NIH Clinical Center Under Stress

Squeezed between a declining patient load and Al Gore's "Reinventing Government" initiative, the heart of the NIH clinical research program may be in for palpitations

Heart trouble is not a promising condition for a patient—and the same applies to institutions. That's why it's discouraging to hear that the intramural program at the National Institutes of Health (NIH) is having trouble with its heart: a 450-bed hospital known as the Clinical Center. One problem is that the esteemed research hospital is in danger of circulating too few patients to maintain proper function. Another lies in the federal government's increasingly bold attempts to save money, which could turn out to be like surgery from an overaggressive surgeon. "They're both huge issues," says John Gallin, who has been running the Clinical Center since last May.

Because the NIH center conducts far more clinical research than any academic hospital in the country, how these issues are resolved has a significance that extends beyond the NIH campus. Wholly devoted to clinical research, the 43-year-old Clinical Center is where basic findings from NIH's vast research enterprise are tested in treatments for everything from rare diseases to cancer. But the system for testing them is now at a critical juncture. Not only has the research patient load been declining for several years, the center's physical plant is in serious disrepair, and NIH is trying to convince Congress to spend nearly $400 million for a new state-of-the-art hospital.

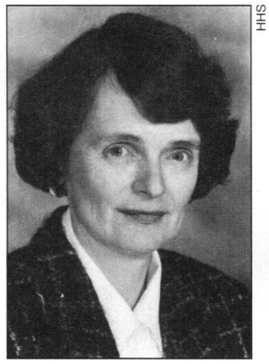
But while NIH pushes Congress for a sparkling new center, the Clinton Administration is scouring the Clinical Center's books for ways to cut costs. As part of that effort, the Administration is weighing the possibility of contracting the management of the hospital out to the private sector. A draft of this proposal, obtained by *Science*, states candidly that the push to privatize management at the Clinical Center could have a "demoralizing impact" and anticipates that "the NIH constituency will oppose this vigorously." There are some signs that this crisis could be resolved, leaving the patient healthier than before, but for the moment, the heart of NIH's clinical research enterprise faces a cold-blooded dilemma that's typical of the 90's: Pump harder while using less fuel.

Reinventing the Clinical Center

The Clinton Administration's proposal, which was mentioned in the *Washington Post* and the newsletter *Washington Fax* last week, is part of Vice President Al Gore's "Reinventing Government II," or Rego II, a far-reaching campaign to streamline government organizations. The belt-tightening effort, which has already trimmed more than $40 billion from various federal agencies and departments, is currently focusing on the Department of Health and Human Services (HHS), NIH's overseer.

The Rego II draft proposals that surfaced last week, written by HHS staffers, are far from final. As HHS Secretary Donna Shalala stressed in a 31 March memo to employees, "a lot more staff work is necessary before they will be ready for the President's review." And Shalala called press reports about HHS's Rego II draft proposals "premature."

Premature or not, the one-page draft proposal about the NIH's Clinical Center indicates that big changes are under consideration to help design a more cost-efficient operation. The most far-reaching proposal in the draft is the suggestion that the center "would be enhanced if such a quality research hospital could be operated more efficiently on a contract basis." Employees singled out for replacement by contract workers include nurses and "support staff," which presumably means housekeepers, nutritionists, and the like. The proposal also suggests that the center consider "contract management" to run it. The proposal even floats the idea that the new Clinical Center could be built entirely with private funds and leased to the NIH.



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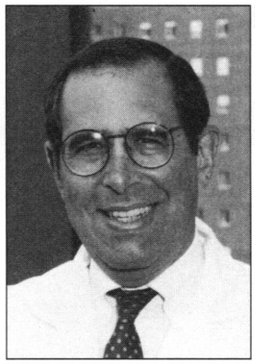


NIH

Reinvention. Helen Smits chairs a committee that's examining the NIH Clinical Center, headed by John Gallin.

And these proposals don't exhaust what might be in the works. HHS insiders tell *Science* that almost everything about the hospital will be on the table during the next 3 to 6 months, as a committee of internal and external advisers evaluates how the center spends more than $200 million a year. Helen Smits, a deputy administrator at HHS's Health Care Financing Administration—which directs Medicare and Medicaid—will head the committee. On 30 March, Smits met with Clinical Center officials, staff, and union representatives for the first time to outline her plans.

