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RESPONSE

Law does not address human error

Alison D. Pohl, MS, MT, rLATg, CPIA & Ron G. Wallace, PhD, CIH, RBP

In evaluating this scenario, we assume that the analgesia schedule called for more than 1 day of analgesics, meaning that the animal may have experienced a higher degree of pain than anticipated because of the missed dose. But analgesics were given, and so it is appropriate to place the animal in category D on the USDA annual report.

There are limitations to the quality of data provided on the annual report. Pain experienced by animals can be categorized as no or momentary pain, pain relieved by administration of analgesics or pain not relieved by administration of analgesics because their use would adversely affect the research results. It would be difficult to justify the placement of these animals in category E, because analgesics were given, albeit late, and the delay was a result of human error and not an IACUC-approved action.

Great Eastern's IACUC concluded that this was an unfortunate error and no sanctions were considered necessary. This denotes an attitude of acceptance and complacency toward human error. It would be nice if there were no mistakes when using animals for research, testing or training; unfortunately, that is not likely to ever be the case. Its inevitability, however, does not mean that human error should not be addressed.

Great Eastern's IACUC should have required the investigator responsible for the research to submit a plan of action to ensure the appropriate administration of analgesics in the future. This plan could include confirmation checks such as checklists, a buddy system or supervisor sign-off to make sure that all required procedures are completed. Confirmation is especially important when a mistake could lead to unnecessary pain or distress to animals, the minimization of which is one of the main focuses of animal welfare in research. The IACUC must find a balance between taking the trouble to ensure that procedures are done correctly and living with mistakes. Will the overall results be better if we aim to make no mistakes (but probably make a few anyway) or if we just accept that mistakes are going to happen and pay the price when they do? Each IACUC should determine what an acceptable balance is and how to bring personnel up to the appropriate level of rigor required to strike that balance. It is the IACUC's responsibility to set the standard.

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RESPONSE

What's right?

Yolanda P. Villarreal Acosta, BA

The IACUC administrator should have provided an explanation of how the USDA pain and distress categories are assigned. The focus in this scenario is whether the animal's experience of more than momentary, pain or distress was relieved (category D) or not relieved (category E)[1]. As the IACUC chair expressed, category E is appropriate because the animal experienced pain prior to relief: "Animals must be listed in Column E if they are subjected to painful procedures and the anesthetics, analgesics, tranquilizing drugs or other palliative treatment did not adequately preclude more than slight or momentary pain or distress"[1].

The *IACUC Guidebook* states, "It is the responsibility of the IACUC to critically evaluate all research protocols for the potential to cause pain or distress and assess the steps that are to be taken to enhance animal well-being"[2]. In this scenario, the lab technicians took the following steps: administer daily analgesia; realize that a dose was missed; reinitiate analgesia schedule; contact the IACUC. If there were no further steps in the approved protocol for the lab technicians to follow, then the IACUC should re-evaluate the protocol and ask the investigator responsible for the research to discuss with the attending veterinarian further steps to be taken, such as recording details of analgesic administration (technician, time, dose, etc.); monitoring animals more than once per day and documenting this monitoring; and having the investigator or other designated individual confirm that duties are completed. If the designated individuals are unable to monitor an animal or provide a scheduled treatment, then arrangements can be made with the veterinary staff to ensure this task is done. The protocol should also include guidance on managing a missed dose and list criteria that warrant intervention by the attending veterinarian, who should have been immediately contacted along with the IACUC.

The IACUC should have also considered re-training the staff members to confirm that the lab technicians and the investigator understand the privilege of working with research animals. The IACUC may require that the investigator submit a follow-up report and that the lab documentation be checked by the IACUC during semi-annual laboratory inspections. Staff members should be reminded that the veterinary staff and IACUC office are available and should feel comfortable contacting either group for assistance at any time. With everyone working together to ensure that research animals receive the proper care, compliance can be maintained while research is carried out responsibly.

Finally, the IACUC, upon being notified of the incident, should have phoned OLAW and USDA to alert them of the incident prior to sending the formal report to OLAW. The USDA inspector will evaluate the report during the annual inspection of the institution.

1. Office of Animal Care and Use. *Guidelines for Preparing USDA Annual Reports and Assigning USDA Pain & Distress Categories* (National Institutes of Health, Bethesda, MD, 2013). <http://oacu.od.nih.gov/ARAC/documents/USDA_Reports.pdf>
2. ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (Office of Laboratory Animal Welfare, Bethesda, MD, 2002).

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