

WORCESTER medicine

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EBOLA CRISIS



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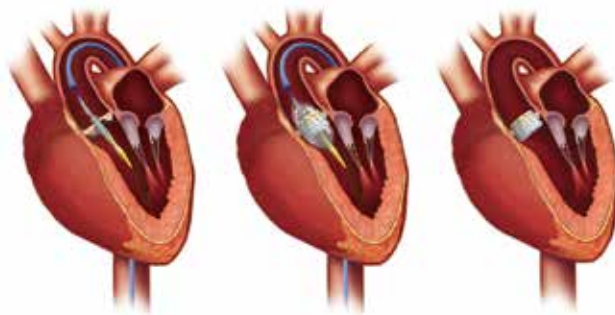
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Editorial

Jane Lochrie, M.D.



Jane Lochrie, M.D.

The Ebola Virus Disease (EVD) epidemic in West Africa is capturing the world's attention, as it should. It is the largest and longest Ebola outbreak in history, affecting multiple West African countries and taking the lives of more people than all other Ebola outbreaks combined. With more 18,500 confirmed or suspected cases, more than 6,800 deaths, and new cases being identified every day, the 2014 EVD epidemic is unlike any of its kind. The ability of some poor, resource-limited, developing countries in sub-

Saharan Africa to efficiently handle the epidemic within their shores provides some lessons learned for the global health community. The global health community must support a sustainable strategy to mitigate the Ebola virus.

This issue of *Worcester Medicine* opens with an article by Drs. George Abraham and Aalok Khole. They provide us with the historical background and scientific information about EVD. They describe the first outbreak of the disease in what was then Zaire in 1976, and they give us a description of the disease, how it spread and how it is treated.

Dr. Anthony Esposito compares and contrasts the current outbreak of EVD with the outbreak in Democratic Republic of the Congo in July 2014. He explains why that outbreak was quickly contained to

a total of 69 cases and why the current one has raged out of control. He reassures us that the possibility of a widespread outbreak in the U.S. is virtually nil.

Dr. Richard Sacra, who has worked in Liberia and is an EVD survivor, suggests that one of the main problems with this epidemic is the late presentation for the care. Patients with severe dehydration and electrolyte abnormalities have a poor prognosis. Early on, the posters all noted the fatality of the disease, and there was no mention of the possibility of survival with early intervention. He opines that the education should be aimed at getting people into a treatment facility sooner rather than later.

Dr. Patricia McQuilkin, her colleagues at UMass and their academic partners have been invested in training health care workers and working to improve the medical education in Liberia since 2006. With a grant from philanthropist Paul G. Allen, they are working to reopen hospitals that have been closed due to the epidemic, leaving virtually no health care for the rest of the country. She describes the importance of this effort, as people are dying needlessly in childbirth and from diseases such as malaria.

Dr. Douglas Waite, et.al., describe how "the backbone of St. Vincent Hospital's Ebola preparedness is education, not just for staff but for patients and the community." The goal is to keep people informed, alleviate anxiety and to avoid stigma. This is an ongoing daily process.

Patrick Muldoon, FACHE, relates how UMass Memorial Medical Center has been preparing for EVD since July. This was put to the test when a physician who had been recently treated for EVD came to the Emergency Department with a fever. UMass Memorial is one of eight centers statewide to be named as an EDV treatment center.

Seth Peters, MPH, describes the Worcester Division of Public Health's efforts to stem the fear of the Worcester community by proving facts and the science behind this information in presentations and pamphlets to health care providers and neighborhood groups.

In addition to reading about Ebola, please take time to read our other articles, including Dr. Baker's President's Message, Dr. Hirsh's As I See It, Peter Martin's Legal Counsel, and Joyce Cariglia's Society Snippets.

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Long Live Physician Free Speech

Frederic Baker, M.D.



Frederic Baker, M.D.

Perhaps the most powerful element of our health care system is the patient-physician relationship, as Dr. Steven Earls so eloquently noted at our recent Worcester District Medical Society Awards dinner meeting. It is the foundation upon which trust, hope, advocacy, continuity of care and positive outcomes arise. No policy or entity should ever disrupt or compromise that precious patient-physician relationship and dialogue.

However, a current statute law in Florida would do just that by making it illegal for physicians to ask a patient about firearm possession. The law has created such an outcry regarding challenges to physician free speech that it has prompted the Massachusetts Medical Society to adopt a resolution soundly rejecting such language. The Florida law has galvanized many patient-physician advocacy groups throughout the country to call for defeat of such and similar measures.

Discussions regarding firearms, nutrition, alcohol, sex and sports can understandably evoke strong emotions about behaviors that are all highly personal and sensitive freedoms protected by the Constitution. Such behaviors are not inherently dangerous when executed responsibly. Yet such dialogues are indeed relevant in medical practice, as they provide opportunities to identify and reduce risks in behaviors that undeniably account for the leading causes of morbidity and mortality, with significant economic, psychological and physical costs, as well as burdens to individuals, families and communities.

Patient-physician dialogues have the power to reconcile and heal relationships that seemed unsalvageable; reduce accidental firearm deaths; reduce suicide attempts and ideation; treat and cure sexually communicable diseases; decrease fetal and infant mortality; reverse heart disease by promoting healthy lifestyle changes; and help people confront and combat addiction, to name a few outcomes.

By virtue of training, experience and ethics, physicians are charged and entrusted to serve as advocates for patients and communities. Physicians ask some of the most probing questions of patients, not out of some perverse curiosity or desire to exert power or pursuit of a political, personal or financial gain, but rather to empower

individuals and communities with resources, knowledge and advice to pursue optimal health and well-being while discouraging toxic behaviors and dissuading negative enabling behaviors. Physicians have a duty to conduct themselves in a professional manner that always upholds patient's dignity, sensitivity and autonomy. No patient should ever feel forced, intimidated or subject to reprisals for choosing to decline to engage or accept a treatment, inquiry or recommendation. Patients exercise that right every day on any and all topics.

Questions about risk factors from physicians do not and must never promote, endorse or condemn a person, activity or agenda. Yet there are some third parties who appear either too eager to distort, impugn or presume the intent of physicians by exploiting fears in an effort to pursue a narrow political agenda or placate a constituency in a manner that runs contrary to the very freedoms that define and unite this country.

How ironic that those who claim to respect and honor the Constitution, where freedom from tyranny and resistance of state oppression inspired the protections of the right to bear arms and the right to free speech, would now carelessly and selectively choose to uphold some freedoms while choosing to violate other freedoms, such as physicians' rights, in a display of the utmost contempt for free speech.

The vast majority of responsible gun-owners, gourmands, drivers and sports enthusiasts have no reason to fear that their rights and pursuit of lifestyle choices are being infringed upon by a physician's appropriate questions or discussion of risk factors. Perhaps the biggest threats to our democracy and public safety come not from physician questions or advocacy groups but rather from those elected officials who lack the courage, wisdom and intellectual honesty to recognize that suppression of free speech has no place in our democracy and choose not to reject, but rather embrace, censorship legislation. Today it's the government; tomorrow it's an insurer, employer or third party that will want to dictate the terms of patient-physician dialogue. Efforts by third parties to censor or micromanage the patient-physician interaction must be soundly rejected. Organized medicine is committed to protecting the rights of patients and physicians in the pursuit of a health care system that is truly meaningful. We will need your help to identify and reject those policies that would seek in any way to compromise or undermine the patient-physician relationship.

We encourage your feedback at fgrillb@aol.com.

The Bumpy Road to Flat

Michael Hirsh, M.D.



Michael Hirsh, M.D.

Tom Friedman, the renowned *New York Times* op-ed contributor, author and social scientist, recently served as a guest speaker at a Becker College-sponsored event at Mechanics Hall in Worcester. There, he praised Becker's emphasis on fostering global educational experiences by reiterating his now-famous phrase, which is also the title of his 2005 book: *The World is Flat*.

