



CODES That KILL

The U.S. government is using its payment system to control the types of medical treatment Americans get, leading to high medical costs and high mortality.

by Richard Fleming, M.D.

The Association of American Physicians and Surgeons (AAPS) recently published several articles telling the story of cardiovascular surgeon John Natale, M.D., who is in prison after being accused of attempting to defraud Medicare. On November 1, 2012, Natale began a 10-month prison sentence, though at trial a jury found him innocent on all charges of fraud.

Here's his story: Between August 2002 and October 2004, Dr. Natale operated on five seriously ill elderly patients, averaging 78 years old. All the patients lived through the surgery, "despite an expected mortality of 90 percent." The 63-year-old Natale, who "routinely worked from 5:30 a.m. until late at night," was "habitually ... behind in dictating his operative reports" and when he filled out the reports weeks after the surgeries, he incorrectly stated that he repaired an aortic aneurysm instead of the type of aneurysm he actually repaired. He was accused of using an incorrect American Medical Association code — a code the government requires doctors use for billing — to bill the government for the procedure he performed, though there is no precise AMA code for the procedure he did.

The charges against Natale were the result of a seven-year government investigation into his records, wherein the government reviewed 2,400 operative reports. Natale's defense rested upon his claims that he simply made some reporting errors and that there was no fraud because if he had billed the government properly, he

actually would have received more money for his services than he actually received. The jury agreed and found him not guilty on all fraud charges. But Natale was imprisoned anyway for making "false statements" in his operative reports, though under the law, according to AAPS, "a false statement is a crime only if made in a deliberate attempt to commit fraud — and, as the jury determined, *there was no fraud*." (Emphasis in original.) He was literally imprisoned for making minor errors — if politicians, judges, prosecutors, and Medicare workers were held to the same standard, it would be safe to say that nearly every one of them would be in prison.

The harsh sentence meted out to Natale was evidently meant to intimidate doctors. Prosecutor Amarjeet Singh Bhachu flatly stated: "A message needs to be sent out to doctors." Yet it could have been worse. Because Natale had the gall to actually defend himself at trial and testify in his own defense, the prosecutor asked for a sentence enhancement for "obstruction of justice," which "could have resulted in 5 years in prison." No kidding.

Calling a Code

The rationale behind using the codes is supposedly to ensure that Medicare — the government — only pays for medically necessary services for disease, disability, infirmity, or impairment. The codes, developed by the AMA, are known as the Physicians' Current Procedural Terminology (CPT) system.

But fiscal probity doesn't seem to be the

actual reason for the codes. They are currently being used to give the government control over patient treatment protocols.

The CPT codes and International Classification of Disease (ICD) codes, which identify the illness or health problem the person is seeing the doctor for, are promulgated by the federal government and are the code numbers any physician or hospital system must provide to the government or insurance companies to determine if the physician or hospital will get paid for tests on or treatment of patients. If you don't follow government guidelines, you don't get paid.

If the government doesn't think a test is "indicated" or the government doesn't have a CPT for a specific procedure — think new, cutting-edge care — the government likely isn't going to pay for it. If doctors and hospitals do bill for a procedure that doesn't have a specific code, using, logically, the closest code they think matches the completed procedure, and the government doesn't agree with the decision, the Centers for Medicare and Medicaid Services (CMS) won't pay for it, and the doctor and hospital might even be accused of committing a crime. If the government doesn't approve of a test or think a medicine should be given, CMS won't pay for it — even if it saved your life. One doesn't have to be a business major to know that if something isn't paid for, it won't get done. With a little "behavior modification" and the threat of a criminal conviction, the government teaches everyone that it is in charge of healthcare, not patients or doctors or hospitals. Thanks to recent congressional

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actions and with the blessings of the U.S. Supreme Court, the federal government — imposing ObamaCare through the Department of Health and Human Services, CMS, and the FDA — *will* determine what medical treatments you will get, if and when you will get care, and how much care you will get — all through the ICD and CPT codes that it approves or rejects.

Moreover, private insurance companies follow the government's lead. When doctors or hospitals bill insurance companies, the first question is, "Does Medicare/Medicaid approve or pay for this?" If the government doesn't recognize or pay for prescribed procedures and medicines, then the insurance companies won't either.

