

Regu-Mate® (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers

A thesis

submitted by

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In partial fulfillment of the requirements

for the degree of

Master of Science

in

Civil and Environmental Engineering

TUFTS UNIVERSITY

August 2013

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ABSTRACT

Regu-Mate, the synthetic progesterone altrenogest, is used to control estrus in horses. Equine caregivers handling Regu-Mate may be exposed through accidental exposure or inadequate safety procedures. This exposure can result in adverse health effects including menstrual cycle changes, uterine/abdominal cramping, headaches and prolonged pregnancy. Surveys asked equine caregivers about Regu-Mate handling procedures, skin exposure to the drug, symptoms associated with exposure to the drug, and general background information. I analyzed results through descriptive statistics. Most respondents do not take sufficient safety precautions when handling Regu-Mate. Respondents most commonly use rubber/latex gloves or do not wear gloves when handling the drug and/or use a non-locking syringe to withdraw the medication. Respondents become complacent, taking fewer precautions the longer and more often they handle Regu-Mate. I developed a risk communication program that outlines the important safe handling discussion topics between veterinarians and clients and recommends a periodic check-in to evaluate a facility's procedures.

ACKNOWLEDGMENTS

I would like to express my sincerest gratitude to Anne Marie Desmarais, Mark Woodin and Brett Gaby for their wisdom and guidance through this project. Thank you to Karen Vagts for helping navigate the research process.

This thesis was made possible by the veterinarians and practices that assisted in the dissemination of my survey: Anoka Equine Veterinary Services, Atlanta Equine Clinic, Battenkill Equine Clinic, Brandywine Equine Veterinary Associates, Cave Creek Equine, Clover Valley Veterinary Services, Eastampton Veterinary Service, El Sol Equine Practice, Equine Reproduction, Equine Reproduction Concepts, Equine Veterinary Services of Leelanau, Essex Equine, Dr. Tera Forbeck DVM, Fox Run Equine Center, Gas Light Equine, Dr. Carlos Gradil DVM, Dr. Paul E. Mennick DVM, Mobile Veterinary Practice, Montana Equine, Ocean State Equine, Pacific Crest Sporthorse, Panhandle Veterinary Services, Piedmont Equine Practice and Hospital, Professional Equine Therapeutics Service, Rutherford Large Animal Services, Santa Sofia Equine, South Shore Equine, Tacoma Equine Hospital, Teigland Franklin and Brokken DVM's PA and Dr. Karen Wolfsdorf DVM.

A special thank you to my family: Mom, Dad and Maris for their never-ending support in every way possible, Brady and Kaylee for “understanding” that the boring computer work truly was more important than a walk in the woods, and Ethan for his constant encouragement. You are all wonderful; thank you for being with me every step along this journey.

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Regu-Mate® (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers

1 Introduction

Equine care givers, from veterinarians to grooms, are exposed to a number of health hazards due to the nature of their jobs. The horse community is small and close-knit but encompasses a wide range of disciplines including performance (jumping, dressage and western), working, racing and breeding industries. The physical risks of working with horses are well understood and governing bodies such as the United States Equestrian Federation (USEF), Fédération Equestre Internationale (FEI) and the Jockey Club (for Thoroughbred Race Horses) have established rules to protect the safety of their members. However, the focus of these rules is on the prevention of physical injuries and not the protection from medications and chemicals routinely used in the field.

Helmet requirements within the USEF, a United States governing body for performance competitions, have evolved since their first mention in the rule books in 1964 and requirements vary greatly based on the specific equine discipline. More currently, juniors (riders under 18 years) engaged in jumping activities are required to wear an “approved” helmet. It was not until a rule change in 2006 that adults were encouraged to wear approved helmets. Since 2006, safety rules have continued to improve, including protective vests in cross country events and approved helmets in breed and dressage shows¹. The FEI, an international governing body for performance competitions, as of January 13, 2013, has required all riders mounted on the show grounds to wear approved helmets with a fastened harness². The physical risks of working around large animals are immediately apparent, with broken bones and concussions being almost commonplace and deaths not unheard of.

Altrenogest, the chemical of focus in this thesis, is used for the control of estrus in horses and is administered to horses in all disciplines of the horse industry^{3,4}. Health effects resulting from physical risks in the equestrian world often have a short lag time between the cause and effect (i.e. a dislocated shoulder from leading a horse without a lead rope or concussion from falling when not wearing a helmet) which allows for one to easily draw connections between the two. Longer lag time can make connections more difficult to draw, as may be the case in exposure to

chemicals where there is a longer period between exposure and the associated health effect. Historically, exposure to veterinary medications has not been a primary focus within the industry nor has extensive exposure assessment research been conducted^{5,6,7,8}. The lack of knowledge about health effects combined with potentially inadequate management practices in the use of long-term medications puts equine care givers at risk of long- and short-term health effects.

1.1 Problem Statement

In this thesis, I will evaluate the risks from exposure to altrenogest through use of the FDA-approved drug Regu-Mate by equine care givers. I distributed surveys to equine care givers through veterinary practices/equine medical professionals. These surveys asked questions regarding Regu-Mate handling procedures, exposure to the drug and symptoms the respondent associates from contact with the drug. In my research, I evaluated respondents' potential exposure and health risk related to their handling practices and self-reported exposure. I used this information to recommend specific risk communication guidelines for use in the equine industry to reduce exposure and risk.

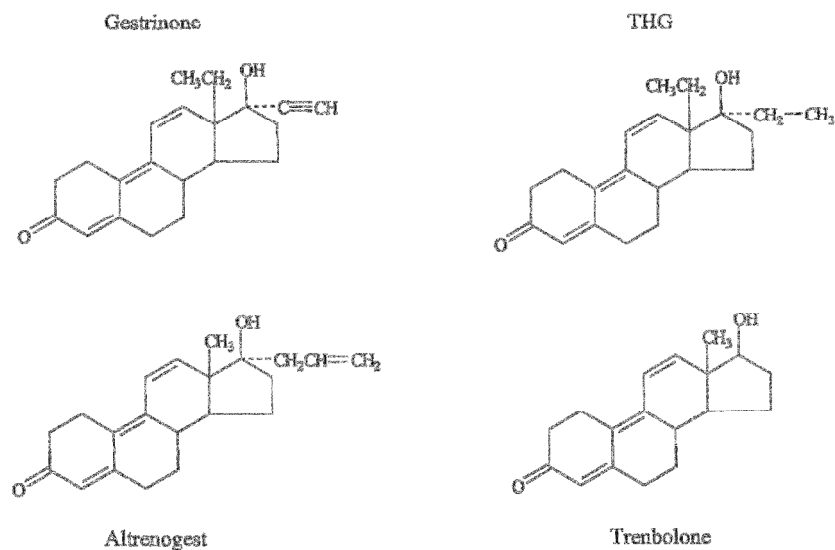
2 Background

Altrenogest, also known as allyl-trenbolone, was originally approved in 1983 (supplemental approval in 1990) by the United States Food and Drug Administration (FDA) under the trade name Regu-Mate for prescription use to control estrus in horses⁹. Altrenogest was also approved as Matrix in 2003 for use over-the-counter in commercial pig operations^{10,11}. In 2012 the FDA approved the generic Altresyn for use in horses¹². The FDA-approved formulations are 0.22% suspensions in vegetable oil^{13,14,15}. Altrenogest is indicated for use to suppress and synchronize estrus in pigs and horses¹⁶; however veterinarians commonly will prescribe Regu-Mate for off-label use in equines to modify behavior as well as to maintain pregnancies in canines¹⁷ and other mammals. Off-label use of medication is a use different from the use specified in the FDA's drug approval. This type of use is not illegal and any medical practitioner (physician or veterinarian) may prescribe drugs for uses other than those approved by the FDA. Although off-label use is permitted, drug companies are not permitted to market off-label uses of drugs.

2.1 Chemical Information

Altrenogest (17-allyl-17 β -hydroxyestra-4,9,11-trien-3-one) is a synthetic progesterone that is a derivative of the C19-nortestosterone series¹⁸. Figure 1 shows the chemical structure. The chemical's primary effect is progestomimetic and anti-gonadotrophic while it has weak estrogenic, anabolic and androgenic effects^{19,20,21,22,23,24}. Altrenogest acts on the hypothalamus and pituitary progesterone receptors that decrease the follicle-stimulating hormone (FSH) and luteinizing hormone (LH) output through increasing the negative feedback²⁵. The medication is administered at varying stages of the horse's life due to either breeding management practices or its behavior modification effect. Mares are started on the medication as early as two years of age (equine puberty is 18-months). Mares on long-term altrenogest may eventually demonstrate estrus behavior even though the estrous cycle has been interrupted. When given the drug a mare will not go into estrus; when it is withdrawn a new estrous cycle will begin and ovulation usually occurs within 12 days²⁶.

Figure 2-1: Chemical Structure of altrenogest and other derivatives²⁷



2.2 Pharmacokinetics in Horses

Altrenogest is administered orally at a dosage of 0.044 mg/kg²⁸ for the suppression of estrus or 0.088 mg/kg when used to maintain pregnancy^{29,30}. The hormone is readily absorbed into the bloodstream and has been detected in as few as 30 minutes after ingestion³¹. Maximal concentrations in blood and plasma occur within 2 to 4 hours after ingestion^{32,33}. Clearance from plasma takes approximately 72 hours, with the clearance rate decreasing with prolonged usage; however it does not appear to bioaccumulate^{34,35}.

In the horse, altrenogest is distributed primarily to the liver followed by kidney, muscle and fat^{36,37,38,39,40} with a multiphasic elimination profile and no single measurable half-life⁴¹. The drug is metabolized by the liver through Phase II conjugation with glucuronic acid (as the principal route) and sulfonation (as a minor route) into glucuronide or sulfate, respectively; no Phase I metabolites have been observed^{42,43}. Phase II conjugation is the rate limiting step of the metabolic process and biotransformation is independent of the dose level⁴⁴. Metabolites of

altrenogest show little or no hormonal activity⁴⁵. Dealkylation, which would result in the steroid trenbolone, does not occur. Plasma, up to 24 hours after the last dose, contains mostly metabolites and only a small proportion of the parent compound⁴⁶. Glucuronide and sulfonated conjugates are the main urinary metabolites, although the parent compound is also excreted⁴⁷. Excretion, primarily as the parent compound, is through the urine and fecal routes with the majority of an applied dose being excreted within 24 hours^{48,49,50,51,52,53}. Levels of the hormone reach peak concentrations in urine within 3 to 6 hours^{54,55,56} after ingestion; levels in urine are below detection limits twelve days after the dosage is withdrawn^{57,58}.

2.2.1 Testing

Testing for altrenogest in the blood is done by sport governing bodies for regulatory purposes in competition (see section 2.9.1 for information on the limitations for use of the drug in competition) to determine if a horse is on the drug. Altrenogest can be analyzed in plasma samples using ultra performance liquid chromatography coupled to tandem mass spectrometry (UPLC-MS/MS)^{59,60}. Urine levels of 13 pg/mL of altrenogest can be detected using LC-MS/MS in the Selected Reaction Monitoring (SRM) mode⁶¹. At the most basic level, altrenogest is tested for by looking for the phase II metabolites^{62,63}.

2.3 Health Effects in Horses

No adverse/toxicological effects are seen in mares at therapeutic dosages of altrenogest, aside from the intended control of estrus. Filly offspring of mares treated with altrenogest had an increased clitoral size and a shorter interval between February 1 (this date is a marker of the “end” of winter) and their first ovulation of the season compared to filly offspring of mares that were not treated with altrenogest. There were no documented differences in stallion offspring of treated and untreated mares as well as no significant differences between the reproductive performance of both male and female offspring in one pivotal and two corroborative safety studies submitted with the Regu-Mate supplemental approval⁶⁴.

Studies show long- and short-term effects on testosterone levels and sperm morphology (resulting in a decrease in normal spermatozoa) in stallions and male rats^{65,66}. Only short-term effects on testosterone levels have been observed in boars however as they have returned to normal following the withdrawal of oral altrenogest⁶⁷. The reduction of scrotal circumference, reduced libido and a minor change in sexually aggressive behavior is observed in younger stallions due to a stronger influence of altrenogest on them than mature stallions^{68,69,70}. Changes in sexually aggressive behavior were considered significant in young stallions⁷¹ and minor in mature stallions⁷². Studies suggest that there may be physiological differences in the response of young and older stallions to altrenogest and suggest that more research on the long-term effects on young stallions is warranted^{73,74}.

2.4 Health Effects in Humans

There are no studies of effects of altrenogest on humans; however other synthetic progestins can be used as surrogates when evaluating the potential health effects. The European Medicines Agency used human studies with norgestomet as a surrogate for altrenogest. Norgestomet, another progestagen that has the same mode of action as altrenogest, shows that humans are not more sensitive to the hormonal effects than monkeys⁷⁵. The warnings on the Regu-Mate product label on the effects of overexposure to humans extrapolate from data available from similar pharmaceutically classed products that are used on humans⁷⁶.

2.4.1 Non-Carcinogenic Effects

Effects of chronic or acute exposure to progestins in humans (specifically females) include headaches, disruption of the menstrual cycle (period coming later/earlier than normal and/or length of period being longer/shorter than normal), uterine and/or abdominal cramping, change (increase or decrease) in menstrual bleeding and prolonged pregnancy^{77,78}. There are no data available on effects in males.

2.4.2 Carcinogenic Effects

In vitro genotoxicity tests determined that altrenogest does not show genotoxic activity and long-term carcinogenicity studies were subsequently not necessary^{79,80,81}. Additional testing with other similar steroid hormones confirmed these tests, determining that genotoxic activity *in vivo* does not occur and any possible carcinogenic activity occurs after long-term exposure at levels higher than those required for a hormonal response⁸².

2.4.3 Sensitive Populations

Pregnant women and women who are of child bearing age are particularly sensitive to the effects of synthetic progesterone and this population is directly referenced in the Material Safety Data Sheet (MSDS) for the drug⁸³. Other segments of the female population who should be particularly aware of their exposure are women with carcinoma of the breast, those who developed tumors during the use of oral contraceptives and/or who have undiagnosed vaginal bleeding⁸⁴. Individuals with thrombophlebitis/thromboembolic disorders, cerebral-vascular/coronary-artery disease, those with estrogen-dependent neoplasia and/or with liver disease are also particularly sensitive to the effects of progestins after chronic exposure⁸⁵.

Children and infants also represent likely sensitive populations due to their size and undeveloped reproductive systems. There is no specific warning for men given on the product's MSDS.

2.4.4 Adverse Drug Experience Reports

Between November 1997 and March 2012 94 human adverse drug experiences (ADE) related to altrenogest were reported to the FDA. Adverse drug experiences for animal drugs are reported directly to the pharmaceutical company which acts as an intermediary and submits that information to the FDA. The detailed report information for altrenogest was obtained for this thesis through a Freedom of Information Act (FOIA) request to the FDA; a copy of the request is in Appendix A. The ADE reports do not indicate or declare causation between exposure to altrenogest and the reported symptoms. Of the 94 reported human experiences during this

time period the most common route of exposure was topical and to the head/face, eyes and/or hands (Table 2-1). Individuals were able to report multiple routes/locations on the body.

Table 2-1: Reported locations on the body for ADE exposures

Location of Exposure	Count of Reported Exposure
Eye(s)	2
Hand(s)	35
Head/Face	5
Mouth	1
Note that this table does not include unspecified human exposure.	

This table does not include unspecified exposures; individuals were able to report multiple routes of exposure/locations on the body. Table 2-2 presents symptoms most commonly reported by respondents; the most common symptoms are abnormal menses, abdominal pain, and reduced fertility. The table includes only symptoms reported three times or more and respondents could indicate multiple symptoms.

Table 2-2: Reported symptoms from ADE exposures

Symptoms	Number of Reports
Abnormal Menses	28
Anestrus	3
Behavior Disorder	4
Diarrhea	4
Estrous Behavior	4
Estrous Cycle Abnormal	6
Headache	11
Nausea	6
No Signs	9
Pain: abdominal	12
Pain: other	10
Pruritus/Itching	4
Rash	7
Reproductive Disorder	6
Swelling on Body	4
Vaginal Bleeding	3
Vomiting	5
Weight Increase	3

2.5 Levels of Human Exposure

An acceptable daily intake (ADI), the amount of a substance that can be ingested daily over a lifetime without an appreciable health risk, for altrenogest in humans was established by the European Medicines Agency in 1999. The ADI of 0.04 micrograms per kilogram of body weight per day ($\mu\text{g}/\text{kg}/\text{day}$) was developed by using the no hormonal effect level observed in monkeys and pigs of 4 $\mu\text{g}/\text{kg}/\text{day}$ with an uncertainty/safety factor of 100 for species differences⁸⁶. In

2011 the Committee for Medicinal Products for Veterinary Use (CVMP) received a request by the United Kingdom to review the ADI based on new approaches in deriving uncertainty factors. The new uncertainty factor of 20, in combination with new pharmacovigilance and residue data, resulted in a new ADI of 0.20 µg/kg/day⁸⁷. In 2005, the Veterinary Drugs Directorate (VDD) of Health Products and Food Branch Health Canada established an ADI of 1.2 µg/day/person⁸⁸. With the body weight of an average adult of 70 kg this is an ADI of 0.017 µg/kg/day. No ADI has been established by the FDA or any other agency of the United States government. The chemical's MSDS indicates that the human inhalation exposure limit is 0.8 micrograms per cubic meter of air (8 hr TWA)⁸⁹.

Table 2-3: Agency-Established Average Daily Intake Values

Agency	Country	ADI (µg/kg/day)
European Medicines Agency (1999)	European Union	0.04 ⁹⁰
European Medicines Agency (2012)	European Union	0.20 ⁹¹
Veterinary Drugs Directorate (2005)	Canada	0.017 ⁹²

A study by Lovatt and Mitchell evaluating potential risks to pregnant farm veterinarians highlighted hormones such as altrenogest as posing a particular risk to this population as the hormone specifically alters the menstrual cycle and prolongs pregnancy^{93,94,95}; however this risk is not exclusive to farm veterinarians but can be expanded to any pregnant woman (groom, farm manager, etc.) who administers or is exposed to the drug. A 2006 study by Capleton et al. determined that altrenogest was a “medium” priority for a detailed risk assessment as the chemical has a high toxicity profile but due to its relatively infrequent use in veterinary medicine (compared to antimicrobial and antibiotic medications) and “unknown” ability to reach the environment the study authors ranked the chemical as a medium priority⁹⁶. My research focuses on a target population that is regularly exposed to altrenogest as opposed to the broader veterinary community of which my population is a small segment.

2.6 Effects on Plant Life and Soils

Plant life and/or soils can potentially be exposed to altrenogest through the feces and/or urine of a treated horse or other animal. This exposure can be through direct deposits in a pasture, urine percolating through a dirt floor in a barn or the use of composted manure as fertilizer for a garden or yard. Produce grown in composted manure used as a fertilizer in a vegetable garden could potentially be consumed by humans. Few data are available on the effect of altrenogest on plant life. Agrisearch UK Limited, Huntington Research Center and Roussel Uclaf (Merck) did research in the 1980s that is referenced in the Finding of No Significant Impact (FONSI) submitted to the FDA in conjunction with Intravet's new animal drug application for Matrix, an altrenogest formulation for use in commercial pig operations. I was unable to obtain copies of the studies referenced by the FONSI despite inquiries and correspondence with the three companies, however summarized information is available in the FONSI⁹⁷.

Table 2-4: Significant Effects on Plants Exposed to Altrenogest⁹⁸

	Crop Emergence	Vigor	Fresh-Weight	Dry-Weight
Radish	N	N	N	N
Lettuce	N	N	Y	N
Soya	Y	Y	Y	Y
Wheat	N	Y	N	N
	Y = statistical significance between control and exposed to altrenogest		N = no statistical significance between control and exposed to altrenogest	

The studies looked at the growth of soya, radish, lettuce and wheat when exposed to altrenogest in the growing medium. No description of what the author defined as “statistically significant” was provided in the report; the significance indicated here is reflective of the author's designations. There were no phytotoxic response or growth effects observed in any of the plants. Soya appears to be the most sensitive with significant dose related effects seen on

crop emergence, fresh and dry weights while a significant transient decrease observed in the vigor of the exposed crop. Lettuce also showed a significant dose related decrease in fresh weight and wheat a significant transient decrease in vigor⁹⁹. There is no information available on the bioaccumulation of altrenogest in the plant.

2.7 Routes of Exposure for Humans

Potential routes of exposure to an equine care giver include dermal, ingestion and inhalation of aerosol; volatilization is not a concern for this drug. Dermal exposure could occur directly through spilling the drug on skin or through indirect exposure (touching the muzzle of a dosed horse, cleaning out buckets, touching a bridle of a treated horse or contact with items touched with protective gloves). Ingestion can occur accidentally by contact with the horse's muzzle or ingesting dust containing feces/urine from cleaning stalls). Inhalation can occur if the drug is aerosolized when emptying the syringe or through the inhalation of dust containing the drug.

Additional routes of exposure for a veterinarian or individual involved with breeding would be direct contact with feces or urine through palpations (both rectal and vaginal) or contact with the amniotic fluid¹⁰⁰ while delivering a foal whose dam was on altrenogest at the end of her pregnancy.

Table 2-5: Potential Routes of Human Exposure

	Dermal	Inhalation	Ingestion
Direct	Spilling of drug on skin Permeable gloves	Aerosolized drug	Accidental ingestion (on horse's grain, etc)
Indirect (primary)	Contaminated buckets/tack Touching of horse's muzzle	Inhalation of dust (containing altrenogest from a direct source)	Eating of food/drink with contaminated hands
Indirect (secondary)	Contact with feces or urine Contact with amniotic fluid	Inhalation of dust (containing altrenogest from an indirect source, i.e. feces or urine)	Ingestion of produce grown in composted manure

Given that there is no information available on the uptake of altrenogest in plants, the ingestion of produce grown in composted manure from mares that were administered altrenogest remains a potential yet unlikely route of exposure. Urine and feces from treated animals also can impact both surface and groundwater^{101,102,103}. These routes of exposure should be evaluated further; however they are outside the scope of this thesis.

As discussed in Section 2.4, there is no research available on effects of altrenogest on human and instead surrogates are substituted when evaluating potential health effects. The research and information addressing effects from different routes of exposure in animals indicates that the drug is used orally and through inhalation and the drug's dosing level remains the same for each^{104,105}.

2.8 Horse Physiology and the Estrous Cycle

There are two parts to a mare's estrous cycle: estrus and diestrus. These phases are primarily described based on their associated behaviors, although they also represent the physical/hormonal state of the mare. Estrus is the period prior to ovulation with high systemic

estrogen levels during which the mare is receptive to the stallion. Diestrus corresponds to a higher ratio of progesterone to estrogen during which the mare is not receptive to the stallion. This cycle takes an average of 20-22 days. Anestrus is a period of time, usually in the winter, during which ovulation does not occur. The horse's estrous cycle is strongly influenced by light, which results in the natural breeding season occurring in the spring and summer months. During the winter, ovulation often does not occur; however as light levels increase towards spring, the mare responds and is pulled out of anestrus and begins to transition into a normal estrous cycle. During the transition period the mare's sexual behavior is often erratic; after the transition period normal cyclic activity resumes^{106,107,108}.

In estrus the mare exhibits behavior to demonstrate to a stallion that she is sexually receptive. This behavior typically includes tail-raising, squatting, urinating and winking with the clitoris. Behaviors that are associated with diestrus are non-receptive in nature and include swishing of the tail, putting the ears back, squealing, kicking with the hind legs and striking out with the front legs. Some mares will exhibit atypical behavior while in estrus and will behave negatively towards a stallion by demonstrating some of the behaviors that are associated with diestrus^{109,110,111}.

2.9 Altrenogest Usage in Horses and Alternatives

Altrenogest is administered to open (non-pregnant) and pregnant mares as well as to geldings or stallions on occasion. The drug is approved by the FDA for the suppression and regulation of estrus in mares¹¹². In non-pregnant mares the drug is used for the control of cycling during the transition period of winter to spring, for long-term suppression of estrus and synchronizing estrous cycles between multiple mares for breeding purposes; in pregnant mares it is used to maintain pregnancy¹¹³. Off-label, which is prescribing the drug for a use not specified under the FDA approval, altrenogest is used in horses to control undesirable behaviors such as sensitivity, attitude changes, difficulty in handling and changes in performance^{114,115}. Veterinarians are able to prescribe drugs for off-label uses if they feel it is appropriate based on their professional judgment.

2.9.1 Behavior Modification

The extent to which individual mares exhibit estrous behaviors varies greatly along a scale from “silent” heats (exhibiting little to no estrous behavior) to demonstrative (exhibiting strong estrous behavior). Behaviors that handlers commonly complain about include attitude changes, difficulty in handling and a decrease in performance. In addition, handlers report/identify mares experiencing mild colic and back pain. Often these can be managed through training methods; however major behavior changes, extreme discomfort (i.e. resembling colic) or aggression signal that another remedy may be required. It is important to rule out other reasons, not caused by the estrous cycle, for the behaviors and confirm the estrous cycle as the source prior to commencing treatment. Some mares will display estrous behavior even while not actively in heat; the reason for this can be determined to be psychological upon physical examination¹¹⁶.

Treating performance (in training or for showing) horses with altrenogest is often for the purpose of creating a more focused animal¹¹⁷; this treatment approach is used in stallions, geldings and mares. Controlling estrus in the female performance horse is often done to manage any adverse behaviors associated with estrus^{118,119}. Drugs, including altrenogest, when used to manage behavior, are forbidden by the governing bodies of equine performance activities although the use of drugs for behavior-altering purposes appears to be fairly widespread^{120,121,122,123}. Altrenogest use in mares continues to be permitted by the governing bodies as it is difficult to control the reason behind administering a drug and there are many competitively legitimate reasons for using this drug in mares. Altrenogest use in stallions and geldings is banned as the drug is only permitted by governing bodies when used for regulating estrus which does not occur in male horses.

The FEI restricts the use of altrenogest for behavior modification in performance mares and prohibits the hormone’s use in performance geldings/stallions¹²⁴. An affidavit authorizing the administration of altrenogest to mares competing at FEI competitions must be signed by the treating veterinarian/responsible party and an FEI veterinary delegate. The affidavit states that the drug is being used only for mares and only according to the manufacturer’s recommended

dose/duration for the purpose of estrus suppression; the FEI reserves the right to test for altrenogest^{125,126}. The USEF does not specifically regulate the use of altrenogest; instead the rules define forbidden substances as any drug that might affect the performance of a horse (unless otherwise specifically defined in the rules)¹²⁷. Currently the USEF is re-evaluating its doping regulations due to increased media attention on drug use in the industry^{128,129,130,131}. The United States Pony Club (USPC), a national non-profit youth organization, restricts use only to animals that have a letter from the prescribing veterinarian and only when administered by an adult¹³². Limitations by these organizations in how altrenogest is used reduce the overall use of the drug in performance animals. The concern of the governing bodies centers around the fairness of competition rather than any health consequence of the drug on the horse or on human handlers.

Mares

For performance mares where the primary goal is to reduce the adverse behaviors that people may associate with estrus and not always to stop estrus the medically acceptable treatment options include natural progesterone, synthetic progesterone, gonadotropin-releasing hormone (GnRH) vaccine, hormonal implants, placement of glass balls in the uterus, herbal supplements, and the surgical removal of ovaries¹³³. The use of the different treatment options varies between veterinary practices and equestrian disciplines. Medroxyprogesterone acetate (marketed as Depo-Provera for human use) does not suppress estrus in mares; however an injection of this hormone is commonly used and anecdotal accounts strongly support its use in modifying behavior¹³⁴. It is often used as a first step in treatment by veterinarians due to its long-term effect and the simplicity/safety of its administration (one injection as opposed to the daily dosing necessary with Regu-Mate). If the adverse behaviors do not diminish to an acceptable level, altrenogest may then be used as a second choice for long-term suppression of estrus¹³⁵.

Stallions and Geldings

The use of altrenogest in geldings and stallions is off-label and not an approved application according to the pharmaceutical companies or the FDA¹³⁶. Stallions treated with altrenogest are usually performance animals that are currently non-breeding but may be intended for breeding careers in the future¹³⁷. Both long- and short-term effects of exposure to altrenogest have been documented in male horses (Section 2.3). As in mares, alternative hormonal treatments to altrenogest that may be used in stallions or geldings for behavior modification include medroxyprogesterone, GnRH vaccine and progesterone^{138,139}.

2.9.2 Breeding Mares

Progestin given early in the breeding season is used to control cycling during the transition period from the winter anestrus and bring the mare into a regular estrous cycle to prepare for breeding. This application accelerates the transition into the breeding season allowing for breeding earlier in the season than naturally might occur^{140,141}. For example thoroughbreds have an artificial birth date of January 1; horses born during that calendar year turn a year older on this date¹⁴². Subsequently it is in the breeder's best interest to produce a more physically mature and advantaged horse in comparison to calendar year peers, to have a foal born as close to (but not before) January 1 as possible.

An alternative to altrenogest for advancing the first ovulation of the year in a mare which is in winter anestrus is the administration of a dopamine antagonist such as domperidone and sulpiride^{143,144}. Dopamine antagonists are most useful in conjunction with putting the mare under lights, particularly when the mare is in deep as opposed to light anestrus¹⁴⁵. Other potential treatments include natural progesterone, prostaglandins and GnRH¹⁴⁶.

Altrenogest is actively used for the synchronization of estrus for artificial insemination in a single mare or multiple mares for embryo transfer. When it is used alone or in conjunction with estradiol or HCG a breeder can accurately predict when a mare will ovulate. Timed ovulation

allows for accurate timing for insemination and the coordination of multiple mares for embryo transfer recipients, resulting in higher progesterone levels in early gestation¹⁴⁷.

2.9.3 Maintaining Pregnancy

Once a mare is pregnant, altrenogest is often used to help maintain a pregnancy, particularly in mares with a history of losing foals^{148,149,150}. In early gestation low endogenous concentrations of progesterone can cause the loss of a fetus and altrenogest increases the serum progestin levels until the placenta is able to take over production or until the end of gestation if adequate levels are not produced. Progesterone deficiency as a cause of pregnancy failure is primarily anecdotal and well-controlled studies to compare pregnancy rates are lacking¹⁵¹. Progesterone supplementation therapy is thus often applied as a preventative measure to protect against fetal loss^{152,153}. When altrenogest is used to maintain pregnancy it is often administered over the course of an entire calendar year.

2.10 Administering Altrenogest

Altrenogest is available in the United States in three FDA approved formulations (Regu-Mate and Altresyn, for horses, and Matrix, for pigs) which are all 0.22% suspensions in vegetable oil to be administered orally^{154,155}. Altrenogest can also be obtained from pharmaceutical compounding companies that re-mix the drug into an injectable solution, an oral paste and time-release formulations (injectable and oral)^{156,157}. Administering altrenogest in these alternative forms may result in a lower risk of exposure to humans since the possibility of direct dermal exposure is reduced in injectable or paste formulations in comparison to the easily dermally absorbed oil suspension. However, these formulations are not FDA approved; use of compounded drugs is controversial and opinions vary among veterinarians¹⁵⁸.

2.10.1 Manufacturer's Recommendations

The manufacturers of Regu-Mate and Altresyn specify the following safety recommendations on the product labels' directions:

While wearing protective gloves, remove shipping cap and seal; replace with enclosed plastic dispensing cap. Remove cover from bottle dispensing tip and connect luer lock syringe (without needle). Draw out appropriate volume of [product name] solution. (Note: Do not remove syringe while bottle is inverted as spillage may result.) Detach syringe and administer solution orally at the rate of 1mL per 110 pounds body weight (0.044 mg/kg) once daily for 15 consecutive days. Administer solution directly on the base of the mare's tongue or on the mare's usual grain ration. Replace cover on bottle dispensing tip to prevent leakage. Excessive use of a syringe may cause the syringe to stick; therefore, replace syringe as necessary^{159,160}.

The product labels indicate that "protective" gloves should be worn and that the solution should not permeate intact rubber or impervious gloves¹⁶¹. The MSDS's for Altresyn and Matrix recommend using vinyl, polyethylene, neoprene, butyl or nitrile gloves^{162,163} while the Regu-Mate MSDS does not specify the type of glove, only that they be "protective"¹⁶⁴.

2.10.2 Handling Guidelines

The Canadian government's website for the Ontario Ministry of Agriculture, Food and Rural Affairs (OMARFA) and the USPC have comprehensive recommendations for protection and handling guidelines available which outline safe manners to handle the drug^{165,166}. Safety recommendations include:

- Store altrenogest and dosing equipment in a leak-proof container and separate from other drugs
- Wearing non-permeable (i.e. vinyl or nitrile) gloves
- Preventing aerosolizing of the drug when removing air from the syringe
- Double up on gloves if working alone to allow for discarding of contaminated gloves prior to opening doors or writing records
- Utilize an assistant to assist in opening doors, writing records and handling horses
- Administer only with dedicated syringes or dosing gun
- If the drug comes in contact with skin wash immediately with soap and water¹⁶⁷.

2.10.3 Safety of Recommendations

OMARFA indicates that rubber/latex gloves that are non-porous are also an acceptable glove type, but that porous rubber/latex gloves will allow the drug to pass through and act as a “patch” against the skin¹⁶⁸. The drug will take longer to permeate nonporous latex gloves however this is still not acceptable as latex gloves are permeable to oil/fats; both porous and non-porous latex gloves have the potential to allow the drug to pass through, causing skin contact. The safest gloves for use with Regu-Mate/Altresyn/Matrix are vinyl, polyethylene, neoprene, butyl or nitrile gloves as these are not permeable to vegetable oil/fat¹⁶⁹.

Storing the altrenogest bottle separate from other drugs/medications prevents the potential of contaminating other medication bottles. Avoiding aerosolizing of the drug reduces the likelihood that one could inhale the drug in an aerosolized form.

Use of the supplied plastic dispensing cap with a Leur-lock syringe or dosing gun will with the inverted bottle technique specified on the product label, if implemented properly, will reduce leaking and accidental spilling of the drug. The oil base of the altrenogest formulation will potentially, with prolonged use, degrade a plastic syringe and create a buildup of oil which can cause sticking of the syringe. Regular replacement of the syringe will prevent issues with syringe function.

¹ United States Equestrian Federation, "USEF Helmet and Body Protector Rule History," (2012).

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- ²⁴ Roussel Uclaf, "Pharmacology-Endocrinology, Dr Schroder (0707021)," (RU 2267 Residue Safety File European Medicines Agency MRL).
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3 Methods

For this thesis, I designed a paper-based cross-sectional survey to investigate how equine care givers handle and manage Regu-Mate (oil-based altrenogest). The survey also asked if they had any health effects that they associated with direct contact (skin, ingestion, etc.) with the drug.

3.1 Survey Design

The survey included a cover page that outlined informed consent and provided potential participants information about the study's purpose, procedures (length of survey and general description), the expected risks/discomforts/benefits/compensation, confidentiality, participation restrictions and contact information for the researcher. The survey (Appendix B) contains twenty-eight questions that cover basic demographic information, handling procedures, habits, personal experiences, potential exposure and education about how to handle this drug. These questions were developed based on a personal knowledge base from more than 10 years in the equestrian industry, a literature review, and correspondence with equine professionals. The survey included close-ended (multiple-choice and yes/no), partial open-ended (multiple choice with an "other" option) questions, and scaled questions.

3.1.1 Languages

The common native languages used in the United States equine industry include English, Spanish and Portuguese. Grooms and barn workers are often immigrants from Mexico, Brazil or other South American nations; to include and accurately survey individuals working in the equestrian industry the survey was translated into Spanish and Portuguese. While participants may speak English at a conversational level, they may not be fully literate in English and a survey in an individual's native tongue allows for full comprehension.

3.1.2 Participants

Participants in this study are equine care givers including barn managers, grooms, veterinarians and horse owners. Those who have used and those who have not used oil-based altrenogest

were able to participate in the study; I anticipated that the majority of respondents would currently use or historically use the drug. The intended utilization of individuals who had not used Regu-Mate was to serve as a control for health and basic knowledge questions even though the majority of the survey is focused on active and historical altrenogest users. The only restrictions to study participation were that individuals must be 18 years of age or older and be based in the United States. The geographical range was limited to those based in the United States as Regu-Mate is available only through a veterinary prescription in the United States and restrictions/availability change in the jurisdictions of other countries.

3.1.3 Institutional Review Board Approval

I submitted this research protocol and a copy of the proposed survey to the Tufts Institutional Review Board for Social, Behavioral, and Education Research (SBEI-IRB) for approval. Initially only the English version of the survey was provided. After receiving IRB approval of the protocol and the English survey approval I arranged for the survey to be translated into Spanish and Portuguese (Appendix B) by native speakers and certified, to document that the translations were accurate, by third parties. The translated surveys with certifications were also provided to IRB for final approval. Copies of the IRB approved surveys are included in Appendix B and the IRB approval letters are included in Appendix C.

3.2 Veterinary Professional Recruitment and Survey Distribution

I identified veterinarians, veterinary practices and facilities that offer equine services and approached them via email and telephone (Appendix D contains the generic initial contact letter) to ask for their assistance identifying potential study participants and to assist in the distribution of surveys to participants. As Regu-Mate is a prescription drug, veterinarians know the individuals or farms that use it and can initiate contact. The veterinarian-client relationship is built on the trust clients have in their veterinarian's knowledge about their animals and their animals' health. The farm/stable employees usually have positive working relationships with the farm's veterinarian. These unique relationships allow veterinarians access to farms and their employees which I, as a researcher, would have difficulty achieving. Veterinarians are able

to utilize their previously established working relationship while these same individuals may be skeptical of a researcher. Using veterinarians as intermediaries allowed me to survey a larger range of individuals than if farms were contacted directly. Additionally using this approach streamlined the process of identifying individuals who use Regu-Mate for their horses.

Veterinary practices provided me with an estimated number of surveys that they expected to be able to distribute based on their clientele that currently use, or historically have used, oil-based altrenogest. I mailed the requested number of surveys along with self-addressed stamped envelopes (to be returned to me at Tufts University) to the participating veterinarians.

Veterinary professionals who assisted with survey dissemination approached their clients, including farm managers, horse owners and farm employees, about study participation using basic guidelines (Appendix D) that I developed. These guidelines were designed to ensure that all potential participants were adequately informed and received the same information about the study. Participants were instructed to place the completed surveys in the provided addressed stamped envelope and return them to me via the United States Postal Service. To ensure that finances were not a factor in completing the surveys I provided postage. Sealing surveys in envelopes maintained confidentiality; they were mailed directly to me and no one else has seen the completed surveys and signed consent forms. I maintained periodic contact via email with the veterinarians, which enabled an ongoing conversation regarding the survey distribution process.

3.3 Data Entry

Upon receipt of a completed survey I verified the presence of a signed and dated consent form. A box on the first page of the corresponding survey was checked and initialed to document that the consent form was correctly signed and dated. The check box on the consent form was marked to document that the check box and initialization was marked on the corresponding survey. Following these checks the consent form was separated from the survey. Surveys were numbered in the order they were received; once the survey and consent form were separated the two documents are unable to be re-linked.

Survey results were entered using the survey software Qualtrics as a data entry tool. In addition to the answers completed by participants, I included additional information during data entry to account for the survey number, whether there was a signed consent form, and the survey language. Following the completion of all data entry the data was exported for analysis in Microsoft Excel.

3.4 Analysis

My hypothesis is that equine care givers using Regu-Mate do not follow handling protocols that protect them from exposure to altrenogest. I compared their handling safety to the information self-reported to have come from their veterinarians, the number of horses that people treat, length of drug use and the reason for using the drug.

The survey questions generated ordinal, nominal and categorical data. Analysis was performed by using cross tabulation/pivot tables, frequency distributions and descriptive statistics in Excel. The descriptive statistics utilized included (as appropriate): count, mean, median and mode.

3.5 Literature Search

I used Tufts University library's electronic "Multi-Search" tool in my literature search, which allowed me to concurrently search databases including but not limited to Academic OneFile, PubMed, Web of Science and JSTOR. Multiple trips to Tufts University's veterinary school library provided a wealth of articles, books and documents that were unavailable through other venues. Articles that I was unable to find at the library or through the library's online network I requested through Interlibrary Loan; I used BLC WorldCat to access articles and books that were unavailable in the United States. I also worked with international sources and reviewed the European Medicines Agency's (EMA) published reports on the drug. Through a document access request, I obtained a list of the studies EMA used in their review as well as copies of the unpublished reports. These unpublished reports included studies performed by the pharmaceutical company. Using a Freedom of Information Act (FOIA) request to the U.S. Food and Drug Administration (FDA) I obtained copies of everything submitted to the FDA related to

Regu-Mate's approval process, including unpublished reports. The FDA has adverse drug experience reports available on their website that provides a summary of all reported adverse events related to the drug; I obtained the detailed report information through an additional FOIA request. All information requests are included in Appendix A.

4 Results

In conducting this research, I provided paper surveys to veterinary professionals for distribution to their clients. A total of 369 surveys (312 in English, 40 in Spanish and 17 in Portuguese) were sent to veterinarians and 66 were completed and returned to me. Of the 66 returned surveys, only 64 were valid and completed surveys that fulfilled all of the requirements of the methodology and Institutional Review Board (IRB) (Section 3.1.3). All the returned surveys are in English.

4.1 Survey Questions

The following section summarizes the findings from the survey questions. The questions are grouped into Basic Demographics, Interaction with Regu-Mate, Exposure and Symptoms, and Education.

4.1.1 Basic Demographics

Counts of responses to survey questions were translated into a percentage which is shown in Appendix E; all the charts in this Chapter show the percentages. Basic demographics are presented in Figure 4-1 through Figure 4-4. Of all respondents, 63% self-identified as owner/riders, 41% as barn managers and 38% as veterinary professionals; veterinary technicians and veterinarians were combined into one category as veterinary professionals. One person identified their role with horses as “other”. Slightly less than two thirds of respondents reported being involved in the equine reproduction and/or breeding industry. Only 5% of respondents did not use Regu-Mate (Figure 4-5).

Figure 4-1: Sex demographics of survey respondents

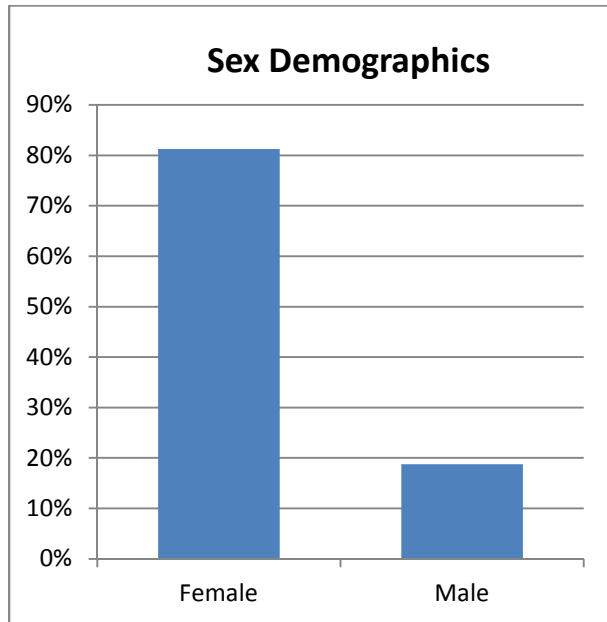


Figure 4-2: Age demographics of survey respondents

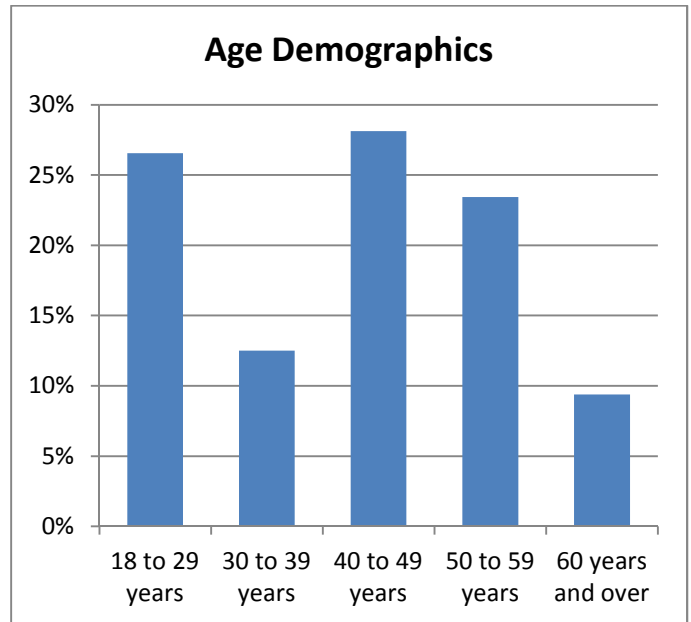


Figure 4-3: Respondent self-identification of equine roles

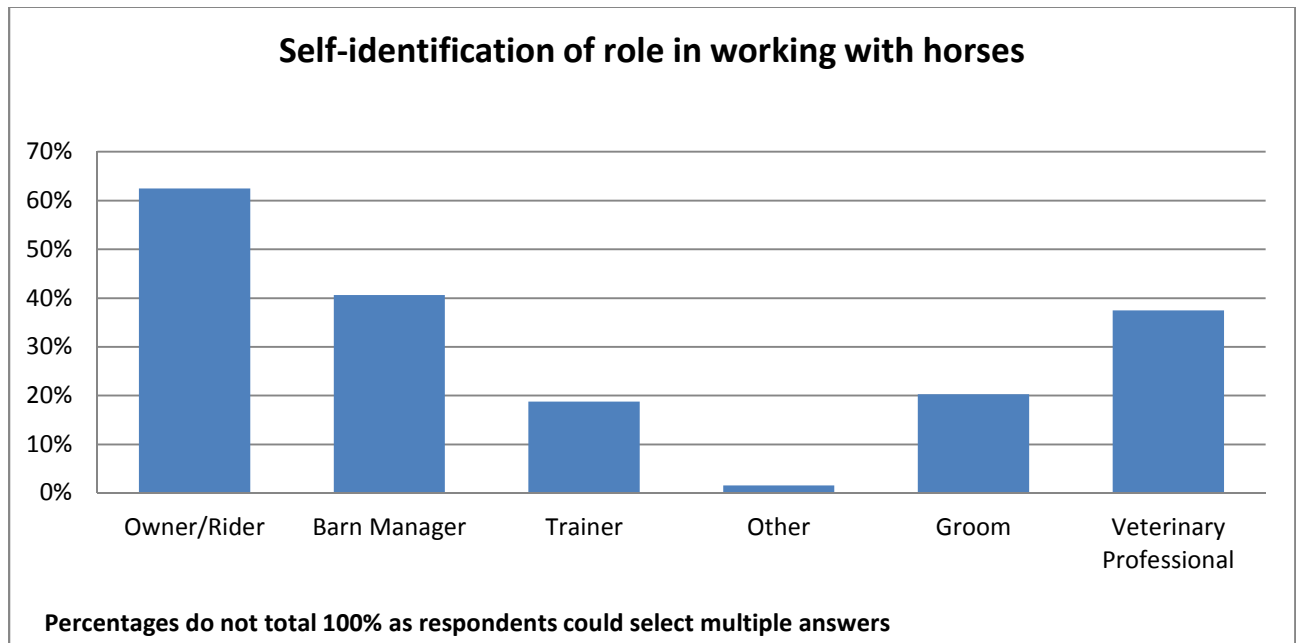


Figure 4-4: Respondent involvement in the equine reproduction/breeding industry

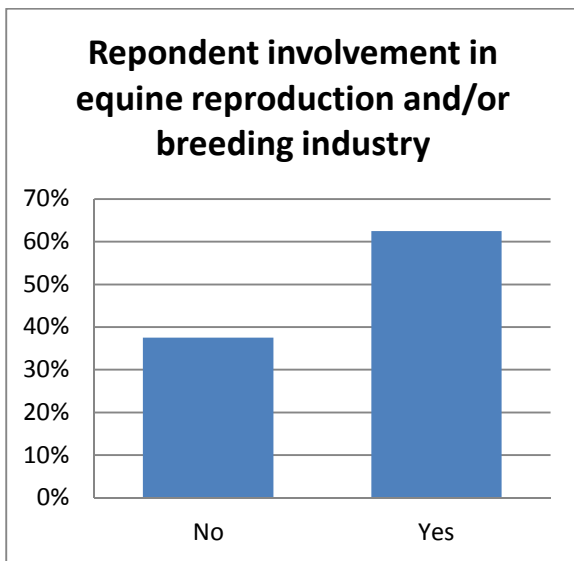
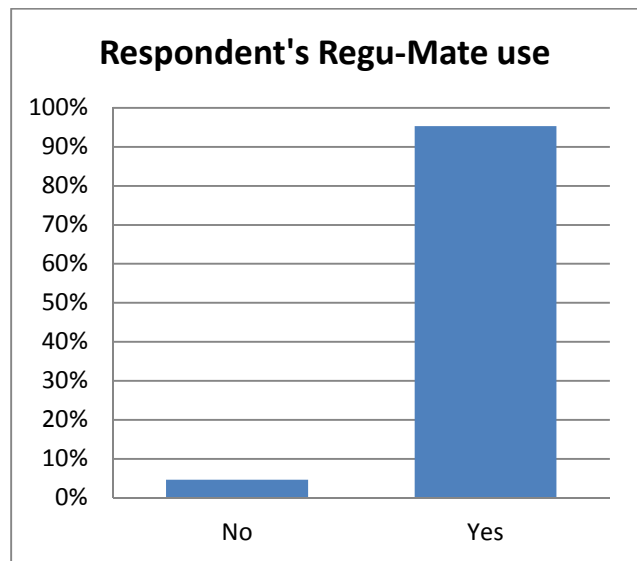
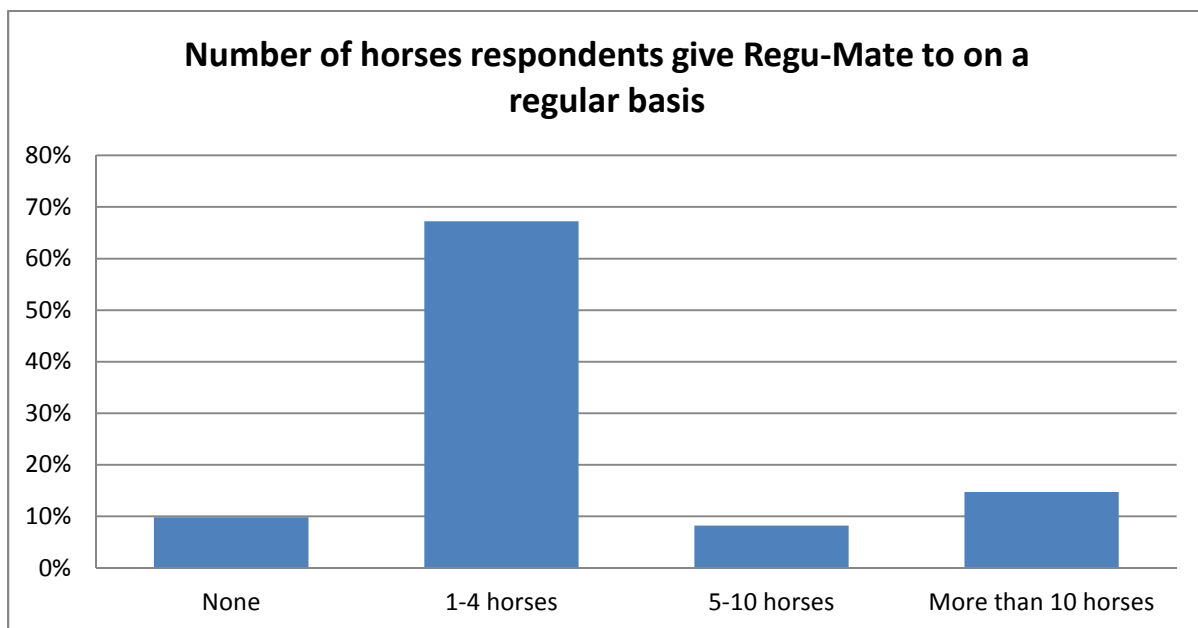


Figure 4-5: Percent of respondents who use Regu-Mate



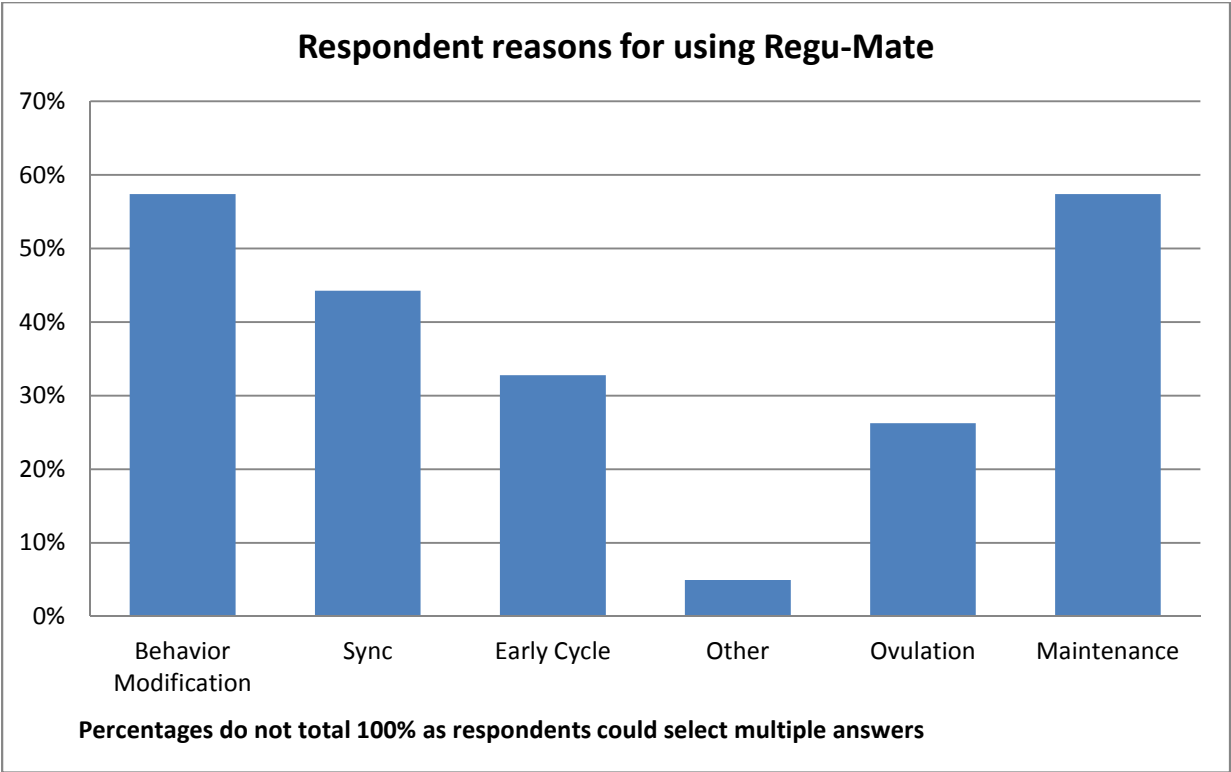
The majority of respondents (67%) regularly give Regu-Mate to 1 to 4 horses, with 15% reporting more than 10 horses and 8% reporting 5 to 10 horses; 10% of respondents are not regularly giving any horses Regu-Mate (Figure 4-6).

Figure 4-6: Number of horses administered Regu-Mate on a regular basis by respondents



Of all respondents, 57% use Regu-Mate for behavior modification, 57% use it for maintaining a pregnancy, 44% for synchronizing estrus with other mares, 33% to help a mare cycle earlier in the spring, 26% to time ovulation, and 5% for other purposes (Figure 4-7). Respondents were able to select more than one answer and percentages do not add to 100%.

Figure 4-7: Respondent reasons for using Regu-Mate



Respondents most commonly (49%) reported handling Regu-Mate five times per week or more with 30% handling it three times per month or less (Figure 4-8). Only one respondent (3%) reported not regularly handling Regu-Mate and one respondent handles Regu-Mate one time per week. Almost half (49%) of all respondents reported having handled Regu-Mate for five or more years with the second most common response (33% of all respondents) having handled Regu-Mate for only one year or less (Figure 4-9).

Figure 4-8: How often respondents report regularly handling Regu-Mate

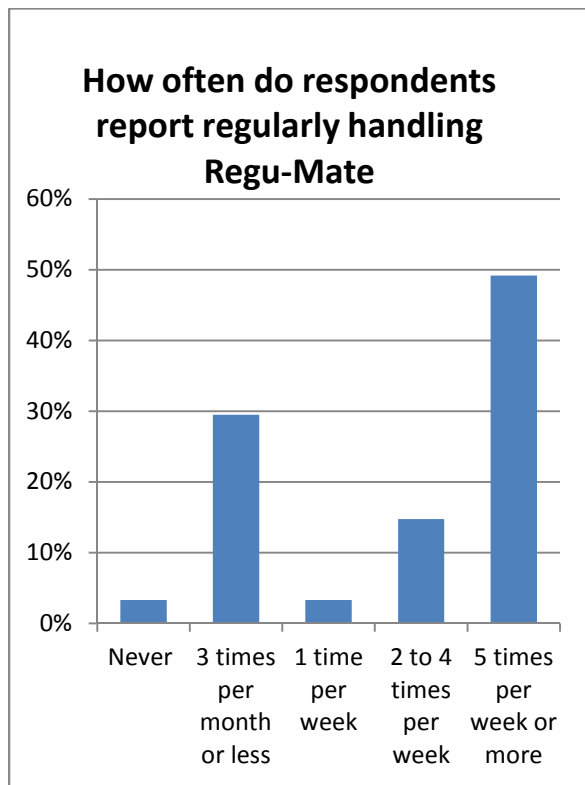
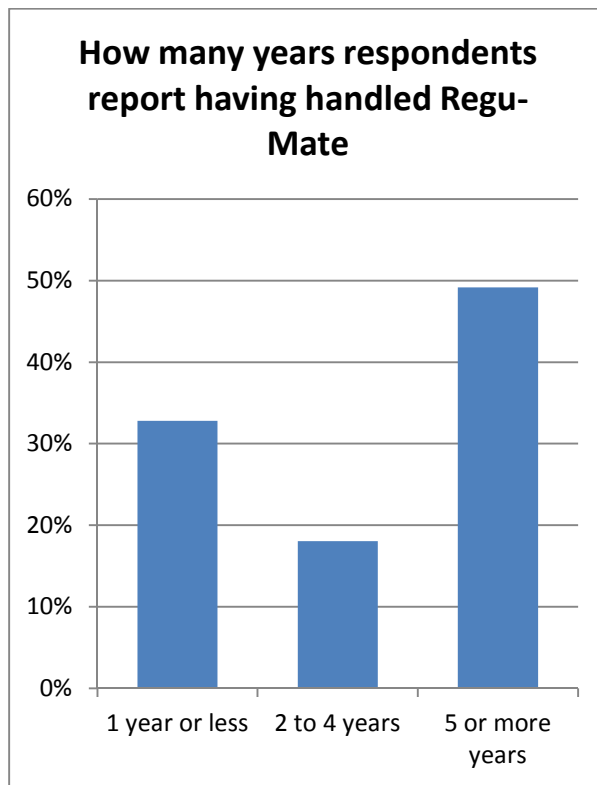


Figure 4-9: Number of years respondents report handling Regu-Mate



4.1.2 Questions about Regu-Mate Interaction

A total of 82% of all respondents wear gloves at least occasionally while 18% report not using gloves (Figure 4-10). Of those who wear gloves 78% report replacing their gloves every time they administer Regu-Mate (Figure 4-11).

Figure 4-10: How often do respondents report using gloves when dosing, dispensing and administering Regu-Mate

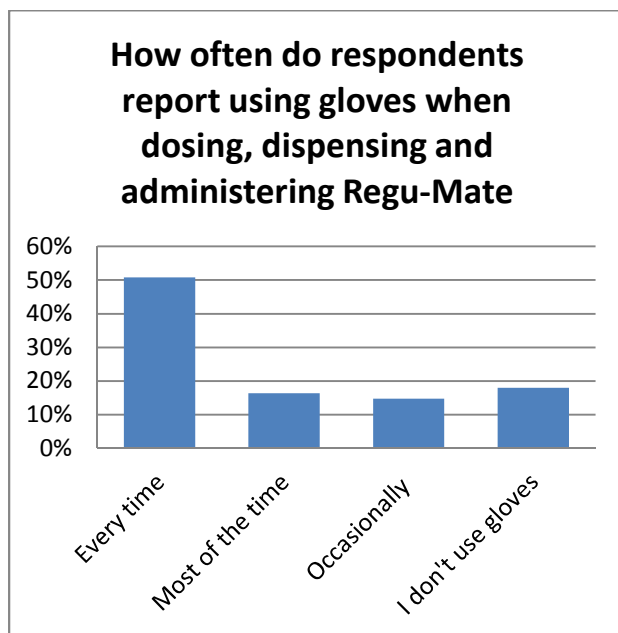
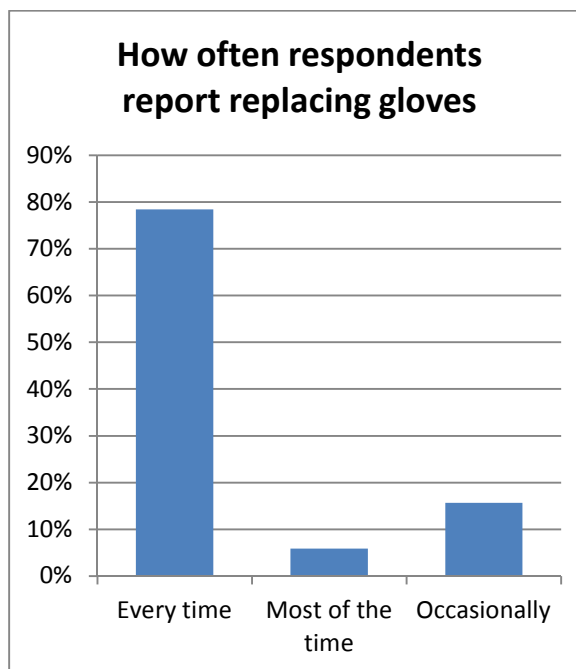
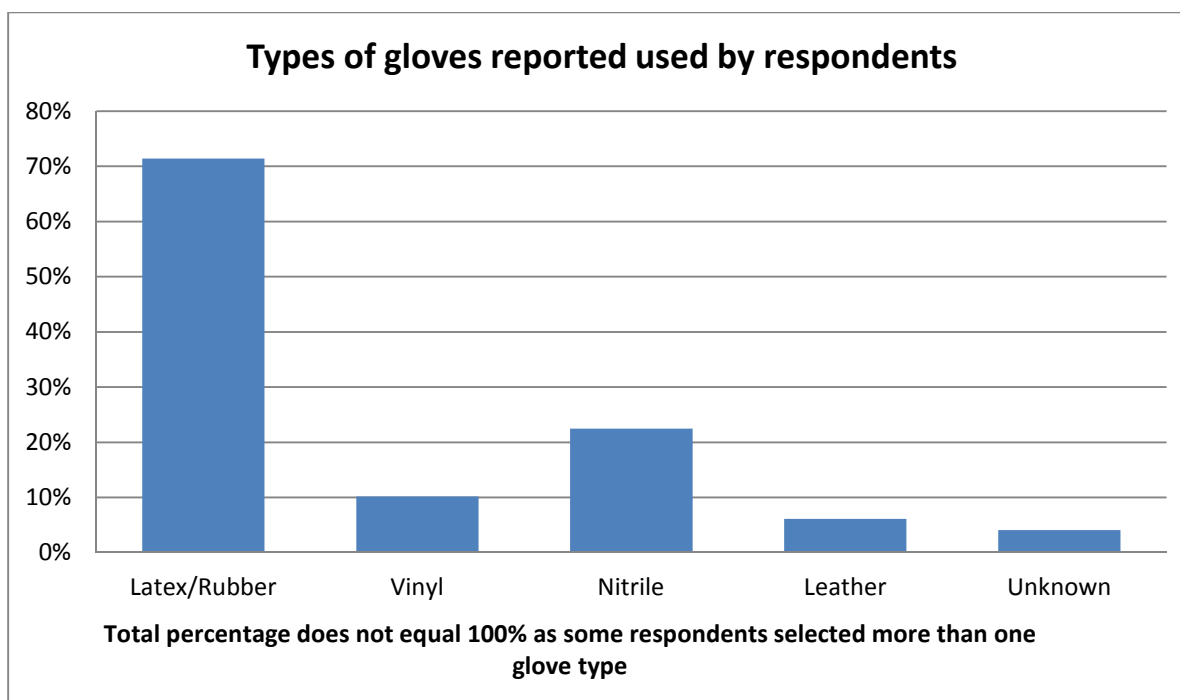


Figure 4-11: How often respondents who wear gloves report replacing gloves



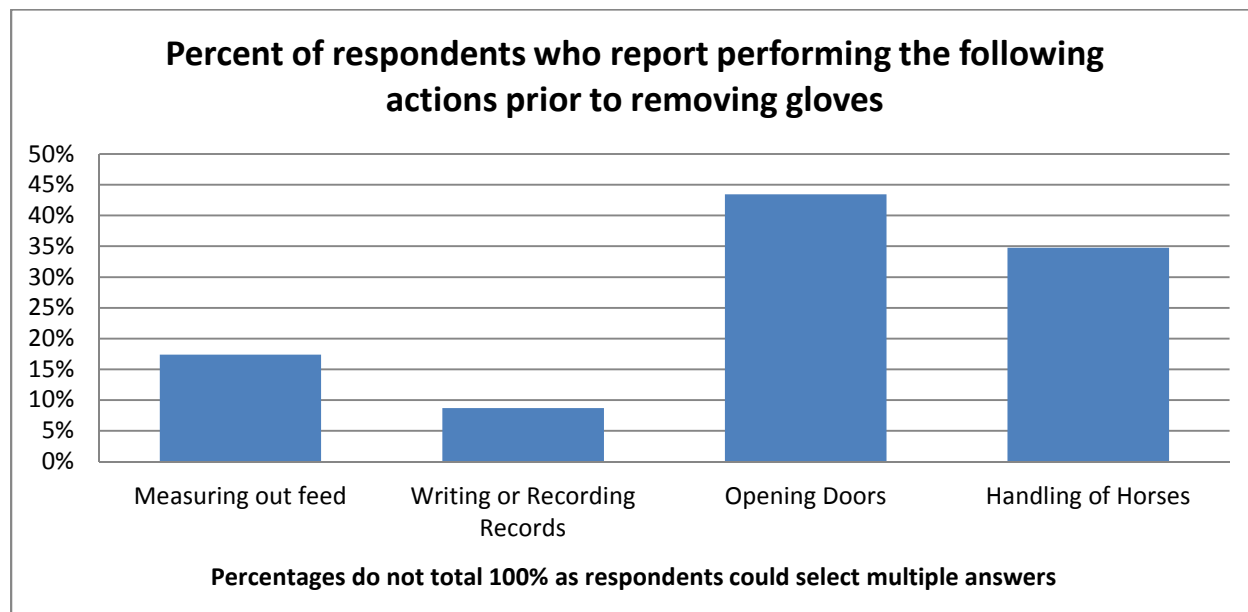
The most commonly used glove type, by 71% of all respondents, is latex/rubber followed by nitrile gloves at 22% (Figure 4-12). More than one option was selected by some respondents.

Figure 4-12: Types of gloves respondents report using



Of the respondents who reported performing actions prior to removing their gloves, 43% open doors, 35% handle horses/equipment, 17% measure out feed, and 9% write/record records (Figure 4-13).

Figure 4-13: Respondents who reported performing the following actions prior to removing their gloves



Of all respondents, 56% reported washing their hands immediately after dosing, dispensing and administering Regu-Mate (Figure 4-14), however 84% who reported performing an action prior to washing their hands reported opening doors and handling horses/equipment. Additionally 26% reported eating/drinking/smoking, 32% write records and 29% measure feed prior to washing their hands (Figure 4-15).

Figure 4-14: Respondent hand washing behavior

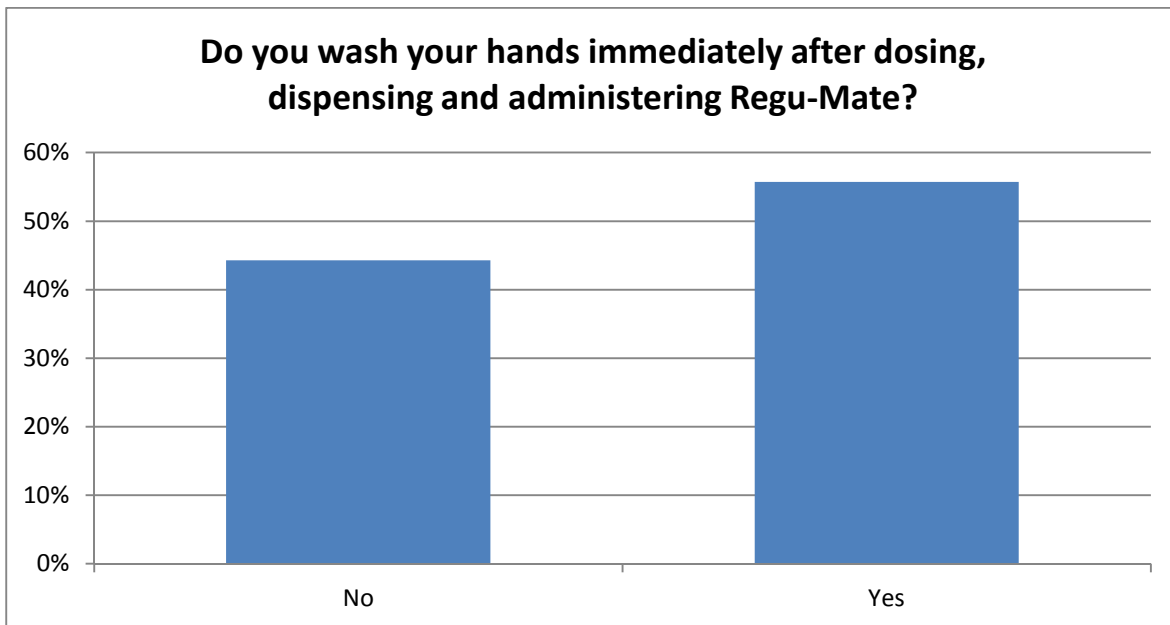
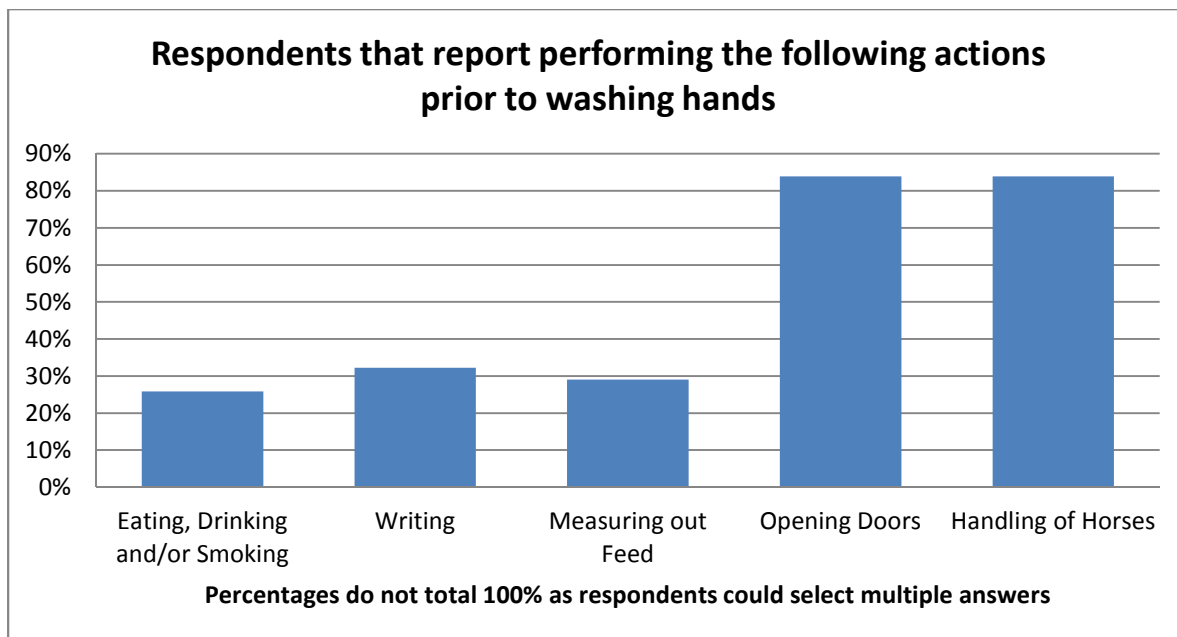
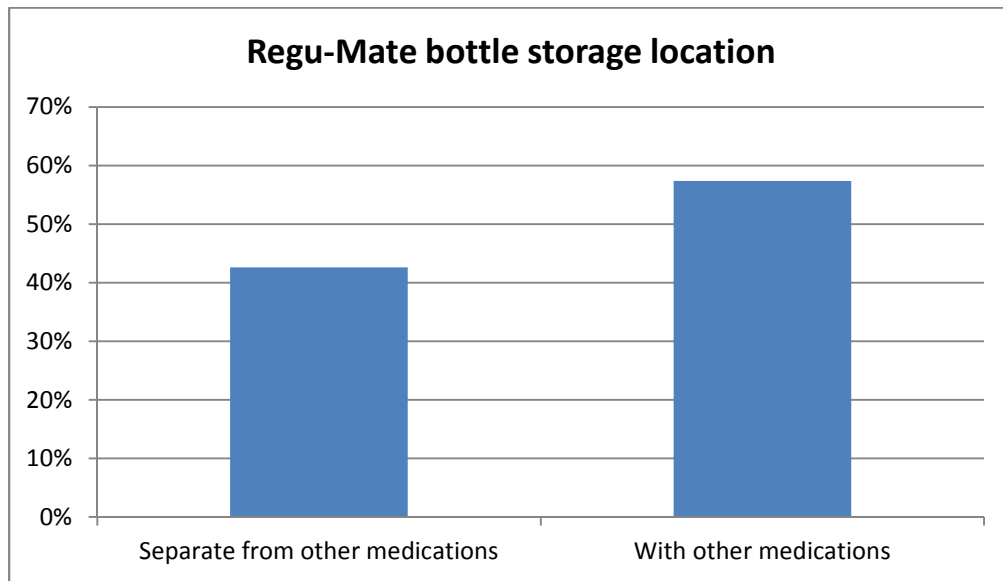


Figure 4-15: Actions performed prior to washing hands



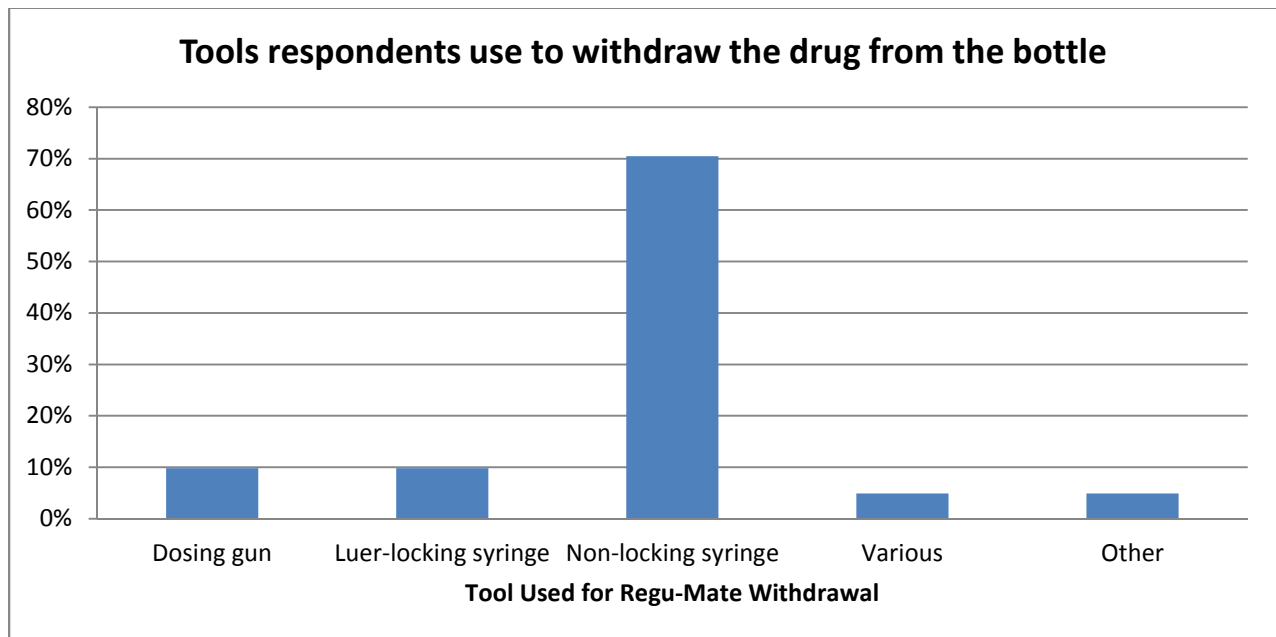
Respondents reported storing their Regu-Mate bottle with other medications more often than separate from other medications, 57% and 43% respectively (Figure 4-16).

Figure 4-16: Regu-Mate bottle storage location



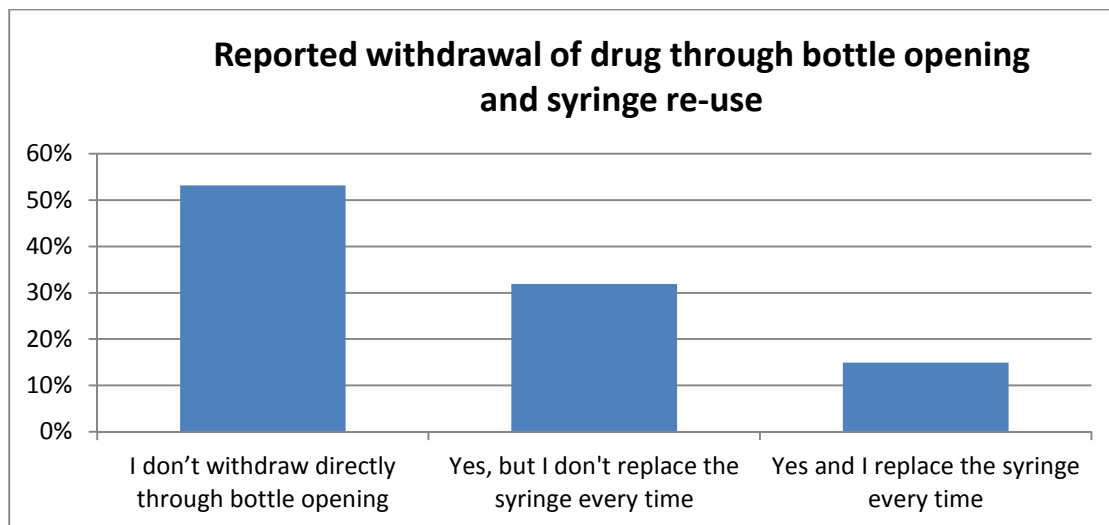
An overwhelming majority of respondents use a non-locking syringe (70%) while 10% or fewer use each of the other methods (Figure 4-17). The category “various” includes any instance where a respondent selected more than one of the tools.

Figure 4-17: Tools respondents use to withdraw the drug from the bottle



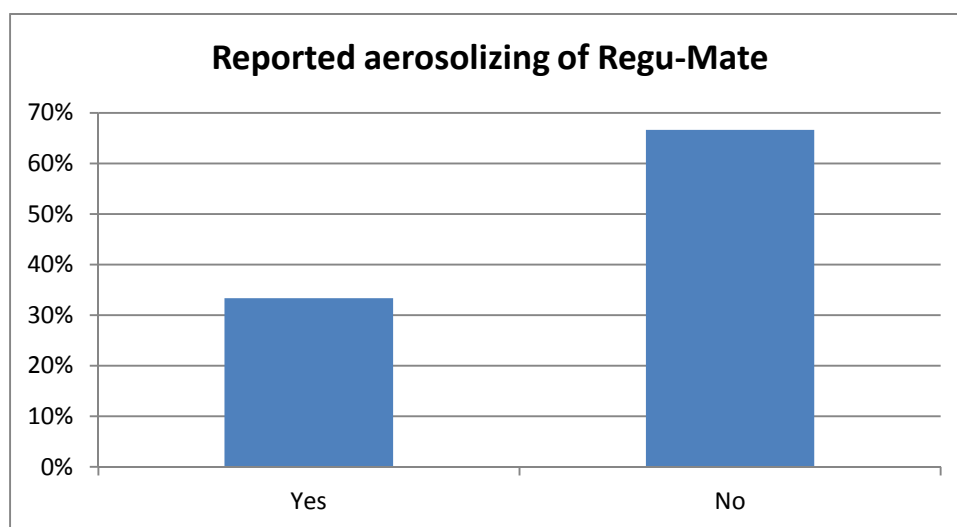
More than half of respondents who reported using a Luer-locking or non-locking syringe; (53%) reported not withdrawing the drug directly through the bottle opening, 32% withdraw through the opening but do not replace the syringe each time, and 15% withdraw through the opening while replacing the syringe every time (Figure 4-18).

Figure 4-18: Reported withdrawal of drug through the bottle opening and reuse of the syringe



One third of respondents reported aerosolizing (forcefully clearing the syringe or dosing gun to remove the last bit of the drug or extra air) Regu-Mate (Figure 4-19).

Figure 4-19: Reported forceful clearing the syringe or dosing gun to remove the last bit of drug or air



Respondents reported only dosing Regu-Mate directly into the horse's mouth (47%), only mixing Regu-Mate with grain (30%), and using both methods of administration (23%) (Figure 4-20). Two thirds of respondents use dedicated grain/feed buckets for use only with Regu-Mate topped feed (Figure 4-21).

Figure 4-20: How respondents administer Regu-Mate to their horses

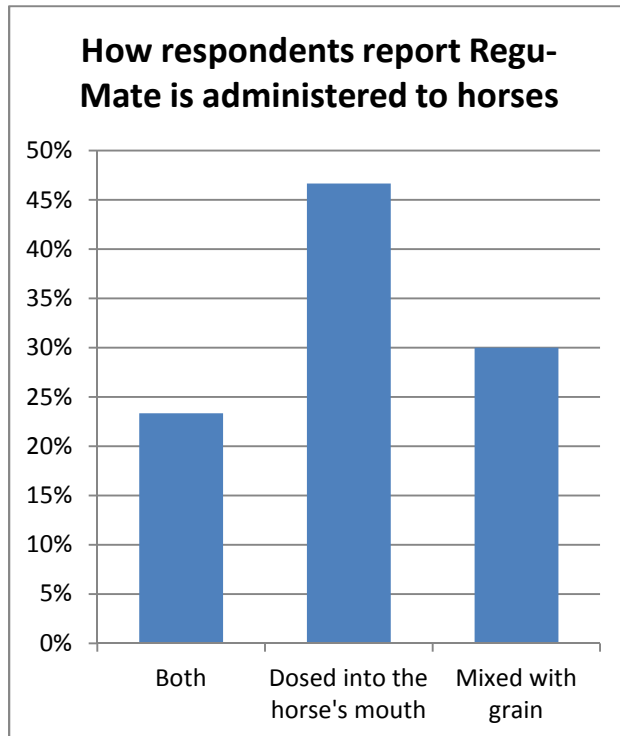
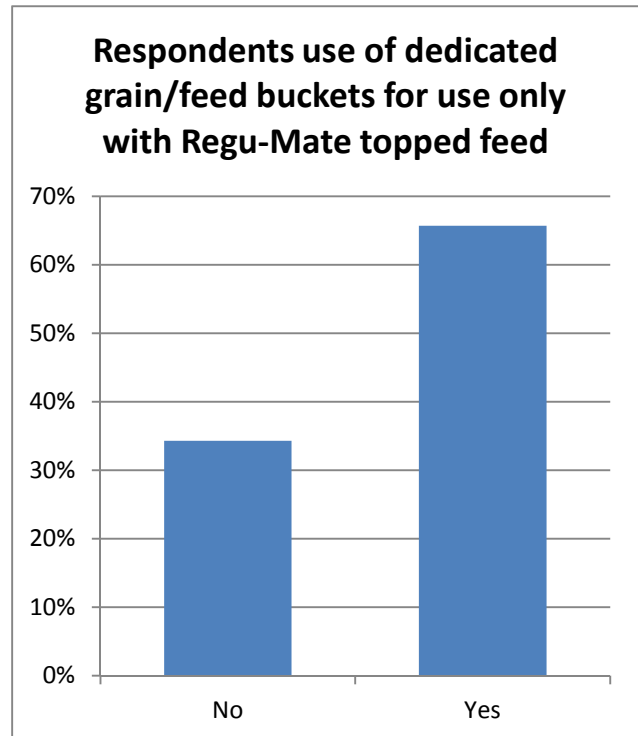


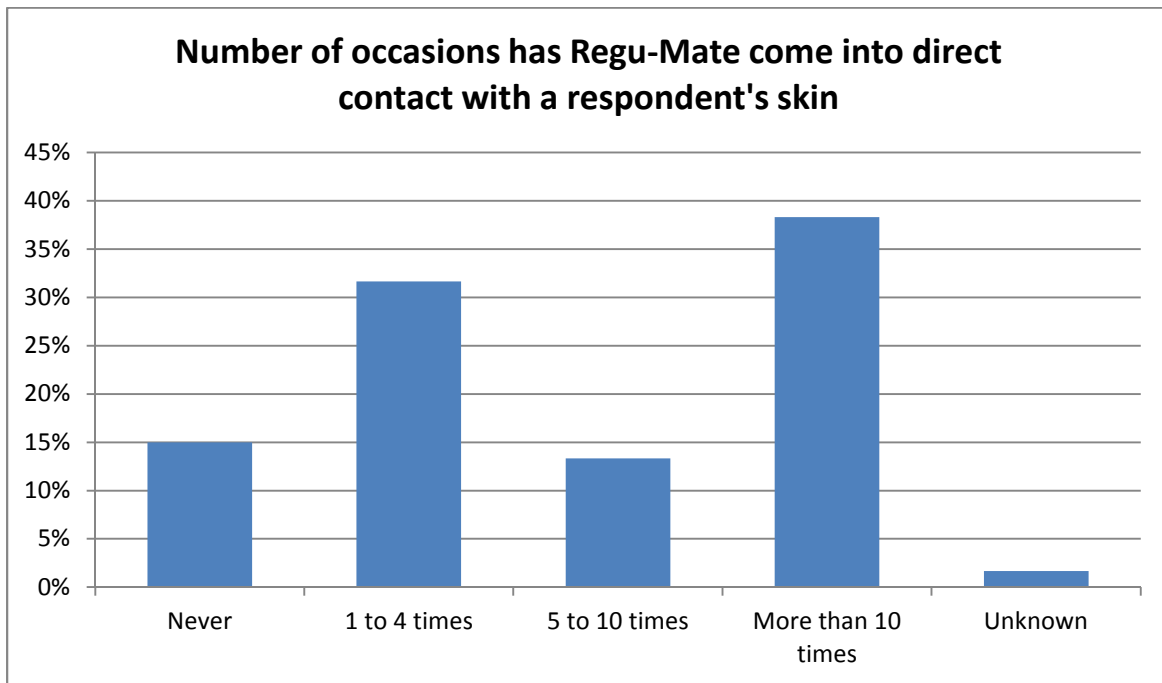
Figure 4-21: Use of dedicated buckets for Regu-Mate topped feed



4.1.3 Exposure and Symptoms

The number of times that respondents reported Regu-Mate coming directly into contact with their skin is shown in Figure 4-22.

Figure 4-22: Reported times Regu-Mate has come into direct contact with a respondent's skin



Of all respondents 21% report symptoms associated with Regu-Mate's direct contact with their skin. Figure 4-23 and Figure 4-24 present the number of occasions that females and males, respectively, reported that Regu-Mate came into direct contact with their skin. The percentage of male and female respondents who reported symptoms are within 1 percentage point. Of female respondents, 18% reported one or more symptoms that they associate with contact with Regu-Mate. Symptoms reported by females include hot flashes, headaches, a change in menstrual period length, change in menstrual flow, change in length of menstrual cycle, skipped period, abdominal/menstrual cramps, prolonged pregnancy, progesterone stimulated fibroid, and acne. The most commonly reported symptoms were changes in menstrual length/flow, cycle length, skipping a period and cramps. All age ranges reported experiencing symptoms except 60 years and over. Of male respondents, 17% reported having one or more symptoms that they associate with contact with Regu-Mate. Symptoms reported by males include hot flashes, headache and change in sex drive.

Figure 4-23: Female respondents who reported symptoms they associate with Regu-Mate contact

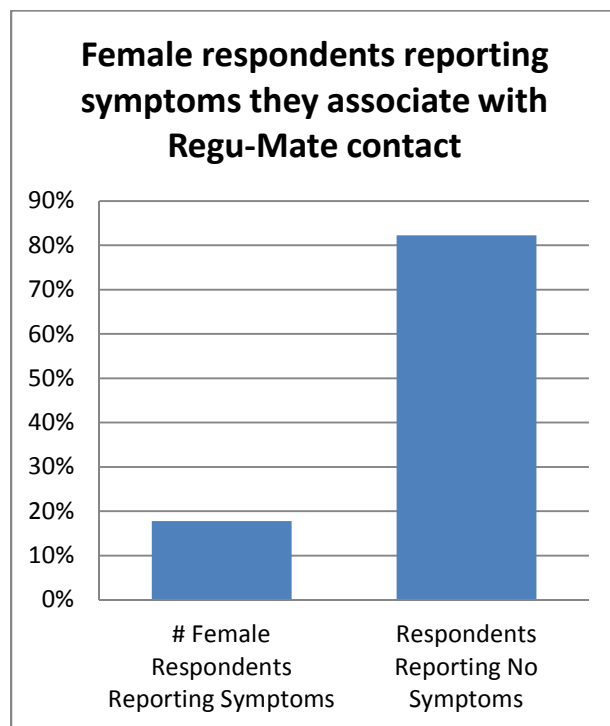
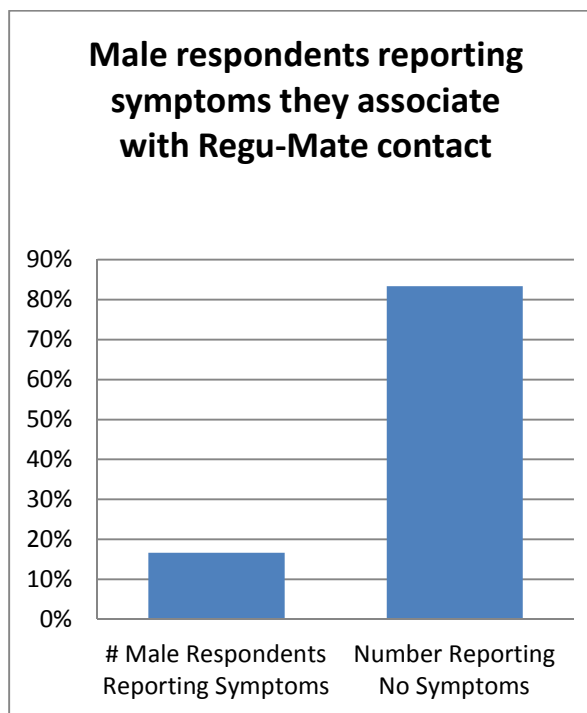


Figure 4-24: Male respondents who reported symptoms they associate with Regu-Mate contact



4.1.4 Education, learning and restrictions

Figure 4-25 shows a breakdown of where respondents learn about precautions that should be taken when administering Regu-Mate and Figure 4-26 shows which aspects of Regu-Mate precautions the respondents reported were discussed with a veterinarian. Both graphs present a breakdown by age group as well as by all respondents. The category of scientific articles was written in as “other” by multiple respondents.

Figure 4-25: Where respondents learn about Regu-Mate Precautions

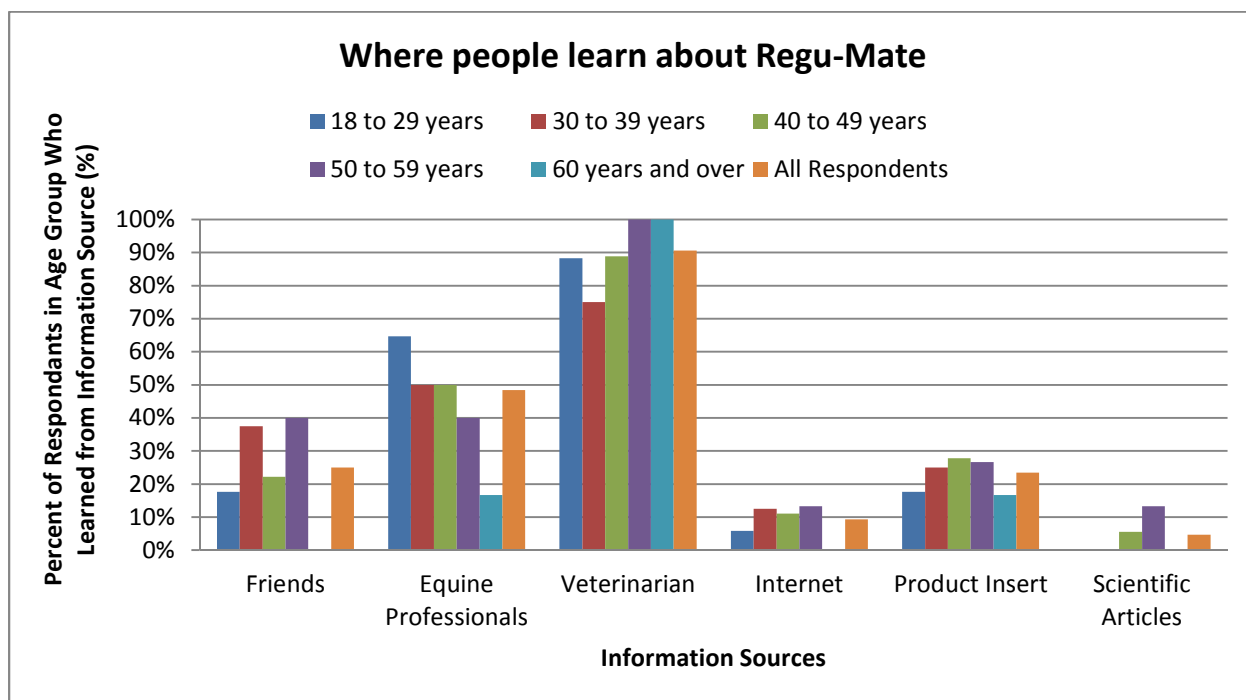
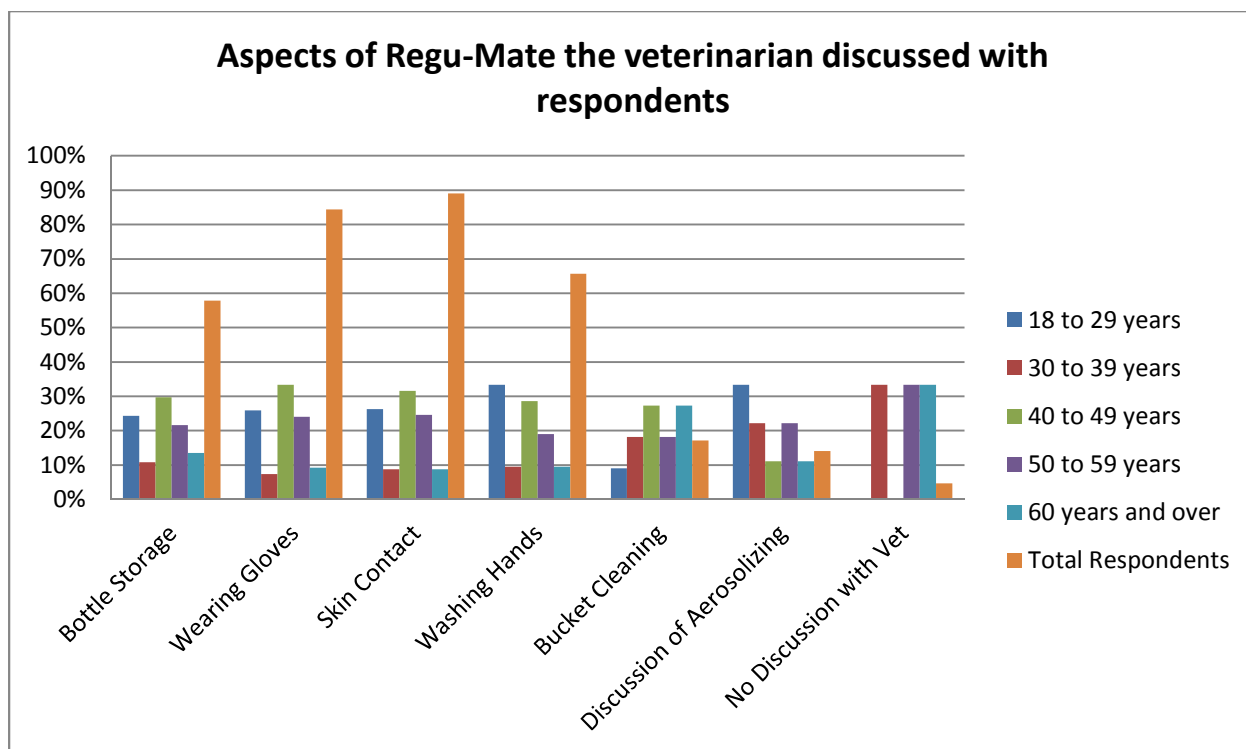
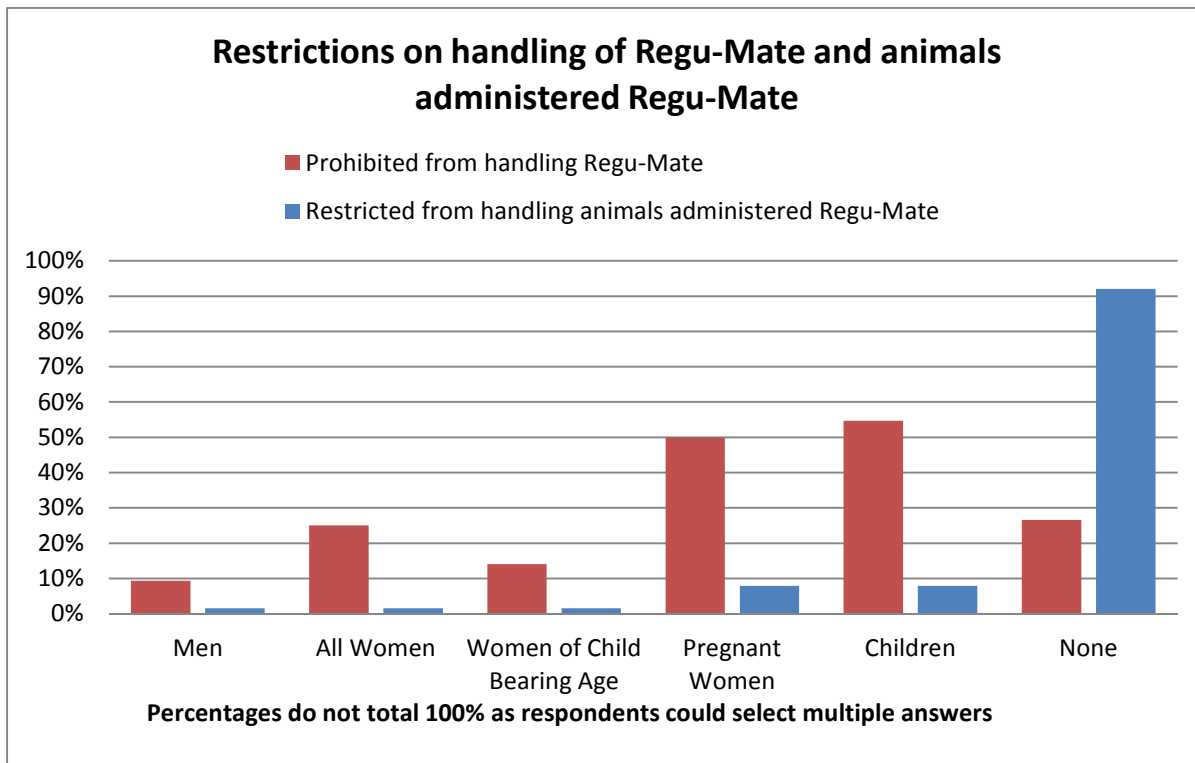


Figure 4-26: Aspects of Regu-Mate precautions the veterinarian discussed with respondents



Children and women who are pregnant (or may become pregnant) are the most common group of people who are prohibited from handling Regu-Mate in the respondents' facilities, yet 27% of all respondents do not prohibit anyone from handling Regu-Mate. Of all respondents, 92% do not have any restrictions on who handles animals that are administered Regu-Mate (Figure 4-27). Respondents could select multiple answers.

Figure 4-27: Restrictions on handling of Regu-Mate and animals administered Regu-Mate



4.2 Comparisons between Questions

Analysis of the data is descriptive. Some comparisons were not possible to examine due to the limited sample size; Section 4.3 presents the comparisons that could not be made.

4.1.5 Demographic Comparisons

Several demographic questions were asked of respondents to provide an overview of the people who responded to the survey.

Sex

Figure 4-28 through Figure 4-31 present the percent of males/females in each age group as well as the glove use, glove replacement and hand washing behavior for males versus females. Of male respondents, 42% reported not using gloves while only 12% of women reported never using gloves. A quarter of men reported using gloves every time they handle Regu-Mate while 57% of women report the same behavior. Glove replacement behavior between sexes is fairly similar. Men are less likely than women to wash their hands following handling Regu-Mate (42% vs. 59%).

