THE CANDLE
"better to light a candle than curse the darkness"

Wednesday, December 18, 2024

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Good Morning President Stokes, Dr. Richards, Ms. Becker and Dr. Finn,

This is a time sensitive matter/request.

I fully realize this is the Holiday Season, however on Tuesday, December 17, 2024, I wrote an email to the UNM HSC communications team (and copied each of you) regarding concerns relative to the following.

I received NO response from anyone at the University of New Mexico (UNM), the UNM Health Sciences Center, the School of Medicine, nor the UNM Hospital.

As I wrote in that email, *"The Candle will be reporting that leaders at UNM SOM knew of, and through the structural/legal association between SOM and UNMH, leaders at UNMH likely knew or should have known, for at least this past year, of reports that the application of a relatively new neurosurgery device at UNM resulted in unnecessary harm (possibly including death) to multiple patients due to careless use and or inadequate training of medical personnel, as well as possible design problems."*

The device referred to above is believed to be an IRRA*flow* catheter, which IRRAS (the company that owns and distributes IRRA*flow*) asserts was developed to be an improvement over traditional external ventricular drain (EVDs).

From the information we have received, this is not a one-time event, and information was revealed in October 2024, through an adverse event report filing, suggesting an urgent need for proper training and guidelines to ensure safe and effective use of the device at UNM.

On October 16, 2024, a report was made to the U.S. FDA via its Manufacturer and User Facility Device Experience(MAUDE) system, which indicates that problems associated with this device, and/or the manner in which it is used, are likely related to multiple adverse events at what appears to be identified as "UNM,", as described by the reporter as follows:

> *"I am deeply concerned about the inappropriate use of the irraflow intraventricular irrigation system within the department of (b)(6). The irraflow system is designed to provide dynamic intracranial pressure control via continuous irrigation and drainage of cerebrospinal fluid (csf) for treating conditions such as intraventricular hemorrhage and infection.* ***However, recent evidence suggests its application at unm has resulted in unnecessary harm to multiple patients due to careless use, inadequate training of medical personnel, and possible design flaws****. Please read below. Reports of severe infections, mechanical failures, and improper pressure settings causing intracranial pressure imbalances highlight the urgent need for proper training and guidelines to ensure safe and effective use of this device."* [Emphasis added.]

From our search of the MAUDE reporting system, there have been more than twenty (20) reports made regarding the use of the IRRAflow device that are at least initially categorized as adverse event reports.

While IRRAS has responded to many of the reports, the latest has no record of response – maybe it was not specific enough - however, the degree of concern represented in the reporter's description of their concern should warrant a review.

I am also aware that communications exist alerting physicians and leaders at the UNM SOM Neurosurgery department of concerns similarly described as those outlined in the MAUDE report referred to above.

As you are likely aware, The Candle submitted an IPRA request regarding, among other things, communications regarding two medical devices used in the neurosurgery department on patients – one of the requests includes communications and records (with appropriate patient information redacted) relative to the use of the IRRAflow device.

Given the knowledge of the communications about information that was provided to those UNM medical leaders, I fully expect that my related IPRA request, if fully complied with by UNM under the New Mexico Inspection of Public Records Act, shall produce the records that support the concerns we are reporting on.

I recently reached out to Dr. Andrew Carlson to discuss some of the work he did related to IRRA*flow* while he was affiliated and employed by UNM School of Medicine.

Dr. Carlson has begun a dialogue via email with me regarding the professional services agreement between UNM and IRRAS and he has offered to discuss further.

As suggested in the email sent to UNM HSC earlier this week (and which was copied to each of you), I would like to speak with appropriate UNM USC, SOM, and UNM personnel regarding the use of the IRRAflow device at UNM facilities by UNM personnel/contractors.

Information I am interested in discussing with the appropriate personnel include the following:

1. The number of IRRAflow devices that have been used on patients under the care of UNM Hospital and/or the School of Medicine physicians and support medical personnel;
2. The UNM HSC policies that involve testing devices and one or more human subjects;
3. The UNM Institutional Review Board, as established under federal law;
4. The manner by which UNM HSC staff and/or contractors sought informed consent from patients that underwent surgical procedures that utilized the IRRAflow device(s);
5. The resolution of concerns raised about the use of the IRRAflow devices;
6. The number of adverse events, including deaths, experienced by patients for which the IRRAflow device was used;
7. The descriptions of the adverse events referred to in item # 6, above, with appropriate patient identity protections observed;
8. The number of IRRAflow devices purchased for use at the UNM Hospital and the UNM School of Medicine in conjunction with the research and testing on human subjects;
9. The monetized value of the IRRAflow devices used at UNM Hospital and the UNM School of Medicine;
10. The number of IRRAflow devices received as an in-kind type of donation or loan by UNM HSC entities/employees/contractors from IRRAS for use at the UNM Hospital and the UNM School of Medicine in conjunction with the research and testing on human subjects;
11. The financial and research relationship between UNM HSC entities and IRRAS, such as (but not limited to) the professional services agreement that Dr. Carlson informed me of in his communication to me earlier this week.

I hope to hear from you as soon as possible – Please send me an email with a time that we can speak with the appropriate personnel regarding the above.

I will clear any events on my calendar to accommodate your schedule.

In the meantime, we expect to be reporting on this important matter.

Sincerely,

Bruce Wetherbee, editor

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