

Reviews: No patients harmed in Minn. hospital ketamine research

Investigations commissioned by Hennepin Healthcare found that its paramedics and research staff acted appropriately in its ketamine study of agitated patients

Jan 27, 2019

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Star Tribune

MINNEAPOLIS — Three investigations commissioned by Hennepin Healthcare found that its paramedics and research staff acted appropriately in its ketamine study of agitated patients.

Hospital leadership requested the reviews last summer, after community criticism about the role of police in paramedics' sedation of patients in the field, as well as the hospital's enrollment of those patients in a study. The drug trial did not require patients to consent beforehand, which two elected officials in the Twin Cities condemned as unethical and unconscionable.



Investigations commissioned by Hennepin Healthcare found that its paramedics and research staff acted appropriately in its ketamine study of agitated patients. (Photo/ADF.org)

The reviewers determined the paramedics who administered the sedatives in emergency scenarios were consistent with national standards and appeared well trained. Disputing the findings of a Minneapolis police oversight office report, the reviewers concluded paramedics “demonstrated independent and appropriate clinical decision,” and didn’t sedate patients at the direction of police officers.

“At a high level, we didn’t do anything egregious,” Hennepin Healthcare CEO Jon Pryor said Thursday. Pryor said the results show there is room for improvement, particularly in communicating with the community about the hospital’s research, which it will do now with a public advisory board.

The reviews say the hospital made mistakes in its description of studies and its Institutional Review Board (IRB) — the board in charge of protecting patients in research — but it “did not increase

the risks of research participation, nor did they cause any participant to be exposed to more than a minimal risk of harm,” according to a memo of the findings.

The reviewers found one case of a Minneapolis police officer appearing to “threaten” a patient with sedation, and incidents in which paramedics “failed to demonstrate the level of professionalism that is expected by Hennepin

Healthcare and the public.” One report described a police body camera video that “showed a patient sedated with Ketamine, patient prone, officer with a knee in the patient’s back, with the patient being hog-tied” and then put in the ambulance.

The investigators made several recommendations, including partnering with Minnesota’s National Alliance on Mental Illness for paramedic de-escalation training. They also recommended training paramedics on how to command an emergency scene alongside police and how to better inform the public about emergency medical research in which they may become participants.

Dr. Michael Carome, director of the health research group for medical watchdog Public Citizen, dismissed the findings as unsatisfactory and biased, saying they don’t comport with findings from the Minneapolis police oversight office or the U.S. Food and Drug Administration.

“These so-called ‘independent’ reviews conducted by individuals hired by Hennepin County predictably resulted in the white wash desperately sought by the county’s healthcare system,” said Carome in an e-mail Thursday. “Further action by the [FDA] and the Office for Human Research Protections is urgently needed to ensure the protection of human subjects in research conducted by Hennepin Healthcare.”

After a complaint from Public Citizen, the FDA visited HCMC eight times in August, finding the IRB failed to follow federal guidelines designed to protect patients when it fast-tracked approval for several studies, including the sedation research, according to FDA inspection reports.

Dr. William Heegaard, the hospital’s chief medical officer, said that HCMC has responded to the FDA but that he could not share the response.

Pryor defended the integrity of the investigations released Thursday. He said that Hennepin Healthcare paid two of the reviewers for their work — the other two did not accept payment.

“I feel extremely confident that these reports are informative, that they were done by experts, that there’s a lot of integrity behind these reports, and we are moving forward,” said Pryor. “I’m not interested in Public Citizen or anyone poking holes in these.”

‘WE ARE BETTER OFF’

Hennepin Healthcare’s release of the findings comes seven months after the Star Tribune reported on a draft study by Minneapolis civil rights investigators that questioned whether Minneapolis police officers inappropriately urged paramedics to sedate people with ketamine. Paramedics had complained to their supervisors that officers were asking them to sedate patients, leading a police commander to issue a memo telling officers they must have no say in medical procedures such as sedation.

The civil rights report detailed several cases, based on body camera video, that questioned the need for a powerful sedative like ketamine, sometimes against the wishes of the patients being drugged and resulting in problems breathing or other health complications.

Police officers joked about the drug’s effects, according to the civil rights report, calling it “the Big K,” referring to ketamine’s intense delirium effect as hitting the “K-hole” and suggesting they be equipped with tranquilizer guns.

Some patients were then automatically enrolled into a drug trial, and informed only after they woke up.

The hospital’s report focuses mostly on HCMC’s role, but disputes some of the city’s findings, including that patients suffered cardiac arrest after sedation.

No paramedics at the hospital faced discipline, said Ross Chavez, assistant chief for EMS at HCMC.

"We have not identified any issues that would lead to any type of discipline or corrective action," Chavez said.

Pryor said the past seven months have been difficult.

"I would say, we are better off because this happened," he said. "I wish there was a better way of getting there because this was so painful. But we are a better institution and we will be better partners with our community because of it."

In addition to the ongoing FDA investigation, the state's Emergency Medical Services Regulatory Board is also looking into the hospital's research, though Pryor said he did not know if the latter would ever issue findings.

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