The theme of that work is that globalization has made boundaries obsolete. Much like our Department of Public Health tries to convince the populace of Central Massachusetts that their individual health choices are interdependent, Mr. Friedman explains that globalization has made individual countries' economic, diplomatic and political decisions inextricably linked.

This issue of *Worcester Medicine* tackles the Ebola crisis that has ravaged West Africa, affected international health agencies and U.S. health care institutions and captured the headlines and airwaves with all kinds of information, some useful, some fanciful, some hysterical. Nothing illustrates the globalization principle better than the Ebola saga. What started out as a seemingly rare, obscure, but clearly deadly, Central African virus in the late '70s has now become a worldwide 21st-century health challenge that has strained the medical resources continents away. Our edition will hopefully trace the

crisis from Africa to our American shores, right to the heart of the Commonwealth of Massachusetts.

Perhaps the cautionary tale is that in the future, if a seemingly obscure health problem pops up in a remote part of the world, we as an international health community should react forcefully with the emergency response, vaccine development and public health education necessary to nip the scourge in the bud. We have to look inward in the case of Ebola to ask why our vaccine manufacturers were allowed to dismiss this research and development because they made the judgment that an African problem would not spread, and its solution would not be profitable. Thousands have paid the ultimate price for that misjudgment. This is an epic failure to recognize that when it comes to infectious diseases, the world is flat.

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Ebola – The River of Death

George M. Abraham, M.D., MPH, and Aalok Khole, M.D.



**George M. Abraham,
M.D., MPH**

The last few months has seen the world consumed, panic-stricken and anxious by the spread of Ebola fever. A companion article by Dr. Anthony Esposito addresses the current pandemic and responses to it in greater detail. Here, we attempt to provide a historical perspective and basic scientific information about the disease.

In 1976, Peter Piot, then a 27-year-old medical school graduate training as a clinical

microbiologist at the Institute of Tropical Medicine in Antwerp, Belgium, was in the lab the day that a shiny, blue thermos flask arrived. In it was the blood of a nun, also from Belgium, who had fallen ill with a mysterious illness. A Belgian doctor based in what was then Zaire, now the Democratic Republic of Congo, had sent it.

Piot and his colleagues were unaware just how dangerous a shipment they were handling. The samples were treated like numerous others the lab had tested before, but when the scientists placed some of the cells under an electron microscope, they saw something they didn't expect: a worm-like structure, gigantic by viral standards, appearing very similar to the Marburg virus. The Marburg virus had been first recognized in 1967, when 31 people became ill with hemorrhagic fever in the cities of Marburg and Frankfurt in Germany and in Belgrade, the capital of Yugoslavia. This Marburg outbreak was associated with laboratory staff who were working with infected monkeys imported from Uganda; seven people died.

While he consulted experts and pondered over his findings, he got word that the nun, who was under the care of the doctor in Zaire, had died. Additionally, many others seemed to be falling ill to the same illness in a remote area in the north of the country. Their symptoms included fever, diarrhea and vomiting followed by bleeding and eventually death.

Two weeks later, Piot was on a flight to Kinshasa. Piot and his team were provided a C-130 aircraft, courtesy of the president of Zaire. Then, the team went further by road to the center of the outbreak, a village in the equatorial rainforest, about 620 miles further north. In a recent interview with the BBC¹, Piot recalled, "When the C-130 landed in Bumba, a river port on the Congo River, the fear was tangible. Even the pilots didn't want to hang around for long; they kept the airplane's engines running as the team unloaded their kit. As they left, they shouted, 'Adieu.' In French, people say 'Au revoir' to say 'See you again,' but when they say 'Adieu' – it was like saying, 'We'll never see you again.' The team's final destination was the village of Yambuku – about 75 miles from Bumba.

Yambuku was home to an old Catholic mission hospital and a school run by a priest and nuns, all of them from Belgium. When Piot arrived, the first people he met were a group of nuns and a priest who had retreated to a guesthouse and established a cordon around the place to prevent the spread of disease. There was a sign on the cord, written in the local Lingala language, which read, "Please stop. Anybody who crosses here may die." They had already lost four of their colleagues to the disease, and the others were praying and waiting for death.

The priority was to stop the epidemic, but first, the team needed to determine how this virus spread from person to person. These were the three questions they asked:

- How did the epidemic evolve?
- Where did the infected people come from? The team visited all the surrounding villages, mapped out the number of infections and determined that the outbreak was closely related to areas served by the local hospital.
- Who gets infected? The team found that more women than men caught the disease, particularly women between 18 and 30 years of age because many of them were pregnant and had attended an antenatal clinic at the hospital where they all received a routine injection. However, there were only five syringes, so the needles were reused, and the virus spread between patients.

Piot's team also observed that people got ill after attending funerals, especially those involved with preparation of the body of someone

who had died of the disease. Using the information they learnt, team members systematically went about instituting a "quarantine" of anyone who was infected, closed the hospital and thus slowly brought the spread of the disease under control.

Piot and his colleagues spent three months in Yambuku, learned a lot about the "mystery illness" that was yet unnamed. He recalled, "We didn't want to name it after the village, Yambuku, because it was so stigmatizing." Therefore, they decided to name the virus after a river, the closest one being the Ebola River. From that point on, the virus that arrived in a flask in Antwerp all those months earlier would be known as the Ebola virus.

Ebola virus disease (EVD) is a zoonotic illness caused by an enveloped, negative, single-stranded RNA virus of the Filoviridae family. It is one amongst five viruses in the family, the others being the Sudan virus, Tai Forest virus, Bundibugyo virus and Reston virus. Fruit bats of the Pteropodidae family are the culprit reservoirs. The incubation period ranges from two to 21 days, and mode of spread is direct contact of mucosal surfaces with infected body fluids or tissues or through parenteral injection.

The initial symptom complex is usually non-specific, with sudden onset fever, chills and malaise being some of the notable complaints. Flu-like symptoms follow, and more severe cases manifest with hemorrhagic symptoms. Diarrhea and vomiting can cause losses of large amounts of body fluids, quickly leading to dehydration and death.

Laboratory findings may include depressed cell counts, elevation of liver enzymes and an abnormal coagulation profile. The pathogenesis isn't well understood, but inhibition of the type 1 interferon response, lymphocytic apoptosis and disruption of the coagulation cascade seem to be some of the proposed mechanisms of injury. Diagnosis is confirmed by polymerase chain reaction (PCR) and enzyme-linked immunosorbent assay (ELISA)-based diagnostic modalities.

Treatment mainly involves supportive care with fluid resuscitation and symptom management. Given the absence of a specific cure, research is ongoing into potential treatments involving combinations of antibodies. One of them is ZMapp, which involves a combination of two different sera made by two different companies²: MB-003, developed by San Diego firm Mapp Biopharmaceutical, and ZMAb, made by Canadian company Defyrus Inc. When Mapp Biopharmaceutical's commercial arm, LeafBio, combined the two,

MB-003 plus ZMAb became ZMapp. Developed in collaboration with the United States Army Research Institute of Infectious Diseases (USAMRIID), it has antibodies to EVD proteins that have been subsequently grown inside genetically engineered *Nicotiana benthamiana*, an indigenous Australian tobacco plant.

The National Institute for Allergy and Infectious Disease (NIAID), in collaboration with GlaxoSmithKline (GSK), have initiated vaccine trials³ of a recombinant type of chimpanzee "cold" virus, called chimp adenovirus type 3 (ChAd3), specifically investigating its ability to prevent EVD.