Figure 4-28: Percent of males/females in each age group

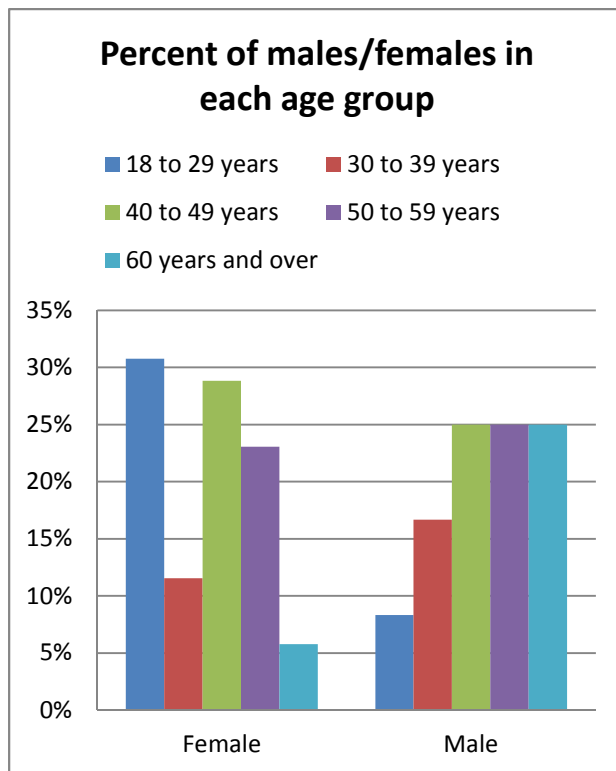


Figure 4-29: Glove use by female/male respondents

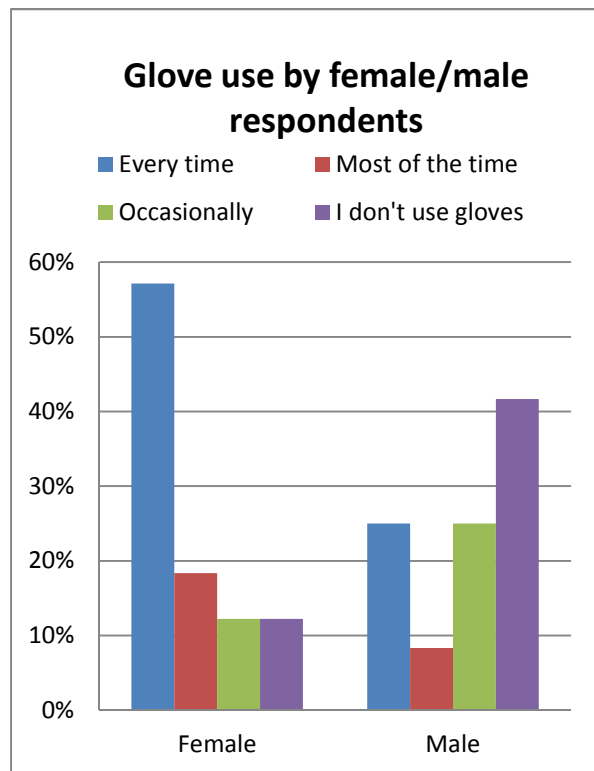


Figure 4-30: Glove replacement by female/male respondents

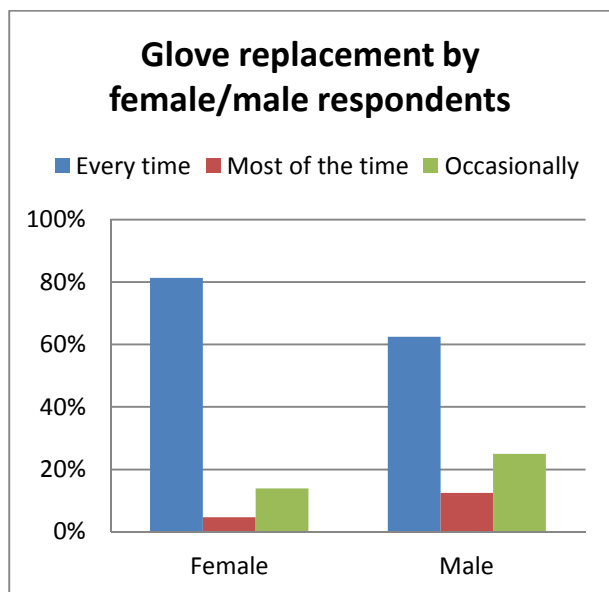
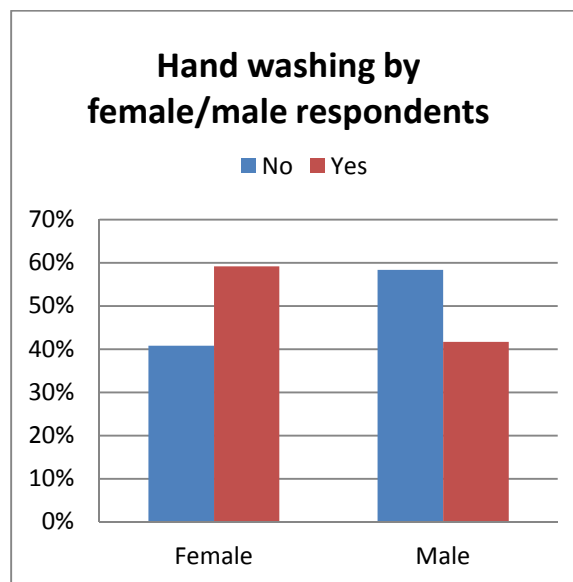


Figure 4-31: Hand washing by female/male respondents



There is little difference between the sexes in how respondents withdraw Regu-Mate from the bottle (Figure 4-32). Men are more likely to report withdrawing Regu-Mate through the bottle opening and of those who do all reported not replacing the syringe with each application (Figure 4-33). A majority of both men and women do not aerosolize Regu-Mate when clearing out their syringe or dosing gun; however this is represented by a larger percentage of women (70%) then men (55%) (Figure 4-34).

Figure 4-32: How male/female respondents withdraw the drug from the bottle

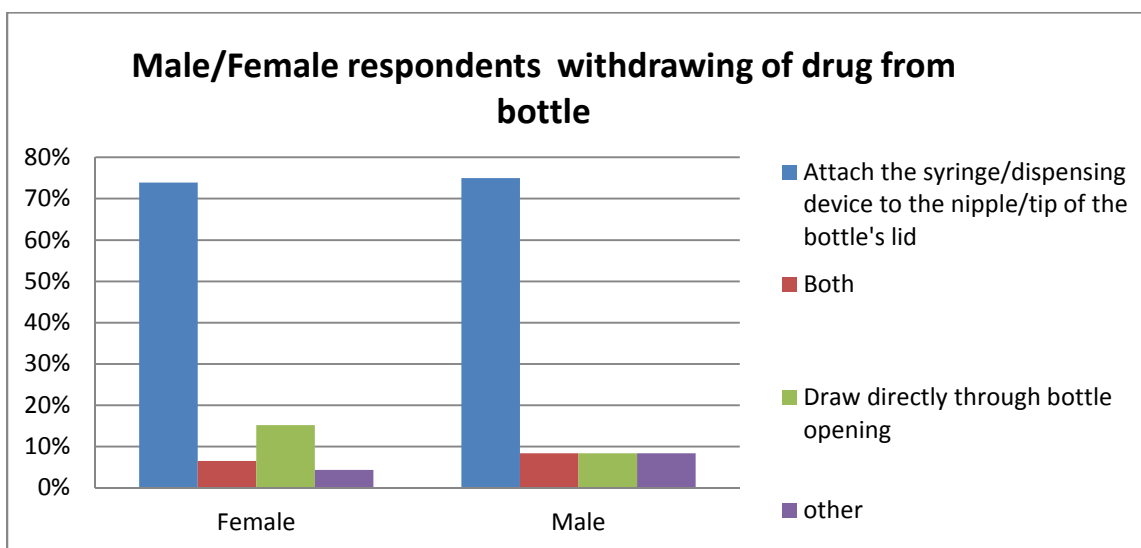


Figure 4-33: Syringe replacement by females/males

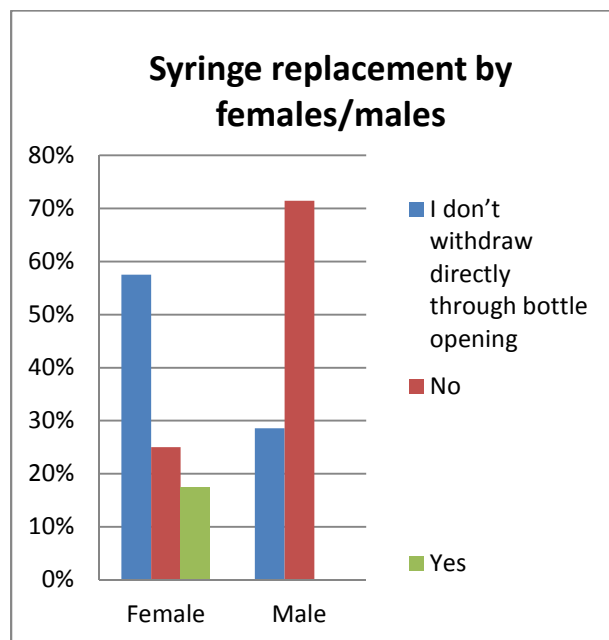
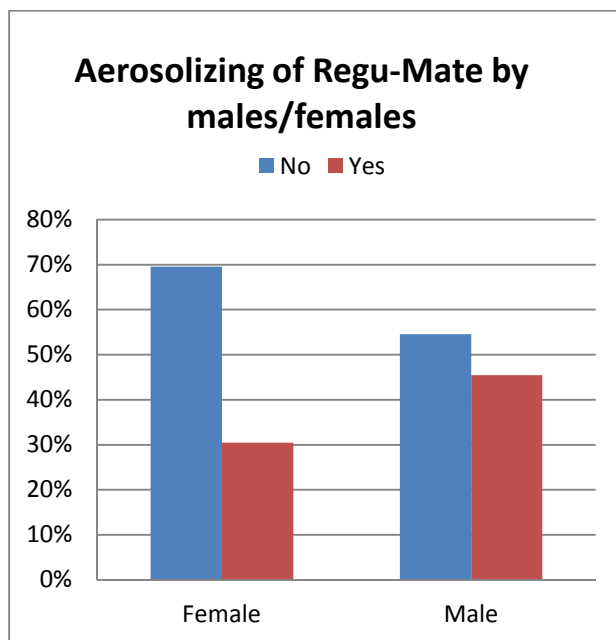


Figure 4-34: Aerosolizing of Regu-Mate by males/females



Male respondents reported learning from veterinary professionals, the internet and the product insert more often than females, while more females reported learning from friends and equine professionals than males (Figure 4-35).

Figure 4-35: Percentage of females/men who report learning from the following sources

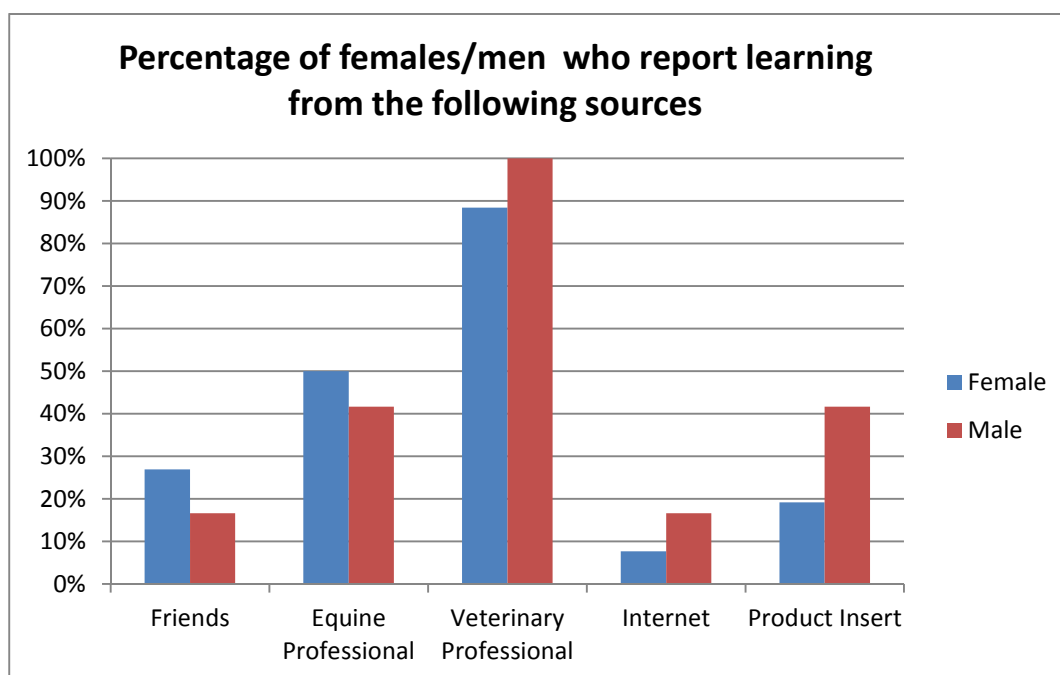


Figure 4-36 presents the percentage of all female respondents who reported females were prohibited from handling Regu-Mate. Figure 4-37 shows these same women when classified by their age; the category all women shows women of all ages who reported prohibitions on women of all ages (this category is the same in both Figure 4-36 and Figure 4-37). Of the female respondents who are of child-bearing-age (18 through 49), 22% reported that women of child-bearing-age were prohibited from handling Regu-Mate at their facility.

Figure 4-36: Females who report handling Regu-Mate is prohibited

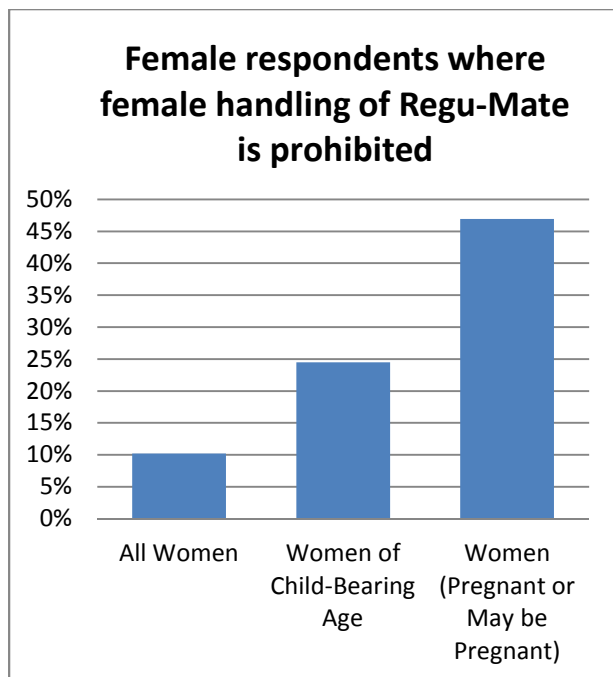
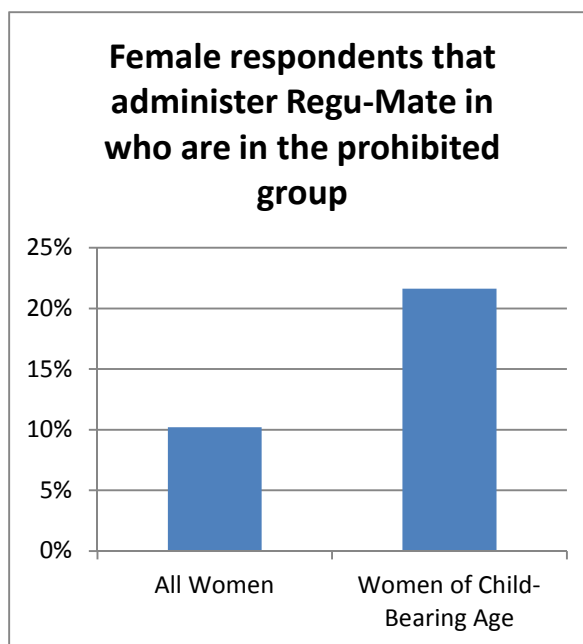


Figure 4-37: Female respondents in the group they report as prohibited from handling Regu-Mate



Age

The largest percentage of trainers and grooms are 40 to 59 years of age while owners/riders and barn managers are more evenly distributed among the ages. Veterinary professionals are the youngest group with 46% being between 18 and 29 years of age (Figure 4-38). Of the respondents who have handled Regu-Mate for two to four years, 45% are between the ages of 50 to 59, of those handling Regu-Mate for five or more years 40% are 40 to 49 years of age and of those handling the drug for one year or less 35% are 18 to 29 years of age (Figure 4-39).

Figure 4-38: Relationship with horses divided by age

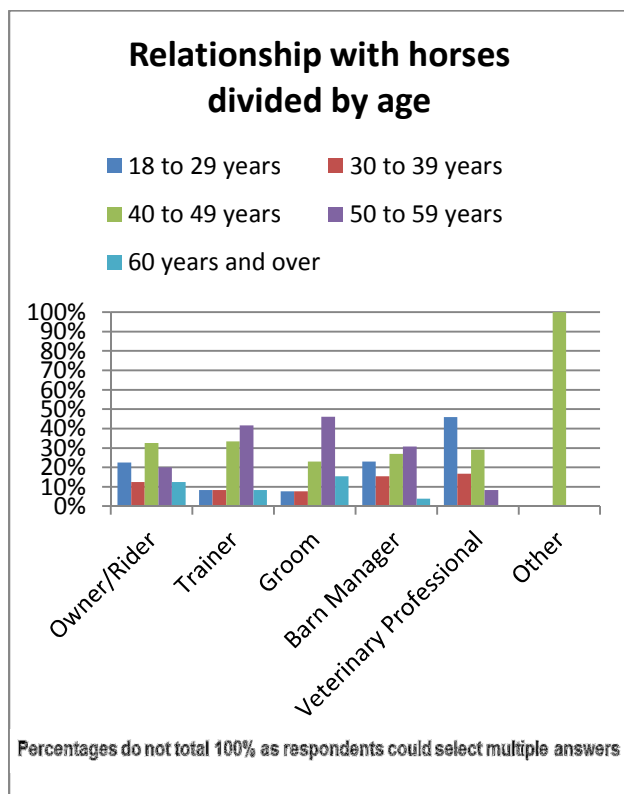
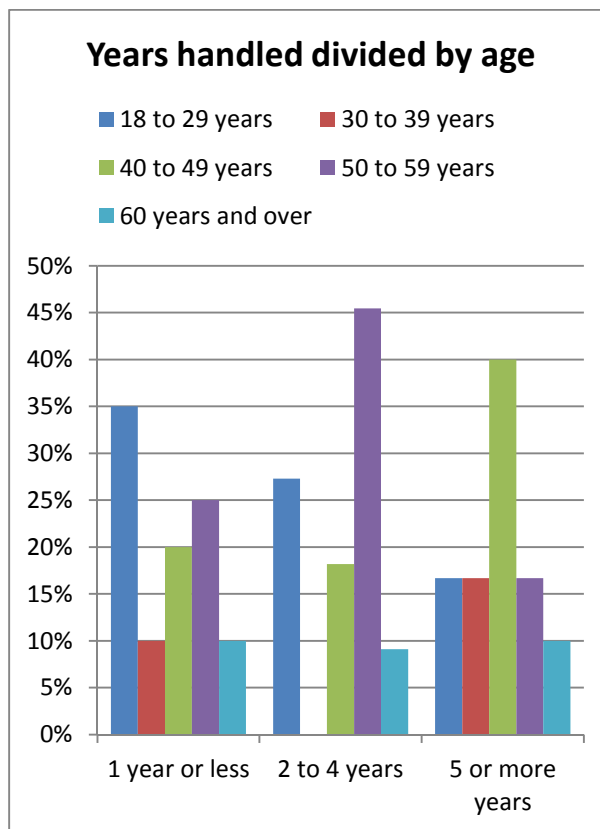


Figure 4-39: Years handled divided by age



A larger percentage of respondents in the age groups of 18 to 29 as well as 60 and over reported using gloves every time they handle Regu-Mate (67% for both) than those in the 30 to 59 year age groups (ranging from 40% to 44%). Respondents in the age range of 30 to 39 are most likely of any age range to report (43%) not using gloves (Figure 4-40). Hand washing behavior follows a similar trend to reported glove use when looking at safe behavior by age groups; a majority of respondents who are 18 to 29, 50 to 59 as well as 60 and over wash their hands after handling Regu-Mate. A majority of respondents who are 30 to 39 do not wash their hands after handling Regu-Mate (Figure 4-41).

Figure 4-40: Glove use by each age group

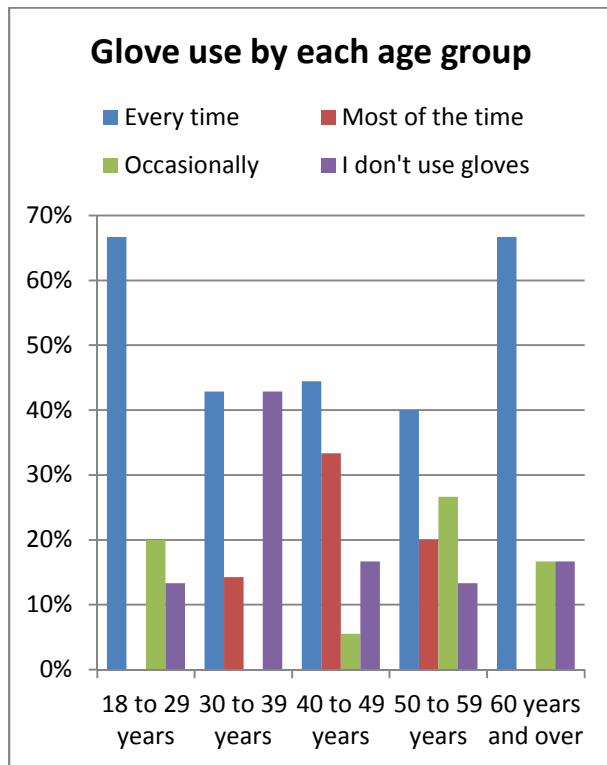


Figure 4-41: Hand Washing by Age Group

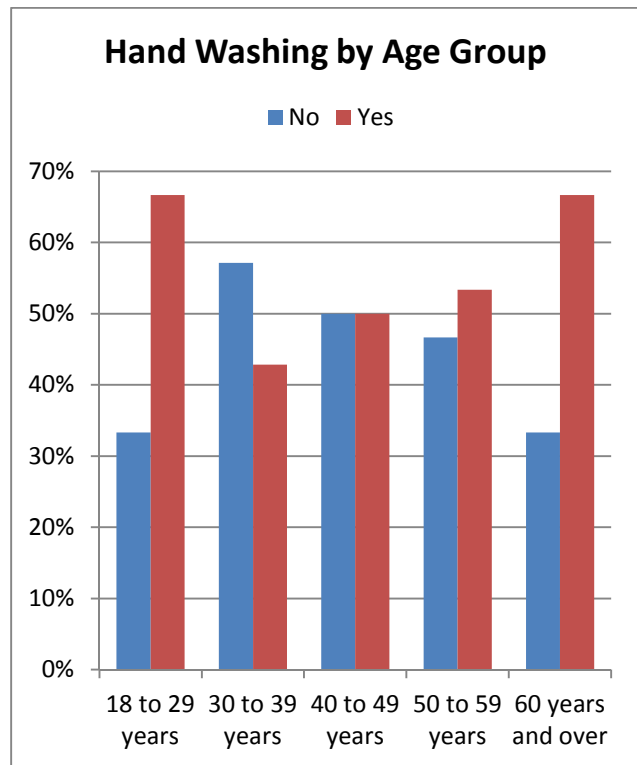


Figure 4-42 presents bottle storage behavior based on the age of the respondent; in all age categories except for 50 to 59 years of age the majority of respondents reported storing Regu-Mate with other medications. Regardless of age, a large majority of respondents withdraw Regu-Mate from the bottle by attaching the dispensing device to the top of the bottle's lid (Figure 4-43). Syringe replacement by those who use syringes and draw through the bottle opening (Figure 4-44) consistently has more than 60% of respondents in each age group (no respondents in the 30-39 year range meet the requirements for this graph) reporting not replacing the syringe. Figure 4-45 shows aerosolizing behavior by age group; of those in the 18 to 29 and 50 years and greater age groups 77% or more in each age group reported not aerosolizing the drug when emptying the dosing device.

Figure 4-42: Bottle storage by age group

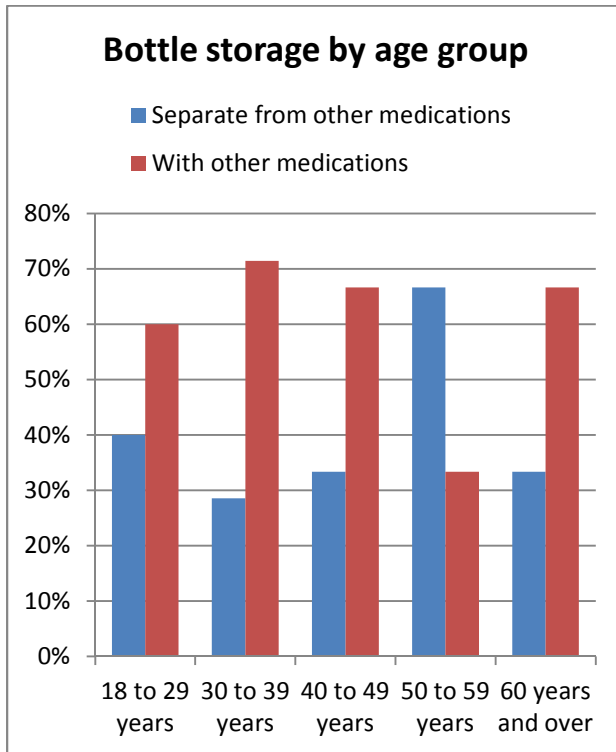


Figure 4-43: Drug withdrawal method by age group

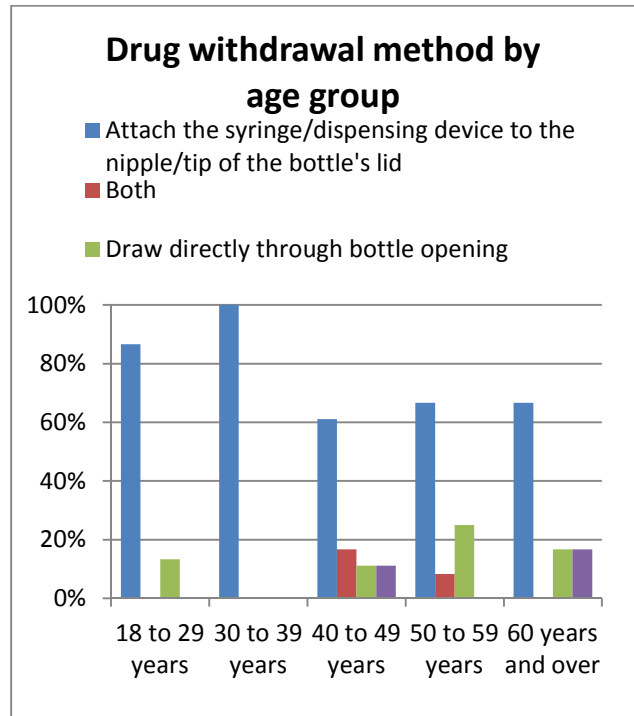


Figure 4-44: Syringe replacement when withdrawing through the bottle opening given age group

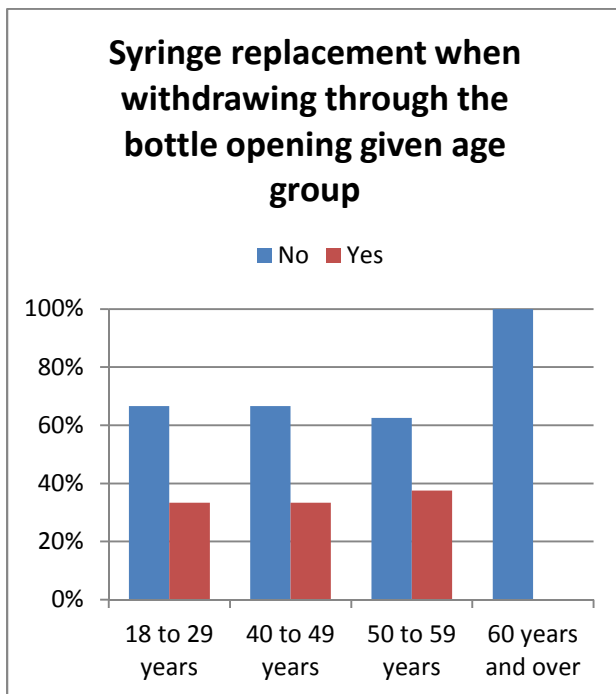
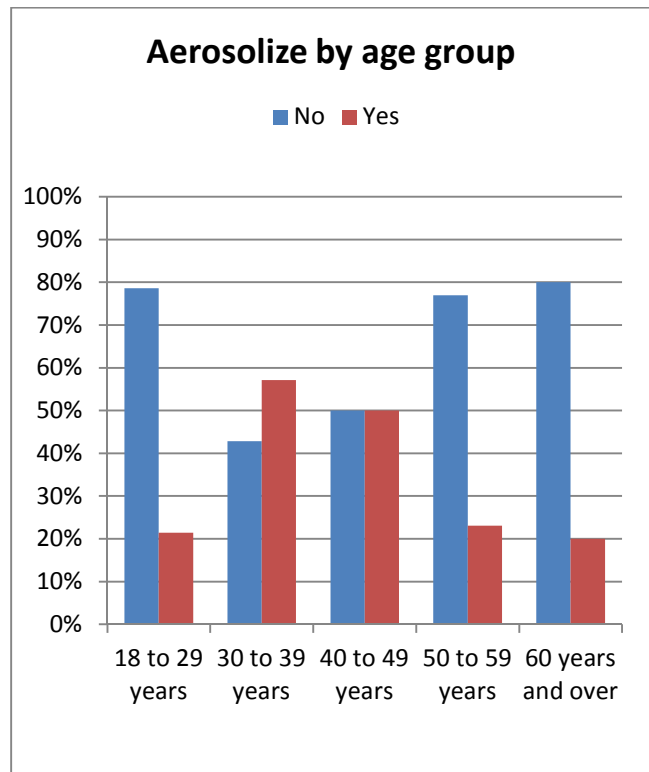
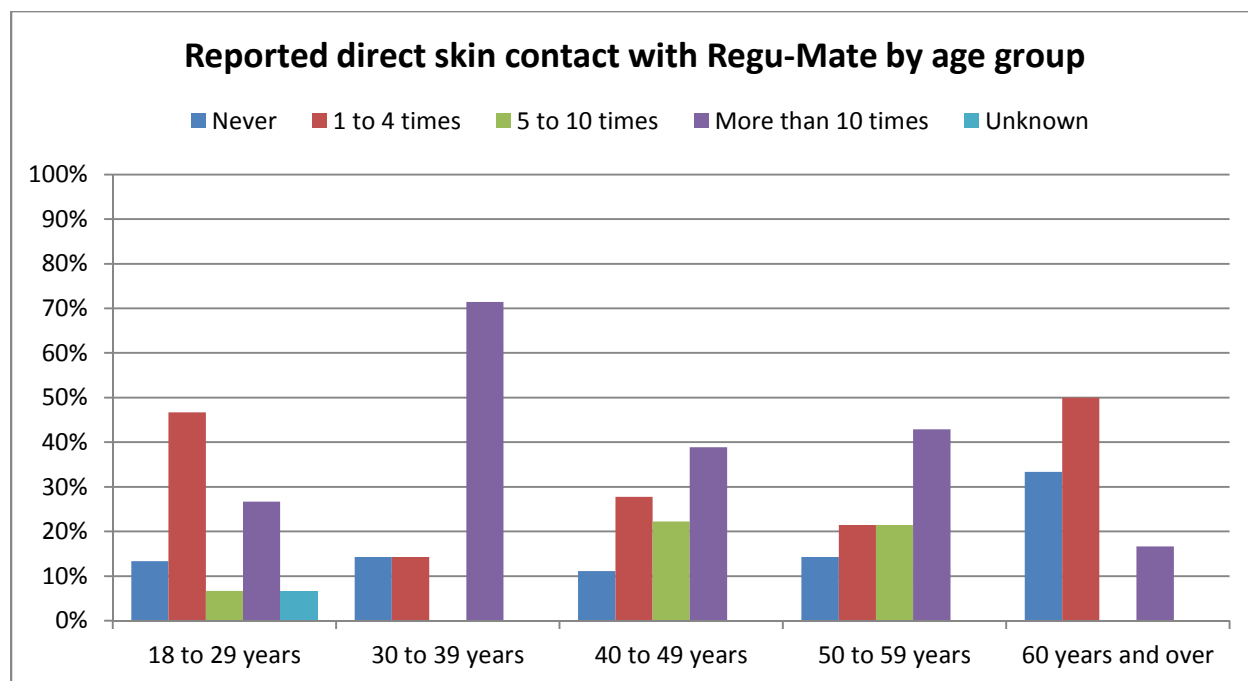


Figure 4-45: Aerosolize by age group



Direct contact with Regu-Mate based on the respondent's age is presented in Figure 4-46; the distribution for each age bracket covers at least three of the four contact categories. Of the respondents in the 30 to 39 year group 71% reported coming into direct contact with Regu-Mate more than 10 times.

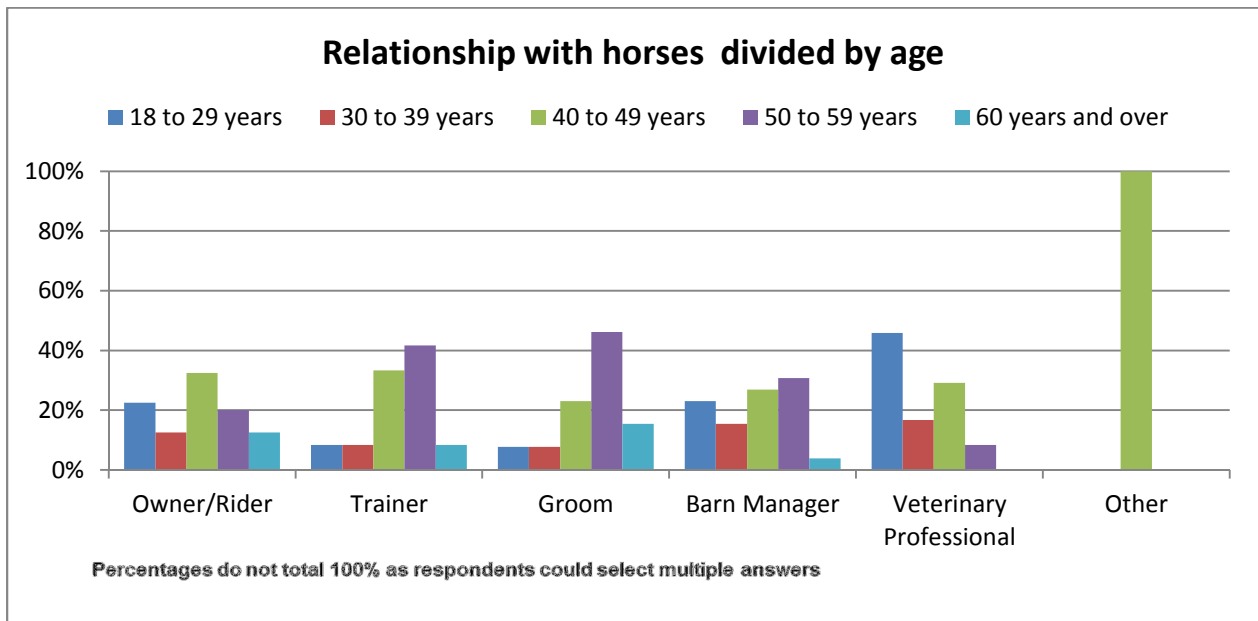
Figure 4-46: Reported direct skin contact with Regu-Mate by age group



4.1.6 Relationship with Horses Comparisons

Figure 4-47 displays the age breakdown of respondent self-identified roles with horses. Only one respondent identified as “other”; this results in all of the breakdowns for the other category being represented as 100%. The largest group of veterinary professionals was 18 to 29 years old, trainers were primarily 40 to 59 years of age and the largest group of grooms was 50 to 59 years old. Owners/riders were fairly evenly distributed among the age range.

Figure 4-47: Role with horses divided by age groups



Almost all respondents who identify as veterinary professionals (92%), 65% of owners/riders, 58% of barn managers, 54% of grooms and half of trainers are involved in the breeding industry; Figure 4-48 shows the breakdown of the self-identified role with horses and involvement in the breeding industry.

Figure 4-48: Role working with horses and involvement in breeding industry

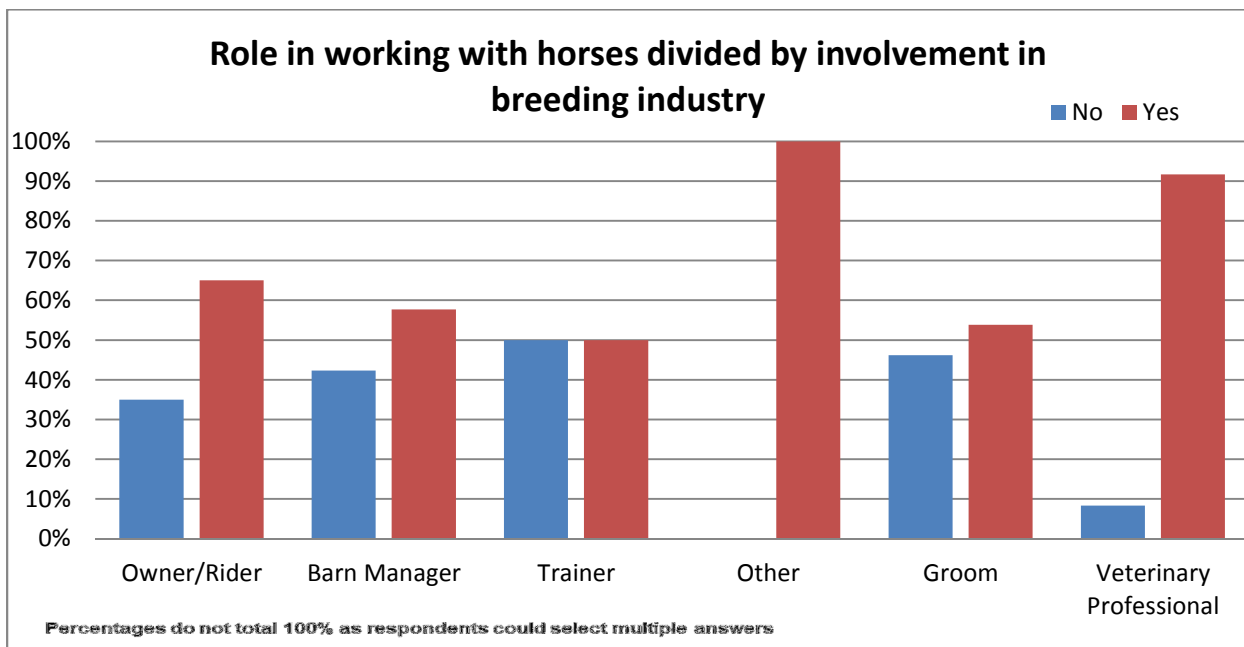
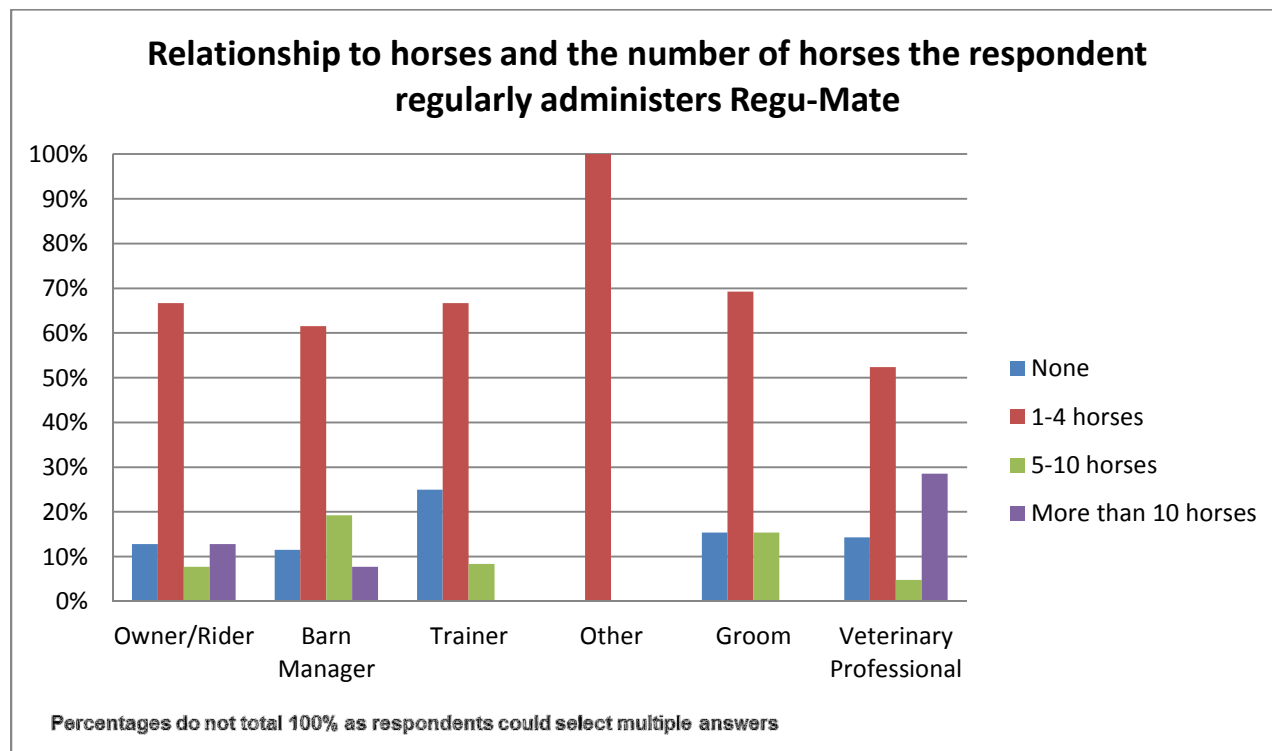


Figure 4-49 displays the reported number of horses that respondents administer Regu-Mate to on a regular basis. The majority of respondents administer horses to one to four horses regardless of their self-described role in the equestrian world.

Figure 4-49: Role in working with horses and number of horses administering Regu-Mate to on a regular basis



The reasons why Regu-Mate is used by people identifying with certain roles in the equine industry are presented in Figure 4-50. Over half of respondents who identify as owners/riders use Regu-Mate for behavior modification, synchronization of estrus in mares and maintaining a pregnancy. Trainers, grooms and veterinary professionals overwhelming (75%, 62% and 71%, respectively) use Regu-Mate for behavior modification. Veterinary professionals also reported using Regu-Mate for maintain pregnancy 71% of the time.

Figure 4-50: Role of horses divided by why the respondent uses Regu-Mate

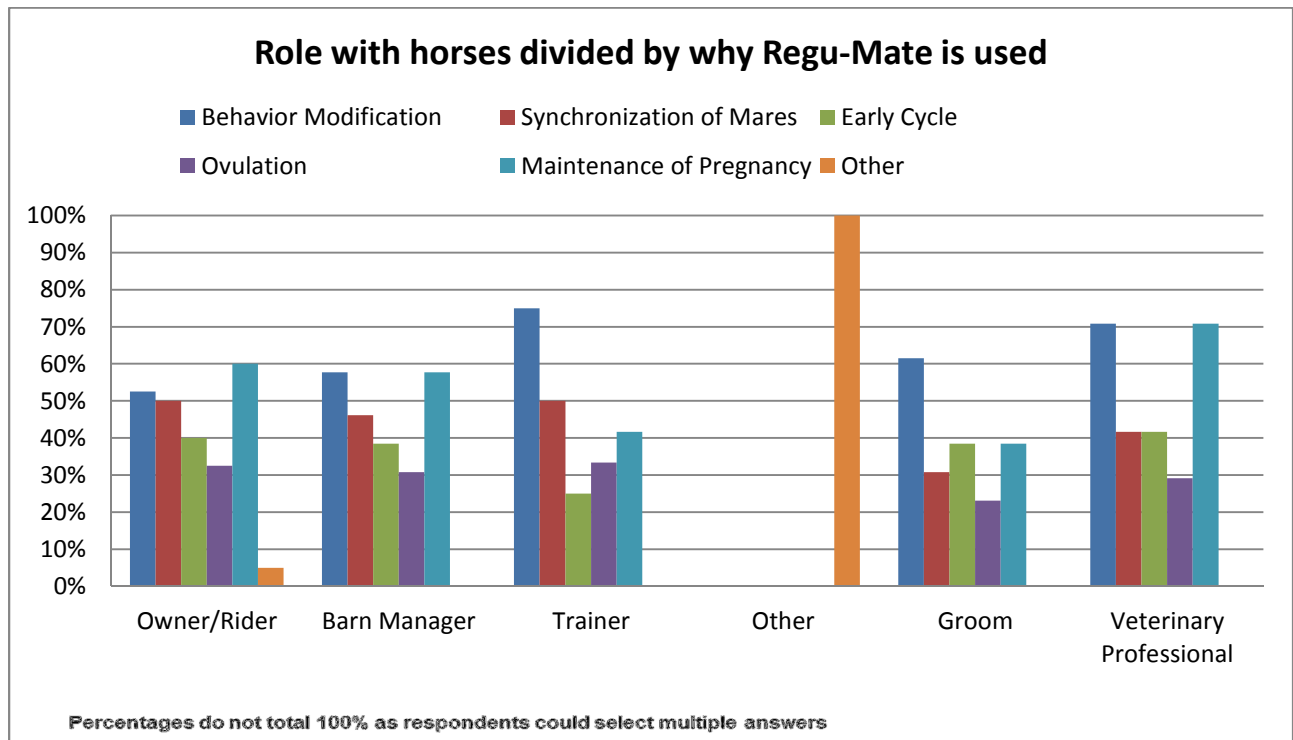


Figure 4-51 and Figure 4-52 present how often the respondent regularly administers Regu-Mate and how many years the respondent has handled the drug, respectively, in relation to their self-identified roles in working with horses. The majority of owners/riders (54%), barn managers (65%), trainers (67%) and grooms (62%) handle Regu-Mate five times per week or more while the veterinary professionals primarily handle Regu-Mate three times per month or less (62%). The majority of respondents self-identifying with all roles are more likely to have been handling Regu-Mate for five or more years, followed by one year or less.

Figure 4-51: Self-identified role with horses given how often the respondent regularly administers Regu-Mate

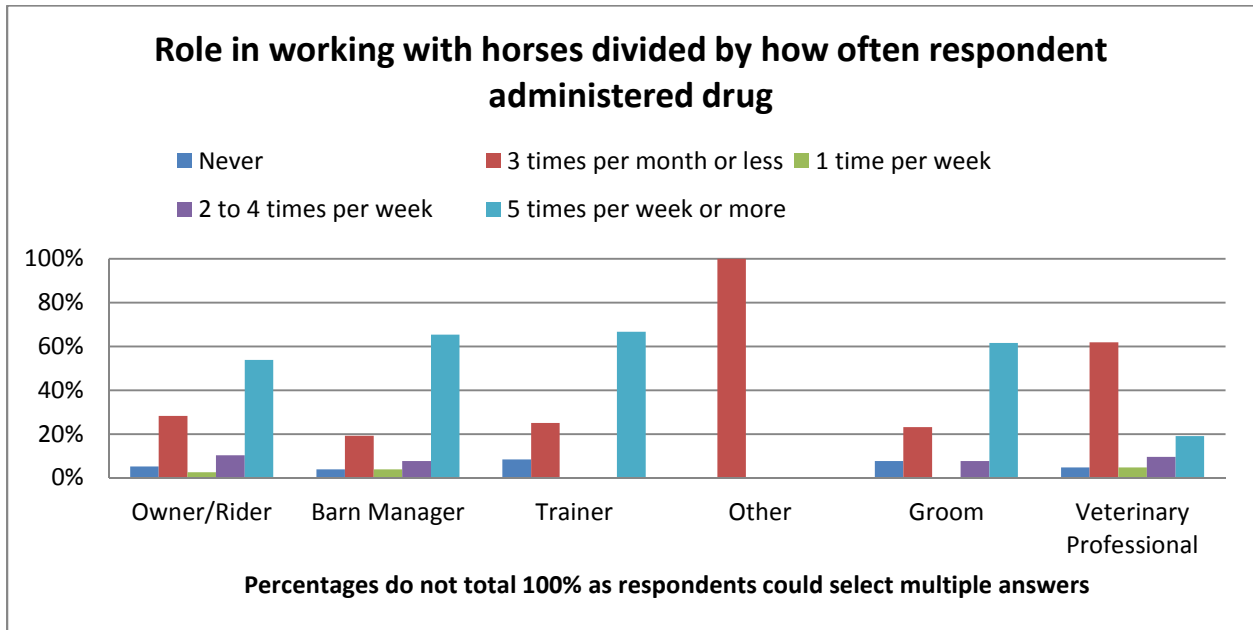


Figure 4-52: Self-identified role with horses given how many years a respondent has handled Regu-Mate

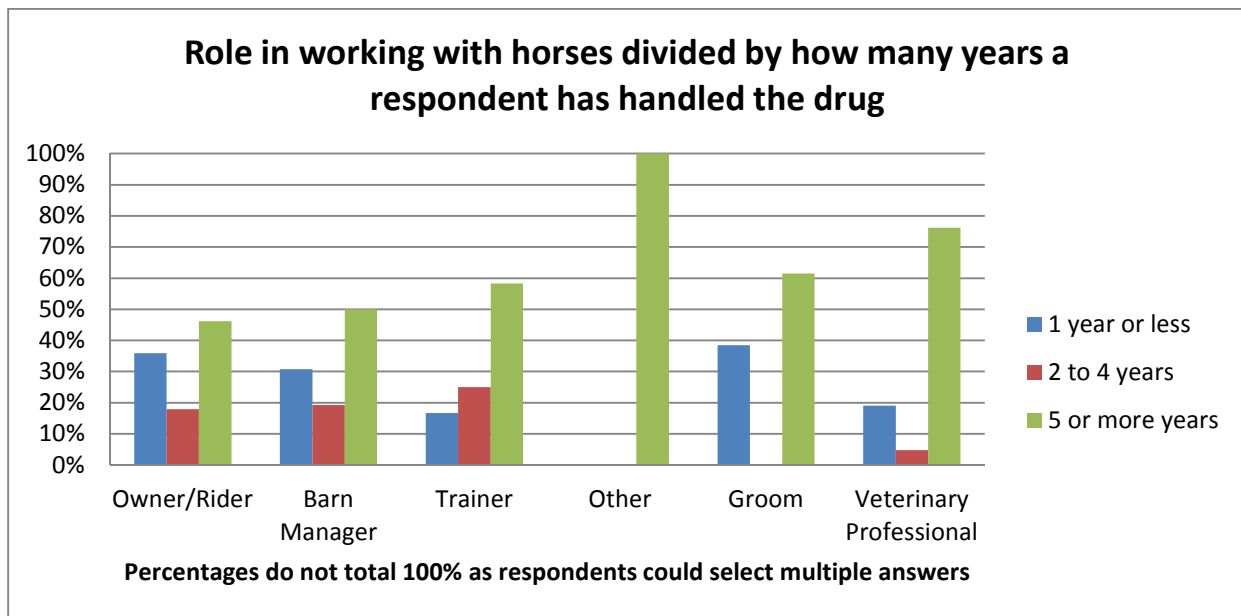


Figure 4-53, Figure 4-54 and Figure 4-55 display reported glove use, glove replacement and types of gloves given the roles working with horses that respondents self-report. The use of gloves every time is equally distributed between the different roles with barn managers

reporting using gloves every time at the smallest percentage (31%); barn managers were also the most likely (27%) along with grooms (23%) to report not using gloves. The distribution of glove replacement and type of gloves were consistent between the roles.

Figure 4-53: Glove use given self-reported role in working with horses

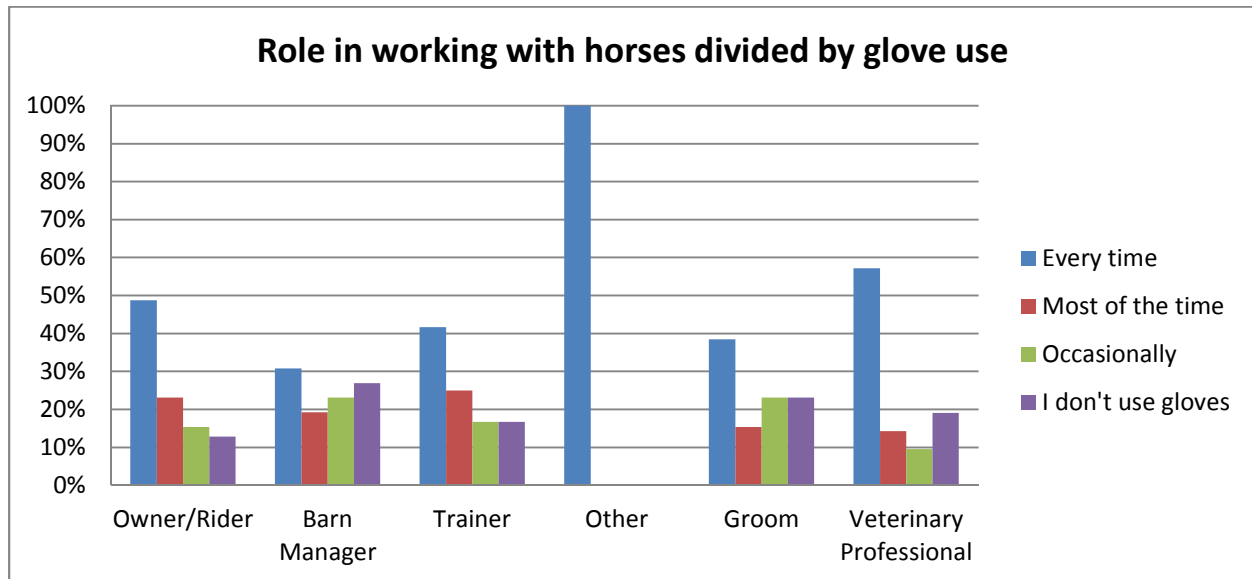


Figure 4-54: Glove replacement given self-reported role in working with horses

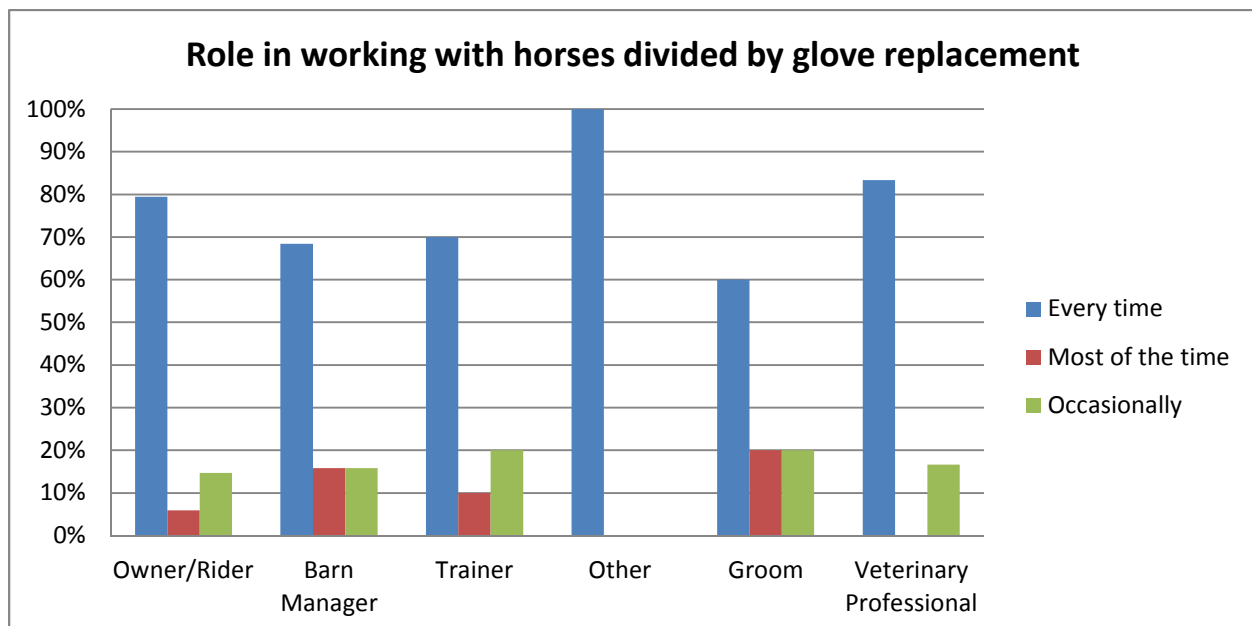
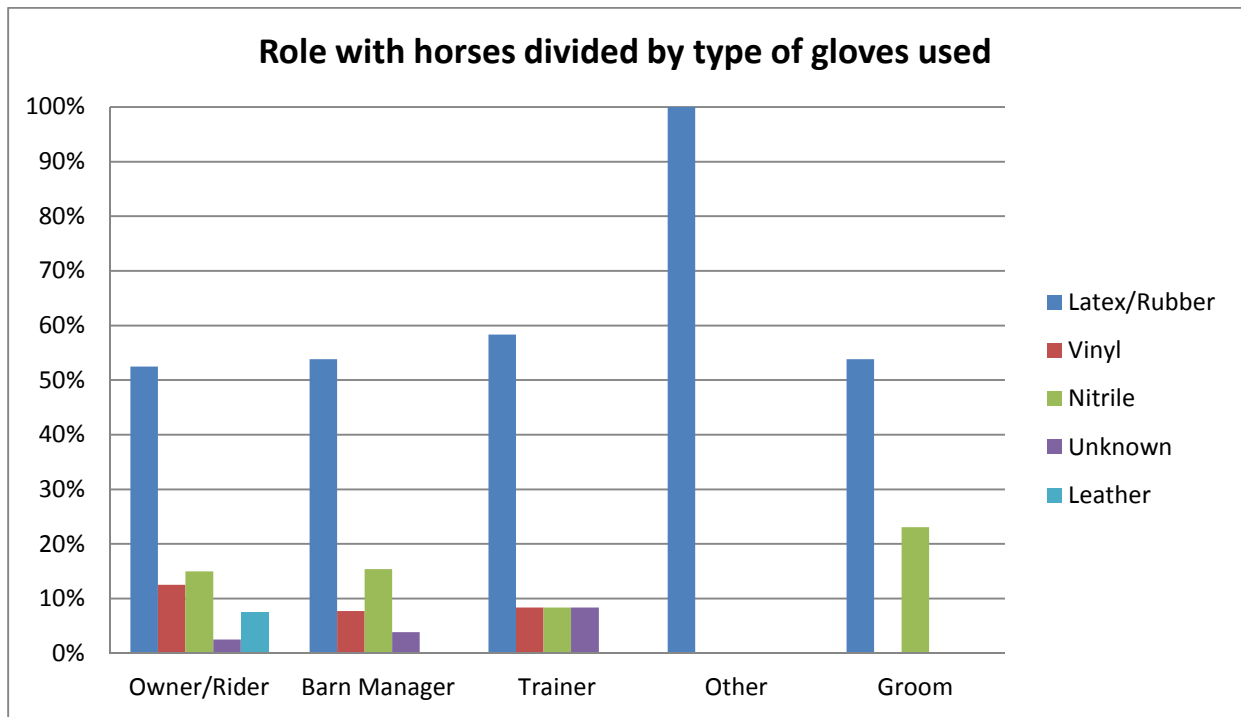


Figure 4-55: Glove type given self-reported role in working with horses



Respondents' hand washing behavior given their reported role(s) in working with horses is seen in Figure 4-56; in all reported roles more respondents reported washing hands following handling Regu-Mate (except trainers which an equal number wash hands as do not wash hands). Bottle storage given the respondents' self-reported role(s) is presented in Figure 4-57. More barn managers, trainers and grooms store the Regu-Mate bottle separate from other medications (62%, 58% and 54%, respectively) while more owner/riders and veterinary professionals (59% and 85%, respectively) reported storing the Regu-Mate bottle with other medications.

Figure 4-56: Reported hand washing given self-reported role in working with horses

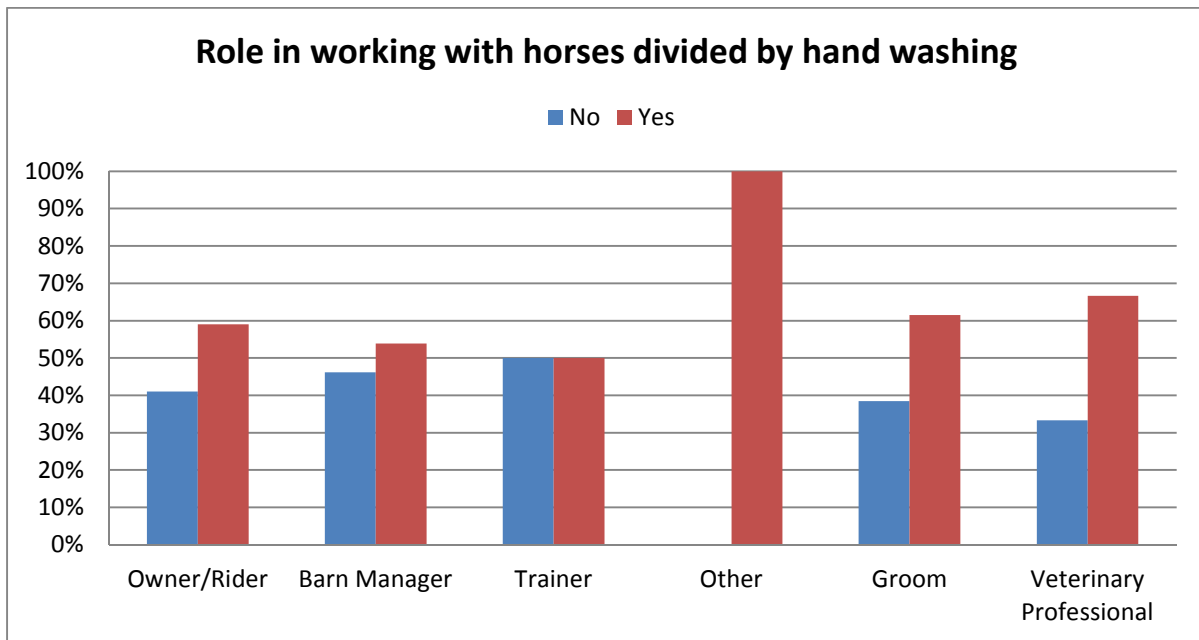
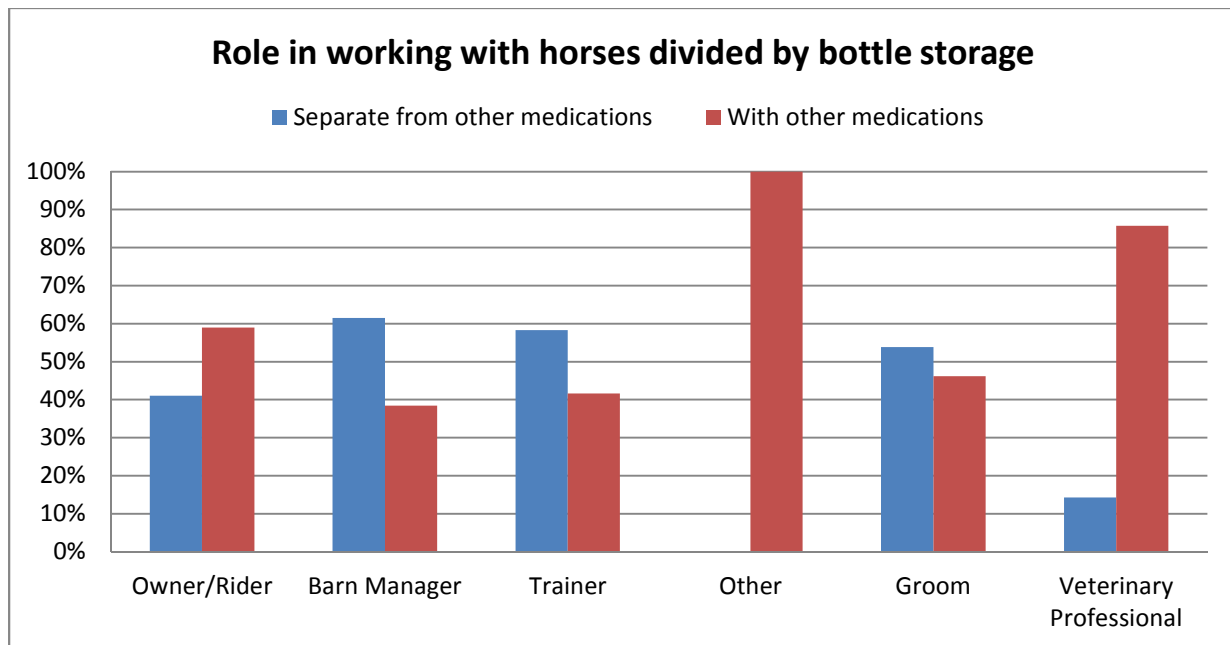


Figure 4-57: Location of Regu-Mate bottle storage given self-reported role in working with horses



The tool most commonly used for drug withdrawal for all respondents regardless of what role they report in working with horses is the non-locking syringe (Figure 4-58). All roles except trainers reported more (71-44%) respondents attaching the syringe/dispensing device to the tip of the bottles lid than drawing directly through the bottle opening while only 9% more trainers

report attaching to the lid than drawing through the bottle opening (Figure 4-59). Figure 4-60 shows the syringe replacement behavior of people in each role that also report using syringes; there is little difference in replacement behavior.

Figure 4-58: Tool used for drug withdrawal given self-reported role in working with horses

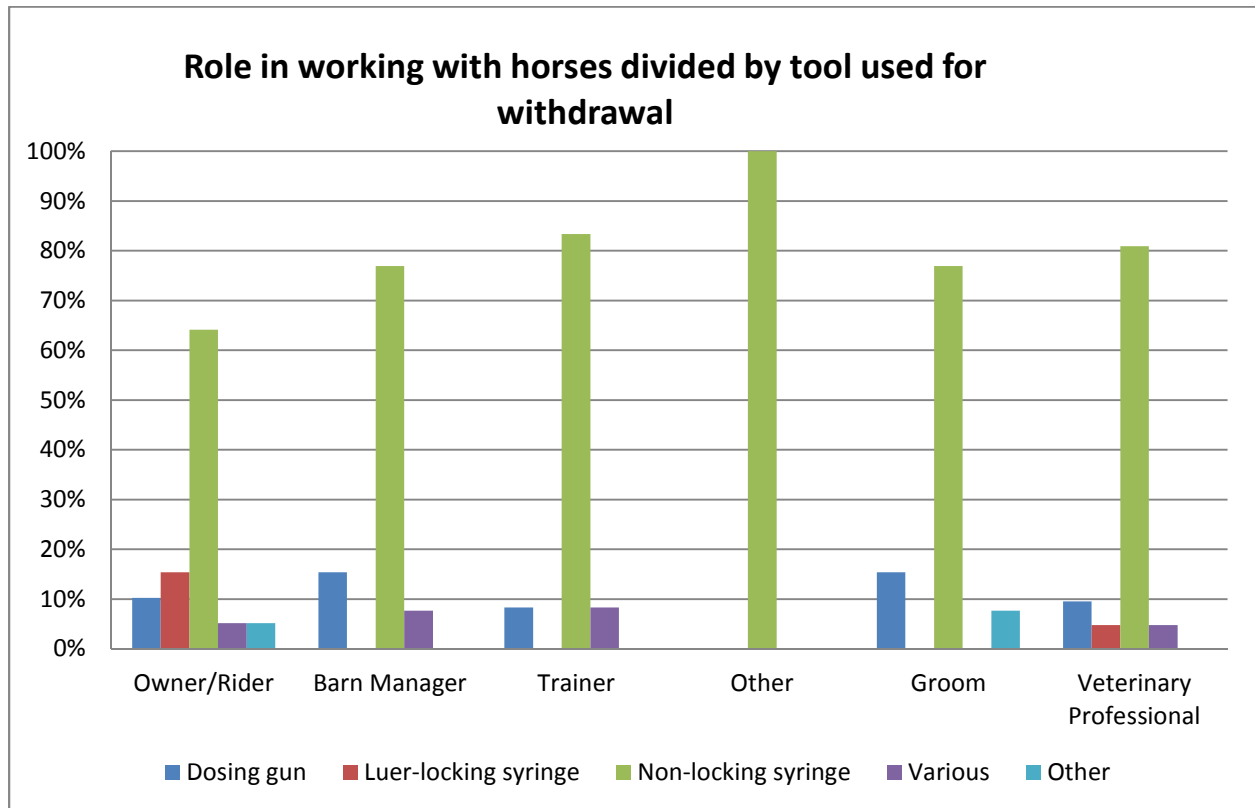


Figure 4-59: How tool is used for drug withdrawal given self-reported role in working with horses

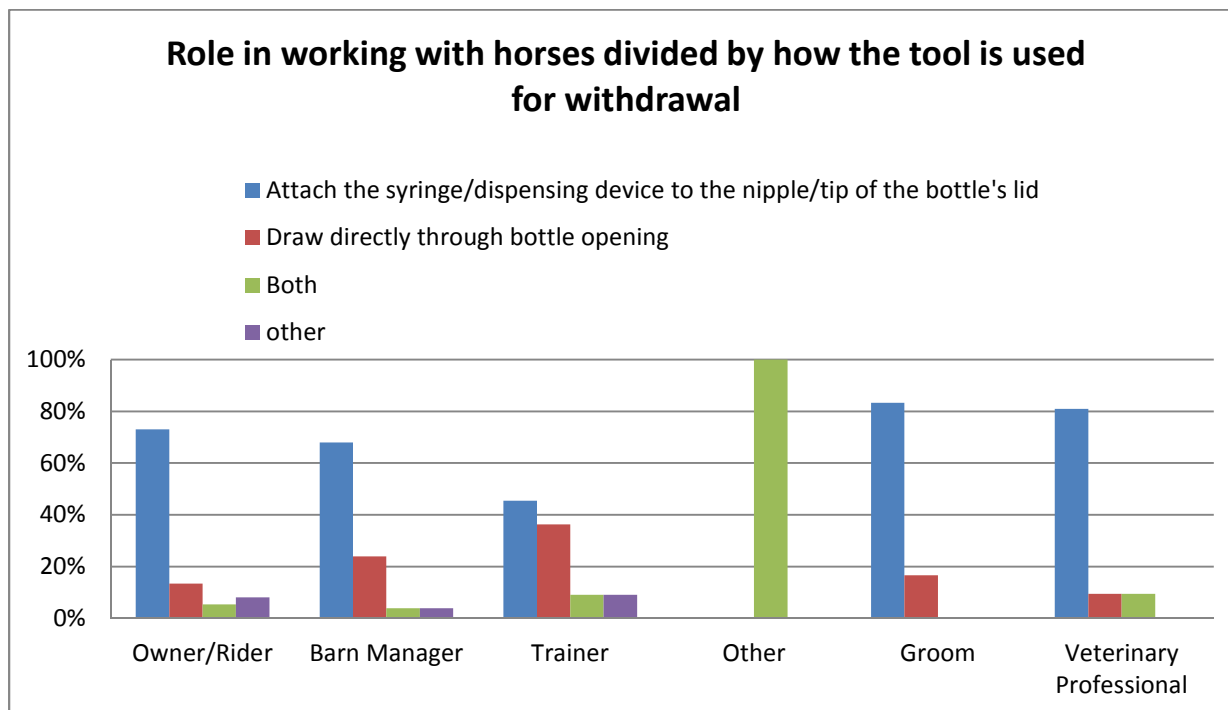
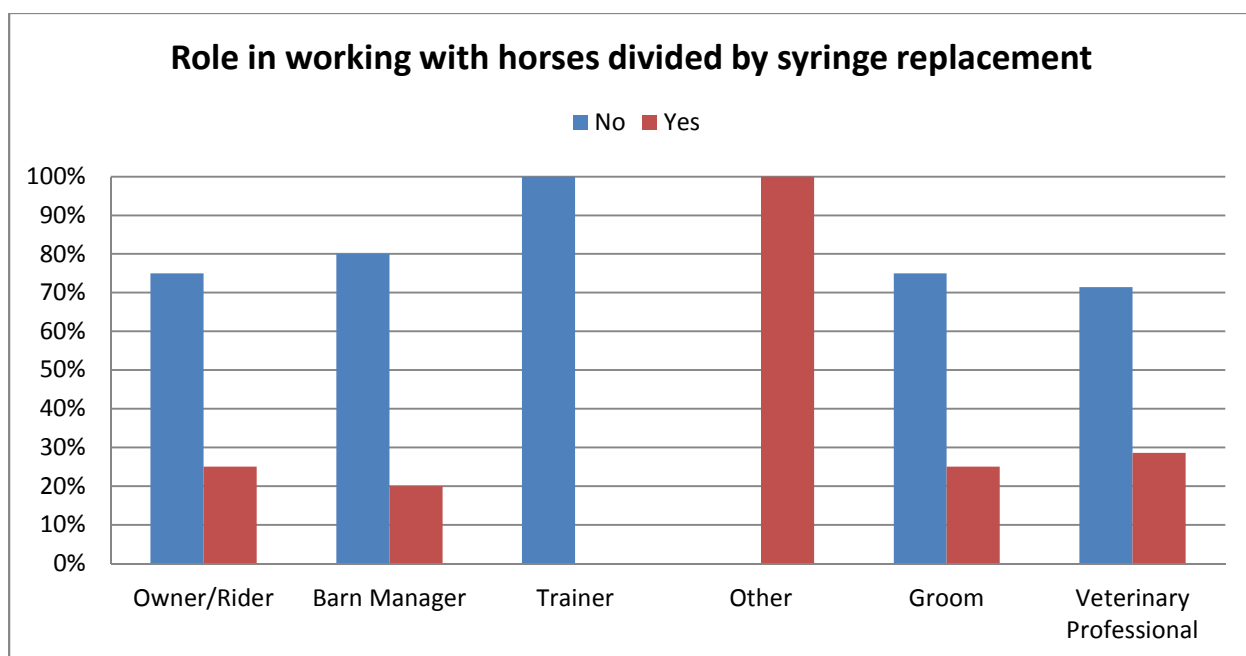


Figure 4-60: Syringe replacement given self-reported role in working with horses



When broken up into their reported roles in working with horses, of those who use a syringe or dosing gun, a majority respondents across the categories (trainers were 50/50) reported not

aerosolizing the drug when emptying their dosing device. This difference was most noted among veterinary professionals (Figure 4-61).

Figure 4-61: Aerosolizing drug given self-reported role in working with horses

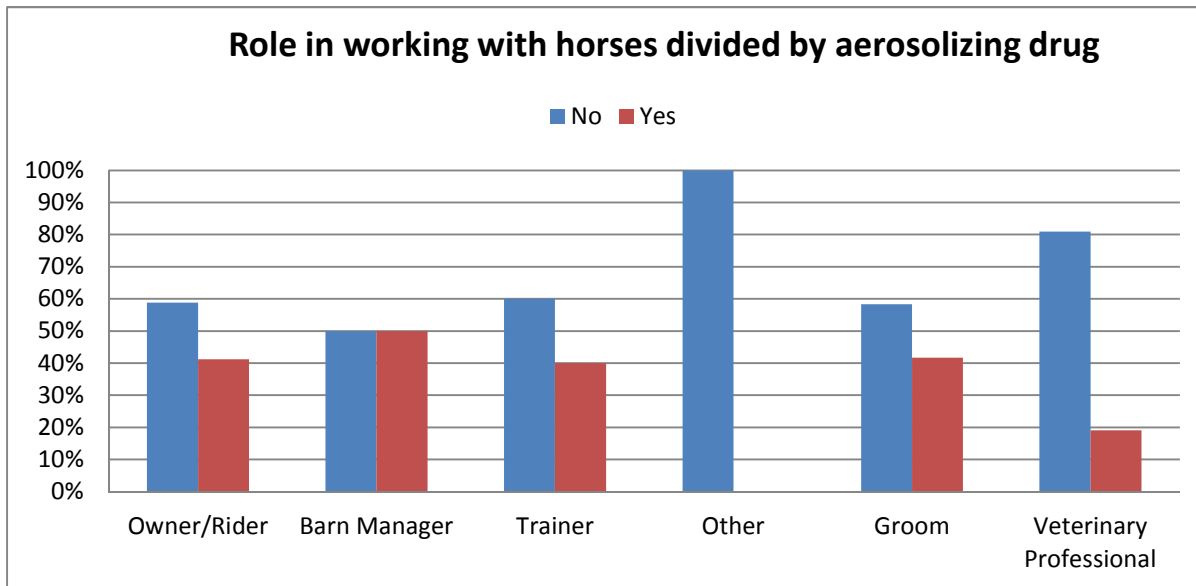
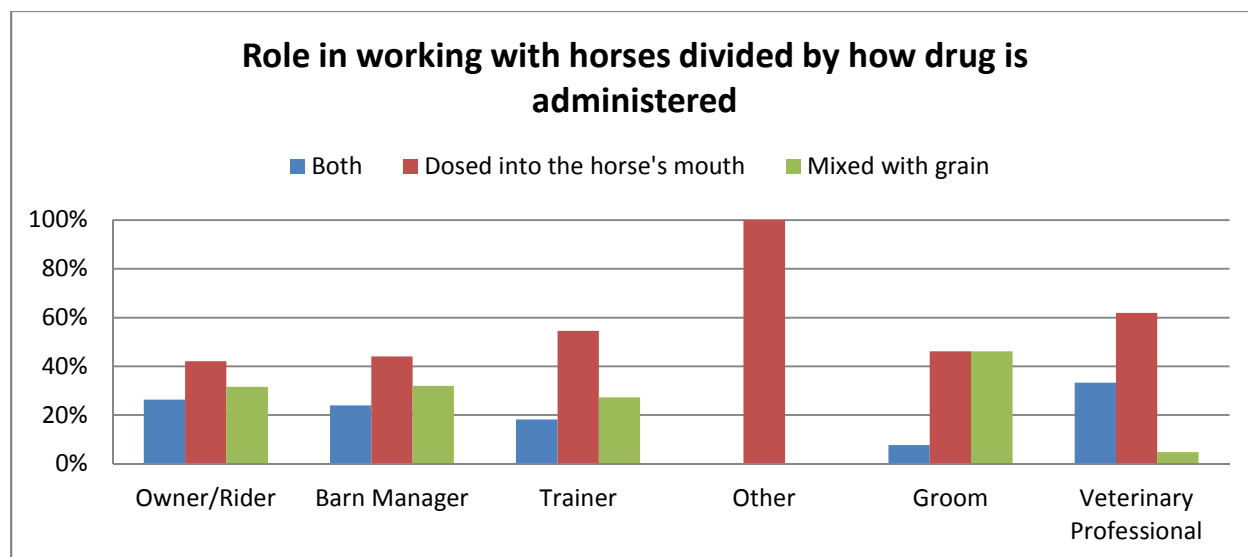


Figure 4-62 shows how respondents administer Regu-Mate to their horses; the distribution is similar for all categories except for veterinary professionals who are less likely to only mix Regu-Mate in grain than any other category.

Figure 4-62: How Regu-Mate is administered given self-reported role in working with horses



For all categories of roles working with horses except for trainers, more respondents use dedicated feed buckets for Regu-Mate than do not (Figure 4-63). Conversely trainers are the only category in which more respondents do not use dedicated Regu-Mate grain buckets.

Figure 4-63: Dedicated buckets for Regu-Mate use given self-reported role in working with horses

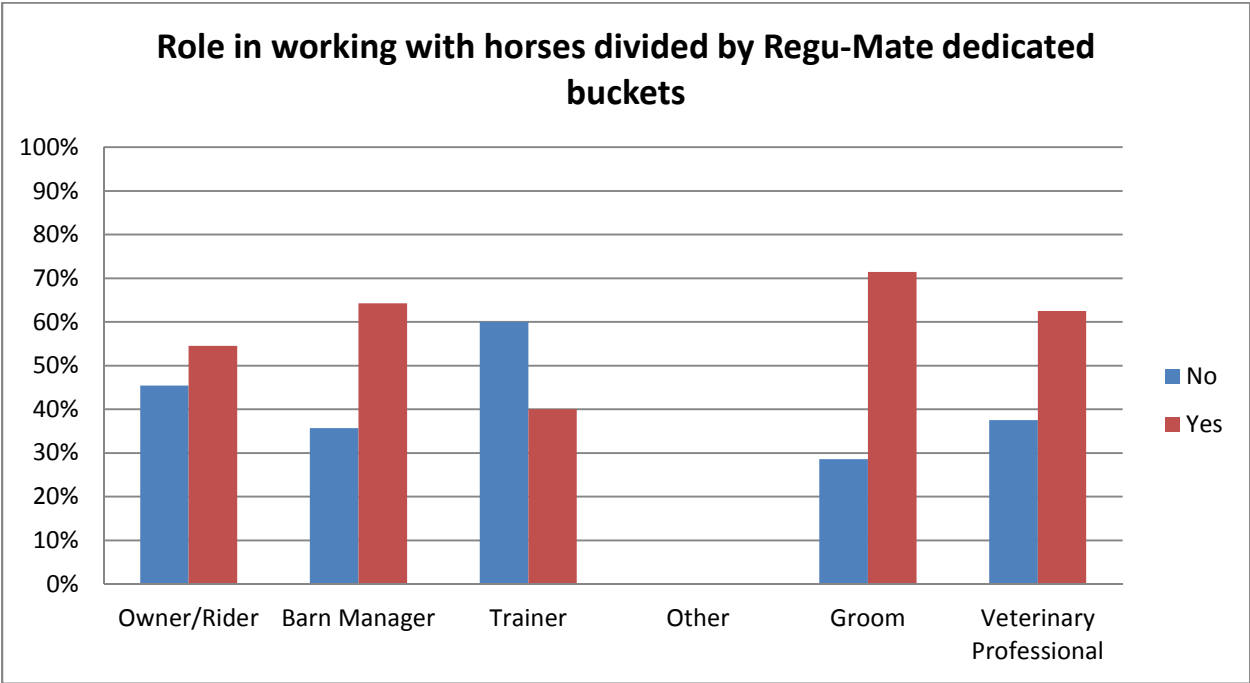
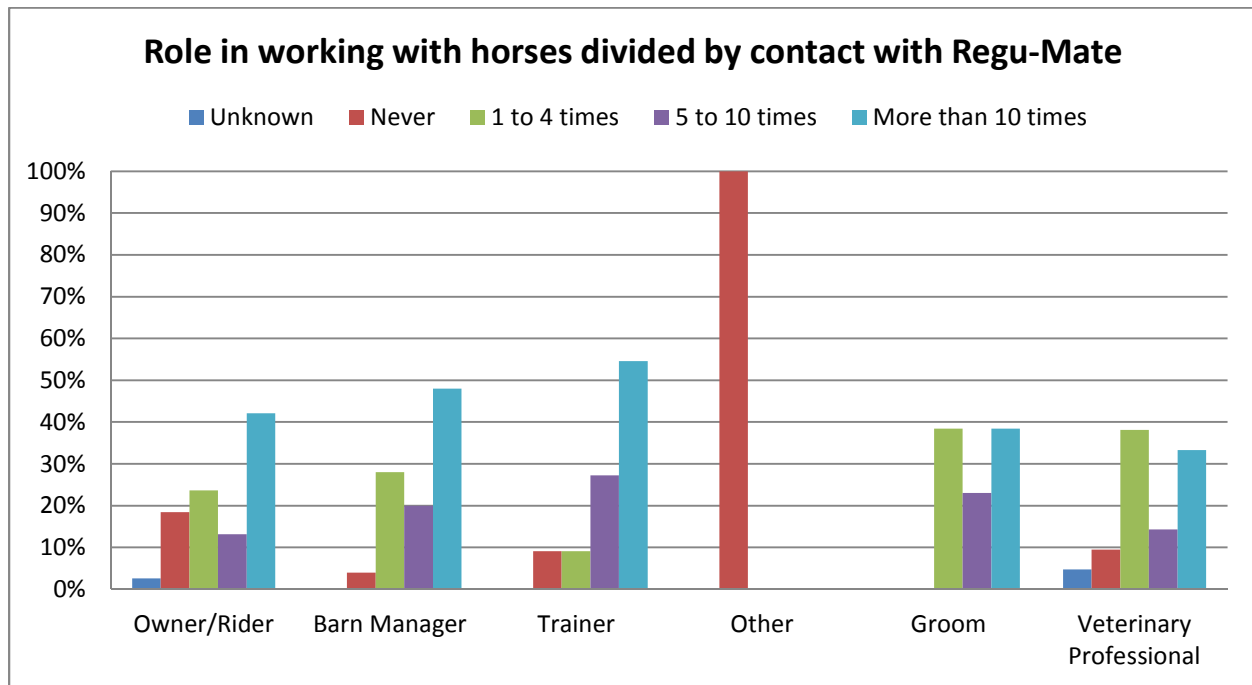


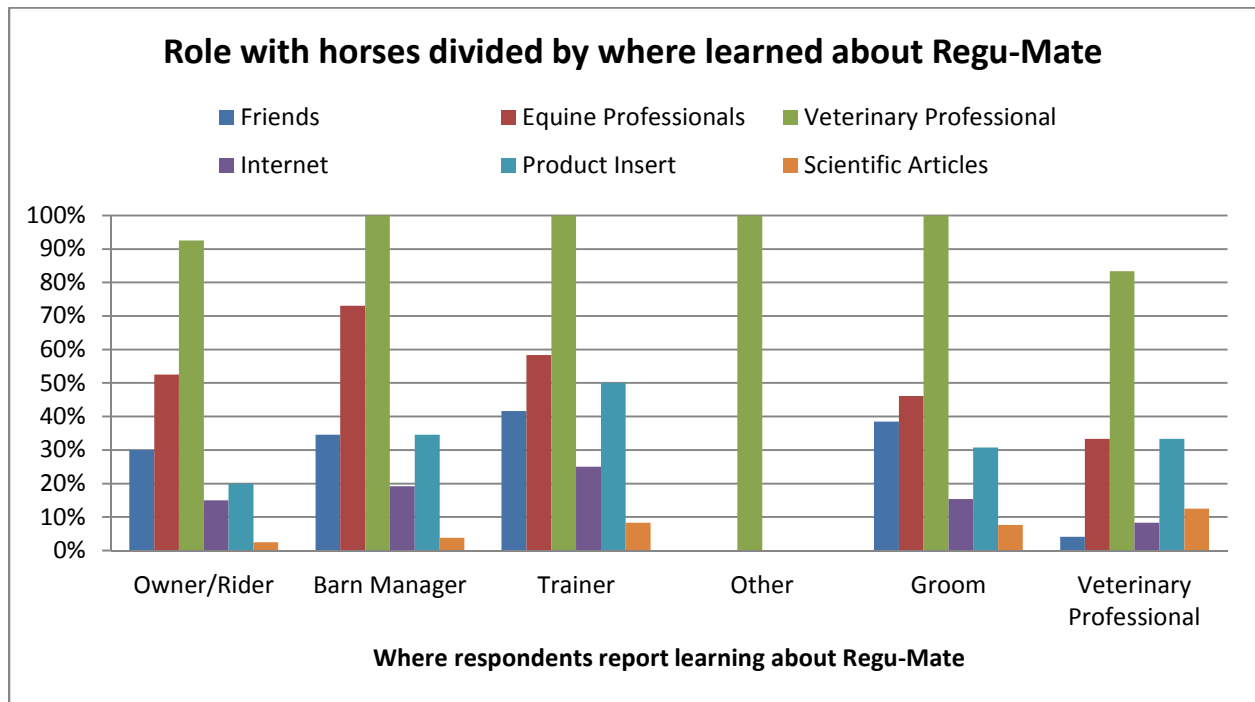
Figure 4-64 shows respondents reported contact with Regu-Mate broken up by the reported roles in working with horses. Of the owner/riders, barn managers and trainers 42%, 48% and 55% of respondents, respectively, report coming in direct contact with Regu-Mate more than 10 times. Grooms and veterinary professionals report more of an equal distribution for contact between one to four times and more than 10 times.

Figure 4-64: Direct contact with Regu-Mate given self-reported role in working with horses



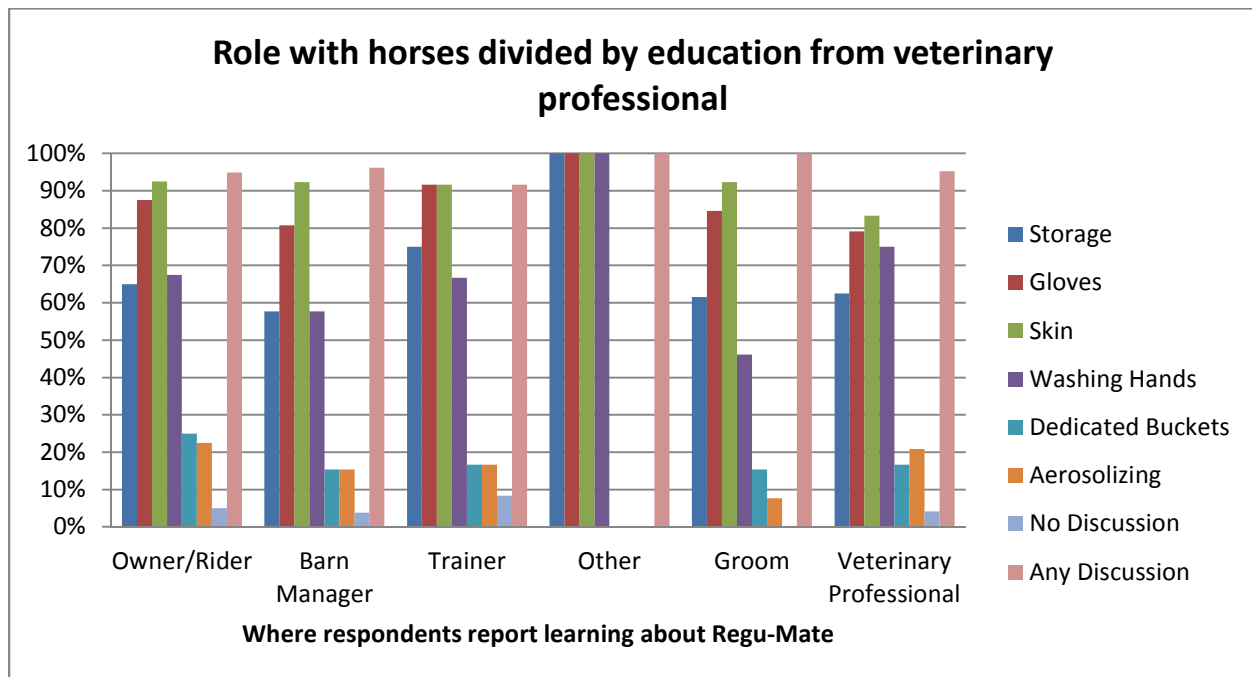
Respondents reported roles in working with horses are broken up in Figure 4-65 by where they report learning about Regu-Mate. Respondents, across all categories, reported over 80% of the time that they learned about Regu-Mate from a veterinary professional. The secondary source for information across categories was equine professionals. Owner/riders were the least likely, with 20% of respondents, to report learning about Regu-Mate from the product insert. Except for veterinary professionals, 30% to 42% of all categories report learning about Regu-Mate from friends.

Figure 4-65: Where learned about Regu-Mate given self-reported role in working with horses



The most commonly discussed aspects of Regu-Mate with veterinarians across reported roles with horses are contact with skin and use of gloves. Trainers were the most likely category (at 8% of all trainers) to report not having a discussion with their veterinarian about Regu-Mate. Over 90% of respondents in each reported role reported at least some discussion of Regu-Mate with their veterinarian.

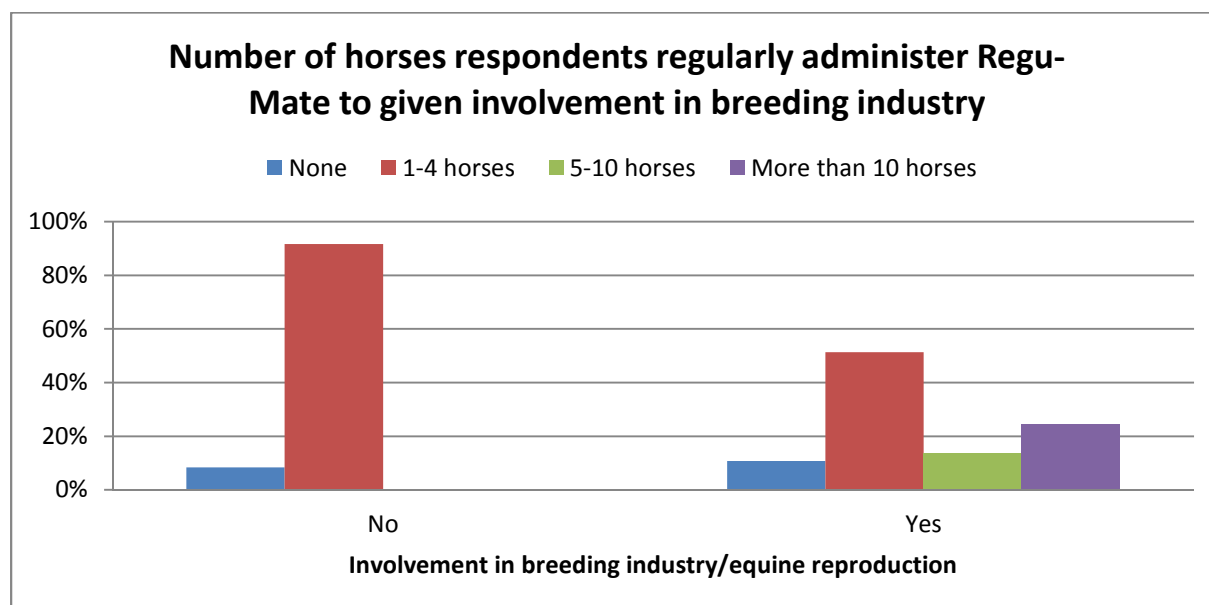
Figure 4-66: Discussion of Regu-Mate with veterinary professional given self-reported role in working with horses



4.1.7 Breeding Industry Comparisons

The basic demographics of respondents involved in the breeding industry are presented in Figure 4-4; 63% of all respondents are involved in the breeding industry. All of those not involved in the breeding industry regularly administer Regu-Mate to four or fewer horses (Figure 4-67).

Figure 4-67: Number of horses respondents regularly administer Regu-Mate to given involvement in breeding industry



Of those who use Regu-Mate for behavior modification, 57% are not involved in the breeding industry; respondents for the remaining reasons for using Regu-Mate (Figure 4-68) are predominantly involved in the breeding industry. There is little difference in the distribution of how often Regu-Mate is handled between those in the breeding industry and those not involved (Figure 4-68).

Figure 4-68: Involvement in breeding industry broken up by reason for drug use

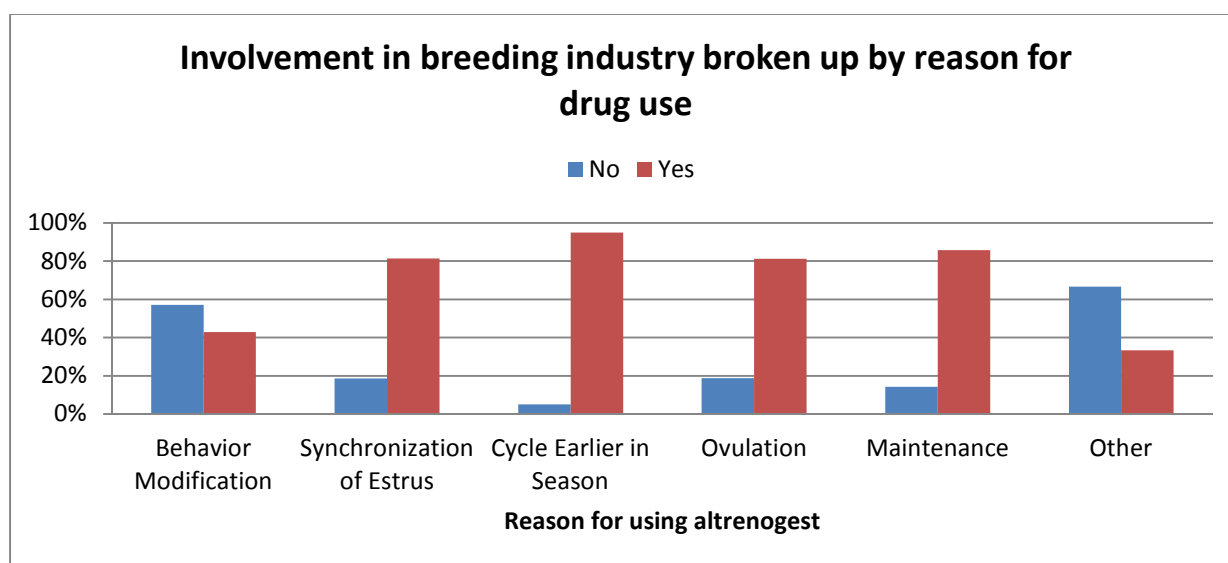
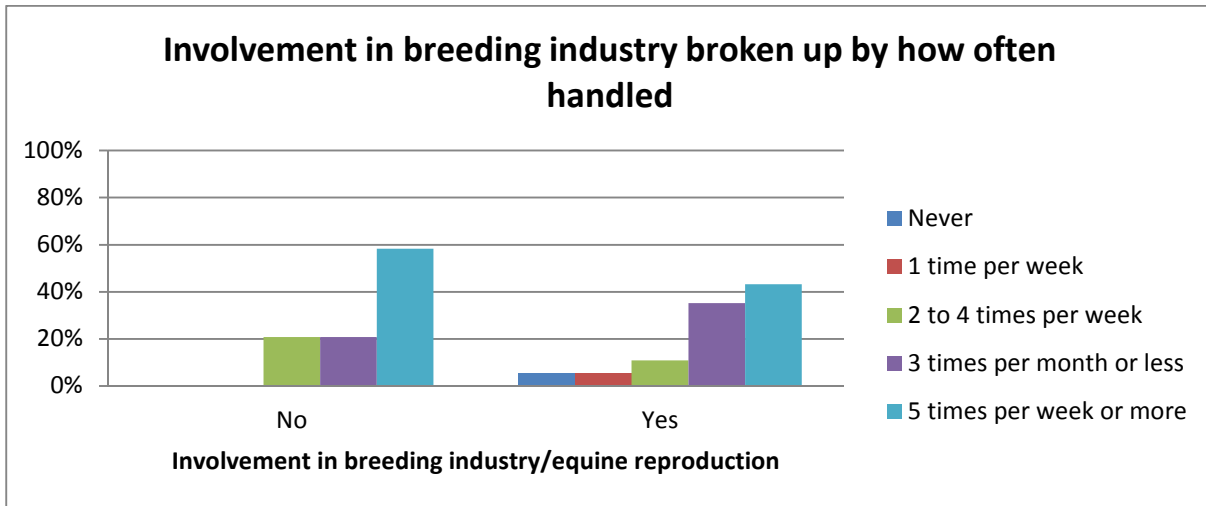
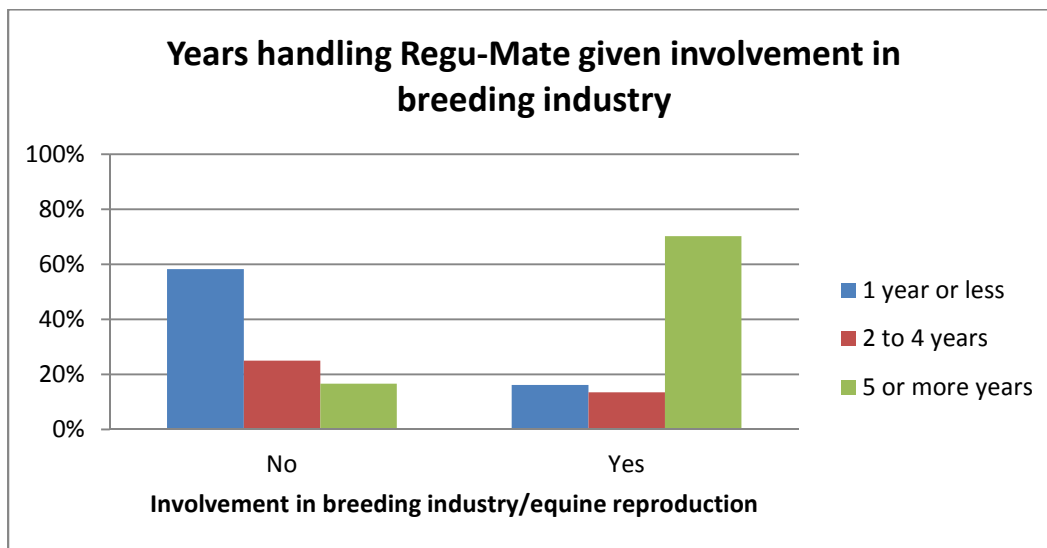


Figure 4-69: Involvement in breeding industry broken up by how often handled



A majority (70%) of respondents involved with the breeding industry have been using Regu-Mate for five or more years whereas only 16% had been handling Regu-Mate for one year or less. With respondents not involved in the breeding industry there is an inverse result, with 58% handling Regu-Mate one year or less and 17% handling it five years or more (Figure 4-70).

Figure 4-70: Years handling Regu-Mate given involvement in breeding industry



The distribution of glove use and glove replacement does not vary much between those involved in the breeding industry and those which are not (Figure 4-71 and Figure 4-72). Half of those not involved in the breeding industry wash their hands after dealing with Regu-Mate

compared to 59% of those involved in the breeding industry (Figure 4-73). Non-breeders are more likely (58% of respondents) than breeders (32%) to store the Regu-Mate bottle separately from other medications (Figure 4-74).

