



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS

Medicaid Cuts Will Compromise Emergency Surge Capacity

BY JOEL B. FINKELSTEIN
Elsevier Global Medical News

WASHINGTON — Cuts to the Medicaid program will hinder emergency departments' ability to cope with a surge of patients resulting from a terrorist attack or natural disaster, physicians and other experts warned a congressional committee in May.

Witnesses told the House of Representatives' Committee on Oversight and Government Reform that planned regulatory changes would result in hospitals' losing billions of Medicaid dollars that they currently use to sustain day-to-day operations.

In particular, limiting payments to only public providers, dropping funding for graduate medical education, and limiting dollars for services in outpatient settings would have a devastating effect on emergency preparedness, said Colleen Conway-Welch, Ph.D., dean of the school of nursing at Vanderbilt University, Nashville, Tenn.

"If Medicaid dollars are reduced in these three areas, a reduction in personnel and readiness will occur in our hospitals and emergency departments across this country," she told the committee.

The cuts would come at a time when emergency departments and trauma centers are struggling to keep up with demand.

At the hearing, the committee's

chairman, Rep. Henry Waxman (D-Calif.), released the results of a survey conducted by Democratic congressional staff showing that emergency departments are already regularly overwhelmed by patient loads. Of 34 level I trauma centers surveyed, more than half were operating above capacity. Three of the five centers in the Los Angeles area were on diversion, and in Washington, D.C., where the two hospitals surveyed were both running over capacity with no available treatment spaces.

In light of those findings, Rep. Waxman said, it's surprising that both the federal Department of Health and Human Services and the Department of Homeland Security failed to consider the impact of the Medicaid changes, which were scheduled to go into effect on May 26.

"When the committee requested documents reflecting an analysis of the potential implication of the Medicaid regulations on hospital emergency surge capacity, neither department was able to produce a single document. This is incomprehensible," he said. "It appears that HHS Secretary Michael Leavitt signed regulations that will take hundreds of millions of dollars away from hospital emergency rooms without once considering the impact on national preparedness."

That contravenes a presidential directive from October 2007 that re-

quires HHS to identify regulatory barriers to medical preparedness and to coordinate with DHS to maintain emergency care capacity, according to Rep. Waxman.

The past 5-10 years have seen increasing demand on emergency departments, coupled with decreasing resources, testified Dr. Roger Lewis, a professor in the department of emergency medicine at Harbor-UCLA Medical Center, Torrance, Calif. The result has been diminished capacity, increased boarding, and more frequent diversion. His own center had effectively been on diversion for 4 days when it was surveyed by committee staff in March, he added.

"Ours is not an isolated situation. It reflects the current state of emergency health care in the United States and a paradoxical, almost incomprehensible, lack of recognition among some policy makers regarding the cause and effect relationships that exist between the fiscal pressures that have led to decreases in hospital capacity, [emergency department] gridlock, and our dwindling surge capacity," Dr. Lewis noted in his written testimony to the committee.

In a second hearing held 2 days later, HHS Secretary Leavitt told lawmakers that the lack of emergency department capacity is a legitimate issue, but that using Medicaid dollars to shore up hospital resources was not the appropriate solution.

"If there were a viable alternative way of maintaining the safety net hospital funding, then it becomes a reasonable argument," Dr. Lewis said in a follow-up interview. "They want to withdraw existing funding, which is already inadequate, prior to having any proposition on the table to make up for it."

Democrats have attached a proposal to war funding legislation that would postpone the Medicaid changes for a year. ■

"Hospital Emergency Surge Capacity: Not Ready for the 'Predictable Surprise'" is available at <http://oversight.house.gov/documents/20080505101837.pdf>.

New Risk Factors Discovered for Developing SSI

BY JEFF EVANS
Elsevier Global Medical News

CINCINNATI — Surgical site infections found in deep wounds or in organs or spaces manipulated during an operation might occur more often after general surgical procedures if patients have low blood albumin or are operated on through a previous incision, according to the results of a case-control study.

These new risk factors for surgical site infection (SSI) join old suspects—such as prolonged operative time and chronic obstructive pulmonary disease (COPD)—as independent predictors of any kind of SSI, according to a study presented by Dr. Manjunath Haridas at the annual meeting of the Central Surgical Association.

