the study. One cannot assume that this particular injury was a result of the study on the basis of a single incident. This animal might have injured itself anyway from the force of kicking out and landing. If bone fractures repeatedly occur in this study with routine handling, the scientific research team and the veterinarian need to maintain open communication on the status of these rabbits. The protocol should be reevaluated by the IACUC and modified to include the possibility of bone fractures and to address clinical management of those fractures as a part of the protocol. Those rabbits would then be reported in category D.

1. 9 CFR Subchapter A—Animal Welfare, §2.36.
2. Animal Care Policies 11.1-2, USDA, APHIS, AC [9 CFR, §2.31(d)(1)(i-iv), §2.31(e)(4)].
3. Animal Care Policies 17.1-4, USDA, APHIS, AC [CFR, Part 2, §2.36].
4. Animal Care Policies 14.1, USDA, APHIS, AC [9 CFR, Part 2, §2.31(d)(1)(x)].

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RESPONSE

C is correct

Gail T. Colbern, DVM, MS, DACT & Lisa Heath, DVM

One of the first considerations in this case should be the proximate cause of the fracture in an animal that suffered a relatively minor mishap (drop of less than one foot). Did the osteoporosis research contribute to the fracture, or was the fracture an isolated accident? The case report suggests that the rabbit may have had 'poor bone density' as a result of the experimental procedures, which could have contributed to the fracture, but goes on to say that the fracture healed well with a simple cast, suggesting that poor bone density might not have been a critical factor. The potential for bone weakness and fracture should have been considered when the study was initially given to pain category C (no pain or distress) and should now be considered in a follow-up by the IACUC and in the annual report for these animals.

If the fracture was indeed related to the reduction in bone density induced by experimental conditions, a change in pain category may be appropriate for all treated animals (controls would continue to be category C). If the investigator determined that affected animals could be treated with analgesics, either within the study or after an animal was removed from the study, then pain category D would be appropriate for all treated animals. Considering this scenario and the appropriate use of anesthesia and analgesia, category D would be appropriate and category E, no analgesics, would not be considered. If the fracture was determined to have been an accident of husbandry and not related to experimental conditions, the animal would remain in category C, as originally classified for the study by the investigator and the IACUC.

The *Animal Care Research Facility Inspection Guide*[1] provides examples that give guidance in this case. In example 1, "an animal that experiences unexpected pain due to the research procedure and has the pain recognized and appropriately treated would be placed in the D pain category". In example 5, "an animal that experiences pain completely unrelated to the research procedure and has the pain recognized and appropriately treated would be reported in the pain category originally determined for the study". Thus, both Margolis and Covelli were incorrect in their assumptions that the cause of the fracture did not determine the pain category for this animal.

The fact that the technician was allowed to adopt the rabbit after the fracture healed also gives us some information about the cause of this fracture. If the research procedures were associated with reduction in bone density sufficient to allow fracture of the tibia during a minor mishap, then the technician should not have been allowed to adopt the rabbit. Assuming that appropriate restrictions are in place for the adoption program at this institution, the research procedures must not have had sufficient effect on bone density to adversely affect the welfare of the rabbits. Thus, the original classification of pain category C for the study and the continued C classification for this particular rabbit would be appropriate.

1. Animal Care/APHIS/USDA. Research Facility Inspection Guide, Records, Annual Report, April, 2001, 14.0.1–14.1.10.

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RESPONSE

Potential complications

Amy Funk, DVM

One of the purposes of the Animal Welfare Act is to address "public concerns for laboratory animal care and treatment to help assure that research will continue to progress". Stress levels promulgated by the USDA exist to help categorize research for better public understanding. Animal Welfare Regulations define stress levels to classify experiments on the basis of the research design and the possible outcomes of the experiment on animal well-being. Spontaneous events unrelated to the project should not be used to define the research stress level, because they are indefinable and limitless.

In this example, the rabbit was not involved in an experiment directly designed to cause unrelieved pain, but being a model for a type of bone abnormality warrants the reasonable possibility of pain. Although the animal did experience pain as a result of the accidental injury and there was a delay of 30 minutes, this should not be defined as category E—"animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests"—because appropriate pain-relieving drugs were given to this rabbit in a timely manner.

Potential for this type of accident exists for animals in any situation. Certainly, a pet at home or in an animal clinic could sustain injuries that jeopardize its well-being. These unanticipated problems should not be used in determining the classification of stress level because they are spontaneous and unintentional. The