ACLAM Position on Medical Records Content and Scope

Establishing and maintaining appropriate medical records is a core component of adequate veterinary care [AVMA 2019]. Medical records provide documentation of the care given and communicate that information to other professionals [Osborne 1983]. Medical record information may be retained in a medical record and/or research record, depending on how the institution wishes to run its program. The institution, under the guidance of the Attending Veterinarian, should determine the method(s) by which medical records are maintained. Medical records may take many forms and have several components, such as written records, computerized records, sentinel animal reports, clinical pathology reports, quality assurance reports, cage cards, and animal disposition reports. These components can be included in the medical and/or research record or can be linked and available. The method of record keeping should be designed to fit the specific needs of each program of veterinary care. Electronic records offer ease of data extraction and can be maintained in various formats, including that offered by electronic patient record software systems [Jones-Diette, 2016]. Oversight of the medical records must fall under the direction of the Attending Veterinarian or his/her designee and the IACUC. The ACLAM recognizes that many research animals, particularly rodents, can be obtained and maintained in a state of good health, without the necessity of a medical record being created. When medical records for such animals are indicated, group records may be acceptable and may be more efficient than individual records [FASS 2010]. Individual medical records should be maintained for animals that receive regular individual health evaluations, as deemed appropriate by the institution and as required by regulations and veterinary standards [Suckow and Doerning 2014]. When a medical record is created, the information should be recorded so that the care and course of treatment for animals can be reconstructed, if necessary [Lees 1981]. The medical record should also contain a sufficient amount of detail to determine the research or training use of the animal. However, clinical notations related to a disease that is experimentally induced in animals do not necessarily need to be maintained in the medical record. Rather, it may be appropriate for this information to be retained within research records, but the information must be readily available for review by the veterinary staff, as well as for appropriate internal (e.g., IACUC) or external (e.g., USDA) oversight uses. Medical records should be retained according to applicable regulatory or institutional requirements.

Components of a Medical Record

When institutional representatives determine that a medical record should be created, the record typically contains the following types of information [NRC 2011]:

1. Identification of the animal(s) or group(s), 2. Clinical information such as results of physical examination, the behavior of the animal, and notations regarding observed abnormalities, illnesses, and/or injuries, and relevant evaluations made during any quarantine that is performed upon receipt of the animal; 3. Immunizations and other prophylactic treatments and procedures as appropriate for the species, 4. Documentation of diagnostic tests and interpretation, 5. Reference to the research intervention, where appropriate, 6. Treatment prescribed and provided, the clinical response, and follow up, 7. Surgery, anesthesia, analgesia and peri/post-operative care, 8. Control of pain and distress,

9. Documentation of euthanasia or other disposition, 10. Documentation of necropsy findings, if indicated.

Medical record components should comply with applicable regulatory requirements. For example, for animals in preclinical studies, Good Laboratory Practice (GLP; 21 CFR Part 58) requires documentation of "diagnosis, authorizations of treatment, description of treatment, and each date of treatment." In addition, while it is recommended as best practice, medical record entries should be recorded "promptly" in accordance with GLP regulations.

Medical records should be written to define and reflect the current level of understanding of a health problem [FASS 2010]. The record should be refined as additional information is acquired and written to communicate the medical logic and case progression through resolution that results in either return to normal health or euthanasia of the animal [Chavis and Hutton, 2018; Lees 1981]. Notations in the medical record should be made by individuals who have administered treatments or made direct observations or evaluations of the animal(s) or their diagnostic results, or their designee. Individuals typically responsible for making notations in the record include veterinary staff (veterinarians and/or veterinary technicians), animal husbandry staff (animal care staff, managers, supervisors), and research staff (e.g., principal investigators, study directors and/or research technicians). All entries in the record should be dated, indicate the originator of the entry (e.g., initials, signature, or electronic signature) and be legible to someone other than the writer. Facilities may wish to consider establishing a list that summarizes the animal's medical history at a glance. This may be particularly valuable for animals that undergo a major survival surgery and/or are reassigned to another project. A copy of the medical record, or a pertinent summary of that animal's medical history, should follow the animal upon reassignment.