So, you see, doctors like myself don't actually get to determine what happens to you; the government does! Government agencies spend a lot of time telling doctors and hospitals how to practice medicine — which tests to order, which medications to use, and when patients *must* be sent home — in order to avoid being penalized for not following the rules. But nowhere is there anything that suggests that these agencies have the knowledge or training necessary to make the types of clinical decisions that doctors and hospitals must make every day. There is not a single study to prove that the U.S. government does a better job of delivering healthcare than a doctor or hospital does.

Government Controlling Agencies

Not surprisingly, there is plenty of proof to show that federal bureaucrats don't do a good job of looking after your health. For instance, the FDA, which is responsible for monitoring the use of medications and food to assure the safety of the American public, can't be bothered to investigate even when health concerns are brought directly to its attention.

As a nuclear cardiologist, for more than two decades I repeatedly warned the FDA of problems with the rubidium-82 (Rb-82) isotope generators, yet the FDA did nothing

for 23 years. Specifically, I told the FDA the generators [where Strontium (Sr) 82 decays to Rb-82] were not safe and were leaking radiation. After more than two decades, the FDA finally had the generators pulled and added additional

warnings for the safety and security of Americans.

If you think that's bad, let me tell you about the government's standard of care for heart disease. Every year 11 million nuclear studies are done in the United States alone to look for heart disease. Of these 11 million, 35 percent are *inaccurate*, and some 70,000 to 90,000 misdiagnosed Americans will go home with such severe disease that, after being told there is nothing wrong with their hearts, they will die soon thereafter.

The cause of the high error rate in these studies lies in the methodology behind how they are performed. In the studies, people are given an injection of a radioactive substance and, a short while later, pictures are taken of the heart. This is referred to as the "rest image." Several hours later, the patient is "stressed" — subjected to physical exercise or drugs which simulate stress — and re-injected with a second dose of radioactive substance, and a second set of heart images are taken. This

is referred to as "stress imaging." To find heart damage, physicians compare the images, looking (qualitatively) at the images and guesstimating if there is heart disease. It's a crude method of determining heart problems, but as they say, "It's good enough for government work."

One of the primary reasons that the test is so inaccurate is simply that humans tend to see what they expect to see, overlooking completely what they don't expect to see — even when "the unexpected" is right in front of them. An online video demonstrates the strength of this tendency. The video instructs viewers to watch two small groups of youths, half dressed in black and half in white and to count how many times the players in white pass a ball back and forth as they walk around. In the midst of the action, someone in a gorilla suit walks between the players, beats his chest, and then walks off-screen. Yet a large percentage of viewers will have never noticed the person in the gorilla suit.

But this couldn't possibly happen to doctors who are specifically looking for disease, right? In fact, the exact same thing happened when doctors were tested. A recent study showed that 83 percent of board certified radiologists didn't see a dancing gorilla on a CT scan of a chest, even when they were looking right at the gorilla. They simply didn't see it, and half



Technology flawed: Doctors use CT scans to search the body for nodules that may indicate cancer. The machines tend to work correctly, but human technicians must visually locate any nodules on the scans, and they miss up to 50 percent of nodules shown by the scans.

