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Prime hospital's stent placements violated state regulations

May 2, 2012 I Christina Jewett, California Watch

Monica Lam/California Watch

Charleen Kerkes said she thought about suing after her husband died at Desert Valley Hospital. She decided against it after an attorney asked to exhume her husband's body to perform an autopsy.

Dale Kerkes was lean and tanned at 71. In retirement, he turned a backyard hillside into a terraced garden and built a two-story garage.

On the morning of April 28, 2008, he and his wife, Charleen, saw his doctor to check into his occasional heart palpitations. Neither expected problems.

But during a stent placement to prop open a blocked artery, Dale Kerkes died on the operating table at Desert Valley Hospital.

Desert Valley had a limited cardiac license, which means it was allowed to place stents only in emergencies, such as after heart attacks. State hospital regulators determined several months later that the San Bernardino County hospital placed Kerkes [1] "at great health risk" by performing the procedure without the trained staff or specialized equipment required.

Since then, in response to inspections, the hospital repeatedly pledged to follow state regulations and enforce its own policies.

Yet regulators found repeat violations when they examined the cases of another patient [2] who died and two who were injured [3] during cardiac care at Desert Valley.

A fourth patient, whose case was not examined by the state, was injured after a stent treatment that a lawsuit alleges should not have been performed at Desert Valley.

The state Department of Public Health – the agency that documented recurring problems and unmet promises – in March granted Desert Valley a full cardiac license for its new heart center. Public Health officials declined to be interviewed for this story but said in a written statement they conducted two [4] thorough inspections and found no deficiencies.

Charleen Kerkes, who had hoped her husband's death would lead to changes, feels defeated. "I do think my husband died in vain," she said. "It's disappointing."

Charleen Kerkes, as well as other patients and family members, said they were not told that until March 20, Desert Valley Hospital had a limited license for cardiac surgeries. Nearby St. Mary Medical Center was in fact the only local hospital with a full license at that time.

The move to expand Desert Valley's cardiac license came as the hospital's interventional cardiologist, Dr. Siva Arunasalam, faces a trial over [5] accusations that he performed heart surgeries for financial gain while working at St. Mary almost a decade ago. Arunasalam is not an employee of Desert Valley; its medical executive committee granted him admitting privileges that allow him to treat patients.

Families of Desert Valley patients also said they didn't know Arunasalam had been banned in 2005 [6] from operating at St. Mary. The hospital's medical executive committee revoked his privileges, citing "hostile and disruptive conduct" that included "dishonesty" and disregard for patients' welfare, according to court records [7].

Medicare records from Dale Kerkes' procedure at Desert Valley, which Charleen Kerkes shared with California Watch, show that 40 minutes after Arunasalam deployed a stent, someone shouted, "code blue."

Charleen Kerkes said she feared the worst when she saw another physician in street clothes sprint toward the operating room. In an instant, she lost the man who brought her coffee in bed each morning for 40 years.

"It was a nightmare," she said.

After her husband's death, Charleen Kerkes considered filing a lawsuit. She said she decided against it when an attorney who reviewed photos of the procedure asked to dig up her husband's body to commission an autopsy.

Arunasalam, who has been treating patients at Desert Valley since 1995, declined to be interviewed and said through an attorney that he could not discuss individual cases due to patient confidentiality.

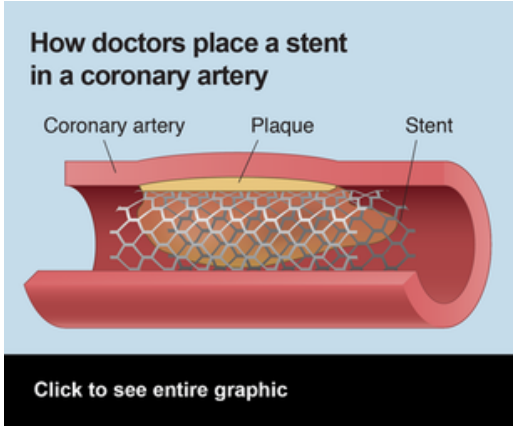
Desert Valley is owned by Prime Healthcare Services, which has been the subject of a yearlong California Watch investigation [9] that uncovered a pattern of billing Medicare for rare ailments that generate lucrative bonus payments for the hospital chain. In recent months, FBI agents have questioned former Prime employees and a former patient about the firm's billing practices.

