

Mrs Donna Anderson

20/4/2016

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To: Research Director  
The Queensland Parliament - Agriculture & Environment Committee  
George St  
Brisbane Q 4000

**Inquiry: Hendra Virus Vaccine & Its Use by Veterinary Surgeons in Queensland**

**Topic: Vaccine Reactions and the Suspected Over- Use of the Vaccine.**

Dear Research Director & Committee Members,

For me personally, as a horse owner who chooses to keep my horses for the length of their lifetimes, I have chosen to weigh up the risks of myself & my horses being infected with HeV versus the risk of vaccination reactions.

- Keeping in mind that HeV affects 4 horses on average per year out of a total of 1.2 million horses in Australia which is a  $3.3 \times 10^{-6}$  (0.0000033 )% chance of one of my horses contracting HeV.
- Transmission of the virus through horse to horse contact has not been proven.
- Transmission from bat to horse has not been proven.
- The human infection rate when wearing appropriate PPE is zero. So I choose to make a PPE kit & wear the relevant items when dealing with my sick horses.
- 2 of my horses are already immune compromised so to vaccinate them would be contrary to Zoetis' own product label use directive & also the AVPMA recommendations.
- My third (much younger horse) has allergies which show as itchy coat & sore, watery eyes. DePaolo recommends that **no** horse should be vaccinated which is known to have allergies or eye problems. (Item 1) In fact, pruritis (itchy coat) & conjunctivitis have been tabled as known reactions to the He vaccination. (Item 2) I spent thousands of dollars purchasing this young mare!!! Do I risk vaccinating a horse that could possibly be another off label candidate? The APVMA will classify this reaction as "Unlikely" to be

caused by the vaccine due to the off label use! (For the record, this mare has previously been diagnosed with conjunctivitis by my local vet.)

I am also greatly **concerned that vaccination reactions that are reported are inaccurate in terms of the numbers of horses actually infected.**

There are two types of vaccination reactions. **Acute reactions** which typically occur in the first 1-3 days; and immune response **delayed reactions** which can occur up to 45 days after vaccinating!! (Item 1, 3)

I believe that both Zoetis & the APVMA would never consider vaccination reactions 30 days or more later from the point of vaccination.

In general conversations, people seem unaware that

- their horse has even had a reaction - such as itch (pruritis)
- they should report all reactions (“It’s just itch, we just treat and in a month’s time my horse is ok.”; “my racehorse’s performance took a dive”)
- and are oblivious to the fact that their horse’s current string of health problems could be linked to the vaccinations their horses have received up to 45 days prior. ( Not that Zoetis or the APVMA would acknowledge these cases.)

Lastly, there is much cause for concern that horses taking part in the vaccination programme are being **OVER-VACCINATED.**

- “...horses receive more vaccinations on a more frequent schedule than any other domesticated animal.” (Item 3)
- Horse owners are beginning to accumulate titre tests results, (which measure the antibody levels in the blood from the vaccine), which are WAY higher than the recommended adequate protection level of 16 - even when the horse(s) have not been vaccinated for 1- 2 yrs !!! Hopefully those submissions will be sent in as evidence to your inquiry by the relevant owners.
- **Over vaccination** is a serious threat & may cause **“Vaccinosis” resulting in permanent negative side effects.** (Item 1)

- CSIRO's Dr Deb Middleton (23 Oct 2015) (Item 4):  
  
"At the moment the evidence we have is that after the six month booster you can maintain levels of protection in horses for at least a further 12 months, **possibly even longer.**"
- The APVMA have requested more data from Zoetis before considering Zoetis' proposal to move to a 12 monthly vaccination booster. June 2015 (Item 5)
- Unfortunately, these high antibody levels from the titre tests do not necessarily get the over vaccinated horse "off the hook". It is up to the attending veterinarian to decide whether they think the horse has adequate protection or not. Once again, our local hard working "in the field" veterinarians hold the "hot potato".

I would like the Committee to consider

- helping in the "set-up" and support of a special group of veterinarians that elect themselves to service the health & welfare of those horses who cannot be vaccinated for whatever reasons. This way the horse owners of Australia truly have choice in whether to vaccinate or not for HeV and our veterinarians truly have choice in the clients that they wish to service without pressure from their governing bodies.
- Until titre testing is considered reasonable enough proof of vaccination cover;
- Until unvaccinated horses can access medical treatment;
- Until 24 hour stall side testing is available (for vaccinated and non-vaccinated horses)
- Until over the over vaccinating stops.....

..... it is our horses left suffering in the paddock.

Sincerely,



Donna Anderson.