Figure 4-71: Glove use given involvement in breeding industry

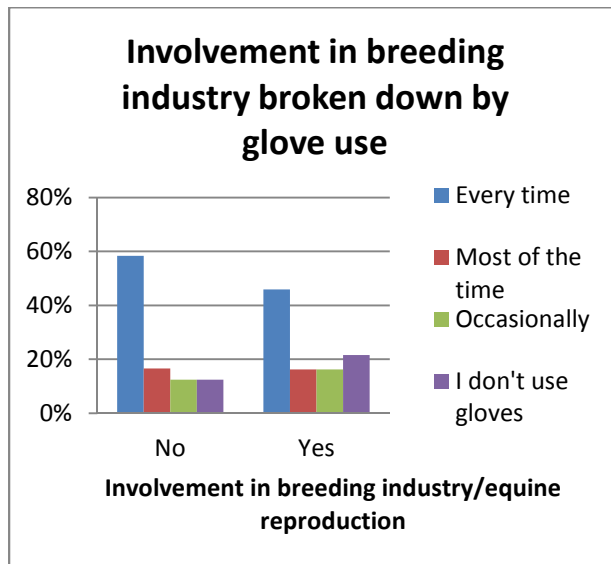


Figure 4-72: Glove replacement given involvement in breeding industry

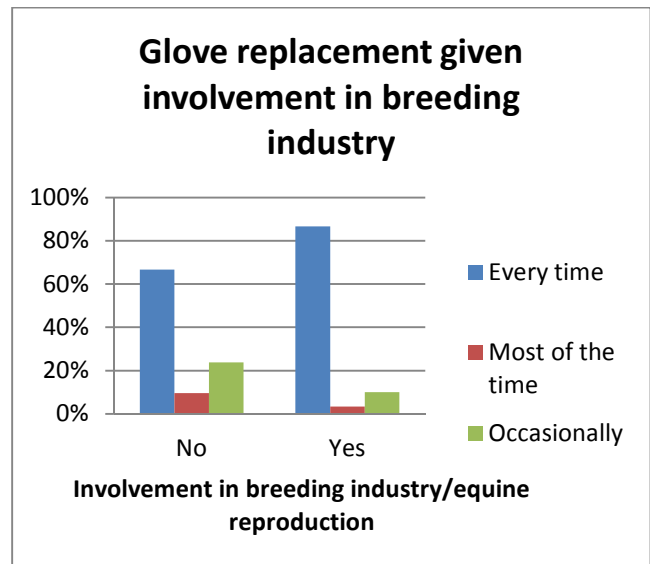


Figure 4-73: Hand washing behavior given involvement in the breeding industry

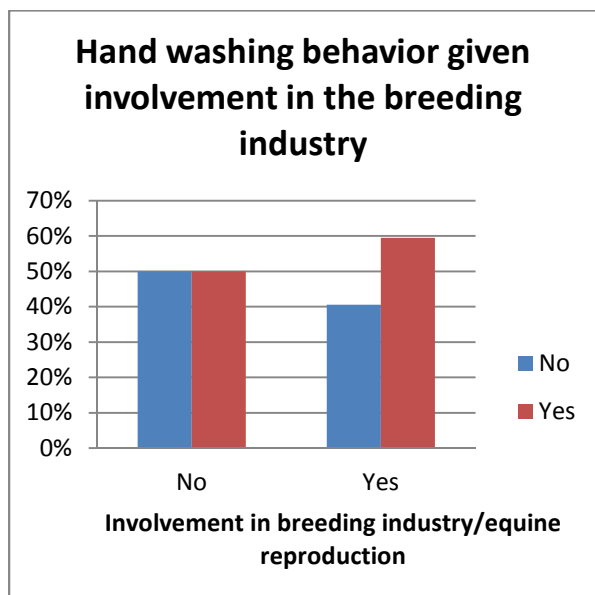
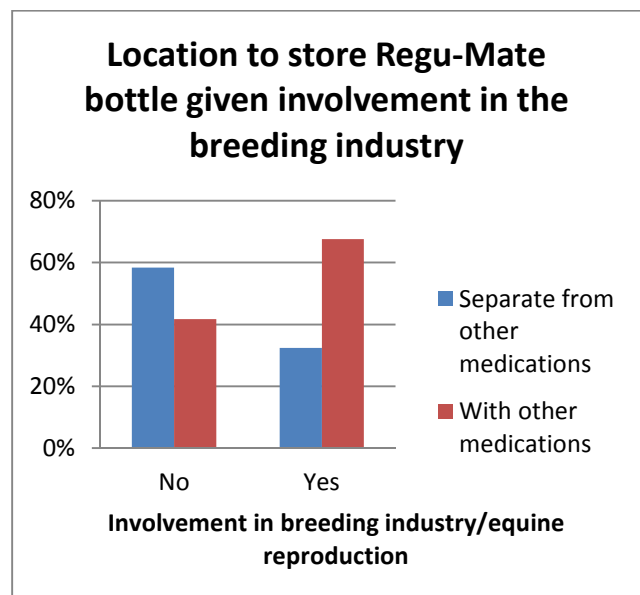
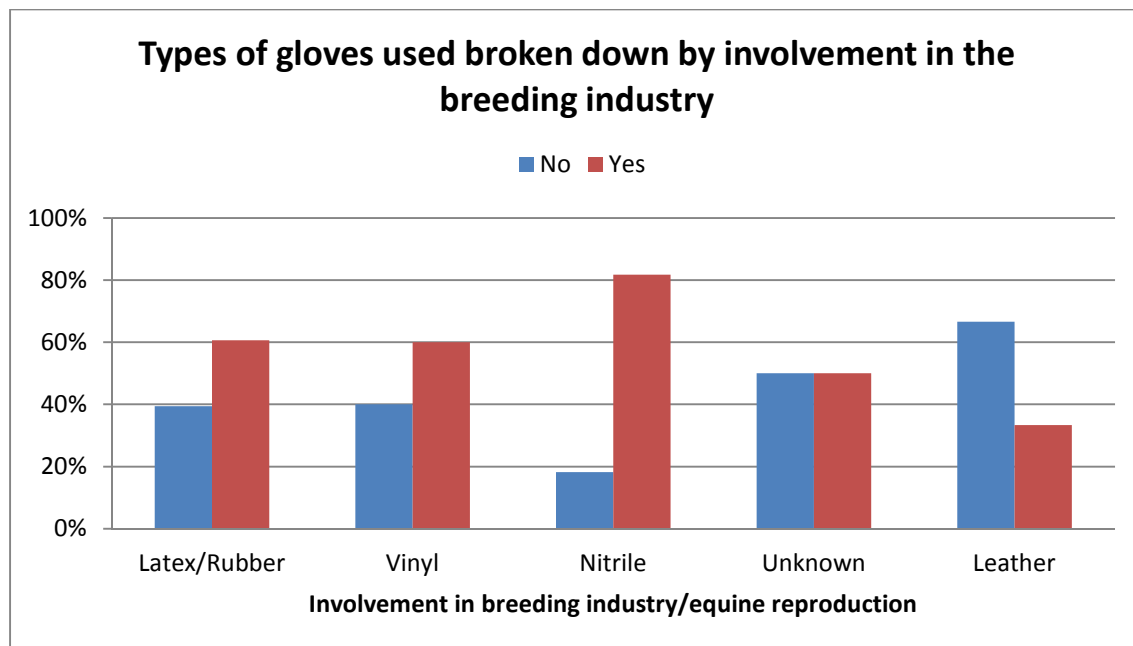


Figure 4-74: Location to store Regu-Mate bottle given involvement in the breeding industry



Of those using nitrile and vinyl gloves 60% and 82%, respectively, are involved in the breeding industry. Two thirds of those that report using leather gloves are not involved in the breeding industry. Figure 4-75 shows the types of gloves used by respondents and their involvement in the breeding industry.

Figure 4-75: Types of gloves used broken down by involvement in the breeding industry



Respondents in the breeding industry use dosing guns more often than those not in the breeding industry (14% vs. 4% of respondents) while the remaining tools are similarly distributed; Figure 4-76 shows tool use. More people involved in the breeding industry than not do not withdraw the drug directly through the bottle opening (57% vs. 47%); however a larger percentage of respondents not associated with the breeding industry do not replace the syringe when withdrawing through the bottle opening than those involved in the breeding industry (Figure 4-77). Aerosolizing behavior between the two groups does not vary (Figure 4-78).

Figure 4-76: Tool use for administering Regu-Mate given involvement in breeding industry

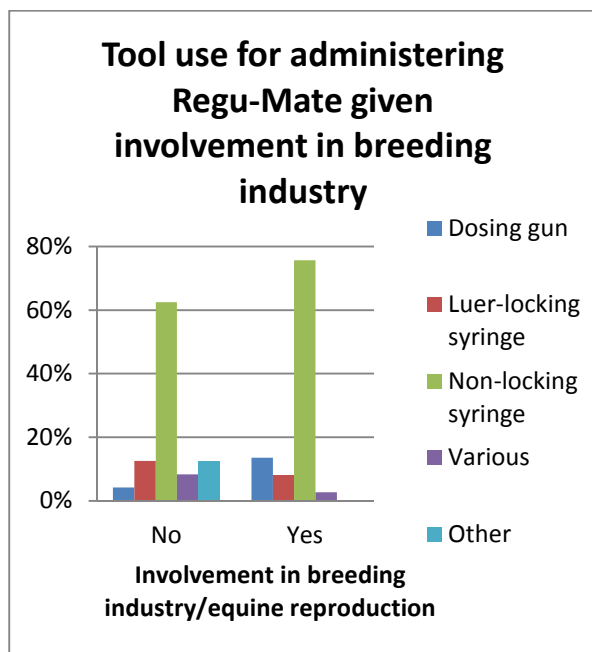


Figure 4-77: Syringe replacement when withdrawing directly through the bottle opening given involvement in the breeding industry

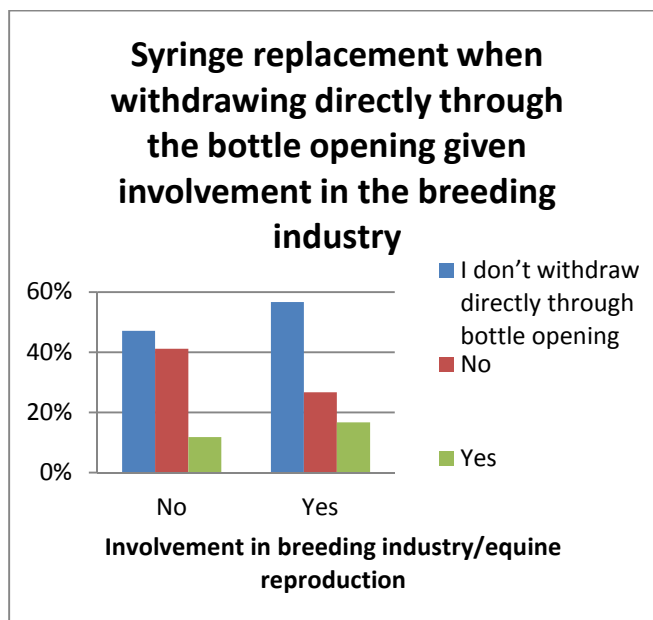
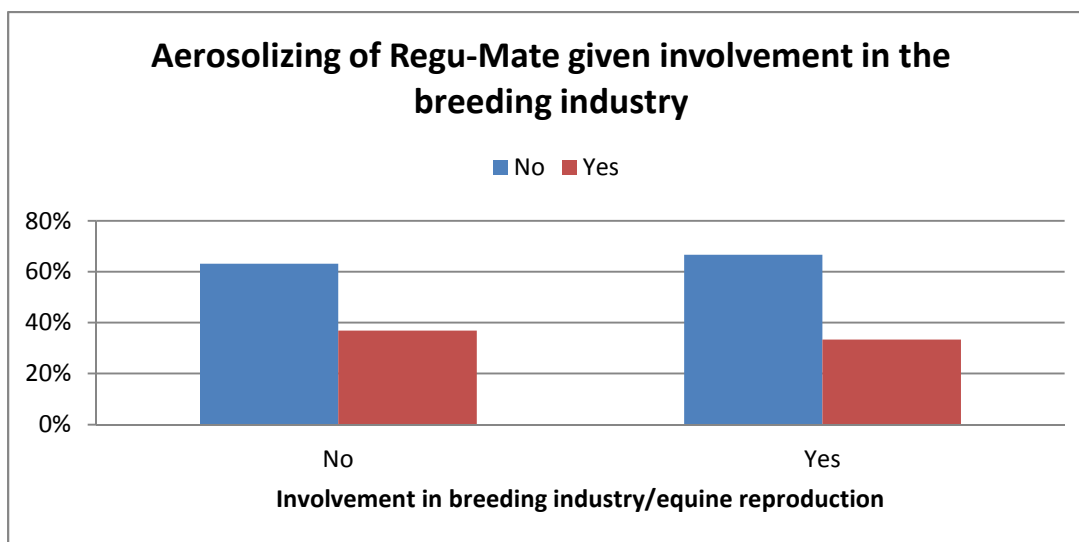


Figure 4-78: Aerosolizing of Regu-Mate given involvement in the breeding industry



Of the respondents who are involved in the breeding industry 57% solely administer Regu-Mate by dosing directly into the horse's mouth and 32% administer the drug both by directly into the mouth and mixed with grain. Of respondents not involved in the breeding industry 30% of respondents only dose directly into their horse's mouth and 9% use a combination of methods (Figure 4-79). While a majority of respondents regardless of their involvement in the breeding

industry use dedicated feed buckets for Regu-Mate (Figure 4-80), the proportion of those who do which are involved in the breeding industry is less (56%) compared to those not involved in the breeding industry (76%).

Figure 4-79: How respondents administer Regu-Mate given involvement in the breeding industry

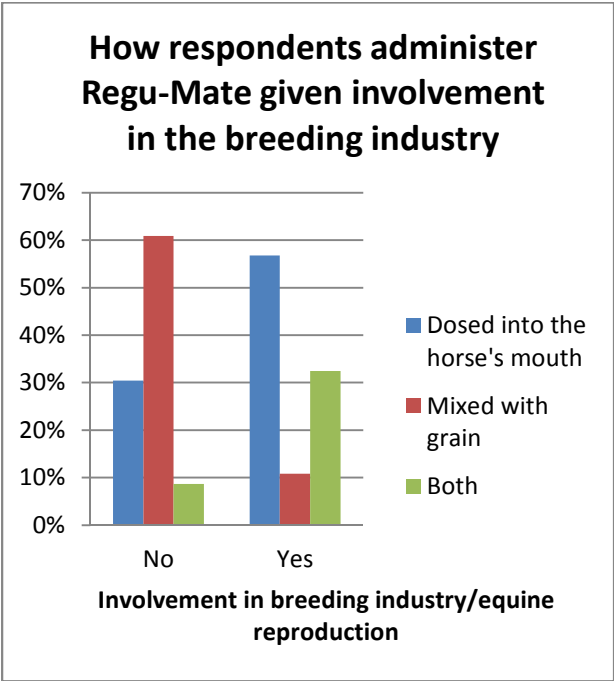


Figure 4-80: Use of Regu-Mate-dedicated feed buckets given involvement in the breeding industry

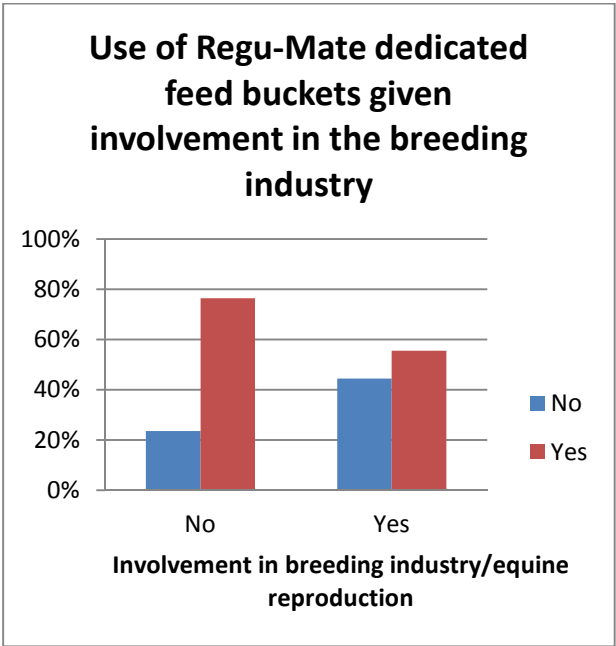


Figure 4-81 shows respondent’s involvement in the breeding industry given where they learned about precautions that should be taken when handling Regu-Mate. Over half of those who reported learning about Regu-Mate precautions from friends are not involved in the breeding industry. Fewer than 20% of those learning this information from the internet or the product insert are not involved in the breeding industry. Of the respondents who reported not discussing Regu-Mate with their veterinarian, 67% are not involved in the breeding industry (Figure 4-82).

Figure 4-81: Involvement in the breeding industry given where the respondent learned about Regu-Mate precautions

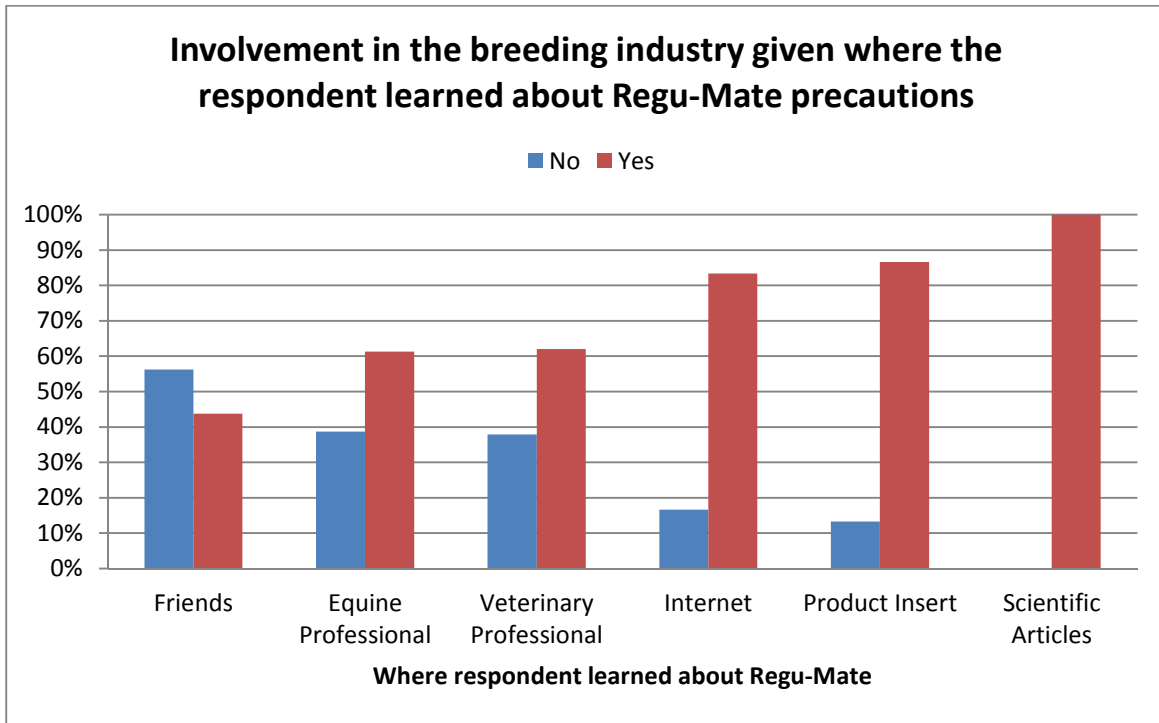
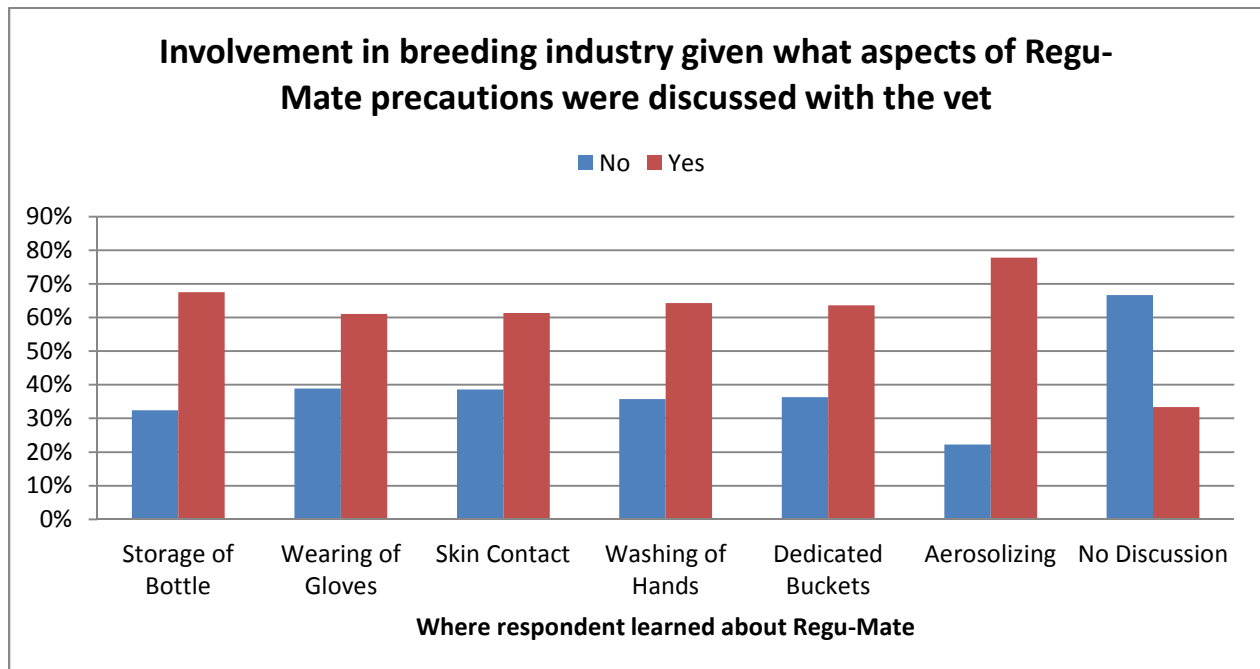


Figure 4-82: Involvement in breeding industry given what aspects of Regu-Mate precautions were discussed with the vet



4.1.8 Reasons for Using Regu-Mate

Figure 4-83 and Figure 4-84 show how often and for how many years, respectively, the respondent has handled Regu-Mate given the reason(s) they use the drug. The distribution of handling frequency is consistent regardless of the reason for using Regu-Mate. People using Regu-Mate for behavior modification are more likely to have been using the drug for one year or less than any other category; “other” had only three respondents.

Figure 4-83: How often Regu-Mate is handled given the reason for using the drug

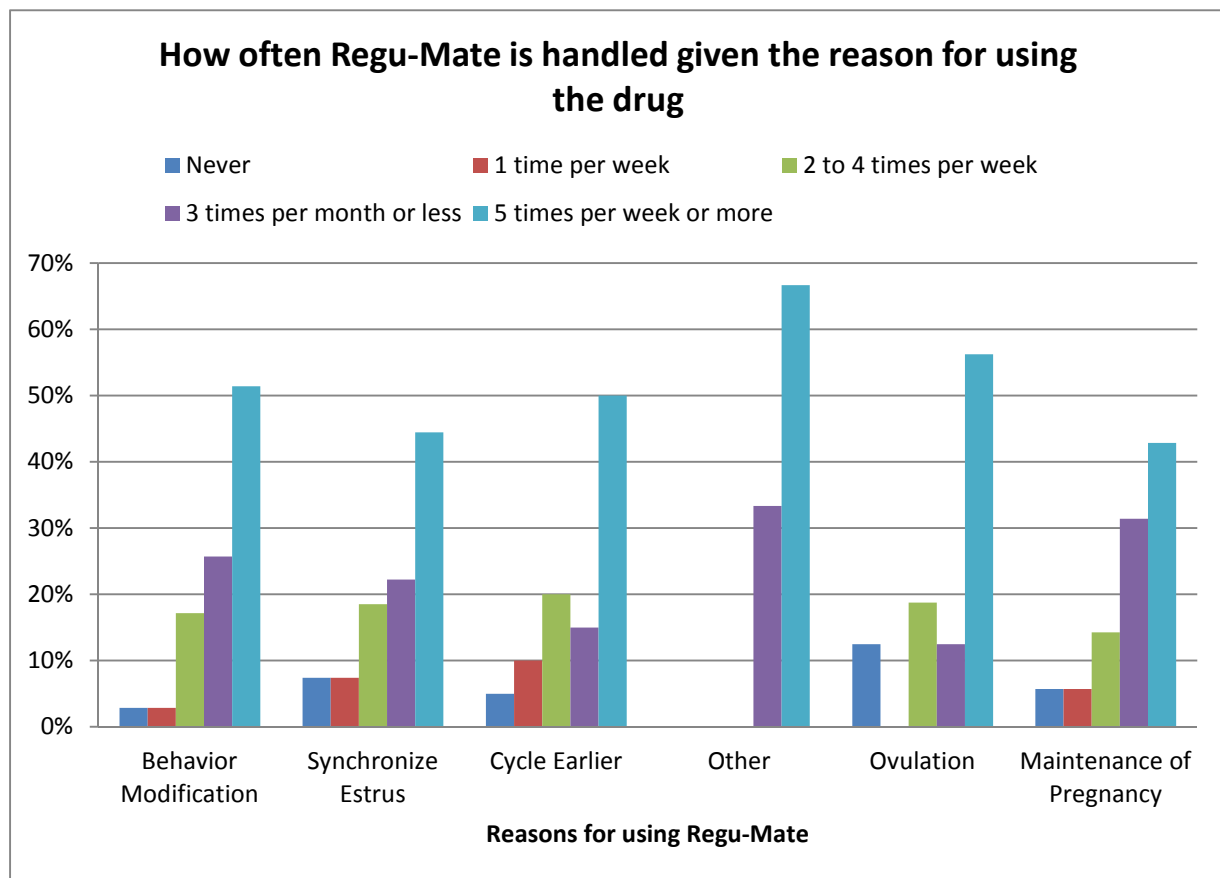
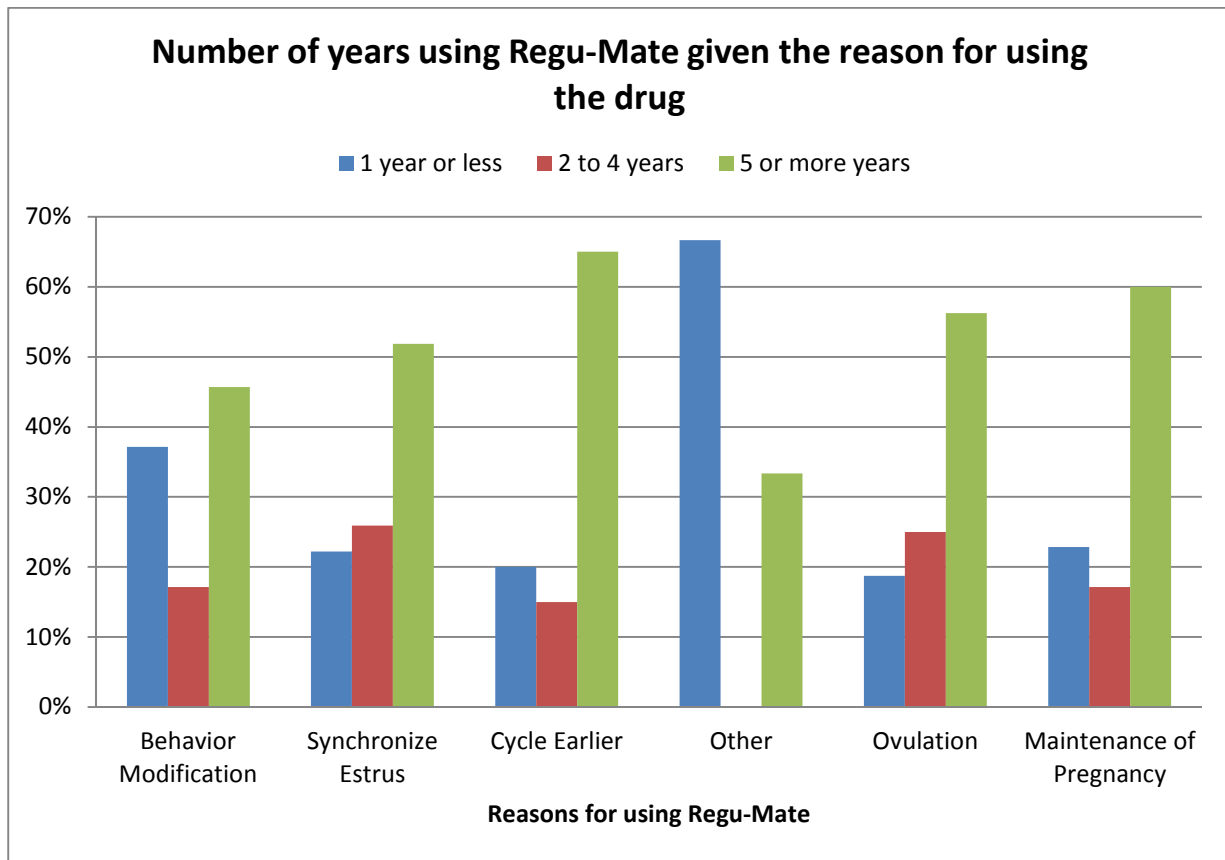


Figure 4-84: Number of years using Regu-Mate given the reason for using the drug



When the reported reasons for using Regu-Mate is divided by glove use (Figure 4-85) it is apparent that those who use Regu-Mate for behavior modification are more likely to use gloves every time they handle the drug than respondents who use the drug for other reasons. Respondents are most likely to report not using gloves when using Regu-Mate to help time ovulation (38%). Hand washing behavior as related to reported reasons for using Regu-Mate is shown in Figure 4-86; there is little difference in hand washing behavior between the categories.

Figure 4-85: Glove use given reasons for using Regu-Mate

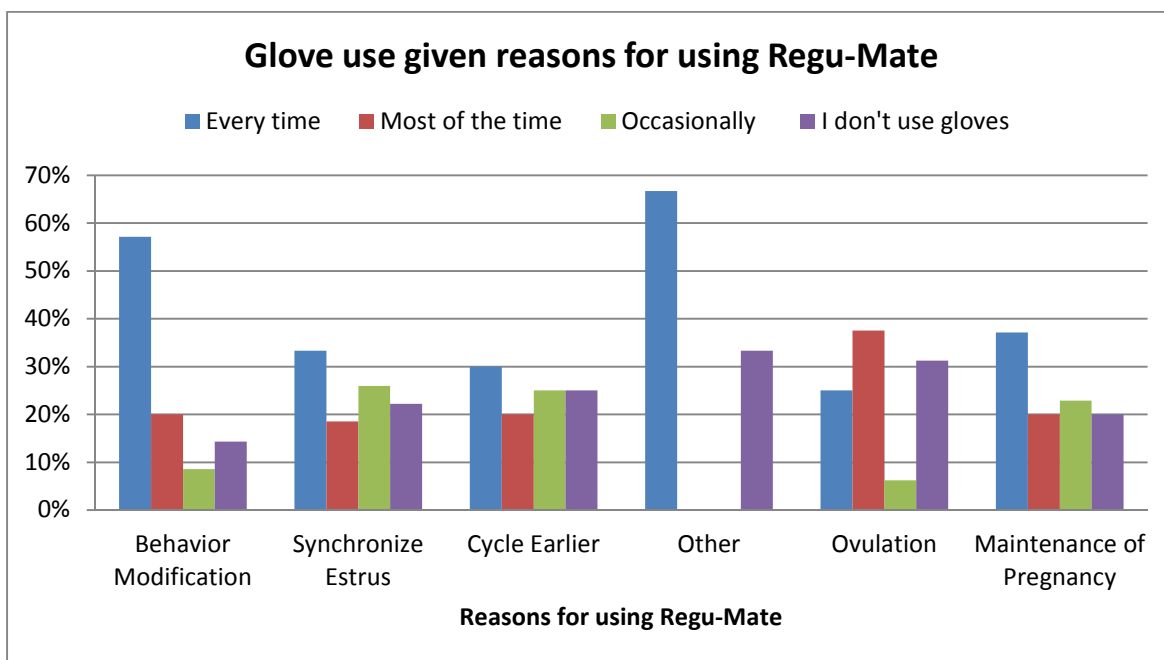
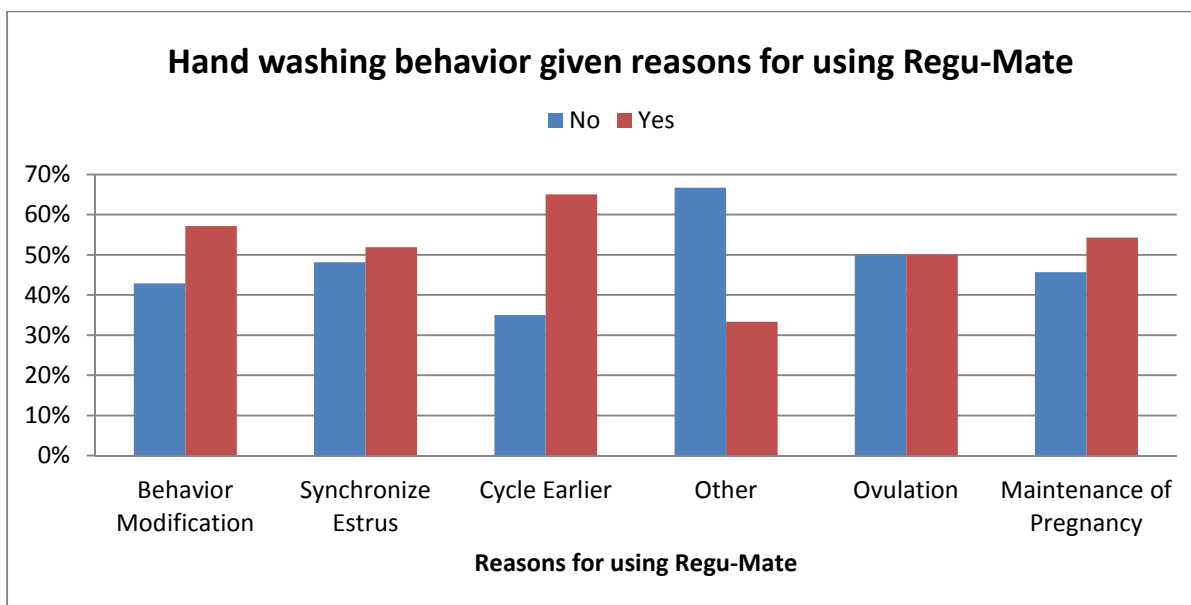


Figure 4-86: Hand washing behavior given reasons for using Regu-Mate



4.1.9 Number of Horses Comparisons

The frequency of regularly handling Regu-Mate given the number of horses the respondent handles is presented in Figure 4-87. Figure 4-88 shows the number of years the respondent has

been administering Regu-Mate classified by the number of horses to which they regularly administer Regu-Mate; the longer respondents have been administering Regu-Mate the more likely they are to be giving the drug to more than 10 horses.

Figure 4-87: How often the respondent regularly handles Regu-Mate given the number of horses to which they give Regu-Mate

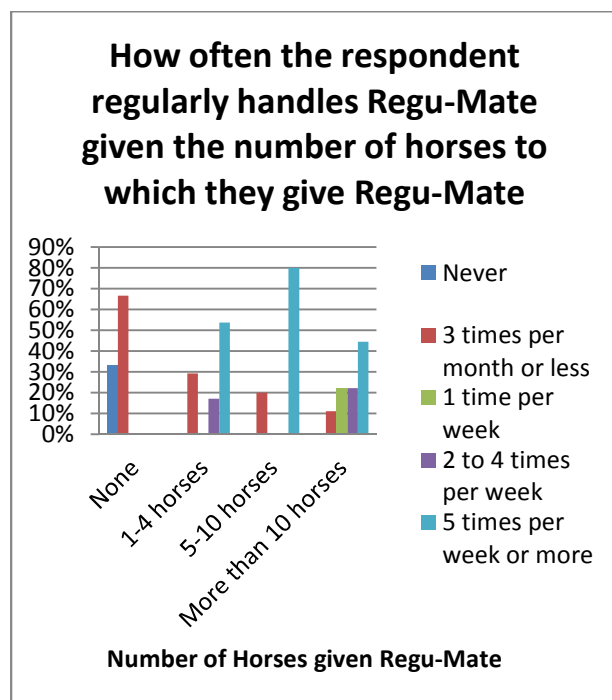
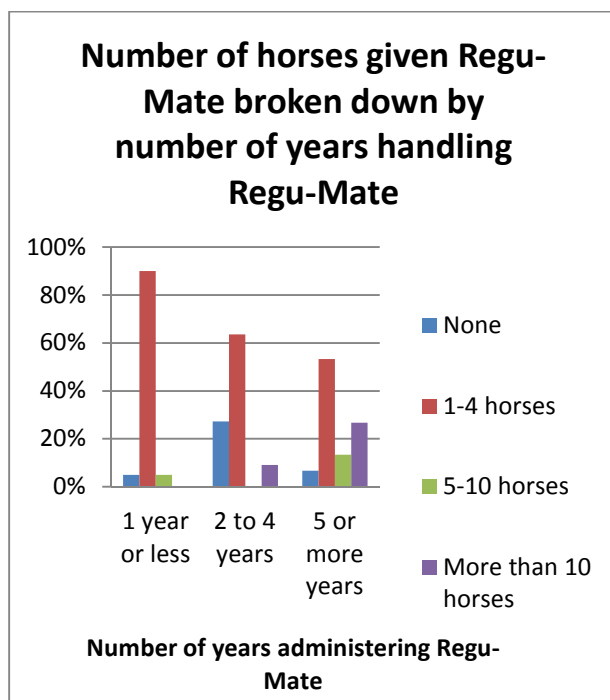


Figure 4-88: Number of horses given Regu-Mate broken down by number of years handling Regu-Mate



A larger percentage of respondents who regularly administer Regu-Mate to more than 10 horses (33%) and to 5 – 10 horses (40%) reported not using gloves than those who administer it to four or fewer horses; Figure 4-89 presents the number of horses to which respondents regularly administer Regu-Mate classified by glove use. Glove replacement distribution is consistent regardless of the number of horses a respondent regularly administer Regu-Mate (Figure 4-90). Of all respondents who regularly administer Regu-Mate to more than 10 horses, 67% do not wash their hands after administering Regu-Mate (Figure 4-91); of respondents who regularly administer to 10 or fewer horses, a majority does wash their hands after handling Regu-Mate. Syringe replacement behavior when withdrawn through the bottle opening is presented in Figure 4-92.

Figure 4-89: Number of horses given Regu-Mate broken down by glove use

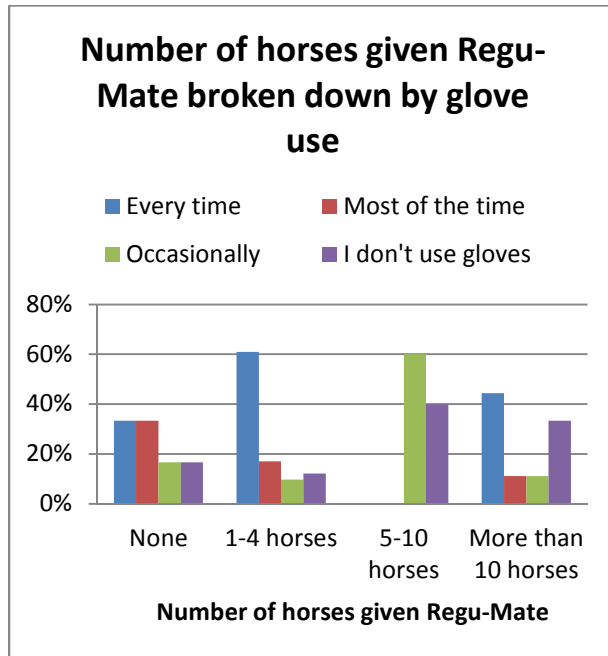


Figure 4-90: Number of horses given Regu-Mate broken down by glove replacement

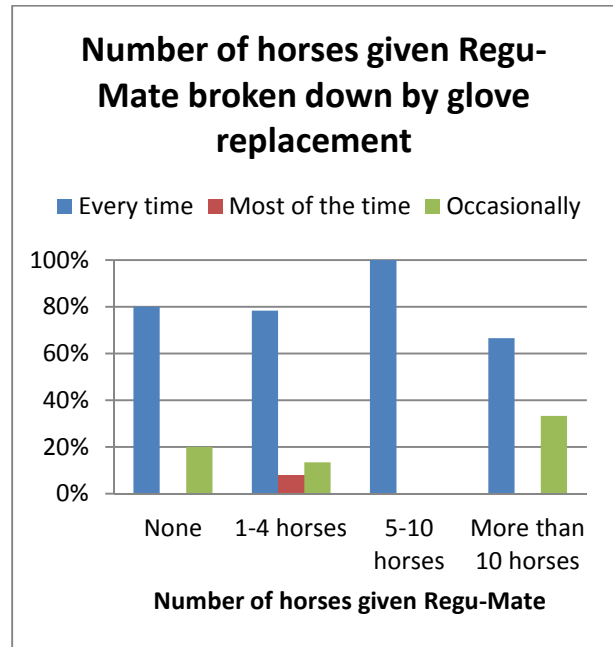


Figure 4-91: Number of horses to which respondent regularly gives Regu-Mate broken down by hand washing behavior

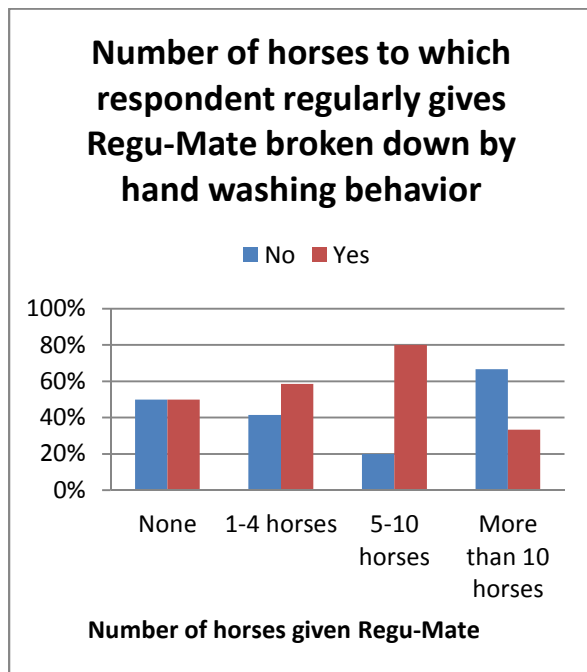
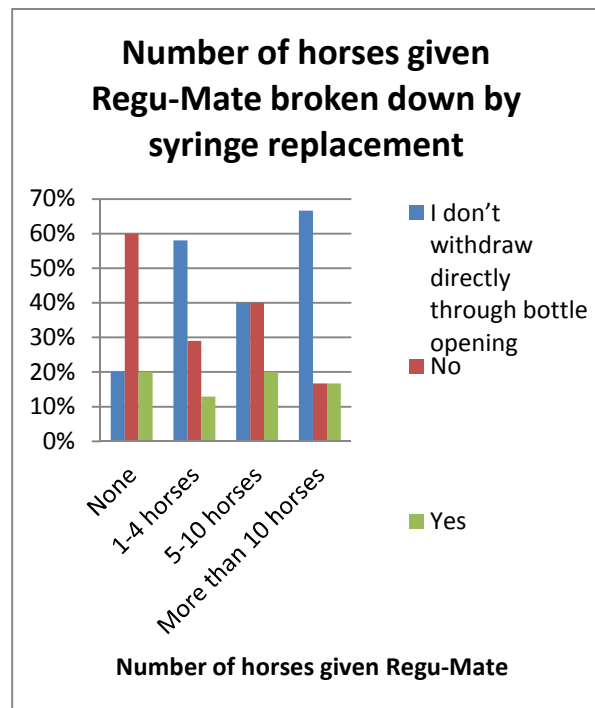
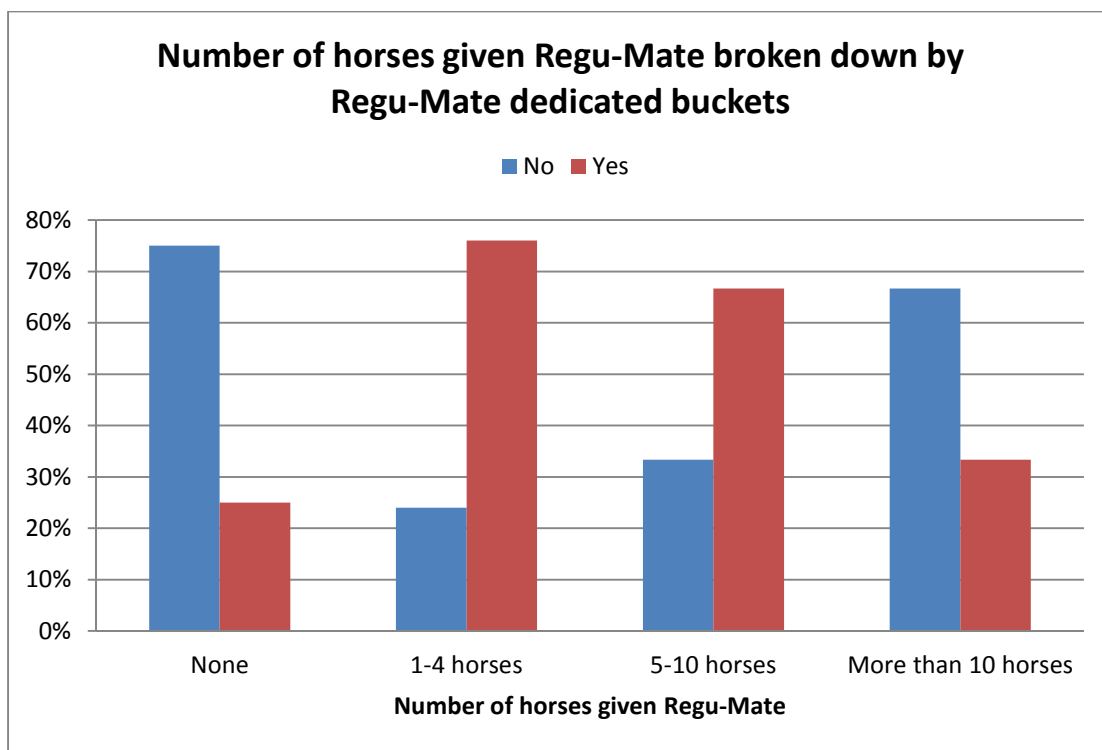


Figure 4-92: Number of horses given Regu-Mate broken down by syringe replacement



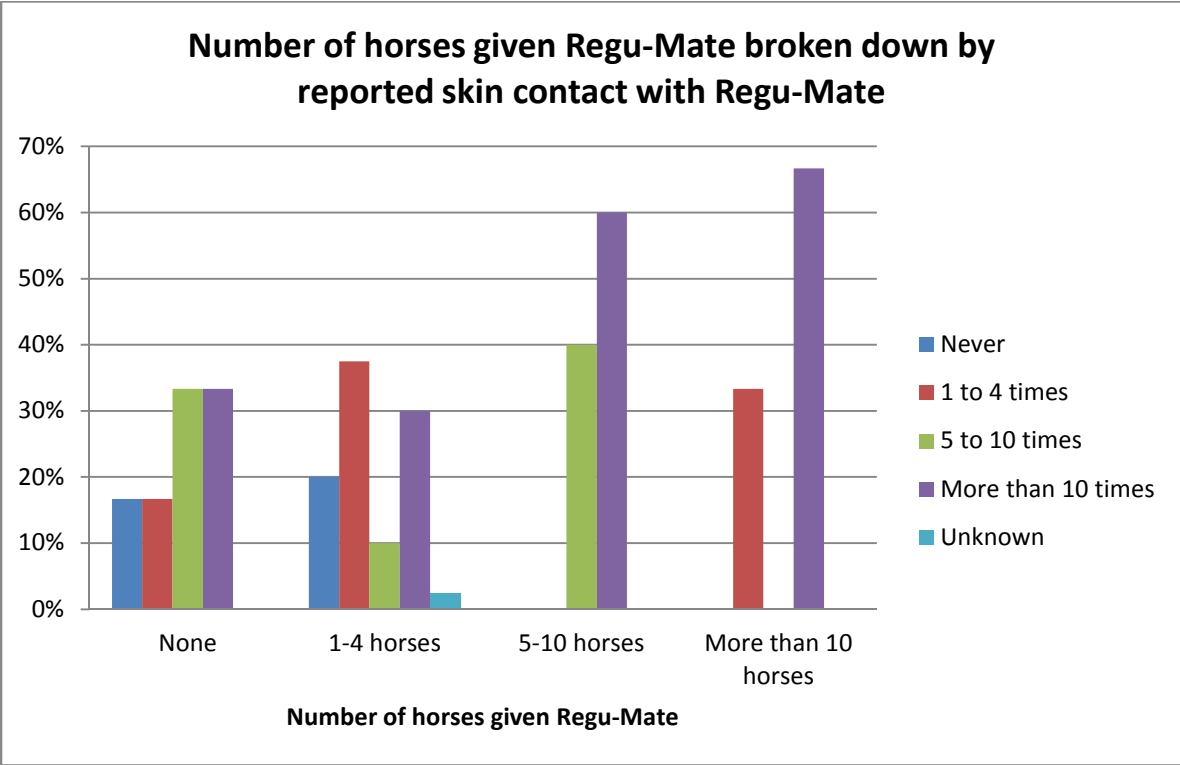
Those respondents who do not regularly administer Regu-Mate to any horses and those who administer to more than 10 horses are more likely (75% and 67%, respectively) than those with one to four or five to ten horses (24% and 33%, respectively) to not use Regu-Mate dedicated buckets (Figure 4-93).

Figure 4-93: Number of horses given Regu-Mate broken down by Regu-Mate dedicated buckets



The majority of respondents who administer Regu-Mate to five or more horses reported having direct skin contact with Regu-Mate more than ten times; Figure 4-94 presents this data.

Figure 4-94: Number of horses given Regu-Mate broken down by reported skin contact with Regu-Mate



Respondents who regularly administer Regu-Mate to one to four horses represent the majority of people who learn about precautions from friends, equine professionals, the product insert, and scientific articles; people who learn about precautions from the internet most commonly administer Regu-Mate to five or more horses (Figure 4-95). Respondents learn similar information from their veterinarian regardless of the number of horses they administer Regu-Mate to (Figure 4-96); the only respondents who had no discussion with their veterinarian about Regu-Mate precautions were those who regularly administer the drug to one to four horses.

Figure 4-95: Number of horses given Regu-Mate broken down by where the respondent learned about Regu-Mate precautions

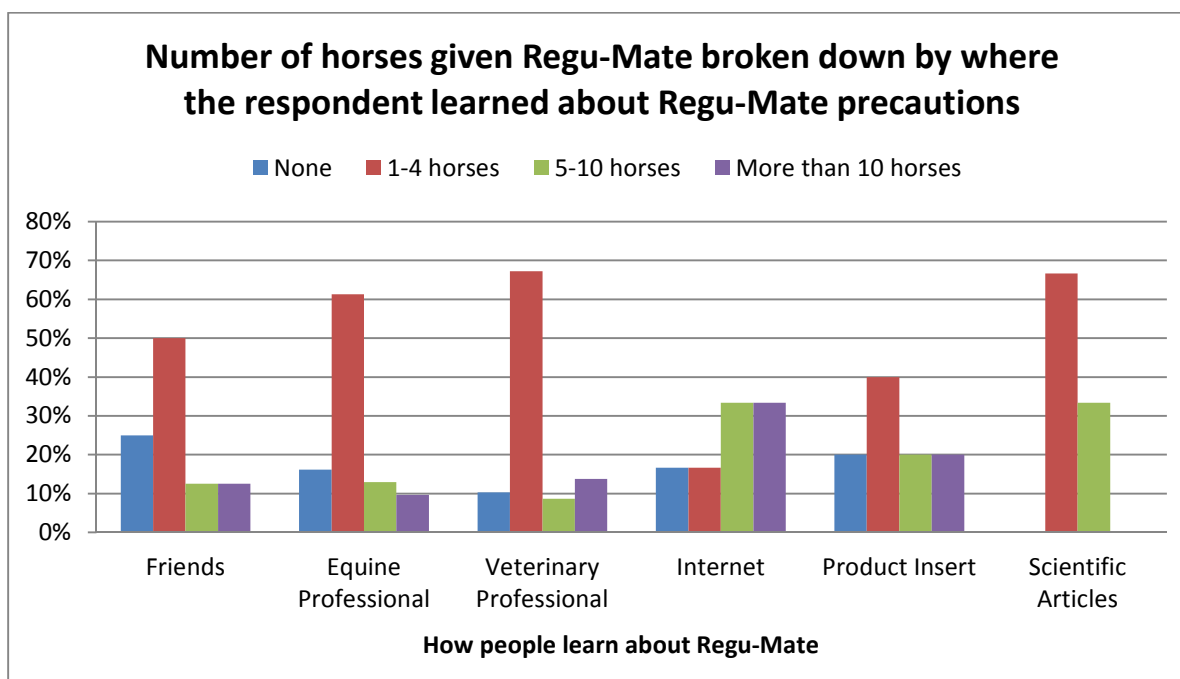
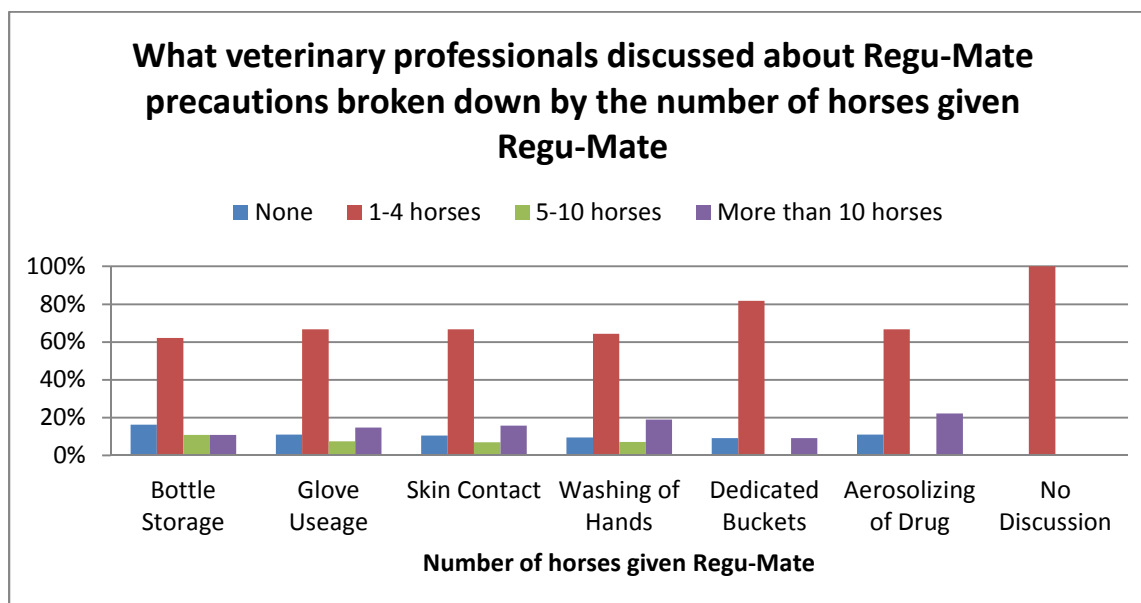


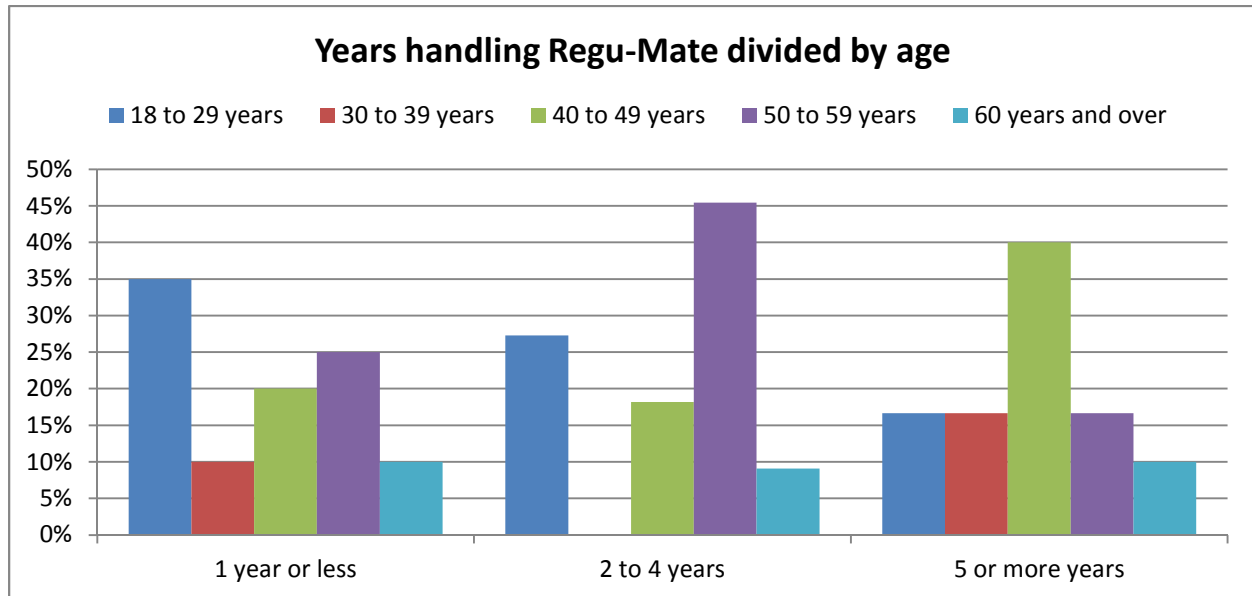
Figure 4-96: What veterinary professionals discussed about Regu-Mate precautions broken down by the number of horses given Regu-Mate



4.1.10 Years Handling Comparisons

The distribution of ages among the length of time that respondents have been using Regu-Mate is presented in Figure 4-97. In all categories, 49% of respondents reported handling Regu-Mate for five years or more.

Figure 4-97: Years handling Regu-Mate given age



Glove use, glove replacement and hand washing behavior are displayed in Figure 4-98, Figure 4-99 and Figure 4-100, respectively. Respondents who have been using Regu-Mate for two to four years are less likely to wear gloves every time they handle the drug, while those who have been using it for five or more years are most likely to fall on either end of the spectrum (50% always using gloves and 20% never using gloves). Glove replacement does not vary depending on how long respondents have been handling Regu-Mate. Hand washing follows a similar trend as the glove use with a greater percentage of respondents who reported using the drug one year or less and five years or more washing their hands than the respondents who reported using the drug for two to four years.

Figure 4-98: Glove use given the number of years handling Regu-Mate

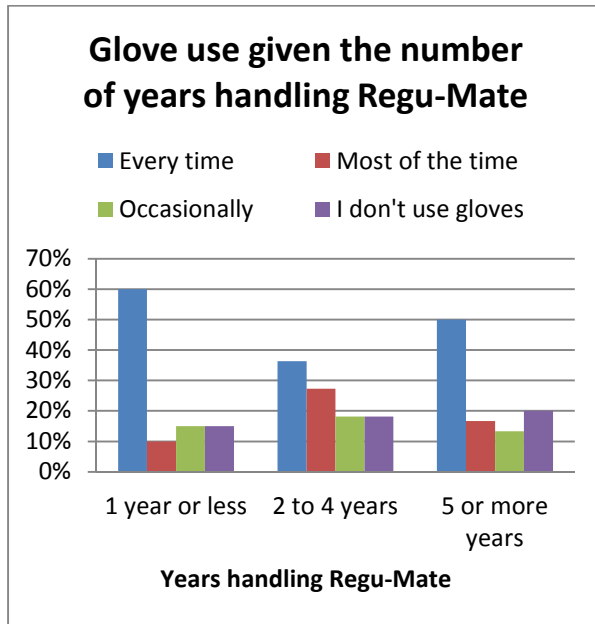


Figure 4-99: Glove replacement behavior given the number of years handling Regu-Mate

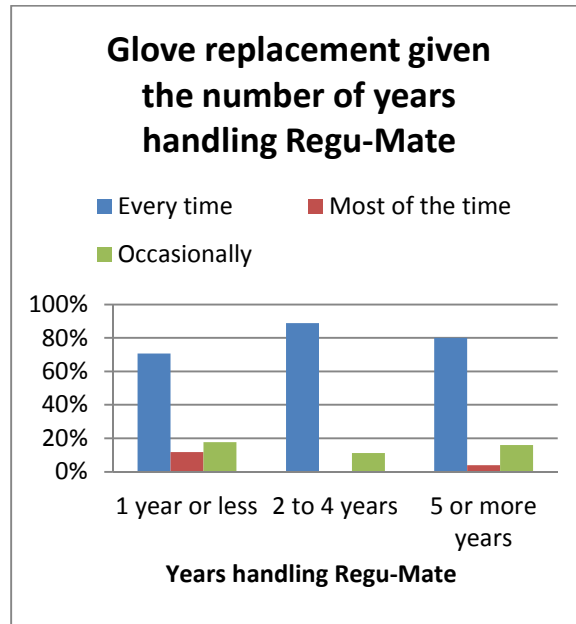
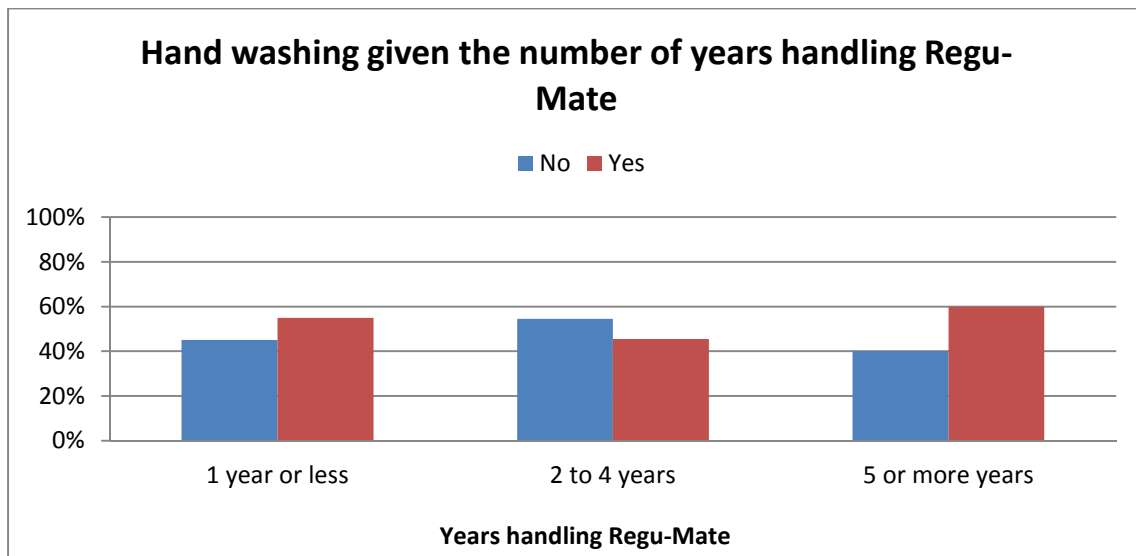


Figure 4-100: Hand washing behavior given the number of years handling Regu-Mate



Respondents who have been handling the drug one year or less and two to four years are more likely to keep the Regu-Mate bottle stored separately from other medications than respondents who have been handling the drug five or more years (Figure 4-101). A majority (58%) of respondents who use only non-locking syringes have been handling Regu-Mate for five or more years, while all respondents who use Luer-locking syringes have been using Regu-Mate for four

years or less (Figure 4-102). Dosing guns are used by only those with two or more years of Regu-Mate use. Figure 4-103 shows how often those who withdraw directly through the bottle opening replace their syringes and Figure 4-104 shows those who reported aerosolizing of the drug given the number of years handling Regu-Mate.

Figure 4-101: Regu-Mate bottle storage given the number of years handling Regu-Mate

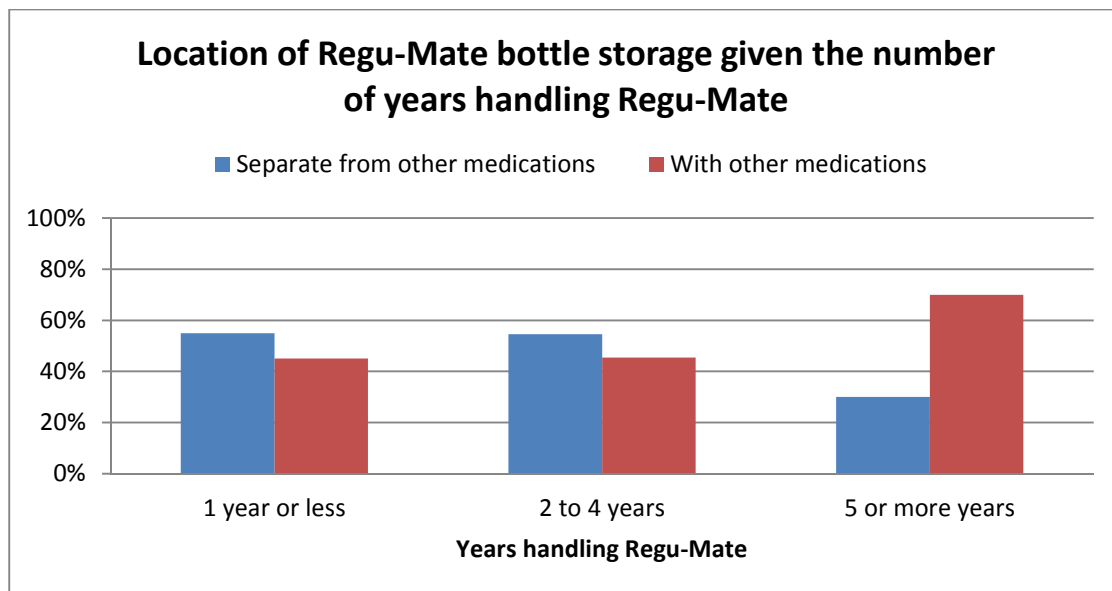


Figure 4-102: Number of years using Regu-Mate given the type of tool used to administer the drug

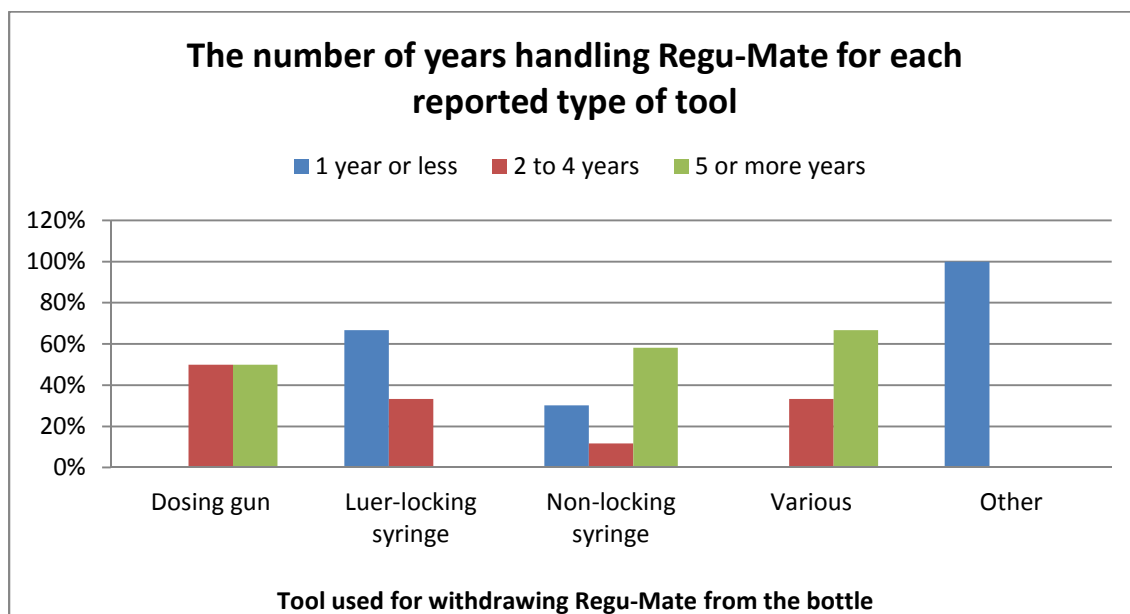


Figure 4-103: Syringe replacement given the number of years handling Regu-Mate

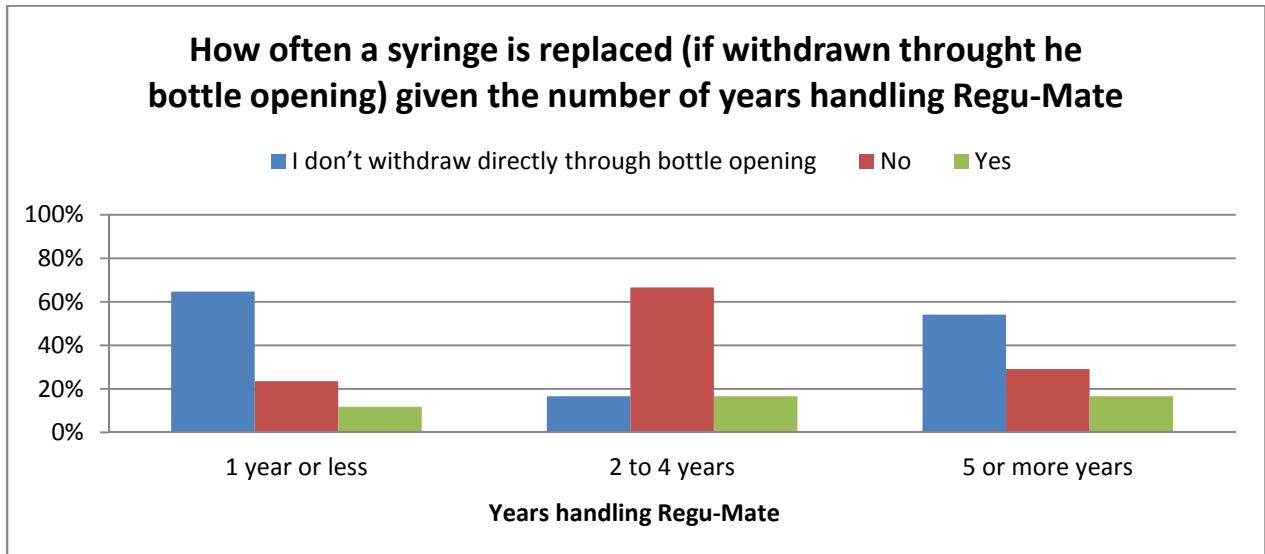


Figure 4-104: Aerosolizing of the drug given the number of years handling Regu-Mate

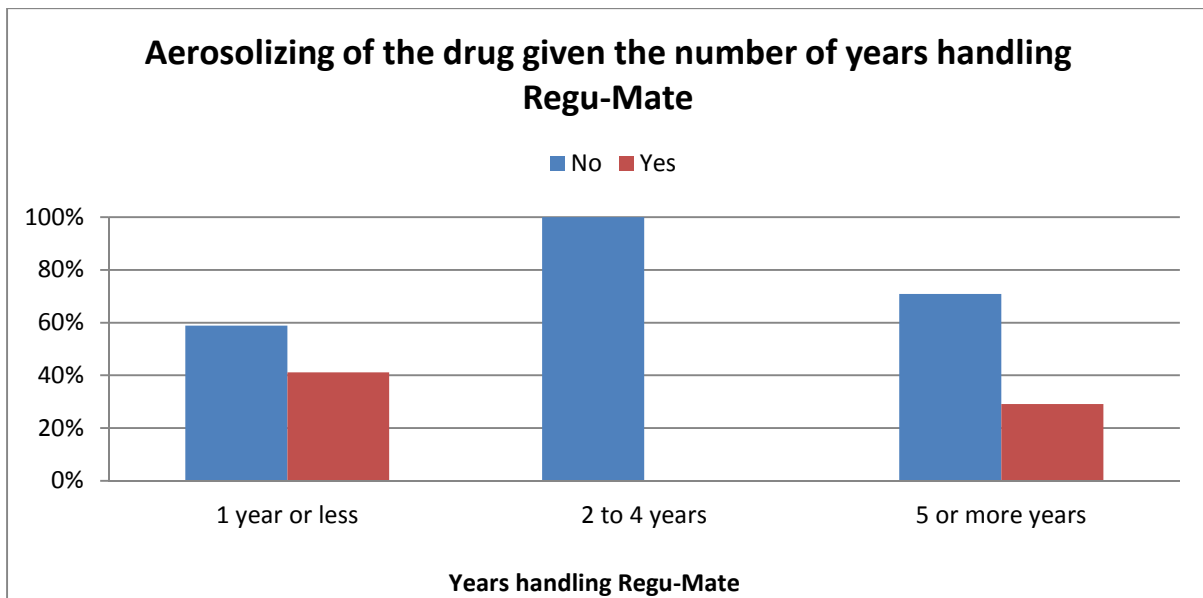
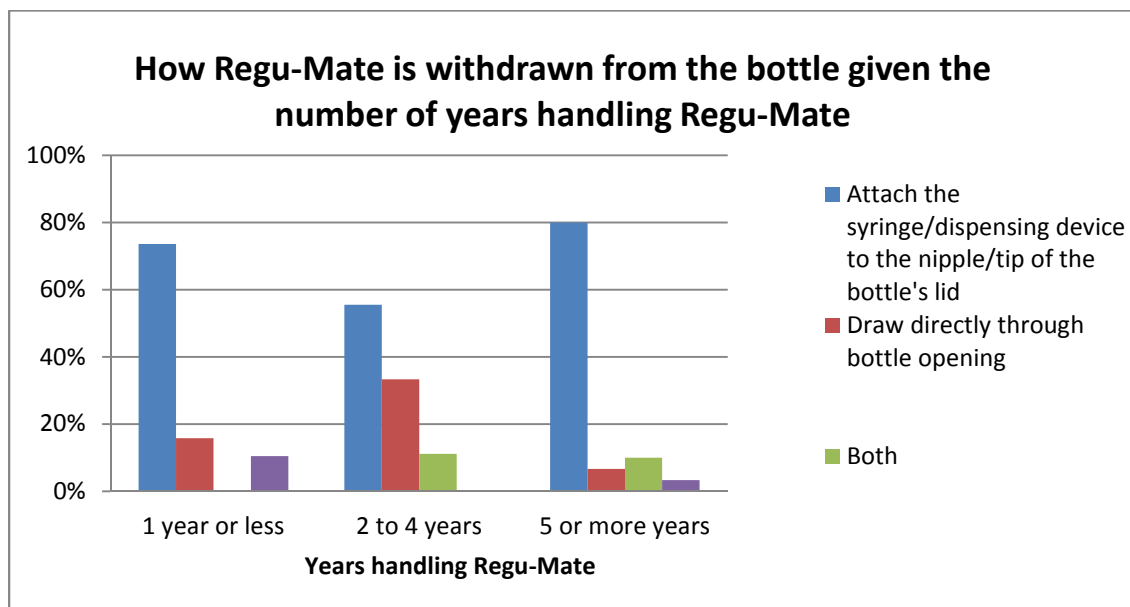


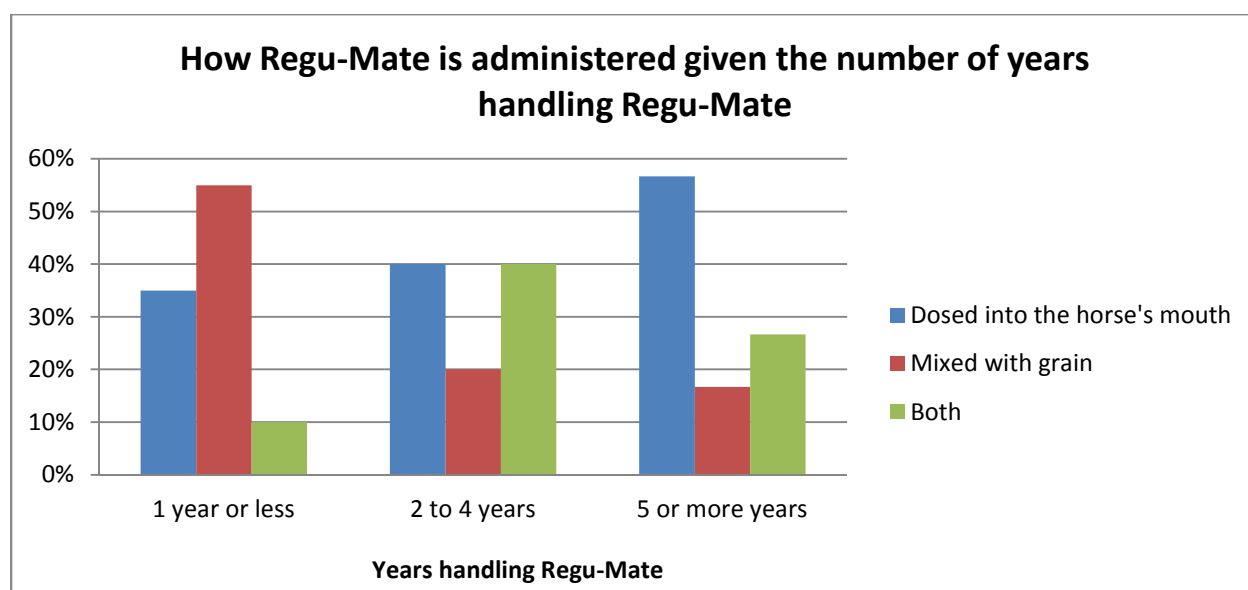
Figure 4-105 displays respondents' method of withdrawing Regu-Mate from the bottle given the number of years they have been handling Regu-Mate. Those who have been handling Regu-Mate one year or less and five years or more are more likely to attach the syringe to the tip of the bottle than those handling the drug for two to four years.

Figure 4-105: How respondents withdraw the drug from the bottle given the number of years handling Regu-Mate



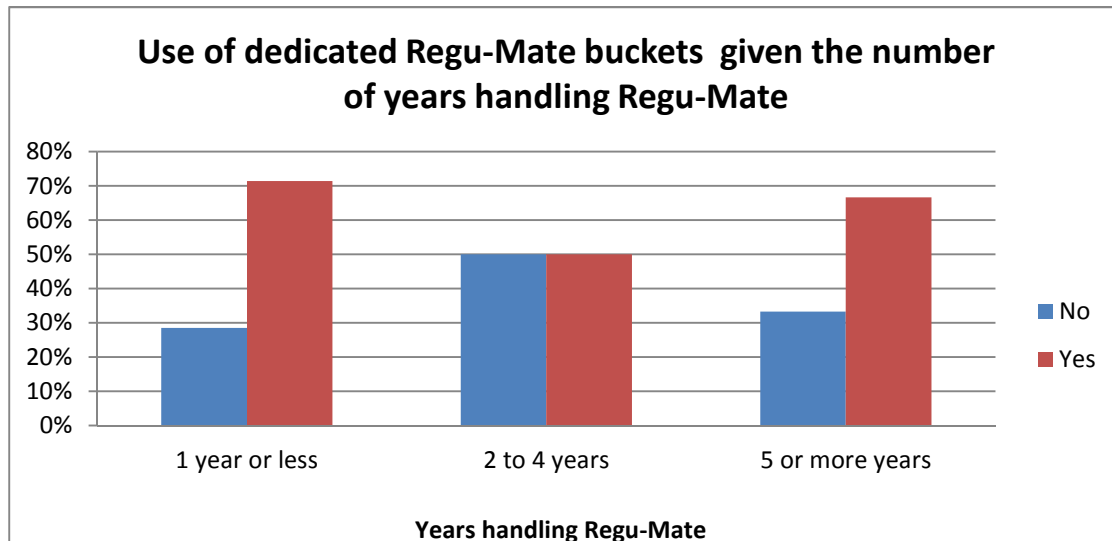
Respondents who have been administering Regu-Mate for one year or less are more likely than those handling it a longer amount of time to mix Regu-Mate with grain. The longer respondents have been handling Regu-Mate the more likely they are to dose directly into the horse's mouth only (Figure 4-106).

Figure 4-106: How Regu-Mate is administered to horses given the number of years handling Regu-Mate



There is little difference in the use of dedicated Regu-Mate buckets given the number of years that respondents have been using Regu-Mate (Figure 4-107).

Figure 4-107: Use of dedicated Regu-Mate buckets given the number of years handling Regu-Mate



Respondents are more likely to report skin contact with Regu-Mate more than 10 times if they have handled Regu-Mate for more than two years. The percentage of respondents who reported never having Regu-Mate come in direct contact with their skin is lower for those who reported using the drug for longer time frames (Figure 4-108).

Figure 4-108: Reported skin contact with Regu-Mate given the number of years handling Regu-Mate

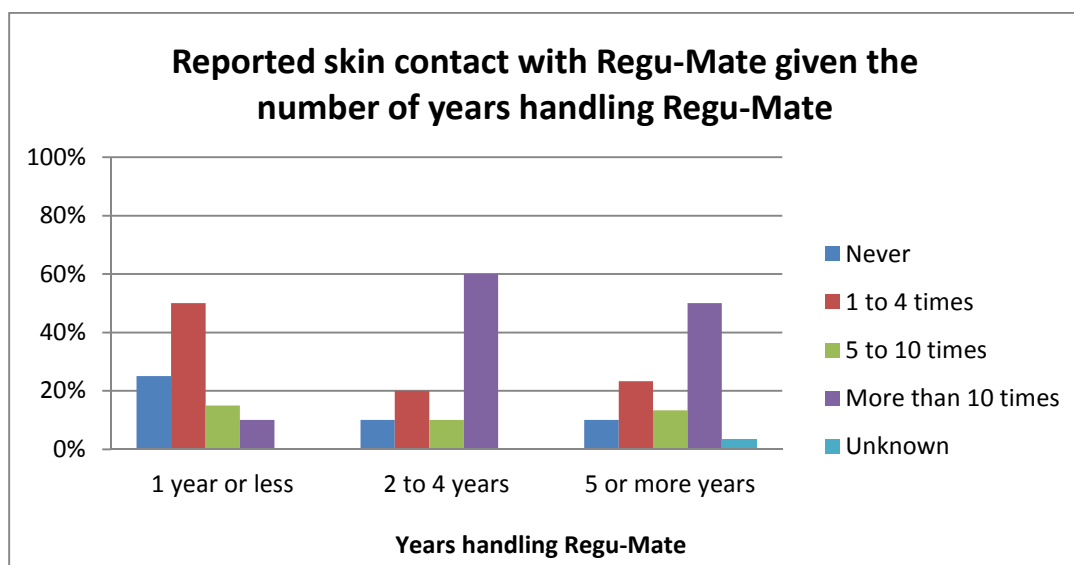


Figure 4-109 and Figure 4-110 depict how respondents learn about Regu-Mate precautions and the handling practices addressed by their veterinarians, respectively, classified by the number of years they reported handling Regu-Mate. Respondents who reported learning about precautions from friends and equine professionals are more likely than those who learn from other sources to have handled Regu-Mate one year or less and those learning about precautions from the internet, veterinary professionals, scientific journals, and product inserts are more likely to have been handling the drug for five years or more. The distribution of years handled between those who reported learning from friends, equine professionals and veterinary professionals is similar. The distribution among years handled for the handling practices addressed by the veterinarian is consistent across the different categories.

Figure 4-109: How respondents learned about Regu-Mate precautions broken down by the number of years handling Regu-Mate

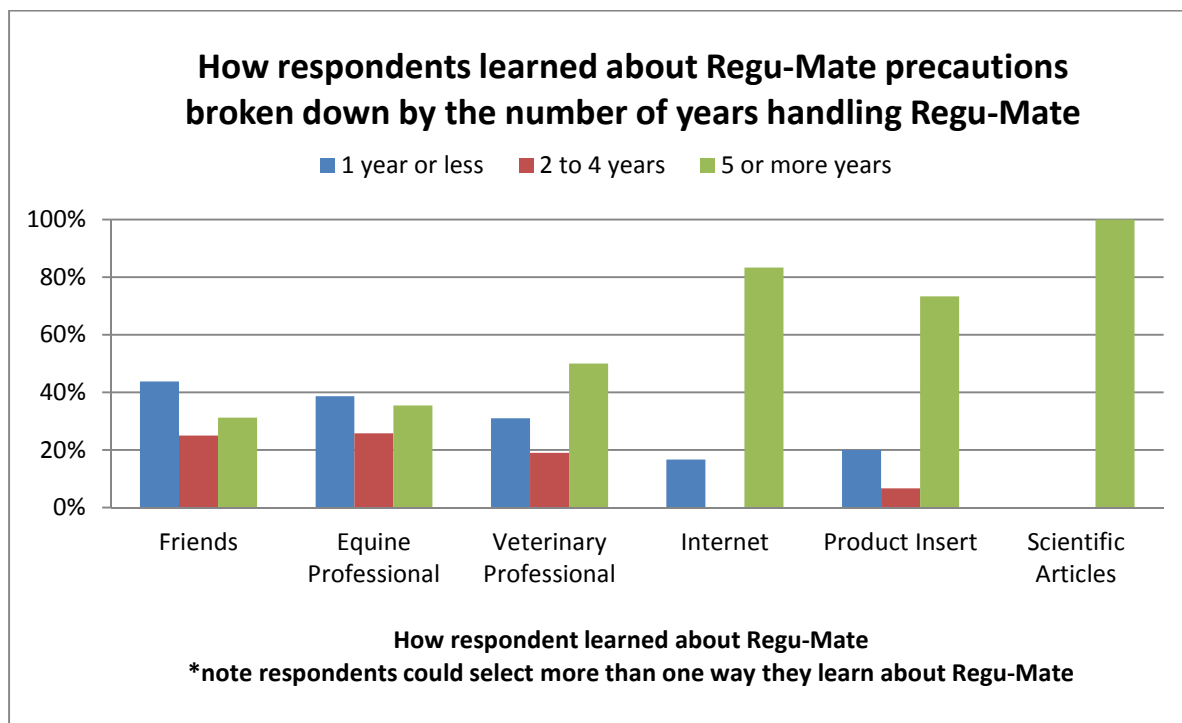
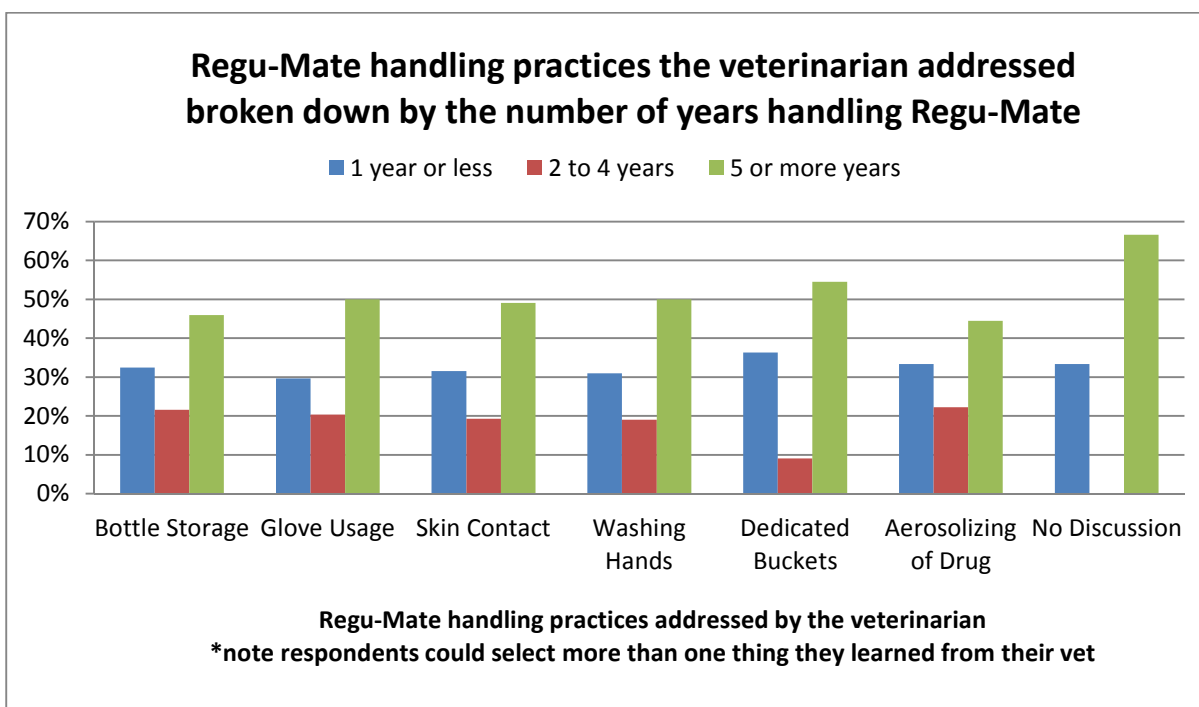


Figure 4-110: Regu-Mate handling practices the veterinarian addressed broken down by the number of years handling Regu-Mate



4.1.11 Frequency handling Regu-Mate

Figure 4-111 through Figure 4-114 present information about glove use, glove replacement, hand washing behavior, and bottle storage given how regularly the respondents handle Regu-Mate. Two respondents reported using Regu-Mate only once a week and also reported that they do not use gloves when handling Regu-Mate. Those who use Regu-Mate five times a week or more do not use gloves 23% of the time. The more often respondents use Regu-Mate the less likely they will replace gloves every time they handle the drug. A majority of respondents handling Regu-Mate three times per month or less and two to five times per week wash their hands after handling Regu-Mate; a majority of respondents who handle Regu-Mate five times per week or more do not wash their hands after handling Regu-Mate.

Figure 4-111: Glove use given how often the respondent regularly handles Regu-Mate

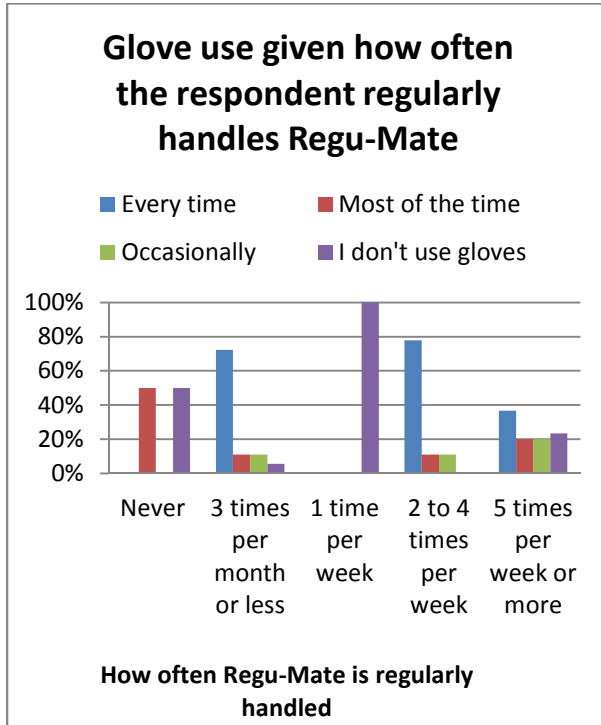


Figure 4-112: Glove replacement given how often the respondent regularly handles Regu-Mate

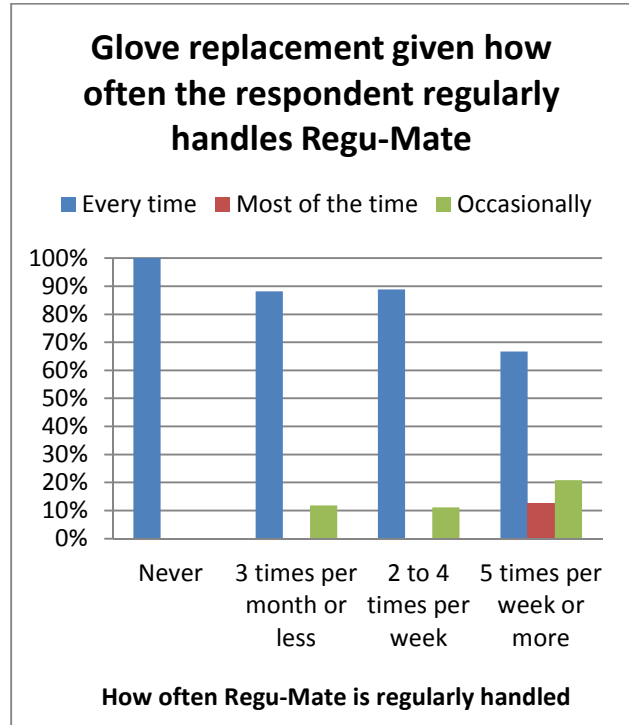


Figure 4-113: Hand washing given how often the respondent regularly handles Regu-Mate

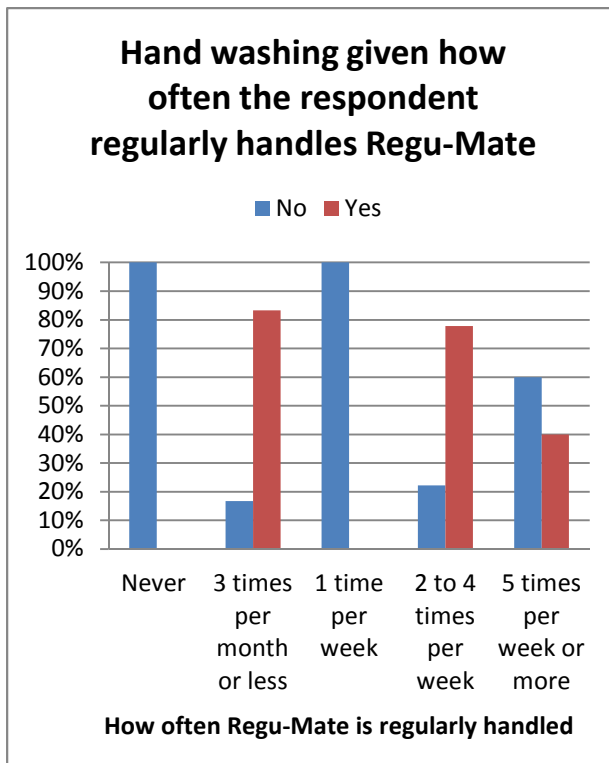
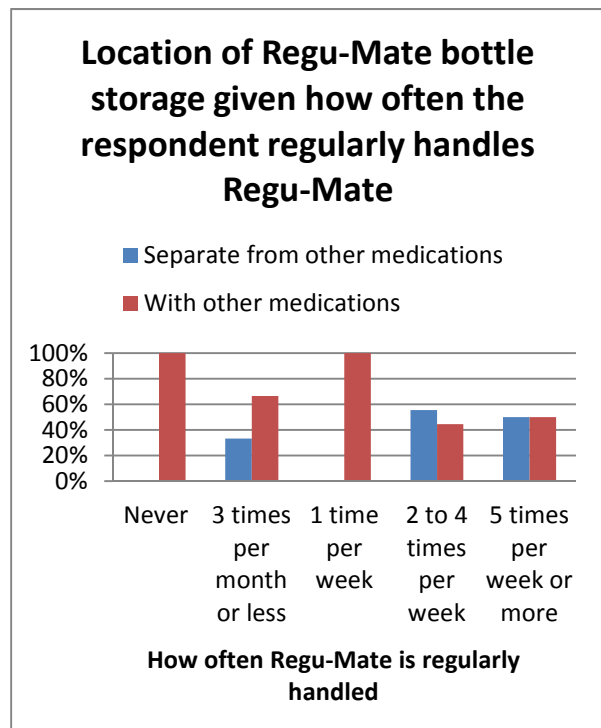


Figure 4-114: Location of Regu-Mate bottle storage given how often the respondent regularly handles Regu-Mate



Most respondents, regardless of how often they use Regu-Mate, withdraw Regu-Mate by attaching the syringe/dispensing device to the tip of the bottle's lid (Figure 4-115). Most of the respondents who use syringes to dispense Regu-Mate, when classified by the frequency with which they handle Regu-Mate, do not withdraw directly through the bottle opening (Figure 4-116). Figure 4-117 shows the aerosolizing behavior of respondents given the frequency with which they regularly handle Regu-Mate.

Figure 4-115: How Regu-Mate is withdrawn from the bottle given how often the respondent regularly handles Regu-Mate

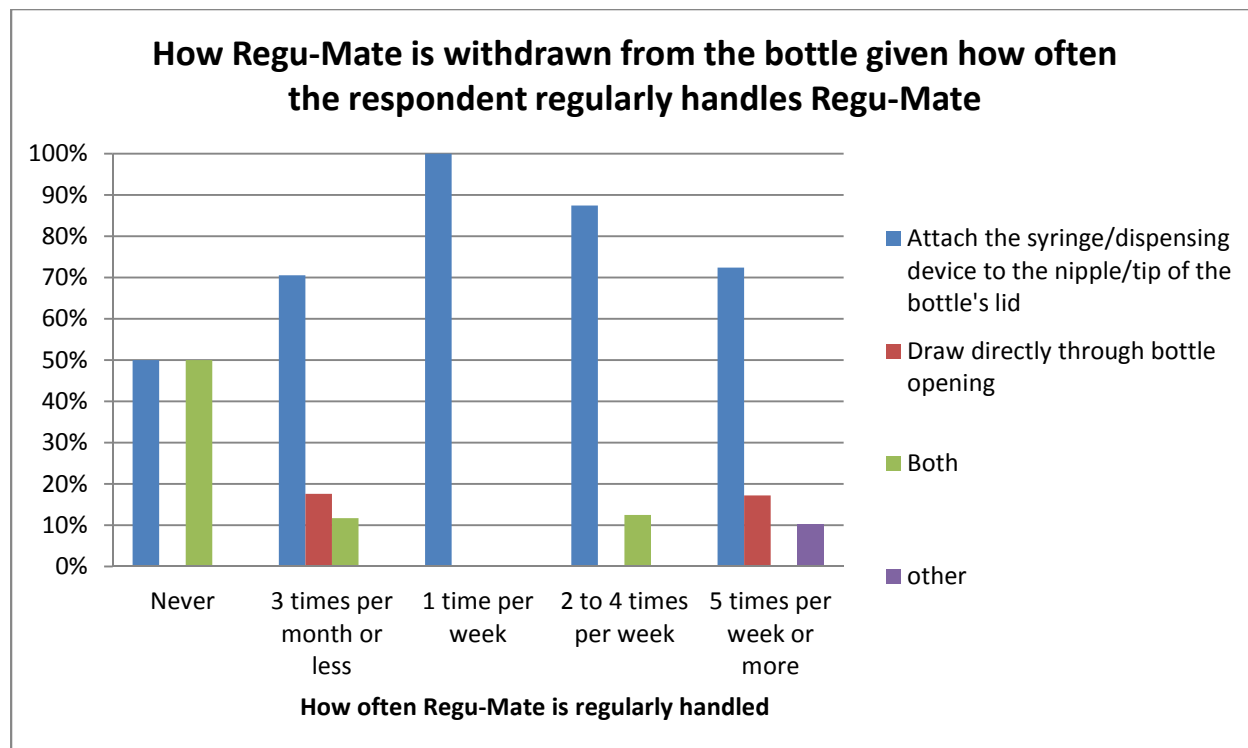


Figure 4-116: How often a syringe is replaced (if withdrawn through the bottle opening) given how often the respondent regularly handles Regu-Mate

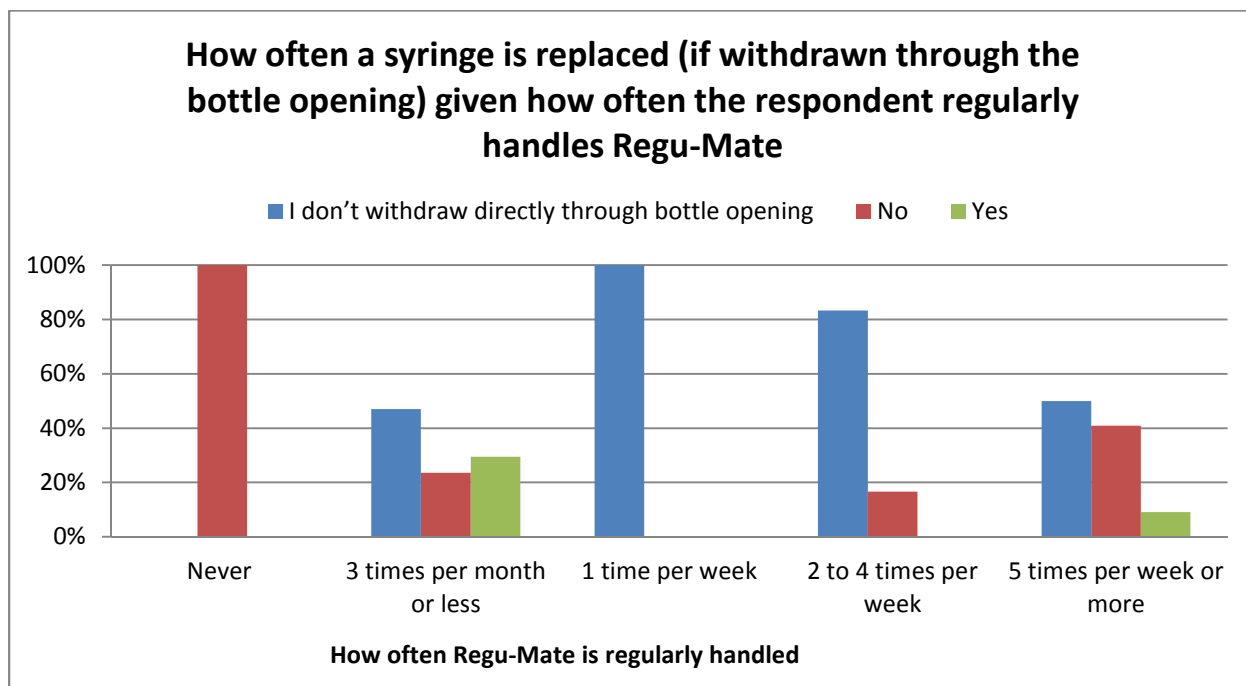
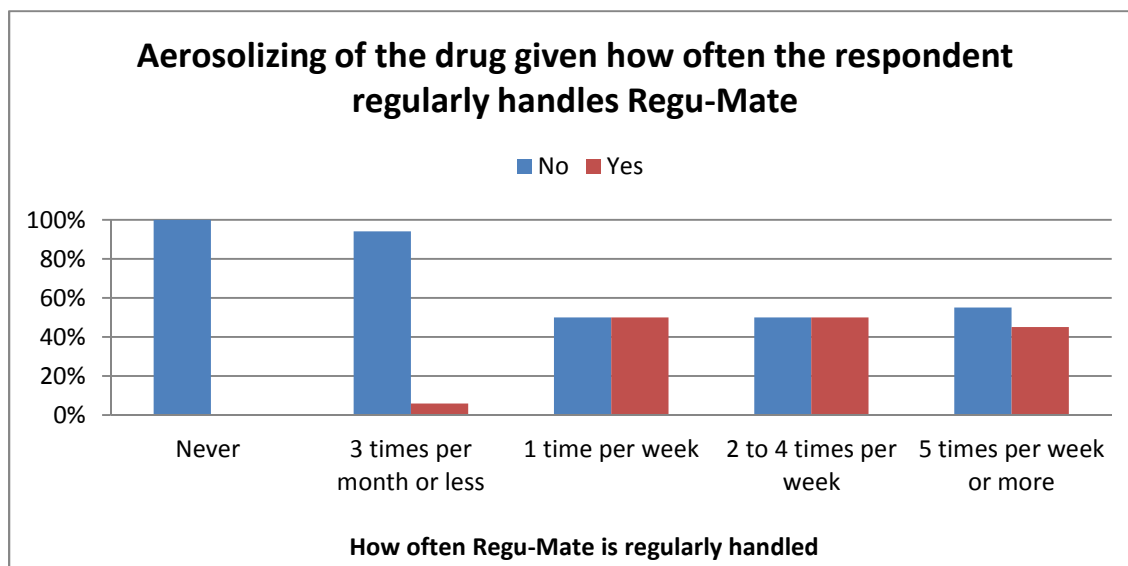


Figure 4-117: Aerosolizing of the drug given how often the respondent regularly handles Regu-Mate



There is little difference in how Regu-Mate is administered (Figure 4-118) or in the use of dedicated buckets for Regu-Mate (Figure 4-119) when broken down by how often Regu-Mate is used. Figure 4-120 presents the reported skin contact with Regu-Mate given the frequency with which the respondent administers Regu-Mate.