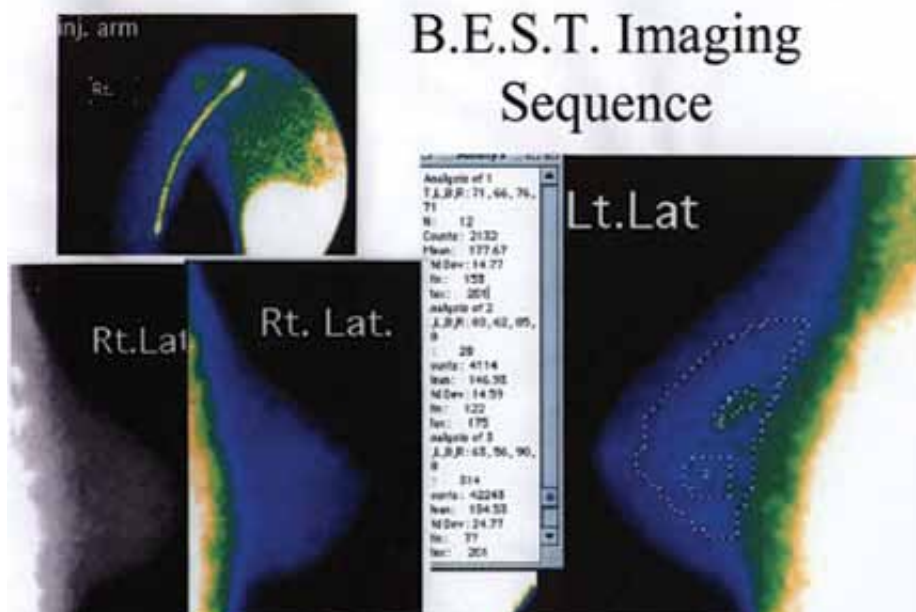
the time they missed masses (nodules) on CT scans that would indicate cancer. Yet this visual guessing game on heart disease is what the federal government is willing to pay for. It's what they recognize, have a CPT code for, and *feel* comfortable with.

All this, despite the fact that there is a much better method available.

During my investigation of isotopes and nuclear testing procedures, I discovered that our nuclear cameras could be used, without any change in equipment or software, to look at the movement (redistribution) of these imaging isotopes and “quantify” the changes over time, indicating, in practice, whether a patient had heart disease or not, without the need for a doctor to guesstimate the likelihood of heart disease. Using this method provides cardiac studies with greater accuracy, in less time, and with less expense. These studies can be done in one-fifth the time and use less radiation, allowing us to make better use of our healthcare dollars and precious resources. Since the studies take less time, hospitals and doctors can do more studies each day, and patients wouldn't have to wait as long to be tested and treated.

To visualize the difference between the old and new methods, think of the heart examination as if you were buying a car. The best way to determine how well a car works is to put the key in the ignition and drive it to see how it performs at different speeds and under different conditions. Merely looking at a picture of a car at rest doesn't tell you anything about how the car performs. Similarly, a single picture of it running doesn't tell you if the car had problems starting, idling, accelerating, etc. The same is true with the engine we call your heart. You have to stress it and inject the isotope and compare what happens to the distribution of the isotope over time to see if there is a problem. More importantly, you want to measure the movement (redistribution) of the isotope to get an accurate picture of what is really happening to your heart. If not, you might just as well go kick the tire — or heart!

The government is sticking with its multiple-injection protocol, notwithstanding the fact that South Korea is already using the new method with great success; that for the government's preferred test protocol to be accurate, isotopes would have to behave like superglue in the body,



Breast Enhanced Scintigraphy Test (B.E.S.T.)© (pat. pend.) images demonstrate an isotope traveling into the body (upper left), with images taken of the right breast several minutes later. The images (lower left) are first displayed as black and white and then converted to blue-green for “qualitative” interpretation. Finally, the results are “quantified” (far right) showing early ductal carcinoma in-situ (DCIS) — the beginning of breast cancer.

sticking in place when they are injected, and this has been demonstrated to be wrong in more than 50 published papers; and that the new method simply makes sense because the computers we use to generate the pretty pictures that the doctors examine couldn't generate an image to look at unless they could actually measure (quantify) what is happening in the first place — using isotopes in the blood, the computers can monitor blood flow and heart function.

South Korea has further demonstrated that this method (FHRWW) is more accurate, faster, uses less radiation, and in the end is more cost effective.

Again, both CMS and the FDA ignored this information, which was repeatedly submitted to it. So much for making medicine more effective, more accurate, and safer for people.

This ability to measure redistribution over time not only allows us to find what we've been missing for so long; it also allows us to determine if your treatment is effective. Imagine that, instead of being told that your heart treatment must be working because you haven't died yet, you could actually be told that the benefit to your heart was “measured” and the treatment works. Or, alternatively, that the treatment was “measured” and doesn't work and you need to try something else,

rather than waiting for you to have a heart attack. This would not only improve the way people are treated, but it would also reduce overall healthcare costs.

With prevention and treatment of heart disease being a *major* emphasis in medicine, it seems to be gross medical malpractice — by government bureaucrats and courts posing as doctors — to stifle this innovation in heart disease remediation. But, you say, maybe this was a rare oversight. Wrong! Consider breast cancer.

