Purpose of "daily shelter rounds"

Daily shelter rounds are performed to ensure that each animal, each day, receives the care and attention it needs to move as safely and efficiently as possible through the shelter. Shelter rounds include not only medical and behavioral care, but also logistical needs to move the animal through its shelter stay. As such, shelter rounds are distinct from, and more inclusive than, daily monitoring of animal health and behavior. Daily shelter rounds are also distinct from veterinary rounds, which focus on examining animals identified as having a medical concern. Veterinary rounds should follow daily shelter rounds and daily monitoring to respond to any concerns identified in those processes. Performing daily rounds can have a dramatic impact on length of stay, which in turn can decrease shelter crowding, lower disease levels and costs, and improve animal care and wellness as problems are identified and quickly addressed.

Instructions for daily shelter rounds

Assess each animal daily and ensure that all needed steps have been taken for that animal that day, including:

- ✓ Accurate description and photograph of animal in computer system and posted to web
- ✓ Vaccination, parasite control on intake and follow up as needed
- ✓ Contact of owner or follow up on identification
- ✓ Behavioral and/or medical care to alleviate suffering and improve adoptability
    - Initiation or discontinuation of treatment
- ✓ Behavioral and/or medical assessment to determine adoptability
- ✓ Spay/neuter surgery or other medical procedures required before adoption
- ✓ Rescue group contact and pick-up
- ✓ Movement from areas such as stray to adoptable areas as soon as required hold is completed
- ✓ Euthanasia – decision and performance

The daily assessment should include the shelter manager, veterinarian and director (or equivalent positions) working together at least once a week. On a daily basis, include staff who are able/empowered to assess clerical issues (e.g. paperwork, owner contact process, issues with legal holds); medical issues; and behavioral issues. Perform daily rounds early in the day if possible (prior to cleaning) at a time when interruptions will be minimized. The assessment includes a look at the overall condition of each ward or holding area (smell, cleanliness, noise, overall presentation to adopters) and attention to each animal's paperwork, cage/kennel, and an assessment of the animal's physical and mental condition. For group housed animals (including litters), specifically note each animal in the group and briefly assess them as described below, the same as for individually housed animals. At least every two weeks, perform a more detailed evaluation of each individual animal still in the shelter.

Components of daily shelter rounds:

Items needed:

- Animal inventory (for shelters using a software system, daily rounds is a good time to reconcile paper and computer records, animal location, etc.)
- Daily to do or action list: note any concerns discovered during daily rounds on this list as you walk through the shelter
- Laminate cards can be used to visually flag animals for follow up in addition the action list, e.g. “needs behavior eval” or “move up to adoption”
- Camera to document issues for follow up if needed
- Cage cards and ID bands on each animal facilitate the daily rounds process

Evaluate the following:

Overall ward:

- General repair and evaluation of hazards (e.g. windows and doors all functioning correctly)
- General impression of cleanliness
- Odor
- Temperature
- Subjective assessment of HVAC with further investigation if unusual odor or temperature concerns are noted (HVAC should also be formally inspected on a routine basis)

Paperwork/computer record:

- Is the paperwork current, in accord with the computer record, and is the animal accurately described?
    - E.g. breed, gender, description, age, identification, weight
- Are intake and due out dates on the paperwork accurate?
- Is there any paperwork on the cage that might unduly discourage adopters (e.g. describing behavioral or medical issues that have since been resolved?)
- Is there any indication on the paperwork that the animal has a behavioral or physical condition that will present special challenges for adoption (e.g. a description that the animal was surrendered for a serious behavior problem)? If so, is there information for adopters describing what steps have been taken to mitigate the problem, or other information that might encourage the animal to be considered for adoption?
- Does the photograph accurately depict the animal sufficient for recognition by an owner?

- For animals awaiting rescue/adoption, has an appealing photograph and description of the animal been provided?

Location/status:

- Are the animal's location within the shelter and in the computer record in accord with one another?
- Is the animal in the correct location within the shelter based on its physical condition, behavioral and hold status? For example, is the animal past its stray hold but still in a holding area rather than an adoption area? Is it in a treatment area even though it has recovered from the illness being treated?

Cage/kennel:

- What is the condition of the animal's environment?
- Is there evidence of illness, such as diarrhea or sneeze marks on the walls? If so, has this been reported through the appropriate channels and is the animal under treatment?
- Are the housing conditions safe, with no damage to the kennel, watering system, bed, food dishes etc. that could harm the animal?
- Does the environment provide the basics for daily comfort/alleviation of stress?
    - Warm and dry?
    - Presence of hiding place?
    - Bed?
    - Toy?
    - Clean food and water?
- Is the environment humane for the amount of time the animal has been held?
    - If the animal has been in that kennel for more than 2-4 weeks, does it have enrichment equivalent to that expected in an adoptive home (e.g. room to move about, stretch to full length, choice of hard and soft surfaces for resting, toys and access to human contact and exercise on a daily basis)?

Flow through

- Have all needed steps been taken to contact owners/interested parties/ rescue?
- Has follow up been performed on any notes on the paperwork or in the record? (e.g. rescue called, pickup time scheduled)
- Does the animal need any service to move to the next step towards an outcome?
    - E.g. behavioral evaluation, spay/neuter, medical testing, physical movement to another area of the building, sign off of quarantine, euthanasia.

Animal:

- Does the animal have any physical condition, such as pregnant, geriatric, juvenile, neonate, requiring special care or environmental considerations? If so, is this being provided? (e.g. appropriate food, bedding, nesting box, foster care contact)
- Is there any evidence of pain or illness? If so, has this been reported and is the animal being treated appropriately?
    - If the animal is on treatment, has an appropriate recheck date been scheduled?
- Is the animal current on all required vaccines, external and internal parasite control, including intake and revaccination/retreatment as needed?
- Does the animal show signs of acute stress or fear? If so, have all possible steps for remediation been implemented, such as provision of a hiding place, bed, movement to a quieter area of the shelter, or plans for transfer to foster care?
- Does the animal have any special dietary needs? If so, is the correct type and amount of food being provided?
- Is the animal comfortable and contented? Does it need a bed, toy, note for special care and attention from volunteers, etc.?
- Is there evidence of kennel stress or other chronic or emerging behavioral concerns? If so, have these been reported through the appropriate channels and a treatment/remedy implemented?
- Is there anything about the animal's behavior or appearance that might deter adopters, such as a very dirty or matted hair coat or aggressive barking at by-passers? Note a specific remedy on the action list if so (e.g. schedule for grooming, move to another kennel with less foot traffic).

Re-evaluation of animals held long term

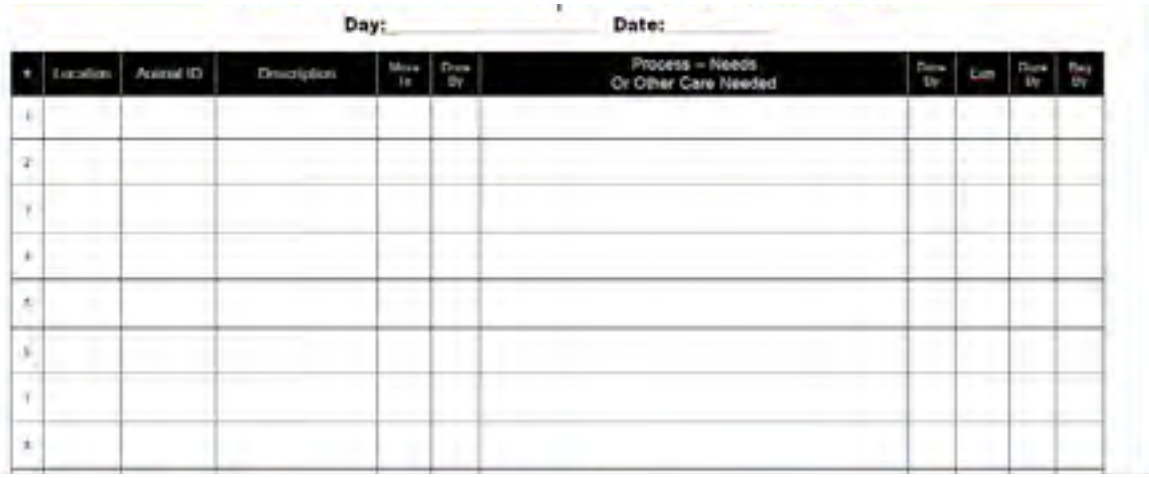
Perform a more extensive evaluation of each animal's physical and mental condition and adoptability at least every two weeks. Take the animal out of the kennel, run your hands over the body to look for weight loss, wounds, sores or other physical problems, and reassess the animal's overall well being. Ideally also weigh animals every two weeks while in the shelter, as weight loss or gain is a common problem in long-term housed animals. Schedule a full physical exam by a veterinarian at least every six months or more often if indicated (e.g. chronic medical condition, geriatric animal).

Daily rounds action list

Except in emergencies (e.g. a severely ill animal is identified that needs immediate action to prevent exposure or other animals or relieve suffering), action on animals should not be taken during rounds. Instead, maintain a "daily action list" noting every single animal that needs action taken to make sure it is in the right location, with current paperwork/ computer record, description and photograph, is scheduled for any needed procedures at a

definite time, all needed contacts have been made (owner reclaim, rescue etc.), the animal is housed safely and appropriately and is receiving all required medical and behavioral care. Most actions should be completed on the same day they are noted. Occasionally, it will be necessary to schedule the animal for an action on a defined date in the near future (e.g. spay/neuter surgery prior to release, pick up by rescue). When scheduled, note this on the animal's paperwork and in its computer record so the action does not need to be re-recorded unless it fails to take place on the day scheduled.

The action list can double as a medical log for the veterinarian, or a separate medical log can be used. Actions requiring veterinary review can be highlighted for easy identification. If the veterinarian does not come in daily, note on the action list the date that the veterinarian is expected to check the animal. Make copies as needed if several people will be working from the action list throughout the day. Review the action list at the end of each day (generally by the shelter manager). Because most actions will be completed on the same day they are noted, it may be easier to rewrite actions carried over from the previous day on a new action list. No more than 2-3 days worth of action lists should be kept at any one time. If actions routinely carry over from one day to the next simply because staff time is not adequate, this is an indication that scheduling or planning needs to be reevaluated. Delaying procedures does not save staff time, since they will ultimately have to be done and in the meantime, the animal will stay longer (increasing daily staff requirements) and will experience a delay in receiving needed care.



Daily Animal Health Monitoring Summary Sheet

Date:_____ Dog / Cat Volunteer(s): _____

#	Kennel #	Animal ID	Animal Description Breed/Color	Day in Shelter	V	D	Not Eat	URI Sign	Behavior	Other	Explanation of Concern	Initials	Review Date	Review By	Data Entry
1															
	Staff action:														
2															
	Staff action:														
3															
	Staff action:														
4															
	Staff action:														
5															
	Staff action:														
6															
	Staff action:														
7															
	Staff action:														

8															
	Staff action:														

Daily Animal Health Monitoring Program

Training Manual/How To Guide

General Overview:

- The goal:
    - To provide daily monitoring of an animal's health parameters (eating, urination, defecation, clinical signs of upper respiratory illness and behavior) to provide medical staff with an individual's current and past condition during their shelter stay and to assist in early identification of health/behavioral concerns and changes.

- Monitoring sheets will be given to every shelter animal at the time of their first observation.
- The daily monitoring sheet will move with the animal as they move through the shelter and will be displayed on their kennel.
- Animals will be observed and scored on the monitoring sheets once a day, prior to cleaning (approximately from 7-8 am).
- Dog monitoring will be done in teams of two. Order of observations will be:
    - Adoptions
    - Holding
    - Isolation
- Cat monitoring can be done singly or in a team. Order of observations will be:
    - Adoption
    - Holding
    - Isolation
- Observations will be recorded in a uniform manner - according to this training manual and using the key provided on the sheet.
- If a Red Flag medical condition is noted, notify medical staff immediately.
- A summary sheet will be used on a daily basis to record health and behavioral concerns of individuals that need to be shared with the staff and medical team. Each volunteer will fill out a summary sheet based on the animals they observe. The volunteers will compile the summary information onto one or more sheets to be shared with shelter staff that day for action to be taken.
- Animals that have lost their sheets will be given a new sheet with monitoring beginning on the appropriate day of shelter stay.
- Animals will be weighed on intake (recorded in pounds) and will be given a body condition score (BCS) on a 1-9 scale. Animals will be weighted and BCS at weekly intervals during their shelter stay.
- Once an animal is outcome, the daily monitoring sheets will be saved in the designated folder.

Filling out the daily monitoring sheet:

If it is the animals first day in the shelter, fill in:

- **Animal ID #:** this is a shelter assigned 8 digit number starting with A found on the kennel card
- **Intake date:** will be on the kennel card
- **Age:** should be on the kennel card and will either be in months or years

- **Weight:** should be on the kennel card and is recorded in pounds

For every day of monitoring, fill in:

- **Date:** fill in correct date
- **Initials:** always initial the day that you do the observations
- **Cage/kennel #:** record the cage/kennel # that the animal is housed in

NOTE: The numerical coding of the health scoring system is based on 1= a normal observation. This allows assessment for deviations from normal via a quick visual review of the monitoring card.

- **Attitude/Vocalization:** B = bright, alert and responsive is for an animal that is interactive, Q = quiet, alert and responsive is for an animal that responds but is quiet, D= depressed and is for an animal that is dull/quiet. If an animal is not vocalizing score a 1, if an animal is whining score a 2, if an animal is panting score a 3 and if an animal is barking score a 4. It is possible for an animal to have more than one score for vocalization, for example if they are whining and panting (2/3).
- **URI signs:** If no signs of respiratory illness are noted score a 1, if the animal is sneezing 2, if the animal is coughing score a 3, if there is nasal discharge (clear or colored) score a 4 and if there is discharge (clear or colored) from one or both eyes score a 5. Additionally if there is something that is not present in the key, please put in the comment section on the back of the sheet.
  **Animals showing clinical signs of upper respiratory illness should be recorded on the daily summary sheet.*
- **Eating:** If the animal has not eaten (all food is present) score a 0, if normal amount of food has been eaten or all food is gone score a 1, if some food has been eaten score a 2, if there is vomit noted that looks like regurgitated food score a 3 and if there is any other vomit present score a 4.
  *******Animals scoring a 0, 3 or 4 should be added to the daily summary sheet.*
- **Stool:** If there is not any stool present score a 0, if the stool is formed and normal score a 1, if the stool is soft score a 2, if there is diarrhea (very soft to runny) score a 3, if there is bloody diarrhea score a 4 and if the feces is outside of the litter box score a 5 (for cats).
  *******If an animal is scored a 3 or 4, record on the daily summary sheet. If there is bloody diarrhea find kennel staff immediately as this is a red flag emergency.*
- **Urine:** If there is no urine present score a 0. If the dog is seen urinating or there is obviously a puddle of urine in the kennel, score a 1. If there is abnormal urine noted, such as bloody urine, score a 2. If the urine is outside of the litter box (for cats) score a 3. If you're not sure, for example if the kennel is wet or messy and it's not clear whether urine is present, note an NA (could not be assessed).
  **If an animal is observed to be straining to urinate, find a staff member to confirm as this is a red flag condition.*
- **Behavior:** record what behaviors the animal is displaying at the time of the observation. Animals will be assessed in each of 3 areas of behavior: interactions with people, acclimation and approachability.
  1. **Interactions with people:**

1 = approaches friendly. This is an animal that approaches the front of the kennel with a loose body posture and is seeking attention

2 = interacts visually. This is an animal that looks at the observer but does not approach

3 = no interaction/unable to determine. This is an animal that does not change what they are doing when the observer approaches the kennel or this is an animal that is sending mixed signals and should be used if the observer if unsure of what the animal is doing. Please make notes in the comment section if this number is used.

4 = moves away. This is an animal that moves further away from the observer.

5 = approaches aggressively. This is an animal that has a stiff body posture, hard eyes and approaches the observer in a rapid, likely barking/growling manner.

2. Acclimation:

1 = calm. This is an animal that is acting very much as they would in a home; resting quietly, interacting calmly or playing with a toy.

2 = excited. This is an animal that is jumping, whining

3 = timid/shaking. This is an animal that may or may not interact and that might be shaking.

4 = cower/hiding. This is an animal that has a low body position in the kennel and/or is hiding if a hiding area has been provided.


5 = stereotypic. This is an animal that is displaying stereotypic behavior such as spinning, moving from side to side in the kennel, licking the kennel bars, or any other repeated behavior.

3. Approachability:

1 = no aggression noted. This is an animal has a loose body posture, is panting or has a relaxed mouth and soft eyes.


2 = questionable. This is an animal that is sending mixed signals or signals that are difficult to interpret. Make notes in the comment section is this number is used.

3 = whale eye. This is an animal whose eyes are wide and gaze is fixed.

4 = growling. This is an animal that is growling when observer approaches the kennel and likely has a low, stiff body position.

5 = snaps. This is an animal that snaps or tries to bite when observer approaches kennel.

- **Location/activity in kennel:** record where the animal spends most of their time during the observation:

  F = front

  M= middle

  B = back

  H = hiding

Also record what the animal's activity is during this time:

1 = sitting or lying down

2 = standing or walking

3 = running/jumping

****Animals displaying signs of marked mental distress should be added to the daily summary sheet.* Signs of marked mental distress include:**

- Frozen or tense/stiff body posture or cowering into corners/gutters etc. for extended periods of time (e.g. > 1hour)
- Pressing head into the corner of the enclosure
- Constant or frequent growling, hissing, or lunging at the front of the cage
- Efforts to escape to the point of self-injury, e.g. blood on mouth or paws from chewing or clawing to escape
- Stereotypic behaviors such as repetitive pacing, spinning or lunging
- For group housed animals (including littermates and "bonded pairs")
  - Food guarding or inability to access guarded food within the enclosure
  - Attacking or being attacking by another animal within the enclosure

Filling out the Daily Summary Sheet:

- Each day there will be one sheet for dogs and one sheet for cats. They are to be filled out by the volunteers during the time that observations are being made. Be sure to include:
    - The correct date
    - Circle if the sheet is for dogs or cats
    - Your name
- Any health or behavior concerns should be recorded on this sheet. The categories covered are:
    - Not eating
    - URI signs (if not already on treatment for URI)
    - Diarrhea
    - Vomiting
    - Behavioral concerns
- Red Flag emergencies should also be recorded on this sheet – see list of emergencies below. *However, a staff member should also be immediately contacted if any of these signs are noted.*
- Other issues can also be noted on this sheet:
    - Primary health other – for example a broken water dish that does not have any water.
    - Secondary health other – for example a broken water dish that drips or dangerous kennel wire.
- Turn these sheets into the designated folder for staff once the daily monitoring is complete.

Red Flag Medical Conditions:

These conditions indicate a health risk for the individual or the population. Please notify kennel staff immediately upon finding any of the following conditions:

- Animal that is not breathing
- Animal that has severe lethargy or is non-responsive
- Animal that is seizuring
- Animal that is actively bleeding or has a large amount of blood in its housing unit
- Animal that has watery diarrhea with or without blood
- Animal that is straining to urinate
- Animal with evidence of pain such as restlessness, vocalizing or panting

If no kennel staff is available – find a veterinary technician (medical treatment room in the cat annex) or any other shelter staff member to help you.

Additionally add any red flag cases to the daily summary sheet to insure this important health information is shared with the entire medical staff.

Generic Infectious Disease Protocol

Basic disease description (ie it's a virus, it causes diarrhea, it can be fatal, etc.)
General policy regarding admission, treatment, adoption or euthanasia
How recognized/diagnosed
    Who authorized to perform test
    Who authorized to make diagnosis
Who notified
    When (immediately, within 24 hours…)
    How (paper, in person, sign on cage, etc.)
Where housed
    Isolation, general population, not housed ever (euthanasia upon disease recognition)
How cleaned
    Cage/run
    Environment
    Special disinfectants or repeated cleaning needed before cage is reused?
    Who responsible for cleaning/how will they be notified that special cleaning is needed (card on cage, written slip, etc.)
Which animals will be treated?
    Only during legally required holding period?
    All animals?
    Only "highly adoptable" animals or rescue candidates?
    Decision making process if only some adoptable animals are treated
Treatment (if applicable)
    Who can initiate treatment
    If other than vet can initiate treatment:
        Standard treatment
        Circumstances under which standard treatment initiated
        Side effects/contra-indications to standard treatment
    Who responsible for daily treatment
Monitoring
    Who responsible for daily monitoring
    Documentation (medical record upkeep)
    Scheduling of rechecks
Recovery/treatment failure
    How defined
    Who can determine
        If other than vet, standardized protocol for determining recovery/treatment failure
Adoption
    Will animal be adoptable prior to recovery?
    Will animal be available prior to recovery?
    Adoption release required notifying adopter of medical condition?
    Medications to go home with animal?
Documentation - where will the following be noted:
    Diagnosis

Test results
Treatment
Rechecks
Adoption release
Home care instructions/prescriptions

Footer should include date of last revision and the initials of the people involved with development of the protocol so questions can be directed appropriately. May also include space for staff to initial that they have read and understand the protocol.

Product	Purpose/Parasite Treated	Dose	Dosing Schedule
Strongid	Dewormer: **hookworms and roundworms** Animals can be infested even though the parasites are not visible in stool samples. The adult worms can look like white or cream-colored thin string or "angel hair pasta."	Dogs: 1mL/10# Cats: 1 mL/5#	For canines and felines: **1 to12 weeks old**: given every 2 weeks until 12 weeks old **3-6 months old**: dose repeated in 2 weeks, then given every 4 weeks until 6 months old **> 6 months old**: dose repeated once in 2 weeks
Panacur	Dewormer: **hookworms, roundworms, and whipworms**	Use granules as directed. Suspension 100 mg/ml 1 ml / 4#	Animals with **whipworms:** Give once a day for 3 days; 3 day treatment repeated in 3 weeks and again in 3 months
Ponazuril - Marquis Paste	Dewormer: **Coccidia**	1 cc per 10 # of diluted paste*	Animals (dogs, cats, rabbits > 3 weeks) with Coccidia: two doses 7-10 days apart
Praziquantel	Dewormer: **tapeworms** Animals with tapeworms need to be treated for fleas	Per Labeled Instructions	Dogs and cats over 6 weeks old diagnosed with tapeworms: One time treatment, but repeated if needed
Capstar	Flea control**	Per Labeled Instructions	Animals over 5 weeks of age: One time treatment, but can be repeated daily if needed

***To dilute Ponazuril (Marquis Paste)**

Dilute one syringe of paste (127 grams at 150 mgs/gm., 120 ml volume) in 21 mls* of water or other carrier (e.g. Val syrup) results in a solution of 135 mgs/ml.

*The math:

(127 grams x 150 mgs/gm) = 19050 mgs/141 mls = 135 mgs/ml

135 mg/4.5 kg = 30 mg/kg dose (and a dosing schedule of 1 ml/10 lb)

2011 AAHA Canine Vaccination Guidelines*†

Members of the American Animal Hospital Association (AAHA) Canine Vaccination Task Force:
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Introduction

The previous versions of the American Animal Hospital Association (AAHA) Canine Vaccine Guidelines, published in 2003 and 2006, and updated in 2007, represented a collaborative effort by academicians, private practitioners, and industry to facilitate efforts of veterinarians in the United States (US) and Canada in making decisions regarding the selection and use of canine vaccines. Vaccination guidelines for shelter-housed dogs were also included in 2006. Since that time, new canine vaccines have been licensed, others have been withdrawn, and new information on existing vaccines has led to the revision of current recommendations. The 2011 AAHA Canine Vaccination Guidelines offer a comprehensive review of canine vaccines currently available in North America, updated recommendations on administration of core versus noncore vaccines, and revised recommendations for vaccination of shelter-housed dogs. Also included are updated recommendations on serologic testing as a means of documenting and monitoring immune responses to vaccines, an expanded discussion on vaccine adverse events (AEs), and an updated review of the legal implications associated with administering vaccines in clinical practice.

The reader is reminded that scientific studies and refereed journal publications are not available to support all of the vaccination recommendations included within this document. Some recommendations are based on unpublished studies, current knowledge of immunology, and the experience of experts in the field. To that point, the reader is referred to a new section of the AAHA Canine Vaccination Guidelines, entitled Frequently Asked Questions (FAQs). Within this section, the Task Force addresses several topical and controversial canine vaccination issues posed by practicing veterinarians. The section is subdivided into four categories to address questions on Administration of Vaccines, Vaccine Products, Adverse Reactions to Vaccines, and Legal Issues related to administration of vaccines, and is intended to provide additional advice on key points of concern where scientific documentation may not be available.

The AAHA Canine Vaccination Task Force developed the 2011 Guidelines in a manner consistent with best vaccination practices. The Guidelines include expert opinion supported by scientific study and encompass all canine vaccines currently licensed in the US and Canada. The Guidelines include recommendations that may differ from statements on product labels and product literature, especially with respect to initial vaccination and revaccination (booster) intervals. It is the view of the Task Force that veterinarians have considerable latitude in the selection and use of veterinary biologic products licensed for dogs, with rabies vaccine being a noted exception, and that these Guidelines, although not intended to dictate an exclusive protocol or standard, do meet accepted standards of professional practice.

This document was developed by AAHA through a collaborative effort among Task Force members to aid practitioners in making decisions about appropriate care of their canine patients with respect to currently available vaccines. The Task Force included experts in immunology, infectious diseases, internal medicine, law, and clinical practice.

The Guidelines are supported by professional, scientific, and clinical evidence, as well as published and unpublished documentation.

These Guidelines and recommendations should not be construed as dictating an exclusive protocol, course of treatment, or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and

* These guidelines were sponsored by a generous educational grant from Boehringer Ingelheim Vetmedica Inc., Merck Animal Health, Merial, and Pfizer Animal Health.

† Reviewers were provided by the American College of Veterinary Microbiologists.

limitations unique to each individual practice setting. The Guidelines are not intended to be an AAHA standard of care.

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Acronyms and Terms

Regulatory Agency Acronyms

AMDUCA *Animal Medicinal Drug Use Clarification Act—applies only to animal drugs regulated by FDA, not veterinary biologics regulated by USDA;* **APHIS** *Animal and Plant Health Inspection Service—an agency of the USDA*; **CFIA** *Canadian Food Inspection Agency—the agency responsible for licensing veterinary vaccines made and/or used in Canada*; **CVB** *Center for Veterinary Biologics*; **FDA** *Food and Drug Administration—licenses all human vaccines and veterinary pharmaceuticals;* **USDA** *United States Department of Agriculture—licenses all veterinary vaccines*

Vaccine Terms and Acronyms

Avirulent live *attenuated bacterial vaccine*; **bacterin** *whole killed cell bacterial vaccine;* **killed antigen** *inactivated vaccine antigen (viral or bacterial);* **infectious vaccines** *vaccines that infect the host's cells to induce a protective immune response (e.g., modified-live [attenuated] viral vaccines [see text for specific examples]);* **noninfectious vaccine** *vaccines that are incapable of infecting host cells to produce additional antigen (e.g., killed [inactivated] vaccines [see text for specific examples]);* **r** *recombinant vaccine antigen—this notation generally precedes the name of the vaccine (e.g., recombinant canine distemper virus [rCDV]);* **subunit vaccine** *a vaccine produced using conventional or recombinant technology that contains specific subunits rather than a complete virus or bacteria;* **viral vector** *a live nonpathogenic (or attenuated) virus in which selected DNA or RNA of a pathogenic virus is recombined for purposes of vaccine development; virus vectored vaccines represent one form of recombinant vaccine technology.*

AAHA *American Animal Hospital Association;* **AE** *adverse event;* **Bb** *Bordetella bronchiseptica;* **CAV-1** *canine adenovirus, type 1 (cause of canine viral hepatitis); protection from CAV-1 infection is provided by parenterally administered CAV-2 vaccine;* **CAV-2** *canine adenovirus, type 2;* **CCoV** *canine coronavirus cause of enteric coronavirus infection (antigenically distinct from the canine respiratory coronavirus [CRCoV]);* **CDV** *canine distemper virus;* **CIV** *canine influenza virus—H3N8;* **CPiV** *canine parainfluenza virus;* **CPV-2** *canine parvovirus, type 2;* **DOI** *duration of immunity;* **HI** *hemagglutination inhibition—a laboratory technology used to measure antibody levels (e.g., parvovirus antibody);* **HOD** *hypertrophic osteodystrophy;* **IgG** *immunoglobulin G—a class of humoral antibody; most common type associated with immune response to parenteral vaccine; also the most common class of antibody measured as serum titers;* **IgM** *immunoglobulin M—a class of antibody, generally short lived and associated with early infection and initial*

vaccination; **IM** *intramuscular (route of administration);* **IN** *intranasal or mucosal (route of administration);* **MDA** *maternally derived antibody;* **MLV** *modified live virus, attenuated virus vaccine;* **MV** *measles virus;* **NSAIDs** *nonsteroidal anti-inflammatory drugs*; **OMC** *outer membrane component—used in reference to bacterial surface proteins (subunit antigens) in selected bacterins; also referred to as "conventional" subunit vaccines;* **OspA** *outer surface protein A (antigen) of* Borrelia burgdorferi*;* **OspC** *outer surface protein C (antigen) of* Borrelia burgdorferi*;* **PCR** *polymerase chain reaction—a very sensitive test that measures the presence or amount of RNA or DNA of a specific organism;* **RV** *rabies virus;* **SAE** *serious adverse event;* **sIgA** *secretory immunoglobulin A—a class of antibody, most commonly associated with a local (mucosal) immune response after IN vaccination;* **SQ** *subcutaneous (route of administration);* **US** *United States;* **VN** *virus neutralization—a laboratory technology used to measure antibody levels (e.g., canine distemper antibody)*

Part I: Canine Vaccination in General Veterinary Practice

Vaccines provide proven life-saving benefits, are associated with minimal risk, and should be part of routine preventative health care. Life stage and lifestyle, risk of exposure, and underlying medical conditions should all be considered when developing a vaccination protocol.

Vaccine Types

Over the last 5 decades, significant advances in vaccine technology have resulted in many types of biologicals (vaccines) being licensed by the U.S. Department of Agriculture (USDA) and Canadian Food Inspection Agency (CFIA) for use in dogs. The two general types of vaccines now available include the noninfectious (inactivated, killed, dead, conventional and recombinant subunit, plasmid DNA, and avenomous) vaccines and the infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines.[1–4] The availability of a wide variety of products provides veterinarians with multiple options when selecting and administering core and noncore vaccines. The following section provides a summary of the theory and technology behind the different types of canine vaccines currently on the market.

Noninfectious (Inactivated, Killed) Vaccines

The noninfectious (inactivated, killed) vaccines include killed viral (e.g., rabies virus [RV], canine influenza virus [CIV], and canine coronavirus [CCoV]), whole killed cell bacterins (certain Lyme, *Leptospira*), bacterial subunit (recombinant outer surface protein A [OspA] Lyme, and conventional subunit *Leptospira* outer membrane component [OMC] vaccines), a cellular antigen extract of the *Bordetella bronchiseptica* (Bb) vaccine, and Western diamondback rattlesnake avenomous vaccine (**Table 1**). As the name "noninfectious" implies, these vaccines do not infect the host to produce new antigen. Thus, they must contain adequate amounts of antigen to immunize. Because the antigen alone may not be adequate to immunize a dog, many of the noninfectious vaccines must also contain adjuvant. Adjuvants include a wide variety of substances that maintain or depot the antigen as well as stimulate an inflammatory response to provide a more robust immune response to the vaccine antigens.[5,6] This increased nonspecific stimulation of the immune system caused by adjuvants is required to induce a protective response to antigens. Some of the killed whole cell bacterial vaccines do not require the addition of adjuvant because the bacterial cell walls or portions of cell wall (e.g., lipopolysaccharide, peptidoglycans) of *Bordetella*, *Leptospira*, or *Borrelia* have adjuvant properties, in addition to serving as antigens.[5,6] Together, the antigen and adjuvant are designed to stimulate a protective immune response.

Critical to production of a noninfectious vaccine is the process used to inactivate the virus or bacteria, to ensure that it is dead. At the same time, this process must not significantly alter the antigenic properties of the organism. Chemicals, ionizing irradiation, and other methods are used to kill the organisms. Chemicals used for inactivation include formalin, β-propiolactone, ethylenediamine, and other agents. Some of these agents cannot be completely eliminated from the final product. Injection site pain or hypersensitivity have sometimes been attributed to the residual chemicals.[7] When compared with infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines, noninfectious vaccines are more likely to produce local and systemic adverse reactions in some dogs.[7–9] These AEs can be caused by the antigen (e.g., virus or bacteria), the adjuvant, serum or cellular proteins, or a combination of vaccine components. Noninfectious vaccines are more stable than infectious vaccines, as the microbial agents do not need to remain viable (i.e., do not need to infect cells) to immunize.

Noninfectious vaccines are often considered to be the safest vaccine type because the immunizing agent (virus or bacteria) is dead; thus, it cannot revert to virulence and cannot cause the disease that the vaccine was intended to prevent.[1–10] However, it should be understood that hypersensitivity reactions are more common with the noninfectious vaccines than infectious vaccines; thus, they may not be perceived to be as safe as the infectious

TABLE 1

2011 AAHA Canine Vaccination Guidelines* for the General Veterinary Practice

Vaccine†	Initial Vaccination (<16 wk of age)	Initial Vaccination (>16 wk of age)	Revaccination (Booster) Recommendation	Comments and Recommendations
CDV (MLV) or rCDV	Puppies should be vaccinated every 3–4 wk between the ages of 6 and 16 wk (e.g., at 6, 10, and 14 wk, or 8, 12, and 16 wk). To minimize the risk of maternal antibody interference with vaccination, the final dose of the initial series should be administered between 14 and 16 wk of age, regardless of the product used.	One dose is considered protective and acceptable. Revaccination is recommended every ≥3 yr after completion of the initial vaccination, regardless of the product used.	Dogs (puppies) completing the initial vaccination series by 16 wk of age or younger should receive a single booster vaccination no later than 1 yr after completion of the initial series and be revaccinated every ≥3 yr thereafter, regardless of the product used.	Core • Among healthy dogs, all commercially available distemper vaccines are expected to induce a sustained protective immune response lasting at least ≥5 yr. • Among healthy dogs, the rCDV vaccine has been shown to induce a protective immune response lasting at least 5 yr. • Although rare, some dogs are genetically predisposed "nonresponders" and are incapable of developing protective immunity subsequent to CDV vaccination. • The rCDV vaccine can be used interchangeably with MLV-CDV vaccine. • It is recommended that all CDV vaccines be administered within 1 hr after reconstitution; vaccine held >1 hr should be discarded. MLV-CDV vaccine is particularly vulnerable to inactivation after reconstitution (rehydration).
MV (MLV–an aid in the prevention of CDV infection in puppies only) (Note: measles antigen is currently available in a 4-way combined MLV vaccine: CDV + measles + CAV-2 + CPiV) and a 2-way combined MLV vaccine: CDV + Measles IM route only	A single dose is recommended for administration to healthy dogs between the ages of 6 and 12 wk.	Not recommended	Not recommended	Noncore • Measles vaccine is only intended to provide temporary immunization of young puppies against CDV. MV has been shown to cross-protect puppies against CDV in presence of MDA to CDV. • These vaccines should not be administered to dog <6 wk or female dogs >12 wk of age that will be used for breeding, as these puppies may have maternally derived measles antibody and will block MV induced immunity. • After administration of a single dose of measles virus-containing vaccine, subsequent vaccination with a CDV vaccine that does not contain MV is recommended at 2–4 wk intervals until the patient is 14–16 wk of age. • Vaccine that contains MV must be administered by the IM route. • It is recommended that MV-containing vaccine be administered within 1 hr after reconstitution; vaccine held >1 hr should be discarded.

(Table continues)

TABLE 1 (continued)

Vaccine[†]	Initial Vaccination (<16 wk of age)	Initial Vaccination (>16 wk of age)	Revaccination (Booster) Recommendation	Comments and Recommendations
CPV-2 (MLV)	Puppies should be vaccinated every 3–4 wk between the ages of 6 and 16 wk (e.g., at 6, 10, and 14 wk, or 8, 12, and 16 wk). To minimize the risk of maternal antibody interference with vaccination, the final dose of the initial series should be administered between 14 and 16 wk of age, regardless of the product used.	One dose is considered protective and acceptable. Revaccination is recommended every ≥3 yr after completion of the initial vaccination, regardless of the product used.	Dogs (puppies) completing the initial vaccination series by ≤16 wk of age should receive a single booster vaccination not later than 1 yr after completion of the initial series and be revaccinated every ≥3 yr thereafter, regardless of the product used.	Core • All MLV-CPV-2 vaccines available today are expected to provide immunity from disease caused by any field variant recognized today (CPV-2a, -2b, and -2c). • As new variants of CPV-2 occur, those variants will need to be evaluated, as the previous ones have, to ensure vaccines in use at the time are protective. • Among healthy dogs, all commercially available MLV-CPV-2 vaccines are expected to induce a sustained protective immune response lasting at least 5 yr. • Although rare, some dogs are genetic nonresponders and are incapable of developing protective immunity subsequent to CPV-2 vaccination no matter how often vaccine is administered. • Today, specific breed-susceptibility to CPV-2 nonresponsiveness is not recognized. There is no value in extending initial CPV-2 vaccination series beyond 16 wk of age. • It is recommended that CPV-2 vaccine, especially when administered in combination with CDV vaccine, be administered within 1 hr after reconstitution; vaccine held >1 hr should be discarded.
CAV-2 (MLV parenteral)	Puppies should be vaccinated every 3–4 wk between the ages of 6 and 16 wk (e.g., at 6, 10, and 14 wk, or 8, 12, and 16 wk). To minimize the risk of maternal antibody interference with vaccination, the final dose of the initial series should be administered between 14 and 16 wk of age, regardless of the product used.	One dose is considered protective and acceptable. Revaccination is recommended every ≥3 yr after completion of the initial vaccination, regardless of the product used.	Dogs (puppies) completing the initial vaccination series by ≤16 wk of age should receive a single booster vaccination not later than 1 yr after completion of the initial series and be revaccinated every ≥3 yr thereafter, regardless of the product used.	Core • CAV-2 induces protection against CAV-1 (canine hepatitis virus) as well as CAV-2 (one of the agents known to be associated with canine infectious respiratory disease). • Among healthy dogs, all commercially available MLV-CAV-2 vaccines are expected to induce a sustained protective immune response lasting at least 7 yr. • It is recommended that CAV-2 vaccine, especially when administered in combination with CDV vaccine, be administered within 1 hr after reconstitution; vaccine held >1 hr should be discarded.

(Table continues)

TABLE 1 (continued)

Vaccine†	Initial Vaccination (<16 wk of age)	Initial Vaccination (>16 wk of age)	Revaccination (Booster) Recommendation	Comments and Recommendations
Rabies 1 yr (killed)	Administer a single dose not earlier than 12 wk of age or as required by state, provincial, and/or local requirements.	Administer a single dose of a "1-yr" rabies vaccine.	Administer a single dose of a"1-yr" rabies vaccine annually. State, provincial, and/or local laws apply.	Core • State, provincial, and local statutes govern the frequency of administration for products labeled as "1-yr" rabies vaccine. • Route of administration may not be optional; see product literature for details.
Rabies 3 yr (killed)	Administer a single dose of a "3-yr" rabies vaccine not earlier than 12 wk of age or as required by state, provincial, and/or local requirements.	Administer a single dose of a "3-yr" rabies vaccine or as required by state, provincial, and/or local requirements.	Administer a single dose of a "3-yr" rabies vaccine within 1 yr after administration of the initial dose, regardless of the animal's age at the time the initial dose was administered. Subsequently, revaccination with a "3-yr rabies" vaccine should be administered every 3 yr thereafter, unless state, provincial, and/or local requirements stipulate otherwise.	Core • State, provincial, and local statutes govern the frequency of administration for products labeled as "3-yr rabies" vaccines. • Use of rabies vaccine multidose ("tank") vials in companion animals is not recommended. • Route of administration may not be optional; see product literature for details.
CPiV (MLV) For parenteral administration only. (Available only as a combined product for parenteral administration)	Parenteral CPiV vaccine is only available in combination with core vaccines (CDV-CPV-2 and CAV-2). Therefore, veterinarians who elect to administer parenteral CPiV vaccine should follow the same administration recommendations as outlined above for the core vaccines.	Veterinarians who elect to administer parenteral CPiV vaccine should follow the same administration recommendations as outlined above for the core vaccines.	Veterinarians who elect to administer parenteral CPiV vaccine should follow the same administration recommendations as outlined above for the core vaccines.	Noncore • Parenterally administered CPiV vaccine does prevent clinical signs but has not been shown to prevent infection and shedding. • Use of the parenteral vaccine is recommended for use in those patients that aggressively resist IN vaccination.
Bb (inactivated-cellular antigen extract) For parenteral administration only.	Administer first dose at 8 wk of age and second dose at 12 wk of age (see comments).	Two doses, 2–4 wk apart are required.	Annually	Noncore • There is no known advantage to administering parenteral and IN Bb vaccines simultaneously. • On initial vaccination, administration should be scheduled such that the second dose can be administered at least 1 wk before exposure (kennel, dog show, daycare, etc). • The parenteral vaccine is not immunogenic if administered by the IN route.
Bb (live avirulent bacteria) For IN administration only.	A single dose should be administered in conjunction with 1 of the core vaccine doses. Note: The initial IN dose may be administered to dogs as young as 3–4 wk of age (depending on manufacturer) when exposure risk is considered to be high (see comments).	A single dose is recommended.	Annually or more often in high-risk animals.	Noncore Transient (3–10 days) coughing, sneezing, or nasal discharge may occur in a small percentage of vaccinates. IN Bb vaccine must not be administered parenterally.

(Table continues)

TABLE 1 (continued)

Vaccine[†]	Initial Vaccination (<16 wk of age)	Initial Vaccination (>16 wk of age)	Revaccination (Booster) Recommendation	Comments and Recommendations
CPiV (MLV) For IN administration only. (IN CPiV vaccine is only available in combination with IN Bb vaccine or Bb + CAV-2)	A single dose should be administered in conjunction with 1 of the core vaccine doses. Note: The initial IN dose may be administered to dogs as young as 3–4 wk of age (depending on manufacturer) when exposure risk is considered to be high (see comments).	A single dose is recommended.	Annually or more often in high-risk animals.	Noncore • When feasible, IN vaccination is recommended over parenteral vaccination. Parenterally administered CPiV vaccine does prevent clinical signs, but has not been shown to prevent infection and shedding. IN CPiV vaccine prevents not only clinical disease but also infection and viral replication (shedding).
CAV-2 (MLV) (for IN administration only) (Available only in combination with IN Bb and CPiV vaccine)	A single dose should be administered in conjunction with 1 of the core vaccine doses. Note: The initial IN dose may be administered to dogs as young as 3–4 wk of age (depending on manufacturer) when exposure risk is considered to be high (see comments).	A single dose is recommended.	Annually or more often in high-risk animals.	Noncore • Administration of IN CAV-2 vaccine is recommended for use in dogs considered at risk for respiratory infection caused by the CAV-2 virus. • IN CAV-2 vaccine may not provide protective immunity against CAV-1 (canine hepatitis virus) infection and should not be considered a replacement for parenteral MLV-CAV-2 vaccination.
Canine influenza vaccine (killed virus)	Administer 1 dose not earlier than 6 wk of age and a second dose 2–4 wk later.	Two doses, 2–4 wk apart are required. A single initial dose will not immunize a seronegative dog.	Annually	Noncore
Borrelia burgdorferi (Lyme disease) (killed whole cell bacterin) or *Borrelia burgdorferi* (rLyme: rOspA)	Administer 1 dose not earlier than 12 wk of age and a second dose 2–4 wk later. For optimal response, do not administer to dogs <12 wk of age.	Two doses, 2–4 wk apart. A single initial dose will not immunize a seronegative dog.	Annually. Alternatively, it has been recommended that initial vaccination or revaccination (booster) be administered before the beginning of tick season, as determined regionally.	Noncore • Generally recommended only for use in dogs with a known risk of exposure, living in or visiting regions where the risk of vector tick exposure is considered to be high, or where disease is known to be endemic. • In addition to vaccination, prevention of canine Lyme borreliosis includes regular utilization of tick control products.
Leptospira interrogans (4-way killed whole cell or subunit bacterin) Contains serovars *canicola* + *icterohemorrhagiae* + *grippotyphosa* + *pomona*	Administer 1 dose not earlier than 12 wk of age and a second dose 2–4 wk later. For optimal response, do not administer to dogs <12 wk of age.	Two doses, 2–4 wk apart. A single initial dose will not immunize a seronegative dog.	Annually. Administration of booster vaccines should be restricted to dogs with a reasonable risk of exposure.	Noncore • Specific vaccination recommendations vary on the basis: (1) known geographic occurrence/prevalence, and (2) exposure risk in the individual patient. • It is recommended that the first dose of leptospira vaccine be delayed until 12 wk of age. • DOI based on challenge studies has been shown to be approximately 1 yr.

(Table continues)

TABLE 1 (continued)

Vaccine†	Initial Vaccination (<16 wk of age)	Initial Vaccination (>16 wk of age)	Revaccination (Booster) Recommendation	Comments and Recommendations
Leptospira interrogans (2-way killed bacterin) Contains serovars *canicola* + *icterohemorrhagiae* only	*Intentionally left blank*	*Intentionally left blank*	*Intentionally left blank*	Not recommended
Canine oral melanoma (plasmid DNA vaccine-expresses human tyrosinase). Availability is currently limited to practicing oncologists and selected specialists.	Not applicable. See Manufacturer's indications for use.	See Manufacturer's indications for use.	See Manufacturer's indications for use.	Use of this vaccine is limited to the treatment of dogs with malignant melanoma. • This vaccine aids in extending survival times of dogs with Stage II or III oral melanoma and for which local disease control has been achieved (negative local lymph nodes or positive lymph nodes that were surgically removed or irradiated). The human tyrosinase protein will stimulate an immune response that is effective against canine melanoma cells that over express tyrosinase. • Vaccination is not indicated for the prevention of canine melanoma.
Crotalus atrox (Western Diamondback rattlesnake vaccine) (toxoid)	Initial vaccination recommendation may depend on size of the individual dog. Refer to manufacturer's label. Current recommendations are to administer 2 doses, 1 mo apart, to dogs as young as 4 mo.	Initial vaccination recommendation may depend on size of the individual dog. Refer to manufacturer's label. Current recommendations are to administer 2 doses 1 mo apart.	Refer to manufacturer's label. Annual revaccination requirements vary depending on prior exposure, size of dog, and risk of exposure. Refer to manufacturer's label.	Field efficacy and experimental challenge data in dogs are not available at this time. • Intended to protect dogs against the venom associated with the bite of the Western Diamondback rattlesnake. Some cross-protection may exist against the venom of the Eastern Diamondback rattlesnake. There is currently no evidence of cross-protection against the venom (neurotoxin) of the Mojave rattlesnake. • Vaccine efficacy and dose recommendations are based on toxin neutralization studies conducted in mice. Conventional challenge studies in dogs have not been conducted. Neither experimental nor field data are currently available on this product. Note: Veterinarians should advise clientele of vaccinated dogs that vaccination does not eliminate the need to treat individual dogs subsequent to envenomation.
Canine coronavirus (CCoV) (killed and MLV)	*Intentionally left blank*	*Intentionally left blank*	*Intentionally left blank*	Not recommended • Neither the MLV vaccine nor the killed CCoV vaccines have been shown to significantly reduce disease caused by a combination of CCoV and CPV-2. Only CPV-2 vaccines have been shown to protect dogs against a dual-virus challenge.

(Table continues)

TABLE 1 (continued)

Vaccine†	Initial Vaccination (<16 wk of age)	Initial Vaccination (>16 wk of age)	Revaccination (Booster) Recommendation	Comments and Recommendations
				• DOI has never been established. In controlled challenge studies, neither vaccinates nor control dogs developed clinical evidence of disease after experimental virus challenge.

*The AAHA 2011 Canine Vaccine Guidelines are provided to assist veterinarians in developing a vaccination protocol for use in clinical practice. They are not intended to represent vaccination standards for all dogs nor are they intended to represent a universal vaccination protocol applicable for all dogs.
†Route of administration is SQ (subcutaneous) or IM (intramuscular) unless otherwise noted by the manufacturer.
Bb, *Bordetella bronchiseptica*; CAV-1, canine adenovirus, type 1 (cause of canine viral hepatitis); protection from CAV-1 infection is provided by parenterally administered CAV-2 vaccine; CAV-2, canine adenovirus, type 2; CCoV, canine coronavirus cause of enteric coronavirus infection (antigenically distinct from the canine respiratory coronavirus [CRCoV]); CDV, canine distemper virus; CIV, canine influenza virus—H3N8; CPIV, canine parainfluenza virus; CPV-2, canine parvovirus, type 2; DOI, duration of immunity; IN, intranasal; MLV, modified live virus, attenuated virus vaccine; MV, measles virus; OspA outer surface protein A (antigen) of Borrelia burgdorferi; RV, rabies virus.

vaccines.[11] In general, all canine vaccines are quite safe and only a small percentage of vaccinated dogs, regardless of type of vaccine, develop severe adverse reactions.[12–24]

Vaccine Stability

Because the antigenic bacteria or virus used in noninfectious (killed) vaccine is incapable of replicating, killed vaccines are prepared and sold as an aqueous (liquid) product that can be directly administered to the patient. During storage, noninfectious vaccines are highly stable. Although refrigeration is recommended, noninfectious vaccines are significantly less susceptible to heat inactivation than infectious vaccines. Noninfectious vaccines can, however, be denatured. If exposed to chemicals (e.g., rewashed, reused syringes), a noninfectious vaccine could become ineffective. Therefore, sterile, unused syringes should be used when administering vaccines. Noninfectious vaccines should be administered before the expiration date printed on the vial.

Both infectious and noninfectious vaccines are important and required in every canine vaccination program. However, it is important not to mix noninfectious vaccines with infectious vaccines in the same syringe, unless specified by the manufacturer.[14,19–24]

Multiple Dose Vials

Multiple dose, also called "tank" vials, of killed rabies vaccine are available. Typically prepared in 10 mL (10 dose) vials, these products should only be used for high volume vaccination clinics or by shelter immunization programs where large numbers of dogs are vaccinated over a short period of time (same day). Multiple dose vials require multiple needle penetrations over time, thereby increasing the risk for contamination. Tank vials should be shaken frequently to ensure the concentration of antigen/adjuvant is consistent among doses withdrawn from a single vial. Single-dose vials are available and are strongly recommended for use in general veterinary practice.

Routes of Administration

Because noninfectious canine vaccines cannot infect or replicate, they must be administered parenterally (subcutaneously [SQ] or intramuscularly [IM]); noninfectious vaccine should not be administered directly onto mucosal surfaces (e.g., intranasal [IN] administration). Noninfectious canine vaccines stimulate primarily systemic humoral immunity (immunoglobulin-M [IgM] and -G [IgG]) with limited or no cell mediated immunity, depending on the antigen and the adjuvant.[11,24]

The canine oral melanoma vaccine is a noninfectious recombinant (DNA) vaccine licensed for needle-free transdermal administration only. It is currently the only vaccine licensed for transdermal administration in dogs.

Initial Vaccination

Most noninfectious vaccines require at least two initial doses to immunize, regardless of the dog's age.[1,14,25,26] The first dose of a noninfectious vaccine generally primes the immune response and the second dose, which should be administered 2–6 wk later, provides the protective immune response. Immunity typically develops approximately 7 days after the second dose. Therefore, the minimum time for onset of immunity is approximately 3 wk after administration of the first dose of a noninfectious vaccine.

When the interval between the initial two doses of a noninfectious vaccine exceeds 6 wk, it is recommended the dog be revaccinated, administering two doses, 2–6 wk apart, to ensure protective immunity has developed.

Rabies vaccine is the obvious exception. Rabies vaccine antigen is highly immunogenic. Throughout the US and Canada, a single dose, administered at ≥12 wk of age, is considered to induce protective immunity. It should be noted that the onset of immunity after administration of the initial rabies vaccine may be defined by applicable legal requirements.

Minimum Age at the Time of Initial Vaccination

Administration of a noninfectious vaccine to a dog <12 wk of age may be blocked by maternally derived antibody (MDA). A second dose, even if given after 12 wk of age, would not be expected to immunize the patient (rabies being the exception). To ensure that puppies are effectively immunized, it is recommended that the first vaccine dose in the initial series of most noninfectious (inactivated, killed) vaccines be administered not earlier than 12 wk of age. Among orphans or those puppies that are known not to have received colostrum, the first dose of a noninfectious vaccine may be administered as early as 6 wk of age.

Immunization in the Presence of Maternally Derived Antibody

The mechanism whereby MDA interferes with noninfectious vaccine is different than that for infectious vaccine. Through a mechanism known as "antigen masking," MDA covers, or "masks," antigenic epitopes on the vaccine virus or bacteria that are necessary to elicit a protective immune response. In an effort to overcome MDA-induced interference with noninfectious vaccines, vaccine manufacturers can use a variety of methods. including the addition of adjuvant as well as increasing the antigen concentration in each dose of vaccine.

Because high titers of MDA specific for protective epitopes are generally required to cause "antigen masking," MDA interference to most bacterins is uncommon after 6–9 wk of age. However, as noted previously, two doses of a noninfectious vaccine are required to induce a protective immune response. If sufficient MDA is present to interfere with the first dose, the second dose will not immunize. Therefore, it is recommended that the earliest age for administering the first dose of a noninfectious vaccine be 12 wk. Also, it is recommended that the noninfectious bacterins (e.g., *Leptospira* or Lyme) be given at ≥12 wk because the immune system is more mature. Thus, it is more likely that a protective immune response, rather than hypersensitive response, will develop.[1]

Onset of Immunity

After initial vaccination, the onset of protective immunity requires more time to develop with noninfectious vaccines than with infectious vaccines. With most noninfectious vaccines, the minimum time from administration of the first dose in the initial vaccination series to development of protective immunity in a naïve dog is 3 wk (2 wk minimum interval between doses plus 1 wk for antibody production, for a minimum of 3 wk).[14]

The immune (antibody) response after administration of a single dose of a noninfectious vaccine in adult dogs that have been vaccinated within the previous year is considered to be rapid (hours to days) and protective.

The legally defined onset of immunity after administration of the first dose of a rabies vaccine is usually stipulated by state, local, or provincial requirements. Because the defined interval between the rabies vaccination and rabies immunization may vary among states and within states, veterinarians are encouraged to contact appropriate authorities regarding a specified onset of immunity interval for rabies.

Missed Dose—Initial Series

When administering a noninfectious vaccine for the first time in the life of a dog, at least two doses, administered 2–6 wk apart, is recommended. If the interval between the first two doses exceeds 6 wk, it is recommended that two additional doses be administered at an interval of 2–6 wk, thereby insuring that both immune priming and immunization occur.

Missed Dose—Adult Booster

Because noninfectious vaccines generally have a duration of immunity (DOI) that is shorter than infectious vaccines, annual

revaccination ("booster") is commonly recommended. A dog that failed to receive a noninfectious vaccine at the recommended interval of 12 mo is unlikely to maintain protective immunity for the same length of time (years) that occurs after administration of infectious viral (core) vaccines. At some point beyond 12 mo, administration of a single dose of a noninfectious vaccine may fail to induce a protective immune response (due to loss of immunologic "memory"); in such cases, administration of two doses, 2–6 wk apart, may be required to immunize.

However, intervals defining when two doses versus one dose would be required to immunize have not been established. Specific intervals will vary, depending on: (1) the vaccine, (2) the patient's (intrinsic) immune response, (3) time elapsed since administration of the last dose, and (4) total lifetime doses the dog received. The decision to revaccinate a dog with two doses versus one dose is left to the discretion of the veterinarian.

The following general guidance is offered for dogs that are overdue for a noninfectious vaccine and are considered to be at risk for exposure.

- Leptospirosis: limited studies have been conducted to assess immune response to a single dose of vaccine in dogs that have not received a booster vaccination in >12 mo. Among dogs with a high risk of exposure, it is reasonable to consider administering two doses of vaccine, 2–6 wk apart, if the interval between doses exceeds 24 mo.[14]
- Lyme disease: only limited (unpublished) studies have been performed to evaluate the immune response to a single dose of vaccine in dogs that have not received a booster vaccination in >12 mo. Although a single dose of Lyme vaccine given years after the initial doses can raise antibody levels, the protective quality of these antibodies has not been confirmed by challenge. Among dogs with a high risk of exposure, it is reasonable to consider administering two doses of vaccine, 2–6 wk apart, if the interval between doses exceeds 24 mo.[27]
- CIV: studies have not been performed to evaluate the immune response to a single dose of vaccine in dogs that have not received a booster vaccination in >12 mo. Among dogs having a high risk of exposure, it is reasonable to consider administering two doses of vaccine, 2–6 wk apart, if the interval between doses exceeds 36 mo.
- Rabies: revaccination with killed rabies vaccine in dogs that exceeded the stipulated interval, 1 yr (initial two doses) or 3 yr (revaccination), is defined by applicable legal requirements. In most states, a dog that exceeded the defined interval for rabies vaccination may receive a single dose of a 3 yr vaccine regardless of the time elapsed since administration of the last dose; that dose will be considered protective for up to 3 yr.

Duration of Immunity and Booster Recommendations

Several noninfectious vaccines are routinely administered to dogs in the US and Canada. Although DOI studies are limited, it is reasonable to recommend annual boosters with most noninfectious vaccine in dogs considered to be at reasonable risk of exposure to the infectious agent.[14,24,28,29]

RV antigen (glycoprotein G) is highly immunogenic, especially in the presence of adjuvant. Therefore, the DOI in dogs vaccinated with two initial doses, 12 mo apart, is expected to be 3 yr (when using a 3 yr rabies vaccine) in dogs that are ≥1 yr of age.