Home

## Horse Vaccination Protocol

Written by Mark DePaolo, DVM. COPYRIGHT © 2012. All rights reserved.

### WHAT IS VACCINE OVERLOAD?

We are increasingly seeing negative side effects that occur from the over-use and un-judicious administration of routine vaccines. This condition of sometimes-permanent negative side effects caused by overuse of vaccines is collectively termed "Vaccinosis".

It's time for us, as proactive horse owners, to rethink all of our traditional ideas on equine vaccinations. If vaccines needed to be given annually (or more often), people would still be getting vaccinated every year for all of those diseases that we were vaccinated for as kids.

Almost all of our horse vaccines last a minimum of 7 years, most last a lifetime. Many horse owners continue to vaccinate their horses too frequently because they believe that vaccines are innocuous (do no harm). Many horses are vaccinated yearly (or more often) for diseases that they are never exposed to or already have immunity to.

Vaccinations in horses are being recommended much more frequently than the same vaccine in their human counterpart. Human and horse immune systems function in exactly the same fashion. Humans are only vaccinated as babies and children but some farms vaccinate their horses 6 plus times a year for a horse's entire life.

### WHAT ARE COMMON VACCINE REACTIONS?

Because most people and veterinarians have been taught that vaccine reactions occur within 48 hours after the vaccine is given, many vaccination reactions go unreported. Often horses have vaccine reactions that go totally unnoticed or occur up to 30 days after the administration of the vaccine so these symptoms are not generally thought of as being linked.

Even the AAEP (American Association of Equine Practitioners) warns: "It should be recognized that: Administration of multiple vaccines at the same time may increase the risk of adverse reactions. Safety and efficacy data are not available regarding the concurrent use of multiple vaccines. Adverse reactions are not always predictable and are inherent risks of vaccination. Therefore, it is recommended that horses not be vaccinated in the 2 weeks prior to shows, performance events, sales or domestic shipment. Some veterinarians may elect not to vaccinate horses within 3 weeks of international shipment.

After receiving a vaccine(s) intramuscularly, some horses experience local muscular swelling and soreness or transient, self-limiting signs including fever, anorexia and lethargy. Severe reactions at sites of injection can be particularly troublesome, requiring prolonged treatment and convalescence. Systemic adverse reactions (such as urticaria, purpura hemorrhagica or anaphylaxis) can also occur. Other systemic adverse reactions have been anecdotally reported".

### WHY SHOULD I ONLY VACCINATE A HEALTHY HORSE?

The label insert for every vaccine warns against vaccinating horses that are unhealthy.



PHOTO OF ACTUAL PRODUCT IN THE MARKET (MAY, MAY 2010)

### No horse should ever be vaccinated that has any of the following:

- Chronic Obstructive Pulmonary Disease (COPD)
- Heaves
- Cushings
- Equine Protozoal Encephalomyelitis (EPM)
- Hypothyroidism
- Equine Polysaccharide Storage Myopathy (EPSM or PPSM)

- Insulin Resistance
- Irritable Bowel Syndrome
- Any disease not listed here

Or any type of:

- Infection
- Skin disease
- Hives
- White Line Disease
- Scratches
- Respiratory Tract Infection
- Diarrhea
- Eye problems
- Allergies or allergic reactions

### HOW DO I KNOW IF MY HORSE NEEDS TO BE VACCINATED?

Most veterinarians recommend what they learned in school (the vaccination schedule developed by the drug companies that manufacture the vaccines). Veterinarians seldom want to be controversial and go against regular western medical training and it is beneficial for them because they are also making a profit by administering the vaccines. Many veterinary clinics make up to 50% of their income by administering "annual vaccinations".

Many holistic veterinarians tout antibody titers as the way to know if your horse is in need of any vaccines. Antibody titers measure the amount of antibodies that are circulating around the blood stream at any given time to a particular disease. These titer tests are wonderful and give us great information as long as the horses' antibody levels are elevated.

The problem with titer tests is that they only measure what is called humoral (liquid) immunity, they can't measure your horses' cellular immunity. Humoral immunity is when the animal is exposed to a certain disease for the first time and it produces antibodies to that disease. Humoral immunity and circulating antibodies will only last for a short while without any reoccurring exposure to that disease.

The body also, at the same time that it produces the humoral immunity, will produce cellular immunity. Cellular immunity consists of a certain type of white blood cell that can differentiate into other cells when needed. These cells, when stimulated by exposure to a pathogen (germ), can then make antibodies. This type of immunity is almost always life-long. Unfortunately, there is no way to measure cellular immunity. Therefore, if you run a titer and the numbers are low, it is quite likely that you're horse is still immune to that disease, but you have no way of knowing. If you have ever run a vaccine titer on your horse and it was protective, your horse has life long immunity to that disease.

