Report from OHSU ONPRC External Committee • December 18, 2020

Introduction:

The morning of August 13, 2020, two non-human primates (*Macaca mulatta*) were present in a 1-over-1 cage rack when it was placed inside a cage washer and the cycle started. While the cycle only ran a few minutes, upon removal from the washer, one monkey was deceased while the other was alive and thereafter sedated, examined, and due to extensive injuries, euthanized for humane reasons. The Program (ONPRC DCM) initiated an investigation which resulted in an internal root cause analysis. The OHSU West Campus IACUC performed its own investigation and released a separate report.

The OHSU ONPRC External Committee was formed by Peter Barr-Gillespie, Chief Research Officer, OHSU. The External Committee was tasked to “review two internal investigations (root cause analysis and IACUC) to determine if OHSU response was appropriate and if other actions are necessary”.

**OHSU ONPRC External Committee Activity**

The OHSU ONPRC External Committee held on-line meetings, reviewed documents provided by the Program and interviewed the following individuals:

1. Names have been redacted

Each interview was conducted online and lasted approximately 30 minutes. The interviewees were asked to give their thoughts and accounting of the incident including issues that they thought may have contributed to the incident.

In the incident, an equipment sanitation technician, working alone for the first time, was tasked with cleaning several monkey cages. Each cage rack contained two monkeys in a 1-over-1 arrangement. The Standard Operating Procedure (SOP) for this task required the technician to transfer (‘jump’) each monkey from its dirty cage to a clean cage. The dirty cages are located on the right side of the room upon entrance and the clean cages on the other side. Though this arrangement is not universal in the various animal housing rooms, it was
intended to help distinguish the dirty from the clean cages. The food and enrichment items would be removed from the dirty cage rack after their inhabitants were transferred and the cage rack pre-washed. The dirty cage rack would then be moved to the cage wash station where all markings would be removed, and the dirty cage rack placed in the cage washer. This process would be repeated with a second cage rack and the cage wash cycle initiated.

The technician assigned this task was working alone for the first time in this particular building. He had received training on this SOP for two days prior to the incident. The technician transferred the monkeys from two cages, placing the clean cages with monkeys across from the dirty, now empty, cages. He correctly followed the SOP for the first cage rack, placing it into the cage washer. He failed to follow the SOP for the second cage rack. Rather than removing food and enrichment devices, then prewashing the cage rack and removing all labelling, he grabbed what he thought was the second dirty cage rack (but was actually a clean cage containing the recently transferred monkeys), rolled it down the hallway into the cage wash room, placed it in the washer, and began the wash cycle. Upon returning to the housing room he realized that instead of placing a dirty, empty cage rack into the washer, he had taken a clean cage rack containing two live monkeys. He immediately ran to the cage wash room and stopped the cycle; the cage rack with the monkeys was removed and taken back to the housing room. Help was requested and veterinarians responded with a few minutes. Initial examination found one monkey deceased. The second monkey was sedated and examined. Due to extensive injuries the decision was made to euthanize the animal for humane reasons.

Assessment:

While failure to follow established SOPs directly resulted in the death of these animals, the Committee focused on underlying and contributing factors beyond the simple failure to follow procedures. Specifically, we focused on training, oversight, and leadership.

Training:

The technician had spent a couple of weeks learning other procedures including working with hanging cages, but he was only given two days of training with the free-standing 1-over-1 caging at the site of the incident, and this training occurred just prior to the incident. The lead trainer had cleared the technician to work alone. When interviewed by the IACUC following the incident, the technician had problems correctly describing the particular cage rack procedures, indicative of a less than clear understanding of the procedures. The lead trainer was supposed to check on the new technician in the morning, and on a video recording the technician can be seen apparently waiting for someone prior to the incident. The lead trainer did not arrive, however, and the technician went back to cage cleaning. As a result, the technician had no direct oversight on the first morning that he worked alone with the responsibility of caring for multiple monkeys. It was also reported that the lead trainer had a history of exhibiting an abusive, condescending attitude towards trainees and focused primarily on efficiency and timeliness rather than quality and following procedures. It was also stated that the lead trainer often cut corners from established SOPs to ensure that cages were cleaned by a specific time every morning. It was reported that at the time of the incident, the technician was 30-45 minutes behind schedule to get the assigned dirty cages into the cage washer.

Interviews with staff indicated that while a training program exists, it is disjointed with a lack of consistency and oversight. Specifically, the training program onboards new hires and teaches them routine, general animal procedures. The specific training for each unit (such as cleaning the cages involved in the incident) is left up to the lead trainers in each unit. These trainers are not part of the training program per se, in that they do not
report to the training manager but, instead, serve as lead technicians in each unit. The lead trainers do not
document their training efforts, or final approval of the employee on a specified, trained task. There was no
apparent oversight of the lead trainers by the training program managers. There were no proficiency checks in
place to ensure that the lead trainers were following Program SOPs. In this incident, the new technician was not
properly trained or given proper oversight. These failures contributed to the incident.

**Oversight:**

The morning of the incident the technician did not have direct oversight by the lead trainer. It is troubling that a
new technician would be given only two days of training on new procedures and then left unsupervised to care
for multiple animals. A training program is essential to the ONPRC, but it must act as a single, unified program in
contrast to the system described above. The Training Manager should have direct authority over trainers to
ensure consistency and proficiency among both the trainers and the trainees.