Figure 4-118: How Regu-Mate is administered given how often the respondent regularly handles Regu-Mate

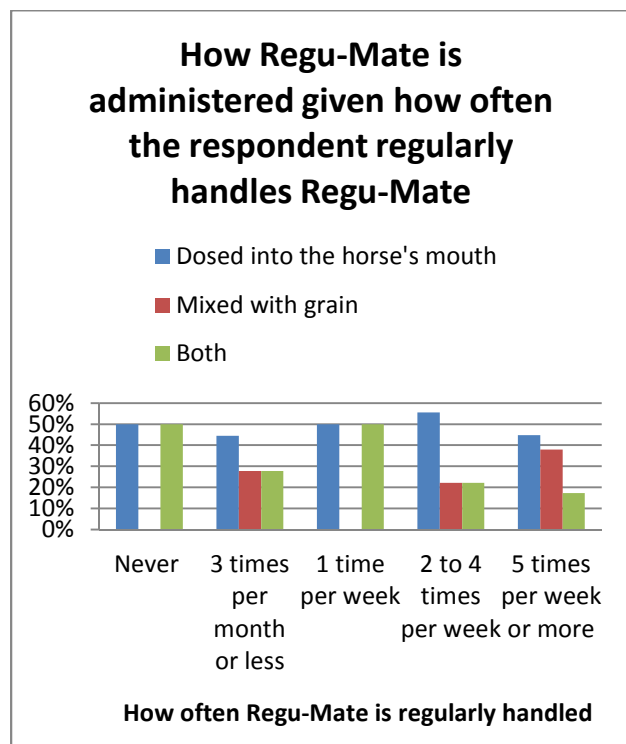


Figure 4-119: Use of dedicated Regu-Mate buckets given how often the respondent regularly handles Regu-Mate

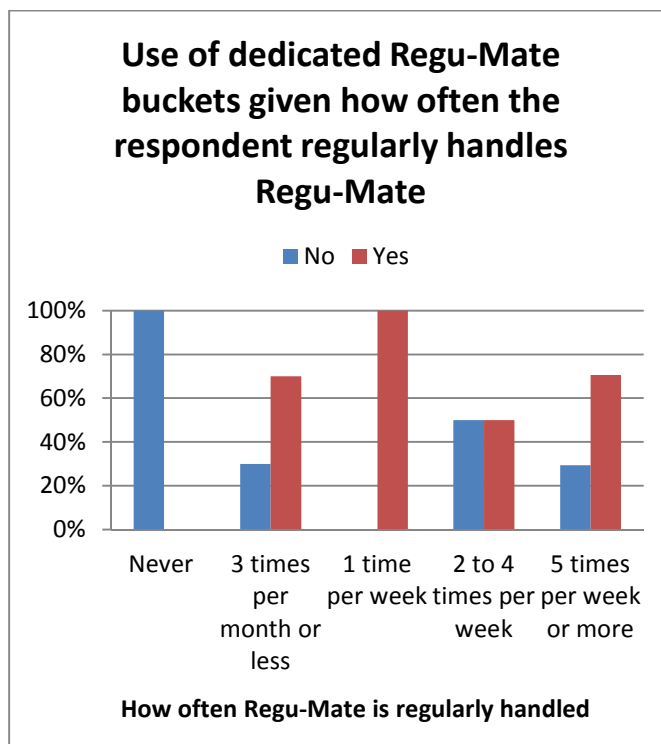
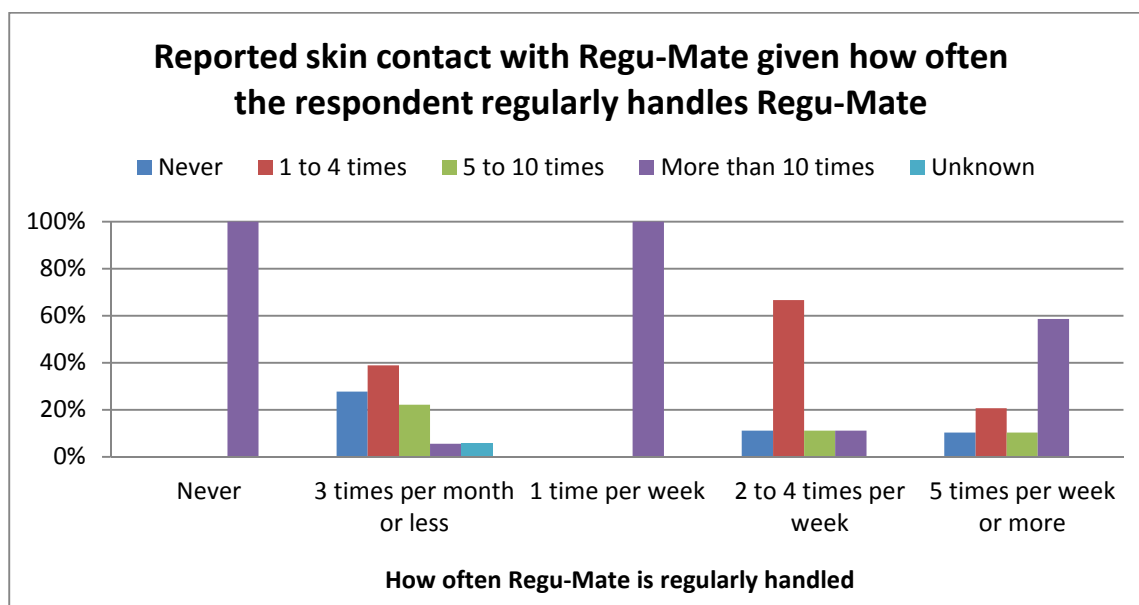


Figure 4-120: Reported skin contact with Regu-Mate given how often the respondent regularly handles Regu-Mate



4.1.12 Preventative Measures

Measures to prevent or limit exposure to Regu-Mate include but are not limited to glove use, hand washing and the type of equipment used.

Glove Use and Hand Washing

Over 50% of respondents who use gloves every time they handle Regu-Mate reported direct skin contact with the drug one to four times whereas 82% of those who don't use gloves reported direct skin contact with Regu-Mate more than 10 times (Figure 4-121). Of the glove-wearing respondents who reported their skin never having come into direct contact with Regu-Mate, 89% replace their gloves every time they handle Regu-Mate. Regardless of the number of times a respondent reported having direct skin contact with Regu-Mate, 50% or more reported wearing gloves all of the time (Figure 4-122).

Figure 4-121: Reported contact with Regu-Mate given how often gloves are used

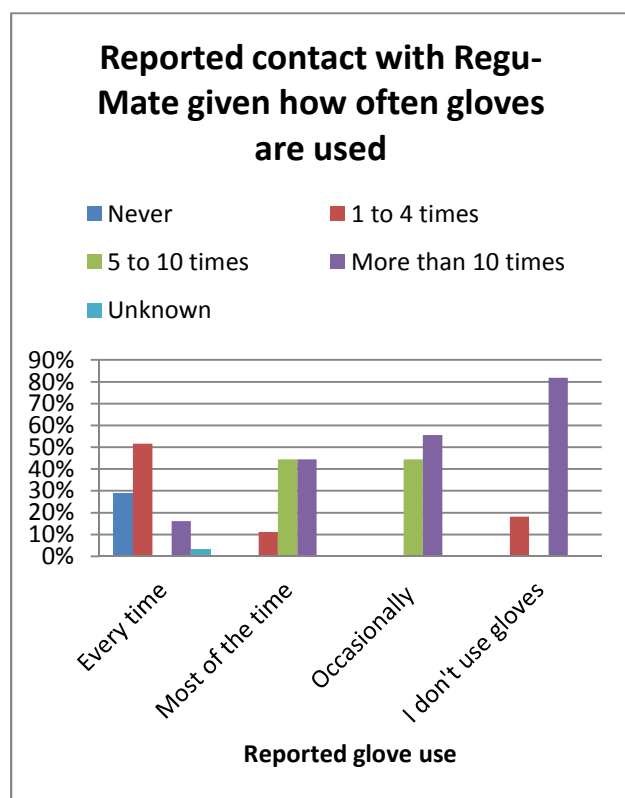
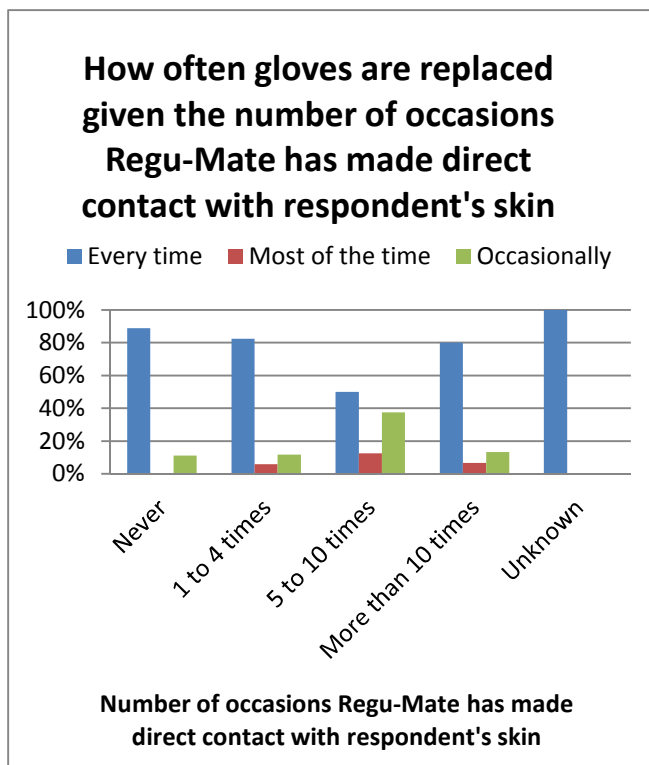


Figure 4-122: How often gloves are replaced given the number of occasions Regu-Mate has made direct contact with respondent's skin



When gloves are used every time Regu-Mate is handled, 90% of respondents reported replacing gloves for each handling occasion and those who use gloves occasionally replace gloves each time they use them 67% of the time (Figure 4-123). Of respondents who use gloves all the time or occasionally, 71% and 78%, respectively, wash their hands after using Regu-Mate. Of the respondents who do not use gloves, 91% do not wash their hands (Figure 4-124).

Figure 4-123: How often gloves are replaced given how often they are used

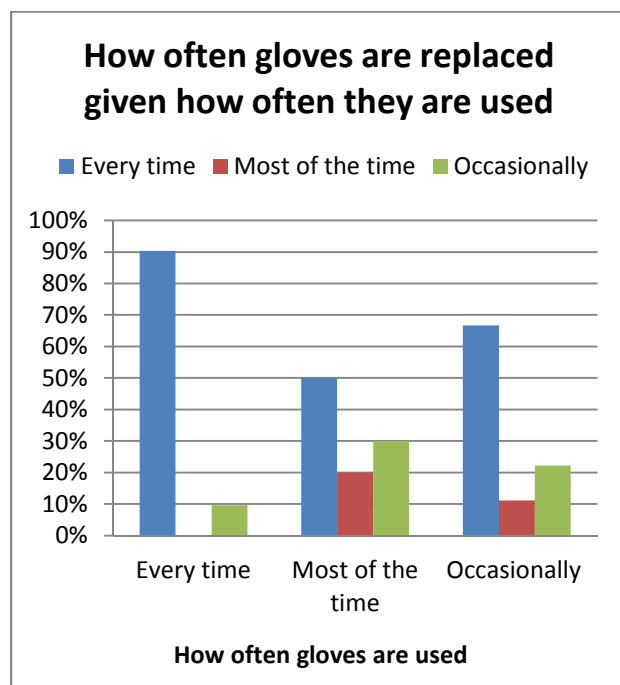


Figure 4-124: How often respondents wash their hands after using Regu-Mate given how often gloves are used

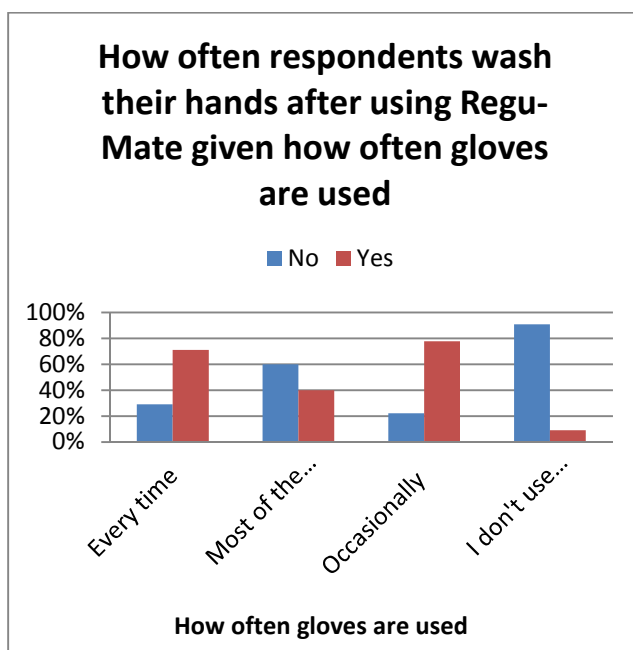
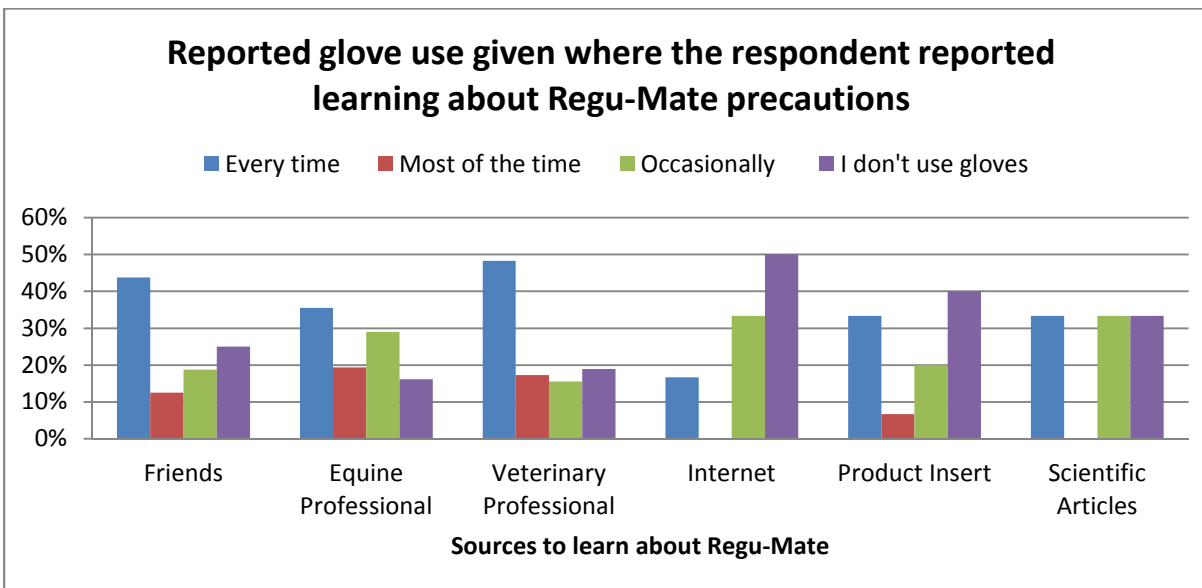


Figure 4-125 shows the reported glove use when respondents are classified by where they learn about precautions for handling Regu-Mate. Over 40% of those who reported learning about precautions from the internet and product insert do not use gloves. Of the respondents who learn from friends, 25% reported not using gloves and 44% wear gloves every time.

Figure 4-125: Reported glove use given where the respondent reported learning about Regu-Mate precautions



Fewer than half of respondents, 43%, who reported having direct skin direct contact with Regu-Mate more than 10 times reported washing their hands after handling Regu-Mate; half or more of those who reported direct skin contact with the drug 10 or fewer times reported washing their hands after handling Regu-Mate (Figure 4-126).

Figure 4-126: Hand washing behavior given the number of occasions Regu-Mate has made direct contact with respondent's skin

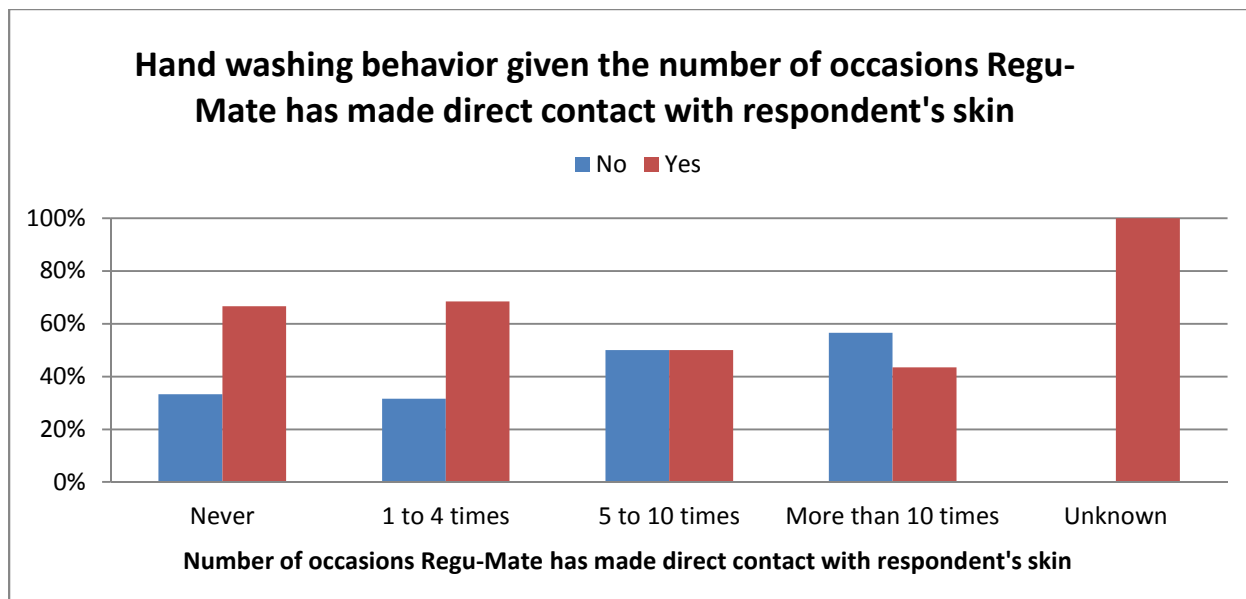


Figure 4-127 and Figure 4-128 show the respondents who reported performing actions prior to washing their hands classified by sex and hand washing behavior. Men are more likely than women to perform actions such as eating/drinking/smoking, writing or measuring out feed prior to washing their hands while the percentages of respondents opening doors and handling horses are similar between the sexes. Of the respondents who wash their hands after handling Regu-Mate the actions reported prior to washing include writing (9%), measuring out feed (3%), opening doors (15%) and handling of horses/equipment (12%).

Figure 4-127: Actions performed by males/females prior to washing hands

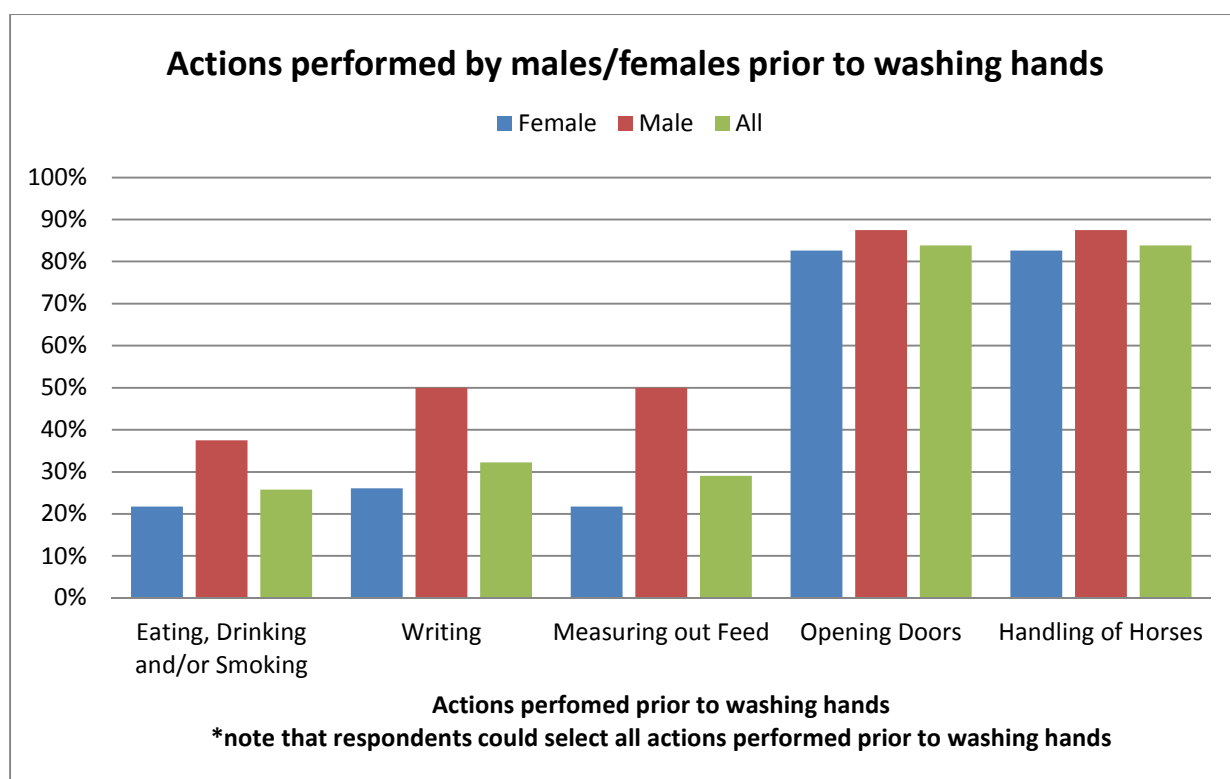


Figure 4-128: Actions performed prior to hand washing given respondent's hand washing behavior



Tool Use and Administering Regu-Mate

Figure 4-129 presents the number of times that respondents reported direct skin contact with Regu-Mate given the type of tool they use for withdrawing the drug from the bottle. Figure 4-130 shows the number of occasions Regu-Mate made direct contact with a respondent's skin given the method that is used to withdraw the drug from the bottle.

Figure 4-129: Times Regu-Mate has made direct contact with respondent's skin given the tool used for withdrawing the drug from the bottle

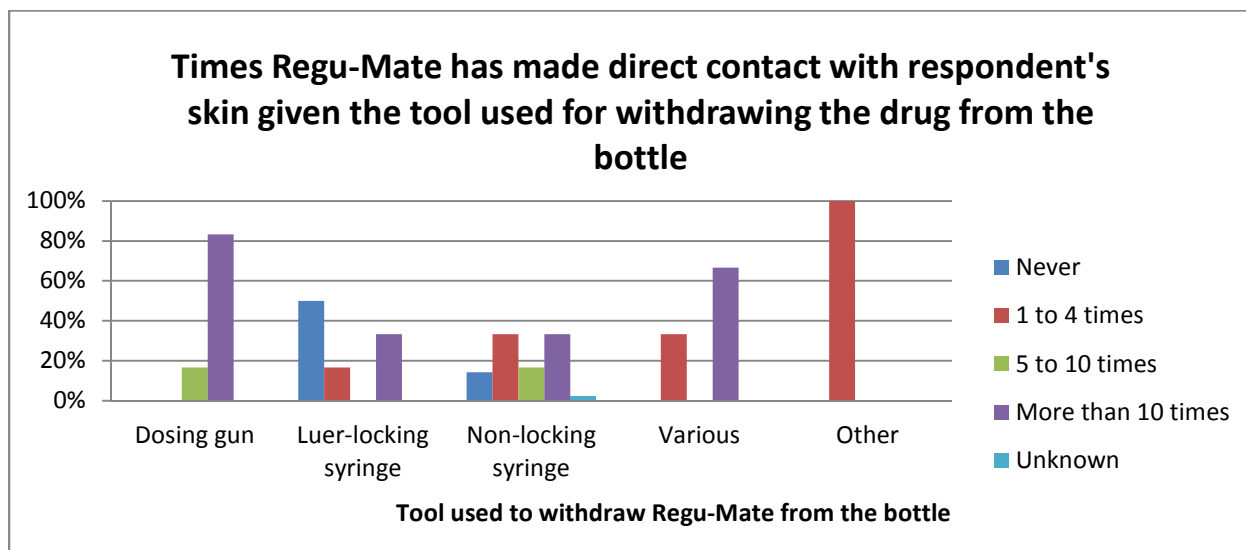
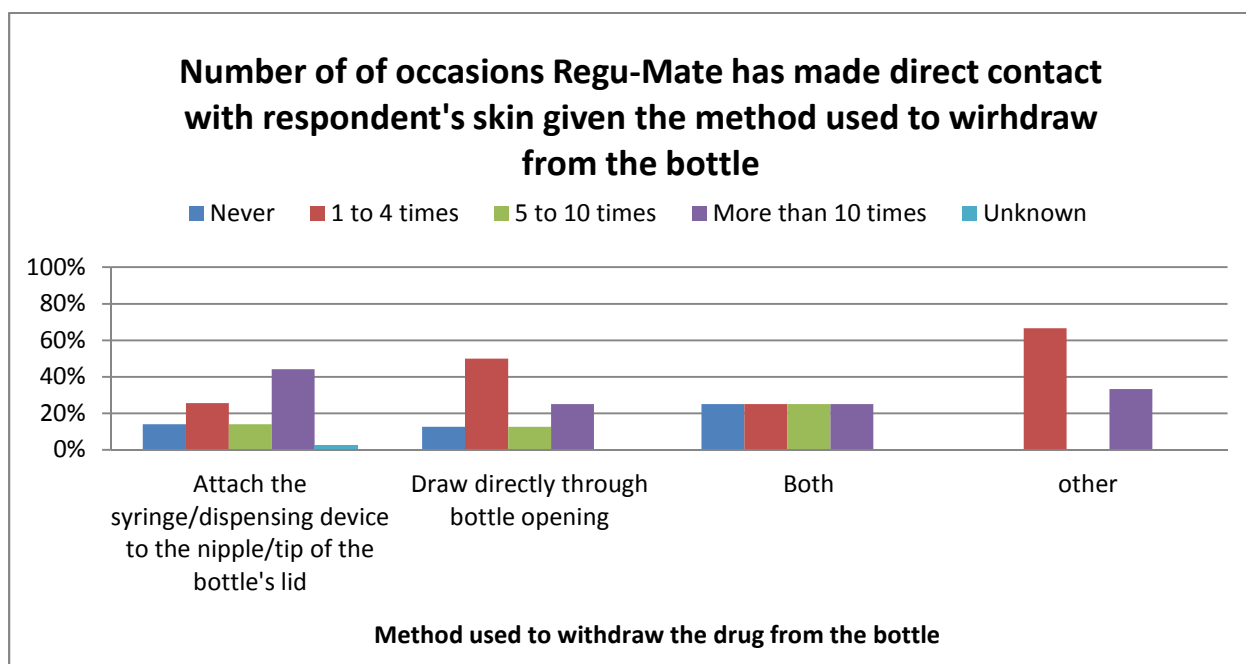
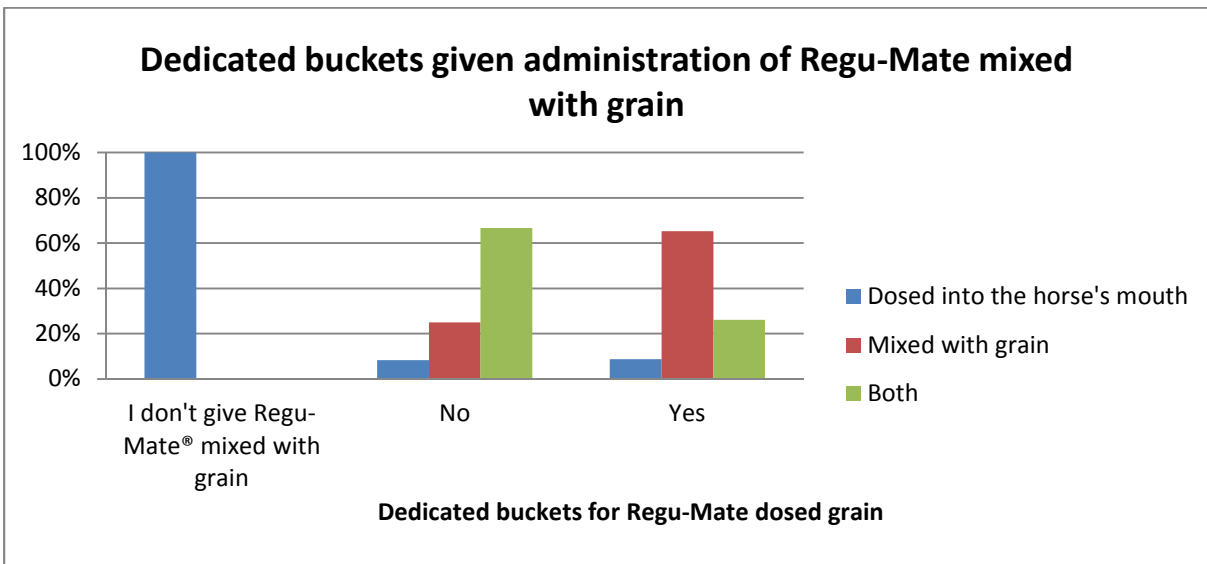


Figure 4-130: Number of occasions Regu-Mate has made direct contact with respondent's skin given the method used to withdraw from the bottle



Of respondents who mix Regu-Mate with grain and do not use grain buckets dedicated for Regu-Mate use, 35% administer Regu-Mate both by mixing with grain and dosing into the horse's mouth (Figure 4-131).

Figure 4-131: Dedicated buckets given administration of Regu-Mate mixed with grain

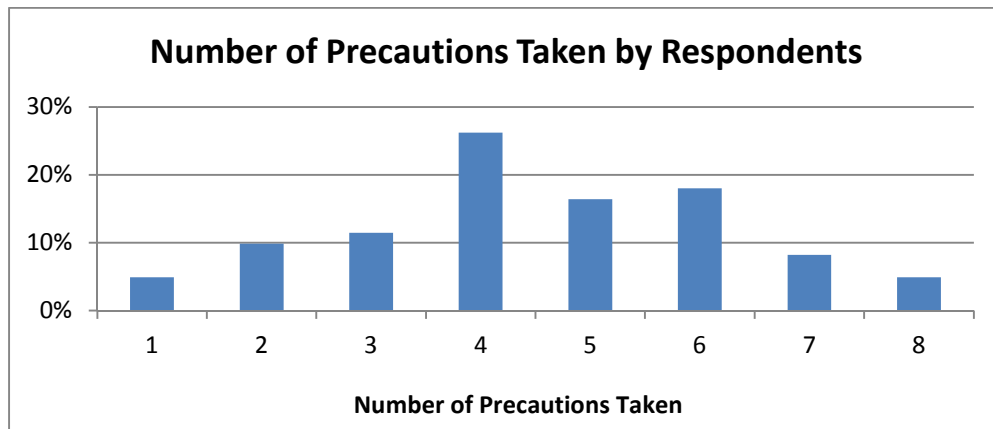


Precautions

Precautionary measures include glove use, replacing gloves every time Regu-Mate is handled, using nitrile or vinyl gloves, washing hands after using Regu-Mate, storing the bottle away from other medications, using a Luer-locking syringe, withdrawing by attaching the dispensing device to the tip of the bottle, not aerosolizing when emptying the syringe and using Regu-Mate-dedicated feed buckets.

Figure 4-132 presents the number of the different precautions taken by respondents; the most common number of precautions taken are four, five and six. The most common precautions taken are glove use, glove replacement, withdrawing by attaching the dispensing device to the tip of the bottle and not aerosolizing the drug when emptying the syringe. All respondents took at least one precaution.

Figure 4-132: Number of Precautions Taken by Respondents



The precautions taken given a respondent's sex, involvement in the breeding industry and self-identified role with horses are shown in Figure 4-133, Figure 4-134 and Figure 4-135, respectively. The most common number of precautions reported by females to take is four to six while males reported one to four precautions. There is little difference in the number of precautions taken with regards to involvement in the breeding industry or self-identified role with horses.

Figure 4-133: Number of precautions taken given sex

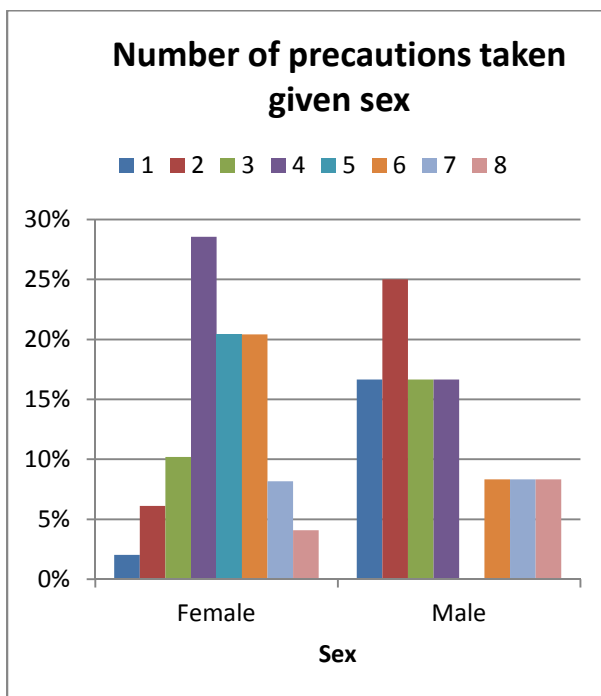


Figure 4-134: Number of precautions taken given involvement in breeding industry

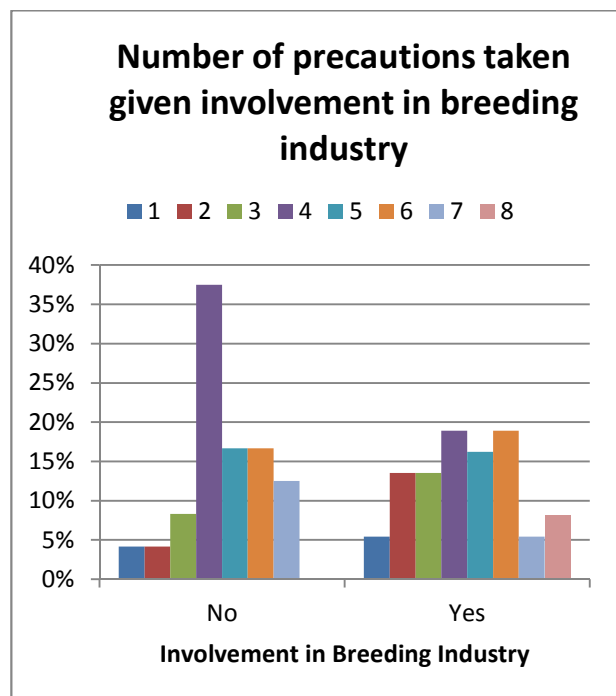


Figure 4-135: Number of precautions taken given self-identified role with horses

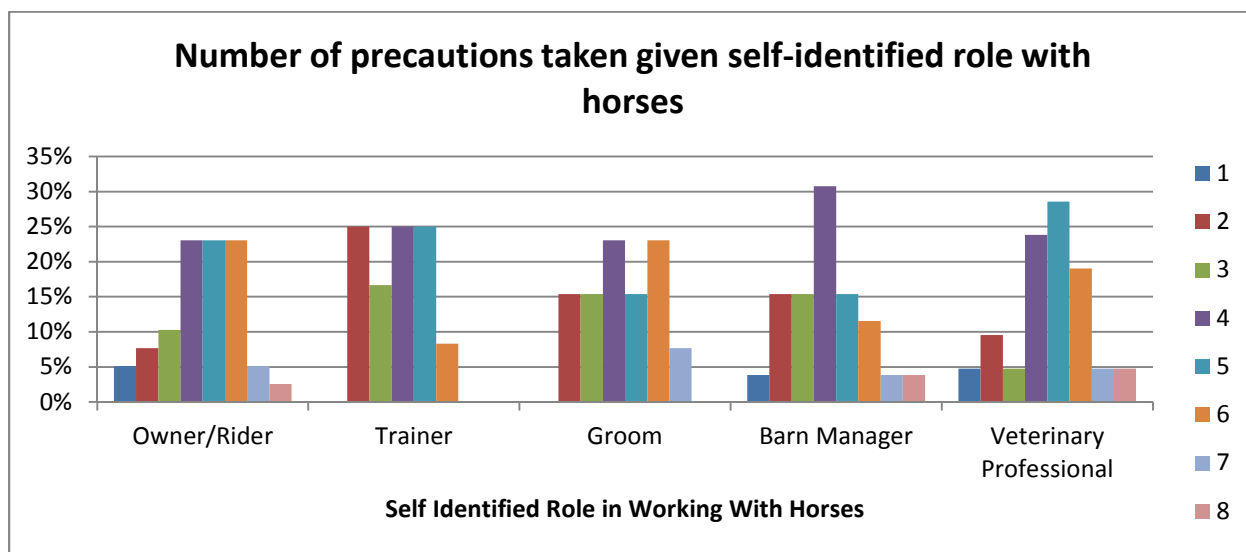


Figure 4-136 and Figure 4-137 present the comparison of the number of safety precautions taken when handling Regu-Mate given the frequency of Regu-Mate use and number of years handling the drug, respectively. Respondents who reported handling Regu-Mate three times per month or less most often took four or five precautions while the mode of those who handled Regu-Mate five times per week or more was four precautions.

Figure 4-136: Number of precautions taken given frequency of Regu-Mate use

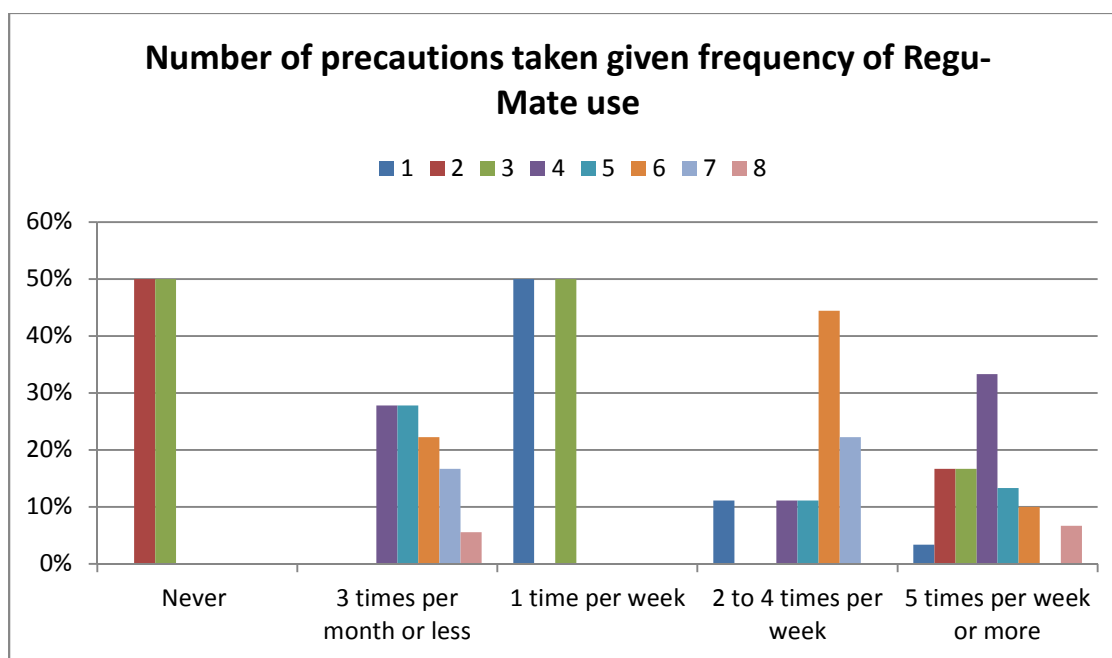
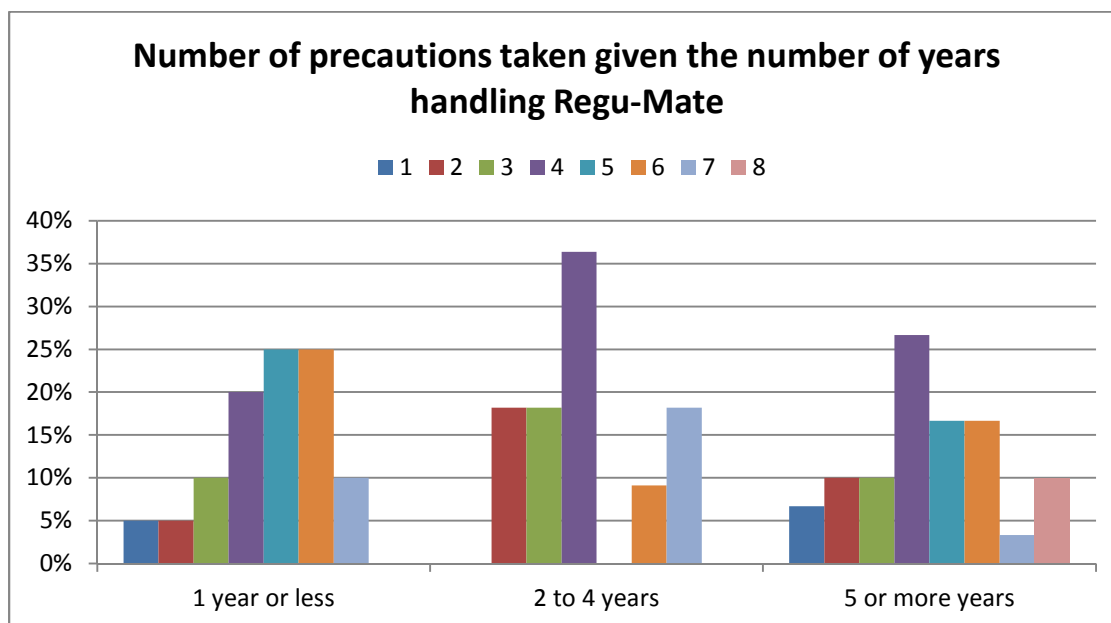
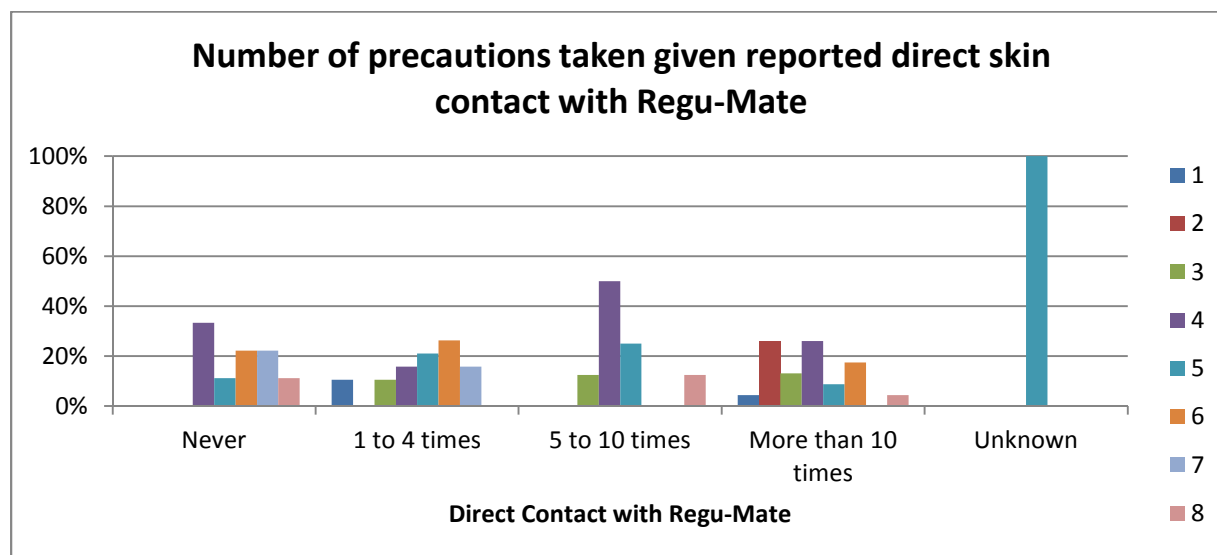


Figure 4-137: Number of precautions taken given the number of years handling Regu-Mate



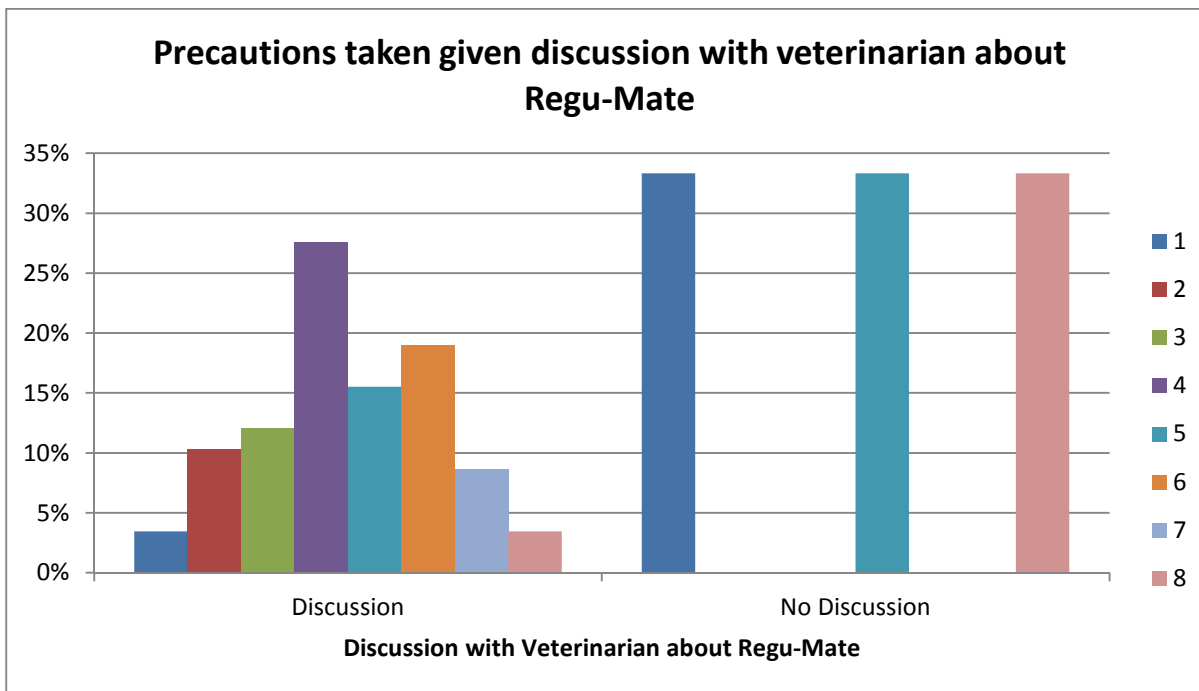
Respondents who reported no direct skin contact with Regu-Mate also reported a minimum of four precautions, those who reported skin contact one to four time reported five or six precautions, and those who reported skin contact with Regu-Mate more than 10 times also reported taking two or four precautions (Figure 4-138).

Figure 4-138: Number of precautions taken given reported direct skin contact with Regu-Mate



The distribution of the precautions taken by respondents who discussed Regu-Mate handling procedures with their veterinarian covers the full range; the most common number of precautions taken by these respondents is four (Figure 4-139).

Figure 4-139: Precautions taken given discussion with veterinarian about Regu-Mate



4.1.13 Where Respondents Learned About Regu-Mate

Almost all respondents, over 90% regardless of the reason for using Regu-Mate, reported learning about its use from a veterinary professional. Those using Regu-Mate for behavior modification are the least likely to have read the product insert (Figure 4-140).

Figure 4-140: Role with horses divided by where learned about Regu-Mate precautions

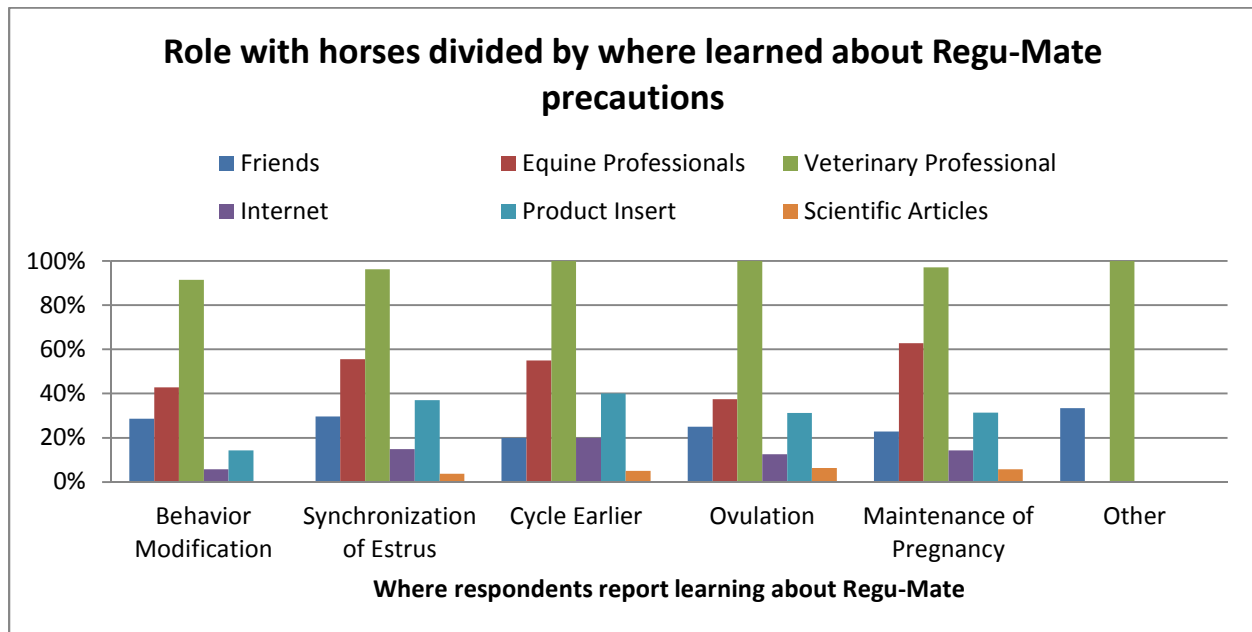


Figure 4-141, Figure 4-142, and Figure 4-143 present information about glove use and hand washing when classified by where respondents reported learning about Regu-Mate precautions. Respondents who learn about precautions from friends, equine professionals and veterinary professionals reported using gloves every time they handle Regu-Mate more often than those who learned this information from the internet or the product insert. Respondents who use latex rubber gloves learned about precautions from multiple sources evenly. Of those who read scientific articles, 67% use nitrile gloves; of respondents who read the product insert 27% use nitrile gloves. A majority of respondents who learned about precautions from friends or the internet do not wash their hands after handling Regu-Mate; a majority of those who learned about precautions from equine professionals, veterinary professionals, the product insert, and scientific articles wash their hands after handling Regu-Mate.

Figure 4-141: Glove use given where the respondent has learned about Regu-Mate precautions

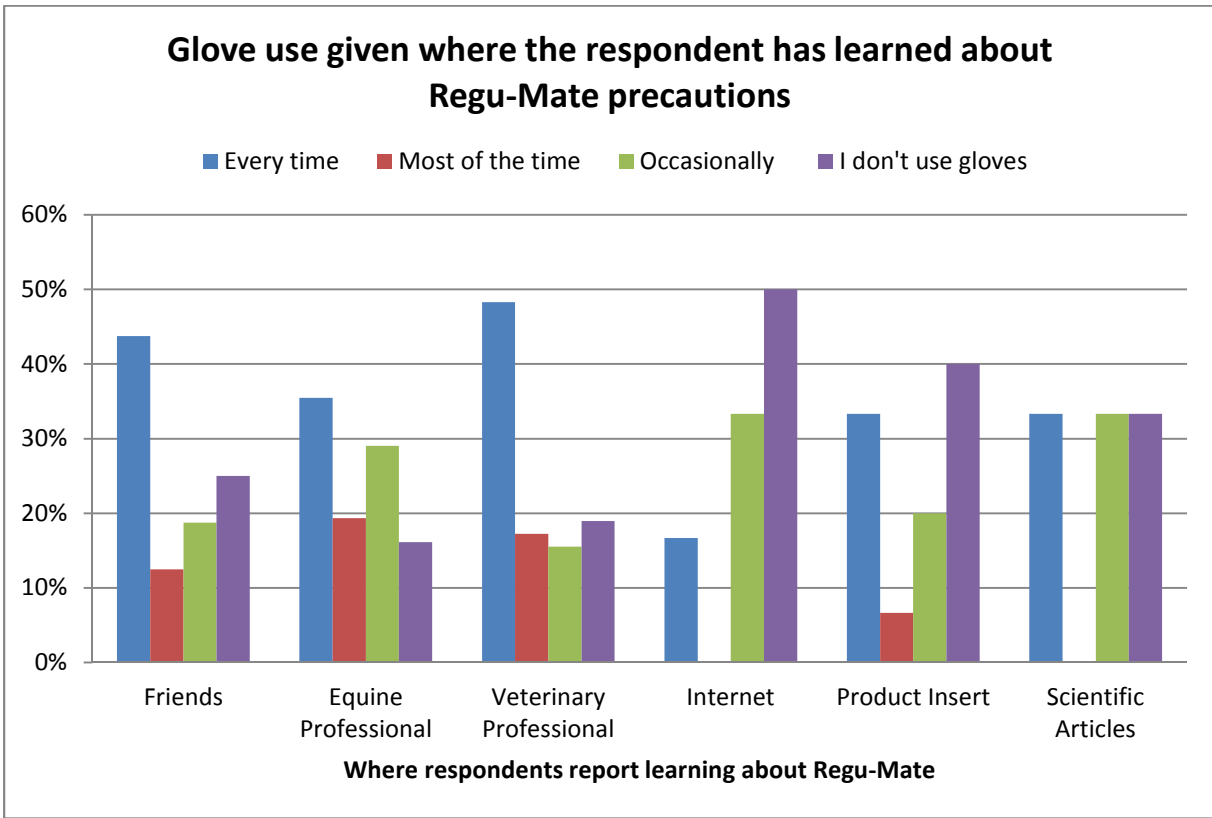


Figure 4-142: Where learned about Regu-Mate precautions given type of glove used

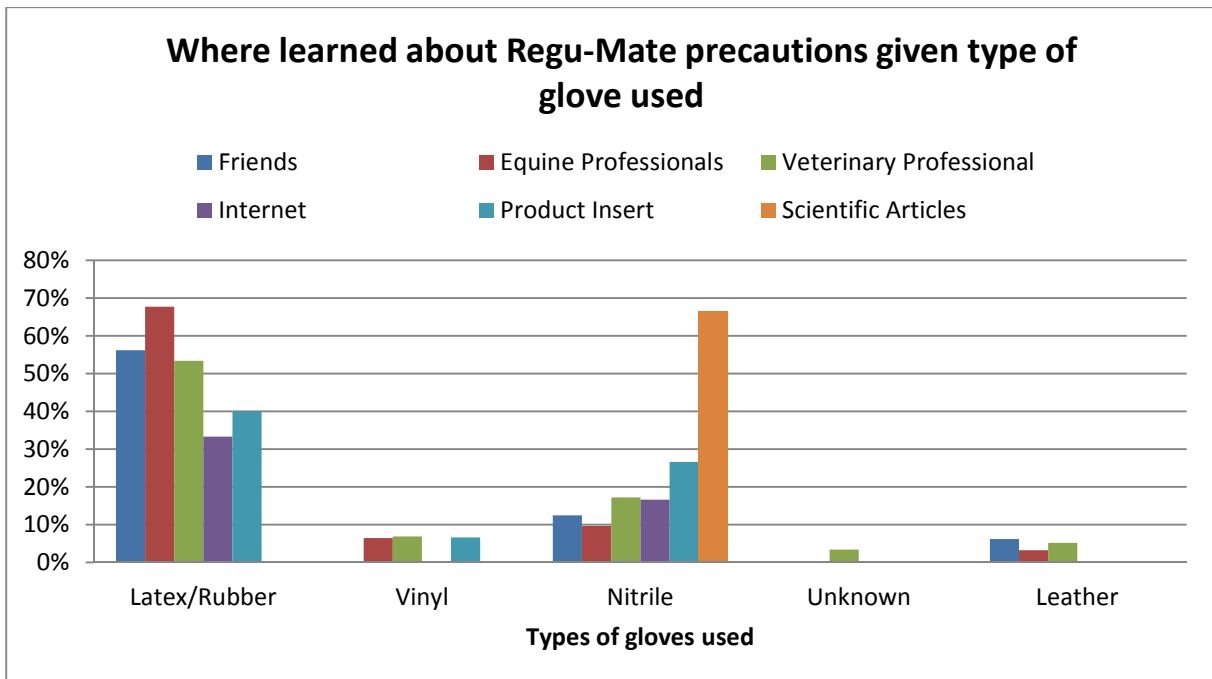
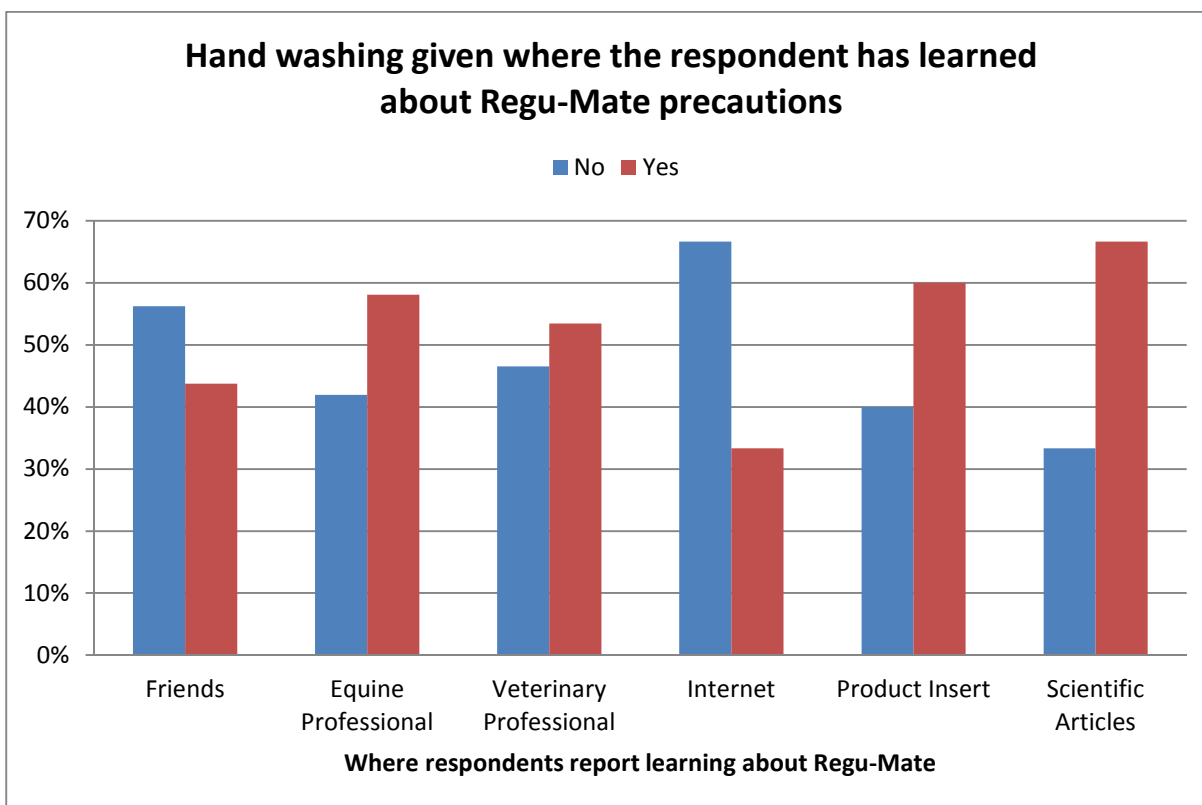


Figure 4-143: Hand washing given where the respondent has learned about Regu-Mate precautions



The majority of respondents regardless of where they learned about Regu-Mate precautions store their Regu-Mate bottle with other medications (Figure 4-144). Figure 4-145 presents how respondents withdraw the drug from the bottle given where they learned about Regu-Mate precautions; the distribution is consistent across where respondents learned about precautions. Between 33% and 28% of respondents in each category do not withdraw Regu-Mate directly through the bottle opening (Figure 4-146). A majority of those who learn from all categories (except the write in of scientific articles) do not aerosolize Regu-Mate when emptying the syringe or dosing gun (Figure 4-147).

Figure 4-144: Bottle storage given where the respondent has learned about Regu-Mate precautions

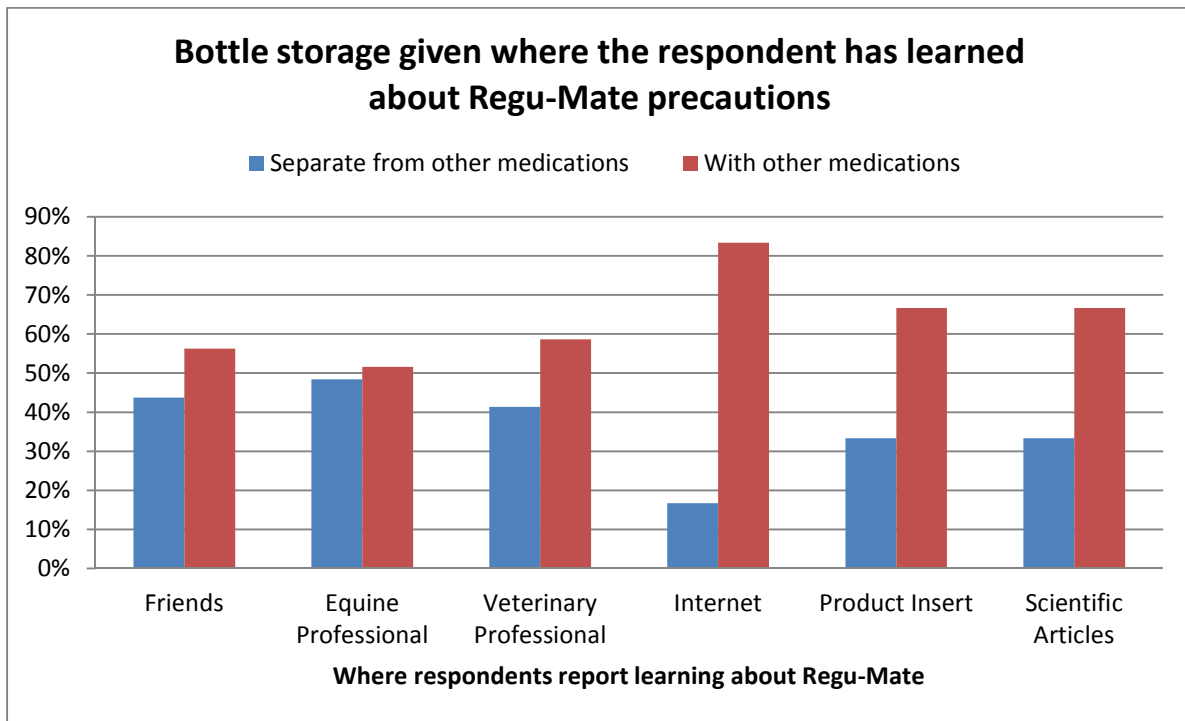


Figure 4-145: Withdrawal of drug from bottle given where the respondent has learned about Regu-Mate precautions

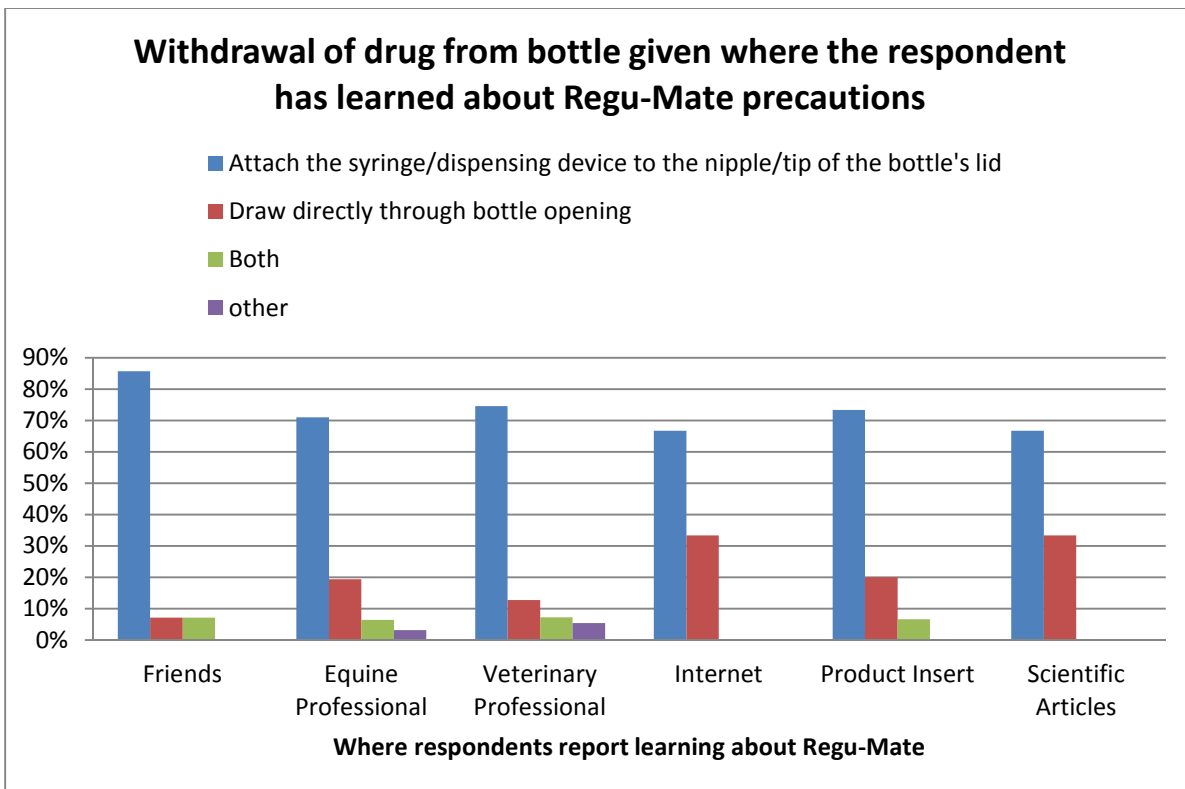


Figure 4-146: Replacement of syringe given where the respondent has learned about Regu-Mate precautions

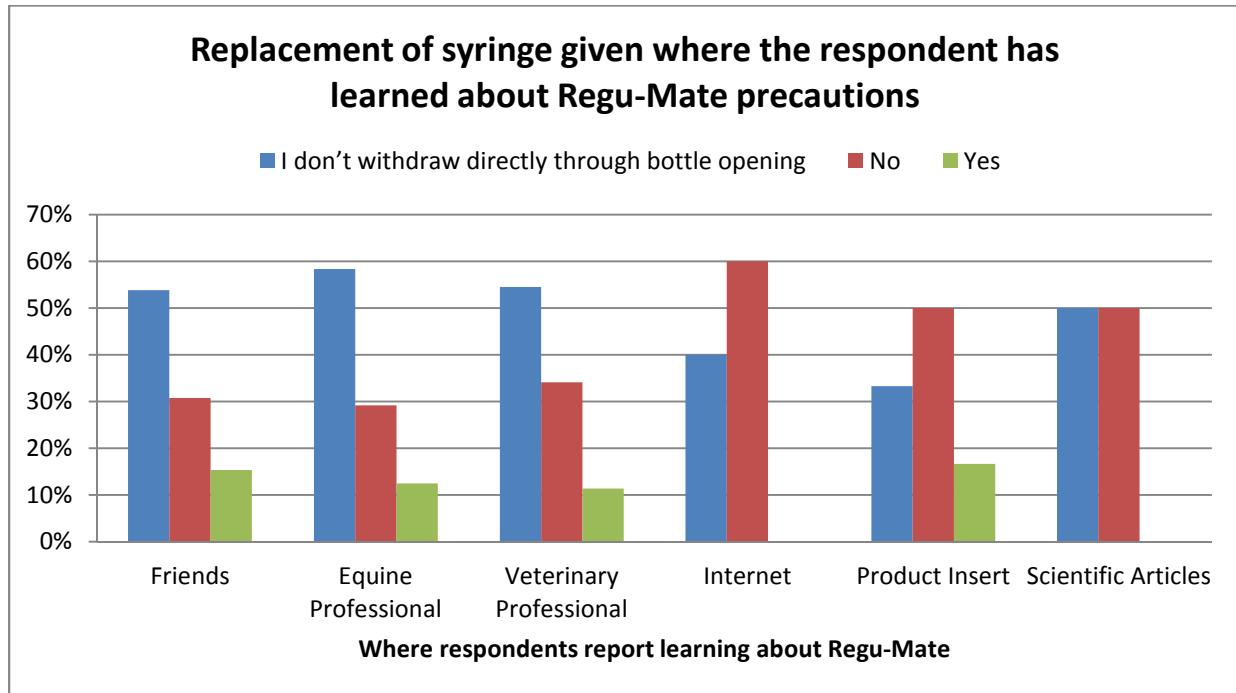


Figure 4-147: Aerosolizing of drug given where the respondent has learned about Regu-Mate precautions

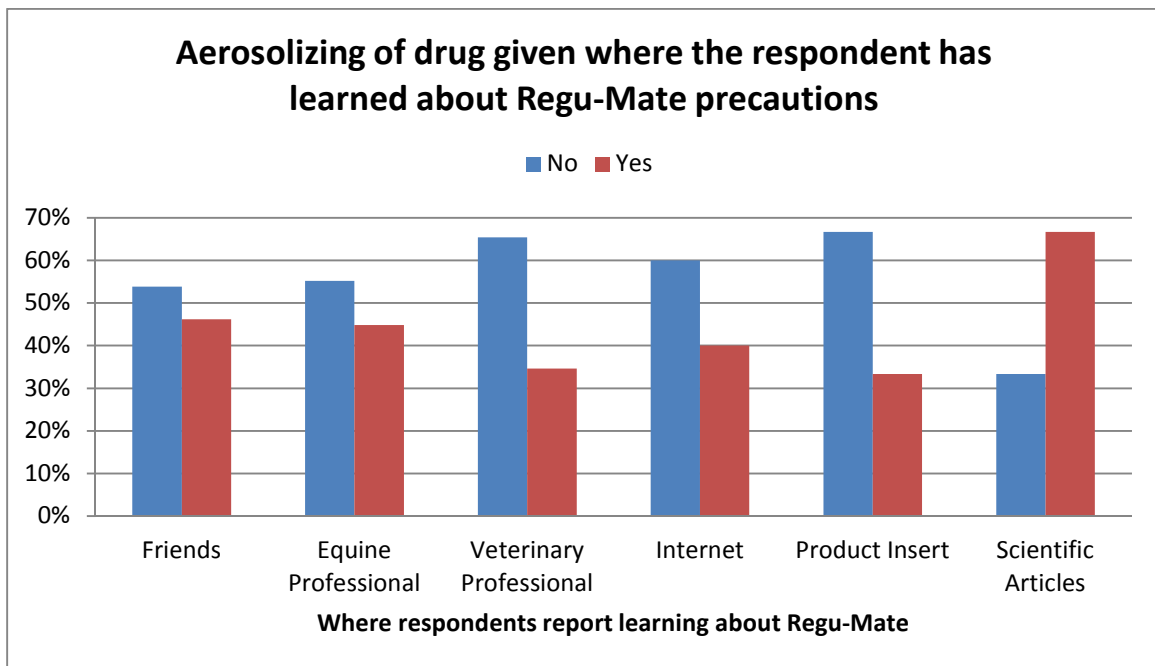
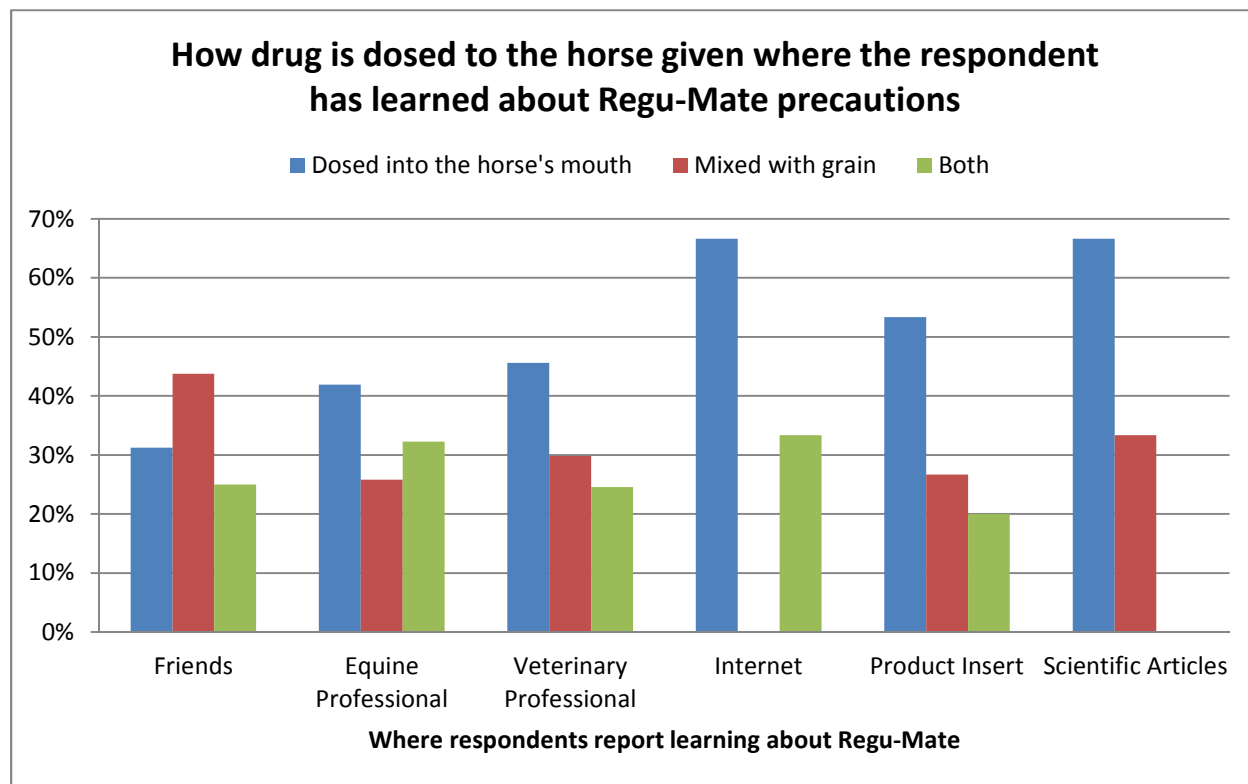


Figure 4-148 presents how respondents administer Regu-Mate to their horses given where they learned about Regu-Mate precautions. Those who learned about precautions from friends are more likely to also report that they administer Regu-Mate only mixed with grain than those who learned about precautions from any other source.

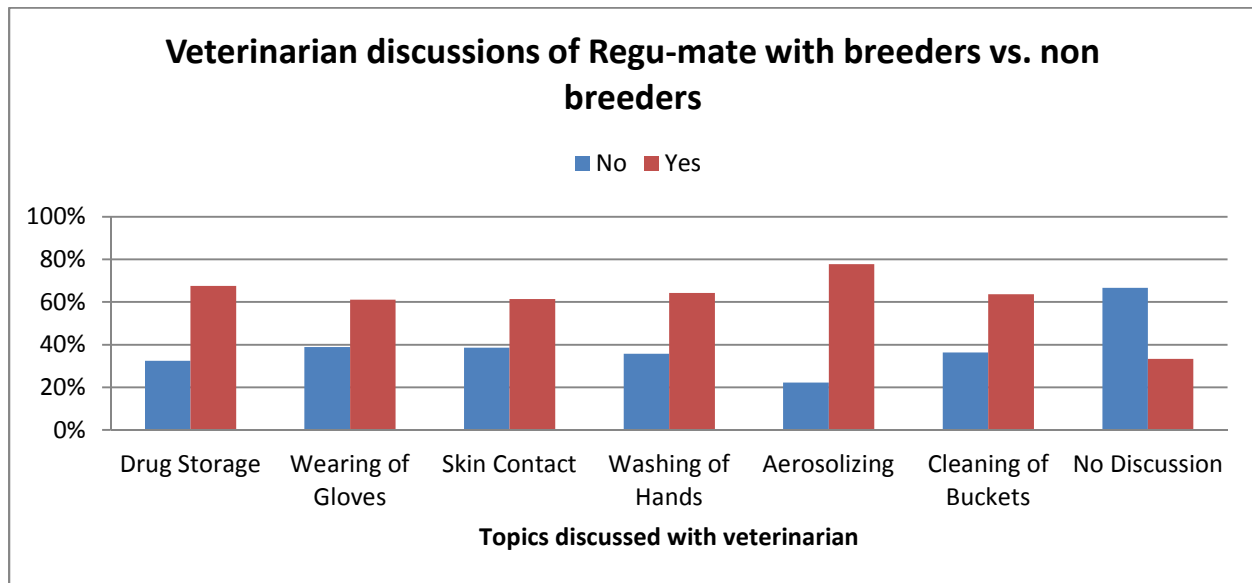
Figure 4-148: How drug is dosed to the horse given where the respondent has learned about Regu-Mate precautions



4.1.14 Regu-Mate Education from Veterinarians

Figure 4-149 shows the topics discussed with veterinarians for those who are involved with the breeding industry compared to those who are not; more people not involved in the breeding industry reported not discussing Regu-Mate topics with their veterinarian than those who are in the breeding industry (67% to 33%).

Figure 4-149: Veterinarian discussions of Regu-Mate precautions with breeders vs. non breeders



Glove use behavior given the discussion of wearing gloves with the veterinarian is shown in Figure 4-150 and hand washing behavior classified by discussion of hand washing and discussion of skin contact is presented in Figure 4-151. A larger percentage of respondents who didn't talk to their veterinarian about Regu-Mate topics reported not using gloves (57%) than those who did discuss glove wearing (13%). Glove use is lower in respondents who did not discuss glove use with their veterinarian. Respondents who discussed skin contact and hand washing are more likely than those who did not discuss these topics to wash their hands after handling Regu-Mate.

Figure 4-150: Glove use given discussion of glove use with veterinarian

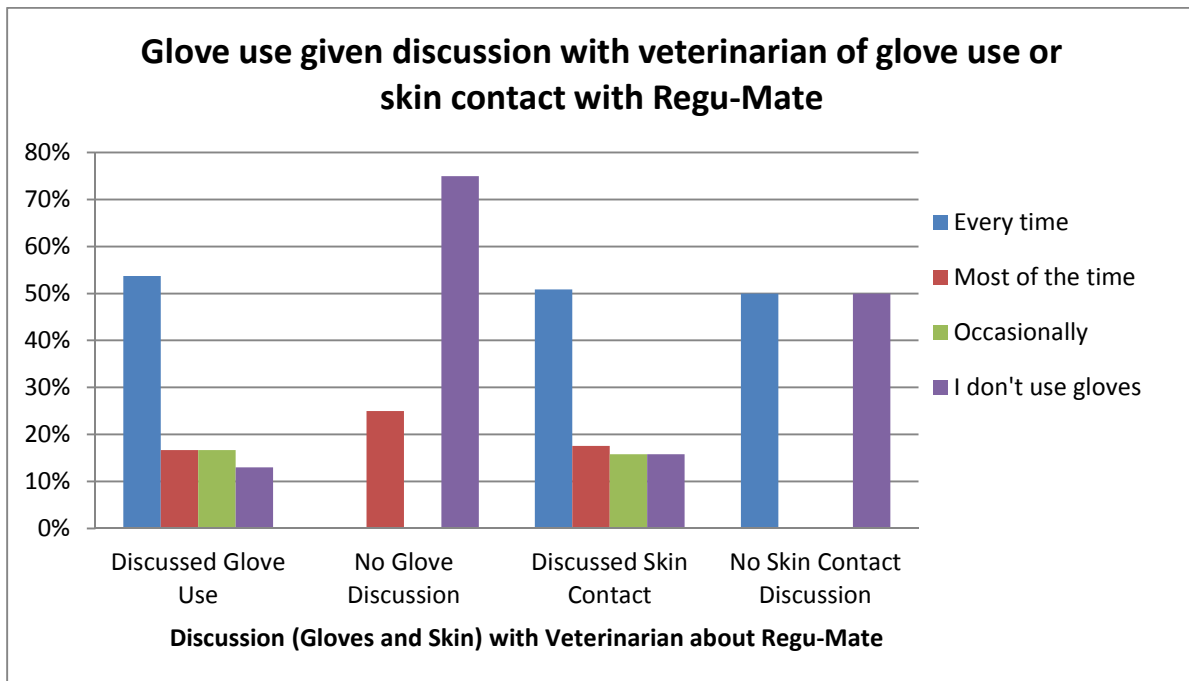
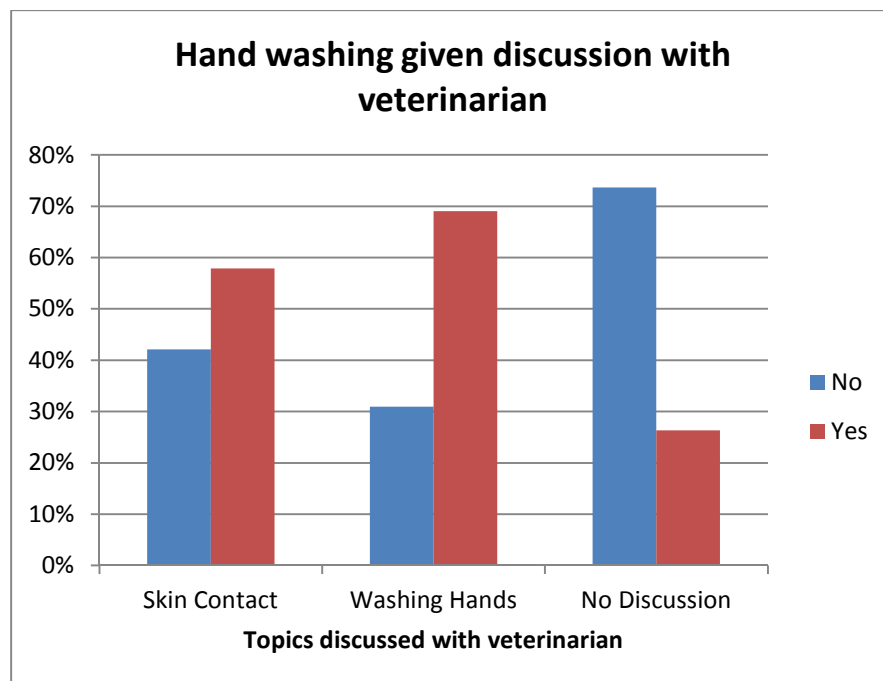


Figure 4-151: Hand washing given discussion with veterinarian



Of the respondents who did not report discussing avoidance of skin contact with their veterinarian, 75% reported having had direct contact with Regu-Mate more than 10 times; of those who did discuss skin contact the distribution is even across the reported contact

categories (Figure 4-152). Figure 4-153 shows bottle storage behavior given discussion of how the Regu-Mate bottle should be stored; more people store the bottle with other medications when they discussed bottle storage with their veterinarian. Figure 4-154 shows the discussion of aerosolizing with the veterinarian and if respondents aerosolized the drug while clearing the dosing device. The use of dedicated buckets for Regu-Mate use as related to a discussion of dedicated buckets with the veterinarian is presented in Figure 4-155.

Figure 4-152: Contact with drug given discussion with veterinarian

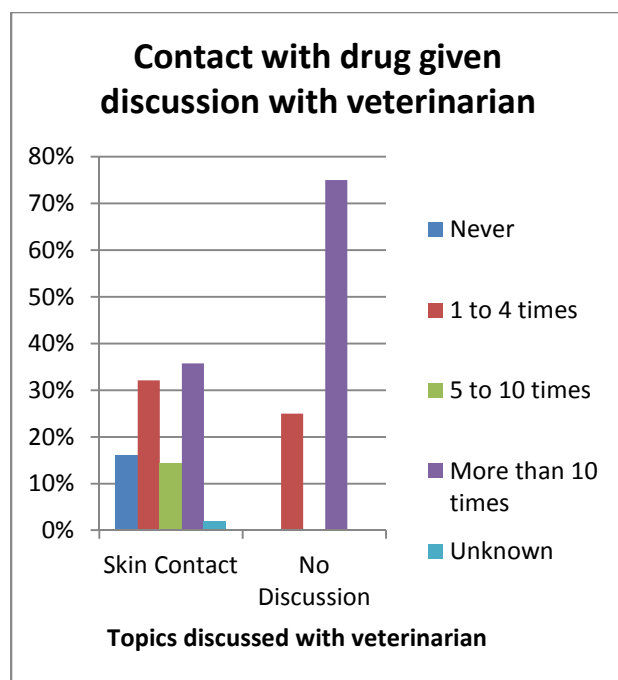


Figure 4-153: Bottle storage given discussion with veterinarian

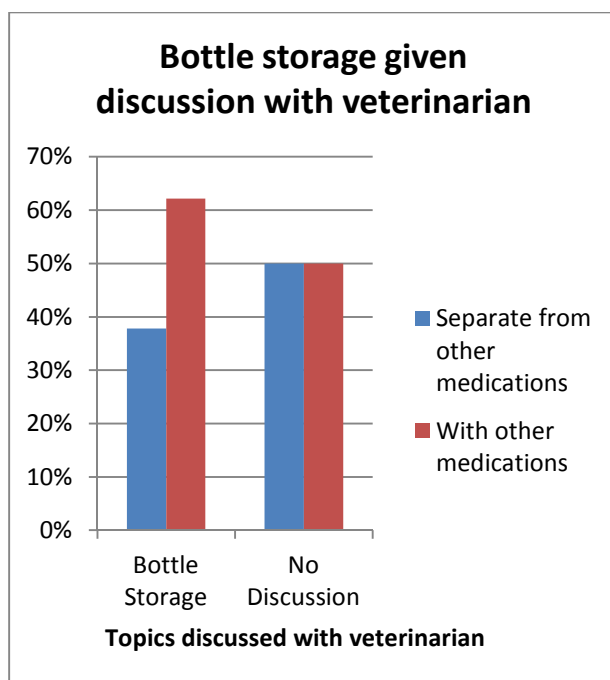


Figure 4-154: Aerosolizing given discussion with veterinarian

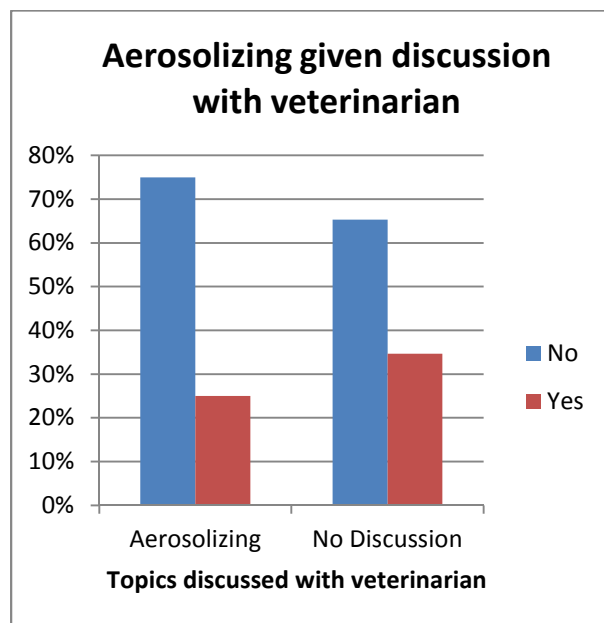
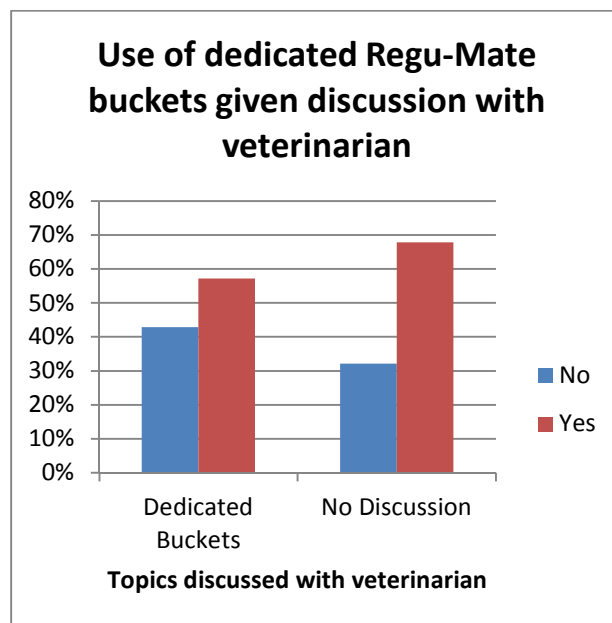
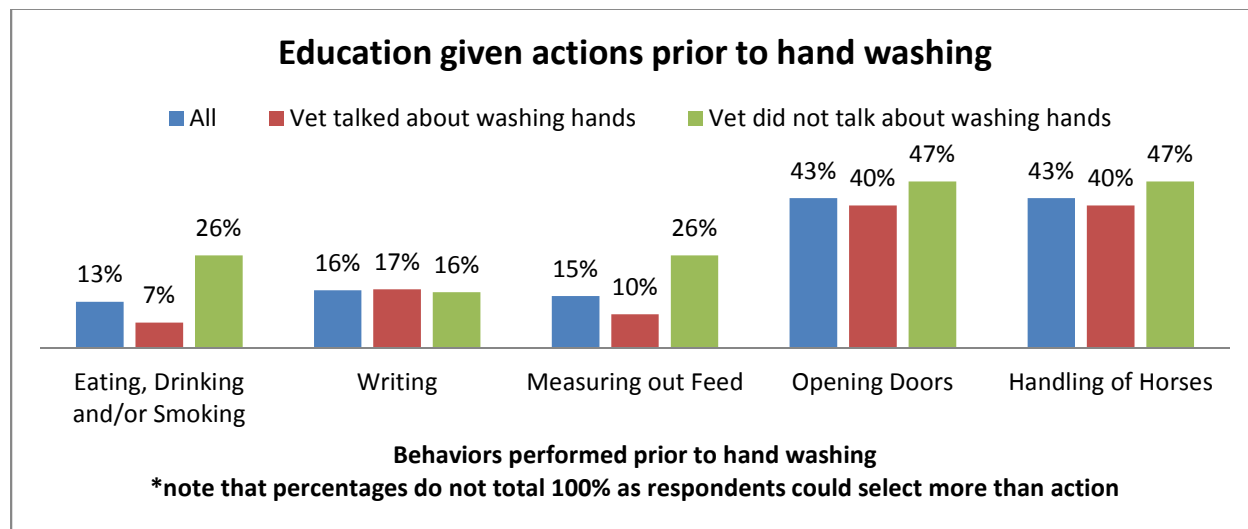


Figure 4-155: Use of dedicated Regu-Mate buckets given discussion with veterinarian



Of the respondents who reported no discussion of hand washing with a veterinarian, 26% reported eating/drinking/smoking prior to hand washing. Conversely only 7% of those who discussed hand washing with a veterinarian reported this same behavior. Little difference is seen in opening doors, handling of horses/equipment or writing when classified by discussion of hand washing with a veterinarian (Figure 4-156).

Figure 4-156: Education given actions prior to hand washing



4.1.15 Reported Symptoms

Figure 4-23 and Figure 4-24 in Section 4.1.14.1.3 presented the number of occasions that females and males, respectively, reported that Regu-Mate came into direct contact with their skin. Comparisons of respondents who reported symptoms for each sex include all respondents who reported at least one symptom.

The figures presented below combine the symptoms reported by all respondents. Respondents who reported symptoms were slightly more likely to wash their hands (Figure 4-157) than those who did not report symptoms (70% vs. 53%, respectively). Figure 4-158 presents respondents' reported glove use based on a report of symptoms; there is little difference in glove use between respondents who report symptoms and those who do not.

Figure 4-157: Hand washing given reported symptoms

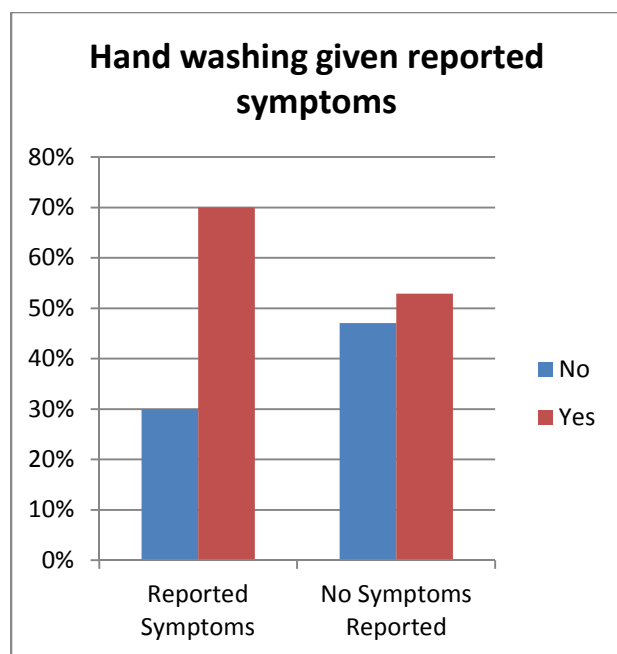
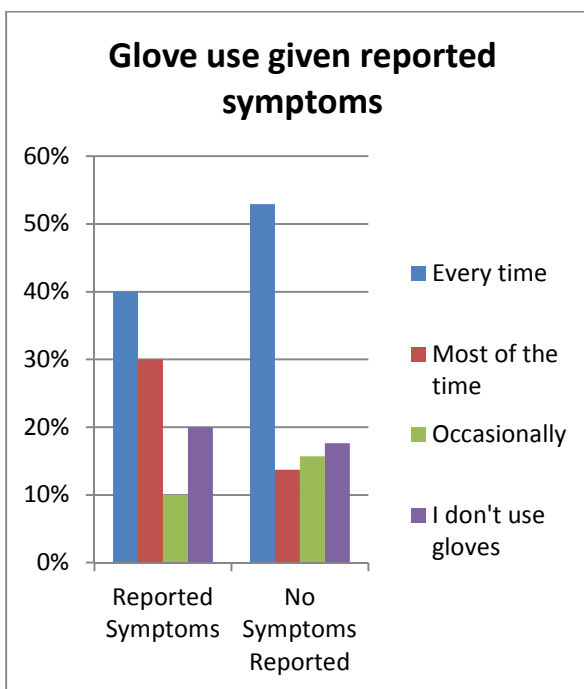


Figure 4-158: Glove use given reported symptoms



The number of years that respondents reported handling Regu-Mate and the frequency of handling Regu-Mate compared to the report of symptoms reported are presented in Figure 4-159 and Figure 4-160, respectively. There is little difference between the backgrounds of respondents who reported symptoms versus those who did not report symptoms.

Figure 4-159: Years handling Regu-Mate given reported symptoms

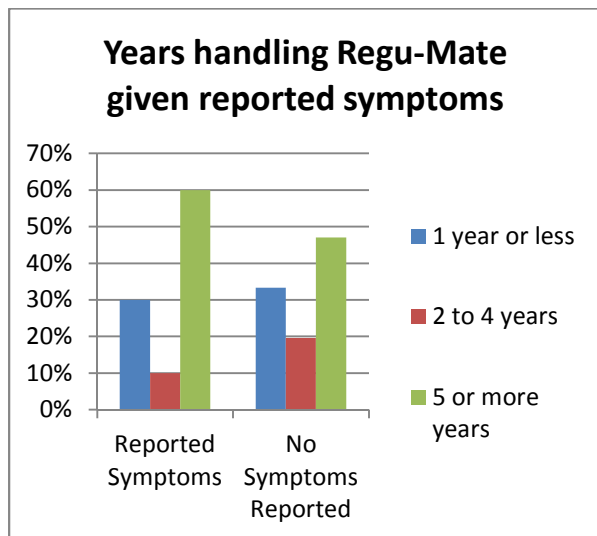


Figure 4-160: Frequency of handling Regu-Mate given reported symptoms

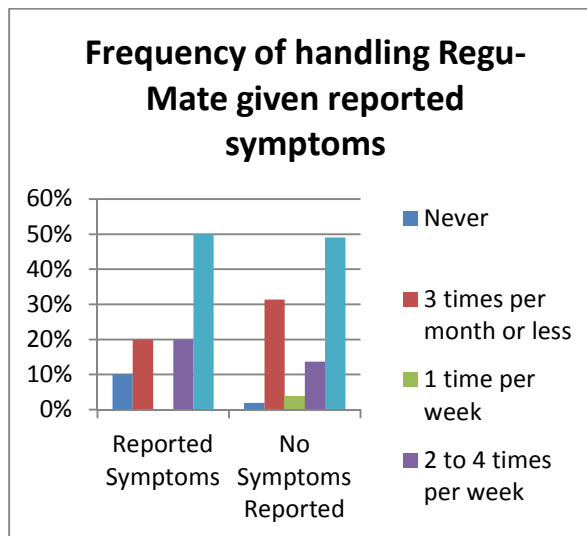


Figure 4-161 presents the precautions taken by respondents and Figure 4-162 presents reported skin contact with Regu-Mate when compared to respondents who reported symptoms following contact with the drug. There is little difference in the distribution of precautions taken by respondents who reported experiencing symptoms following contact (skin, ingestion, etc.) with Regu-Mate compared to those who did not report experiencing symptoms. The respondents who reported no direct skin contact with Regu-Mate were eliminated from the comparison in Figure 4-162 to ensure an equal comparison as it is impossible to experience effects from contacting the drug with no reported exposure.

Figure 4-161: Number of precautions taken and reported symptoms

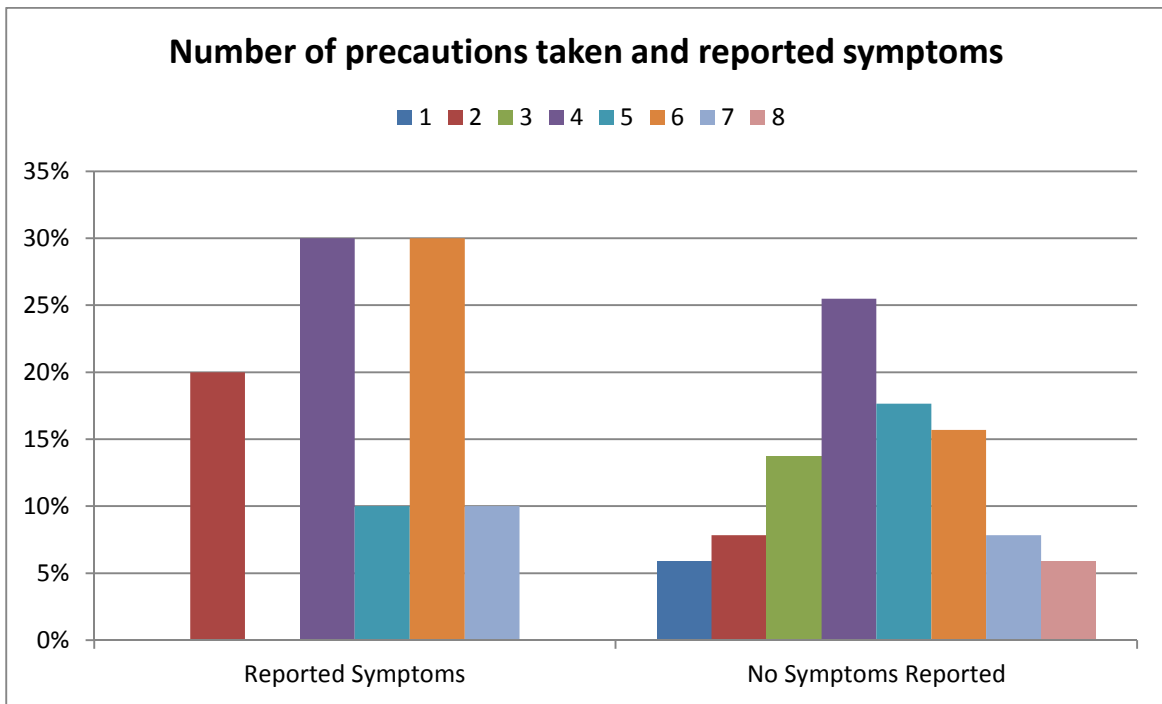
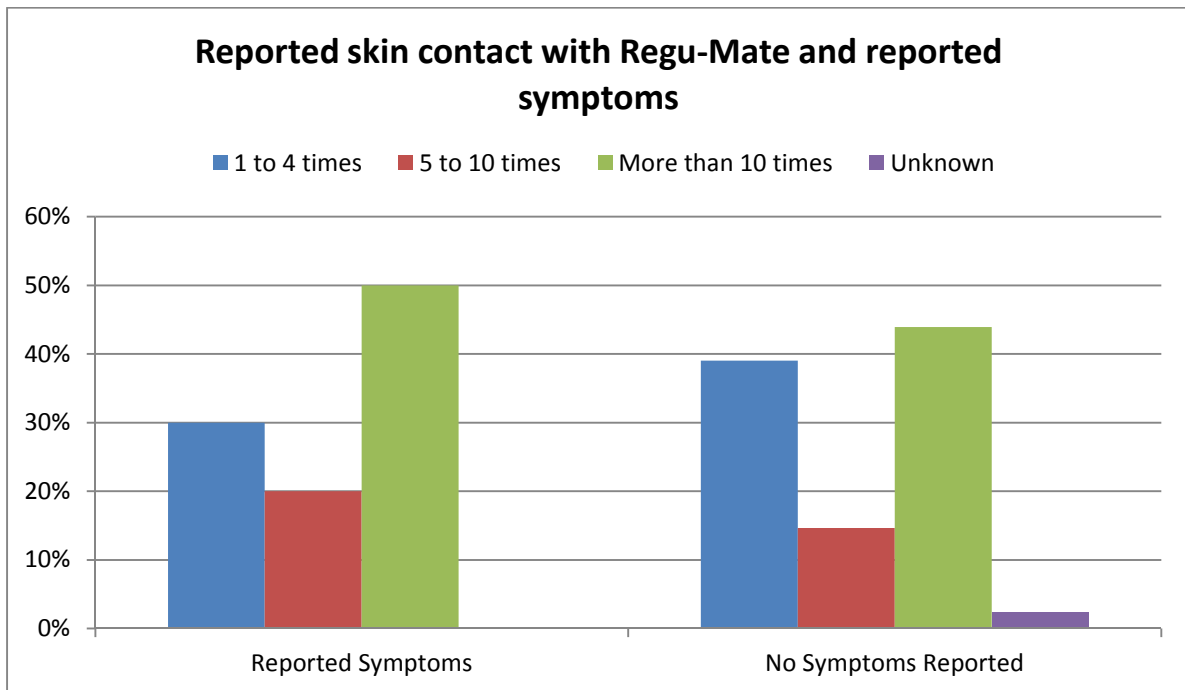


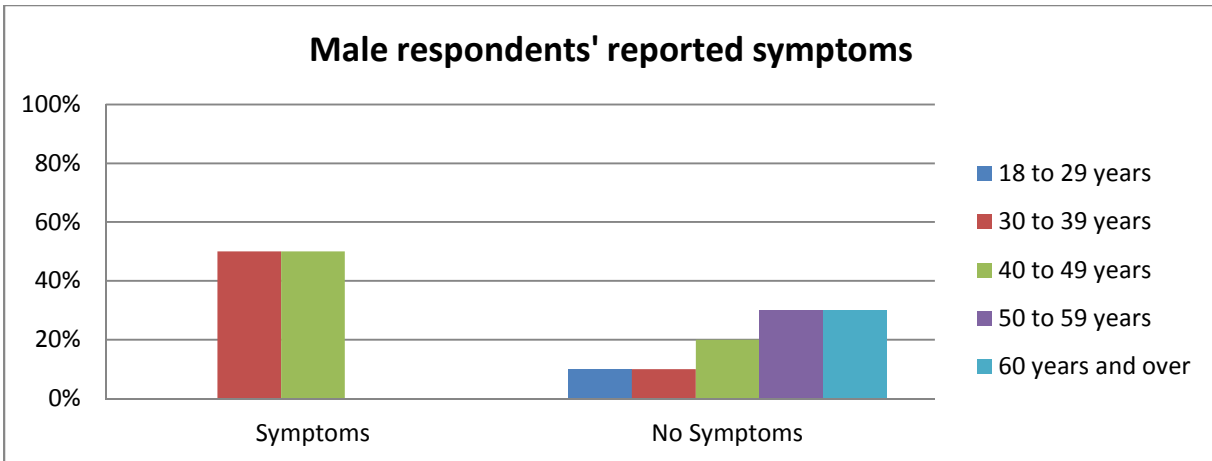
Figure 4-162: Reported skin contact with Regu-Mate and reported symptoms



Male Symptoms

Only two men reported symptoms that they associated with direct skin contact with Regu-Mate and they are between the ages of 30 to 49 (Figure 4-163).