### HOW CAN I TELL IF THERE IS AN OUTBREAK IN MY AREA?

You can go on the internet and search for the incidence of certain diseases on the website of your state veterinary board or the Center for Disease Control. Remember that just because a certain number of cases have been reported in your state, it doesn't necessarily mean that those animals became sick or even needed to be treated. We are trying to look at all of the information with an open mind and then make a decision based on common sense, not fear. We may need to "read between the lines" some, to make the most informed decisions when it comes to the delicate health of our beloved horses.

### WHAT IS A COMMON SENSE APPROACH TO VACCINES?

A common sense vaccine protocol would be to treat our horses like we were treated as kids. We were given three or four vaccines at certain strategically timed intervals and then we were covered, for life!

Foals are not born immune-competent, which means they do not have the ability to mount a normal immune response until sometime after 6 months of age. This is why a mare will pass antibodies to the foal in the colostrum (first milk). This is the only immunity that the foal possesses for the first half-year or so of life. Because that foal can't make its own antibodies, if you vaccinate it prior to immunocompetence you force the foal to use up the antibodies that were passed to it in the colostrum. Adequate colostrum intake is essential. If vaccines are administered to foals too early they interfere with colostrum antibodies.





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## Summary of adverse experience reports made to the APVMA about Hendra virus vaccine

The information presented below was collected under a mandatory reporting regime that was required as a condition of the permit authorising the supply and use of the product. A mandatory reporting regime may yield a higher reporting incidence than would be the case under a voluntary reporting arrangement.

### How the APVMA classifies an adverse experience

The APVMA makes an independent assessment about the relationship between exposure to or use of a product and a reported adverse experience – the likelihood that the product was involved in causing the adverse experience. The outcome of the assessment is a classification of probable, possible, unlikely or unknown.

[Further information about the classification process.](#)

### Number of equine reports classified by the APVMA to 30 June 2015

Reaction year	Possible	Possible/off-label	Probable	Probable/off-label	Unknown	Unlikely	Total
2012	4		25		4	8	41
2013	52	3	250	1	28	32	366
2014	66	1	335	1	36	27	466
2015	14		64	1	15	10	104
<b>Total</b>	<b>136</b>	<b>4</b>	<b>674</b>	<b>3</b>	<b>83</b>	<b>77</b>	<b>977</b>

### What do the classifications mean?

#### Probable

A 'probable' classification is given when there is a reasonable association between exposure to a product and the onset of the reported adverse experience, and the description of the presenting signs is consistent (or plausible)

NOTE: The data in this table describe a single horse. The data in this table may describe a presenting sign in multiple horses.

Presenting signs	Probable	Possible
Injection site reaction	440	11
Oedema	246	14
Lethargy	197	39
Pain	174	16
Anorexia	113	17
Pyrexia	105	24
Stiffness	63	9
Swelling (local)	65	1
Muscle stiffness	48	3
Urticaria	38	8
Lump (local)	44	5

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Restless	4	0
Pruritis	4	0
Epistaxis	1	0
Conjunctivitis	1	0
Bradycardia	1	0
Adipsia	1	0
Polymyositis	1	0
Walking difficult	1	0
Welts	1	0
Death	0	7

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LETTER 3 : ITEM 3

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# Rethinking Equine Vaccinations - Part 1

by **W. JEAN DODDS, DVM**

FEATURED IN IVC JOURNAL - SUMMER 2012

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Horses receive more vaccinations on a more frequent schedule than any other domesticated animal. Based on a protocol of fear, not fact, this practice has horse people from all walks of life asking questions. To explain this controversial issue so you can make informed decisions for your patients, we turned to one of the foremost authorities on vaccination in the veterinary world – researcher, lecturer and veterinarian Dr. W. Jean Dodds. In this, the first of a two-part series, Dr. Dodds provides an overview of vaccination and raises some interesting points about this complex topic.



We all want the best for our patients. That includes providing them with proper nutrition and good health care. It also includes protecting them against disease, which is why researchers first developed vaccines. Vaccines are intended to protect against disease; so why are we causing disease by weakening the immune system with frequent use of combination vaccine products?

Vaccine manufacturers seek to achieve minimal virulence (infectivity) while attaining maximum protection. This desired balance may be relatively easy to achieve in clinically normal, healthy animals but what about those with compromised immune systems? Animals harboring latent viral infections may not be able to withstand the additional immunological challenge induced by vaccines. In addition, the stress associated with weaning, transportation, surgery, and subclinical illness can also compromise immune function. It's no surprise, then, that reports of vaccine reactions and vaccine-related diseases are on the rise throughout the animal world.