Infectious (Attenuated, Avirulent, Modified Live, Recombinant Viral Vectored) Vaccines

Infectious vaccines must infect the host's cells to immunize. These vaccines are the most effective because they can provide the same types of immunity (cellular, humoral, systemic, and local) that are produced by natural exposure (i.e., immunity after recovery from infection or disease). However, the vaccine organisms are attenuated and will not cause disease.[14,19,22,26,30–33]

When the first modified live canine distemper virus (CDV) vaccines were made in the 1950s and 1960s, some vaccines were highly virulent, causing distemper-like disease, including encephalitis, in a high percentage of vaccinated dogs.[20,31,34] Since the late 1980s, recombinant DNA technology, or genetic engineering, has been used in the production of veterinary vaccines. The first canine vaccine developed and licensed in 1997 using recombinant DNA technology was the canarypox-vectored recombinant CDV (rCDV) vaccine. The advantage of this technology is that the recombinant viral vectored CDV vaccine, unlike the modified live CDV virus vaccines, cannot revert to a virulent form, because there is no CDV virus present in the canarypox vaccine. Furthermore, rCDV vaccine cannot replicate in lymphocytes or in the brain of vaccinated dogs or in wildlife and exotic species that are susceptible to CDV.[35–38]

Current canine parvovirus, type 2 (CPV-2) vaccines contain either CPV-2 or the CPV-2b variant. Vaccines from all the major manufacturers have been shown to provide sustained (several years) protection from all the current CPV-2 variants (CPV-2a, b, and c).[20,39–44]

The original canine adenovirus, type 1 (CAV-1) vaccines, which are no longer available in the US or Canada, caused allergic uveitis and other allergic reactions in a high percentage of dogs; therefore, CAV-1 vaccines were replaced in the US and Canada by the safer, but equally or more effective, CAV-2 vaccines. CAV-2 vaccines are used to provide immunity to CAV-1 virus, the cause of canine infectious hepatitis. Also, they provide protection

against CAV-2, a virus that causes and contributes to canine infectious respiratory disease complex.[1,20,22,45]

Vaccine Stability

Because antigenic virus/bacteria in infectious vaccines is live, these products often inherently lack thermostability.[33] To extend the stability of infectious vaccines during shipment and storage and to sustain vaccine efficacy, manufacturers typically prepare and sell infectious vaccines in a lyophilized (freeze-dried) state. Dehydrating the product into a "cake" significantly extends the shelf-life of perishable infectious vaccine antigens. Once diluent is added to the lyophilized product, the vaccine antigens quickly regain instability and may lose efficacy over time. Stability after reconstitution can vary among the various vaccine antigens in combination (multivalent) products (e.g., modified live virus [MLV] CDV + CPV-2 + CAV-2). It is recommended that infectious vaccines, after reconstitution, be administered within 1 hr. Reconstituted vaccine that is not administered within 1 hr should be discarded.

Once rehydrated, infectious vaccines are highly susceptible to chemical inactivation. For this reason, it is generally not recommended to cleanse the skin with alcohol before inoculation. Furthermore, syringes should never be washed and reused. Chemical residues in the syringe can easily inactivate the infectious vaccines. Infectious vaccines should be administered before the expiration date printed on the vial, as infectivity is lost over time.

It is important not to mix noninfectious vaccines with infectious vaccines in the same syringe, unless specified by the manufacturer, and even then, there may be advantages to administering a noninfectious vaccine in a different site on the animal from the infectious vaccine's administration site.[1,14,25]

Multiple Dose Vials

Infectious vaccines licensed for use in dogs are not commonly sold in multiple dose (also called "tank") vials. For the same reasons outlined previously for noninfectious vaccines, use of multiple dose vials of infectious (parvovirus) vaccine is not generally recommended.

Routes of Administration

Infectious vaccines contain avirulent live virus or bacteria that are capable of infecting cells in much the same manner as the virulent virus or bacteria does during natural infection. Therefore, infectious vaccines may be administered by the IN route (e.g., Bb + canine parainfluenza virus [CPiV]) as well as by the parenteral route (SQ or IM). Vaccines intended for IN administration must never be administered parenterally. Furthermore, IN vaccines administered orally are quickly inactivated and will not immunize.

Initial Vaccination

One dose of infectious vaccine will prime, immunize, and boost the immune response, provided the MDA does not interfere with the vaccine antigen (virus or bacteria). Because it is not practical to establish the level of maternal antibody in every puppy presented for initial vaccination, it is recommended that puppies receive doses of infectious vaccine (e.g., CDV + CPV-2 + CAV-2) every 3–4 wk between 8 and 16 wk of age. The final dose administered at 14–16 wk of age should insure the puppy will receive at least one dose of vaccine at an age when the level of MDA is insufficient to prevent active (vaccine-induced) immunity. Administration of infectious vaccine to dogs $<$6 wk of age, even in the absence of MDA, is not recommended.[1,14,24]

Because dogs older than 14–16 wk of age are not likely to have interfering levels of MDA, administration of a single initial dose of an infectious vaccine to an adult dog can be expected to induce a protective immune response. The administration of a single, initial dose of infectious vaccine to dogs $>$16 wk of age is considered protective and acceptable (Table 1). It is common practice, however, in the US and Canada, to administer two initial doses, 2 to 4 weeks apart, to adult dogs without a history of prior vaccination.

Minimum Age at the Time of Initial Vaccination

In practice, predicting the exact age at which a puppy will first respond to administration of an infectious vaccine is difficult. MDA is the most common reason early vaccination fails to immunize. Puppies that received colostrum from an immunized dam might not respond to vaccination until 12 wk of age. In contrast, orphan puppies and puppies that were denied colostrum might respond to initial vaccination much earlier. The minimum age recommended for initial vaccination with an infectious (core) vaccine is 6 wk. Even in the absence of MDA, administration of an infectious vaccine to any dog $<$6 wk of age may result in a suboptimal immune response due to age-related immunologic incompetency.

In contrast, administration of an infectious vaccine labeled for IN administration (e.g., IN Bb + parainfluenza virus) may induce a protective, local (mucosal) immune response as early as 3–4 wk of age. MDA does not interfere with local immunity.

Immunization in the Presence of Maternally Derived Antibody

In general, MDA is more effective at interfering with infectious vaccines than noninfectious vaccines. Various mechanisms have been suggested, including rapid neutralization of infectious vaccine

virus by maternal antibodies, prevention of replication, and insufficient antigen to prime B cells.[1,14,25]

Different vaccine manufacturing methods have been successful in developing infectious vaccines that are able to overcome MDA in puppies at an earlier age. Such methods include increasing the virus titers within the product (e.g., "high titer" CPV-2 vaccine), using a more infectious virus (which often means more virulent), or administering the infectious vaccine via the IN route where the MDA is either limited or not present.

Like the heterotypic measles virus (MV) vaccine, the rCDV canarypox vectored vaccine has been shown to immunize puppies 2–4 wk earlier than MLV CDV vaccines.[46,47] However, neither of these vaccines can immunize puppies that have very high levels of MDA because of antigen masking. Thus, with all the methods used to avoid blocking by MDA, it may be possible to immunize earlier (days or weeks), but not to immunize all puppies at any age.[19,22,30,37,45–49]

Onset of Immunity

The onset of immunity after administration of a single dose of infectious core vaccine is approximately 4±3 days in the absence of MDA. Variability among individual dogs and among different vaccines may alter these times slightly, with CDV providing the earliest protection within 1–2 days, CPV-2 providing protection in about 3 days, and CAV-2 providing protection in 5–7 days.[38,50,51] However, a small percentage of dogs are genetically incapable of developing an immune response to CPV-2 vaccines (estimated 1/1,000 dogs) or to CDV vaccines (estimated 1/5,000 dogs). These dogs are described as "nonresponders." Immunologic unresponsiveness to vaccination is determined by genetic factors.

Because the number of nonresponders and low responders within the canine population is considered low, and nonresponder status is difficult to confirm, unique breed-specific vaccination recommendations for dogs are not stipulated in the Guidelines, but they may be recommended by some breed organizations.

Missed Dose—Initial Series

When administering an infectious vaccine for the first time in the life of a dog that is ≥6 wk of age, a single dose, in the absence of MDA, will immunize. If a puppy exceeds the recommended interval between doses of the initial vaccination series, it is left to discretion of the veterinarian whether to administer one or two additional doses.

If a puppy receives the first dose in the initial series of core vaccines between 6 and 8 wk of age but fails to return until 12 or 14 wk of age, administration of two doses, at least 2 wk apart, is recommended. In contrast, if the same puppy is >14 wk of age when returning to the veterinarian, administration of a single dose of an infectious vaccine is expected to immunize.

Missed Dose—Adult Booster

The DOI conferred by infectious core vaccines is known to last for many years. Even if serum antibody levels are determined to be below "protective" levels, immunologic memory (T- and B-lymphocytes) is likely to be sustained. Therefore, a single dose of infectious vaccine administered to an adult dog is considered protective regardless of the time since a previous vaccine was administered.[20,31,43,52–54]

Duration of Immunity and Booster Recommendations

In general, DOI to infectious viral and bacterial vaccines is longer than to noninfectious viral and bacterial vaccines, and immunity conferred is generally much longer to viral vaccines than to bacterial vaccines. DOI is often related to the immunologic mechanisms of killing or control of the pathogens, and also to the complexity of the disease and the disease agent.

Infectious core vaccines are not only highly effective, they also provide the longest DOI, extending from 5 yr up to the life of the dog. A ≥3 yr interval is currently recommended for revaccinating adult dogs with infectious viral core vaccines. In contrast, revaccination of dogs with infectious bacterial vaccines (specifically IN Bb vaccine) is recommended annually. The ≥3 yr recommendation for core vaccines is made on the basis of minimum DOI studies over the past 30 yr for canine vaccines. These studies were done by all of the major vaccine companies, as well as by independent researchers. The results of the studies conducted by the major manufacturers for canine core vaccine demonstrated that a minimum DOI for their core vaccines (CDV, CPV-2, CAV) was ≥3 yr, based on challenge and/or serologic studies. Similar minimum DOI studies were conducted for the 3 yr rabies vaccines using challenge studies only.[14,20,30,52–68]

Box 1 summarizes key immunologic features of noninfectious and infectious vaccines.

Vaccine Licensure in the United States

Requirements

In the US, the Animal and Plant Health Inspection Service (APHIS), a multifaceted agency of the USDA, is responsible for regulating veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biologic origin) intended for the diagnosis, prevention, or treatment of animal diseases. For domestic manufacture, a facility license is required, along with a license for each product to be distributed. Imported products are

Box 1

Key Immunologic Features of Noninfectious and Infectious Vaccines

	Noninfectious Vaccines (inactivated/killed/conventional and recombinant [r] subunit /avenomous/plasmid DNA)	Infectious Vaccines (MLV/attenuated/recombinant viral vectored)
Vaccine examples	RV CCoV CIV Bb–injectable *Leptospira*–2 way/4 way/whole cell and conventional subunit Lyme–whole cell/recombinant OspA subunit *Crotalus atrox* (Western Diamondback rattlesnake avenomous vaccine) Canine oral melanoma (plasmid DNA vaccine)	CDV, rCDV CAV-2 CPV-2 CCoV MV Bb–IN CPiV
Initial doses to immunize (in absence of MDA)	• Generally 2 doses Interval of time between doses: minimum: 2 wk; maximum: 6 wk. Exceptions: • Rabies–1 dose initially at ≥12 wk of age, followed with a second dose within a year after the first dose • Melanoma vaccine–4 doses	1 dose adequate. Optional–2 doses (not <2 wk interval between doses)
Parenteral (IM or SQ) route of administration	Required to be given parenterally	Yes Exception: Never give infectious (IN) *Bordetella* parenterally, as it can cause severe disease and death.
Mucosal (IN) route of administration	No–should never be given locally on mucosal surface	Yes, when recommended
Transdermal route of administration	The oral melanoma vaccine is required to be administered transdermally with a bioinjector.	No
Maternal antibody interference	Yes, but less likely, especially in dogs ≥12 wk of age because of higher antigenic mass in vaccine and because the agent does not need to infect and replicate.	Yes. However, MV and rCDV can immunize at an earlier age in presence of MDA than MLV CDV. Infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines are more readily inactivated (blocked) by MDA than noninfectious (inactivated, killed) vaccines, thus it is necessary to give final dose of puppy series at 14–16 wk of age.
Replicates in host	No (inactivated virus and bacteria are incapable of replication)	Yes (must) Recombinant viral vectored canarypox CDV infects host cells, but new infectious canarypox virus is not produced
Onset of immunity in absence of MDA	Minimum 3–4 wk from the first dose, can be longer	1–2 days for CDV, 3–5 days for CPV-2, CAV-2, (parenteral), as well as IN Bb, CPiV, and/or CAV-2
Duration of immunity	Leptospirosis, Lyme, parenteral *Bordetella* are probably the shortest (≤1 yr) Rabies vaccine longest (≥3 yr)	Many years to a life time (e.g., parenteralCDV/CPV-2/CAV-2) 1 yr for IN Bb, CPiV, and CAV-2
Revaccination booster	Yes. Annually or more often. Exception: Rabies–3 yr booster after 1st dose and dose at 1 yr	≥3 yr longer for viral vaccines (CDV, CPV-2, CAV-2) IN–annual
Humoral (antibody) response	Systemic: excellent Local (mucosal) immunity: little or none	Systemic (IgM, IgG) and local (sIgA): excellent
Cell mediated immunity (CMI)	Limited, but some systemic CMI may be stimulated depending on type of adjuvants used	Excellent–both systemic and local CMI with parenteral and local (IN) vaccination.

(Box continues)

Box 1 (continued)

	Noninfectious Vaccines (inactivated/killed/conventional and recombinant [r] subunit /avenomous/plasmid DNA)	Infectious Vaccines (MLV/attenuated/recombinant viral vectored)
Stability	Excellent, but limited to expiration date and must be stored properly	Lyophilized—excellent, but limited to expiration date and must be stored properly Reconstituted—hours depending on the vaccine components Administration should occur within 1 hr after reconstitution of all infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines.
Adjuvant	Generally required, but not always	Rarely, if ever, required
Use in pregnant dogs	Not recommended	Not recommended
Prophylactic	Yes	Yes
Therapeutic	Only the transdermally administered oral melanoma vaccine is labeled for therapeutic use.	No
Safety Issues		
Reversion to virulence	No reversion to virulence	Reversion to virulence is of minimal concern with current infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines when used in dogs ≥6 wk of age and not used in pregnant dogs. However, reversion to virulence is a major concern when the MLV vaccines are used in certain exotic or wild animal species or used in puppies <4 wk of age. These practices are not recommended. Reversion to virulence is not a concern with the recombinant vectored CDV vaccine.
Acute adverse reactions (e.g., hypersensitivities)	Anaphylaxis, injection site pain, angioedema (facial edema), injection site granulomas, local inflammation abscesses, lameness, reactivation of immune-mediated diseases in predisposed dogs	Fever, lethargy, injection site pain, anaphylaxis, reactivation of immune-mediated diseases in predisposed dogs
Delayed adverse reactions (e.g., hypersensitivities)	Ischemic vasculitis (skin), increase in severity of type I atopic disease, reactivation of immune-mediated diseases (e.g., IMHA, IMTP, RA, etc.), and other hypersensitivity disorders possible in predisposed dogs (rarely occurs).	Reactivation of immune-mediated diseases (e.g., IMHA, IMTP, RA, etc.), and other hypersensitivity disorders possible in predisposed dogs (rarely occurs).

Bb, *Bordetella bronchiseptica*; CAV-1, canine adenovirus, type 1 (cause of canine viral hepatitis)—protection from CAV-1 infection is provided by parenterally administered CAV-2 vaccine; CAV-2, canine adenovirus, type 2; CCoV, canine coronavirus cause of enteric coronavirus infection (antigenically distinct from the canine respiratory coronavirus [CRCoV]); CDV, canine distemper virus; CIV, canine influenza virus—H3N8; CPiV, canine parainfluenza virus; CPV-2, canine parvovirus, type 2; DOI, duration of immunity; IgG, immunoglobulin G—a class of humoral antibody; most common type associated with immune response to parenteral vaccine; also the most common class of antibody measured as serum titers; IgM immunoglobulin M—a class of antibody, generally short lived and associated with early infection and initial vaccination; IM, intramuscular (route of administration); IMHA, immune-mediated hemolytic anemia; IMTP, immune-mediated thrombocytopenia; IN, intranasl; MLV, modified live virus—attenuated virus vaccine; MV, measles virus; OspA, outer surface protein A (antigen) of Borrelia burgdorferi; RA, rheumatoid arthritis, RV, rabies virus; sIgA, secretory immunoglobulin A—a class of antibody, most commonly associated with a local (mucosal) immune response after IN vaccination; SQ, subcutaneous.

issued a permit for sale and distribution. This work is done by APHIS's Center for Veterinary Biologics (CVBs).

Before the issuance of a license or permit, the manufacturer of a vaccine intended for sale and distribution within the US must demonstrate, to the satisfaction of the USDA CVB, that the proposed product is pure, safe, potent, and efficacious. The facility in which the product is prepared must meet USDA standards and pass inspection by the CVB. After licensure, each batch of vaccine is subject to random premarketing testing by the CVB to verify the manufacturer's quality assurance and quality control.

Purity assures the final product is free of extraneous microorganisms and extraneous material (organic or inorganic).

Safety is defined as freedom from properties causing undue local or systemic reactions when the vaccine is used as labeled. As part of the prelicense process, attenuated (live, whole agent) vaccines are evaluated in dogs to assess the potential of the vaccine organism to revert to virulence and the potential for dogs to shed the vaccine virus and/or bacteria. In addition, field safety studies are performed in a large group of dogs (typically at least 600), a substantial proportion of which must be at the minimum age indicated for administration. Postmarketing surveillance, including investigation of consumer complaints, is intended to identify relatively rare or uncommon safety issues that might not be detected in a prelicense field safety study. It should be noted safety studies are not a guarantee that a vaccine, once released for sale, will be entirely free of risk.

Efficacy is the ability or capacity of the product to effect the result for which it is offered when the product is used according to its label. Vaccine efficacy is conventionally determined through defined vaccination-challenge studies conducted by the manufacturer. Although challenge methods and criteria for evaluating protection will vary with the immunizing agent, tests are generally conducted under controlled conditions using seronegative dogs of the youngest age recommended on the label.

Potency is the relative strength of a biologic product as determined by test methods approved by the CVB. Potency testing is intended to assure that each serial (batch) of vaccine marketed is equal to, or more potent than, a defined reference serial of known efficacy.

DOI is noted here due to its interest to practitioners. However, the definition of the term is often interpreted differently in different contexts. The CVB views DOI as confirming, typically by a vaccination-challenge study, that the immunity conferred by the product lasts at least as long as indicated on the label. Practitioners may view these studies as confirming efficacy at a specified point, rather than a demonstration of the maximum reasonable duration of immunologic protection conferred to patients. Traditionally, vaccine challenge models were intended to demonstrate the onset of immunity in younger dogs using products titrated to the minimum protective dose. These products typically carried the historically based label recommendation for annual revaccination. Therefore, for most of the canine vaccines licensed in veterinary medicine, the CVB has not required manufacturers to conduct DOI studies, unless making a specific claim differing from 1 yr. Current CVB policy requires manufacturers to conduct DOI studies for all rabies vaccines and all new (novel) antigens, regardless of the revaccination interval.

Conditional Licensure

The time to market for a new vaccine can require several years. The USDA utilizes a pathway called conditional licensure to speed the availability to veterinarians of vaccines that address unmet needs, emergencies, or other special circumstances. In this process, a manufacturer is required to demonstrate that the product is safe, pure, has a reasonable expectation of efficacy, and that it is manufactured in compliance with standard USDA regulations. The USDA typically places time limits on such a license, during which the manufacturer must provide data to fully demonstrate efficacy or appropriate progress toward so doing. The USDA requires distinctive labeling to differentiate those products marketed under a conditional license, and the label must state that the product is conditionally licensed. The DOI of a conditionally licensed vaccine has not been confirmed by a vaccination-challenge study at the time the product is released for sale in the US.

(Conditional canine vaccines at this writing are: Crotalus atrox toxoid [Western Diamondback rattlesnake vaccine].)

Vaccine Licensure in Canada

The CFIA, under the legislative authority of the Health of Animals Act and Regulations, is responsible for regulating veterinary biologics in Canada. This regulatory program forms an integral part of Canada's National Animal Health Program, which strives to protect the health of food producing animals, domestic pets, wildlife, and the Canadian public, as well as to safeguard the environment by preventing the introduction and spread of infectious animal diseases.

Responsibilities of the CFIA in licensing vaccines for use in veterinary medicine include:

- Licensing of veterinary biologics, including verification of master seeds and prelicensure product evaluation
- Licensing of veterinary biologics manufacturing facilities
- Issuance of import and/or export permits to Canadian importers and/or exporters of veterinary biologics
- Postlicensure monitoring, including:

  - –serial release monitoring of veterinary biologics for purity, potency, and safety
  - –investigations of consumer complaints
  - –inspections of manufacturers and Canadian importers of veterinary biologics
- Scientific research in support of regulations
- Technology development, including collaborative research with industry partners.

The standards for licensure of any veterinary vaccine in Canada are similar to those required in the US. Regulated products include vaccines, immunoglobulin products, and diagnostic kits that are used for the prevention, treatment, or diagnosis of diseases in animals, including domestic livestock, poultry, pets, wildlife, and fish. To meet the requirements for licensure, veterinary biologics must be shown to be pure, potent, safe, and effective when used in the target species according to the manufacturer's label recommendations. In addition, the licensing submission must also contain supporting data demonstrating that the product can be manufactured and used without adversely affecting animal health, human health, food safety, or the environment.

Serologic Testing to Determine and Monitor Immunity

Interpreting Results of Serologic Tests

Despite the confusion and controversy surrounding antibody testing, these serologic tests are useful for monitoring immunity to CDV, CPV-2, CAV-1, and RV. Because of this, many practitioners perform large numbers of tests for antibodies on a routine basis at state diagnostic and commercial laboratories or the tests are done with in-house diagnostics. The tests are also medically useful to ensure that a dog responds to a specific core virus vaccine and/or to determine if immunity is present in a previously vaccinated dog. Those tests are also used to demonstrate protective immunity as well as DOI.[56–69]

Antibody assays for CDV and CPV-2—the two tests performed most often—are the tests of greatest benefit in monitoring immunity, especially after the puppy vaccination series. The serologic test considered the "gold standard" for CDV is virus neutralization (VN). VN and hemagglutination inhibition (HI) are the gold standard tests for antibodies to CPV-2.[1,14,67] Although most state diagnostic laboratories use the gold standard tests, most commercial laboratories use other methods, such as immunofluorescence assays or enzyme immunoassays. During the past 5 yr, most, if not all, laboratories have qualified and standardized their methodologies with samples that were tested by the gold standard methods. Also, standardization of these tests was done with samples collected from dogs protected from challenge with virulent virus.[54]

Notwithstanding this development, titer results may vary among tests and between laboratories. Most state diagnostic laboratories report classic titers, in which two-fold dilutions of serum are made and the highest dilution that neutralizes the virus (CDV, CPV-2, CAV-1, RV), inhibits hemagglutination by the virus (CPV-2), or binds to viral antigen and is detected with a fluorescent or enzyme probe (CDV, CPV-2, RV) is reported. Using the standard two-fold dilution technique, the amount of error is approximately a four-fold dilution. The titer of a single serum sample would be in the range of one doubling dilution below the reported value and one doubling dilution above the reported value. For example, a CDV virus neutralization titer reported at 128 in reality is between 64 and 256; similarly, a CPV-2 HI titer of 1,280 is between 640 and 2,560. Some laboratories simply report results of >5 as positive and <5 as negative, and other tests are simply positive (antibody is present) or negative (no antibody was detected).

There are currently two in-hospital tests that provide a positive or negative result that have been approved by the USDA. A positive CDV result on these tests indicates that a serum sample has an antibody titer that is >8 on the VN test. A positive result for CPV-2 indicates the serum sample has an antibody titer that is >20 with the HI test. A negative test indicates that the dog has a titer less than these values or that it has no antibody. Obviously, some dogs with a negative result on this test are immune, but most of these dogs would benefit from revaccination by developing a higher titer. After performing and comparing many serologic tests for thousands of dogs, researchers found that approximately $15\pm5\%$ of dogs will have low ($\leq$32 VN) or no antibody to CDV. A similar percentage but different dogs will have low or no antibody to CPV-2 ($\leq$80 HI) on the test. With CDV and/or CPV-2 tests, dogs with a negative result, regardless of the test used, should be considered as having no antibody and may be susceptible to infection with CDV and/or CPV-2; thus, these dogs should be revaccinated to ensure there is immunity. In contrast, any dog with a positive result, regardless of the test performed, should be considered immune and does not need to be revaccinated.[42,54]

Applications of Serologic Testing

On completion of the puppy core vaccination series with the last dose given at 14–16 wk of age, a dog can be expected to have an antibody titer or positive test result, regardless of the serologic test performed, provided the serum sample is collected $\geq$2 wk after the last dose of vaccine. If the dog does not have antibody, it should be revaccinated, perhaps using a different product, and then retested $\geq$2 wk later. If the antibody test is again negative,

the individual dog should be considered a low responder or a nonresponder (see Part I, Types of Vaccines) and possibly incapable of developing a protective antibody response.

Challenge with virulent virus or serologic testing is the only practical way to ensure a puppy develops an immune response after vaccination. The serologic test is the only acceptable way to ensure a client-owned dog develops an immune response. Young dogs are at greatest risk of infection from CDV and CPV-2, and these infections lead to severe disease and death in ≥50% of susceptible puppies. Antibody tests are useful as a medical procedure to ensure the dog develops an immune response to CDV and CPV-2 vaccines after the primary series of vaccinations. Vaccines can fail for various reasons.[25] However, the following are the three main reasons for vaccination failure: (1) the puppy has a sufficient amount of MDA to block the vaccine; (2) the vaccine is not immunogenic (e.g., if the vaccine was improperly stored); or (3) the dog is a poor or nonresponder (i.e., the immune system fails to recognize the antigenic determinants of the specific vaccine).

The most common reason for vaccination failure in young dogs is that MDA blocked the vaccine response. During the initial puppy vaccination series, the last dose of CDV and CPV should be administered at 14–16 wk of age. At this age, MDA should be at a level that will not block active immunization in most puppies (>98%) when a combination MLV vaccine is administered.[1,24,25] When the puppy fails to produce antibody ≥2 wks after a dose of vaccine administered at 14–16 wk, the practitioner must consider the other two explanations for vaccine failure. If, after one or more attempts at revaccination with a product different than the one originally used, the dog fails to develop an antibody response to CDV or CPV-2 by VN or HI test, the dog should be considered a transient or permanent nonresponder.

Because immunologic nonresponsiveness is genetically controlled, certain breeds or families of dogs may be suspected to have a higher prevalence of low or nonresponders than the general canine population. It is believed by some (but not proven) that the increased susceptibility to CPV-2 recognized in certain rottweilers and Doberman pinschers during the early and mid-1980s (regardless of their vaccination history) was due to an increased prevalence of nonresponders; it was also demonstrated that some early vaccination failures were attributable to the poor quality vaccines available at that time. Today, these two breeds appear to have no greater numbers of low or nonresponders than other breeds.[52,68]

A high titer of antibody to CDV and/or CPV-2 as a result of active immunization from vaccination or from natural exposure protects from infection; therefore, no detectable virus replication occurs. Although a virus may be capable of replicating in a dog whose antibody titers have decreased, memory B and T cells should provide an anamnestic (secondary) humoral- and cell-mediated immune response that limits virus replication and prevents disease. Immune responses to modified live vaccines like CDV, CPV-2, and CAV-2, because of their complexity, always stimulate both humoral- and cell-mediated immunity. Although antibody is a product of humoral immunity, cellular immunity is always required for antibody production, as T-helper cells must be activated by the virus to produce a B-cell response. Therefore, although rarely considered, the presence of antibody in the dog to specific viruses demonstrates not only humoral immunity but also that cell-mediated immunity was stimulated as well. It is also incorrectly assumed that antibody to MLV vaccines containing CDV, CPV-2, and CAV-2 often disappears after relatively short periods of time (e.g., months or a few years). It was shown in many studies that antibody to those viruses persisted for many years, even in the absence of the viruses or revaccination.

The persistence of antibody to these viruses is from a population of long lived plasma cells that has been referred to as "memory effector B cells." This is a population of cells that continues to produce the antibody they were programmed to produce (e.g., CDV) long after vaccination. Too much emphasis has been placed on the antibody titer (dilution of antibody that is positive). It was found repeatedly in controlled challenge studies with CDV, CPV-2, and CAV-1 that actively immune dogs (vaccinated at 14–16 wk of age or younger dogs without MDA) with actively produced antibody, regardless of titer or test used to detect the antibody, were resistant to challenge. Therefore, it is not necessary, as some have suggested, to have an antibody titer of ≥32 with the serum neutralization test for CDV or a titer of ≥80 on the HI test for CPV-2 for the vaccinated dog to be completely protected when challenged. Thus, most of the concerns expressed about the variability in titers among serologic tests have little or no validity when applied to protection from CDV, CPV-2, CAV-1, and RV. Furthermore, with the development of some of the in-hospital tests, serum dilutions are not performed and titers are not the end point; instead, the test is considered positive or negative.[43,54]

Application of Serology to Evaluate Duration of Immunity

Antibody tests can also be used to demonstrate the DOI to vaccines or from natural immunization. As discussed previously, dogs were shown to maintain antibody titers to the core viruses CDV, CPV-2, and CAV-1 in viral-free environments for many years. In a study reported in 1997, dogs vaccinated with a product containing CDV and then placed in an environment without CDV maintained

antibody titers for at least 10 yr.[61] In a more recent controlled study of puppies without MDA vaccinated at 7 and 10 wk of age (and housed with nonvaccinated dogs to ensure CDV, CPV-2, and CAV-1 were not present), it was shown that vaccinated dogs maintained antibody titers for >4 yr.[61,54,69] These and other studies clearly demonstrated that antibody correlated with protection from infection and/or protection from disease because the vaccinated antibody-positive dogs remained healthy after experimental challenge with virulent strains of the viruses. These and other studies also clearly demonstrated that antibodies to the core vaccine viruses might persist in the absence of revaccination for many years. All of the major vaccine manufacturers have products that were shown to provide a minimum DOI of 3 yr. In addition, it was demonstrated that antibody correlated with protection from infection and/or protection from disease because the vaccinated antibody-positive dogs remained healthy after experimental challenge with virulent strains of the viruses.[55–57,69] In contrast, vaccinated dogs that did not develop antibody to CDV, as well as unvaccinated control dogs that were antibody negative, became infected. Many dogs develop disease and die when challenged. When antibody is absent (irrespective of the serologic test used to determine this fact), it should be assumed the dog is susceptible to infection and may develop disease. Therefore, antibody negative dogs should be revaccinated. Similarly, dogs that have been actively immunized by vaccination or naturally by infection that have antibodies to CDV, CPV-2, or CAV-1 do not need to be revaccinated. Some clients are now having titers performed for CDV and CPV-2 in lieu of revaccinating.

Antibody titers to additional vaccine antigens are sometimes determined to diagnose susceptibility to disease, but the best correlations between antibody and protective immunity are as stated previously for CDV, CPV-2, CAV-1, and RV. Very sensitive and well-documented titers to RV are done by a small number of approved laboratories. Although most widely used when shipping dogs to rabies-free countries, rabies titers are sometimes performed in dogs that developed an adverse reaction to the vaccine.[70–72] However, RV titers cannot currently be used in place of revaccination, which is required on an annual or triennial basis depending upon governing law. Medical exemption laws exist in certain areas where a dog with a known medical condition can be exempted from rabies vaccine. However, a titer cannot be used in place of vaccination. When RV vaccination is not current, the dog must be considered unvaccinated, and if it bites someone, it must be quarantined.

Antibody titers to vaccines other than CDV, CPV-2, CAV-1, and RV have limited or no value because the antibody may persist for a short time (e.g., *Leptospira* products), or there is no known correlation between serum antibody test routinely performed and protection (e.g., CPiV, Lyme, *Leptospira*). However, researchers are attempting to find serologic correlates of protective immunity for diseases other than the four core viruses (CDV, CPV-2, CAV, and RV).

Vaccine Adverse Events

Since the original canine vaccines were developed and licensed >50 yr ago, there has been a continuing effort to make canine vaccines safer and more efficacious. Today, it is generally agreed that canine vaccines have an excellent safety record. Although AE documentation in veterinary medicine is limited, severe adverse reactions are considered uncommon. Vaccines are, however, biologic products and can cause unpredictable adverse effects in some dogs after administration. The following section is intended to characterize types of vaccine AEs possible in dogs, provide information on how to report known and/or suspected AEs, and offer suggestions for mitigating the risk of vaccination in patients with a history of AEs.

Vaccines are biologic products and, as such, provoke a series of complex immune reactions that may culminate in rapid-onset side effects lasting from a few hours to a few days. Rarely do these self-limiting side effects escalate into serious AEs (SAEs). For this reason, veterinarians are encouraged to inform clientele that their pet, regardless of breed or size, may manifest transient side effects for up to 2, and possibly 3, days after administration of any vaccine or any combination of vaccines. Side effects commonly observed include: reduced or loss of appetite (lasting for one or two feedings), pain at the injection site, lethargy (lack of activity), reluctance to walk and/or run, and mild fever. Treatment is usually not indicated; however, some veterinarians have reported administering short-term symptomatic treatment (e.g., a nonsteroidal anti-inflammatory drug [NSAIDs]). It is recommended that clientele be advised to contact the practice in the event any physical and/or behavioral manifestations progressively worsen or continue beyond 2–3 days. Clientele should be advised to contact the practice at any time if signs of systemic illness, such as vomiting, diarrhea, seizures, facial swelling, collapse, or difficulty breathing, develop.

Vaccine AEs are underreported in veterinary medicine. However, mechanisms are in place for reporting such reactions; veterinarians are strongly encouraged to participate by reporting all known or suspected AEs associated with vaccine administration.

In the US and Canada, vaccine AEs should be reported to the Technical Services section of the manufacturer of the vaccine(s) believed to be associated with the AE. If multiple vaccines from different manufacturers were administered to an individual patient

at the same appointment, reports should be submitted to each manufacturer. Furthermore, it is recommended that reports include reference to any concurrently administered drug and/or therapy. Reports can be made directly to the manufacture via (toll-free) telephone call.

In the US, vaccine AEs may also be reported on-line to the CVB (reporting information is outlined in the following).

In Canada, vaccine AEs may also be reported to the CFIA (reporting information is outlined in the following).

What Constitutes a Vaccine Adverse Event?

A vaccine AE is generally defined as any undesirable side effect or unintended effect (including lack of desired result) associated with the administration of a licensed biologic product (vaccine). For vaccines administered to dogs, AEs are those involving the health of the treated dog and include the apparent failure to protect against a disease. An AE event includes any injury, toxicity, or sensitivity reaction associated with the use of a vaccine, whether the event can be directly attributed to the vaccine. In other words, it is appropriate to report any known or suspected negative event associated with vaccination.

Although the incidence of vaccine AEs is unknown and causality cannot always be confirmed, the list that follows includes categories of adverse reactions that have been attributed to vaccine administration. The list of categories is not considered comprehensive; other, undocumented adverse reactions associated with vaccine administration could occur. Furthermore, causality has not been definitively established for each of the categories listed:

- **Injection-site reactions**: lumps (abscess, granuloma, seroma), pain, swelling, hair loss associated with ischemic vasculitis
- **Transient postvaccinal nonspecific illness**: lethargy, anorexia, fever, regional lymphadenomegaly, soreness, abortion, encephalitis, polyneuritis, arthritis, seizures, behavioral changes, hair loss or color change at the injection site, respiratory disease
- **Allergic (hypersensitivity) and immune-mediated reactions**:
  - –Type 1 (acute anaphylaxis): angioedema (especially the head), anaphylaxis (shock), and death
  - –Type 2 (cytolytic): immune-mediated hemolytic anemia, immune-mediated thrombocytopenia (suspected only; causality has not been confirmed)
  - –Type 3 (immune-complex): cutaneous ischemic vasculopathy associated with rabies vaccine, corneal edema ('blue-eye') associated with CAV-1 vaccine, immune-mediated disease
- **Failure to immunize**: maternal antibody interference with vaccination is considered the most common cause; administration of vaccine at a volume and/or dose less than that prescribed by the manufacturer; "nonresponder" (genetic predisposition?); inactivation of vaccine antigen (e.g., allowing reconstituted infectious [attenuated, avirulent, modified live, recombinant viral vectored] vaccine to stand at room temperature for >2 hr), mixing of incompatible vaccines in the same syringe
- **Tumorigenesis**: vaccine-associated sarcoma or other tumors
- **Multisystemic infectious/inflammatory disorder of young Weimaraner dogs**: may be genetically linked to both a poorly characterized immunodeficiency and to autoimmune disorders (e.g., hypothyroidism and hypertrophic osteodystrophy [HOD] that are detected shortly after vaccination
- **Vaccine-induced immunosuppression**: associated with first or second dose of combination MLV vaccines containing CDV and CAV-1 or CAV-2 with or without other vaccines (e.g., CPV-2, CPI). Immunosuppression begins 3 days after vaccination and persists for 7–10 days. The suppression may be associated with increased susceptibility to other diseases.[17]
- **Reactions caused by the incorrect or inappropriate administration of vaccine**: fatalities have been reported after subcutaneous administration of an avirulent-live Bb bacterin (intended for IN administration); inadvertent or intentional administration of vaccine by the intravenous route
- **Reactions associated with residual virulence attenuated vaccine**: postvaccinal sneezing associated with IN administration of attenuated vaccine (e.g., Bb + parainfluenza virus)
- **Vaccine-induced interference with diagnostic tests**: false-positive polymerase chaine reaction (PCR) test results for parvovirus antigen in feces in dogs recently receiving a MLV parvovirus vaccine. Not an adverse reaction.
- **Reversion of vaccine virus to a virulent pathogen**: generally considered rare to nonexistent among currently licensed canine vaccines when vaccines are used in the species for which they were licensed. This can become a significant problem when vaccine is used in the wild and/or exotic animals.[8,9,12,13,16–18]

How to Report a Known or Suspected Vaccine Adverse Event

Veterinarians are encouraged to participate in the vaccine AE reporting process by reporting suspected and known AEs to one of the following:

- **Vaccine Manufacturer:** Companies that manufacture vaccines maintain a technical services section that will accept and address AE reports from veterinarians who use their product(s). Veterinarians are encouraged to report AEs to the manufacturer(s) before contacting the appropriate regulatory agency. Manufacturers are required to maintain files of any reported vaccine AE. However, manufacturers are under no obligation to compensate the owner or the veterinarian for diagnostic or treatment services related to a known or suspected AE.

- **CVB:** Subsequent to reporting a known or suspected vaccine AE to the manufacturer, veterinarians practicing within the US may contact the USDA, APHIS CVB in one of the following ways:

Once an adverse event has been reported to the manufacturer, the CVB may be contacted:

- Online: https://web01.aphis.usda.gov/CVB/adverseeventreport.nsf/Adverse%20Event%20Report%20Form?OpenForm
- By fax or mail: download the PDF form at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/adverseeventreportform.pdf and FAX to (515) 337–6120 or by mail to the CVB.
- By telephone: AEs may also be reported by calling the CVB at (800) 752–6255.

Canadian Food Inspection Agency

In Canada, CFIA is responsible for licensing veterinary biologics, including veterinary vaccines, manufactured and/or used in Canada. The licensing program operates under the Health of Animals Act and Regulations, and is administered by the Canadian Centre for Veterinary Biologics.

The Canadian Health of Animals Regulations require all holders of product licenses and import permits to report all "serious expected" or "serious unexpected" suspected AEs, including lack of efficacy, to the Canadian Centre for Veterinary Biologics of the CFIA within 15 days of receiving notice of the event from a veterinarian or animal owner. This can be done by notifying Canadian Centre for Veterinary Biologics directly or through the licensed vaccine manufacturer or importer.

In Canada, Form CFIA/ACIA 2205 "Notification of Suspected Adverse Events to Veterinary Biologics" can be used to report suspected AEs: http://inspection.gc.ca/english/for/pdf/c2205e.pdf

The Canadian "Veterinary Biologics Guideline 3.15E: Guideline for Reporting Suspected Adverse Events Related to Veterinary Biologics" (available: http://www.inspection.gc.ca/english/anima/vetbio/info/vb315e.shtml) provides guidelines for defining a suspected AE related to veterinary biologics as one of the following: AE, SAE, unexpected AE, and lack of efficacy. The definitions for AE, SAE, and unexpected AE are found in Section V of this guideline and are consistent with the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)*'s Guideline 24: Pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs)*. A causality assessment should also be assigned to each SAE. Each case should be classified as probable, possible, unlikely, or unknown.

Managing Adverse Event Risk in Individual Patients

Specific recommendations for mitigating the risk of a vaccine AE in dogs have not been validated. Efforts to manage risk are highly varied and largely unsubstantiated. It is not possible to completely avoid a vaccine AE in any patient. Vaccine risk management should focus on dogs having a known or suspected history of a vaccine reaction and in small breeds. Recommendations are outlined in the following.

The reduction of vaccine volume to mitigate risk of an AE is not recommended. Doing so may result in suboptimal immunization or no immune response without reducing risk of an AE. Vaccine dose is not based on size (body mass); therefore, small dogs require the same dose of vaccines as large dogs.

Patients with a Known or Suspected Vaccine Adverse Event History

Acute hypersensitivity (nonsystemic) and injection-site reactions are among the most common vaccine AEs reported because they occur within hours or a few days after vaccination. The decision to administer vaccine to any patient with a history of having experienced an acute-onset (minutes to 1–2 days postvaccination) reaction is left to the discretion of the veterinarian. History of an acute-onset AE is not predictive of future risk.

Administration of an antihistamine or NSAID before vaccination to prevent transient postvaccinal nonspecific illness has not been studied adequately in dogs to make specific recommendations on their use or benefit. However, it is common practice to administer an antihistamine (diphenhydramine, 2–4 mg/kg orally or 1 mg/kg parenterally) to patients with a history of an acute adverse reaction. A single dose is generally administered 15–30 min before administering vaccine. In such cases, it is recommended that the patient remain at the practice and be monitored for at least 30 min postvaccination.

In an attempt to mitigate the risk associated with administering vaccine to any patient with acute-onset vaccine AE, veterinarians may also elect to administer the same vaccine type but one produced by a different manufacturer.

The decision to administer pretreatment and/or a vaccine produced by a different manufacturer to any patient with a history of having a known or suspected vaccine AE does not guarantee that an AE will be prevented.

It is reasonable to avoid administration of any vaccine to patients with a history of systemic disease suspected to be associated with previous vaccination (e.g., immune-mediated hemolytic anemia, immune-mediated thrombocytopenia) or known to be caused by vaccine (vaccination-site cutaneous ischemic vasculitis after administration of rabies vaccine). In lieu of annual or

triennial revaccination, assessment of antibody titers can be determined (CDV and CPV) (see "Serologic Testing"). Dogs with a "positive" titer are considered protected. These patients can be considered to have sufficient immune memory to mount a protective humoral immune response for several years and may not require vaccination. Dogs with a "negative" antibody titer may be susceptible to infection. Whether to administer vaccine to dogs with a negative antibody titer is left to the discretion of the veterinarian. However, a negative antibody test for CDV and/or CPV-2 may indicate the dog is susceptible to either of these significant diseases.

The decision not to administer rabies vaccine for health reasons is problematic in locations that require rabies vaccinations yet do not grant rabies exemption authority to veterinarians. Some states and/or provinces do grant rabies vaccination exemption authority to veterinarians who have examined a patient and determined, for health reasons, vaccine should not be administered. Such waivers generally remain in effect until the patient is deemed sufficiently healthy to receive the vaccine. Veterinarians are urged to contact state, provincial, and/or local authorities to determine whether such exemption authority exists.

Small Breed Dogs

One study addressed vaccine AEs in >1.2 million dogs that received >3.4 million doses of vaccine.[73] This study provided important insight on risk associated with administration of multiple vaccine doses to small breed dogs at the same appointment. History of a vaccine AE in a small breed dog is not predictive of future risk. Any dog, regardless of size, breed, gender, or age, can experience a vaccine AE.

Mitigating risk in small dogs (puppies and small breeds) by reducing the volume of vaccine is not recommended. Doing so may result in a suboptimal response to the vaccine and may not eliminate risk associated with hypersensitivity to one or more vaccine constituents. As with all dogs, small breed dogs should be assessed for risk of exposure to infectious pathogens and only those vaccines considered essential should be administered. Furthermore, prioritizing administration of core vaccines (CDV, CPV-2, CAV-2, and rabies) to all dogs at the appropriate age (see Table 1) is recommended.

The decision to administer one or more noncore vaccines to a dog should be based on reasonable knowledge of exposure risk in the individual patient. It should also be noted that most of the noncore vaccines listed within the Guidelines are inactivated (killed) vaccines and that these vaccines may be associated with a higher incidence of AEs when administered at the same time as other vaccines, particularly in small breed dogs. Therefore, veterinarians may wish to delay administration of inactivated noncore vaccines to small breed dogs until after completion of the initial core vaccine series.

Legal Considerations

- Veterinarians have considerable ability to use biologics in a discretionary manner.
- Continuous medical decision making is an inherent aspect of veterinary medicine. There is no reason to believe that decisions regarding vaccine selection and use will carry any greater legal risk than the myriad of other medical decisions made in daily practice. Relative risk for utilizing these guidelines in developing patient vaccination protocols is considered low.
- The best method for insulating a practitioner from legal liability relative to vaccination or anything else is effective client communication. Client communication of risk and/or benefit information should be in direct and simple terms.
- With respect to documentation, practitioners must determine the method that best suits their practice and level of risk tolerance.

Do Veterinarians Have Professional Discretion in the Use of Vaccines in Their Practice?

Yes, with a few limitations. The recommendations contained in the Guidelines may differ in places from statements on product labels. However, veterinarians in small animal practice in the US have considerable discretion in exercising their judgment relative to the use of veterinary biologic products licensed by the USDA within their professional practice.[a] The same is true for veterinarians in Canada using biologic products approved under the Canadian Food and Drug Act.[b] As such, practitioners have the ability to incorporate use of the Guidelines into their practices.

The USDA CVB regulates the licensure and preparation of most veterinary biologics, including all material on their labeling. CVB does not regulate the practice of veterinary medicine. Although CVB does have the statutory authority to stop the sale, barter, or exchange of "any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product," they would only take action against a small animal practitioner under extraordinary circumstances. Before initiating such action, CVB would most likely contact the veterinarian and/or undertake a profession-wide educational initiative.[c]

Vaccines licensed by the USDA and prepared in establishments licensed by the USDA are not directly subject to the Animal Medicinal Drug Use Clarification Act (AMDUCA) or Food and Drug Administration's (FDA) implementing regulations. However, it is possible for the FDA's Center for Veterinary Medicine to regulate some products that most practitioners would consider

biologicals. Products that are approved by the FDA are subject to AMDUCA's and FDA's established specific rules for "extra-label" drug use. Products regulated by the USDA may be identified by the "USDA Establishment Number" that appears on labeling.

States may also regulate the discretionary use of biologic products by veterinarians. This can be confusing, as the state and federal terminology may be similar but applied differently. The state's definition of "drug" may include biologic products, and the state may use the term "extra-label" differently than the federal application.[d] Veterinarians should be aware of any state-specific restrictions in their state's veterinary practice act or implementing regulations. However, it is the authors' belief that such restrictions are sufficiently general that they should not interfere with the ability to use these Guidelines. In Canada, the provinces have the legal authority to regulate the veterinary profession but no authority whatever relating to trade in drugs, medications, and biologics. In this context, the provincial veterinary legislation may, for instance, require that a veterinarian obtain the informed consent of the client before using a substance in a manner that differs from its labeled indications.

Rabies vaccine represents a unique class of products due to the public health concern. The USDA places restrictions on the licenses for rabies products, such that their distribution in each state is limited to authorized recipients as designated by proper state officials (e.g., the state veterinarian) and under such additional conditions as these authorities may require. Each state, in turn, has its own rabies control program. The substance of this law varies among jurisdictions and can encompass state, provincial, and/or local requirements. A common theme to this regulation is compulsory vaccination, irrespective of the label statements that the products are for use in healthy animals. Sometimes veterinarians and/or clients desire to forego rabies vaccination, believing it to be contraindicated due to the health or age of the dog. Veterinarians must be very careful in such circumstances. Although some states have procedures for addressing this situation, it is not addressed in most states.[e] Veterinarians must not assume they have the discretion to recommend against vaccination in the face of mandatory state vaccination laws. Therefore, it is imperative that veterinarians investigate, understand, and follow the legal requirements for rabies vaccination in the areas in which they practice. The same approach is prudent in Canada.

Potential for Liability Associated with Vaccine Administration

Potential liability for medical decision making is a fact of life for any health care provider, including veterinarians. This potential professional liability encompasses all aspects of veterinary practice, including the selection and use of vaccines and other biologic products. Most lawsuits against practitioners are grounded in negligence, although the range of possible legal liability theories is broad and limited only by the creativity of the plaintiff's attorney. There is no reason to believe a veterinarian's use of vaccines would be treated differently or carry any greater risk than other areas of small animal practice.

Medical Negligence

Legal actions against a veterinarian alleging professional negligence are commonly called "malpractice" or "medical malpractice" cases. The body of law for professional medical negligence has evolved in the context of human medicine. Most jurisdictions apply many of the legal concepts developed in the litigation of physician malpractice cases to veterinary malpractice cases, particularly the requirement for expert testimony. The traditional elements of a medical malpractice lawsuit are the duty to conform to a certain standard, a failure to conform to the required standard, actual injury or damage, and a legally sufficient causal connection between the conduct and the injury.[f]

Medical Negligence as It Applies to Vaccination Decisions

The basic scenarios that could potentially give rise to a claim or lawsuit are where (1) a patient that is not vaccinated contracts the disease for which vaccination was forgone; or (2) a patient experiences an AE attributed to a vaccination later considered unnecessary by the client. In either case, the plaintiff would be required to have expert testimony that the defendant's professional judgment under the specific circumstances was a departure from the standard of care and the cause of the injury to the dog. Although such claims do occur, the risk of a lawsuit is considered low and can be mitigated through effective, documented communication with the client.

Consent Versus Informed Consent

Consent is the giving of permission, approval or agreement. Consent can be expressed or implied, written or verbal, documented or not. A veterinarian should understand regulations relative to obtaining or documenting consent in states where they practice, as a state's practice act or regulations may address necessary documentation of client consent.[g]

Informed consent is consent based upon the disclosure of the material risks of a proposed treatment or procedure and potential alternatives, including the risk of no treatment.[h] The legal doctrine of informed consent developed as human medicine evolved from a paternalistic profession to one that recognizes the importance of a patient's self-determination. It is based upon the theory that a competent human being has the right to determine what is done with their body. To date, most states and provinces have not formally addressed the question of applying informed consent law

to veterinarians. There are, however, a few states and provinces with reported court decisions addressing the application of the doctrine of informed consent to veterinary practice in some fashion.[i] Additionally, there are a few states and provinces where the veterinary practice act and/or implementing regulations incorporate either the doctrine of informed consent or elements of it, and the American Association of Veterinary State Boards has developed a model practice act that recommends to states the incorporation of the requirement to obtain informed consent by board regulation.[j] However, within the US there remains ongoing debate about whether informed consent law should be applied to veterinary practice. This is not the case with Canada, where the incorporation into veterinary practice is readily accepted, either by regulation or convention. Some within the veterinary community advocate forgoing use of the term "informed consent" for other terms while incorporating risk communication elements in an analogous manner. The intent here is not to advocate for or against the doctrine of informed consent or its particulars. Rather, it is to acknowledge that allegations of a failure to obtain consent or informed consent, historically common in physician medical malpractice litigation, are not uncommon in complaints against veterinarians as well. Therefore, it is prudent to understand the issue and to understand that one of the best deterrents to an informed consent lawsuit (or other legal action for that matter) is effective communication with clients.

Documentation of Consent

Documentation of consent discussions is always helpful if there is ever need to defend a veterinarian's actions. Such documentation could include a note in the chart that such a discussion took place (with or without co-signature by the client); a note in the chart that in addition to discussion, a specific client handout was given[k]; or use of a consent form signed by the client. Although defense lawyers like more documentation, the task for practitioners is to determine the method that best suits their practice and level of risk tolerance.

Where consent forms are used, the more general the language used, the less helpful the documentation may prove in court; conversely, the more specific the language, the more helpful to the defense of a case. However, the practitioner should have a medically or scientifically defensible basis for making any representations in a consent document. If precise numbers cannot be justified, then more general statements are preferable.

Medical Record Documentation (AAHA Accreditation Standards)

At the time of vaccine administration, the following information should be recorded in the patient's permanent medical record:

- Vaccines recommended for this patient
- Date of vaccine administration
- Identity (name, initials, or code) of the person administering the vaccine
- Vaccine name, lot or serial number, expiration date, and manufacturer of vaccines actually administered
- Site and route of vaccine administration
- Any concurrent medications/therapy
- Future recommended vaccinations

AEs should be recorded in a manner that will alert all staff members during future visits. Consent should be documented in the medical record to demonstrate that relevant information was provided to the client and that the client authorized the procedure.

Part II: Vaccination of Shelter-Housed Dogs

The AAHA Canine Vaccination Task Force developed vaccination guidelines to facilitate the efforts of individuals responsible for purchasing vaccines, administering vaccines, and/or developing vaccination policy for shelter-housed dogs. The objective of writing vaccination guidelines for shelter-housed dogs is to provide essential recommendations to reduce, or eliminate when possible, the risk of infectious disease outbreak or illness in shelter animals. The Task Force recognizes that unique staffing and cost constraints may preclude the ability of all animal shelters to implement these Guidelines fully. However, the guidance provided in this section is intended to provide a basis for developing and implementing a rational vaccination program for animal shelters because these dogs are at particularly high risk of exposure to infectious disease.

The time and effort dedicated to controlling infectious diseases among shelter-housed dogs is only one of many variables in the complex shelter medicine and husbandry equation. The recommendations provided here attempt to address shelter-unique issues as they pertain to rational selection and use of vaccines. Other important factors, such as population density, ventilation, sanitation, staff training, etc., must be taken into consideration when implementing an infectious disease control plan.

Definition of a Shelter Environment

As used in the context of the Canine Vaccination Guidelines, an animal shelter is a holding facility for homeless animals, usually awaiting adoption, rescue, or reclaim by owners. In general, animal shelters are predominantly characterized as a random source population of dogs, as well as other animal species with a largely unknown health and vaccine history, high population turnover,

and significant potential for relatively high levels of infectious disease risk.

Within this broad definition, however, there is wide variation. The term "shelter" encompasses situations ranging from sanctuaries that possess a stable population to facilities that admit dozens or even hundreds of animals per day to rescue and foster homes that care for multiple litters or individuals at any given time. Just as the appropriate vaccine strategy varies with each individual pet, there is no one-size-fits-all strategy for vaccinating shelter animals. Shelters should interpret these Guidelines in light of the infectious disease risk and turnover rate within their own populations.

Special Considerations of a Shelter Vaccination Program

The relatively high likelihood of disease exposure in most shelters and the potentially devastating consequences of infection necessitate a clearly defined shelter vaccination program with exacting requirements. It is necessary to define not only what vaccines are appropriate, but also when vaccines should be administered with respect to shelter entry, which animals are candidates for vaccination, and how and by whom vaccines should be administered, including record keeping and documentation of AEs. For vaccines that offer significant protection against common and severe infectious diseases, the appropriate vaccination program may be one that is more aggressive than is generally indicated in private practice. Such a program may include, for example, vaccinating dogs at the short end of the suggested intervals or at a relatively early age.

With the use of vaccines at shorter intervals or in an expanded population, it is also important to minimize the vaccines given to those that are clearly indicated by the immediate and significant disease risks. Vaccines are often administered to stray dogs not legally belonging to the shelter and may be given by lay staff under indirect veterinary supervision. These considerations make it even more crucial to develop a vaccine program that minimizes the risk of vaccine-induced adverse reactions. Furthermore, cost differences that are trivial for one individual become significant when multiplied by thousands of doses. Therefore, only those vaccines that demonstrate a clear benefit against common and significant shelter diseases should be used. Adopters should be encouraged to discuss an individually tailored vaccination program with their own veterinarian after adoption.

Vaccination Guidelines for Shelters

Core Vaccines for Shelter-Housed Dogs

Vaccines for shelter use are categorized for pet dogs, as core and noncore (optional) (**Table 2**). A number of other vaccines discussed in the following are not recommended. Although the Task Force acknowledges that variable shelter circumstances make it impractical to provide universally applicable recommendations, those vaccines categorized as core are essential vaccines that should be administered to all dogs at the time of entry (CDV, CPV-2, CAV-2, IN Bb + CPiV) or at the time of release (RV).[51,74–77]

It is recommended that all dogs be vaccinated for rabies before release from a shelter. If a long-term stay is anticipated or for shelters where virtually all dogs will be adopted, rabies vaccine should be administered on intake with the other core vaccines. The earliest age at which rabies vaccine should be given is 12 wk, and it is recommended that it be given at a site on the body different than where the CDV, CPV-2, CAV-2 vaccines are administered. At open-intake shelters, rabies vaccine should be administered at the time of release. Although ideally vaccines should be given at least 2 wk apart to avoid vaccine interference, the public health benefit of ensuring rabies vaccination before release is considered to outweigh the small risk of interference in this case. If state or local requirements prevent issuance of a rabies certificate for vaccines administered at the shelter (e.g., due to lack of veterinary supervision), vaccination for the purpose of legal recognition and licensing should be repeated at the owner's veterinarian 2–4 wk later. Unless a certificate documenting previous rabies vaccination is available, it should be assumed that previous vaccination has not been received, and revaccination 1 yr later will be required.[69]

Noncore Vaccines for Shelter-Housed Dogs

The CIV vaccine may be recommended (noncore) in selected shelters located within endemic communities or in shelters that transport dogs to or from communities considered to be endemic for canine influenza. This is a killed vaccine that requires two doses be given at least 2 wk apart. Immunity is expected 1 wk after the second dose. Therefore, even in shelters located within endemic communities, the benefit of this vaccine will be limited if exposure cannot be prevented before onset of protection or in dogs unlikely to stay long enough to receive the full series of vaccines.[78,79]

Vaccines Not Recommended for Use in the Shelter Environment

The vaccines listed in the not recommended category are for diseases that do not represent a significant threat to the population of dogs residing in shelters, would not provide protection because there is inadequate time for immunity to develop, or that have limited efficacy against clinical disease. Among the various canine vaccines licensed for use within the US, the following vaccines are not recommended for routine use in shelter-housed dogs:

TABLE 2

2011 Canine Vaccination Guidelines for Shelter-Housed Dogs

Vaccine	Initial Vaccination	Revaccination (if indicated)	Comments
CDV + CAV2 + CPV2 Note: Use of a combination CDV vaccine + CAV-2 + CPV-2 vaccine with or without MLV CPiV is recommended. Killed (inactivated) virus vaccines are not recommended. Administer SQ or IM	Administer a single dose immediately before or at the time of admission to all dogs unless there are veterinary records showing the dog has been vaccinated at 18–20 wk of age or older with these core vaccines. Alternatively, if the dog is 18–20 wk of age or older and tested positive for antibody to CDV and CPV-2, it would not be necessary to vaccinate. Minimum age: It is recommended that vaccine not be administered to shelter dogs <4 wk of age.	Puppies (≤18 wk of age): Revaccination every 2 wk is recommended until 18–20 wk of age. Dogs (≤18–20 wk of age): Revaccinate at 1 year of age then revaccinate at 3 or more year intervals as for pet animals as long as the dog remains in the facility.	Core • When feasible, puppies should be housed separately from adult dogs, regardless of their vaccination status. All MLV-CPV-2 vaccines available today are expected to provide immunity from disease caused by any field variant recognized today (CPV-2a, -2b, and -2c). All current CDV vaccines are expected to provide immunity from disease caused by any of the current variants of CDV viruses. • MDA, if present, can interfere with immunization up to 16–18 wk of age. When distemper risk is high, inoculation with the rCDV and measles/distemper vaccines have been shown to protect puppies with MDA 2 wk earlier than the MLV CDV vaccines. The MLV or rCDV vaccine should be used when dogs are 16–18 wk or older, as both are highly effective in the absence of MDA. Because it is often difficult to know the exact age of puppies and because MDA are often higher in shelter puppies, they may still be sufficient to block immunization at 14–16 wk in a small percentage of puppies. Therefore, when feasible, shelter puppies should receive a final vaccine when estimated to be 18–20 wk of age. • Once the vaccine has been reconstituted and kept at room temperature, the dose should be administered within 1 hr to avoid inactivation of the vaccine virus, especially MLV CDV vaccine.
Intranasal Bb + CPiV. Use of a combination (bivalent) INI MLV (avirulent) Bb + MLV CPiV, vaccine is recommended, with or without CAV-2. Administer IN only. Do not administer SQ or IM.	Administer a single dose immediately before or at the time of admission. Vaccine can be administered as early as 3–4 wk of age (see manufacturer's administration recommendations). Do not administer SQ or IM.	Dogs ≤6 wk of age: For best results, an additional dose is recommended after 6 wk of age at a minimum vaccination interval of 2 wk. Dogs >6 wk of age: Administer a single intranasal dose every 6–12 mo as indicated. Do not administer SQ or IM	Core • Administration of MLV (avirulent) IN Bb by the SQ or IM route can lead to severe reactions, including death. • Onset of protective immunity after initial IN vaccination occurs within 72 hr; vaccines can reduce the severity of disease but will not entirely prevent canine respiratory disease complex. • Use of a trivalent IN vaccine that also contains MLV CAV-2 should be considered in shelter-housed dogs when the 2-way IN fails to provide acceptable protection.
Parenteral Bb Administer SQ. This vaccine is not effective if administered by the IN route.	Administer the first dose at the time of admission. Administer a 2nd dose 2 wk later if still in the facility. (see comments).	Regardless of the dog's age, 2 doses, 2 wk apart, are required to induce immunity unless previously vaccinated within the past 12 mo. Dogs that have previously received a 2-dose initial vaccination series or a booster vaccination within the past year require only a single dose at the time of admission.	Parenteral Bb vaccine is recommended only as an alternative when it is not possible or not feasible to administer an INI vaccine (above). Note: In previously unvaccinated dogs, a single dose of parenterally administered vaccine will not immunize. Immunity is expected 7–10 days after administration of the 2nd dose. • The parenteral Bb vaccine does not include protection against parainfluenza virus.