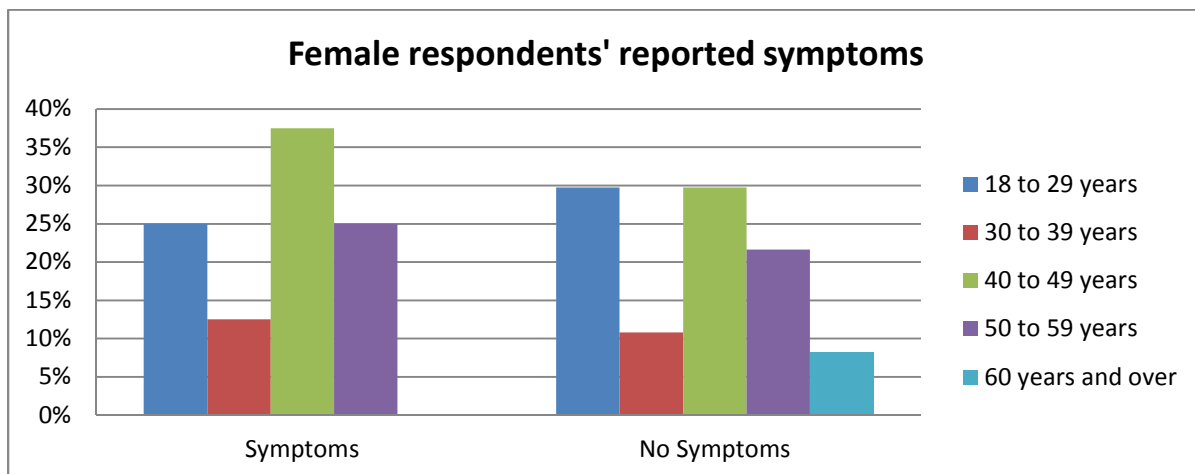
Figure 4-163: Male respondents' reported symptoms



Female Symptoms

Women in all age brackets except 60 years and older reported symptoms they associated with direct skin contact with Regu-Mate (Figure 4-164).

Figure 4-164: Female respondents' reported symptoms



4.3 Unable to Compare

Table 4-1 shows the questions that had insufficient responses to allow for comparisons with other questions.

Table 4-1: Questions comparisons unable to be performed

Question #	Question	Reason
5	Do you use and/or administer Regu-Mate (oil based altrenogest)?	Insufficient balance of responses (too few respondents who don't use Regu-Mate)
13	Do you wear the same gloves used while dosing, dispensing and administering Regu-Mate when performing any of the following activities?	Too few respondents reported performing actions prior to removing gloves
27	At your facility, are any of the following groups prohibited from handling Regu-Mate?	Too few men responded to this question to compare men's use with their reported prohibition in using
28	At your facility, are any of the following groups restricted from contacting horses that are actively being treated by Regu-Mate?	Too few respondents report restrictions on handling horses being given Regu-Mate

5 Discussion

Veterinarians assisting in distribution of surveys provided an estimate of the number of surveys they would be able to distribute to their clients. Of the 369 surveys given to veterinarians for distribution, only 64 acceptable surveys were returned. I do not know the number of surveys that veterinarians distributed to clients that were not returned. Correspondence with the participating veterinarians suggests that potential reasons for the low response rate included overestimating the number of clients they would be able to distribute the surveys to, farm managers' reluctance to participate because they were concerned that responding to the survey could result in changes in Regu-Mate's use, and Spanish/Portuguese speakers possibly being concerned about participating due to their immigration status. Because of the small number of responses, only descriptive statistics were performed on the data.

5.1 Assignment of Questions

Survey questions (Appendix B) 1 through 9 provide basic demographic information about the respondents. Questions 10, 14, 16, 17, 18, 20, 21 and 25-28 provide information about each respondent's primary protective behaviors while using Regu-Mate. Table 5-1 outlines the protective answer(s) vs. non-protective answer(s). Questions 11 - 13, 15, 19 and 22 provide background and expanded information on the primary protective behaviors (Table 5-2). Survey questions 23 and 24 ask about the respondent's experience with Regu-Mate.

Table 5-1: Questions asking about primary protective behaviors

Question	Protective	Non-Protective
Q.10. How often do you use gloves when dosing, dispensing and administering Regu-Mate?	Occasionally Most of the time Every time	I don't use gloves
Q.14. Do you wash your hands immediately after dosing, dispensing and administering Regu-Mate?	Yes	No
Q.16. Where is the Regu-Mate bottle stored?	Separate from other medications	With other medications
Q.17. What tool do you use to withdraw the drug from the bottle?	Luer-lock syringe	Non-locking syringe Dosing gun Other
Q.18. How do you withdraw the drug from the bottle?	Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	Draw directly through bottle opening
Q. 20. Do you ever forcefully clear the syringe or dosing gun to remove the last bit of the drug or extra air?	No	Yes

Table 5-2: Background information on precautionary actions

Question	Background	Protective	Non-Protective
Q.11. How often are the gloves replaced?	Occasionally Most of the time Every time		
Q. 12. What type of gloves do you use?		Vinyl Nitrile	Latex/Rubber I Don't Know
Q.13. Do you wear the same gloves used while dosing, dispensing and administering Regu-Mate when performing any of the following activities?			Writing or recording of records Measuring out feed Opening or closing of doors Handling of horses and/or equipment
Q. 15. After dosing, dispensing and administering Regu-Mate do you perform any of the following activities prior to washing your hands?			Eating, drinking and/or smoking Writing or recording of records Measuring out feed Opening or closing of doors Handling of horses and/or equipment
Q.19. If you withdraw the drug directly through the bottle opening, do you use a new syringe for each application?		I don't withdraw directly through bottle opening	Yes No
Q.22. Are the grain/feed buckets dedicated for use with only Regu-Mate topped feed?	Yes No I don't give Regu-Mate mixed with grain		

5.2 Background Information Comparisons

The proportion of women to men among respondents (81% vs. 19%, respectively) is not atypical of the equestrian industry as the industry tends to attract a strong female presence; however, there is an insufficient number of male respondents to adequately compare men's and women's behavior and all comparisons will be analyzed with the sexes combined. With only three respondents (5%), there were too few respondents who did not administer Regu-Mate to allow for additional comparisons. Respondents overwhelmingly reported regularly administering Regu-Mate to one to four horses (67%) which results in too few respondents administering to other classifications for additional comparisons against the number of horses regularly administered Regu-Mate.

Background information that has sufficient responses for analyzing comparisons include age, self-identification of the role in working with horses, involvement in the breeding industry, frequency of Regu-Mate handling, and years handling Regu-Mate. Table 5-3 presents the classifications that were eliminated or combined for evaluation in the discussion due to lack of responses.

Table 5-3: Use of the answers from demographic survey questions for comparisons

Question	Answers Kept	Answers Eliminated
Q.3. Which of the roles listed below best describes your role in working with horses?	Owner/rider Barn manager Trainer Groom Veterinary Professional	Other
Q.7. Do you use Regu-Mate for any of the following purposes?	Behavior modification Synchronizing estrus Earlier cycling Timing of ovulation Maintenance of pregnancy	Other
Q.8. How often do you handle Regu-Mate?	3 times per month or less 5 times per week or more	Never 1 time per week 2 to 4 times per week

5.3 Precautionary Comparisons

Primary precautionary behavior includes glove use, hand washing, where the Regu-Mate bottle is stored, the tool used to withdraw the drug from the bottle, how Regu-Mate is withdrawn from the bottle, and aerosolizing of Regu-Mate. Secondary precautionary behavior includes how often the gloves are replaced, the type of gloves used, activities performed prior to removing gloves and/or hand washing, withdrawal of syringe through bottle opening, replacement of syringe, and Regu-Mate dedicated grain buckets. These behaviors were compared to each other and to basic demographics and are discussed in the following sections.

5.3.1 Glove Use and Hand Washing

Of all respondents 82% wear gloves at least occasionally and 56% wash their hands after handling Regu-Mate while 18% don't use gloves at all and 44% don't wash their hands; Glove use and hand washing after handling Regu-Mate becomes less consistent when the frequency of Regu-Mate handling increases. When handling Regu-Mate three times per month or less is compared to handling it five times per week or more I found that 6% vs. 23%, respectively, never use gloves and 83% vs. 40%, respectively, wash their hands. A majority of respondents who have handled Regu-Mate one year or less and five or more years wash their hands after handling Regu-Mate (55% and 60%) while 44% of respondents who have handled the drug for two to four years wash their hands; this comparison shows no clear association between the number of years spent handling Regu-Mate and hand washing behavior. Complacency may develop in individuals the longer and more often they handle Regu-Mate, resulting in less safe handling procedures over time. An increased familiarity with the drug can make people overly comfortable and lax in handling it. An individual who has had direct skin contact with the drug and did not experience ill effects from that contact may assume that Regu-Mate is safe or that they are not susceptible to its effects. As a result people become less cautious over time resulting in decreased glove use and hand washing. Not using gloves and not washing hands puts people at higher risk for increased and more sustained skin contact with Regu-Mate.

Respondents who reported learning about Regu-Mate precautions from the product inserts are more likely to report not using gloves (40%) than those who discussed precautions with friends (25%), veterinarian (19%) or equine professional (16%). Respondents who reported learning about Regu-Mate precautions from a product insert were more likely to have used Regu-Mate for five or more years (73%) than those that learned about precautions from friends (31%), equine professionals (35%) and veterinary professionals (50%). Glove use behavior does not appear to be associated with the methods through which a respondent learned about Regu-Mate precautions, but the length of time a respondent has handled Regu-Mate shows an association with taking precautions. The association between glove use and length of time over which the respondent has handled the drug may be due to increased complacency over time as discussed in the previous paragraph.

If a respondent does not use gloves he or she is more likely to also report not washing hands after use (91%) than those who use gloves every time they handle Regu-Mate (29%); respondents who use gloves most of the time or occasionally, 60% and 22%, respectively, do not wash their hands after handling Regu-Mate. People who always wear gloves when handling Regu-Mate are likely more concerned about their exposure to the drug than those who do not wear gloves; washing their hands after using the drug is an extension of this awareness and concern. Those who are not as regular in their glove wearing behavior may not be as concerned about skin contact with the drug and therefore hand washing is likely not as important to them. A lack of concern about skin contact may stem from people who never experienced ill effects from their own skin contact with the drug, know people who have never experienced ill effects from skin contact, or who don't know about the potential health effects that can result from skin contact.

Respondents who reported more direct skin contact (one to four times vs. more than 10 times) with Regu-Mate were less likely to report that they wash their hands after using the drug (68% vs. 43%, respectively). This result seems counter intuitive as I would have thought people would be more likely to wash their hands if they reported more direct skin contact; however this comparison may indicate that people who are less likely to wash their hands may also take

fewer precautions, resulting in more direct exposure to the drug. Hand washing in a barn is not always an easy or commonplace activity. Facilities may not have bathrooms with sinks instead only offering an outhouse or portable chemical toilet and a hose for running water. Minimal facilities like these do not offer amenities that encourage hand washing, particularly in winter weather. Even in facilities that have sinks routine hand washing is usually not part of a barn culture where getting dirty is expected.

Respondents who reported discussing glove use and skin contact avoidance with their veterinarian use gloves more often (88% and 85%, respectively) than those who did not discuss these topics with their veterinarian (25% and 50%, respectively). The “no discussion” group is less robust due to the small number of respondents in this group. Respondents who discussed skin contact and hand washing with their veterinarian were more likely (58% and 69%, respectively) to wash their hands than those who reported not discussing skin contact or hand washing with their veterinarian (26%). There is an association between discussion of glove use, skin contact and hand washing with the veterinarian and safer glove use and hand washing behavior by the respondents. I do not know from this data if the respondent or the veterinarian brought up the discussion topics; if a respondent brought up the topic they may be more proactive or concerned about drug handling safety, which would prompt more protective behavior.

The frequency with which a person administers Regu-Mate and discussion of glove use/hand washing/skin contact with the veterinarian all are indications that respondents may take protective glove and hand washing measures.

Glove Replacement

Respondents who administer Regu-Mate five times per week or more replace their gloves less often (67%) than those who administer Regu-Mate three times per month or less (88%). There is little association between glove replacement behavior and any other behaviors or demographic characteristics; of all respondents who report wearing gloves, 78% replace them every time that they handle Regu-Mate.

If a respondent uses gloves every day when handling Regu-Mate he or she may try to re-use gloves to save money. Disposable gloves can be difficult to remove in a manner that allows for easy reuse since many people will grab the cuff, turning the glove inside-out as it is removed from the hand. A glove removed in this manner would need to be re-inverted for re-use; alternatively one could pull the glove off by pulling on the tips of the fingers. Both attempts to re-use disposable gloves allows for possible contamination and an additional risk of skin exposure.

Glove Types

The Regu-Mate and Altresyn labels recommend using protective non-porous gloves when handling the drug; the labels indicate the drug should not penetrate intact rubber or impervious gloves but that leakage through a glove could result in increased absorption^{1,2}. Latex or other rubber gloves are not recommended for use with oils as oils are able to penetrate these gloves over time; chemically the safest disposable gloves to use are nitrile and/or vinyl. Among the respondents latex or rubber are the most commonly used (71%) type of glove.

Respondents who use nitrile gloves (22% of all respondents) learned about Regu-Mate precautions from all the classifications. Only three respondents provided a write-in comment that they learned about Regu-Mate precautions from scientific articles and two of these respondents use nitrile gloves. I did not come across any articles during my literature review that directly referenced using nitrile gloves while handling Regu-Mate and due to the limited availability of scientific articles these respondents are likely more educated or pro-active in the handling and understanding of Regu-Mate than the average horse care provider.

As gloves are only worn for a short time, Regu-Mate will likely not permeate through latex/rubber gloves in one use. Therefore use of any type of disposable non-permeable protective glove and not reusing it is more important for adequate protection than using chemically safe nitrile or vinyl gloves. Education about glove use from veterinarians should

include the type of protective glove to use (nitrile and vinyl being preferable) along with how often the gloves should be replaced.

Actions While Wearing Gloves

The most common behaviors reported by respondents while they were still wearing gloves are opening doors (43%) and handling of horses/equipment (35%). Too few respondents reported performing actions prior to removing their gloves to perform comparisons with other questions. If a person is dosing Regu-Mate via a dispensing device directly into the horse's mouth it is understandable they may keep gloves on until they have completed dosing the drug, resulting in their still wearing gloves while opening the stall door and handling the horse. Wearing gloves for these alternative actions, however, creates a potential for contamination if the drug spills on the glove.

Actions Prior to Washing Hands

Eighty four percent of respondents reported that they opened doors and/or handled horses/equipment prior to washing their hands after dispensing Regu-Mate. Most of the respondents who reported performing actions prior to washing hands do not wash their hands at all after handling Regu-Mate; however a small number who reported that they did wash their hands also reported writing records (9%), measuring out feed (3%), opening doors (15%), and handling horses/equipment (12%) prior to washing their hands. Respondents who reported discussing hand washing with a veterinarian also reported less eating/drinking/smoking (7%) and measuring of feed (10%) prior to washing their hands than those who did not discuss hand washing (26% for both activities).

People who wash their hands after handling Regu-Mate but still perform some of these actions prior to washing their hands could have a false sense of security because they could be contaminating their environment. Those who don't wash their hands are potentially more broadly contaminating their environment by touching objects. One way to enhance recognition of potential contamination risks is to ensure that veterinarians who dispense the drug discuss

the need to wash hands prior to undertaking other activities such as eating/drinking/smoking, handling cell phones, writing records, opening/closing doors, measuring feed and handling horses/equipment. This survey did not ask about cell phone use prior to washing hands; however this use should also be addressed by veterinarians. Some facilities, as mentioned above, may not have sinks for hand washing. In these cases veterinarians should remind clients that a viable alternative is washing their hands in a wash stall or just with the watering hose.

General Precautions

In order to provide a more robust overview of whether respondents took precautions when they handled Regu-Mate, I combined protective measures and evaluated how many of the individual measures the respondents reported overall. The following general protective measures were considered: glove use, replacing gloves every time Regu-Mate is handled, using nitrile or vinyl gloves, washing hands after using Regu-Mate, storing the bottle away from other medications, using a Luer-locking syringe, withdrawing by attaching the dispensing device to the tip of the bottle, not aerosolizing residual Regu-Mate when emptying the syringe, and using Regu-Mate-dedicated feed buckets. Most respondents reported that they practiced between four and six of the precautions, and all respondents took at least one precaution. Respondents who reported that they experienced skin contact with Regu-Mate more than 10 times took fewer precautionary measures (mean 3.8; modes 2 and 4) when handling the drug than respondents who reported some skin contact only one to four times (average 4.7; mode 6). This association suggests that taking fewer precautions to avoid skin contact with the drug allows for more opportunities for direct skin exposure.

Respondents who handle Regu-Mate three times per month or less take more precautions (mean 5.4; mode 4 and 5) than respondents who handle the drug five times per week or more (mean 4; mode 4). The decreasing number of precautions taken with an increased frequency of handling Regu-Mate suggests that there may be complacency with respect to safe handling practices as handling of the drug becomes more frequent.

Eliminated or Disregarded Comparisons

Table 5-4 summarizes comparisons that were eliminated from additional analysis due to insignificant differences between the comparisons. The figures referenced are in Chapter 4, Results.

Table 5-4: Comparisons with glove use and hand washing that show little to no difference

Comparison		Figure Number	Additional Comment
Q.11. Glove replacement	Q.1. Sex	4-30	
Q.10. Glove use	Q.3. Role with horses	4-53	
Q.11. Glove replacement	Q.3. Role with horses	4-54	
Q.10. Glove use	Q.4. Breeding industry	4-71	
Q.11. Glove replacement	Q.4. Breeding industry	4-72	
Q.14. Hand washing	Q.4. Breeding industry	4-73	
Q.12. Glove type	Q.4. Breeding industry	4-75	Leather gloves were a write-in with few responses
Q.14. Hand washing	Q.7. Reasons to use	4-86	
Q.11. Glove replacement	Q.6. Number of horses	4-90	
Q.10. Glove use	Q.9. Years handling	4-98	
Q.11. Glove replacement	Q.9. Years handling	4-99	
Q.11. Glove replacement	Q.10. Glove use	4-123	
Precautions Taken	Q.4. Breeding industry	4-134	
Precautions Taken	Q.3. Role with horses	4-135	
Precautions Taken	Q.9. Years handling	4-137	
Precautions Taken	Q.26. Discussion with vet	4-139	Too few respondents who did not discuss Regu-Mate with their veterinarian to compare

A higher percentage of respondents in the 30-39 year age range reported not using gloves (43%) or washing hands (57%) than any other age range. This age range represents only 13% of total respondents, however, and these respondents were predominantly owner/riders, barn managers and veterinary professionals. Glove use across the other age groups is similar with an average of 15% of respondents not using gloves. It is unclear why the 30-39 year age range displays different behavior than other age groups, but the small sample size may have resulted in a non-representative sample of this group.

Respondents who reported using Regu-Mate for horse behavior modification use gloves more often (86% of the time) than those who use Regu-Mate for any other reason (average of 75%). However, there is a larger difference in how often gloves are used, with 57% of those using Regu-Mate for behavior modification wearing gloves every time they handle the drug compared with an average of 31% who use Regu-Mate for other reasons. Respondents using Regu-Mate for behavior modification were more likely to report not being involved in the breeding industry (57%) than any other reason for using Regu-Mate (an average of 14%). This apparent difference in glove use is likely not significant; neither glove use nor glove replacement behavior are associated with involvement in the breeding industry in any of the other comparisons that resulted from the survey.

5.3.2 Bottle Storage

Regu-Mate bottles are designed so that a dispensing device can be attached to the nozzle of the bottle opening. After the device is attached, the bottle is inverted to withdraw the drug, after which the bottle is turned to its upright position for storage on a shelf. This method should, if done properly, result in minimal spilling of the drug. However, if proper technique is not used to withdraw and dispense the drug from the bottle, some Regu-Mate can be spilled, which can result in drug residue on the outside of the bottle, with subsequent transfer to the storage area and to other surfaces that come into contact with the bottle. Storing the Regu-Mate bottle separate from other medications and items prevents the potential for contamination.

Respondents who are between 50 and 59 years old reported practicing safer bottle storage than the other age groups; trainers, grooms and barn managers reported the highest percentages of respondents in this age category. Over 50% of respondents self-identifying as trainers, grooms and barn managers store Regu-Mate separately from other medications; the difference in bottle storage for the 50 to 59 year old classification may be due to their role in working with horses rather than their age. Equine veterinary professionals often are mobile and therefore may not have the space to store Regu-Mate separately from other medications. Owners/riders may also have limited space to store Regu-Mate in the barn, which could also result in storing Regu-Mate with other medications. Barn managers, trainers and grooms often work in barn environments where the feed room may have more space to separate the drug from other medication.

Those not involved in the breeding industry store their Regu-Mate bottles separately from other medications more often than those involved in the breeding industry. Respondents who have been handling Regu-Mate less than five years are more likely to store the drug separately from other medications than those who have been handling the drug for longer periods of time. I am unable to draw a conclusion as to the reason for this from the responses to the survey. People in the breeding industry or who have handled the drug for five years or more may be more aware of the potential for contamination if bottles are stored with other medication than other respondents.

Respondents who reported that they discussed the proper storage of Regu-Mate with a veterinarian were more likely to store Regu-Mate with other medications (62%) than those who did not discuss storage with their veterinarian (50%). This association is not expected as the veterinary recommendation should be to store the bottle separately from other medications due to contamination concerns. Veterinarians may not be providing the correct information about storing the Regu-Mate bottle. Instead of discussing potential contamination issues caused by storing the bottle with other medications the discussion with veterinarians may instead have focused on how the drug itself should be stored (ie. cool, dark area). If the recommendations in the conversation did discuss storing the bottle separately from other

medications it was inadequate and/or ineffective. The advice being given by veterinarians is not sufficient to induce protective bottle storage behavior in their clients.

Handling Regu-Mate for a longer period of time and involvement in the breeding industry had the highest association with safely storing bottles of Regu-Mate separately from other medications.

Eliminated Comparisons

Table 5-5 summarizes comparisons that were eliminated from additional analysis due to insignificant differences between the comparisons.

Table 5-5: Comparisons with bottle storage that show little to no difference

Comparison		Figure Number	Additional Comment
Q.16. Bottle storage	Q.8. Frequency of handling	4-114	3 times per month or less is compared to 5 times per week or more; the other frequency categories have too few respondents to be useful for this comparison
Q.16. Bottle storage	Q.25. Where learned about Regu-Mate	4-144	

5.3.3 Tool Use and Administering Regu-Mate

Figure 5-1 and Figure 5-2 show the three commonly used dispensing devices: a non-locking/slip syringe, Luer-lock syringe and dosing gun. The syringes are used with the nozzle tip that comes with the bottle. A syringe is attached to the nozzle tip and the drug is withdrawn while the bottle is inverted. Luer-lock syringes are twisted to lock onto the nozzle tip while the slip syringe is pressed over the nozzle tip; product labels for the Food and Drug Administration (FDA) approved drugs specify use of a Luer-lock syringe^{3,4}. The dosing gun works with a pump action using its own customized bottle top; a dial on the gun pumps out a specified dosage when the handle is pressed.

Figure 5-1: Slip (non-Luer-lock) syringe on left and Luer-lock syringe on right⁵



Figure 5-2: Regu-Mate dosing gun⁶



A large majority of respondents (70%) use a non-locking/slip syringe to withdraw Regu-Mate from the bottle. There is no consistent trend between the type of tool used and the number of times the respondent reported exposure to the drug. Too few respondents reported using other types of tools to administer Regu-Mate to adequately assess additional comparisons.

No trend was identified in this data set for potential reasons or links to why non-locking syringes are most commonly used for Regu-Mate dispensing. This use may be because non-locking syringes are usually less expensive than Luer-lock syringes and more readily available through the prescribing veterinarian. Clients may want to buy only one type of syringe and non-locking syringes are commonly used for injections or for dosing of other drugs. There is

potentially a lack of education for both veterinarians and clients regarding the bottle tip design and locking syringes.

Many clients may be unaware of the availability of dosing guns; when working properly, dosing guns are a relatively safe although more expensive option. The primary potential problem with a dosing gun is that the plastic tubing that connects the bottle to the gun needs replacement periodically because the plastic degrades over time due to contact with the oil solution, potentially causing cracks or leaks. This setup makes the most sense when it is used to top-dress grain as opposed to dosing directly into a horse's mouth. Carrying the dosing gun and bottle to the horse is not safe as the bottle can be dropped. Another potential problem with a dosing gun setup is getting the last bit of the drug out of the bottle as pumps tend to leave a small portion in the bottom of the bottle. Regu-Mate is expensive and clients would not want to waste the drug resulting in using alternative, and potentially unsafe, measures to dose the last bit of the bottle.

Syringe Replacement

Of respondents who use a syringe to dispense Regu-Mate, 32% withdraw directly through the bottle opening, not replacing the syringe each time they use the drug, while 15% replace it each time. Respondents who administer Regu-Mate three times per month or less (29%) are more likely to replace the syringe each time they administer the drug when compared to respondents who administer Regu-Mate five times per week or more (9%).

If the person using the drug withdraws it through the bottle opening (i.e. sticking the syringe through the opening and not connecting the tip of the device to the tip of the bottle), there is a potential for contamination when a syringe is re-used or when it is stored in-between uses.

Of respondents who use a syringe to administer Regu-Mate, 53% do not withdraw directly through the bottle opening. Re-use of a syringe used in this manner has minor potential for contamination due to the horse's saliva on the syringe (if dosed directly into the mouth), leaking of residual drug from the tip during storage, and any spilling that may have occurred in

the withdrawal process. Regular replacement of syringes used in this manner is a good management practice as oil will build up in the syringe over time as well as degrade the rubber seal, which may result in sticking and/or leaking.

Aerosolizing

Fewer respondents who administer Regu-Mate three times per month or less (6%) reported forcefully expelling the last of the drug from the dosing device (i.e. aerosolizing) the drug than those who administer the drug five times per week or more (45%).

Based on this data set, the frequency that the respondent handles the drug is associated with whether a respondent is likely to aerosolize Regu-Mate while emptying the syringe. This behavior may be due to carelessness, an increased comfort in using the drug, and general complacency. As Regu-Mate is an expensive medication, people may be forcefully pushing the last of the drug out of the dosing device to ensure that none is wasted. If aerosolizing is happening when dosing directly into the horse's mouth it may be related to the horse's compliance in the dosing process. The horse may be difficult to dose due to previous poor experiences, general poor behavior, or dislike of the taste of the drug and forcefully expelling the last of the medication could be a reaction to the difficult horse. When dosing directly into the horse's mouth forcefully expelling the last of the medication should not aerosolize the drug as it would be contained within the mouth.

Administering Regu-Mate: Dedicated Buckets and Direct Oral Dosing

A majority of respondents (66%) use dedicated grain buckets for Regu-Mate use, which is the protective choice. Trainers are less likely to use Regu-Mate-dedicated buckets than respondents who identify with any other role in working with horses (40% vs. an average of 63%); it is unclear why trainers may be less likely to use dedicated buckets as barn managers and grooms usually are dealing with a similar barn layout and number of horses. A majority of respondents, regardless of involvement in the breeding industry, use dedicated Regu-Mate feed buckets; however, more of those involved in the breeding industry use dedicated buckets

than those who are not involved in the breeding industry (76% vs. 56%, respectively).

Respondents who administer Regu-Mate directly into the horse's mouth and mixed with grain (67%) are more likely not to use dedicated Regu-Mate grain buckets than respondents who only administer Regu-Mate mixed with grain (25%).

Involvement in the breeding industry is the characteristic most commonly linked with use of dedicated grain buckets for Regu-Mate use. People who use mixed methods of administering Regu-Mate may be associated with not using dedicated Regu-Mate buckets due to their inconsistency in the method of administering the drug. If the drug is dosed directly into the mouth one day and put over grain the next, it can be hard to ensure consistent bucket use. When buckets for Regu-Mate use are not dedicated there is a risk of contamination for horses and humans.

Oral dosing directly into the horse's mouth is performed by 47% of respondents and 30% top-dress their grain (23% use both methods of administering Regu-Mate). Problems can arise with direct dosing if a horse is not willing to cooperate with the process. Difficulties can include the horse refusing to swallow, spitting out the medication and/or refusing to open the mouth; all these miss-behaviors can result in the drug being expelled from the horse's mouth and onto the handler and/or surroundings. Horses may be selective eaters who dislike the smell or consistency of oil-topped grain; this selectivity results in the need for oral dosing. If a horse spills its grain or doesn't eat it all, the care giver would have difficulty ascertaining how much of the medication was ingested. Direct oral dosing gives more certainty that the entire amount of the drug was ingested. Both methods of administration can be safe given the right circumstances and is dependent on the individual horse.

Eliminated Comparisons

Table 5-6 displays the comparisons that were not further evaluated because they demonstrated little or no difference in the comparison and/or there was insufficient data to support the results of the comparison.

Table 5-6: Comparisons with aerosolizing that show little to no difference

Comparison		Figure Number	Additional Comment
Q.19. Syringe replacement	Q.2. Age	4-44	
Q.17. Tool	Q.3. Role in working with horses	4-58	
Q.19. Syringe replacement	Q.3. Role in working with horses	4-60	
Q.20. Aerosolizing	Q.3. Role in working with horses	4-61	
Q.17. Tool	Q.4. Breeding industry	4-76	
Q.19. Syringe replacement	Q.4. Breeding industry	4-77	
Q.20. Aerosolizing	Q.4. Breeding industry	4-78	
Q.19. Syringe replacement	Q.6. Number of horses	4-92	The “none” category is disregarded for this assessment as they are not reporting regular contact
Q.19. Syringe replacement	Q.9. Years handled	4-103	Respondents in the 2-4 years are minimal
Q.20. Aerosolizing	Q.9. Years handled	4-104	Respondents in the 2-4 years are minimal
Q.22. Dedicated buckets	Q.9. Years handled	4-107	
Q.22. Dedicated buckets	Q.8. Handling frequency	4-119	3 times per month or less is compared to 5 times per week or more; the other frequency categories have too few respondents to be useful for this comparison
Q.19. Syringe replacement	Q.25. Where learn about Regu-Mate	4-146	Scientific articles was a write-in with minimal responses
Q.20. Aerosolizing	Q.25. Where learn about Regu-Mate	4-147	Scientific articles was a write-in with minimal responses
Q.20. Aerosolizing	Q.26. Discussion with veterinarian	4-154	

Only one third of respondents reported aerosolizing the drug when emptying the syringe. A higher percentage of respondents in the 30-39 year age range report aerosolizing Regu-Mate than any other age range. Seeing this age range represents only 13% of the total respondents

and included predominantly owner/riders, barn managers and veterinary professionals the sample size may be too small to make any comparisons. There is little difference between the roles in working with horses when looking at aerosolizing behavior and it is likely that as a small number of respondents are in this classification they may not be representative of the large population.

5.4 Restrictions and Prohibitions on Handling Regu-Mate

The survey focused on how handling of the drug is prohibited at facilities based on the sex and age or reproductive status of people. The product insert recommends that women who are or suspect they are pregnant should not handle the drug and women of child bearing age should exercise extreme caution when handling the product^{7,8}. The label also recommends that people with a variety of health conditions, including but not limited to known/suspected estrogen-dependent neoplasia, breast carcinoma, undiagnosed vaginal bleeding and tumors developed during use of oral contraceptives/estrogen-containing products^{9,10}, not handle the drug. The survey did not ask respondents if their facility restricted the handling of Regu-Mate by people with this or other health conditions.

A small percentage (10%) of female respondents reported handling Regu-Mate and also reported that the handling of Regu-Mate by all women is prohibited at their facility. Twenty-two percent of female respondents of child bearing age administer Regu-Mate at facilities where handling of Regu-Mate by women of child bearing age is prohibited. These responses may indicate that the handling of Regu-Mate is prohibited only for anyone other than the primary caregiver or employee. It could be part of the women's job description to handle all medications and without another person to assist in this task it will remain her responsibility, while limitations on the drug's handling are placed on the remainder of the barn population. Depending on the facility the remainder of the barn population could include grooms, students/riders and/or horse owners.

Slightly less than half (47%) of respondents reported that their facility prohibits the handling of Regu-Mate by women who are pregnant or may be pregnant; 55% of the respondents' facilities

prohibit children from handling the drug, and 14% prohibit women of child-bearing age from handling it. Twenty seven percent of respondents reported no groups that are prohibited from handling Regu-Mate. Children (under 18 years of age) are not mentioned in the product insert but if they handle the drug precautions similar to those for women of child-bearing age should be followed. The product insert specifically recommends that women who are pregnant or may be pregnant should not handle Regu-Mate. The facilities of respondents are not sufficiently following this guideline. Facilities may not prohibit handling of Regu-Mate if they believe that their handling protocol is sufficiently protective to prevent exposure to the drug. Unawareness or disregard of potential health effects and/or recommended handling restrictions could also contribute to the small percentage of respondents who prohibit specific groups from handling Regu-Mate.

Some respondents may have selected none or not selected a particular category if there were no people in that category on the property; for example no children are at the facility and they do not need to prohibit them from handling Regu-Mate. Therefore the percentages reported for each category prohibited from handling Regu-Mate may be lower than the actual prohibitions.

5.5 Experiences

The survey asked respondents to report past skin contact exposures to Regu-Mate and also to report any symptoms they may have experienced.

5.5.1 Direct Contact with Regu-Mate

Sixty five percent of all respondents in the 30-39, 40-49, and 50-59 year age ranges reported direct skin contact with Regu-Mate five or more times. These age groups also make up a larger percentage of respondents who have handled the drug for two to four and five or more years. The number of years handling Regu-Mate and not the respondent's age is a more likely reason for increased skin contact with Regu-Mate as respondents handling the drug for more years reported higher incidence of skin contact to Regu-Mate (60% and 50%, respectively) compared

to those who have handled it for one year or less. Respondents who administer Regu-Mate five times per week or more reported more skin contact with Regu-Mate (59% exposed ten times or more) than those who administer the drug three times per month or less (6%). The more frequently Regu-Mate is handled and the longer it is handled means more opportunities for exposure to the drug. This is independent of any precautions taken by respondents.

The more regularly respondents report using gloves the less they report skin contact with Regu-Mate; 82% of those who don't use gloves reported skin contact more than ten times compared to 16% of respondents who use gloves every time they dispense the drug. Wearing protective gloves is an immediate barrier to spilled Regu-Mate reaching the skin and reduces potential exposure to the drug. Respondents who reported less skin contact with Regu-Mate are more likely to wash their hands after handling the drug; this may be because respondents who wash their hands also practice better overall protective practices, resulting in less skin contact with the drug.

Respondents who discussed with their veterinarian the need to avoid skin contact with Regu-Mate reported skin contact with the drug that ranged from "never" to more than 10 times. More than 70% of respondents who did not discuss skin contact with their veterinarian reported having had skin contact with Regu-Mate more than 10 times. However, only a small number of respondents reported not having this discussion, and "no discussion" is less robust than "discussion" It is possible to conclude, however, that people who do not discuss the importance of avoiding skin contact with Regu-Mate may not take proper precautions to avoid skin contact and thus be exposed to the drug more frequently.

Glove use, handling frequency, years handling Regu-Mate and discussions with the veterinarian about skin contact are indicators of the amount of direct skin contact a respondent may have had with Regu-Mate.

Eliminated Comparisons

Table 5-7 displays the contact comparisons that show little or no difference between the categories or lack data for comparison.

Table 5-7: Comparisons with contact that show little to no difference or lack data for comparison

Comparison		Figure Number	Additional Comments
Q.23. Contact	Q.3. Role in working with horses	4-64	
Q.23. Contact	Q.11. Glove replacement	4-122	
Q.23. Contact	Q.17. Tool	4-129	Insufficient data to properly evaluate tools other than non-locking syringe
Q.23. Contact	Q.18. Method to withdraw	4-130	

5.5.2 Symptoms

Twenty-one percent of all respondents reported at least one symptom that they associated with Regu-Mate exposure. Both males and females reported hot flashes and headaches. Males also reported a change in sex drive. Females reported changes in menstrual period, menstrual flow, and in length of menstrual cycle, in addition to skipped periods, abdominal/menstrual cramps, prolonged pregnancy, progesterone-stimulated fibroid, and acne. Changes in menstrual length/flow, cycle length, skipping a period and cramps were the most commonly reported symptoms. It is reasonable to expect symptoms in women who have not yet gone through menopause as their reproductive system is still actively functioning and the woman is more likely to notice a difference in their cycle. Females naturally do experience fluctuations in their menstrual cycle/flow and hot flashes during menopause. While these symptoms could be due to other reasons they are all similar to those that are warned about on the product label^{11,12}. The symptoms could be related to the Regu-Mate exposure, however it is also

possible that women are attuned to changes in their body and/or reproductive cycle and due to knowledge about the drug through education or reading of the product label assume that the changes are related to a known exposure. On the other hand it is equally possible that women are experiencing symptoms but not associating them with exposure due to a lack of body awareness and/or perceiving the irregularities as normal for her. As males do not have the red flag symptoms related to the menstrual cycle that women do, they may be less likely to note symptoms that could be associated with exposure to Regu-Mate.

Similar percentages of male and female respondents (17% and 18%, respectively) reported symptoms that they associated with Regu-Mate contact. Females 59 years and younger as well as males between 30-49 years reported having experienced symptoms they associated with skin contact with Regu-Mate. Males and females were combined in this analysis because there were few male respondents (19% males).

Respondents who reported symptoms they associated with exposure to Regu-Mate were more likely (70%) to wash their hands than respondents who did not report symptoms (53%). If a person experienced symptoms from handling or contacting the drug they may be more likely to wash their hands in an effort to prevent symptoms in the future. A person who does not experience symptoms they associate as being related to Regu-Mate exposure may believe that the drug does not affect them which would perpetuate the non-protective behavior.

Eliminated Comparisons

Table 5-8 displays the comparisons that show little or no difference between the categories or lack data for comparison.

Table 5-8: Comparisons with contact that show little to no difference or lack data for comparison

Comparison		Figure Number	Additional Comments
Q.10. Glove use	Q.24. Reported symptoms	4-158	Glove use at all compared to no glove use
Q.9. Years handled	Q.24. Reported symptoms	4-159	
Q.8. Frequency handled	Q.24. Reported symptoms	4-160	
Precautions	Q.24. Reported symptoms	4-161	
Q.23. Reported skin contact	Q.24. Reported symptoms	4-162	

5.6 Education

Almost all respondents (95%) reported that their veterinarian talked about Regu-Mate with them in some capacity. Topics that were covered least often are aerosolizing the drug after withdrawal into a syringe (14%) and use of dedicated Regu-Mate buckets (17%) to prevent cross-contamination. Respondents discussed skin contact (89%), wearing gloves (84%) and hand washing (66%) most often with veterinarians. Respondents not involved in the breeding industry are more likely to report no discussion with a veterinarian (67%) than those involved in the breeding industry (33%). The distribution of breeders and non-breeders who discussed these topics with a veterinarian is similar to the distribution of breeders and non-breeders in the survey responses and therefore does not indicate an association between involvement in the breeding industry and veterinary discussions.

Discussion of glove use, skin contact and hand washing are associated with more protective glove use and hand washing behaviors. Discussion of these topics with a veterinarian is more likely to result in greater awareness of what protective behaviors are and why they may be necessary. It is possible that people who are inclined to be concerned about their health or contact with the drug are more likely to have discussions with their veterinarian regarding the drug. From these data I am unable to determine if the veterinarian or the client initiated the conversation.

Discussion with the veterinarian regarding bottle storage, dedicated Regu-Mate buckets, and aerosolizing from the syringe are not associated with more protective behaviors. There is little

to no difference between respondents' behavior if they discussed or did not discuss each topic with their veterinarian. Discussions about bottle storage, as mentioned in Section Bottle Storage5.3.2, may have focused on how the drug itself was stored to ensure quality control rather than the problems associated with storing Regu-Mate with other medications. Using dedicated buckets for Regu-Mate use can be difficult in large facilities and therefore respondents may not have the capability or inclination to follow through on this management technique. Aerosolizing the drug is less common than not aerosolizing regardless of the topic's discussion with a veterinarian; however there is little decrease in the respondent's reported behavior (10%) when the discussion did occur.

The lack of proper protective behavior even when a conversation took place between the veterinarian and client could be due to a number of factors. The veterinarian could have glossed over topics and not discussed them in enough depth to make a difference in the client's handling behavior. Information could also be incomplete or incorrect, both of which can lead to unsafe management practices even when the client is trying to be safe. Conversely the client may not be interested in safety, ignoring or consciously dismissing the recommended protective practices. Other clients could be dismissive of warnings with the thought "I've never been affected before" or "no one I know has been affected"; these reactions can be difficult to combat during the education process but should be directly addressed by the veterinarian.

5.7 Anecdotes

This section describes anecdotes about human exposure as well as about care giver's personal feelings towards Regu-Mate.

5.7.1 Human Exposure Anecdotes

As a young rider I was involved in the competitive equestrian world and knew of a number of horses on Regu-Mate. Individuals told me of their own experiences including stomach cramps and heavy menstrual bleeding. One anecdote which stuck with me was a "friend of a friend" story about a woman who had been dealing with reproductive health issues for a few years and

her doctor was unable to determine the cause. Ultimately they decided she needed a hysterectomy with bilateral oophorectomy. A nurse who was preparing her for surgery asked how she kept her hands so soft; the patient replied that she used her horse's Regu-Mate medication as a moisturizer as she noticed it made them incredibly soft after spilling it on them once. Upon further conversation they cancelled the surgery. The woman stopped using Regu-Mate as a moisturizer and her reproductive health issues diminished.

A female equine dentist had an irregular menstrual cycle and tests with her doctor showed high progesterone levels, yet she was not on hormonal birth control. Her doctors determined that she was regularly working in the mouths of mares that had been administered Regu-Mate only a few hours prior to her working on them. Since she did not wear gloves she was "bathing" her hands in the residue of the drug remaining the horse's mouth. She started wearing gloves and her symptoms went away¹³.

5.7.2 Attitudes toward Regu-Mate

As noted in the introduction to this chapter, the veterinarians who assisted in distribution of the survey mentioned farm managers' concern that their responses to the survey may alter how Regu-Mate is allowed to be used and this concern was related to the importance of the product to their livelihood. This concern highlights how people in the equine industry perceive altrenogest and how they may weigh the risks versus benefits of the drug. People may understand that some risk is involved in using the drug but the benefits from its use are more important to them and outweigh the risks. The benefits of the drug depend on the reason it is used, but it can offer a competitive advantage in show horses and is not easily replaced in the breeding industry when used for reproductive purposes. If people perceive the potential risk from the drug as bad enough to worry about increased controls placed on its use, there may be a disconnect in education on protective handling measures. While skin contact with Regu-Mate can have potentially negative side effects, with proper protocols the risk of contact can be minimized.

5.8 Risk Communication Program

This survey shows that people do not take sufficient measures to protect them from exposure to Regu-Mate. Protective behavior such as hand washing and glove use is less common the longer and more often a respondent has handled Regu-Mate. The overwhelming majority of people use gloves and dispensing devices that are not ideal to protect them from skin contact with the drug. Respondents do not regularly read the product bottle insert and do not regularly follow the protective recommendations on the label. Undertaking the primary protective measures outlined above is the first line of defense against direct skin contact with the drug and enough respondents do not follow these protections to suggest that there is potential risk to equine care givers. It should fall on the prescribing veterinarian to ensure that their client has an educated understanding of the risks and benefits of the drug, knows how to take appropriate protective management decisions and is provided with the opportunity to purchase the correct types of syringes/gloves.

There is an inconsistency in how people learn about Regu-Mate and its potential hazards as well as in the quality of information they receive. A comprehensive risk communication program to establish a regular, reoccurring dialogue between veterinarians and their clients will inform equine care givers about proper handling practices and ensure that correct and complete information is available. The risk communication program will include the risks and protective actions which the veterinarian should cover, a written guidance document that can be distributed with the drug, and a placard that can be posted in each barn near the Regu-Mate bottle. This program can be utilized by veterinarians as an easy and informative reference when discussing altrenogest as a treatment option with their clients as well as a reference for equine care givers when developing handling guidelines in their own facilities. By distributing the guidance document with the drug, it will help facilitate communication between veterinarians and clients regarding proper safe management practices. The guidance document outlines specific management practices; the veterinarian can use it as a guide to ensure that each topic is discussed with the client when he or she dispenses or prescribes the drug.

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- ¹ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."
- ² CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."
- ³ Ibid.
- ⁴ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."
- ⁵ ATI Nursing Education, "Medication Administration 3: Syringes," http://www.atitesting.com/ati_next_gen/skillsmodules/content/medication-administration-3/equipment/syringes.html.
- ⁶ Heartland Veterinary Supply and Pharmacy, "Regu-Mate," <http://www.heartlandvetsupply.com/p-3699-regu-mate.aspx>.
- ⁷ CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."
- ⁸ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."
- ⁹ CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."
- ¹⁰ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."
- ¹¹ CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."
- ¹² Intervet Inc, "Regu-Mate Solution 0.22% Product Label."
- ¹³ Dr. Frank Reilly, email communication, 9/14/12 2012.

6 Conclusions and Recommendations

Regu-Mate is widely used in the equestrian industry. While the data generated from this survey is not representative of the entire industry and I am unable to make conclusions about the industry as a whole, the results of this study indicate that safety measures taken by equine care givers who administer Regu-Mate are usually inadequate to prevent potential health effects that are associated with direct skin contact. The recommendations resulting from this study should help foster a safer working environment for equine care givers when they use Regu-Mate for their horses.

6.1 Conclusions

People do not take sufficient measures to protect themselves from exposure to Regu-Mate. The complacency that appears to develop over time shows that people do not acknowledge the drug is not innocuous and that there can be health effects resulting from exposure. The following are conclusions from the survey.

- The most commonly used equipment (latex or rubber gloves worn and non-locking/slip syringe) by respondents are not ideal to protect from skin contact
- Slightly more than half of all respondents use gloves every time they handle Regu-Mate
- Almost half of all respondents do not wash their hands after handling Regu-Mate
- Almost all respondents who don't use gloves do not wash their hands after handling Regu-Mate
- Glove use and hand washing are less common the longer and more often a respondent has handled Regu-Mate
- An increased frequency of handling Regu-Mate is associated with taking fewer safety precautions
- Respondents who take fewer precautions reported more direct skin exposure to the drug
- Storing Regu-Mate separately from other medications is associated with handling Regu-Mate for a longer period of time and involvement in the breeding industry.

Clients need to be aware of safety equipment and how to use it properly. Safety equipment should be readily available from the prescribing veterinarian. Based on the results of the survey, discussion with the veterinarian about glove use, skin contact, and hand washing was positively associated with safe glove use and hand washing behavior, but discussion of bottle storage, use of dedicated Regu-Mate buckets, aerosolizing was not associated with more protective behaviors. Veterinarians need to discuss glove use, hand washing, avoiding skin contact and safe handling precautions with their clients upon first prescribing Regu-Mate and ensure that there are regular follow up discussions over time. Most respondents do not regularly read the product inserts and respondents do not routinely follow the recommendations on the product label. The quality of information received about Regu-Mate and how people learn about Regu-Mate and its potential hazards is inconsistent. Veterinarians need to provide full information about Regu-Mate in a proactive manner; the results of the survey indicate that most respondents do not read the inserts that are provided with the medication and do not follow safety recommendations.

6.2 Recommendations

Based on the conclusions outlined above I recommend a comprehensive Regu-Mate risk communication program for veterinarians and equine care givers that includes an in-depth discussion along with distribution of an information sheet and instructional placard that can be posted in the barn. Topics to be covered in the veterinarian/client safe handling discussions are outlined below. A comprehensive risk communication program to help veterinarians create a regular and reoccurring dialogue with their clients about safe Regu-Mate handling will make correct and complete information available to equine care givers.

6.2.1 Education

General education of clients, when their horse is prescribed Regu-Mate, is an important part of fostering safe handling behavior. Educational discussions between the veterinarian and client about Regu-Mate should include glove use, avoiding skin contact, hand washing, how to

dispense the drug, and who should handle the medication. Safe handling practices are described in detail in the following sections.

Glove Use, Skin Contact and Hand Washing

Disposable gloves, preferably nitrile or vinyl, should be worn whenever administering, dosing or handling Regu-Mate. Gloves should not be re-used because of the potential for contamination of other surfaces or items. Non-porous rubber or latex gloves are most commonly used as they are less expensive and more easily obtained than nitrile or vinyl gloves. As rubber and latex are penetrable by oil over time this material is not recommended for use with Regu-Mate; however a one-time short-term use of rubber or latex disposable gloves is preferable to using no gloves at all. The overwhelming majority of respondents used gloves that are not ideal for protecting against skin contact with the drug; veterinarians should stock nitrile or vinyl gloves for distribution to clients using Regu-Mate.

After handling Regu-Mate and prior to removing their gloves people should avoid touching anything (doors, horses, cell phones, records, etc.) to prevent contamination of other surfaces. To avoid contaminating other items, a partner can help open and close doors and/or in handling horses and equipment. If no partner is available the caregiver can wear two or three gloves on top of each other, and remove the top glove prior to touching doors, equipment and/or horses.

Gloves should be removed from the hand by grabbing the cuff and pulling it over the fingers until it comes off inside out. The glove removed first is then gripped in the palm of the other hand while the removal technique is repeated; the first glove will end up inside the glove just taken off. When removed in this manner no surface area of the glove that may have come into contact with the medication will be exposed to the surface or the caregiver's hand and result in skin exposure. Gloves can then be disposed of with normal refuse.

All skin contact with Regu-Mate should be avoided as the drug, which is an oil-based suspension, is readily absorbed through the skin. If skin contact does occur, hands should be

washed immediately with soap and water. For best practices, I recommend washing hands after removing gloves regardless of an observed skin contact with the drug. Gloves may contain small holes that a person did not observe, resulting in dermal exposure to Regu-Mate. Hand washing can occur at a sink, wash rack or even an outdoor hose; veterinarians should emphasize the alternatives to using a sink as many equestrian facilities do not have immediate access to sinks.

Storage, Dispensing and Administering

A Regu-Mate bottle should be stored separately from all other medications in a leak-proof container to avoid cross contamination of other medications. If space limits the ability to store the Regu-Mate bottle in a different location from other medication it can be contained in a bucket, which will reduce contamination from leaks or spills. The drug should be stored at or below 25° C (77°F)^{1,2}.

The nozzle supplied with the Regu-Mate bottle is designed to be used with a Luer-locking syringe. The overwhelming majority of respondents used a slip/non-locking syringe, which may result in leaking protect from skin contact with the drug; veterinarians should specifically stock Luer-locking syringes for their clients who use Regu-Mate. Syringes should be replaced on a regular schedule as the oil will slowly degrade the syringe's rubber seal and buildup on the syringe can cause it to stick. Regu-Mate should be withdrawn from the bottle using a Luer-locking syringe in the following manner:

1. The Luer-lock syringe is attached onto the nozzle by twisting while the bottle is upright
2. The bottle is inverted and the syringe is used to withdraw the Regu-Mate solution
3. The bottle is righted and the syringe is removed from the nozzle with a twisting action
4. The dispensing tip of the bottle is re-covered

If the handler is administering Regu-Mate to many horses over the long term, potential contamination from loading and unloading multiple syringes per day may be reduced by investing in a dosing gun. A dosing gun is properly used when dosing is done by top-dressing the grain instead of dosing directly into the horse's mouth. The tubing of the dosing gun should be

inspected regularly for cracks as well as for buildup on and degrading of the plastic due to contact with the oil solution. A reoccurring problem with using a dosing gun is that a small amount of solution that cannot be taken up by the device's pumping action remains in the bottle; this leftover Regu-Mate needs to be carefully dispensed using a syringe after removing the dosing gun from the bottle. If this leftover amount is not dispensed safely it can result in exposure and contamination of items or and surfaces in the area.

If the horse is well-mannered and does not resist direct dosing, administering the drug via syringe directly to the back of the horse's mouth is the safest option and offers the least possibilities for contamination of other items and surfaces. However, if the horse resists direct dosing and tries to spit out the medication, top dressing grain reduces the risk of the handler coming into direct contact with the drug. Using a grain bucket dedicated for Regu-Mate will reduce the risk of contamination. When emptying the syringe onto the grain or into the horse's mouth, care should be taken to avoid aerosolizing the drug. Aerosolizing Regu-Mate puts the drug into the air where it can be inhaled, ingested and/or come in contact with the skin or eyes.

Restrictions on Handling

Women who are pregnant or may become pregnant should not handle Regu-Mate and extra precautions should be taken by women of child bearing age. Children should not handle Regu-Mate. Clients should be made aware of other health problems listed on the product insert which should preclude their handling of the drug.

- Anyone with thrombophlebitis or thromboembolic disorders or history of these events.
- Anyone with cerebral-vascular or coronary artery disease.
- Women with known or suspected carcinoma of the breast.
- People with known or suspected estrogen-dependent neoplasia.
- Women with undiagnosed vaginal bleeding.
- People with benign or malignant tumors that developed during the use of oral contraceptives or other estrogen-containing products.
- Anyone with liver dysfunction or disease^{3,4}.

As clients may not want to discuss their personal health, veterinarians should generally discuss with them that people with certain health problems should not handle Regu-Mate and then direct their client to the product label for further information. The product insert is not regularly read by equine care givers so veterinarians should specifically direct clients to read the insert. Adverse health effects from direct skin contact can arise from acute (one exposure) or from chronic (long-term regular exposure) exposure. Complacency in using the drug may be related to assuming that because a person has not experienced ill effects from skin contact with the drug in the past, they will not have any symptoms in the future. Veterinarians should emphasize that just because a person does not notice a health effect from one known skin contact they could potentially experience health impacts from repeated exposures; health effects are not always immediately apparent.

Health Effects

The client should be informed about the potential health effects from exposure to altrenogest. These effects may include headaches, disruption of the menstrual cycle (period coming later/earlier than normal and/or length of period being longer/shorter than normal), uterine and/or abdominal cramping, change (increase or decrease) in menstrual bleeding and prolonged pregnancy^{5,6}. Other health effects that were reported in this survey included hot flashes, acne and a progesterone-stimulated fibroid as well as changes in sex drive for males.

6.3 Risk Communication Program

Currently there is inconsistency in how people learn about Regu-Mate and its potential hazards as well as the quality of information they receive before they use the drug. The comprehensive risk communication program outlined here will establish a regular, reoccurring dialogue between veterinarians and their clients and inform equine care givers to ensure that correct and complete information is available. Veterinarians can utilize the information sheet and instructional placard to encourage dialogue between them and their client as well as serve as a reminder of the proper safety precautions to avoid Regu-Mate exposure.

6.3.1 Information Sheet

Based on the findings from my research, I developed written best practices guidelines (Appendix F) that outline the important risks and safe management practices to discuss with equine care givers who use oral oil-based altrenogest. This information sheet summarizes the broader description of veterinarian educational discussions with clients in Section 6.2.1. Veterinarians can use the information sheet as an easy and informative reference when discussing Regu-Mate as a treatment option with their clients. It can also be used as reference for equine care givers when developing handling guidelines in their own facilities. Veterinarians can distribute the information sheet with the drug as a reminder of previous conversations and to facilitate communication with clients regarding proper safe management practices. The goal of the handling guidelines is to use risk communication to help equine caregivers develop safe management practices to mitigate risk from and exposure to altrenogest.

6.3.2 Instructional Placard

In collaboration with graphic designer Tristan Elliot, I created an instructional placard (Appendix G) for equine care givers to post near the Regu-Mate bottle. The instructional placard is designed to highlight a few of the most important safety precautions which need to be taken using representational graphics. The highlighted precautions are glove use, hand washing, syringe type and cross-contamination. The purpose of the placard is to remind Regu-Mate handlers of safety precautions in a simple manner which increases retention and ultimately the number of precautions taken by an individual. Text in the placard was kept minimal to highlight the images and increase comprehension across demographics. It is designed to be printed in color or in black and white without losing clarity.

6.3.3 Specifics on Discussion

When discussing Regu-Mate, veterinarians must ensure that clients are actively listening and actually understand the importance of safe handling procedures. If the client seems unwilling or uninterested in creating a safe atmosphere it should fall upon the veterinarian to consider and offer alternative treatments. The oil based solutions, under the trade names Regu-Mate and

Altresyn, are the only Federal Drug Administration (FDA) approved formulations for altrenogest; compounding pharmacies, however, offer alternative, non-FDA approved formulations. Compounding is controversial among veterinarians even though it is extensively used⁷. Formulations include intramuscular injections (daily and Biorelease)^{8,9} and an oral paste¹⁰. The likelihood of direct dermal exposure is reduced in injectable or paste formulations in comparison to the easily dermally absorbed oil suspension.

A continued dialogue between the veterinarian and client is necessary even when a client administers Regu-Mate frequently, has used the drug a number of years and/or to a large number of horses. Protective behavior such as hand washing and glove use is less common the longer and more often a respondent has handled Regu-Mate. Veterinarians should not assume that clients involved in the breeding industry or who have handled the drug for many years will be taking proper safety precautions. As clients become more comfortable with using the drug, over time or sustained use, they may become more relaxed in their handling protocol. To ensure safe behavior, periodic discussions about Regu-Mate handling safety should be initiated by the veterinarian. During these yearly conversations the veterinarian should ask if the client has experienced skin contact with Regu-Mate; if there is repeated skin contact the veterinarian and client should reevaluate the facility's safety protocol to ensure that it is sufficient.

The information sheet and placard will be distributed to the veterinarians and practices that assisted in the dissemination of surveys for this thesis. These documents will also be available to veterinarians, barn managers and equine care givers who use Regu-Mate in their facilities. Distribution of the information sheet and placard will encourage dialogue, serve as a passive reminder of safe handling and encourage the development of safe handling practices in every facility.

6.4 Summary

Most equine caregivers, based on the results of this survey, do not take sufficient precautions to protect them from exposure to Regu-Mate. Undertaking proper protective measures outlined in Section 6.2 is the first line of defense against direct skin contact with the drug and

enough respondents do not follow these protections to suggest that there is potential risk to equine care givers. As Regu-Mate is a prescription drug the responsibility falls on the prescribing veterinarian to ensure that the client has an educated understanding of the risks and benefits of the medication, knows how to take appropriate protective management decisions and is provided with the opportunity to purchase the correct type of syringes and gloves. The risk communication program outlined above addresses the risks and protective actions which the veterinarian should cover, a written guidance document which can be distributed with the drug and an instructional graphic to post in the facility near the Regu-Mate bottle. This program can be utilized by veterinarians as an easy and informative reference when discussing oil-based altrenogest as a treatment option with their clients as well as a reference for equine care givers when developing handling guidelines in their own facilities. Use of this program when prescribing the medication will help facilitate communication between veterinarians and clients regarding proper safe management practices.

¹ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."

² CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."

³ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."

⁴ CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."

⁵ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."

⁶ CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."

⁷ American Association of Equine Practitioners, "Equine Veterinary Compounding Guidelines."

⁸ BET Pharmacy.

⁹ Wedgewood Pharmacy.

¹⁰ Ibid.

Appendix A: Information Requests

Ariel Newman

Altrenogest European public MRL assessment report 2012

1 message

Ariel Newman
To: vet-phv@ema.europa.eu

Sat, Mar 10, 2012 at 6:52 PM

Hello,

I am a graduate student at Tufts University in the United States and I am doing my masters thesis on altrenogest (a progestin hormone) exposure in equine professionals. I am very interested in your latest European public MRL assessment report which was released on February 14th 2012. I have had trouble locating/accessing the animal studies you have discussed in the report and would be interested in the information contained within them for my own reading/citation purposes.

Is there a database which you could point me to which may have these studies available for review? Can you provide me with the studies you reviewed/referenced to come to your determination on the new ADI values? There is little government reports/data available within the US and I am primarily looking to Europeans for information.

Thank you for your time and I look forward to hearing from you.

Sincerely,

Ariel Newman



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

DATE July 19, 2012

In response refer to: 2012-2129

Dear Requester:

In response to your request (copy enclosed) for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act:

- ☐ After searching our files, we did not find the requested records
- ☐ We have no disc losable information as requested.
- ☒ We are enclosing the requested record(s) **FOI Summary NADA 131-310 and Adverse Event Reports**
- ☐ This is a partial response

**Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, Maryland 20857**

Should the agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal."

☐ The following charges will be included in a monthly invoice:

Reproduction: \$ 2.40 Search: \$ Review: \$ Other: \$ Total: \$ 2.40

☐ See addendum for comment(s).

The above total may not reflect final charges for this request. Please **DO NOT** send payment unless you secure an invoice for the total monthly fee.

If you need further assistance please contact Sandy McGeehan at (240) 276-9120

Sincerely yours,

Laura Bradbard
Laura Bradbard

Director , Communications Staff
Center for Veterinary Medicine
Food and Drug Administration

Re: FDA FOIA Request
Fax number: (301) 827-9267

Commercial _____
Nonprofit/Media _____
Other _____

To whom it may concern:

MAR 23 2012

2012-2129

I am looking for information regarding the chemical altrenogest. It is also known as allyl trenbolone and is marketed under the trade name Regu-mate.

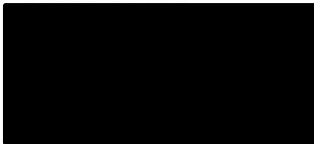
Specifically I would like copies of ADE reports (human, horse, etc) and any studies which were provided to the FDA in support of the drug's approval.

As a graduate student my ability to pay fees is limited, however I am willing to pay for some. These would have to be on a case by case basis.

Thank you for your assistance and feel free to contact me for any additional information or questions:

Sincerely,

Ariel Newman



C76R
CVM

Attached are the ADE reports contained in CVM's ADE database regarding Regu-Mate® (altrenogest solution), NADA 131-310. Each report includes the narrative and associated clinical sign and event coding. Also included is a summary listing of the reports, which lists the events in decreasing order of reporting frequency.

When reviewing these reports, please keep in mind:

The primary purpose for maintaining the CVM ADE database is to provide an early warning or signaling system to CVM for adverse effects not detected during pre-market testing of FDA-approved animal drugs. Information from these ADE reports is coded and entered into a computerized FDA/CVM ADE database. CVM scientists use the ADE database to make decisions about product safety which may include changes to the label or other regulatory action.

The CVM ADE reporting system depends on detection of adverse clinical events by veterinarians and animal owners, associating the clinical event to the use of a particular drug, and reporting of the ADE to the manufacturer of the drug or directly to FDA. Reporting of ADEs by veterinarians and animal owners is voluntary. Drug sponsors have mandatory ADE reporting obligations described in the Code of Federal Regulations.

There are several limitations to interpretation of passively reported adverse event data, and it is especially important to remember that ADE reports cannot be used to estimate drug risk comparing one drug with another. When looking at the reports, the reader should be aware that:

1. For any given ADE report, there is no certainty that the reported drug caused the adverse event. The adverse event may have been related to an underlying disease, using other drugs at the same time, or other non-drug related causes.
2. The accuracy of information regarding the ADE is dependent on the quality of information received from the veterinarian or animal owner.
3. Accumulated ADE reports should not be used to calculate incidence rates or estimates of drug risk, because there is no accurate way to determine how many animals were given the drug, which is needed as the denominator in calculations of relative risk.
4. It is inappropriate to make use of adverse event data to compare the safety of different products. For example, if a drug is widely used to treat certain conditions, there may be more ADEs for that drug than another product that is not used as often. This would not mean that the first drug was more unsafe than the second. The number of reports simply represents the number of ADEs received for a particular drug and should not be used for any type of comparison purposes.

CVM provides a list of definitions for abbreviations used in ADE reports on our web site at: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055389.htm>.

More information about CVM's ADE Reporting System can be found on our web site at: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/default.htm>.

Appendix B: Surveys

English

Informed Consent Form

Study Title: Regu-Mate® (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers

Introduction

The purpose of this study is to understand Regu-Mate® (altrenogest) management practices by equine care givers and the potential for exposure to the drug.

Procedures

You will be asked a series of questions that will take approximately 15 minutes or less to complete. The questions are designed to learn about your use, knowledge of and potential exposure to Regu-Mate® (altrenogest).

Risks/Discomforts/Benefits/Compensation

No risks or discomforts are anticipated from taking part in this study. There are no direct benefits or compensation for participants. Through your participation in this brief survey, researchers will learn valuable information about the management practices of equine care givers and this information may be used to facilitate development of safe management guidelines.

Confidentiality

All data obtained from participants will be kept confidential and will only be reported in the aggregate. Consent forms will be separated from completed surveys and results from individual surveys will not be viewed by anyone except the primary investigator. These will be kept in a secure location and no person other than the primary investigator will have access to them.

Participation

You must be **18 years of age or older** to participate in this research study. Participation is completely voluntary; you are free to withdraw your participation from this study at any time.

Questions

If you have questions regarding this study, you may contact Ariel Newman at ariel.newman@tufts.edu or 978-505-8227. In addition, you may contact Lara Sloboda, Ph.D. at the Office of the Institutional Review Board at 617-627-3417.

I confirm that I understand the purpose of the research, the study procedures and I have read this consent form. My signature below certifies the above statement.

Signature: _____

Date: _____

Printed Name: _____

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1. What is your sex?

- ☐ Male
☐ Female

2. What is your age?

- ☐ 18 to 29 years
☐ 30 to 39 years
☐ 40 to 49 years
☐ 50 to 59 years
☐ 60 years and over

3. Which of the roles listed below best describes your role in working with horses? Please select all that apply.

- ☐ Owner/rider
☐ Trainer
☐ Groom
☐ Barn manager
☐ Veterinarian
☐ Other _____

4. Are you involved with equine reproduction and/or the breeding industry?

- ☐ Yes
☐ No

5. Do you use and/or administer Regu-Mate® (oil based altrenogest)?

- ☐ Yes
☐ No (Please skip to question #27)

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Signed Consent: _____

☐

Number: _____

6. To how many horses do you regularly give Regu-Mate®?

- ☐ None
- ☐ 1 to 4 horses
- ☐ 5 to 10 horses
- ☐ More than 10 horses

7. Do you use Regu-Mate® for any of the following purposes? Please select all that apply.

- ☐ Behavior modification; to create a more focused animal (mare/stallion/gelding) for performance/training and/or to reduce aggressiveness
- ☐ Synchronization of estrous/heat cycle
- ☐ To help mare cycle earlier in the spring (end the winter anestrus transition period)
- ☐ To help time ovulation
- ☐ Maintenance of a mare's pregnancy
- ☐ I don't know
- ☐ Other _____

8. How often do you handle Regu-Mate®?

- ☐ Never
- ☐ 3 times per month or less
- ☐ 1 time per week
- ☐ 2 to 4 times per week
- ☐ 5 times per week or more

9. How long have you regularly handled Regu-Mate®?

- ☐ 1 year or less
- ☐ 2 to 4 years
- ☐ 5 or more years

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10. How often do you use gloves when dosing, dispensing and administering Regu-Mate®?

- ☐ I don't use gloves (Skip to question #14)
- ☐ Occasionally
- ☐ Most of the time
- ☐ Every time

11. How often are the gloves replaced?

- ☐ Occasionally
- ☐ Most of the time
- ☐ Every time

12. What type of gloves do you use?

- ☐ Latex/Rubber
- ☐ Vinyl
- ☐ Nitrile
- ☐ I Don't Know
- ☐ Other _____

13. Do you wear the same gloves used while dosing, dispensing and administering Regu-Mate® when performing any of the following activities? Please select all that apply.

- ☐ Writing or recording of records
- ☐ Measuring out feed
- ☐ Opening or closing of doors
- ☐ Handling of horses and/or equipment
- ☐ Other _____

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14. Do you wash your hands immediately after dosing, dispensing and administering Regu-Mate®?

- ☐ Yes
☐ No

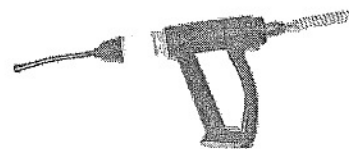
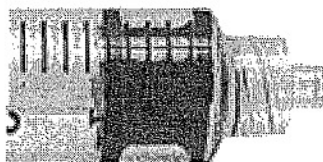
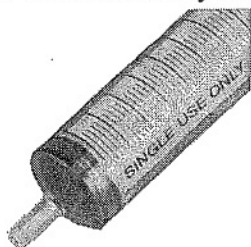
15. After dosing, dispensing and administering Regu-Mate® do you perform any of the following activities prior to washing your hands? Please select all that apply.

- ☐ Eating, drinking and/or smoking
☐ Writing or recording of records
☐ Measuring out feed
☐ Opening or closing of doors
☐ Handling of horses and/or equipment
☐ Other _____

16. Where is the Regu-Mate® bottle stored?

- ☐ With other medications
☐ Separate from other medications

17. What tool do you use to withdraw the drug from the bottle?



- ☐ Non-locking syringe ☐ Luer-lock syringe
☐ Other _____

☐ Dosing gun

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18. How do you withdraw the drug from the bottle?
- ☐ Attach the syringe/dispensing device to the nipple/tip of the bottle's lid
 - ☐ Draw directly through bottle opening
 - ☐ Other _____
19. If you withdraw the drug directly through the bottle opening, do you use a new syringe for each application?
- ☐ Yes
 - ☐ No
 - ☐ I don't withdraw directly through bottle opening
20. Do you ever forcefully clear the syringe or dosing gun to remove the last bit of the drug or extra air?
- ☐ Yes
 - ☐ No
21. How do you give Regu-Mate® to the horse?
- ☐ Dosed into the horse's mouth
 - ☐ Mixed with grain
22. Are the grain/feed buckets dedicated for use with only Regu-Mate® topped feed?
- ☐ Yes
 - ☐ No
 - ☐ I don't give Regu-Mate® mixed with grain
23. On how many occasions has Regu-Mate® come in direct contact with your skin while dosing, cleaning buckets/equipment or touching the horse?
- ☐ Never
 - ☐ 1 to 4 times
 - ☐ 5 to 10 times
 - ☐ More than 10 times
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24. Have you experienced any of these symptoms within a few days after contact (skin, ingestion, etc.) with the drug? Please select all that apply.

If you are **FEMALE**:

- ☐ Hot Flashes
- ☐ Headaches
- ☐ Longer or shorter menstrual period
- ☐ Increased or decreased menstrual flow
- ☐ Longer or shorter menstrual cycle
- ☐ Skipped Period
- ☐ Abdominal/Menstrual Cramps
- ☐ Prolonged Pregnancy
- ☐ No Symptoms
- ☐ Other _____

If you are **MALE**:

- ☐ Hot Flashes
- ☐ Headaches
- ☐ Change in sex drive
- ☐ Abdominal Cramps
- ☐ No Symptoms
- ☐ Other _____

25. From which of these have you learned about Regu-Mate®? Please check all that apply.

- ☐ Friends
- ☐ Equine Professional (i.e. Trainer, barn manager, etc)
- ☐ Veterinarian
- ☐ Internet/Magazine/Newspaper
- ☐ Product Insert
- ☐ No Resources
- ☐ Other _____

26. Check any of the categories below which the veterinarian has addressed regarding handling of Regu-Mate®. Please select all which apply.

- ☐ Storage of the drug
- ☐ Wearing of gloves
- ☐ Avoidance of skin contact
- ☐ Washing of hands
- ☐ Cleaning of feed buckets
- ☐ Preventing aerosolizing of the drug when removing air from the syringe
- ☐ The vet has not discussed Regu-Mate® with me

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27. At your facility, are any of the following groups prohibited from handling Regu-Mate®?

Please select all which apply.

- ☐ Men
- ☐ Women (all)
- ☐ Women (child bearing age)
- ☐ Women (pregnant or may-be-pregnant)
- ☐ Children (under 16 years)
- ☐ None

28. At your facility, are any of the following groups restricted from contacting horses that are actively being treated by Regu-Mate®? Please select all which apply.

- ☐ Men
- ☐ Women (all)
- ☐ Women (child bearing age)
- ☐ Women (pregnant or may-be-pregnant)
- ☐ Children (under 16 years)
- ☐ None

Please return your completed survey to your veterinarian in the provided envelope.

Thank you for your participation in this survey! If you have any further questions regarding this study, you may contact Ariel Newman at ariel.newman@tufts.edu or 978-505-8227.

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Spanish
Formulario de consentimiento informado

Nombre del estudio: Practicas de manejo de Regu-Mate® (altrenogest) y posible exposición en cuidadores de caballos.

Introducción

El propósito de este estudio es entender las practicas de manejo empleadas por cuidadores de caballos para el uso de Regu-Mate® (altrenogest) y su posible exposición al medicamento.

Procedimientos

A usted se le harán una serie de preguntas, las cuales tomara n aproximadamente 15 minutos o menos en ser respondidas. Se han formulado las preguntas para aprender sobre su uso, conocimiento y potencial exposición a Regu-Mate® (altrenogest).

Riesgos/Molestias/Beneficios/Compensación

No se prevén riesgos o molestias por participar de este estudio. Para los participantes en el estudio no hay ningún beneficio directo o compensación alguna. Por medio de su participación, los investigadores podrán obtener información valiosa sobre las prácticas de manejo empleadas por cuidadores de caballos y esta información podría ser utilizada para facilitar el desarrollo de pautas para el manejo seguro durante el uso de este medicamento.

Confidencialidad

Toda la información obtenida de los participantes se mantendrá de manera confidencial y solo será reportada en conjunto. Los formatos de consentimiento informado serán separados de las encuestas realizadas y los resultados de las encuestas individuales no estarán al alcance de nadie, excepto el investigador principal. Estos documentos se mantendrán guardados en un lugar seguro y ninguna persona otra aparte del investigador principal tendrá acceso a estas.

Participación

Para participar en este estudio, usted debe tener **18 años o más**. La participación es este estudio es completamente voluntaria, usted es libre de retirarse del estudio en cualquier momento.

Preguntas

Si usted tiene alguna pregunta con respecto al estudio, favor contactar a Ariel Newman al correo electrónico ariel.newman@tufts.edu o al número telefónico 978-505-8227. Además puede ponerse en contacto con Lara Sloboda, en la oficina de la junta de revisión institucional (IRB) al número telefónico 617-627-3417.

Confirno que entiendo el propósito de este proyecto de investigación, los procedimientos de estudio y he leído este formato de consentimiento informado. Mi firma abajo certifica la declaración anterior.

Firma: _____ Fecha: _____

Nombre en letra imprenta: _____

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1. ¿Cuál es su sexo?
☐ Hombre
☐ Mujer

2. ¿Cuál es su edad?
☐ 18 a 29 años
☐ 30 a 39 años
☐ 40 a 49 años
☐ 50 a 59 años
☐ 60 años o más

3. ¿Cuál de los trabajos descritos abajo describen mejor su rol en su trabajo con caballos. Por favor marque todos los que apliquen.
☐ Propietario/ Jinete
☐ Entrenador
☐ Cuidador
☐ Administrador del establo
☐ Veterinario
☐ Otro _____

4. ¿Está involucrado en la reproducción equina y/o en la industria de cría?
☐ Sí
☐ No

5. ¿Utiliza y/o administra usted Regu-Mate® (altrenogest en base aceite)?
☐ Sí
☐ No (Por favor continúe con la respuesta #27)

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Signed Consent: _____

☐

Number: _____

6. ¿A cuántos caballos administra usted Regu-Mate® regularmente?
- ☐ Ninguno
 - ☐ 1 a 4 caballos
 - ☐ 5 a 10 caballos
 - ☐ Más de 10 caballos
7. ¿Utiliza usted Regu-Mate® con cualquiera de los siguientes propósitos? Por favor marque todos los que apliquen.
- ☐ Cambio de comportamiento para crear un animal más enfocado (yegua/macho entero/ macho castrado), para rendimiento/entrenamiento y/o reducir la agresividad
 - ☐ Sincronización del ciclo estral/celo
 - ☐ Para ayudar a la yegua a ovular temprano en la primavera (terminar el periodo de transición de anestro invernal)
 - ☐ Para ayudar a controlar el momento de la ovulación
 - ☐ Mantener la preñez en la yegua
 - ☐ No sé
 - ☐ Otro _____
8. ¿Con que frecuencia maneja usted Regu-Mate®?
- ☐ Nunca
 - ☐ 3 veces por mes o menos
 - ☐ 1 vez por semana
 - ☐ 2 a 4 veces por semana
 - ☐ 5 veces por semana o más
9. ¿Por cuanto tiempo ha manejado regularmente Regu-Mate®?
- ☐ 1 año o menos
 - ☐ 2 a 4 años
 - ☐ 5 años o más

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10. ¿Que tan frecuentemente usa usted guantes al dosificar, preparar/alistar y administrar Regu-Mate®?

- ☐ No uso guantes (Por favor continuar con la pregunta #14)
- ☐ Ocasionalmente
- ☐ La mayoría del tiempo
- ☐ Siempre

11. ¿Con que frecuencia se cambian los guantes entre administraciones o retirado del producto del frasco?

- ☐ Ocasionalmente
- ☐ La mayoría de las veces
- ☐ Siempre

12. ¿Qué tipo de guantes utiliza?

- ☐ látex/Caucho
- ☐ Vinilo
- ☐ Nitrilo
- ☐ No sé
- ☐ Otro _____

13. ¿Utiliza usted los mismos guantes usados durante la dosificación, preparación/alistado o administración de Regu-Mate® para realizar alguna de las siguientes actividades? Por favor marque todas las que apliquen.

- ☐ Escribir o registrar los datos
- ☐ Medir el alimento
- ☐ Abrir o cerrar la puertas
- ☐ Manejar los caballos y/o el equipo
- ☐ Otro _____

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14. ¿Se lava usted las manos inmediatamente después de dosificar, preparar/alistar o administrar Regu-Mate®?

☐ Sí

☐ No

15. Después de la dosificación, preparación/alistado y administración de Regu-Mate®, ¿realiza usted alguna de las siguientes actividades antes de lavarse las manos? Por favor marque todas las que apliquen.

☐ Comer, beber y/o fumar

☐ Escribir o registrar los datos

☐ Medir el alimento

☐ Abrir o cerrar las puertas

☐ Manejar los caballos o el equipo

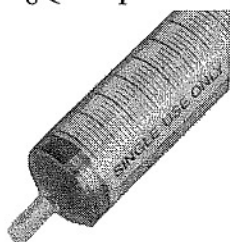
☐ Otro _____

16. ¿Dónde se mantiene guardada el frasco de Regu-Mate®?

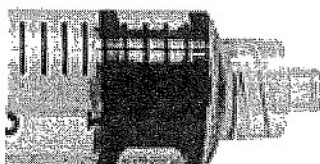
☐ Con otros medicamentos

☐ Aparte de otros medicamentos

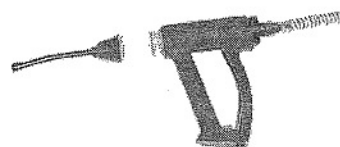
17. ¿Que tipo de dispositivo utiliza para extraer el medicamento del frasco?



Jeringa sin bloqueo



Jeringa Luer-Lock



Jeringa dosificadora

☐ Otro _____

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18. ¿Cómo retira usted el medicamento del frasco?
- ☐ Conecto la jeringa/dispositivo de administración a la punta dispensadora ubicada en la tapa del frasco
 - ☐ Retiro el producto directamente a través de la boca del frasco
 - ☐ Otro _____
19. Si usted retira el producto directamente a través de la boca del frasco, ¿usa usted una nueva jeringa para cada administración?
- ☐ Sí
 - ☐ No
 - ☐ Yo no retiro el producto directamente a través de la boca del frasco.
20. ¿Alguna vez intenta limpiar la jeringa dosificadora aplicando fuerza para remover hasta la última gota del producto o la presencia de aire adicional?
- ☐ Sí
 - ☐ No
21. ¿Cómo administra usted Regu-Mate® a los caballos?
- ☐ En la boca del caballo
 - ☐ Mezclado con el grano/concentrado
22. ¿Se tienen reservados baldes para su uso exclusivo en la administración de alimento mezclado con Regu-Mate®?
- ☐ Sí
 - ☐ No
 - ☐ No administro Regu-Mate® mezclado con el grano/concentrado
23. ¿En cuántas ocasiones ha estado Regu-Mate® en contacto directo con su piel durante la dosificación del producto, la limpieza de los baldes/equipo o al tocar el caballo?
- ☐ Nunca
 - ☐ 1 a 4 veces
 - ☐ 5 a 10 veces
 - ☐ Más de 10 veces

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24. ¿Ha experimentado usted alguno de estos síntomas a los pocos días después del contacto (piel, ingestión, etc.) con el medicamento? Por favor marque todos los que apliquen.

Si usted es **MUJER**:

- ☐ Bochorno
- ☐ Dolor de cabeza
- ☐ Menstruación dura más o menos tiempo que normalmente
- ☐ Incremento o disminución del flujo durante la menstruación
- ☐ Ciclo menstrual más largo o corto
- ☐ Falta de algún periodo menstrual
- ☐ Calambres abdominales o menstruales
- ☐ Embarazo prolongado
- ☐ Ningún síntoma
- ☐ Otro _____

Si usted es **HOMBRE**:

- ☐ Bochorno
- ☐ Dolor de cabeza
- ☐ Cambios en deseo sexual
- ☐ Calambres abdominales
- ☐ Ningún síntoma
- ☐ Otro _____

25. ¿A través de cuál de las siguientes maneras ha aprendido usted sobre Regu-Mate®? Marque todas las que apliquen.

- ☐ Amigos
- ☐ Un profesional equino (por ejemplo: Entrenador, Administrador del establo, etc.)
- ☐ Veterinario
- ☐ Internet/Revista/Periódico
- ☐ Instrucciones de uso/ folleto del producto
- ☐ Ningún recurso
- ☐ Otro _____

26. Seleccione las categorías descritas abajo que le ha mencionado un veterinario en cuanto al manejo de Regu-Mate®. Marque todas las que apliquen.

- ☐ Almacenamiento del medicamento
- ☐ El uso de guantes
- ☐ Evitar el contacto con la piel
- ☐ El lavado de manos
- ☐ La limpieza de los baldes de comida
- ☐ Evitar el salpicado o aerosolizado del medicamento al remover el aire de la jeringa
- ☐ El veterinario no ha discutido el uso de Regu-Mate® conmigo

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27. En las instalaciones donde trabaja usted, ¿queda prohibido el manejo de Regu-Mate® a alguno de los siguientes grupos? Marque todos los que apliquen.

- ☐ Hombres
- ☐ Mujeres (todas)
- ☐ Mujeres (en edad fértil)
- ☐ Mujeres (embarazadas o con posibilidad de estar embarazadas)
- ☐ Niños (menores de 16 años)
- ☐ Ninguno

28. En las instalaciones donde trabaja usted, ¿se restringe el contacto de alguno de los siguientes grupos de personas con caballos que están siendo tratados activamente con Regu-Mate®? Marque todos los que apliquen.

- ☐ Hombres
- ☐ Mujeres (todas)
- ☐ Mujeres (en edad fértil)
- ☐ Mujeres (embarazadas o con posibilidad de estar embarazadas)
- ☐ Niños (menores de 16 años)
- ☐ Ninguno

Por favor devuelva la encuesta completa a su veterinario en el sobre adjunto.

¡Gracias por su participación en esta encuesta! Si usted tiene alguna pregunta adicional acerca de este estudio puede contactar a Ariel Newman al correo electrónico ariel.newman@tufts.edu o al teléfono número 978-505-8227.

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Portuguese

Termo de Informação e Autorização

Título do estudo

Práticas de manejo de Regu-Mate® (altrenogest) e potencial de exposição em cuidadores de equinos.

Introdução

O propósito deste estudo é entender as práticas de manejo de Regu-Mate® (altrenogest) por cuidadores de equinos e o potencial de exposição com o medicamento.

Procedimentos

Você passará por um questionário com uma série de perguntas que vão tomar aproximadamente 15 minutos ou menos para completar. As perguntas foram formuladas para aprender sobre o uso, conhecimento e potencial de exposição ao Regu-Mate® (altrenogest).

Riscos/Desconfortos/Benefícios/Compensação

Nenhum risco ou desconforto é previsto em participar deste estudo. Não há benefícios diretos ou compensação para os participantes. Através da sua participação nesse breve questionário, pesquisadores irão aprender informações valiosas sobre as práticas de manejo de equinos por seus cuidadores e essas informações podem ser usadas para facilitar o desenvolvimento de gestão de segurança.

Confidencialidade

Todos os dados obtidos pelos participantes serão mantidos em sigilo e somente serão relatados de forma conjunta. Formulários de consentimento serão separados a partir dos questionários respondidos e resultados de pesquisas individuais não serão vistos por ninguém exceto o investigador principal. Essas informações serão mantidas em um local seguro e nenhuma outra pessoa além do investigador principal terá acesso a elas.

Participação

Você precisa ter 18 anos de idade ou mais para participar deste estudo. Participações serão completamente voluntárias; você é livre para se retirar do estudo em qualquer momento

Perguntas

Se você tiver perguntas em relação a este estudo, você pode contactar Ariel Newman pelo email ariel.newman@tufts.edu ou número 978-505-8227. Além disso, você pode contactar Lara Sloboda, Ph.D. no Escritório do Conselho de Revisão institucional em 617-627-3417.

Eu confirmo que entendi o propósito desta pesquisa, os procedimentos de estudo e eu li esse formulário de autorização. Minha assinatura abaixo certifica a afirmação acima.

Assinatura: _____ Data: _____

Nome por extenso: _____

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For Office Use Only:



1. Qual é seu sexo?
 - ☐ Masculino
 - ☐ Feminino

2. Quantos anos você tem?
 - ☐ 18 a 29 anos
 - ☐ 30 a 39 anos
 - ☐ 40 a 49 anos
 - ☐ 50 a 59 anos
 - ☐ 60 anos ou mais

3. Qual das funções listadas abaixo descreve melhor seu papel no trabalho com cavalos? Por favor, marque todas as respostas que se aplicam.
 - ☐ Proprietário/cavaleiro
 - ☐ Treinador
 - ☐ Cocheiro
 - ☐ Gerenciador do celeiro
 - ☐ Veterinário
 - ☐ Outro _____

4. Você está envolvido com a reprodução equina e/ou com a indústria de reprodução?
 - ☐ Sim
 - ☐ Não

5. Você usa e/ou administra Regu-Mate® (altrenogest a base de óleo)?
 - ☐ Sim
 - ☐ Não (Por favor pule para a questão #27)

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Signed Consent: _____



Number: _____

6. Para quantos cavalos você regularmente dá Regu-Mate®?

- ☐ Nenhum
- ☐ 1 a 4 cavalos
- ☐ 5 a 10 cavalos
- ☐ Mais de 10 cavalos

7. Você usa Regu-Mate® para algum dos propósitos seguintes? Por favor selecione todas as opções que se aplicam.

- ☐ Modificação de comportamento; para criar um animal mais focado (égua/garanhão/castrado) para desempenho/treinamento e/ou para reduzir a agressividade
- ☐ Sincronização de ciclo térmico
- ☐ Para ajudar no ciclo da égua no início da primavera (fim do inverno como período de anestro)
- ☐ Para ajudar no tempo de ovulação
- ☐ Manutenção de gravidez de uma égua
- ☐ Eu não sei
- ☐ Outro _____

8. Quantas vezes você lida com Regu-Mate®?

- ☐ Nunca
- ☐ 3 vezes por mês ou menos
- ☐ 1 vez por semana
- ☐ 2 a 4 vezes por semana
- ☐ 5 vezes por semana ou mais

9. Há quanto tempo você lida regularmente com Regu-Mate®?

- ☐ 1 ano ou mais
- ☐ 2 a 4 anos
- ☐ 5 anos ou mais

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10. Com qual frequência você usa luvas quando dosando, dispensando ou administrando Regu-Mate®?

- ☐ Eu não uso luvas (pule para a questão #14)
- ☐ Ocasionalmente
- ☐ Na maioria das vezes
- ☐ Sempre

11. Com qual frequência as luvas são substituídas?

- ☐ Ocasionalmente
- ☐ Na maioria das vezes
- ☐ Sempre

12. Que tipo de luvas você usa?

- ☐ Látex/Borracha
- ☐ Vinil
- ☐ Nitrilo
- ☐ Eu não sei
- ☐ Outro _____

13. Você veste as mesmas luvas usadas enquanto dosando, dispensando ou administrando Regu-Mate® quando realizando alguma das seguintes atividades? Por favor selecione todas que se aplicam.

- ☐ Escrevendo ou fazendo registros.
- ☐ Dosando a alimentação
- ☐ Abrindo ou fechando portas
- ☐ Manuseando cavalos e/ou equipamentos
- ☐ Outro _____

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14. Você lava suas mãos imediatamente após dosar, dispensar ou administrar Regu-Mate®?

☐ Sim

☐ Não

15. Depois de dosar, dispensar ou administrar Regu-Mate® você realiza alguma outra atividade em seguida e antes de lavar suas mãos? Por favor, selecione todas as opções que se aplicam..

☐ Comer, beber e/ou fumar

☐ Escrever ou fazer registros

☐ Dosar alimentação

☐ Abrir ou fechar portas

☐ Manipular cavalos e/ou equipamentos

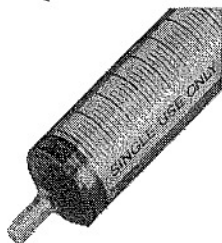
☐ Outro _____

16. Onde a garrafa de Regu-Mate® está armazenada?

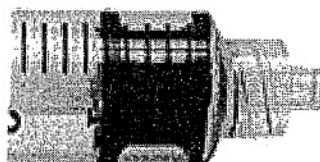
☐ Com outros medicamentos

☐ Separada dos outros medicamentos

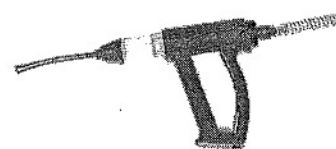
17. Que ferramenta você usa para tirar o medicamento do frasco?



☐ Seringa sem bloqueio



☐ Seringa com bloqueio



☐ Pistola dosadora

☐ Outro _____

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18. Como você retira o medicamento da garrafa?
- ☐ Coloco a seringa/dispositivo de dosador no bico/lacre da tampa da garrafa
 - ☐ Coloco diretamente na garrafa aberta
 - ☐ Outro _____
19. Se você retira o medicamento através da garrafa aberta, você usa uma nova seringa para cada aplicação?
- ☐ Sim
 - ☐ Não
 - ☐ Eu não retiro diretamente da garrafa aberta
20. Você sempre limpa vigorosamente a seringa ou pistola para remover a última gota de medicamento ou ar extra?
- ☐ Sim
 - ☐ Não
21. Como você dá Regu-Mate® para o cavalo?
- ☐ Administra dentro da boca do cavalo
 - ☐ Mistura com grãos
22. Os baldes de grãos/ração dedicados somente ao uso com Regu-Mate® são tampados?
- ☐ Sim
 - ☐ Não
 - ☐ Eu não administro Regu-Mate® misturado com grãos
23. Em quantas ocasiões o Regu-Mate® esteve em contato direto com sua pele enquanto dosando, limpando baldes/equipamentos ou tocando o cavalo?
- ☐ Nunca
 - ☐ 1 a 4 vezes
 - ☐ 5 a 10 vezes
 - ☐ Mais que 10 vezes

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24. Você experimentou algum desses sintomas alguns dias após contato (pele, ingestão, etc) com o medicamento? Por favor, selecione todas que se aplicam.

Se você é **MULHER**:

- ☐ Ondas de calor
- ☐ Dores de cabeça
- ☐ Aumento ou diminuição do período menstrual
- ☐ Aumento ou diminuição do fluxo menstrual
- ☐ Aumento ou diminuição do ciclo menstrual
- ☐ Ausência de período menstrual
- ☐ Cólicas abdominais/menstruais
- ☐ Gravidez prolongada
- ☐ Nenhum sintoma
- ☐ Outro _____

Se você é **HOMEM**:

- ☐ Ondas de calor
- ☐ Dores de cabeça
- ☐ Alteração no desejo sexual
- ☐ Cólicas abdominais
- ☐ Nenhum sintoma
- ☐ Outro _____

25. Através de qual das opções abaixo você soube sobre Regu-Mate®? Por favor, marque todas que se aplicam.

- ☐ Amigos
- ☐ Profissional de Equinos (ou seja, treinador, chefe de celeiro, etc)
- ☐ Veterinário
- ☐ Internet/Revista/Jornal
- ☐ Panfleto sobre o produto
- ☐ Nenhum recurso
- ☐ Outro _____

26. Marque qual das categorias abaixo foi abordado pelo veterinário sobre o manuseio de Regu-Mate®. Por favor, selecione todas que se aplicam.

- ☐ Armazenamento do medicamento
- ☐ Uso de luvas
- ☐ Evitar contato com a pele
- ☐ Lavar as mãos
- ☐ Lavagem do balde de ração
- ☐ Prevenir inalação do medicamento quando remover ar da seringa
- ☐ O veterinário não discutiu sobre Regu-Mate® comigo

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27. Nas suas instalações, algum dos grupos seguintes é proibido de manusear Regu-Mate®? Por favor, selecione todos que se aplicam.

- ☐ Homens
- ☐ Mulheres (todas)
- ☐ Mulheres (em idade fértil)
- ☐ Mulheres (grávidas ou possivelmente grávidas)
- ☐ Crianças (abaixo de 16 anos)
- ☐ Nenhum

28. Nas suas instalações, algum dos grupos seguintes é proibido de entrar em contato com cavalos que estão ativamente sendo tratados com Regu-Mate®? Por favor, selecione todos que se aplicam.

- ☐ Homens
- ☐ Mulheres (todas)
- ☐ Mulheres (em idade fértil)
- ☐ Mulheres (grávidas ou possivelmente grávidas)
- ☐ Crianças (abaixo de 16 anos)
- ☐ Nenhum

Por favor devolva seu questionário respondido para seu veterinário no envelope fornecido.

Obrigado pela sua participação nesta pesquisa! Se você tiver alguma dúvida a respeito deste estudo, você pode contactar Ariel Newman através do email ariel.newman@tufts.edu ou 978-505-8227.

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Appendix C: Institutional Review Board Approvals



OFFICE OF THE VICE PROVOST

Social, Behavioral, and Educational Research
Institutional Review Board
FWA00002063

July 16, 2012 | Notice of Action

IRB Study # 1206026 | Status: ACTIVE

ATTENTION: BEFORE CONDUCTING ANY RESEARCH, PLEASE READ THE ENTIRETY OF THIS NOTICE AS IT CONTAINS IMPORTANT INFORMATION ABOUT PROPER STUDY PROCEDURES.

Title: Regu-Mate(R) (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers

PI: Ariel Newman

Faculty Advisor: Anne Marie Desmarais

The PI is responsible for all information contained in both this notice of action and on the following **Investigator Responsibilities Sheet**.

Only copies of approved stamped consent forms and other study materials may be utilized when conducting your study.

This research protocol meets the requirements set forth by the Office for Human Research Protections in 45 CFR 46 and is approved under Expedited Category 7.

Reviewed 7/13/2012 – Expires 7/12/2013

- Approved for 500 participants for the duration of the study.
Protocol Management:
 - For all changes to the protocol, submit: *Request for Protocol Modification* form
 - All Adverse Events and Unanticipated Problems must be reported to the Office of the IRB promptly (no later than 7 calendar days after first awareness of the problem) using the appropriate forms.
 - Six weeks prior to the expiration of the protocol on 7/12/2013, investigators must submit either a *Request for Continuing Review* or a *Request for Study Closure*
 - All forms can be found at: <http://www.tufts.edu/central/research/IRB/Forms.htm>

IRB Administrative Representative Initials: _____

A handwritten signature in black ink, appearing to be "Kerab", written over a horizontal line.



OFFICE OF THE VICE PROVOST

Social, Behavioral, and Educational Research
Institutional Review Board
FWA00002063

August 24, 2012 | Notice of Action

IRB Study # 1206026 | Status: ACTIVE

ATTENTION: BEFORE CONDUCTING ANY RESEARCH, PLEASE READ THE ENTIRETY OF THIS NOTICE AS IT CONTAINS IMPORTANT INFORMATION ABOUT PROPER STUDY PROCEDURES.

Title: Regu-Mate(R) (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers

PI: Ariel Newman

Faculty Advisor: Anne Marie Desmarais

The PI is responsible for all information contained in both this notice of action and on the following **Investigator Responsibilities Sheet**.

Only copies of approved stamped consent forms and other study materials may be utilized when conducting your study.

The *Request for Protocol Modification* has been reviewed by the IRB under the guidance set forth by the Office for Human Research Protections in 45 CFR 46, and approved under Expedited Category 7.

Reviewed 8/21/2012 – Expires 7/12/2013

The approved revisions are detailed below:

1) Addition of "other" to question #24

- Approved for 500 participants for the duration of the study.

Protocol Management:

- For all changes to the protocol, submit: *Request for Protocol Modification* form
- All Adverse Events and Unanticipated Problems must be reported to the Office of the IRB promptly (no later than 7 calendar days after first awareness of the problem) using the appropriate forms.
- Six weeks prior to the expiration of the protocol on 7/12/2013, investigators must submit either a *Request for Continuing Review* or a *Request for Study Closure*
- All forms can be found at: <http://www.tufts.edu/central/research/IRB/Forms.htm>

IRB Administrative Representative Initials:

Handwritten initials, likely "JMS", in black ink.



OFFICE OF THE VICE PROVOST

Social, Behavioral, and Educational Research
Institutional Review Board
FWA00002063

Re: IRB Study # 1206026
Title: Regu-Mate(R) (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers
PI: Ariel Newman
Faculty Advisor: Anne Marie Desmarais
IRB Review Date: 8/21/2012

August 21, 2012

Dear Ariel,

Thank you for submitting the Portuguese and Spanish translations of study documents for the above referenced study.

These translations of previously approved study materials meet the requirements set for by the IRB and are hereby approved. Approval is valid from the date of this letter and expires on 7/12/2013.

Enclosed you will find stamped consent forms and other study materials that show the date through which these materials are valid. Only copies of these stamped consent forms and materials may be utilized for conducting your study.

Any changes to the protocol, consent forms or study materials must be submitted to the Office of the IRB for approval by completing the *Request for Protocol Modification* form. In addition, all Adverse Events and Unanticipated Problems must be reported to the Office of the IRB promptly, and by utilizing the appropriate reporting forms.

Investigators are required to submit a *Request for Continuing Review* or a *Request for Study Closure* six weeks prior to the expiration date of the protocol.

Please know that the PI is responsible for all information contained in both this letter and on the Investigator Responsibilities Sheet. If anything is unclear or if you have any questions, please contact the IRB office at (617) 627-3417.

Sincerely,

A handwritten signature in black ink, appearing to read "Lara N. Sloboda".

Lara N. Sloboda, Ph.D.
IRB Administrator



OFFICE OF THE VICE PROVOST FOR RESEARCH

Social, Behavioral, and Educational Research
Institutional Review Board
FWA00002063

June 7, 2013 | Notice of Action

IRB Study # 1206026 | Status: ACTIVE

ATTENTION: BEFORE CONDUCTING ANY RESEARCH, PLEASE READ THE ENTIRETY OF THIS NOTICE AS IT CONTAINS IMPORTANT INFORMATION ABOUT PROPER STUDY PROCEDURES.

Title: Regu-Mate(R) (altrenogest) Management Practices and Potential for Exposure in Equine Care Givers

PI: Ariel Newman

Faculty Advisor: Anne Marie Desmarais

The PI is responsible for all information contained in both this notice of action and on the following **Investigator Responsibilities Sheet**.

Only copies of approved stamped consent forms and other study materials may be utilized when conducting your study.

The *Request for Continuing Review* has been reviewed by the IRB under the guidance set forth by the Office for Human Research Protections in 45 CFR 46, and approved under Expedited Category 7.

Reviewed 6/7/2013 – Expires 6/6/2014

- Approved for 500 participants for the duration of the study.

