REVIEWER REPORT TO THE
OFFICE OF THE HENNEPIN COUNTY ATTORNEY
November 15, 2018

Brian H. Williams, MD and Raymond L. Fowler, MD

Questions for this review: (replies are in the lettered lines beneath the numbered questions, and are bolded)

1. Are Ketamine, Versed or other sedatives appropriate medications for use in the field by Hennepin EMS personnel?
    a. **Yes**
2. Did Hennepin Healthcare's EMS use sedatives in the cases you reviewed follow our standards? If not, give examples and suggest why we did not follow our standard protocol.
    a. **Yes, though some concern is raised regarding direct patient monitoring by EMS personnel post-drug administration.**
    b. **Do the standards (the protocol) need to be changed?**
3. Is Hennepin Healthcare's protocol related to the use of the medication Ketamine or other sedative by EMS personnel consistent with the standard of medical care?
    a. **The use of Ketamine for the management of agitation is common in the EMS industry.**
    b. **Appropriate training is essential prior to the use of Ketamine in this setting.**
    c. **Appropriate CQI and case review is essential to prehospital utilization of ketamine**
4. Based on the review, do you have any suggested changes to our clinical practice or research protocol in the administration of Ketamine or other sedatives by EMS staff while in the field?
    a. **The altered mental status scale utilized might bear additional scrutiny and review, including by outside consultation with other agencies such as the National Association of EMS Physicians**
    b. **See comments that follow below regarding community consultation.**
5. Is the use of Ketamine for in-field sedation an appropriate off-label use?
    a. **Yes**

Introduction:

Two individuals were invited by Hennepin Healthcare to conduct an independent review of its use of pre-hospital sedation by emergency medical services staff. These reviewers provided their reviewing services free of charge, other than basic travel expenses. The reviewers are physicians with extensive experience in the emergency and pre-hospital setting. A summary of the experience of the reviewers follows:

Brian Williams is an accomplished trauma surgeon, speaker, and activist. He completed a residency in general surgery at Harvard Medical School and a fellowship in trauma surgery and surgical critical care at Emory University School of Medicine. He served as Associate Professor of Surgery at the University of Texas Southwestern Medical Center and a staff trauma surgeon at Parkland Memorial Hospital in Dallas, Texas. As Chairman of the Dallas Citizens Police Review Board, which is tasked with police oversight, he interfaces with multiple stakeholders such as the Dallas Police Department, Dallas City Hall, community activists, board members, and police unions. Dr. Williams is a sought-after public speaker on racial trauma, resilience, and social justice. He is also a member of a local hospital rapid response team studying the use of Ketamine as an agent for induction for patients who are deteriorating and may require intubation. That study is in pre-publication.

Ray Fowler is Professor and Chief, Division of Emergency Medical Services, Department of Emergency Medicine, at the University of Texas Southwestern Medical Center in Dallas, TX. A practicing emergency medicine and emergency medical services physician for over 40 years, he has been involved in EMS as a leading educator, author, and medical director for decades. Dr. Fowler was a founding member and former president of the National Association of EMS Physicians, the subspecialty organization for Emergency Medical Services.

During the fall of 2018, the reviewers separately visited Hennepin Healthcare, and conducted interviews with the following:

- Leadership from Hennepin EMS, including its Medical Director
- Individuals conducting research on sedatives in the field, including principal investigators for the studies at issue
- Leadership of Hennepin Healthcare's Institutional Review Board
- Clinicians who have treated agitated patients in the pre-hospital setting, emergency departments, ICU, and post-discharge

During the review the following materials were presented to the reviewers for their consideration:

- Clinical and training protocols from Hennepin EMS
- Research protocols and relevant IRB submissions
- Research publications regarding Ketamine and other sedatives
- EMS records and video footage for seven patients identified by the

Minneapolis Police Department in conjunction with an investigation conducted by its Office of Police Conduct Review
- Statutes regarding EMS in Minnesota

The reviewers approached this opportunity with the perspective that all agree that no one should be injured during an encounter: Not the patient, not law enforcement (LE), not EMS, and not the fire service. Thus, during this review, the reviewers examined the material provided and the information gathered from the interviews from a position of demonstrating "safety first" for all involved. This was a remarkable experience for both of the reviewers – to be able to share in the review and comment to an outstanding prehospital patient care system – and they remain available for further assistance in this matter.

1. The reviewers feel that this occasion is an opportunity for the Hennepin system to be transparent, and be a model for bridging the cultural gap with an under-served medical community that may be distrustful of medical providers. Many of these patients were from a lower socioeconomic status in communities of color who may be distrustful of the healthcare system, and of LE.

2. The personnel that were giving the meds were in uniform and wearing badges. Citizens may make no distinction between healthcare providers and LE and erroneously assume they are being medicated by a police officer. That will require public education to broaden the realization that the EMS providers are separate from LE, and that they both are there for the health and safety of the patient.

3. One observation out of seven cases reviewed revealed prone positioning post sedation of a patient, and the hog-tying of the patient by LE post-sedation during this procedure.