With current totals of 18,498 cases and 6,856 deaths⁴ (CDC, Dec 15, 2014), primarily in the three West African nations of Liberia, Sierra Leone and Guinea, this epidemic has been significant in several ways. Among the many lessons learnt is the fact that poor understanding of the disease can lead to mass hysteria and panic, often unfounded, and our treatment of infected individuals, even in a developed country like ours, leaves much to be desired. It behooves us in the medical community to educate and reassure the public of the facts and dispel the numerous "myths" associated with this difficult disease. In particular, the fact that individuals are infectious only when they develop a fever and are symptomatic cannot be overemphasized.

The current epidemic has exposed our vulnerability in dealing with novel infectious diseases, even if they are not directly in our hemisphere; that global travel can cause global spread of disease; and that resource-poor nations need help controlling epidemics of illnesses, else they will spread to other parts of the world. Partnerships between the World Health Organization and governments of various nations, like the Global Health Security Agenda, which hinges on the principles of prevention, early detection and effective response, will help us combat a local problem and prevent it from becoming global.

Dr. George M. Abraham is associate chief of medicine at Saint Vincent Hospital, clinical professor of medicine at the University of Massachusetts Medical School and governor of the American College of Physicians (Massachusetts chapter). Dr. Aalok Khole is a PGY-II resident in internal medicine at Saint Vincent Hospital.

Footnotes:

¹ <http://www.bbc.com/news/magazine-28262541>

² <http://mashable.com/2014/08/17/ebola-serum-zmapp/>

³ <http://www.niaid.nih.gov/news/QA/Pages/EbolaVaxQA.aspx>

⁴ <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/>

Concurrent but Contained: Insight from a 2014 Ebola Outbreak in the Democratic Republic of Congo

Anthony L. Esposito, M.D.



Anthony L. Esposito, M.D.

For the past nine months, the wary gaze of much of the world has focused on the Western African countries of Guinea, Sierra Leone and Liberia, where an unprecedented outbreak of Ebola virus disease (EVD) has spawned heartbreaking images of the mortally ill, gruesome photos of the abandoned dead and chilling pictures of masked figures in yellow gowns spraying tainted ground. The harrowing pictures of human suffering have been magnified by the equally

harrowing mathematical models projecting worst-case scenarios of 1 million Ebola cases before the outbreak is contained. Given the graphic imagery, the magnitude of the problem and the grim forecasts, it is easy to appreciate how the word “Ebola” elicits fear.

What has not been publicized is the fact that a second and distinct outbreak of EVD occurred in 2014 in the Democratic Republic of Congo, a country about 2,000 miles southeast of Liberia. Though much smaller in magnitude, the concurrent outbreak offers insight into the epidemic in West Africa and reassurance to those in the United States and elsewhere who wonder if Ebola could overwhelm their medical systems and devastate their countries.

As noted elsewhere in this issue of *Worcester Medicine*, EVD was first recognized in 1976, following an outbreak of a febrile and often fatal illness in a northern region of the equatorial African country of Zaire, now known as the Democratic Republic of Congo. Since the cardinal 1976 epidemic, six other outbreaks have evolved in the Democratic Republic of Congo. The most recent, which began in late July 2014, has been traced to human contact with Ebola-infected “bush meat.” In particular, a pregnant woman was exposed to the virus in the process of preparing a monkey for consumption. After handling the carcass, the woman (“the index case”) became infected with the Ebola virus and subsequently died. A local doctor and several assistants who performed a postmortem Cesarean section for the purpose of separating the mother and baby prior to burial, as required by tribal beliefs and custom, also became infected and thus, the infection spread. Remarkably, 21 of the 69 total cases had direct contact with the index patient. The initial infections occurred in a remote area with no paved and few dirt roads and thus unconnected to population centers. Equally important: Because the Republic of Congo had experience with six prior outbreaks,

the problem was quickly recognized, and health care teams were dispatched to institute basic infection control practices, such as isolating symptomatic persons.

Like the July 2014 outbreak in the Democratic Republic of Congo, the current Ebola epidemic in West Africa has been linked to contact with an infected animal. A 2-year-old (the index case or “child zero”) from a village in the Guéckédou region of Guinea was exposed through contact with an infected fruit bat, likely hunted by the child’s parents. The child died on Dec. 6, 2013. In contrast to the location of the outbreak in the Democratic Republic of Congo, the Guéckédou region is contiguous with the countries of Sierra Leone and Liberia and connected to populous areas through paved and unpaved roads and innumerable footpaths that traverse porous national borders, allowing, among other things, frightened patients to flee Ebola treatment units to another country. In addition, ethnic tribes spill over these borders, resulting in ill patients returning to their villages in an adjacent country to die and highly infectious corpses being transported to ancestral homes for funeral services and burial. A second distinction that facilitated dissemination was the fact that outbreaks of Ebola have not previously occurred – or at least, have not been recognized – in Guinea, Liberia or Sierra Leone. As a result, local and international public health officials did not appreciate the problem until March. By summer, the disease was surging in populous areas, especially the poorest districts of Monrovia, the capital of Liberia. Finally, resistance to Ebola response teams, which are sometimes viewed as the source of the deadly disease, occurred in both rural and urban areas. Resistance included repelling health care workers by blocking roads and assaulting vehicles and personnel.

Because the Democratic Republic of Congo had experienced prior outbreaks of Ebola, public health authorities were familiar with the management of the problem and the importance of rapidly isolating ill individuals. As a result, the epidemic in that country was quickly contained. The total number of cases was 69, the last infection occurring in early October. In West Africa, public health officials did not have the personnel or experience to quickly institute isolation and other infection control activities that might have mitigated the spread of the virus. In addition, as Ebola has swept through West Africa, the disease has killed more than 300 physicians, nurses and other providers, impeding efforts to control the epidemic.

The source of both outbreaks is believed to be fruit bats, which harbor the Ebola virus. Fruit bats carrying the Ebola virus in West Africa are carrying a virus that is genetically almost identical to that present in the Democratic Republic of Congo. No scientific

evidence exists to suggest the Ebola virus ravaging West Africa is more contagious, more virulent or more lethal than that associated with the recent or prior outbreaks in the Democratic Republic of Congo.

As long as there exists an animal reservoir (i.e., certain fruit bats) and a susceptible population of humans and other mammals, other outbreaks must be anticipated; national and international public health officials are certainly aware of that possibility in the Democratic Republic of Congo and now West Africa. The development of a vaccine offers the potential for protecting human populations, although many obstacles remain before such a vaccine could have an impact. These obstacles include the acceptance of a vaccine by the population at risk, the duration of immunity and efficacy in the face of genetic changes in prevalent strains. Rapid diagnosis through innovative laboratory tests should also help in containing outbreaks.

Because so much is known about the transmission of the virus, the possibility of a widespread outbreak in the United States, or in any western country, is nil. Certainly, secondary cases may occur among health care providers or others who inadvertently have direct contact with the infectious blood, vomitus or diarrhea of a patient with later-stage EVD. However, as the nurses, physicians and other providers who cared for Ebola patients at Nebraska Medical Center, Emory University Hospital, the National Institutes of Health Clinical Center, and Bellevue Hospital in New York City have reassuringly proven, even secondary cases will be few and far between.

Anthony L. Esposito, M.D., is chief of the Department of Medicine at Saint Vincent Hospital. He is also a professor of medicine at the University of Massachusetts Medical School.

Selected Reading:

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Maganga G.D., Kapetshi J., Berthet N., et al. "Ebola Virus Disease in the Democratic Republic of Congo." *N Engl J Med* 2014;371:2083-91.

Fairhead, J. "The significance of death, funerals and the after-life in Ebola-hit Sierra Leone, Guinea and Liberia: Anthropological insights into infection and social resistance," October 2014 (<http://opendocs.ids.ac.uk/opendocs/handle/123456789/4727>).

