAP therapy, defined as use of CPAP at least 4 hours per night.4 Thus, it is important to develop methods of enhancing compliance with CPAP treatment for OSA.

The VA provides CPAP therapy for veterans with proven OSA of at least moderate severity after evaluation and prescription of CPAP by a pulmonary physician. The VA requires that patients be re-evaluated periodically for need for CPAP; in addition to home visits by the CPAP vendor. We developed a novel group—CPAP Clinic—managed by a pulmonary nurse practitioner and a respiratory therapist. Veterans for whom CPAP is provided by the VA are required to attend this clinic every 12-18 months. About 10 patients attend each group clinic session. Their equipment is checked for proper function and prescriptions for supplies are provided at each session. Compliance with CPAP is assessed by review of records of machine use, and patient symptoms and complications of CPAP therapy are assessed and treated. In addition, at each clinic session, a group educational session is held, with nurse practitioner and respiratory therapist plus compliant patients providing encouragement of CPAP use.

In a retrospective review, we assessed compliance with CPAP therapy between patients who attended CPAP clinic, compared with patients who did not attend the clinic. We found that compliance with therapy, as defined by 5 hours of machine use per night, improved in 29% of patients attending CPAP clinic.5 The success of CPAP clinic is dependent upon use of physician extenders (nurse practitioner and respiratory therapist) for patient assessment and education and upon the encouragement provided to non-compliant patients by compliant patients also attending the group clinics.

Multiple Cardiovascular Risk Factor Intervention

Control of modifiable cardiac risk factors for the prevention and treatment of coronary artery disease (CAD) in patients with diabetes mellitus decreases the risk of cardiovascular events. However, many patients do not achieve target goals for low density lipoprotein (LDL) cholesterol, systolic blood pressure, glycemic control, and tobacco cessation, despite intensive efforts. Control of multiple risk factors is expensive, requiring multiple follow-up physician visits in the traditional practice setting.

The Cardiology Section and the Pharmacy Department at the Providence VA Medical Center, in conjunction with the School of Pharmacy at the University of Rhode Island, have implemented novel pharmacist-led, multidisciplinary clinics (Cardiovascular Risk Reduction Clinic, CRRC) with interventions to control hyperlipidemia, hypertension, hyperglycemia, and tobacco use. The clinics are coordinated by a clinical pharmacist, working in close collaboration with a physician cardiologist. Because clinical pharmacists have prescribing privileges in the VA system within their scope of practice, they are able to implement medication changes, in addition to providing education and advice on lifestyle modifications. Furthermore, the VA drug formulary is limited and controlled, according to results of clinical studies. Finally, treatment of cardiovascular risk can be expressed in algorithms that are strongly supported by clinical trials. Thus, cardiovascular risk reduction is well suited for a pharmacist-led clinic.

In retrospective reviews, all cardiovascular risk factors were significantly improved after attendance at CRRC programs6 with sustained improvements.7 The VA is funding a prospective study to assess the effectiveness of the pharmacist-led model CRRC clinic, under the leadership of Wen-Chih Wu, MD, VA staff cardiologist and Assistant Professor of Medicine at Brown, and Tracey Taveira, PharmD, Associate Professor of Clinical Pharmacy at the University of Rhode Island.

Because of the success of the CRRC, pharmacist-led clinics in conjunction with cardiology have also been established at the Providence VAMC for congestive heart failure, another condition for which strong evidence from clinical trials supports algorithms for clinical management.

Teledermatology

Workforce surveys have documented a national shortage of dermatologists.8 This problem is exacerbated in rural areas with long travel distances to dermatology providers. The practice of medical dermatology is well suited for telemedicine, since skin lesions are easily documented and transmitted. The availability of an electronic medical record with robust security for personal health information, such as the VistA system used by the VA, is critical for successful teledermatology.
The Dermatology Section of the Providence VA Medical Center has been providing teledermatology services to VA facilities in rural Maine since 1997, under the leadership of Dr. Martin Weinstock, MD, PhD, Chief of the PVAMC Dermatology Section. This teledermatology practice was the first in the VA system nationally. A "store-and-forward" approach is used with clinical history, physical examination, and digital photos of affected skin taken by a nurse practitioner or physician assistant in Maine, who forwards the skin photos and clinical information to the physician dermatologist in Providence. Epiluminescence microscopic images are also taken, as indicated. These data are reviewed by the dermatologist in Providence who provides an impression and plan that are transmitted electronically and implemented in Maine by the nurse practitioner or physician assistant. When necessary, in person consultation with a dermatologist can also be implemented. This "store-and-forward" approach is very economical, as compared with face-to-face dermatology consultation or real-time teledermatology consultation. A review of patient satisfaction with the PVAMC teledermatology services revealed that more than half of patients were satisfied with the service and most indicated that they would not have otherwise have had dermatology evaluation due to inability to travel to the nearest VA dermatology clinic. Overall, 74% of providers rated the program as excellent or good and would recommend the teledermatology program for their patients.9

Telemedicine approaches are economical and useful for many dermatological problems. The experience at the Providence VAMC has been an example for the VA system nationally, and implementation of teledermatology for other underserved areas is now underway. Indeed, telemedicine has been implemented by the VA for other conditions, such as "Telebuddy" home monitoring for patients with hypertension, congestive heart failure, and chronic obstructive pulmonary disease.

These examples of innovative approaches to difficult clinical problems were pioneered and implemented at the Providence VAMC. All have been assessed for effectiveness, with ongoing patient satisfaction and clinical effectiveness surveys.

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References

Sharon Rounds, MD, is Chief, Medical Service, Providence VA Medical Center, and Professor of Medicine and of Pathology and Laboratory Medicine, The Warren Alpert Medical School of Brown University.

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The author has no financial interests to disclose.

Correspondence
Sharon Rounds, MD
Providence VA Medical Center
830 Chalkstone Ave
Providence, RI 02908
e-mail: Sharon.Rounds@va.gov
I was working at the Providence VA Medical Center emergency room when I was asked to see a new, confused, diabetic patient, who was visiting her family in Providence. The nurse informed me that her blood sugar was low. We took measures to correct her blood sugar immediately. The patient was not clear regarding her medications. Her primary care physician was at a VA hospital in California. Logging into the VA Computerized Patient Record System (CPRS), I gained access to the patient’s recent outpatient office visit notes, and obtained the most current medication list. It became clear that the patient was not taking her diabetic medications as prescribed and that she was hypoglycemic because of overmedication. Via the electronic medical record, VA physicians can ascertain not only the patient’s latest data, but also a complete medical record going back as far as the mid-1980s, including records of care performed in any other Veterans Health Administration (VHA) hospital or clinic.

More than $1.2 trillion spent on health care each year is estimated to be wasted—about half the $2.2 trillion spent in the United States on health care each year, according to the most recent data from Price Waterhouse Cooper Health Research Institute. Much of the waste is a result of disorganization and lack of accurate information. This results in orders for unneeded tests and ineffective procedures and in simple human error. Advanced health information technology can reduce these consequences substantially in the following ways:

1. Improved communication
2. More readily accessible knowledge
3. Assistance with calculations
4. Performance of checks in real time
5. Assistance with monitoring
6. Decision support
7. Requirement for key pieces of information (dose, e.g.)

Based on a well-specified definition of electronic health records, only 17% of US physicians used either a minimally functional or a comprehensive electronic records system in 2009. Twenty-four functionalities have been identified as the essential components of comprehensive electronic records system.

In 1995 the VA launched a major re-engineering of its health care system that included better use of information technology, measurement and reporting of performance, integration of services, and realigned payment policies. Health Information technology benefited from significant investments and the CPRS was implemented nationally throughout the VHA in 1999.

In any VA hospital clinicians can navigate the electronic medical records by logging into CPRS. Via a graphical user interface, physicians can access complete patient records from inpatient visits, subspecialty consults, primary care visits, emergency room visits, laboratory data, radiology reports, medication history, surgical notes and discharge summaries. All physicians’ work on any patient utilizes the same medical record and all entries are legible. This facilitates communication among care providers, makes the data collection process efficient, saves time, and eliminates difficulty deciphering illegible handwriting.

The Clinical Decision Support (CDS) component of CPRS provides clinical data, clinical guidelines, clinical reminders, situation-specific advice, and makes relevant information available in

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<td>4. Drug-drug interaction alerts</td>
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<td>5. Drug-laboratory interaction alerts</td>
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<td>6. Drug-dose support (renal dose guidance)</td>
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real time to facilitate clinical decision making. Availability of these components makes information collection a smooth process, provides decision support automatically as part of workflow and provides actionable recommendations.3 CDS reminds the clinician to evaluate for different JCAHO-required indicators such as pain scale, signs of abuse, safety in the living place, counseling for smoking cessation, assessment for pressure ulcers, medicine reconciliation, and verification of advance directives. The same CDS system reminds doctors to prescribe appropriate care for patients when they leave the hospital, such as prescription of beta blockers after heart attacks, ACE inhibitors for congestive heart failure, left ventricular function assessment by echocardiogram for heart failure, anti-coagulation in patients with atrial fibrillation, and daily weight measurement in patients with congestive heart failure.

All patient care orders are entered into CPRS through a Computerized Physician Order Entry (CPOE) system. All inpatient orders (for diet, activity, intravenous fluid, medication, lab, radiology, consultations, etc) and outpatient orders are entered through this system.

The CPRS has an active clinical decision support system focused on drugs, laboratory testing and radiology procedures. For example, when a physician enters a new medication order in CPRS, the system immediately alerts the physician to any previous allergic reaction to the same medication and to any relevant drug-drug interactions. CPRS checks for duplicate therapy, provides basic drug dosing guidance, and makes formulary data available. It also checks dosing for renal insufficiency and geriatric patients, medication-related lab testing (e.g. PT, PTT before intravenous heparin initiation), and drug-pregnancy and drug-disease contraindications. The laboratory generates view alerts to the provider on any abnormal testing results through the CPRS. For example, orders for CT scan with contrast generate alerts to the provider if the patient is on metformin, if serum creatinine is abnormal, or if a recent serum creatinine is not available in order to caution the provider regarding potential contrast-related complications. The radiologist can generate a computerized alert to primary care providers (inpatient and outpatient) whenever an abnormal radiology image is reviewed.

Computerized Clinical Reminders (CCR) are just-in-time reminders at the point of care that reflect evidence - based clinical practice guidelines and reduce reliance on memory. This system keeps track of when veterans are due for a flu shot, pneumococcal vaccine, diabetic eye exam, diabetic foot exam, lipid profile, screening colonoscopy, breast cancer screen, or other screening and generates a computerized reminder to the provider at the time of the patient visit.