4. The reviewers have not had the opportunity to speak to members of the community. Their perceptions of what is happening, or what was done, may not be based on accurate facts. Until this is clarified, this is what the citizens will go on. We base this on our experience in Dallas. The analogy these reviewers would make is that all of these stakeholders see the issue differently and desire different outcomes for reform. For the Chairman to be effective, he has to understand the perspectives and understanding of all stakeholders. What happened in Hennepin County – as to how the citizens feel – came from news reports. Neither reviewer had the opportunity to interface with community leaders. Hennepin government officials may have input to this as well. More information would be helpful in this regard to expand this recommendation.

In summary, information might be made available to the reviewers as to how the community feels and to garner any suggestions that they may have for moving forward.

EMS General Considerations:

1. It seemed apparent that the management in place at Hennepin EMS was relatively young. A significant portion of the EMS staff has less than 5 years of experience. The reviewers were told that approximately 150 personnel currently work for the Hennepin EMS system, and the leadership expressed that they need as many as 180 personnel.
2. Limited resources were available for providing CQI of EMS cases.
3. The EMS Medical Director, interviewed separately by the reviewers, expressed during both interviews that the Hennepin EMS CQI effort needs dedicated personnel for this purpose.

EMS Use of Ketamine:

1. The reviewers wish to point out that in Ketamine doses sufficient to manage agitation, the effect of the drug is often to induce a clinical state approaching deep sedation. The reviewers stress that in such a condition, these patients must have the trained provider physically at the patient's side, with an ECG monitor in place, suction available, frequent vital signs being taken, and continuous pulse oximetry and waveform capnography in place. In one of the seven body camera videos reviewed, it showed a patient sedated with Ketamine, patient prone, officer with a knee in the patient's back, with the patient being hog-tied. This patient was then taken to the ambulance in the hog-tied position and remained so until the video terminated. EMS should have been continuously monitoring the patient following deep sedation and should have removed the restraints placed by law enforcement.
2. The reviewers would hope to learn more about how the EMS providers are trained to determine where the patient falls on the scale of when to give Ketamine.
    - Is there significant inter-observer variability as to who falls "where" on the agitation scale"? The reviewers recommend that potential inter-observer variability be studied in your system.
3. The EMS scale being utilized by Hennepin: It seems to be appropriate for research, but is it the best one available for patients in the field, e.g. where patients fall on the scale? The dynamic nature of patients, and LE officers that may implicitly or explicitly influence a decision for patient dosing, give pause for concern. Perhaps a more binary agitation scale would be best. The reviewers feel that there are significant variables in the scale that MIGHT result in the patient receiving a higher dosage of the drug than necessary. A key point here is that constant physical attendance and presence of the EMS

provider performing monitoring of the patients who have been medicated may ameliorate this concern.

4. One of the reviewers is a member of a local hospital rapid response team studying the use of Ketamine as an agent for induction of patients who are deteriorating and may require intubation. This scientific study is in pre-publication.
5. One of the interviewees – a consultant psychiatrist – stated that Ketamine should not be utilized without input from a physician. Moreover, this consultant expressed significant concern that patients waking up in the ICU post Ketamine administration may exhibit concerning psychiatric symptoms possibly related to the administration of Ketamine. He stated that these psychiatric effects may be delayed in onset, and that follow-up of these patients is essential. He went on to say that the field environment needed MORE mental health expertise, indeed possibly embedding psychiatric professionals with LE. He discussed a psychiatric professional individual that currently responds to the field in your area, but went on to say that more personnel were needed.
6. In discussion with the ICU interviewees, however, they did not relate adverse outcomes for patients who had received Ketamine in the field. The reviewers would welcome further review of these outcomes.

The Matter of the Research Protocol:

1. As citizens responsible for public service and patient protection, you can tell us that you have done everything "by the book", but, to be candid, these are just words. To members of vulnerable patient populations, "waiver of consent" translates to the Tuskegee experimentation and the use of persons of color for human experimentation. The knowledge among minorities has been that the Tuskegee experiment might have been one of the less egregious research protocols compared to others before and since. So that is why it is difficult to communicate to a vulnerable patient population that even "IRB-approved research protocols" are not taking unnecessary risks with their health."
2. One reviewer stated that he is well aware of the difficulty of explaining research strategies to the community. This is an opportunity for Hennepin to "get this right". This is why the voice of the community is so important: What do THEY think, and what do THEY suggest?
3. The reviewers felt that the efforts made to set up the study were generally acceptable. It was unclear to the reviewers, however, what steps were taken in advance to engage the community to ensure that appropriate education was in place regarding the nature of the research protocol.

Concluding thoughts:

EMS, the fire service, LE, and other responding agencies must confront, evaluate, and manage the breath of the spectrum of the emergent human condition. In doing so, a commitment to accuracy, fairness, and humanity must be imbued in their actions. Difficult interactions and clinical situations abound in this arena, from cardiac arrest to gun violence to agitation. In each and all of presenting conditions, the assembled providers must work collectively – and individually – to respond in the most appropriate manner indicated by the advance of evidence both in medicine and in public policy.

It is evident that the members of the collective responding community for this present review exhibit extensive training, inter-agency cooperation, and innovative approaches to these particularly challenging patients. The reviewers herein present their assembled impressions for the explicit purpose of offering suggestions for consideration by these dedicated individuals and their leadership.

Respectfully submitted,

Brian H. Williams, MD (electronically signed)

Raymond L. Fowler, MD (electronically signed)