(Table continues)

TABLE 2 (continued)

Vaccine	Initial Vaccination	Revaccination (if indicated)	Comments
RV 1 yr. Use of a killed (inactivated) monovalent, single dose vaccine is recommended. Administer SQ or IM.	Administer 1 dose at the time of release from the facility. Dogs may be vaccinated as early as 12–16 wk of age depending on local regulations. If a long-term stay is anticipated, administer 1 dose on entry to the facility.	Revaccinate 1 yr after initial vaccination and then at 3 yr intervals with a 3 yr rabies vaccine as for pet animals as long as the dog remains in the facility.	Core: recommended for all dogs before release from shelter • Unless valid (signed) documentation of prior rabies vaccine administration is available, administration of a rabies vaccine is indicated for all dogs leaving the facility, regardless of age. Revaccination 1 yr later is required by most jurisdictions. • If local, state, or provential law does not permit issuance of rabies certificate for vaccines given at the shelter, vaccination can be repeated by the owner's veterinarian 2–4 wk after leaving the shelter. • Single dose vials are preferred to reduce the risk of contamination and ensure proper mixing and dosage of antigen and adjuvant.
CIV. A killed 2 dose vaccine. Administer SQ or IM.	Administer 2 doses 2 wk apart, with the first dose given before or immediately upon intake. Vaccine can be administered as early as 6 wk of age. Two doses must be given to provide immunity.	Revaccination with the 2nd dose should occur 2 wk after the first. For those dogs in long stay shelters, annual revaccination is recommended.	Noncore • Do not vaccinate a dog unless it is possible to give the initial 2 doses 2 wk apart, as 1 dose has not been shown to provide any benefit. • This vaccination should be considered for shelters in endemic communities or those that transport dogs to or from these locations.

leptospirosis; canine coronavirus; canine Lyme borreliosis (Lyme disease); *Crotalus atrox* (rattlesnake) vaccine; parenterally administered Bb (see Table 2 for exception); and parenterally administered CPiV. Because most of these vaccines are killed (inactivated) and, therefore, require two doses at least 2 wk apart, use of these vaccines is viewed as impractical and unnecessary in most shelter-housed dogs.

Vaccination Recommendations for Specific Cases in the Shelter Environment

Dogs with a Documented Vaccination History at Time of Admission

There is no compelling reason to administer vaccines to an individual dog at the time of admission to a shelter if clear documentation confirms current vaccination administered after the age of 16 wk is provided. The following is the minimum information acceptable as documenting proof that a valid vaccination has been administered:

- Proprietary name of product
- Manufacturer name
- Serial/lot number
- Date vaccine was administered (at least month and year)
- Expiration date of vaccine administered
- Signature of a licensed veterinarian

This information should be associated with a medical record that clearly describes the dog in question. If any of this information is not available at the time of admission or cannot be associated with a formal record for the dog, then immediate vaccination is indicated.

Long-Term Shelter-Housed Dogs

It is recommended that all dogs entering a long-term care facility (or any dog entering a shelter for which a long-term stay is anticipated) be inoculated with all core vaccines, including rabies vaccine, at the time of admission to the facility. If a dog is routinely exposed to the outdoors, then noncore (optional) vaccines should be considered (as for pet dogs), depending on the dog's risk profile.

Because it can be difficult or impossible to determine whether young dogs (<4 mo of age) have received any vaccines at all, implementation of an initial series (CDV, CPV-2, CAV-2 [IM, SQ], Bb, and CPiV [IN]), beginning as early as 4 wk of age (as early as 3–4 wk of age for IN administered vaccines), may be indicated. Parenterally administered core vaccines should not be administered before 6 wk of age. When it is the decision of the facility to initiate the series (i.e., "puppy shots") to an individual dog, then the recommended vaccines should be administered at 2 wk (rather than 3 or 4 wk) intervals until the dog reaches ≥16 wk of age.

Contact Information for Biologics Manufacturers

Company Name	Tech Services Phone (US)	Tech Services Phone (Canada)
Boehringer Ingelheim Vetmedica Inc.	866–638–2226	800–263–2425
Merck Animal Health	800–224–5318	800–361–2353
Merial	888–637–4251 (ext. 3)	888–637–4251 (ext. 57320)
Pfizer Animal Health Inc.	800–366–5288	800–461–0917
Red Rock Biologics	866–897–7625	No Canadian number provided

In the event that an individual dog resides in the facility long enough to justify booster vaccination, it is recommended that the revaccination schedule recommended for individual pets be followed (Table 1).[29,51,74,76,80–82]

Vaccination of Pregnant Dogs in the Shelter Environment

Shelter personnel may be faced with the dilemma of whether to vaccinate a pregnant dog upon admission to a facility. Historically, vaccination during pregnancy has not been recommended in small animal medicine. This is due in part to the paucity of data concerning vaccine safety and efficacy during gestation and the expectation that, in nonimmune pregnant bitches, MLV vaccine can cause fetal damage or death.[22,30,49] When the immunity of the dog is unknown, however, the risk of maternal, fetal, and neonatal infection with field strain virus must be weighed against the risk of vaccination. If nonimmune pregnant dogs are likely to be exposed to field strain infection with pathogens such as parvovirus or distemper, serious illness or death of both bitch and fetuses may result. Unless facilities are available to completely isolate them from other dogs, pregnant bitches should either be vaccinated or not remain in the shelter.

Vaccination of Sick Dogs in the Shelter Environment

As with pregnant dogs, veterinary medicine has advised against vaccination during illness, due to concerns about suboptimal protection, or worse, vaccine-induced illness. The decision to administer or delay vaccination because of a current illness depends on the severity of disease and its etiology.

The shelter environment does not usually permit the luxury of isolating dogs and delaying their vaccination until concurrent illness is resolved. Therefore, vaccination is advised upon admission for dogs with minor illness (e.g., otitis, dermatitis, upper respiratory tract infection with or without fever) or injuries. Vaccination of dogs with severe signs of disease ideally should be delayed whenever feasible. However, unvaccinated shelter dogs may develop more severe disease if left unvaccinated, and thus would be at greater risk of dying. In the high-risk shelter environment, vaccination of sick dogs with core vaccines should be the rule with very few exceptions.[51]

Appendix

PDF form for adverse event reporting (US).

PDF form for adverse event reporting (CANADA).[m]

2011 AAHA Canine Vaccination Guidelines Frequently Asked Questions

The frequently asked questions (FAQs) that follow are based on questions raised by practicing veterinarians regarding the use and selection of vaccines in dogs. The FAQs have been arranged in four categories: Adminisration of Vaccines, Vaccine Products, Vaccine Adverse Events, and Legal Issues Pertaining to Vaccination. Many of the FAQs included have been derived from, or are edited versions of, FAQs developed by the World Small Animal Veterinary Association's (WSAVA) Vaccine Guidelines Group (VGG). AAHA wishes to acknowledge the WSAVA and the VGG for their contributions and support.

Due to the nature of the questions listed in the following, scientific studies and publications supporting each response may not be available. However, the reader is reminded that the FAQ answers represent a consensus of opinion from Task Force members and are based on scientific literature in companion animal immunology and infectious diseases. Although some of the recommendations outlined may be viewed as controversial, these are not intended to be requirements. They are only intended to provide guidance on key points of concern to practicing veterinarians. Implementation of any of these recommendations is left to the discretion of the practicing veterinarian.

Questions Related to Administration of Vaccines

1. *Can different types of vaccines be mixed in the same syringe?* One should never mix different vaccine preparations in the same syringe unless specified on the label.
2. *Is it safe to inject different vaccines (not part of a single commercial product) into the same dog at the same appointment?* Different vaccine types can be injected into the same patient, but they should be injected into separate sites that are drained by different lymph nodes. For example, if a combination MLV (attenuated) vaccine (such as, CDV + CAV-2 + CPV-2) is administered SQ over the left shoulder, a killed (inactivated) leptospirosis or rabies vaccine could be administered SQ over the right shoulder.

3. *To reduce the risk of an adverse reaction, can the volume of an individual dose of parenteral vaccine be reduced for administration to small breed dog?*
   The volume (e.g., 1.0 mL) as recommended by the manufacturer generally represents the minimum immunizing dose; therefore, the total amount should be given to induce a protective immune response.
4. *Is it necessary to administer the entire volume of an IN "kennel cough" vaccine?*
   Although administration of the entire dose and/or volume of an intranasal vaccine is recommended, loss of some reconstituted vaccine is expected (induced sneezing or drainage) after administration. IN vaccines are attenuated (MLV and/or avirulent live bacteria) and, as such, will infect and replicate after administration (see FAQ 7). Loss of some vaccine volume after proper administration is not expected to compromise the local immune response.
5. *Should the large dog (e.g., Great Dane) be injected with the same volume of vaccine as the small dog (e.g., Chihuahua)?*
   Unlike pharmaceuticals (the dose of which is usually based on weight), a vaccine dose is not based on volume per body mass (size), but rather on the minimum immunizing dose (inactivated vaccine) or the minimum infectious dose (attenuated vaccine). Therefore, the entire dose should be administered as directed by the manufacturer. Administering less than the prescribed dose may not induce a protective immune response (see also FAQ 3).
6. *Should vaccine be administered to the anesthetized patient?*
   Doing so is not generally recommended. There is a small risk that a postvaccinal hypersensitivity reaction may lead to vomiting and an increased risk of aspiration. Also, some anesthetic agents may modulate the immune response to a vaccine.
   However, in the event there is limited opportunity to administer a vaccine (e.g., spay and neuter programs), administering vaccine during, or immediately on recovery from, anesthesia is acceptable.
7. *What's the difference between an "infectious" vaccine and a "noninfectious" vaccine?*
   An "infectious" vaccine is capable of replicating within the host after administration. All modified live (attenuated) viral and bacterial vaccines and virus-vectored recombinant vaccines are infectious (e.g., MLV-CDV, IN Bb, and rCDV).
   A "noninfectious" vaccine is not capable of replicating within the host after administration. All killed (inactivated) viral vaccines (e.g., rabies, CIV) and bacterial vaccines (e.g., *Leptospira* spp., Lyme, *Bordetella)* and certain subunit recombinant (rLyme OspA) vaccines are noninfectious.
8. *Should a pregnant dog be vaccinated?*
   Vaccination with MLV (attenuated) and/or killed (inactivated) vaccines during pregnancy should be avoided, if possible, to avoid potential injury to the fetus. There are exceptions, especially in shelters, where vaccination would be advised if the pregnant dog has never been vaccinated and there is risk of exposure to a highly pathogenic virus (e.g., CDV, CPV-2).
9. *Does glucocorticoid treatment in the dog interfere with core vaccine immunity during the primary or secondary (booster) vaccination programs?*
   Studies in dogs suggest that short-term glucocorticoid treatment, even at high doses (2.5 mg/kg) before or at the time of vaccination does not have a significant suppressive affect on antibody production. However, it is reasonable to revaccinate ≥2 or more weeks after long-term therapy has ended, especially when treatment occurred during administration of the initial series of core vaccines.
10. *Should vaccine be administered to pets that are receiving immunosuppressive drugs or cytotoxic therapy (other than glucocorticoids) (e.g., for cancer or autoimmune diseases)?*
    Manufacturers only recommend administration of vaccine to healthy dogs. Dogs receiving immunosuppressive chemotherapy should not be vaccinated. Doing so may result in a suboptimal immune response or may aggravate (reactivate) an immune-mediated illness.
11. *Can vaccine be administered weekly to puppies that may be at high risk of exposure to an infectious pathogen?*
    Ideally, vaccines should not be given more often than every 2 wk, even if different vaccines are administered. Transient downregulation of the immune system after administration may interfere with subsequent vaccine administration for up to 10 days. However, in certain situations (short-term stay in shelters), it may be necessary to vaccinate at intervals of <2 wk.
12. *When should the last vaccine dose of core vaccines be given during the initial (puppy) vaccine series?*
    The last dose of core vaccine, regardless of the number of doses previously administered, should be given at 14 to 16 wk of age or older (see Tables 1 and 2).
13. *Vaccines are indicated for administration to healthy dogs only. In locations that require dogs to be vaccinated against rabies, is the veterinarian still required to administer vaccine to a dog that has a chronic or systemic illness?*
    Rabies vaccination requirements for dogs are generally defined by state or provincial law; however, local municipalities

(counties or cities) may impose rabies vaccination requirements that are more restrictive, but never less restrictive, than those defined by the state or province.

Some, but not all, government agencies grant rabies vaccination waiver authority to veterinarians in the event an individual dog is determined by the veterinarian to be sufficiently ill that vaccination should be delayed. Physical examination and medical record documentation of the illness is generally required; it is the responsibility of the owner and the veterinarian to ensure the dog is revaccinated when or if the underlying medical condition is resolved.

Note: any dog that has exceeded the stipulated rabies revaccination ("booster") interval is not legally considered immunized against rabies, although a rabies vaccination waiver may be in effect. Due to the potential implications of a biting incident involving a dog that is not legally considered as immunized against rabies, the owner should be involved in the decision-making process of whether to vaccinate, and the veterinarian should document the discussion in the patient's medical record.

Veterinarians practicing in locations where rabies vaccination waiver authority is not specifically defined should contact the state or provincial Veterinary Medical Board or the Department of Health for guidance on this issue before vaccinating a dog with a medical condition that, in the veterinarian's judgment, precludes administration of rabies vaccine.

14. *What would happen if an avirulent live IN Bb vaccine is administered by the SQ or IM route?*

    IN Bb vaccine contains live, avirulent gram-negative bacteria that, if parenterally administered, can cause abscess formation at the injection site and may culminate in death associated with bacterial replication, bacteremia, and release of hepatotoxic proteins.

15. *Should a noninfectious (inactivated, killed) parenteral Bb vaccine be administered by the IN route?*

    No. Doing so will not stimulate a protective immune response to Bb.

16. *Have vaccination site recommendations been stipulated for the dog as they have for the cat?*

    Vaccination guidelines for the dog do not specify injection site recommendations. Veterinarians are strongly encouraged to document the inoculation site and vaccine type in the patient's medical record.

17. *Can different vaccine brands (different manufacturers) be administered to the same patient at the same time?*

    Doing so is safe and effective. However, vaccines should not be mixed within the same syringe or administered in the same location.

18. *Should a disinfectant (e.g., alcohol) be applied to the injection site before administering a vaccine?*

    Because disinfectant might inactivate an MLV (attenuated) product, and is not known to provide any benefit to the patient, doing so is not generally recommended.

19. *Will a single dose of infectious (attenuated, avirulent, modified live, recombinant viral vectored) core vaccines provide any benefit to the dog?*

    In the absence of MDA (especially dogs ≥16 wk of age), one dose of a MLV (attenuated) canine core vaccine (CDV, CPV-2, CAV-2) is likely to provide long-term immunity.

20. *When administering the initial doses of killed vaccines that require two doses to immunize (e.g., Leptospira, Lyme disease, CIV), and the dog does not return for the second dose within 6 wk after the first dose, is the dog considered to be immunized?*

    Noninfectious (inactivated, killed) vaccines require two doses on initial vaccination. The first dose primes the immune system, the second dose immunizes. If a second dose is not given within 6 wk of the first, two additional doses, administered from 2 to 6 wk apart, are recommended. Rabies vaccine is the exception.

21. *For how long can a reconstituted MLV vaccine remain at room temperature without losing activity?*

    At room temperature (e.g., 60–80°F), some of the more sensitive MLV vaccines (e.g., CDV) may lose their ability to immunize after 2–3 hr. It is recommended that MLV vaccines be discarded if kept at room temperature for ≥1 hr after reconstitution.

22. *What is the recommendation for revaccinating a dog with an infectious (modified-live, attenuated, or recombinant) core vaccine if that patient has not been properly revaccinated within the recommended time period stipulated for that vaccine?*

    A single dose of infectious (MLV, attenuated, or recombinant viral vectored) core vaccine is considered sufficient to ''boost' immunity in a dog that has previously been vaccinated (e.g., ≥3 yr). Because a single dose of MLV or recombinant core vaccine will both prime and immunize, it is not necessary to administer a series of two or three doses to "boost" the patient's immunity. *Note*: The reason for administration of an initial infectious core vaccine series to puppies is to administer at least one dose that will avoid interference by MDA.

23. *Does severe nutritional deficiency affect the immune response to vaccines?*
    It has been shown that certain severe deficiencies of vitamins and trace minerals (e.g., Vitamin E/Se) can interfere with the development of a protective immune response to certain vaccines, especially in puppies. Known or suspected nutritional deficiencies should be corrected by appropriate nutritional supplementation, and the dog should be revaccinated to ensure there is adequate protective immunity.
24. *If a puppy fails to receive colostrum (MDA) during the first 3 days of life, will it derive any passive antibody protection from the dam?*
    A puppy receives little or, most likely, no immune protection in the absence of colostrum. Approximately ≥95% of passive antibody for a newborn puppy is obtained from the colostrum, which is absorbed via the intestine into the systemic circulation for up to 72 hr after birth.
25. *If a puppy fails to receive colostrum (MDA), should it be vaccinated during the first few weeks of life?*
    To reduce the risk of the MLV core vaccine causing an adverse reaction, colostrum-deprived puppies should not be vaccinated until ≥4 wk of age. In the absence of MDA, certain modified live vaccines, when administered to colostrum-deprived pups <2 wk of age, can infect the central nervous system (e.g., CDV, CPiV) and/or the heart (CPV-2), and can cause disease.
26. *How can colostrum-deprived puppies be protected against the core diseases?*
    Artificial colostrum can be orally administered if the puppy is <3 days old and has never been fed a protein diet. Artificial colostrum can be formulated by administering a mixture of 50% milk replacer (e.g., Esbilac[n] or other similar product) and 50% immune serum (preferably from the dam or other well vaccinated dog living in the same environment as the dam). *Note*: If a puppy received protein (e.g., milk replacer) orally or is ≥3 days of age, serum from a well-immunized adult dog can be given SQ or intraperitoneally (absorption via the intestinal tract does not occur in dogs that are >3 days of age). Alternatively, citrated plasma can be administered intravenously. Depending on size of the dog, approximately 3–10 mL of serum or plasma should be administered twice daily for up to 3 days.

Questions Related to Vaccine Products

27. *Will the administration of vaccine to a puppy "bind" or otherwise deplete MDA, leaving the dog susceptible to infection?*
    Vaccination in the presence of MDA can interfere with the vaccine but will not deplete, or measurably alter, the level of protection a puppy derives from passive (maternal) immunity.
28. *Is it possible to immunize puppies in the presence of MDA?*
    Although MDA may interfere with any vaccine, multiple factors influence the ability of any vaccine to immunize a dog in the presence of MDA; for example, antibody titer of dam, nursing history, concentration of MDA in the puppy, age of the puppy, health status of the puppy, the type of vaccine, and virulence and concentration of the vaccine antigen, etc. Limited studies demonstrated that the viral vectored rCDV vaccine and MV can immunize puppies in the presence of CDV MDA about 2 wk earlier than a MLV CDV vaccine. *Note:* High levels of MDA can still interfere with MV and recombinant (viral vectored) CDV vaccines.
29. *Can MDA interfere with active immunization by both modified-live (attenuated) and killed (inactivated) vaccines?*
    To some extent, all vaccines, both noninfectious (inactivated, killed) and infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines, are susceptible to MDA interference.
    Noninfectious vaccines require a minimum of two initial doses (2–6 wk apart) to immunize: the first dose "primes" the immune response; the second dose immunizes. In dogs vaccinated at <12 wk of age, there is risk that MDA will interfere with (block) the first dose of inactivated vaccine. In such cases, the priming immune response does not occur. The second dose, therefore, would not immunize.
30. *It has been suggested that certain canine infectious (attenuated, avirulent, modified live, recombinant viral vectored) core vaccines need only be administered twice, with the last dose at an age as young as 10–12 wk. Is that accurate?*
    Some canine vaccines are recommended (label) for administration of two initial doses: the first dose at approximately 6 wk and a second dose at 10 wk of age. Serious reservations exist about discontinuing the initial core vaccine series in any dog before 14–16 wk of age. No combination core vaccine product currently available will immunize an acceptable percentage of puppies when the last dose is given at 10–12 wk of age.
    It is strongly recommended that the last dose in the initial series be administered at 14–16 wk of age, regardless of the product used or the number of doses administered earlier. If the initial vaccination series is discontinued by 10–12 wk, it is recommended that an antibody titer to CDV and CPV be obtained to ensure the animal develops an

immune response. During the interim, the individual dog's exposure to other dogs should be strictly limited.

31. *When two vaccine types (MLV and killed) are available for the same antigen, is there any benefit to administering both vaccines, parenterally and topically (e.g., Bb or parainfluenza virus), to an individual dog at the same appointment?*
    Doing so is not considered harmful. Beneficial effects associated with simultaneous administration of an IN and parenteral vaccine for the same antigen (e.g., Bb and parainfluenza virus) have not been clearly documented.
32. *Are there advantages to administering either IN Bb or parenteral Bb vaccine?*
    Studies have shown that both vaccine types, parenteral and IN, mitigate the severity of clinical signs among dogs challenged and/or exposed to Bb.
    Initial vaccination using an IN Bb vaccine provides rapid onset (within 3 days) protective immunity after a single dose. Initial vaccination with parenteral (cellular antigen extract) Bb vaccine requires administration of two doses, at least 2 wk apart, then an additional 7–10 days before immunity develops.
    Dogs vaccinated with IN Bb had significantly lower cough scores and shed significantly fewer challenge organisms (challenged 63 days postvaccination) compared with dogs vaccinated with parenteral Bb. Therefore, in high-risk environments (e.g., shelters), IN Bb vaccine, in combination with parainfluenza virus vaccine, is recommended over parenteral vaccine.
    Use of parenteral vaccine is recommended for use in those patients that aggressively resist IN vaccination.
33. *How long after administration of the core vaccines does it take for a healthy dog that does not have MDA to develop immunity that will prevent severe disease?*
    This is dependent on the dog, the vaccine, and the vaccine virus. After a single dose of core vaccine:
    - MLV and rCDV: immunity to CDV begins within hours after administration. This very early immunity does not prevent infection but does prevent severe disease (especially neurologic), and death, if administered 2–3 days before exposure.
    - MLV CPV-2: immunity to CPV-2 develops in as few as 3 days and is usually protective (based on challenge studies) by 5 days postvaccination.
    - MLV CAV-2: parenterally administered CAV-2 vaccine provides protection against canine hepatitis virus infection (CAV-1) and is expected to induce protective immunity by 5–7 days postvaccination. In contrast, IN administered CAV-2 vaccine (combined with Bb and CPiV vaccine) provides protection against CAV-2, one of the pathogens associated with canine infectious respiratory disease and is likely to induce protective immunity within 3 days postvaccination.
34. *How efficacious are the core vaccines in the properly vaccinated puppy/dog?*
    Ninety-eight percent or more of dogs vaccinated at 14–16 wk of age with a MLV CPV-2, a MLV CAV-2, and a MLV or rCDV vaccine should develop a protective immune response after parenteral administration of a single dose.
35. *Are there new variants of CDV in the field for which current CDV vaccines do not provide protective immunity?*
    All of the current infectious CDV (MLV and recombinant) vaccines provide protection against all the known isolates (variants) of CDV.
36. *Do the current infectious CPV-2 vaccines provide protection from disease caused by the new variant CPV-2C?*
    All current infectious CPV-2 vaccines induce a protective immune response (e.g., antibody response) that provides long term (≥4 yr) protection from all known CPV-2 variants (2a, 2b, and 2c). Protection was documented after both natural and experimental challenge.
37. *Can parvovirus vaccines (e.g., CPV-2) be administered orally?*
    CPV-2 vaccines, when administered orally, will not immunize. The most effective route of administration is parenteral (SQ or IM) vaccination.
38. *Are serum antibody titers useful in determining vaccine immunity?*
    Serum antibody titers correlate with protective immunity against CDV, CPV-2, and CAV-1 immunity (induced by CAV-2 vaccine). RV antibody titers can be determined for individual patients (certificated laboratories only) and do reflect an immune response to vaccination; however, at the present time, such titers generally are not used to establish protective immunity in an individual dog. Likewise, postvaccination rabies titers generally cannot be used to replace the requirement for revaccination.
    Serum antibody titers currently available are of limited or no value as a measure of protective immunity for the noncore vaccines. See also page 17 of the Guidelines for additional information on serum antibody titers.
39. *When a noninfectious (inactivated, killed) Leptospira vaccine (bacterin) is administered, should it be a product containing 2 serovars or 4 serovars.*
    There is little or no cross protection induced by the various *Leptospira* serovars. Therefore, it is recommended that for dogs deemed to be at risk for exposure, a four-way

leptospirosis vaccine should be administered annually after the initial puppy series of two doses (see also Table 1).

40. *Do Leptospira vaccines provide the same degree of long-term immunity as core vaccines?*
    Leptospira vaccines provide short-term immunity (e.g., up to 12 mo) and the efficacy may be <70% for certain serovars. The immunity among the serovars varies and immunity varies among vaccinated dogs. Persistence of detectable antibody after vaccination will often be only a few months and immunologic memory for protective immunity may only last approximately 1 yr. Therefore, when a dog is at risk for leptospirosis and has not been revaccinated during a period of ≥2 yr, two doses 2–6 wk apart should be given instead of a single dose.
41. *How many doses of vaccine should be given to a dog presented for their initial vaccine series if the patient is older than 14–16 wk of age?*
    Most manufacturers recommend administering two doses, 3–4 wk apart. When using noninfectious (inactivated, killed) vaccine, two doses are essential to immunize (rabies is the only exception). However, when administering an infectious modified-live attenuated or a recombinant distemper virus vaccine to healthy dogs older than 14–16 wk of age, 1 dose is considered sufficient to immunize.
42. *Can infectious (attenuated, avirulent, modified live, recombinant viral vectored) vaccines be administered to dogs already infected as a means of "treating" the clinical disease or shortening the course of infection?*
    Administering vaccine to clinically ill patients as a means of treating the disease is neither effective nor is it recommended. By the time clinical signs develop, the infection is well established. However, in a kennel or shelter situation, because dogs are in various stages of exposure, vaccination of the entire group will often prevent or end a significant outbreak.
43. *What is "nonsterile immunity"?*
    Many vaccines serve only as an "aid in the prevention of clinical signs" associated with exposure to pathogenic viruses/bacteria. Such vaccines do not prevent infection, may not completely prevent development of clinical signs and, may not completely prevent shedding (CIV, CAV-2, parenteral Bb, and leptospirosis are vaccine examples), but should prevent or reduce disease.
44. *What is "sterile immunity"?*
    Some vaccines induce protective immunity, and prevent infection, thus clinical signs will not occur following exposure. These vaccines induce "sterile" immunity (e.g., CPV and CDV).
45. *Will the current 'kennel cough' vaccines provide protection from disease caused by the CIV?*
    None of the current vaccines used to prevent Bb, parainfluenza virus, or CAV-2 (causes of canine infectious respiratory disease; also called "kennel cough"), provide any protection against CIV.
46. *Is there a vaccine available to aid in the prevention of disease caused by CIV?*
    There are licensed vaccines available that are designed to aid in the prevention of influenza in dogs caused by the H3N8 influenza virus. The products are adjuvanted killed vaccines that, like all noninfectious (inactivated, killed) vaccines, requires two initial doses, administered parenterally, given 2–4 wk apart. Immunity develops approximately 1 wk after the second dose. This vaccine is monovalent and is not currently available in combination with any other vaccines.
47. *Can nosodes (holistic preparations) be used to immunize pets?*
    Nosodes cannot be used for the prevention of any infectious disease. They do not immunize because they do not contain antigen, which is required for the development of cell mediated and/or humoral immunity.

Questions Related to Adverse Reactions to Vaccines

Note: Vaccine adverse events are significantly underreported in veterinary medicine. The USDA, the CFIA, and the vaccine manufacturers strongly encourage reporting of any known, or suspected, adverse event following administration of a veterinary vaccine. Reporting instructions can be found on page 20 of the guidelines.

48. *Is there a risk of over-vaccinating a pet (e.g., injecting it too often, or using vaccines that are not required for the specific pet)?*
    Vaccines are biologic products; administration should be tailored to the needs of the individual dog and should never be given needlessly. All vaccines have the potential to cause adverse reactions following administration. See page 19 of the guidelines for additional discussion on vaccine AEs.
49. *Are certain vaccines or combinations of vaccines more likely to cause adverse reactions than others?*
    Although the development of an adverse reaction may be dependent on the genetics of the dog (e.g., small breeds), certain vaccines have a higher likelihood of producing adverse reactions, especially reactions caused by Type I (anaphylaxis due to IgE) and/or Type III (Ag-Ab complex)

hypersensitivities. See page 19 of the guidelines for additional discussion on vaccine AEs.

50. *Should dogs with a history of acute postvaccinal adverse reaction (hives, facial edema, anaphylaxis, etc.) or immune-mediated diseases (such as IMHA) receive booster vaccines?*
    There may be risk in doing so. If the vaccine known or suspected to have caused the adverse reaction is an attenuated (MLV) core vaccine (e.g., CDV or CPV-2), a serological (serum antibody) test can be performed. If the dog is found to be positive, the dog is considered immunized and revaccination is not necessary.
    If the vaccine is a noncore vaccine (e.g., *Leptospira*, *Bordetella*, Lyme bacterin), revaccination is discouraged (serum antibody titers are not reflective of the patient's immune status).
    If rabies vaccine is implicated as the cause of an adverse event, appropriate authorities should be consulted to determine whether rabies vaccination can be exempted (waivered).
    In the event vaccination is deemed necessary, administration of an alternative product (by a different manufacturer or different type of vaccine) may be helpful. However, there is no guarantee that a dog will not develop an adverse event if a different product is administered.
    Hypersensitivity reactions are not necessarily linked to the immunizing antigen; in fact, the sensitizing protein(s) are often linked to constituent proteins associated with the manufacturing process (bovine serum albumin, tissue culture antigens). See page 19 of the guidelines for additional discussion on vaccine AEs.
51. *Can vaccines cause autoimmune diseases?*
    Vaccines themselves do not cause autoimmune disease, but in genetically predisposed dogs, vaccination may induce immune-mediated disease. *Note*: immune-mediated disease can also be linked to infection, oral or parenteral drug administration, and possibly other environmental factors.
52. *Is there any risk to clientele or veterinary staff, especially immune compromised individuals, subsequent to intranasal vaccination with an avirulent live (attenuated) Bb vaccine?*
    It is possible for transient shedding of attenuated Bb to occur following intranasal administration. There are two known reports identifying a temporal relationship between the identification of human *Bordetella* infection and exposure to attenuated live Bb canine vaccine, one of which was in an immunocompromised patient.
53. *How common are postvaccination adverse reactions?*
    There are no reliable data that provide information on the true incidence of postvaccination adverse events (reactions) in companion animals. In the US and Canada, there is no vaccine adverse event database maintained that is available for public review. Although serious postvaccinal adverse reactions among dogs are considered to be uncommon, a prior history of a known or suspected postvaccinal adverse event should be taken into consideration when recommending vaccines for individual patients
    Current studies have shown that, among dogs, the risk of an acute-onset (within 3 days) adverse reaction is greatest among small breed dogs receiving multiple vaccines at the same appointment. Such practices should be avoided (see page 22 of the guidelines).
54. *Are there dogs that cannot develop an immune response to vaccines?*
    Although uncommon, it does appear that some dogs have an inability to respond to specific vaccine antigens. Dogs vaccinated with a CDV-CPV-2-CAV-2 may respond to two of the constituent vaccines but not a third. This is attributed to a genetic trait; dogs affected in this way are called 'nonresponders'. Genetically related (same family or same breed) dogs will often share this nonresponsiveness. If the dog is a nonresponder to a highly pathogenic agent, like canine parvovirus virus (estimated at 1/1,000 dogs), the dog may die if infected. In contrast, if the individual dog is a nonresponder to a pathogen that rarely causes death (Bb), clinical signs may develop following exposure despite prior vaccination, and the dog is not likely to die, but it may become a carrier.
55. *Does the adverse reaction risk of a noninfectious (inactivated, killed) vaccine (e.g., acute hypersensitivity) persist in the individual patient for an extended period or is it of short duration?*
    Immune memory associated with acute (type I) hypersensitivity (IgE) to a leptospira bacterin may be sustained for at least 4 yr (as determined by intradermal testing) even though the protective immune response (IgG) may only last a year.
56. *Is there a vaccination program that could be recommended for those owners only wanting the least number of vaccines possible or for those dogs that are not likely to be seen again by a veterinarian?*
    The vaccination protocol that includes the minimum number of vaccines yet still provides a reasonable opportunity to immunize the dog would be: a single dose of a combined infectious (attenuated, avirulent, modified live, recombinant viral vectored) CDV, MLV CPV-2, with MLV CAV-2, administered at 16 wk of age or older, plus a rabies vaccine at the same time (but inoculated at a separate site on the body).

Questions Related to Legal Issues

57. *How should communications between the veterinarian and client associated with vaccinations differ from communications associated with other medications?*
    The issues related to consent and client discussions relative to risk/benefit profiles do not differ in their essence between vaccines and other medications. That does not mean that every practitioner must have the same level of discussion with every client for every vaccine or other medication. Wherever there are meaningful risk/benefit considerations, it is strongly recommended to include the client in the decision making process.
58. *Is it necessary to explain the risks associated with every individual vaccine during each visit in which vaccinations are administered?*
    It is advisable to have an initial vaccine discussion about vaccines with the client that is documented and more thorough, followed by periodic and less extensive discussion at subsequent vaccination. If the practitioner believes that the risk/benefit profile for the various antigens administered in a visit is essentially the same, they could be discussed as a group. If an individual antigen was considered to carry a significantly different risk/benefit profile, then it could be addressed individually. At subsequent vaccination appointments, it is a good idea to briefly remind the client of the clinical approach taken to vaccination and ask if the client has any questions. Additionally, if over time there is a change in the perceived risk/benefit profile, then additional discussion with the client is indicated. Finally, practitioners must be in a position to know their clients and identify those that will benefit from more discussion.
59. *Can a veterinarian be held legally liable for withholding a core vaccine from a dog with immune mediated disease that later succumbs to one of the diseases prevented by the core vaccines?*
    The risk should be low if the client is involved in the process and the discussion is documented in the chart. For example, a note in the chart that: (1) a discussion was held with the client regarding the relative risks of exacerbating the patient's autoimmune disease or other adverse event versus the potential for disease/death if the patient contracts a disease for which vaccination has been foregone, (2) that the client chose not to vaccinate, and (3) that the client was given an opportunity to ask questions, would go a long way to reducing legal risk.
60. *What is a reasonable degree of documentation for risk/benefit discussions with clients concerning vaccination?*
    There is no one size fits all answer to this question. The Guidelines purposefully do not say "document consent in this manner …." Why? In large measure this is opinion. The current level of legal risk relative to small animal vaccination protocols is considered low. However, whenever claims are made against veterinarians, they often include allegations that appropriate consent was not obtained. Different people have different levels of risk tolerance. One veterinarian may be very satisfied with making a note in the chart that the risks and benefits of vaccination were discussed with the opportunity for questions and/or providing a client handout. Others may not be comfortable with anything less than obtaining a client's written consent. However, given the current risk level, the recommendation is to focus on client communication with a level of documentation that does not disrupt the practice. It is also recommended that practitioners consider use of a specific client handout. If handouts are used, it is important to date or otherwise identify and archive them, such that the specific handout provided to a client can later be retrieved if necessary.

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Additional Reading

Guidelines such as these rarely have complete references and, when provided, they are limited to only a few specific references. For those wanting more general information on vaccines and vaccination and/or immunology and the immune response to vaccines, the authors suggest the following:

American Animal Hospital Association Canine Vaccine Task Force, 2003. Report of the AAHA canine vaccine task force: executive summary and 2003 canine vaccine guidelines, recommendations. *J Am Anim Hosp Assoc* 2003;39:119–131.

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FOOTNOTES

[a] Any relevant state law (e.g., for rabies administration) should be followed. It is also possible for vaccines, such as those used in official USDA disease eradication programs or to combat foreign diseases, to carry specific labeled restrictions on their use. Veterinarians should adhere to any such restrictions.

[b] The authors thank Douglas C. Jack, Solicitor, for providing the Canadian perspective included in this section of the Guidelines.

[c] It does not appear that CVB has taken an enforcement action against a small animal veterinarian relative to their exercise of professional judgment in the discretionary use of a vaccine for at least 30 years. It is believed they have never done so. The most likely reason for any such action would be a significant safety issue.

[d] *See* 811 IAC 12.2(169) (IA—a board rule titled "extra-label use of veterinary drugs and immunization products" specifies one of the requirements for extra-label use as: "For drugs used in animals not intended for food, there are no marketed drugs and immunization products specifically labeled for the conditions diagnosed; or in the veterinarian's clinical judgment the labeled dosage is inappropriate for the condition or the extra-label use should result in a better outcome for the patient."); Ala Admin Code r. 420-4-.02 & .07 (AL—rabies control program defines "extra label use of vaccine" as "use of an animal vaccine in a species that is not specified on the product label or product insert.")

[e] For example, Colorado is a state that provides a mechanism for waivers for rabies vaccination. *See* C.R.S. 25-4-607 (provides that with the consent of the owner, a veterinarian may issue a written waiver for rabies vaccination when following the rules of the local health department if the rabies vaccination is contraindicated due to the health of the animal.)

[f] The duty arises out of the veterinary–client–patient relationship and is typically stated as the duty to exercise reasonable care, i.e., the same level of care and competence as a reasonably prudent practitioner would, with the same or similar training, under the same or similar circumstances. This duty is often referred to as the "standard of care." In this context, standard of care is a legal term and does not necessarily equate with professional practices or standards. With few exceptions, establishment of the relevant standard of care and whether a practitioner deviated from it must be established by competent expert testimony.
In practice, many medical negligence cases become a battle of experts. The plaintiff uses an expert witness to establish a standard of care and then presents the opinion that the practitioner failed to meet the standard and that such failure caused the plaintiff's injury or damages. In turn, the defense offers differing expert testimony, establishing a different standard of care, and attests that the defendant practitioner met the standard and that the defendant's conduct did not legally cause the plaintiff's injury or damage. Faced with conflicting evidence, the jury arrives at a verdict on the basis of innumerable variables, including the qualifications and presentation of the various experts and the defendant.

[g] For example, Louisiana, Missouri, and Pennsylvania have administrative regulations covering this area. *See* LAC 46: LXXXV.1039 (Louisiana—must obtain written consent before general anesthesia, except in emergency); 20 CSR 2270-6.011(19) (Missouri—must obtain written informed consent before anesthesia or surgical procedure, except in emergency); and 49 Pa. Code § 31.22 (Pennsylvania—client communications relative to consent for recommended diagnostic tests, treatments, and drugs must be documented in patient record).

[h] There are two primary standards by which informed consent cases involving physicians have been evaluated, with a fairly even division between those states that use a practitioner-focused inquiry and those that use a patient-focused inquiry. In some states the standard is set by the courts and in others it is set by statute. Such statutes may or may not apply to veterinarians. In those states that would allow an informed consent case against a veterinarian to proceed, it is likely they would look to the standard used in physician cases as instructive. Under the practitioner-focused standard, the inquiry focuses on whether the defendant provided the information that a reasonable practitioner would disclose under the circumstances. The level of the required disclosure is established by expert testimony. Under the patient-focused standard, the inquiry is whether the practitioner provided sufficient information (in understandable terms) to allow a "reasonable person" to make decisions about the course of treatment. The real issue becomes what information a reasonable person would need to make informed, rational decisions. Regardless of which standard is used, the other elements of a negligence case, including the causal connection, must be established for a plaintiff to prevail.

[i] In Canada, it is now generally accepted that as long as the veterinary practitioner obtains the informed consent of the client to either proceed or not proceed with a particular use or nonuse of a vaccine, having explained all of the material and probable risks, then such conduct would not constitute malpractice, unless, of course, the generally accepted standard of practice was compromised by so doing.

[j] *See Lawrence v. Big Creek Veterinary Hosp., L.L.C.,* 2007 Ohio 4627 (Ohio Ct. App., Geauga County Sept. 7, 2007) ("The informed consent doctrine is not codified in Ohio. However, such practice is clearly indicative of the veterinarian's duty of care. This is an evidentiary issue that goes directly to the standard of care in a malpractice case. Finally, we note that experts should also be able

to testify regarding this standard, as it goes to the central issue of compliance with professional conduct. Informed consent is part of and necessary to a veterinarian's duty of care."); *Ullmann v. Duffus*, 2005 Ohio 6060, P27 (Ohio Ct. App., Franklin County Nov. 15, 2005). (Court found no Ohio precedent for an informed consent action against a veterinarian but did not resolve the question as the plaintiff's failure to present expert testimony was fatal to an informed consent claim under practitioner-focused standard.); *Zimmerman v. Robertson*, 259 Mont. 105 (Montana 1993) (Court did not address substantive application of informed consent claims to veterinarians holding that plaintiff had not raised the issue on a timely basis); *Emes Stable v. University of Pennsylvania*, 1988 U.S. Dist. LEXIS 2972 (E.D. Pa. Apr. 4, 1988) (The question of whether veterinarians obtained informed consent for operation was submitted to jury. It is not clear if this was contested by the defendants); *Ladnier v. Norwood*, 781 F.2d 490 (5th Cir. La. 1986). (Applied practitioner-focused standard to find veterinarian met duty to warn); *Hull v. Tate*, 1974 Okla. LEXIS 423 (Oklahoma 1974). (Court applied practitioner-focused standard to find no duty to warn of remote risk of anaphylaxis from drug injection); *Hoffa v. Bimes*, 2008 PA Super 181 (Pennsylvania Super. Ct. 2008) (Under facts of the case, the Veterinary Immunity Act dispensed with need to obtain informed consent before emergency care).

[k] *See* LAC 46:LXXXV.1039 (Louisiana—Required written anesthesia consent form must indicate that the client has been advised as to the nature of the procedures and the risks involved in performing anesthesia); Minn. R. 9100.0800 (Minnesota—client must be informed of the treatment choices and reasonable medical or surgical alternatives); Miss. Code Ann. § 73-39-53 (Mississippi—practice act uses patient/client–focused standard to define informed consent to require informing client, "in a manner that would be understood by a reasonable person, of the diagnostic and treatment options, risk assessment and prognosis…."); 20 CSR 2270-6.011(19) (Missouri—must obtain written informed consent before anesthesia or surgical procedure, except in emergency); NAC 638.0175 (Nevada—a required element for establishment of a veterinarian–client–patient relationship is obtaining informed consent before medical treatment.); American Association of Veterinary State Boards, *Veterinary Medicine and Veterinary Technology Practice Act Model with Comments*, Comments to Section 107(y), available at http://www.aavsb.org/PAM/ (recommends incorporation by board rule of requirement to obtain informed consent into code of conduct or standards of practice).

[l] If client handouts are used in connection with a note in the chart that the handout was discussed and provided to the client, the handout should be dated and archived so that if ever necessary, a copy of the specific handout provided to the client can be retrieved.

[m] The online version of this article (available at www.jaaha.org) contains supplementary data in the form of two forms.

[n] Esbilac, PetAg, Hampshire, IL

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Adverse Event Report

Pharmacovigilance
United States Department of Agriculture
Center for Veterinary Biologics
1920 Dayton Avenue
Ames, IA 50010
Phone: (515)337-6100 FAX: (515)337-6120

*Required Fields

Product information

List ALL immunobiological products used.

*Brand Name or Generic Name	*U.S. Vet. License (ESt. No.) or Manufacturer Name	Serial (lot) Number	Type of Product[1]
1			
2			
3			
4			

1. Type of Product (select one for each product) = Viral, Bacterial, Combination, Antibody, Coccidia, Immunomodulator, Protozoa, Recombinant, Rickettsia, Other, or Do Not Know.

Administration of products

Dose	Route	Site	Needle Size	Date Reconstituted
1				
2				
3				
4				

Administered by:[2]	*Date of Product Use (MM/DD/YYYY):
Concurrent Drugs or Procedures:	

2. Administered by (select one) = Veterinarian or Veterinary staff or Nonveterinarian

Event Information

*Event description:[3]
Explain the event description and treatment in a concise paragraph:

3. Event description (select one) = Anaphylaxis-hypersensitivity, autoimmune, birth defect, lack of expected efficacy, local, neoplasia, reproductive, systemic, other

Onset (How long after product use did the event begin?) : (Specify whether units are in mins,hrs, days, wks, mos, yrs)

Attending veterinarian's level of suspicion that product caused event: High Medium Low Not Listed	*Outcome: (Select One) Recovered without treatment Recovered with treatment Did not recover Died Other

Animal Information

Case identification number:		
*Species[4]	Breed:	Age (i.e., 2 yrs or 2 mos):
Sex: (male, female , not listed) Neutered: (yes, no, not listed)	For animals handled in a group (herd, litter, etc) Number in group: _____ Number affected:_____ Number vaccinated:_____ Number dead: _____	

4. Species (Select One) = Porcine, Bovine, Canine, Feline, Ferret, Ovine, Caprine, Equine, Exotic, Fish, Poultry, or Other

History and Enviroment (e.g., acquisition, vaccination, and medical histories; housing, diet, contacts, etc)

Personal Information

Veterinarian	Owner
*Name:	Name:
Address:	Address:
City: State Zip:	City: State: Zip:
*Phone: FAX: E-mail:	Phone: E-mail:

Submitter's information

This event has been reported to the manufacturer(s): (Select one) = yes or no	
*Submitter's first name: *Submitter's phone number:	*Submitter's last name: * Today's Date:
Relationship to animal:[5]	

5. Relationship to animal (select one) = veterinarian, owner, other, not listed)

For internal use:

Product Code	Other comment(s):
1.	
2.	
3.	
4.	

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

File No. / N° de dossier

NOTIFICATION OF SUSPECTED ADVERSE EVENTS TO VETERINARY BIOLOGICS

DÉCLARATION DES ÉVÈNEMENTS INDÉSIRABLES SOUPÇONNÉS À L'ÉGARD DES PRODUITS BIOLOGIQUES VÉTÉRINAIRES

Mail notification to:
Canadian Centre for Veterinary Biologics
59 Camelot Drive
Ottawa, Ontario K1A 0Y9
Tel: 613-773-7408 Fax: 613-773-7570

Envoyer la déclaration à :
Centre canadien des produits biologiques vétérinaires
59, promenade Camelot
Ottawa (Ontario) K1A 0Y9
Tél.: 613-773-7408 Téléc.: 613-773-7570

Product Information / Information sur le produit

Assigned and Trade name of product Nom commercial et attribué au produit	Manufacturer / Fabricant	Serial number Numéro de série	Expiration date Date de péremption

Owner's name, description of animal Nom du propriétaire, description de l'animal	Clinic, address and tel. No. and name of attending veterinarian Clinique, adresse et n° de tél. et nom du vétérinaire traitant

History and Symptoms / Anamnèse et symptomatologie

Veterinarian Submitting Reports / Vétérinaire présentant le rapport

Signature _____ Date _____

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CFIA / ACIA 2205 (2011/02)

Canada

Journal of Feline Medicine and Surgery (2013) **15**, 785–808

SPECIAL ARTICLE

2013 AAFP Feline Vaccination Advisory Panel Report

Rationale: This Report was developed by the Feline Vaccination Advisory Panel of the American Association of Feline Practitioners (AAFP) to provide practical recommendations to help clinicians select appropriate vaccination schedules for their feline patients based on risk assessment. The recommendations rely on published data as much as possible, as well as consensus of a multidisciplinary panel of experts in immunology, infectious disease, internal medicine and clinical practice.

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Introduction

The AAFP produced the first organization-driven vaccination guidelines in 1998. These were updated in 2000 and again in 2006.[1] Each version has offered a comprehensive review of the literature and has provided recommendations for vaccine protocols based on known science along with some extrapolation between studies and between species when feline studies were not available. This Report has used the same criteria.

The practicing veterinarian is in the best position to determine how to put these Guidelines into practice for an individual patient. The veterinarian should undertake a clinical risk/benefit assessment for each animal and discuss recommended vaccination schedules with the owner so that they can make an informed choice. The assessment should include discussion on the likelihood of exposure, the health and lifestyle of the animal, and the risks related to vaccination.

The Advisory Panel recognizes that situations differ in different countries, and that every country will have slightly different issues and priorities; thus these Guidelines will not necessarily be applicable to every country and the practitioner must interpret accordingly.

The three international panels that have produced feline vaccination guidelines (AAFP, World Small Animal Veterinary Association and European Advisory Board on Cat Diseases) recommend that an annual health examination be performed irrespective of whether vaccines are administered. While the optimal frequency of health examinations for cats is unknown, it is generally

CONTENTS page

See page 799 for list of Disease Information Fact Sheets and other resources available online as Supplementary Files.

The AAFP welcomes endorsement of these guidelines by the International Society of Feline Medicine (ISFM).

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What's new in this version

- Updated recommendations on vaccination frequency and interval
- Vaccination recommendations for specific situations
- Vaccinations for Your Cat – Pet Owner Guide
- Frequently asked questions
- Considerations and management options for feline injection-site sarcoma risk reduction

Information presented in depth in the 2006 AAFP Feline Vaccine Advisory Panel Report[1] that may be of interest to the reader includes:

- Vaccine licensing
- Vaccine labels
- Vaccination in kitten socialization classes
- Appendix 1: Certificate of Exemption from Rabies Vaccination
- Appendix 3: Vaccination documentation
- Appendix 4: Vaccine handling and storage
- Appendix 5: Vaccine preparation
- Appendix 6: Vaccine administration tips

This material may be found in the 2006 Guidelines posted at: http://www.catvets.com/guidelines/practice-guidelines/feline-vaccination

accepted that healthy adult cats should be examined at least once a year. In the past, annual veterinary visits were structured around vaccinations as the primary focus. With the increasing body of knowledge about duration of immunity (DOI) from vaccinations, their potential adverse effects, and the increased awareness of pet owners about these issues, it is clear that vaccination no longer justifies the need for annual visits.

Practitioners are encouraged to help cat owners understand the value of regular health care and that it ideally should be proactive rather than reactive. A useful approach is for health care to be tailored to the various feline life stages, which improves early recognition of potential health-related issues and can facilitate treatment.[2]

A Pet Owner Guide, discussing the risks and benefits of vaccination, is included as Appendix 2 (pages 807 and 808).

At least once a year, as part of a routine health care program, the vaccination needs of all cats should be reassessed, in conjunction with a comprehensive physical examination and consultation.

Figure 1 **Kittens are more susceptible to infection than adult cats are, and are a principal primary target population for vaccination.** *Courtesy of Dr Deb Givin*

Vaccination principles

Vaccination plays an important role in the control of infectious diseases, both for an individual as well as for the cat population (ie, herd health). Some vaccine antigens are also used to lessen the potential for zoonotic spread of disease (eg, rabies). The benefits of routine and widespread vaccination are clear: the incidence of serious disease caused by highly pathogenic organisms, such as feline parvovirus (panleukopenia), can be reduced in populations in which widespread vaccination is practised. However, the level of protection conferred by a particular vaccine in an individual patient varies. The quality of vaccine-induced immunity in any patient is influenced by a complex interaction of factors unique to the individual patient, the patient's environment, and the nature of the vaccine and pathogen. Precisely predicting either the outcome of vaccination or subsequent exposure to a pathogen is difficult (or impossible) and, therefore, vaccination should never be offered as a guarantee of protection.

The risk of infection and subsequent development of disease varies with a number of factors including the age and health of the cat, magnitude of exposure to the infectious agent, the pathogenicity of individual agents, the geographic prevalence of infection and the vaccination history of the cat. Some of the factors that negatively affect an individual animal's ability to respond to vaccination include interference from maternally derived antibodies (MDA), congenital or acquired immunodeficiency, concurrent disease or infection, inadequate nutrition, immunosuppressive medications, chronic stress and an aging immune response. Additionally, some vaccinal agents (eg, FPV) will induce a much stronger protective immune response than others (eg,

Patient risk variables to take into consideration

- Age of cat
- Health of cat
- Magnitude of exposure to agent
- Agent pathogenicity
- Geographic prevalence
- History
- MDA interference
- Congenital or acquired immunodeficiency
- Immunosuppressive therapy
- Concurrent disease
- Nutritional status
- Chronic stress
- Aging immune response

Vaccination categories

Core versus non-core

- The Advisory Panel has revised which vaccines are considered core and non-core, recognizing that antigens other than feline parvovirus, herpesvirus-1 and calicivirus may not be required or available in all situations or in all countries. The specific circumstances in which non-core vaccines may be appropriate vary considerably.
- CORE VACCINES are those recommended for all cats. The Advisory Panel recommends that feline panleukopenia (FPV), feline herpesvirus-1 (FHV-1) and feline calicivirus (FCV) vaccines fall into this category.
- NON-CORE VACCINES should be administered to cats in specific risk categories on the basis of an individual risk/benefit assessment. The Advisory Panel believes that rabies, feline leukemia virus (FeLV), feline immunodeficiency virus (FIV), *Chlamydophila felis*, *Bordetella bronchiseptica*, feline infectious peritonitis (FIP) and dermatophyte vaccines fall into this category.
- Vaccination against rabies is essential in regions where it is required by statute/law or where the virus is endemic.
- The Advisory Panel recommends that all cats under 1 year of age be vaccinated against FeLV and receive a booster vaccination 1 year later. After 1 year of age, the need for subsequent vaccination is determined by risk factors that the individual is exposed to.

The reader is referred to the section on risk/benefit assessment (pages 788–789) and the accompanying Disease Information Fact Sheets (details on page 799) for further specifics regarding each vaccine antigen.

feline herpesvirus [FHV-1]). As vaccine-afforded protection against both infection and disease is thus variable and not absolute, exposure to infected animals and infectious agents should be minimized, even after vaccination.

Kittens are generally more susceptible to infections than adult cats are and typically develop more severe disease (Figure 1). Thus, they represent a principal primary target population for vaccination. As part of a routine health care program, the vaccination needs of all cats, including adults, should be assessed at least once a year, in conjunction with a comprehensive physical examination and consultation, modifying vaccination recommendations as necessary on the basis of altered risk/benefit ratio.

Vaccination is a medical procedure, and the decision to vaccinate, even with core vaccines (see box above), should be based on a risk/benefit assessment for each cat and for each vaccine antigen. Vaccination may indeed be beneficial, but it is not innocuous, and the benefit of vaccinating an animal (eg, the induction of clinically meaningful immunity) must be balanced against the risk of adverse events, likelihood of exposure and severity of disease. Where practical, every effort should be made to ensure that cats are healthy prior to vaccination; however, concurrent illness should not necessarily preclude vaccination.

The overall objectives of vaccination are shown on the right.

Overall objectives of vaccination

- To vaccinate each cat only against infectious agents to which it has a realistic risk of exposure
- To vaccinate against infectious agents that cause significant disease
- To vaccinate a cat only when the potential benefits outweigh the potential risks
- To vaccinate each cat no more frequently than necessary
- To vaccinate the greatest number of cats possible in the population at risk
- To vaccinate appropriately to protect human/public health

General information on types of feline vaccines

Vaccines, including different products licensed to protect against the same pathogen, are not necessarily alike. Different vaccine technologies may directly influence efficacy, safety, DOI and route of administration of individual products. Awareness of fundamental differences is necessary.

The following terminology is used throughout these Guidelines to describe types of vaccines: inactivated (killed), modified-live (attenuated) and recombinant. The attributes of each vaccine type are summarized in Table 1.

Characteristics of vaccine types have been reviewed as recently as 2011.[3] All veterinary vaccines, prior to licensing, are subjected to testing for efficacy, safety, potency and purity. Testing methods may vary among different manufacturers and licensing authorities. While all licensed vaccines need to meet minimum efficacy standards, the level of protection induced can vary depending on many factors, including the method used to manufacture the product. For further information on licensing, readers should refer to the 2006 Guidelines (see box on page 786) and to individual licensing authorities (United States Department of Agriculture [USDA]; Canadian Food Inspection Agency [CFIA]; Veterinary Medicines Directorate [VMD], Department for Environment, Food, and Rural Affairs [DEFRA], UK; European Medicines Agency [EMA], EU).

The principal differences between inactivated, modified-live and recombinant vaccines are discussed below.