The risk factors should guide clinicians in their assessment of SSI risk and identify potential targets for intervention to reduce their incidence, said Dr. Haridas, a resident in the department of surgery at Case Western Reserve University, Cleveland.

During 2000-2006, 316 SSIs occurred in 10,253 general surgical procedures performed at one center. Dr. Haridas and his coinvestigator at Case Western, Dr. Mark Malangoni, compared 300 of these patients with SSIs with 300 matched control patients who also underwent surgery but did not develop an SSI (16 patients were excluded because no suitable matches could be found).

The patients, whose mean age was 56 years, underwent operations for the gastrointestinal tract, including the hepatobiliary system and pancreas (39% of patients); hernia repair (19%); and vascular (16%), breast (13%), and extra-abdominal areas (13%). They developed superficial (84%), deep (7%), or organ/space infections (9%).

Multivariate logistic regression revealed that reoperation through a previous incision was independently associated with 2.4-times higher odds of developing an SSI, whereas a prolonged operation, a blood albumin level of 3.4 mg/dL or less, and COPD each were independently associated with 70%-80% greater odds of developing an SSI.

Patients who had either low blood albumin or a reoperation through a previous incision were between two and three times more likely to develop a deep or organ/space SSI than were those in which neither condition occurred.

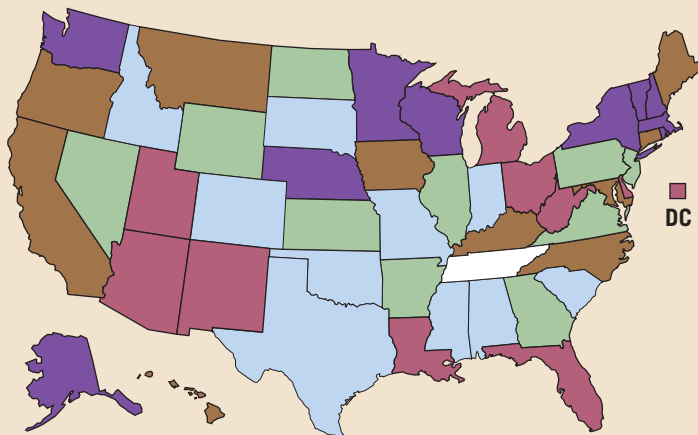
Take a postoperative surgical time-out to "reassess where you have been"; if more blood was lost or the operation took longer than expected, it could be worth keeping a closer eye on the patient, suggested Dr. Hiram C. Polk Jr., an ACS Fellow with the University of Louisville (Ky.) and a discussant at the meeting.

Although the investigators did not record how many SSIs occurred in previously operated wounds that also had already had an SSI, Dr. Malangoni, an ACS Fellow, thought that reoperation through a previously infected wound incision should be avoided because of the likelihood of reinfection after the second operation. ■

DATA WATCH

Rankings of State Medicaid Programs

1-10 11-20 21-30 31-40 41-50 Data not available



Note: Ranking is based on eligibility, quality of care, reimbursement, and scope of services. Source: 2000-2006 data, Public Citizen Health Research Group

ECMO Beats Conventional Ventilatory Support

Improved survival seen in a randomized trial of adults treated in intensive care.

BY BETSY BATES
Elsevier Global Medical News

HONOLULU — One additional patient survived for every six patients treated with extracorporeal membrane oxygenation in a large randomized study comparing the modality to conventional ventilatory support in patients with severe but potentially reversible adult respiratory failure.

Among 90 patients assigned to receive extracorporeal membrane oxygenation (ECMO), 57 (63%) were alive without severe disability 6 months following treatment, compared with 41 of 87 patients (47%) who received conventional mechanical ventilation in specialized intensive care units throughout the United Kingdom.

The results of the CESAR trial (Conventional Ventilation or ECMO for Severe Adult Respiratory Failure) were particularly striking because British researchers used an intent-to-treat analysis that included 22 patients who ultimately failed to receive ECMO, either because they began improving on their own or died before treatment could be initiated. That leaves the possibility that the magnitude of ECMO may be even greater among well-selected patients.