As the writers of the draft anticipated, their proposal led to a sharp rise in blood pressure at NIH. "The NIH is very concerned about the implications of doing this and is not at all enthusiastic about total contracting out of the Clinical Center. ...We want to do it cautiously, if at all," says center director Gallin, a clinical researcher who came to the Clinical Center from the National Institute of Allergy and Infectious Diseases (NIAID). The worry, explains the clinical director in charge of clinical research done by NIAID, Clifford Lane, is that too much contracting could lead to "absolute boundaries between research and service" that create a "two-caste system."

But Gallin says that in the 30 March meeting, Smits, an internist who once headed the University of Connecticut Health Center, was "very refreshing" and "very concerned that no damage be done." NIH Director Harold Varmus, who says he's "a big believer in the Clinical Center," was equally impressed. "We think she's going to do a very fair and useful job," he says. Smits refused to comment on the meeting.

Indeed, Rego II drafters are loath to speak publicly about their aims, but one insider allows that the most drastic idea that's been floated in preliminary discussions—abolishing the Clinical Center as an entity by contracting out all intramural clinical research to academic hospitals—has already been nixed. "It's too important of an institution for the nation, and it also needs to be on the NIH campus," says this HHS staffer. And there's wide recognition that, as the proposal notes, the center "will play an increasingly important role nationally" because pressures to trim health care costs will "squeeze academic health centers and reduce their ability to support clinical research."

Gallin and Varmus say they are not against contracting out some clinical services; right now, in fact, the center contracts out radiology and anesthesiology. But, as Varmus says, "contracting out clinical services is not always problem-free." Indeed, during the past few years, the hospital had a notoriously bad experience contracting out its radiology services: Last August, mismanagement of the contract was highlighted by the television magazine show *Prime Time Live* in a segment on "Washington waste." A Clinical Center whistle-blower who once monitored the contract told *Prime Time Live* that the radiologists worked only 25 hours a week on average—while drawing twice the salary they would have earned had they been government employees. Gallin, who calls that radiology contract a "sad story in history," says "it went awry because of an upside-down situation" in which NIH technicians were supervising the contracted radiologists.

In addition to reviewing how to save money by contracting out staff, the Rego II committee will attempt to gauge whether research at the Clinical Center truly is as high-risk and unique as it is said to be by NIH insiders—and to trim out work that's subpar. The committee will also review whether there are cheaper ways for the center to buy goods. "If we could bulk purchase with other federal hospitals, maybe we could save money," says Gallin.

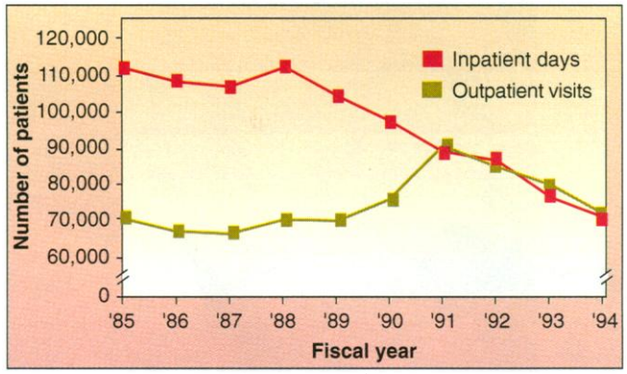
Although Rego II-inspired changes may not be seen for many months, the winds of change are already being felt by the Clinical Center staff, who last week received a memo from Gallin about the possibility of contracting out some jobs. "The impact that this announcement has had on morale is enormous," says Gallin, who explains that he is even having difficulty hiring a secretary because people are afraid to take a job they may soon lose. The draft Rego II proposal acknowledges that staffing could well be a problem if the center is "reinvented." "It may be difficult to retain key professional staff during the transition (analysis) period," it concludes.