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**The electronic medical record has strongly supported performance improvement throughout the VHA.**

When the quality of care in the Veterans Health Administration (VHA) health care system was assessed from 1994 (before re-engineering) through 2000, it was found that quality of care improved dramatically in all domains studied. These improvements were evident from 1997 through fiscal year 2000. Compared with Medicare fee – for –service programs, the VA performed significantly better on all eleven similar health quality indicators for the period from 1997 through 1999. In 2000 the VA out-performed Medicare on 12 of 13 indicators. The VA also out-performed other health systems in the community on standardized measures of health care quality. Performance in the VHA outpaced that of a national sample for both chronic care and preventive care. In particular, the VHA sample received significantly better care for depression, diabetes, hyperlipidemia and hypertension.

The electronic medical record has strongly supported performance improvement throughout the VHA. The VHA instituted a performance measurement initiative nationally in 1996. As a part of this initiative, evidence - based clinical performance measures were identified and performance on these measures was ascertained via an External Peer Review Program (EPRP). In EPRP, a non-VHA contractor abstracts records of a sample of VHA patients from each VHA facility, derived from electronic health records. These measures are incorporated into an annual performance contract, and senior managers are held accountable to meet or to exceed specific performance targets. This VHA performance measurement initiative has been enhanced by the comprehensive electronic medical record system that facilitated the use of electronic decision support such as clinical reminders. The use of these reminders is at the discretion of the local facilities. The search for strategies contributing to high clinical performance measures throughout the VHA showed that the second most commonly cited strategies across all performance categories were clinical reminders (41.4%). The computerized clinical reminders are often based on standing orders and are proven interventions to enhance preventive care (e.g. immunizations, cancer screening).

The significant improvement in the health care provided by VHA was achieved by transformation into a culture based on accountability for continuous improvement of performance. The VA’s superior quality relative to that of Medicare for the period from 1997 through 2000 probably has more to do with the quality—improvement initiatives that were instituted in the mid-1990s than with structural differences.

In conclusion, the re-engineering of the VHA has resulted in dramatic improvements in the quality of care provided to veterans. In fact, the Institute of Medicine recently recommended many of the principles adopted by the VA in its quality improvement projects, including emphasis on the use of information technology and performance measurement and reporting.

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**CORRESPONDENCE**

Tanya Ali, MD  
Providence VA Medical Center  
830 Chalkstone Ave  
Providence, RI 02908  
Phone: (401) 457-3020  
e-mail: tanya.ali@va.gov
Almost one out of ten Rhode Island residents is a US veteran. About 30,000 of them get their care at the VA. Their needs reflect both the aging demographic of World War II and Korean War veterans now in their 80s and younger men and women returning from the Iraq and Afghanistan wars. The veteran population also tends to be sicker, with more medical conditions, overall poorer health, and to use more medical resources than the US general population.1

From a primary care perspective, caring for today’s veteran requires a focus in three core areas: (1) chronic disease management including early detection, reducing the risk of disease progression and preventing/treating acute exacerbations; (2) the interface between public health and clinical medicine which encompasses everything from universal screening for post traumatic stress disorder, depression and substance abuse to implementing a first-line response to the H1N1 pandemic and promoting weight reduction and smoking cessation; and (3) the capacity to address health disparities and the needs of vulnerable populations disproportionately represented in veteran populations.2

To address these areas, primary care within the VA began a major transformation about 15 years ago in its organization.3 VA-based care is organized around the Patient-Centered Medical Home (PCMH) Model. Every veteran is assigned a primary care provider and clinical team. Comprehensive care is coordinated within an integrated medical system model that promotes continuity along with population and patient-based disease management and health promotion.4 A comprehensive electronic medical record system allows for timely communication across services as well as care planning, population tracking, and clinical feedback. It also allows the provider to have access to records of all care across all VA facilities nationwide. Together the medical home model and electronic medical record provide the capacity and tools needed to apply the Chronic Care Model within a primary care setting: promoting patient self-management, engaging community resources, use of decision support, optimizing organization of care, tailoring delivery systems to chronic disease care, and utilizing clinical information systems for population health.5

At the Providence VA, about 18,000 patients receive care at the Providence Medical Center campus; the remaining 12,000 patients receive their care in one of three Community-Based Outpatient Clinics (CBOCs) located in Middletown, RI, New Bedford, MA and Hyannis, MA. In 2006, the Providence VA Primary Care Service underwent a further reorganization to better align itself with VA objectives and to prepare for anticipated challenges facing our veterans. Three initiatives stemming from this reorganization are described in further detail.

VA-based care is organized around the Patient-Centered Medical Home (PCMH) Model.

THE VA PRIMARY CARE MEDICAL HOME

Core to the primary care reorganization was the need to strengthen the medical home model as a treatment entity. This required re-organizing the existing “Firm” system into smaller clinical units of 3,500 to 4,500 patients each and re-assigning clinical staff to increase the number of “hands-on” providers involved in day-to-day patient care. Each patient is assigned to a primary care provider and a medical team based on specific needs and preferences. Each general medicine clinic team consists of 4-5 primary care providers, an RN, 2 nursing assistants and a shared social worker and LPN. In addition, intensive metabolic disease management and cardiac risk reduction clinics are available for short term intensive management of patients with difficult-to-control diabetes and hyperlipidemia, telehealth services are available for high-risk patients, and an integrated primary care-mental health team can assist in the on-site management of patients presenting with depression or anxiety disorders. Monthly clinical reports drawn from the electronic medical record are provided to each clinician, RN and team that includes aggregated chronic disease management measures (most recent blood pressures, LDL and hemoglobin A1C) and a listing of all outlier patients in that team. These data are used in bi-weekly team meetings to both promote effective care planning and serve as the benchmark for team-based quality improvement initiatives. Since implementing this care structure in 2006, we have seen a significant improvement in chronic disease management performance and the proportion of patients at target for blood pressure, lipid and diabetes control, exceeding both national VA targets and community standards.

PROMOTING PATIENT SELF-CARE

A significant component of the Chronic Care Model is the promotion of patient self-care and self-empowerment. Patients who are able to assume more proactive roles in their care tend to feel better and have better care outcomes.7 To help achieve this goal, we established several self-care initiatives within primary care that can be accessed independent of a PCP referral and are intended to promote enhanced chronic disease self-management or disease prevention goals. Structured as either group or individual education and/or medication management sessions, they include: (1) MOVE, a program led by the PVAMC dietician service to assist patients trying to lose weight; (2) Smoking Cessation Program, co-led by a primary care provider and clinical pharmacist and structured as a walk-in group session with follow-up one-on-one counseling and medication prescribing; (3) Diabetes Self-Management groups led by a diabetes nurse educator; (4) Economic Hardship Program led by the primary care clinical social workers to assist patients having difficulties following through on prescribed medical care due to financial hardship; and (5) a Caregiver Support Group led by the Special Populations social worker to assist families of loved ones suffering from Alzheimer’s...
Disease. Taken together, these efforts are intended to complement the efforts of the clinic team, improving compliance and patient satisfaction.

THE ENHANCED MEDICAL HOME FOR VULNERABLE POPULATIONS

Within the VA as well as in our country, vulnerable populations of patients have difficulty accessing care, navigating the health system or have specific health needs that are difficult to address in traditional settings. For example, veterans represent between one quarter and one third of all adult homeless and have well documented challenges accessing care with resulting high rates of premature morbidity and mortality. Similarly, veterans with serious persistent mental illnesses (e.g. schizophrenia, bipolar disorder) have repeatedly been shown to have a higher physical health disease burden and difficulty engaging in primary care.

Female veterans suffering from post traumatic stress disorder have both poorer health and higher rates of hospitalizations and emergency department visits underscoring specific and unique challenges in developing care models for this population. Finally, the fastest growing population within the VA are veterans >80 years old, many of whom are cognitively impaired, frail, and at high risk for hospitalization and institutionalization. Together, these four groups have substantially more co-morbidity, use emergency departments and inpatient medical services at much higher rates and have much worse health outcomes.

As part of the reorganization of the Providence VAMC Primary Care Service, we tailored clinical programs based on the Medical Home model to better engage each of these “high risk populations” in treatment and to optimize clinical and social outcomes. The Homeless Oriented Primary Care Clinic was established in November, 2006 followed by the Geriatrics Primary Care Clinic in July, 2007. A clinic for female veterans suffering from PTSD or military sexual trauma was also started in 2007. The Serious Mentally Ill (SMI) clinic, co-located with mental health, was established in the Fall of 2007 for patients with serious persistent mental illnesses who were unable to successfully access and/or navigate the general medicine primary care clinics. The clinics are defined by four consistent features: (1) Access to care is modeled after the needs of that population. For example, the homeless clinic operates as an open-access model with no appointments needed on fixed clinic days to accommodate the difficulties many homeless persons have keeping appointments set within narrowly defined times. The SMI clinic is co-located within the outpatient mental health unit and runs concurrently with scheduled mental health appointments to create a more seamless transition from mental to physical health service delivery. (2) All the clinics also have case management incorporated into their care models with the use of patient registries to minimize loss to follow-up. (3) Care within the clinics is tailored to issues relevant to that population. For example, the initial assessment at the homeless clinic specifically queries patients on food security, current sheltering needs and benefits status. There is also a multidisciplinary team on-site during clinic days that includes primary care, a VA housing coordinator, a VA benefits representative, and a mental health practitioner. The Geriatrics Clinic has specific assessments and supports for caregivers of those veterans suffering from Alzheimer’s Disease and other cognitive impairments. (4) Lastly, each clinic team is trained in care nuances and priorities relevant to that population. For the homeless clinic, the emphasis is on harm reduction; for women’s health, on integrated care with a mental health practitioner. The SMI clinic is co-located within the outpatient mental health unit and runs concurrently.

To date, over 800 patients are enrolled in these “special-populations enhanced medical homes” with significant clinical outcomes to date. In all four clinics primary care contacts per patient have increased significantly and the rate of potentially preventable, ambulatory sensitive admissions (e.g., congestive heart failure, COPD) among patients transferred to these clinics has declined by 12%. Chronic disease management has also significantly improved; less than 40% of the patients in the SMI and homeless cohorts were at lipid target (LDL <100) in 2006; now over 70% are at goal. There has also been a 48% reduction in the number of homeless patients accessing the emergency department and a 40% drop in overall ED visits since creating this clinic model. A sophisticated electronic medical record makes possible this data gathering regarding the outcomes of clinic reorganization.