So profound was the impact of ECMO, in fact, that the data monitoring committee stopped the trial early, when 90 patients out of the planned enrollment of 120 patients had been randomized to each group.

The CESAR trial was conducted throughout the United Kingdom, and

more than half of the intensive care units in the country participated by referring potential candidates for randomization.

All ECMO was performed at Glenfield Hospital in Leicester (England), and the modality was available at no other center in the country during the study period.

Patients in the two groups were well balanced by age, hours of high pressure and/or high fraction of inspired oxygen (FiO₂) ventilation, underlying diagnosis (pneumonia, trauma, obstetric, or other acute respiratory distress syndrome), number of organs failed, and type of referral hospital.

Those randomized to receive customary care were managed in specialized intensive care units at the discretion of intensivists and could receive steroids, inhaled nitric oxide, prone ventilation, and positive pressure ventilation.

Dr. Giles Peek, who presented preliminary study findings at the annual congress of the Society of Critical Care Medicine, said the “real-world” study design reflects current practice in the United Kingdom. “I would suggest to you, this is right here, right now,” he said during a late-breaking papers session held at the meeting.

Currently, ECMO is widely used in neonatal intensive care units to temporarily provide gas exchange in order to provide rest for the lungs during respiratory failure.

While ECMO is also in widespread use for children and newborns in the United States and Canada, only a handful of U.S.

and Canadian hospitals practice adult ECMO, said Dr. Peek.

In both adults and infants, high airway pressures and oxygen concentrations associated with conventional mechanical ventilation are known to traumatize the lungs, yet previous studies of ECMO in adults have been inconsistent and inconclusive.

The CESAR trial was designed to determine on a large scale, in a randomized fashion, whether ECMO offers lung-protective advantages to adults with a variety of conditions leading to respiratory distress.

SO PROFOUND WAS THE IMPACT OF ECMO, IN FACT, THAT THE DATA MONITORING COMMITTEE STOPPED THE TRIAL EARLY.

Eligible patients included individuals who were aged 18-65 years with severe, potentially reversible adult respiratory failure, defined as having a Murray score of 3 or greater or hypercapnia with a pH of less than 7.2.

If they met these criteria, they were randomized to be transferred to Glenfield Hospital, where all ECMO was performed, or to receive continued conventional care at a tertiary center.

Patients were excluded if they had experienced prolonged (more than 7 days) of high peak pressure or high FiO₂ ventilation (more than 0.8), or if they had a contraindication to heparin.

Most enrolled patients suffered from pneumonia or nonobstetric acute respiratory distress syndrome (ARDS), followed by trauma. A significant number had failure of more than one organ system, demonstrating ECMO’s usefulness in multiorgan failure, said Dr. Peek.

The median time on ventilation prior to randomization was about 35 hours in both treatment groups. Among patients randomized to receive venovenous ECMO, the mean time to beginning ECMO was 6.1 hours. The mean duration of ECMO was 9 days.

The majority of patients had hypoxia, with a small number of patients experiencing uncompensated hypercapnia. The mean APACHE score assessing severity of illness was 20.

Patients in the ECMO arm received more steroids than did those assigned to conventional care, but the doses were primarily for replacement, rather than treatment, he said.

More patients died in the conventional treatment arm than in the ECMO group, 45 vs. 33, but the difference was not statistically significant. Among patients who died, those receiving conventional care died more quickly.

Overall, ECMO reduced death or significant morbidity at 6 months regardless of patients’ stratification criteria, including age, number of organs involved, or severity of illness.

“I expect conventional practice to slowly embrace the use of ECMO for adults with severe but potentially reversible respiratory failure,” Dr. Peek predicted. “I expect that more centers will branch out into adult ECMO or set up satellite programs in sister hospitals.” ■

Staging Systems for Carcinoid Tumors Determine Prognosis

BY ROBERT FINN
Elsevier Global Medical News

HUNTINGTON BEACH, CALIF. — Two proposed staging systems would divide patients with rectal and colon carcinoid tumors, respectively, into statistically significant prognostic groups based on survival data, Dr. Christine S. Landry reported at the Academic Surgical Congress.