Inactivated vaccines Vaccinal pathogens can be completely inactivated (ie, killed) by various means, eliminating risk of replication post-inoculation or 'reversion to virulence'. For these reasons, inactivated vaccines have historically been regarded as the safest vaccines. However, the inclusion of a variety of extraneous chemicals (stabilizers, preservatives), antibiotics, adjuvants and excipient proteins has been implicated as a cause of both acute and delayed adverse reactions in cats.[4]

Modified-live vaccines For some agents, intact pathogens can be modified so that they

Table 1 Examples of different types of feline vaccines and their attributes

	Inactivated (killed)	Modified-live (attenuated)	Recombinant
Examples	Panleukopenia, herpesvirus-1, calicivirus, FeLV, FIV, *Chlamydophila*, rabies, dermatophytosis	Panleukopenia, herpesvirus-1, calicivirus, *Chlamydophila*, *Bordetella bronchiseptica*	rRabies, rFeLV
Replication following administration	Does not replicate (non-infectious)	May replicate locally and in sites beyond the inoculation site (infectious)	Does not replicate (non-infectious)
Initial vaccination, in the absence of maternal antibody *NB It is not practical to determine the persistence of MDA for individual kittens; vaccination until ≥16 weeks of age is advisable*	Two initial doses are required, 3–4 weeks apart. Protective immunity is expected within 7–10 days following the second dose. Rabies vaccine is the exception as only one initial dose is required; protective immunity is expected to develop by 28 days	Two initial doses are required, 3–4 weeks apart. Protective immunity is expected within 7–10 days following the second dose	rRabies: One dose is required. Protective immunity is expected to develop by 28 days. rFeLV: Two initial doses are required, 3–4 weeks apart. Protective immunity is expected within 7–10 days following the second dose
Route(s) of administration as stipulated by the manufacturer	Injectable: SC or IM*	Injectable: SC or IM* Mucosal: Intranasal (IN)**	Injectable: SC
Adjuvanted	Yes – the majority	Not required	Some individual products contain an adjuvant
Therapeutic indications	Dermatophytosis (in some European countries)	None	None
Reversion to virulence	Not possible	Theoretically possible, but highly unlikely	Not possible

NB Availability of different vaccines (type, antigen and route of administration) varies among countries
*The Advisory Panel recommends that when a vaccine is designed for either subcutaneous (SC) or intramuscular (IM) use, the SC route is used, both for patient comfort as well as for earlier detection of injection-site sarcomas
**Several products (two FHV-1, FCV; one FPV, FHV-1, FCV; *Bordetella;* FIP) are licensed for intranasal administration, though availability varies among countries
MDA = maternally derived antibodies, r = recombinant

retain the ability to replicate in the host and provoke an immune response, but not cause clinical disease. Altered pathogenicity effectively induces subclinical infection and can result in a more rapid onset of immunity for some vaccine antigens than with comparable inactivated vaccines.[5,6] All bacterial and viral vaccines licensed for mucosal (intranasal) administration are modified-live, as are a number of injectable vaccines.

✣ **Recombinant vaccines** Discrete genetic sequences can be isolated from a pathogenic virus or bacterium that encode immunogenic proteins. These sequences can either be recombined with the DNA of a live, non-pathogenic virus, which can then be administered as a vaccine (vectored vaccine), or they may be inserted in bacterial plasmids to enable in vitro production of antigens that can be harvested and purified for incorporation into a vaccine (ie, subunit vaccine). Examples of both types of vaccines are licensed for use in veterinary medicine.

Risk/benefit assessment

In assessing the risk for an individual cat, information about the cat, the environment and infectious agents to which the cat will be realistically exposed needs to be considered. Specifically, questions need to be asked that address the cat's lifestyle as well as the lifestyle of any other cats in the same household. Queries should also be posed regarding other sources of exposure, such as excursions outside the home, boarding and travel.

Patient

Age is an important element in assessing an individual's risk profile. Most infectious diseases are more prevalent in kittens, and kittens less than 6 months old are generally more susceptible to infection and disease than adult cats are. Kittens, therefore, represent a principal primary target population for vaccination.

MDA provide important protection for the kitten, but may also interfere with, or neutralize, vaccines. As the level of MDA varies among individuals, the age at which a kitten may be able to respond to vaccination will also vary, and in some cases may be 16 weeks or older. While information is available on the variability of MDA as pertains to FHV-1, FCV and FPV, limited data is available for other antigens; thus the role of MDA in interference with vaccination against rabies, FeLV or other pathogens is unknown. Stopping a vaccination course too early (when MDA are still interfering) is thought to be the single most common cause of vaccination failure in kittens.

Patient's environment

Population density and opportunity for exposure to other cats (eg, whether the cat is free-roaming or has access to the outdoors) are among the most critical issues affecting risk of exposure to an infectious agent. Cats and kittens living in multiple-cat households and environments (eg, boarding, breeding, foster or shelter facilities) are likely to have a substantially higher risk of infection than are cats living indoors in one- or two-cat households. Furthermore, the introduction of new cats into a household poses a potential risk – not only to the cat entering the household, but also to the whole group because of possible exposure to new infectious agents. The immunosuppressive effects of stress inherent in the change of social demographics may also result in recrudescence and an increased susceptibility to infection and disease. Conversely, cats that are naturally exposed to infectious agents after vaccination may have an opportunity for 'natural boosting of immunity' that may not be afforded to cats kept alone.

Indoor cats generally have a low risk of exposure to infectious agents, particularly where the agent in question is only transmitted by direct contact among cats. However, they may also be exposed to infection from other cats in the household (ie, subclinically infected or carrier cats), or by indirect transmission of pathogens brought in from outside on owners' clothing, shoes, etc. In theory, strictly indoor cats may be more susceptible to developing panleukopenia because they do not receive boosting through the possibility of natural exposure. It is important to ask owners about other exposure that indoor cats may have, such as supervised visits out of doors (eg, on harness/leash, in the garden, etc), visiting other cats in an apartment building, balconies or roof gardens, visiting cats that belong to other family members, and staying in boarding facilities. Fostering shelter cats alters the risk for the resident cats, both through potential direct exposure to infectious agents as well as through stress-induced immunosuppression.

Veterinarians should reassess risk factors for exposure to infectious disease at least once a year, as changes in the health of the animal or its lifestyle may dictate modifications in vaccinations needed.

Trap–neuter–return (TNR) and other special situations are discussed on pages 791–794.

Geographic distribution of infectious agents may result in substantially different risks of exposure for cats living in different areas (eg, rabies). Questions regarding future travel should be included in determining the risk of exposure to specific infectious agents. Periodic housing in boarding facilities, shelters or breeding facilities or other multiple-cat households also places cats at increased risk of exposure to a variety of infectious agents, although the risk will vary substantially between different situations.

Infectious agent

Independent agent-associated variables, such as virulence, strain variation and mutation, challenge dose and stability in the environment, influence the outcome of infection. These are difficult to assess objectively.

Recommendations for vaccination of household pet cats

Developing universal guidelines for vaccination of household pet cats is complicated by the lack of a clear definition of what is, and what is not, a 'pet cat'. What follows are reasonable recommendations, based on scientific evidence and expert advice, applicable to most cats presented to private practitioners. Differences in cat population density, introduction of new cats, and exposure risk are dynamic variables that the veterinarian must take into consideration when recommending any vaccine for any cat. It is advised that veterinarians reassess risk factors for exposure to infectious disease at each visit (at least once a year), as changes in factors such as the health of the animal or its lifestyle may dictate changes to vaccination needs.

Table 2 summarizes vaccination recommendations for household pet cats.

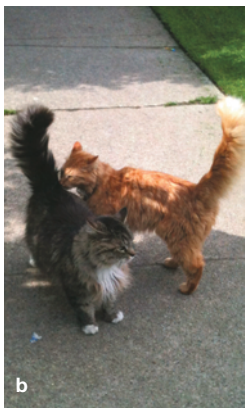


Figure 2 **Pet cats that spend any time outdoors are at greater risk of exposure to many infectious diseases compared with indoor-only pet cats.** *Images courtesy of Dr Terry Curtis (a), Dr Margie Scherk (b) and Karen James (c)*

Table 2 Recommendations for vaccination of household pet cats

Vaccine	Initial vaccination: Kittens (<16 weeks old)	Initial vaccination: Adults (16+ weeks old)	Revaccination (boosters)	Comments
Panleukopenia + herpesvirus-1 + calicivirus (FPV, FHV-1, FCV) Modified-live and inactivated. Recommended for all cats	Administer the first dose as early as 6 weeks of age, then every 3–4 weeks until 16–20 weeks of age[7–11]	Administer two doses, 3–4 weeks apart	Revaccinate 1 year after primary series; thereafter, boost every 3 years, lifelong	Modified-live and inactivated vaccines are available for parenteral administration; in some countries intranasal vaccines are also available. For cats going into boarding or another high exposure, stressful situation, a booster 7–10 days prior to boarding may be warranted, particularly if the cat has not been vaccinated in the preceding year
Feline leukemia (FeLV) Inactivated and recombinant	Administer two doses, 3–4 weeks apart, beginning as early as 8 weeks of age	Administer two doses, 3–4 weeks apart	Administer a single dose 1 year following administration of the initial two-dose series. Results of several studies indicate that FeLV vaccine-induced immunity persists for at least 12 months following vaccination.[12–14] Thereafter, the Advisory Panel recommends revaccination every 2 years for cats at low risk of infection and annually for cats at higher risk. A study by Jirjis et al suggests that DOI induced by some FeLV vaccines may last for at least 2 years.[15] Another guidelines group (European Advisory Board on Cat Diseases) recommends that for cats older than 3–4 years of age, a booster vaccination every 2–3 years is sufficient.[16] (see accompanying Disease Information Fact Sheet on FeLV – details on page 799)	Test first to verify FeLV antigen-negative status. As kittens are more susceptible to progressive FeLV infection,[17] and as the eventual environment into which a kitten will go can rarely be predicted with certainty, the Advisory Panel recommends routine FeLV vaccination for all kittens up to and including 1 year of age.[18] At-risk adult cats should continue to be vaccinated against FeLV
Rabies Inactivated and recombinant. Necessary for all cats where legally mandated or in an endemic region	Administer a single dose at not less than 12 weeks/ 3 months of age	Administer a single dose	Administer a single dose 1 year following the initial dose; then repeat annually (or every 3 years if using a vaccine licensed for this interval)	Where rabies vaccination is required, the frequency of vaccination may differ from these recommendations based on local statutes or requirements. Veterinarians should be familiar with, and adhere to, local requirements

NB Unless otherwise stipulated, all parenteral vaccines should be administered by the subcutaneous route

Additional considerations when vaccinating household pet cats

Because vaccination requirements and risk of exposure to infectious agents vary among household pet cats, individual vaccination protocols will vary. The following recommendations address some alternative situations and offer insights on vaccination of pet cats using non-core vaccines.

✣ **Vaccination of pet cats in indoor/outdoor households** Cats housed exclusively indoors generally do not require vaccination beyond the aforementioned vaccines (ie, FPV, FHV-1, FCV ± FeLV, rabies). However, in multiple-cat households where some cats are housed exclusively indoors, yet other cats are permitted outside unmonitored, the entire household may be at risk of exposure to additional agents. Veterinarians should consider recommending vaccination of the entire household for selected diseases (eg, FeLV ± rabies) if exposure risk is deemed significant.

Pet cats that spend most (or all) of their lives outdoors are at greater risk of exposure to most infectious diseases compared with predominantly indoor pet cats (Figure 2). Offsetting this is the natural boosting of immunity they may receive if they are exposed to infectious agents. Among outdoor adult cats, exposure risk for rabies, FeLV and FIV is generally higher than for indoor cats. In addition to the conventional vaccines recommended in Table 2, FIV vaccination could be considered for outdoor cats. (See accompanying Disease Information Fact Sheet on FIV – details on page 799.)

✣ **Vaccination of pet cats entering boarding facilities** Although, in general, healthy adult cats only require boosters to FPV, FHV-1, FCV vaccines every 3 years, an additional booster 7–10 days prior to boarding may be warranted (and may be required by some catteries), particularly if the cat has not been vaccinated in the previous year. Boarding may be stressful for a cat and also, depending on the cattery and the situation at the time, may lead to exposure to infectious agents. However, disease control measures vary between facilities, with many providing individual housing, sneeze barriers and good hygiene, whereas others permit co-mingling of cats, which will clearly facilitate disease

transmission. In the event that kittens must enter a boarding facility, it is recommended that they should have received at least two doses of FPV, FHV-1, FCV vaccine, with the last dose 7–10 days prior to entry. In addition, it is strongly recommended that kittens be isolated from the general population of adult cats at all times while boarding.

✣ **Vaccination during pregnancy and lactation** Vaccination of pregnant or lactating cats is generally not recommended. Whenever possible, queens should be vaccinated before breeding. Vaccines are not evaluated for use in pregnant queens unless specifically stated on the label. However, the benefits of vaccination may outweigh the risks in endemic disease situations. Modified-live FPV vaccines should not be administered to pregnant queens as this has been associated with cerebellar hypoplasia in the kittens.[19] (For a more comprehensive discussion, see 'Recommendations for vaccination of cats housed in breeding catteries', page 793.)

✣ **Overdue for vaccination** If the cat has been vaccinated previously and is overdue for revaccination (irrespective of the interval), generally a single vaccination is all that is required. If prior vaccination status is unknown, the cat should be treated as unvaccinated.

✣ ***Bordetella bronchiseptica*, *Chlamydophila felis*, FIP and FIV vaccination** For information on the use of these vaccines, see accompanying Disease Information Fact Sheets (details on page 799).

✣ **Dermatophytosis vaccination** At the time of writing, a monovalent (*Microsporum canis*) and a multivalent (*Microsporum* and *Trichophyton* species) inactivated product are licensed for the prevention and treatment of dermatophytosis in cats in some countries in Europe. None are currently available in the USA or Canada. Limited evidence exists to support the safe use of these products as part of a comprehensive treatment protocol in cats with proven infection, but little evidence is available to support their use for prevention of infection.[20,21]

Vaccination in shelters should be limited to those diseases that are likely to be transmitted within the shelter itself (notably FPV and respiratory infections).

Recommendations for vaccination of shelter-housed cats

Generally, shelter-housed cats (Figure 3) can be considered to be at especially high risk of exposure to infectious disease. Endemic disease, high rates of turnover, stress and sustained exposure are contributing factors. Vaccination in shelters should be limited to those diseases that are likely to be transmitted within the shelter itself. For diseases of concern in shelters (notably FPV and upper respiratory infections), vaccines may be indicated at an earlier age, and be administered at shorter intervals compared with schedules for pet cats. Rapid onset of protection is critical; therefore, administration of FPV, FHV-1, FCV vaccines should be considered for all cats at the time of (or ideally, before) intake.

Table 3 summarizes vaccination recommendations for shelter-housed cats.

Additional considerations when vaccinating shelter-housed cats

✣ ***Bordetella bronchiseptica* and *Chlamydophila felis* vaccination** The benefit of routine vaccination of shelter-housed cats against these disease agents is limited. The association between *B bronchiseptica* isolation and disease in shelters is inconsistent[31–34] and *C felis* is not commonly isolated from shelter cats with upper respiratory infection.[31] These vaccines should only be considered if the pathogens have been demonstrated as a current problem by laboratory diagnostics. *B bronchiseptica* vaccination should also be used where there is potential direct or indirect contact between cats and dogs on the same site, and the dogs have a recent or current history of infectious respiratory disease.

✣ **FIV and FIP vaccination** Vaccination of shelter-housed cats against these agents is not generally recommended.

✣ **Dermatophytosis vaccination** See comments in the household pet cats section.

Figure 3 Generally, cats in shelters, whether individually (a) or group (b) housed, are at especially high risk of exposure to infectious disease. *Images courtesy of UC Davis Koret Shelter Medicine Program Team Members*

For diseases of concern in shelters, vaccines may be indicated at an earlier age and administered at shorter intervals compared with schedules for pet cats.

Table 3 Recommendations for vaccination of shelter-housed cats

Vaccine	First inoculation	Subsequent inoculations		Comments
		Kittens	Adults	
Panleukopenia + herpesvirus-1 + calicivirus (FPV, FHV-1, FCV) Modified-live (use of inactivated vaccine is not generally recommended except where panleukopenia risk is low). Recommended for all cats	Administer a single dose at intake or, where possible, at least 1 week prior to shelter entry. In kittens, administer the first dose as early as 4–6 weeks of age	Revaccinate every 2–3 weeks until 16–20 weeks of age[7–10]	Revaccinate once, 2–3 weeks following administration of the initial vaccine	Recent studies show that ML SC vaccination may provide better protection in the face of MDA than inactivated vaccines do, and may protect against illness even when cats are placed in a contaminated environment soon after vaccination.[22,23] ML injectable or IN vaccines containing FPV should not be given to kittens less than 4 weeks of age due to the risk of cerebellar hypoplasia[19] or clinical panleukopenia (see Appendix 1 [Shelter FAQs] 'Are there special considerations for vaccinating and housing very young kittens in shelters?', page 803). For pregnant queens, risk of exposure versus risk of vaccination should be balanced (see Appendix 1 [Shelter FAQs] 'Should pregnant queens in shelters be vaccinated?', page 804). Inactivated multivalent calicivirus vaccines exist and may provide broader cross-protection against calicivirus infection than single strain vaccines.[24,25] Calicivirus may be more prevalent in shelters housing cats long term in group settings;[26,27] a multivalent vaccine may be preferable in this context. If FCV disease occurs in fully vaccinated cats housed in groups, changing to a product with a different vaccine strain(s) may be of benefit[27]
Intranasal herpesvirus-1 + calicivirus (IN FHV-1, FCV) Modified-live If IN* vaccination is used for control of respiratory viruses, all shelter cats over 4–6 weeks of age should simultaneously receive a SC ML FPV vaccine (with or without respiratory viral antigens)	Administer a single dose at intake or, where possible, at least 1 week prior to shelter entry. In kittens, administer the first dose as early as 4–6 weeks of age	Revaccinate every 2–3 weeks until 16–20 weeks of age[8–10]	Revaccinate once, 2–3 weeks following administration of the initial vaccine	IN vaccination may result in onset of protection as early as 4–6 days post-inoculation.[6,28] Study results have been mixed* regarding reduction in risk for upper respiratory tract infection in shelters from IN vaccination.[29,30] When using IN vaccination, use only products licensed and approved for administration by this route. Transient, mild signs of upper respiratory infection may develop following administration of vaccine by the IN route
Rabies Inactivated or recombinant	Administer a single dose at the time of entry or release from the facility, depending on risk and length of stay	As for household pet cats (Table 2). NB Rabies vaccine should not be administered to kittens less than 12 weeks/ 3 months old	As for household pet cats (Table 2)	Necessary for all cats where legally mandated or in an endemic region. For shelters adopting out virtually all cats, or where the length of stay is commonly months or longer, rabies vaccine should be administered on intake. For shelters with shorter lengths of stay or where not all cats are adopted, rabies vaccination at the time of release is acceptable. If local regulations prohibit issuance of a rabies certificate for vaccines administered at the shelter, cats should receive a rabies vaccination from a local veterinarian within 4 weeks of adoption
Feline leukemia (FeLV) Inactivated or recombinant	Administer a single dose of vaccine at the time of intake if group-housed. If group (rather than individual) housing for kittens is used, vaccinate as early as 8 weeks of age	Revaccinate with a second dose 2–3 weeks later	Revaccinate once, 3–4 weeks following administration of the initial vaccine	Unlike group-housed cats, risk of FeLV transmission is very low for individually housed cats. FeLV vaccination is recommended for cats in long-term shelters or in group-housing of unrelated cats. Vaccination is not a substitute for testing and segregation of infected cats

NB Unless otherwise stipulated, all parenteral vaccines should be administered by the subcutaneous (SC) route

*IN vaccination may provide protection against herpesvirus infection within 4–6 days, providing a hypothetical benefit in shelters.[6,28] However, results of IN vaccination for respiratory viruses in addition to parenteral vaccination in shelters are mixed, showing a modest reduction in upper respiratory disease in one shelter[29] but no difference in another.[30] Although simultaneous use of IN and parenteral vaccination is not generally tested by manufacturers and licensed for such use, there was no evidence in either study of reduced efficacy of the parenteral vaccine due to concurrent IN vaccine administration.[29,30] No information on safety was reported in these studies; however, there was no significant increase in respiratory signs within the first 7 days of administration in cats receiving the IN with the parenteral vaccine versus the parenteral vaccine alone, suggesting that vaccine-induced respiratory signs were not a significant concern. ML = modified-live, IN = intranasal, MDA = maternally derived antibodies

Recommendations for vaccination of cats in trap–neuter–return programs

Most community cats (Figure 4, ie, free-roaming unowned feral and stray cats) lack protective antibody titers against FPV, FHV-1 and rabies.[9,35] In one study, the vast majority of feral cats vaccinated once at the time of TNR surgery developed protective antibody titers against FPV and FCV by the time they were re-trapped for testing 2–3 months later, regardless of whether inactivated or modified-live vaccines were used.[35] In contrast, only inactivated vaccines resulted in a high rate of protective antibodies against FHV-1.[35]

In the same study, nearly all cats developed high antibody titers against rabies after a single dose of inactivated rabies vaccine.[35] Vaccine licensing studies have demonstrated 3–4 year DOI following a single vaccine administered to laboratory kittens. This suggests that, while the first rabies vaccine may only be recognized by regulatory agencies as valid for a single year, it is likely that vaccinated cats are protected for much longer.

It is the recommendation of the Advisory Panel that cats in TNR programs receive FPV, FHV-1, FCV and rabies vaccines at the time of surgery.

Figure 4 Community cats in TNR programs (a,b) should receive FPV, FHV-1, FCV and rabies vaccines at the time of surgery. *Images courtesy of International Cat Care*

Recommendations for vaccination of cats housed in breeding catteries

Breeding catteries are variable in size, population and the nature of available facilities. The cat population may number less than 10 individuals or more than 50. Cats of various ages and life stages are typically present and many catteries continue to house retired breeding individuals that have been neutered. Some also contain household pets that may or may not have access to outdoors. The facilities may be sophisticated enough to allow for segregation of subpopulations or all individuals may be housed together. Generally, the medical and vaccination history of the residents is well known, but some diseases, such as upper respiratory tract disease, may be endemic.

Vaccination programs for breeding catteries should be limited to those diseases that are relevant, determined by analysis of risk factors.

Vaccination programs should be limited to those diseases that are relevant to the cattery and should be determined by analysis of risk factors. When assessing the level of disease risk in catteries, factors to consider include:

- Rate of population turnover.
- Population size and density.
- Number of litters/year (Figure 5).
- Presence of endemic disease.

Transmission of infectious diseases is facilitated by group living, young kittens mixing with older kittens and adults, contact during mating, introduction of new cats, and movement of cats into and out of the cattery (eg, queens going to other catteries for breeding, return of previously sold cats, travel for cat shows or other exhibitions). Catteries assessed as low risk would be considered similar to pet homes (Table 2), whereas catteries assessed as high risk would be considered similar to shelters (Table 3), pet stores, etc. In high-risk environments, vaccines may be used at an earlier age than in pet cats, particularly for control of endemic upper respiratory tract disease.

In general, vaccination may be started at an earlier age than in the pet cat population and revaccination intervals may be shortened. Breeders should be encouraged to work with a veterinarian to develop a comprehensive wellness program that includes appropriate vaccinations for their specific situation. Vaccination records should be kept for each individual in the cattery that include all relevant information (eg, antigen, brand, date, vaccination site, adverse events, etc). Management and husbandry have an important impact on the health of individual cats in catteries. Relevant references and resources should be consulted.[36,37]

Figure 5 The number of litters produced per year in a breeding cattery is one of the key factors in determining the level of disease risk, and devising an appropriate vaccination program. *Courtesy of Betsy Gaither*

Table 4 Recommendations for vaccination of cats in breeding catteries

Vaccine	Breeding adults	Kittens	Pregnant and lactating queens
Panleukopenia + herpesvirus-1 + calicivirus (FPV, FHV-1, FCV) Recommended for all cats	**Low risk** As for household pet cats (Table 2) **High risk** Consider FHV-1 and FCV vaccination every 1–2 years. Consider ML vaccines for rapid onset of protection. Bi- or multivalent FCV vaccines may provide broader cross-protection than single strain vaccines.[24,25] If FCV disease occurs in fully vaccinated cats housed in groups, changing to a product with a different vaccine strain(s) may be of benefit[27]	**Low risk** As for household pet cats (Table 2) **High risk** ML injectable vaccine starting at 4–6 weeks, boosters every 2–3 weeks until 16–20 weeks[7–11] **Endemic upper respiratory tract disease** IN vaccination (FHV-1, FCV only) starting at 3–4 weeks for rapid onset of protection,[6] followed by injectable ML FPV, FHV-1, FCV every 2–3 weeks until 16–20 weeks. The efficacy of administering one or two drops of IN vaccine per kitten instead of a full dose is unknown and is not recommended. Avoid ML IN or injectable vaccines containing FPV in kittens less than 4 weeks of age due to the risk of cerebellar hypoplasia[19] or clinical panleukopenia. Kittens can be vaccinated around or at the time of spay/neuter surgery without compromising serologic response[8]	Whenever possible, queens should be vaccinated before breeding. However, benefits of vaccination may outweigh risks in endemic disease situations. Though not generally licensed for such use, vaccines administered early in pregnancy may protect the queen and provide enough MDA to protect kittens during the first weeks of life.[38] No increase in abortions or stillbirths was documented in one study using an inactivated vaccine in this way.[39] ML injectable or IN vaccines containing FPV should not be given to kittens less than 4 weeks of age due to the risk of cerebellar hypoplasia[19] or clinical panleukopenia. For pregnant queens, risk of exposure versus risk of vaccination should be balanced. Queens may be vaccinated during lactation if the benefits outweigh the risks

NB Unless otherwise stipulated, all parenteral vaccines should be administered by the subcutaneous route
ML = modified-live, IN = intranasal, MDA = maternally derived antibodies

Table 4 summarizes vaccination recommendations for cats in breeding catteries.

Additional considerations when vaccinating cats in breeding catteries

✣ **FeLV and FIV vaccination** Vaccination of cats in breeding catteries against these agents is not generally recommended. Vaccinate if necessary by analyzing risk, as for household pet cats and kittens (Table 2). The retrovirus status of all cats should be known: vaccination is not a substitute for testing and isolation. Vaccination may be unnecessary if a good testing program is in place and no cats have access to the outdoors.[13] If queens are routinely sent to another cattery for breeding, vaccination of breeding queens may be considered.

✣ **Rabies vaccination** Cats in breeding catteries in the USA must be vaccinated against rabies according to state regulations. Elsewhere, vaccination against rabies is not generally recommended. Vaccinate if necessary by analyzing risk, as for household pet cats and kittens (Table 2).

✣ ***Bordetella bronchiseptica* and *Chlamydophila felis* vaccination** The benefit of routine vaccination of cats in breeding catteries against these disease agents is limited. These vaccines should only be considered if the pathogens have been demonstrated as a current problem by laboratory diagnostics. When used, the primary series should be administered according to the manufacturer's instructions, with annual revaccination if the problem remains endemic. In some countries, the manufacturer states that *Bordetella* vaccination is considered safe for pregnant queens. However, in other countries, datasheets advise that the vaccine should not be used in pregnant or lactating queens or in kittens less than 1 month of age.

✣ **FIP vaccination** Vaccination of cats in breeding catteries against FIP is generally not recommended as there is insufficient evidence that the vaccine induces clinically relevant protection. (See accompanying Disease Information Fact Sheet – details on page 799.)

✣ **Dermatophytosis vaccination** See earlier comments in the household pet cats section (page 791).

It is important to report any known or suspected negative events associated with vaccination, recognizing that a temporal relationship between an event and vaccine administration does not necessarily imply causality.

Vaccine adverse events

Although the administration of biological products can never be entirely free of risk, in general currently available feline vaccines have an excellent safety record. It is important to report any known or suspected negative events associated with vaccination, recognizing that a temporal relationship between an event and vaccine administration does not necessarily imply causality. In the United States, veterinarians are requested to contact the manufacturer (Veterinary Technical Services) of the vaccine(s) considered to be involved; veterinarians may also report known or suspected adverse events directly to the US Department of Agriculture. In other countries procedures may vary, but, in general, veterinarians should contact the manufacturer and notify the appropriate regulatory agency to report a vaccine adverse event (eg, the Canadian Centre for Veterinary Biologics [Canada]; the Veterinary Medicines Directorate [UK]; the European Medicines

Pre-vaccination testing

FeLV and FIV

The retrovirus status of all cats should be known and this is important if administration of FeLV or FIV vaccines is being considered.[18] There is no recognized clinical benefit in administering vaccine against the retrovirus a cat is infected with, nor are there any known harmful effects. However, when the true retrovirus status of a vaccinated and infected cat eventually becomes known, not having known the cat's status before vaccination could result in questions about failure to recommend testing before vaccination and vaccine efficacy.

Use of serology

The use of serology (serum antibody titers) to assess protective immunity has been reviewed.[1,40,41] It is important to be aware that a variety of methods (immunofluorescence assay, ELISA, virus neutralization, haemagglutination inhibition, etc) are utilized to determine titers. The methodology used may not be reported with the test results. Titer results in individual cats determined at the same point in time, therefore, may vary depending on the methodology used. When electing to submit serum for antibody titers, it needs to be appreciated that a 'positive' antibody titer result obtained on one day is not necessarily predictive of a 'positive' titer at any point in the future.

In general, cats having a 'positive' antibody titer against FPV are immune. In fact, the protective immunity that develops following FPV vaccination is expected to be sustained for several years. By contrast, serum antibody titers for FHV-1 and FCV may not necessarily correlate well with protective immunity and should not be used to predict protection in the future. Antibody titers to FeLV and FIV do not correlate with immunity and should not be used to determine the need for vaccination. Although feline rabies titers can be determined (by a certificated laboratory) in individual animals, a rabies titer is only an indication of serological response to vaccination. Rabies titers are not recognized as an index of immunity.

In addition, the absence of significant levels of antibody (a 'negative' titer) is not necessarily an indication of susceptibility. For example, a previously vaccinated cat may, over time, lose antibody. Immunologic 'memory', however, may prevail. In the event this individual is exposed to a virulent virus, a rapid anamnestic and protective response could result. In some diseases (eg, FHV-1), cell-mediated immunity is important and a cat may be immune even though no antibodies are detectable.

Because antibody titers may not reliably correlate with, or predict, the degree of protection or susceptibility for an individual cat, the Advisory Panel recommends employing defined revaccination intervals rather than measuring antibody titers to assure protection.

Because antibody titers may not reliably correlate with, or predict, the degree of protection or susceptibility for an individual cat, the Advisory Panel recommends employing defined revaccination intervals to assure protection.

Agency [EU]. (See Appendix 1 [Adverse Event FAQs] on page 805 for specific reporting forms and instructions.)

The most commonly reported vaccine reactions are lethargy, anorexia and fever for a few days after vaccination, or local inflammation at the site of injection.[4,42,43] Rarely anaphylaxis is seen. Because vaccines are biologically active products, occasional adverse reactions associated with vaccination are inevitable. It should be recognized, however, that establishing causality is often difficult, especially if the suspected reaction is delayed (days or weeks).[43]

Prevalence and type of adverse reactions

Although post-vaccinal adverse events in cats are considered rare, the true prevalence is likely to be underestimated due to underreporting by both veterinarians and owners.[44] In the most substantial survey to date, adverse reactions were reported for all cats presented to Banfield Pet Hospitals in the United States between 2002 and 2005.[4] During this period, more than 1.25 million doses of various vaccines were administered to nearly 0.5 million cats. Adverse reactions within 30 days of vaccination were reported at a rate of 51.6/10,000 cats vaccinated (0.52%), with 92% of these reactions occurring within the first 3 days. Clinical signs described for 1699 of 2560 cats with vaccination-associated adverse events included lethargy (± pyrexia) in 54%, local pain or swelling at the vaccine site (25%), vomiting (10%), facial or periorbital edema (6%) and generalized pruritus (2%). Death was reported in four cats, and in at least two of these it was attributed to anaphylaxis.

Although the vaccines used were predominantly from one manufacturer, no vaccine type was found to be significantly more likely to cause local reactions. Administration of multivalent FPV, FHV-1, FCV and *Chlamydophila* vaccines was significantly more likely to be associated with lethargy (± pyrexia) than administration of vaccines without the *Chlamydophila* component. The risk of an adverse reaction was greatest in cats around 1 year of age and/or increased as the number of vaccines administered concurrently increased.[4] In another extensive study specifically investigating local post-vaccine reactions, a prevalence of 0.23% was reported.[45] Previous large

Suggested approach to the treatment of anaphylaxis

- Place intravenous catheter
- Administer epinephrine (adrenaline): 0.1 ml of a 1:1000 dilution IV
- Administer 20–30 ml/kg balanced isotonic crystalloid by slow infusion over 10 mins
- Provide oxygen
- Administer an H_1-blocker: eg, diphenhydramine, 2 mg/kg IM or IV
- Administer soluble glucocorticoid: eg, methylprednisolone sodium succinate, 30 mg/kg IV

studies have suggested adverse vaccine reaction rates of around 1–3%,[46–48] but some variation in prevalence can be expected with the use of different products, administration of multiple vaccines at the same appointment, and surveillance methods.

Hypersensitivity reactions

Anaphylaxis and allergic reactions

Anaphylaxis is perhaps the best characterized immune-mediated hypersensitivity (type I) reaction to vaccination, but it is rare (approximately 1–5/10,000 vaccines).[4,46] In cats it may manifest as vomiting, diarrhea, respiratory distress, facial or generalized pruritus, facial swelling and collapse.[1,43,49]

A careful risk assessment is needed when considering the revaccination of cats with a history of anaphylaxis. In cats that have experienced an allergic reaction with true anaphylaxis, revaccination should usually be avoided. Vaccine excipients (inactive ingredients) are thought to cause most type I hypersensitivity reactions.[4] Hence, where revaccination is considered necessary, using a different vaccine formulation and premedicating with an antihistamine and glucocorticoids 20–30 mins prior to vaccine administration is recommended, followed by close observation of the patient for several hours.[1,4]

Depending on geographic location, the requirement to vaccinate cats for rabies may take precedence over medical considerations. Veterinarians are urged to contact the appropriate authorities to determine what the local status is when concerns arise and whether the individual may be excused from vaccination. (See also 2006 Guidelines, Appendix 1: Certificate of Exemption from Rabies Vaccination – details on page 786.)

Other reactions

While other forms of hypersensitivity reactions (types II, III and IV) almost certainly occur in cats after vaccination, these are rarely documented. Some forms of local reaction probably reflect type IV reactions. Polyarthritis is occasionally seen after FCV vaccination. Rarely it may represent a form of type III reaction, but it is mainly due to co-infection with field virus or vaccine virus itself.[50,51] (See Appendix 1 [General FAQs] 'What is the cause of lameness occasionally seen after FCV vaccination?', page 802.)

Update on feline injection-site sarcomas (FISS)

Vaccine-associated sarcoma was first recognized as an issue in cats in the early 1990s. While initial studies suggested a risk of sarcoma development in around 2/10,000 doses of vaccine administered,[52] which increased to 13–36/10,000 doses in other studies,[53–55] current estimates based on larger epidemiologic studies (published between 2002 and 2007[4,45,56]) suggest that the risk of sarcoma development following vaccination is actually very low (probably well below 1/10,000 doses of vaccine).[4,45]

Although initial reports linked development of sarcomas at vaccination sites with the use of inactivated rabies[57] or FeLV vaccines,[52] and aluminum-based adjuvants, more recent studies found no relationship between vaccine type, brand or use of inactivated versus modified-live vaccines and the risk of subsequent sarcoma formation.[56,58,59] The impact of using the canarypox-vectored rabies vaccine is still unclear. One retrospective study of histopathology samples showed no reduction in the prevalence of FISS after the introduction of this vaccine; however, the types of vaccine used were not reported.[58] In a recently published case control study it was suggested that there may be a lower risk of inducing sarcomas with this vaccine than with other rabies vaccines.[59] Many of these studies have also clearly shown that injections other than vaccines also have the ability to induce sarcoma formation.

No studies have been published that define objective methods for reducing the risk of FISS in individual cats presented for routine vaccination. Based on our current understanding of this problem, it is likely that vaccines are not uniquely implicated in the development of injection site sarcomas in cats.[56,60] FISS risk following vaccination likely results from a complex interaction of multiple extrinsic (eg, frequency and num-

Figure 6 **While vaccines are not uniquely implicated in sarcoma formation, there are certain actions that can be taken to reduce the risk of FISS, as summarized in Table 5.** *Courtesy of Albert Lloret*

Table 5 Summary of considerations and management options for FISS risk reduction

Action suggested	Objective	Comments
Recommend/administer vaccines on the basis of reasonable risk for exposure to the infectious pathogen	To avoid unnecessary vaccination of cats	Studies have suggested that the risk of FISS increases as the number of vaccines received over time increases[37,62–64]
Administer vaccines only as frequently as needed to provide protective immunity	To avoid unnecessary vaccination of cats	Administer FPV, FHV-1, FCV no more often than every 3 years, except in high-risk situations[1,63]
Administer parenteral feline vaccines by the SC route only	To facilitate early detection of tumor	Vaccine administered by the IM route does not reduce the risk of tumorigenesis and may delay the detection of a mass located within muscle (vs skin). It is recommended that all parenteral vaccines be administered by the SC route[65]
Use recommended vaccination sites	To facilitate complete tumor removal by limb amputation in the event that FISS develops	See vaccination site recommendations on page 798
Consider vaccine type	To reduce the risk of chronic local inflammation at the injection site, which may occur in some cats[56]	The role of adjuvants (including those containing aluminum) and local inflammation in the pathogenesis of FISS is not clear.[52,57,61,64–68] Both adjuvanted and non-adjuvanted vaccines induce local inflammation, although the magnitude and type of inflammation varies among vaccines, adjuvants and individual cats. However, some authors recommend considering non-adjuvanted vaccines to try to reduce local inflammation[61]
Biopsy of a post-vaccination 'lump': the '3-2-1 rule'	To establish the presence or absence of malignant tumor formation as early as possible	Perform an incisional (vs excisional) biopsy if a lump: (a) persists for 3 months or longer after injection; or, (b) ever becomes larger than 2 cm in diameter; or, (c) continues to increase in size 1 month after injection[58]
Perform additional assessment pre-surgically when FISS is confirmed	To evaluate the feasibility of attempting definitive treatment	Tumors are locally aggressive; thoracic metastasis occurs in over 25% of cases. Thorough pre-surgical evaluation of individual cases, including physical and laboratory assessment, thoracic radiography and other imaging as indicated, is recommended prior to surgical excision[63,69,70]
Remove tumor surgically	To completely excise the tumor	Surgery offers the best opportunity for cure. Radical surgery is usually required to prevent recurrence. Local excision ('lumpectomy') of FISS is not recommended. In addition to surgery, radiation therapy and/or chemotherapy may be recommended based on consultation with an oncologist[71–75]

FISS = feline injection-site sarcoma, SC = subcutaneous, IM = intramuscular

ber of vaccines administered over time, composition of the injected product, etc) and intrinsic factors (eg, genetic predisposition, tissue response following injection, etc). The presumed relationship between types of vaccine, inflammation at the site of vaccination[61] and subsequent FISS development appears complex at best and, if involved, is likely only one among many factors that contribute to FISS development.

Table 5 provides a brief review of considerations and management options for the reduction of FISS risk, taken from current publications. None of these suggestions are known to prevent or cure FISS.

When considering vaccine type, the Advisory Panel recommends that the following be taken into consideration. Recent studies demonstrate that all vaccines carry some risk of inducing FISS, as do at least some other injectable products. Although current information as outlined above does not clearly show differences in risk of FISS development between modified-live and inactivated vaccines, some Advisory Panel members consider that, on balance, risk might be mitigated by the use of modified-live vaccines. There are also other factors that may influence the choice of live versus inactivated vaccines (see Table 6 and Appendix 1 [General FAQs],

Table 6 Indications for the use of inactivated vaccines in cats

Indication	Objective	Comment
Vaccination of pregnant queens	To avoid the risk of fetal/neonatal infection with ML FPV	ML FPV may replicate in cerebellar tissue of fetal and/or neonatal kittens, leading to clinical signs associated with cerebellar hypoplasia[19]
Vaccination of cats known to be retrovirus positive	To avoid unlikely, but potential consequences of exposing an immune-suppressed cat to ML, replicating vaccine virus	The risks associated with administering ML vaccine virus to an immune-suppressed (retrovirus-positive) cat are unknown
High-density housing environments where upper respiratory infections are not known to be present	To avoid the risk of accidental or inadvertent oral/nasal exposure to ML FHV-1 and FCV vaccines	ML FHV-1 and FCV vaccine virus, if inadvertently aerosolized or inoculated by the oral or nasal routes, may cause upper respiratory signs associated with vaccine virus replication on mucosal surfaces
Rabies vaccine: when 3-year DOI is indicated or required	To provide licensed 3-year DOI	The only rabies vaccines currently licensed to provide 3-year DOI are inactivated vaccines

ML = modified-live, DOI = duration of immunity

page 803). Overall, however, the Advisory Panel concluded that, at the current time, there is insufficient information to make definitive recommendations to use particular vaccine types to reduce the risk of FISS.

Post-vaccination monitoring

The Advisory Panel recommends that clinicians and their staff instruct clients to monitor the vaccine site for swelling or lumps in order to detect potential sarcomas while they may still be removed successfully. Biopsy of any mass present is warranted if it (a) remains present 3 months after vaccination; (b) is larger than

Injectable vaccine administration

Vaccination site recommendations

There is a lack of clinical information to make evidence-based vaccine site recommendations. The majority of safety and efficacy data comes from licensing studies in which vaccines are administered subcutaneously in the interscapular region. Due to concerns of potential sarcoma development, practitioners may consider giving vaccines in other locations. Current research indicates that radical surgical resection of injection-site sarcomas, including margins of 5 cm when possible, is associated with the highest response rate and long-term survival.[75] A 2009 paper reported an increase in lateral abdominal injection-site sarcomas since the publication of the Vaccine-Associated Feline Sarcoma Task Force vaccination recommendations in 1996.[76]

The Advisory Panel recommends, as in the 2006 Guidelines, that veterinarians administer:

- FPV, FHV-1, FCV vaccines below the right elbow (Figure 7).
- FeLV vaccines below the left stifle (Figure 8).
- Rabies vaccines below the right stifle (Figure 9).

Vaccines should be administered as low on the leg as possible. Caution is warranted when vaccinating cats resting in a crouched position as this may result in inadvertent injection of the skin fold of the flank. Veterinarians should note that data on the safety and efficacy of administering vaccines in very distal limb locations are lacking. Figure 10 shows recommended vaccination sites, as well as sites to avoid.

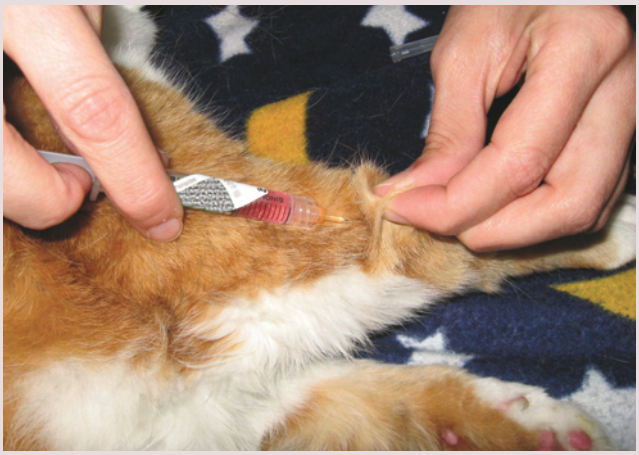


Figure 7 Administration of FPV, FHV-1, FCV vaccine subcutaneously below the right elbow. *Courtesy of Dr Susan Little*

Figure 8 Administration of FeLV vaccine subcutaneously below the left stifle. *Courtesy Dr Susan Little*

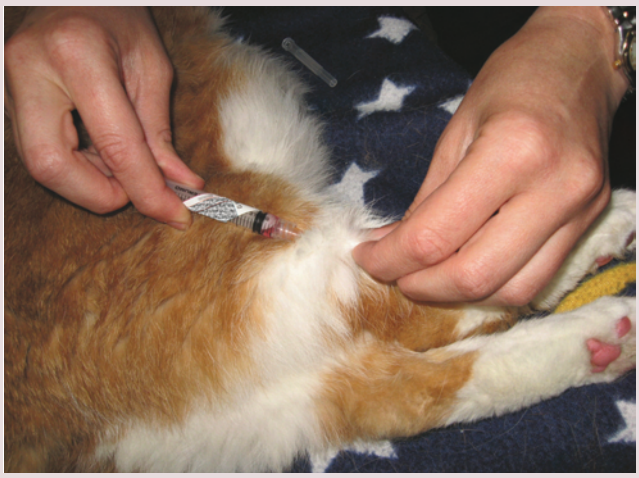


Figure 9 Administration of rabies vaccine subcutaneously below the right stifle. *Courtesy Dr Susan Little*

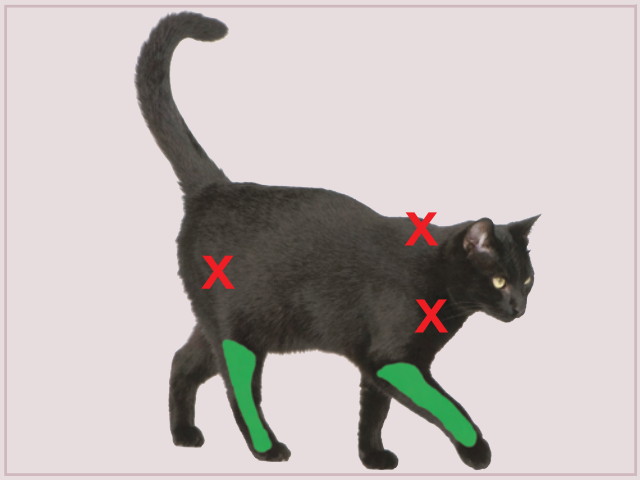


Figure 10 Regions indicated in green are recommended. Those in red are key sites that should be avoided. *Image ©iStockphoto.com/GlobalP*

Abbreviations used in the Report and Disease Information Fact Sheets

AAFP	American Association of Feline Practitioners
ADE	Antibody-dependent enhancement
APHIS	Animal and Plant Health Inspection Service
CPV-2	Canine parvovirus type 2
CVB	Center for Veterinary Biologics
DOI	Duration of immunity
ELISA	Enzyme-linked immunosorbent assay
EMA	European Medicines Agency
FCoV	Feline coronavirus
FCV	Feline calicivirus
FECV	Feline enteric coronavirus
FeLV	Feline leukemia virus
FHV-1	Feline herpesvirus-1
FIP	Feline infectious peritonitis
FIPV	Feline infectious peritonitis virus
FISS	Feline injection-site sarcoma
FIV	Feline immunodeficiency virus
FPV	Feline parvovirus
FPV, FHV-1, FCV	Three-way panleukopenia + herpesvirus 1 + calicivirus vaccine (often referred to in North America as FVRCP)
IA	Inactivated [vaccine] (also known as killed)
IM	Intramuscular
IN	Intranasal
ISFM	International Society of Feline Medicine
IV	Intravenous
MDA	Maternally derived antibodies
ML	Modified-live [vaccine] (also known as attenuated)
r	When preceding a vaccine, denotes a recombinant vaccine (eg, rRabies)
SARSS	Suspected Adverse Reaction Surveillance Scheme
SC	Subcutaneous
TNR	Trap–neuter–return
URD	Upper respiratory tract disease
USDA	United States Department of Agriculture
VMD	Veterinary Medicines Directorate
VS-FCV	Virulent systemic feline calicivirus

Rabies vaccination of cats

Where rabies vaccination of cats is required, veterinarians may not have discretion to vary from the manufacturer's recommendations or from requirements set forth by regulatory agencies. Rabies vaccination requirements vary from country to country and can vary significantly within individual countries. In locations where feline rabies vaccination is required by law, veterinarians are obligated to be familiar with and follow legal requirements when administering rabies vaccines. Rabies vaccination recommendations contained in these Guidelines do not constitute vaccination requirements.

Medical record documentation of vaccination

At the time of vaccine administration, the following information should be recorded in the patient's permanent medical record:

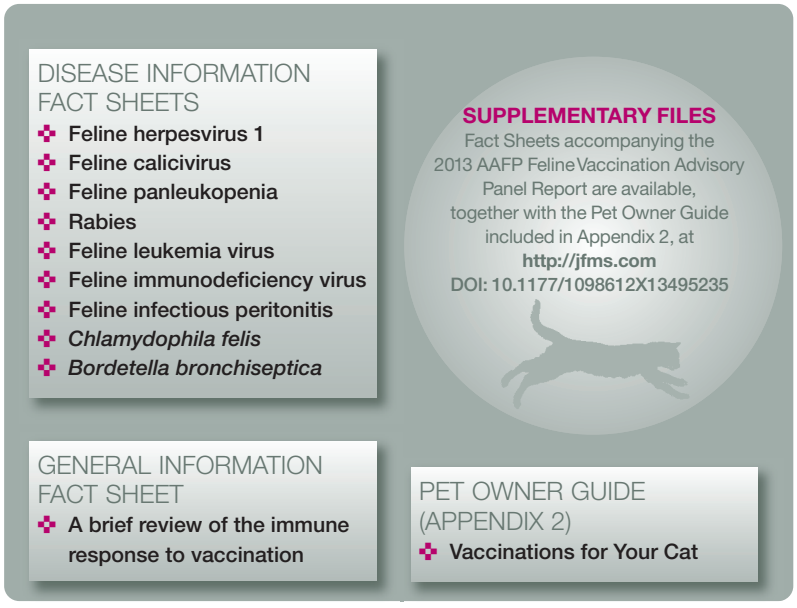
- Vaccine(s) recommended for this patient.
- Date of vaccine administration.
- Identity (name, initials or code) of the person administering the vaccine(s).
- Vaccine name, lot or serial number, expiration date, and manufacturer of vaccine(s) actually administered.
- Site and route of vaccine administration.
- Concurrent medications/therapy.
- Recommendations for future vaccinations.

Adverse events should be recorded in a manner that will clearly alert all staff members during future visits. Risks and benefits of vaccination should be discussed with the owner so that they can make an informed choice. Consent should be documented in the medical record to demonstrate that relevant information was provided to the client and that the client authorized the procedure.

2 cm in diameter; or (c) is increasing in size 1 month after vaccination (the '3-2-1 rule' – see Table 5). It is recommended that multiple needle biopsies or an incisional wedge biopsy are obtained to reduce the risk of harvesting non-representative biopsy material and to minimize the risk of tracking tumor cells outside of the future surgical field.

Legal considerations associated with vaccination

Veterinarians in most countries are permitted to use professional judgment in the selection and use of licensed vaccines. Reference to these Guidelines, therefore, is appropriate when developing vaccination protocols for individual patients even though the guidance may vary from the manufacturer's label recommendations or data sheet (eg, annual revaccination vs triennial revaccination for core vaccines).



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Conflict of interest

RBF consults with IDEXX Laboratories (Westbrook, ME), Merial Ltd (Duluth, GA) and Elanco (Greenfield, IN). RMG is a co-investigator on a project funded by MSD. KFH runs a shelter medicine residency program at UC Davis sponsored by Boehringer Ingelheim. JKL has worked with various pharmaceutical, vaccine and diagnostic test companies over the years to complete research studies, student and house officer training, to present at veterinary conferences, and to serve on expert advisory panels.

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Appendix 1: Frequently asked questions

General FAQs

What is the optimal interval between vaccines?
The minimum vaccination interval during the primary series is 2 weeks, and the maximum recommended interval is 4 weeks. Kittens presented 6 weeks or longer following administration of the previous dose of vaccine should receive at least two doses of vaccine, 3–4 weeks apart. Although feline-specific data do not exist, extrapolation from mice and humans suggests that a 3-week interval is optimal for induction of memory T cells after administration of a modified-live virus.[1,2]

When should kittens be vaccinated?
The primary vaccination series in kittens is scheduled between 6 and 16 weeks of age; vaccines should be administered at an interval of 3–4 weeks. Under high-risk circumstances (eg, in shelters and catteries with endemic upper respiratory tract disease or panleukopenia risk), vaccination may begin as early as 4–6 weeks of age and be repeated every 2–3 weeks until 16 weeks of age.

How often should senior/geriatric cats be vaccinated? How should I vaccinate cats with stable chronic disease?
Whether older cats respond to vaccination in the same manner as younger animals do is inadequately studied.[3] In the absence of data, the Advisory Panel recommends that healthy older cats and those with chronic but stable disease conditions receive vaccines in the same manner as younger adults. Less frequent vaccination is not advised due to inherent immunosenescence. Further, more frequent immunization is not warranted in aged patients with a lifelong history of immunization as data from other species suggests the memory response remains intact throughout life and protective immunity can be effectively maintained between boosts.[4–6]

Should cats be vaccinated against rabies in areas where it is not required by law?
With the exception of Hawaii, cats in all of the states of the United States and cats in all countries or counties with endemic rabies of any species should be vaccinated against rabies, even if not required in that jurisdiction.

Should I vaccinate immunocompromised cats?
Patients with impaired immune responses, either due to infection with FIV/FeLV or the use of immunosuppressive therapies, are at increased risk of infection and may be candidates for vaccination. Although there is limited feline-specific data, inactivated vaccines are generally regarded as safer in patients with underlying immunosuppression.[7] Because immune responses are hampered in immunocompromised patients, vaccination should ideally be updated before immunosuppressive therapies are started. Retrovirus-infected cats should not be vaccinated against the retrovirus they are infected with.

Should I vaccinate a kitten or cat with mild illness such as chronic upper respiratory tract infection or diarrhea?
In kittens and cats with mild illness, vaccination does not need to be delayed if the patient is eating and is not febrile. Should the illness be severe enough to result in fever or significant inappetence, vaccination should be delayed until these clinical signs have resolved. If the interval between vaccinations is delayed to greater than 6 weeks in primary immunizations, the series should be re-initiated. (See Shelter/Trap–Neuter–Return FAQs, pages 803–804, for alternate recommendations for those settings.)

Does it matter if the brand of vaccine used for revaccination is different from the brand administered previously?
While there are no studies comparing all vaccines for a particular antigen (or group of antigens), based on the available information the Advisory Panel believes that, subsequent to the initial series, booster vaccinations do not have to be of the same brand or vaccine type.

Can a parenteral FPV, FHV-1, FCV vaccine that is meant to be administered via the subcutaneous route be administered intranasally?
No, nor should it be administered by any other mucosal route. It will not stimulate an appropriate immune response and may cause clinical disease.

What is the cause of lameness occasionally seen after FCV vaccination?
In most cases, the lameness and pyrexia are due to coincidental infection with field feline caliciviruses, though a small proportion may be due to vaccine virus itself.[8,9] There is also some evidence of immune complex formation in the joints of cats infected with some strains of feline calicivirus,[10,11] but this is likely to be an uncommon cause of lameness after vaccination.

How useful are the dermatophyte vaccines available in some European countries?
Dermatophyte vaccines have been marketed for years, but scientific studies to prove their efficacy have been unsatisfactory. Although some fungal vaccines may improve clinical signs compared with placebo, there does not seem to be a difference in infection rate between vaccinated and unvaccinated cats, and reliable protection has not been documented.[12,13]

Is it safe to mix and administer vaccine from one manufacturer with vaccine from another manufacturer?
No. Only vaccines from the same manufacturer, and only when stipulated on the product label/data sheet, may be mixed in the same syringe and administered simultaneously. Mixing vaccines from different manufacturers in the same syringe at the same time carries significant risk that one product (due to such factors as pH, osmolality, etc) may rapidly and completely inactivate the immunogenic antigen in the other product, or even in both products.

For this reason, it is recommended that when administering

vaccine from two different manufacturers to the same patient at the same appointment, separate inoculation sites should be selected (eg, left side vs right side).

How long is a vaccine stable for after being reconstituted?

Vaccines should always be stored and handled according to the manufacturer's instructions. After reconstitution, a vaccine should ideally be used immediately, but certainly within 1 hour.

Should the skin be disinfected before administering a vaccine?

No, the disinfectant could potentially inactivate modified-live vaccine antigens. Cleaning and reusing of syringes is discouraged for this reason, as well as the risk of contamination.

Under what circumstances might an adjuvanted vaccine be preferable to vaccines that do not contain added adjuvants?

There are a number of factors that may play a role in the causation of FISS. Although initial reports linked development of sarcomas at vaccination sites with the use of inactivated vaccines and aluminum-based adjuvants, recent studies show that all vaccines carry some risk of inducing FISS, as do at least some other injectable products.

Although current information does not clearly show differences in risk of FISS development between modified-live and inactivated vaccines, some Advisory Panel members feel that risk might be mitigated by the use of modified-live vaccines. However, overall the Advisory Panel concluded that, at the current time, there is insufficient information to make definitive recommendations to use particular vaccine types to reduce the risk of FISS.

There are indications for using an inactivated vaccine. The risks and benefits should be discussed fully with the client. Some examples of situations where this might be considered are given in Table 6 of the Guidelines (page 797).

Shelter FAQS

Are there special considerations for vaccinating and housing very young kittens in shelters?

It is preferable that kittens younger than 8 weeks of age be kept in foster care in clean homes. Interference from MDA and lack of immune competence has a negative impact on the ability of vaccines to induce a protective immune response, and kittens placed in shelters are at high risk of disease. If kittens younger than 8 weeks of age must be kept in shelters, they should be kept in areas isolated from the general population. When challenge dose is high and exposure is unavoidable, FHV-1 and FCV intranasal or injectable vaccines may be administered to kittens younger than 4–6 weeks of age. Some facilities administer one or two drops of intranasal vaccine rather than the entire dose to each kitten. However, unless specifically stated on the label, manufacturers have not evaluated the safety and efficacy of these vaccines when used in this manner, nor have such practices been independently evaluated. As such, use of a partial dose is not recommended. As in older cats, signs of upper respiratory disease may be caused by the vaccine. Nonetheless, in environments with endemic upper respiratory disease where the risk of serious disease is high, the benefits of vaccinating in this manner may outweigh the risks.

Injectable or intranasal modified-live FPV vaccine may cause cerebellar hypoplasia if administered to kittens prior to 4 weeks of age.[14] Kittens in high-risk shelters should, therefore, be vaccinated with a modified-live, injectable FPV vaccine no earlier than 4–6 weeks of age. Vaccination should be repeated every 2–3 weeks until 16–20 weeks of age. The shorter end of the inter-vaccination interval and earlier age of first vaccination is appropriate when risk of infectious disease is high, such as during an outbreak or in a known contaminated environment.

Are there any special vaccine considerations for cats living long term (months or years) in shelters or sanctuaries?