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Topics for Research in the Ebola Crisis

Richard Sacra, M.D.



Richard Sacra, M.D.

As a medical provider who has worked in Liberia, West Africa, for more than 15 years and also a survivor of Ebola virus disease, I count it a privilege to share some thoughts with the Worcester District Medical Society. I would like to comment on three “links” I would like to propose, which may be possible subjects for further study or evaluation. Continued long-term investment of personnel and resources in the health care system in West Africa will be necessary to both recover from the current Ebola epidemic and to prevent future tragedies like this one.

My personal experience in Liberia, along with a review of papers and news articles from elsewhere in West Africa, suggests that one of the major problems in controlling the Ebola epidemic has been the late presentation of cases for care. Late presentation to an Ebola Treatment Unit means longer time in the community, visiting other clinics or informal/home-based medical care, and likely more spread of the disease. Therefore, a major goal of the public health campaign to contain Ebola should be getting people into care earlier.

Of the first 17 confirmed Ebola cases treated at the first Ebola Treatment Unit (ETU) in Monrovia, Liberia, there was only one survivor¹. These cases all received standard supportive care with both oral and IV rehydration, and staffing was adequate, at least at the level provided at comparable ETUs in Liberia. My hypothesis about the reason for this low survival rate is late presentation of sick patients to the ETU for care. People who present with severe dehydration and/or organ failure have a poor prognosis.

My observations suggest several factors that may be linked to late presentation for care and may be areas for possible future study. The first factor is the content of education materials used to inform the general public about Ebola and the level of knowledge about the virus in the community. Observation of posters, handbills and newspaper headlines early in the Ebola outbreak in Monrovia show that many of them used phrases such as “Ebola – It quickly kills” or “Ebola is a virus that spreads quickly and kills.” Also, phrases were found such as “There is no cure or vaccine.” Notably absent from early posters was information about early treatment leading to a higher survival rate. Conversations with Liberians in August suggested that most of them felt that Ebola was always fatal – that there would be no survivors, or very few. Later posters and educational materials, as seen in August 2014 or later, contained phrases like “You can survive Ebola” or “Early treatment improves survival rates.”² It seems to me that targeted educational materials specifically aimed at linking early presentation for treatment with improved survival, especially if combined with interviews or quotes from actual survivors, might reduce delays in presenting for treatment of Ebola Virus Disease.

A second area for research would be the possible link between improved care at Ebola treatment centers, combined with better education about

the higher level of care available, and earlier presentation for care. Early on, there was a lot of denial in the community at large, with theories about the origin of Ebola ranging from the idea that Ebola was brought to West Africa by Westerners seeking to create a market for anti-Ebola drugs to the prevalent idea that witchcraft was behind most of the deaths. I feel that this denial was in large part a response to the bleak prognosis. People felt early on that the main purpose of the treatment centers was to isolate people with Ebola while they died, rather than to improve survival rates. Several papers appearing in the *New England Journal of Medicine* speak to the issue of improving survival rates. Proposals include more intensive supportive care for all patients, including laboratory monitoring of electrolytes, anemia and other metabolic parameters³; a triage approach to identify those most in need and most likely to benefit from IV fluids⁴; or more intensive hydration with IV fluids and better staffing at ETUs⁵. Some of the opinions expressed in these articles seem directed at the medical community to reduce therapeutic nihilism (“No matter what we do, most of these patients will die.”) and to encourage the idea that supportive care, including IV hydration, is specific therapy for Ebola. In any case, publicity about these improved methods of care and results might attract patients to come for evaluation sooner if they felt that doing so would lead to a higher likelihood of survival.

Finally, as clinical trials of drugs to treat Ebola and other treatment methods, such as convalescent plasma treatment, get underway, it would be instructive to observe numbers of patients presenting for care, as well as the time since symptom onset, to see if the availability of specific drug or antibody therapy may reduce delays in care-seeking. During the early period of the HIV epidemic in Liberia, it was observed that the availability of drug therapy increased willingness to be tested and to enter into care at earlier stages of the disease. Perhaps a similar result will occur with Ebola.

I am encouraged that faculty members at the University of Massachusetts and other medical practitioners in Worcester County are getting involved in the effort to contain Ebola in West Africa. It is especially encouraging that UMass has already been working in Liberia for nearly a decade and so has both the personal connections and the cultural understanding to make a significant and lasting contribution. Intensive investment in training physicians at several levels – medical school, internship, residency and post-residency/CME – will be a critical component in building up the health care system so that outbreaks such as this one can be dealt with more effectively in the future.

Richard Sacra, M.D., is assistant professor in the Department of Family Medicine and Community Health at the UMass Medical School.

Footnotes:

¹ Brantly, K. and Eisenhut, D. Personal Communication with the Author, Nov 2014.

² Author's Personal Observation, Monrovia, Liberia. May-August 2014.

³ Bah, E.I., et al. “Clinical Presentation of Patients with Ebola Virus Disease in Conakry, Guinea.” *N Engl J Med* 2014; 10.1056/NEJMoa1411249.

⁴ Chertow, D.S., et al. “Ebola Virus Disease in West Africa – Clinical Manifestations and Management.” *N Engl J Med* 2014; 371:2054-2057.

⁵ Lamontagne, F., et al. “Doing Today's Work Superbly Well – Treating Ebola with Current Tools.” *N Engl J Med* 2014; 371:1565-1566.

Rebuilding Liberia's Health Care System Amid the Ebola Crisis

Patricia A. McQuilkin, M.D.

It was a dinner months in the making and one for which I braced myself for an unusual combination of both joy and heartbreak. Many of us who love Liberia and its people were forced to the sidelines as the Ebola crisis raged out of control. Over the summer, we followed the fate of at least five physicians we had worked alongside for many years who became infected. Four did not survive.

Now, in the weeks before Thanksgiving, we were both eager to be back at work on African soil and, on this night, heading to a reunion dinner with a handful of the faculty, interns and residents we've trained in recent years. We found them to be physically well but clearly processing a great emotional toll. We listened as they shared their frontline encounters with the epidemic – hypotheses about

how their unfortunate colleagues were exposed, how they became ill and how they died. One told a touching story about a physician who cared for his Ebola-stricken colleague, only to contract the disease himself. We were moved by their harrowing accounts of what it was like to be a patient in an Ebola treatment unit, to be on the brink of death and then to survive.

Since 2006, my colleagues at UMass Medical School and our academic partners have been heavily invested in training Liberian health care workers and partnering to improve their system of medical education after years of civil strife.

Now, we are honored to work side by side with our Liberian partners to tackle what may be the most intense crisis of all – rebuilding the nation's fragile health care system in the face of Ebola and helping to ensure they have the training and tools needed to safely return to work. It is an initiative we are proud to undertake, thanks to \$7.5 million in funding from the Paul G. Allen Family Foundation.

The dire circumstances at Liberia's district hospitals may be the untold story at this stage in the crisis. While deaths from the virus have been widely reported, many people remain unaware of the needless suffering and tragedy unfolding for Liberians who present with any number of more routine medical needs. Countless women, some of whom have been unsuccessfully laboring for days and need C-sections, are dying because there is no safe place for such an operation. Children with severe malaria have nowhere to go. Most of the country's nearly 40 hospitals remain closed because health care workers had no personal protective equipment and were too afraid to come back.

UMMS and a team of academic partners on the grant are working to reopen 16 such hospitals by hiring teams of Liberian health care workers, training them to become experts in safely handling Ebola cases and then dispatching them to train colleagues. Starting in the early days of 2015, the teams of master trainers – to include a Liberian doctor, nurse, midwife, psychologist and sanitation expert – will be dispatched to spend one week at each hospital to train staff on the Liberian Ministry of Health's "Keep Safe, Keep Serving" infection prevention control standards for Ebola safety, triage, patient care, sanitation and donning and doffing personal protective equipment. Everyone in the hospital will be trained, including janitors and laundry and kitchen staff. Two nurses at each hospital will be trained extensively on infection control and will monitor compliance closely, making corrections where needed.