The potentials of an integrated, population-based care system are being realized in the primary care model at the Providence VA. However, our model needs to adapt to the challenges posed by the stagnant economy, the evolving needs of the aging World War II and Korean War era veterans and those new veterans returning home from Iraq and Afghanistan, and the need to provide care in a patient-centered, evidence-based and cost-efficient manner. Health care delivery in the United States is at a watershed moment as policy leaders grapple with burgeoning costs, disparate access and inadequate outcomes. The VA system serves as a model for what can be accomplished and should be referenced in the ongoing health care debate.

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Thomas P. O’Toole, MD, is Chief, Primary Care Service, Providence VA Medical Center, and Associate Professor of Medicine, The Warren Alpert Medical School of Brown University.

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The author has no financial interests to disclose.

CORRESPONDENCE
Thomas P. O’Toole, MD
Providence VA Medical Center
830 Chalkstone Ave.
Providence, RI 02908
e-mail: Thomas.OToole@va.gov
Mental Health Care at the Providence VA Medical Center: Providing Integrated Comprehensive Mental Health Services

Michael G. Goldstein, MD

Though mental health care has always been a core element of the Veterans Affairs (VA) health care system, in recent years mental health care has received greatly increased attention, support and resources from the Veterans Health Administration (VHA). The VHA’s 2004 Comprehensive Mental Health Strategic Plan (MHSP) included over 200 initiatives designed to enhance mental health care and integrate mental health care with other VHA healthcare services, particularly in Primary Care. The MHSP led to the funding of the VA’s Mental Health Enhancement Initiative, which allocated funds to create a number of new mental health services and the expansion of several others at PVAMC.

The VHA Handbook, Uniform Mental Health Services in VA Medical Centers and Clinics, issued in June 2008 and updated in September 2008, establishes minimum clinical requirements for VHA mental health services and serves as a blueprint for the implementation of the MHSP at all VA Medical Centers. The Uniform Mental Health Services initiative seeks to create “a system providing ready access to comprehensive, evidence-based mental health care.” The handbook outlines those services that must be provided at each VA Medical Center (VAMC), as well as the general principles that must guide the delivery of all mental health care.

These principles include: 1) mental health care is an essential component of overall health care; 2) mental health care must be integrated or coordinated with other health care, especially primary care; 3) care must be patient-centered, recovery-focused and strength-based and must emphasize the importance of engaging patients in decision-making, treatment planning and self-management; 4) clinicians must be culturally competent, including having an understanding of military and veterans’ culture; 5) care should be evidence-based and consistent with current research and practice guidelines; 6) family involvement in care and treatment decisions should be offered when desired by the veteran; and 7) program and services should be linked to programs and resources in the community to enhance the veteran’s access to these resources and to allow him or her to become a more engaged and supported member of community-based social networks.

In this paper, we will provide several examples of these new services.

The Growth of Mental Health Services at the PVAMC

Of the 30,000 veterans enrolled at the PVAMC, more than 8,000 received mental health care in the fiscal year 2008-2009. We are on track to record over 90,000 outpatient encounters in 2008-9 within a wide variety of outpatient mental health treatment programs. The majority of these veterans are treated at the Providence VA Medical Center’s main campus, while a rapidly growing number of veterans receive care at our 3 Community-Based Outpatient Clinics (CBOCs) in Middletown, RI, and in New Bedford and Hyannis, MA. Veterans requiring supervised living receive clinical and care management services within VA-approved community-based residential care facilities throughout Rhode Island and southeastern Massachusetts. Figures 1 and 2 show substantial growth of our patient population and the number of outpatient mental health encounters at PVAMC over the last 7 years. Since 2003, we have experienced a 68% increase in the number of veterans served and a 58% increase in outpatient encounters. PVAMC supports 115 full time equivalent positions across MHBSS programs, a dramatic increase over the past 7 years. Our staff includes social workers, psychologists, psychiatrists, nurses, pharmacists, administrative/clerical staff and addiction and vocational counselors. We also provide training opportunities for trainees from virtually all these disciplines and we enjoy academic affiliations with the Warren Alpert Medical School of Brown University, the University of Rhode Island, and Rhode Island College.

These increases in patients and staffing are largely a result of significant expansion and enhancement of mental health programs and services at PVAMC, spurred by the VHA’s Comprehensive Mental Health Strategic Plan and Mental Health Enhancement Initiatives. As noted, the VHA is deeply committed to putting mental health care on a par with other health care services. At PVAMC, we are grateful for having received our fair share of enhancement funds from the VHA. Enhancement Initiatives have led to the launching of a number of new services at PVAMC over the last several years, including: the Opiate Treatment Program; an Intensive Outpatient Substance Abuse Treatment Program; a Mental Health Intensive Case Management (MHICM) program for patients with serious and persistent mental illness, based on the evidence-based Assertive Community Treatment model; a Returning Veterans Mental Health program; an Integrated Mental Health-Primary Care Program.
MEDICAL SERVICES HANDBOOK

ASSISTING VETERANS WITH MENTAL HEALTH PROBLEMS

Mental Health for Returning Veterans 1

The VHA Uniform Mental Health Services Handbook ambitiously requires that all veterans who are homeless, or at risk for homelessness, must be offered shelter through collaborative relationships with providers in the community. Facility staff must ensure that homeless veterans have a referral for emergency services and shelter or temporary housing. To meet this mandate, MHBSS staff at PVAMC administer a range of programs, including: outreach and linkages with local shelters and community agencies that offer emergency shelter and provisions to homeless veterans; participation in the homeless primary care clinics developed by Dr. O’Toole and described in this issue; a Grant and Per Diem transitional housing program that includes 24/7 on call support and case management; and a Department of Housing and Urban Development (HUD)-VA Supported Housing (VASH) Program. The HUD-VASH Program is noteworthy. Through a partnership agreement, HUD provides permanent rental assistance vouchers to homeless veterans referred by MHBSS social workers. MHBSS social workers also provide case management and other clinical services to veterans in this program. A case worker is provided for every 35 veterans who receive HUD-VASH vouchers. In the last year, PVAMC staff distributed 35 HUD-VASH vouchers to local veterans and their families; in the coming year we expect to provide another 100 vouchers. During this same period, 159 patients were placed in the Grant Per Diem transitional housing program.

RECOVERY-FOCUSED CARE

An emphasis on recovery-focused care is consistent with recent efforts, within and outside the VA, to shift the focus of mental health care from traditional clinician-centered goals (e.g., symptom management, medication taking, following through with treatment) to broader, patient and family-centered goals that include increased social functioning and integration within the patient’s community. According to the National Consensus Statement on Mental Health Recovery, “Mental health recovery is a journey of healing and transformation enabling a person with a mental health problem to live a meaningful life in a community of the person’s choice while striving to achieve ... full potential.” Within the VA, clinicians are encouraged to promote 14 fundamental components of recovery-focused care: 1) self-direction; 2) individualized and person-centered; 3) empowerment; 4) holistic; 5) non-linear; 6) strengths-based; 7) peer support; 8) respect, 9) responsibility; 10) hope; 11) privacy; 12) security; 13) honor; and 14) support for VA patient rights.

In 2007, each VA medical center, including PVAMC, appointed a Local Recovery Coordinator (LRC), who is responsible for promoting the integration of recovery principles into all mental health services pro-
vided at PVAMC and providing training and consultation to facility leadership, staff, veterans, and family members. At PVAMC, our LRC conducted or supported multiple training sessions for MHBSS staff in recovery-focused principles and strategies. Of note is the close alignment between the recovery-oriented model of mental health care and the patient-centered, empowerment, patient activation and self-management models that have been associated with enhanced outcomes of care when adopted within primary care settings. Dr. O’Toole, Chief of Primary Care at the PVAMC, discusses the integration of these patient-centered models into primary care in this issue.

The growth and expansion of the PVAMC’s Veterans Resource and Recovery Center (VRRC) provides veterans with programs and services designed to enhance their social, behavioral and vocational skills. Vocational programs include Compensated Work Therapy (CWT), Transitional Work Experience (TWE), Supported Employment (SE) and Incentive Work Therapy (IWT). These occupational rehabilitation, maintenance and therapeutic programs are designed to: 1) assist the veteran to develop skills needed to return to competitive work; 2) facilitate the veteran’s transition into the workforce at-large; and (3) assist the veteran to engage in other activities that enhance self-esteem, self-worth and gainful activity. Other VRRC programs linked to the occupational programs include Job Club, Computer Lab, Horticultural Program, the Vet-to-Vet Peer Support Group Program, and the WRAP self-management support skills groups. The PVAMC VRRC has enrolled scores of veterans into its rehabilitative and recovery-focused programs. Each year the VRRC programs place approximately 30 veterans into permanent jobs in the community.

MH-PC INTEGRATION

The VHA’s Uniform Mental Health Services Handbook stipulates that all VA Medical Centers have integrated mental health services co-located within primary care clinics. These programs must utilize a blended model that includes collaborative care and care management programs. To meet this mandate, the PVAMC has co-developed an integrated Mental Health-Primary Care (MH-PC) program staffed by psychologists, social workers, psychiatric clinical nurse specialists and a consulting psychiatrist to work alongside primary care colleagues to meet the mental health needs of patients in primary care clinical settings. Primary care providers routinely employ mental health diagnostic screening protocols for substance abuse (including tobacco), depression and PTSD. Embedded mental health staff are available within the primary care setting to accept “warm hand-offs” and provide follow-up mental health assessments, psychopharmacologic consultations, depression care management, brief on-site treatment of mental health conditions, smoking cessation interventions, and referral to more intensive mental health services when indicated. Programmatic efforts to enhance patient self-management of chronic medical conditions, manage chronic pain, address adherence to medical treatment and reduce risky health behaviors (e.g., sedentary behavior, obesity) are being co-developed by primary care and mental health staff at the PVAMC. In his article, Dr. O’Toole describes several efforts at PVAMC to tailor services to meet the combined mental health and primary care needs of 4 especially vulnerable populations.

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Michael G. Goldstein, MD, is Chief, Mental Health and Behavioral Sciences Service, Providence VA Medical Center, and Professor of Psychiatry and Human Behavior, the Warren Alpert Medical School at Brown University.

Disclosure of Financial Interests

The author has no financial interests to disclose.

Correspondence

Michael G. Goldstein, MD
Providence VA Medical Center
830 Chalkstone Ave.
Providence, RI 02908
Phone: (401) 273-7100 x3156
E-mail: Michael.goldstein2@va.gov

...of the OEF/OIF [Afghanistan and Iraq] veterans entering VA health care from 2002-2008, approximately 37% received mental health diagnoses...