Cats entering a long-term care facility (or any cat for which a long-term shelter stay is anticipated) should be vaccinated against rabies at the time of admission, unless in a rabies-free region. FeLV vaccination is recommended for cats that will be group housed, with the two vaccine primary series ideally completed prior to placement in group housing. Other non-core vaccines (ie, other than FPV, FHV-1, FCV) should be considered as for household pet cats (see Table 2, page 790), depending on risk profile. In the event that a cat resides in the facility for a sufficiently long period to justify booster vaccination, it is recommended that the same schedule for revaccination be followed as is recommended for pet cats. There is no indication for more frequent vaccination in a long-term shelter facility with a stable population. Cats in long-term care facilities are at increased risk of calicivirus infections. Use of dual- or multi-strain calicivirus vaccines in such facilities may be indicated. If FCV disease occurs in fully vaccinated cats, changing to a product with different vaccine strain(s) may be beneficial.

Are vaccine recommendations different for shelter cats that are ill or injured?

The great majority of shelter kittens and cats should be vaccinated regardless of physical condition. If the cat's immune system is so weakened that a modified-live vaccine will induce disease, exposure to the wide variety of infectious pathogens present in most shelters will very likely be fatal. In general, if a cat cannot be safely vaccinated, it cannot safely remain in an animal shelter except in strict isolation. Cats that were injured or ill at the time of initial vaccination should be revaccinated when healthy (no sooner than 2 weeks after recovery).

Should pregnant queens in shelters be vaccinated?

In general, vaccines are not licensed for use in pregnant queens unless specifically stated on the product label. The use of modified-live vaccines in naive queens (ie, those that have never been naturally exposed or vaccinated) during pregnancy is particularly not recommended due to potential adverse effects of FPV on developing fetuses.[15] Nonetheless, the likelihood of exposure to FPV is very high in many shelters, and infection may result in the death of the mother as well as her offspring. Therefore, the risks posed by modified-live vaccination must be weighed against the risks of not vaccinating (ie, maternal, fetal or neonatal infection and death). When pregnant queens are being placed into shelters where FPV exposure is likely, the Advisory Panel believes that the overall benefits of modified-live FPV vaccination outweigh the risks and are preferable in the shelter environment due to the more rapid onset of protection. (See also Tables 3 and 6, on pages 792 and 797, respectively.)

Vaccination against FHV-1 and FCV during pregnancy may actually be beneficial for both mother and offspring, although vaccines are not actually licensed for such use. Vaccines administered early in pregnancy will not only protect the mother, but may provide the offspring with higher levels of MDA to protect them during the first few weeks of life. Reduced morbidity and mortality from feline upper respiratory infection was seen in kittens born to queens vaccinated with an inactivated vaccine against FHV-1 and FCV during early pregnancy, compared with offspring of queens not vaccinated during pregnancy. There was no increase in abortions or stillbirths associated with this practice.[16]

Should previously vaccinated cats receive booster vaccines at the time of shelter intake?

In theory there is no reason to administer vaccines at the time of shelter admission if clear documentation of previous vaccination within the timeframe recommended by these Guidelines can be provided. An exception may be for the respiratory viruses (FHV-1 and FCV). While protection generally persists for 3 years,[17] the degree of protection may wane over time. It may be helpful to revaccinate cats for FHV-1 and FCV if they have not received a vaccine in the previous year. If there is any question about the vaccine history, re-administering vaccines is preferable to reliance on uncertain records.

Should cats be vaccinated even if most of them are likely to be euthanased a few days after intake?

Yes, the primary reason to vaccinate cats in high-euthanasia shelters is to prevent the development of endemic FPV transmission. Protection against FPV develops in a high proportion of cats within the first few days of vaccination (if there is no MDA interference). Vaccinating all cats at intake is associated with a decreased risk of widespread FPV outbreaks.

Should cats be vaccinated on intake even if they are stray and, therefore, not the property of the shelter?

Yes, stray cats should be vaccinated on intake. Many community cats have no antibodies to protect against serious illness;[18,19] thus, the benefit of vaccination for population and individual health generally greatly outweighs the risk of vaccination. To decrease risks associated with vaccination, antigens and vaccines should be limited to those that present a threat in a given shelter environment, and the clinical signs and procedure for responding to an adverse vaccine reaction should be prominently posted in all areas where vaccines are administered.

Does performing spay/neuter surgery at the time of vaccination diminish immune responses?

Kittens sterilized a week before, a week after, or at the time of vaccination had similar antibody titers to kittens that were vaccinated without surgery.[20] Anesthesia and surgery do not appear to impede serological responses to vaccination.

Trap–neuter–return FAQs

Does the susceptibility of feral cats to common infectious diseases justify investment in vaccination during trap–neuter–return programs?

The majority of feral cats admitted to one TNR program lacked protective antibody titers against FPV, FHV-1 and rabies.[18] The fact that some cats were seropositive suggests that this population of cats was exposed to infectious diseases and would benefit from immunization.

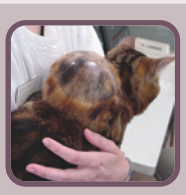
Are feral cats that receive only a single vaccination during the stressful experience of trapping and neutering effectively immunized?

The vast majority of feral cats vaccinated at the time of surgery developed protective antibody titers against FPV-1 and FCV by the time they were re-trapped for testing 2–3 months later, regardless of whether inactivated or modified-live vaccines were used.[18] In contrast, only inactivated vaccines resulted in a high rate of protective antibodies against FHV-1. Nearly all cats developed high antibody titers against rabies after a single dose of inactivated rabies vaccine.

How long does a single rabies vaccine protect feral cats against infection?

Although there are no reports of long-term evaluation in feral cats, vaccine licensing studies have demonstrated 3–4 year DOI following a single vaccine administered to laboratory kittens. This suggests that while the first rabies vaccine may only be recognized by regulatory agencies as valid for a single year, it is likely that vaccinated cats are protected for much longer. It is recommended that TNR programs offer vaccine booster services for community cats.

Adverse event FAQs



What constitutes a vaccine adverse event and what should I advise clients to watch for?

Vaccines are biological products that stimulate a series of complex immune reactions that may manifest transient side effects for up to 2 or 3 days following vaccination. It is rare that these self-limiting side effects escalate into serious adverse events. It is advisable to inform clients that their cat may experience reduced appetite or loss of appetite (lasting for two meals), pain at the injection site, lethargy, reluctance to play/walk/run, or mild fever. Treatment is seldom required.

Clients should contact the veterinary practice should any physical or behavioral effects worsen or continue beyond 2–3 days. In the rare event that signs of systemic illness (such as vomiting, diarrhea, seizures, facial swelling, collapse or difficulty breathing) develop, the owner should contact the veterinary practice immediately.

How do I report a vaccine adverse event?

The Advisory Panel strongly encourages veterinarians to report all known or suspected vaccine adverse events to the manufacturer and the appropriate regulatory agency responsible for monitoring post-vaccinal adverse events (see details below).

Am I legally required to report vaccine adverse events?

There is no legal mandate to report post-vaccinal reactions in the USA, Canada or the European Union.

Am I legally liable for using a protocol based on my patient's risk that differs from the one on the vaccine insert?

Continuous medical decision-making is an inherent aspect of veterinary medicine. There is no reason to believe that decisions regarding vaccine selection and use will carry any greater legal risk than the myriad other medical decisions made in daily practice. Relative risk for utilizing these Guidelines in developing patient vaccination protocols is considered low. Some of the recommendations included in the 2013 AAFP Feline Vaccination Advisory Panel Report will differ from the manufacturer recommendations published in the product package insert/label. However, in most countries, veterinarians in small animal practice have considerable discretion in exercising their judgment relative to the selection and use of licensed veterinary biological products within their professional practice. Rabies vaccination is the obvious exception – veterinarians are required to follow local laws. (Continued on page 806)

Vaccine manufacturer

Known or suspected adverse events should first be reported to the technical services staff of the vaccine manufacturer. If multiple vaccines from different manufacturers were administered at the same time, reports should be submitted to each manufacturer.

Although vaccine manufacturers are required to maintain adverse event reports, they are not required to disclose that information. They are under no obligation to offer compensation for diagnosis or treatment for alleged injury associated with vaccine administration.

Licensing/regulatory agencies

United States Veterinarians practicing within the United States may contact the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB):

- *Web:* http://www.aphis.usda.gov/animal_health/vet_biologics/vb_adverse_event.shtml
- **Fax or mail:** Download the PDF form at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/adverseeventreportform.pdf and FAX to (515) 337-6120 or MAIL to the CVB, 1920 Dayton Avenue, PO Box 844, Ames, Iowa 50010, USA
- *Telephone:* (800) 752-6255

Canada The Canadian Food Inspection Agency (CFIA) is responsible for licensing veterinary biologics, including veterinary vaccines that are manufactured and/or used in Canada. The licensing program operates under the Health of Animals Act and Regulations, and is administered by the Canadian Centre for Veterinary Biologics. Form CFIA/ACIA 2205 'Notification of Suspected Adverse Events to Veterinary Biologics' may be found at: http://inspection.gc.ca/english/for/pdf/c2205e.pdf

European Union Oversight lies with the European Medicines Agency (EMA) and the national veterinary medicines agencies. For example, in the United Kingdom, the Veterinary Medicines Directorate (VMD), an agency of the Department for Environment, Food and Rural Affairs, is responsible for the Suspected Adverse Reaction Surveillance Scheme (SARSS) for veterinary medicines.

- *Adverse reactions in animals in the UK should be reported at:* http://www.vmd.defra.gov.uk/adversereactionreporting/default.aspx
- *Suspected human reactions to veterinary medicines in the UK should be reported at:* http://www.vmd.defra.gov.uk/adversereactionreporting/default.aspx
  Or contact the VMD at Freepost KT4503, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3BR, UK.
  Telephone: 01932 338427 Fax: 01932 336618

Veterinarians may be held liable for injury or death caused by administration of a vaccine or any other medication. Effective client communication is the best way to avoid legal consequences. Communication of risk and benefit information to clients should be in direct and simple terms. With respect to documentation, practitioners should determine what best suits their practice and their level of risk tolerance. For more information on informed consent (legal considerations), Certificate of Exemption from Rabies Vaccination, or vaccination documentation, please refer to the 2006 Guidelines (see box on page 786).

What do I do if a patient has had a previous vaccine adverse event?

Refer to page 796 for recommendations regarding the approach to anaphylaxis and allergic reactions.

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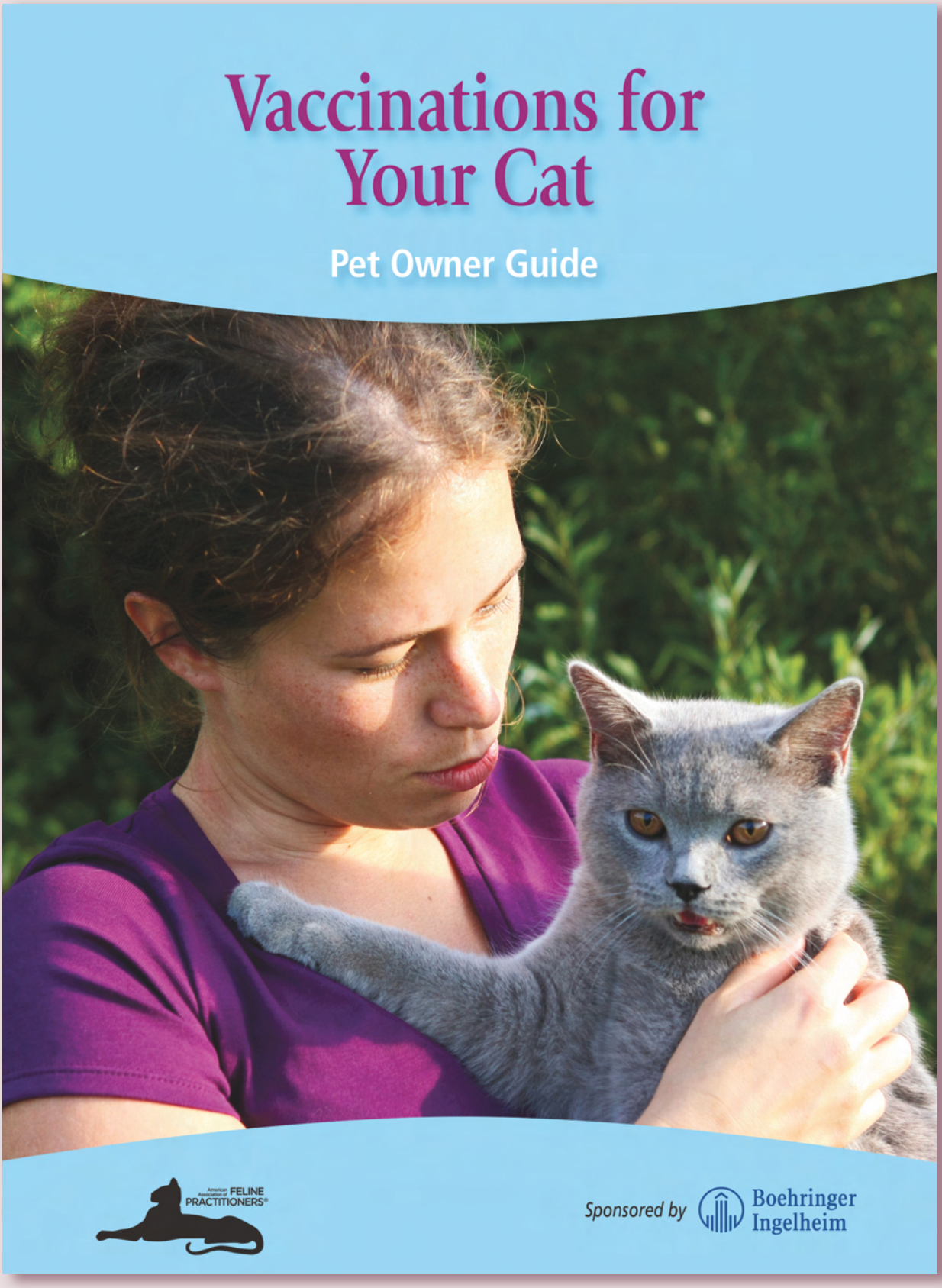
Appendix 2: Pet Owner Guide



Vaccinations for Your Cat

Pet Owner Guide

WHY DOES MY CAT NEED TO BE VACCINATED?

Vaccines help to protect against specific infectious diseases caused by some viruses and bacteria. They stimulate the body's immune system to destroy the organism and 'remember' it so that it can fight against infection again if necessary in the future. Without vaccination, many cats become seriously ill or may even die from diseases that their immune system is unable to fight effectively on its own. The use of vaccines has prevented death and disease in millions of cats. In addition, vaccines protect people from disease, such as rabies, that could be transmitted from cats.

Some diseases are easier to vaccinate against than others. For example, vaccination is very effective against feline parvovirus infection (panleukopenia) but does not completely protect against respiratory virus infections. However, cats vaccinated against respiratory tract infections generally have milder illness than if they hadn't been vaccinated and are far less likely to die from the disease.

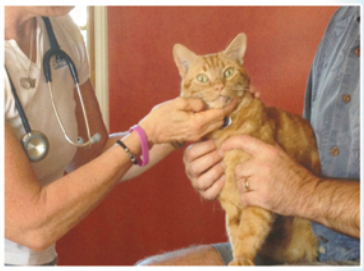
WHY DOES MY KITTEN NEED A SERIES OF MORE THAN ONE VACCINE?

Newborn kittens depend on their mothers not just for food and warmth, but also for protection against infectious diseases. The first few times they nurse, kittens get antibodies from their mother's milk that will help to keep them safe for a few weeks to several months. This immunity provided by "maternally derived antibodies" (MDA) is protective while a kitten's own immune system is immature. However, if the antibody levels decrease before the kitten has developed his/her own immunity, gaps in protection will occur, leaving the kitten susceptible to disease. Also while the kitten has high levels of MDA, their immune system will not respond optimally to vaccination. Since we cannot predict for each kitten when MDA has decreased adequately to allow an effective response to vaccination, guidelines have been developed to protect as many kittens as possible against disease by giving a series of vaccinations. An incomplete series of kitten vaccinations may leave your kitten vulnerable to infection, so it is important to follow your veterinarian's recommendations and vaccinate up to at least 16 weeks of age.

HOW OFTEN DOES MY CAT NEED TO BE RE-VACCINATED?

Many things need to be taken into consideration when deciding how often your cat needs to be vaccinated. These include such things as:

- health status
- age and lifestyle of the cat
- how long a specific vaccine provides protection for ("duration of immunity")
- how likely the cat is to be exposed to the infectious agent
- how dangerous this agent might be
- licensing regulations in each country



This is why re-vaccination intervals may vary, both from cat to cat, home to home, and with different diseases. Your veterinarian will be able to customize a vaccination schedule for your individual cat.

WHAT ARE THE RISKS OF VACCINATIONS?

The benefits of vaccination greatly outweigh possible risks. Just as in children, following vaccination your cat may experience mild and short-lived reactions (malaise), such as poor appetite, lethargy, and fever that resolve without treatment. Any symptoms that persist for more than a day or two should be discussed with your veterinarian. Rarely, more serious allergic reactions occur and may include vomiting, diarrhea, facial swelling, or difficulty breathing. These serious reactions appear within minutes or hours of vaccination and require *immediate* veterinary care. Another uncommon reaction is a tumor at the injection site that develops months or years after vaccination. Talk to your veterinarian about any persistent lumps or swellings at injection sites.

WHAT VACCINATIONS DOES MY CAT REQUIRE?

The vaccines *your* cat needs will depend on his/her health status, age, lifestyle, and what diseases are common in your area. In some areas, rabies vaccination is required by law to protect both animals and people. If you travel with your cat, your veterinarian may advise vaccination against diseases in the areas you visit. It is important to remember that even cats living totally indoors require regular vaccination as they may be exposed to diseases in many circumstances (such as travel or boarding, interaction with other cats, the addition of a new cat to the home and even viruses carried on your clothing). Your veterinarian is the best person to evaluate your cat's individual needs in order to discuss which vaccines are necessary and how often they should be given to provide the best protection for your cat.

You are an important member of your cat's healthcare team.
You can be instrumental in helping with the success of treatments and improved healthcare for your cat.

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2013 AAFP Feline Vaccination Advisory Panel Report

M A Scherk, R B Ford, R M Gaskell, K Hartmann, K F Hurley, M R Lappin, J K Levy, S E Little, S K Nordone and A H Sparkes

Regrettably, an error appeared in the 'Injectable vaccine administration' box on page 798: the pictures in Figures 8 and 9 were swapped with each other. (*The error appears in the printed copies of the journal, and in online versions downloaded before mid-October 2013.*) The amended box is reproduced here in full.

DOI of original article: 10.1177/1098612X13500429

Injectable vaccine administration

Vaccination site recommendations

There is a lack of clinical information to make evidence-based vaccine site recommendations. The majority of safety and efficacy data comes from licensing studies in which vaccines are administered subcutaneously in the interscapular region. Due to concerns of potential sarcoma development, practitioners may consider giving vaccines in other locations. Current research indicates that radical surgical resection of injection-site sarcomas, including margins of 5 cm when possible, is associated with the highest response rate and long-term survival.[75] A 2009 paper reported an increase in lateral abdominal injection-site sarcomas since the publication of the Vaccine-Associated Feline Sarcoma Task Force vaccination recommendations in 1996.[76]

The Advisory Panel recommends, as in the 2006 Guidelines, that veterinarians administer:

- FPV, FHV-1, FCV vaccines below the right elbow (Figure 7).
- FeLV vaccines below the left stifle (Figure 8).
- Rabies vaccines below the right stifle (Figure 9).

Vaccines should be administered as low on the leg as possible. Caution is warranted when vaccinating cats resting in a crouched position as this may result in inadvertent injection of the skin fold of the flank. Veterinarians should note that data on the safety and efficacy of administering vaccines in very distal limb locations are lacking. Figure 10 shows recommended vaccination sites, as well as sites to avoid.

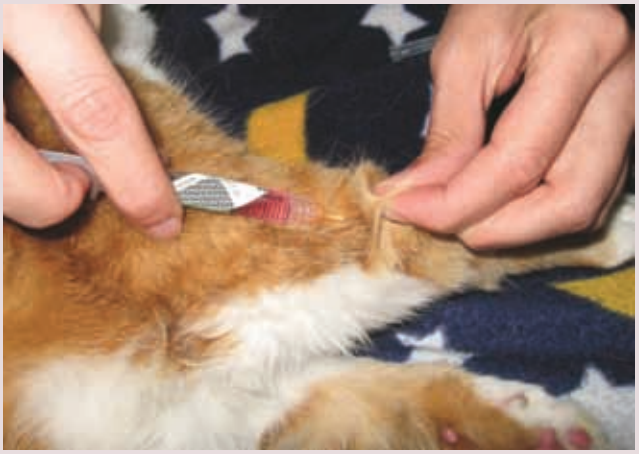

Figure 7 Administration of FPV, FHV-1, FCV vaccine subcutaneously below the right elbow. *Courtesy of Dr Susan Little*

Figure 8 Administration of FeLV vaccine subcutaneously below the left stifle. *Courtesy Dr Susan Little*

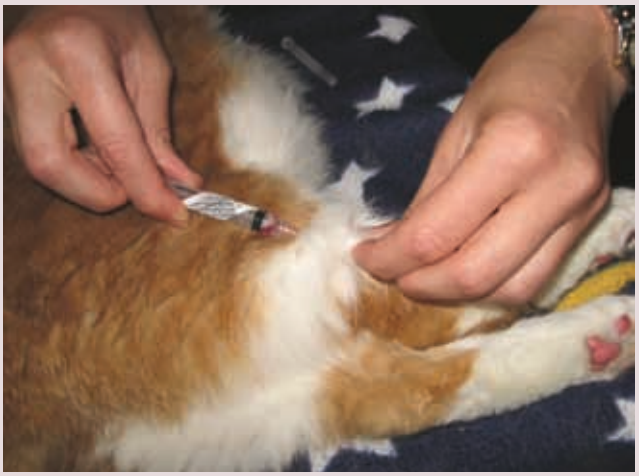

Figure 9 Administration of rabies vaccine subcutaneously below the right stifle. *Courtesy Dr Susan Little*

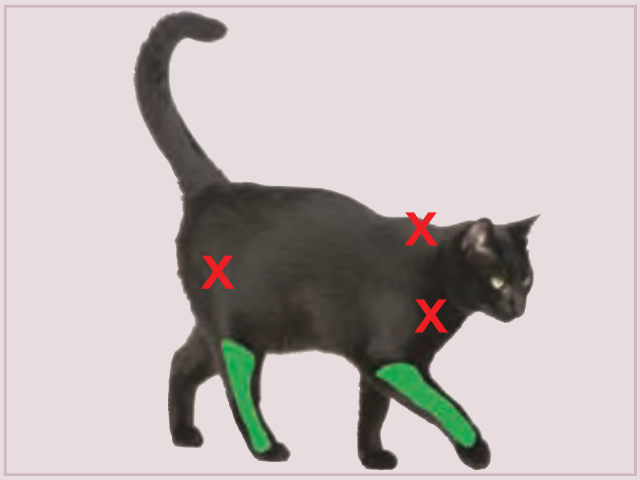

Figure 10 Regions indicated in green are recommended. Those in red are key sites that should be avoided. *Image ©iStockphoto.com/GlobalP*

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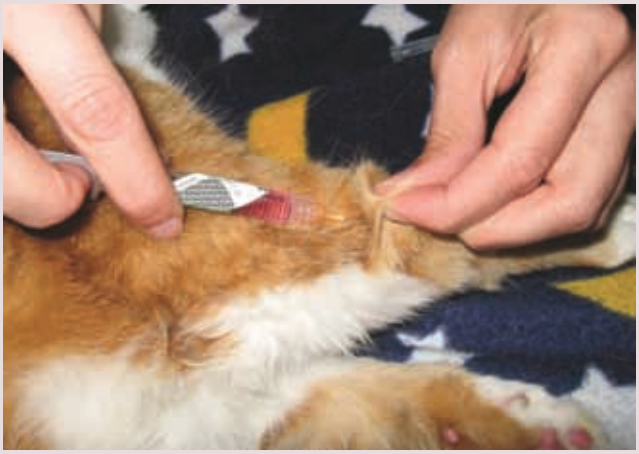

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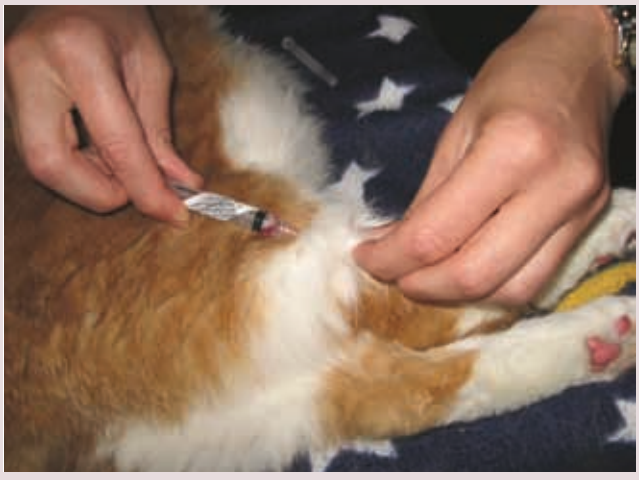

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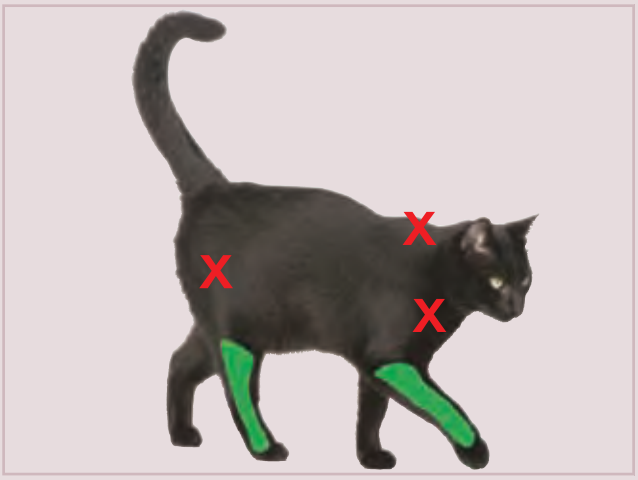

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ANIMAL SHELTER MEDICAL INTAKE CHECKSHEET

Animal identification #:		**Animal Name:**	
Date:		**Time of intake:**	
Stray: ☐ **Owner Surrender:** ☐ **Transfer:** ☐ **Court Order:** ☐ **Other:** ☐		**Medical Records?** **YES** ☐ **NO** ☐	**Your Name:**

BRIEF INTAKE EXAMINATION

Staff Initials:

_____ **1. Initiate written and computer examination records**

_____ **2. Take photo of animal for record**

_____ **3. Document animal's signalment (species, sex, breed, identifying features)**

_____ **4. Check for identification**

- ☐ **Microchip scan** ☐ **Ear tip**
- ☐ **Tattoo check** ☐ **Collar**
- ☐ **Tag information:**_____

_____ **5. Write animal's shelter identification number in permanent marker on paper collar and place on animal**

_____ **6. Weigh animal and record weight**

_____ **7. Take temperature, pulse and respiration and record ("TPR")**

_____ **8. Perform a head to toe full body physical exam and record information**

EMERGENCY SIGNS

If any box below has been checked, staff member must directly notify the shelter veterinarian. Initial here and indicate the time at which veterinarian was contacted.

Initials:_____**Time:**_____

	Check only if noted		Check only if noted
Temp > 105F		**Female trouble delivering**	
Temp <97F		**Altered consciousness**	
Seizures		**Swollen abdomen**	
Labored breathing		**Major wound**	
Abnormal gum color		**Unable to urinate**	
Hit by car		**Severe emaciation**	
Bleeding or bruising		**Severe dehydration**	
Broken bone/lameness		**Possible abuse**	

INFECTIOUS DISEASE SIGNS

If any box below has been checked, staff member must write animal ID# on shelter veterinarian's exam board.Record your initials and time that this has been done.
Initials:_____Time:_____

	Check only if noted
Eye or nose discharge	
Cough or sneeze	
Conjunctivitis	
Ulcers in mouth/nose	
Enlarged lymph nodes	
Patchy or circular hair loss	
Vomiting	
Diarrhea	

PREVENTIVE CARE

Staff Initials:

_____ **1. Vaccines administered per shelter vaccination protocol**
_____ **2. Oral dewormer administered per shelter parasite protocol**
_____ **3.Topspot flea and tick product applied per shelter parasite protocol**

HOUSING CHOICE

	Check where animal is housed
Healthy hold	
Adoption	
Quarantine	
Isolation	

NOTES:_____

_____

_____

_____

~WASH HAND WITH SOAP AND WATER~

Nestlé PURINA

BODY CONDITION SYSTEM

TOO THIN

1 Ribs, lumbar vertebrae, pelvic bones and all bony prominences evident from a distance. No discernible body fat. Obvious loss of muscle mass.

2 Ribs, lumbar vertebrae and pelvic bones easily visible. No palpable fat. Some evidence of other bony prominence. Minimal loss of muscle mass.

3 Ribs easily palpated and may be visible with no palpable fat. Tops of lumbar vertebrae visible. Pelvic bones becoming prominent. Obvious waist and abdominal tuck.

IDEAL

4 **Ribs easily palpable, with minimal fat covering. Waist easily noted, viewed from above. Abdominal tuck evident.**

5 **Ribs palpable without excess fat covering. Waist observed behind ribs when viewed from above. Abdomen tucked up when viewed from side.**

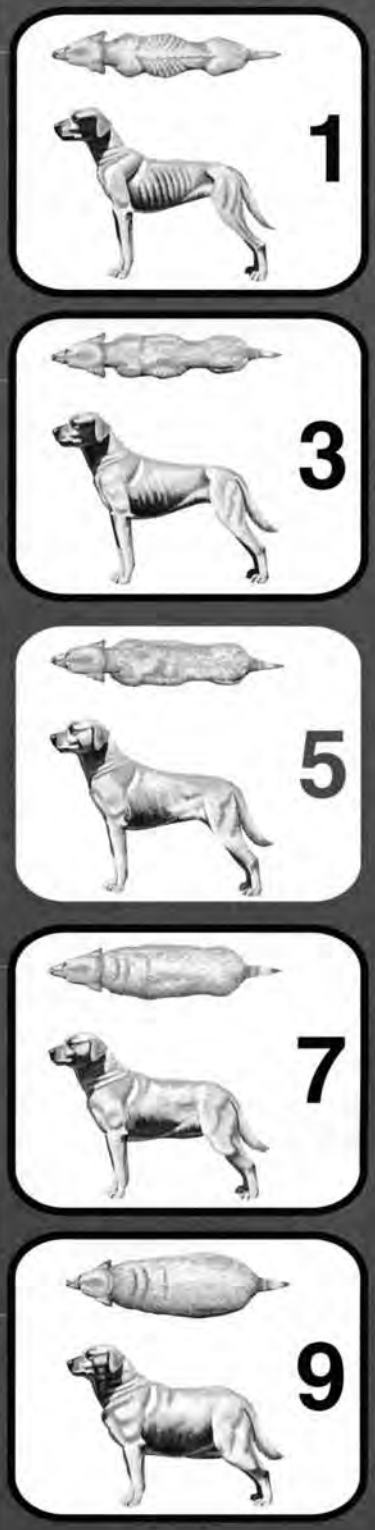
TOO HEAVY

6 Ribs palpable with slight excess fat covering. Waist is discernible viewed from above but is not prominent. Abdominal tuck apparent.

7 Ribs palpable with difficulty; heavy fat cover. Noticeable fat deposits over lumbar area and base of tail. Waist absent or barely visible. Abdominal tuck may be present.

8 Ribs not palpable under very heavy fat cover, or palpable only with significant pressure. Heavy fat deposits over lumbar area and base of tail. Waist absent. No abdominal tuck. Obvious abdominal distention may be present.

9 Massive fat deposits over thorax, spine and base of tail. Waist and abdominal tuck absent. Fat deposits on neck and limbs. Obvious abdominal distention.



The **BODY CONDITION SYSTEM** was developed at the Nestlé Purina Pet Care Center and has been validated as documented in the following publications:

Mawby D, Bartges JW, Moyers T, et. al. ***Comparison of body fat estimates by dual-energy x-ray absorptiometry and deuterium oxide dilution in client owned dogs.*** *Compendium 2001; 23 (9A): 70*

Laflamme DP. ***Development and Validation of a Body Condition Score System for Dogs.*** *Canine Practice July/August 1997; 22:10-15*

Kealy, et. al. ***Effects of Diet Restriction on Life Span and Age-Related Changes in Dogs.*** *JAVMA 2002; 220:1315-1320*

Call 1-800-222-VETS (8387), weekdays, 8:00 a.m. to 4:30 p.m. CT

Nestlé PURINA

Body Condition Tool

Too Thin

1 Severely Underweight

- Ribs, backbone and hip bones all highly visible[1] with complete absence of any fat
- Severely exaggerated waistline[2]
- Tummy non-existent[3]

2 Very Thin

- Ribs and backbone easily seen[1] with no overlying fat layer
- Exaggerated waistline[2]
- Severe tummy tuck[3]

3 Thin

- Ribs and backbone are easily felt and seen[1] with minimal overlying fat layer
- Noticeable waistline[2]
- Distinct tummy tuck with no belly fat[3]

4 Slightly Underweight

- Ribs can be felt and may/may not be seen[1] with very thin layer of overlying fat
- Obvious waistline[2]
- Slight tummy tuck with minimal belly fat[3]

Ideal

5

- Ribs can be felt and may/may not be seen[1] with a small layer of overlying fat
- A clear waistline can be seen[2]
- Visible tummy tuck[3]

Too Heavy

6 Overweight

- Ribs can be felt, but generally can't be seen[1], with a distinct layer of overlying fat
- Waistline is not clear[2]
- Tummy may bulge slightly outwards and sag downwards[3], with a small fat pad

7 Very Overweight

- Ribs are hard to feel and see[1] with a thickened layer of overlying fat
- Waistline is difficult to see[2]
- Tummy bulges outwards and may sag downwards[3], with noticeable fat pad that may wobble when cat moves

8 Obese

- Ribs can't be felt or seen with a very thick layer of overlying fat
- Additional fat pads present over the lower back
- Waistline is absent[2]
- Tummy bulges outwards and sags downwards[3], with obvious fat pad that probably wobbles or sways when cat moves

9 Clinically Obese

- Ribs are impossible to feel with a marked layer of very thick overlying fat
- Additional heavy fat pads are noticeable over the lower back, legs and around the face
- Waistline is absent[2]
- Tummy distinctly bulges outwards and sags downwards[3], with a substantial fat pad that wobbles or sways when cat moves

[1] In short-haired dogs. [2] When viewed from above. [3] When viewed from the side. The Body Condition System was developed at the Nestlé Purina Petcare Centre and has been validated in the following publications Laflamme DP. Feline Practice 1997; 25:13-17. Laflamme et al. Compendium 2001; 23 (Suppl 9A):88

PURINA
Your Pet, Our Passion.®

Meow ... Cat Chow!

Feeding kitties in the shelter

BY BRENDA GRIFFIN, D.V.M.

While shelters can't always feed their cats the equivalent of a five-star meal, providing proper nutrition is a key element of kitty care.

Nutrition has a profound impact on animal health. Not only is it essential for management of body weight and condition, good nutrition also supports immune function—a particularly important factor in a shelter setting. Keeping in mind that cats are true carnivores, it's no wonder that they possess much higher protein requirements than do dogs and humans. They also lack the ability to synthesize essential nutrients like taurine and vitamin A, which would have been present in their prey. This makes it crucial to feed cats only nutritionally complete, commercially prepared feline diets specifically designed to meet their unique nutritional needs. And of course, clean fresh water should always be available.

That's just the beginning. Here's a guide to help you keep your cats well-fed, trim, and healthy.

Dinner in the Wild

The ancestors of domestic cats hunted to eat, typically feeding many times each day—whenever they captured a bug or other prey. This style of feeding behavior is still preferred by many domestic cats who like to nibble throughout the day and night, consuming many small meals.

That said, most cats are capable of adapting to either free-choice or meal feeding. There are advantages and disadvantages to each approach.

Free-choice feeding is a method where food is always available, so the animal can eat as much as she wants whenever she chooses. Dry food should be used for this method of feeding, as canned products left at room temperature are prone to spoil.

The major advantage of free-choice feeding is that it is quick and easy: Caregivers simply need to ensure that fresh dry food is always available. Major disadvantages include the fact that animals who are not eating may not be spotted for several days, especially when cats are being fed in a group. Some animals may choose to continually overeat and become obese.

AFRICA STUDIO/SHUTTERSTOCK.COM

Cats should be weighed at intake and have their body condition scored. Weight measurements should be taken again at routine intervals throughout their stay.

Free-choice feeding is an excellent method for cats who require frequent food consumption. These include kittens up to 5-6 months of age and queens who are in late gestation or nursing. Unlike dogs, who are competitive eaters by nature, cats who are group housed may benefit from free-choice feeding, as it ensures that there will be ample time for all members to eat, provided that dominant members of the colony do not block the access of subordinate cats.

Feeding controlled-size portions of dry and/or canned food may be done as an alternative to or along with free-choice feeding. When used alone, a minimum of two meals should be fed each day. Meal feeding is ideal for any cat who requires controlled food intake, and it allows for monitoring of the cat's appetite. Meal feeding also has the benefit of enhancing caregiver-cat bonding and, when done on a regular daily schedule, provides a pleasant and predictable experience for cats.

Using a combination of free-choice plus once daily meal feeding takes advantage of the positive aspects of both methods, and works well for most cats in the shelter. Typically, dry food is available free-choice, and a small meal of canned food is offered once daily. This combination approach accommodates the normal feeding behavior of cats by allowing them to eat several smaller meals, and allows caregivers to monitor the cat's appetite for the canned food meal. As necessary for the individual cat, some may be fed additional meals of canned food to ensure adequate nutritional support.

Proper Dinnerware

Many cats prefer to eat from shallow dishes or plates, and you should take care to select dishes and bowls that are large enough to easily accommodate the cat's entire face and whiskers. A bowl that's too small can discourage the cat from eating or drinking. Paper plates are ideal for canned foods as they are sanitary, inexpensive, easy to use, and disposable. In addition to offering food in the usual way, you can also try some methods to encourage "pseudopredatory activity"—this can be used as a source of enrichment for some cats. For example, dry cat food or treats can be hidden in commercially available food puzzle toys, or in cardboard boxes, tubes, or rolling toys with holes, so that the cat has to work to extract pieces of food. This method of feeding may be a very useful addition, especially for those cats housed for more than a couple of weeks.

Which Food Works Best?

Many shelter staff wonder whether to feed a regular commercial brand of cat food or a premium brand diet. Compared to regular commercial brands, premium diets typically are more consistent in their ingredients, have a higher calorie content, and some are more highly digestible, resulting in less fecal output. But such brands are usually more expensive than other commercially available feeds, and the cost may not be justifiable in a shelter setting. Whatever brand is selected, it should be one that has been through feeding trials to validate its nutritional adequacy. You can determine this by checking the label, which should state that the diet is adequate for the life stages indicated based on the Association of American Feed Control Officials (AAFCO) feeding trials.

Although some cats tolerate changes in food without apparent problems, others may experience loss of appetite and/or gastrointestinal upset. For this reason, it is generally best to provide the most consistent diet possible. Some pet food companies offer feeding programs, providing a consistent food for purchase at a special rate for shelters. However, some shelters rely heavily on donations of food. In these cases, shelters should try to request donations of certain brands, which will enable them to provide a consistent diet whenever possible. You can also mix donated foods with the shelter's usual feed to minimize problems caused by abrupt diet changes while taking advantage of donations.

Regardless of food type, proper storage—away from heat and humidity, espe-

A cat's appetite is closely related to his sense of smell, so the nasal congestion that occurs with URI will often result in loss of appetite. Offer these cats canned foods; they typically smell stronger than dry food and are easier to swallow.

cially for dry food—is essential to prevent contamination or spoilage. Foods should be used within their recommended expiration date. Containers for food and water should be kept clean and sanitary—washed periodically with soap and water as needed—and must be completely disinfected or discarded between individual cats or group enclosures. Plastic or metal containers are acceptable.

Both dry and canned products should be stored according to manufacturers' recommendations. Bagged foods can be kept in the original bag (roll the top of the bag down) and placed an airtight container. Partially used canned food should be tightly covered and refrigerated immediately, then used within two to three days of the date it was opened.

Eyeing Your Eaters

Proper nutrition is especially important during times of stress or illness, since malnutrition compromises immune function, making animals more prone to infectious disease. Both appetite and stool quality should be monitored daily, and abnormalities should be tracked. Normal stools should be well-formed and medium to dark brown. Adult cats typically defecate once daily, although healthy adults may defecate anywhere between twice a day and twice a week. Kittens tend to produce a larger volume of stool more frequently, which is often lighter in color and softer formed than that of adults. Simple scales can be used for

THIS PAGE: BRENDA GRIFFIN. OPPOSITE PAGE: SERGIO PIUMATTI

How Much Should We Feed?

There are formulas for calculating the daily energy requirements of cats based on their body weight, age, or life stage and activity level (see below). These formulas are meant to serve as guidelines and not absolutes; they are starting points that must be adjusted to suit the unique metabolic requirements of each individual to maintain a healthy body condition. The specific calorie content of various cat foods can usually be found via simple Internet searches. In general, the calorie content ranges from 350-500 kcal per cup for dry food and 120-190 kcal per 5.5-ounce can of wet food. As a rule of thumb, treats should compose no more than 10 percent of the animal's total daily intake.

Life stage and activity level	Kilocalories required per day
Very active adult	80 kcal X body weight in kg
Moderately active adult	70 kcal X body weight in kg
Inactive adult	60 kcal X body weight in kg
Kitten 2-5 months of age	250 kcal X body weight in kg
Kitten 5-7 months of age	130 kcal X body weight in kg
Kitten 7-12 months of age	100 kcal X body weight in kg
Adult pregnancy	1.25-1.5 X adult maintenance last trimester
Adult lactation	2-3.5 X adult maintenance

From Linda P. Case's *The Cat: Its Behavior, Nutrition and Health*.

Calculation of Calorie Requirements for Weight Gain

Record baseline body weight and body condition score

1. Resting energy requirement at present weight (RER) = 30 X body weight in kg + 70
   30 x (PRESENT WEIGHT KG) + 70 = (RER) kcal / day
2. Daily energy requirements for weight gain (DER) = RER (DESIRED WEIGHT) X 1.3 (WEIGHT GAIN FACTOR)
   30 x (DESIRED WEIGHT KG) + 70 =_____kcal / day X 1.3 = DER for weight gain
   - Start feeding at 50-100 percent RER at present weight, divided into 4 meals over the day.
   - Increase amount fed by approximately 25 percent each day to reach DER for weight gain.
   - If cat is doing well clinically after the initial 48 hours, feedings may be increased a little more rapidly.
   - Record body weight daily for the first week, then biweekly or weekly as indicated based on cat's progress.

From *Small Animal Clinical Nutrition*, 4th edition, 2002.

Make sure that any food you provide to cats comes in a container they can eat from—one that's not too deep or narrow for their faces. Cardboard trays and paper plates can work very well.

monitoring appetite (e.g., good, some, none) and fecal scoring charts are available (e.g., the Purina Fecal Scoring System chart; this is available by calling Purina or online at *foothillpethospital.com/fecalscoring.html*).

In addition to appetite and stool quality, monitor body weight and condition. These elements, along with a healthy hair coat, are evidence of proper nutritional management. Body condition can be subjectively assessed via a process called "body condition scoring," which involves assessing fat stores and, to a lesser extent, muscle mass. Fat cover is evaluated over the ribs, down the top line, tail base, and along the ventral abdomen and inguinal (groin) areas. Body condition score charts have been established on scales of 1-9. Purina provides a score chart for this as well (*purina.com/cat/weight-control/bodycondition.aspx*).

Cats should be weighed at intake and have their body condition scored then and at routine intervals throughout their shelter stays. Ideally, body weight should be recorded at intake, and then weekly during the initial month of shelter care. After a month, it can be recorded once a month, or more often as indicated by the animal's condition. This is especially important for cats, since significant weight loss may be associated with stress or upper respiratory infection during the first few weeks of confinement.

On the other hand, in some cats housed long-term, excessive weight gain may occur. Therefore, protocols must be in place to identify and manage unhealthy trends in body weight, since both weight loss and gain can compromise health and well-being.

Sick, or Just Finicky?

Cats may lose their appetite or refuse to eat due to illness or stress. As a result, they risk the development of severe complications. Small kittens (especially those less than 4 months of age) can suffer from hypoglycemia (low blood sugar), resulting in weakness and even death. Hand-feeding (including syringe-feeding) young kittens can be lifesaving, provided they swallow the food; in some cases, it may help to jump-start their appetites.

If kittens refuse food for more than a day, seek veterinary attention. If you have the resources and know-how, syringe- or tube-feeding may help, but if additional resources for focused care are not available, consider humane euthanasia to prevent needless suffering. If small kittens don't eat, you need to act fast, because they will go downhill quickly. Adult cats can go a few days without eating, but little kittens cannot.

While they can go longer without food than the youngsters, adult cats who do not eat at least half of their daily energy requirements for several days or more risk developing hepatic lipidosis (fatty liver), a life-threatening condition that causes liver failure and other metabolic problems that can lead to death without aggressive veterinary care. Rapid weight loss is a serious threat to health and welfare, and overweight cats are especially prone to developing hepatic lipidosis when they don't eat. When adult cats refuse to eat for more than three to five days, they should be examined by a veterinarian. In some cases, force-feeding via syringe can help; however, it is difficult to feed a sufficient amount to meet feline caloric requirements. For example, an average 9-pound cat will require approximately 240 calories per day for maintenance (considerably more than a typical 5.5-ounce can of cat food).

Stress can also induce anorexia, resulting in hepatic lipidosis and liver failure. This is not uncommon, especially when timid housecats are housed in the shelter. This underscores the critical importance of both stress management and weight monitoring.

Appetite and URI: The Connection

A cat's appetite is closely related to his sense of smell, so the nasal congestion that occurs with URI (coupled with a sore throat) will often result in loss of appetite.

To encourage their appetite, cats with signs of URI should be offered canned foods since they typically smell stronger than dry food and are easier to swallow. Selecting fishy smelling food and warming it slightly may help to stimulate the appetite of some cats. In addition, because canned foods are composed of approximately 80 percent water, they help promote normal hydration. It is usually easier to get sick cats to eat canned food than it is to get them to drink water.

Many shelters feed meat-based baby food to cats to stimulate their appetites, but only those foods that do not contain onion powder should be used. Onion powder is a common ingredient in some baby foods and can be toxic to cats, causing serious anemia.

To complicate matters, some cats (particularly adults) develop food aversions when they are ill. This occurs when they are continually offered foods and learn to associate the sight and smell of the food with feeling sick or nauseated. Consequently, they may refuse to eat even once they are feeling better. For this reason, when cats refuse to eat, it may be best to offer them food periodically, but not to leave it in their cage all the time. That said,

BRENDA GRIFFIN

Hiding dry food or treats inside a toy—or even a plastic tub, with strategically placed holes—can alleviate boredom and provide cats with stimulation as they try to figure out how to get the tidbits out.

it's important to allow shy cats (who may not eat in front of caregivers) an opportunity to eat in privacy. But leaving food next to them when they are sick may lead to food aversion in some cases.

Too Fat or Too Thin

Cats who are severely obese pose unique nutritional challenges. Deciding whether or not to institute a weight-reduction plan for such cats during their stays requires careful consideration.

To prevent overeating, controlled meal feeding is required for weight reduction. To accomplish this, an obese cat would probably need to be individually housed for at least a portion of the day for individual feeding. But individual cat housing may be very confining, and obese cats may benefit more if they are housed in a colony-style enclosure where they will likely get more exercise. However, this is confounded by the fact that free-choice feeding is generally preferred for colonies. Some combination of confinement for fixed-portion meals and communal housing to encourage exercise is ideal. Sometimes, compatible obese cats can be co-housed to facilitate both exercise and diet restriction.

Reduced-calorie cat foods and formulas for calculating calorie requirements for weight loss are available, but it often takes several months for cats to achieve meaningful weight loss. In addition to the logistical challenges, some obese cats will refuse novel low-calorie food in the shelter—and rapid weight loss is dangerous for obese cats. Obesity does not necessarily hinder a cat's chances for adoption. Curiously, the popular "fat cat" image may even draw attention to overweight cats! In these cases, weight-reduction plans may best be left for the new owner, who should be educated on the risks associated with obesity for cats (e.g., diabetes) and instructed to consult a veterinarian for a safe weight-reduction plan once the cat has acclimated to her new home.

On occasion, cats who've been victims of starvation may enter the shelter, malnourished and underweight, or even in emaciated body condition. These cats should be examined by a veterinarian, and careful consideration should be given to possible causes of weight loss and poor body condition. If the cat is bright, alert, and readily eats when offered food, an in-shelter feeding program designed for weight gain can be implemented (see box on page 49). Vaccination and parasite control should be performed as usual on entry. In addition, other appropriate documentation (for example, lab work and photographs) should be obtained if the cat is part of a court case. If weekly weight gain does not occur or other symptoms arise, the cat should be further evaluated by a veterinarian. ***AS***

Resources

For more on raising kittens in a shelter setting, see "Kittens: Coming Now to a Shelter Near You" in the July-August 2010 *Animal Sheltering*, available at *animalsheltering.org/kittenseason*.

FOOD DISPENSING TOYS

GOAL: To provide our dogs with enrichment when they are alone, and to teach dogs to enjoy eating their meals out of a Food Dispensing Toy (FDT) such as a Kibble Nibble, Stuffed Kong, PVC pipe FDT, Kong, Wobbler etc. This form of enrichment allows the dog to work for their food by pushing the FDT around on the ground to get the food to fall out. The best FDTs are toys that the dog does not destroy and are easy to clean and sanitize after each use.

INITIAL INTRODUCTION OF FDT:

- Do not disturb the dog while eating meals from a bowl for at least the first 2-3 meals.
- Closely monitor and record the dog's appetite on the Canine Enrichment Chronicle
- Once you have determined that the dog enjoys eating meals, give the dog the easiest type of FDT, usually a handmade PVC FDT. Feed this to the dog at mealtime in place of their usual meal.

NOTE: Do not use FDTs with dogs that have a history of food aggression (food, rawhides, pig's ear, etc.) unless approved by the behavior department.

RECORDING CONSUMPTION:

- During morning cleaning, staff remove the toy from the kennel and record food consumption on the Canine Enrichment Chronicle.
  - A (all)
  - S (for some)
  - 0 (zero for none)

CONTINUING FEEDINGS:

- If the dog enjoys FDTs, the dog should receive one AT LEAST once daily, for as long as they are in the shelter.
- Consider a more challenging FDT as a dog gets skilled at eating meals out of them.
- ALWAYS monitor the dog's consumption of food from the FDT.

(recipes on next page)

RECIPES

GOAL: To provide our dogs with enrichment when they are alone, and to teach dogs to enjoy eating their meals out of a Food Dispensing Toy (FDT) such as a Kibble Nibble, Stuffed Kong, PVC pipe FDT, Kong, Wobbler etc. This form of enrichment allows the dog to work for their food by pushing the FDT around on the ground to get the food to fall out. The best FDTs are toys that the dog does not destroy and are easy to clean and sanitize after each use best FDTs are toys that are not destroyed by the dog and are easy to clean and sanitize after each use.

PVC FOOD DISPENSING TOY:

Give them a mix of dry with some wet food mixed into it very lightly so it doesn't stick to the toy. Fill the bottom with Dry Kibble, middle with a small amount of the wet/dry mix and fill the remainder with dry kibble.

KIBBLE NIBBLE FOOD DISPENSING TOY:

Mix in a very small amount of dry/wet mix and the rest is all dry kibble.

STUFFED KONG:

This is the best for wet/dry mix and is more challenging than the PVC and Kibble Nibble. Fill the bottom half with dry kibble and the top half with a dry/wet mix and then coat the opening with wet only to entice licking. Note that you will be unable to put an entire meal into a stuffed Kong, so you will need to provide multiple Kongs at mealtimes.

KONG WOBBLER:

Dry kibble only and the smaller the better. This is a more challenging FDT; use only after the dog is consistently and easily eating out of the easier FDT's.

DAILY FOOD CALCULATOR FOR: Dogs and Puppies

Use this calculator to determine how much of a specific food to provide daily based on an individual dog's weight and activity level or life stage.

Note: *The nutrition information on most dog food packaging lists the kcalories (kcals) per cup of the food. The kcalories (kcals) can vary among different foods, even of the same brands. Be sure you are entering the correct kcals for each product you use.*

Cups of Food for Dogs Over 1 Year

Enter the kcalories per cup of food in field to the right. Press Enter to update the rows below. ▸ **340**

Weight (lbs)	Active >12 Mos	Inactive >12 Mos
10	1.5	1.0
20	3.0	1.5
30	4.0	2.0
40	5.0	2.5
50	5.5	3.0
60	6.5	3.5
70	7.5	4.0
80	8.0	4.5
90	9.0	5.0
100	9.5	5.5
110	10.0	6.0
120	11.0	6.5

Cups of Food for Dogs 1 Year or Younger, and Pregnant or Nursing Females

Enter the kcalories per cup of food in the field to the right. Press Enter to update the rows below. ▸ **422**

Weight (lbs)	2 to 5 Months	5 to 7 Months	7 to 12 Months	Pregnant	Nursing
10	2.0	1.5	1.0	1.5	2.5
20	3.5	2.5	2.0	2.5	4.5
30	4.5	3.5	2.5	3.5	6.0
40	5.5	4.5	3.5	4.5	7.5
50	6.5	5.0	4.0	5.0	8.5
60	7.5	6.0	4.5	6.0	10.0
70	8.5	6.5	5.0	6.5	11.0
80	9.5	7.5	5.5	7.5	12.5
90	10.0	8.0	6.0	8.0	13.5
100	11.0	8.5	6.5	8.5	14.5
110	12.0	9.5	7.0	9.5	15.5
120	12.5	10.0	7.5	10.0	16.5

This chart uses the Waltham calculation method, which calculates Maintenance Energy Requirement (ME) based on the animal's weight and activity level/life stage. ME is the number of kcalories per day the animal requires. The chart then calculates cups of food for each ME requirement and the kcals per cup in a specific dog food. The formula to calculate ME is: Maintenance Energy Requirement = N x (body weight in kilograms) $^{0.75}$ *= kcal, where N is a factor that adjusts the requirement based on activity level and life stage.*

ASPCAPro.org | Food Calculator

APPETITE MONITORING

INFORMATION SHEET

NAME: _____ **A#**_____

INSTRUCTIONS: _____

DATE	TIME	APPT	HOW MUCH EATEN?	TECH	OTHER COMMENTS
AM					
MID					
PM					
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Operational Guide

Companion Animal Zoonotic Diseases

AMERICAN HUMANE

Protecting Children & Animals Since 1877

About the Author

Jim Babbitt, DVM
Senior Veterinarian, San Diego Humane Society & SPCA

Table of Contents

Introduction

A zoonotic disease or zoonoses is defined as an infectious disease shared by people and animals.

In general, the risk of acquiring a zoonotic disease in a shelter is low. In fact, healthy people who contract most zoonotic diseases will be asymptomatic or only experience very mild symptoms. However, education about these diseases and ways to reduce the risk of transmission is important for a number of reasons.

First, animals coming into a shelter are more likely to have or to acquire a zoonotic disease. Uncertain (or non-existent) prior veterinary care, prior history of roaming or scavenging, and uncertain temperament put animals coming into our shelters at greater risk for zoonotic diseases than the general population of pets.

Second, as the number of immune-compromised people in our population increase, these diseases take on added importance. Immune-compromised people (e.g., cancer patients, organ transplant patients, HIV patients, people receiving large doses of glucocorticoids, pregnant women, those with chronic alcohol malnutrition, splenectomized people) often experience more serious symptoms with these diseases and are generally more susceptible to such illnesses.

Third, any outbreak of zoonotic disease associated with a shelter creates these possible consequences:

- Members of the shelter staff or general public become ill or even die.
- The shelter attracts unfavorable publicity. News media may be quick to publicize or even sensationalize any human disease outbreak traced back to exposure to shelter animals.
- Staff morale suffers, not only due to human illness, but also by the possible need to destroy animals suspected in an outbreak.
- Legal implications complicate the situation. The potential legal liability greatly increases if you cannot show you have made every effort to minimize the possibility of a human contracting a zoonotic disease in your shelter.
- Monetary losses put the shelter in financial danger. This might result from the direct costs of dealing with an outbreak, the loss of staff time due to illness, and even decreased contributions as a result of unfavorable publicity.

Transmission

Zoonotic diseases can be transmitted from animals to humans in two ways:

1. **Direct transmission** requires immediate, or close, contact between the reservoir (sick animal) and the susceptible individual (person). This contact may also be with body secretions (i.e., blood, urine, stool, saliva) from a sick animal.
2. **Indirect transmission** of a zoonotic disease occurs when a susceptible person comes into contact with the disease-causing organism (“germs”) on objects (animate or inanimate) that serve merely as passive carriers of the disease (commonly referred to as “fomites” or “vehicles”). In an animal shelter, human hands are the most important fomite. By coming into contact with germs on

a sick animal, in body secretions from a sick animal, or on inanimate objects (like cage doors), our hands become contaminated with these germs. The germs are then transferred to another animal, our own mouths or eyes, or to another person.

While we cannot usually control what diseases "walk through" our front doors, once that diseased animal is inside, we can influence the outcome of that disease. This influence is not only important for the sick animal but also for any other animals or humans exposed to that original sick animal.

Many factors influence the likelihood of disease transmission from animals to people. We must look at these factors because any action taken in direct response helps to reduce the potential of disease transmission. These same factors also influence the spread of other diseases between animals (non-zoonotic diseases). Any steps we take to minimize the possibility of zoonotic diseases automatically reduce the possibility of transmission of non-zoonotic diseases (i.e., URI, canine and feline distemper, ringworm, canine parvovirus) between animals. These factors control the probability of disease transmission from animals to people (or other animals):

- How long the animal sheds (passes) the disease-causing germs in question. Obviously, the longer the germs are being passed, the greater are the chances of a susceptible individual being exposed to them. Treatment for the disease in question may help to reduce this time.
- The length of the incubation period for the disease in question. The incubation period is the time between exposure of a susceptible individual and the appearance of symptoms. The longer this is, the more likely that a diseased animal will escape disease detection when it enters into our shelter. The animal may already be in the general population before it starts to show symptoms.
- How obvious the symptoms of the disease are in the animal. The more subtle the symptoms, the more likely it is to be overlooked until exposure of people or other animals has already taken place. An example of this is ringworm (superficial dermatophytosis). Often the first sign of a problem in the shelter is a volunteer or employee who develops symptoms of ringworm infection.
- The stability or resistance of the germ that causes the disease. A germ that is extremely resistant to environmental factors or disinfection remains viable for longer periods of time in our shelters.
- Population density of animals within our shelters. The more animals we have per cubic foot, the easier it is for diseases to spread directly from animal to animal. It is also more stressful on the individual animals, which make them more susceptible to disease in the first place. Another, more subtle, challenge is that large, dense populations of animals make it more difficult for staff to evaluate individual animals for the initial signs of disease.
- Husbandry practices. How well you are able to clean, feed, and house the animals either reduces or

increases the likelihood of disease transmission.
- Control of pests like fleas and ticks. Some diseases are only spread by the bites of these parasites. These pests also may debilitate the animals making them more susceptible to disease.