Simultaneously, hospitals will be fully stocked with personal protective equipment and all necessary safety supplies. The training and medical supplies will provide a measure of confidence and allow the hospitals to reopen.



From left to right: Roseda Marshall, M.D., chairman of Pediatrics at Liberia's A.M. Dogliotti College of Medicine; Michelle Niescierenko, M.D., pediatric emergency physician and director of the Global Health Program at Boston Children's Hospital; Philip Ireland, Liberian medical resident who survived Ebola; and Patricia A. McQuilkin, M.D. (the author). Photo taken in Liberia in November 2014.



The desolate wards inside the JFK Medical Center in Liberia, shut down, as the piece describes, as a consequence of the Ebola crisis. Taken in November 2014.

The timing of an initiative that focuses on reopening district hospitals is becoming a critical priority now that efforts to control the spread of the outbreak appear to be making an impact.

“I’m excited that this aligns with the country’s ensuring essential services strategy,” said Michelle Niescierenko, M.D., pediatric emergency physician and director of the Global Health Program at Boston Children’s Hospital, who is project leader on the grant, along with me. Dr. Niescierenko is in Liberia coordinating the relief efforts. “We’ve just hired 25 Liberian health care workers who are experienced and eager to get to work training their fellow health care workers on how to stay safe.”

Building on a years-long relationship between UMMS and Liberia, the UMass Medical School Ebola Relief efforts funded by the grant are a component of philanthropist Paul G. Allen’s increased commitment of at least \$100 million to the Tackle Ebola campaign he has launched. The collaborative comprises UMMS, Boston Children’s Hospital, Mt. Sinai Medical School, the University of Florida Medical School, the University of Maryland Medical School, Vanderbilt University, and its newest member, the Massachusetts Institute of Technology Center for Transportation and Logistics.

Visit www.umassmed.edu/ebola to learn more, including how to contribute to the UMass Medical School Ebola Relief Effort.

Dr. McQuilkin is a clinical associate professor of pediatrics and is the director of the Global Health Program for the Department of Pediatrics at UMass Medical School and is also project lead for the UMass Tackle Ebola Project.

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Saint Vincent Hospital Preparedness: Commitment to Community

Douglas Waite, M.D., Alexander Kaiser, M.D., and Samantha Brillon, EMS



From left to right: Alexander Kaiser, M.D., Samantha Brillon, EMS, Douglas Waite, M.D.

Amid the deadliest Ebola virus disease outbreak in history, Americans are faced with a threat never before realized: Ebola on U.S. soil. As the Centers for Disease Control and Prevention, Massachusetts Department of Public Health and other government agencies work to study, understand and contain the spread of Ebola, Saint Vincent Hospital turns its focus locally. As a large community hospital in the heart of Worcester, SVH believes its duty to patients, staff and community is to prepare for Ebola with planning, education and action.

When first reports surfaced several months ago of a growing Ebola epidemic with possible global implications, SVH laid the cornerstone of its preparations by forming the Ebola Preparedness Team (EPT). This group of 20 individuals consists not only of hospital executives

— many with backgrounds in infectious diseases — but also managers, coordinators and front-line representatives from the Emergency Department, Intensive Care Unit, Labor and Delivery, Infectious Diseases, Housekeeping, Security and Outpatient Services. Through this team, SVH cemented a foundation of coordination and solidarity, from which Ebola preparedness could develop as an extension of its comprehensive Emergency Operations Plan.

Initially, the primary focus of the Ebola Response Plan was to establish a working protocol for any imminent patient presentation. After reviewing accounts and expert consensus detailing other American health care systems' first encounters with Ebola patients, it was clear that a new era of infection control had arrived. Much like previous crises such as H1N1 influenza, SARS or HIV — which drove

the evolution of how to best protect patients and health care providers – SVH understood the advent of Ebola in the U.S. would catalyze change in infection control practices. As the CDC was updating its guidelines, the SVH EPT was already coordinating with local and state government agencies, the Tenet home office and other health organizations to revise its protocols. The EPT reviewed quarantine procedures, patient rooms, department layouts, equipment, supplies and patient care and flow protocols to update, renovate and restock where necessary to ensure that SVH is ready. The EPT developed a progressive cycle of re-evaluation and improvement through almost daily meetings. This was done by reviewing all guideline updates from the CDC, weekly conference calls with DPH officials, regular meetings with Worcester DPH and other local health care institutions, and discussions with supply companies and vendors. Establishment of the EPT and revamping protocols and resources was only the foundation for Ebola preparedness; the next step was to put planning into practice.

One of Saint Vincent Hospital's strengths lies in action through information. The backbone of Saint Vincent Hospital's Ebola preparedness is education – not just for staff but also for patients and the community. Experts have commented on how an “epidemic of fear” has resulted in many quick, inappropriate and sometimes dangerous responses from individuals, governments and communities that are contrary to scientific data and expert opinion. Despite its stigma, it actually is very difficult to become infected with Ebola, as transmission requires very close contact from symptomatic patients. SVH believes the best way to alleviate public and workplace anxiety is to be prepared and to educate all. Therefore, the EPT instituted a broad information campaign. Conspicuous postings at all patient entry points clearly inform patients to self-screen for travel and Ebola symptoms (such as fever, aches, abdominal pain, nausea/vomiting or bleeding), then how to self-isolate and contact staff should they meet these criteria. Numerous educational initiatives have been offered to SVH employees. The EPT continued to keep hospital staff informed and current through signage, newsletters, lectures, “town hall” meetings, grand rounds, department-specific seminars and Q&A's, equipment and procedural training, and focused unit discussions during lean daily management rounds. Another important initiative was the CDC guideline-derived “Just Ask the Question!” campaign that instructs front-line hospital staff on simple but effective epidemiological screening that can rule out a majority of patients with Ebola-like symptoms. SVH also reached out to the public through numerous local media outlets, including newspapers, radio and television, as well as local symposiums and social groups. The goals were to keep people informed, to alleviate anxiety and to avoid stigma.

Concurrent with informing was putting the education into practice via SVH employee training. Personal protective equipment (PPE) has been a major concern for health officials since the beginning of the Ebola outbreak, not just regarding what equipment and measures were appropriately safe, but also the proper dressing and removal of equipment to minimize exposure. This “donning and doffing” training was central to SVH employee education, especially for front-line department staff at risk for exposure. Nearly 100 percent of employees in these departments were trained within a month, with quick expansion to support departments such as security and housekeeping. Other protocols beyond PPE measures were also addressed, including patient care flow, laboratory work and waste management. Many full-length drills have been conducted in the Emergency Department to evaluate “presentation-to-isolation” procedures, training and equipment. The experience and information gained from these drills helped refine the Ebola algorithms and to stock the ideal equipment for all aspects of potential Ebola patient care.


Ebola preparedness at Saint Vincent Hospital is an ongoing process, with daily review of up-to-date information and guidelines, combined with rigorous self-examination, to identify areas or items for improvement. Weekly EPT meetings and drills continue today, and communication and educational initiatives are ongoing within and outside of SVH. As a large community hospital, SVH is committed to serving the community through Ebola preparedness now and to whatever challenges present themselves next.

Dr. Douglas Waite is chief medical officer at Saint Vincent Hospital. Dr. Alexander Kaiser is a PGY-I Prelim in the Internal Medicine Program at Saint Vincent Hospital. Samantha Brillion is emergency management, EMS and switchboard manager at Saint Vincent Hospital.