Conclusion

The Mental Health and Behavioral Sciences Service (MHBSS) at the Providence VA Medical Center (PVAMC) provides an array of services, resources and programs to meet the mental health, psychosocial and behavioral health needs of veterans in Rhode Island and Southeastern Massachusetts. Recovery-focused, veteran-centered, evidence-based mental health care is offered in a variety of settings including an acute inpatient unit, general and specialty outpatient mental health units, innovative integrated Mental Health-Primary Care Programs, residential programs for homeless and seriously mentally ill veterans, special programs for veterans returning from current conflicts in Afghanistan and Iraq, and a Veterans Resource and Recovery Center, which offers vocational, rehabilitative and self-management services. Through links and partnerships with community and military service organizations, the PVAMC also provides educational and preventive services to veterans and their families. We are planning the expansion of services in geriatric mental health care, outpatient detoxification, mental health care for women veterans, peer-peer interventions, family involvement in care, and primary care-based interventions to enhance chronic illness self-management and health risk behavior change. The VA’s approach to providing integrated and comprehensive mental health care serves as a model for a publicly funded public health care system.
Military Blast Injury In Iraq and Afghanistan: The Veterans Health Administration’s Polytrauma System of Care

Stephen T. Mernoff, MD, FAAN, and Stephen Correia, PhD

The proportion of veterans cared for by the Veterans Health Administration (VHA) is rapidly shifting to those deriving from the Gulf War, which began in 1990 and the Global War on Terror, which began in 2001. The conflicts in Afghanistan (Operation Enduring Freedom, OEF) and Iraq (Operation Iraqi Freedom, OIF), have produced 1,016,213 veterans; and 454,121 of them have received care through the VHA as of the second quarter of 2009.2 As of July 31, 2009, 3980 US service members have been killed and almost 35,000 have been wounded in action in OEF/OIF.3 Explosive blasts have accounted for about 60% of these injuries.3–5 Other mechanisms of injury include projectiles (bullets, shrapnel), motor vehicle collisions, falls, and non-combat-related assaults. Service members are surviving combat injuries at much higher rates than in past conflicts3 and a high percentage of these individuals have traumatic brain injury (TBI), which has led to TBI’s label as the “signature injury” of OEF/OIF.4 Estimated rates of TBI in OEF/OIF reported in the media vary widely with some being alarmingly high. However, empirical support for these estimates is limited due to the small sample size, reliance on self-report data, use of data derived from a single center, and restrictive inclusion criteria.5 Epidemiological data for injuries in these conflicts continues to develop but a rigorous scientific study of the prevalence of TBI has not been done.5

Blasts, TBI, and PTSD in the Military Population

Blasts are by far the most common cause of wounded-in-action injuries and death in OEF/OIF.5,6 The majority of blasts are from improvised explosive devices. The most commonly involved organ systems include skin and muscle, skeletal, pulmonary, gastrointestinal, cardiovascular, vestibular, and neurological including brain, spinal cord, and peripheral nerves.

The mechanisms by which blasts cause TBI are unclear but likely arise from a combination of primary and secondary effects. The primary effect derives from the blast pressure wave. Evidence that these pressure waves can cause brain injury derives from animal studies.7,8 Secondary effects contributing to blast-related TBI include impact from projectiles launched by the blast or from the victim striking his or her head against the ground or other stationary objects as a result of the blast.

The definition of mild TBI (mTBI) adopted by the VHA and Department of Defense (DOD) is based on the 1993 American Congress of Rehabilitation Medicine criteria:

Mild traumatic brain injury is a traumatically-induced structural injury or physiological disruption of brain function resulting in one of the following: brief alteration in consciousness (dazed, disoriented, or confused), or loss of consciousness (LOC) of 30 minutes or less, or 24 hours or less of posttraumatic amnesia (PTA, i.e., a loss of memory for the period surrounding the event that may occur with or without LOC).

It is unknown whether the nature or prognosis of blast-related mTBI differs from other causes of mTBI. Recent data suggest that the cognitive profiles of patients with blast-related vs. impact-related mTBI are similar.9 Blast-related mTBI may have a stronger association with PTSD than other causes of mTBI.8 Recent studies have demonstrated a high rate of comorbidity with post traumatic stress disorder (PTSD).10–12 As of the first quarter of 2009 approximately 102,000 of OEF/OIF veterans have been diagnosed with PTSD.2

Postconcussive and PTSD symptoms overlap considerably but not completely.13 Shared symptoms include depression/anxiety, insomnia, appetite changes, irritability/anger, concentration difficulty, fatigue, hyperarousal, and avoidance. Symptoms more uniquely associated with persistent postconcussive syndrome include headache, heightened sensitivity to light and sound, dizziness and disequilibrium, and memory impairment. Symptoms that are more unique to PTSD include re-experiencing, shame, and guilt. Nonetheless, accurately parsing the extent to which an individual’s symptoms are attributed to PTSD vs. TBI is difficult, especially when relying on retrospective self-report of a temporally remote event. Many believe that it is more parsimonious and clinically useful to conceptualize these symptoms as a single syndrome rather than two distinct entities. One term that has been proposed is Combat-Related Brain Injury and Stress Syndrome (David X. Cifu, personal communication, October 2007). One of the authors (S.M.) has used the term “Deployment-Related Cognitive Impairment” to refer to the frequent cognitive complaints of inattention and forgetfulness. This term aligns well with previous findings of deployment-related neuropsychological deficits in army personnel deployed in the Iraq war.14

Polytrauma System of Care

The rate of survival of combat injuries in OEF/OIF, including TBI, is approximately 90%15—considerably higher than in previous conflicts. The high survival rate is due mainly to improvements in helmet and body armor and to improved delivery of medical care including battlefield and in-theater hospital innovations.5 This has led to a high number of veterans with re-
Polytrauma Support Clinic Teams (PSCT) are interdisciplinary teams that manage medically stable outpatients with an interdisciplinary treatment plan. Patients are monitored for progress and the team identifies unresolved problems and implements solutions. Eighty one PSCTs have been established nationally.

Polytrauma Points of Contact (PPOC) are staff members at all remaining VA facilities who assist veterans in accessing the Polytrauma system.

Patients can be referred up or down the hierarchy in accordance with their medical needs and the services provided at the various facilities.

POLYTRAUMA SYSTEM: SCREENING FOR TBI

VHA Directive 2007-13 established screening of all service members returning from deployment in OEF/OIF to determine if they had possibly sustained a deployment-related traumatic brain injury that had not already been diagnosed. In response, the VA Polytrauma Program developed a standard, two-tier screening process implemented nationally. The data collected is entered into the VA's electronic medical record system and is tracked nationally.

The initial screen, called the “TBI Clinical Reminder,” is required for all OEF/OIF veterans who enter the VA health care system. The Reminder consists of a set of yes-no questions organized into four sections that determine whether or not the veteran experienced the following: exposure to a deployment-related event with risk for TBI; acute alteration of consciousness; postconcussive symptoms during the immediate post-acute phase; persistence of such symptoms currently. A positive screen is defined as an affirmative response to all four sections; a negative response to any section results in a negative screen. The reliability and validity of the screen have not been established, and is under research investigation.

Veterans who screen positive are referred for a “Comprehensive Second-Level Evaluation” which consists of a standard, more detailed assessment of TBI. It is intended to determine more accurately the likelihood that a veteran sustained a TBI and to estimate the severity of the injury. It also assesses symptoms, elicits clinicians’ opinions about the likelihood that the symptoms reflect the effects of TBI and/or other factors (e.g., psychiatric disorder), and establishes a treatment plan. At most VA facilities, the “Second-Level Evaluation” is performed by a “TBI specialist,” typically a psychiatrist or neurologist, who leads the polytrauma team at that facility.

Except in relatively rare cases in which documentation is available, the initial screen and the Second-Level Evaluation typically rely on patients’ recall of their injuries. This is an important limitation to the system because retrospective self-report of an event or events that occurred many months or years earlier may be unreliable. Moreover, the intense emotional reaction to the chaotic event of a blast may well acutely and transiently alter cognitive function which could masquerade as TBI or enhance its effects and it can be very difficult teasing these factors apart. At the PVAMC, we have adopted a fairly parsimonious clinical guideline for determining the presence of absence of TBI: a patient who can re-late a continuous narrative before/during/after an event seems unlikely to have suffered a physiologic disruption of brain function. We have found this guideline to be quite helpful in ambiguous cases but its reliability and validity have not been determined.

DIAGNOSIS OF TBI IN THE POLYTRAUMA SYSTEM

National Experience (data rounded off to nearest 1000):

The TBI Clinical Reminder was implemented in April 2007. Through May 31, 2009, 316,000 veterans have completed the Clinical Reminder; 63,000 (20%) screened “positive” for possible TBI. Of these, 41,000 completed the Comprehensive Second-Level Evaluation which confirmed the mTBI diagnosis in 20,000 (49%). This estimate does not include an additional 9440 veterans who self-reported having been previously diagnosed with TBI during their deployment.

There is considerable variability across VA Medical Centers in the rate at which mTBI is diagnosed by this process. Potential reasons include variability in the combat roles of military units based in different geographical regions of the U.S. (some combat roles carry...
greater risk for TBI than others), variability in TBI experience of clinicians performing the evaluations, and the institutional learning curve given the fact that the process was introduced relatively recently.

Providence VAMC Experience:

Through May 31, 2009, the PVAMC has screened 1672 veterans with the Clinical Reminder; of these, 262 (15.7%) have screened “positive.” Of these positive screens, 184 have completed the Comprehensive Second-Level Evaluation, which confirmed the mTBI diagnosis in 120 (65%).

Our Polytrauma Team functions as a PSCT (official designation by VHA is pending). The team is led by a neurologist specializing in neurorehabilitation/TBI and includes a social worker/case manager, neuropsychologist, primary care physician, and a psychologist specializing in PTSD, as well as a physical therapist, occupational therapist, speech therapist, ENT nurse practitioner, and hearing and vision specialists. Other disciplines are consulted as needed. The team meets weekly to review veterans new to the Polytrauma Team and to provide periodic review of established patients.

A weekly Polytrauma intake clinic (neurologist, neuropsychologist, social worker/case manager) screens newly referred veterans to identify ongoing problems and develop a treatment plan. In addition, the neurologist and case manager have a weekly Polytrauma/TBI follow-up clinic in which veterans with ongoing medical and psychosocial problems are seen as needed. The majority of patients seen by our team likely sustained mTBI during their OEF/OIF deployment without concomitant severe somatic injuries.