We will look at each step of an animal's journey through an animal shelter and look at some things we can do to reduce the danger of disease transmission to our staff, volunteers, adopters, and animals. In general, we strive to achieve two main goals — first, to reduce the disease load in the shelter (decrease the number of diseased animals and reduce the severity and duration of the disease in those animals that are sick); second, to reduce exposure by susceptible individuals to the germs that cause these diseases. Again, keep in mind that although we are specifically discussing prevention of zoonotic diseases, these steps are exactly the same as those to prevent spread of diseases between animals. Remembering this fact justifies the expense and difficulty of implementing a program to prevent rarely seen zoonotic diseases.

Shelter Design

Before an animal starts its journey through the shelter, consider the overall design and layout of the physical facility. Obviously available finances play a role, but even relatively minor changes in the structure, materials used, and furnishings influences the ease or difficulty of disease transmission. Available resources on this subject include the American Humane Association's Operational Guide for building design. However, here are some of the specific, zoonoses-related building concerns:

Isolating known or suspected ill animals. The more separation the better, but even if ill animals must be mixed (e.g., ringworm cats mixed with URI cats), it is better than mixing well individuals with ill ones. The longer the isolation lasts the better. Isolation or segregation of animals according to age is also important. Do not house kittens or puppies with adults.

Minimizing stress on all animals. Separating dogs and cats, minimizing noise pollution, allowing an animal to occupy the same cage throughout its stay at the shelter (to minimize "moving" stress), and creating areas in the runs or cages that allow an animal to "hide" are just some of the considerations that may influence the type and location of cages and wards. For example, having cages for cats or dogs that can be cleaned without having to handle or move them (double sided condos for cats or guillotine runs for dogs) can be helpful.

Having rooms, cages, and countertops that are easy to clean and disinfect. Avoid, therefore, carpeting, non-washable bedding, or non-washable toys. While non-porous surfaces meet this criteria, these surfaces are also rather "sterile" looking and often not very appealing when the animal is on display to the public. Sometimes compromises need to be made — weighing the needs of disease prevention against the need to make our animals as appealing as possible to potential adopters.

Providing barriers to minimize the direct transmission of diseases. These barriers may be separate rooms (better to have numerous smaller rooms than one large one). On the other hand, barriers to minimize aerosolization of germs can be nothing more than hanging towels over

cage fronts or the use of "sneeze guards" that cover the front of cages or runs. Use distance as an effective barrier. Place facing cages at least 5 feet apart. Do not put animals with infectious problems (like diarrhea) in cages that are over other cages.

Monitoring the symptoms of disease. If you house 15 kittens in a room and find severe diarrhea in the litterbox in the morning, how do you determine which kitten(s) is involved? Can you separate them if needed? How do you determine who is eating and who isn't? Sometimes confining animals at specific times (nights or at feeding time) and then housing them communally can help.

Enhancing staffs ability to monitor animals for disease then communicating this information to the veterinary staff or other staff members. This may be as sophisticated as a computer system or as simple as a chalkboard in a central location. The use of quarantine or contagious signs on cages or wards is essential.

Ensuring adequate air ventilation. In general, the more air circulation the better. This helps to ensure a drier environment, minimizes the number of germs per cubic foot of air in the rooms, and minimizes odors and materials in the air that might irritate the mucus membranes of the animals. The ideal is 10 to 15 exchanges of air per hour, but any airflow is better than nothing. Certainly, centralized heating and air conditioning systems, with proper ventilation, are ideal, but just opening a window or having outdoor access can help. The use of fans is controversial due to risks of driving airborne disease from one area to another, but certainly they can increase airflow and dry the environment. Using a fan to direct the flow of air outward through a window is better than directing the flow of air inward.

Directing traffic flow. Ideally, shelter traffic progresses from well animals to sick animals. The less that staff or animals must move from the "sick" wards or cages to the "well" wards or cages the better. Isolate any areas used for known zoonotically ill animals from day-to-day shelter traffic and designate them as staff-only areas, keeping them off limits to the public and volunteers. Clearly mark these areas as containing a known ill animal.

Animal Entry

The first step in an animal's journey through our shelters is initial entry.

Examine incoming animals as soon as possible. Ideally, do this before placing them in the general population. While an extended quarantine period is ideal, it is not possible in most shelters. Therefore, educate staff about the symptoms of common zoonotic diseases. Run appropriate tests on any animals with suspicious disease signs. Unfortunately, there are no simple, accurate tests for many of these diseases. If an animal shows symptoms possibly associated with a zoonotic disease, isolate it away from all other animals. Also, place some form of identification (i.e., collar, microchip) on the animal so that staff can positively identify it at any time for examination or follow-up during its stay in the shelter.

Administer all appropriate vaccines and treatments to all healthy animals as soon as possible. These include routine treatment for external and internal parasites. Use some form of reminder or notification system to alert staff to any

animals that need a repeat treatment or vaccine in the future. Vaccines are important, but it is critical to realize that vaccines are of limited value in any animal exposed to disease prior to coming into the shelter or exposed within a short period of time after coming into the shelter. Emphasis on husbandry and stress reduction will yield far better results in disease reduction than using a different or "better" vaccine.

Set up a system of rechecks and treatments for any animals suspected of being sick. Isolate any sick animal at least until the symptoms of the disease disappear. In some diseases, keep animals isolated for some time after symptoms disappear. How effectively you isolate sick animals will depend on your facility.

Put a system in place to notify other staff members and the veterinary department about animals that may be exhibiting symptoms of a zoonotic disease. Do it in a way that other people who are not as informed about the dangers of disease transmission, like volunteers, can understand the danger and the need to avoid contact with that animal or that ward. You can use signs, a centralized chalk or "Dry Write" board, or a computer system.

Allow an animal some time to "de-stress" before doing any major procedures, such as surgery. The amount of time allowed depends on age, species, temperament, population of animals in shelter, and the ability of a shelter to house animals for extended periods.

Assuming an animal arrived healthy when it first came into the shelter, its care and treatment after it enters is crucial to its ability to resist disease.

How do staff members monitor the animal while it is in the shelter? Educate staff about the zoonotic disease symptoms. Also, remember that many animals affected with zoonotic diseases show no or very few symptoms. That means staff must take all the described steps with all animals entering the shelter.

Weighing animals on a regular basis often gives an early warning signal to the presence of disease or even stress. This is especially important in puppies, kittens, and in animals kept in a communal setting. Keep weight measurements in a log or on the animal's individual cage card or record.

Cleaning and Disinfection

Clearly spell out the shelter's cleaning and disinfection protocols, then educate staff on the proper use of chemical cleansers and disinfectants. Four levels of cleaning are possible: physical cleaning, sanitation (bringing the level of germs present to a safe level, where most exposed animals will not become sick), disinfection (killing most germs present, including all viruses, bacteria, or fungi), and sterilization (killing of all life forms, including bacterial spores, fungal spores, and parasite eggs). While we strive for true disinfection, good sanitation is the best that we accomplish in most shelter environments.

Follow these general techniques:

Proceed in cleaning of cages and wards from "clean" rooms or cages to "dirty" (germ contaminated). Ideally, the personnel that clean a room with a known ill animal should not clean or even handle the well animals. Remove all toys, dishes, blankets, and such. Launder or dispose of these objects as appropriate. Use of

disposable litter boxes, bowls, and the like facilitates this process. Wash all towels and bedding in the hottest water available. Although laundering these materials does not disinfect them, it does mechanically remove most germs present. Remember to clean all objects that an animal comes into contact with; this includes collars, leashes, carriers, muzzles, and scales. If you use mops, remove the heads frequently, launder them and then allow them to dry thoroughly between uses. Alternating mop heads can be useful and inexpensive. Using disposable mops (e.g., Swiffer) can be very useful, although expensive. The ideal situation is to make your supplies area specific. That is each area has its own set of brushes, blankets, and bowls. This way, healthy animals are not exposed to sick or isolated animals even indirectly.

The first level of cleaning is the most important and unfortunately the most overlooked in many shelters. This is the physical removal of waste like stool, urine, hair, skin dander, or nasal secretions. None of the other steps in the cleaning or disinfection process will be effective if this is not done first. In fact, many chemicals used for disinfection are not effective in the face of organic waste material. In addition, many of the disease causing germs we face are resistant to common disinfectants.

Ultimately, perform physical cleaning without further contaminating the environment. For example, do not just spray the material with a high-pressure hose to move it out of the kennel or cage. This just aerosolizes the material contaminating walls, cage doors, and the air. Ideally, pick it up with a shovel or scoop; then wet down the run down with water and squeegee the material down to the drain. After removing large waste material, wash the area well with soap and water. Rinse very well and squeegee the water down the drain. Do not allow pools of standing water to just air dry. This merely redeposits suspended contaminants on the floor. Standing pockets of water also dilute many of disinfectants beyond the concentration required to be effective. Do not use the same cloth to dry different cages or runs. Ideally use paper towels for this purpose.

After the floor is dry, apply a chemical agent to sanitize the surfaces. The specific agent used depends on the type of disease that may have been present in that area, the type of surface material present (non porous vs. porous), and training of staff performing the task. For all disinfectants, contact time and dilution are important. Because time is always at a premium in most of our shelters, in a common day-to-day setting it is often difficult to allot the time for these agents to “sit.” However, if a known outbreak of a zoonotic disease takes place, allow this time. Most disinfectants used in animal shelters require a minimum contact time of 10 minutes; more time is required if the water is hard or the temperatures are cold.

Quaternary Ammonium Compounds (“Quats”) such as Roccal®, Parvosol®, and A33®, are commonly used. They are less corrosive than bleach, less irritating to mucus membranes, good at controlling odors, and in general more “forgiving” concerning technique of usage than other disinfectants. Quats are not effective at killing non-enveloped virus agents like Parvovirus (or at least not very effective). Dilute at 1:32 or 1:64 for best results in a shelter environment.

Bleach (sodium hypochlorite) diluted at 1:32 is probably the most common

disinfectant used today. It is effective against most of the germs present in a shelter environment. When used in a ringworm-contaminated area, dilute it at 1:10. Bleach is inexpensive and easy to use, but there are some important limitations and drawbacks. First, it is NOT effective in the presence of organic material. Very small amounts of organic material (like stool, hair, skin dander) will render it less or even non-effective. It also requires a minimum of 10 minutes contact time for it to be completely effective (30 minutes for ringworm). Rinse it thoroughly with plain water. It is very corrosive to metals and very irritating to mucus membranes. Once diluted, it is only effective for 24 hours. Train staff thoroughly in its usage. Bleach is often used in footbaths, but it is relatively ineffective because the bath quickly becomes contaminated with organic material.

Potassium peroxymononsulfate (Trifectant®, VirkonS®) is a relatively new class of disinfectant. These have all the advantages of Quats, but they also are reported to kill non-enveloped viruses like Parvovirus. It is also effective in the face of moderate amounts of organic material, so its use in footbaths would seem to be effective. It is not, however, effective against ringworm spores.

The most overlooked, but perhaps single-most-important objects to wash and clean well in shelters, are the hands of everyone involved with caring for and handling animals, including prospective adopters. Numerous studies have shown how easy it is for germs to not only survive on our hands, but to easily passed from one animal to another or from an animal to us or another person. This is especially important with children. It is important to wash often and thoroughly. This is much more readily accomplished with plentiful and convenient sinks. The actual scrubbing of our hands is the important step, so it is not as important to use a "disinfectant" soap. Wash your hands in between each animal or at least in between each ward where you work, especially after handling known ill animals. Using liquid soap dispensers rather than bar soap is best.

The use of hand sanitizers is NOT a substitute for washing. These materials rely on alcohol for their disinfection. Hand sanitizers require a 60-second contact time for complete effectiveness, and very few people use enough to have it on their hands for a full minute.

In the face of a known zoonotic disease outbreak, the use of personal protection materials like gowns, booties, gloves, and masks can be useful. In general, these materials are too cumbersome and time consuming in a day-to-day setting. Instead, emphasize regular hand washing.

Take these additional steps to minimize the spread of zoonotic diseases:

- Use separate refrigerators for human food and animal supplies (e.g., dog and cat food, veterinary supplies, laboratory materials, fecal samples).
- Do not allow eating, application of cosmetics, or applying contact lens in animal areas. In addition, these activities should also be done only after thorough hand washing.
- Do not use your mouth as a "third hand."

Education About Zoonotic Diseases

The final step we hope most animals take in their journey through the shelters is adoption, so you must inform potential adopters what steps to take to minimize the possibility of exposure to zoonotic diseases from their new pet. This can be difficult to do without frightening some people and requires extensive staff training and preparation. Therefore, an organized and ongoing program of education including manuals, training sessions, informative signs, and a system of evaluation is very important. This step is not only important because it helps minimize the spread of diseases between animals and to people but also if your shelter is ever subjected to an OSHA review or worse, media scrutiny after an incident of zoonotic disease in your community.

Direct the first stage of your education program toward staff and include the following:

- **Usual symptoms of common zoonotic diseases in animals.** Early recognition of diseases in animals minimizes the number of people exposed. Early treatment of some diseases may also shorten the amount of time an animal is contagious.
- **Steps taken to minimize the transmission of these diseases within the shelter.** Include those steps taken every day in the shelter to minimize disease transmission, but also discuss specific extra steps to be taken in the face of an outbreak of zoonotic disease.
- **Symptoms of specific diseases in humans.** Staff members need to recognize any problem early and know how to seek appropriate care. Remember that early detection is a must, not only for the welfare of the people involved, but because there are many diseases that are not only contagious from animals to people but also from people to animals. In other words, an infected staff member can spread the disease to other people and to other animals. An example of this is common ringworm (superficial dermatophytosis).

Direct the second stage of your education program toward the public. Educating the public about zoonotic diseases is not only useful for preventing diseases, but it may also boost adoptions. There is a great deal of misinformation concerning zoonotic diseases and the "danger" of pet ownership. We must honestly inform the public of the risks and emphasize that in the vast majority of cases, the proven benefits of pet ownership outweigh the risks.

When formulating a program of public education, try to not direct it to any one group of people (i.e., immune-compromised people) but rather direct efforts to the population as a whole. Certainly, when we realize that immune-compromised people (e.g., cancer patients, HIV patients, organ transplant recipients, or splenectomized patients) are at more risk, we can alleviate some of their fear. However, the basic steps of zoonotic disease prevention are the same for everyone and should be emphasized as such.

Include printed materials in your public education program, such as putting them into adoption packets. The program should also involve training adoption counselors to properly answer basic questions about

zoonotic diseases. When formulating your program, keep the following in mind:

- Keep it basic and simple.
- Make sure it is up to date.
- Emphasize to the staff that any information a person shares with them is confidential.
- Emphasize the benefits of pet ownership, but do not downplay the risks.
- Above all, do not offer veterinary or medical advice. Refer people to their own personal physician or veterinarian for specific information and recommendations.

When formulating your program, consider seeking the advice of your local occupational health agency or the state or local public health agencies to help prepare materials.

Suggested Diseases to Include Information on in Adopter Information Packets

These diseases are so common and/or public knowledge (misconceptions?) is so widespread that having printed information in your standard adoption packs would be helpful to both the public and to your adoption counselors.

- Fleas
- Ticks
- Visceral Larval Migrans (roundworms)
- Cutaneous Larval Migrans (hookworms)
- Tapeworms
- Rabies
- Ringworm

Major or Common Zoonotic Diseases

There are literally hundreds of diseases classified as zoonotic. It is beyond the scope of this manual to cover even a significant percentage of them. Therefore, the diseases covered here are common, have received some degree of publicity, or experience some degree of public awareness. In other words, you may get questions concerning them. Check the References appendixes for sources of more detailed information concerning zoonoses.

Disease coverage is divided into three parts.

1. Those diseases considered most important in the management of a shelter. This might be because of the frequency of the disease itself, because of the degree of public awareness of the disease, or because of the potential seriousness of any outbreak.
2. Those diseases that have been seen with reasonable frequency and for which a definite zoonotic link has been established.
3. Emerging or new diseases

Animal Bites and Scratches

General Facts

- Certainly, this is one of the most common sources of zoonotic diseases.
- Many different bacteria can be involved (Pasteurella, Capnocytophaga).
- Depth of wound, location of wound, and type of animal involved are all factors that determine the severity of infection.

Symptoms in Animals

N/A

Symptoms in People

- Swelling, pain, drainage, loss of function of area of body bitten, fever
- Septicemia ("blood poisoning"); can be life threatening

Prevention or Control

- Use of protective equipment like gloves, catch poles, squeeze cages, and nets
- Proper design of cages and runs to facilitate restraint of animals
- Euthanasia of aggressive animals
- Education concerning proper techniques of animal handling
- Education concerning proper methods of reading animals' body language
- Promptly and thoroughly cleaning all wounds with antiseptic soap and copious amounts of water
- Seeking medical attention for all but the most superficial wounds
- Keeping tetanus vaccinations up to date for all staff members

References: 3

Bubonic Plague

Other Names

Plague, Black Death, Pneumonic Plague

Cause

Yersinia pestis (bacteria)

Transmission

- Primary source of exposure of humans and animals is through direct contact with rodents or more importantly the rodent flea. A rodent flea that is infected can carry the bacteria for months. Rats are the most important reservoir, but in Southwest United States, ground squirrels and prairie dogs are very important reservoirs.

- Rodent fleas can also be present on dogs, cats, rabbits, and other warm-blooded animals.
- Airborne droplets that originate from coughing or sneezing can spread pneumonic form of the disease. This can occur from human to human or from animal to human.
- Cats can become infected from ingestion of an infected rodent.

Symptoms in Animals

- Dogs usually have brief self-limiting illness.
- Rodents may rapidly die, or more often are asymptomatic.
- Cats have fever, lymph gland swelling, abscesses (from lymph glands), and often rapidly die.

Symptoms in Humans

- Lymph gland swelling, fever, pneumonia
- Development of black patches of skin that die ("Black Death")

Diagnosis in Animals

- It can be suspected based on clinical signs, especially swollen lymph glands and fever, but must be positively diagnosed using laboratory tests.
- Only qualified personnel should handle any animal that is suspected of plague when diagnostic tests are attempted.
- Microscopic examination of impression smears from aspirates of infected lymph nodes show large numbers of the bacteria ("safety pin" appearance).
- Blood tests
- Cultures from aspirates or draining abscesses

Treatment of Animals

Although various antibiotics can be used, because of the extreme danger these animals pose to humans, it is very questionable to attempt treatment in a shelter setting.

Prevention or Control

- Flea treatment in all animals admitted into the shelter. Advantage® is one flea treatment safely used in a wide variety of animals seen in a typical shelter.
- Avoid taking wild rodents into the shelter.
- Prevent dogs and especially cats from hunting or coming into contact with wild rodents.
- Report any confirmed cases to your local public health authorities.
- Recommend that all people with even casual contact with animals diagnosed with plague see their physicians immediately.
- Vaccines for humans are available but are not widely used or recommended.

References: 5-6

Camphylobacter

Other Names

Vibriosis

Cause

Camphylobacter jejuni (bacteria)

Transmission

- Most human cases are of unknown origin, but ingestion of undercooked meat is the most common identified cause.
- Exposure to the stool of infected dogs and cats, especially kittens and puppies, can be involved.

- Numerous cases of human infection from aerosolized bacteria have occurred in shelters, zoos, or reserves. These result primarily from using high-pressure hoses to clean or flush stool from cages or runs.
- Animals can shed the bacteria in their stool for weeks to months after their active infection has resolved.
- Camphylobacter is a very common cause of diarrhea in puppies and kittens in a high-stress, crowded environment like animal shelters.

Symptoms in Animals

- Diarrhea, especially in young animals, the nature and duration of which can vary widely
- Adult animals are often asymptomatic carriers.

Symptoms in Humans

- Acute gastrointestinal illness — the classic "food poisoning"
- Diarrhea, vomiting, abdominal pain
- Usually of short duration and self limiting in humans with normal immune systems

Diagnosis in Animals

- Culture of bacteria by qualified laboratory, requiring special techniques and conditions
- Probably not indicated in individual cases of diarrhea, but may be useful in widespread outbreaks within a shelter

Prevention or Control

- Good hygiene (Wash your hands!)
- Physically pick up fecal matter and dispose of before cleaning wards or cages.
- Do not hose runs or cages with high-pressure devices before fecal matter is physically picked up.
- Thoroughly cook all meat eaten by humans or animals.

References: 6-7

Cat Scratch Fever

Other Names

Cat Scratch Disease

Cause

Bartonella hensale (bacteria)

Transmission

- Exposure to infected cat by bite or scratch wound. Licking of a pre-existing wound.
- Bite or scratch from other animal (rodents).
- Some cases have no history of exposure to cats or other animals.
- Cats are exposed to the bacteria through the bite of an infected flea.
- Ticks and ear mites may also play a role in cat-to-cat transmission.

Symptoms in Animals

- Most cats (maybe all of them) are asymptomatic.
- The bacteremia (active infection) is of short duration (10-14 days). This is the only time that the cat is contagious to humans.

Symptoms in Humans

- Pustule develops near bite or scratch wound within 10 days after bite occurs. This can persist for one to two weeks.
- Swollen lymph glands develop 14-21 days after bite or scratch occurs.
- Most cases resolve within two to four months.
- Some people can develop lesions in their eyes or central nervous systems.

Diagnosis in Animals

Blood tests (serology) can detect antibodies to the bacteria, but this only determines that the cat has been exposed previously. Approximately 65 percent of the cats in the United States test positive. Cats only become seropositive (develop antibodies) after the bacteremia is resolved — in other words, after they are no longer contagious.

Treatment in Animals

- No effective treatment has been shown, but antibiotics may be useful.
- Cats are rarely treated because disease is asymptomatic and self limiting.

Prevention or Control

- Wash hands after handling cats.
- Avoid bites and scratches. Wash wounds quickly if they do occur.
- Flea control is very important.
- By the time disease is recognized in humans, the cat is no longer contagious; in other words; it is not necessary to get rid of the cat.
- Declawing the cat has been shown to not reduce the incidence of the disease.

References: 8-9

Cutaneous Larval Migrans

Other Names

Creeping Eruptions

Cause

The larva of the dog or cat hookworm penetrates the skin of humans and migrates under the surface of the skin (Ancylostoma brazilienze, Ancylostoma caninium).

Transmission

- Direct skin contact with the larva of hookworms, usually from the soil.
- Seen primarily in warm climates (The Southeast United States has much higher incidence than the rest of the country.)
- Seen mostly in children.
- Areas with moist sandy soil (playgrounds, sandboxes, beaches) are often heavily contaminated with hookworm larva.

Symptoms in Animals

- Most animals are asymptomatic or only occasionally show symptoms
- Diarrhea, often with blood
- Anemia, especially in puppies or kittens
- Sudden death, especially in puppies or kittens

Symptoms in Humans

- Inflamed tracts under the skin that are intensely pruritic (itchy). These usually start near or on the feet. They are linear and move 2-3 mm per day.

Diagnosis in Animals

Microscopic examination of the feces. A centrifuged Zinc Sulfate flotation is much more accurate that a routine “fecalizer” type of examination. Commercial laboratories usually perform these Zinc Sulfate floatations. Remember that a negative floatation test does not eliminate the possibility that the animal has hookworms.

Treatment in Animals

- Pyrantel (Strongid®) or fenbendazole (Panacur®) are very effective worming medications.
- Routinely administer worming medications to all animals coming into

the shelter upon entry. Repeat medication at two- to three-week intervals in puppies and kittens until they are 16 weeks of age.
- Preventative medications are commonly contained in the medications given for heartworm prevention and in some flea medication (Revolution®).

Prevention or Control

- Wear shoes, and encourage children to do so.
- Pick up the stools of all animals quickly and dispose them appropriately.
- Avoid walking (especially barefoot) in areas where many dogs or cats have defecated like "dog beaches" or "dog parks."
- Prevent dogs and cats from using public areas to defecate in (school yards or parks).
- Cover sandboxes when not in use.
- Provide good public education as to the danger of allowing dogs and cats to free roam.
- Provide good public education to stress the importance of picking up after their animals.

References: 10

Giardiasis

Other names

Beaver Fever

Cause

Giardia lamblia (protozoa)

Transmission

- Giardia is the most common protozoan parasite of humans.
- Many animals are capable of being infected and passing cysts in their stool, including dogs, cats, birds, horses, and cattle.
- It is most commonly contracted by ingesting water or food contaminated with cysts of Giardia.
- Humans are considered the natural host for Giardia, so human to animal transmission can also occur.

Symptoms in Animals

- Diarrhea, especially in puppies and kittens, possibly severe enough to cause weight loss and dehydration
- Adults are often asymptomatic.

Symptoms in Humans

- Diarrhea of varying degrees of severity and duration
- Abdominal cramps and discomfort

Diagnosis in Animals

- Giardia ELISA test on stool available both through commercial laboratories and as an "in house" SNAP test
- Zinc Sulfate centrifuged fecal examination, more accurate than standard "fecalizer" examination
- Giardia IFA test available but not as sensitive as ELISA test

Treatment in Animals

- No treatment is universally successful in preventing the shedding of cysts in the stool. Treatment is effective in minimizing diarrhea or symptoms in infected animals.
- Metronidazole (Flagyl®) or fenbendazole (Panacur®) have been used commonly.
- A vaccine is available that may help to minimize shedding of cysts.

Prevention or Control

- Hand washing and good hygiene are very important.

- Promptly pick up stools in runs and cages.
- Diagnose and treat any animals showing diarrhea, especially kittens and puppies.
- Bathing of animals in addition to treating them when they are infected with Giardia will help to prevent re-infection from feces on their haircoat.
- Quaternary ammonium disinfectants ("Quats") are very effective in killing the cysts in the environment, but these compounds rapidly lose their effectiveness in the presence of large amounts of organic matter. Therefore, physically picking up all fecal matter prior to disinfection is essential.

References: 11-13

Lyme Disease

Other Names

Lyme arthritis

Cause

Borrelia burgdorfei (spirochete bacteria)

Transmission

- Tick bite
- Ixodes ("Deer Tick") mainly involved, but the germ has been found in virtually all common tick species.
- The disease is not spread directly from animals to humans. Animals can bring ticks into areas of human habitation, which increases the exposure risk for people.
- Lyme Disease is now the most common tick transmitted disease in the United States.

Symptoms in Animals

- Cats are usually asymptomatic.
- Dogs can have fever, lethargy, or lameness (often "shifting leg" lameness).
- Symptoms often occur months after the tick bite took place.
- In some dogs, serious kidney disease can be seen.
- The arthritis that develops can be progressive and prolonged. Over time it can lead to permanent bone damage within the joints (osteoarthritis).

Symptoms in Humans

- Skin rash that develops in the area of the original tick bite is the prime symptom initially (erythema chronicum migrans).
- Fever, lethargy, and arthritis are common.
- Heart involvement is seen in some humans.
- Symptoms are often chronic waxing and waning.

Diagnosis in Animals

- Animals usually have elevated antibody titers (serology), but this only means the animal has been exposed and may or may not be suffering from the disease at this point.
- Clinical symptoms must be present to even consider a diagnosis.
- History of tick exposure
- At best, it is a difficult disease to positively diagnose in animals.

Treatment in Animals

- Antibiotics may be useful in early stages but they need to be given over an extended period of time (30 days minimum).
- Symptoms often recur after the antibiotic treatment.
- NSAIDS like Rimadyl® may help to ease pain of arthritis.

Control or Prevention

- Vaccines for dogs help to prevent symptoms, but because dogs do not directly transmit the disease to humans, vaccinating the dog does not prevent human infection.
- Tick control on dogs is important. Monthly flea/tick treatments like Frontline® or Advantix® are helpful.
- Prevention of tick exposure in humans. Avoiding areas likely to be tick infested like brushy or forested areas. Wearing long pants and long-sleeved shirts.
- Prompt removal of attached ticks.
- Studies in animals have shown that the risk of disease transmission from an infected tick is very low during the first 24 hours of attachment. The risk is 50 percent after 48 hours of attachment. The risk is 100 percent after 72 hours.
- DEET can repel ticks from humans.
- Use caution not to squeeze the body of the tick when removing. Only put traction on the head and neck of the tick to avoid expressing the stomach contents of the tick into the bloodstream of a person.

References: 14-15

Psitticosis

Other Names

Parrot Fever, Ornithosis, Chlamydiosis

Cause

- Chlamydia psittaci (bacteria)
- Possibly other strains of Chlamydia

Transmission

- Inhalation of dried feces or respiratory secretions from an infected bird
- Direct contact with contaminated feces or respiratory secretions
- Mammalian species of Chlamydia (from cats, for example) only rarely spread to humans

Disease in Birds

- Many birds may be asymptomatic until stressed (like coming into a shelter).
- Virtually any symptom that an ill bird can have may be seen.
- Respiratory, heart, liver, and gastro-intestinal problems; arthritis

Disease in Humans

- Symptoms typically develop one to two weeks following exposure.
- Fever, malaise, headaches, and respiratory signs like coughing and pneumonia are seen.
- Heart problems sometimes occur.
- Abortion and uterine infections can be seen in late-term pregnant women.
- Symptoms can be life threatening.

Diagnosis in Birds

- Clinical signs
- Antibody titers (serology)
- Reportedly African Greys, cockatiels, and budgies typically have negative titers even when they are actively shedding the germs.
- ELISA test for germs in the stools of the infected birds are reliable but should be run by qualified laboratory.

Treatment in Birds

- Antibiotics
- In a shelter environment, the decision to treat is questionable because of the zoonotic potential.

Prevention or Control

- Ask all people relinquishing birds, what the original source of the bird

was. If the bird was bred and/or sold through a reputable dealer in the United States, it is likely certified Psittacosis free. If the bird was purchased overseas (Mexico), it has to be treated as a suspect.
- Only trained personnel that are clothed properly (masks, gloves, gowns) should handle birds suspected of having psittacosis.
- Birds can be treated prophylactically with Chlortetracycline, but it questionable in a shelter setting if this is justified.

References: 16-17

Rabies

Other Names

Hydrophobia, Lyssa

Cause

Rhabdovirus or Lyssavirus (virus)

Transmission

- Bite from an infected animal
- Salivary contamination of preexisting wound
- Cases with no history of bite/scratch transmission are considered very rare.
- Most cases that initially of unknown exposure have a bite wound of which the victim was unaware (especially bites from bats).
- In the United States, few cases involve domestic animals. This is primarily because of the extreme public health measures that have been taken — like mandatory vaccinations of dogs and cats, enforcement of leash laws, and the reduction in the stray dog population.
- The current main reservoirs of rabies are:
    - East Coast of United States — Raccoons
    - West Coast of United States — Skunks and bats
    - Mexico — Domestic dog
- Most all warm-blooded animals are susceptible in varying degrees to rabies, including dogs, cats, horses, cattle, rabbits, rodents, and birds.
- Realistically, most small animals, like rabbits, are unlikely to survive the initial exposure (bites) to rabies. Therefore, they are rarely diagnosed with rabies.

Symptoms in Animals

- Central nervous system signs
- Most animals exhibit fairly distinct stages or groups of symptoms, but atypical cases are sometimes seen.
- Prodromal stage lasts two to three days. Usually animals show apprehension, anxiety, and a change in personality.
- Furious stage lasts one to seven days. Usually animals are restless and show increased response or sensitivity to visual and auditory stimuli. As they become more restless, they start to roam, becoming progressively more irritable and vicious. They start to have seizures and develop muscle incoordination.
- Paralytic or dumb stage lasts two to four days. Usually animals show progressive paralysis starting in the hind limbs and ascending. Often they will show a change in their voices as the vocal cords become paralyzed.
- Death occurs within five to 14 days after the onset of clinical signs.
- Virus is only shed in the saliva during the active stages of the disease. This is why only a 10-day quarantine is

required. (It is possible that the CDC may recommend a longer quarantine in the future, but 10 days is the current requirement.)

Symptoms in Humans

- Pain and swelling at bite site
- Paresis/paralysis follows, including paralysis of the muscles of the larynx and the muscles of swallowing, which leads to difficulty and pain on swallowing, hence the name "Hydrophobia," fear of water.
- Death invariably occurs.

Diagnosis in Animals

- Microscopic examination of the *unfrozen* brain by a qualified pathologist gives the definitive diagnosis.
- Microscopic examination of skin taken from the muzzle of the dog can give an ante mortem (before death) diagnosis, but is not a substitute for proper quarantine and if needed, brain examination.
- Clinical symptoms

Treatment

There is no treatment.

Prevention or Control

- Mandatory vaccination of all dogs.
- Cats also should be vaccinated for rabies.
- Prompt and vigorous washing of all bite wounds with soap and water.
- Pre-exposure rabies vaccines for all persons in high-risk jobs (like shelter personnel).

Protocols for Animals Suspected of Exposure to Rabies

- Any domestic animal that has been bitten or scratched by a wild carnivorous animal or bat that is not available for testing is assumed to be exposed to rabies.
- If the domestic animal is unvaccinated for rabies, either euthanize it immediately, or hold it for a six-month quarantine in a licensed facility (like a shelter or veterinary hospital).
- If the domestic animal has proof of current rabies vaccine, home quarantine for 45 days is considered adequate.
- More information, see Rabies Protocol Chart

References: 18-20

Ringworm

Other Names

Superficial Dermatophytosis, Fungal Dermatitis

Cause(s)

- Microsporum canis (fungus), most commonly seen in dogs and cats
- Microsporum gypseum (fungus), found living in the soil
- Trichophyton mentagrophytes (fungus), most commonly seen in rodents

Transmission

- Direct contact with infected animal, most common means of transmission.
- Contact with fomite or object contaminated with fungal spores from infected animal
- Spores can live for years in environment.

Symptoms in Animals

- Many animals (e.g., dogs, cats, rodents, horses) are asymptomatic or show only very minimal symptoms

that are difficult or impossible to note on basic physical examination.
- Typically causes patchy hair loss in a roughly circular pattern.
- Hairs break off at the level of the skin, leaving "stubbles" of hair.
- Often hairless areas are scaly, and the skin may be darkly pigmented.
- In young animals (kittens especially) the lesions are most commonly seen around the head, face, and ears.
- It can affect the toenails causing odd toenail growth patterns.
- Most cats do not have pruritis (itching).
- It can cause a wide variety of skin and hair coat lesions, so consider any animal showing hair loss or other dermatitis a ringworm suspect.
- In general, dogs are over diagnosed with ringworm. In other words, most dogs with skin lesions do not have ringworm.
- Cats are under diagnosed with ringworm. In other words, more cats have ringworm than we suspect.
- Longhaired cats (Persians) may be more susceptible to ringworm, or it just may be more difficult to diagnose because of subtle symptoms.

Symptoms in People

- Similar symptoms to those described in animals
- Lesions are usually reddened, scaly and may be pruritic (itchy).
- Lesions most commonly occur on hands, arms, neck, and face. These are the areas that come into contact with the infected animal.
- Often is mild and self-limiting

Diagnosis in Animals

- Physical appearance of lesions and the age and type of animal involved are important considerations. View any skin lesion on the face of a young kitten as a probable ringworm case until proven otherwise.
- A Woods Light® is an ultraviolet lamp that emits a very specific wavelength ultraviolet light that causes some ringworm lesions to fluoresce. This can be a very valuable, simple screening test, but it is very easy to both under and over diagnose ringworm.
    - 50 percent of ringworm cases will not fluoresce, so negative results do not rule out ringworm.
    - In those animals that do have fluorescence, it is very important to note that it is the hairs that are important. Fluorescing hairs are significant, not fluorescing skin or scabs. The fluorescence should be a bright "apple green" color.
    - It may be helpful to allow the light to warm up for several minutes before using it and to shine it for several minutes on the animal's hair coat before attempting to read any fluorescence.
    - A 110 V Woods Light with a magnifying glass built into it is easier to use than a small battery powered light.
- DTM fungal culture (Dermatophyte Test Media) is the most accurate test, but again it must be used and read properly to be accurate.
- The flat petri dish type of culture media containers is easier to use and probably more accurate that the "jar" type of containers.
    - Pluck some of the hairs from the periphery of the lesions and

place them onto the media. If fluorescing hairs can be used, all the better.
    - Use a toothbrush (a new wrapped toothbrush is not sterile, but it is very unlikely that any pathogenic fungi are present) to vigorously brush the hair on the lesion and also the entire body and then place the hairs and skin dander on the DTM media.
    - Do not tighten the cap on the media. The fungi need air to grow.
    - Look at the DTM daily. Any color change (to red) should take place before or immediately after any visible fungal colony is present to be significant. Almost any fungi will cause the media to change color if you wait long enough.
    - After fungal colonies are visible, send them to a commercial laboratory to identify the exact species of fungi involved. This may be valuable if you are trying to determine the source of a zoonotic outbreak in the absence of a known ringworm-infected animal.

Treatment in Animals

- It is very questionable to attempt treatment of ringworm in a shelter setting. In general, do so only if your shelter can meet the following criteria:
    - You have the ability to isolate the affected animal(s) for a minimum of six weeks.
    - You are willing to treat vigorously for a minimum of six weeks.

Keep in mind that the priorities of treatment in a shelter setting are somewhat different than in a home with an individual animal. Preventing transmission of the disease to humans, other animals and preventing environmental contamination are the first priorities to consider. Curing the affected animal is the secondary goal.

When you diagnose ringworm in a shelter animal, you should assume that the infection is generalized (affects the whole body) even if you can only see localized lesions.

If you do decide to treat an affected animal the following steps are useful:

Clip the hair. Although you can clip just visible lesions, clipping the entire body of the animal is best. Remember that shed and broken hairs are the primary means of transmission. Anything that can be done to minimize these will minimize the risk of zoonotic disease transmission or environmental contamination. Also whole body clipping makes it easier for your staff to treat the animal and to monitor the progression of the disease as it responds to treatment. Use a dedicated pair of clippers, and dispose of the hair as infected biological waste. Any staff members involved should wear gloves and disposable gowns. Ideally use a separate room and/or table from your regular treatment or surgical tables is best. Sedation or general anesthesia is often needed to do a good safe job.

Dip or rinse the animal in Lyme Dip at weekly or biweekly intervals for a minimum of six weeks. Topical dilute bleach has also been used, but bleach loses its effectiveness in the face of organic matter (e.g., hair, skin dander). Lyme Dip has been shown to be effective and safe in

the vast majority of animals. In a clipped animal, it is easy to dip or sponge on.

Use a systemic (internal) medication. Itraconazole (Sporonox®) and Griseofulvin (Fulvicin®) have been used successfully. Itraconazole is probably the treatment of choice at this point and is available through compounding pharmacies in liquid form. Both of these medications are expensive, but because the majority of ringworm patients are small kittens, the cost per animal is still low.

Treat for a minimum of six weeks. If the lesions are visibly filling in with hair, start taking toothbrush samples for DTM cultures. A series of three consecutive negative cultures is needed to be comfortable with discontinuing treatment. Even then, warn a prospective adopter that recurrence is possible, but very unlikely.

Any treatment approach less than described is an invitation for zoonotic disease to occur in your staff and in adopters. Even casual visitors to your shelter may be at risk.

Prevention or Control

Design any prevention measures to minimize the contamination of the environment, staff, or other animals with broken, shed hairs from a ringworm-infected animal.

Thoroughly sweep cages and wards (the use of disposable "Swiffer" type of mops may help). Only vacuum after the gross hairs and skin dander has been removed. Dispose of the vacuum bag promptly. It is possible to contaminate your cleaning tools.

Known ringworm animals should only be handled by trained staff members wearing protective clothes (gowns and gloves). Fortunately, the contagion of ringworm decreases quickly after aggressive treatment is started.

Disinfection of contaminated rooms and cages can be difficult. The spores of these fungi are very resistant to disinfection and environmental factors. A 10 percent bleach solution with a 30-minute contact time can be effective, but prior physical removal of hair and other organic material is essential.

Have staff routinely use tape hair rollers to minimize the transfer of potentially contaminated hair from room to room.

Rooms and cages can be cultured using material taken by using a toothbrush to wipe down the room (e.g., floors, cage doors). This can be useful to try to determine where a zoonotic outbreak may have originated if no infected animals can be identified.

Vaccination for ringworm is generally not recommended in a shelter environment. The vaccine has not been shown to prevent or cure ringworm. It only seems to be effective in hiding or clearing the visible lesions, making it harder to identify affected animals.

References: 21-23

Salmonellosis

Other Names

Enteric Paratyphosis

Cause

Salmonella typhimurium (bacteria)

Transmission

- Passed in feces of infected animal

- Many animals harbor and carry Salmonella in their digestive tracts but show no symptoms themselves.
- It can be directly transmitted by fecal-soiled hand-to-mouth contact.
- More commonly transmitted by contaminated fomites
- Food and water are the most common fomites.
- Veterinary equipment like thermo-meters or endoscopes can be involved.
- Respiratory spread possible but not common
- Salmonella is quite resistant and can survive in environment for long periods.
- Carnivorous animals that have access to raw meat have high incidence.

Symptoms in Animals

- Many are asymptomatic and are only carriers.
- Fever, lethargy, and anorexia can be seen in acute or early phase of disease.
- Gastrointestinal signs like diarrhea and vomiting are the most common symptoms.
- Bacteria can gain entry into blood stream (septicemia) and cause serious and widespread disease in internal organs.
- Conjunctivitis has been seen occasionally in cats.
- Only a small number of animals will die of the disease, but those that recover will continue to shed germs in their stools for six weeks following recovery.

Symptoms in Humans

- Acute gastrointestinal disease, with vomiting, diarrhea, and abdominal cramps most common symptoms
- May also cause blood infection as in animals

Diagnosis in Animals

- Fecal cultures with special culture media are most accurate, but because germs are only shed intermittently, negative culture does not eliminate diagnosis.
- Three consecutive negative fecal cultures are needed before an individual animal can be declared free of Salmonella.
- You may need commercial lab to determine specific type of Salmonella present in the face of an outbreak of unknown origin. Certain strains of Salmonella are more likely to originate from specific sources or species.

Treatment in Animals

- Symptomatic supportive treatment in acute phase of disease
- Antibiotics can be used, but are often reserved for animals with more serious symptoms.
- Antibiotic resistance is becoming a serious problem in many locations.

Prevention or Control

- Public education about the dangers of Salmonella in certain types of pets, like reptiles
- Emphasize the importance of good hygiene especially in the children of prospective adopters rather than just emphasizing the potential danger that the animal poses.
- Prompt and aggressive physical removal and cleaning of fecal matter from runs, cages, and yards
- Remember that even an animal with normal appearing stool may be carrying and shedding Salmonella germs.
- Emphasize good hygiene among staff and volunteers. Hand washing, especially prior to eating, drinking, or

applying cosmetics is particularly important.
- Control wild bird populations, as these can be source of contamination.
- Thoroughly cook all human food.

References: 1-2

Scabies

Other Names

Sarcoptes, Sarcops, Sarcoptic Mange

Cause

- Sarcoptes scabei (mite)
- Many varieties can cause human disease. Specific species will have a preferred host. For example, the dog scabies mite will only reproduce on dogs, but it will infect any animal causing skin lesions.

Symptoms in Animals

- Intense itching (pruritis). This often causes self-trauma from scratching that in turn, will cause hair loss, thickening and scaling of the skin.
- Secondary bacterial skin infections are common.
- It most commonly starts in elbows, ears, and face.
- Many animals will have a positive pedal-pinna reflex, meaning that if you rub the margin of the ear flap (pinna) between your fingers, the dog will start to move its hind leg on that side in a scratching motion.

Symptoms in Humans

Papules or rash that is intensely pruritic

Diagnosis in Animals

- Microscopic examination of skin scrapings
- Many times only a few mites are present on the animals. Therefore, they can be difficult to find on scrapings. Negative scrapings do not completely eliminate the possibility of mites being present.
- Trial treatment with ivermectin can be used. If ivermectin is used and the animal shows marked improvement within seven to 14 days, this is strong evidence that Sarcoptes mites were present.

Treatment in Animals

- Ivermectin is the simplest and most effective treatment that is widely used.
- Some of the topical flea medications (Frontline®, Revolution®) are reportedly effective against Sarcoptes mites, but there are conflicting anecdotal results.
- Topical organo-phospate or Lyme Sulfur dips can be used, but in general these are less effective and more difficult to use than ivermectin. May be of value in Collies or Shetland Sheepdogs that are more sensitive to ivermectin.

Prevention or Control

- Promptly diagnose and treat any infected animal.
- Because the mites do not reproduce on humans, if the original source animal is cured, the problem will go away in any humans infected.
- Good hygiene measures
- Physically clean the environment, but the mites do not survive off the animals for long periods of time.
- Discard any non-washable items from cages or runs like blankets or pillows.

Shigellosis

Other Names

Dysentery

Cause

Shigella (bacteria), many different strains

Symptoms in Animals

- Primarily affects primates
- Causes much the same symptoms as Salmonella

Symptoms in Humans

Causes much the same symptoms as Salmonella

Diagnosis in Animals

Fecal cultures (much the same as Salmonella)

Treatment in Animals

Similar to treatment for Salmonella, but antibiotic resistance is uncommon.

Prevention or Control

Similar to Salmonella, but primarily involves primates.

References: 24-25

Toxoplasmosis

Cause

Toxoplasmosis gondii (protozoan)

Life Cycle

Cats are the definitive host. Although many warm and cold-blooded animals can contract it, only in cats can the parasite complete its life cycle, which is very complicated and involves many stages.

Eggs (oocytes) are passed in the stool of an acutely infected cat.

These are unsporulated at first. At this stage the eggs are not infective to other animals. They are also very susceptible to disinfectants and environmental factors (drying).

After 24-72 hours the eggs sporulate. Now they are infective and very resistant to disinfectants and environmental factors.

After eggs are ingested by another animal they hatch and form cysts (bradyzoites) in various body tissues. These cysts persist for the life of the animal. They stimulate an inflammatory reaction, and this is what causes any symptoms that may be seen.

Transmission to Cats

Cats contract the disease by ingesting raw meat from an animal that has the dormant cysts present in its tissues.

Transmission to Humans

Humans can become infected by any of the following routes:

- Ingesting cysts located in muscle tissue (meat) that is undercooked or raw.
- Ingesting sporulated eggs (oocytes) that have passed in the feces of an acutely infected cat. The most common source of these eggs is in food, soil, or water that has been contaminated with the feces of an infected cat.
- An unborn fetus can contract the disease from the blood of a newly infected pregnant woman. This is transplacental infection.

Symptoms in Animals

- Cats rarely develop any symptoms.
- Can cause eye, brain, lung, or muscle symptoms
- After a cat becomes infected, it only passes eggs in its stool for two to three weeks. It never again passes eggs.

Symptoms in Humans

- Symptoms are caused by the inflammatory reaction to the dormant cysts.

- Eye, brain, respiratory, and muscle symptoms can be seen.
- Most immune-competent humans have no symptoms.
- If a pregnant women contracts the disease, the unborn fetus can contract the disease and develop severe symptoms before birth. Eye and brain symptoms are most common. Abortion can also be seen.

Diagnosis in Animals

- Perform microscopic examination of the stool for the eggs (oocytes). These eggs are only passed by the cat for two to three weeks and are very small and difficult to find.
- Serology or blood tests for antibodies to Toxoplasmosis are of limited usefulness because by the time the cat shows antibodies, they are no longer passing eggs in their stool. A cat that tests negative should be considered at risk. In other words, it has never had the disease and can contract it, if exposed.

Treatment in Animals

- Cats are rarely treated because they are usually asymptomatic.
- By the time a diagnosis is made, the cats are no longer a danger because they are no longer passing eggs in their stool.
- Various antibiotics have been used.

Prevention in Cats

- Keep cat indoors to prevent hunting.
- Avoid feeding raw meat.

Prevention or Control in Humans

- Avoid eating raw or undercooked meat.
- Avoid eating unwashed vegetables, especially those that grow on or near the ground.
- Avoid gardening outdoors or at least wear heavy rubber gloves.
- Outdoor garden areas have often been used as community litterboxes for long periods of time and are heavily contaminated with the eggs of Toxoplasma.
- Have someone (not the pregnant woman) clean the cat's litterbox. Clean it at least once every 24 hours, as the eggs are not infective at this time. Dispose of the stool properly.

Advice to Families of Pregnant Women

- Do they have to get rid of the family cat? NO!
- Cats are only infective for a very short period of their lives.
- A few precautions in dealing with the litterbox will be very effective in reducing the risk even further.
- Extensive studies have never shown any evidence of contamination of the cat's haircoat or body with Toxoplasmosis eggs.
- There are conflicting reports, but most studies have shown no higher evidence of Toxoplasmosis antibodies in cat owning AIDs patients, pregnant women, or veterinary personnel than in the general population in the United States.

References: 26-27

Visceral Larva Migrans

Other Names

Toxocariasis

Cause(s)

- Toxocara canis (dog roundworm)
- Toxocara cati (cat roundworm)
- Baylisacaris procyonis (raccoon roundworm)

Transmission

- Eggs are passed in the stool of an infected animal. These eggs survive for long periods of time in soil. An infected dog can pass a hundred thousand eggs per day in their stool. Soil samples taken from parks, schoolyards, and sandboxes in the Southeastern United States have contained millions of eggs per square foot.
- Humans, especially children, ingest the eggs either directly from the stool or more commonly, from contaminated soil.

Symptoms in Animals

- Puppies can be infected before birth and will start to pass eggs before they are two weeks of age.
- Diarrhea and vomiting are seen especially in puppies and kittens.
- Unthriftiness, failure to grow, or a pot-bellied appearance is commonly seen.
- Coughing or respiratory signs are also common, especially in puppies.

Symptoms in Humans

- Symptoms are primarily caused by larva of the worms that form after the ingested eggs hatch. These larva start to migrate through body tissues and organs and create a marked inflammatory reaction. It is this reaction that causes the symptoms seen. The specific symptoms depend on which organ the larva are migrating through.
- Fever, cough, or respiratory symptoms are sometimes seen.
- The eyes are a common location of symptoms. Visceral (Ocular) larval migrans is the most common source of acquired blindness in children in the United States.

Diagnosis in Animals

- Microscopic examination of the stool of dogs or cats. A Zinc Sulfate centrifuged sample is most accurate.
- Physical symptoms and age of animal. Assume that any puppy under 16 weeks of age that has not been treated with an effective broad spectrum deworming medication is infected.

Treatment in Animals

- There are a variety of good, safe, broad spectrum deworming agents (antihelmenthics) available today. Pyrantel (Strongid®) and fenbendazole (Panacur®) are the most common.
- Treat all puppies and kittens starting as early as two weeks of age, and treat every two weeks until they are 16 weeks.
- Recommend that all adopters follow up with worming treatments.
- Pregnant dogs can be treated prophylactically to minimize transplacental transmission.
- Preventive medications in some heartworm or flea treatments can be useful.

Prevention or Control

- Emphasize good hygiene, especially hand washing. Children are most susceptible. They are also the most difficult to get to comply with good hand-washing practices.
- Prevent dogs and cats from having access to public grounds like playgrounds or schoolyards.
- Emphasize need to pick up the stools of animals promptly.
- Cover all children's sandboxes when not in use.
- Children should avoid dog parks and dog beaches.
- There is nothing that is effective against the eggs in the soil.

References: 50

Less Common Zoonotic Diseases

Anthrax

Other Names

Woolsorter's Disease, Malignant Edema, Malignant Pustule, Charbon

Cause

Bacillus anthracis (bacteria)

Transmission

- Herbivorous animals ingest spores in the soil.
- Most animals are susceptible, but cattle, horses, goats, and sheep are most commonly infected.
- Humans become infected by handling contaminated carcasses, hair, or wool.
- It can be contracted by inhalation or ingestion of spores. This is the means involved in several well-publicized cases involving Anthrax spores sent through the mail.

Symptoms in Animals

- Acute onset of fever, body swelling (edema), and spontaneous bleeding
- Usually die within one to three days

Symptoms in Humans

- Cutaneous form is the most common naturally occurring form in humans. Red papules develop on skin within one to seven days of exposure. These gradually turn black, and the skin sluffs away (dies). After this, the bacteria gain entry into the blood and causes generalized body organ failure to occur.
- Pneumonia can be seen.
- Fatality rate depends of route of exposure, but many (more than 50 percent) will die unless treated very early.

Diagnosis in Animals

- Microscopic examination of blood, saliva, or body tissues
- Culture of blood or respiratory secretions

Treatment in Animals

- This is a disease that should not be treated or dealt with in a shelter setting.
- Various antibiotics are used.

Prevention or Control

- Vaccine is available for livestock.
- Vaccine is available for high-risk humans.
- Avoid contact with any animals or animal body parts that have been suspected of having Anthrax.
- Spores are very difficult to kill or remove from environment.
- This is a reportable disease. Notify public health authorities at once.

References: 28

Babesiosis

Other Names

Piroplasmosis

Cause

Babesia divergins (protozoa)
Babesia microti

Transmission

- Naturally found in certain species of mice and deer
- Transmitted to animals and to humans by Ixodes ticks
- Rare in humans, but much more common in AIDs patients,

splenectomized people, and the elderly.

Symptoms in Animals

- Most animals only show mild transient fever and lethargy.
- It can cause anemia and thromboembolism (blood clots).

Symptoms in Humans

- Fever, chills, headache, and fatigue that waxes and wanes over two to four weeks
- Most people recover spontaneously.

Diagnosis in Animals

Microscopic examination of blood for the protozoan parasite

Treatment in Animals

Various anti-Babesia drugs are available.

Prevention or Control

- Tick control is most important.
- Also control deer and mice populations.

This is not the same type of Babesia that causes disease in Pit Bull dogs and Greyhounds. There has only been one reported case of disease in humans caused by the species of Babesia (B. gibsoni and B. canis) that causes disease in dogs.

References: 29-30

Brucellosis

Other Names

Bang's Disease, Contagious Abortion, Malta Fever, Undulant Fever

Cause

- Brucella canis in dogs (bacteria)
- Brucella abortus in cattle and sheep
- Brucella suis in pigs
- Brucella melitnesis in sheep and goats

Transmission

- Ingestion of unpasteurized milk
- Direct contact with infected animals, especially contact with aborted fetuses, birthing fluids, urine, or birthing membranes

Symptoms in Animals

- Reproductive system problems are the primary symptom.
- Abortion, stillbirths, testicular abnormalities, infertility
- Backbone (spinal) problems are common in dogs.
- Fever and lethargy are usually mild and of short duration.

Symptoms in Humans

Swollen lymph glands, fever headache, chills, often waxing and waning over long periods of time

Diagnosis in Animals

- Blood tests, including serology
- Culture of germ from blood stream or from reproductive system secretions
- Difficult to diagnose

Treatment in Animals

Various antibiotics can be used, but recurrences are very common even following prolonged treatment periods.

Prevention or Control

- Avoid contact with birthing fluids in animals that have aborted or that have any history of infertility.
- Suspect that any male dog that has evidence of testicular abnormalities, including swelling or atrophy of having Brucellosis. Most dogs, however, will not be infected.

- Although many people will keep dogs with Brucellosis (breeders especially) all people involved should be educated about the risk of zoonotic infections.

References: 31

Colibacillosis

Other Names

White Scours, Colitoxemia, Food Poisoning

Cause

- Escherichia coli (E coli) (bacteria)
- Many different strains (serotypes), some of which are species specific and some of which aren't

Transmission

- Milk, eggs, and meat products contaminated with fecal matter of infected animal are the most common means of transmission.
- Direct contact with infected dogs/cats

Symptoms in Animals

- Gastrointestinal problems like vomiting and diarrhea
- Blood infection (septicemia) with generalized internal organ damage and even death occasionally seen

Symptoms in Humans

- Acute gastrointestinal disease with vomiting, diarrhea, and abdominal cramps
- Blood infections can also be seen.

Diagnosis in Animals

- Stool culture
- Tests (immunoassays) for bacterial toxins in stool

Prevention or Control

- Good hygiene (Wash your hands!)
- Physically pick up fecal matter and dispose of before cleaning wards or cages.
- Do not hose runs or cages with high-pressure devices before fecal matter is physically picked up.
- Thoroughly cook all meat eaten by humans or animals.

References: 51

Cryptosporidosis

Cause

Cryptosporidium (protozoa related to the common coccidia organism)

Transmission

- Ingestion of contaminated food or water most common
- Direct fecal-oral contamination

Symptoms in Animals

- Most cases asymptomatic
- Diarrhea and general digestive upset

Symptoms in Humans

- Most cases are either asymptomatic or have very mild symptoms.
- Usually self-limiting
- In immune-compromised people, it can cause severe diarrhea, fever, marked weight loss, and dehydration.
- It can also cause multi-organ involvement and be life threatening.

Diagnosis in Animals

- Microscopic examination of stool for eggs (oocysts) requires special stains and equipment that are only available through commercial laboratories.
- PCR and ELISA tests can be run on stool.

Treatment in Animals

- Usually not considered because disease is self limiting and mild
- Antibiotics
- Supportive

Prevention or Control

- Emphasize the importance of good hygiene, especially in the children of prospective adopters rather than just emphasizing the potential danger that the animal poses.
- Prompt and aggressive physical removal and cleaning of fecal matter from runs, cages, and yards
- Remember that even an animal with normal appearing stool may be carrying and shedding Cryptosporidium germs.
- Emphasize good hygiene among staff and volunteers. Hand washing, especially prior to eating, drinking, or applying cosmetics is especially important.

References: 32-33

Dipylidiasis

Other Names

Tapeworm, Flea Tapeworm, Pinworms (not correct)

Cause

Dipylidium canium (tapeworm)

Transmission

- Ingestion of a flea infected with the larva of the Dipylidium organism
- Ingestion of the segments of the tapeworm (proglottids) that are passed in the stool of an infected animal is NOT infective to humans or to other animals

Symptoms in Animals

- Most asymptomatic
- Mild digestive symptoms
- Perianal dermatitis
- Passage of the tapeworm segments in the stool or around the anus of an infected animal

Symptoms in Humans

Most asymptomatic or very mild digestive upsets

Diagnosis in Animals

Segments of the tapeworm seen in the stool or around the anus area of an infected animal

Treatment in Animals

- Droncit® (praziquantel)
- Broad spectrum dewormers like pyrantel (Strongid®) are NOT effective.

Prevention or Control

- Flea control
- Good personal hygiene
- Treat all animals promptly that show symptoms.

References: 52

Echinococcosis

Other Names

Hydatid Disease

Cause

Echinococcus granulosis (tapeworm)

Transmission

- Ingestion of eggs passed in the stool of infected animal
- Dogs that are used in herding sheep and goats are the most common source.