Breast Enhanced Scintigraphy Test

Every year 40,000 women die from breast cancer. And though much emphasis is placed on defeating this cancer — understandable since breasts are something that interest both men and women — the process whereby breast cancer is detected and treated is almost to the level of a bad joke. Today, up to 30 percent of women who have breast cancer are missed using “screening” mammography. If that isn't bad enough, when a woman has a mammogram 10 years in a row, there is a 50-50 chance she will have surgery to remove part or all of her breast because her screening mammograms made someone think she might have cancer, when she really didn't.

In spite of this, doctors are still using the same archaic breast-smashing x-ray-machine method developed in the 1960s

to radiate breasts. This machine looks for... calcium. The main problems with this approach are that the goal isn't to find calcium (it's to find cancer) and that calcium may or may not be present if you have breast cancer. No wonder mammography has *never been* proven to correctly screen breast cancer! So why is breast cancer treated this way? Because there are CPT codes for it, and some entity can be billed for it without a doctor going to jail.

Unfortunately, the detection of breast cancer is often complicated by other irregularities in breast tissue, such as fibrous tissue and cysts. Distinguishing these anomalies and normal breast tissue apart from cancer, which is, simply, highly metabolic tissue, can be very difficult. I always refer to cancers as teenagers, or if you've had the pleasure of teaching student physicians like I have, cancers are a lot like residents: They eat a lot, don't do much,

and over time become bigger and take up more space. To make matters worse, the U.S. Preventive Services Task Force recommends that women over 40 have a mammogram every one to two years. Because mammograms are imprecise, women like Angelina Jolie have bilateral prophylactic mastectomies out of fear of developing breast cancer, owing to the fact that they have certain genetic markers (BRCA1 and BRCA2). Unfortunately, the genetic markers show only that a person has a predisposition to develop breast cancer, not that she has it. Americans deserve a better method of detecting breast cancer than fear.

Then, if there is something suspicious on your mammogram, more than likely you will now get an ultrasound, though ultrasounds don't tell you if you have cancer.



Fear rules: Having to rely upon government-accepted diagnostics for breast cancer discovery, some women, such as Angelina Jolie, have gotten mastectomies to prevent breast cancer.

They are used to see if a lump is cystic or solid, though having a cyst (a fluid-filled ball) in your breast doesn't exclude cancer 100 percent of the time and having a solid mass doesn't always mean you have cancer.

But CMS has heard of ultrasounds so it doesn't "frighten" them, and there's a CPT code so the government will pay for it. Then you will need a biopsy, despite having had the ultrasound, which, as you might have guessed, has its own CPT code (19100). More CPT codes, more tests, more costs, and more money. Just remember, use the right CPT code! If you get an ultrasound with a biopsy, it's a 76492, and if you leave something in the breast to find the spot later, it's a 19291.

The dean of my medical school was right — *there are* easier ways to make money. Much easier!

As with our heart-disease discussion, there's a better way to detect differences between normal breast tissue, fibrocystic disease (frequently confused for cancer), and breast cancer itself.

Several years ago, a pharmaceutical company working with one of the isotopes used for detecting heart disease asked me if I could help them in the diagnosis of breast cancer. In the end I developed a method for tricking cancers into giving themselves away, and I measured ("quantified") what I was seeing. As with heart disease, today's nuclear cameras can be used to measure differences between normal breast tissue, fibrocystic tissue, and breast cancer, by taking advantage of the greedy characteristics of cancers themselves. Not only does this provide an accurate method for finding cancer, just as it provided a "quantitative" method for finding heart disease; but as with heart disease, it means we can actually determine if your treatment for breast cancer or fibrocystic disease is working.

As documented in multiple peer-reviewed studies published in a medical textbook

and academic medical journals, nearly 700 women have been examined using this new method, with a 100-percent success rate at discerning whether breast tissue was normal, inflamed, or cancerous. Though this method for finding breast cancer involves using radioactive material, it would be cost effective and could be done when a patient gets her/his (yes, men get breast cancer too) heart tested for heart disease. The information on the efficacy of this procedure has been available to the government for more than seven years but has yet to be acted upon. Until it's graced with its own CPT code, you probably won't get this in the United States.