Desert Valley implanted 118 stents in 2010, according to information supplied by Prime. That was four times the statewide average for hospitals with a limited heart care license, a California Watch analysis of hospital billing datashows.

Hospitals earn from [10] $5,500 to $16,300 for stent procedures, depending on whether the case is done on an inpatient basis. For many patients, stents are not the only tool to manage clogged arteries. Leading medical research shows that medications and lifestyle changes can be just as effective [11] as stents.

Prime Healthcare spokesman Edward Barrera said Desert Valley, which Prime bought in 2001, "has followed and continues to follow all applicable laws and regulations." He said it is important "to remember that there are unexpected complications with coronary interventions at all hospitals that no one can predict or prevent."

Barrera said two patients died during stent procedures in 2011 at Desert Valley. Statewide, the California Watch analysis shows that about 2 percent of patients undergoing a stent procedure die, about the same percentage for Desert Valley last year.



[8]
Brian Cragin/California Watch

Kathleen Billingsley, chief deputy director of policy and programs at the state Department of Public Health, wrote hospital executives [12] in November saying the new heart center would not be approved until the department is "assured of the absence of systemic health and safety issues in the hospital."

Since then, state authorities said they performed extensive examinations of the hospital and its cardiac services, on Feb. 14 and March 20. Because the hospital was in compliance with regulations on both of those days, the full cardiac care license was granted, according to the public health department.

Inspections find repeated deficiencies

Of the 57 hospitals in the state with a limited heart care license, five facilities implanted more stents than the number Desert Valley says it placed recent years.

But only Desert Valley has been cited repeatedly for its heart care, state inspection records show. Since 2007, the state has found deficiencies in cases involving 40 patients seen in Desert Valley's cardiac lab.

The California Department of Public Health has inspected Desert Valley Hospital dozens of times since 2007. During five reviews of cardiac care, it cited lax enforcement of hospital policies or failures to warn patients of surgical risks.

In response to Kerkes' death, regulators inspected Desert Valley in July 2008 and determined that [13] the hospital violated state regulations by implanting a stent "they were not licensed to provide." An inspection in 2011 found that Arunasalam had performed a stent procedure that, for the second time, violated state regulations and resulted in a patient's death.

Monica Lam/California Watch
Desert Valley Hospital in Victorville was the first in the Prime Healthcare chain. State health inspectors have found repeat violations at its cardiac lab.

Hospitals that don't correct violations face penalties ranging from loss of their state operating licenses to severance of Medicare funding. After each violation at Desert Valley, state public health officials have required the hospital to submit a "corrective action plan," but they have not sanctioned the facility.

The key difference between hospitals with a limited cardiac license and a full open-heart surgery license is staffing and equipment. Limited-license hospitals are expected to diagnose heart conditions through imaging procedures and intervene only in emergencies.

Hospitals with a full license operate with a heart-lung machine and staff trained to crack open a patient's chest and perform an emergency operation in case of complications.

The state is studying whether [14] to allow coronary stent placements at limited-license hospitals. Legislators are expected to vote on any proposed changes.

But for now, "you're not allowed to do it," said George Smith, past president of the California chapter of the American College of Cardiology and an adviser for the state study overseen by the Department of Public Health.

Regulations defied

Although Desert Valley was allowed to implant stents only in emergencies, state inspectors found several cases over the last four years that did not meet that criterion.

As part of the July 2008 inspection [15] in the Kerkes case, public health authorities found that the hospital performed stent procedures on 18 other patients in defiance of regulations. Some stent cases were scheduled ahead of time, records show, and some took place amid no evidence of an emergency.