- Dogs contract it most commonly from eating infected rodents.

Symptoms in Animals

Most asymptomatic or have very mild digestive upset

Symptoms in Humans

- After eggs are ingested, larva hatch and migrate to different organs of the body (e.g., liver, brain, lungs). These larva later form a cyst that can grow to a very large size. The specific symptoms that develop depend on the organ involved and the size of the cyst.
- It may require five to 20 years for the cyst to grow large enough to cause symptoms.

Diagnosis in Animals

Microscopic examination of stool for the eggs requires special techniques and equipment that only commercial laboratories commonly have.

Treatment in Animals

- Droncit® (praziquantel)
- Broad-spectrum dewormers such as pyrantel (Strongid®) are NOT effective.

Prevention or Control

- Emphasize the importance of good hygiene, especially in the children of prospective adopters rather than just emphasizing the potential danger that the animal poses.
- Prompt and aggressive physical removal and cleaning of fecal matter from runs, cages, and yards
- Emphasize good hygiene among staff and volunteers. Hand washing, especially prior to eating, drinking, or applying cosmetics is especially important.
- Rodent control

Ehrilicosis

Other Names

Tick-borne fever

Cause

Ehrlicia canis (bacteria-rickettsia)

Transmission

Bite from infected tick (Rhipicephalus sanguineus or Brown Dog Tick)

Symptoms in Animals

- Dogs most commonly affected
- Fever, lymph gland swelling, lethargy
- Nosebleeds (epistaxis) common
- Generalized organ involvement
- Can wax and wane over long period of time

Symptoms in Humans

- Fever and lethargy
- Heart problems
- Blood problems

Diagnosis in Animals

- Serology (blood tests for antibodies to the germ)
- Complete blood counts

Treatment in Animals

- Antibiotics for long periods of time (months)
- Recurrences are common even after long periods of treatment.

Prevention or Control

- Tick control on dogs important.
- Monthly flea/tick treatments like Frontline® or Advantix® helpful.
- Prevention of tick exposure in humans such as avoiding areas likely to be tick

infested like brushy or forested areas. Wearing long pants and long sleeved shirts.
- DEET can repel ticks from humans.
- Use caution not to squeeze the body of the tick when removing. Only put traction on the head and neck of the tick to avoid expressing the stomach contents of the tick into the bloodstream of a person.

References: 53

Encephalitozoonosis

Other Names

Nosematosis

Cause

- Encephalitozoan cunniculi (protozoa)
- Different strains affect different animals.
- Strain I affects rabbits and humans.
- Strain III affects dogs and humans.

Transmission

Ingestion or inhalation of spores found in urine or stool from infected animal

Symptoms in Animals

- Can affect many different organs
- Neurological symptoms most common in rabbits
- Puppies often show "failure to thrive"

Symptoms in Humans

- Most are asymptomatic.
- In immune-compromised people, a wide variety of symptoms may develop.

Diagnosis in Animals

Serology (blood tests for antibodies to the germ)
- Microscopic examination of tissues from infected animal
- Microscopic examination of urine or stool for germ requires special techniques and equipment.

Treatment in Animals

Fenbedazole (Panacur®), Oxibendazole®, Albendazole®.

Prevention or Control

- Good personal hygiene measures
- Good sanitation to remove spores from environment contaminated with urine or stool from infected animal
- Quats very effective

References: 34

Hantavirus

Cause

Hantavirus (Sin Nombre strain) (virus)

Transmission

- Most commonly transmitted by inhalation of dust contaminated with urine or dried feces of infected rodents
- Cats can also contract from same source.

Symptoms in Animals

Most are asymptomatic.

Symptoms in Humans

- Respiratory symptoms, primarily pulmonary edema or pneumonia
- Often fatal

Diagnosis in Animals

Serology (blood tests for antibodies to the germ)

Treatment in Animals

None

Prevention or Control

- Rodent control
- Do not allow feral rodents to be kept as pets or admitted to shelter.
- Control areas where cat or dog food is kept to minimize access to rodents.

References: 35-36

Leptospirosis

Other Names

Weil's Disease, Hemorrhagic Fever, Dairy Worker's Disease

Cause

- Leptospira, many different strains (bacteria)
- Not species specific although certain strains are more likely to be found in certain species.
    - L. canicola (dogs)
    - L. icterohaemorrhagiaerats (rodents)
    - L. Pomona (pigs)

Transmission

- Ingestion of germs from surfaces or materials contaminated with urine from infected animal
- Standing water, most common (lakes, puddles, ponds)
- Inhalation can occur.
- Through the conjunctiva of the eye (by rubbing eyes with contaminated hands)
- Bite wounds or through pre-existing wounds contaminated with urine

Symptoms in Animals

- Fever, lethargy, and loss of appetite
- Liver symptoms, including jaundice
- Kidney failure

Symptoms in Humans

- Many are asymptomatic.
- Fever, weakness, lethargy
- Pain in testes of males affected
- Skin rashes
- Kidney failure
- Liver symptoms, including jaundice

Diagnosis in Animals

- Microscopic examination of urine for germ requires special techniques and equipment available at commercial laboratories.
- Culture is difficult and takes a long time.
- Serology (blood tests for antibodies)
- Special tests (microscopic agglutination) only available through commercial laboratories

Treatment in Animals

- Antibiotics
- Supportive

Prevention or Control

- Good personal hygiene
- Good sanitation of areas where dogs urinate
- Rodent control
- Avoid high pressure washing of areas where standing urine present.
- Vaccines for dogs; however, vaccines do not protect against all strains of Leptospira.

References: 38-39

Newcastle Disease

Other Names

Pseudo Fowl Pest

Cause

Paranyxoviridae (Newcastle Disease Virus)

Transmission

Inhalation of dust contaminated with respiratory secretions from infected birds, both wild and domestic

Symptoms in Animals

- Affects birds primarily
- Respiratory symptoms, like coughing and congestion
- Central nervous system symptoms, like paralysis or twisting of the head and neck

Symptoms in Humans

- Primarily severe conjunctivitis (inflammation of eyes)
- Fever, lethargy, loss of appetite

Diagnosis in Animals

- ELISA test for virus
- Microscopic examination of tissues at autopsy

Treatment in Animals

None

Prevention or Control

- Good personal hygiene
- Wear mask, gloves, eye protection, and gowns when working with large numbers of birds in close quarters like during an impound or investigation of cock fighting or bird smuggling.
- Vaccine for birds

References: 54

Q-Fever

Other Names

Query Fever, Balkan Influenza, Abattoir Fever

Cause

Coxiella burnetti (bacteria-rickettsia)

Transmission

- Although primarily associated with sheep, goats and cattle, dogs and cats can be infected.
- Germs are shed in all body secretions, including urine, stool, and milk.
- Inhalation or ingestion of germs from birthing fluids and/or membranes is the primary source of infection.

Symptoms in Animals

- Dogs and cats are usually asymptomatic.
- Reproductive problems can be seen, especially abortions (primary symptom in sheep and goats).

Symptoms in Humans

- Fever and lethargy
- Heart problems, including endocarditis (infection/inflammation of the lining of the heart)
- Headaches
- May wax and wane, but most cases resolve within two to three months

Diagnosis in Animals

Serology (blood tests for antibodies).

Treatment in Animals

- Antibiotics can minimize or eliminate symptoms but does not always eliminate infection.
- Recurrences common

Prevention or Control

- Good hygiene measures
- Wear protective clothing, including gloves, masks, and gowns, when handling birthing fluids or materials. This should be done especially when dealing with abortions, miscarriages, or early deliveries.
- Germ is easily killed by disinfection with bleach.

- Do not use high pressure cleaning devices in areas where birthing fluids are present.

References: 40-41

Rocky Mountain Spotted Fever

Other Names

American Tick Typhus

Cause

Rickettsia rickettsia (bacteria-rickettsia)

Transmission

- Seen in dogs, rabbits and wild rodents
- Transmitted by tick bites

Symptoms in Animals

- Fever and lethargy
- Skin lesions, like swelling and redness of lips, nose, prepuce and ears
- Vesicles (blisters) on skin
- Bruising (petechial and ecchymotic hemorrhages) under skin
- Heart and kidney symptoms

Diagnosis in Animals

- Serology (blood tests for antibodies)
- PCR testing for germs in blood or in skin wounds

Treatment in Animals

- Antibiotics
- Supportive care

Prevention or Control

- Tick control on dogs important
- Monthly flea/tick treatments like Frontline® or Advantix® helpful.
- Prevention of tick exposure in humans. Avoiding areas likely to be tick infested like brushy or forested areas. Wearing long pants and long sleeved shirts.
- Prompt removal of attached ticks.
- Studies in animals have shown that the risk of disease transmission from an infected tick is very low during the first 24 hours of attachment. The risk is 50 percent after 48 hours of attachment. The risk is 100 percent after 72 hours.
- DEET can repel ticks from humans.
- Use caution not to squeeze the body of the tick when removing. Only put traction on the head and neck of the tick to avoid expressing the stomach contents of the tick into the blood-stream of a person.

References: 42-43

Sporotrichosis

Cause

Sprothrix schenchii (fungus)

Transmission

- Fungus lives in soils rich in decaying organic material.
- Dogs and cats primarily are infected though puncture wounds like bites, scratches, or thorns.
- Humans primarily are exposed from draining wounds in cats and dogs. Pre-existing wounds are contaminated with material from these wounds.

Symptoms in Animals

- Non-healing infected wounds that do not respond to antibiotics
- Swollen lymph nodes

Symptoms in Humans

- Non-healing infected bite wounds that do not respond to antibiotics
- Swollen lymph nodes

Diagnosis in Animals

- Microscopic examination of fluids from draining wounds
- Serology (blood tests for antibodies)

Treatment in Animals

Antifungal drugs

Prevention or Control

- Wear gloves and protective clothing when cleaning or treating any open wounds especially in cats.
- Good personal hygiene
- Wash hands with Chlorhexiderm or Povidone-Iodine soaps.

References: 44-45

Streptococcosus

Cause

Streptococci, many different species and strains (bacteria)

Transmission

- Can occur from animal to humans and from humans to animals
- Bite or scratch wounds
- Contamination of pre-existing wounds with material from draining wounds or abscesses of infected animal
- Ingestion of contaminated food

Symptoms in Animals

- Abscesses or wound infections that can involve Necrotizing Fascitis or "flesh eating infections"
- Pharyngitis and tonsillitis ("sore throat")
- Umbilical infections in kittens

Symptoms in Humans

- Abscesses or infected wounds that can also involve Necrotizing Fascitis
- Sore throat or "Strep throat"
- Heart problems
- "Scarlet Fever"

Diagnosis in Animals

- Symptoms
- Culture of bacteria

Treatment in Animals

- Drainage and treatment of abscesses and wounds
- Antibiotics

Prevention or Control

- Good hygiene
- Dogs and cats probably not major source of infection for humans
- Gloves and masks when treating open wounds in dogs and cats

References: 54-55

Trichostrongylus

Other Names

Trichostrongyliasis

Cause

Trichostrongylus different species (intestinal worm)

Transmission

- Common intestinal parasite of sheep, goats, horses, and cattle
- Oral ingestion of raw vegetables, especially those that grow on or in the ground, that are contaminated with feces from infected animals most common source (Use of manure for fertilizer increases risk.)

Symptoms in Animals

- Digestive signs, like vomiting and diarrhea
- Weight loss

Symptoms in Humans

- Most asymptomatic
- Digestive signs, like vomiting, diarrhea, or abdominal pain

Diagnosis in Animals

Microscopic examination of stool for eggs

Treatment in Animals

Broad spectrum deworming medications like pyrantel (Strongid®)

Prevention or Control

- Good hygiene
- Wash all raw vegetables.
- Diagnose and treat all animals as soon as possible.

References: 56

Tularemia

Other Names

Francis' Disease, Rabbit Fever

Cause

Francisella tularensis (bacteria)

Transmission

- Major reservoir is rabbits, but it has been seen in many animals, including dogs and cats.
- It can be spread through bite wounds, more commonly spread by contamination of pre-existing wounds with body fluids or tissues of infected animals.
    - Examples would be cleaning and dressing rabbits used for food or performing autopsies on infected rabbits.
- Tick bites

Symptoms in Animals

- Fever
- Lymph gland swelling
- Swellings under skin that ultimately develop into abscesses

Symptoms in Humans

- Fever, headache, and nausea
- Local swellings under skin near original wound that ultimately ulcerate and drain

Diagnosis in Animals

- Serology (blood tests for antibodies)
- Culture of draining wounds

Treatment in Animals

Antibiotics

Prevention or Control

- Good hygiene
- Wear gloves when handling draining wounds or abscesses especially in rabbits.
- Wear gloves when performing autopsies on rabbits.
- Tick control

References: 46-47

Tuberculosis

Other Names

Consumption

Cause

Mycobacterium different species (bacteria)

Transmission

- Inhalation of respiratory secretions from infected animal
- Ingestion or contamination of pre-existing wounds with secretions from infected anima
- May spread from human to animal and animal to human

- Requires more prolonged and frequent exposure to infect susceptible animal or human than most bacteria
- Often a bigger concern in dogs and cats living in areas where homeless people, drug users, migrant workers, or HIV patients live.

Symptoms in Animals

- Respiratory signs, including coughing, often with blood in the sputum
- Skin signs, including draining wounds and nodules under the skin
- Gastrointestinal signs, including vomiting and diarrhea

Symptoms in Humans

- Respiratory signs, including coughing, often with blood in the sputum
- Fever, weight loss, and lethargy
- Skin signs, including ulcers, draining wounds, and nodules under the skin

Diagnosis in Animals

- History — Where did the animal originate from?
- Microscopic examination of respiratory secretions or fluid from draining wounds requires special techniques and stains.
- Skin testing (does not work well in cats)
- Serology (blood tests for antibodies).
- Can be difficult to diagnose
- Microscopic examination of biopsies from skin nodules

Treatment in Animals

- Very questionable if treatment should be considered in shelter setting
- Antibiotics (requires long-term usage, years)

Prevention or Control

- Vaccine available for humans
- Diagnose and either treat or euthanize any infected or suspect animals.
- Public education about the danger faced by both people and animals living in circumstances that promote the transmission of this disease.
- Good hygiene
- Wear gloves and masks when handling animals suspected of having disease.

References: 58-59

Rare, Emerging, or Questionable Zoonotic Diseases

Bordetellosis

Other Names

Kennel Cough, Infectious Tracheobronchitis, Canine Cough

Cause

Bordetella bronchiseptica (Bacteria)

Transmission

- Inhalation of respiratory secretions from infected animal
- The risk of human infection from dogs is considered very low even in immune-compromised people.

Symptoms in Animals

- Coughing
- Nasal discharge
- Pneumonia

Symptoms in Humans

Respiratory signs, like coughing, nasal discharge, pneumonia

Diagnosis in Animals

- Symptoms and history
- Cultures of respiratory secretions

Treatment in Animals

Antibiotics

Prevention or Control

- Diagnosis and treatment of infected animals
- Good hygiene
- Masks, protective clothing when handling known infected animals

Reference 62

Leishmaniasis

Cause

Leishmania different species (protozoa)

Transmission

- Most common in Texas and Oklahoma
- Bite from infected sand fly
- Contamination of pre-existing wounds with blood or fluid from draining wound of infected animal

Symptoms in Animals

- Painful ulcers and nodules in area where original sand fly bite took place
- Lesions may occur in other places over time.
- Fever, weight loss (often dramatic), anemia
- Diarrhea occasionally seen

Symptoms in Humans

- Ulcers and nodules under skin in area where original sand fly bite took place
- Lesions may occur in other places over time.
- Fever, weight loss, diarrhea
- Can be fatal

Diagnosis in Animals

- Questionable if this should be treated in shelter setting
- Anti-protozoa drugs
- Treatment rarely curative

Prevention or Control

- Control of sand flies
- Keep dogs and cats indoors, especially at night.
- Wear gloves when handling or treating animals with suspicious symptoms, especially wounds that have not

responded to traditional antibiotic treatment.

References: 48

Rat Bite Fever

Other Names

Haverhill Fever, Streptobacillary Fever

Cause

- Streptobacillus moniliformis
- Spirillum minus

Transmission

- Bite from infected rodent, especially rats
- Bite from infected dog or cat

Symptoms in Animals

- Rats are usually asymptomatic.
- Guinea pigs and mice usually die very suddenly with few signs, but draining wounds or abscesses can be seen.

Symptoms in Humans

- Fever
- Rash on skin in areas away from bite
- Arthritis
- Respiratory signs, including pneumonia
- Heart signs, including endocarditis

Diagnosis in Animals

Culture fluids from draining wounds or pharynx

Treatment in Animals

Antibiotics

Prevention or Control

- Wash any bite wounds from rodents very aggressively.
- Wear protective gloves when handling any rodents.
- Educate staff how to properly handle rodents.
- Wild rodent control

References: 3

West Nile Virus

Cause

Flaviivirdae (virus)

Transmission

- Bite from infected mosquito
- Dogs, cats, horses, and other mammals have been diagnosed with WNV but certain species of birds are the main reservoir for WNV.
- Direct transmission from animals to humans has not been seen.

Symptoms in Animals

- Most dogs and cats are probably asymptomatic, but a few cases of encephalitis (brain inflammation) have been seen.
- Many infected horses will show encephalitis.

Symptoms in Humans

- Most infected humans will be asymptomatic.
- The risk of more serious symptoms (encephalitis) is greater in older people or in immune-compromised people.

Diagnosis in Animals

- Serology (blood test for antibodies)
- PCR test for virus in brain of dead animal

Treatment in Animals

- None — most animals will be asymptomatic.
- Symptomatic treatment is all that is available.

Prevention/Control

- Mosquito control
- Stay indoors during evening hours and use DEET repellants.
- Mosquito abatement programs
- Vaccination available for horses

References: 60-61

Glossary

Amphixenoses
Disease normally spread from either human to animals or from animals to humans.

Anthropozoonoses
Disease normally spread from animals to humans

Antibodies
Proteins that a living organism has that provide immunity or protection from a specific disease

Active Antibodies
Antibodies that organism produces on its own in response to exposure to disease-causing organisms or vaccinations

Passive Antibodies
Antibodies that are derived by an organism from another source like its mother's milk or from an injection

Common Source Exposure
Simultaneous exposure of many susceptible individuals within a population (shelter staff) to a disease (Example would be contaminated food eaten by many people at the same time.)

Course of Disease
Time from the onset of symptoms of a specific disease to either resolution of the disease or the death of the infected organism

Disease
A dysfunction in or an abnormality of a living organism

Emerging Zoonoses
Zoonotic disease caused by apparently new germ or by previously known germs that are appearing in places or in species in which they were previously not known to cause disease

Fomite
Object that passively transfers disease-causing organisms (germs) from reservoir (animal) to susceptible individual (Examples would be hands, bowls, towels, bedding.)

Germ
Disease causing organism; may be virus, bacteria, fungus, protozoa, or worm

Incubation Period
Length of time from initial exposure to specific disease to the onset of symptoms of that disease

Infectious Disease
A disease caused by an infectious organism (germ)

Latent Period
Time between onset of disease and the shedding of the disease causing organisms

Reservoir
Alternative host or passive carrier of disease causing germ; often the place where a disease-causing germ persists in an environment

Virulence
How likely a germ is to cause symptoms in a susceptible individual; the more likely symptoms are to be seen, the higher the virulence of the germ

Zooanthropozoonoses
Disease normally spread from humans to animals

Zoonosis
Disease spread from animals to humans

Diseases Carried by Different Species of Animals

Reptiles

Salmonellosis
Yersiniosis
Amphibians
Salmonellosis
Marsupials
Rabies

Rodents

Salmonellosis
Yersiniosis
Plague
Tuberculosis
Leptospirosis
Lyme Disease
Campylobacteriosis
Tularemia
Rat Bite Fever
Dermatophytosis
Hantavirus
Rabies
Babesiosis
Giardiasis
Trichinosis

Carnivores (dogs and cats)

Rabies
Trichinosis
Visceral Larval Migrans
Echinococcosis
Cutaneous Larval Migrans
Dipylidiasis
Giardiasis
Salmonellosis
Cat Scratch Disease
Dermatophytosis
Ehrlichiosis
Hantavirus
Campylobacteriosis
Shigellosis
Yersiniosis
Animal Bites and Scratches
Bubonic Plague
Lyme Disease
Ringworm
Sarcoptes Mange
Toxoplasmosis
Brucellosis
Colibacillosis
Cryptosporidosis
Encephalitozoonosis
Leptospirosis
Q-Fever
Rocky Mountain Spotted Fever
Sporotrichosis
Streptococcosus
Tularemia
Tuberculosis
Leishmaniasis
Bordetellosis

Rabbits

Salmonellosis
Tularemia
Dermatophytosis
Rabies
Trichostrongylidosis
Birds
Salmonellosis
Yersiniosis
Colibacillosis
Tuberculosis
Psittacosis
Newcastle's Disease
These are very important zoonotic diseases associated with this particular species of animal.

Zoonotic Disease Fallacies

Fallacy: Children get pinworms from the family dog or cat.

Fact: Dogs and cats do not get pinworms. It is impossible for people to contract pinworms from the family pet. Often people mistake tapeworm segments visible around the pet's anus for pinworms. These are two completely different parasites. See Dipylidiasis.

Fallacy: Children get lice from the family dog (cat).

Fact: Lice are very species specific. Dog lice do not infect cats or people, for example. Children get lice from other children.

Fallacy: Children will get worms if the family puppy licks them.

Fact: While the puppy may be a potential source of danger, children contract the parasites by ingesting the feces of the puppy or more often, dirt contaminated with eggs of parasites. See Visceral Larval Migrans.

Fallacy: Pregnant women should never touch a cat for fear of contracting Toxoplasmosis.

Fact: People contract Toxoplasmosis from ingestion of the eggs of the organism that have typically contaminated soil or food. Eating uncooked meat or raw vegetables is also a potential source of infection. See Toxoplasmosis.

Fallacy: People can contract Canine Distemper and get Multiple Sclerosis.

Fact: Although the symptoms in a person with Multiple Sclerosis and a dog with Distemper are similar, there is no known connection between the two diseases. There has been no reduction in the numbers of people diagnosed with MS since 1960 while the number of dogs diagnosed with Distemper has fallen drastically primarily due to an effective vaccine for Distemper.

Fallacy: Because there are many states in which there has not been a case of Rabies diagnosed in dogs or cats for many years, we can relax our guard against the disease.

Fact: Although we have greatly reduced the incidence of Rabies in our pet animals, the incidence of the disease in the wild population of animals (especially raccoons and skunks) has increased greatly. Many of these animals adapt very readily to suburban life and are a major risk factor to start a Rabies epidemic in many areas. See Rabies.

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Rabies Protocol Chart

BITE SOURCE	SITUATION	ANIMAL DISPOSITION	POST-EXPOSURE PROPHYLAXIS IN HUMANS
Rodent	Any episode	Usually not examined	None, but consult public health officials if circumstances of bite warrant
Dog, cat, ferret	Healthy, owned	Confine; observe for at least 10 days, especially if unprovoked attack	None or consider, if unprovoked; Yes, if CNS signs develop in animal
	Healthy, stray available or escaped	Euthanize immediately; submit head for exam	Yes; stop if lab results negative, continue if animal unavailable
	CNS signs or illness	Euthanize immediately; submit head for exam	Yes; if negative FA result, stop.
Wild carnivore	Any episode	If captured, euthanize immediately; submit head for examination	Yes, if positive or animal at large; if negative, FA result, stop.
Inoculation of attenuated vaccine	Any episode	Not applicable	No post-exposure treatment required.

Controlled Substance P&P

Policy: The objective of the AHAB Controlled Substances Policy is to ensure compliance with state and federal regulations governing the use of Drug Enforcement Agency (DEA) controlled substances. The AHAB requires that all individuals conducting activities with DEA controlled substances be registered with the DEA and comply with state and federal regulations regarding the acquisition, storage, use and disposal of the substances. Bideawee will be responsible for costs incurred with registration.

Procedure:

Definitions: All employees handling and administering controlled substances must be familiar with the classification system and regulations surrounding the ordering, usage, recording, dispensing and wasting of said substances. The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations, 21 C.F.R. Sections 1308.11 through 1308.15. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Some examples of controlled substances in each schedule are outlined below.

> NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in schedules II-V have some accepted medical use and may be prescribed, administered, or dispensed for medical use.

Some commonly used drugs at the AHAB are:

- Schedule 2 Narcotics – Hydromorphone, Morphine, Oxymorphone, Fentanyl
- Schedule 2 Non Narcotics – Pentobarbital (Euthanasia Solution)
- Schedule 3 Narcotics – Buprenorphine, Hydrocodone,
- Schedule 3 Non Narcotics – Ketamine, Thiopental
- Schedule 4 – Diazepam, Midazolam, Butorphanol, Phenobarbital,

The DEA Controlled Substance Act and the State of NY Controlled Substance Act can be found in the AHAB Controlled Substance Manual located in the office of the Practice Manager.

Licensure: Bideawee requires All FT and PT veterinarians to have a DEA license. This license must be readily available for inspection.

Placing a Controlled Substance Order:

Schedule 2 substances must be ordered using a 222 form. This form can be a hard copy triplicate form OR via the Controlled Substance Online Ordering system located at http://www.deaecom.gov/. All other scheduled drugs are ordered through our vendors, who will require a current DEA number of one veterinarian in the practice

Receipt of Controlled Substances: Immediately, upon receipt of a controlled substance order:

- The quantity of the order must be reconciled with the packing slip
- The drugs must be logged into Impromed
- The individual bottles must be numbered/lettered in sequential order and logged into the paper drug log book, which keeps the inventory of full bottles in the safe.
- On the invoice a notation should be made regarding the assigned number/letter.
- Drugs are placed in the safe

- All steps must be witnessed

Storage: There will be two safes. One to keep the full bottles of controlled substances and one small one to keep the bottles that are in use. There should never be more than one "in use" bottle of any controlled substance in the small safe at any one time. Only the Practice Manager, Head Technician, one veterinarian and the VP of Operations should have the combination to the safe where the full bottles are kept. When any bottle is removed from the "in use" safe and brought into the surgery/treatment area, it must be kept in a locked box until such times as the drugs are drawn out.

When removing or adding bottles to any safe two licensed personal (LVT, DVM) and/or the PM must accompany one another.

Record Keeping:

- All 222 forms, vendor invoices and packing slips for Schedule II substances must be kept separately from all other invoices and forms of the practice. All Schedule III, IV and V substances must be maintained separately or in such a form that they are readily retrievable from the ordinary business records of the practitioner.
- All records related to controlled substances must be maintained and be available for inspection for a minimum of two years.
- Chain of custody of each bottle will be maintained in the following manner
    1. Upon receipt –
        - Logged into Impromed
        - Logged into full bottle inventory in main safe
            - 2 people witness the entry into the main safe
    2. When placed into use
        - Logged out of Full Bottle Inventory in main safe
            - Two people witness the moving of the bottle from the main safe into the in-use safe.
        - accounted for accurately in milligrams on Daily Surgery Log –on the daily surgery log, it will be noted which bottle the drug was withdrawn from.
        - Accounted for accurately in Impromed by way of client invoice
            - The invoice will reflect what was used and will prompt for what was wasted so the inventory is managed properly. Note: what is used it the total drawn up. What is wasted is included in the total. For example: you draw up 1 mg ketamine and only use 0.5 mg. in Impromed the first quantity you log is 1mg, when prompted for wastage, you enter 0.5mg
            - The person entering the invoice must initial the Impromed record after they document what the use was for.
    3. Client/Patient Medical Records must have what was drawn up and what was actually used. It is not sufficient to state "to effect" . This can be noted as drawn/given

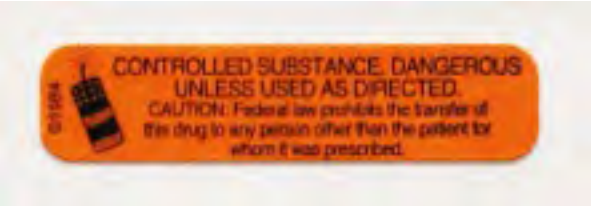
Inventory:

- Any time a bottle is removed from the Full Bottle Inventory in the main safe, reconciliation of the remaining full bottles should be taken and checked against the log
- A weekly audit of on hand controlled substances will be taken and reconciled against the Impromed Records. This audit will be conducted by the Head

Technician. A hard copy of this audit needs to be kept on file and a PDF file of the audit placed on the S drive in the CS Log. This inventory needs to include:

- Time the inventory was taken
- Name of controlled substance
- Each finished form of the substance (ie: 100 mg tablet)
- The number of dosage units of each finished from in the commercial container (ie: 100 tablet bottle)
- The number of each commercial containers of each finished form (four 100 tablet bottles)
  - Impromed inventory
  - actual physical count
- Highlight any discrepancies and make a notation of the action taken
  - Actions include:
    - Making corrections to math and transcription errors after review of medical records and surgery logs
    - Recording any breakage or wastage not logged out. Breakage goes into hospital account. Wastage must be tied to a patient.
    - Accounting for acceptable hub loss (typically 0.05 ml) per dose drawn, within reason, if not employing the use of hub-less syringes.
- All records must be kept for 2 years.

Dispensing Controlled Substances: No substance may be dispensed unless it is enclosed within a suitable and durable container and:

- Affixed with a permanent label that includes:
  - Name of Animal
  - Species
  - Name and address of owner
  - Name, address and telephone number of practice
  - specific directions
  - Name of substance
  - date of dispensing
  - CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED
  - AND an orange label
  - 

  - On the 15th of every month, information related to all dispensed controlled substances must be filed electronically over the Health Provider Network.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Practitioner's Manual

An Informational Outline of the Controlled Substances Act

2006 Edition

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Deputy Assistant Administrator
Office of Diversion Control

Mark W. Caverly
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This manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession.

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Appendices

SECTION I - INTRODUCTION

This practitioner's manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), 21 USC 801-890, and the DEA regulations, Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316. Pertinent citations to the law and regulations are included in this manual.

Printed copies of the CFR and the complete regulations implementing the CSA may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Both the CFR and the *Federal Register* (which includes proposed and final regulations implementing the CSA) are available on the Internet through the U.S. Government Printing Office (GPO) website. This website, which provides information by section, citation and keywords, can be accessed at:

www.gpoaccess.gov/cfr/index.html

Unofficial copies of pertinent CFR citations may be found at:

www.DEAdiversion.usdoj.gov

This practitioner's manual may also be found on the Internet at DEA's Web Site (under "publications"):

www.DEAdiversion.usdoj.gov

Should any pertinent provisions of the law or regulations be modified in the future, DEA will issue a revised electronic version of this document, which will be published on the DEA Diversion Website.

If you encounter errors in this document, please notify:

Editor, DEA Practitioner's Manual
c/o DEA, Office of Diversion Control
Liaison and Policy Section
Washington, D.C. 20537

Inquiries regarding topics within this document may be addressed to your local DEA field office (listed in Appendix E) or the address above.

This Document is Authorized for Public Dissemination

Message from the Administrator

The Drug Enforcement Administration is pleased to provide this updated edition of the 1990 Practitioner's Manual to assist you in understanding your responsibilities under the Controlled Substances Act (CSA) and its implementing regulations. This manual will help answer questions that you may encounter in your practice and provide guidance in complying with federal requirements.

DEA remains committed to the 2001 Balanced Policy of promoting pain relief and preventing abuse of pain medications. In enforcing the CSA, it is DEA's responsibility to ensure drugs are not diverted for illicit purposes. Unfortunately, this country is now experiencing an alarming prescription drug abuse problem:

- Today, more than 6 million Americans are abusing prescription drugs—that is more than the number of Americans abusing cocaine, heroin, hallucinogens, and inhalants, combined.

- Researchers from the Centers for Disease Control and Prevention report that opioid prescription painkillers now cause more drug overdose deaths than cocaine and heroin combined.

- Today more new drug users have begun abusing pain relievers (2.4 million) than marijuana (2.1 million) or cocaine (1.0 million).

It is more important now than ever to be vigilant in preventing the diversion and abuse of controlled substances. This manual will help you do that by listing some safeguards you can take to prevent such diversion. It also explains registration, recordkeeping, and valid prescription requirements.

As a practitioner, your role in the proper prescribing, administering, and dispensing of controlled substances is critical to patients' health and to safeguarding society against the diversion of controlled substances. DEA is committed to working jointly with the medical community to ensure that those in need are cared for and that legitimate controlled substances are not being diverted for illegal use.

Karen P. Tandy
Administrator
September 2006

Preface

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary federal agency responsible for the enforcement of the Controlled Substances Act (CSA). The CSA sets forth the federal law regarding both illicit and licit (pharmaceutical) controlled substances. With respect to pharmaceutical controlled substances, DEA's statutory responsibility is twofold: to prevent diversion and abuse of these drugs while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works in close cooperation with state and local authorities and other federal agencies.

Under the framework of the CSA, the DEA is responsible for ensuring that all controlled substance transactions take place within the "closed system" of distribution established by Congress. Under this "closed system," all legitimate handlers of controlled substances – manufacturers, distributors, physicians, pharmacies, and researchers – must be registered with DEA and maintain strict accounting for all distributions.

To carry out DEA's mission effectively, this 2006 Practitioner's Manual seeks to aid DEA registrants in complying with the CSA and its implementing regulations. The DEA understands that it can best serve the public interest by working with practitioners to prevent diversion of legal pharmaceutical controlled substances into the illicit market.

The federal controlled substances laws are designed to work in tandem with state controlled substance laws. Toward this same goal, DEA works in close cooperation with state professional licensing boards and state and local law enforcement officials to ensure that pharmaceutical controlled substances are prescribed, administered, and dispensed for legitimate medical purposes in accordance with federal and state laws. Within this cooperative framework, the majority of investigations into possible violations of the controlled substances laws are carried out by state authorities. However, DEA also conducts investigations into possible violations of federal law as circumstances warrant.

In the event a state board revokes the license of a practitioner, the DEA will take action and request a voluntary surrender of the practitioner's DEA registration. If the practitioner refuses to voluntarily surrender the registration, the DEA will pursue administrative action to revoke the DEA registration. The DEA may also pursue judicial action if there is sufficient evidence of illegal distribution or significant recordkeeping violations. All such actions are intended to deny the practitioner the means to continue to divert or abuse controlled substances as well as to protect the health and safety of the public and the practitioner.

The DEA is authorized under federal law to pursue legal action in order to prevent the diversion of controlled substances and protect the public safety. A lack of compliance may result in a need for corrective action, such as administrative action (that is, Letter of Admonition, an informal hearing or "order to show cause"), or in extreme cases, civil, or criminal action.

SECTION II – GENERAL REQUIREMENTS

Schedules of Controlled Substances

The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A complete list of the schedules is published annually on an updated basis in the DEA regulations, Title 21 of the Code of Federal Regulations, Sections 1308.11 through 1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States and their relative abuse potential and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are outlined below.

IMPORTANT NOTE:

All drugs listed in Schedule I have no currently accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in Schedules II through V all have some accepted medical use and therefore may be prescribed, administered, or dispensed for medical use.

Schedule I Substances

Substances in this schedule have no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of substances listed in Schedule I are: heroin; lysergic acid diethylamide (LSD); marijuana (cannabis); peyote; methaqualone; and methylene-dimethoxy-methamphetamine ("ecstasy").

The CSA allows for bona fide research with controlled substances in Schedule I, provided that the FDA has determined the researcher to be qualified and competent, and provided further that the FDA has determined the research protocol to be meritorious. Researchers who meet these criteria must obtain a separate registration to conduct research with a Schedule I controlled substance.

Schedule II Substances

Substances in this schedule have a high potential for abuse with severe psychological or physical dependence.

Examples of single entity Schedule II narcotics include morphine, codeine, and opium. Other Schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).

Examples of Schedule II stimulants include amphetamine (Dexedrine® or Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other Schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

Schedule III Substances

Substances in this schedule have a potential for abuse less than substances in Schedules I or II.

Examples of Schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (i.e., Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (i.e., Tylenol with codeine®).

Examples of Schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, dronabinol (Marinol®), ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

Schedule IV Substances

Substances in this schedule have a lower potential for abuse relative to substances in Schedule III.

Examples of a Schedule IV narcotics include propoxyphene (Darvon® and Darvocet-N 100®).

Other Schedule IV substances include alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Substances

Substances in this schedule have a lower potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs. These are generally used for antitussive, antidiarrheal and analgesic purposes.

Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, and Phenergan with Codeine®).

Registration Requirements

Under the CSA, the term "practitioner" is defined as a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the practitioner practices or performs research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research. Every person or entity that handles controlled substances must be registered with DEA or be exempt by regulation from registration.

The DEA registration grants practitioners federal authority to handle controlled substances. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located. When federal law or regulations differ from state law or regulations, the practitioner is required to abide by the more stringent aspects of both the federal and state requirements. In many cases, state law is more stringent than federal law, and must be complied with in addition to federal law. Practitioners should be certain they understand their state as well as DEA controlled substance regulations.

Application for Registration

To obtain a DEA registration, a practitioner must apply using a DEA Form 224. Applicants may submit the form by hard copy or on-line. Complete instructions accompany the form. To obtain the application, DEA may be contacted at:

- www.DEAdiversion.usdoj.gov (DEA Diversion Internet Web Site)
- any DEA field office (see listing in Appendix E of this manual)
- DEA Headquarters' Registration Section in Washington, D.C. at 1-800-882-9539 (Registration Call Center)

The DEA Form-224 may be completed on-line or in hard copy and mailed to:

Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083

A sample DEA Form 224 – New Application for Registration, is located at Appendix H, DEA Forms.

Certificate of Registration

The DEA Certificate of Registration (DEA Form 223) must be maintained at the registered location in a readily retrievable manner and kept available for official inspection.

The CSA requires that a separate registration be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed. DEA has historically provided an exception that a practitioner who is registered at one location, but also practices at other locations, is not required to register separately for any other location at which controlled substances are only prescribed. If the practitioner maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the separate location the practitioner must obtain a separate DEA registration for that location. The exception applies only to a secondary location within the same state in which the practitioner maintains his/her registration. DEA individual practitioner registrations are based on state authority to dispense or conduct research with respect to controlled substances. Since a DEA registration is based on a state license, it cannot authorize controlled substance dispensing outside that state. Hence, the separate registration exception applies only to locations within the same state in which practitioners have their DEA registrations.

A duplicate Certificate of Registration may be requested on-line. It appears on DEA's website, www.DEAdiversion.usdoj.gov, as follows:

Registration Renewals

Practitioner registrations must be renewed every three years. Renewal registrations use DEA Form 224a, Renewal Application for DEA Registration (see example at Appendix H, DEA Forms). The cost of the registration is indicated on the application form.

A renewal application is sent to the registrant approximately 45 days before the registration expiration date. The renewal application is sent to the address listed on the current registration certificate. If the renewal form is not received within 30 days before the expiration date of the current registration, the practitioner should contact the DEA registration office for their state, or DEA Headquarters at 1-800-882-9539, and request a renewal registration form.

The registration renewal application may be completed on-line at www.DEAdiversion.usdoj.gov, or in hard copy and mailed to:

Drug Enforcement Administration
Registration Unit
Central Station
P.O. Box 28083
Washington, D.C. 20038-8083

Drug Registration > ODWIF

Registration Applications

Office of Diversion Control Web Interactive Forms (ODWIF)

RENEWAL APPLICATIONS

Log-in to Begin Renewal Process	Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner, Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter, Domestic Chemicals
Obtain Receipt	This link may be used ONLY if you have previously submitted a Renewal Application through this tool and need an additional receipt.
Duplicate Certificate	On-line tool to request certificates for additional, misplaced, illegible, or destroyed originals.

MINIMUM ON-LINE REQUIREMENTS

The DEA Forms listed below are for those applying to DEA for a controlled substance registration. Data will be entered through a **secure connection** to the **ODWIF** on-line web application system. **Your web browser must support 128-bit encryption.**

You will need to have the following information handy in order to complete the form:

- Tax ID number and/or Social Security Number
- State Controlled Substance Registration Information
- State Medical License Information
- Credit Card (VISA, MasterCard, Discover or American Express)

The ODWIF system can only process credit card transactions at this time. If you are paying by check, you will need to use the PDF version of the form, then print and mail the form to the address listed on the form.

Change of Business Address

A practitioner who moves to a new physical location must request a modification of registration. A modification of registration can be requested on-line at www.DEAdiversion.usdoj.gov or in writing to the DEA field office responsible for that state. If the change in address involves a change in state, the proper state issued license and controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new Schedule II order forms (DEA Form-222, Official Order Form). A Renewal Application for Registration (DEA Form-224a) will only be sent to the registered address on file with DEA. It will not be forwarded.

Termination of Registration

Any practitioner desiring to discontinue business activities with respect to controlled substances must notify the nearest DEA field office (see Appendix E) in writing. Along with the notification of termination of registration, the practitioner should send the DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222) to the nearest DEA field office.

Denial, Suspension or Revocation of Registration

Under the CSA, DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has:

1. Materially falsified any application filed
2. Been convicted of a felony relating to a controlled substance or a List I chemical
3. Had their state license or registration suspended, revoked, or denied
4. Committed an act which would render the DEA registration inconsistent with the public interest
5. Been excluded from participation in a Medicaid or Medicare program

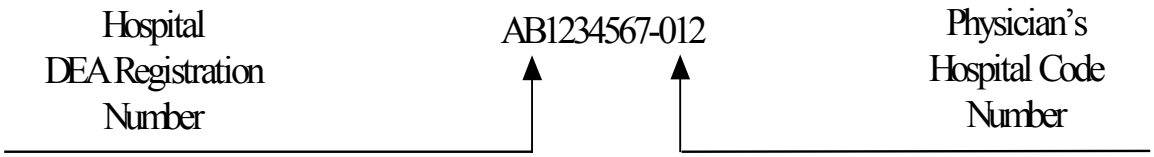
In determining the public interest, the CSA states the following factors are to be considered:

1. The recommendation of the appropriate state licensing board or professional disciplinary authority
2. The applicant's experience in dispensing or conducting research with respect to controlled substances
3. The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances
4. Compliance with applicable state, federal, or local laws relating to controlled substances
5. Such other conduct which may threaten the public health and safety

Practitioner's Use of a Hospital's DEA Registration Number

Practitioners (e.g., intern, resident, staff physician, mid-level practitioner) who are agents or employees of a hospital or other institution may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which they are employed, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice
2. Practitioners are authorized to do so by the state in which they practice
3. The hospital or institution has verified that the practitioner is permitted to dispense, administer or prescribe controlled substances within the state
4. The practitioner acts only within the scope of employment in the hospital or institution
5. The hospital or institution authorizes the practitioner to dispense or prescribe under its registration and assigns a specific internal code number for each practitioner so authorized (See example of a specific internal code number below):



A current list of internal codes and the corresponding individual practitioners is to be maintained by the hospital or other institution. This list is to be made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

Inappropriate Use of the DEA Registration Number

DEA strongly opposes the use of a DEA registration number for any purpose other than the one for which it was intended, to provide certification of DEA registration in transactions involving controlled substances. The use of DEA registration numbers as an identification number is not an appropriate use and could lead to a weakening of the registration system.

The Centers for Medicare and Medicaid Services has developed a National Provider Identification (NPI) number unique to each healthcare provider. The Final Rule for establishment of the NPI system was published in the Federal Register (FR 3434, Vol. 69, No. 15) by the Department of Health and Human Services on January 23, 2004. The effective date of this Final Rule was May 23, 2005; all covered entities must begin using the NPI in standard transactions by May 23, 2007.

Exemption of Federal Government Practitioners from Registration

The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in Title 21, CFR § 1306 regarding prescriptions, but shall state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his/her Social Security identification number.

If Federal Government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, they must be fully licensed to handle controlled substances by the state in which they are located. Under these circumstances, the Federal Government practitioner will not be eligible for the fee exemption and must pay a fee for the registration.

SECTION III – SECURITY REQUIREMENTS

Required Controls

Title 21, CFR Section 1301.71(a), requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances. A list of factors is used to determine the adequacy of these security controls. Factors affecting practitioners include:

1. The location of the premises and the relationship such location bears on security needs
2. The type of building and office construction
3. The type and quantity of controlled substances stored on the premises
4. The type of storage medium (safe, vault, or steel cabinet)
5. The control of public access to the facility
6. The adequacy of registrant's monitoring system (alarms and detection systems)
7. The availability of local police protection

Practitioners are required to store stocks of Schedule II through V controlled substances in a securely locked, substantially constructed cabinet. Practitioners authorized to possess carfentanil, etorphine hydrochloride and/or diprenorphine, must store these controlled substances in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

Registrants should not employ as an agent or employee who has access to controlled substances:

1. Any person who has been convicted of a felony offense related to controlled substances
2. Any person who has been denied a DEA registration
3. Any person who has had a DEA registration revoked
4. Any person who has surrendered a DEA registration for cause

Lastly, practitioners should notify the DEA, upon discovery, of any thefts or significant losses of controlled substances and complete a DEA Form 106 regarding such theft or loss.

Safeguards for Prescribers

In addition to the required security controls, practitioners can utilize additional measures to ensure security. These include:

1. Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.

2. Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.

3. Use prescription blanks only for writing a prescription order and not for notes.

4. Never sign prescription blanks in advance.

5. Assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.

6. Contact the nearest DEA field office (see Appendix E) to obtain or to furnish information regarding suspicious prescription activities.

7. Use tamper-resistant prescription pads.

SECTION IV – RECORDKEEPING REQUIREMENTS

Recordkeeping Requirements

Each practitioner must maintain inventories and records of controlled substances listed in Schedules I and II separately from all other records maintained by the registrant. Likewise, inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or in such a form that they are readily retrievable from the ordinary business records of the practitioner. All records related to controlled substances must be maintained and be available for inspection for a minimum of two years.

A registered practitioner is required to keep records of controlled substances that are dispensed to the patient, other than by prescribing or administering, in the lawful course of professional practice. A registered practitioner is not required to keep records of controlled substances that are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment. A registered practitioner is not required to keep records of controlled substances that are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. A registered practitioner is also required to keep records of controlled substances administered in the course of maintenance or detoxification treatment of an individual.

Inventory

Each registrant who maintains an inventory of controlled substances must maintain a complete and accurate record of the controlled substances on hand and the date that the inventory was conducted. This record must be in written, typewritten, or printed form and be maintained at the registered location for at least two years from the date that the inventory was conducted. After an initial inventory is taken, the registrant shall take a new inventory of all controlled substances on hand at least every two years.

Each inventory must contain the following information:

1. Whether the inventory was taken at the beginning or close of business
2. Names of controlled substances
3. Each finished form of the substances (e.g., 100 milligram tablet)
4. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
5. The number of commercial containers of each finished form (e.g., four 100 tablet bottles)

6. Disposition of the controlled substances

It is important to note that inventory requirements extend to controlled substance samples provided to practitioners by pharmaceutical companies.

Disposal of Controlled Substances

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office (See Appendix E) for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

SECTION V – VALID PRESCRIPTION REQUIREMENTS

Prescription Requirements

A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also include:

1. drug name
2. strength
3. dosage form
4. quantity prescribed
5. directions for use
6. number of refills (if any) authorized

A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature.

The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

Who May Issue

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice
2. Registered with DEA or exempted from registration (that is, Public Health Service, Federal Bureau of Prisons, or military practitioners)
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered provided that additional requirements as set forth in the CFR are met.

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. In addition, a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription within the meaning and intent of the Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Schedule II Substances

Schedule II controlled substances require a written prescription which must be signed by the practitioner. There is no federal time limit within which a Schedule II prescription must be filled after being signed by the practitioner.

While some states and many insurance carriers limit the quantity of controlled substance dispensed to a 30-day supply, there are no specific federal limits to quantities of drugs dispensed via a prescription. For Schedule II controlled substances, an oral order is only permitted in an emergency situation.

Refills

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited (Title 21 U.S. Code § 829(a)).

Issuance of Multiple Prescriptions for Schedule II Substances

DEA has revised its regulations regarding the issuance of multiple prescriptions for schedule II controlled substances. Under the new regulation, which became effective December 19, 2007, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

2. The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.

3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

4. The issuance of multiple prescriptions is permissible under applicable state laws.

5. The individual practitioner complies fully with all other applicable requirements under the Controlled Substances Act and Code of Federal Regulations, as well as any additional requirements under state law.

It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a prescriber may transmit a Schedule II prescription to the pharmacy by facsimile. The original Schedule II prescription must be presented to the pharmacist for review prior to the actual dispensing of the controlled substance.

In an emergency, a practitioner may call-in a prescription for a Schedule II controlled substance by telephone to the pharmacy, and the pharmacist may dispense the prescription provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. The prescribing practitioner must provide a written and signed prescription to the pharmacist within seven days. Further, the pharmacist must notify DEA if the prescription is not received.

Exceptions for Schedule II Facsimile Prescriptions

DEA has granted three exceptions to the facsimile prescription requirements for Schedule II controlled substances. The facsimile of a Schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing Schedule II narcotic controlled substances to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further prescription verification is required. All normal requirements of a legal prescription must be followed.

2. Practitioners prescribing Schedule II controlled substances for residents of Long Term Care Facilities (LTCF) may transmit a prescription by facsimile to the dispensing pharmacy. The practitioner's agent may also transmit the prescription to the pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy.

3. A practitioner prescribing a Schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent may transmit the prescription to the pharmacy. The practitioner or agent will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription.

Schedule III-V Substances

A prescription for controlled substances in Schedules III, IV, and V issued by a practitioner, may be communicated either orally, in writing, or by facsimile to the pharmacist, and may be refilled if so authorized on the prescription or by call-in.

Refills

Schedule III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date on which the prescription was issued. After five refills or after six months, whichever occurs first, a new prescription is required.

Facsimile Prescriptions for Schedule III-V Substances

Prescriptions for Schedules III-V controlled substances may be transmitted by facsimile from the practitioner or an employee or agent of the individual practitioner to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription.

Telephone Authorization for Schedule III-V Prescriptions

A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription, except for the signature of the practitioner.

Delivery of a Controlled Substance to Persons Outside the U.S.

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in another country. Any such delivery or shipment is a prohibited export under the CSA.

SECTION VI – OPIOID (NARCOTIC) ADDICTION TREATMENT PROGRAMS

The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 amended the CSA with respect to the use of controlled substances in the medical treatment of addiction. These laws established the procedures for approval and licensing of practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.

Practitioners wishing to administer and dispense approved Schedule II controlled substances (that is, methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program. Application for registration as a Narcotic Treatment Program is made using DEA Form 363. In addition to obtaining this separate DEA registration, this type of activity also requires the approval and registration of the Center for Substance Abuse Treatment (CSAT) within the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (HHS), as well as the applicable state methadone authority.

If a practitioner wishes to prescribe, administer, or dispense Schedule III, IV, or V controlled substances approved for addiction treatment (i.e., buprenorphine drug products), the practitioner must request a waiver (Form SMA-167) and fulfill the requirements of CSAT. CSAT will then notify DEA of all waiver requests. DEA will review each request. If DEA approves this waiver, the practitioner will receive a Unique Identification Number. If a practitioner chooses to dispense controlled substances, the practitioner must maintain, separate from all other records, for a period of at least two years, all required records of receipt, storage, and distribution. If a practitioner chooses to prescribe these controlled substances, the practitioner must utilize their Unique Identification Number on the prescription in addition to his/her regular DEA registration number. The practitioner must also maintain a record of each such prescription for a period of at least two years. Practitioners should be aware that there may be limits on how many patients they may treat for opioid addiction at any given time and should check with SAMHSA to determine these limits.

Note that not all treatment programs utilize controlled substances, that is, some are drug free. Accordingly, these activities do not require DEA registration or approval.

Practitioners can find additional information regarding addiction treatment by visiting DEA's Office of Diversion Control website at www.DEAdiversion.usdoj.gov. Click on "Publications," then "Narcotic Treatment Programs: Best Practices Guidelines." The DEA application Form 363 may be completed on-line.

To learn more about CSAT's requirements, practitioners may visit one or more of the following websites: www.samhsa.gov/centers/csat2002/csat_frame.html, www.csat.samhsa.gov, or www.buprenorphine.samhsa.gov.

If the practitioner has a patient who is in need of addiction treatment, but does not wish to treat the individual, the practitioner can refer the patient to an existing facility through the following website: www.findtreatment.samhsa.gov.

APPENDICES

APPENDIX A

CSA & CFR Definitions

Administer

The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner or (in his presence) by his authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means.

Dispense

To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

Dispenser

An individual practitioner, institutional practitioner, pharmacy or, pharmacist who dispenses a controlled substance.

Individual Practitioner

A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Institutional Practitioner

A hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Inventory

All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

Long Term Care Facility

A nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.

Mid-level Practitioner

An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

Pharmacist

Any pharmacist licensed by a state to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

Prescription

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Readily Retrievable

Certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

APPENDIX B

Questions and Answers

The following questions are those that are frequently encountered by DEA's Office of Diversion Control and its field units. These questions and their accompanying answers are provided in context of the CSA and its federal regulations.

Q Are separate registrations required for separate locations?

A A separate registration is required for each principal place of business or professional practice where controlled substances are stored or dispensed by a person.

Q Does a practitioner need a separate registration to treat patients at remote health care facilities?

A Separate registration is not required in an office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

Q Do all practitioners in a group practice need to be registered?

A An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

Q Do medical residents assigned to hospitals need to register?

A An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered provided that additional requirements as set forth in the CFR are met.

Q Are military personnel exempted from registration?

A Registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, or Coast Guard who is authorized to prescribe, dispense, or administer, but not procure or purchase, controlled substances in the course of his/her official duties. Such officials must follow procedures set forth in 21 CFR Part 1306 regarding prescriptions. Branch of service or agency and the service identification number of the issuing official is required on the prescription form in lieu of the DEA registration number.

If any exempted official engages as a private individual in any activity or group of activities for which registration is required, that individual must obtain a registration for those private activities.

Further, practitioners serving in the U.S. Military are exempt from registering with DEA, but are not authorized to procure or purchase controlled substances in the course of their official duties.

A number of states also require military practitioners to acquire a separate state license if they issue prescriptions that are filled outside the military facility where they practice.

Q Are contract practitioners working at U.S. Military Installations also exempt from registration?

A They are not exempt. A contract practitioner who is not an official of the military on active duty, but is engaged in medical practice at a military installation, must possess a current DEA registration. The individual must also possess a valid state license for the same state in which he/she is registered with DEA.

Q What should a practitioner do if he/she discovers a theft or loss?

A Registrants must notify the DEA field office in their area of the theft or significant loss of any controlled substances upon discovery. The registrant must also complete DEA Form 106 documenting the loss or theft.

Q What is meant by "acceptable medical practice?"

A The legal standard that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice has been construed to mean that the prescription must be "in accordance with a standard of medical practice generally recognized and accepted in the United States."

Federal courts have long recognized that it is not possible to expand on the phrase "legitimate medical purpose in the usual course of professional practice" in a way that will provide definitive guidelines to address all the varied situations physicians may encounter.

While there are no criteria to address every conceivable instance of prescribing, there are recurring patterns that may be indicative of inappropriate prescribing:

- An inordinately large quantity of controlled substances prescribed or large numbers of prescriptions issued compared to other physicians in an area;
- No physical examination was given;
- Warnings to the patient to fill prescriptions at different drug stores;
- Issuing prescriptions knowing that the patient was delivering the drugs to others;
- Issuing prescriptions in exchange for sexual favors or for money;
- Prescribing of controlled drugs at intervals inconsistent with legitimate medical treatment;
- The use of street slang rather than medical terminology for the drugs prescribed; or
- No logical relationship between the drugs prescribed and treatment of the condition allegedly existing.

Each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient.

For example, what constitutes "an inordinately large quantity of controlled substances," can vary greatly from patient to patient. A particular quantity of a powerful Schedule II opioid might be blatantly excessive for the treatment of a particular patient's mild temporary pain, yet insufficient to treat the severe unremitting pain of a cancer patient.

Q What information is required to be provided on a written prescription?

A All written prescriptions for controlled substances must be dated as of, and signed on, the date when issued. Each prescription must indicate the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed,

directions for use and the name, address, and DEA number of the practitioner. Further, prescriptions must be written in ink, indelible pencil, or by typewriter, and must be manually signed by the practitioner.

Q What is meant by "date of issuance?"

A The date a prescription is issued is the same date that the prescribing practitioner actually writes and signs the prescription.

Q Is there a time limit for filling Schedule II prescriptions?

A There is no federal time limit for filling Schedule II prescriptions. However, some state laws do set time limits.

APPENDIX C

Summary of Controlled Substances Act Requirements

	Schedule II	*Schedule III & IV*	*Schedule V*
Registration	**Required**	**Required**	**Required**
Receiving Records	**Order Forms (DEA Form-222)**	**Invoices, Readily Retrievable**	**Invoices, Readily Retrievable**
Prescriptions	**Written Prescription (See exceptions*)**	**Written, Oral, or Fax**	**Written, Oral, Fax, or Over The Counter****
Refills	**No**	**No more than 5 within 6 months**	**As authorized when prescription is issued**
Distribution Between Registrants	**Order Forms (DEA Form-222)**	**Invoices**	**Invoices**
Security	**Locked Cabinet or Other Secure Storage**	**Locked Cabinet or Other Secure Storage**	**Locked Cabinet or Other Secure Storage**
Theft or Significant Loss	**Report and complete DEA Form 106**	**Report and complete DEA Form 106**	**Report and complete DEA Form 106**

Note: ***All records*** must be maintained for 2 years, unless a state requires a longer period.

* **Emergency prescriptions** require a signed follow-up prescription.
Exceptions: A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, Hospice patients, or compounded IV narcotic medications.

** Where authorized by state controlled substances authority.

APPENDIX D

Internet Resources

DEA's Diversion Control Program Website
www.DEAdiversion.usdoj.gov

DEA Homepage
www.dea.gov

U.S. Government Printing Office
www.gpoaccess.gov/cfr/index.html

Provides access to the Code of Federal Regulations (21 CFR, Parts 1300 to end), primary source for the Practitioner's Manual, and the Federal Register which contains proposed and finalized amendments to the CFR.

Office of National Drug Control Policy (ONDCP)
www.whitehousedrugpolicy.gov

Food and Drug Administration
www.FDA.gov

HHS & SAMHSA's National Clearinghouse for Alcohol and Drug Information
www.health.org

SAMHSA/CSAT
www.csat.samhsa.gov

Federation of State Medical Boards
www.FSMB.org

National Association of Boards of Pharmacy
www.nabp.net

National Association of State Controlled Substances Authorities
www.nascsa.org

APPENDIX E

Drug Enforcement Administration
Diversion Field Office Locations

For address and telephone number updates, please see the DEA website:
www.deadiversion.usdoj.gov/offices_n_dirs/index.html

Appendix E pages 34-39 of this manual contained outdated Field Office Information and therefore have been removed. Please refer to the above link for current Diversion Field Office Locations.

