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The Science Has Been Done

References are provided to support the following

1. Duration of Immunity studies on large numbers of animals have been done.
2. Endogenous antibody interference with vaccines, blocks re-administered vaccines from enhancing immunity.
3. Dogs over 8 weeks of age do not develop any disease from canine corona virus
4. Dogs are at low risk of developing Leptospirosis in Texas.
5. We do not have Lyme disease in Texas.
6. Vaccines can cause Injection Site Fibrosarcomas, or Vaccine Associated Sarcomas VAS. Non- Adjuvanted Vaccines are safer than adjuvanted vaccines, in that they are less likely to cause VAS.
7. Titers do not accurately predict which dogs will respond to another vaccination.
8. It is misrepresentation, a deceptive trade practice, for a Veterinarian to recommend, charge for, or administer a vaccine, where there is no scientifically proven benefit to the patient, or that a reasonable client would not elect to purchase or have administered if given the information necessary to make an informed decision .

1. The **duration of immunity** for **Rabies vaccine, Canine distemper vaccine, Canine Parvovirus vaccine, Feline Panleukopenia vaccine, Feline Rhinotracheitis, feline Calicivirus**, have all been demonstrated to be a **minimum of 7 years** by serology for rabies and challenge studies for all others.

Schultz, Ronald D, *Duration of Immunity to Canine Vaccines: What We Know and What We Don't Know*, Proceedings – Canine Infectious Diseases: From Clinics to

Molecular Pathogenesis, Ithaca, NY, 1999, 22.

Minimum Duration of Immunity for Canine Vaccines:

Distemper- 7 years by challenge/15 years by serology

Parvovirus – 7 years by challenge/ 7 years by serology

Adenovirus - 7 years by challenge/ 9 years by serology

Canine rabies – 3 years by challenge/ 7 years by serology

Fishman B & Scarnell J, *Persistence of protection against infectious canine hepatitis virus*, Vet Rec, 99, 509. 1976

Scott FW, Geissinger C, *Long-term immunity in cats vaccinated with an inactivated trivalent vaccine*, Am J Vet Res, 60(5): 652-8, May 1999.

7.5 years DOI by challenge

Lappin M R, Andrews J, Simpson D, Jensen WA, *Use of serologic tests to predict resistance to Feline Herpesvirus 1, Feline Calcivirus, and Feline Parvovirus infection in cats*, J AVMA, 220(1): 38-42, Jan 1, 2002

3 years DOI by challenge.

Vaccines for diseases like distemper and canine parvovirus, once administered to adult animals, provide lifetime immunity.

Schultz, Ronald D., “*Are we vaccinating too much?*” JAVMA, No. 4, August 15, 1995, pg. 421.

Canine distemper and adenovirus 2 vaccines both provide lifelong immunity. (Schultz)

There is the mistaken assumption that if we recommend annual re-vaccination a greater percentage of the population will be vaccinated. It doesn't do any good to over vaccinate one segment of the population and not vaccinate the rest. (Macey)

With modified live virus vaccines like canine parvovirus, canine distemper and feline panleukopenia, calicivirus, and rhinotracheitis the virus in the vaccine must replicate to stimulate the immune system. **In a patient that has been previously immunized**, antibodies from the previous vaccine will block the replication of the new vaccinal virus. Antibody titers are not significantly boosted. Memory cell populations are not expanded. **The immune status of the patient is not enhanced.**

After the second rabies vaccination, re-administration of rabies vaccine does not enhance the immune status of the patient at one or two year intervals.

We do not know the interval at which re-administration of vaccines will enhance the immunity of a significant percentage of the pet population, but it is certainly not at

one or two year intervals.

Tizard Ian, Yawei N, *Use of serologic testing to assess immune status of companion animals*, JAVMA, vol 213, No 1, July 1, 1998.

Modified live vaccines rely on the replication of the agent to trigger a protective immune response. When an animal has maternal or endogenous antibodies at the time of vaccination, the vaccine agent may be neutralized before it can replicate. ... It may not be possible to stimulate an additional immune response in that animal.