Healthcare Agency Run Amok

As you might have guessed, even while the government refuses to grant codes for cutting-edge care, it continues to pay for care that has been proven to be ineffective. As the *New York Times* reported in a 2011 article entitled "Cut Medicare, Help Patients,"

Late last year, the Food and Drug Administration determined that the

Today, up to 30 percent of women who have breast cancer are missed using "screening" mammography.

drug Avastin, which has serious side effects, is not effective for treating breast cancer. Astonishingly, Medicare declared it will still pay for Avastin — at a cost of about \$88,000 per year for each patient.

Consider colonoscopies. The United States Preventive Services Task Force recommends not doing colonoscopies for most people over 75 because there is no evidence that they save lives in this population. Moreover, the risk of perforating the intestines rises with age. Yet Medicare pays for the procedure regardless of the patient's age.

Every year more than 1 million cardiac stents are placed in patients to open blocked arteries. Stents are essential immediately after a heart attack, but a 2007 randomized trial conducted at 50 medical centers in the United States and Canada showed that for patients with stable heart disease, stents do not reduce the number of heart attacks or save lives when compared with drug therapy. And they are substantially more expensive.

The list goes on. Whether such flagrant foolery is the result of incompetence or pressure from lobbying groups, the result is the same: We are abandoning best medical practices as determined by “evidence-based medicine.”

Evidence-based medicine was established by Archie Cochrane, who demonstrated that true medical breakthroughs are established by looking at the real results. As we have already seen, these real results can dramatically improve the quality of healthcare for Americans in both the diagnosis and treatment of heart disease and breast cancer. As doctors learn about what does and doesn't work, the medical standards of care should change. In fact, standards of medical care can and frequently do change every few years, depending upon advancements in the field. Unfortunately, the government and the courts are less focused on “evidence-based

medicine” and more focused on protecting its ICD and CPT codes and setting payments in stone — tombstones.

And while it may be true that most government workers in the healthcare business mean well, government involvement in healthcare decisions means disastrous diagnostic treatment for many. Let's examine why.

To start with, CMS, the agency that handles Medicare and Medicaid, is not composed of doctors or hospital administrators interested in improving the quality of American healthcare. Its workers don't know the clinical difference between a 78464 and a 78465, or between a 90592 and a 87798. Yet its determination of what it will pay for determines what treatments are available. And using these numbers, the government tries to get doctors to behave in a manner that uses less of “the government's resources.” Rather than adapting to new, more cost-efficient and effective standards of care that doctors have developed — which bureaucrats either don't know about or ignore — the bureaucrats will push doctors to do fewer tests or otherwise reduce costs while ad-

hering to the codes.

The whole goal is to limit the amount of money being spent without asking, “What diagnosis and treatment does the doctor think is needed?”

What a difference from what I was taught in medical school. My medical training taught me to look at the patient and not his insurance plan.

Let me pose a simple question that should highlight the ludicrousness of the present situation. “Should a hospital and doctor treating someone with heart failure who has a heart attack receive a different amount of money for taking care of that person than for treating a person who has a heart attack *and then* develops heart failure?” Based upon CPT and ICD codes, they do. The patients have the same problems; flip the codes and the government and insurers pay different amounts. Moreover, there's nothing in these codes or in guidelines from the government's agencies that asks, “Did the patient receive the type of healthcare an American has a right to expect?”

Ironically, even as the U.S. government fails to assign a code to these more accurate methods of detecting heart disease or breast cancer described above, the U.S. Centers for Disease Control (CDC) actually requested that I present these new methods at a meeting held in Greece in 2005. That's right, eight years ago! Their request for me to present might be due to the fact that the CDC is concerned with world health and less interested in telling doctors and hospitals how to administer it.

Let Doctors Do Their Job!