Symptom Management

The most common complaints of patients in the Polytrauma Clinic include pain (mostly headaches and back pain), dizziness, hearing loss/tinnitus, sleep difficulty, anxiety and symptoms of PTSD, and cognitive complaints such as forgetfulness and diminished concentration.

As there is no “specific” treatment for cognitive complaints in mTBI, emphasis is placed on identifying and treating modifiable factors such as PTSD, depression, substance abuse, sleep deprivation, pain, and other factors such as loss of employment and marital distress, that might be contributing to veterans’ symptoms and which, if adequately treated or addressed, could have a positive impact on their quality of life. The Polytrauma Team makes referrals to specialists and VA programs as needed and promotes veterans’ compliance with treatment plans. The most common referrals are to the PVAMC Mental Health and Behavioral Science Service, particularly to the PTSD Clinic, the Returning Veterans Program, the Substance Abuse Treatment Program, and to the Neuropsychology Clinic. Referrals to Physical Therapy and Speech and Language Pathology services (the latter for cognitive retraining) are also common. The Polytrauma Team emphasizes educating patients and their families about the expected trajectory of recovery from mTBI and the possible treatable factors. Such interventions have been shown to reduce the likelihood of patients with mTBI developing persistent postconcussion syndrome.17,18

As of the first quarter of 2009 approximately 102,000 of OEF/OIF veterans have been diagnosed with PTSD.

Mild TBI: Controversies

Hoge et al19 raise several concerns about the DOD/VA process for diagnosis and management of mTBI. First, they postulate that the screening process risks incorrect attribution of non-specific symptoms to mTBI. Second, they suggest that disability may be overly attributed to mTBI, and they raise the possibility that “post-deployment screening is…likely to promote negative expectations for recovery.” They also assert that misattribution of symptoms to mTBI potentially places veterans at risk of negative consequences, including medication adverse effects, failure to adequately address concurrent conditions (e.g., depression, PTSD, substance abuse, etc.), and inappropriate use of rehabilitation procedures. They suggest development of improved definitions and diagnostic criteria and processes.

The VHA’s standardized team approach aims to minimize over-diagnosis and misattribution errors via thorough Second-Level Evaluations that assess for co-existing conditions that may be contributing to symptoms and addressing them appropriately. Many believe that the benefit derived from the thoroughness of this process in identifying and addressing previously untreated symptoms outweighs the risk of over-diagnosis, and that when managed by trained physicians and ancillary providers, the risk of negative consequences is minimal, if present at all. Finally, the data to design improved diagnostic criteria are not yet available.

Conclusions

Veterans of conflicts occurring over the last nineteen years often have complex, multisystem injuries, and a large number are being diagnosed with mild TBI with significant comorbidities including PTSD and somatic injuries, particularly auditory/vestibular injuries. The Polytrauma System of Care is designed to standardize the diagnosis and management of these conditions nationwide. Although making the diagnosis of mTBI requires ongoing assessment, our experience at PVAMC has been that the Polytrauma Team has been effective in bringing veterans with multiple injuries and/or medical conditions into the health care system, helping them access the care they need, and monitoring their progress.

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Stephen T. Mernoff, MD, FAAN, is Chief, Neurology Section, and Leader, Polytrauma Team, Providence VA Medical Center, and Assistant Professor of Neurology (Clinical), The Warren Alpert Medical School of Brown University.

Stephen Correia, PhD, is Neuropsychology Section Chief, Providence VA Medical Center, and Assistant Professor of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University.

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The authors have no financial interests to disclose.

CORRESPONDENCE
Stephen T. Mernoff, MD
Providence VA Medical Center
830 Chalkstone Ave
Providence, RI 02908
e-mail: Stephen.Mernoff@va.gov
Neurorehabilitation Research Laboratory at the Providence VAMC

Albert Lo, MD, PhD

Although there has been tremendous progress in treating neurological injuries and disorders, there remains ample opportunity to improve recovery and to restore function in chronic and progressive conditions, particularly during the acute and subacute phases. As our understanding of neuroplasticity has advanced along with technology, attention has focused on novel methods to augment more traditional procedures to reverse impairment and regain function.

The field of rehabilitative therapy has recently seen an explosion in the development of robotic technology for rehabilitation. A MEDLINE search for therapeutic robotics yields only 15 results prior to 1990, but as of September 16, 2009, there were 2095 results. The consequent technological and methodological advances have been particularly exciting. These devices provide high-volume, repetitive, reproducible, safe therapy and also allow for reliable, instrumented outcomes of motor performance. One of the best examples of such devices with a large quantity of pilot human data is the MIT-Manus (InMotion Technologies, Inc., Watertown, MA), which includes modules for shoulder, elbow and hand. Other upper-extremity robotics include the ARM Guide, the MIME, the InMotion Shoulder-Elbow Robot, and the Bi-Manu-Track. There also exist computer-aided non-robotic therapy orthotics such as the T-WREX, which allows upper-extremity movement with 5 degrees of freedom and passively eliminates the force of gravity via a system of elastics and metal linkages. For the lower extremities, there exist gait training devices such as the Lokomat (Hocoma, Zurich, Switzerland), a body weight-supported treadmill with robotic orthotics which guide the legs through an idealized gait cycle. The Lokomat has been used in research interventions for neurological disorders such as spinal cord injury, stroke, and multiple sclerosis. As with the upper extremity, there also exist more focused devices for the lower extremity, such as the MIT Anklebot (InMotion Technologies, Inc., Watertown, MA), which focuses on training ankle plantar- and dorsiflexion as well as in- and eversion. The data from randomized controlled trials of robotics will yield further improvements in methodology and understanding, allowing rehabilitation centers to provide more efficient and efficacious care. One can imagine an eventual “robotic gym” incorporating highly specialized robots capable of addressing every form and degree of physical and cognitive disability, all run in concert with talented therapists.

Despite the enthusiasm for robot-assisted therapy, there is not yet full understanding of how, when, and in which patient populations these devices should be used. In order to gain the full potential of this new technology, careful clinical research is necessary to establish safe, effective protocols and optimal doses, as well as to eventually understand how these robotic devices should be combined with conventional pharmacological and rehabilitative methods. While robots are a new resource for clinicians to deliver therapy and to measure changes in motor performance, they will likely never replace human interaction, but rather enhance interactions with therapists.

The Neurorehabilitation Research Laboratory at the Providence VA Medical Center, established in the summer of 2007, has been conducting several projects examining the efficacy of robotic technology in improving motor function in individuals with stroke, multiple sclerosis (MS) and Parkinson’s disease. Additionally, our interests have expanded broadly to other projects dealing more inclusively with other aspects of neurological injury, repair, and disability, such as an epidemiological study on MS and another study to develop and improve methods for diagnosis and tracking of cognitive function for mild traumatic brain injury. A summary of our current research is provided below.

Robotic Assisted Upper-Limb Neurorehabilitation in Stroke Patients

A phase II/III multi-center clinical trial funded by the Department of Veterans Affairs is now testing the most advanced MIT-Manus system (including separate shoulder, elbow, wrist and hand modules) in chronic stroke patients with upper extremity impairment. The study was initiated in November of 2006, and enrollment has closed with a total of 127 participants at the VA Medical Centers in Baltimore MD, Gainesville FL, Seattle WA, and West Haven CT. This is the first multicenter randomized-controlled trial to test a robot-assisted rehabilitation device for stroke. The baseline characteristics for the study were just published; final results are expected to be released in early 2010.

Gait & Mobility in Multiple Sclerosis using Robot-Assisted Body Weight Supported Treadmill Training

Impairment in walking is an important source of disability and cause for concern for people with MS. Even at the earliest stages of disease, MS patients have observable gait problems which, in the majority of patients, will progressively worsen. Body weight-supported treadmill training has been identified as a promising gait-specific intervention for MS, and robotic assistance might prove to be a technological enhancement. The inclusion of robotic assistance, such as on the Lokomat, has the added advantage of delivering consistent, guided movement to the legs throughout the gait cycle.

Thirteen MS subjects have completed a randomized, cross-over trial comparing body weight-supported treadmill training with and without robotic assistance on the Lokomat. In that study, participants improved gait velocity and endurance by over 30%. Approximately 20 people have participated in our vari-
ous research protocols using the Lokomat. Additional studies will continue to refine the optimal dose, treatment regimen, and most relevant outcomes; identify the patients most likely to respond; and explore the characteristics and neurological mechanisms of motor recovery. Dr. Elizabeth Triche from the Department of Community Health at Brown University has collaborated on this project and is closely involved in many of the others presented.

ROBOT-ASSISTED TRAINING AND FOOT DROP IN MULTIPLE SCLEROSIS

Our clinical and research experience has suggested that approximately 30% of MS patients experience foot drop. Although gait rehabilitation using the Lokomat can improve ambulation in MS patients, people with foot drop still have difficulty translating task-repetitive gait training to normative gait patterns over ground. One of the key limitations of the Lokomat is a lack of robotic assistance for the ankle joint. The MIT Anklebot has the potential to address that limitation through focused ankle training, but it does not train the knee or hip.

The results of a case-series with 2 MS subjects with foot drop have been published. Additional subjects with MS and foot drop are being recruited to test whether Anklebot therapy alone or in combination with Lokomat results in better mobility. The project is currently enrolling patients. Collaborators include Dr. Hermano Igo Krebs (MIT) and Dr. Jacob Berger (PVAMC, Department of Neurology; Brown University).

ROBOT-ASSISTED GAIT TRAINING AND FREEZING OF GAIT IN PARKINSON’S DISEASE

Parkinson’s disease, the most common movement disorder in neurology, can present with a wide range of motor manifestations, such as bradykinesia, tremor and postural abnormalities. Freezing of gait (FOG) is one of the most disturbing symptoms, but there are no effective treatments for FOG. Studies have shown that uncoordinated, asymmetrical gait and reduced step length are related to FOG, but no group has previously studied the effect of robot-assisted gait training on FOG.

In collaboration with Drs. Joseph Friedman and Victoria Chang, 4 participants have been examined in a pilot study. Pilot data have suggested a reduction in episodes of freezing as well as an improvement in quality of life in Parkinson’s disease as a result of robot-assisted gait training. A larger study is planned.