HogenenEsch Harm, Dunham Anisa D, Scott-Moncrieff Catharine, Glickman Larry, DeBoer Douglas J, *Effect of vaccination on serum concentrations of total and antigen-specific immunoglobulin E in dogs*, AJVR, Vol 63, No. 4, April 2002, pg 611-616.

Dogs were injected with rabies vaccine at 16 weeks of age and then annually. Vaccination had no effect on serum concentrations of IgA, IgG and IgM as measured at 2 and 3 years of age. Dogs were vaccinated 5 times as puppies and then at 6-month intervals with multivalent (Vanguard 5 L, DAPPCL) vaccines. Such a protocol is rarely used in pet dogs and in kennels. There were no significant differences in the concentration of IgA and IgM at 2 years and 3 years of age

Gorham, J.R., "Duration of vaccination immunity and the influence on subsequent prophylaxis" JAVMA 149:699-704; 1966.

Larson L J, Sawchuck S, Bonds M D, Schultz RD, *Comparison of Antibody Titers Among Dogs Vaccinated, One, Two, Three Years Previously*, Proceedings of 80th Meeting of the Conference of Research Workers in Animal Diseases, CRWD, Chicago, IL, 1999.

Wolf, Alice M., *Vaccinations-What's right? What's not?* Compendium on Continuing Education, Schering-Plough Animal Health, 1999, pg. 32.

In studies Schultz performed at the Univ. of Wisconsin, 106 dogs vaccinated within the previous 1 to 4 years, were each given a canine parvovirus booster vaccination. Only one of the 106 dogs showed a significant increase in serum antibody titer following the booster. These results show that revaccination does not enhance antibody levels or improve immunity because the vaccine virus is neutralized before it can reach the memory T and B cells. The immunity provided by previous vaccination not only protects against the virulent disease but also prevents response to revaccination.

Wolf Alice, *Vaccines of the Present and Future*, Proceedings of the World Animal Veterinary Congress, Vancouver 2001.

The recommendation for annual re-vaccination is a practice that was officially started in 1978. This recommendation was made without any scientific validation of the need to booster immunity so frequently. In fact the presence of good humoral antibody levels blocks the anamnestic response to vaccine boosters just as maternal antibody blocks the response in some young animals.

Schultz, Ronald D., "Current and future canine and feline vaccination programs", *Veterinary Medicine*, March 1998, pg. 243.

The patient receives no benefit and may be placed at serious risk when an unnecessary vaccine is given. Few or no scientific studies have demonstrated a need for cats or dogs to

be revaccinated. Annual vaccination for diseases caused by CDV, CPV2, FPLP and FeLV has not been shown to provide a level of immunity any different from the immunity in an animal vaccinated and immunized at an early age and challenged years later. We have found that annual revaccination with the vaccines that provide long-term immunity provides no demonstrable benefit.

Schultz, Ronald D, *The Vaccine Controversy: What Vaccines Do Cats and Dogs Really Need and How Often Do They Need To Be Vaccinated?* Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison.

There was never a scientific study performed to show that CDV, CAV, CPV, or rabies virus needs to be given annually to be effective, or that if they are given annually they are more effective. There is data available for the dog and cat to show that modified live CDV, CAV, and CPV given seven years previously and killed PLP, FeCV, and FeHV given seven years previously provided the same immunity as if these products had been given one year prior to challenge with virulent organisms.

Phillips, Tom R. and Schultz, Ronald D, “*Canine and Feline Vaccines*”, Current Veterinary Therapy XI, ed. Kirk and Bonagura, pg. 202, 205, WB Saunders Co, Philadelphia, PA 1992.

Almost without exception there is no immunologic requirement for annual re-vaccination. Immunity to viruses persists for years or for the life of the animal. Furthermore re-vaccination with most viral vaccines fails to stimulate the anamnestic response as a result of interference by existing antibody. The practice of annual vaccination in our opinion should be considered of questionable efficacy.

Klingborg Donald, Principles of Vaccination, AVMA Council on Biologic and Therapeutic Agents, Policy on Biologics, April 2002.

The one- year re-vaccination frequency recommendation found on many vaccine labels is based on historical precedent, and not on scientific data.