Footnotes:

¹ Pugh, Tony. “‘Epidemic of fear’ has driven Ebola debate, experts say.” McClatchy Washington Bureau. N.p. 10 Nov. 2014. Web. 12 Dec. 2014. <http://www.mcclatchydc.com/2014/11/10/246394/epidemic-of-fear-has-driven-ebola.html>

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Ebola: Ready and Willing

Patrick Muldoon, FACHE



Patrick Muldoon, FACHE

Those of us fortunate to work in health care recognize the value in being prepared for all of life's "what ifs." Hurricanes, blizzards, mass-casualty events like chemical spills and exposures – emergencies of all sorts can occur without warning, leaving no time to prepare. Even less sudden "events" like SARS, H1N1 or an increase in seasonal flu can take turns that surprise the health care community.

As the region's tertiary care provider, UMass Memorial Medical Center has a long history of successfully managing the medical impact of such emergencies. We plan for

the unexpected and conduct drills to hone our skills. We've built a solid foundation, upon which we tailor plans to manage any incident that might arise – including Ebola.

Our medical center has been preparing for Ebola since late July, long before the disease dominated the evening news. Our infectious disease staff had been monitoring outbreak activity in West Africa for months, and in August, we convened an Ebola Task Force with representatives from departments across the institution to identify challenges, brainstorm solutions and implement plans. In early November, preparation shifted to the Emerging Infectious Diseases Preparedness Leadership Team, a smaller team that guides the medical center's efforts to safely care for patients with Ebola, as well as the next wave of infectious diseases that emerge.

In early October, our preliminary plans were put to the test when a potential patient unexpectedly walked through the door in the person of Dr. Richard Sacra – a Central Massachusetts physician with UMass Memorial's Family Health Center.

Dr. Sacra, the third American doctor to contract Ebola, had become ill in September while caring for pregnant patients in Liberia; he was successfully treated at Nebraska Medical Center and shown to be virus-free. He presented Oct. 4 in our Emergency Department with a suspicious respiratory infection. Because of his recent medical history, UMass Memorial physicians consulted with the CDC, and all agreed it would be prudent to proceed as if this illness were a possible recurrence of Ebola until lab testing could confirm otherwise.

What unfolded was a complex emergency drill we could not have scripted better ourselves: It was a Saturday. The patient arrived with no warning. Staff was busy with other patients. Challenges arose. Solutions had to be brainstormed. Action had to be taken. And at the center of it all, a patient and his family needed care, compassion and privacy.

Dr. Sacra was admitted to our ICU, which our Ebola Task Force had already deemed best prepared to manage a high-risk patient in isolation. His care involved a vast team of paramedics, emergency and ICU nurses and doctors, infectious disease staff, respiratory therapists, housekeeping staff, materials management, laboratory services, pharmacy, security and more.

Although our "official" Ebola management plans were not yet finalized, we

had the utmost confidence in our staff as seasoned medical professionals. Well-versed in the hospital's overall emergency management plans, our team also has considerable expertise in infection control, critical care and personal and patient safety. Adding a dose of ingenuity and resourcefulness, team members managed an unexpected and potentially very serious situation with skill, grace and support for our patient and each other.

This incident provided valuable insight for further strengthening our plans. First and foremost was communication and training. We found in the wake of Dr. Sacra's stay, and as fears of Ebola grew across the country, some staff members were understandably nervous; they worried that a patient might be admitted to their floor before they were ready. We held a series of employee forums to answer questions and gauge our staff's sense of readiness and confidence. We gave updates on the activity of our Ebola Task Force, which had been ordering equipment and developing protocols based on CDC guidelines. More than 450 people attended our forums, and it was clear they wanted to learn more in order to feel fully prepared. Their concerns arose from a dedication to patients and each other and a drive to provide excellent care in all situations.

Since late October, we've conducted basic training of 300 staff – including front-line clinic staff and those likely to encounter a walk-in patient – and more than 150 have received advanced training in the use of protective equipment and current best practices for delivering quality care while wearing cumbersome gear. Training continues, and we have established protocols and procedures to safely isolate and screen suspected cases of Ebola; established guidelines for use of personal protective equipment (PPE); secured sufficient supplies of PPE; customized a dedicated ambulance to safely transport high-risk patients; and expanded our point-of-care lab capabilities. We are furthering Ebola education of our workforce and the broader community. We've also supported the preparedness efforts of our network of 80 community-based physician practices and our member community hospitals.

UMass Memorial has been named by the Massachusetts Department of Public Health Commissioner as one of eight centers statewide prepared to treat a limited number of Ebola cases. In December, the CDC's Rapid Ebola Preparedness team visited the Medical Center to assess our readiness and make recommendations for further preparations. This work continues, and we are confident UMass Memorial can be of great assistance to our community and the Commonwealth should the need arise.

Likewise, we applaud our colleagues at the University of Massachusetts Medical School who are involved in on-the-ground relief efforts in Liberia. It is entirely fitting that the Paul G. Allen Family Foundation awarded UMass Medical School a \$7.5 million grant to help strengthen Liberia's fragile health care system, given the school's public service mission and its long-standing relationship with the country.

As of this writing, Ebola continues to ravage West Africa, but there are signs of hope: The World Health Organization reports some success with its outreach and awareness campaign and efforts with health agencies to isolate infected patients and implement safe burial practices – important measures in stopping the spread of disease. Still, Ebola is expected to cause continued illness and death for months to come. Thus, UMass Memorial remains committed to our efforts to ensure the safety of our patients, staff and community.

Patrick Muldoon, FACHE, is president of UMass Memorial Medical Center.

Worcester Perceptions and Response to Ebola

Seth Peters, MPH



Seth Peters, MPH

In the first week of August 2014, the Worcester Division of Public Health (WDPH) began preparing for Ebola Virus Disease (EVD) in the wake of Massachusetts Department of Public Health (MDPH) statewide conference calls. Over the next two months, WDPH officials disseminated public health guidance, attended numerous health care planning meetings and hosted meetings to educate all schools, colleges and universities on federal and state guidelines for Ebola precautions. WDPH also met

with community members and benevolent organizations regarding the outbreak and the growing response in Worcester to help with the outbreak overseas. The focus among locals knowledgeable about the 2014 Ebola epidemic was how the community can support the affected countries in West Africa. Approaching the end of September, the overall sense of the community seemed to be calm, informed and prepared.

Soon, the cliché became reality when the calm was replaced by a storm of fear and anxiety in the wake of rampant nationwide media coverage over the first half of October. On Sept. 30, 2014, the Centers for Disease Control and Prevention (CDC) provided laboratory confirmation of the first case of Ebola in the United States. The patient died Oct. 8, which was quickly followed Oct. 10 by the first evidence of human-to-human transmission of Ebola in the United States. This was confirmed by the first nurse at Texas Presbyterian Hospital being diagnosed with EVD. The event was quickly followed by a second nurse also being diagnosed with Ebola on Oct. 15. Both nurses provided direct care to the index case. Panic set in following media reports of these cases of EVD.

Locally, deep concern was apparent in the community and health care workers alike. Frequent questions or comments such as “Do I need to be afraid of my neighbor?” and “I will not go near someone who has Ebola,” were not uncommon, even though there had been no cases in Worcester and the likelihood of seeing a case was low. From the perspective of WDPH, the burden of Ebola locally lay within the realm of education, reassuring the community and allaying fears through facts and science. WDPH convened a number of meetings to assess the level of concern and misinformation and to determine the best way to present such information to the community. Representatives of the Worcester population, hospitals, health centers, schools and community organizations provided WDPH with input on the current perceptions and educational needs of the community. WDPH used the information gathered to develop presentations and pamphlets to be distributed throughout the area to health care providers and neighborhood groups.