RHODE ISLAND MULTIPLE SCLEROSIS STUDY (RIMSS)

The Rhode Island Multiple Sclerosis Study (RIMSS) is a community-based epidemiological study of MS in Rhode Island. This project, in collaboration with Dr. Stephen Buka, Brown University Professor of Community Health (Epidemiology), is being conducted as a part of the Brown University BioBank initiative. An initial group of neurologists (Drs. Elaine Jones, Stephen Mernoff, William Stone, Meryl Goldhaber, Mason Gasper, and Syed Rizvi) has generously contributed in a pilot collection of data as well as in gauging potential patient participation. The Rhode Island Neurological Society and the Rhode Island Chapter of the National Multiple Sclerosis Society have also extended enthusiastic support for this project.

Much of MS epidemiology and clinical course has been derived from cohort studies collected outside of the United States or from short-term pharmaceutical clinical trials: these sources may have inherent biases that limit their usefulness to typical patients in the United States. The RIMSS study proposes to establish a prospective population-based cohort study of MS, collecting rich epidemiologic and clinical data critical to both scientific understanding and accurate treatment. Overall goals include enumerating and providing accurate data on incident and prevalent cases of MS, as well as collecting demographic and diagnostic data from medical records. Study data will describe the distribution of physical and cognitive disability, symptomatic areas, magnetic imaging changes, disease subtypes, duration of disease, quality of life, and treatment with disease modifying agents. The second phase is a longitudinal examination which will follow a group of recently diagnosed patients with genetic, neuroimaging, clinical and patient-related outcomes. The scope of this multidisciplinary study provides an opportunity to build a unique MS cohort based in Rhode Island to capture critical information and thus better understand the clinical and epidemiological characteristics of MS in the United States.

NEW RAPID ASSESSMENT OF MILD TRAUMATIC BRAIN INJURY

As Mernoff and Correia report in this issue, there are no rapid, reliable, valid, and easily administered tests to gauge attention and executive cognitive capabilities following mild traumatic brain injury (mTBI). Multiple investigators at Brown University and the Providence VAMC (Drs. Stephen Correia, Leigh Hochberg, Albert Lo, Stephen Mernoff, Michael Worden) are currently developing an easily administered computerized assessment of attention, cognition and motor reaction.

The aforementioned projects have attracted the interest of neurology residents, fellows, graduate students, and undergraduates, all of whom sense the excitement and importance of applying the best technology and methodology toward restoring function in individuals with severe disability from neurological disorders. In addition to the physicians and scientists with whom we collaborate at Brown and the Providence VAMC, our laboratory includes postdoctoral fellow Tara Patterson, PhD, as well as full time research assistants and program coordinators Milena Gianfrancesco, Douglas Benedicto, and Elizabeth Jackvony, MPH.

Neurorehabilitation research is responsive to the health needs of veterans. The Providence VAMC has supported this unique research, and the Neurorehabilitation Research Laboratory looks forward to completion of the Center for Restorative and Regenerative Medicine which will soon be the new site for this research.

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14. Albert Lo, MD, PhD, is Staff Neurologist, Providence VA Medical Center, and Assistant Professor of Neurology at The Warren Alpert Medical School of Brown University.

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The author has no financial interests to disclose.

Correspondence
Albert Lo, MD, PhD
Providence VA Medical Center
830 Chalkstone Ave.
Providence, RI 02908
e-mail: Albert_Lo@brown.edu
A 65-year-old woman presented to a hospital with confusion, shortness of breath, and ecchymotic skin lesions. She was afebrile. Her hemoglobin was 3.6 g/dL (normal [nl] 11-15 g/dL), platelet count was 62 x 10^3/mm^3 (nl 150-450 x 10^3/mm^3), white blood cell count was 5.9 x 10^3/mm^3 (nl 3.5-11 x 10^3/mm^3), mean corpuscular volume (MCV) was 114 fl (nl 80-99 fl), creatinine was 1.9 mg/dL (nl 0.4-1.3 mg/dL), and serum lactate dehydrogenase (LDH) was 2,200 IU/L (nl 50-175 IU/L). Based on her confusion, anemia, thrombocytopenia, and elevated serum creatinine and LDH, a diagnosis of thrombotic thrombocytopenic purpura (TTP) was made.

The patient received four units of packed red blood cells and was transferred to our hospital for urgent plasma exchange (PEX). Upon arrival, her history was unremarkable while physical examination was notable for tangential speech, conjunctival pallor, slight macroglossia, and ecchymotic areas on her extremities. Cardiopulmonary exam was normal and there was no lymphadenopathy or hepatosplenomegaly.

The patient’s peripheral blood smear showed 1% to 5% schistocytes per high-power field that further suggested a microangiopathic process. However, macroovalocytes, hypersegmented neutrophils, polychromasia, and occasional teardrop cells were observed. (Figure 1). The patient received 2 units of fresh frozen plasma (FFP) to correct her coagulopathy and to partially replenish her presumptively low ADAMTS13 while a serum cobalamin level and anti-IF antibody were checked. The patient was empirically given a dose of intramuscular cyanocobalamin.

The patient’s serum cobalamin level returned at 51 pg/ml (nl 211-911 pg/ml) and her anti-IF antibody was positive. After fourteen days of intramuscular cobalamin her peripheral blood smear showed resolution of megaloblastic changes and her mental status and ecchymotic areas improved.

Figure 1. Peripheral blood smear of our patient with hallmarks of cobalamin deficiency. There is marked anisopoikilocytosis. Ovalocyte (1), macroovalocyte (2,3), hypersegmented neutrophil with 5 lobes (4), schistocyte (5) and teardrop cell (6).
Peripheral blood smear and rapid confirmatory laboratory testing, PEX may be avoided in patients presenting with severe cobalamin deficiency mimicking TTP.

Clinicians should be aware of unusual clinical presentations of cobalamin deficiency masquerading as a serious microangiopathic hemolysis. The prompt recognition, diagnosis, and treatment of cobalamin deficiency is vital because therapy is safe, inexpensive, and corrects hematologic abnormalities while bringing about a complete or partial correction of the neuropsychiatric abnormalities in the majority of patients.

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Samir Dalia, MD, is a resident in internal medicine.
Cannon Milani, MD, is a Fellow in Hematology/Oncology.
Jorge Castillo MD, is Assistant Professor of Medicine, Department of Hematology/Oncology.
Anthony Mega, MD, is Associate Professor of Medicine (Clinical), Department of Hematology/Oncology.
Fred J Schiffman, MD, is Professor of Medicine, Department of Hematology/Oncology.
All are at the The Warren Alpert Medical School of Brown University.

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The authors have no financial interests to disclose.

CORRESPONDENCE
Samir Dalia, MD
The Miriam Hospital
164 Summit Ave
Providence, RI 02906
Phone: (401) 444-4000
e-mail: sdalia@lifespan.org

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Dear Colleague,

This past summer marked a historic victory for anti-tobacco advocates. On June 22, 2009, President Obama signed into law the new Family Smoking Prevention and Tobacco Control Act giving the U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products and stop the harmful practice of marketing tobacco to children. This law will help significantly reduce the number of children who start to use tobacco, the number of adults who continue to use tobacco, and the number of people who die as a result.

While this is all good news, it is evident that the Family Smoking Prevention and Tobacco Control Act cannot by itself put an end to tobacco use. Its intent is to complement, not replace, the successful work that we have been doing over the years to educate our children about the importance of being tobacco-free. Interestingly enough, in late August, major tobacco manufacturers filed suit to overturn portions of the new law, specifically the restrictions on advertising, marketing and labeling of tobacco products.

Since there is more that can be done, the Rhode Island Medical Society would welcome your support of our Tar Wars Rhode Island Program, the national tobacco-free educational program developed by the American Academy of Family Physicians. We are looking for physician presenters to volunteer to talk with students about the dangers of tobacco use. The program involves teaching an hour-long lesson to the students (RIMS provides you all materials); and then returning to the school to judge a half-hour poster contest. The Tar Wars flyer provides further details about the Tar Wars program as well as details about the Family Smoking Prevention and Tobacco Control Act. You can also go to www.tarwars.org for more information.

If you are interested, please contact Catherine Norton at 528-3286 or cnorton@rimed.org. We anticipate school presentations to be scheduled during the months of January, February, and March 2010. We also have available for your use, “How to Present Tar Wars Guidelines.”

Thank you for your support!

Sincerely,

Arthur A. Frazzano, MD
Past President
Tar Wars Rhode Island

Tar Wars, a national tobacco-free educational program developed by the American Academy of Family Physicians, is coordinated locally by the Rhode Island Medical Society, the Rhode Island Academy of Family Physicians, and the Rhode Island Chapter of the American Academy of Pediatrics.
Sudden Cardiac Death and Implantable Cardioverter Defibrillations (ICD) and the Older Adult

Omar Hyder, MD, and Obad Ziv, MD

Sudden cardiac arrest (SCA) usually results from a hemodynamically unstable heart rhythm-ventricular fibrillation or ventricular tachycardia. Failure or absence of resuscitation results in sudden cardiac death (SCD). There are 450,000 cases of SCD annually in the United States. Rate of survival following SCA has not changed over the past three decades. Survival after hospital discharge, however, has improved, partly due to the development of implantable cardioverter defibrillators (ICDs). In 2005, the Centers for Medicaid and Medicare Services estimated that 500,000 Medicare beneficiaries were candidates for ICD placement. ICD prescription in elderly patients entails particular considerations, given common co-morbidities and higher rates of non-cardiac mortality. ICD implantation should not be regarded as routine in elders; each case should be considered individually. Geriatricians and other primary care physicians play a key role in the judicious selection of candidates for this potentially life-saving therapy.

Risk of SCD in Elderly

The prevalence of coronary artery disease (CAD) increases with age, along with risk of SCD. The proportion of CAD deaths attributed to SCD, however, decreases with age. In the Framingham study, 62% in men aged 45-54 years old who died of CAD experienced SCD. This percentage fell to 58% in men aged 55-64 years and to 42% in men aged 65-74 years. Congestive heart failure is responsible for a higher proportion of deaths in the elderly population. Advanced age, however, is associated with a poor outcome following cardiac arrest. In a review of 5,882 cases of out-of-hospital cardiac arrest, octogenarians experienced a hospital discharge rate of 9%, compared to 19% in a younger group. In a second series of 12,000 patients treated by emergency medical service personnel for SCA, every one-year increase in age was associated with a significantly lower likelihood of survival.

Indications for ICD Prescription

Over the past two decades, studies identified ICDs as an effective prevention strategy of SCD. In survivors of SCA, ICDs are the secondary prevention strategy of choice. Patients at high risk also benefit from prophylactic ICD implantation. The MADIT II and MUSTT studies demonstrated a survival benefit in patients with reduced ejection fraction (<35%) and history of CAD when ICDs are utilized as a primary prevention strategy. The SCD-HeFT trial expanded this population to include patients with an ejection fraction <55%, irrespective of CAD history. Patients with severe symptomatic heart failure and life expectancies less than 6 months were excluded from these studies. The mean age of participants ranged between 60 and 66 years, and the majority of these patients suffered heart failure symptoms.