Protocol Management:

- All translated study documents must be submitted for review, approval, and stamping prior to use.
- For all changes to the protocol, submit: *Request for Protocol Modification* form
- All Adverse Events and Unanticipated Problems must be reported to the Office of the IRB promptly (no later than 7 calendar days after first awareness of the problem) using the appropriate forms.
- Six weeks prior to the expiration of the protocol on 6/6/2014, investigators must submit either a *Request for Continuing Review* or a *Request for Study Closure*
- All forms can be found at: <http://www.tufts.edu/central/research/IRB/Forms.htm>

IRB Administrative Representative: _____

A handwritten signature in black ink, appearing to be "Lara S.", written over a horizontal line.

Appendix D: Generic Contact Information

_____, _____ XX, 2012

Dear Dr. _____,

I am a master of science graduate student in the Department of Civil and Environmental Engineering at Tufts University. As a part of my masters research in Environmental Health I am studying Regu-Mate® (altrenogest) management practices in equine care givers and the potential for exposure to the drug. The purpose of this research is to determine risk communication and safe management guidelines for using Regu-Mate®.

I am working with veterinarians and veterinary practices to distribute a survey to equine care givers. Clients who wish to participate can be provided a survey during farm calls or office visits. Three language versions (Spanish, Portuguese and English) are available. The diversity of languages is designed to enable the participation of non-native English speakers. All participants will put their completed survey in a blank sealed envelope (which will be provided); the sealed envelopes will ensure the necessary confidentiality. Completed surveys will be returned to you in the course of the initial farm visit, follow up farm visits or directly to your office at the leisure of the participant. I will coordinate directly with your office to return the completed surveys to me.

I will share the results of the research with your veterinary practice upon the completion of the study.

Feel free to contact me with any questions or concerns at ariel.newman@tufts.edu or 978-505-8227. You may also contact my advisor, Anne Marie Desmarais, at annemarie.desmarais@tufts.edu or 617-627-3763.

If you are interested in participating and/or assisting in the dissemination of my survey please contact me at ariel.newman@tufts.edu or 978-505-8227. Thank you for your time and I look forward to the opportunity of working with your practice.

Sincerely,

Ariel Newman

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_____, _____ XX, 2012

Dear Dr. _____,

Thank you for agreeing to facilitate the distribution of a questionnaire as a part of my masters research in Environmental Health through the Department of Civil and Environmental Engineering at Tufts University. I am studying Regu-Mate® (altrenogest) management practices in equine care givers and the potential for exposure to the drug. The purpose of this research is to determine risk communication and safe management guidelines for using Regu-Mate®. I will share the results of the research with your veterinary practice upon the completion of the study.

Requirements for participation in the study are:

- Individuals must be 18 years or older due to the requirements of informed consent
- Involvement in the equine industry directly dealing with horses

You have been provided with the same survey in three different languages (Spanish, Portuguese and English). The diversity of languages is designed to enable the participation of non-native English speakers. Please distribute the proper language version to the appropriate participant.

Please use the following language as a guideline in communicating with potential survey participants:

"I am working with a graduate student at Tufts University for research on the management practices and potential exposure to Regu-Mate ® in equine caregivers. Would you be interested in filling out a questionnaire/survey to help with the research? Everything is confidential; no one (ie. your boss, me or anyone at my office) will see your answers except for the researcher and they won't be able to link your answers to you. No individual information will be published or released. To participate in this survey you must be 18 years of age or older."

When approaching potential participants for participation in the survey, please allow them at least 15 minutes to decide if they want to participate. Participants should return their completed surveys to you in a sealed envelope (which will be provided); the sealed envelopes will ensure the necessary confidentiality. I will coordinate the bulk return of completed surveys to me directly with your office.

Feel free to contact me with any questions or concerns at ariel.newman@tufts.edu or 978-505-8227. You may also contact my advisor, Anne Marie Desmarais, at annemarie.desmarais@tufts.edu or 617-627-3763. Thank you for your assistance.

Sincerely,

Ariel Newman

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Script which will be used as a guideline when verbally contacting veterinarians/veterinary practices:

Hello. I am a master of science graduate student in the Department of Civil and Environmental Engineering at Tufts University. As a part of my masters research in Environmental Health I am studying Regu-Mate® (altrenogest) management practices in equine care givers and the potential for exposure to the drug. The purpose of this research is to determine risk communication and safe management guidelines for using Regu-Mate®.

I am working with veterinarians and veterinary practices to distribute a survey to equine care givers and was hoping you/your practice would be interested in participating.

Clients who wish to participate can be provided a survey during farm calls or office visits. Three language versions (Spanish, Portuguese and English) are available. The diversity of languages is designed to enable the participation of non-native English speakers. All participants will return their completed surveys to you in a sealed envelope (which will be provided); the sealed envelopes will ensure necessary confidentiality. I will coordinate directly with your office to return the completed surveys to me.

If you are interested in participating and/or assisting in the dissemination of my survey please contact me at ariel.newman@tufts.edu or 978-505-8227 at your leisure. Additionally I can provide you (via email, USPS or in person) a letter documenting what we have discussed during this conversation. Thank you for your time and I look forward to the opportunity of working with your practice.

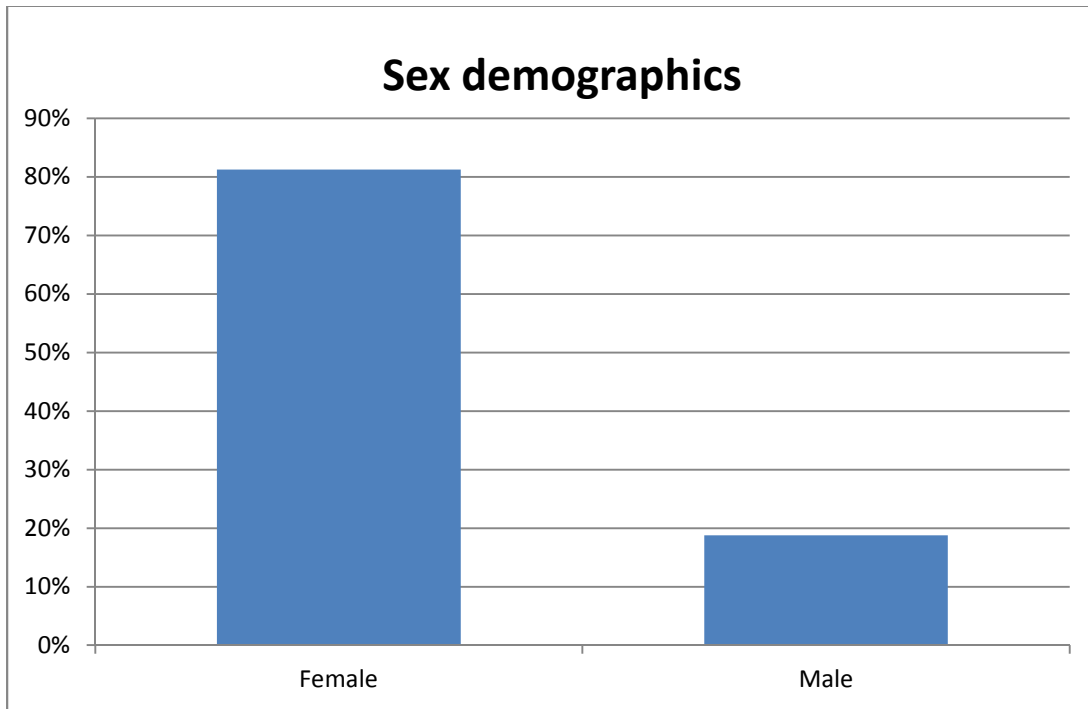
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Appendix E: Tables and Graphs

SURVEY QUESTION RESPONSES

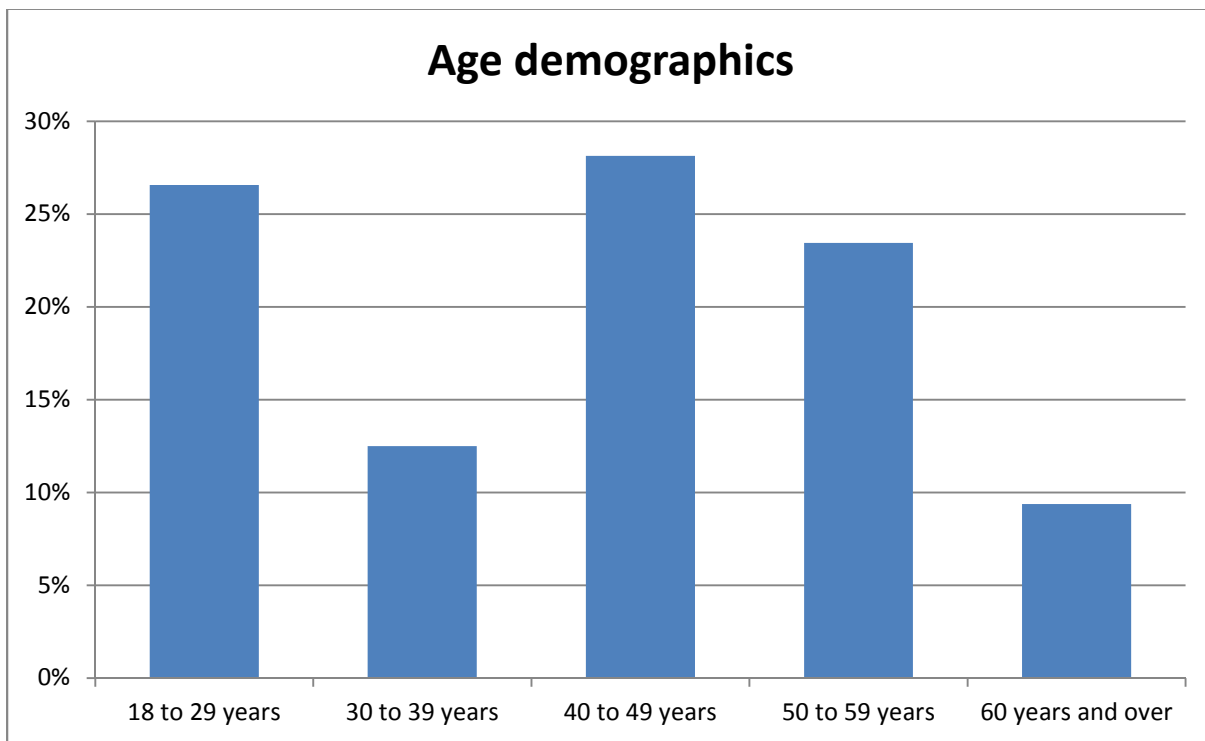
Responses to: What is your sex?

Row Labels	Count of Survey #
Female	81%
Male	19%
Grand Total	100%



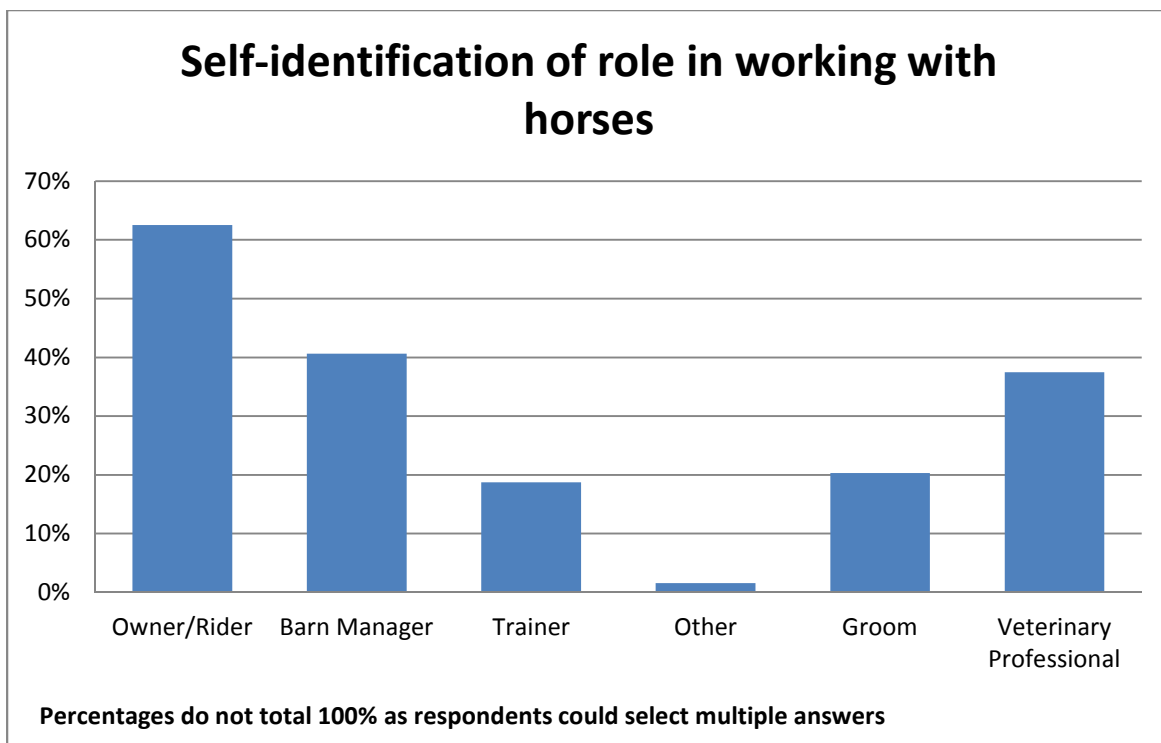
Responses to: What is your age?

Row Labels	Count of Age
18 to 29 years	27%
30 to 39 years	13%
40 to 49 years	28%
50 to 59 years	23%
60 years and over	9%
Grand Total	100%

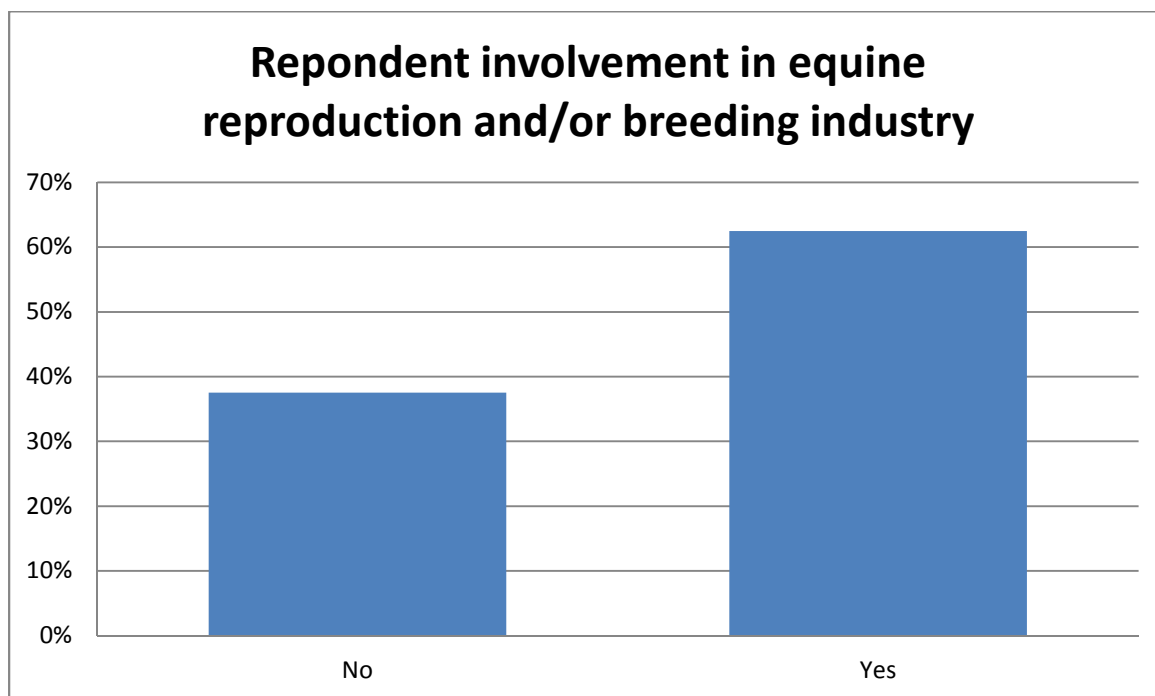


Which of the roles listed below best describes your role in working with horses?

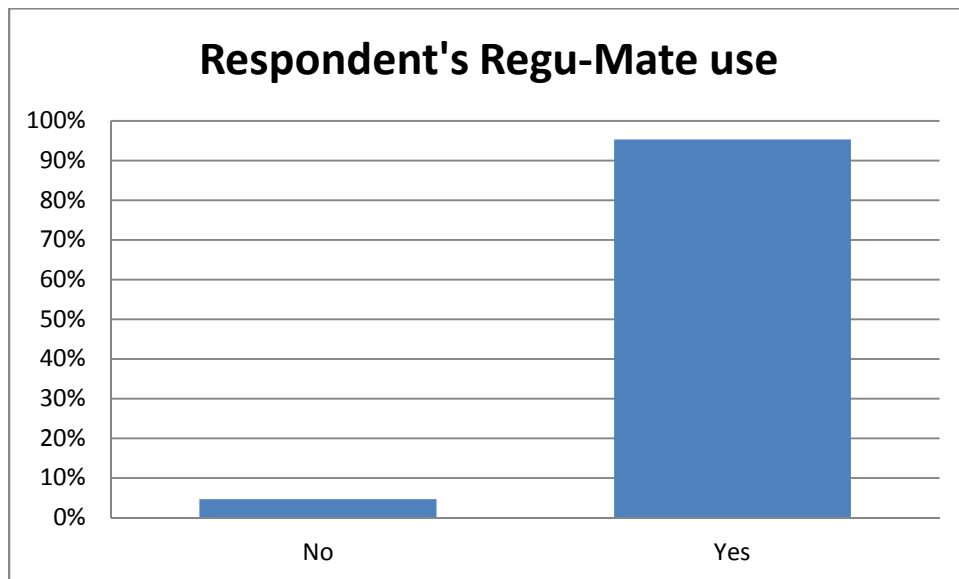
Values			% of All Respondents
Count of Relationship_owner/rider	40	Owner/Rider	63%
Count of Relationship_barn manager	26	Barn Manager	41%
Count of Relationship_trainer	12	Trainer	19%
Count of Relationship_other	1	Other	2%
Count of Relationship_groom	13	Groom	20%
Count of Relationship_veterinarian professional	24	Veterinary Professional	38%



Involved in Breeding Industry	
Row Labels	Count of Breeder
No	38%
Yes	63%
Grand Total	100%

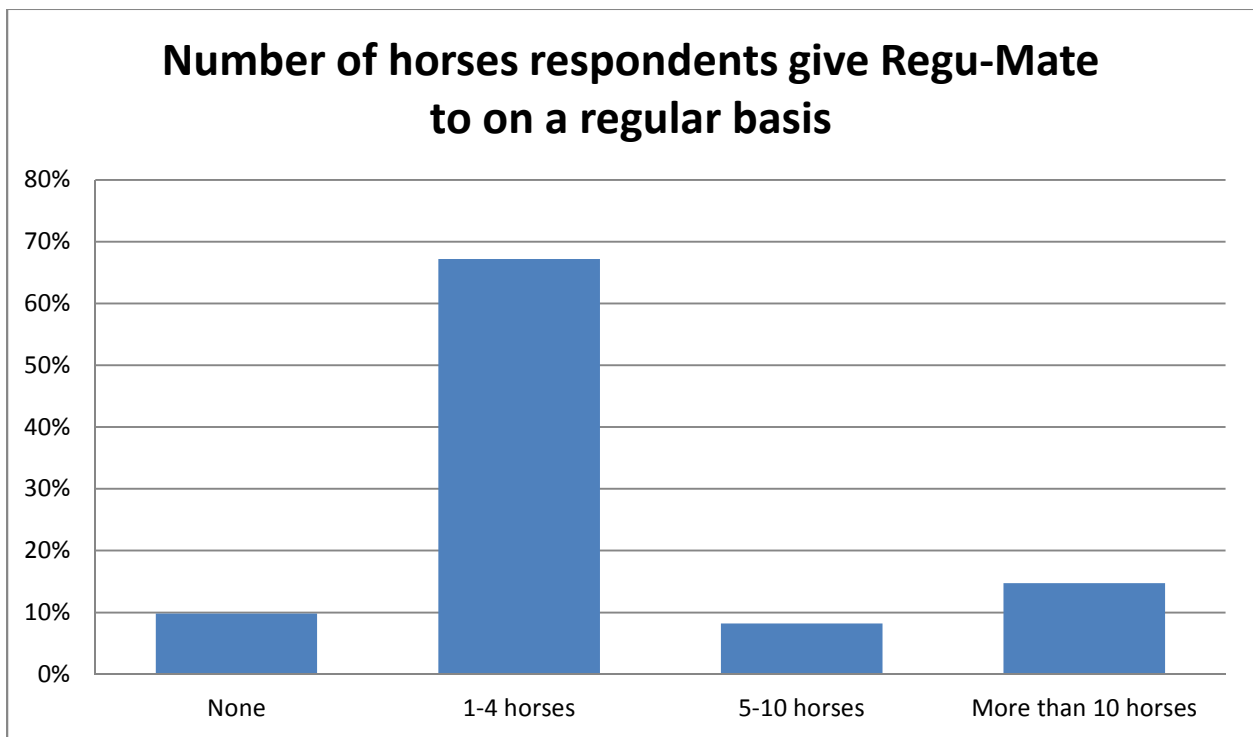


Use Regumate	
Row Labels	Count of Administer_Regumate
No	5%
Yes	95%
Grand Total	100%



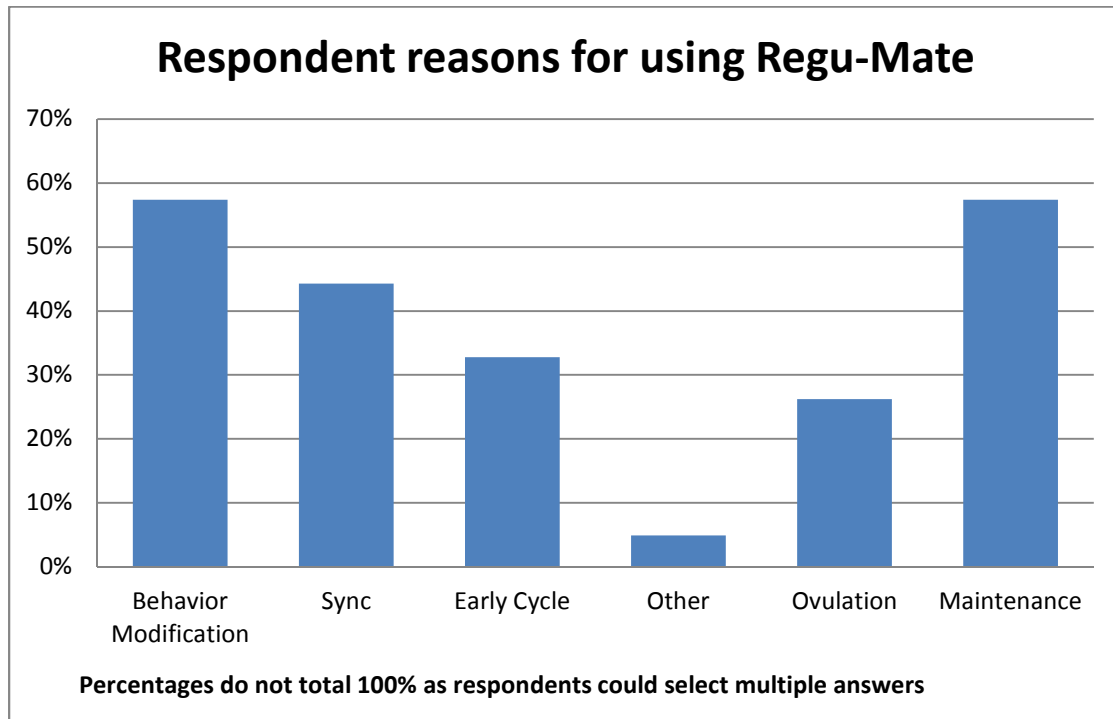
How many horses do you regularly give Regu-Mate

Row Labels	Count of number_horses
None	10%
1-4 horses	67%
5-10 horses	8%
More than 10 horses	15%
Grand Total	100%



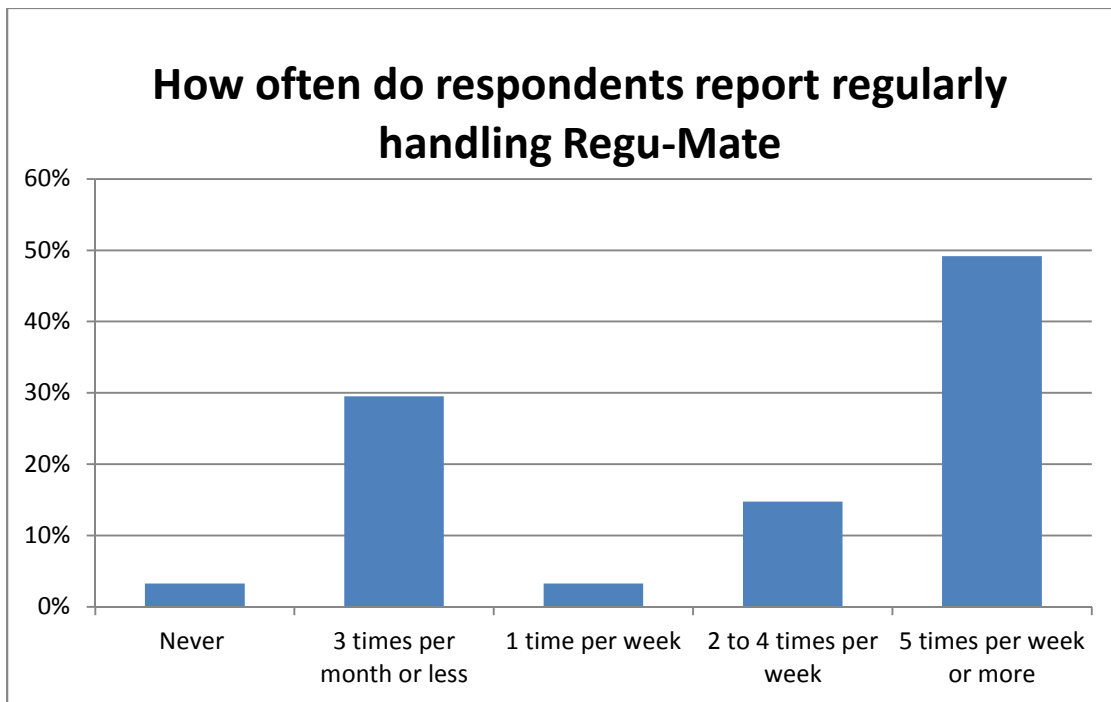
Use of Drug Breakdown

Values		% of Respondents	
Count of		Behavior	
Use_BehaviorModification	35	Modification	57%
Count of Use_Sync	27	Sync	44%
Count of Use_EarlyCycle	20	Early Cycle	33%
Count of Use_Other	3	Other	5%
Count of Use_Ovulation	16	Ovulation	26%
Count of Use_Maintenance	35	Maintenance	57%
Count of Use_NR	3		
Respondents to this Question	61		



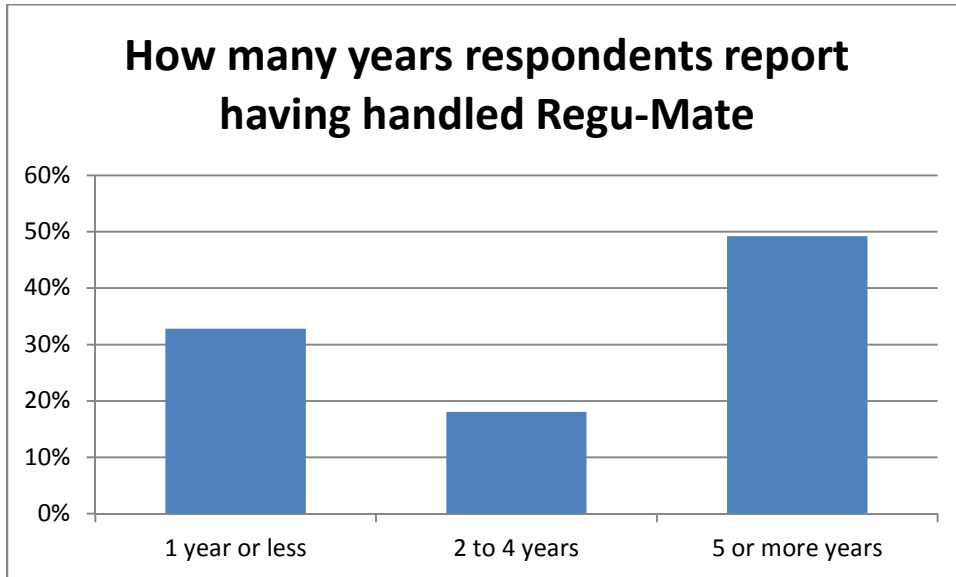
How often do you handle Regu-Mate?

Row Labels	Count of Often_Handle
Never	3%
1 time per week	3%
2 to 4 times per week	15%
3 times per month or less	30%
5 times per week or more	49%
Grand Total	100%



How long have you regularly handled Regu-Mate?

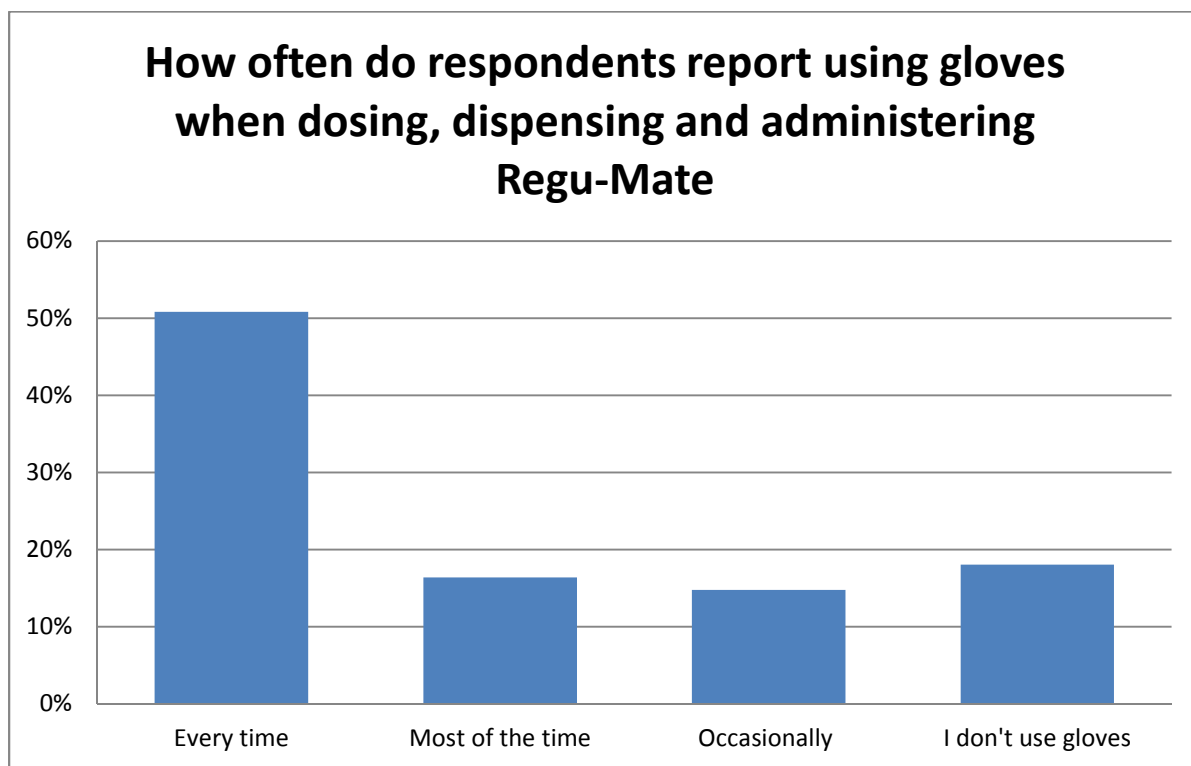
Row Labels	Count of YearsHandled
1 year or less	33%
2 to 4 years	18%
5 or more years	49%
Grand Total	100%



How often do you use gloves when dosing, dispensing and administering Regu-Mate?

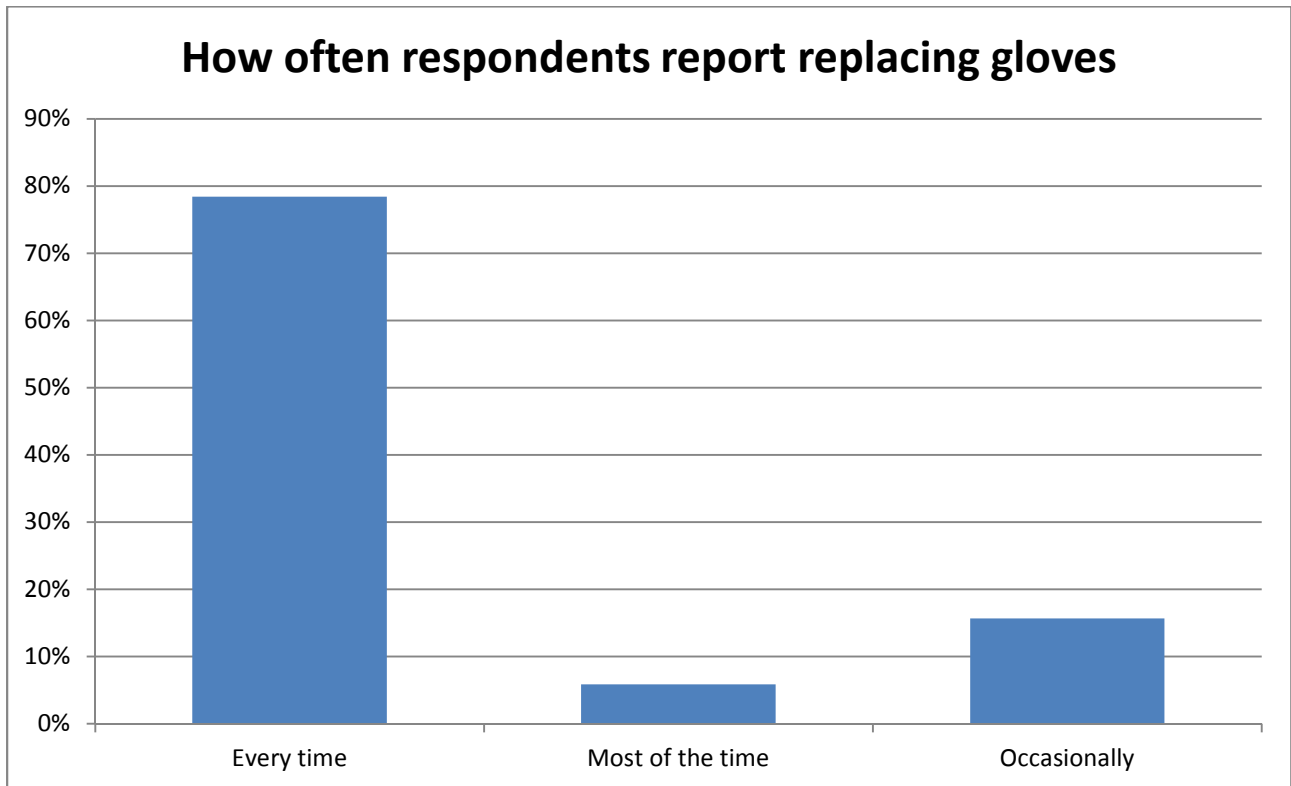
Row Labels	Count of Glove Use
Every time	51%
Most of the time	16%
Occasionally	15%
I don't use gloves	18%
Grand Total	100%

Percentage of Respondents who Wear Gloves
82%



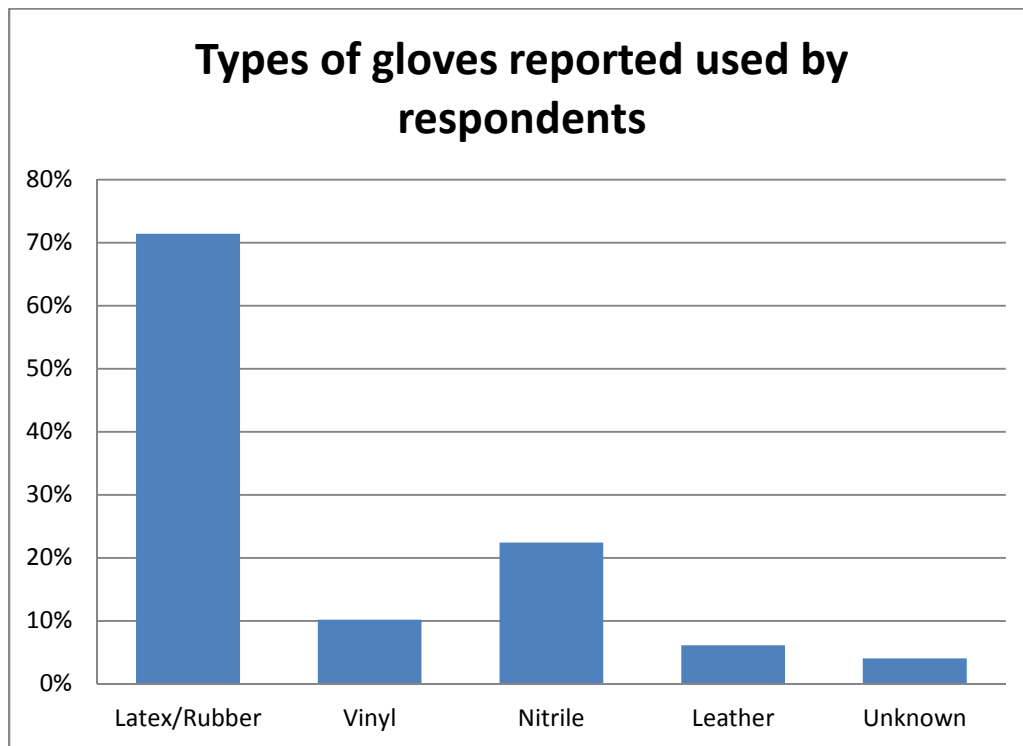
How often are the gloves replaced?

Row Labels	Count of GloveReplacement
Every time	78%
Most of the time	6%
Occasionally	16%
Grand Total	100%



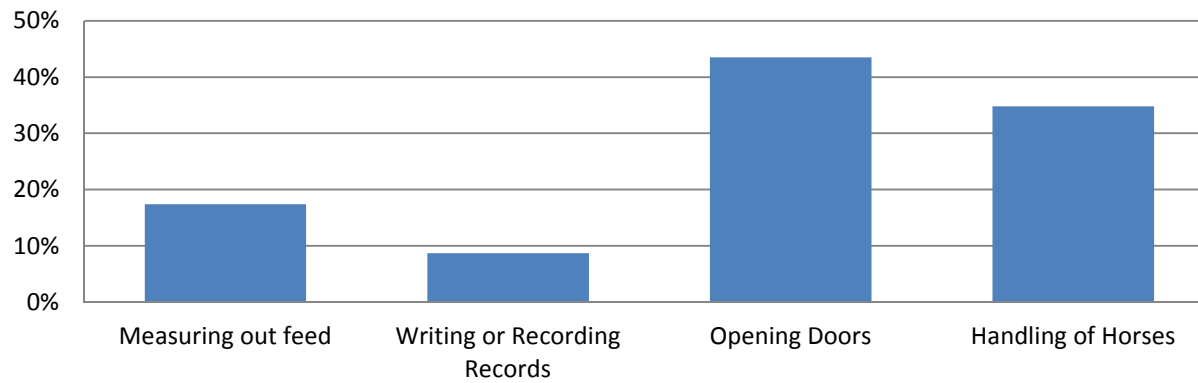
What type of gloves do you use?

Values		% of Respondents	
Count of			
GloveType_LatexRubber	33	Latex/Rubber	71%
Count of GloveType_Vinyl	5	Vinyl	10%
Count of GloveType_nitrile	11	Nitrile	22%
Count of GloveType_leather	3	Leather	6%
Count of GloveType_unknown	2	Unknown	4%
Count of GloveType_NR	15		
Respondents to this Question	49		



Glove Use		(Multiple Items)		
Actions performed prior to removing gloves?				
Values			% of Respondents performing action prior to removing gloves	
Count of ActionsWGloves_feed	4	Measuring out feed	17%	
Count of ActionsWGloves_writing	2	Writing or Recording Records	9%	
Count of ActionsWGloves_doors	10	Opening Doors	43%	
Count of ActionsWGloves_handling	8	Handling of Horses	35%	
Count of ActionsWGloves_none	23			Non Respondents
Count of ActionsWGloves_NR	18		41	23

Percent of respondents who report performing the following actions prior to removing gloves



Percentages do not total 100% as respondents could select multiple answers

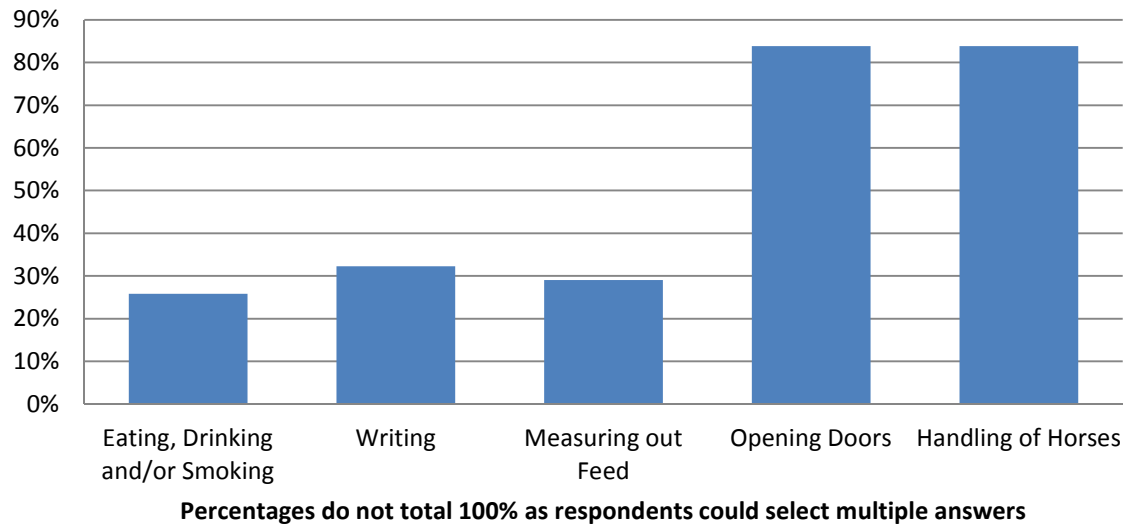
Row Labels	Count of WashHands
No	44%
Yes	56%
Grand Total	100%



What actions do you perform prior to washing your hands?

Values		% of Respondents performing action prior to washing hands	
Count of ActionsWash_eating	8	Eating, Drinking and/or Smoking	26%
	1		
Count of ActionsWash_writing	0	Writing	32%
Count of ActionsWash_feed	9	Measuring out Feed	29%
	2		
Count of ActionsWash_doors	6	Opening Doors	84%
Count of	2		
ActionsWash_handling	6	Handling of Horses	84%
	2		
Count of ActionsWash_NR	0		
	1		
Count of ActionsWash_none	3		
		Non Respondents	Respondents
		33	31

Respondents that report performing the following actions prior to washing hands



Vet discussed bottle storage

Education_NoDiscussion	(All)
Education_NR	(All)

Count of BottleStorage	Column Labels
Row Labels	TRUE
Separate from other medications	38%
With other medications	62%
Grand Total	100%

Vet didn't discuss drug storage

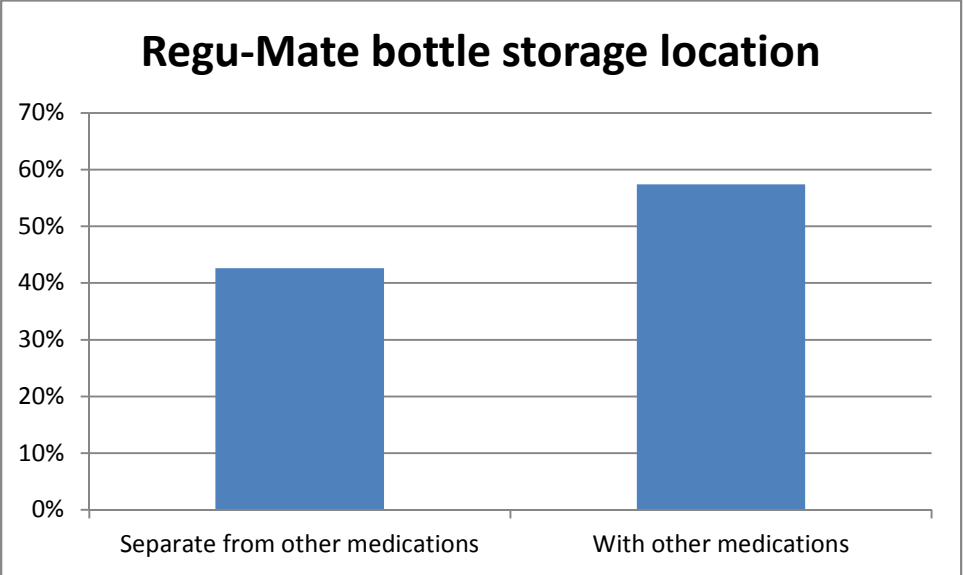
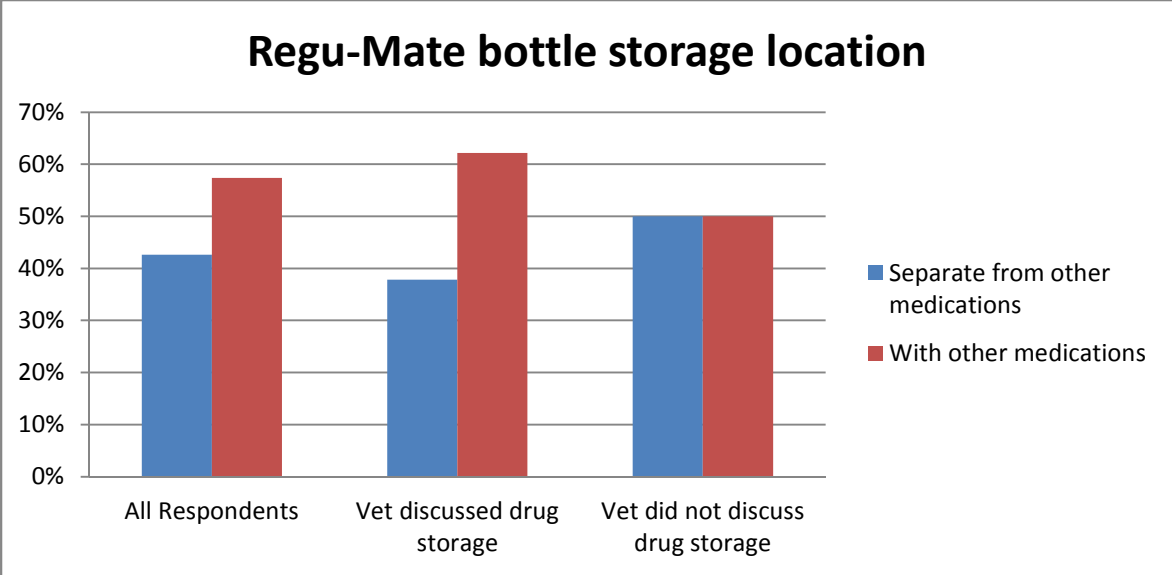
Education_NR	(blank)
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Count of BottleStorage	Column Labels
Row Labels	(blank)
Separate from other medications	50%
With other medications	50%
Grand Total	100%

Reported Drug Bottle Storage

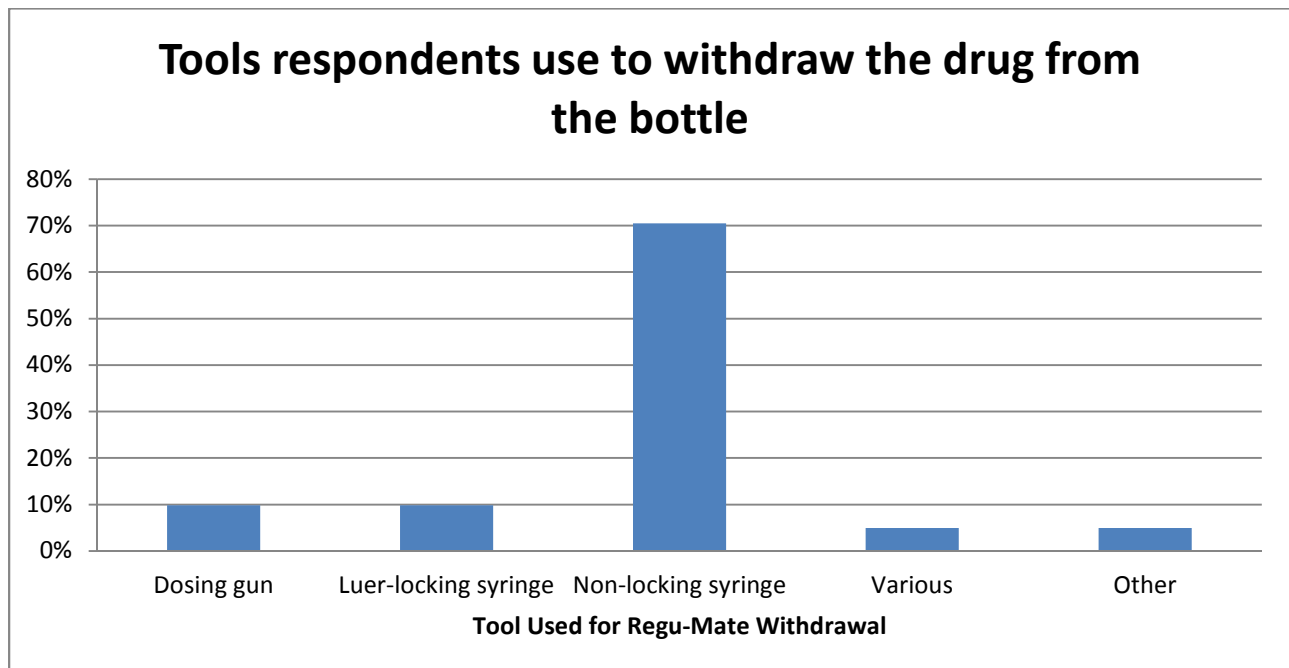
Row Labels	Count of BottleStorage
Separate from other medications	43%
With other medications	57%
Grand Total	100%

	All Respondents	Vet discussed drug storage	Vet did not discuss drug storage
Separate from other medications	43%	38%	50%
With other medications	57%	62%	50%

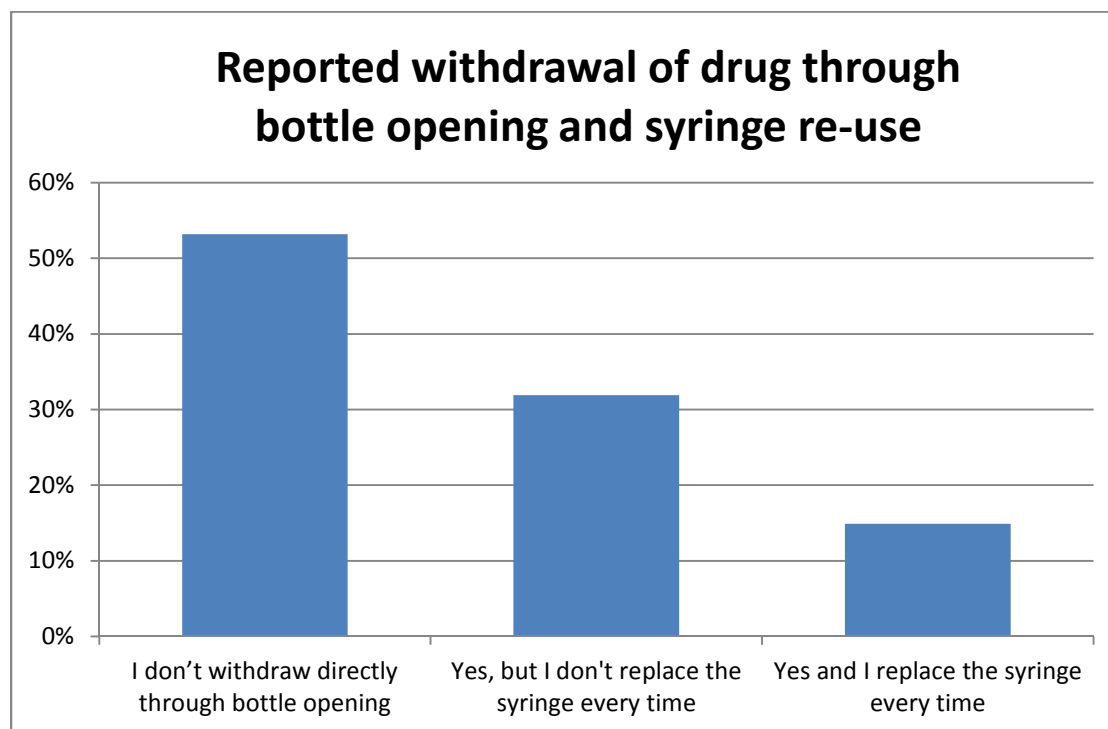


What tool do you use to withdraw the drug from the bottle?

Row Labels	Count of Tool	Percentage of respondents that use a particular tool	
Dosing gun	6	Dosing gun	10%
Luer-locking syringe	6	Luer-locking syringe	10%
Non-locking syringe	43	Non-locking syringe	70%
Various	3	Various	5%
Other	3	Other	5%
NR	3	Total Respondents	
Grand Total	64		61

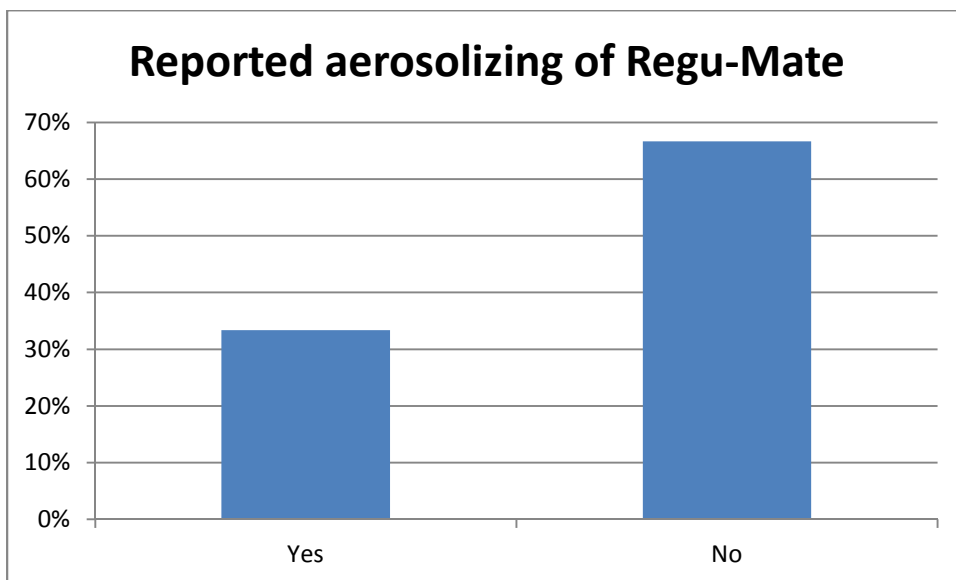
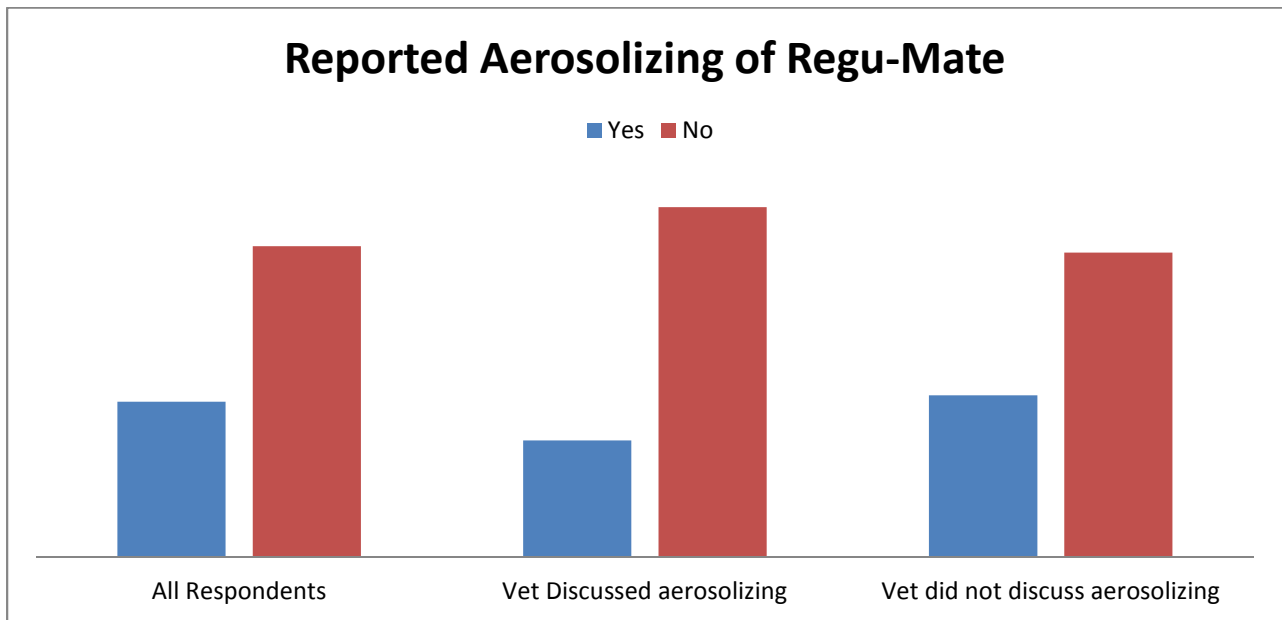


Tool	(Multiple Items)
Row Labels	Count of NewSyringe
I don't withdraw directly through bottle opening	53%
Yes, but I don't replace the syringe every time	32%
Yes and I replace the syringe every time	15%
Grand Total	100%



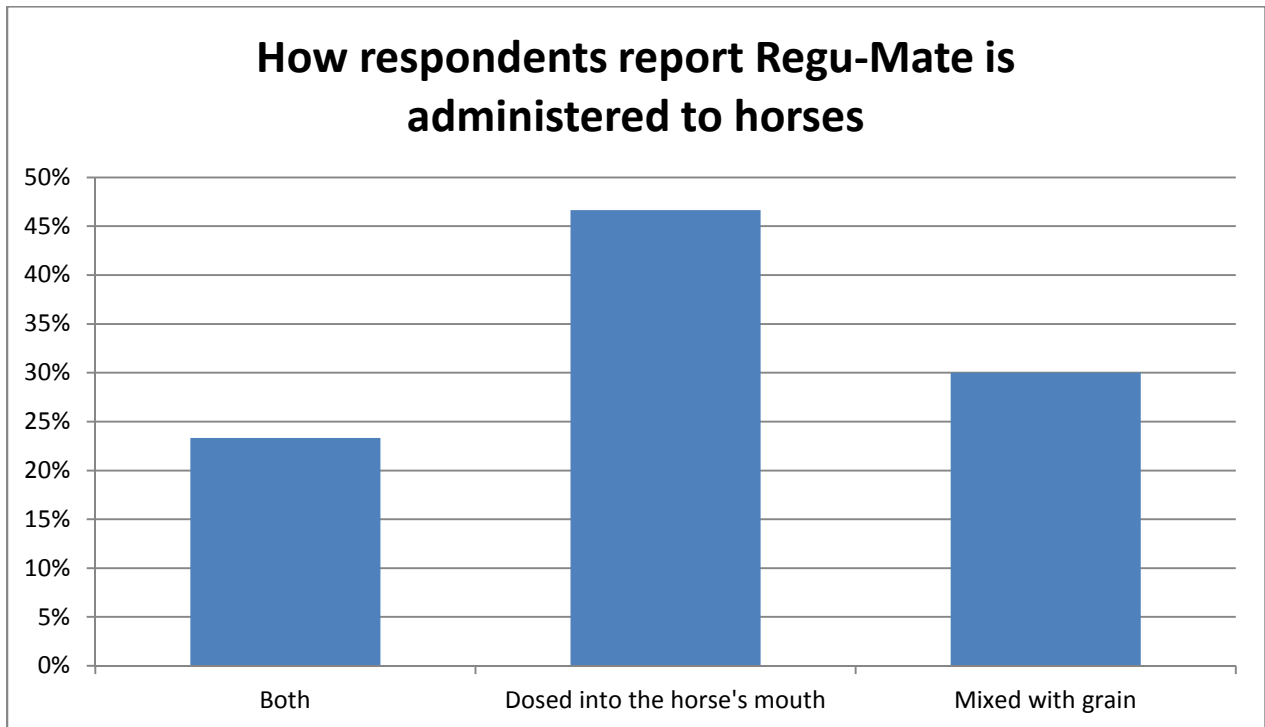
Do you ever forcefully clear the syringe or dosing gun to remove the last bit of the drug or extra air?

Tool	(Multiple Items)
Row Labels	Count of Aerosolize
No	65.45%
Yes	34.55%
Grand Total	100.00%



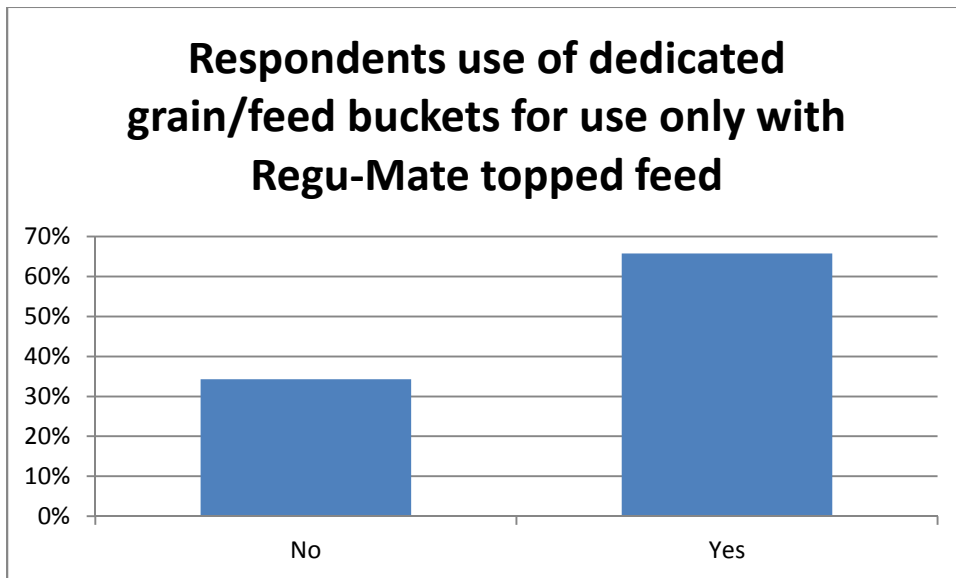
How is Regu-Mate Dosed/Administered to the horse?

Row Labels	Count of Dosage
Both	23%
Dosed into the horse's mouth	47%
Mixed with grain	30%
Grand Total	100%



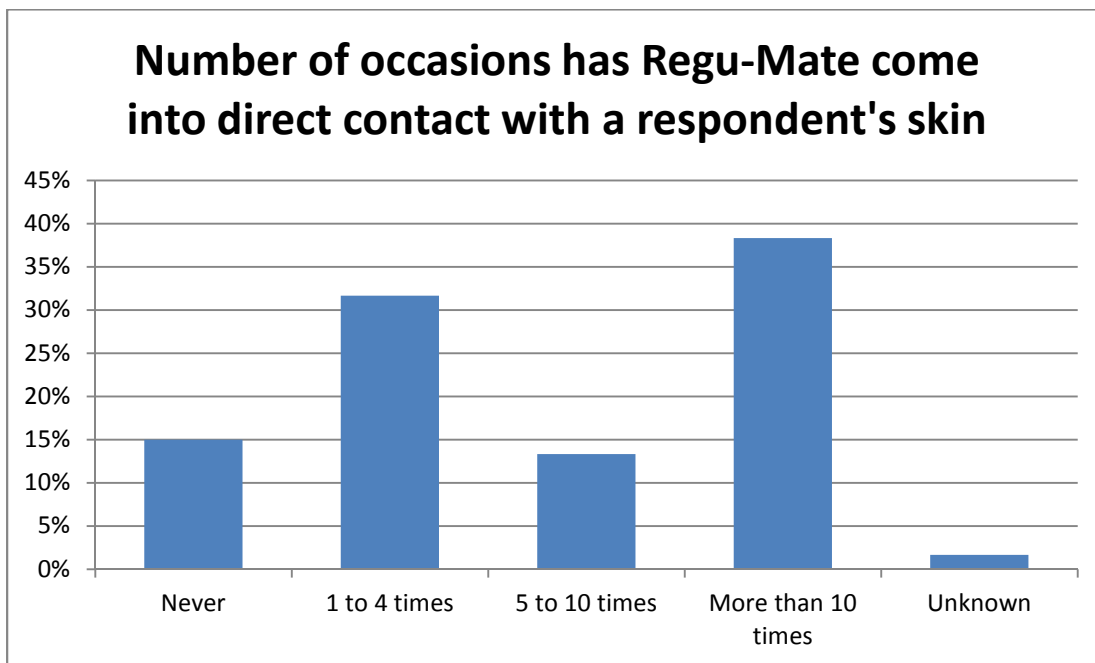
Are the buckets dedicated for only Regumate use?

Row Labels	Count of Buckets
No	34%
Yes	66%
Grand Total	100%



How many occasions has Regu-Mate come in direct contact with your skin?

Row Labels	Count of Contact
Never	15%
1 to 4 times	32%
5 to 10 times	13%
More than 10 times	38%
Unknown	2%
Grand Total	100%



# Female Respondents Reporting Symptoms	8
Respondents Reporting No Symptoms	37

18%

82%

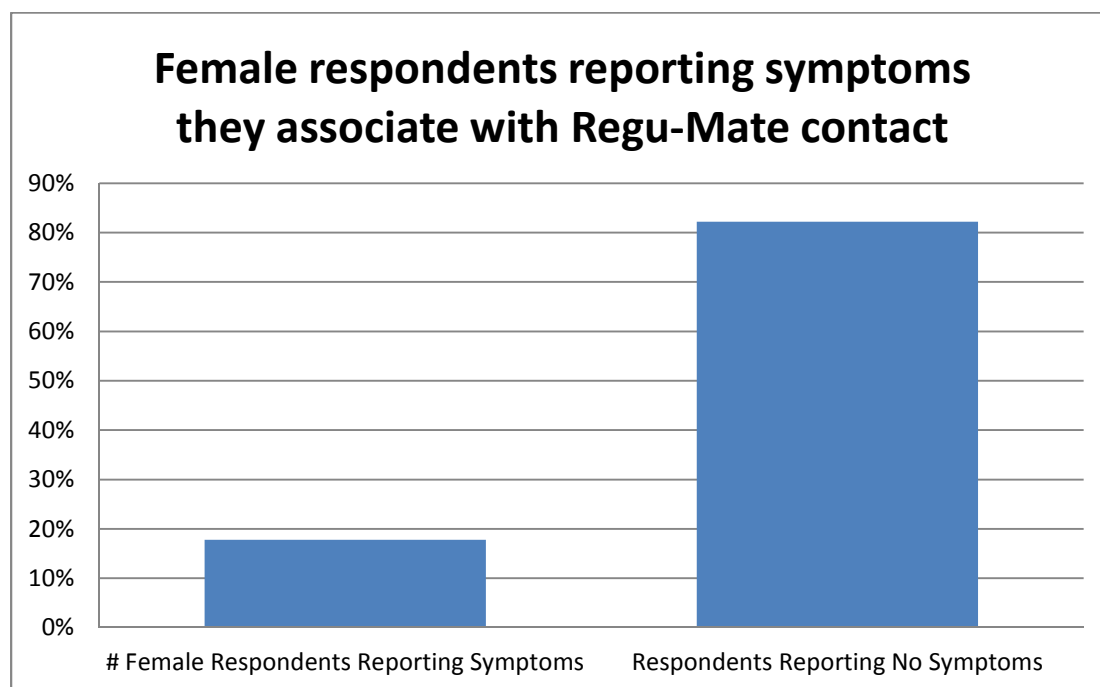
Sex (All)

Count of Fsymptoms_NR

19

Total Respondents

45



Sex (All)

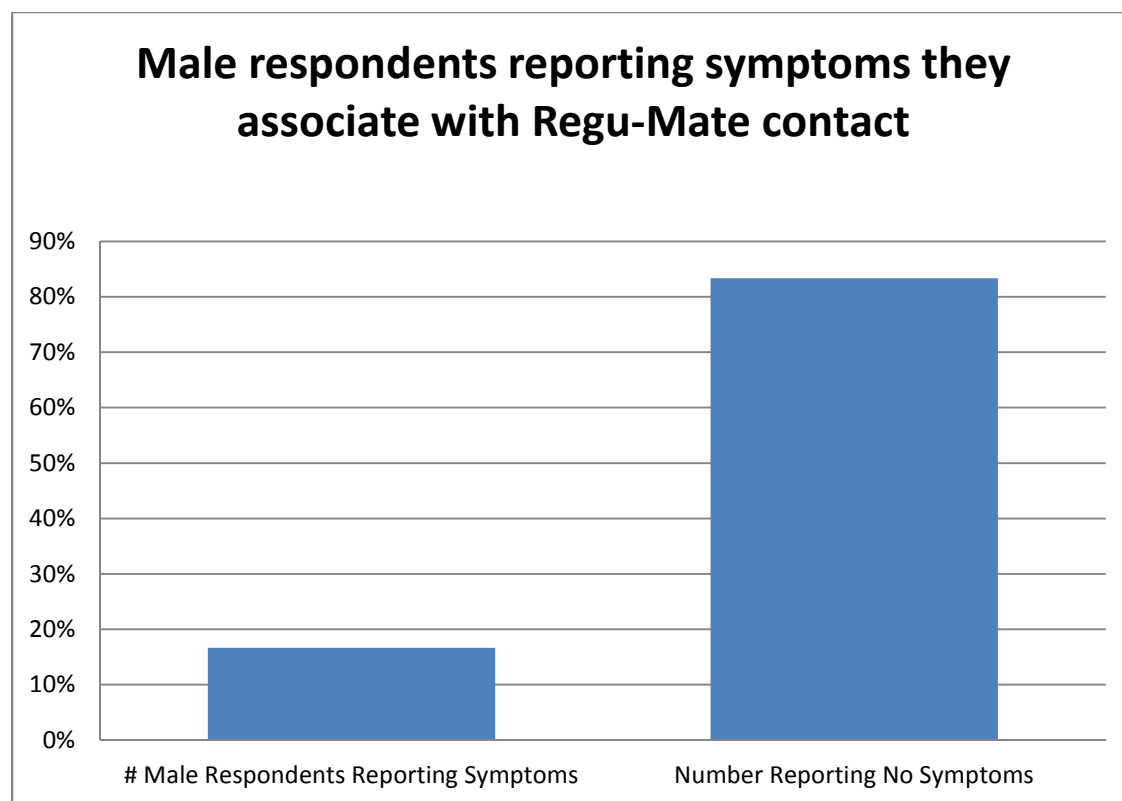
Count of
Msymptoms_NR

52
Total Respondents 12

# Male Respondents Reporting Symptoms	2
Number Reporting No Symptoms	10

17%

83%



**Breakdown of those Prohibited from Handling
Regumate**

Values			% of Respondents
Count of Prohib_Handling_Men	6	Men	9%
Count of Prohib_Handling_AllWom	9	All Women	25%
	1	Women of Child Bearing	
Count of Prohib_Handling_ChildWom	6	Age	14%
	3		
Count of Prohib_Handling_PregWom	2	Pregnant Women	50%
	3		
Count of Prohib_Handling_Child	5	Children	55%
	1		
Count of Prohib_Handling_None	7	None	27%
Count of Prohib_Handling_	0		

**Breakdown of those Prohibited from Handling
Animals on Regumate**

Values			% of Respondents
Count of Prohib_Contact_Men	1	Men	2%
Count of Prohib_Contact_AllWom	1	All Women	2%
		Women of Child	
Count of Prohib_Contact_ChildWom	1	Bearing Age	2%
Count of Prohib_Contact_PregWom	5	Pregnant Women	8%
Count of Prohib_Contact_Child	5	Children	8%
	5		
Count of Prohib_Contact_None	8	None	92%
Count of Prohib_Contact_NR	1		
	6		
Respondents to this Question	3		

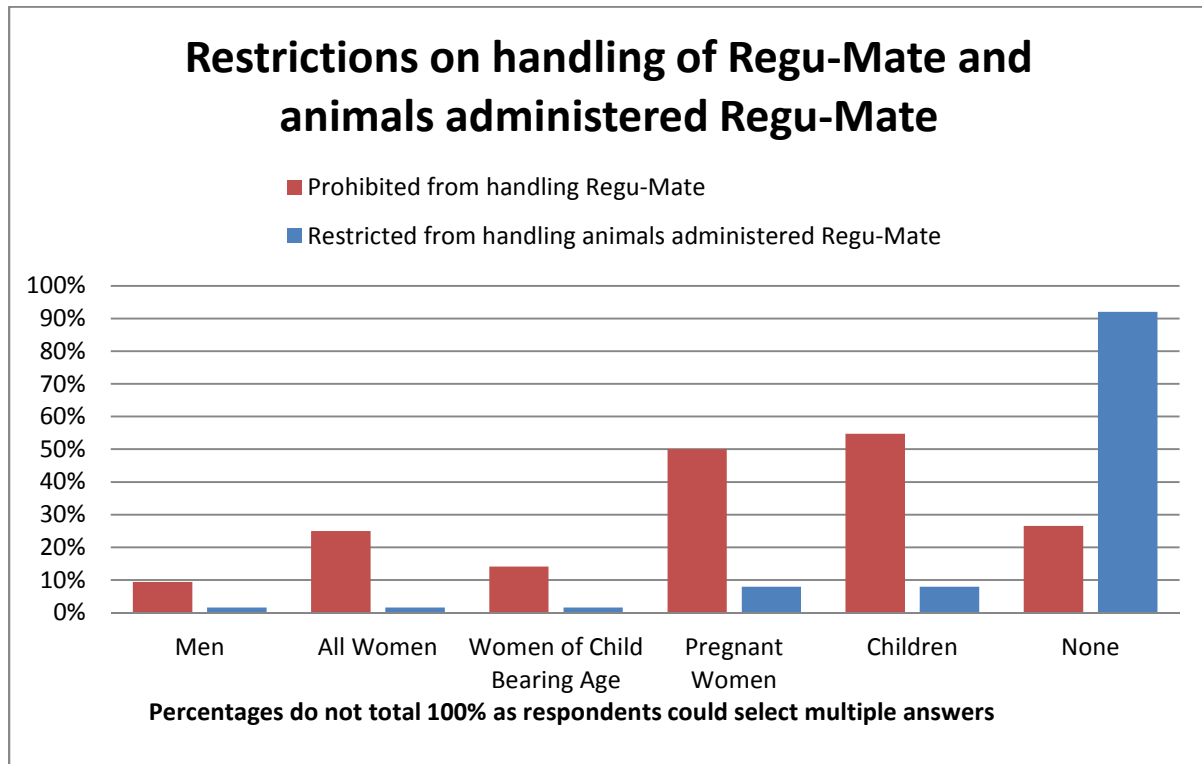
Prohibited from Handling Animals and Regumate

	Prohibited from handling Regu-Mate	Prohibited from handling animals administered Regu-Mate
Men	9%	2%
All Women	25%	2%
Women of Child		
Bearing Age	14%	2%
Pregnant Women	50%	8%

Children
None

55%
27%

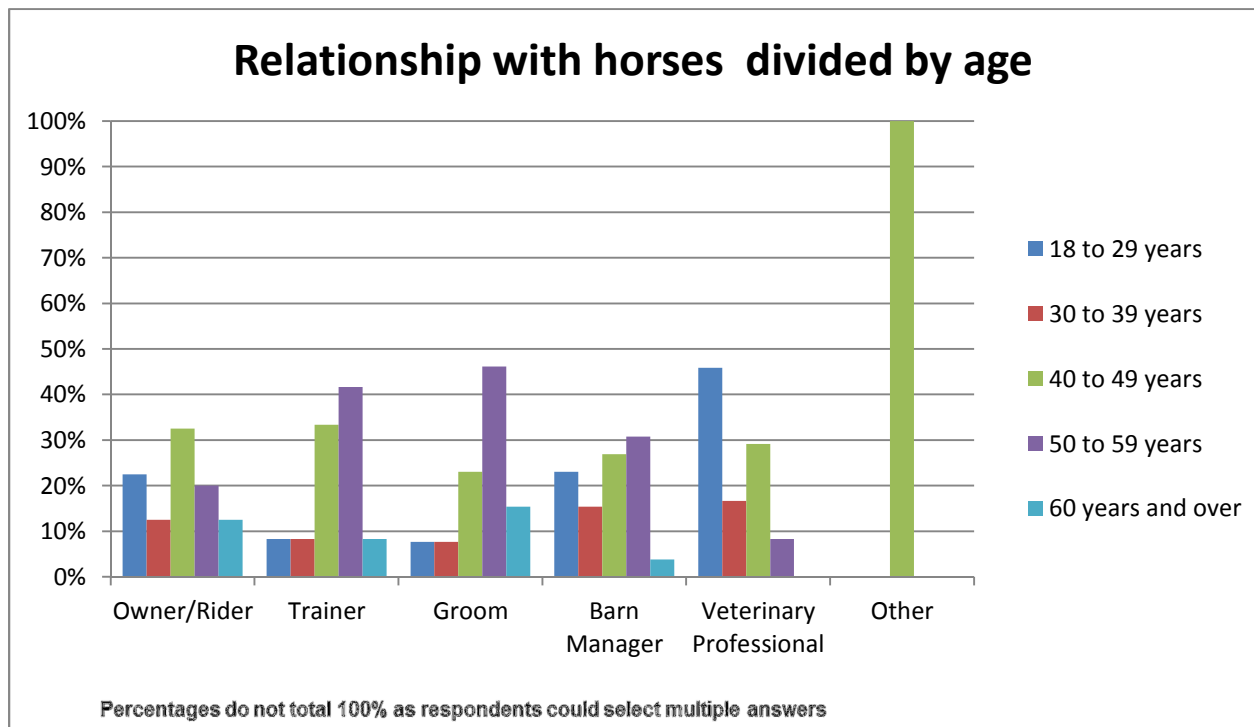
8%
92%



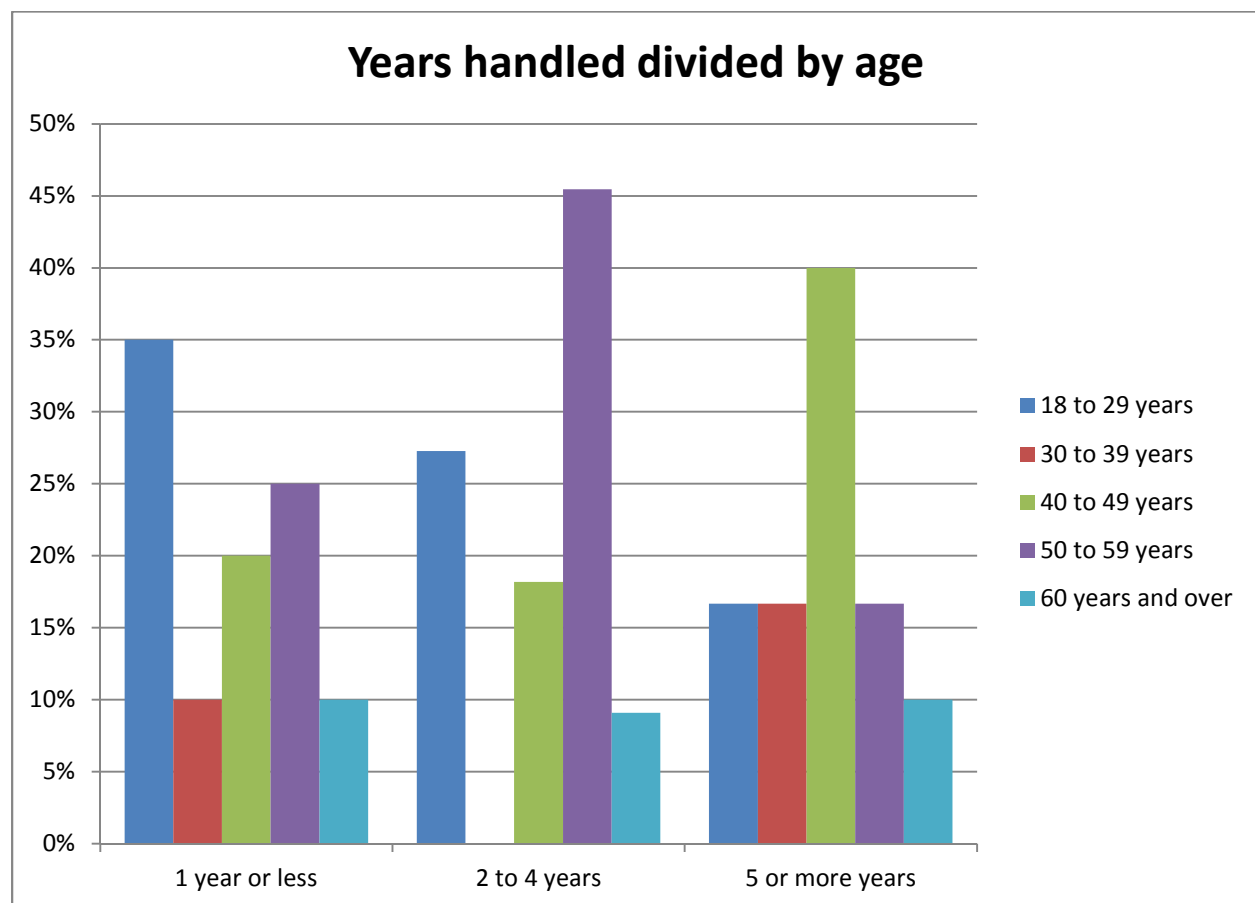
AGE COMPARISONS

Age x Role with Horses

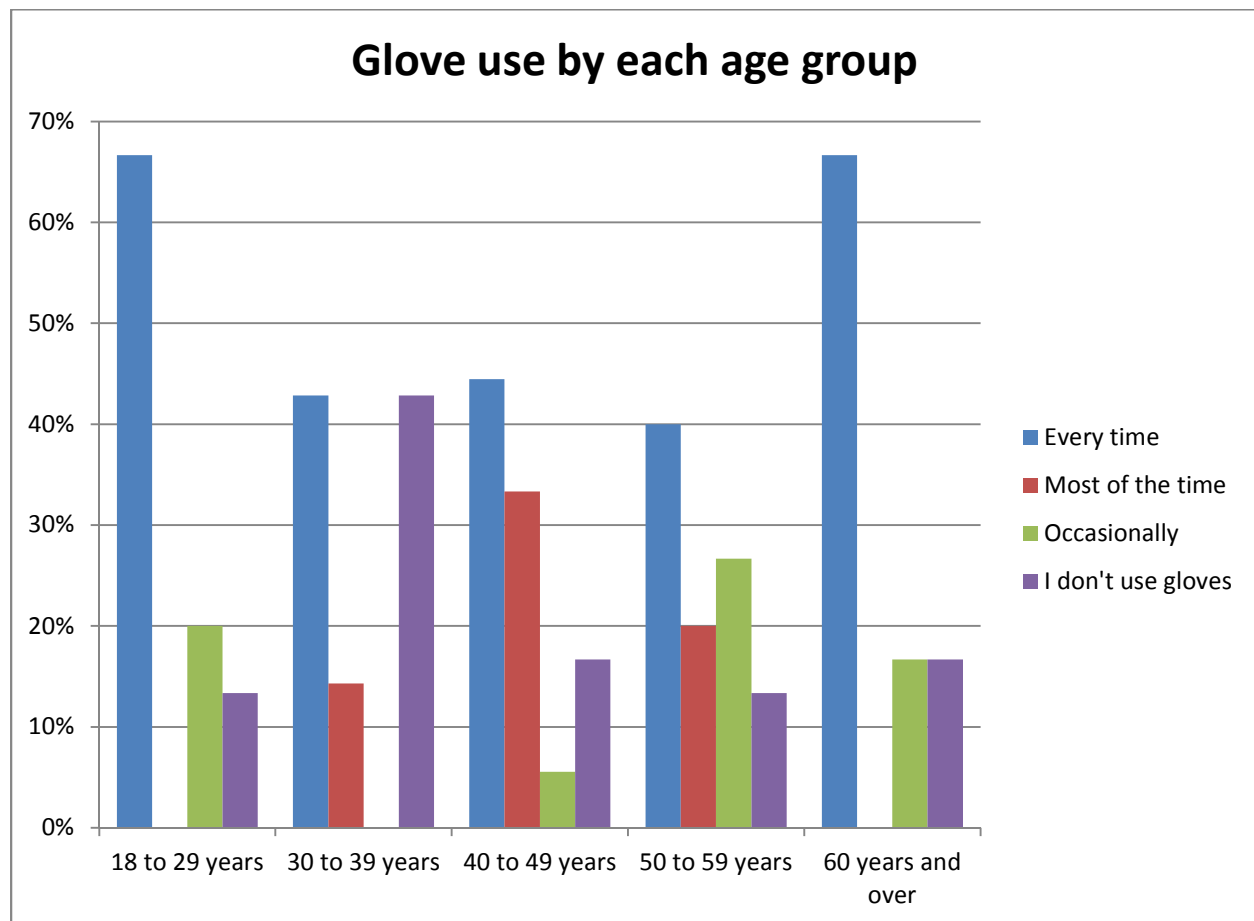
Values	Column Labels 18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	Grand Total
Owner/Rider	23%	13%	33%	20%	13%	100%
Trainer	8%	8%	33%	42%	8%	100%
Groom	8%	8%	23%	46%	15%	100%
Barn Manager	23%	15%	27%	31%	4%	100%
Veterinary Professional	46%	17%	29%	8%	0%	100%
Other	0%	0%	100%	0%	0%	100%



Age x Years Handled						
Count of Age	Column Labels					
Row Labels	18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	Grand Total
1 year or less	35%	10%	20%	25%	10%	100%
2 to 4 years	27%	0%	18%	45%	9%	100%
5 or more years	17%	17%	40%	17%	10%	100%
Grand Total	25%	11%	30%	25%	10%	100%

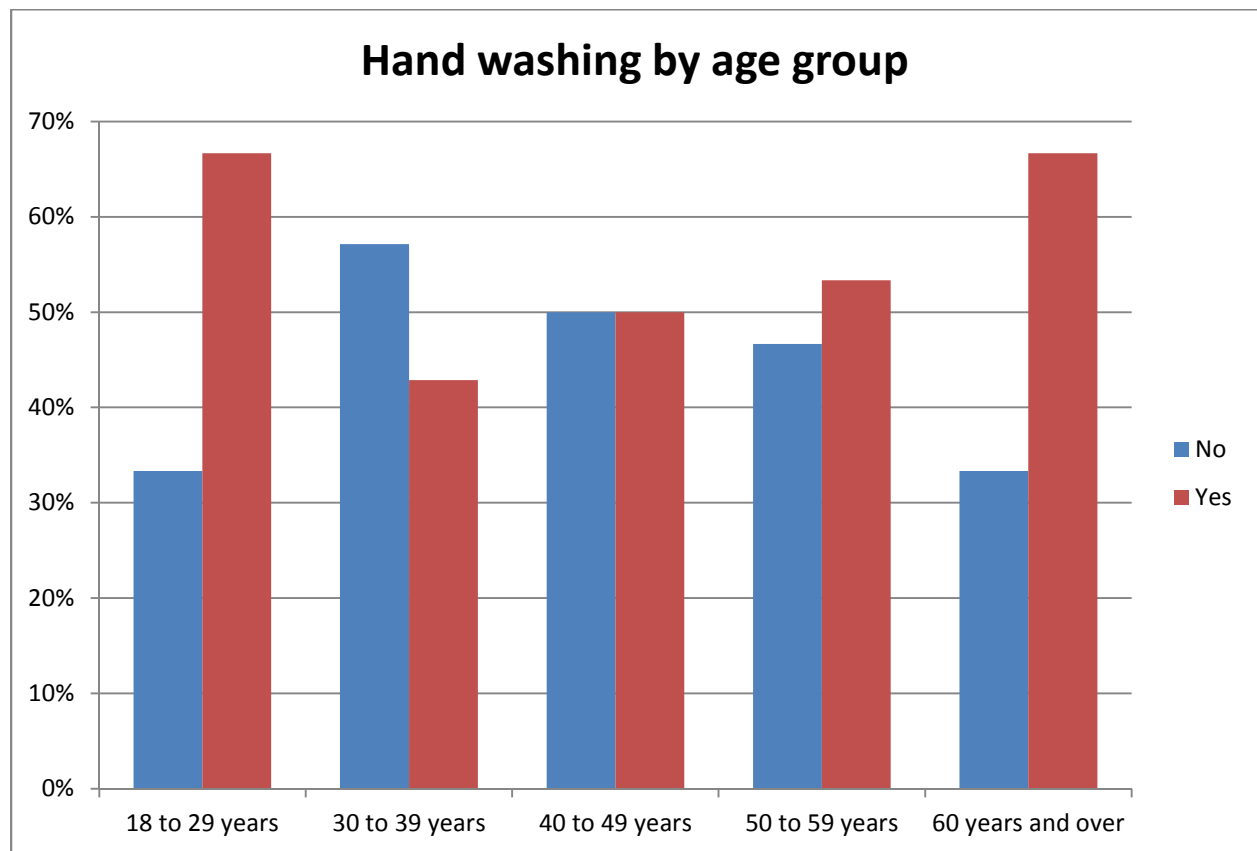


Age x Glove Use						
Count of Age	Column Labels					
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total	
18 to 29 years	67%	0%	20%	13%	100%	
30 to 39 years	43%	14%	0%	43%	100%	
40 to 49 years	44%	33%	6%	17%	100%	
50 to 59 years	40%	20%	27%	13%	100%	
60 years and over	67%	0%	17%	17%	100%	
Grand Total	51%	16%	15%	18%	100%	



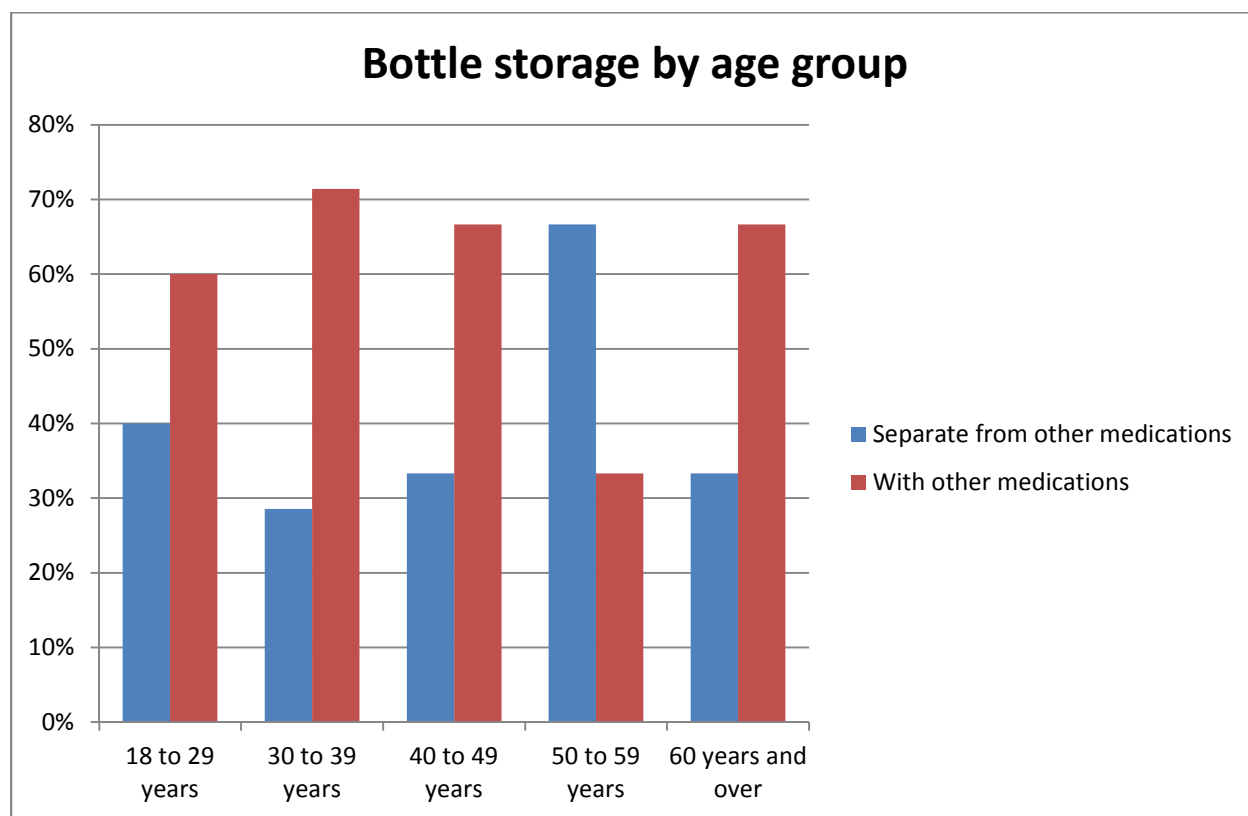
Age x Hand Washing

Count of Age	Column Labels		Grand Total
Row Labels	No	Yes	
18 to 29 years	19%	29%	25%
30 to 39 years	15%	9%	11%
40 to 49 years	33%	26%	30%
50 to 59 years	26%	24%	25%
60 years and over	7%	12%	10%
Grand Total	100%	100%	100%



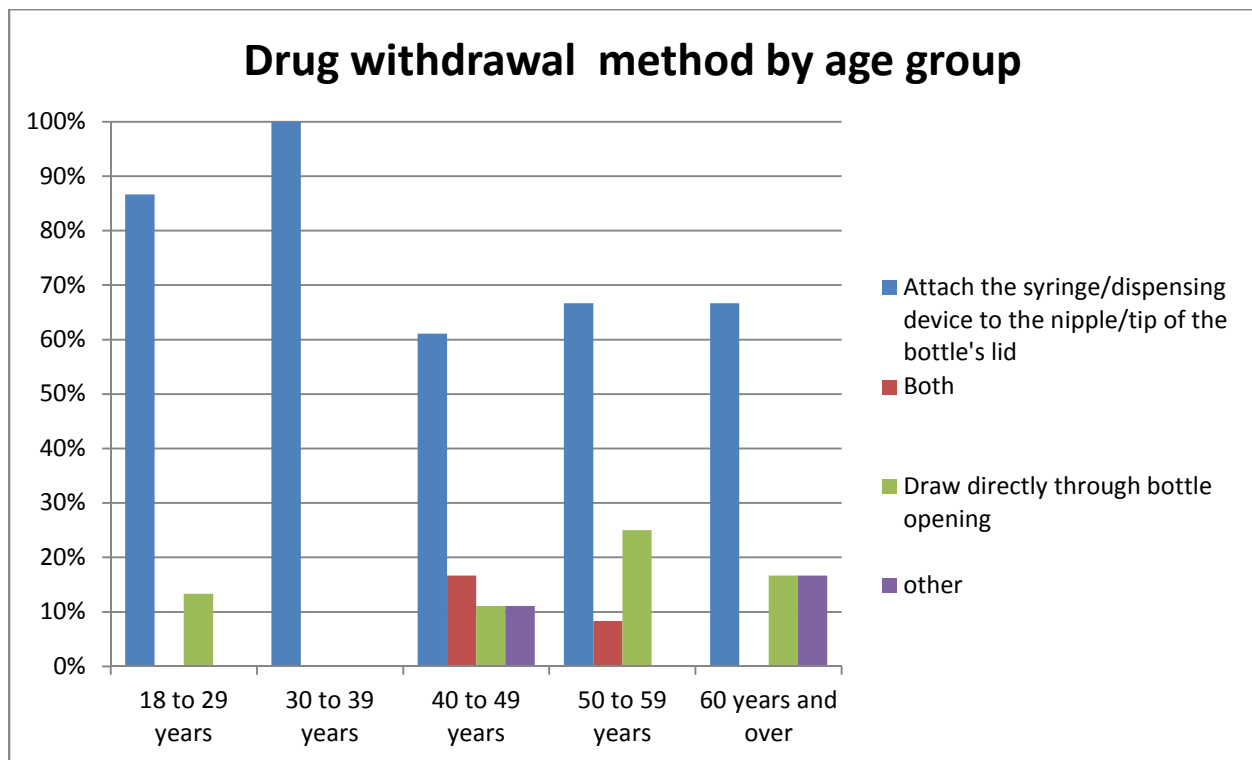
Age x Bottle Storage

Count of Age	Column Labels		
Row Labels	Separate from other medications	With other medications	Grand Total
18 to 29 years	40%	60%	100%
30 to 39 years	29%	71%	100%
40 to 49 years	33%	67%	100%
50 to 59 years	67%	33%	100%
60 years and over	33%	67%	100%
Grand Total	43%	57%	100%



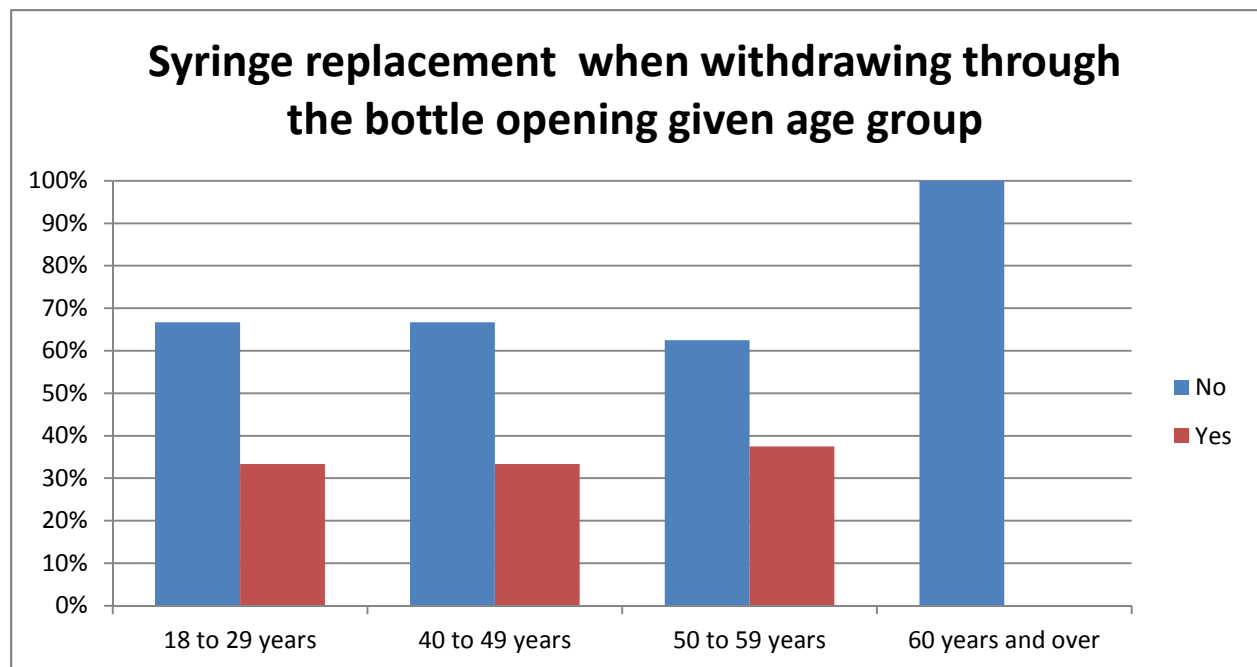
Age x Withdrawal Method

Count of Age	Column Labels					
Row Labels	Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	Both	Draw directly through bottle opening	other	Grand Total	
18 to 29 years	87%	0%	13%	0%	100%	
30 to 39 years	100%	0%	0%	0%	100%	
40 to 49 years	61%	17%	11%	11%	100%	
50 to 59 years	67%	8%	25%	0%	100%	
60 years and over	67%	0%	17%	17%	100%	
Grand Total	74%	7%	14%	5%	100%	



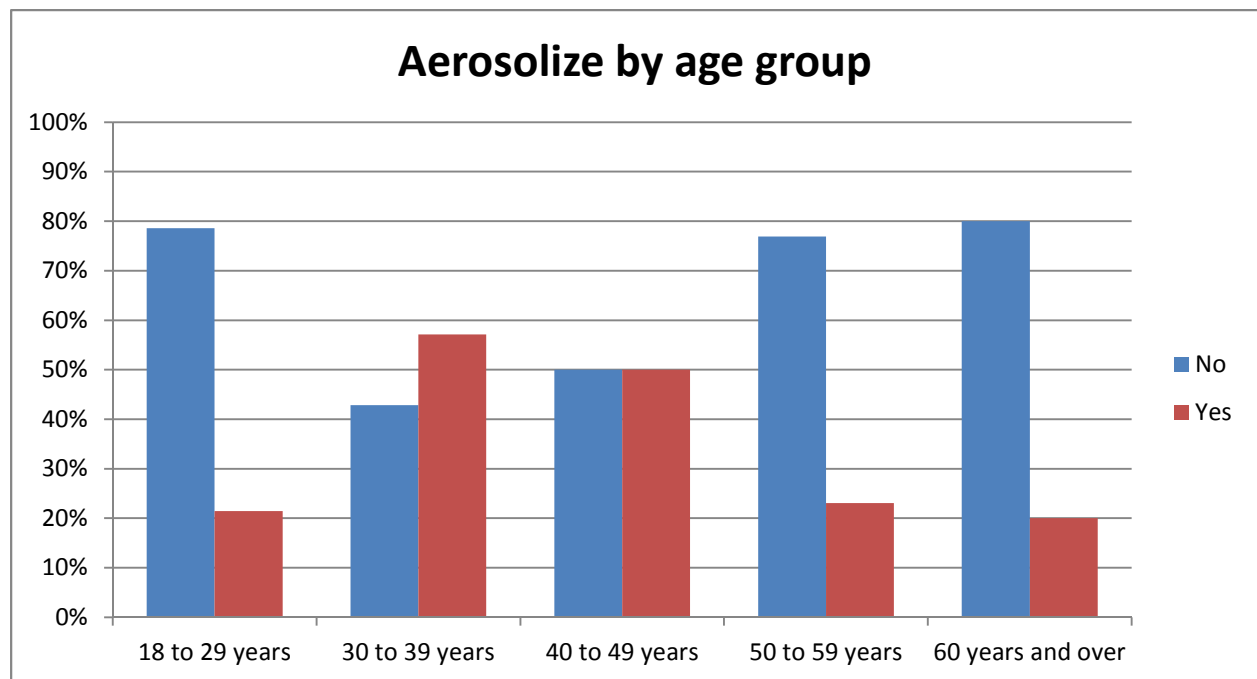
Age x New Syringe	
Tool	(Multiple Items)

Count of Age	Column Labels		Grand
Row Labels	No	Yes	Total
18 to 29 years	67%	33%	100%
40 to 49 years	67%	33%	100%
50 to 59 years	63%	38%	100%
60 years and over	100%	0%	100%
Grand Total	68%	32%	100%



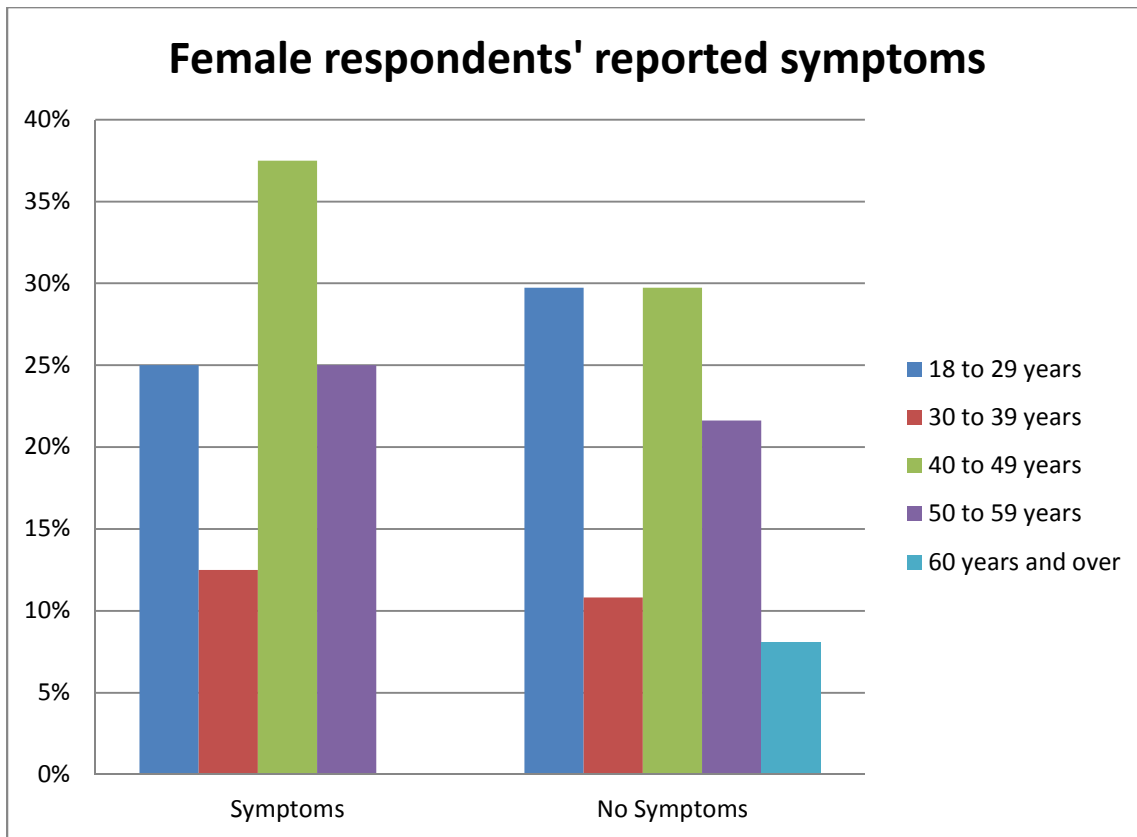
Age x Aerosolize	
Tool	(Multiple Items)

Count of Age	Column Labels		Grand
Row Labels	No	Yes	Total
18 to 29 years	79%	21%	100%
30 to 39 years	43%	57%	100%
40 to 49 years	50%	50%	100%
50 to 59 years	77%	23%	100%
60 years and over	80%	20%	100%
Grand Total	65%	35%	100%



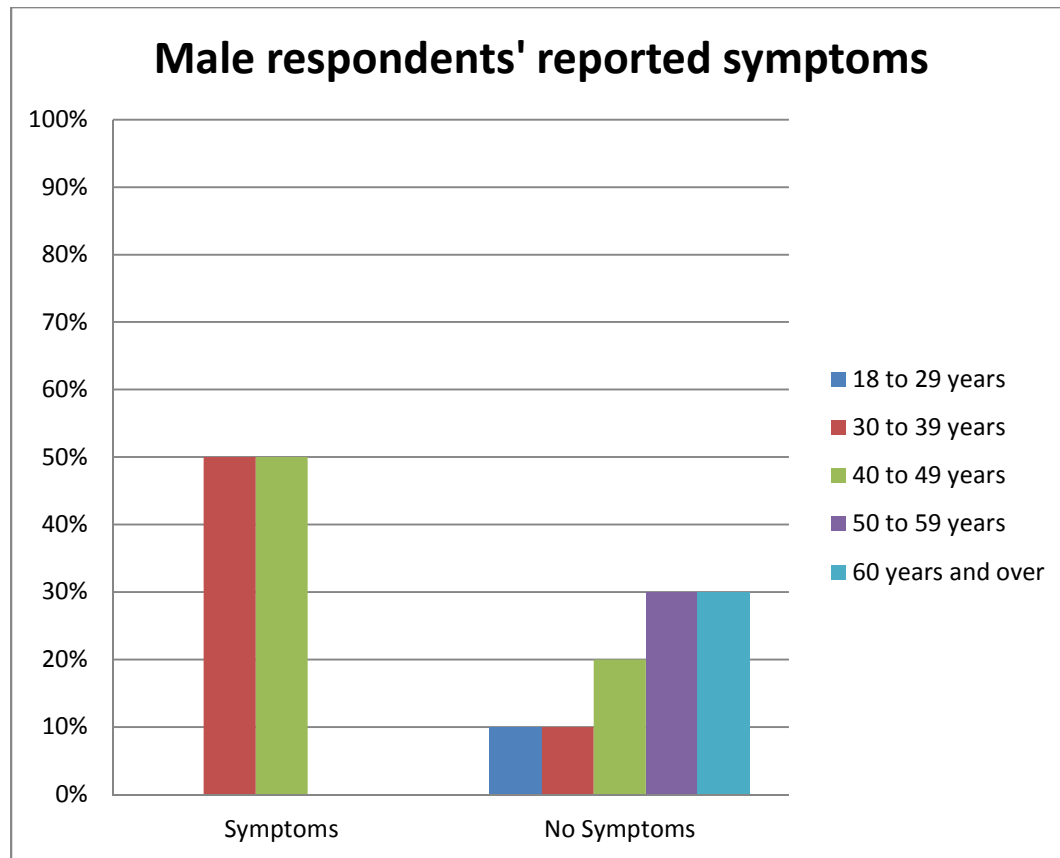
Age x Female Symptoms

	Column Labels					
Values	18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	Grand Total
Symptoms	25%	13%	38%	25%	0%	100%
No Symptoms	30%	11%	30%	22%	8%	100%

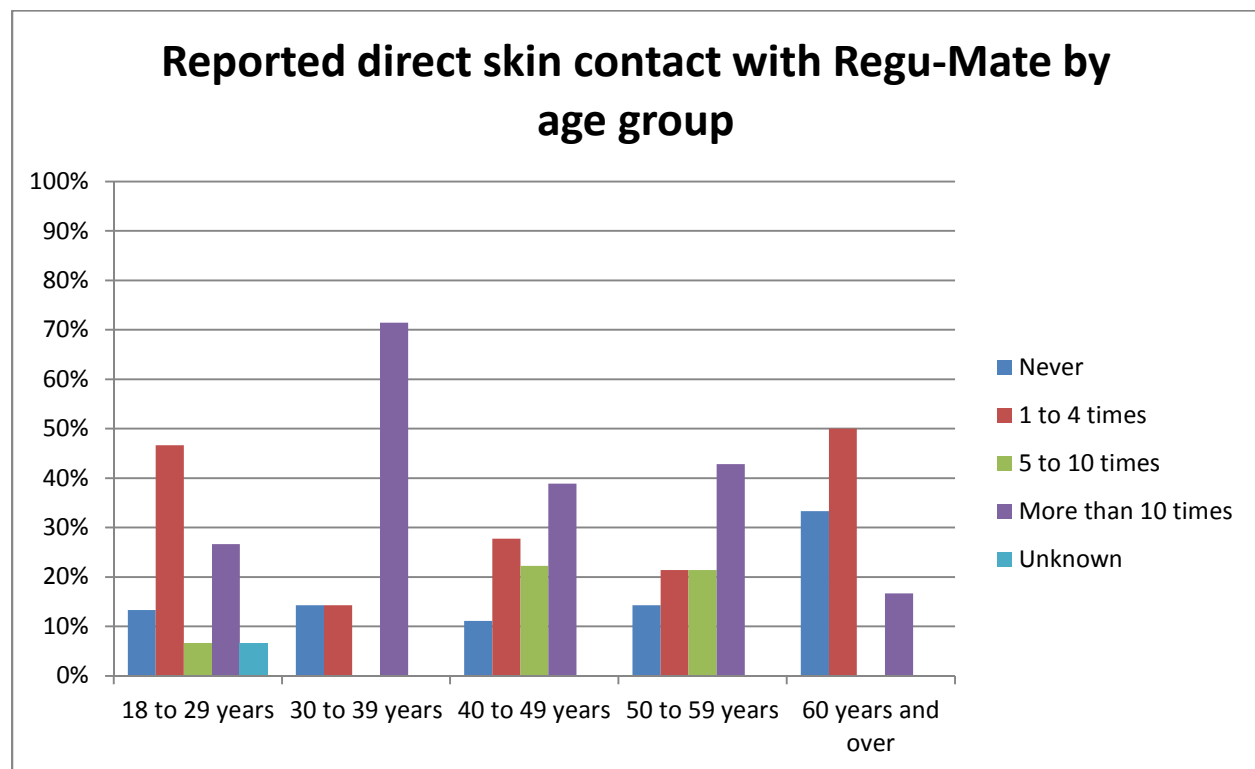


Age x Male Symptoms

	Column Labels					
Values	18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	Grand Total
Symptoms	0%	50%	50%	0%	0%	100%
No Symptoms	10%	10%	20%	30%	30%	100%



Age x Contact							
Count of Age	Column Labels						
Row Labels	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total	
18 to 29 years	13%	47%	7%	27%	7%	100%	
30 to 39 years	14%	14%	0%	71%	0%	100%	
40 to 49 years	11%	28%	22%	39%	0%	100%	
50 to 59 years	14%	21%	21%	43%	0%	100%	
60 years and over	33%	50%	0%	17%	0%	100%	
Grand Total	15%	32%	13%	38%	2%	100%	



Articles

Percentage of Total Respondents Learning from Each

Friends	25%
Professionals	48%
Vet	91%
Internet	9%
Product Insert	23%
Scientific	
Articles	5%

Percentage of 40-49 Year Old Respondents Learning from Each

Friends	22%
Professionals	50%
Vet	89%
Internet	11%
Product Insert	28%
Scientific	
Articles	6%

Percentage of 18-29 Year Old Respondents Learning from Each

Friends	18%
Professionals	65%
Vet	88%
Internet	6%
Product Insert	18%
Scientific	
Articles	0%

Percentage of 50-59 Year Old Respondents Learning from Each

Friends	40%
Professionals	40%
Vet	100%
Internet	13%
Product Insert	27%
Scientific	
Articles	13%

Percentage of 30-39 Year Old Respondents Learning from Each

Friends	38%
Professionals	50%
Vet	75%
Internet	13%
Product Insert	25%
Scientific	0%

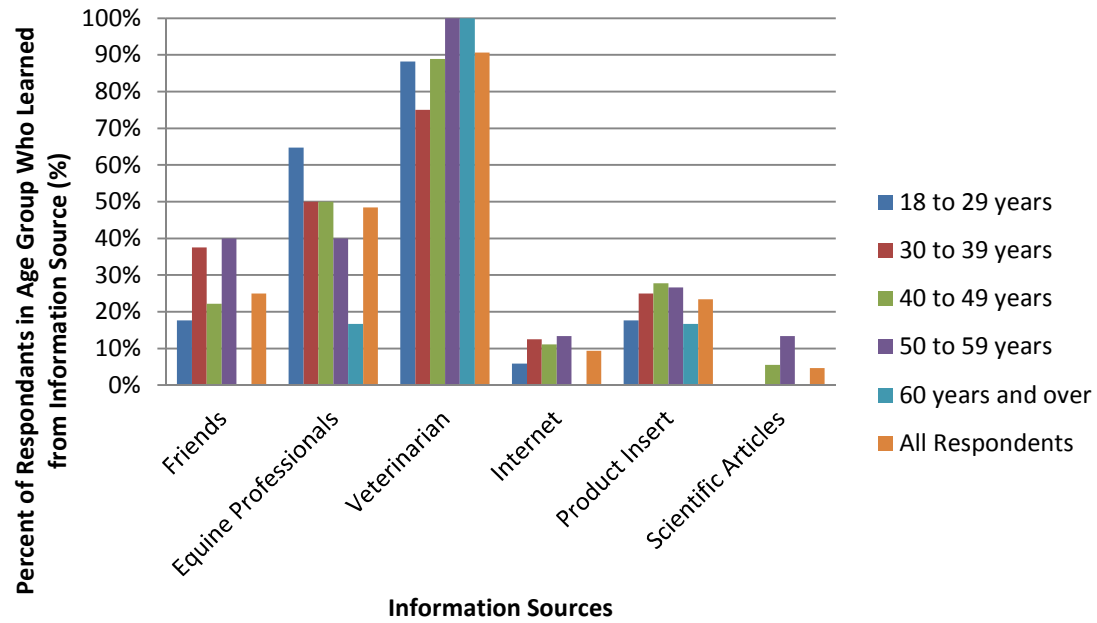
Percentage of 60+ Year Old Respondents Learning from Each

Friends	0%
Professionals	17%
Vet	100%
Internet	0%
Product Insert	17%
Scientific	0%

Articles

	Learned from X as % of Total In Age Group					
	Friends	Equine Professionals	Veterinarian	Internet	Product Insert	Scientific Articles
18 to 29 years	18%	65%	88%	6%	18%	0
30 to 39 years	38%	50%	75%	13%	25%	0
40 to 49 years	22%	50%	89%	11%	28%	6%
50 to 59 years	40%	40%	100%	13%	27%	13%
60 years and over	0%	17%	100%	0%	17%	0
All Respondents	25%	48%	91%	9%	23%	5%

Where people learn about Regu-Mate



Responses to: What is your age?