Types of Medical Records

A. Individual Health Records

In general, individual health records should be maintained for animals that receive regular individual health evaluations, and as deemed appropriate by the institution [Hampshire and Davis, 2008]. Examinations performed on the animal should be recorded; however, performance of routine preventive medical procedures on an entire group of animals may be recorded as a group record. Clinical records maintained on individual animals are used to document routine preventive care (e.g., physical examinations, vaccinations, dental prophylaxis), as well as spontaneous (non-induced) illnesses or injuries [NRC 2011]. These records should also document peri-surgical and peri-anesthetic care.

B. Group Health Records

Group health records may be appropriate for animals that are members of a larger cohort (e.g. a colony/school/flock/ herd/room), as well as for animals that undergo periodic evaluation by means of examination of several representative individuals of the group [Hampshire and Davis, 2008; Suckow and Doerning 2014]. Documentation of peri-surgical and peri-anesthetic care may also be done as a group record.

C. Records of Sedation or Anesthesia and Peri-surgical/Peri-procedural Care for Survival and Terminal Procedures

Documentaion of adequate veterinary care and the alleviation of pain and distress during the conduct of sedation and anesthesia (with or without surgery), and peri-surgical / peri-procedural care should be regarded as a component of adequate medical records, [Hampshire and Davis, 2008], whether the procedure is survival or terminal. Procedures of this nature should be documented in a medical record and/or research record, or can be linked and available to the record, as deemed appropriate by the institution. The procedural documentation may contain:

1. Animal or group identification and the date of the procedure, 2. All drugs administered, including dosage, route, time, and the ability to identify the person administering the drugs, 3. A description of the surgical procedure and identification of the surgeon(s), 4. Ongoing findings during monitoring, 5. Notation of any variations from the normal and expected events during the anesthetic and recovery periods, including the actions taken and the time performed, the animal's response to these actions, and the ability to identify the person performing these actions, 6. Assessment for pain and distress, 7. Actions taken to alleviate pain and distress, including non-pharmacologic interventions, and the response to these actions, 8. A notation defining the end of the monitoring period (euthanasia or functional recovery from the sedation or anesthesia), including the time, date, and the ability to identify the person performing this observation.

Other Types of Records

Experimentally induced disease/research records, and breeding records, are not necessarily a part of the medical record, but they may provide useful adjunctive information about the animal's welfare. The information in these records may be included as part of the medical record when deemed appropriate by the Attending Veterinarian.

A. Experimentally Induced Disease/ Research Record

A distinction must be made between spontaneous disease (rare in young, microbiologically-defined research animals) and experimentally induced diseases. Clinical notations for disease which is experimentally induced in animals do not necessarily need to be recorded in the medical record. Rather, it may be appropriate for this information to be retained within the research records, which must then be readily available for review by the veterinary staff. Recording of such information is particularly useful if it is used to support humane endpoint determination. If research data in a researcher's notebook or computerized database cannot be readily retrieved, then essential clinical data should be included within the medical record. Research records can be maintained for an individual or a group of animals and may take on many forms and have several components, such as a laboratory notebook, cage cards, or other suitable records, including those in electronic format. Such information may include animal identification information (may be group ID); date and type of procedure performed/compound administered/etc.; routine observations defined by the protocol; adverse or unexpected complications; and date of euthanasia or termination of study.

An example of a research procedure for which rigorous record keeping can help ensure animal well-being is fluid or food restriction. While withholding of food or fluid is part of some experimental paradigms, documentation of the extent and duration of withholding is essential to more clearly understand the animal's overall history with respect to health and physiological challenge.

B. Breeding Records

Records for breeding animals may be maintained to document medical information relevant to reproduction. When maintained, these records can be included within the animal's medical record or can be linked and available to the record. These records should allow the veterinary and/or research staff to identify the pedigree of the animal, when appropriate [NRC 2011]. Typically, useful information includes the animal identification, genotype, sire and dam, animals with which the individual has been paired, and the outcome of each breeding attempt. Additional information which allows identification of the animal's breeding history and productivity may be included as needed [FASS 2010].

Conclusions

Medical records for animals used in research, teaching and testing are a core component of adequate veterinary care. They should document information associated with management of clinical disease, diagnostic and therapeutic procedures performed, and preventive medical procedures. The methods by which medical records are developed and maintained should be determined by the institution, with the guidance and professional judgment of the Attending Veterinarian. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.

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