**Leadership:**

In interviews with Program leadership (DCM, ONPRC, and OHSU), it was felt that there is a disconnect between
them and mid- and lower-level staff relative to the status of day-to-day operations in primate husbandry and
care. Notably, Program leaders were surprised to learn of problems in the training and oversight of technical
staff as well as issues and concerns brought forward by a group of staff members following this incident. Staff
raised concerns regarding the pressure placed on them to complete tasks by a certain time but having
insufficient time to complete these tasks. Senior leadership should re-evaluate staffing levels including metrics
used to determine appropriate staffing needs, including time allowed for adequate training and orientation to
assigned tasks whenever those tasks are new for the given employee.

Several staff remarked on their disappointment about how quickly the technician directly at fault was
terminated. The rapid release from employment resulted in the inability of the IACUC, the RCA committee, and
this external committee to interview the technician shortly after the incident. The rapid termination also gave
the appearance of blaming the entire incident on the technician rather than focusing on underlying causes for
the incident. Staff members remarked that while the technician failed to follow SOPs, the Program failed the
technician by not providing proper training and oversight and a chance to help improve the process for others.
Also, the technician was devastated and deeply remorseful about the incident and they could likely have
benefited (and still may) from employee assistance/counseling.

**ONPRC Responses to Incident:**

**Root Cause Analysis Recommendations:**

**Strong:**

1. Simplify the process: process one rack at a time.

2. Limit a maximum of two clean racks in a room at any time.

3. Work with cage wash manufacturer to develop and install a movement or heat sensor to detect the presence
   of an animal.

**Intermediate:**

1. Have a second person verify that the cage is empty prior loading the cage washer.
2. Incorporate hard stops in the process (following animal transfer, prior to moving cage out of housing room, prior to cage entering housing room).

3. Divide the task (starting with transferring the animals all the way to starting the cage wash) between two staff members.

4. Consider placing tag on back wall of cage prior to cage wash that is verified after cage wash.

5. Review and refinement of training program for new Equipment Sanitation staff.

6. Include formal checklists in cage change SOP during initial training and periodic skill assessments. Review purpose and effectiveness of signage.

Weak:

1. Build upon “Good Catch Program” by expanding to promote staff engagement.

IACUC Recommendations (related to incident; broader programmatic recommendations are not included in this report):

1. The IACUC approved the mitigation plan which requires two staff members to verify cages are empty and SOP followed prior to cage wash.

2. The IACUC recommended that the Institute should investigate engineering controls and possible architectural changes that may simplify the processes.

3. IACUC-mandated mitigations by the Institution:

   A. Implement procedures and expectations for appropriate training, supervision, proficiency checks and documentation.

   B. Reports in adequacy of training provided to IACUC for review.

   C. Institute review and adjusted if needed, of adequate resources, staffing, and supervision in operations. This includes workload and resources of cage crew and other operational areas.

   D. Improve cross-training and cross-functional support.

   E. Develop an incident response plan.

   F. IACUC must be involved in HR decisions regarding staff involved in incidents.

   G. Background checks on staff should include social media, public information, and public safety searches.

   H. Recommend mandatory drug testing following an incident.

   I. Staff must have immediate access to SOPs when in the animal facilities.
External Committee Response and Recommendations:

OHSU and ONPRC leadership are commended for their extensive intervention and outreach provided immediately after the incident. The Committee’s recommendations as outlined below are provided to help OHSU and ONPRC further develop as a program and help prevent other incidents from occurring.

1. The recommendations in the above two internal reports represent appropriate measures to avoid identical accidents in the future. In addition, because the processes are different for the different racks and cages and washers throughout ONPRC, training and memory is relied upon too much. To address this, further facilitate the processes and training by making the order of steps visually clear at multiple locations within each process (e.g., “You are at This Step – The Next Step is ______”) and at all of the various cage wash locations throughout ONPRC.

2. Beyond those specific corrective interventions, ONPRC should re-evaluate the philosophy, organization, and management of its training program to ensure proper full-time staffing levels in the training program and proper oversight by Training Managers of all training, including the individual trainers. All training and proficiency checks should be clearly documented and reviewed on a regular basis. Likewise, it is critical to insure that for the 2-step verification now required, that sufficient personnel are approved to be cage verifiers, so two people are present when needed for this work to continue without disruption or haste.

3. DCM leadership should improve communication with staff at all levels, including, but not limited to, (1) soliciting employee concerns; (2) considering and responding to those concerns in a transparent (where appropriate), prompt, and sincere fashion; and (3) establishing and sustaining a framework for inclusive, continuous improvement in relevant aspects of laboratory animal husbandry, veterinary care, and regulatory compliance (to be addressed under broader programmatic recommendations in a subsequent report). For example, OHSU Healthcare has a tiered daily huddle structure and performance improvement program that ONPRC can learn from and access resources in order to act on this long-term recommendation.

4. The Committee was concerned about how and how quickly the technician was terminated. The termination occurred prior to the Root Cause Analysis investigation being completed. This gives the appearance of a termination without a full focus on underlying causes. Given the lack of training and oversight for this technician, there is a concern that the termination was premature and lacked any acknowledgement of responsibility on the part of the ONPRC training program.

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