APPENDIX F

Small Business and Agriculture Regulatory Enforcement Ombudsman

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, you may contact the Ombudsman at 1-888-REG-FAIR (1-888-734-3247).

APPENDIX G

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the Controlled Substances Act and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding the DEA's requirements or regulatory activities, please contact your local DEA Diversion field office (see Appendix E). Every effort will be made to respond promptly to your inquiry.

Plain Language

The Drug Enforcement Administration has made every effort to write this manual in clear, plain language. If you have suggestions as to how to improve the clarity of this manual, please contact us at:

Drug Enforcement Administration
Office of Diversion Control
Liaison and Policy Section
Washington, D.C. 20537
Telephone: (202) 307-7297

APPENDIX H – DEA FORMS

The following pages provide samples of several forms frequently encountered by DEA registrants. Included are:

DEA Form 41 Registrants Inventory of Drugs Surrendered

DEA Form 106 Report of Theft or Loss of Controlled Substances

DEA Form 222 U.S. Official Order Form for Controlled Substances

DEA Form 224 Application for Registration

DEA Form 224a Renewal Application for DEA Registration

DEA Form 363 Application for Registration as a Narcotic Treatment Program

DEA Form 363a Renewal Application for DEA Registration as a Narcotic Treatment Program

OMB Approval No. 1117 - 0007	U. S. Department of Justice / Drug Enforcement Administration **REGISTRANTS INVENTORY OF DRUGS SURRENDERED**	PACKAGE NO.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: *(Include Name, Street, City, State and ZIP Code in space provided below.)*

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS *(Number of grams, tablets, ounces or other units per container)*	Controlled Substance Content, *(Each Unit)*	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	*2*	*3*	*4*	*5*	*6*	*7*
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

FORM DEA-41 (9-01) Previous edition dated 6-86 is usable. *See instructions on reverse (page 2) of form.*

DEA-41 (6/1986) Pg. 2

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content, (Each Unit)	FOR DEA USE ONLY DISPOSITION	QUANTITY GMS.	 MGS.
1	2	3	4	5	6	7
17						
18						
19						
20						
21						
22						
23						
24						

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in _____packages purporting to contain the drugs listed on this inventory and have been: ** (1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; (3) Forwarded tape-sealed after verifying contents.

DATE _____ DESTROYED BY: _____

** *Strike out lines not applicable.*

WITNESSED BY: _____

INSTRUCTIONS

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (32mg.), etc.
2. All packages included on a single line should be identical in name, content and controlled substance strength.
3. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.
4. There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.
5. Drugs should be shipped tape-sealed via prepaid express or certified mail (**return receipt requested**) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

PRIVACY ACT INFORMATION

AUTHORITY: Section 307 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.
ROUTINE USES: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated.
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project no. 1117-0007, Washington, D.C. 20503.

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001

1. Name and Address of Registrant (include ZIP Code)

ZIP CODE

2. Phone No. (Include Area Code)

3. DEA Registration Number
2 ltr. prefix | 7 digit suffix

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
1 ☐ Pharmacy
2 ☐ Practitioner
3 ☐ Manufacturer
4 ☐ Hospital/Clinic
5 ☐ Distributor
6 ☐ Methadone Program
7 ☐ Other (Specify)

6. County in which Registrant is located

7. Was Theft reported to Police?
☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has experienced in the past 24 months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 ☐ Night break-in
2 ☐ Armed robbery
3 ☐ Employee pilferage
4 ☐ Customer theft
5 ☐ Other (Explain)
6 ☐ Lost in transit (Complete Item 14)

11. If Armed Robbery, was anyone:
Killed? ☐ No ☐ Yes (How many) _____
Injured? ☐ No ☐ Yes (How many) _____

12. Purchase value to registrant of Controlled Substances taken?
$

13. Were any pharmaceuticals or merchandise taken?
☐ No ☐ Yes (Est. Value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer?
☐ Yes ☐ No

E. If received, did it appear to be tampered with?
☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past?
☐ No ☐ Yes (How Many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report theft or loss of Controlled Substances.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a ly valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 30 minutes per response , including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FORM DEA - 106 (11-00) *Previous editions obsolete*

CONTINUE ON REVERSE

FORM DEA-106 (Nov. 2000) Pg. 2

LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
Examples: Desoxyn	Methamphetamine Hydrochloride	5 mg Tablets	3 x 100
Demerol	Meperidine Hydrochloride	50 mg/ml Vial	5 x 30 ml
Robitussin A-C	Codeine Phosphate	2 mg/cc Liquid	12 Pints
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49.			
50.			

I certify that the foregoing information is correct to the best of my knowledge and belief.

Signature _____ Title _____ Date _____

DEPICTION of PAGE 1 of DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*	STREET ADDRESS
CITY and STATE	DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ **LAST LINE COMPLETED** ***(MUST BE 10 OR LESS)***

SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT

Date Issued	DEA Registration No.	Name and Address of Registrant
Schedules		
Registered as a	No. of this Order Form	

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is not intended to be used as an actual order form.

Form-224

APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

APPROVED OMB NO 1117-0014
FORM DEA-224 (9-05)
Previous editions are obsolete

INSTRUCTIONS

1. To apply by mail complete this application. Keep a copy for your records.
2. Print clearly, using black or blue ink, or use a typewriter.
3. Mail this form to the address provided in Section 7 or use enclosed envelope.
4. Include the correct payment amount. FEE IS NON-REFUNDABLE.
5. If you have any questions call 800-882-9539 prior to submitting your application.
6. Save time - apply online at www.deadiversion.usdoj.gov.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ONLINE.

REGISTRATION INFORMATION :

$390.00

FEE IS NON-REFUNDABLE

SECTION 1 APPLICANT IDENTIFICATION

Last Name (If registration is for individual) -OR- Business or Facility Name (If registration is for business entity)

First Name (If registration is for individual) Middle Initial

Business or Facility Name 2 ("doing business as", continuation of business name, or name of fee exempt institution)

Address Line 1 (street address)

Address Line 2

City State Zip Code

Business Phone Number Business Fax Number

DEBT COLLECTION INFORMATION

Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number (If registration is for business)

Social Security Number (If registration is for individual)

Provide SSN or TIN. See note #3 on bottom of page 2

SECTION 2

BUSINESS ACTIVITY

Check one box only

See page 3 for additional instructions

- ☐ Hospital/Clinic
- ☐ Ambulance Service
- ☐ Practitioner (DDS, DMD, DO, DPM, DVM, MD or PHD)
- ☐ Nursing Home
- ☐ Animal Shelter
- ☐ Practitioner Military (DDS, DMD, DO, DPM, DVM,MD or PHD)
- ☐ Central Fill Pharmacy
- ☐ Teaching Institution
- ☐ Mid-level Practitioner (MLP) (DCM, HMD, MP, ND, NP, OD, PA, or RPH)
- ☐ Retail Pharmacy
- ☐ Automated Dispensing System
- ☐ Euthanasia Technician

PROFESSIONAL DEGREE

Practitioners and MLPs : Enter your professional degree from list

FOR Automated Dispensing System (ADS) ONLY:

DEA Registration # of Retail Pharmacy for this ADS

An ADS is automatically fee-exempt. Skip Section 6 and Section 7 on page 2. You must attach a notorized affidavit.

SECTION 3

DRUG SCHEDULES

Check all that apply

- ☐ Schedule II Narcotic
- ☐ Schedule II Non-Narcotic
- ☐ Schedule III Narcotic
- ☐ Schedule III Non-Narcotic
- ☐ Schedule IV
- ☐ Schedule V
- ☐ Check this box if you require official order forms for purchase of schedule II narcotic/schedule II non-narcotic controlled substances

NEW - Page 1

SECTION 4

STATE LICENSE(S)

Be sure to include both state license numbers if applicable

Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate?

	YES	PENDING	NO	
State License Number	☐	☐	☐	
State Controlled Substance License Number (if required)	☐	☐	☐	

SECTION 5

LIABILITY

IMPORTANT

All questions in this section must be answered.

	YES	NO
1. Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law?	☐	☐
2. Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied?	☐	☐
3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? Is any such action pending?	☐	☐
4. If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a federal controlled substance registration revoked, suspended, restricted, denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?	☐	☐

EXPLANATION OF "YES" ANSWERS

Applicants who have answered "YES" to any of the four questions above must provide a statement to explain such answers

Use this space or attach a separate sheet and return with application

Date(s) of Incident: _____ Location(s) of Incident: _____

Nature of Incident:

Result of Incident:

SECTION 6

CERTIFICATION OF EXEMPTION from application fee

☐ Check this box if the applicant is a federal, state, or local government operated hospital, institution or official.
Be sure to enter the name and address of the exempt institution in Section 1.

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government-operated hospital, institution or official, and is exempt from payment of the application fee.

Provide the name and phone number of the certifying official

Signature of certifying official (other than applicant) _____ Date _____

Print or type name and title of certifying official _____ Telephone No. (required for verification) _____

SECTION 7

METHOD OF PAYMENT

Check one form of payment only

☐ Check — Make check payable to: Drug Enforcement Administration. See page 4 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number _____ Expiration Date _____

Sign if paying by credit card

Signature of Card Holder _____

Printed Name of Card Holder _____

Mail this form with payment to:

U.S. Department of Justice
Drug Enforcement Administration
P.O. Box 28083
Washington, DC 20038-8083

FEE IS NON-REFUNDABLE

SECTION 8

APPLICANT'S SIGNATURE

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

Signature of applicant _____ Date _____

Print or type name and title of applicant _____

WARNING: Section 843(a)(4)(A) of Title 21, United States Code states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to imprisonment for not more than four years, a fine of not more than $30,000, or both.

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).
2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 1117-0014. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.
3. The Debt Collection Improvements Act of 1996 (PL 104-134) requires that you furnish your Taxpayer Identifying Number and/or Social Security Number on this application. This number is required for debt collection procedures should your fee become uncollectable.
4. PRIVACY ACT INFORMATION

AUTHORITY:	Section 302 and 303 of the Controlled Substances Act of 1970 (PL 91-513) and Debt Collection Improvements Act of 1996 (PL 104-134) (for taxpayer identifying number and/or social security number).
PURPOSE:	To obtain information required to register applicants pursuant to the Controlled Substances Act of 1970.
ROUTINE USES:	The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated: A. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes. B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes. C. Persons registered under the Controlled Substances Act (PL 91-513) for the purpose of verifying the registration of customers.
EFFECT:	Failure to complete form will preclude processing of the application.

NEW - Page 2

Form-224 **APPLICATION FOR REGISTRATION**
Supplementary Instructions and Information

ADDITIONAL INSTRUCTIONS

SECTION 1. APPLICANT IDENTIFICATION - Information must be typed or printed in the blocks provided to help reduce data entry errors. Fee exempt applications must list the name and address of the fee exempt institution. A physical address is required; after the street address a post office box may be included. Applicant must enter a valid social security number (SSN), or a tax identification number (TIN) if applying as a business entity.
Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.

SECTION 2. BUSINESS ACTIVITY - Indicate only one. Practitioners also enter one degree from this list: DDS, DMD, DO, DPM, DVM, MD or PHD. Mid-level practitioners also enter one degree from these choices: DOM, HMD, MP, ND, NP, OD, PA, or RPH.

ADS must provide current DEA registration number of parent retail pharmacy and attach a notorized affidavit (21 CFR Part 1301.17).
Affidavit must include 1) Name of parent retail pharmacy and complete address 2) Name of Long-term Care (LTC) facility and complete address
3) Permit or license number(s) and date issued of State certification to operate ADS at named LTC facility
4) Required Statement: *This affidavit is submitted to obtain a DEA registration number. If any material information is false, the Administrator may commence proceedings to deny the application under section 304 of the Act (21 U.S.C. 824(a)). Any false or fraudulent material information contained in this affidavit may subject the person signing this affidavit, and the named corporation/partnership/business to prosecution under section 403 of the Act (21 U.S.C 843).*
5) Name of corporation operating the retail pharmacy 6) Name and title of corporate officer signing affidavit 7) Signature of authorized officer

SECTION 3. DRUG SCHEDULES - Applicants should check all drug schedules to be handled. However, applicants must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you inland to purchase or to transfer schedule II controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration.

SECTION 4. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant 's compliance with applicable state and local laws. Applicants should contact the local state licensing authority prior to completing this application. If your state requires a separate controlled substance number, provide that number on this application. If a state license has not yet been issued, indicate "Pending". If state licensing authority is not required, indicate "No".

SECTION 5. LIABILITY - Applicants must answer all four questions for the application to be accepted for processing. If you answered "Yes" to any question, provide an explanation in the space provided. If additional space is required, you may attach a separate sheet of paper.

SECTION 6. CERTIFICATE OF EXEMPTION - Exemption from payment of application fee is limited to federal, state or local government operated hospitals, institutions and officials. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided.

SECTION 7. METHOD OF PAYMENT - Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. FEES ARE NON-REFUNDABLE.

SECTION 8. APPLICANT'S SIGNATURE - Must be the original signature (in ink) of the applicant.

CONTACT INFORMATION

1. INTERNET

www.deadiversion.usdoj.gov

2. TELEPHONE

Headquarters Call Center
(800) 882-9539

3. WRITTEN INQUIRIES

DEA
P.O. Box 28083
Washington DC 20038-8083

4. DEA OFFICES

DEA Offices are listed
(800, 877, and 888
are toll-free numbers)

ATLANTA DIVISION OFFICE
ATTN: Registration
75 Spring Street, SW, Suite 800
Atlanta, GA 30303

Georgia	(888) 882-9935
North Carolina	(888) 219-8888
South Carolina	(866) 533-6953
Tennessee	(888) 219-7935

BOSTON DIVISION OFFICE
JFK Federal Building
15 New Sudbury Street, Room E400
Boston, MA 02203-0131

Connecticut	(617) 557-2200
Maine	(888) 272-5174
Massachusetts	(617) 557-2485
New Hampshire	(888) 272-5174
Rhode Island	(617) 557-2200
Vermont	(888) 272-5174

CARIBBEAN DIVISION OFFICE
P.O. Box 2167
San Juan, PR 00922-2167

Puerto Rico	(787) 775-1788
U.S. Virgin Islands	(787) 775-1788

CHICAGO DIVISION OFFICE
Kluczynski Federal Building
230 S. Dearborn Street, Suite 1200
Chicago, IL 60604

Illinois	(312) 353-1234
Indiana	(312) 353-1236
Minnesota	(312) 353-9188
North Dakota	(312) 353-9188
Wisconsin	(312) 353-1236

DALLAS DIVISION OFFICE
10160 Technology Blvd., East
Dallas, TX 75220

Oklahoma	(888) 338-4704
Texas (Northern)	(888) 338-4704

DENVER DIVISION OFFICE
115 Inverness Drive, East
Englewood, CO 80112

Colorado	(800) 328-6900
Montana	(800) 328-6900
Utah	(800) 328-6900
Wyoming	(800) 328-6900

DETROIT DIVISION OFFICE
431 Howard Street
Detroit, MI 48226

Kentucky	(800) 230-6544
Michigan	(800) 230-6544
Ohio	(800) 230-6544

EL PASO DIVISION OFFICE
El Paso Federal Justice Center
660 South Mesa Hills Drive, Suite 2000
El Paso, TX 79912

New Mexico	(915) 832-6014

HOUSTON DIVISION OFFICE
1433 West Loop South, Suite 600
Houston, TX 77027-9508

Texas (S. & Central)	(800) 743-0595

LOS ANGELES DIVISION OFFICE
255 East Temple Street, 20th Floor
Los Angeles, CA 90012

California (S. Central)	(213) 621-6960
Hawaii	(888) 415-9622
Nevada	(888) 415-9622
Trust Territory	(213) 894-2216

MIAMI DIVISION OFFICE
8400 N.W. 53rd Street
Miami, FL 33166

Florida	(305) 590-4660

NEWARK DIVISION OFFICE
80 Mulberry Street, 2nd Floor
Newark, NJ 07102

New Jersey	(888) 356-1071

NEW ORLEANS DIVISION OFFICE
3838 N. Causeway Blvd
Lakeway III, Suite 1600
Metairie, LA 70002

Alabama	(888) 514-5051
Arkansas	(888) 514-7302
Louisiana	(888) 514-7302
Mississippi	(888) 514-7302

NEW YORK DIVISION OFFICE
99 Tenth Avenue
New York, NY 10011

New York	(877) 883-5769
	(212) 337-1593
	(212) 337-1594

PHILADELPHIA DIVISION OFFICE
William J. Green Federal Building
600 Arch Street, Room 10224
Philadelphia, PA 19106

Delaware	(888) 393-8231
Pennsylvania	(888) 393-8231

PHOENIX DIVISION OFFICE
3010 N. 2nd Street, Suite 301
Phoenix, AZ 85012

Arizona	(800) 741-0902

SAN DIEGO DIVISION OFFICE
4560 Viewridge Avenue
San Diego, CA 92123-1687

California (Southern)	(800) 284-1152

SAN FRANCISCO DIVISION OFFICE
450 Golden Gate Avenue, 14th Floor
P.O. Box 36035
San Francisco, CA 94102

California (Northern)	(888) 304-3251

SEATTLE DIVISION OFFICE
400 Second Avenue, West
Seattle, WA 98119

Alaska	(888) 219-4261
Idaho	(888) 219-4261
Oregon	(888) 219-4261
Washington	(888) 219-1416

ST. LOUIS DIVISION OFFICE
317 South 16th Street
St. Louis, MO 63103

Iowa	(888) 803-1179
Kansas	(888) 803-1179
Missouri	(888) 803-1179
Nebraska	(888) 803-1179
South Dakota	(888) 803-1179

WASHINGTON, D.C. DIVISION OFFICE
Techworld Plaza
800 K Street, N.W., Suite 500
Washington, D.C. 20001

District of Columbia	(877) 801-7974
Maryland	(877) 330-6670
Virginia	(877) 801-7974
West Virginia	(877) 330-6670

NEW INST - Page 3

DRUG SCHEDULES

Listed below are examples of the schedules with assigned drug code numbers. If you are in need of additional information, see 21 CFR 1308 or contact the DEA office serving your area.

SCHEDULE I

NARCOTIC & NON-NARCOTIC BASIC CLASSES	CODE
Acetorphine	9319
Acetylmethadol	9601
Allylprodine	9602
Alphacetylmethadol (except LAAM)	9603
Bufotenine	7433
Dextromoramide	9613
Diethyltryptamine (DET)	7434
2,5 - Dimethoxyamphetamine (DMA)	7396
Dimethyltryptamine (DMT)	7435
Etorphine (except hydrochloride salt)	9056
gamma-Hydroxybutyric acid (except drug product)	2010
Heroin	9200
Ibogaine	7260
Ketobemidone	9628
Lysergic acid diethylamide (LSD)	7315
Marihuana	7360
Mescaline	7381
Methaqualone	2565
3,4 - Methylenedioxyamphetamine (MDA)	7400
3,4 - Methylenedioxymethamphetamine (MDMA)	7405
n- Ethyl - 1 - Phenylcyclohexylamine (PCE)	7455
Peyote	7415
1 - (1-Phenylcyclohexyl)pyrrolidine (PCP)	7458
Psilocybin	7437
Psilocyn	7438
Tetrahydrocannabinols (THC)	7370
1-[1-(2-Thienyl)-cyclohexyl]-piperidine	7470

SCHEDULE II

NARCOTIC BASIC CLASSES	CODE
Alphaprodine	9010
Anileridine	9020
Cocaine	9041
Codeine	9050
Dextropropoxyphene (bulk)	9273
Diphenoxylate	9170
Diprenorphine (M50-50)	9058
Ethylmorphine	9190
Etorphine Hydrochloride (M-99)	9059
Glutethimide	2550
Hydrocodone	9193
Hydromorphone	9150
Levo-alphacetylmethadol (LAAM)	9648
Levorphanol	9220
Meperidine	9230
Methadone	9250
Morphine	9300
Opium, powdered	9639
Opium, raw	9600
Oxycodone	9143
Oxymorphone	9652
Poppy Straw	9651
Poppy Straw Concentrate	9670
Thebaine	9333

NON-NARCOTIC BASIC CLASSES	CODE
Amobarbital	2125
Amphetamine	1100
Methamphetamine	1105
Methylphenidate	1724
Pentobarbital	2270
Phencyclidine (PCP)	7471
Phenmetrazine	1631
Phenylacetone	8501
Secobarbital	2315

SCHEDULE III

NARCOTIC BASIC CLASSES	CODE
Buprenorphine	9064
Codeine up to 90 mg/du plus other ingredients	9319
Dihydrocodeineup to 90 mg/du plus other ingredients	9807
Ethylmorphine up to 15 mg/du plus other ingredients	9606
Hydrocodone up to 15 mg/du plus other ingredients	9806
Morphine up to 30 mg/100ml or gm plus other ingred.	9810
Opium up to 500 mg/100m. plus other active ingred.	9809

NON-NARCOTIC BASIC CLASSES	CODE
Anabolic Steroids	4000
Benzphetamine	1228
Butalbital	2100
Dronabinol Pharmaceutical Product	7369
GHB Drug Product (gamma-Hydroxybutyric acid)	2010
Ketamine	7285
Methyprylon	2575
Pentobarbital plus noncontrolled active ingredients	2271
Pentobarbital suppository	2271
Phendimetrazine	1615
Secobarbital plus noncontrolled active ingredients	2316
Secobarbital suppository	2316
Thiopental	2329
Vinbarbital	2335

SCHEDULE IV

NARCOTIC BASIC CLASSES	CODE
Dextropropoxyphene du	9278
Difenoxin 1mg/25ug atropine SO4/du	9167

NON-NARCOTIC BASIC CLASSES	CODE
Alprzolam	2882
Barbital	2145
Chloral Hydrate	2465
Chlordiazepoxide	2744
Clorazepate	2768
Diazepam	2765
Diethylpropion	1610
Fenfluramine	1670
Flurazepam	2767
Halazepam	2762
Lorazepam	2885
Mazindol	1605
Mebutamate	2800
Mephobarbital (Methylphenobarbital)	2250
Meprobamate	2820
Methohexital	2264
Midazolam	2884
Oxazepam	2835
Paraldehyde	2585
Pemoline	1530
Pentazocine	9709
Phenobarbital	2285
Phentermine	1640
Prazepam	2764
Quazepam	2881
Temazepam	2925
Triazolam	2887
Zolpidem	2783

SCHEDULE V

	CODE
Codeine Cough Preparation (200mg/100ml or 100g)	9100

Notice to Registrants Making Payment by Check

Authorization to Convert Your Check: If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

Insufficient Funds: The electronic funds transfer from your account will usually occur with 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two times.

Transaction Information: The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions." You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights: You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

NEW INST - Page 4

Form-224a

RENEWAL APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

APPROVED OMB NO 1117-0014
FORM DEA-224a (1-05)

INSTRUCTIONS

1. To renew by mail complete this application. Keep a copy for your records.
2. Print clearly, using black or blue ink, or use a typewriter.
3. Section 5 should be completed only if your information has changed.
4. Mail this form to the address provided in Section 6 or use enclosed envelope.
5. Include the correct payment amount. FEE IS NON-REFUNDABLE.
6. If you have any questions call 800-882-9539 prior to submitting your application.
7. Save time - **renew online at www.deadiversion.usdoj.gov**.

IMPORTANT: DO NOT SEND THIS APPLICATION **AND** RENEW ONLINE.

REGISTRATION INFORMATION :
DEA #
REGISTRATION EXPIRES

FEE IS NON-REFUNDABLE

SECTION 1

DRUG SCHEDULES

Check all that apply

- ☐ Schedule II Narcotic
- ☐ Schedule II Non-Narcotic
- ☐ Schedule III Narcotic
- ☐ Schedule III Non-Narcotic
- ☐ Schedule IV
- ☐ Schedule V

SECTION 2

☐ Check this box if you need official order forms - for the purchase of schedule II narcotic/schedule II non-narcotic controlled substances.

SECTION 3

STATE LICENSE(S)

Be sure to include both state license numbers if applicable

A. Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate?

YES	NO		
☐	☐		State License Number
☐	☐		State Controlled Substance License Number (if required)

LIABILITY

IMPORTANT:
If you answered yes to these question(s) on previous application, you must continue to answer yes and provide a statement of explanation.

All questions in this section must be answered.

	YES	NO
B. Has the applicant ever been **convicted of a crime** in connection with controlled substances under state or federal law?	☐	☐
C. Has the applicant ever surrendered (for cause) or had a **federal** controlled substance registration revoked, suspended, restricted, or denied?	☐	☐
D. Has the applicant ever surrendered (for cause) or had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? **Is any such action pending?**	☐	☐
E. If the applicant is a **corporation** (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been **convicted of a crime** in connection with controlled substances under state or federal law, or ever surrendered, for cause, or had a **federal** controlled substance registration revoked, suspended, restricted, denied, or ever had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?	☐	☐

SECTION 4

EXPLANATION OF "YES" ANSWERS

Applicants who have answered "YES" to questions B, C, D, or E above **must provide a statement to explain such answers**

Use this space or attach a separate sheet and return with application

Date(s) of incident: _____ Location(s) of incident: _____

Nature of incident:

Result of incident:

RENEWAL - Page 1

SECTION 5

CHANGES TO APPLICANT IDENTIFICATION

Last Name (if registration is for individual) -OR- Business Name (if registration is for business)

First Name and Middle Initial

DEBT COLLECTION INFORMATION

Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number (if registration is for business) Social Security Number (if registration is for individual)

Provide SSN or TIN. See note #3 on bottom of page 2

Address Line 1 (street address)

IMPORTANT

Leave this section blank unless the registration information on front page is incorrect.

Address Line 2

City State Zip Code

Business Phone Number Business Fax Number

FOR CHANGES ONLY

SECTION 6

METHOD OF PAYMENT

Check one form of payment only

☐ Check Make check payable to: **Drug Enforcement Administration** See page 4 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number Expiration Date

Sign if paying by credit card

Signature of Card Holder

Printed Name of Card Holder

Mail this form with payment to:

U.S. Department of Justice
Drug Enforcement Administration
P.O. Box 105616
Atlanta, GA 30348-5616

FEE IS NON-REFUNDABLE

SECTION 7

CERTIFICATION OF EXEMPTION from application fee

☐ Check this box if the applicant is a federal, state, or local government operated hospital, institution or official. **Be sure to enter the name and address of the exempt institution on address lines 1 and 2 in Section 5, if it is not already on your current registration certificate.**

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government operated hospital, institution or official, and is exempt from payment of the application fee.

Provide the name and phone number of the certifying official

Signature of certifying official (other than applicant) Date

Print or type name and title of certifying official Telephone No. (required for verification)

SECTION 8

APPLICANT'S SIGNATURE

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

Signature of applicant Date

Print or type name and title of applicant

WARNING: Section 843(a)(4)(A) of Title 21, United States Code states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to imprisonment for not more than four years, a fine of not more than $30,000, or both.

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).
2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 1117-0014. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.
3. The Debt Collection Improvements Act of 1996 (PL 104-134) requires that you furnish your Taxpayer Identifying Number and/or Social Security Number on this application. This number is required for debt collection procedures should your fee become uncollectable.
4. PRIVACY ACT INFORMATION

AUTHORITY: Section 302 and 303 of the Controlled Substances Act of 1970 (PL 91-513) and Debt Collection Improvements Act of 1996 (PL 104-134) (for taxpayer identifying number and/or social security number).

PURPOSE: To obtain information required to register applicants pursuant to the Controlled Substances Act of 1970.

ROUTINE USES: The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (PL 91-513) for the purpose of verifying the registration of customers.

EFFECT: Failure to complete form will preclude processing of the application.

RENEWAL - Page 2

Form-224a

APPLICATION FOR RENEWAL
Supplementary Instructions and Information

ADDITIONAL INSTRUCTIONS

SECTION 1. DRUG SCHEDULES - Applicants should check all drug schedules to be handled. However, applicants must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you intend to purchase or to transfer schedule II controlled substances.

SECTION 2. ORDER FORMS - Order forms will be mailed to the registered address following issuance of a Certificate of Registration.

SECTION 3. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant 's compliance with applicable state and local laws. Applicants should contact the local state licensing authority prior to completing this application. If your state requires a separate controlled substance number, provide that number on this application. If a state license has not yet been issued, indicate "Pending". If state licensing authority is not required, indicate "No".

SECTION 4. LIABILITY - Applicants must answer all four questions for the application to be accepted for processing. If you answered "Yes" to any question, provide an explanation in the space provided. If additional space is required, you may attach a separate sheet of paper.

SECTION 5. APPLICANT IDENTIFICATION - Entry of missing data or corrections ONLY must be typed or printed in the blocks provided to help reduce data entry errors. Enter changes in previously provided registration information, such as name change, address correction, or new phone numbers. Fee exempt individuals should list the name and address of the fee exempt institution. A physical address is required; after the street address a post office box may be included. Individuals renewing should ensure that the social security number (SSN) on record is correct. If renewing a business entity, a valid tax identification number (TIN) must be supplied. ***Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.***

SECTION 6. METHOD OF PAYMENT - Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. FEES ARE NON-REFUNDABLE.

SECTION 7. CERTIFICATE OF EXEMPTION - Exemption from payment of application fee is limited to federal, state or local government operated hospitals, institutions and officials. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided.

SECTION 8. APPLICANT'S SIGNATURE - Must be the original signature (in ink) of the applicant.

CONTACT INFORMATION

1. INTERNET: Information can be found on our web site at www.deadiversion.usdoj.gov
2. TELEPHONE: Headquarters Call Center: (800) 882-9539
3. WRITTEN INQUIRIES: Drug Enforcement Administration
P.O. Box 28083
Washington, D.C. 20038-8083
4. DEA OFFICES: DEA Offices are listed below (800, 877, and 888 are toll-free numbers).

ATLANTA DIVISION OFFICE
ATTN: Registration
75 Spring Street, SW, Suite 800
Atlanta, GA 30303

Georgia	(888) 869-9935
North Carolina	(888) 219-8689
South Carolina	(866) 533-6983
Tennessee	(888) 219-7898

BOSTON DIVISION OFFICE
JFK Federal Building
15 New Sudbury Street, Room E400
Boston, MA 02203-0131

Connecticut	(617) 557-2200
Maine	(888) 272-5174
Massachusetts	(617) 557-2468
New Hampshire	(888) 272-5174
Rhode Island	(617) 557-2200
Vermont	(888) 272-5174

CARIBBEAN DIVISION OFFICE
P.O. Box 2167
San Juan, PR 00922-2167

Puerto Rico	(787) 775-1766
U.S. Virgin Islands	(787) 775-1766

CHICAGO DIVISION OFFICE
Kluczynski Federal Building
230 S. Dearborn Street, Suite 1200
Chicago, IL 60604

Illinois	(312) 353-1234
Indiana	(312) 353-1236
Minnesota	(312) 353-9186
North Dakota	(312) 353-9186
Wisconsin	(312) 353-1236

DALLAS DIVISION OFFICE
10160 Technology Blvd., East
Dallas, TX 75220

Oklahoma	(888) 336-4704
Texas (Northern)	(888) 336-4704

DENVER DIVISION OFFICE
115 Inverness Drive, East
Englewood, CO 80112

Colorado	(800) 326-6900
Montana	(800) 326-6900
Utah	(800) 326-6900
Wyoming	(800) 326-6900

DETROIT DIVISION OFFICE
431 Howard Street
Detroit, MI 48226

Kentucky	(800) 230-6844
Michigan	(800) 230-6844
Ohio	(800) 230-6844

EL PASO DIVISION OFFICE
El Paso Federal Justice Center
600 South Mesa Hills Drive, Suite 2000
El Paso, TX 79912

New Mexico	(915) 832-6014

HOUSTON DIVISION OFFICE
1433 West Loop South, Suite 600
Houston, TX 77027-9506

Texas (S. & Central)	(800) 743-0595

LOS ANGELES DIVISION OFFICE
255 East Temple Street, 20th Floor
Los Angeles, CA 90012

California (S. Central)	(213) 621-6960
Hawaii	(888) 415-9822
Nevada	(888) 415-9822
Trust Territory	(213) 894-2216

MIAMI DIVISION OFFICE
8400 N.W. 53rd Street
Miami, FL 33166

Florida	(305) 590-4880

NEWARK DIVISION OFFICE
80 Mulberry Street, 2nd Floor
Newark, NJ 07102

New Jersey	(888) 356-1071

NEW ORLEANS DIVISION OFFICE
3838 N. Causeway Blvd
Lakeway III, Suite 1800
Metairie, LA 70002

Alabama	(888) 514-8051
Arkansas	(888) 514-7302
Louisiana	(888) 514-7302
Mississippi	(888) 514-7302

NEW YORK DIVISION OFFICE
99 Tenth Avenue
New York, NY 10011

New York	(877) 883-5789
	(212) 337-1593
	(212) 337-1594

PHILADELPHIA DIVISION OFFICE
William J. Green Federal Building
600 Arch Street, Room 10224
Philadelphia, PA 19106

Delaware	(888) 393-8231
Pennsylvania	(888) 393-8231

PHOENIX DIVISION OFFICE
3010 N. 2nd Street, Suite 301
Phoenix, AZ 85012

Arizona	(800) 741-0902

SAN DIEGO DIVISION OFFICE
4560 Viewridge Avenue
San Diego, CA 92123-1637

California (Southern)	(800) 284-1152

SAN FRANCISCO DIVISION OFFICE
450 Golden Gate Avenue, 14th Floor
P.O. Box 36035
San Francisco, CA 94102

California (Northern)	(888) 304-3251

SEATTLE DIVISION OFFICE
400 Second Avenue, West
Seattle, WA 98119

Alaska	(888) 219-4261
Idaho	(888) 219-4261
Oregon	(888) 219-4261
Washington	(888) 219-1418

ST. LOUIS DIVISION OFFICE
317 South 16th Street
St. Louis, MO 63103

Iowa	(888) 803-1179
Kansas	(888) 803-1179
Missouri	(888) 803-1179
Nebraska	(888) 803-1179
South Dakota	(888) 803-1179

WASHINGTON, D.C. DIVISION OFFICE
Techworld Plaza
800 K Street, N.W., Suite 500
Washington, D.C. 20001

District of Columbia	(877) 801-7974
Maryland	(877) 330-6670
Virginia	(877) 801-7974
West Virginia	(877) 330-6670

RENEWAL INST - Page 3

DRUG SCHEDULES

Listed below are examples of the schedules with assigned drug code numbers. If you are in need of additional information, see 21 CFR 1308 or contact the DEA office serving your area.

SCHEDULE I

NARCOTIC & NON-NARCOTIC BASIC CLASSES	CODE
Acetorphine	9319
Acetylmethadol	9601
Allylprodine	9602
Alphacetylmethadol (except LAAM)	9603
Bufotenine	7433
Dextromoramide	9613
Diethyltryptamine (DET)	7434
2,5 - Dimethoxyamphetamine (DMA)	7396
Dimethyltryptamine (DMT)	7435
Etorphine (except hydrochloride salt)	9056
gamma-Hydroxybutyric acid (except drug product)	2010
Heroin	9200
Ibogaine	7260
Ketobemidone	9628
Lysergic acid diethylamide (LSD)	7315
Marihuana	7360
Mescaline	7381
Methaqualone	2565
3,4 - Methylenedioxyamphetamine (MDA)	7400
3,4 - Methylenedioxymethamphetamine (MDMA)	7405
n- Ethyl - 1 - Phenylcyclohexylamine (PCE)	7455
Peyote	7415
1 - (1-Phenylcyclohexyl)pyrrolidine (PCP)	7458
Psilocybin	7437
Psilocyn	7438
Tetrahydrocannabinols (THC)	7370
1-[1-(2-Thienyl)-cyclohexyl]-piperidine	7470

SCHEDULE II

NARCOTIC BASIC CLASSES	CODE
Alphaprodine	9010
Anileridine	9020
Cocaine	9041
Codeine	9050
Dextropropoxyphene (bulk)	9273
Diphenoxylate	9170
Diprenorphine (M50-50)	9058
Ethylmorphine	9190
Etorphine Hydrochloride (M-99)	9059
Glutethimide	2550
Hydrocodone	9193
Hydromorphone	9150
Levo-alphacetylmethadol (LAAM)	9648
Levorphanol	9220
Meperidine	9230
Methadone	9250
Morphine	9300
Opium, powdered	9639
Opium, raw	9600
Oxycodone	9143
Oxymorphone	9652
Poppy Straw	9671
Poppy Straw Concentrate	9670
Thebaine	9333

NON-NARCOTIC BASIC CLASSES	CODE
Amobarbital	2125
Amphetamine	1100
Methamphetamine	1105
Methylphenidate	1724
Pentobarbital	2270
Phencyclidine (PCP)	7471
Phenmetrazine	1631
Phenylacetone	8501
Secobarbital	2315

SCHEDULE III

NARCOTIC BASIC CLASSES	CODE
Buprenorphine	9064
Codeine up to 90 mg/du plus other ingredients	9319
Dihydrocodeineup to 90 mg/du plus other ingredients	9807
Ethylmorphine up to 15 mg/du plus other ingredients	9808
Hydrocodone up to 15 mg/du plus other ingredients	9806
Morphine up to 50 mg/100ml or gm plus other ingred.	9810
Opium up to 500 mg/100m. plus other active ingred.	9809

NON-NARCOTIC BASIC CLASSES	CODE
Anabolic Steroids	4000
Benzphetamine	1228
Butalbital	2100
Dronabinol Pharmaceutical Product	7369
GHB Drug Product (gamma-Hydroxybutyric acid)	2010
Ketamine	7285
Methyprylon	2575
Pentobarbital plus noncontrolled active ingredients	2271
Pentobarbital suppository	2271
Phendimetrazine	1615
Secobarbital plus noncontrolled active ingredients	2316
Secobarbital suppository	2316
Thiopental	2329
Vinbarbital	2335

SCHEDULE IV

NARCOTIC BASIC CLASSES	CODE
Dextropropoxyphene du	9278
Difenoxin 1mg/25ug atropine SO4/du	9167

NON-NARCOTIC BASIC CLASSES	CODE
Alprzolam	2882
Barbital	2145
Chloral Hydrate	2465
Chlordiazepoxide	2744
Clorazepate	2768
Diazepam	2765
Diethylpropion	1610
Fenfluramine	1670
Flurazepam	2767
Halazepam	2762
Lorazepam	2885
Mazindol	1605
Mebutamate	2800
Mephobarbital (Methylphenobarbital)	2250
Meprobamate	2820
Methohexital	2264
Midazolam	2884
Oxazepam	2835
Paraldehyde	2585
Pemoline	1530
Pentazocine	9709
Phenobarbital	2285
Phentermine	1640
Prazepam	2764
Quazepam	2881
Temazepam	2925
Triazolam	2887
Zolpidem	2783

SCHEDULE V

	CODE
Codeine Cough Preparation (200mg/100ml or 100g)	9100

Notice to Registrants Making Payment by Check

Authorization to Convert Your Check: If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

Insufficient Funds: The electronic funds transfer from your account will usually occur with 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two times.

Transaction Information: The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions." You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights: You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

RENEW AL INST - Page 4

Form-363

APPLICATION FOR REGISTRATION
Under the Narcotic Addict Treatment Act of 1974

APPROVED OMB NO 1117-0015
FORM DEA-363 (11-05)
Previous editions are obsolete

INSTRUCTIONS

1. To apply by mail complete this application. Keep a copy for your records.
2. Print clearly, using black or blue ink, or use a typewriter.
3. Section 1 should be completed only if your information has changed.
4. Mail this form to the address provided in Section 8 or use enclosed envelope.
5. Include the correct payment amount. FEE IS NON-REFUNDABLE.
6. If you have any questions contact 800-882-9539 prior to submitting your application.
7. Save time - apply online at www.deadiversion.usdoj.gov.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ONLINE.

REGISTRATION INFORMATION :

Fee for 1 year is $130
FEE IS NON-REFUNDABLE

SECTION 1 APPLICANT IDENTIFICATION

Business or Facility Name (if registration is for business entity or is fee exempt)

Business or Facility Name 2 ("doing business as", continuation of business name, or name of fee exempt institution)

Address Line 1 (street address)

Address Line 2

City | State | Zip Code

Business Phone Number | Business Fax Number

DEBT COLLECTION INFORMATION

Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number

See note #3 on bottom of page 2.

SECTION 2 BUSINESS ACTIVITY

Check one box only

- ☐ NTP - Maintenance
- ☐ NTP - Detoxification
- ☐ NTP - Maintenance and Detoxification
- ☐ NTP - Compounder / Maintenance
- ☐ NTP - Compounder / Detoxification
- ☐ NTP - Compounder / Maintenance and Detoxification

SECTION 3 DRUG SCHEDULES

Check all that apply

- ☐ Schedule II
- ☐ Schedule III
- ☐ Check this box if you require official order forms - for purchase or transfer of schedule II controlled substances.

SECTION 4 FDA PERMIT

Mandatory for approval

Are you currently authorized by the Food and Drug Administration for the business activity described in this application?

YES ☐ PENDING ☐ NO ☐

FDA Number

SECTION 5

Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate?

STATE LICENSE(S)

- ☐ YES, I have a license — State License Number
- ☐ NOT REQUIRED by this state

NEW - Page 1

SECTION 6 — LIABILITY

IMPORTANT: All questions in this section must be answered.

	YES	NO
1. Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law?	☐	☐
2. Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied?	☐	☐
3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? Is any such action pending?	☐	☐
4. If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substances under state or federal law, or ever surrendered, for cause, or had a federal controlled substance registration revoked, suspended, restricted, denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?	☐	☐

EXPLANATION OF "YES" ANSWERS

Applicants who have answered "YES" to any of the four questions above must provide a statement to explain such answers

Use this space or attach a separate sheet and return with application

Date(s) of incident: _____ Location(s) of incident: _____

Nature of incident:

Result of incident:

SECTION 7 — CERTIFICATION OF EXEMPTION from application fee

☐ Check this box if the applicant is a federal, state, or local government-operated narcotic treatment program.
Be sure to enter name and address of the exempt institution in Section 1.

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government-operated narcotic treatment program, and is exempt from payment of the application fee.

Provide the name and phone number of the certifying official

_____ Signature of certifying official (other than applicant) _____ Date

_____ Print or type name and title of certifying official _____ Telephone No. (required for verification)

SECTION 8 — METHOD OF PAYMENT

Check one form of payment only

☐ Check — Make check payable to: Drug Enforcement Administration
See page 3 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Expiration Date ☐☐ - ☐☐

Sign if paying by credit card

_____ Signature of Card Holder

_____ Printed Name of Card Holder

Mail this form with payment to:

U.S. Department of Justice
Drug Enforcement Administration
P.O. Box 28083
Washington DC 20038-8083

FEE IS NON-REFUNDABLE

SECTION 9 — APPLICANT'S SIGNATURE

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

_____ Signature of applicant _____ Date

_____ Print or type name and title of applicant

WARNING: Section 843(a)(4)(A) of Title 21, United States Code states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to imprisonment for not more than four years, a fine of not more than $30,000, or both.

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).
2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 1117-0015. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.
3. The Debt Collection Improvements Act of 1996 (PL 104-134) requires that you furnish your Taxpayer Identifying Number and/or Social Security Number on this application. This number is required for debt collection procedures should your fee become uncollectable.
4. PRIVACY ACT INFORMATION

AUTHORITY:	Section 302 and 303 of the Controlled Substances Act of 1970 (PL 91-513) and Debt Collection Improvements Act of 1996 (PL 104-134) (for taxpayer identifying number and/or social security number).
PURPOSE:	To obtain information required to register applicants pursuant to the Controlled Substances Act of 1970.
ROUTINE USES:	The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated: A. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes. B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes. C. Persons registered under the Controlled Substances Act (PL 91-513) for the purpose of verifying the registration of customers.
EFFECT:	Failure to complete form will preclude processing of the application.

NEW - Page 2

Form-363	**APPLICATION FOR REGISTRATION** Supplementary Instructions and Information
ADDITIONAL INSTRUCTIONS	SECTION 1. APPLICANT IDENTIFICATION - Information must be typed or printed in the blocks provided to help reduce data entry errors. Fee exempt applicant should list the name and address of the fee exempt institution. A physical address is required; a post office box may be included after the street address. Applicant must enter a valid tax identification number (TIN). ***Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.*** SECTION 2. BUSINESS ACTIVITY. Indicate only one. SECTION 3. DRUG SCHEDULES - Applicant should check all drug schedules to be handled. However, applicant must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you intend to purchase or to transfer schedule II controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration. SECTION 4. FDA PERMIT - Authorization by the Food & Drug Administration is mandatory for DEA Registration approval. Enter the status of your FDA authorization and the FDA number. SECTION 5. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant 's compliance with applicable state and local laws. Applicant should contact the local state licensing authority prior to completing this application. Check that you are currently authorized by the state and provide your state license number. If state licensing is not required, indicate "Not required by this state". SECTION 6. LIABILITY - Applicant must answer all four questions for the application to be accepted for processing. If you answered "Yes" to any question, provide an explanation in the space provided. If additional space is required, you may attach a separate sheet of paper. SECTION 7. CERTIFICATE OF EXEMPTION - Exemption from payment of application fee is limited to federal, state or local government-operated narcotic treatment program. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided. SECTION 8. METHOD OF PAYMENT - Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. FEES ARE NON-REFUNDABLE. SECTION 9. APPLICANT'S SIGNATURE - Must be the original signature (in ink) of the applicant.

Notice to Registrants Making Payment by Check

Authorization to Convert Your Check: If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

Insufficient Funds: The electronic funds transfer from your account will usually occur with 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two times.

Transaction Information: The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions." You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights: You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

NEW INST - Page 3

Form-363

APPLICATION FOR REGISTRATION

Supplementary Instructions and Information

CONTACT INFORMATION

1. INTERNET: Information can be found on our web site at www.deadiversion.usdoj.gov
2. TELEPHONE: Headquarters Call Center: (800) 882-9539
3. WRITTEN INQUIRIES: Drug Enforcement Administration
P.O. Box 28083
Washington DC 20038-8083
4. DEA OFFICES: DEA Offices are listed below (800, 877, and 888 are toll-free numbers).

ATLANTA DIVISION OFFICE
ATTN: Registration
75 Spring Street, SW, Suite 800
Atlanta, GA 30303

Georgia	(888) 869-9935
North Carolina	(888) 219-8689
South Carolina	(866) 533-6983
Tennessee	(888) 219-7898

BOSTON DIVISION OFFICE
JFK Federal Building
15 New Sudbury Street, Room E400
Boston, MA 02203-0131

Connecticut	(617) 557-2200
Maine	(888) 272-5174
Massachusetts	(617) 557-2468
New Hampshire	(888) 272-5174
Rhode Island	(617) 557-2200
Vermont	(888) 272-5174

CARIBBEAN DIVISION OFFICE
P.O. Box 2167
San Juan, PR 00922-2167

Puerto Rico	(787) 775-1766
U.S. Virgin Islands	(787) 775-1766

CHICAGO DIVISION OFFICE
Kluczynski Federal Building
230 S. Dearborn Street, Suite 1200
Chicago, IL 60604

Illinois	(312) 353-1234
Indiana	(312) 353-1236
Minnesota	(312) 353-9166
North Dakota	(312) 353-9166
Wisconsin	(312) 353-1236

DALLAS DIVISION OFFICE
10160 Technology Blvd., East
Dallas, TX 75220

Oklahoma	(888) 336-4704
Texas (Northern)	(888) 336-4704

DENVER DIVISION OFFICE
115 Inverness Drive, East
Englewood, CO 80112

Colorado	(800) 326-6900
Montana	(800) 326-6900
Utah	(800) 326-6900
Wyoming	(800) 326-6900

DETROIT DIVISION OFFICE
431 Howard Street
Detroit, MI 48226

Kentucky	(800) 230-6844
Michigan	(800) 230-6844
Ohio	(800) 230-6844

EL PASO DIVISION OFFICE
El Paso Federal Justice Center
600 South Mesa Hills Drive, Suite 2000
El Paso, TX 79912

New Mexico	(915) 832-6014

HOUSTON DIVISION OFFICE
1433 West Loop South, Suite 600
Houston, TX 77027-9506

Texas (S. & Central)	(800) 743-0595

LOS ANGELES DIVISION OFFICE
255 East Temple Street, 20th Floor
Los Angeles, CA 90012

California (S. Central)	(213) 621-6960
Hawaii	(888) 415-9822
Nevada	(888) 415-9822
Trust Territory	(213) 894-2216

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8400 N.W. 53rd Street
Miami, FL 33166

Florida	(305) 590-4880

NEWARK DIVISION OFFICE
80 Mulberry Street, 2nd Floor
Newark, NJ 07102

New Jersey	(888) 356-1071

NEW ORLEANS DIVISION OFFICE
3838 N. Causeway Blvd
Lakeway III, Suite 1800
Metairie, LA 70002

Alabama	(888) 514-8051
Arkansas	(888) 514-7302
Louisiana	(888) 514-7302
Mississippi	(888) 514-7302

NEW YORK DIVISION OFFICE
99 Tenth Avenue
New York, NY 10011

New York	(877) 883-5789
	(212) 337-1593
	(212) 337-1594

PHILADELPHIA DIVISION OFFICE
William J. Green Federal Building
600 Arch Street, Room 10224
Philadelphia, PA 19106

Delaware	(888) 393-8231
Pennsylvania	(888) 393-8231

PHOENIX DIVISION OFFICE
3010 N. 2nd Street, Suite 301
Phoenix, AZ 85012

Arizona	(800) 741-0902

SAN DIEGO DIVISION OFFICE
4560 Viewridge Avenue
San Diego, CA 92123-1637

California (Southern	(800) 284-1152

SAN FRANCISCO DIVISION OFFICE
450 Golden Gate Avenue, 14th Floor
P.O. Box 36035
San Francisco, CA 94102

California (Northern)	(888) 304-3251

SEATTLE DIVISION OFFICE
400 Second Avenue, West
Seattle, WA 98119

Alaska	(888) 219-4261
Idaho	(888) 219-4261
Oregon	(888) 219-4261
Washington	(888) 219-1418

ST. LOUIS DIVISION OFFICE
317 South 16th Street
St. Louis, MO 63103

Iowa	(888) 803-1179
Kansas	(888) 803-1179
Missouri	(888) 803-1179
Nebraska	(888) 803-1179
South Dakota	(888) 803-1179

WASHINGTON, D.C. DIVISION OFFICE
Techworld Plaza
800 K Street, N.W., Suite 500
Washington, D.C. 20001

District of Columbia	(877) 801-7974
Maryland	(877) 330-6670
Virginia	(877) 801-7974
West Virginia	(877) 330-6670

NEW INST - Page 4

Form-363a **RENEWAL APPLICATION FOR REGISTRATION**
Under the Narcotic Addict Treatment Act of 1974

APPROVED OMB NO 1117-0015
FORM DEA-363a (11-05)
Previous editions are obsolete

INSTRUCTIONS

1. To apply by mail complete this application. Keep a copy for your records.
2. Print clearly, using black or blue ink, or use a typewriter.
3. Section 1 should be completed only if your information has changed.
4. Mail this form to the address provided in Section 7 or use enclosed envelope.
5. Include the correct payment amount. FEE IS NON-REFUNDABLE.
6. If you have any questions contact 800-882-9539 prior to submitting your application.
7. Save time - **renew online at www.deadiversion.usdoj.gov.**

IMPORTANT: DO NOT SEND THIS APPLICATION **AND** APPLY ONLINE.

REGISTRATION INFORMATION :
DEA #
REGISTRATION EXPIRES

FEE IS NON-REFUNDABLE

SECTION 1 **APPLICANT IDENTIFICATION**

Business or Facility Name (if registration is for business entity or is fee exempt)

Business or Facility Name 2 ("doing business as", continuation of business name, or name of fee exempt institution)

Address Line 1 (street address)

Address Line 2

City State Zip Code

Business Phone Number Business Fax Number

FOR CHANGES ONLY

DEBT COLLECTION INFORMATION

Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number

See note #3 on bottom of page 2.

SECTION 2 **DRUG SCHEDULES**

Check all that apply

☐ Schedule II ☐ Schedule III

☐ Check this box if you require official order forms - for purchase or transfer of schedule II controlled substances.

SECTION 3 **FDA PERMIT**

Mandatory for approval

Are you currently authorized by the Food and Drug Administration for the business activity described in this application?

YES ☐ PENDING ☐ NO ☐

FDA Number

SECTION 4

Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate?

STATE LICENSE(S)

☐ **YES, I have a license**

State License Number

☐ **NOT REQUIRED by this state**

RENEWAL - Page 1

SECTION 5
LIABILITY

IMPORTANT: **All questions in this section must be answered.**

	YES	NO
1. Has the applicant ever been **convicted of a crime** in connection with controlled substances under state or federal law?	☐	☐
2. Has the applicant ever surrendered (for cause) or had a **federal** controlled substance registration revoked, suspended, restricted, or denied?	☐	☐
3. Has the applicant ever surrendered (for cause) or had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? **Is any such action pending?**	☐	☐
4. If the applicant is a **corporation** (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been **convicted of a crime** in connection with controlled substances under state or federal law, or ever surrendered, for cause, or had a **federal** controlled substance registration revoked, suspended, restricted, denied, or ever had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?	☐	☐

EXPLANATION OF "YES" ANSWERS

Applicants who have answered "YES" to any of the four questions above must provide a statement to explain such answers

Use this space or attach a separate sheet and return with application

Date(s) of incident: _____ Location(s) of incident: _____

Nature of incident:

Result of incident:

SECTION 6
CERTIFICATION OF EXEMPTION from application fee

☐ Check this box if the applicant is a federal, state, or local government-operated narcotic treatment program.
Be sure to enter name and address of the exempt institution in Section 1.

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government-operated narcotic treatment program, and is exempt from payment of the application fee.

Provide the name and phone number of the certifying official

Signature of certifying official **(other than applicant)** _____ Date _____

Print or type name and title of certifying official _____ Telephone No. **(required for verification)** _____

SECTION 7
METHOD OF PAYMENT

Check one form of payment only

☐ Check Make check payable to: **Drug Enforcement Administration** See page 3 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Expiration Date ☐☐ - ☐☐

Sign if paying by credit card

Signature of Card Holder _____

Printed Name of Card Holder _____

Mail this form with payment to:

U.S. Department of Justice
Drug Enforcement Administration
P.O. Box 28083
Washington DC 20038-8083

FEE IS NON-REFUNDABLE

SECTION 8
APPLICANT'S SIGNATURE

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

Signature of applicant _____ Date _____

Print or type name and title of applicant _____

WARNING: Section 843(a)(4)(A) of Title 21, United States Code states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to imprisonment for not more than four years, a fine of not more than $30,000, or both.

1. No registration will be issued unless a completed application form has been received (21 CFR 1301.13).
2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 1117-0015. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.
3. The Debt Collection Improvements Act of 1996 (PL 104-134) requires that you furnish your Taxpayer Identifying Number and/or Social Security Number on this application. This number is required for debt collection procedures should your fee become uncollectable.
4. PRIVACY ACT INFORMATION

AUTHORITY:	Section 302 and 303 of the Controlled Substances Act of 1970 (PL 91-513) and Debt Collection Improvements Act of 1996 (PL 104-134) (for taxpayer identifying number and/or social security number).
PURPOSE:	To obtain information required to register applicants pursuant to the Controlled Substances Act of 1970.
ROUTINE USES:	The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated: A. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes. B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes. C. Persons registered under the Controlled Substances Act (PL 91-513) for the purpose of verifying the registration of customers.
EFFECT:	Failure to complete form will preclude processing of the application.

RENEWAL - Page 2

Form-363a **APPLICATION FOR RENEWAL**
Supplementary Instructions and Information

ADDITIONAL INSTRUCTIONS

SECTION 1. APPLICANT IDENTIFICATION - Entry of missing data or corrections ONLY must be typed or printed in the blocks provided to help reduce data entry errors. Enter changes in previously provided registration information, such as name change, address correction, or new phone numbers.

Fee exempt applicant should list the name and address of the fee exempt institution.

A physical address is required; a post office box may be included after the street address.

Applicant should ensure that the tax identification number (TIN) on record is correct. ***Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.***

SECTION 2. DRUG SCHEDULES - Applicant should check all drug schedules to be handled. However, applicants must still comply with state requirements; federal registration does not overrule state restrictions.

Check the order form box only if you intend to purchase or to transfer schedule II controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration renewal.

SECTION 3. FDA PERMIT - Authorization by the Food & Drug Administration is mandatory for DEA Registration approval. Enter the status of your FDA authorization and the FDA number.

SECTION 4. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant 's compliance with applicable state and local laws.

Applicant should contact the local state licensing authority prior to completing this application. Check that you are currently authorized by the state and provide your state license number. If state licensing is not required, indicate "Not required by this state".

SECTION 5. LIABILITY - Applicant must answer all four questions for the application to be accepted for processing.

If you answered "Yes" to any question, provide an explanation in the space provided. If additional space is required, you may attach a separate sheet of paper.

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The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided.

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Insufficient Funds: The electronic funds transfer from your account will usually occur with 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two times.

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RENEWAL INST - Page 3

Form-363a **APPLICATION FOR RENEWAL**
Supplementary Instructions and Information

CONTACT INFORMATION

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North Dakota	(312) 353-9166
Wisconsin	(312) 353-1236

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Utah	(800) 326-6900
Wyoming	(800) 326-6900

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Michigan	(800) 230-6844
Ohio	(800) 230-6844

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El Paso Federal Justice Center
600 South Mesa Hills Drive, Suite 2000
El Paso, TX 79912

New Mexico	(915) 832-6014

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Houston, TX 77027-9506

Texas (S. & Central)	(800) 743-0595

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Los Angeles, CA 90012

California (S. Central)	(213) 621-6960
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Nevada	(888) 415-9822
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Florida	(305) 590-4880

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80 Mulberry Street, 2nd Floor
Newark, NJ 07102

New Jersey	(888) 356-1071

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Mississippi	(888) 514-7302

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New York, NY 10011

New York	(877) 883-5789
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	(212) 337-1594

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California (Southern	(800) 284-1152

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450 Golden Gate Avenue, 14th Floor
P.O. Box 36035
San Francisco, CA 94102

California (Northern)	(888) 304-3251

SEATTLE DIVISION OFFICE
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Seattle, WA 98119

Alaska	(888) 219-4261
Idaho	(888) 219-4261
Oregon	(888) 219-4261
Washington	(888) 219-1418

ST. LOUIS DIVISION OFFICE
317 South 16th Street
St. Louis, MO 63103

Iowa	(888) 803-1179
Kansas	(888) 803-1179
Missouri	(888) 803-1179
Nebraska	(888) 803-1179
South Dakota	(888) 803-1179

WASHINGTON, D.C. DIVISION OFFICE
Techworld Plaza
800 K Street, N.W., Suite 500
Washington, D.C. 20001

District of Columbia	(877) 801-7974
Maryland	(877) 330-6670
Virginia	(877) 801-7974
West Virginia	(877) 330-6670

RENEWAL INST - Page 4