From mid-October through mid-December, WDPH attended dozens of community meetings to present facts about Ebola to the community. WDPH epidemiology staff presented to health care workers at hospitals, health centers, schools, colleges and universities, as well as nursing and medical students. Sometimes, the Division gave as many as six presentations per day to educate on facts about Ebola. Notably, some of the most prevalent questions were: “How does it spread?” “Why is this outbreak so much bigger than any previous outbreak?” and “Is the virus mutating?” Attendees were well engaged during each presentation, which consisted of a 30- to 45-minute lecture and 30 to 45 minutes of questions from every group. WDPH received ample verbal feedback at the conclusion of the presentations, and the audiences consistently reported feeling reassured and informed. Facts allayed fears.

Toward the end of November and moving into December, the tone in the community and among health care workers calmed. In addition to the local campaign, there were many factors nationally that contributed to this change. Two adjustments by the CDC were particularly important to reducing anxiety about Ebola. First, the CDC updated guidance on personal protective equipment (PPE), the process to put on and take off the PPE and training recommendations. Next, the CDC announced a screening process to assess 100 percent of travelers from the countries where Ebola is actively circulating. All persons who were potentially exposed to Ebola would be monitored by state or local public health agencies for 21 days after the exposure. WDPH now monitors all people identified by federal health officials as being potentially exposed. If anyone in the monitoring program develops symptoms, he or she would call state or local public health officials, who would alert the receiving health care facility and control the entry of the suspect case into isolation at a hospital. Better protection for health care workers and reducing the potential for an unannounced patient were big factors in reassuring the community.

Over time, contacts of both the index and subsequent cases in Dallas were clear of the 21-day incubation period without developing symptoms of EVD. Moreover, a case developed in New York City went into treatment and recovered with no human-to-human transmission. This reinforced the protective effect of the screening and monitoring program, as well as the improved PPE recommendations in preventing transmission. Although there have been numerous false alarms – suspect Ebola cases that are later ruled out – there have not been any new Ebola cases diagnosed in the U.S. since Oct. 23. This bolsters the assertion that with the current level of preparation of health care facilities and public health agencies, EVD will not spread easily if imported to the United States.

Seth Peters, MPH, is chief of Epidemiology and Health Protection Services for the Worcester Division of Public Health.

Protect Doctor-Patient Speech

Michael Hirsh, M.D. and David J. Rothman, Ph.D.

The next time you speak with your physician, you may find the conversation oddly stilted. This is because the United States Court of Appeals for the Eleventh Circuit upheld the right of the State of Florida to prohibit physicians from exercising free speech.

The court defined the counseling that physicians offer a patient as conduct, not speech, and therefore not protected by the First Amendment.

The case arose when the Florida Legislature passed a bill to prohibit physicians from inquiring about patients' gun ownership, including their mode of storing the firearm and the access that family and friends might have to it.

After Gov. Rick Scott signed it into law, the Florida Chapter of the American Academy of Pediatrics (AAP) persuaded a federal judge to issue an injunction prohibiting its enforcement pending the Court of Appeals' ruling.

Now that the three-judge panel for the Court of Appeals for the Eleventh Circuit has vacated the District Court's injunction, the Florida AAP has appealed and is urging the full, en banc Eleventh Circuit to reconsider the decision.

Whatever the result, the case may well go to the Supreme Court. These proceedings have profound implications for the doctor-patient relationship and medical professionalism more generally.

The AAP has long considered a physician's inquiry about gun ownership to be one of the most important questions that he or she can ask. As Dr. David Hemenway at the Injury Control Center at the Harvard School of Public Health has explained in *Private Guns, Public Health*, a gun in the home greatly increases the likelihood of homicide, domestic violence and suicide.

A physician who asks questions about gun ownership is trying to reduce the likelihood of harm for the patients and their families. Needless to say, patients can always refuse to answer.

However, raising such questions might help lower the current rate of 10,000 children and teens injured or killed by gunshots and the 30,000 total firearm deaths in the U.S. each year.

Surely, exploring this issue is in patients' and citizens' best interests and is fully consistent with physicians' professional obligations.

Moreover, after taking this unprecedented government intrusion into the doctor-patient relationship, why would activist legislators stop with gun ownership gag orders? Why not prohibit physician counseling on reproductive rights or addiction problems or any other controversial subject that disturbs the legislature?

If this incursion on guns sets the precedent, then nothing about the doctor-patient relationship is sacrosanct or privileged.

We decry the decision by the Court of Appeals and applaud the courage of the Florida AAP in its fight to protect physicians' First Amendment rights.

The constitutional right to bear arms does not abrogate the physician's right and responsibility to educate patients and protect them, their families and their neighbors. The pro-gun lobby should have no standing in the examination room.

We earnestly hope the next decision that comes down from the judiciary will bar the government – state or federal – from gagging medical providers. Providers and their patients cannot and should not be left at the mercy of legislative whim.

Dr. Michael P. Hirsh is surgeon-in-chief at UMass Memorial Children's Medical Center, a professor of surgery and pediatrics at UMass Medical School and chief of the Division of Pediatric Surgery and Trauma. David J. Rothman, Ph.D., is a professor at Columbia University and director of the Center for the Study of Society and Medicine and the Center for Medicine as a Profession.

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Losing Medicare Enrollment

Peter J. Martin, Esq.



Peter J. Martin, Esq.

Hardly a month goes by without news of some provider having Medicare enrollment revoked due to some infraction or misdeed. Recently issued rules will make it easier for the Medicare program to revoke Medicare enrollment on grounds that might give providers cause for alarm.

The new rules, effective Feb. 3, 2015, expand the instances in which the Medicare program can either deny initial Medicare enrollment or revoke the enrollment of health care providers. Two of those grounds seem problematic. The first reason is that within the previous 10 years,

an owner or managing employee of a Medicare provider was convicted of a federal or state felony “that CMS determines to be detrimental to the best interest of the Medicare program and its beneficiaries.” The second reason is that the provider has a pattern or practice of submitting claims that “fail to meet Medicare requirements.”

The old felony conviction rule was limited to serious crimes against the person, such as rape, murder and assault; financial crimes such as extortion, embezzlement, income tax evasion or insurance fraud; felonies that placed Medicare beneficiaries at immediate risk, such as malpractice resulting in a conviction of criminal neglect or misconduct; and felonies that under statute lead to mandatory exclusion from the Medicare program, such as convictions for patient abuse or neglect, financial fraud involving a federal health care program or unlawful activities concerning controlled substances. The new rule expands on these relatively precise categories of felonies to include a relatively vague category of offenses determined to be detrimental to the Medicare program or its beneficiaries. This new rule applies not just to “owners” of a health care provider, meaning a partner or an owner of more than 5 percent of the health care provider. The rule also applies to the “managing employees” of a health care provider; this latter category encompasses any individual, whether an employee or independent contractor, who is a business manager or administrator of the provider or who manages or conducts the provider’s day-to-day operations.

The published text of the rule contains CMS’s responses to a large variety of comments on this new approach. Would felonies related to drug use, alcohol or traffic violations be considered detrimental to the Medicare program? Well, CMS does not believe that they cannot be detrimental to the program and thus should not be excluded as a basis for revocation. What about conviction for a non-violent firearm felony? CMS will evaluate such a conviction based on its specific facts. What if an employer makes a good-faith effort to screen a new employee for relevant felony convictions? “The core issue is not whether the organization made a good-faith effort to determine whether a current or prospective owner or managing employee has a felony conviction.” What is relevant is the felony conviction itself. CMS adds that it is not requiring providers to conduct criminal background checks. Will the new rule be used to review the backgrounds of current owners and managing employees of an enrolled Medicare provider for purposes of revoking that enrollment? The new rule does not preclude CMS from doing just that. Will CMS publish a specific list of the felony convictions it considers detrimental to the Medicare program? No.