Mortality Benefit of ICD Therapy in Elderly

No randomized control studies investigate the role of ICDs specifically in older adults. Major trials include significant numbers of older patients; mean participant age ranged between 60 and 66 ± 10 years. Post-hoc subgroup analysis investigating role of ICD in these patients was performed in two major primary prevention trials. The MADIT-II trial demonstrated a 31% relative risk reduction of all-cause mortality in ICD recipients, compared to recipients of anti-arrhythmic medications. Subgroup analysis of the MADIT-II population indicated that ICD recipients older than 75 years experienced a 46% relative risk reduction in mortality. In the SCD-HeFT trial, despite greater mortality reduction in patients younger than 60 years, ICD implantation was still the superior primary prevention strategy in patients older than 65.

Similar mortality benefit of ICD placement is demonstrated in elderly survivors of cardiac arrest. Two of the three major secondary prevention trials performed post hoc subgroup analyses based on age. In the largest of these trials, Anti-arrhythmic Versus Implantable Defibrillators (AVID), ICD placement was associated with reduction in mortality, regardless of age at time of device implant. Mean age in the AVID study was 65 ± 10 years. In the Canadian Implantable Defibrillator Study (CIDS), patients older than 70 derived greatest benefit from ICD implantation.

Patients with terminal diagnoses, multiple co-morbidities and severe symptomatic heart failure were excluded from the above trials. Clinical characteristics of excluded patients have not been published. Although smaller studies demonstrate a reduction in SCD regardless of age, rates of non-cardiac death are higher in the elderly population. In one single center study, ICD placement eliminated risk of SCD in older and younger patients alike. However, survival at four years was 57% and 78% in patients older and younger than 75 years, respectively. In retrospective studies reporting pre-selection of healthy elderly patients with good functional status, overall survival is similar among older and younger ICD recipients. The role of ICD in elderly patients with multiple illnesses has yet to be determined, as they are underrepresented in trials that shape current guidelines.

Data are lacking to identify specific co-morbidities, lab criteria or age limits that preclude ICD implantation in older patients. Patients with irreversible terminal prognoses are not considered for ICD implantation. Furthermore, patients with severe symp-
Automatic heart failure were excluded from the landmark trials, and are not considered for routine ICD placement if mean expected survival is less than 6 months. Elderly patients with renal disease are a population that may derive diminished mortality benefit from ICD 13 although chronic renal failure was not an exclusion criterion in major trials. There are no age restrictions on ICD implantation, although octogenarians are underrepresented in trials despite the fact they constitute 28% of possible ICD recipients. 20 As a result, patients with multiple co-morbidities must be considered for ICD placement on an individual basis. Furthermore, for the elderly patient, as with all patients, ICD implantation requires careful assessment of the individual's estimated risk of cardiac arrest based on the patient's risk profile. 15

**Procedural Complications**

Peri-operative risks of ICD implantation include, but are not limited to infection, system malfunction requiring a repeat procedure, pneumothorax, tamponade and, rarely, death. A limited number of studies have investigated age differences in complication rates. Available data suggest that safety of ICD implantation in the elderly patient is comparable to a younger population. One observational study from a decade ago reports a similar rate of peri-operative death of 2% and 3% in patients younger and older than 65 years, respectively. 16 Exclusion of older generation devices implanted via a thoracotomy reduces peri-operative death to less than 1% in both groups. A more recent study corroborates these findings; peri-operative mortality was less than 1% in patients younger and older than 70 years 8 Based on these data, placement of this generation of ICDs is considered safe in patients of all ages.

**Quality of Life and End-of-Life Issues**

Studied investigating quality of life have found either no change or an improvement following ICD implantation. 17,18,19 Numerous ICD shocks, history of anxiety disorders and preexisting poor functional status are associated with poor quality of life following implantation. Advanced age is not identified as an independent predictor of compromised quality of life in the above studies. As a result, a careful review of a patient's co-morbidities and preexisting functional status must be considered prior to ICD implantation. Patients must be counseled about the potential for painful ICD discharges. Despite the discomfort associated with discharges, a high rate of acceptance of ICD therapy is reported in device recipients. Patients should also be informed that ICD therapy is not a permanent prevention strategy, and devices can be explanted or simply deactivated at the patient's discretion. Furthermore, patients and families should be informed that ICDs reduce risk of SCD, but do not prevent death from other causes.

Management of ICD at the end of life requires specific counseling to the patient and family. Frequency of shocks may increase as a result of multiple terminal tachy-arrhythmias. This can be a source of severe discomfort to both patient and family. If the patient or proxy is amenable, ICDs should be deactivated when at the end of life. Unfortunately, this practice is not routinely performed. Interviews conducted with family members of deceased ICD recipients revealed that counseling regarding deactivation of devices did not occur in 75% of cases. 20

**Conclusions**

Older patients are at higher risk of SCA, and have low survival rates following an episode. ICDs are the strategy of choice in the primary and secondary prevention of SCD. ICD placement in patients with multiple co-morbidities should be evaluated judiciously, as these individuals are underrepresented in major trials that define accepted guidelines. Complication rates in older patients are similar to younger cohorts. The data also suggest either no impact or an improved quality of life among ICD recipients, regardless of age. In the elderly population, device implantation should not be considered routine. Decisions should be made on a case by case basis, taking into consideration the patient's wishes, co-morbidities and estimated risk of cardiac arrest.

**References**


Omar Hyder, MD, is House Staff Officer in Internal Medicine, Rhode Island Hospital.

Ohad Ziv, MD, is Clinical Instructor in Internal Medicine, The Warren Alpert Medical School of Brown University.

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The authors have no financial interests to disclose.

**Correspondence**

Omar Hyder, MD
Phone: (401) 533-2070
e-mail: ohyder@lifespan.org

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Intimate partner violence (IPV) can be any form of physical, psychological, economic, verbal, or sexual abuse by current and former spouses and dating partners. Each year in the United States, IPV affects approximately 1.5 million women, including as many as 324,000 pregnant women. IPV during pregnancy can lead to unintended pregnancy, smoking, depression, premature delivery, vaginal bleeding, miscarriage, and serious physical injury or even death of the mother and fetus. The American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA), and the American Academy of Family Physicians (AAFP) recommend routine screening of all women for IPV.

This report describes 1) the prevalence of IPV before or during pregnancy in Rhode Island and 2) the associations of IPV with maternal health and well-being.

METHODS
Data from the 2004-2007 Rhode Island Pregnancy Risk Assessment Monitoring System (PRAMS) were analyzed to assess IPV before or during pregnancy. PRAMS, a surveillance project of the Centers for Disease Control and Prevention (CDC) and state health departments, collects state-specific, population-based data on maternal behaviors and experiences before, during, and after delivery of a live infant. During 2004-2007, a total of 5,662 women completed the survey, with an average 73.8% weighted response rate. (Response rates were weighted to account for the sample design and unequal probabilities of selection of the survey.)

Four survey questions focused on physical abuse by partner/ex-partner or husband/ex-husband: two concerned the year prior to pregnancy and two the months of pregnancy. Physical abuse includes pushing, hitting, slapping, kicking, choking, or other forms of physical hurting. Maternal health and well-being were assessed by the presence or absence of health risk behaviors (delayed or no prenatal care, smoking during and after pregnancy, unintended pregnancy, no current breastfeeding, alcohol use during pregnancy) and pregnancy complications (vaginal bleeding, urinary tract infection, severe nausea, vomiting or dehydration, preterm or early labor, premature rupture of membranes (PROM), diagnosed depression during pregnancy). PRAMS data were weighted and analyzed to estimate the prevalence of IPV, 95% confidence intervals (CI), p-values, and adjusted odds ratios (aOR). Data analyses were performed using SUDAAN software, which accounts for the complex sample design of the survey. All unknown and missing responses were excluded from the analysis.

RESULTS
Prevalence of IPV
Overall, 5.5% of RI women reported physical IPV before and/or during the most recent pregnancy: 4.2% for before pregnancy and 3.2% for during pregnancy. (Figure 1) IPV was significantly higher among teenagers (14.3%), Hispanics

| Table 1. Prevalence of Intimate Partner Violence before/during Pregnancy by selected characteristics, Rhode Island, 2004-2007 |
|---|---|---|---|
| Maternal Age |
| < 20 | 1170 | 14.5 | (11.0 - 18.1) |
| 21-25 | 2466 | 7.8 | (6.2 - 9.7) |
| 26-35 | 1087 | 2.2 | (1.5 - 3.1) |
| ≥35 | 1727 | 1.4 | (0.9 - 2.1) |
| Maternal Ethnicity |
| Hispanic | 1172 | 14.0 | (11.9 - 17.0) |
| Non-Hispanic | 3597 | 5.0 | (4.2 - 5.9) |
| Maternal Race |
| White | 4597 | 5.3 | (4.6 - 6.0) |
| Black | 553 | 7.5 | (5.2 - 10.7) |
| American Indian | 76 | 13.0 | (6.1 - 21.5) |
| Asian/Pacific Isl | 253 | 2.2 | (0.7 - 6.3) |
| Maternal Education |
| < High School | 185 | 10.3 | (8.1 - 13.0) |
| High School | 1531 | 8.9 | (7.3 - 10.9) |
| > High School | 2937 | 2.1 | (1.6 - 2.8) |
| Household Income |
| < $15K | 1382 | 15.2 | (11.1 - 18.6) |
| $15K - < $25K | 307 | 6.0 | (4.1 - 8.8) |
| $25K - < $50K | 1013 | 5.9 | (3.7 - 8.7) |
| ≥$50K | 2001 | 1.3 | (0.9 - 2.1) |
| Marital Status |
| Married | 3991 | 1.9 | (1.4 - 2.5) |
| Not married | 2167 | 11.2 | (9.7 - 13.0) |
| Insurance for Prenatal Care |
| Public | 2208 | 9.8 | (8.4 - 11.4) |
| Private | 3031 | 1.9 | (1.4 - 2.6) |
| WIC Participation |
| Yes | 2406 | 5.4 | (3.8 - 7.1) |
| No | 3134 | 2.7 | (2.1 - 3.3) |

