Post-approval monitoring: the CCAC perspective

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Post-Approval Monitoring (PAM)

Objective

To ensure animal use protocols and standard operating procedures are applied in practice as approved in principle by the Animal Care Committee (ACC).

Section 2 of the CCAC policy statement on: terms of reference for animal care committees

Section 5.8 and Appendix IV of the CCAC policy statement for: senior administrators responsible for animal care and use programs
The Institutions must have procedures in place to monitor ongoing work and to ensure conformity with federal and provincial guidelines, regulations, and laws covering the use of animals in research, teaching and testing.
What PAM is...

- A combination of policies, practices and procedures designed to manage risk

- A series of institutional safeguards to **prevent** difficulties and address them when they do occur

- The responsibility of the ACC
  (working with “compliance” staff in some cases)
What PAM is...

An opportunity to improve:

- Animal welfare
- Communications
- Conditions for animal-based projects
- Training for individual animal users
- The animal care and use program overall, including through visible support from the senior administration
What PAM is not....

- Policing!!

- Solely the responsibility of veterinary and animal care staff who are responsible for animal care services
An ounce of prevention…

… is worth a pound of cure!!

Create conditions for ethical and successful animal-based projects:

- Solid structure for animal care and use program
- Effective ACC
- Complete veterinary and animal care services
- Comprehensive training and evaluation of competency
- Sufficient and appropriate facilities and equipment
- Frequent and open communications
PAM is based on information from a variety of sources

- Animal users
- Veterinarians and facility management/animal care staff
- PAM meetings with animal users
- Mechanisms for checking animal user competency (training)
- Animal use data
- ACC site visits
Information from animal users

- Animal use protocols are agreements between animal users and ACCs
- Amendments need to be encouraged and facilitated where useful
- Records of animal use need to be kept and shared
- Concerns should be reported
- Protocol renewals need to focus on what actually happened to the animals
Information from veterinarians and animal care staff

- Need to keep records of animal care and specific treatments, to be available for the ACC
- Serious concerns should be reported to the ACC, including discrepancies with the approved protocol that cannot be simply resolved
Information from PAM meetings

- Meetings scheduled to observe and discuss animal-based work, often using a checklist or form for consistency, thoroughness and ease of reporting back to ACC

- Not all protocols need to be monitored on a yearly basis, a risk assessment should be made

- In some cases, designated staff members are responsible for these visits, but having ACC members participate in turn:
  - provides direct information to the ACC
  - allows individual ACC members to better understand the work being done
  - visibly demonstrates that it is the ACC that is responsible for PAM, rather than an individual staff member
Information confirming competency

- Training can be provided in a variety of ways, what is most important is the competency of a person to carry out given animal-based procedures.

- The competency of animal users should be confirmed to the ACC before their animal-based protocol is undertaken.

- Where animal users have difficulty carrying out their procedures, whether identified during PAM visits or at other times, training assistance should be provided.
Animal use data information

- Numbers of animals acquired (or bred) and used need to be tracked per protocol, with:
  - **Numbers of animals ordered** deducted from the total number approved
  - **Animal breeding** being accurately recorded and tracked against approved numbers
  - **Animals captured for field studies** being reported by field teams, with the total of target and non-target animals captured and the total of target animals used for research/teaching
  - **Numbers of animals acquired in other ways** deducted from the total number approved
Information from ACC site visits

Site visits may not focus specifically on PAM, but can be used as opportunities for the ACC to:

- review records of animal care and use
- have discussions on whether appropriate facilities (e.g. enough well adapted procedural space) and appropriate equipment (e.g. inhalant anesthesia equipment with the necessary gas scavenging system) are in place for the needs of all animal users
- have discussions with available animal care personnel and animal users with regard to any comments or concerns they may have
PAM in specific situations

**Small programs**

- All or almost all animal users may be on the ACC, making it less “independent” of animal users. Non-animal users (community representatives) and external members (consulting veterinarians) should play a more active role in PAM in these cases.

**Medium or large programs**

- Normally need at least one employee to be responsible for PAM and assist the ACC.
**PAM in specific situations**

**Field work**
- Written reports from animal users during or after their field season
- Photos/videos showing animal care and use in the field
- Meetings with animal users to discuss their work, using elements such as reports, photos/videos and the traps or other equipment used to review the work and discuss any possible improvements

**Studies focused on treatments of groups of animals vs. procedures on individual animals**
- Records can be reviewed and discussions held with research groups for studies where impact on individual animals is not obvious
- Observations of procedures can be added in cases where there is an important impact on individual animals
PAM in specific situations

Collaborations
- ACCs of the collaborating institutions should agree in advance about how PAM will be covered

Private institutions
- ACC members can join quality assurance visits as an opportunity to carry out PAM
Compilation and analysis of information

ACCs should work from all categories of information towards a good understanding of the “level of compliance” within the institution. They should track the trends being shown by the information gathered and analysed, and determine:

- What is the nature of any compliance problems being noted? Are the problems related to:
  - communications? At what level?
  - animal user technical competency
  - quality of facilities or equipment
  - the structure of the animal care and use program
  - clarity/frequency of direction/communications from the senior administration
  - other issues?

- Are the problems widespread or limited to one area or type of study?

- Is improvement being noted over time? In certain areas or all?
PAM findings – what next?

- General improvements in the animal care and use program based on the concerns identified
- Addressing serious or repeated instances of non-compliance:
  - the ACC must act on the information provided, and must involve the senior administrator responsible for the program where the ACC cannot address the problem alone
  - Senior administrators should develop and implement processes for addressing instances of non-compliance, and these processes and any attendant consequences should be communicated to all members of the program
In conclusion

- Prevent problems by building good communications, solid program and comprehensive services
- Check for any remaining problems and work collegially to address them
Thank you to all CCAC constituents for your work on post-approval monitoring