Where does that leave health care providers that participate in the Medicare

program who may be contemplating adding an owner or managing employee? While felony convictions of any nature are serious matters and are not to be taken lightly, this new rule affords CMS a worrisome level of discretion to decide which felonies “count” for purposes of Medicare revocation. Although Medicare is not requiring them, clearly criminal background checks ought to be considered, as would contractual and employee handbook provisions allowing for immediate termination should a relevant felony conviction be committed or not disclosed. The larger question of which felony convictions are “detrimental to the best interest of the Medicare program and its beneficiaries” remains unanswered, however.

The second new revocation authority provided under the new rule pertains to a pattern or practice of submitting claims that fail to meet Medicare requirements. In this instance, CMS is careful to specify that sporadic billing errors would not result in revocation under the new rule. It notes that under its current practices, a provider making billing errors would receive information and education about the reasons for the claim denials and that the provider then has the responsibility to review the denied claims and take necessary remedial action.

Again, the comment and response portion of the rule promulgation is instructive. Would CMS revoke billing privileges only where there is a finding of fraud? No; the lack of fraud does not mean that the billing practices were compliant with Medicare requirements. What about claim denials that are based on inadequate documentation – could those justify revocation? Yes; repeated claims denials due to inadequate documentation indicate the provider’s unwillingness to become compliant with Medicare requirements. Shouldn’t the rule be limited to situations in which the provider knew the claims did not meet Medicare requirements? No; it would be too hard for CMS to determine the provider’s intent, and besides, other statutes, such as the False Claims Act, cover non-compliant claims submitted knowingly or with reckless disregard of applicable requirements. Shouldn’t CMS give a warning letter to the provider prior to imposing revocation in such cases? No; frequent claim denials are sufficient to put the provider on notice of problems with its claim submissions.

CMS seeks to alleviate providers’ concerns about the vagueness of this new rule by stating: “Our sole focus is on providers and suppliers that engage in a systemic, ongoing, and repetitive practice of improper billing notwithstanding the public availability of CMS educational materials or guidance and CMS’ issuance of claim denial notices to the provider . . . [W]e plan to issue written guidance to and communicate with the public once this final rule is implemented, whereby we will once again reiterate the objective . . . and, as necessary, discuss certain operational aspects of this provision.” The new rule is “only intended to address the most severe of situations,” but CMS will monitor the operation of the new rule and, if necessary, issue additional rules providing for other sanctions as appropriate.

Clearly, providers must take very seriously any pattern of repeated claim denials that might form the basis for CMS determining the provider has made, not a series of innocent mistakes, but a systemic, ongoing and repetitive practice of improper billing. The complexity and evolving nature of billing requirements, coupled with CMS’s evident disinclination to provide extra educational support in light of this enhanced revocation power, puts the onus on the provider to take additional steps to keep up to date on Medicare claims submission requirements and to act quickly to rectify billing errors to avoid creating a “pattern or practice” of such errors.

Peter J. Martin, Esquire, is a partner in the Worcester office of Bowditch & Dewey, LLP, his practice concentrating on health care and nonprofit law.

Worcester District Medical Society 2014 Fall District Meeting and Awards Ceremony

Wednesday, November 12th 2014

David C. Kim, MD, FACS

*4th Annual Dr. A. Jane Fitzpatrick
Community Service Award Recipient*



(left to right) Joel Popkin, MD; Nominator; David Kim, MD, FACS; Award Recipient; and George Abraham, MD; Chair, WDMS Awards Committee

Carol Bova, PhD, RN, ANP

2014 WDMS President's Award Recipient



(left to right) George Abraham, MD; Chair, WDMS Awards Committee, Paulette Seymour-Route, PhD, RN, Nominator; Carol Bova, PhD, RN, ANP; Award Recipient and Terence R. Flotte, MD; Nominator

Stephen T. Earls, MD

*2014 WDMS Career Achievement
Award Recipient*



(left to right) Stephen Earls, MD; Award Recipient, Dennis Dimitri, MD; Nominator and George Abraham, MD; Chair, WDMS Awards Committee

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Wake Forest University of Medicine
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Priyanka Chilikamarri-2016

The University of Vermont College of Medicine
The Dr. Burte Guterman Award

Erin M. Corsini-2016

Albany Medical College
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University of Massachusetts Medical School
The Saint Vincent Hospital Dr. Gilbert E. Levinson Award

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The Worcester District Medical Society

Christopher R. LaChapelle-2017

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Jessica Long-2017

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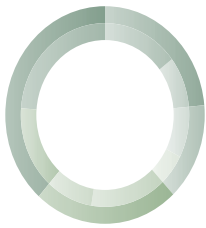
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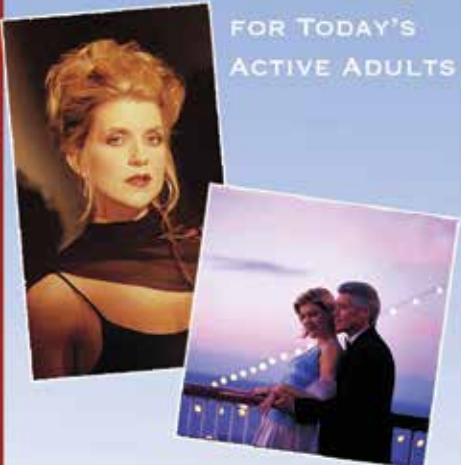
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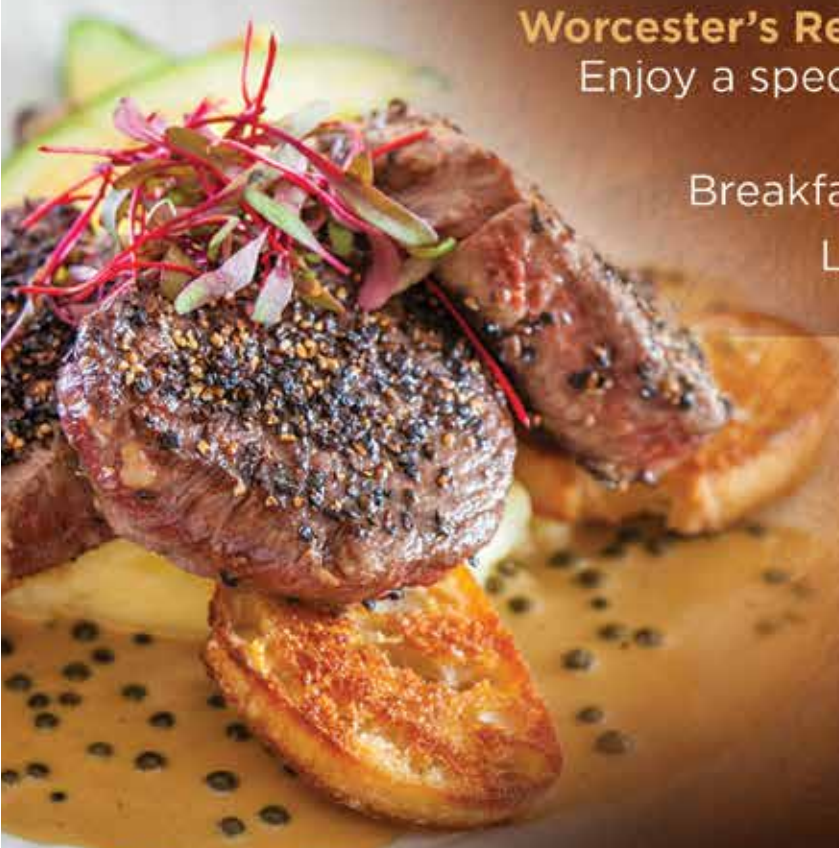
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