## Overview of the immune system

When an animal is vaccinated, his immune system responds by producing two types of specialized white blood cells called lymphocytes. As the name suggests, lymphocytes are produced by the lymphatic organs (bone marrow, thymus, lymph nodes and spleen). You'll find them throughout the body — in circulating blood and



attention has been paid to the hormonal status of the patient. The same principle that applies for illness (don't vaccinate when a horse is sick) should apply to times of physiological hormonal change. This is particularly important because the combination of hormonal change along with infectious agents can trigger an autoimmune disease.

Regardless of what you hear, vaccinating animals at the beginning, during or immediately after an estrous cycle is unwise, as is vaccinating animals during pregnancy or lactation. In horses, the WNV vaccine is stated to be safe for pregnant mares, although in 2005 the American Association of Equine Practitioners recommended vaccinating mares before breeding when possible.

Research in cattle shows the MLV herpes virus vaccine induces necrotic changes in the ovaries of heifers that were vaccinated during estrus. Even heifers that were not vaccinated but shared the same pasture were affected. In addition, vaccine strains of these viral agents are known to be causes of abortion and infertility. If one extrapolates these findings from cattle to other species, including horses, the implications are obvious.

### **Adverse reactions**

When we refer to vaccine reactions, we're talking about more than just immediate hypersensitivity reactions such as redness and inflammation. Clinical signs associated with reactions typically include fever, stiffness, sore joints and abdominal tenderness, susceptibility to infections, neurological disorders including seizures and encephalitis, collapse with autoagglutinated red blood cells and jaundice (autoimmune hemolytic anemia, AIHA), or generalized pin point or blotchy hemorrhages (immune-mediated thrombocytopenia, ITP) and laminitis. Liver and kidney laboratory values may be significantly elevated, and liver or kidney failure may occur by itself or accompany bone marrow suppression.

Regardless of species, acute events tend to occur 24 to 72 hours after vaccination, or seven to 45 days later in a delayed immunological response. Even more delayed adverse effects include death in infants from high-titered measles, joint diseases in dogs from canine distemper antibodies, and feline injection-site fibrosarcomas. Though not as clearly documented, laminitis can occur soon after vaccination, but can also be delayed.

Viral disease and recent vaccination with single or combination vaccines are increasingly recognized contributors to immune-mediated diseases of blood and other tissues, bone marrow failure, and organ dysfunction. We know that potent adjuvanted killed vaccines like those for rabies virus can trigger immediate and delayed (vaccinosis) adverse vaccine reactions. It's likely that the genetic predisposition to these disorders in humans has parallel associations in domestic animals, including horses.

Health issues in horses attributed to adverse vaccine reactions have included fever and nasal discharge, temporary blindness, thrombocytopenia, muscle wasting or weakness, anasarca or purpura hemorrhagica, lymphangitis and laminitis.

### **Over-vaccination**

Curiously, while concerns about over-vaccination have been raised for years in dogs and cats, little has been said about the fact that horses routinely receive more vaccines more frequently than other species. For example, many horses are vaccinated annually for rabies, even though this vaccine is known to confer a longer duration of immunity — at least three and likely more years! Perhaps this just reflects the lack of awareness that the vaccine issues pertaining to dogs and cats also apply in principle to other species such as horses

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LETTER 3 ITEM 4

# NEWS



## Hendra virus vaccine: CSIRO scientist recommends fewer injections; owners say vaccine killed healthy horses

By the National Reporting Team's Suzanne Dredge and Philippa McDonald  
Updated Fri 23 Oct 2015, 9:33am

**Editor's note (October 23, 2015): A video excerpt and still photos have been removed from this story.**

The CSIRO scientist who developed the Hendra virus vaccine is recommending fewer injections be given to horses to protect against the deadly illness.

Currently boosters have to be given every six months and horse owners have told the ABC they fear their horses are becoming ill and in several cases dying as result of "over-vaccination".

"At the moment the evidence we have is that after the six-month booster you can maintain levels of protection in horses for at least a further 12 months, possibly even longer," CSIRO's Deborah Middleton said.

"I certainly have sympathy for owners who feel their horses are being over-medicated because I think any vaccination carries the risk of a vaccine reaction and all the more reason to be very certain that we're only giving horses the minimum number of vaccines we need to give them protection against Hendra virus."

Vaccine manufacturer Zoetis' veterinary operations manager, Richard L'Estrange, said the industry would support changing the interval between vaccinations from six months to 12.