Inspectors returned to the hospital in October 2008 and discovered that Arunasalam had injured a patient by delaying care, records show. On July 31, 2008, a 43-year-old uninsured patient suffered a heart attack, an emergency condition that would have allowed Desert Valley to implant a stent.

But instead of rapidly treating the man or transferring him to another hospital, Arunasalam waited too long, and the patient's heart muscle became severely damaged, the inspection report says. The patient may need a heart transplant, Arunasalam wrote in the medical record and noted, "Overall prognosis was poor."

In response to inspectors' questions, Arunasalam said that after the July inspection, a Department of Public Health doctor told him to "let patients die before performing cardiac interventions," according to an inspection report. Arunasalam – who has been licensed in California since 1989 – had scrawled on the medical records of several other patients that their care was "suboptimal" due to the state health department "protocol," according to the inspection report.

Desert Valley administrators say they told Arunasalam to stop citing protocols that "did not exist."

Again, the hospital pledged to change. An outside reviewer would look at all coronary stent cases, a new cardiac lab director would be appointed, and an attorney would train the hospital governing board on its oversight duties, according to a February 2009 report Desert Valley Hospital submitted to Medicare.

Former patient sues

Three months later, in May 2009, Steve Wong, a 54-year-old machine operator at a Rancho Cucamonga textile warehouse, received two stents in a procedure that left him in need of a heart transplant, according to a lawsuit [16] Wong filed against Desert Valley and Arunasalam.

Ilan Heimanson, Wong's attorney, said a cardiologist paid to review the case found that Arunasalam should have implanted one stent and transferred Wong to a better-equipped hospital to implant the second one. Instead, Arunasalam placed stents in both vessels and did not prescribe medication strong enough to prevent major bloodclots, court records contend.

Both Desert Valley Hospital and Arunasalam said in court filings that their conduct in the case did not cause damage to Wong's heart. "(Wong's case) is replete with speculation and wrongfully attempts through smoke and mirrors to place responsibility on DVH personnel," attorneys for the hospital [17] wrote.

Arunasalam testified in a deposition that he placed Wong's stents because the case was a true emergency. Wong's team did not prove that Arunasalam caused any injuries, according to the [18] cardiologist's attorneys.

Wong has said he wasn't aware that Desert Valley was limited in the cardiac care it could provide. He testified in a deposition that he's expected to live two to six more years unless he gets a heart transplant.

"I am scared of this operation because I had a narrow escape on my last operation," he testified, noting that he hadn't gotten on a transplant wait list or discussed it with his wife. "I'm not prepared myself emotionally."

In November, San Bernardino County Superior Court Judge Steven Malone denied Arunasalam's motion [19] to be dismissed from Wong's lawsuit. Malone cited Wong's medical expert, who said Arunasalam should have returned Wong to the operating table as soon as it became apparent that he had a postoperative heart attack.


Courtesy Steve Wong
Steve Wong went to Desert Valley Hospital with chest pain. His attorneys allege that the hospital and Dr. Siva Arunasalam made mistakes that badly damaged his heart.

Public health inspectors made no note of Wong's case or other catheterization lab deficiencies in a 90-page report documenting a wide-ranging inspection in August 2009. Department of Public Health spokeswoman Anita Gore said authorities did not receive a complaint about the case.

Prime spokesman Barrera said Prime could not comment on details of the case, but stated, "We are completely confident that we will prevail based on the facts." Barrera said the hospital "cannot interfere with the clinical judgment of a highly trained cardiologist" as to which case is an emergency.

Doctor faces civil trial

Arunasalam attracts hundreds of patients with cardiac troubles to his medical office, the High Desert Heart Institute [20] in San Bernardino County. Records show that he is board certified in internal medicine and cardiology and obtained his medical degree at Emory University in Atlanta.

During a 2005 employment trial that covered a wide range of practices at Desert Valley, Arunasalam testified [21] on behalf of Prime chain owner and fellow cardiologist Dr. Prem Reddy. On the witness stand, Arunasalam dismissed doctors' accusations against Reddy, saying the hospital owner is the only area [22]cardiologist he trusts.