Re-vaccination of patients with sufficient immunity does not add measurably to their disease resistance, and may increase their risk of adverse post vaccination events.

Schultz, Ronald D., “*Are we vaccinating too much?*” JAVMA, no. 4, August 15, 1995, pg. 421.

Dr Schultz said “The client is paying for something with no effect or the potential for an adverse reaction.”

2. Dogs over 6 weeks of age do not develop disease from canine corona virus.

Schultz, Ronald D., “*Are we vaccinating too much?*” JAVMA, No. 4, August 15, 1995, pg. 421.

Schultz, Ronald D., “*Current and future canine and feline vaccination programs*”, Veterinary Medicine, March 1998, pg. 251.

Wolf, Alice M., *Vaccinations-what’s right? What’s not?* Compendium on CE, Schering-

Plough Animal Health, 1999, pg. 32,33.

Paul, Michael A., *Vaccinations-what's right? What's not?* Compendium on CE, Schering-Plough Animal Health, 1999, pg. 32,33.

3. In Texas, there are an average of twelve cases per year of Leptospirosis in dogs testing positive at the Texas Veterinary Medical Diagnostic Lab. It is estimated by the Texas Department of Health that there are 6 million dogs in Texas.

*(Antec samples are all sent to the TVMDL, Idexx samples are sent to Michigan, consequently Texas results are not available.)

Angulo, A. B. DVM, MS, PhD, ACVM, Texas Veterinary Medical Diagnostic Lab, College Station, Texas, Personal phone conferences 1998, 1999, 2000, 2001.

Tizard, Ian R. Veterinary Immunology an Introduction, 6th Ed, Saunders 2000 pg ix

It serves no useful purpose to exaggerate the importance of an infection in order to sell vaccines.

Carter C, Angulo AB, Sneed L, Ronald N, Arvizo ER, A Diagnostitc Laboratory Update On Leptospirosis in Texas, Texas Veterinarian, April 2003, pg 30-43.

4. Lyme disease is not found in Texas
Lyme disease is caused by a bacterial organism, *Borrelia burgdoferi*. It is spread by the vector tick, *Ixodes scapularis*.

Propagation and Transmission requires a complex reservoir host relationship, whereby the vector tick nymphal stages feed on the reservoir deer mouse for two years. In Texas the *Ixodes* tick feed on lizards, which are not a reservoir for Lyme disease.

Ticks take two years to mature in the colder Northern climates where snow stays on the ground for prolonged periods of time in the winter. In southern climates the ticks mature in one year ,which would not allow for concentration of enough *Borrelia* organism to spread the disease.

The incubation period for Lyme disease is 5 months. Although a dog could become infected with Lyme disease while traveling to the New England area, Texas A&M University has not documented one case of Lyme disease in a dog that has lived exclusively in Texas.

Confusion and misdiagnosis of Lyme disease arises from the following:

1. Lyme disease is a vogue diagnosis, and is therefore potentially over-diagnosed.
2. Commonly used testing for Lyme disease will yield false positive test results for dogs with periodontal disease, Ehrlichia, and other tick borne rickettsial diseases, and

rheumatoid arthritis.

3. In Texas we have a disease that look identical to Lyme disease. Southern Tick Associated Rash Illness or STARI, also called Masters Disease, is caused by *Borrelia lonestari*, and spread by the vector tick *Amblyomma americanum*, or the Lone Star Tick. Vaccination for Lyme disease will not protect against STARI.

Greene CE, Appel MJG, Straubinger RK, Lyme Borreliosis, *Greene's Infectious Diseases of the Dog and Cat*, 2nd ED, 1998, WB Saunders,P 282-292.

Schillhorn van Veen TW, Murphy AJ, Colmery B, False positive *Borrelia burgdorferi* antibody titers associated with periodontal disease in dogs, *Veterinary Record*, 1993, 132, 512.

Little S, Southern tick-associated rash illness; A newly recognized tick-borne disease, *DVM Best Practices*, June 2003, pg 13-15.