Most doctors and nurses I know got into healthcare to make a difference. Trust me, there's nothing glamorous about cleaning blood, feces, vomit, or somebody's body parts off you, your colleague, or where you're trying to walk. Despite doctors' dedication, the U.S. government can't be bothered to listen to them. Yet even as the U.S. government ensures that progress bypasses American patients, much of the rest of the world is listening. More impor-



Fraud? Though precedent-setting *Prabhu v. U.S.* found that doctors are not guilty of a crime for using an imprecise billing code that most closely fits the procedure they perform, other courts have disagreed.

tantly, doctors in the rest of the world have been independently verifying the efficacy of new techniques and technology (including mine) and are making improvements within their own medical systems. They have asked me to edit medical textbooks; they communicate with me to find out how to implement these studies in their countries; and they ask me to present at their meetings so that they can use these approaches to more accurately detect and treat their people and reduce their overall healthcare costs.

We should be doing the same here, as medical costs continue to soar upwards while the quality of care stagnates or spirals downward. It's noteworthy that the problem is getting progressively worse. Under ObamaCare's mandates, not only is the quality of treatment set to decline drastically using these CPT codes, but the cost of care is set to explode.

Michael Tennant reported for THE NEW AMERICAN online on May 15, 2013: That's the message of a new report from the House Energy and Commerce Committee.

"Consumers purchasing health insurance on the individual market may face premium increases of nearly 100 percent on average, with potential highs eclipsing 400 percent," the report claims. Businesses, it says, will face smaller but still quite significant rate hikes as well.

... The report is based on data provided to the committee by 17 of the

nation's largest insurance companies, who ought to know better than anyone else how much premiums are likely to rise when the Patient Protection and Affordable Care Act (PPACA) is fully implemented in January.

Such cost hikes were to be expected. When I entered medical school at the University of Iowa in 1981, we were told that since the passage of Medicare, the costs associated with healthcare had risen dramatically. We were also told that when the cost of healthcare exceeded 15 percent of the GDP, the system would break. We have already exceeded that breaking point, reaching 18.2 percent in 2011. In real numbers this currently equals \$2.6 trillion. The cost for unfunded Medicare and Medicaid promises have been estimated at around \$50 trillion. If these numbers are correct, that equals \$255,280 for every American household.

I will state the obvious, just so it's out there: *The system is broken and, as you have already seen, it is just as dysfunctional as a meth addict.* There's obviously a problem, but what needs to be done?

If a doctor were to prescribe a cure for a patient, he would be careful to distinguish between the symptoms of the disease and the actual disease itself so that he could prescribe the correct treatment. Since the primary complaint about healthcare in the United States by patients is that it costs too much and it's sometimes difficult to see doctors, and the primary complaint by

physicians and hospitals is that they are being micromanaged and regulated into incompetency by the government and insurance companies, the disease is evident: too much regulation.

Similarly, the course of treatment is obvious: amputation to get rid of the invader altogether. Yes, like many things it sounds scary at first, but the alternative is the death of the American healthcare system through high costs, and fears of physicians and healthcare providers of being tried as criminals.

And this amputation can't wait. Like the patient with a serious infection or a cancer that threatens the loss of an arm or leg, most people are somewhat afraid and hesitant to do what is needed. People want to pretend everything will be all right and they won't have to make those difficult decisions to cut off that which is killing them. When antibiotics and cleaning don't stop the progression of an infection, or chemotherapy or radiation don't stop the cancer, a difficult decision has to be made in an effort to save the patient's life.

Failure to correct a mistake is what makes it a real mistake. Hesitancy and the failure to amputate cancer, or a diseased arm or leg, may very well cause the person's death. So it is with the American healthcare system.

Change will be scary for most at first, but some of us are old enough to remember when hospitals were associated and run by different religious or philanthropic groups, which helped to fund what patients needed. If you don't think that's still possible, take a look at the St. Jude Children's Hospitals. Doctors should determine your treatment, not the government or insurance companies. This system works and we should work to get back to this.

If you care about your healthcare or that of your husband, wife, mother, father, children, grandchildren, or friends, this is the time for you to act. Because the federal government cannot demonstrate that it improves the quality of healthcare — or makes it more affordable so that there is not rationing of care as doctors leave the field — Americans must pressure politicians to not only rescind ObamaCare but to refrain any of the branches of government from having any influence whatsoever on the care of patients. ■



AP Images

Charity in the works: The St. Jude Children's Research Hospital treats children regardless of an ability to pay, using donated funds. Even before the advent of government-controlled healthcare, those who could not pay received medical care.