That same year, the state Medical Board filed an accusation [23] to revoke Arunasalam's license, alleging gross negligence and failure to keep adequate medical records. Thomas Douvan, an attorney for Arunasalam, said the case was dismissed.

Arunasalam faces a civil trial in coming weeks over St. Mary's accusations that from 2002 to 2004, he implanted 59 [5] medically unnecessary defibrillators in patients. A cardiac defibrillator is implanted to regulate the heartbeat. The hospital says it discovered the cases during an internal audit and refunded Medicare [24] the $1.4 million it was paid for the procedures.

Arunasalam has denied all accusations [25] in court records, saying Medicare never deemed the procedures improper. Also, his attorneys said St. Mary administrators attempted to ruin Arunasalam's reputation because he planned to build a competing heart hospital.

Despite Wong's case and others cited by inspectors, Desert Valley continued to implant stents in cases that did not meet emergency criteria.

Courtesy the Smith family

William "Ned" Smith, 72, died during a stent procedure at Desert Valley Hospital. State inspectors say he did not sign a consent agreeing to the procedure.

William "Ned" Smith, 72, died during a stent procedure at Desert Valley Hospital.On Dec. 30, 2010, William "Ned" Smith, 72, of Hesperia died during a stent [2] placement at Desert Valley, just weeks before the Air Force veteran was planning a vacation to a vintage air show with his wife.

Patricia Smith, who was married to Ned Smith for 48 years, said Arunasalam did not explain the hospital's limited license status to the couple. She also said he told her that he was only going to examine her husband's heart. Smith said she didn't know a stent was placed until after her husband had died.

A Medicare report shows that when Arunasalam began the procedure, Ned Smith was pain-free [2] and had stable vital signs.

A report approved by Arunasalam that Patricia Smith shared with California Watch says one of her husband's arteries was perforated, which set off uncontrolled bleeding. According to the report, Arunasalam said he tried to plunge a needle into Ned Smith's chest to draw out the excess blood, but the effort failed.

Patricia Smith said she remembers seeing Arunasalam emerge from the cardiac lab, somberly shaking his head. "I started crying, 'No, no, no, this can't be right,'" Smith said.

Smith said Arunasalam told her family that Ned Smith's vessels may have been fragile because of his diabetes. Patricia Smith said she is upset that no one at Desert Valley told her that nearby St. Mary Medical Center had the staff and equipment to attempt to rescue her husband if something went wrong.

"He's not God," she said of Arunasalam. Smith and her son have shared her husband's medical records with an attorney who has not yet filed suit.

Inspectors discovered Ned Smith's case while investigating another Desert Valley complaint late last year. Inspectors determined that the hospital put patients in "immediate jeopardy" [26] of injury or death when Arunasalam performed interventions in cases that didn't meet the hospital's definition of a cardiac emergency. In addition to Smith, another patient [3] was rushed to a local hospital after a vessel ruptured during an October stent placement.

In November, the Department of Public Health said in yet another report that the hospital had once again failed to hold doctors [27] accountable for violating hospital policies. And Desert Valley, the report said, had failed to send all of its stent cases for review by outside parties, breaking a promise to regulators.

Patricia Smith, who reviewed state inspection reports, said she is concerned patients at Desert Valley's new heart center might not get clear explanations of surgical risks.

"I feel like they will take more advantage of the system by opening up the heart center," she said. "They will have free reign."

This story was edited by Denise Zapata. It was copy edited by Nikki Frick.

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Links:
[1] https://www.documentcloud.org/documents/293186-dvh-08-stent-poc.html#document/p19/a21
[2] https://www.documentcloud.org/documents/293188-dvh-2567-medicare-2011.html#document/p27/a54616
[3] https://www.documentcloud.org/documents/293188-dvh-2567-medicare-2011.html#document/p38/a54680
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[11] http://www.nejm.org/doi/full/10.1056/NEJMoa070829
[12] https://www.documentcloud.org/documents/293190-dvh-oct-11-letter-to-reddy.html
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