Yet the Rego II drafters say the staff of the Clinical Center need fret only if there are inefficiencies. Says one: "If it turns out everything is wonderful and can't possibly be better, we'll leave it alone."

Losing patients

While NIH officials respond to the Administration's proposal and try to shape it to their liking, they are being confronted by another trend that will have just as large an influence on the future of the center—and surely will attract the attention of the Smits committee: the steady drop in the number of patients. Since 1991, the Clinical Center has experienced a decline in both inpatients and outpatients, falling in each category from about 90,000 to just over 70,000 in 1994 (see graph). The reduction means the hospital is now running at roughly half its capacity. For NIH researchers, the falloff is troublesome, because the declining patient census means fewer patients for clinical studies; as a result, basic research is increasingly divorced from the clinic.

In the eyes of its top administrators, including Gallin, the reduction may also threaten the health status of the hospital itself. They argue that the Clinical Center must treat a minimum number of patients to function properly—although no one can say with certainty what that number is. And the patient census can't be easily raised, because the center's patient base is strictly limited by its policy of admitting only patients receiving experimental treatments.



SOURCE: NIH

Slippery slope. Both inpatient and outpatient numbers at the Clinical Center have been falling in recent years. Part of the decline may be due to an accounting change in fiscal 1987.

"Anytime you don't have a hospital with a critical mass of patients, retaining critical skills is difficult," says NIAID's Lane. Gregory Curt, clinical director for the National Cancer Institute—which does more than 40% of all research at the center—agrees. "If you're not doing enough transfusion medicine, like stem-cell transplants, people lose their skills," Curt offers as an example. "That's the danger right now." Henry Masur, chief of critical care medicine at the center, says the decline in numbers of patients makes it difficult for divisions such as the intensive care unit (ICU) and infectious diseases, which he oversees, to do research. The ICU and infectious-disease clinicians, explains Masur, rely on patients enrolled in various protocols at the center.

No one can say for sure why the decrease in patient load has taken place. "Almost everyone around here is asking that same question," says Gallin. "It's obvious that very complex forces have contributed." One force may be increased competition from academic hospitals that do clinical research—competition that was virtually nonexistent when the center opened in 1952. In addition, NIH pays for patients to travel to the center, and travel funds have been tight. An even more important factor, according to Gallin, was an accounting change made in the late 1980s, a time when the cost of providing care was skyrocketing.

Until fiscal 1987, explains Gallin, each institute paid a fixed amount for using the center, based on how many hospital beds they said they needed for the year. But this formula was widely considered to be unfair, because it assumed that an ailing cancer patient uses the same amount of resources as a relatively healthy patient in, say, a mental health study. So the center switched to a fee-for-service arrangement that billed institutes for the resources they consumed.

That arrangement seemed to address fairness concerns, but, coming at a time when inflation was beginning to drive up Clinical Center expenses faster than the NIH budget was rising, it had unintended consequences. Cash-strapped institutes began cutting back on their clinical work, says James Balow, clinical director at the National Institute of Diabetes and Digestive and Kidney Diseases. "You won't find anything on paper, but there was a psychology that was set in motion that the best way to cut costs was to reduce the quantity of clinical research," Balow says. As a result, he says, "a lot of excellent and vibrant programs have contracted more than they should have, based on scientific merit."

Gallin says he hopes to revisit the payment issue to remove such disincentives. "We're trying to restructure it so it's a little bit more like it was before the fee-for-service began," says Gallin. "I'm quite optimistic that the Clinical Center will see a major turnaround." In fact, there are signs that the steep drop-off in patient numbers has ended: Gallin says that for the first few months of 1995, inpatient and outpatient numbers have both been stable.

Furthermore, because the plans for the proposed new Clinical Center that NIH is urging on Congress include only 250 beds, the current patient load might be just what the doctor ordered. Although a new, smaller hospital might have too few patients to keep clinicians' routine skills honed, Gallin thinks this problem could be alleviated by having staff rotate through local hospitals.

These signs indicate that the future of NIH's Clinical Center might not be quite so bleak after all. But given the mix of external and internal stresses that are impacting the center today, it may be a while before even a skilled clinician can offer an accurate prognosis.

–Jon Cohen