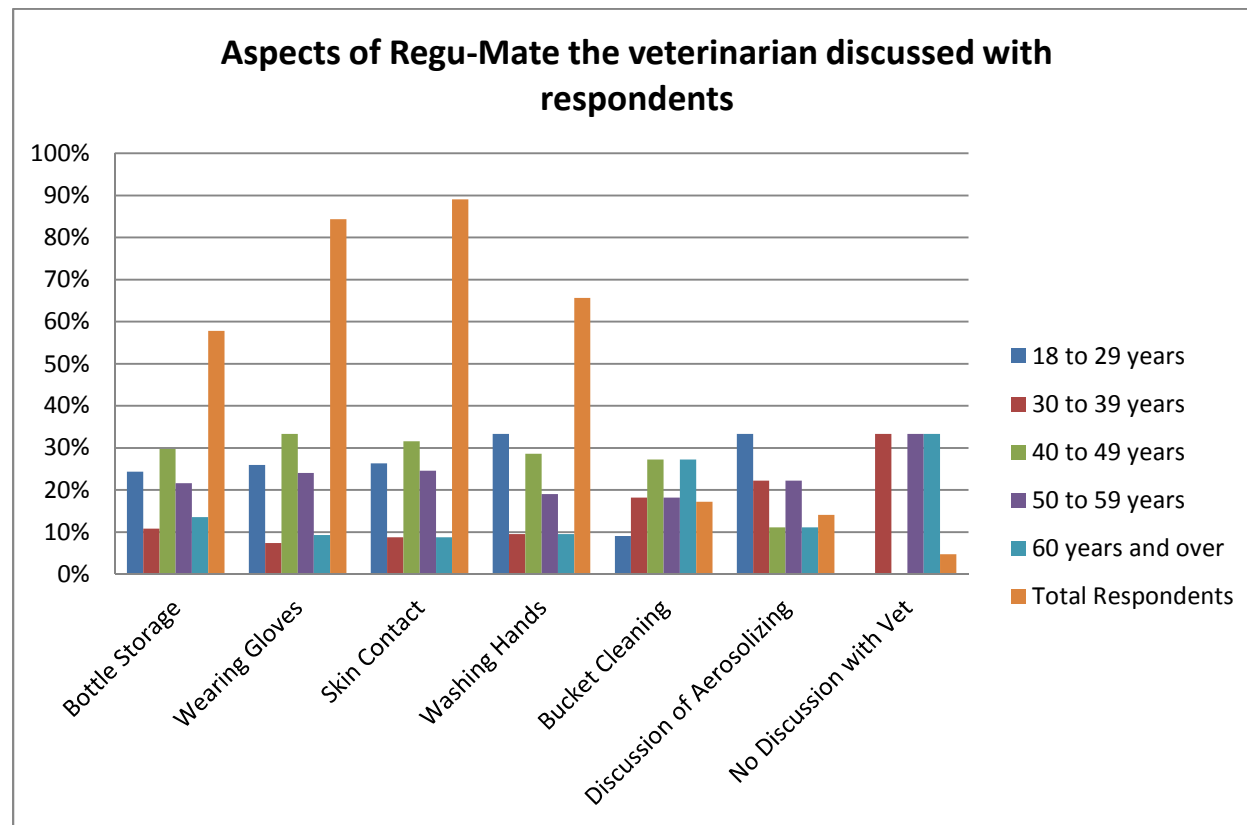
Values	Column Labels					Grand Total
	18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	
Bottle Storage	24%	11%	30%	22%	14%	100%
Wearing Gloves	26%	7%	33%	24%	9%	100%
Skin Contact	26%	9%	32%	25%	9%	100%
Washing Hands	33%	10%	29%	19%	10%	100%
Bucket Cleaning	9%	18%	27%	18%	27%	100%
Discussion of						
Aerosolizing	33%	22%	11%	22%	11%	100%
No Discussion with Vet	0%	33%	0%	33%	33%	100%

Values

Bottle Storage	37	58%
Wearing Gloves	54	84%
Skin Contact	57	89%
Washing Hands	42	66%
Bucket Cleaning	11	17%
Discussion of		
Aerosolizing	9	14%
No Discussion with Vet	3	5%

	18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	Total Respondents
Bottle Storage	24%	11%	30%	22%	14%	58%
Wearing Gloves	26%	7%	33%	24%	9%	84%
Skin Contact	26%	9%	32%	25%	9%	89%
Washing Hands	33%	10%	29%	19%	10%	66%

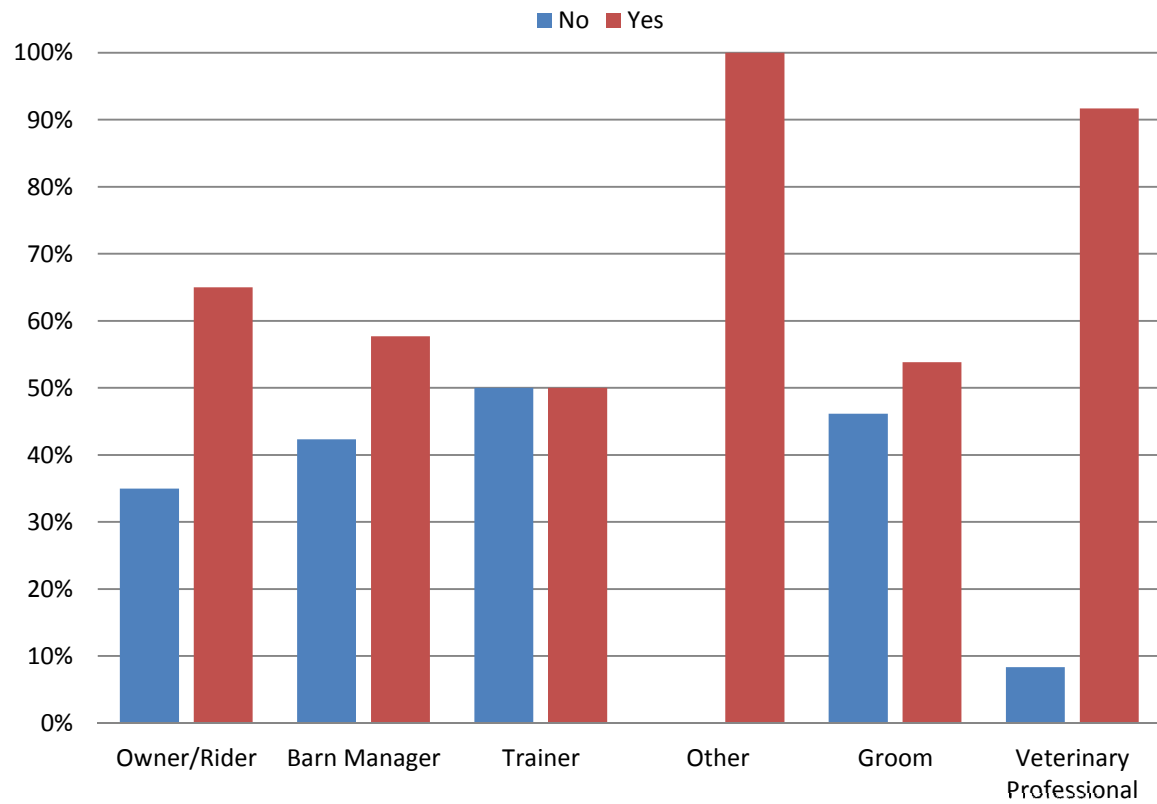
Bucket Cleaning	9%	18%	27%	18%	27%	17%
Discussion of						
Aerosolizing	33%	22%	11%	22%	11%	14%
No Discussion with Vet	0%	33%	0%	33%	33%	5%



RELATIONSHIP WITH HORSES

Relationship w/ Horses x Breeding Industry				
Values	Column Labels		Grand Total	
	No	Yes		
Owner/Rider	35%	65%	100%	
Barn Manager	42%	58%	100%	
Trainer	50%	50%	100%	
Other	0%	100%	100%	
Groom	46%	54%	100%	
Veterinary Professional	8%	92%	100%	

Role in working with horses divided by involvement in breeding industry

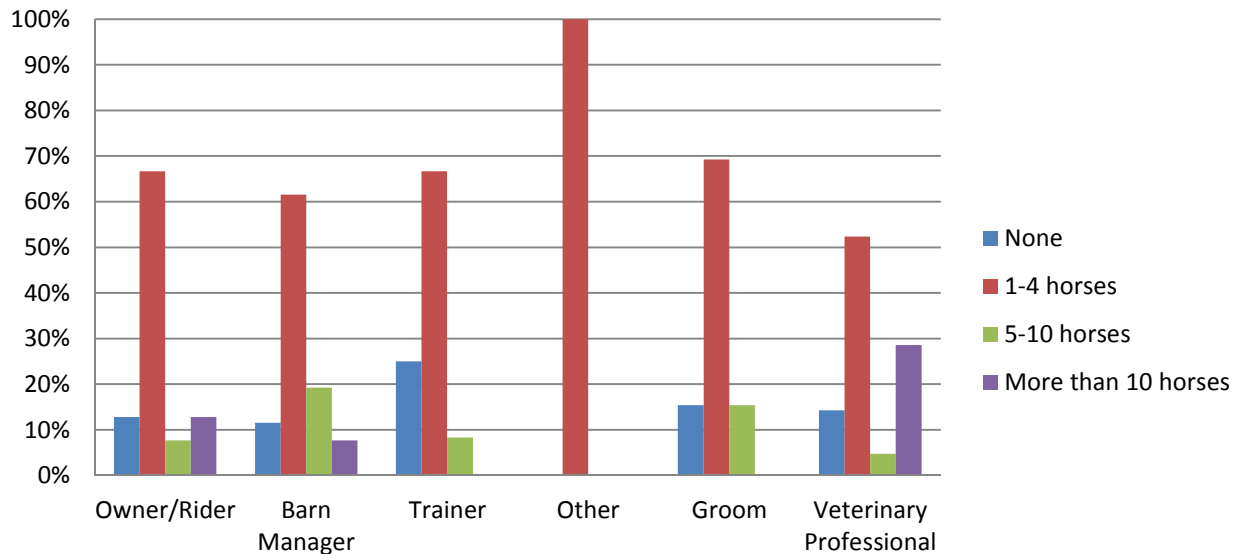


Percentages do not total 100% as respondents could select multiple answers

Which of the roles listed below best describes your role in working with horses?

Values	Column Labels				Grand Total
	None	1-4 horses	5-10 horses	More than 10 horses	
Owner/Rider	13%	67%	8%	13%	100%
Barn Manager	12%	62%	19%	8%	100%
Trainer	25%	67%	8%	0%	100%
Other	0%	100%	0%	0%	100%
Groom	15%	69%	15%	0%	100%
Veterinary Professional	14%	52%	5%	29%	100%

Relationship to horses and the number of horses the respondent regularly administers Regu-Mate



Percentages do not total 100% as respondents could select multiple answers

Role w/ horses x Use

Behavior Modification

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	21	15	9		8	13
Grand Total	21	15	9		8	13

Synchronization of Mares

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	20	12	6		4	10
Grand Total	20	12	6		4	10

Early Cycle

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	16	10	3		5	10
Grand Total	16	10	3		5	10

Ovulation

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	13	8	4		3	7
Grand Total	13	8	4		3	7

Maintenance

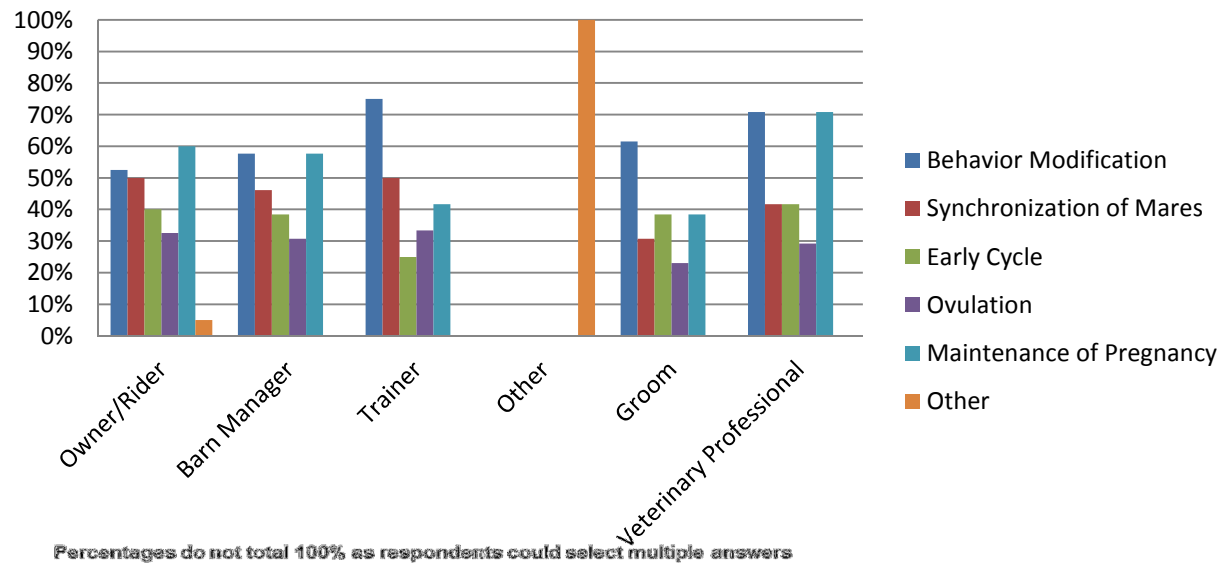
Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	24	15	5		5	17
Grand Total	24	15	5		5	17

Other

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	2			1		
Grand Total	2			1		

	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
Behavior Modification	53%	58%	75%	0%	62%	71%
Synchronization of Mares	50%	46%	50%	0%	31%	42%
Early Cycle	40%	38%	25%	0%	38%	42%
Ovulation	33%	31%	33%	0%	23%	29%
Maintenance of Pregnancy	60%	58%	42%	0%	38%	71%
Other	5%	0%	0%	100%	0%	0%

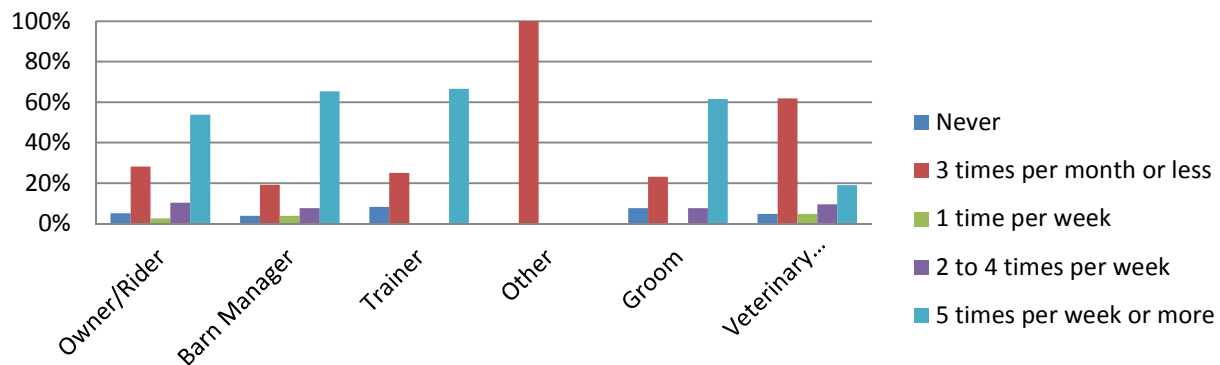
Role with horses divided by why Regu-Mate is used



Role x How Often

	Column Labels						
Values	Never	1 time per week	2 to 4 times per week	3 times per month or less	5 times per week or more	Grand Total	
Owner/Rider	5%	3%	10%	28%	54%	100%	
Barn Manager	4%	4%	8%	19%	65%	100%	
Trainer	8%	0%	0%	25%	67%	100%	
Other	0%	0%	0%	100%	0%	100%	
Groom	8%	0%	8%	23%	62%	100%	
Veterinary Professional	5%	5%	10%	62%	19%	100%	

Role in working with horses divided by how often respondent administered drug

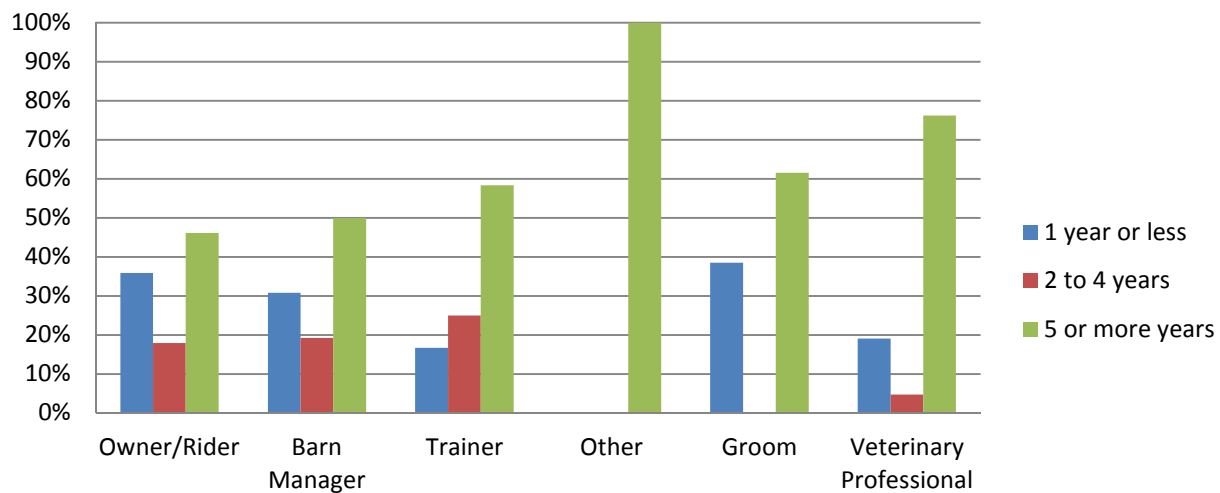


Percentages do not total 100% as respondents could select multiple answers

Role x Years Administering

Values	Column Labels			Grand Total
	1 year or less	2 to 4 years	5 or more years	
Owner/Rider	36%	18%	46%	100%
Barn Manager	31%	19%	50%	100%
Trainer	17%	25%	58%	100%
Other	0%	0%	100%	100%
Groom	38%	0%	62%	100%
Veterinary Professional	19%	5%	76%	100%

Role in working with horses divided by how many years a respondent has handled the drug

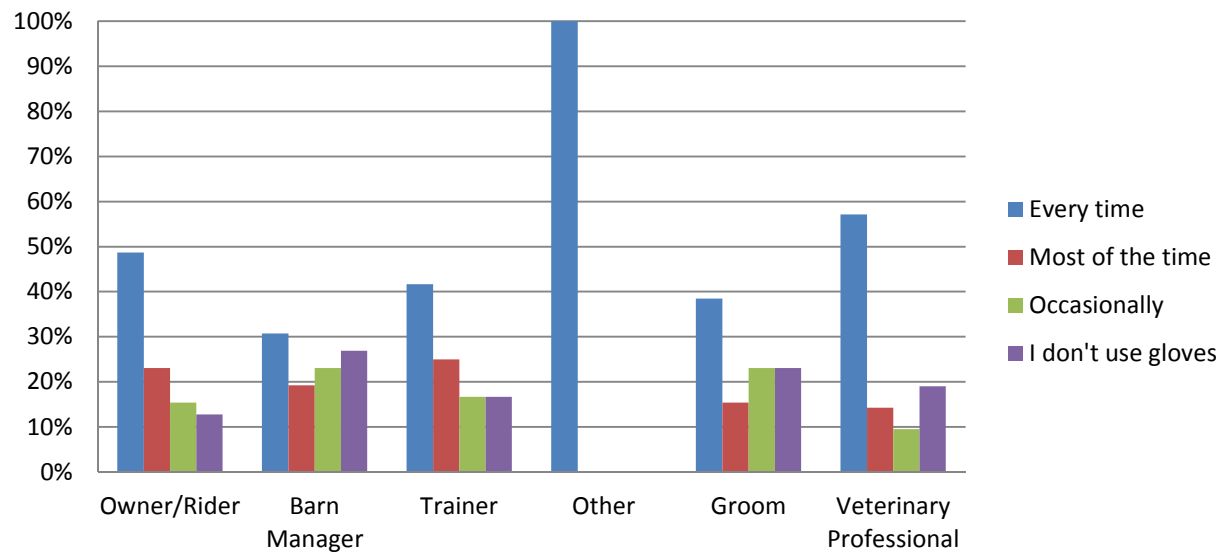


Percentages do not total 100% as respondents could select multiple answers

Role x Glove Use

Values	Column Labels				Grand Total
	Every time	Most of the time	Occasionally	I don't use gloves	
Owner/Rider	49%	23%	15%	13%	100%
Barn Manager	31%	19%	23%	27%	100%
Trainer	42%	25%	17%	17%	100%
Other	100%	0%	0%	0%	100%
Groom	38%	15%	23%	23%	100%
Veterinary Professional	57%	14%	10%	19%	100%

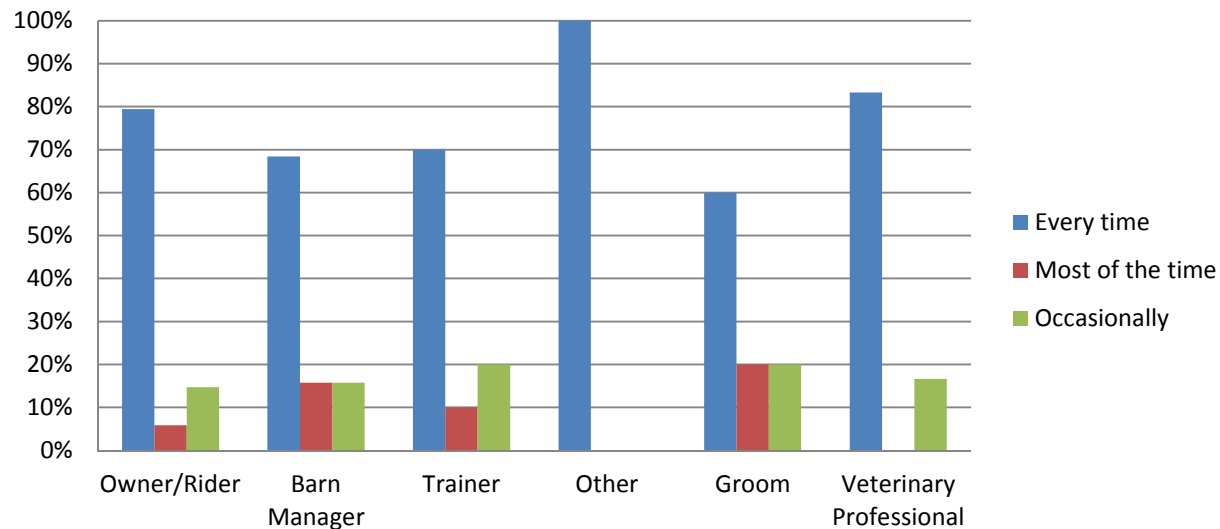
Role in working with horses divided by glove use



Which of the roles listed below best describes your role in working with horses?

Values	Column Labels			Grand Total
	Every time	Most of the time	Occasionally	
Owner/Rider	79%	6%	15%	100%
Barn Manager	68%	16%	16%	100%
Trainer	70%	10%	20%	100%
Other	100%	0%	0%	100%
Groom	60%	20%	20%	100%
Veterinary Professional	83%	0%	17%	100%

Role in working with horses divided by glove replacement



Role x Glove Type

Latex/Rubber

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	21	14	7	1	7	10
Grand Total	21	14	7	1	7	10

Vinyl

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	5	2	1			2
Grand Total	5	2	1			2

Nitrile

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	6	4	1		3	7
Grand Total	6	4	1		3	7

Unknown

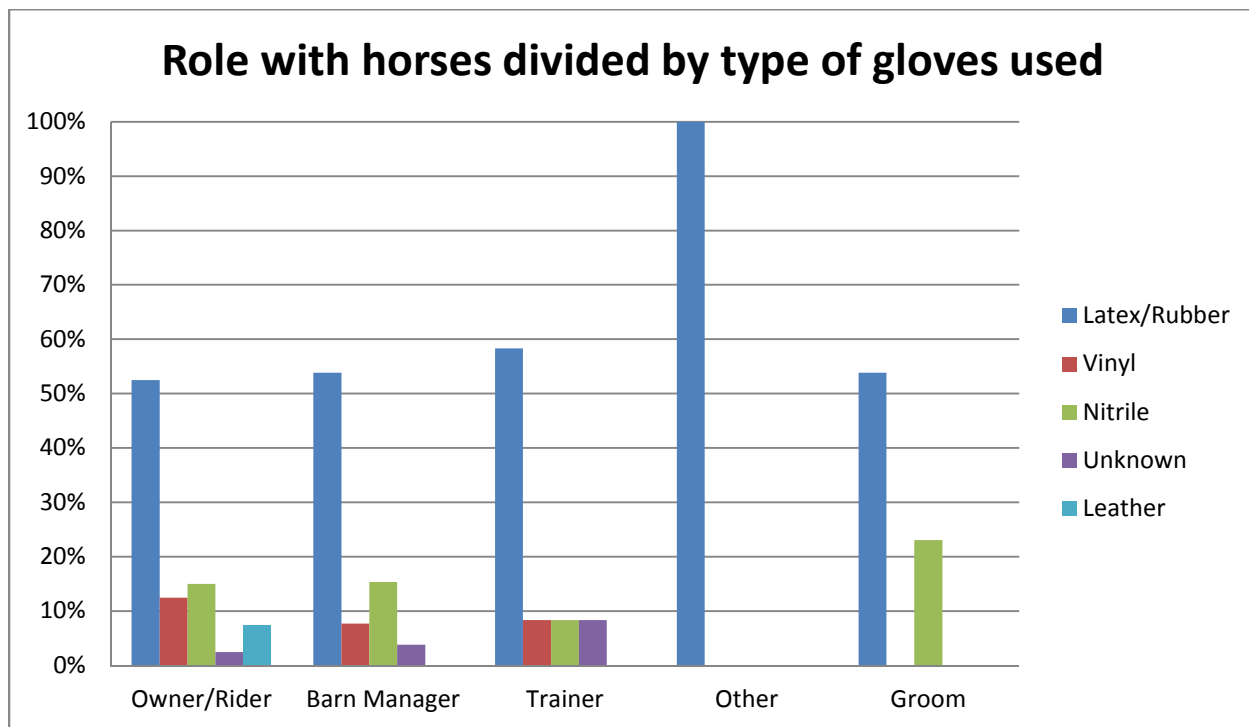
Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	1	1	1			1
Grand Total	1	1	1			1

Leather

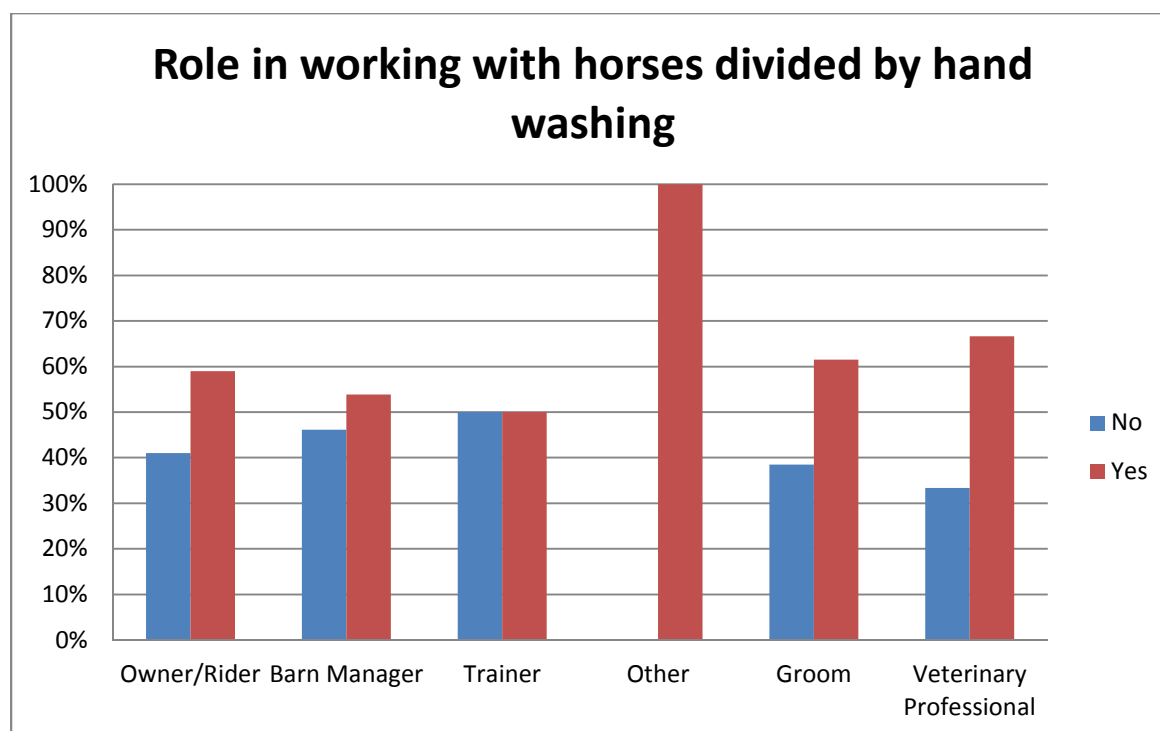
Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	3					1

Grand Total	3	1
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	Owner/Rider	Barn Manager	Trainer	Other	Groom
Latex/Rubber	53%	54%	58%	100%	54%
Vinyl	13%	8%	8%	0%	0%
Nitrile	15%	15%	8%	0%	23%
Unknown	3%	4%	8%	0%	0%
Leather	8%	0%	0%	0%	0%

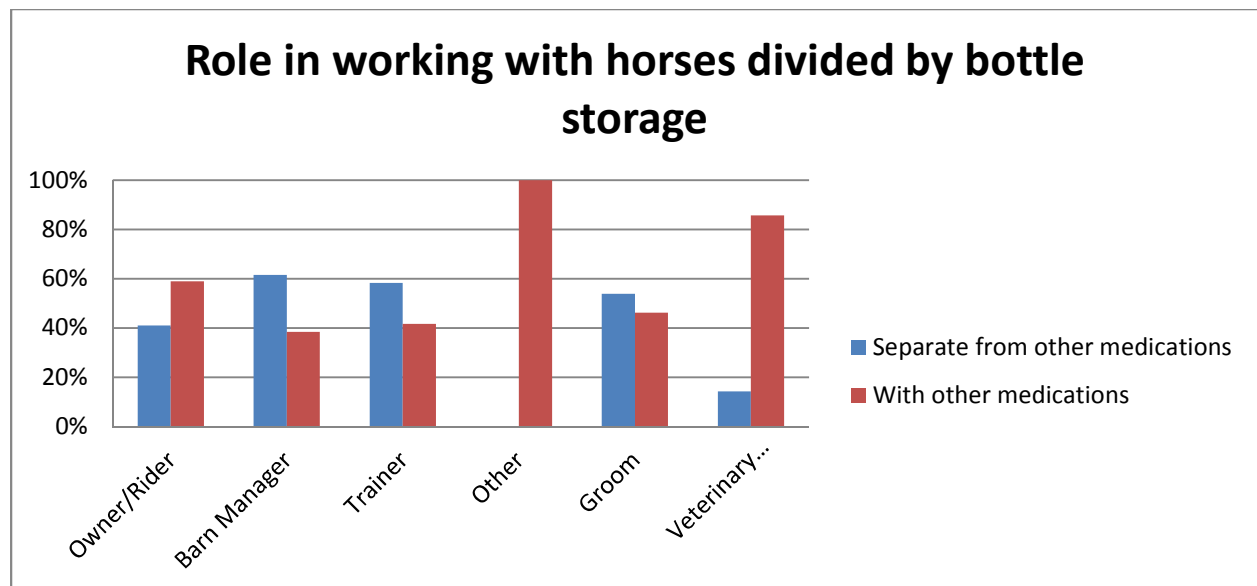


Role x Hand Washing				
Values	Column Labels		Grand Total	
	No	Yes		
Owner/Rider	41%	59%	100%	
Barn Manager	46%	54%	100%	
Trainer	50%	50%	100%	
Other	0%	100%	100%	
Groom	38%	62%	100%	
Veterinary Professional	33%	67%	100%	



Role x Bottle Storage

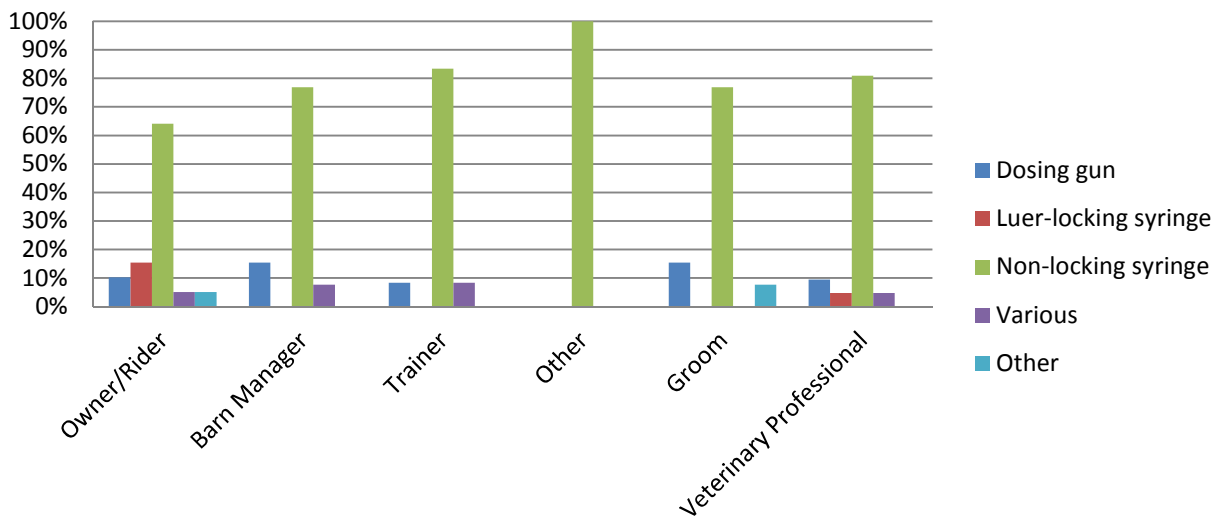
Values	Column Labels		Grand Total
	Separate from other medications	With other medications	
Owner/Rider	41%	59%	100%
Barn Manager	62%	38%	100%
Trainer	58%	42%	100%
Other	0%	100%	100%
Groom	54%	46%	100%
Veterinary Professional	14%	86%	100%



Role x Tool Use

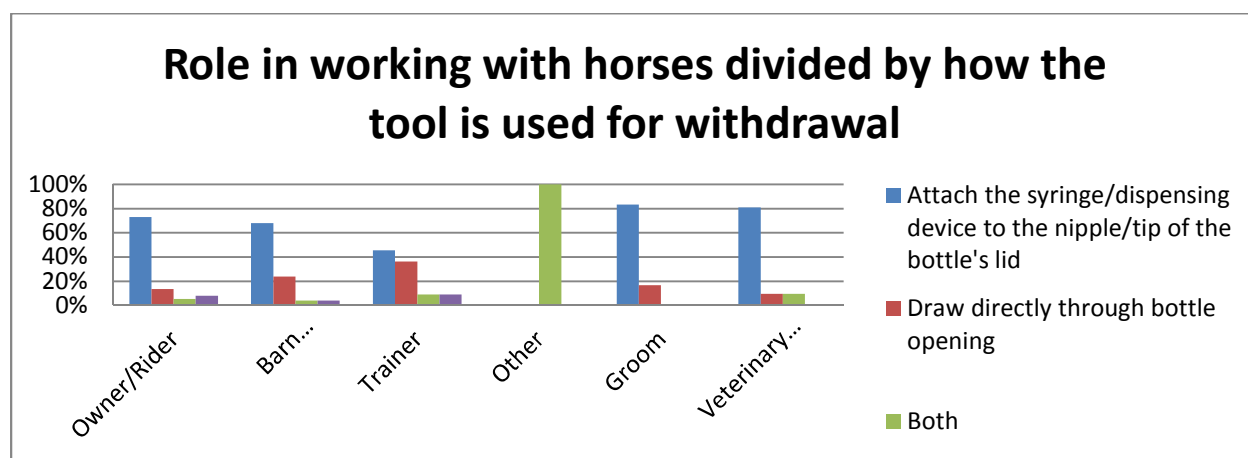
Values	Column Labels					Grand Total
	Dosing gun	Luer-locking syringe	Non-locking syringe	Various	Other	
Owner/Rider	10%	15%	64%	5%	5%	100%
Barn Manager	15%	0%	77%	8%	0%	100%
Trainer	8%	0%	83%	8%	0%	100%
Other	0%	0%	100%	0%	0%	100%
Groom	15%	0%	77%	0%	8%	100%
Veterinary Professional	10%	5%	81%	5%	0%	100%

Role in working with horses divided by tool used for withdrawal



Role x Withdrawal

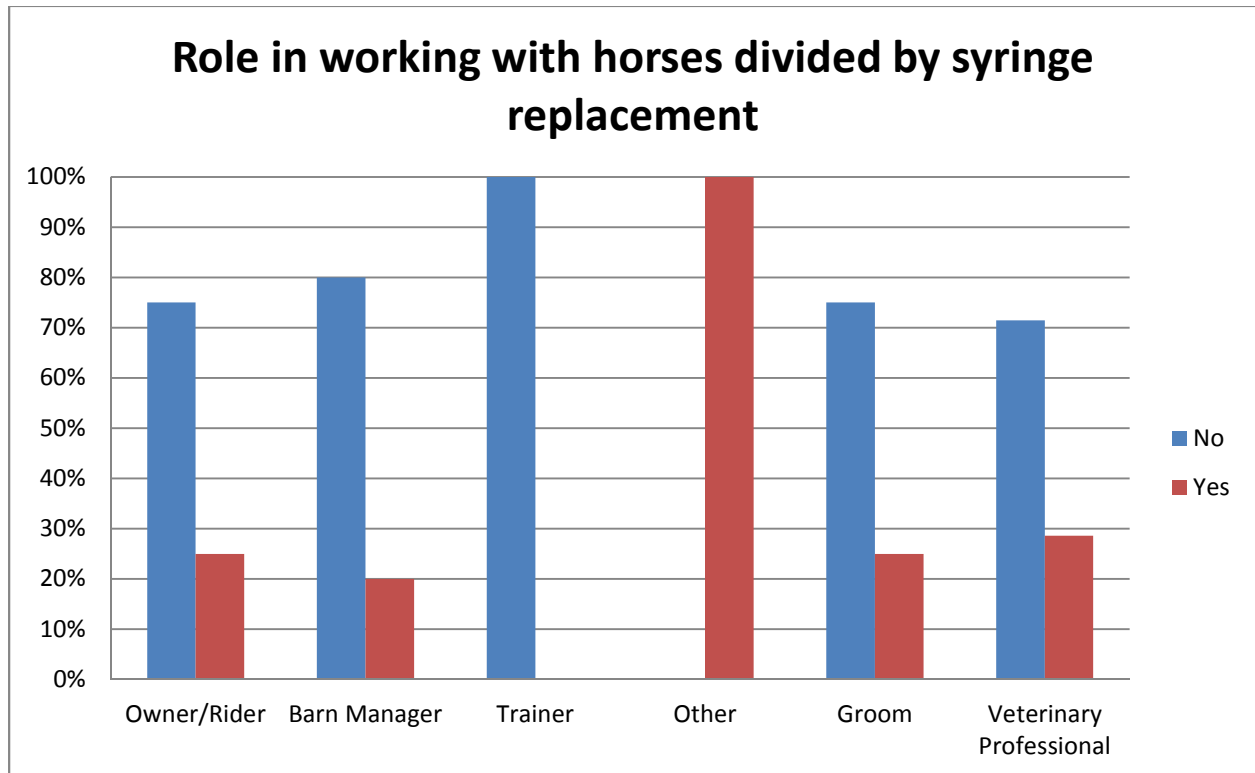
Values	Column Labels				Grand Total
	Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	Draw directly through bottle opening	Both	Other	
Owner/Rider	73%	14%	5%	8%	100%
Barn Manager	68%	24%	4%	4%	100%
Trainer	45%	36%	9%	9%	100%
Other	0%	0%	100%	0%	100%
Groom	83%	17%	0%	0%	100%
Veterinary Professional	81%	10%	10%	0%	100%



Role x Syringe
Replacement

Tool (Multiple Items)

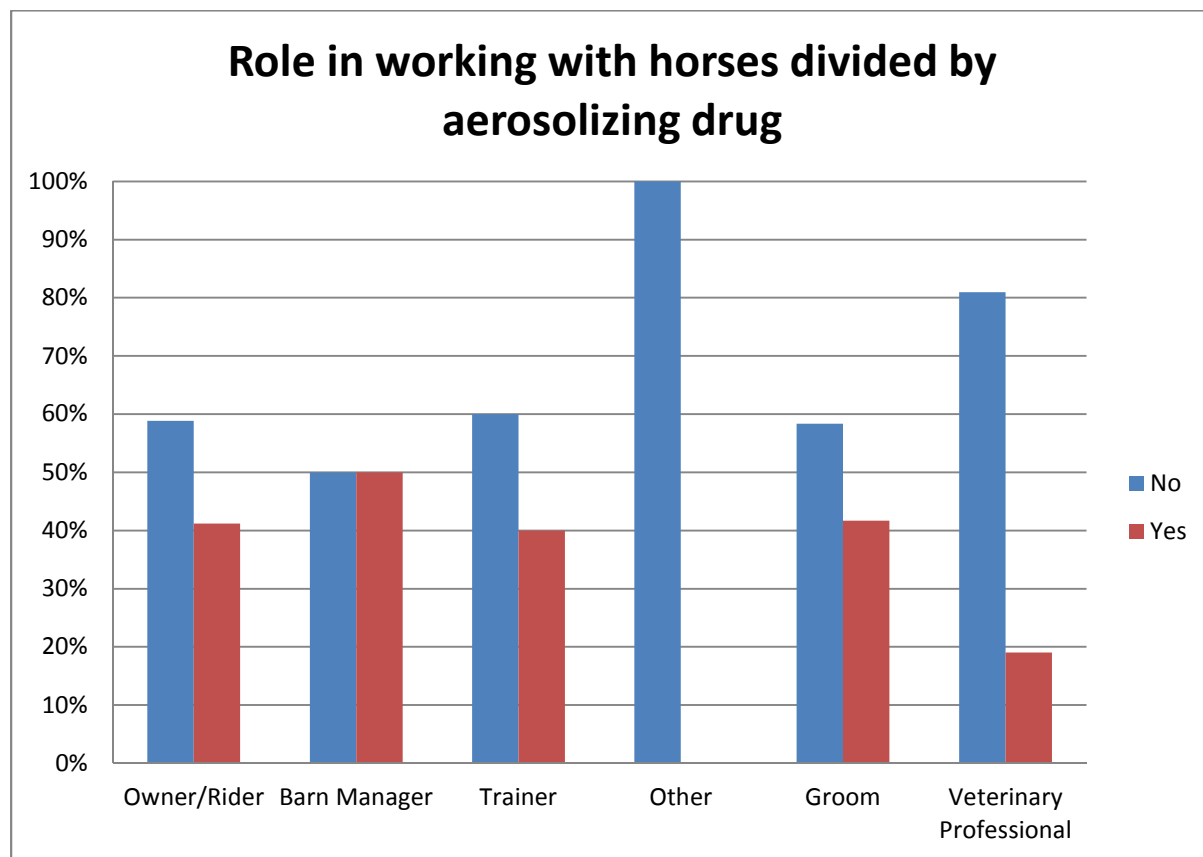
Values	Column Labels		Grand Total
	No	Yes	
Owner/Rider	75%	25%	100%
Barn Manager	80%	20%	100%
Trainer	100%	0%	100%
Other	0%	100%	100%
Groom	75%	25%	100%
Veterinary Professional	71%	29%	100%



Role x Aerosolizing

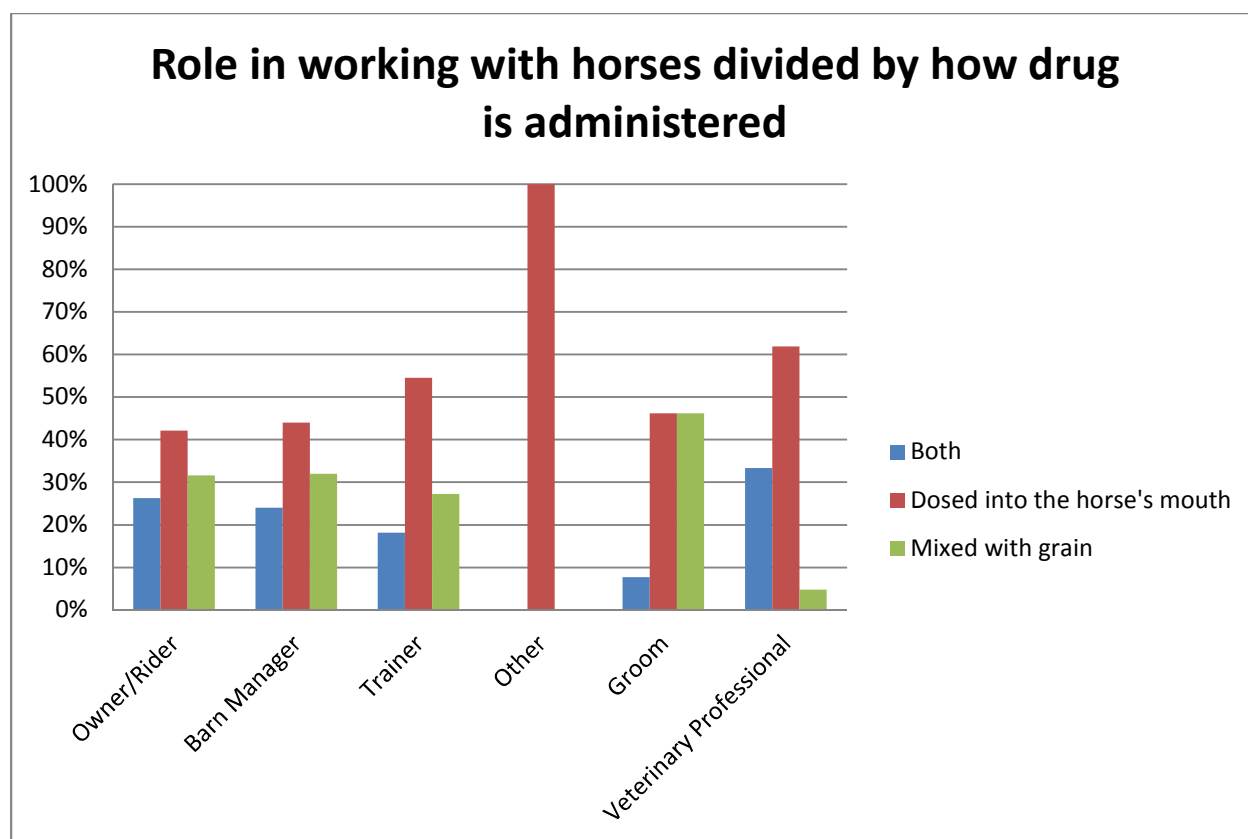
Tool (Multiple Items)

Values	Column Labels		Grand Total
	No	Yes	
Owner/Rider	59%	41%	100%
Barn Manager	50%	50%	100%
Trainer	60%	40%	100%
Other	100%	0%	100%
Groom	58%	42%	100%
Veterinary Professional	81%	19%	100%



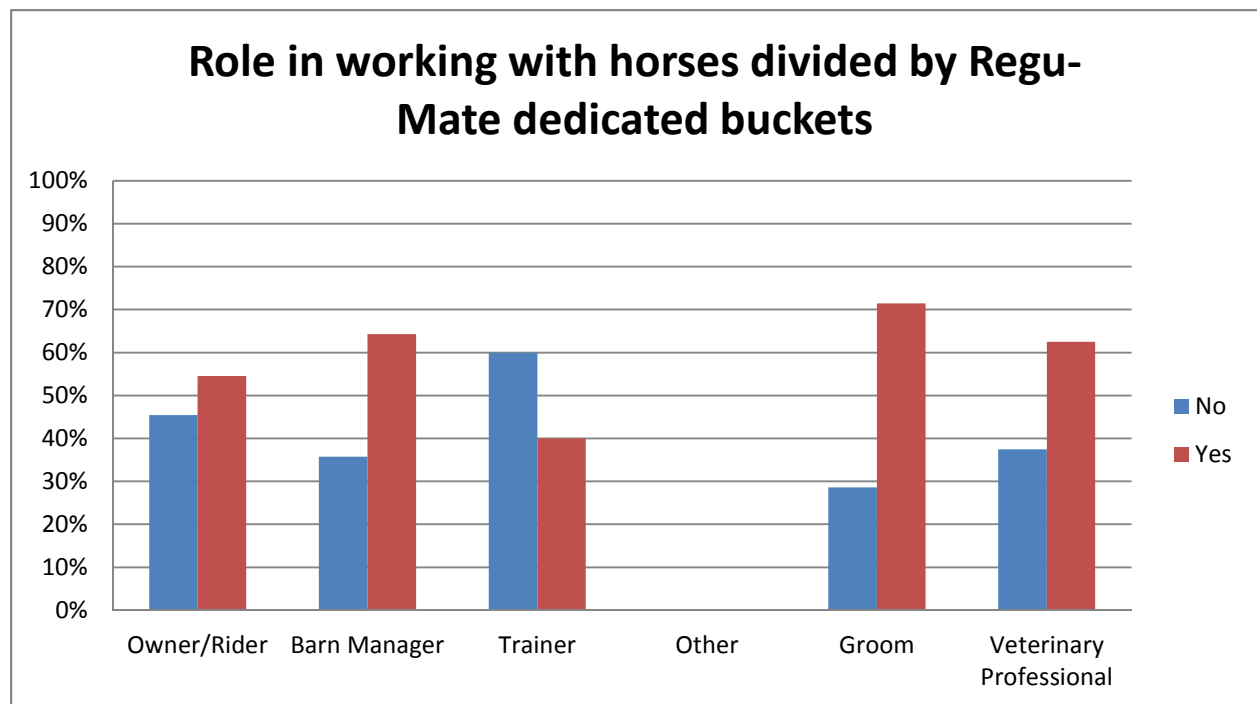
Role x How Dosed

Values	Column Labels				Grand Total
	Both	Dosed into the horse's mouth	Mixed with grain		
Owner/Rider	26%	42%	32%		100%
Barn Manager	24%	44%	32%		100%
Trainer	18%	55%	27%		100%
Other	0%	100%	0%		100%
Groom	8%	46%	46%		100%
Veterinary Professional	33%	62%	5%		100%



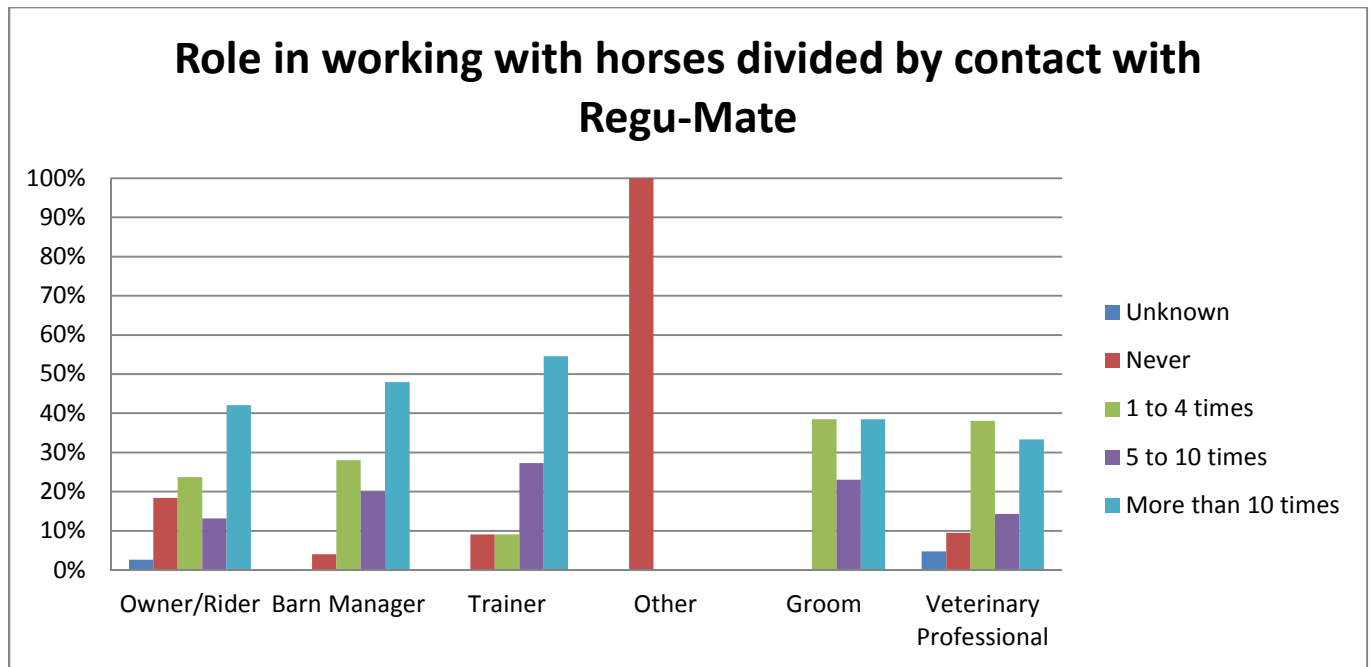
Role x Dedicated Buckets	
Dosage	(Multiple Items)

Values	Column Labels		Grand Total
	No	Yes	
Owner/Rider	45%	55%	100%
Barn Manager	36%	64%	100%
Trainer	60%	40%	100%
Other	0%	0%	0%
Groom	29%	71%	100%
Veterinary Professional	38%	63%	100%



Role x Contact with
Regu-Mate

Values	Column Labels					Grand Total
	Unknown	Never	1 to 4 times	5 to 10 times	More than 10 times	
Owner/Rider	3%	18%	24%	13%	42%	100%
Barn Manager	0%	4%	28%	20%	48%	100%
Trainer	0%	9%	9%	27%	55%	100%
Other	0%	100%	0%	0%	0%	100%
Groom	0%	0%	38%	23%	38%	100%
Veterinary Professional	5%	10%	38%	14%	33%	100%



Role x Where Learned about Regu-Mate

Friends

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	12	9	5		5	1
Grand Total	12	9	5		5	1

Equine Professionals

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	21	19	7		6	8
Grand Total	21	19	7		6	8

Veterinary Professional

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	37	26	12	1	13	20
Grand Total	37	26	12	1	13	20

Internet

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	6	5	3		2	2
Grand Total	6	5	3		2	2

Product Insert

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	8	9	6		4	8
Grand Total	8	9	6		4	8

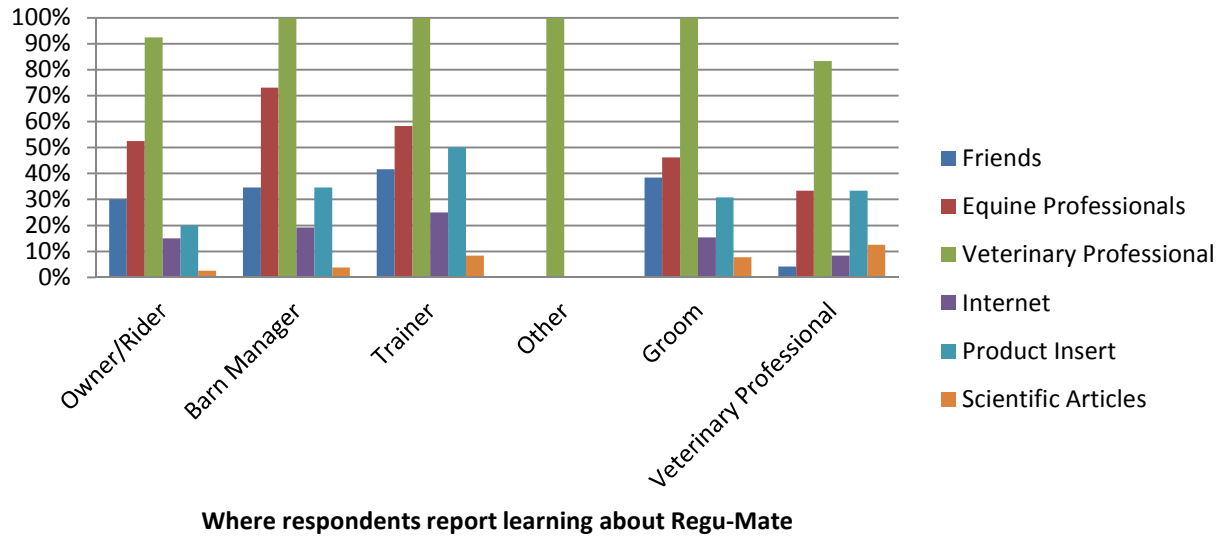
Scientific Articles

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	1	1	1		1	3
Grand Total	1	1	1		1	3

	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
Friends	30%	35%	42%	0%	38%	4%
Equine Professionals	53%	73%	58%	0%	46%	33%
Veterinary Professional	93%	100%	100%	100%	100%	83%
Internet	15%	19%	25%	0%	15%	8%
Product Insert	20%	35%	50%	0%	31%	33%
Scientific Articles	3%	4%	8%	0%	8%	13%

Percent of those that report a role with horses who learn about Regu-Mate from a specific source

Role with horses divided by where learned about Regu-Mate



Role x Education from Veterinarian

Storage

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	26	15	9	1	8	15
Grand Total	26	15	9	1	8	15

Gloves

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional

TRUE	35	21	11	1	11	19
Grand Total	35	21	11	1	11	19

Skin

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	37	24	11	1	12	20
Grand Total	37	24	11	1	12	20

Washing Hands

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	27	15	8	1	6	18
Grand Total	27	15	8	1	6	18

Dedicated Buckets

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	10	4	2		2	4
Grand Total	10	4	2		2	4

Aerosolizing

Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
TRUE	9	4	2		1	5
Grand Total	9	4	2		1	5

No Discussion

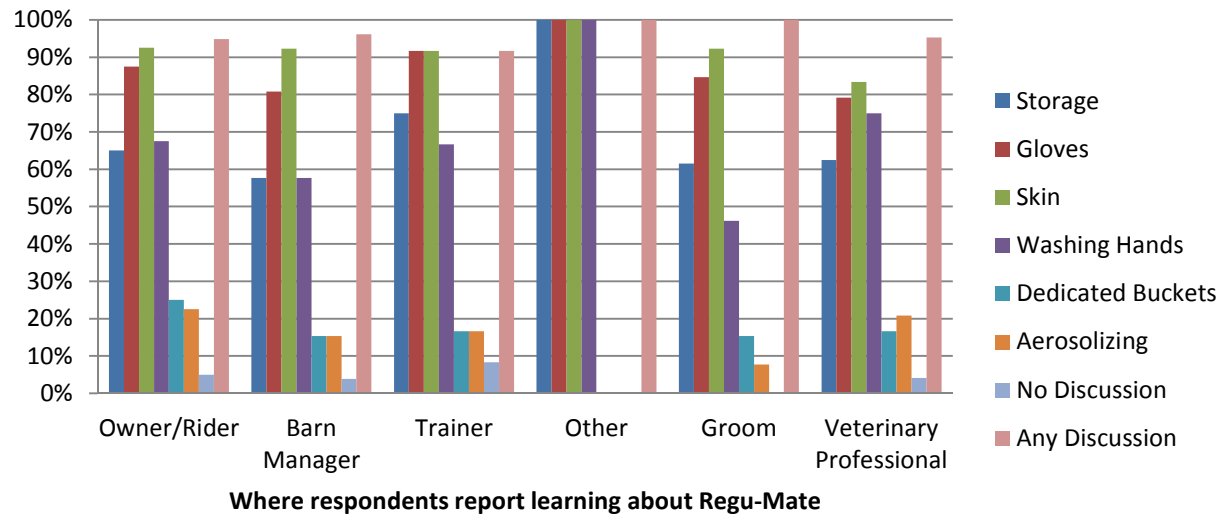
Row Labels	Owner/Rider	Barn	Trainer	Other	Groom	Veterinary
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	Manager		Professional	
TRUE	2	1	1	1
Grand Total	2	1	1	1

Education_NR		(Multiple Items)				
Row Labels	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
Discussion With Veterinarian	95%	96%	92%	100%	100%	95%
No Discussion With Veterinarian	5%	4%	8%	0%	0%	5%
Grand Total	100%	100%	100%	100%	100%	100%
	Owner/Rider	Barn Manager	Trainer	Other	Groom	Veterinary Professional
Storage	65%	58%	75%		100%	62%
Gloves	88%	81%	92%		100%	85%
Skin	93%	92%	92%		100%	92%
Washing Hands	68%	58%	67%		100%	46%
Dedicated Buckets	25%	15%	17%		0%	15%
Aerosolizing	23%	15%	17%		0%	8%
No Discussion	5%	4%	8%		0%	0%
Any Discussion	95%	96%	92%		100%	100%

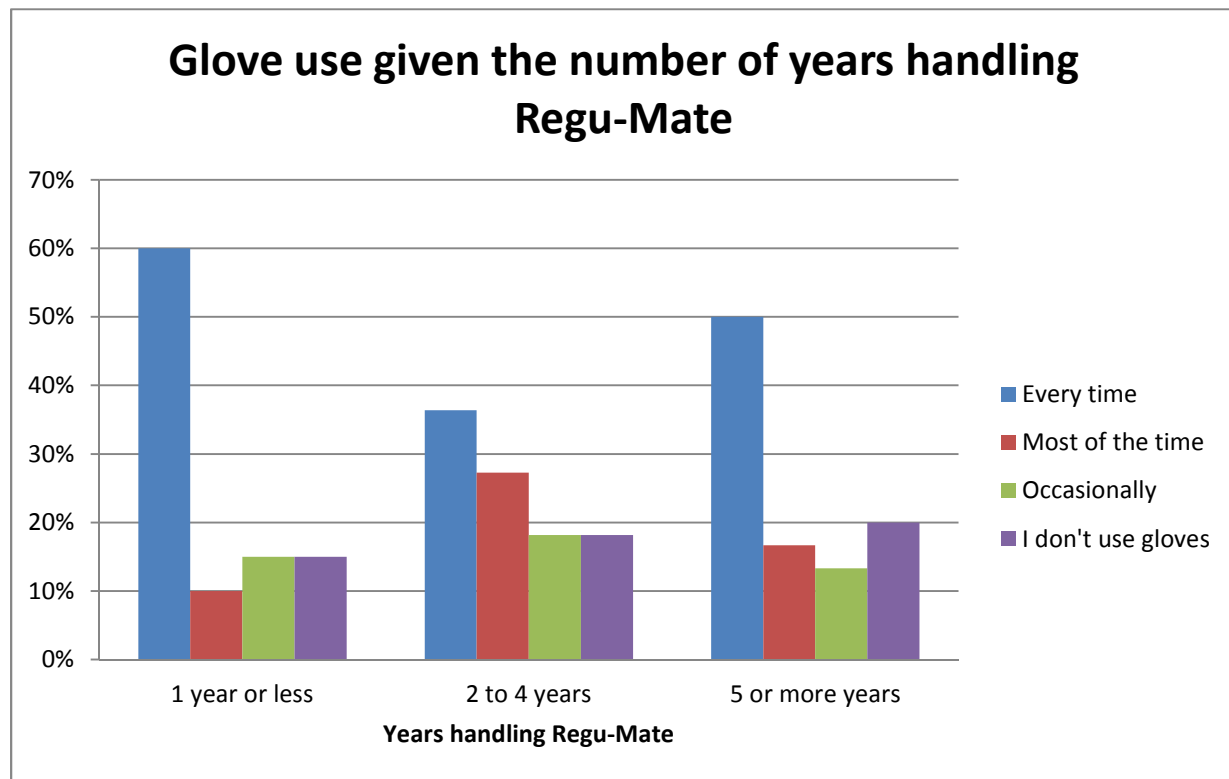
Percent of those that report a role with horses whose vet educated about topics

Role with horses divided by education from veterinary professional



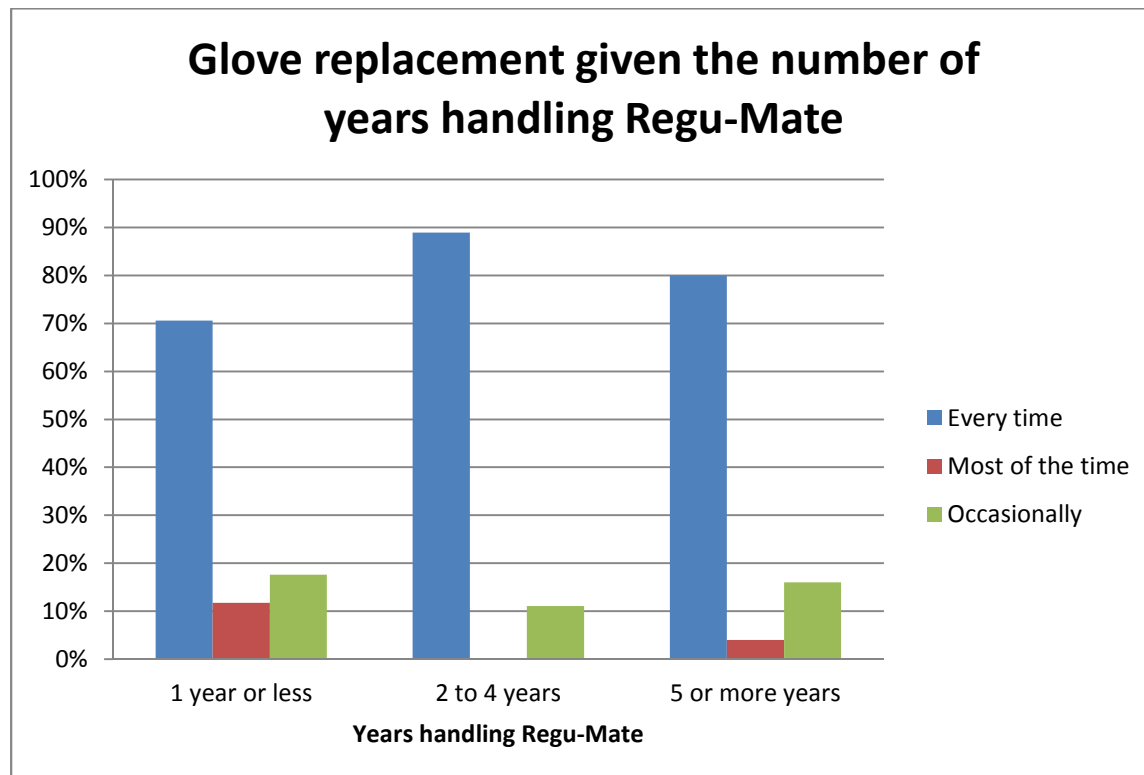
YEARS HANDLING REGU-MATE

Years Handled x Glove use						
Count of YearsHandled	Column Labels					
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total	
1 year or less	60%	10%	15%	15%	100%	
2 to 4 years	36%	27%	18%	18%	100%	
5 or more years	50%	17%	13%	20%	100%	
Grand Total	51%	16%	15%	18%	100%	



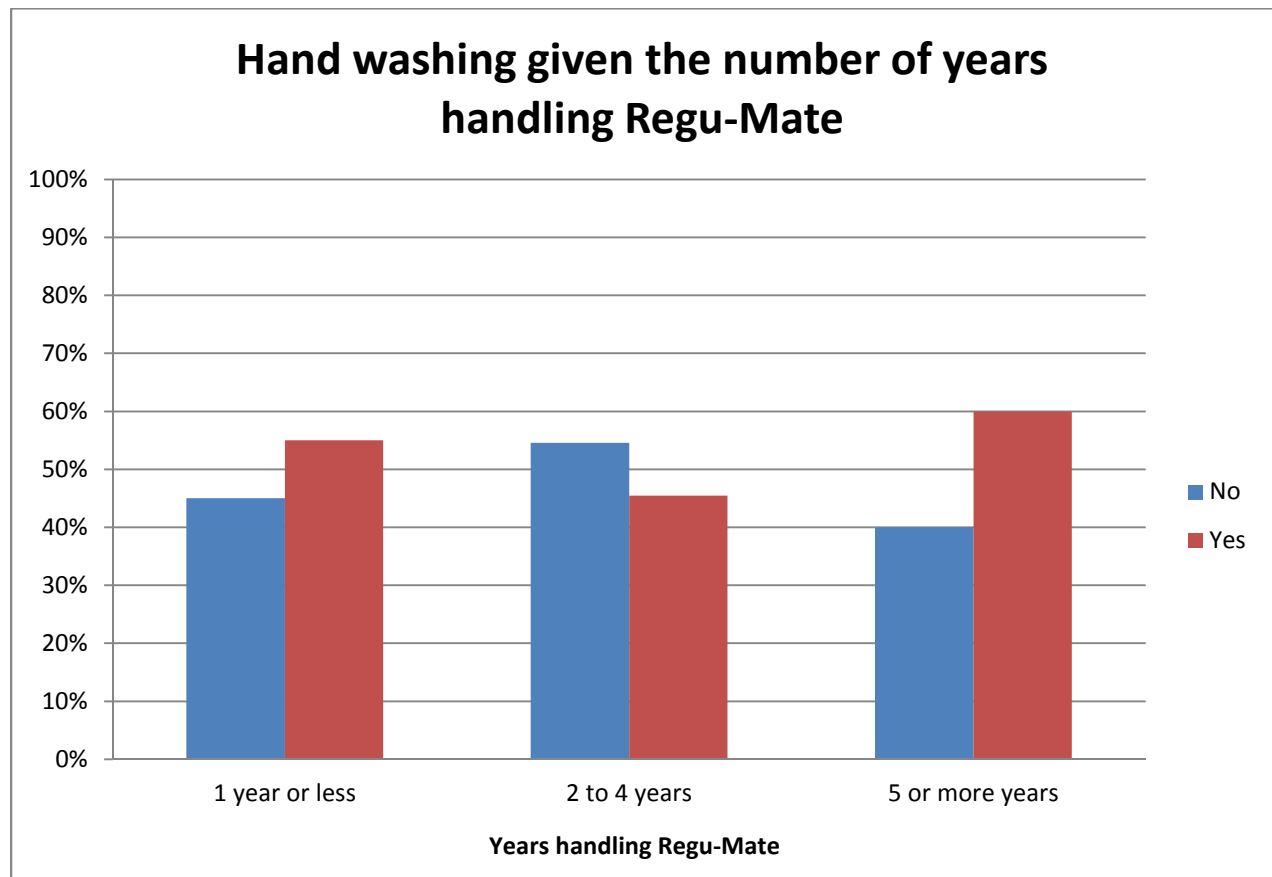
Years Handled x Glove Replacement

Count of YearsHandled	Column Labels			
Row Labels	Every time	Most of the time	Occasionally	Grand Total
1 year or less	71%	12%	18%	100%
2 to 4 years	89%	0%	11%	100%
5 or more years	80%	4%	16%	100%
Grand Total	78%	6%	16%	100%



Years Handled x Hand Washing

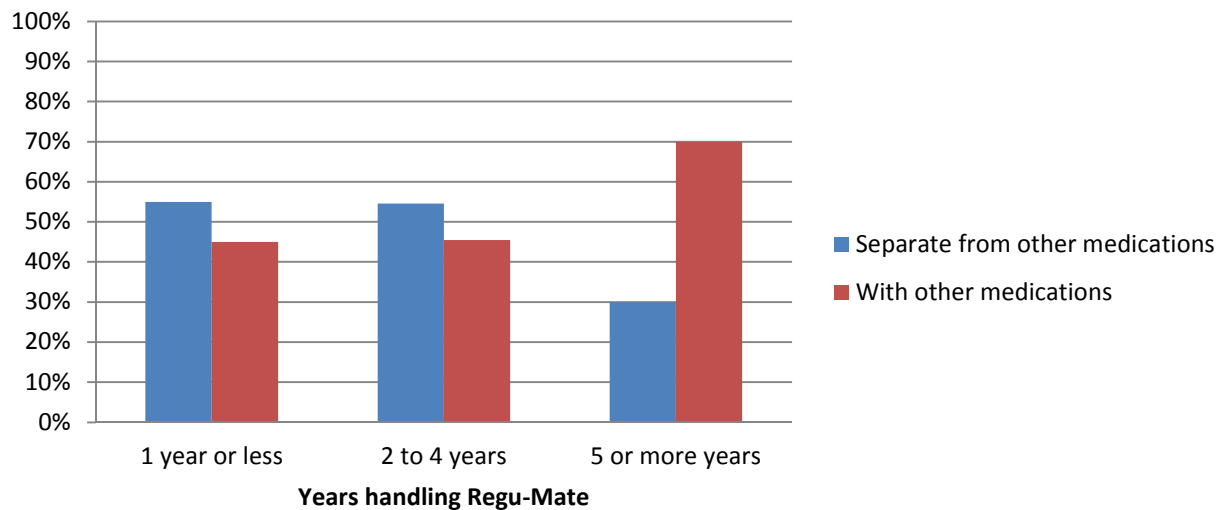
Count of YearsHandled	Column Labels		
Row Labels	No	Yes	Grand Total
1 year or less	45%	55%	100%
2 to 4 years	55%	45%	100%
5 or more years	40%	60%	100%
Grand Total	44%	56%	100%



Years Handled x Bottle Storage

Count of YearsHandled	Column Labels		Grand Total
Row Labels	Separate from other medications	With other medications	
1 year or less	55%	45%	100%
2 to 4 years	55%	45%	100%
5 or more years	30%	70%	100%
Grand Total	43%	57%	100%

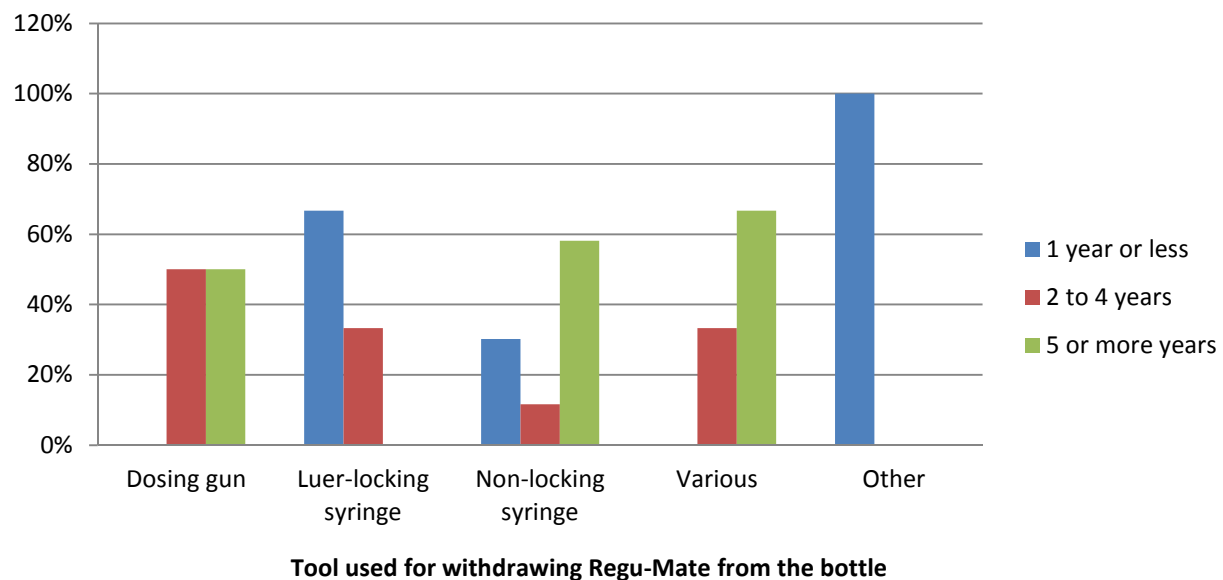
Location of Regu-Mate bottle storage given the number of years handling Regu-Mate



Years Handled x Tool Use

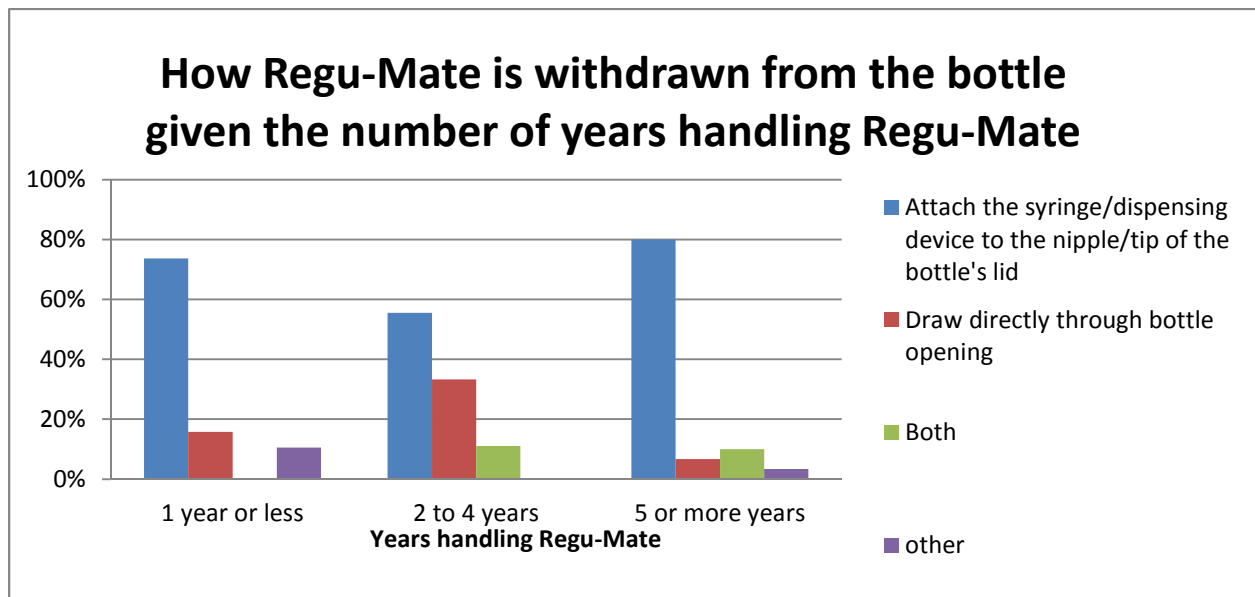
Count of YearsHandled	Column Labels			
Row Labels	1 year or less	2 to 4 years	5 or more years	Grand Total
Dosing gun	0%	50%	50%	100%
Luer-locking syringe	67%	33%	0%	100%
Non-locking syringe	30%	12%	58%	100%
Various	0%	33%	67%	100%
Other	100%	0%	0%	100%
Grand Total	33%	18%	49%	100%

The number of years handling Regu-Mate for each reported type of tool



Years Handled x Withdrawal

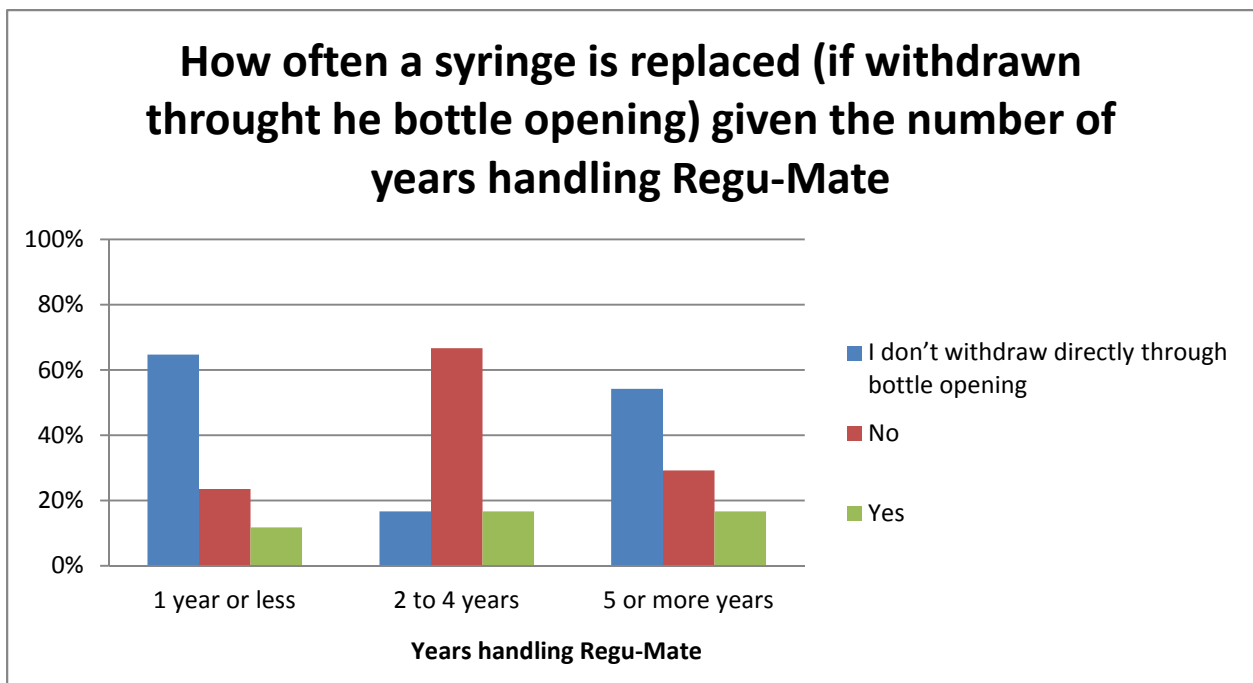
Count of YearsHandled	Column Labels				
Row Labels	Attach the syringe/dispensin g device to the nipple/tip of the bottle's lid	Draw directly through bottle opening	Both	other	Grand Total
1 year or less	74%	16%	0%	11%	100%
2 to 4 years	56%	33%	11%	0%	100%
5 or more years	80%	7%	10%	3%	100%
Grand Total	74%	14%	7%	5%	100%



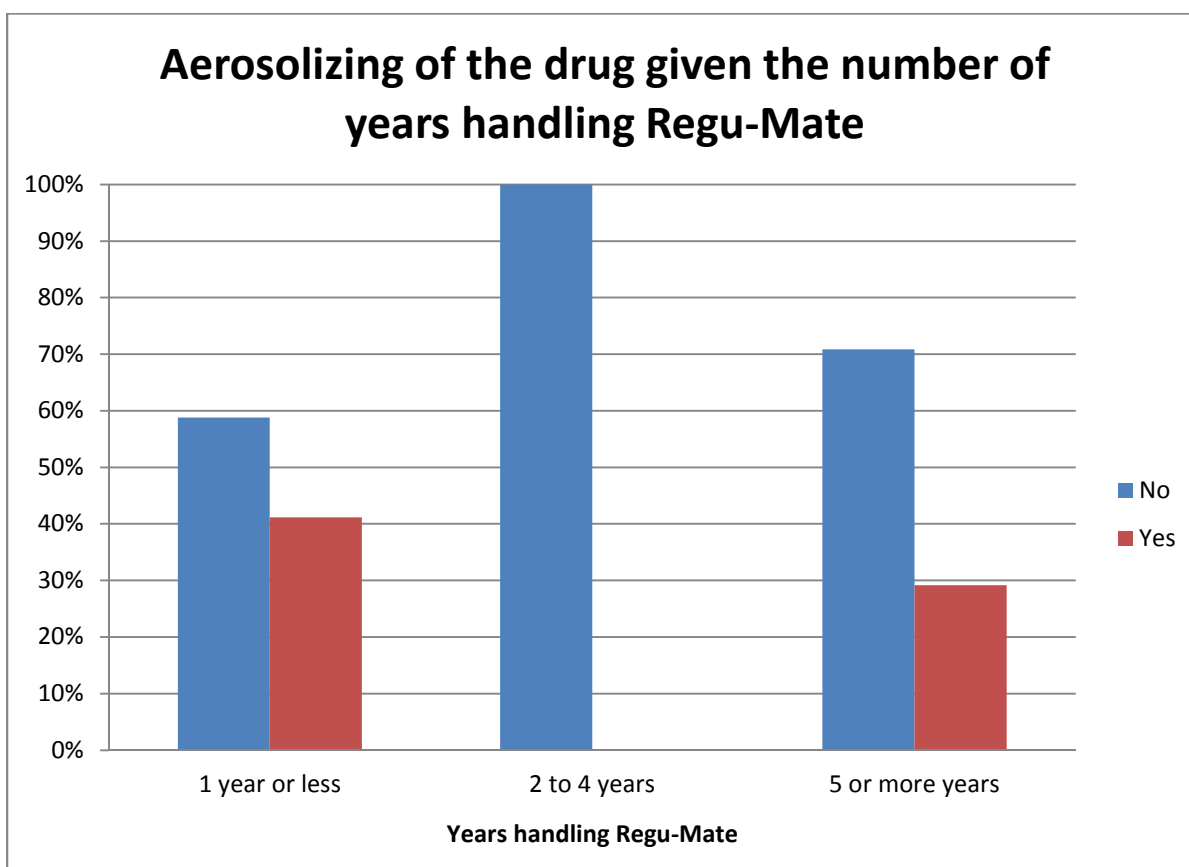
Tool (Multiple Items)

Years Handled x
syringe replacement

Count of YearsHandled	Column Labels				
Row Labels	I don't withdraw directly through bottle opening	I don't withdraw directly through bottle opening		Grand Total	
		No	Yes		
1 year or less		65%	24%	12%	100%
2 to 4 years		17%	67%	17%	100%
5 or more years		54%	29%	17%	100%
Grand Total		53%	32%	15%	100%

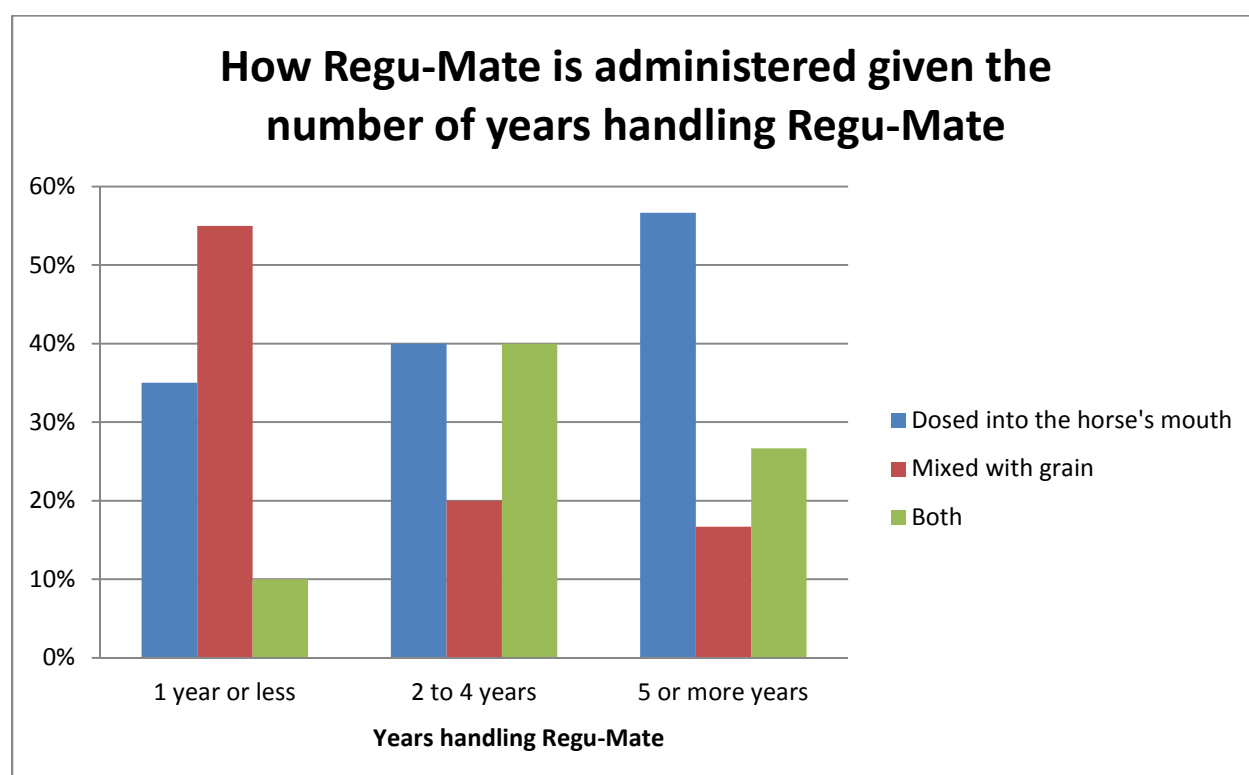


Years Handled x Aerosolize Count of YearsHandled		Column Labels		Grand Total
Row Labels	No	Yes		
1 year or less	59%	41%	100%	
2 to 4 years	100%	0%	100%	
5 or more years	71%	29%	100%	
Grand Total	70%	30%	100%	