The proposed staging systems show overall survival at 5 years ranging from 100% for stage I rectal carcinoid tumors to 18% for stage IV, and from 96% for stage I colon carcinoid tumors to 20% for stage IV (see boxes). No system is currently accepted for carcinoid tumors, according to the National Cancer Institute (NCI).

The stages are based on an analysis of the NCI’s Surveillance, Epidemiology, and End Results database for 1977-2004, said Dr. Landry of the University of Louisville (Ky.).

Size of primary tumor, depth of invasion, lymph node metastasis,

distant metastasis, and surgical resection were all significantly associated with prognosis for both rectal and colon carcinoid tumors in univariate analysis. Differences between the two tumors appeared in multivariate analysis.

For rectal carcinoid tumors, only primary tumor size and depth of invasion proved significant prognostic indicators after controlling for the other factors. For colon carcinoid tumors, however, lymph node metastasis and distant metastasis were the only significant independent prognostic indicators.

Dr. Landry and her colleagues then looked at different combinations of these indicators to see how best to separate patients into different survival groups. For rectal carcinoid tumors, it proved best to divide patients into T stages based on a tumor size greater than or less than 2 cm and whether the depth of invasion went beyond the muscularis propria.

They proposed designating tumors as T1 if they had not grown beyond the muscularis propria and

were less than 2 cm in diameter; T2 if they were beyond the muscularis propria and less than 2 cm in diameter or not beyond the muscularis propria and 2 cm or more in diameter; and T3 if they were beyond the muscularis propria and 2 cm or more in diameter.

Colon carcinoid tumors, on the other hand, would be designated T1 if they were less than 2 cm in diameter, T2 if they were 2-4 cm in diameter, and T3 if they were 4 cm or more in diameter.

Both rectal and colon carcinoid tumors would be designated N0 if there was no nodal metastasis, N1 if there was nodal metastasis, and M1 if there was distant metastasis.

“Incorporating the staging systems into clinical practice will help us determine the best treatments for rectal [and colon] carcinoid tumors as well as predict overall survival,” Dr. Landry said.

Dr. Landry disclosed that she did not have any relevant financial relationships associated with her presentation. ■

Proposed Staging for Rectal Carcinoid Tumors

Stage	T	N	M	5-Year Survival
Stage I	T1	N0	M0	100%
Stage II	T1	N1	M0	77%
	T2	Any N	M0	
	T3	N1	M0	
Stage III	T3	N1	M0	43%
Stage IV	Any T	Any N	M1	18%

Note: Based on analysis of 1977-2004 Surveillance Epidemiology and End Results databases for 4,701 patients with rectal carcinoid tumors.

Source: Dr. Landry

Proposed Staging for Colon Carcinoid Tumors

Stage	T	N	M	5-Year Survival
Stage I	T1	N0	M0	96%
Stage II	T1	N1	M0	79%
	T2	Any N	M0	
Stage III	T3	Any N	M0	38%
Stage IV	Any T	Any N	M1	20%

Note: Based on analysis of 1977-2004 Surveillance Epidemiology and End Results databases for 2,459 patients with colon carcinoid tumors.

Source: Dr. Landry

Smaller Ventricular Assist Device Gets Nod From FDA

BY ELIZABETH
MECHCATIE

Elsevier Global Medical News

The Food and Drug Administration has approved an implantable ventricular assist device that is markedly smaller than previously available devices and is the first that can be used in smaller adults, which will make this technology available to many more women with heart failure.

On April 21, the FDA announced the approval of the HeartMate II LVAS (Left Ventricular Assist System), a continuous flow left ventricular assist device manufactured by Thoratec Corp., for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular heart failure. Intended for use inside and outside the hospital, the device is contraindicated in patients who cannot tolerate anticoagulation therapy, according to the FDA.

The HeartMate II, which uses a continuous flow pump instead of the standard pulsatile pump, measures 3 inches long and weighs about a pound, according to the FDA. It is about one-seventh the size and about one-fifth the weight of previously available devices and is noiseless, easier to implant, and easier to wear and tolerate than the previous

generation of devices, said Dr. Leslie Miller, chair of cardiology, Washington (D.C.) Hospital Center, who is an investigator and author of studies of the device.