Sample size in each category, unknown and missing categories were excluded.
(8.0%), American Indians (13.0%), Blacks (7.5%), and those who were unmarried (11.2%), had household incomes <$15,000 (13.2%), had <high school education (10.3%), had public insurance (9.8%), and were enrolled in the Women, Infants and Children (WIC) Food Supplement Program during pregnancy (9.4%) than among their counterparts. (Table 1)

Maternal Health Risk Behaviors

Compared with women who did not experience IPV before or during pregnancy, women who experienced IPV were more likely to have delayed or no prenatal care (24.8% vs 14.4%), smoke during pregnancy (35.5% vs 10.8%), smoke at the time of the survey (44.8% vs 15.2%), report their pregnancy was unintended (62.8% vs 36.4%), and report not breastfeeding at the time of the survey (81.8% vs 61.4%). The likelihood of drinking alcohol during pregnancy was not significantly different for women experiencing IPV (9.7%) compared to women who did not experience IPV (9.4%). (Figure 2)

Pregnancy Complications

Women who experienced IPV before or during pregnancy, compared to their counterparts, were more likely to report vaginal bleeding (22.4% vs 16.1%), urinary tract infections (28.7% vs 13.4%), severe nausea, vomiting, or dehydration (50.8% vs 27.7%), preterm or early labor (32.9% vs 18.8%), premature rupture of membranes (9.9% vs 5.3%), and diagnosed depression (22.8% vs 7.2%). (Figure 3)

Even after adjusting for socio-demographic factors (maternal age, race, ethnicity, marital status, household income, and educational level) in the logistic regression models, women who experienced IPV were still at increased risk for vaginal bleeding (aOR=1.7; 95% CI=1.2-2.4), urinary tract infections (aOR=1.8; 95% CI=1.3-2.5), severe nausea, vomiting, or dehydration (aOR=2.0; 95% CI=1.5-2.8), preterm or early labor (aOR=1.7; 95% CI=1.3-2.4), premature rupture of membranes (aOR=1.8; 95% CI=1.2-2.8), and diagnosed depression (aOR=2.6; 95% CI=1.8-3.7) during their pregnancy.
DISCUSSION

Each year, about 12,500 women in Rhode Island deliver live-born infants. Based on our estimates, about 690 RI women would experience IPV before or during pregnancy each year. This number may be low: it excludes women whose pregnancies did not result in live births. The data consider only physical abuse as a measure of IPV, not sexual, psychological or verbal abuse. Finally, women tend to underreport IPV.

Women who experienced IPV before or during pregnancy were more likely to have pregnancy complications and to engage in unhealthy behaviors.

Although the ACOG and CDC recommend that all health care providers screen all patients for violence at regular intervals, many health care providers do not. A survey conducted in Alaska indicates that only 17% of prenatal care providers routinely screened for IPV at the first prenatal visit, and only 5% at follow-up visits. In Rhode Island, according to the PRAMS data, 55% of new mothers reported their health care providers talked about IPV during their prenatal care visits.

If a patient screens positively for IPV, physicians are recommended to validate the patient’s experience and concerns, conduct safety assessment/develop a safety plan, offer information about/provide referrals to local agencies, document findings in the medical record, and schedule a follow-up appointment.

REFERENCES


Hyun (Hanna) Kim, PhD, is Senior Public Health Epidemiologist in the Center for Health Data and Analysis, Rhode Island Department of Health, and Clinical Assistant Professor in the Department of Community Health, The Warren Alpert Medical School of Brown University.

Samara Viner-Brown, MS, is Chief of the Center for Health Data and Analysis, Rhode Island Department of Health.

Rachel Cain is the PRAMS Program Coordinator in the Center for Health Data and Analysis, Rhode Island Department of Health.

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Poets, philosophers—even physicists—have vainly sought to define the character and dimensions of nothingness. And physicians, too busy to explore the epistemology of nothingness, have been satisfied merely to gather their own assemblage of words defining pathologic nothings, spaces, when encountered within the human body.

Thus, we confront the word, lacuna, a diminutive of the Latin, *lacus*, meaning a pond or a hollow; as in English words such as lake and lagoon. Small spaces, *lacunae*, are commonly encountered in arterially-compromised brain tissue and are then described in phrases such as lacunar encephalopathy. A very small lacuna is called a lacunule (representing a Latin diminutive of a diminutive). The word, lacuna, however, is not related to the Greek name, *Lacoon*, the Trojan prophet who had predicted the perils lurking within the Horse built by the Greeks besieging Troy. It was he who said: "Beware of Greeks bearing gifts."

A vacuole, an empty space, generally of pathologic origin, is a diminutive of the Latin, *vacuus*, and is the source of such English words as vacuous, vacuity, vacant, and vacuum.

The word, void, also meaning an emptiness, is descended through late (vulgar) Latin and is derived ultimately from *vacare*, meaning to be empty, as in English words such as vacation and evacuation. Cognate English words of void include devoid and avoid.

The adjective, spongiform, is a Greek term describing abnormal tissue filled with small cavities and thus resembling the marine invertebrates (*Porifera*), the sponges. A spongiossarcoma is an archaic term for an aggressive astrocytoma.

The word cavity descends from the Latin, *cavus*, meaning a hollow, and gives rise to cognate words such as concavity and cavitation. The word, empty, is of Old English origin, *entig*, meaning idle or vacant.

The letter, 'p', called by semanticists ‘an ex crescent letter’ was added belatedly as seen also in words such as glimpse or sempstress (now usually spelled seamstress.)

The medical profession thus has access to a handfull of words (lacuna, vacuole, void, cavity, empty-space) offering almost identical meanings. Some distinctions, necessarily, are drawn. Thus, if the abnormal space is very small, barely visible and in great numbers, the word spongiform might be employed. If of medium dimension, perhaps the word lacuna might be used. And if quite large, as encountered in tuberculous pneumonitis, the lesion might then be described as a cavity. Usage, over the centuries, has sharpened the intent of erstwhile synonyms so that the sentence, “The hotel room is empty” is no longer equivalent to, “The hotel room is vacant.”

– STANLEY M. ARONSON, MD
Ninety Years Ago, January 1920

Murray S. Danforth, MD, in “Advances in the Surgery of the Extremities during the War,” recounted: “My first recollection...is of seeing a patient lying in bed with a weight at the foot of the bed for treatment on the lower fragment of the fractured femur, and with a long board splint and coaptation splints for maintaining the fragments in position. With that method a result in a simple fracture was rated as good, when the shortening was not more than an inch or even an inch and a half. This meant a limp and subsequent back strain with a not inconsiderable disability.” Post-war, therapists emphasized “not forcible manipulation”… but “more reliance on hot and cold showers, whirlpool baths, massage, exercise...” Prewar the mortality from a fracture of the femur was 83%; post-war, it had fallen to 15%. In a comment to Dr. Danforth’s paper, a Society member urged members to be cautious about applying lessons from the complicated injuries of war to civilian fractures.

Elizabeth M. Gardiner, MD, in “Child Welfare – Yesterday and To-Day,” traced the Children’s Federal Bureau to the 1909 White House Conference on Children’s Welfare, convened by President Theodore Roosevelt. “It used to be said that once a child is born, the parents and the state must accept responsibility for its well-being. We now go a step further. The very fact that state after state...is creating new departments for child welfare...is evidence enough that the state recognizes its obligation to afford to every mother the necessary education and health facilities to insure a safely born child.” The War had demonstrated the sorry state of children’s health: many would-be soldiers were disqualified for health: “…a greater proportion of them represented preventable childhood diseases which we neglected to prevent.”

Bennett L. Richardson, MD, in “Erythema Multiforme following Diphtheria Antitoxin,” described the case of a four year-old boy, sick with diphtheria, admitted to Providence City Hospital. His brother was admitted a week later, with the same symptoms. On admission, the four year-old was given 2,000 units of antitoxin intramuscularly; two weeks later, he had a fever of 100.5 and was itching.

An Editorial, “The Encore,” described the Society’s decision to renew publication of the Journal: “Now that the smoke of battle is cleared away and everyone is back home again, trying to pick up the loose ends of a practice, the need of a Journal...has become more and more evident.”

Fifty Years Ago, January 1960

C. Miller Fisher, MD, Assistant Professor of Neurology, Harvard Medical School, spoke on “Present Trends in the Treatment of Cerebral Vascular Disease” at the Neuropsychiatric Rounds at Rhode Island Hospital. The Journal reprinted his talk.

Orland F. Smith, MD, and Richard S. Rosen, MD, in “Colovesical Fistula: A Complication of Diverticulitis,” noted that 20 years ago the surgical mortality for large bowel procedures at the Mayo Clinic was 14.7%. The authors reported on two recent cases, treated successfully.

Warren W. Francis, MD, in “Spontaneous Rupture and Herniae,” described two patients – a 68 year-old man and a 2 year-old girl —where treatment called for “immediate surgical repair.”

Raymond N. MacAndrew, MD, in “The Other Appendiceal Conditions,” discussed the carcinoid, the mucocele, and adenocarcinoma.

An Editorial supported “A New Brown University Medical School.” The Providence Journal had been lukewarm to the proposal.

Twenty-Five Years Ago, January 1985

An Editorial, “Deinstitutionalization in Rhode Island,” cited an article in the International Herald Tribune that called de-institutionalization “a quick fix that backfired.” That article had cited decreased funding, leading to an increased number of people in slum housing. The Journal editor called Rhode Island “a shining example of a successful experience,” crediting Dr. Joseph Bevilaqua, former director of the state Department of Mental Health Rehabilitation and Hospitals, and his successor, Tom Romeo.

Charles E. Kaufman, MD, and Elliot M. Perlman, MD, in “Orbital Causes of Red Eye,” noted: “Differential diagnosis is essential to initiate appropriate and possibly life-saving therapy.”

In the “Clinico-pathological Conference: Case Report,” Maurice M. Albala, MD, George F. Meissner, MD, Tom J. Wachtel, MD, and Mark Fagan, MD, editors, presented the case of a 60 year-old woman with a history of hypertension and alcohol abuse “admitted for abdominal pain.” This woman, who smoked a pack a day, had been in good health until a week before admission. She was initially given 2 units of packed red blood cells. On the second hospital day “endoscopy revealed mild distal esophagitis and mild to moderate gastritis. No bleeding was seen.” She was given antacids and cimetidine. On the 4th hospital days, after a barium enema, she passed bright red blood clots. On the 9th hospital day, she went into cardiac arrest and died. The anatomic diagnosis: “Aortoduodenal fistula with massive gastrointestinal hemorrhage s/p right renal artery.” After 14 years, the patient showed a weakening of the suture line from an aortorenal bypass graft.
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