5. Antibody Titers do not predict if a patient will respond to re-administration of a vaccine with enhanced immunity.

Titers don't take into effect cell mediated immunity, which is the most important aspect of disease protection for a number of diseases. Titers don't assess the ability of memory cells, B and T lymphocytes, which can live up to 20 years or more, to regenerate an immune response. You can have a negative titer and if the pet is exposed, memory cells can respond within hours to regenerate enough antibodies for protective immunity.

Paul M, Report of the American Animal Hospital Association Canine Task Force: 2003 Canine Vaccine Guidelines, Recommendations, and Supporting Literature, AAHA Foundation, March 2003.

2000 Report of American Association of Feline Practitioners and Academy of Feline Medicine Advisory Panel on Feline Vaccines, pg. 15 & 16.

Tizard Ian, Yawei N, *Use of serologic testing to assess immune status of companion animals*, *JAVMA*, vol 213, No 1, July 1, 1998.

Wolf, Alice M., *Vaccinations-what's right? What's not?* Compendium on CE, Schering-Plough Animal Health, 1999, pg. 32,33.

Wolf Alice M, *Just the Facts About Vaccs: Frequently Asked Questions About Current Vaccination Recommendations and Practice Guidelines*, Proceedings from the North American Veterinary Conference, 13, 1999, pg 681.

Klingborg Donald, Principles of Vaccination, AVMA Council on Biologic and Therapeutic Agents, Policy on Biologics, April 2002.

Lappin M R, Andrews J, Simpson D, Jensen WA, *Use of serologic tests to predict resistance to Feline Herpesvirus 1, Feline Calicivirus, and Feline Parvovirus infection in cats*, *J AVMA*, 220(1): 38-

42, Jan 1, 2002

Legal Aspects: Standard of Care, Informed Consent

2000 Report of American Association of Feline Practitioners and Academy of Feline Medicine Advisory Panel on Feline Vaccines, pg. 11 & 12.

If in a court of law, the quality of care provided by a practitioner is being called into question, the practitioner's action will likely be compared to the prevailing "standard of care".

Although many Veterinarians will, for various reasons resist and delay the adoption of new protocols they should know that adherence to old protocols may, in the light of new knowledge, not protect them as ...conformity to custom is not in itself an exercise of care as a matter of law. (30Am Jur2nd Evidence: 1123). Questions about the Veterinarians actions will focus on the following types of inquiry: Did the animal need the vaccine? Was it administered at the proper interval? Did the client give informed consent?

The current informed consent standard is "the reasonable patient standard."

Under this standard, the scope of disclosure is not measured by the physician's standards, but rather by the patient's needs and whether the information is material to the patient's decision. Would a person in the client's position, if given the information a reasonable person would use to make an intelligent decision, decide to accept or reject the vaccination? Under this standard a Veterinarian should disclose the nature of the condition, the risk of vaccination vs the benefit, and reasonable alternatives to vaccination. Failure to specifically obtain informed consent could in itself be negligent, and result in liability.

In the U.S. licensed vaccines are subject to the Virus, Serum, and Toxin Act (VSTA) of 1913. The USDA and not the FDA regulates use of animal vaccines.

In 1996 in the U.S. Supreme Court Case; Lynbrook Farms vs Smith Kline Beecham the court upheld the contention that VSTA pre-empts all remedies, and in effect eliminates vaccine manufacturers as defendants in all cases. The Veterinarian bears all liability for professional negligence and breach of warranty. There are no federal regulations concerning the after the sale (by manufacturers) use of animal vaccines by Veterinarians. The Animal Medicinal Drug Use Clarification Act (AMDUCA) gives Veterinarians "discretionary" use of vaccines.

The Texas Deceptive Trade Practice Act of 1967

17.46 False, misleading, or deceptive trade practices in the conduct of any trade or commerce are hereby declared unlawful and are subject to

action by the consumer protection division of this code. The term false or misleading includes but is not limited to the following acts:

5. Representing that goods or services have ... benefits,.... which they do not have.

24 failing to disclose information concerning goods or services which was known at the time of a transaction, if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

* In the case of a Doctor of Medicine, with a licensed professional, intent does not have to be proven, and lack of knowledge is not a defense, as the doctor has held himself/herself out to be the learned professional.

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