Referring to the HeartMate II as “an important advance in mechanical heart technology,” Dr. Daniel Schultz, director of the FDA’s Center for Devices and Radiological Health, said in the statement that until this approval, “some heart transplant candidates have been underserved due to the large size of previously approved heart assist devices.”

The HeartMate II, an axial flow, rotary ventricular assist system that can generate flows of up to 10 liters of blood per minute, is attached to the apex of the left ventricle, and “diverts blood from the weakened left ventricle, and propels it to the rest of the body,” according to the product labeling. The device is being studied as destination therapy.

The device can be implanted in women with a body surface area as small as 1.3 m², which is in the 90-100-pound range, and in smaller males, as well as in adolescents, Dr. Miller said. Thoratec has provided some funding for an investigator-initiated study with which he is involved.

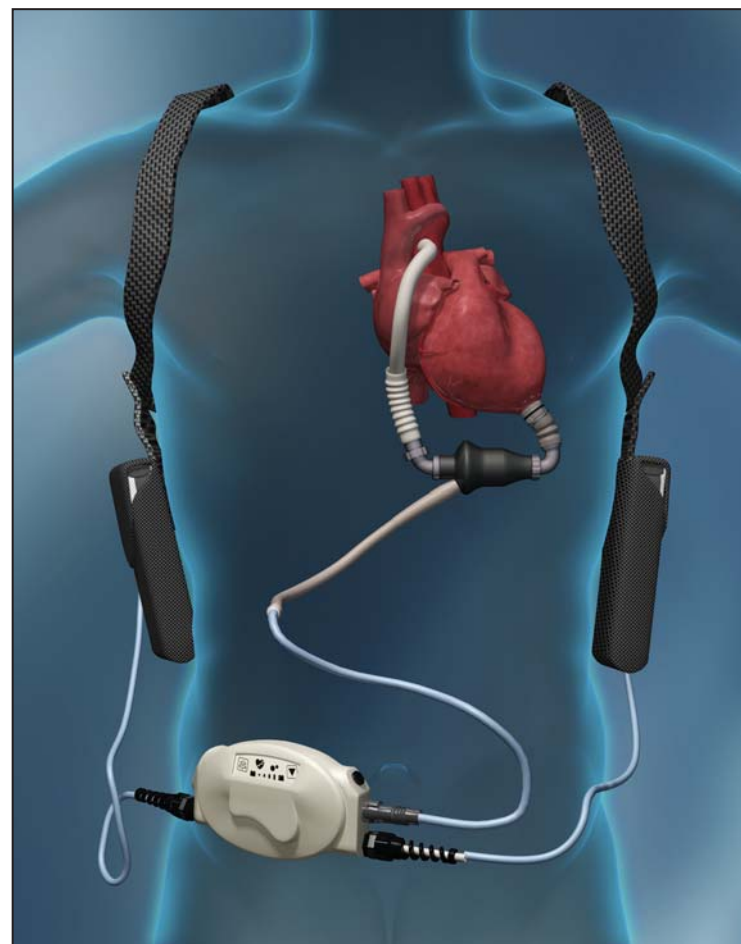
The FDA statement cited a multicenter, nonrandomized prospective study of 126 patients with New York Heart Associa-

tion class IV heart failure (mean age, 51 years), with a body surface area of 1.5 m² or more, who had no severe end-organ damage and who were on a transplant list. In this group of patients, 72 (57%) survived to a heart transplant, which is comparable with survival among patients treated with currently approved LVADs, the FDA said. An additional 4 patients (3%) recovered and 13 (10%) were supported for at least 180 days while remaining on the United Network for Organ Sharing 1A/1B list. There were an additional 10 patients with a small body surface area (at least 1.2 m² to less than 1.5 m²); 7 (70%) survived to cardiac transplantation.

During the study, 29 patients died, including 6 of sepsis, 5 of ischemic cerebrovascular events, and 4 of multisystem organ failure. One death was thought to be because of failure of the device. Regarding serious adverse events, 74 of the patients (59%) had a bleeding episode, and 37 (29%) required surgery to stop the bleeding.

In addition, 11 of the patients (9%) had a stroke and 25 (20%) had sepsis. And 80 patients—about two-thirds of them during the first 30 days—had to have a reoperation, most often for bleeding.