Do you know more about this story? Email [investigations@abc.net.au](mailto:investigations@abc.net.au)

"I think everyone would like to see that change made and everyone would like to see that change made as soon as possible, but we need to allow the regulator to make their assessment and they will give us their answer in due course," Mr L'Estrange said.

In a statement to the ABC, the Australian Pesticides and Veterinary Medicines Authority (APVMA) said it would require solid evidence to consider making any change.

"To support an application for a 12-month vaccination interval, Zoetis would need to make an application to the APVMA with evidence that horses retain sufficient immunity 12 months after vaccination," the statement said.

Queensland is a known Hendra zone, as are areas of northern New South Wales.

There have been two recent outbreaks of the Hendra virus in Queensland and a total of 50 outbreaks in the past 20 years in both states.

Four people have died along with 90 horses.

Seven horse owners had to be treated for potential exposure to the bat-borne virus last year.

While the virus was identified in 1994, a vaccine was not available until November 2012.

Since it was registered earlier this month, 380,000 doses have been given to 110,000 horses.

Brisbane vet Nathan Anthony has vaccinated 5,000 horses at his practice.

"We have only seen minor reactions at the injection site so this is some swelling



PHOTO: Horse owners fear their animals are becoming ill and dying after receiving too many doses of the Hendra vaccine. (ABC News)

RELATED STORY: Vets reject claims Hendra vaccine is killing horses

RELATED STORY: Vet says unvaccinated horses are being treated differently

MAP: Hendra 4011

Sadly for us it hasn't been an easy road ... I think at last count it was about 60 odd horses vaccinated here, sadly two are dead.

Natalie Roach



PHOTO: The controversial Equivac medicine (ABC News)



# Vaccinating horses against Hendra is expensive, but drug manufacturer says that could soon change

ABC Rural By Marty McCarthy

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Updated Wed 24 Jun 2015, 12:22pm

## The Hendra vaccine could soon become cheaper for horse owners.

The drug's manufacturer, Zoetis, lodged an application with the Australia Pesticides and Veterinary Medicines Authority to extend the drug's duration of immunity to 12 months.

The current injection regime requires ongoing boosters every six months after the initial two injections, so the change would halve the amount of injections a horse needs.

However, Richard L'Estrange, veterinary operations manager with Zoetis, said it could be a while before the application was successful.

"The APVMA have reviewed our application for a change from six to 12 months and they liked the data that we gave them, but they would like more data," he said.

"They have advised us to gather extra data and resubmit the application when we have it, so it may be 18 months or more before we see another decision."

The chief executive officer of the APVMA, Kareena Arthy, was not available for an interview, but in a statement said "to support an application for a 12-month vaccination interval, the APVMA would need to see evidence that horses retain sufficient immunity 12 months after vaccination".

"This means we would need to see the data that shows horses can withstand a viral challenge 12 months after vaccination."

Dr L'Estrange said the research used in the application was conducted by the CSIRO, but any further data would need to be supplied by Zoetis.

"The CSIRO are involved in the challenge trials, but there are no more challenge trials planned as far as I'm aware," he said.

"The future data we will be submitting will be data on field horses, which will be collected by Zoetis."

"The data that the CSIRO and Zoetis have gathered in support of 12 months is good data, but at this point is time is insufficient to convince the APVMA to make a change."

Deborah Middleton is the lead Hendra researcher at the CSIRO's Australian Animal Health Laboratory in Geelong, where the vaccine was developed.

She was unavailable for an interview, but in email correspondence with a Queensland horse owner obtained by ABC Rural, Dr Middleton suggest 12-month boosters could be sufficient.

"I do agree with you that continuing with the six-month boosters after [the first three injections] would appear to be over the top based on our current knowledge," she said in an email to Madeline Horne, a horse owner at Hunchy on Queensland's Sunshine Coast.

"For horses which have received the first series of three injections (at day 1, day 21 and 6 months), there is no evidence that a further booster at 12 months (from the initial injection) will add significant value in terms of protection.

"It may be in future that that timeline is pushed out even more (too soon yet to say for sure as it depends on data from field trial horses that is being gathered over time)."



PHOTO: A vet holds a syringe of the Hendra virus vaccine. (AAP: Dan Peled)

RELATED STORY: Hendra virus kills horse on north coast of NSW

MAP: Brisbane 4000

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AUDIO: Marty McCarthy reports that the Hendra vaccine could become more affordable for horse owners (ABC Rural)

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AUDIO: Richard L'Estrange from Zoetis says a horse may be immune to Hendra for up 12 months following an injection, but more data is needed (ABC Rural)