In November 2007, the FDA’s Circulatory System Devices Panel unanimously recommended



The HeartMate II is connected to external equipment by means of a percutaneous cable.

approval of the HeartMate II, with conditions that included a postapproval study, with a comparator, and the need to obtain more data in smaller patients (those with a body surface area of less than 1.3 m²).

Thoratec will conduct a post-

approval study of the HeartMate II, which will follow 169 recipients and will collect data on survival, adverse events, patient gender, small patients, and anticoagulation levels, and will include a comparator group, according to the company. ■

NovoSeven RT, Yulex Patient Examination Glove Also Win FDA Approval

NovoSeven RT

(Coagulation Factor VIIa [Recombinant], Novo Nordisk A/S) A new formulation of recombinant factor VIIa that can be stored at room temperature for up to 2 years, approved by the Food and Drug Administration in May for the same indications as NovoSeven Coagulation Factor VIIa (Recombinant): prevention of bleeding in surgical interventions or invasive procedures in patients with hemophilia A or B with inhibitors to factor VIII or factor IX and in patients with acquired hemophilia; and prevention of bleeding in surgical interventions or invasive procedures in patients with congenital factor VII deficiency.

► **Recommended Dosage:** Administered only as an IV bolus injection and at various intervals depending on the indication and factors such as when homeostasis is achieved. Dosing is based on weight.

► **Special Considerations:** Fever, bleeding, injection site reaction, joint discomfort, headache, nausea, vomiting, pain, swelling, rash, and elevations or drops in blood pressure are the most common adverse reactions.

An increased risk of arterial thromboembolic events has been reported in some elderly patients treated with NovoSeven for off-label indications. Not recommended for use in combination with other NovoSeven formulations.

► **Comment:** Because it contains sucrose and L-methionine, this new formulation is stable at room temperature (up to 77° F), which is helpful for facilities with limited refrigeration space, according to the FDA statement announcing approval. The original formulation, also manufactured by Novo Nordisk, could be stored for 3 years at temperatures between 36° and 46° F.

“Approval of this product for room temperature storage creates greater flexibility in disease management for patients and physicians,” Dr. Jesse Goodman, director of the FDA’s Center for Biologics Evaluation and Research, said in the statement.

Yulex Patient Examination Glove

(Yulex Corporation)

Guayule latex rubber gloves, approved by the Food and Drug Administration in April. Guayule latex is a new form of

natural rubber latex derived from the guayule bush, a desert plant native to the southwestern United States. The gloves, which are regulated as a device, are the first device made from this form of latex.

► **Special Considerations:** Despite data showing that even people who are highly allergic to traditional latex do not react the first time they are exposed to guayule latex proteins, there are no long-term data, so the product will have a warning about the potential for allergic reactions, according to the FDA.

► **Comment:** In an FDA statement, Dr. Daniel Schultz, director of the FDA’s Center for Devices and Radiological Health, said that guayule latex gloves “may prove to be a safer alternative for some people with sensitivity to traditional latex,” and would provide flexibility, strength, and other positive features of traditional latex gloves, which are made from the sap of the rubber tree *Hevea brasiliensis*.

A unique property of guayule rubber is its very low protein content, even before it has been subjected to the manufacturing process, said Robert G.

Hamilton, Ph.D, professor of medicine and pathology at Johns Hopkins University, Baltimore, in an interview. He is on the latex task force at Johns Hopkins Hospital, which has eliminated latex from the hospital and converted entirely to synthetic gloves “because we don’t know what levels of allergenic protein, even in the low levels that are now in the *Hevea* latex gloves being produced, can sensitize an individual.”

An in vitro cross-reactivity study he and his associates conducted in the mid-1990s, before Yulex Corporation was formed, showed that *Hevea* latex proteins do not cross-react with guayule protein.

But before his institution would consider using guayule rubber gloves, a carefully controlled prospective study showing they are safe to use in people highly sensitized to *Hevea* latex is necessary, Dr. Hamilton said. He is planning such a study in adults with spina bifida who were sensitized to *Hevea* latex as children.

A potential application of guayule rubber is for indwelling urinary catheters, he said. Dr. Hamilton is on the scientific board of Yulex Corporation.