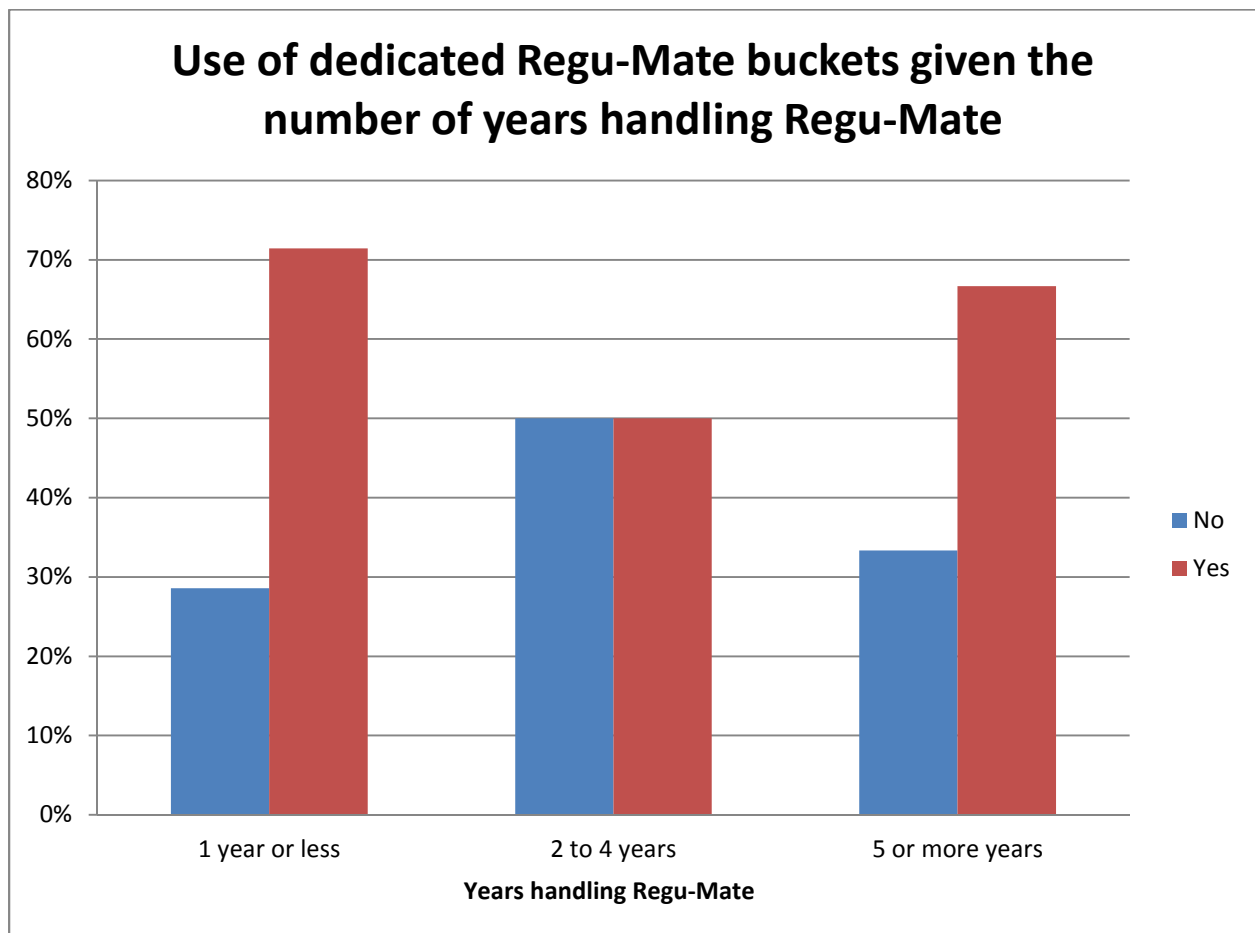
Years Handled x
administered

Count of YearsHandled	Column Labels			
	Dosed into the horse's mouth	Mixed with grain	Both	Grand Total
Row Labels				
1 year or less	35%	55%	10%	100%
2 to 4 years	40%	20%	40%	100%
5 or more years	57%	17%	27%	100%
Grand Total	47%	30%	23%	100%



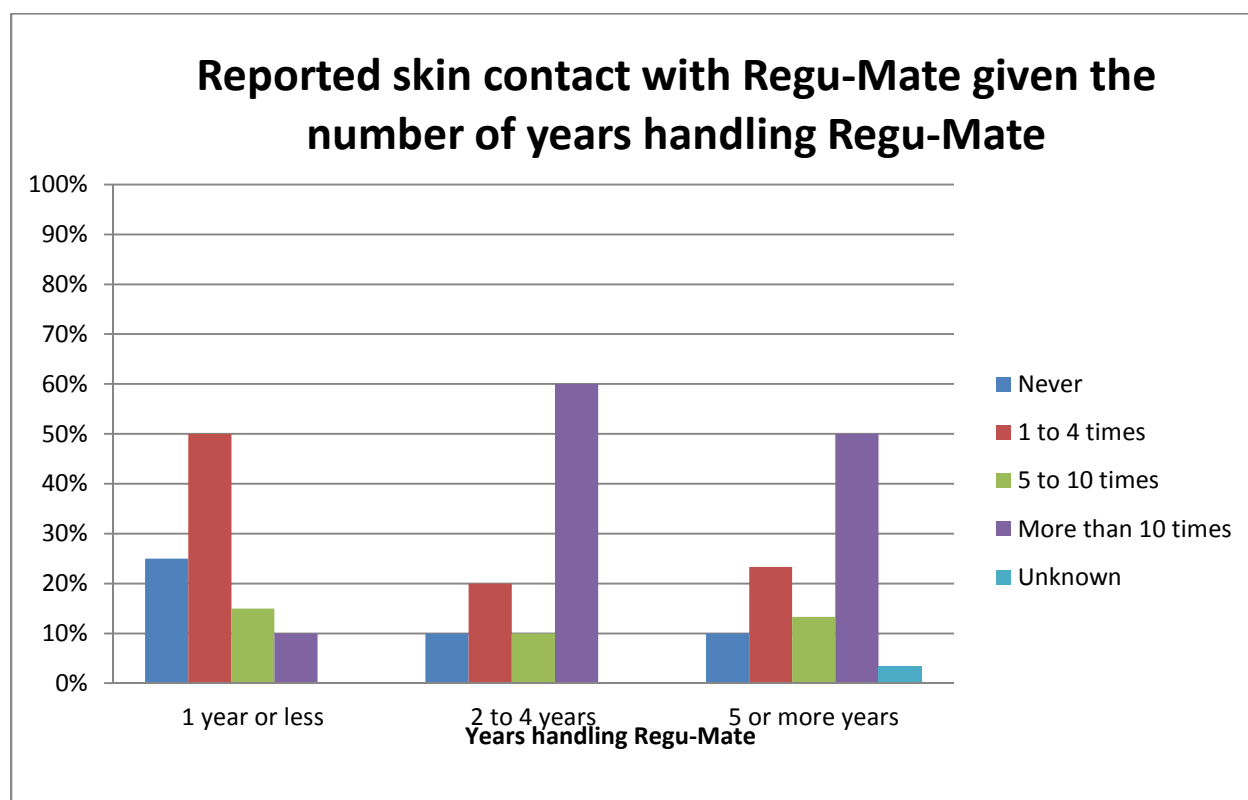
Years Handled x
Dedicated Buckets

Count of YearsHandled	Column Labels		
Row Labels	No	Yes	Grand Total
1 year or less	29%	71%	100%
2 to 4 years	50%	50%	100%
5 or more years	33%	67%	100%
Grand Total	34%	66%	100%



Years Handled x
Contact

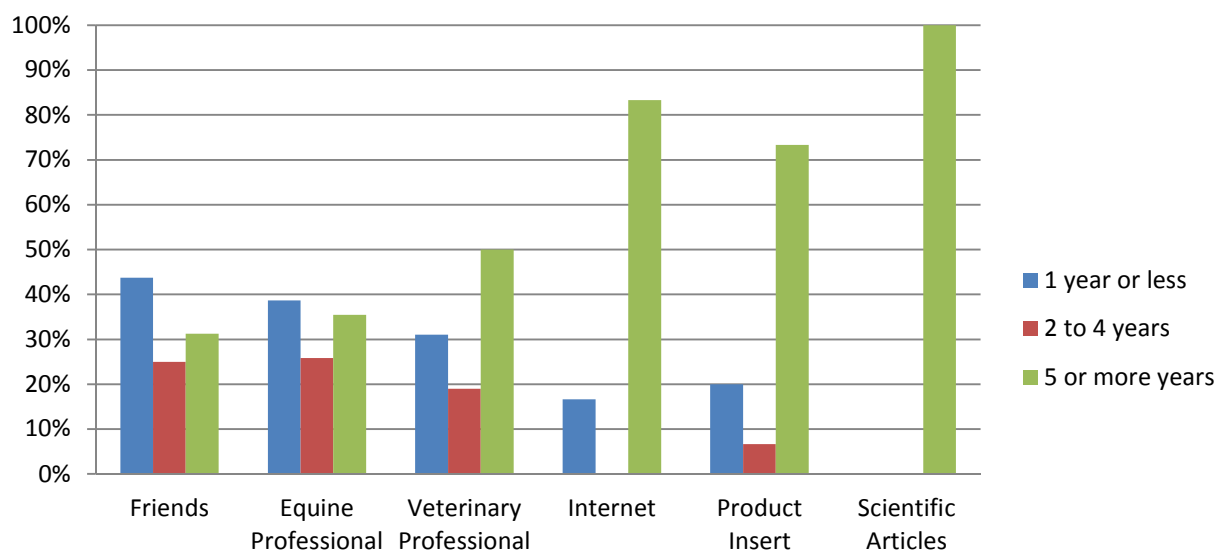
Count of YearsHandled	Column Labels					
Row Labels	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total
1 year or less	25%	50%	15%	10%	0%	100%
2 to 4 years	10%	20%	10%	60%	0%	100%
5 or more years	10%	23%	13%	50%	3%	100%
Grand Total	15%	32%	13%	38%	2%	100%



Years handled x Learn

Values	Column Labels			Grand Total
	1 year or less	2 to 4 years	5 or more years	
Friends	44%	25%	31%	100%
Equine Professional	39%	26%	35%	100%
Veterinary Professional	31%	19%	50%	100%
Internet	17%	0%	83%	100%
Product Insert	20%	7%	73%	100%
Scientific Articles	0%	0%	100%	100%

How respondents learned about Regu-Mate precautions broken down by the number of years handling Regu-Mate

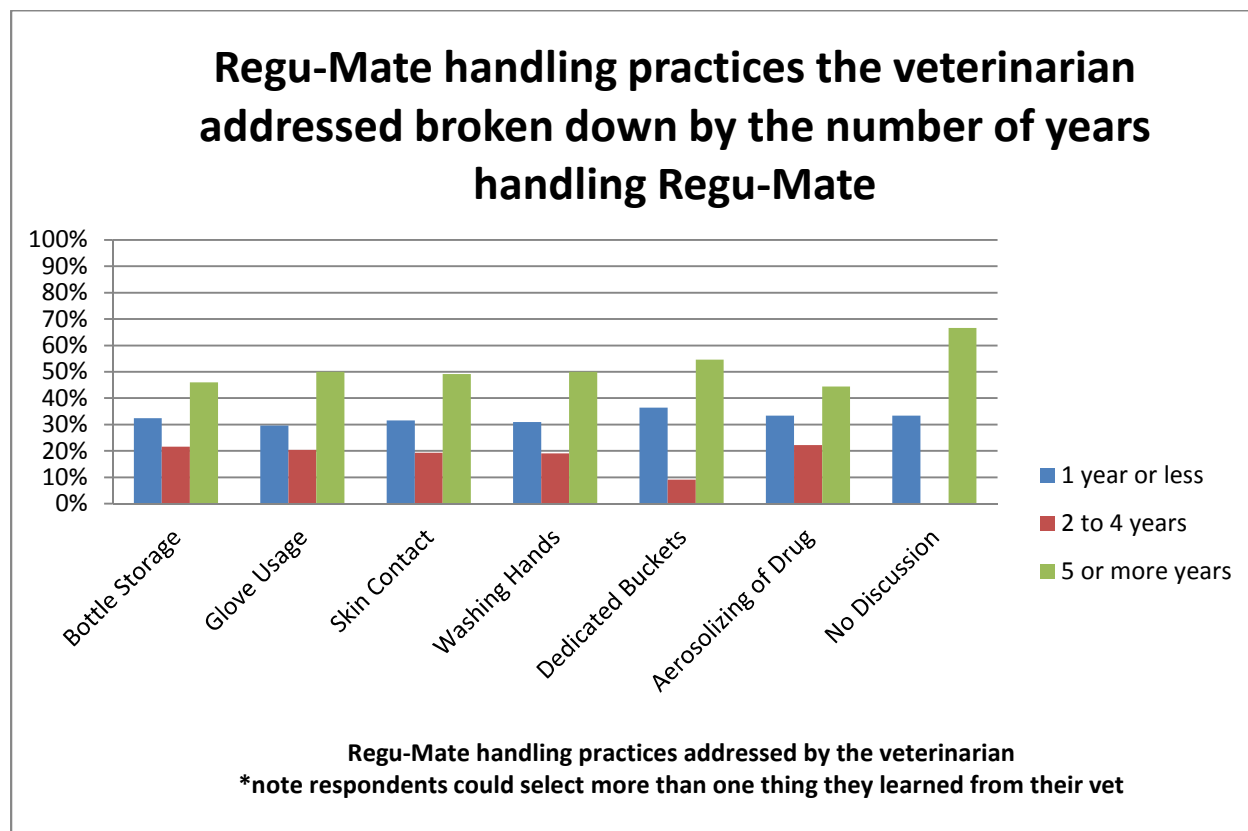


How respondent learned about Regu-Mate

*note respondents could select more than one way they learn about Regu-Mate

Years Handled x
Education

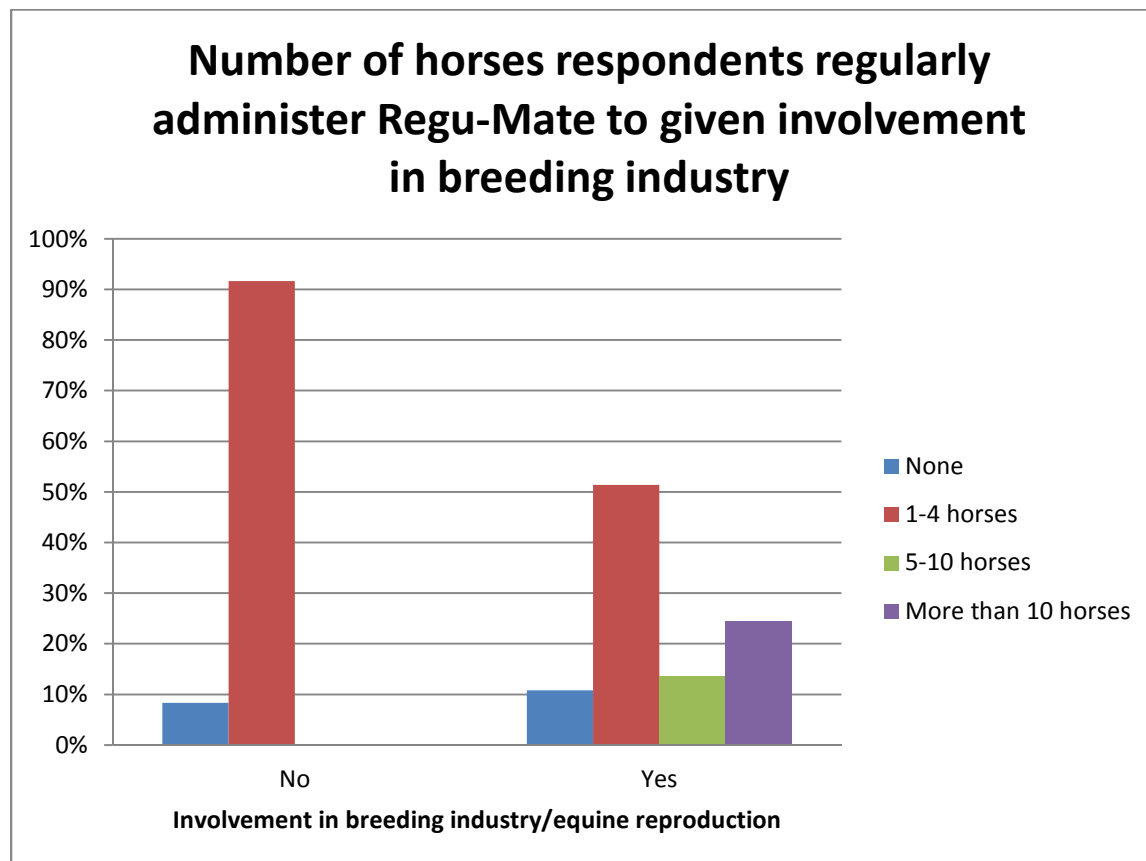
	Column Labels			
Values	1 year or less	2 to 4 years	5 or more years	Grand Total
Bottle Storage	32%	22%	46%	100%
Glove Usage	30%	20%	50%	100%
Skin Contact	32%	19%	49%	100%
Washing Hands	31%	19%	50%	100%
Dedicated Buckets	36%	9%	55%	100%
Aerosolizing of Drug	33%	22%	44%	100%
No Discussion	33%	0%	67%	100%



BREEDING INDUSTRY

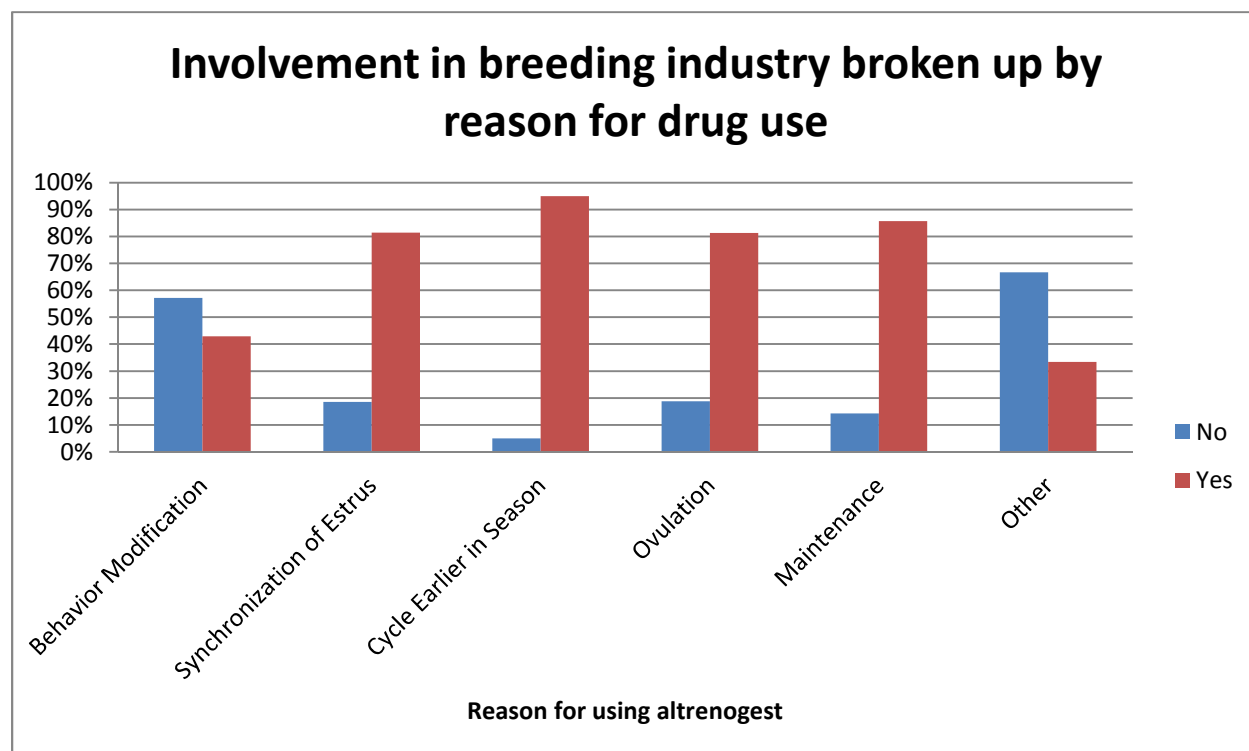
Involved in Breeding Industry

Count of Breeder	Column Labels				
Row Labels	None	1-4 horses	5-10 horses	More than 10 horses	Grand Total
No	8%	92%	0%	0%	100%
Yes	11%	51%	14%	24%	100%
Grand Total	10%	67%	8%	15%	100%



Involved in Breeding Industry

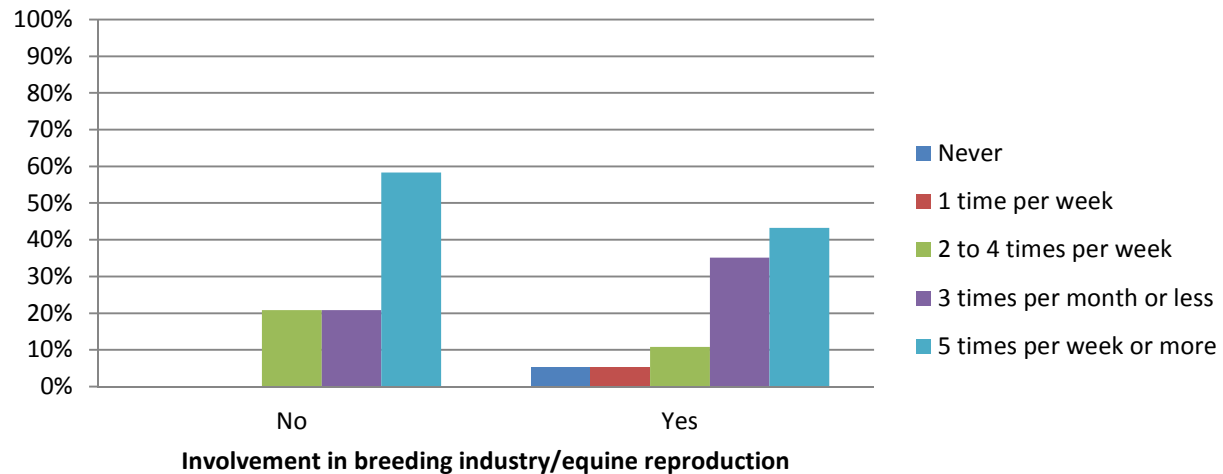
Values	Column Labels		
	No	Yes	Grand Total
Behavior Modification	57%	43%	100%
Synchronization of Estrus	19%	81%	100%
Cycle Earlier in Season	5%	95%	100%
Ovulation	19%	81%	100%
Maintenance	14%	86%	100%
Other	67%	33%	100%



Involved in Breeding Industry

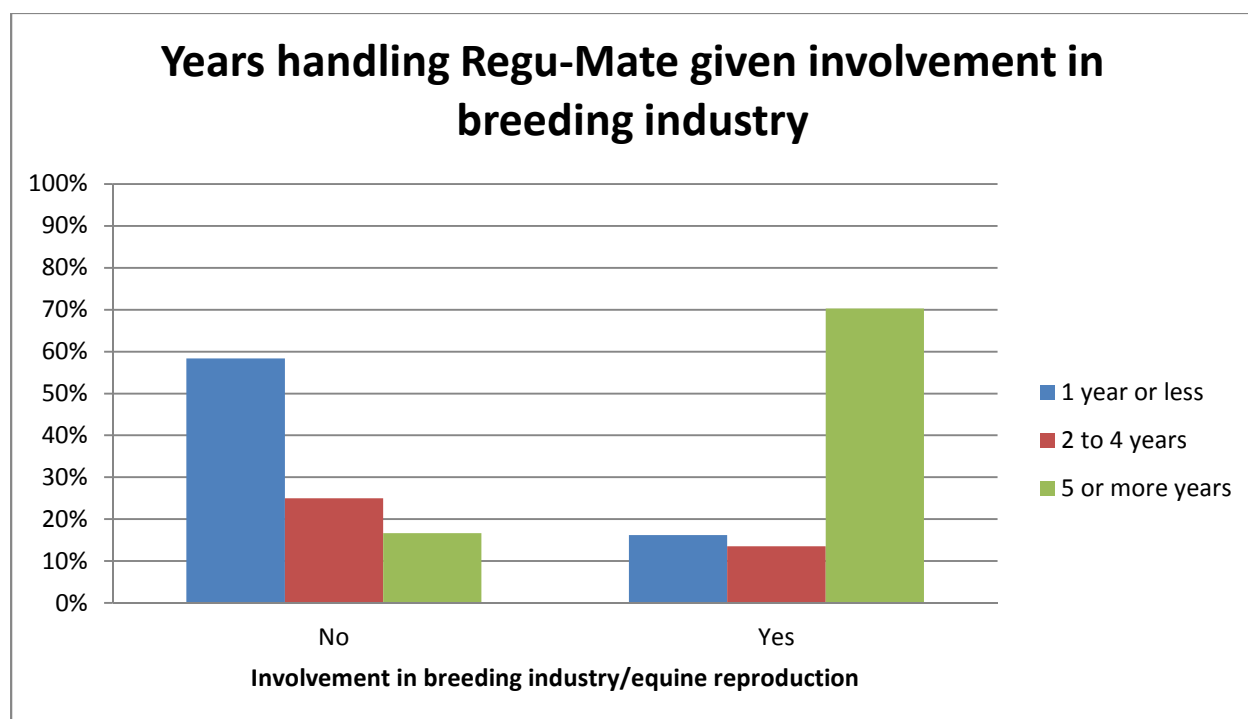
Count of Breeder	Column Labels					
Row Labels	Never	1 time per week	2 to 4 times per week	3 times per month or less	5 times per week or more	Grand Total
No	0%	0%	21%	21%	58%	100%
Yes	5%	5%	11%	35%	43%	100%
Grand Total	3%	3%	15%	30%	49%	100%

Involved in breeding industry broken up by how often handled

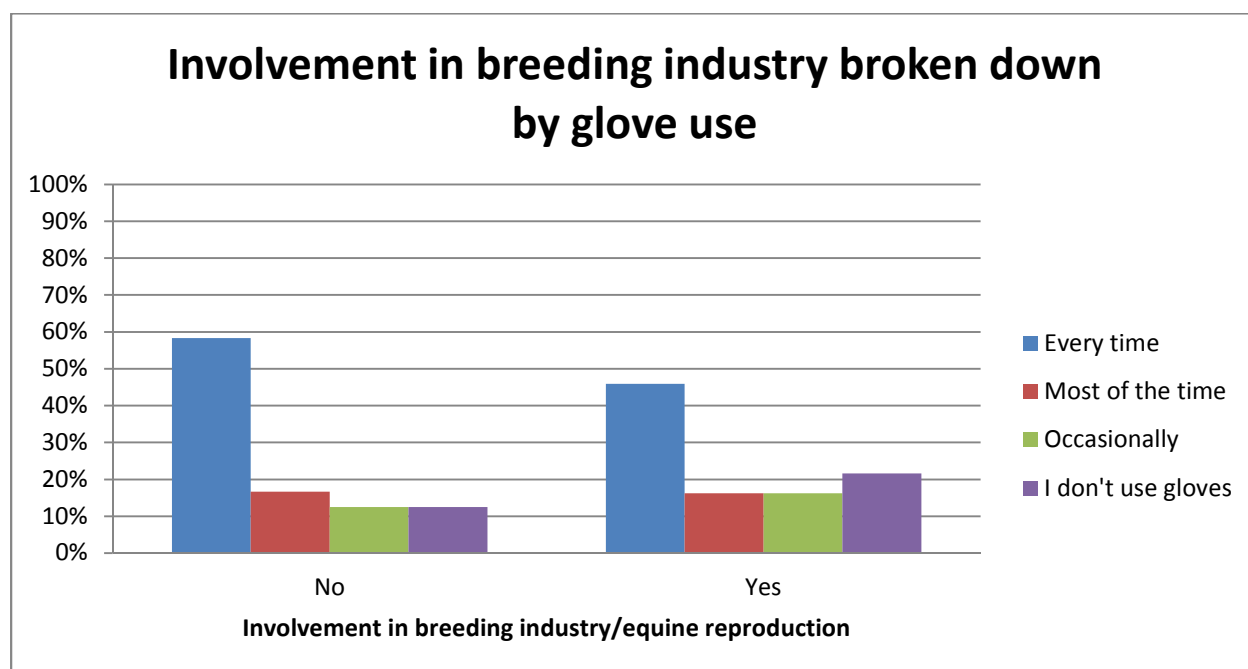


Involved in Breeding Industry

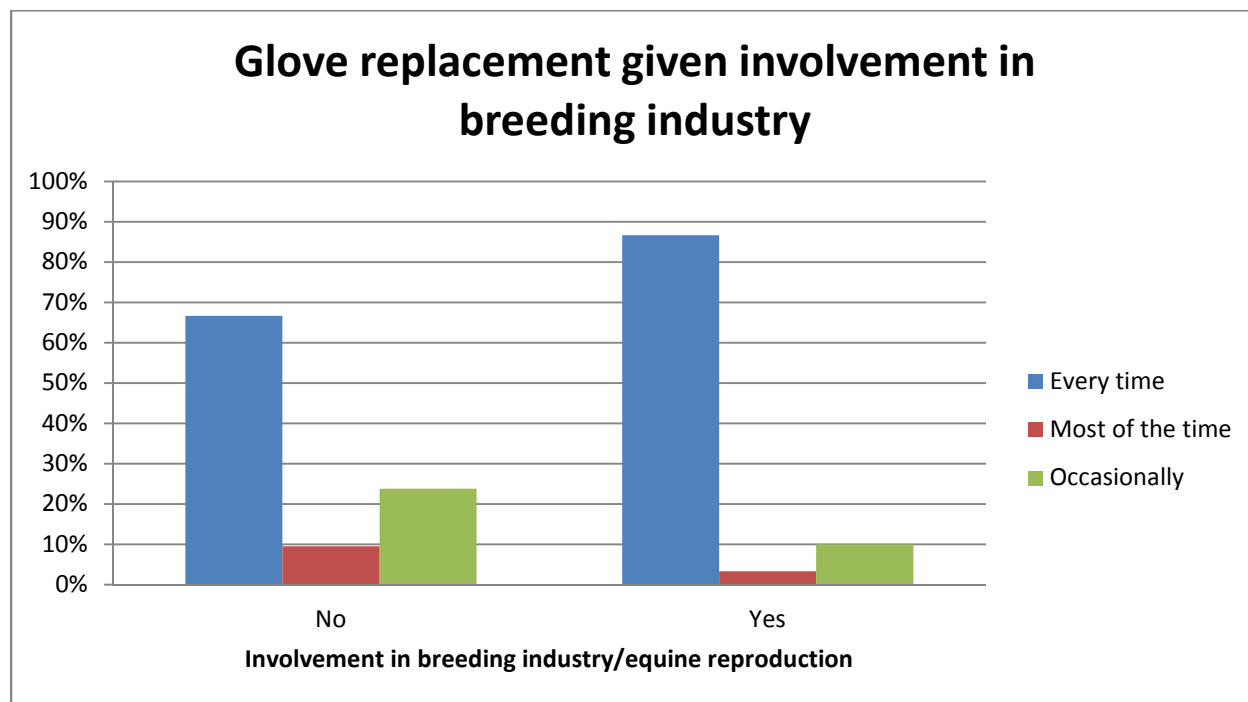
Count of Breeder	Column Labels			
Row Labels	1 year or less	2 to 4 years	5 or more years	Grand Total
No	58%	25%	17%	100%
Yes	16%	14%	70%	100%
Grand Total	33%	18%	49%	100%



Count of Breeder	Involved in Breeding Industry					Grand Total
	Column Labels					
Row Labels	Every time	I don't use gloves	Most of the time	Occasionally		
No	58%	13%	17%	13%		100%
Yes	46%	22%	16%	16%		100%
Grand Total	51%	18%	16%	15%		100%



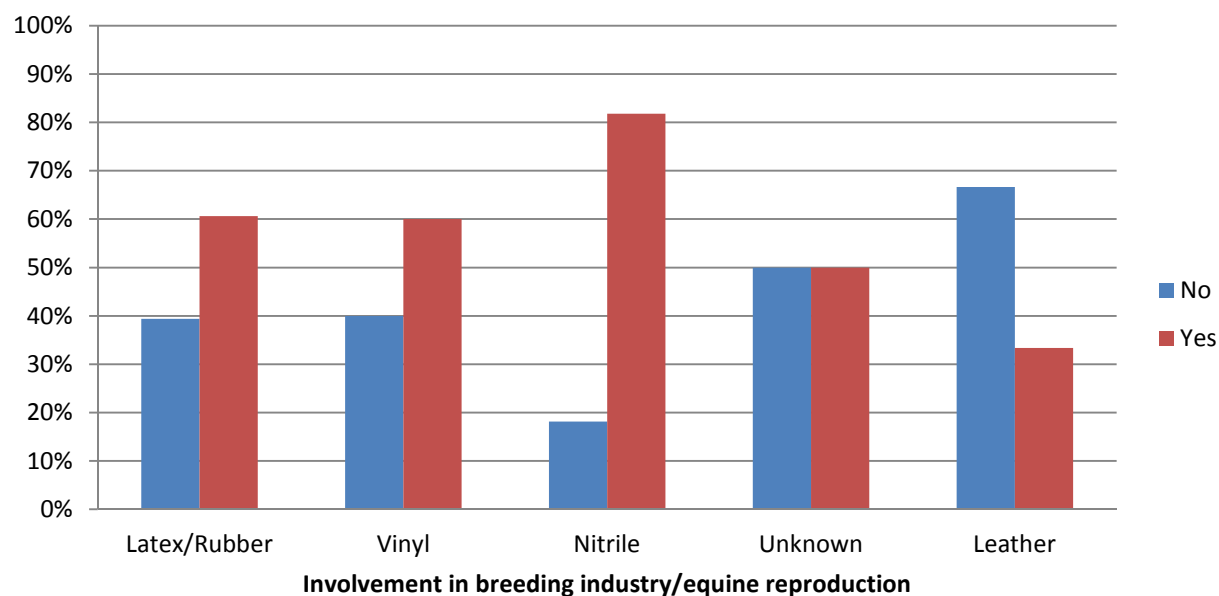
Count of Breeder	Involved in Breeding Industry			Grand Total
	Column Labels	Most of the time	Occasionally	
Row Labels	Every time			
No	67%	10%	24%	100%
Yes	87%	3%	10%	100%
Grand Total	78%	6%	16%	100%



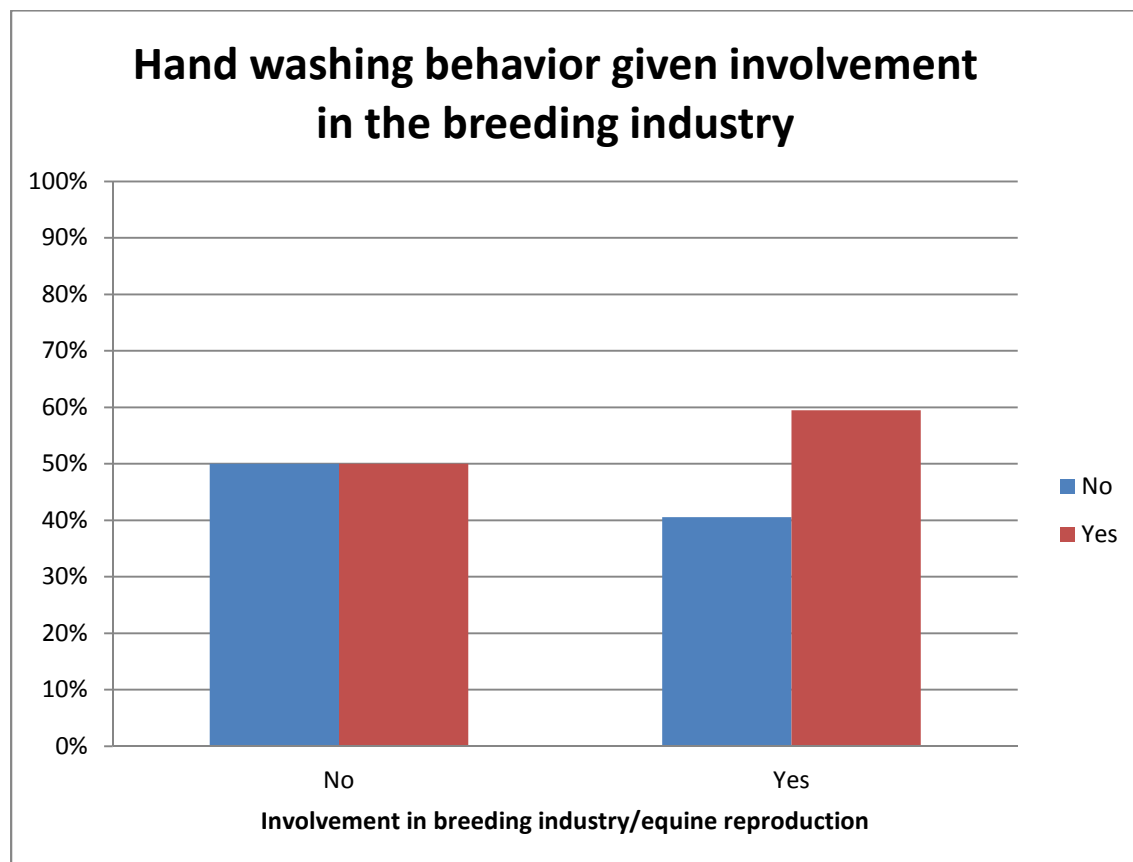
Involved in Breeding Industry

Values	Column Labels		Grand Total
	No	Yes	
Latex/Rubber	39%	61%	100%
Vinyl	40%	60%	100%
Nitrile	18%	82%	100%
Unknown	50%	50%	100%
Leather	67%	33%	100%

Types of gloves used broken down by involvement in the breeding industry

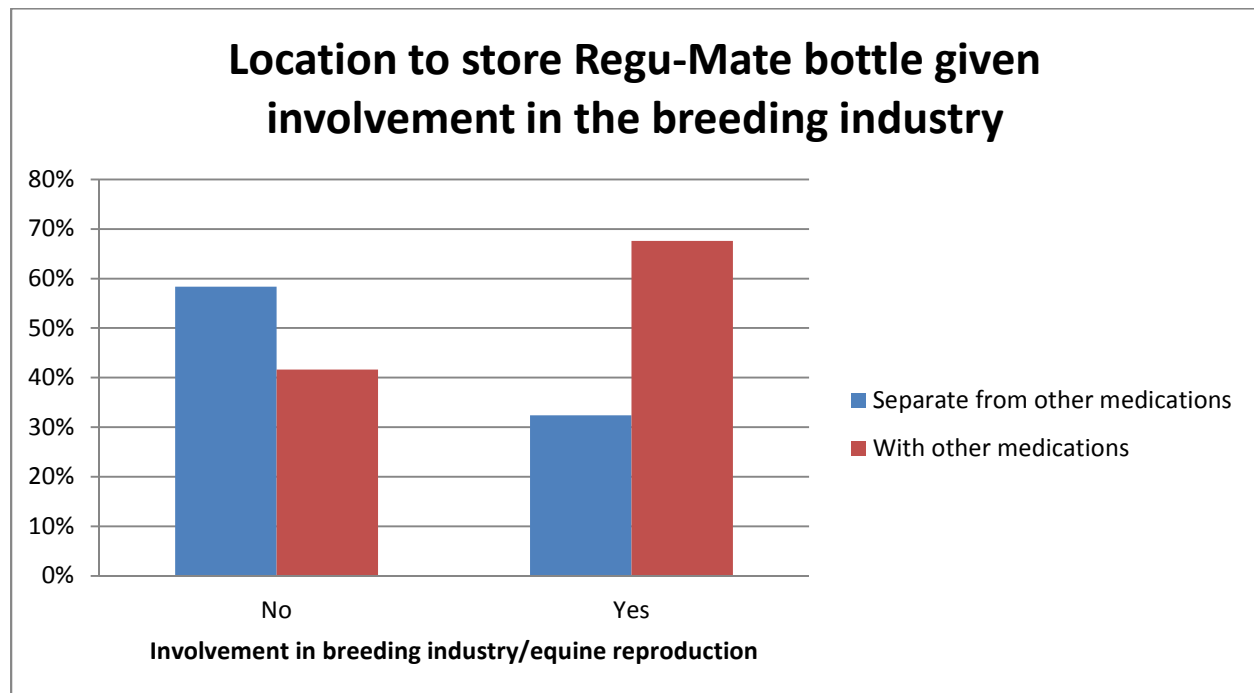


Involved in Breeding Industry				
Count of Breeder	Column Labels			Grand Total
Row Labels	No	Yes		
No	50%	50%	100%	
Yes	41%	59%	100%	
Grand Total	44%	56%	100%	

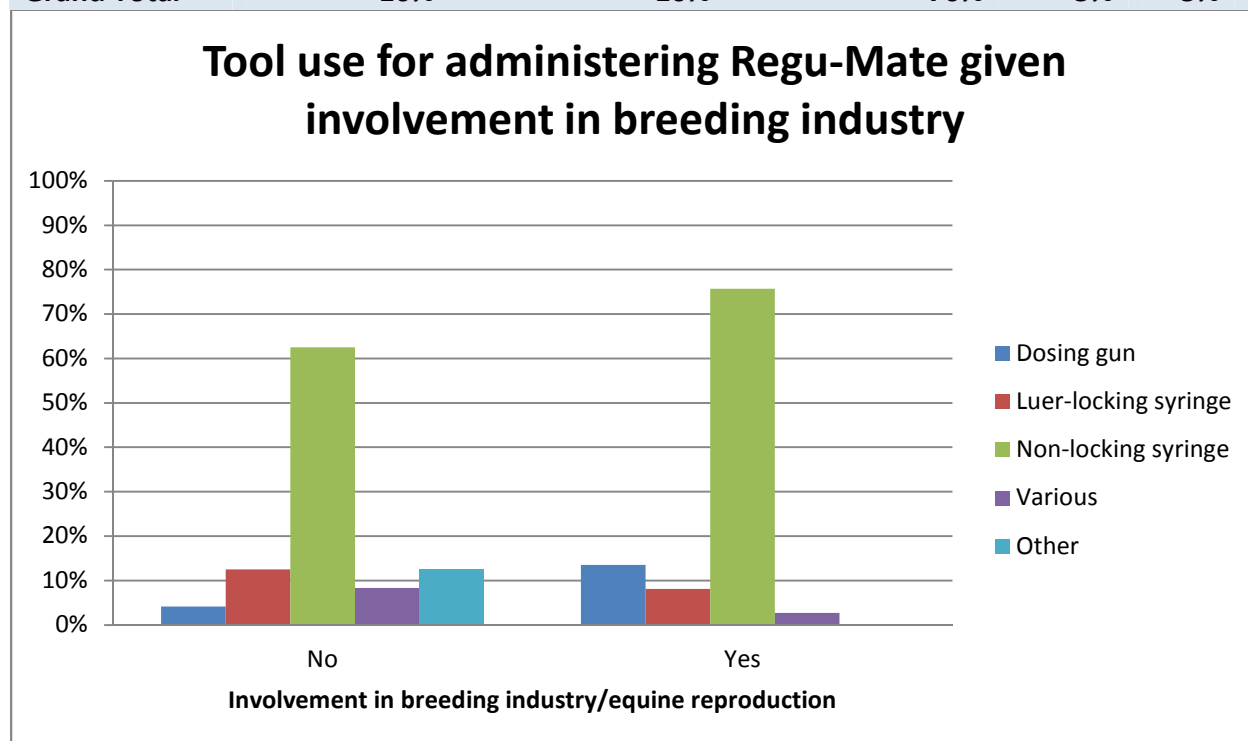


Involved in Breeding Industry

Count of Breeder	Column Labels		Grand Total
Row Labels	Separate from other medications	With other medications	
No	58%	42%	100%
Yes	32%	68%	100%
Grand Total	43%	57%	100%



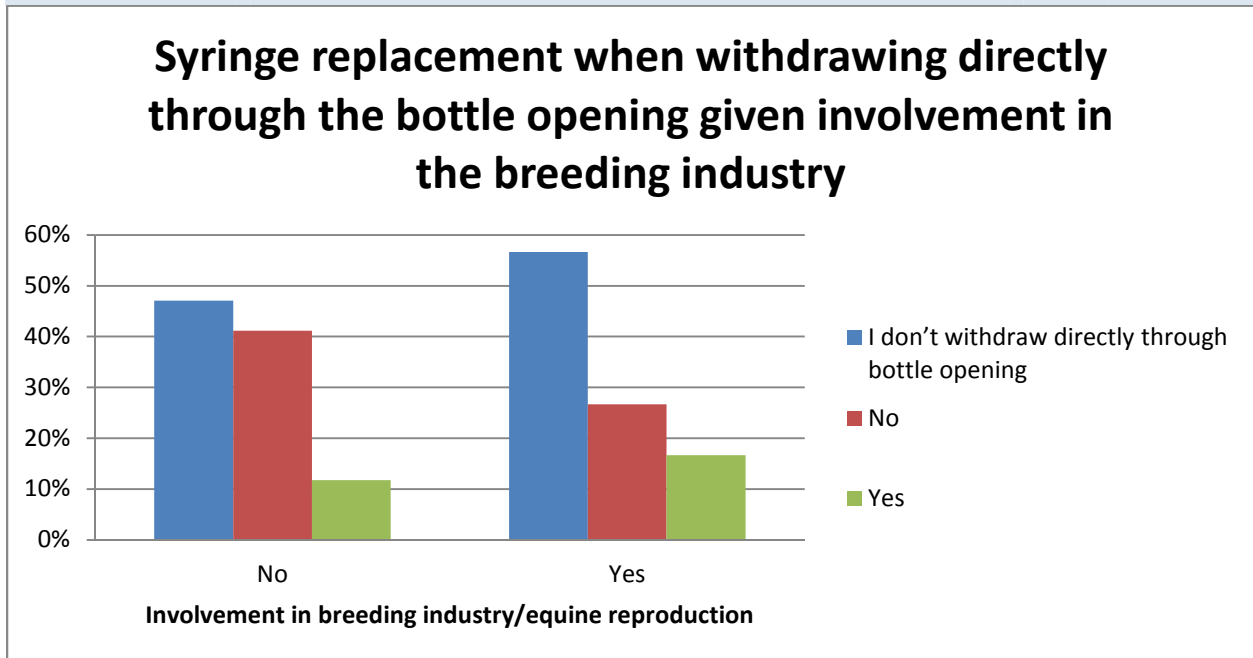
Involved in Breeding Industry							
Count of Breeder	Column Labels						
Row Labels	Dosing gun	Luer-locking syringe	Non-locking syringe	Various	Other	Grand Total	
No	4%	13%	63%	8%	13%	100%	
Yes	14%	8%	76%	3%	0%	100%	
Grand Total	10%	10%	70%	5%	5%	100%	



Involved in Breeding Industry

Tool (Multiple Items)

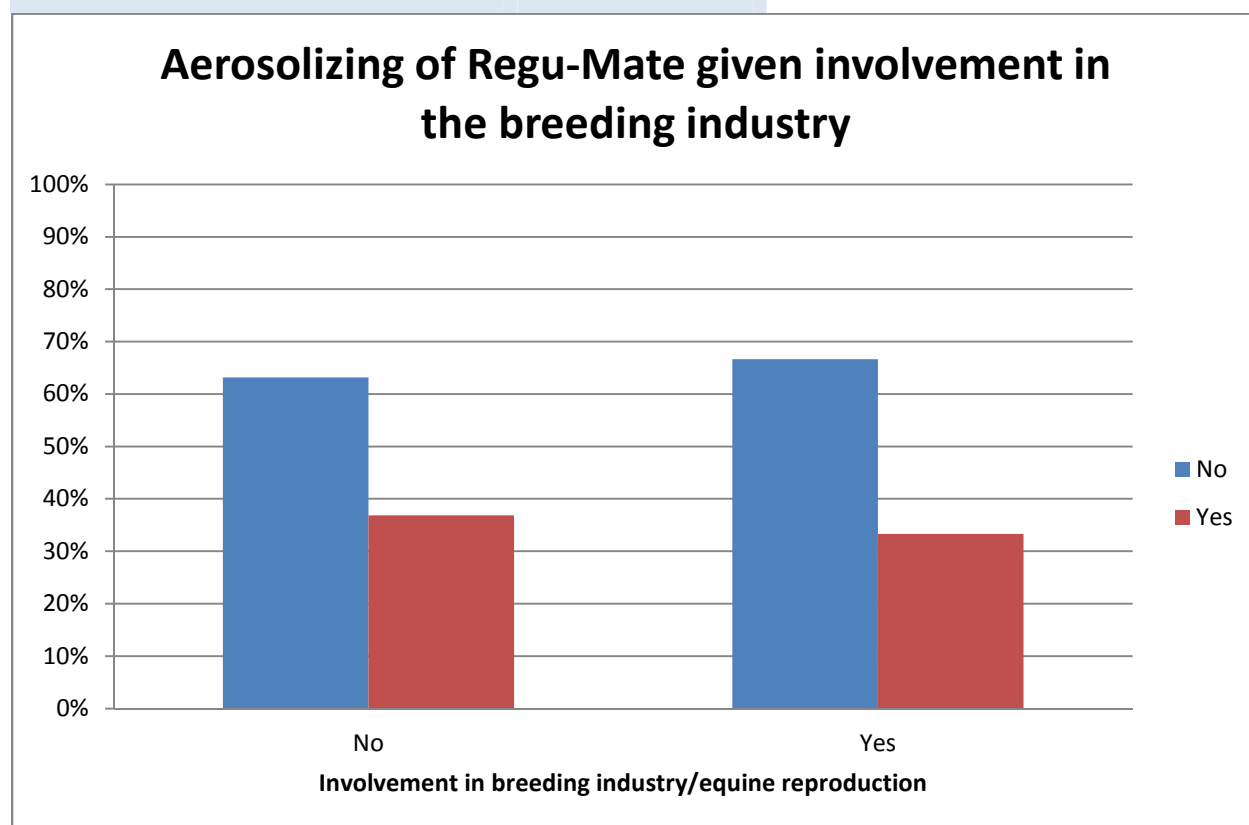
Count of Breeder	Column Labels				Grand Total
Row Labels	I don't withdraw directly through bottle opening	No	Yes		
No	47%	41%	12%	100%	
Yes	57%	27%	17%	100%	
Grand Total	53%	32%	15%	100%	



Involved in Breeding Industry

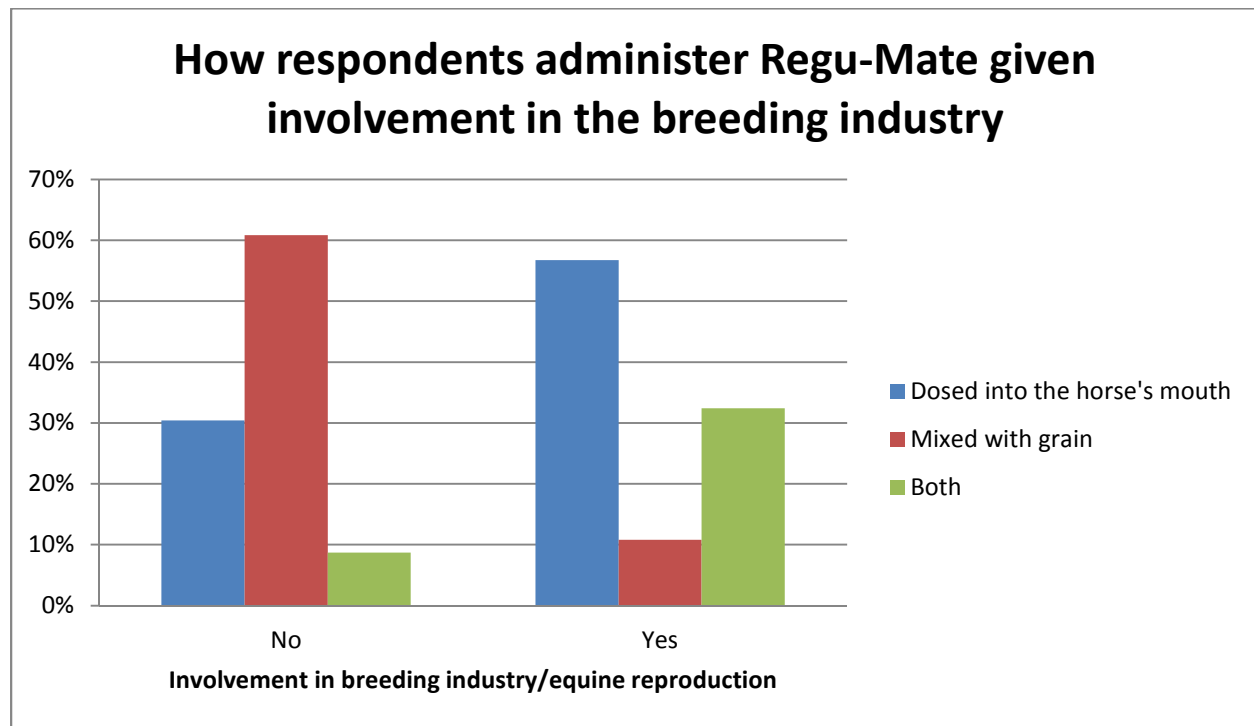
Tool	(Multiple Items)
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Count of Breeder	Column Labels		
Row Labels	No	Yes	Grand Total
No	63%	37%	100%
Yes	67%	33%	100%
Grand Total	65%	35%	100%



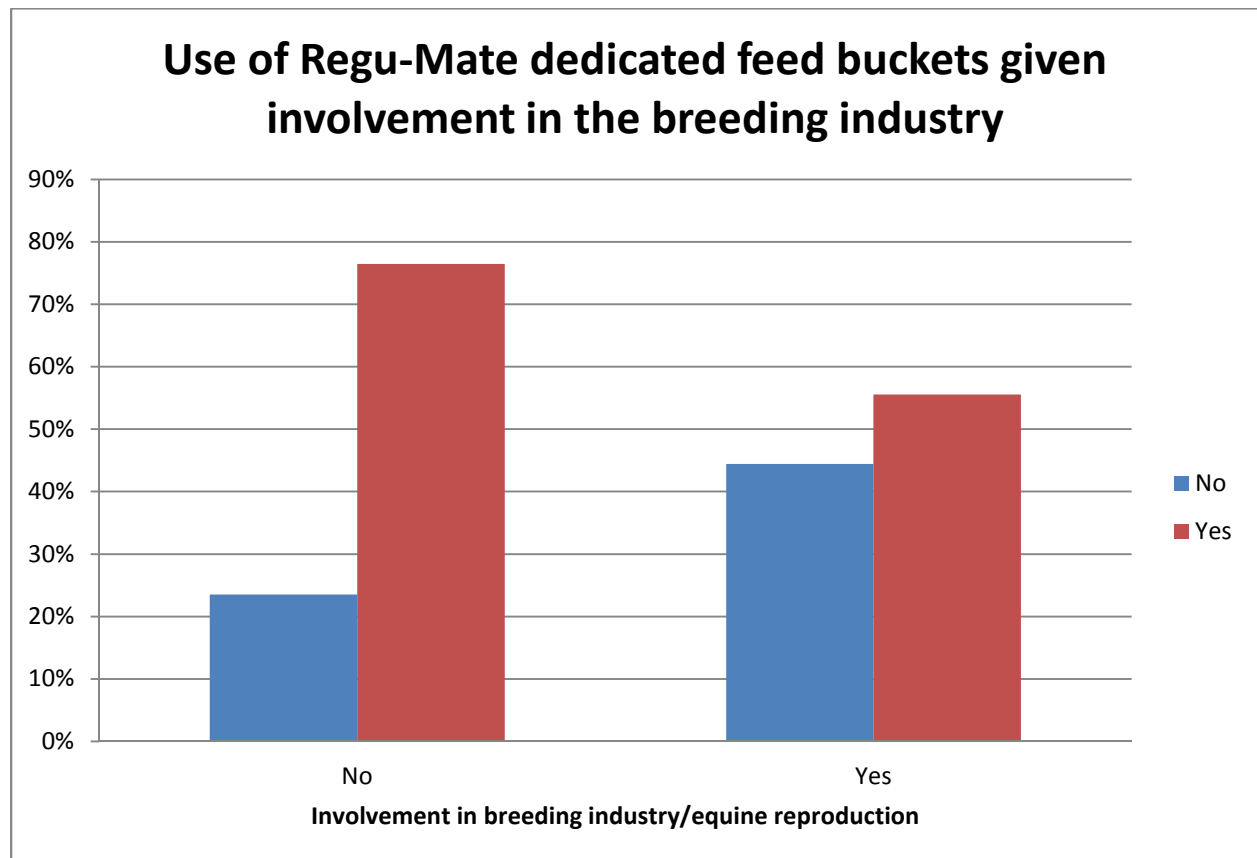
Involved in Breeding Industry

Count of Breeder	Column Labels				
Row Labels	Dosed into the horse's mouth	Mixed with grain	Both	Grand Total	
No	30%	61%	9%	100%	
Yes	57%	11%	32%	100%	
Grand Total	47%	30%	23%	100%	

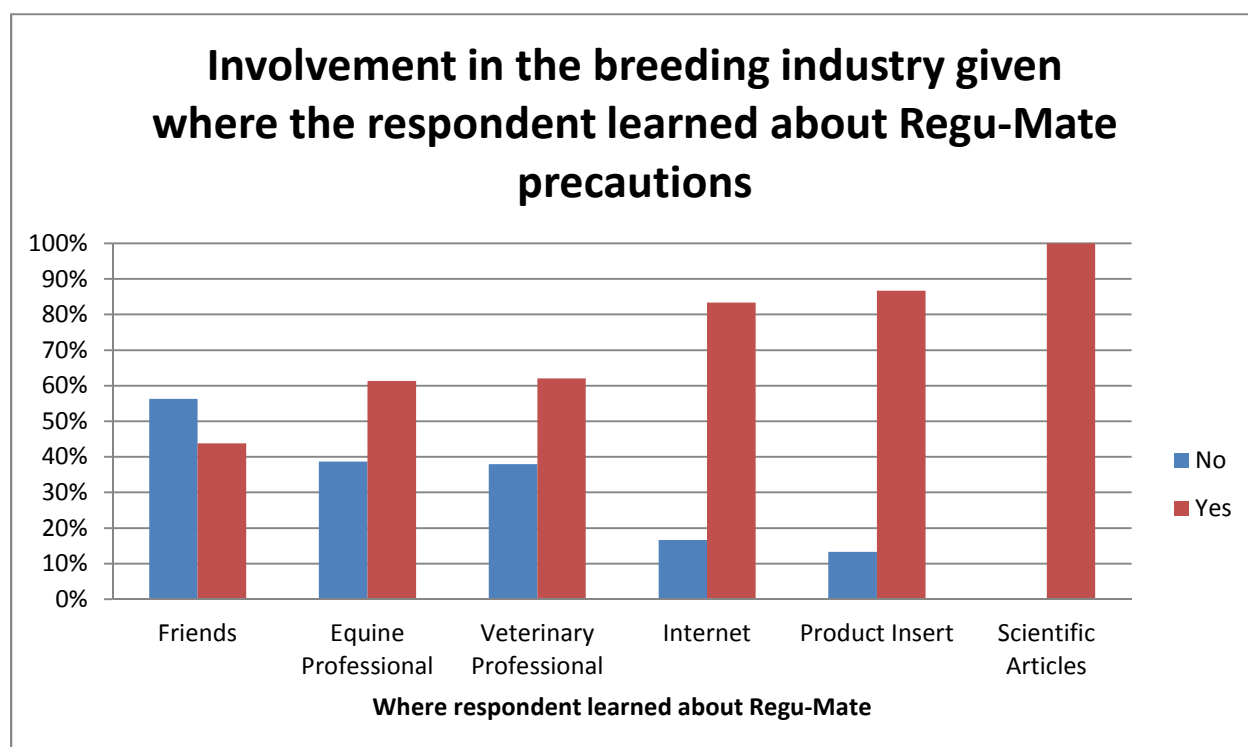


Involved in Breeding Industry

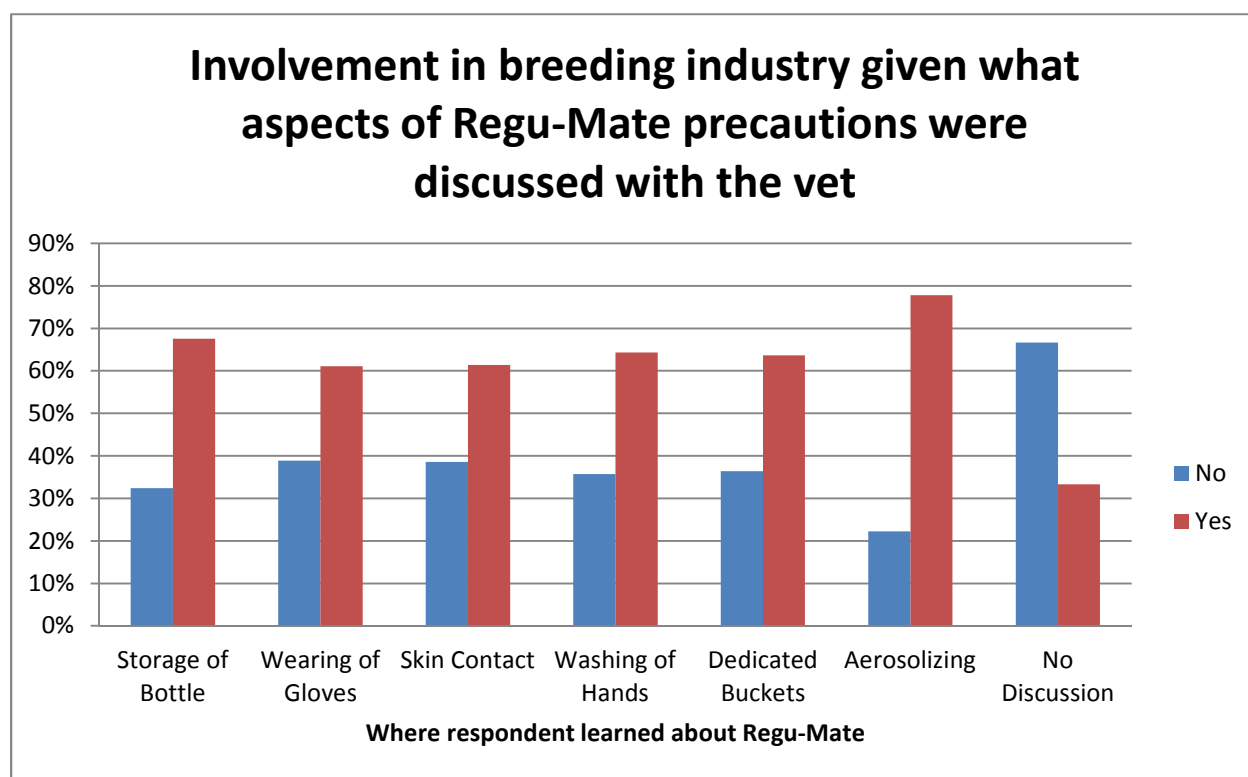
Count of Breeder	Column Labels		Grand Total
Row Labels	No	Yes	Total
No	24%	76%	100%
Yes	44%	56%	100%
Grand Total	34%	66%	100%



Values	Column Labels		Grand Total
	No	Yes	
Friends	56%	44%	100%
Equine Professional	39%	61%	100%
Veterinary Professional	38%	62%	100%
Internet	17%	83%	100%
Product Insert	13%	87%	100%
Scientific Articles	0%	100%	100%



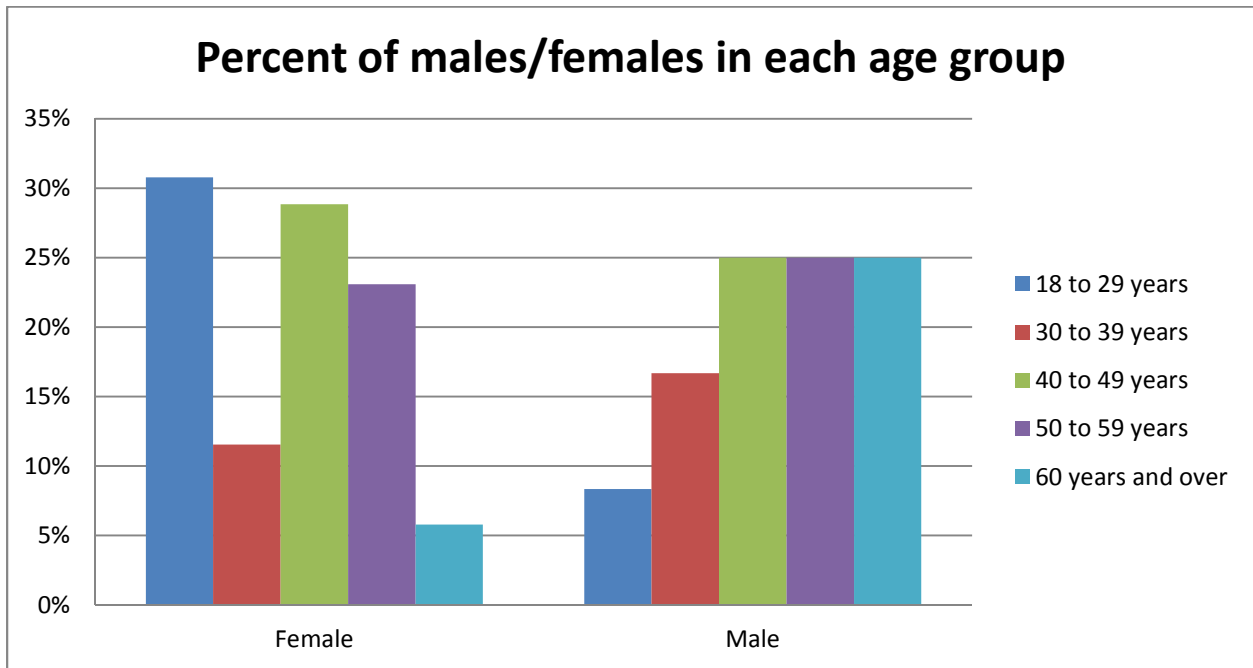
Values	Column Labels		Grand Total
	No	Yes	
Storage of Bottle	32%	68%	100%
Wearing of Gloves	39%	61%	100%
Skin Contact	39%	61%	100%
Washing of Hands	36%	64%	100%
Dedicated Buckets	36%	64%	100%
Aerosolizing	22%	78%	100%
No Discussion	67%	33%	100%



SEX

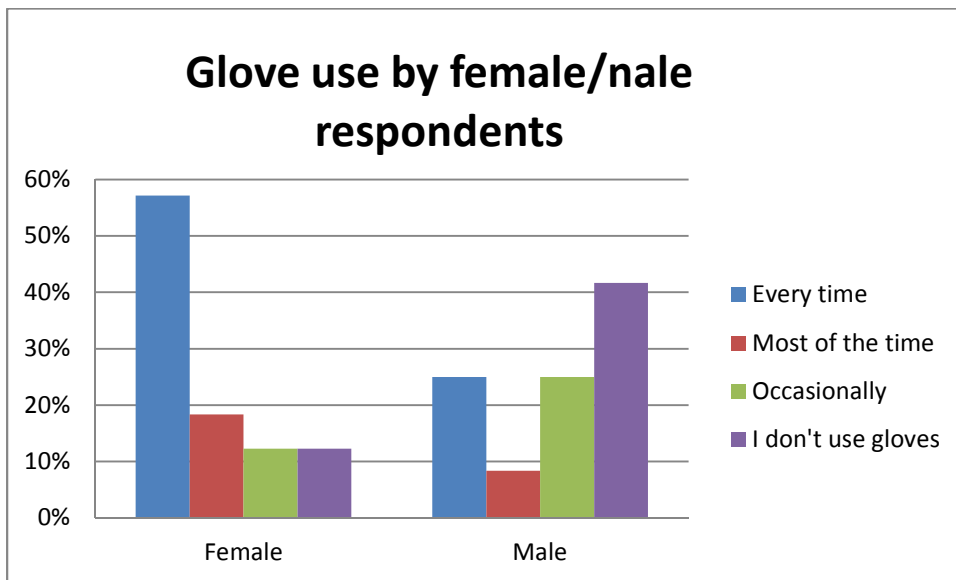
Responses to: What is your sex? Divided by age

Count of Sex Row Labels	Column Labels 18 to 29 years	30 to 39 years	40 to 49 years	50 to 59 years	60 years and over	Grand Total
Female	31%	12%	29%	23%	6%	100%
Male	8%	17%	25%	25%	25%	100%
Grand Total	27%	13%	28%	23%	9%	100%



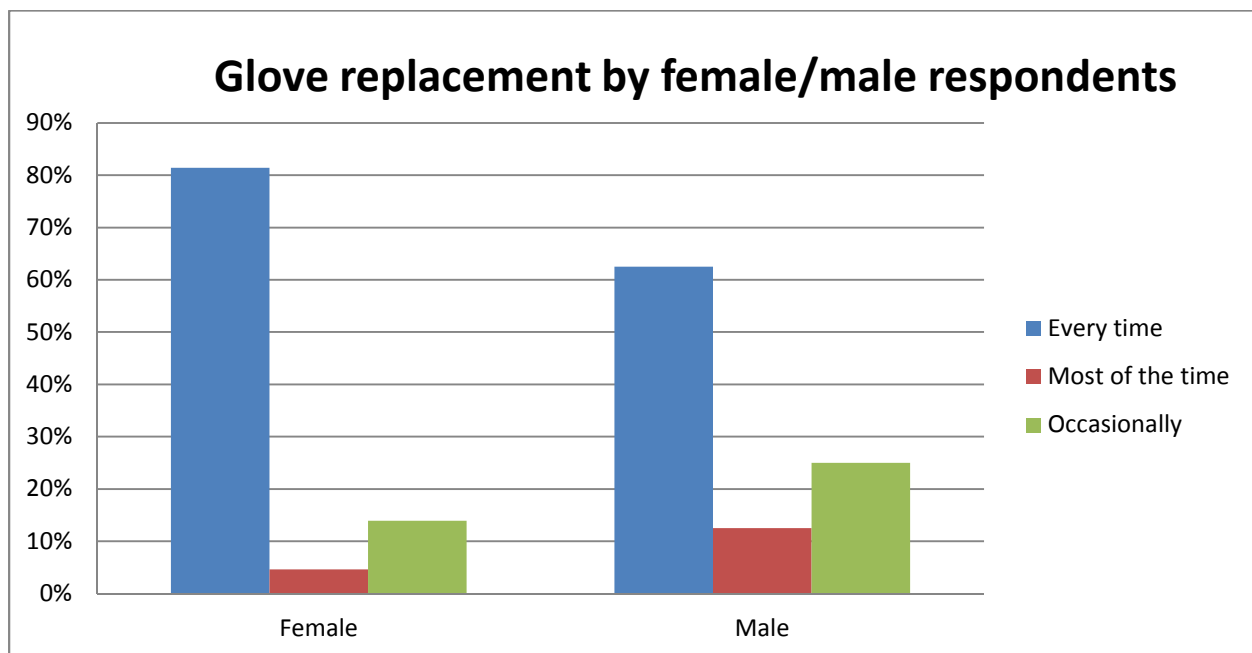
Responses to: What is your sex? Divided by Glove Use

Count of Sex	Column Labels				
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total
Female	57%	18%	12%	12%	100%
Male	25%	8%	25%	42%	100%
Grand Total	51%	16%	15%	18%	100%



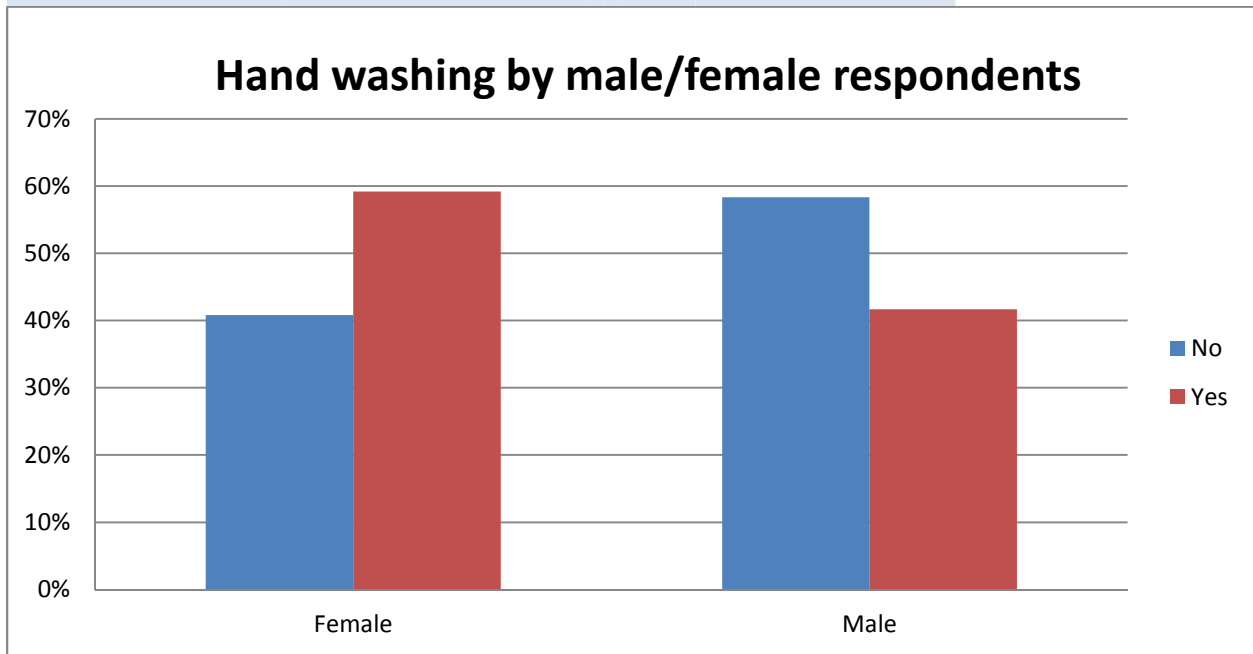
Responses to: What is your sex? Divided by Glove Use

Count of Sex	Column Labels			Grand Total
Row Labels	Every time	Most of the time	Occasionally	
Female	81%	5%	14%	100%
Male	63%	13%	25%	100%
Grand Total	78%	6%	16%	100%



Responses to: What is your sex? Divided by Hand Washing

Count of Sex Row Labels	Column Labels		Grand Total
	No	Yes	
Female	41%	59%	100%
Male	58%	42%	100%
Grand Total	44%	56%	100%

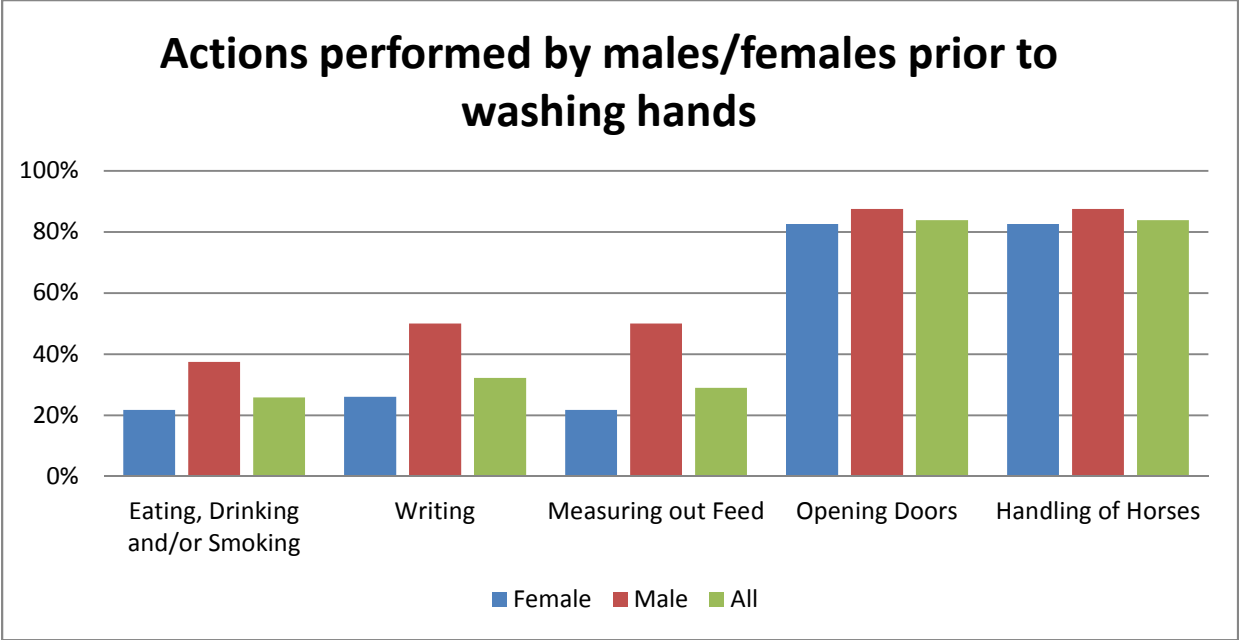


Responses to: What is your sex? Divided by Glove Use

Row Labels	Count of ActionsWash _eating	Count of ActionsWash _writing	Count of ActionsWas h_feed	Count of ActionsWash _doors	Count of ActionsWash_ handling
Female	5	6	5	19	19
Male	3	4	4	7	7
Grand Total	8	10	9	26	26

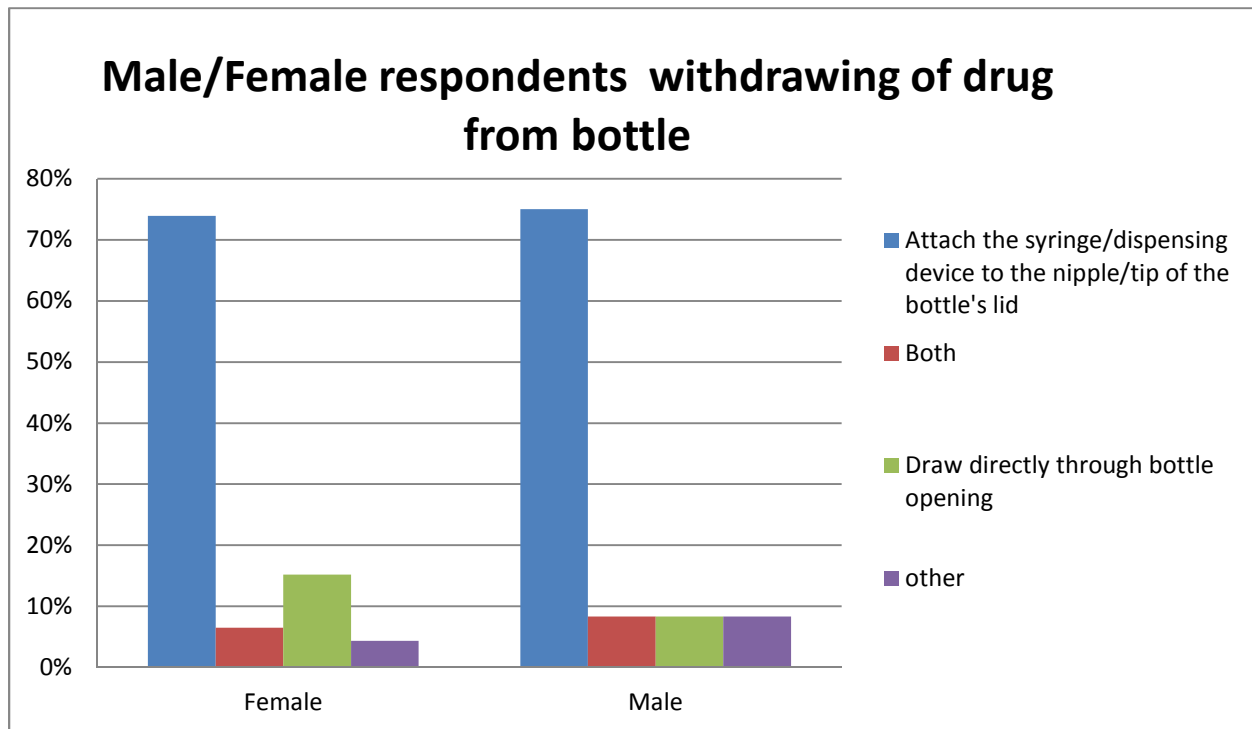
Row Labels	Count of ActionsWash _none	Count of ActionsWash _NR	No Response	Response
Female	10	19	29	23
Male	3	1	4	8
Grand Total	13	20		31

	Female	Male	All
Eating, Drinking and/or Smoking	22%	38%	26%
Writing	26%	50%	32%
Measuring out Feed	22%	50%	29%
Opening Doors	83%	88%	84%
Handling of Horses	83%	88%	84%



Responses to: What is your sex? Divided by Withdrawing

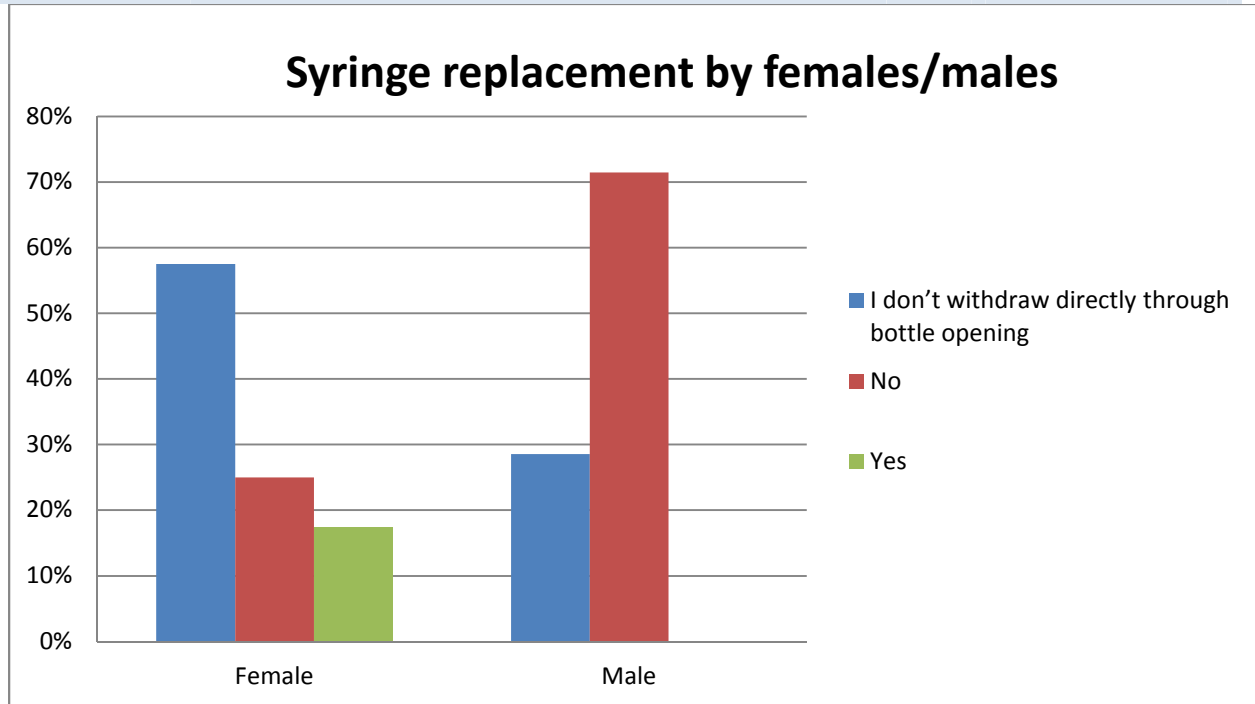
Count of Sex	Column Labels				
Row Labels	Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	Both	Draw directly through bottle opening	other	Grand Total
Female	74%	7%	15%	4%	100%
Male	75%	8%	8%	8%	100%
Grand Total	74%	7%	14%	5%	100%



Responses to: What is your sex? Divided by Withdrawing

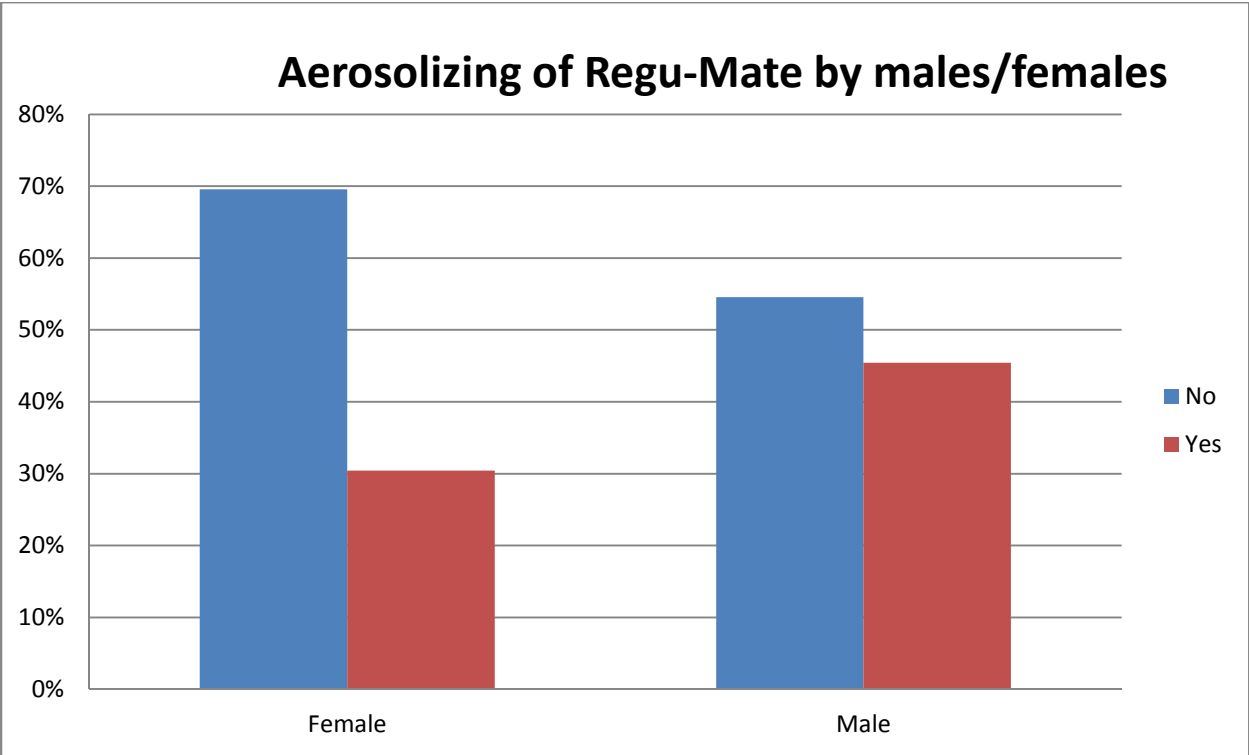
Tool (Multiple Items)

Count of Sex	Column Labels			
Row Labels	I don't withdraw directly through bottle opening	No	Yes	Grand Total
Female	58%	25%	18%	100%
Male	29%	71%	0%	100%
Grand Total	53%	32%	15%	100%



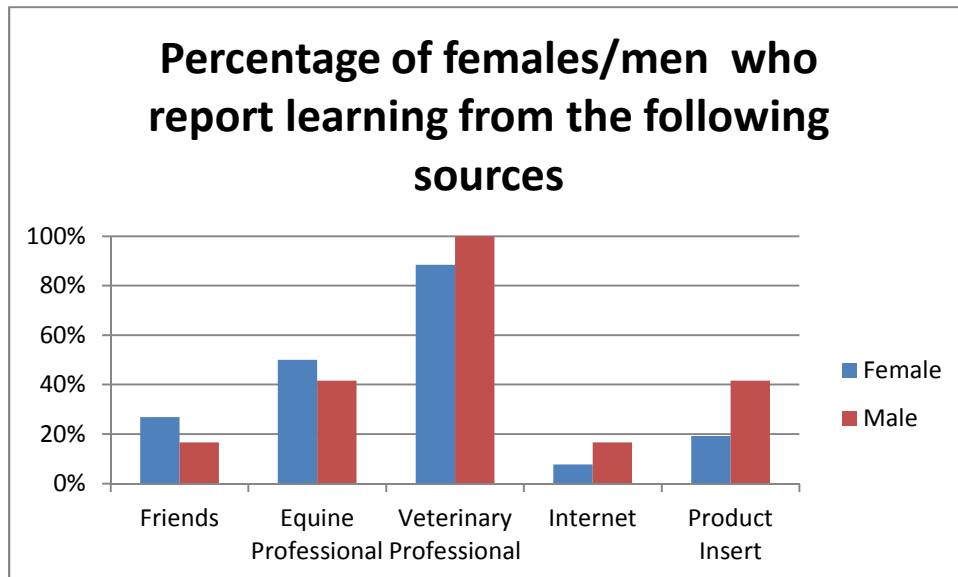
Responses to: What is your sex? Divided by Withdrawing

Count of Sex Row Labels	Column Labels		Grand Total
	No	Yes	
Female	70%	30%	100%
Male	55%	45%	100%
Grand Total	67%	33%	100%



Row Labels	Count of Learn_Friends	Count of Learn_Professional	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInsert
Female	14	26	46	4	10
Male	2	5	12	2	5
Grand Total	16	31	58	6	15

	Friends	Equine Professional	Veterinary Professional	Internet	Product Insert
Female	27%	50%	88%	8%	19%
Male	17%	42%	100%	17%	42%



Prohibited from handling drug divided by sex

Administer_Regumate	Yes
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Row Labels	Count of Prohib_Handling_AllWom	Count of Prohib_Handling_ChildWom	Count of Prohib_Handling_PregWom	Count of Prohib_Handling_Men	Count of Prohib_Handling_None	Count of Prohib_Handling_
Female	5	12	23	5	14	
Male	3	4	8	1	3	
Grand Total	8	16	31	6	17	

Administer_Regumate	Yes
---------------------	-----

Row Labels	Count of Sex
Female	49
Male	12
Grand Total	61

	Female	Male
All Women	10%	
Women of Child-Bearing Age	24%	
Women (Pregnant or May be Pregnant)	47%	
Men		8%

Prohibited from handling drug divided by sex

Administer_Regumate	Yes
Sex	Female

Row Labels	Count of Prohib_Handling_AllWom	Count of Prohib_Handling_ChildWom	Count of Prohib_Handling_PregWom	Count of Prohib_Handling_Men	Count of Prohib_Handling_None	Count of Prohib_Handling_
18 to 29 years	1	2	7	1	3	
30 to 39 years	2	3	3	2	2	
40 to 49 years	1	3	7	1	3	
50 to 59 years		3	5		5	
60 years and over	1	1	1	1	1	
Grand Total	5	12	23	5	14	

In Category of

Prohibited

5

8

Total in

49

37

10%

22%

Percent of women who report that people who are of their description are prohibited from handling Regu-Mate

Female respondents in who are in the prohibited group

All Women

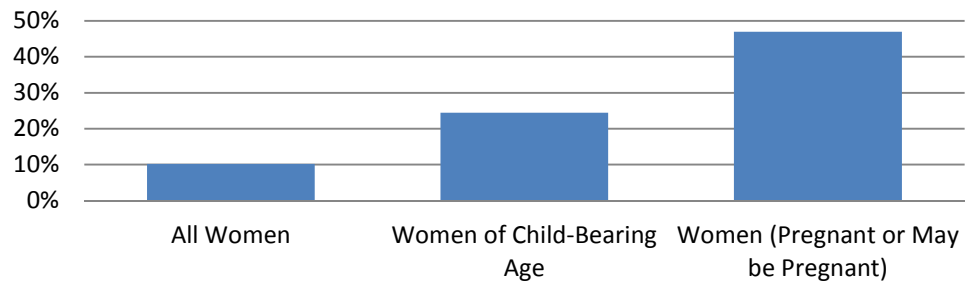
10%

Women of Child-

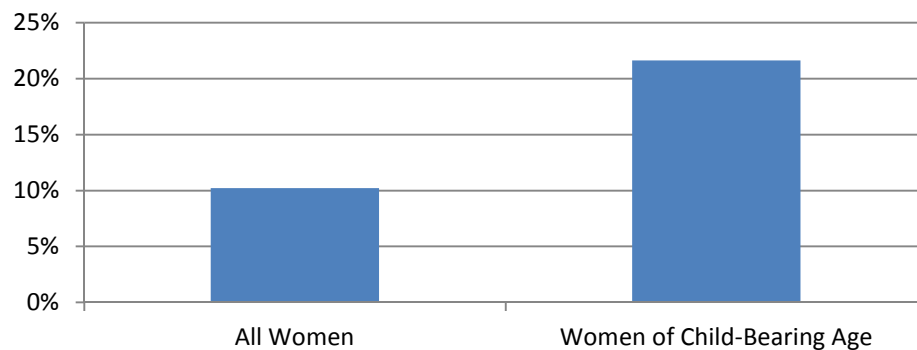
Bearing Age

22%

Female respondents where female contact with the drug is prohibited



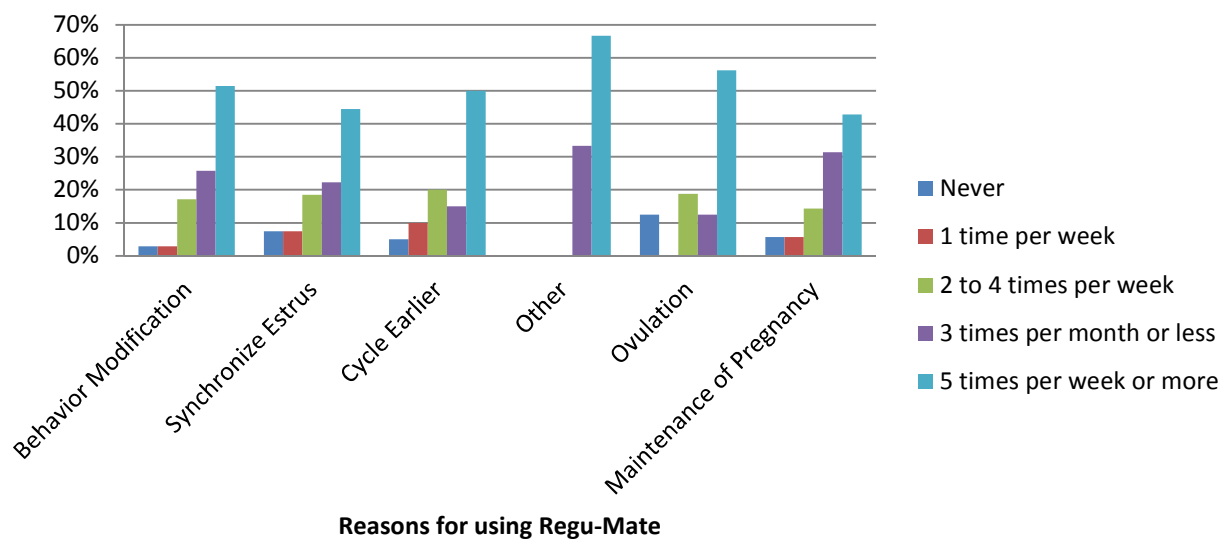
Female respondents that administer Regu-Mate in who are in the prohibited group



REASONS TO USE REGU-MATE

	Reason for Using Regu-Mate					
	Column Labels					
Values	Never	1 time per week	2 to 4 times per week	3 times per month or less	5 times per week or more	Grand Total
Behavior Modification	3%	3%	17%	26%	51%	100%
Synchronize Estrus Cycle Earlier	7%	7%	19%	22%	44%	100%
Other	5%	10%	20%	15%	50%	100%
Ovulation	0%	0%	0%	33%	67%	100%
Maintenance of Pregnancy	13%	0%	19%	13%	56%	100%
	6%	6%	14%	31%	43%	100%

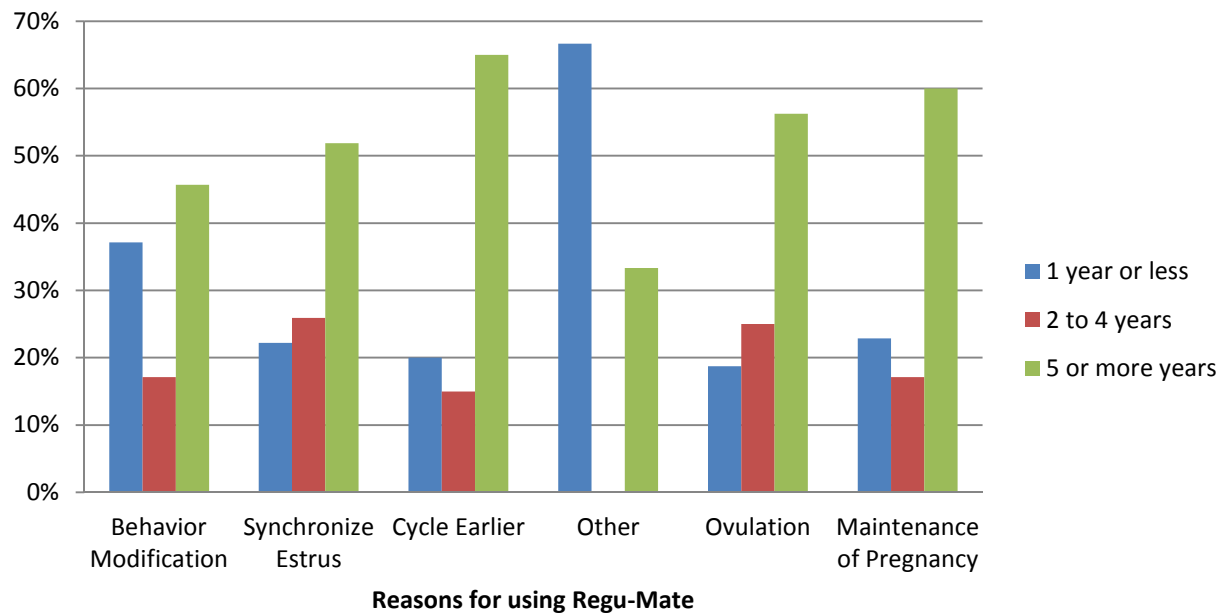
How often Regu-Mate is handled given the reason for using the drug



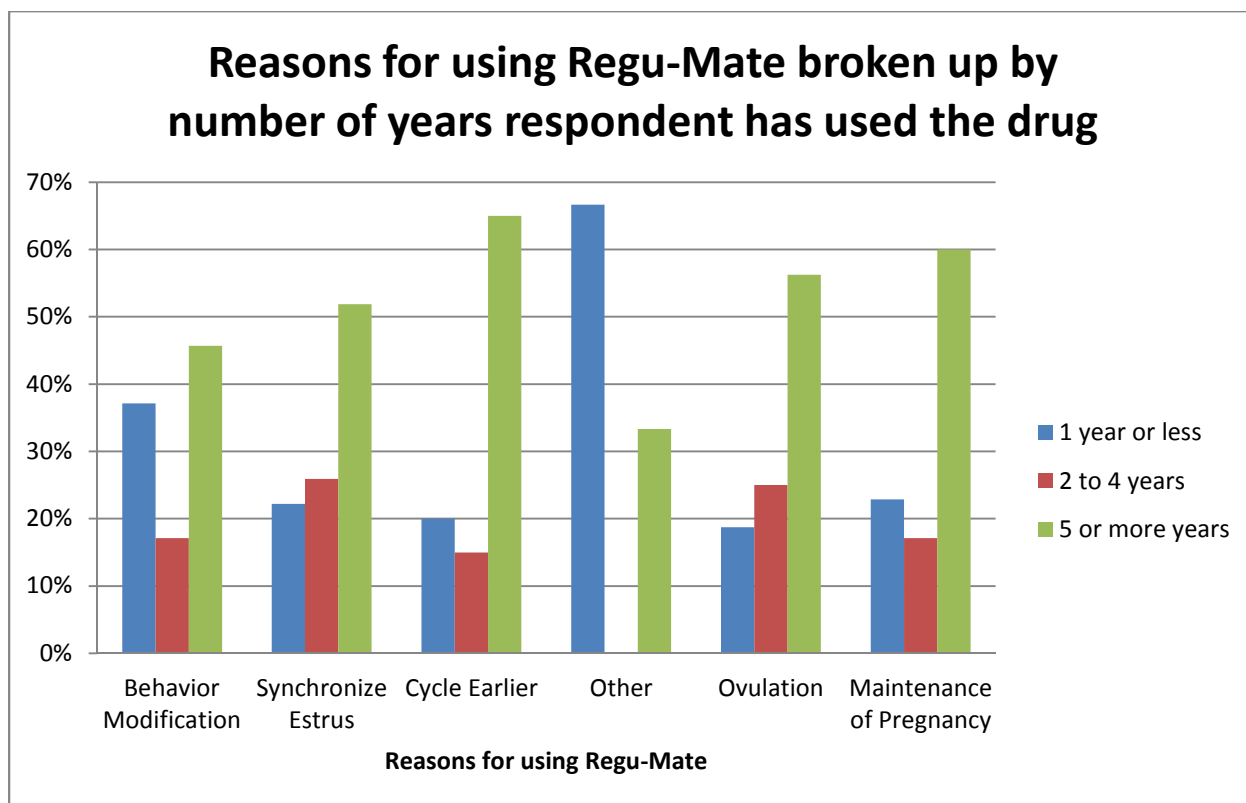
Reason for Using Regu-Mate

Values	Column Labels			
	1 year or less	2 to 4 years	5 or more years	Grand Total
Behavior Modification	37%	17%	46%	100%
Synchronize Estrus	22%	26%	52%	100%
Cycle Earlier	20%	15%	65%	100%
Other	67%	0%	33%	100%
Ovulation	19%	25%	56%	100%
Maintenance of Pregnancy	23%	17%	60%	100%

Number of years using Regu-Mate given the reason for using the drug



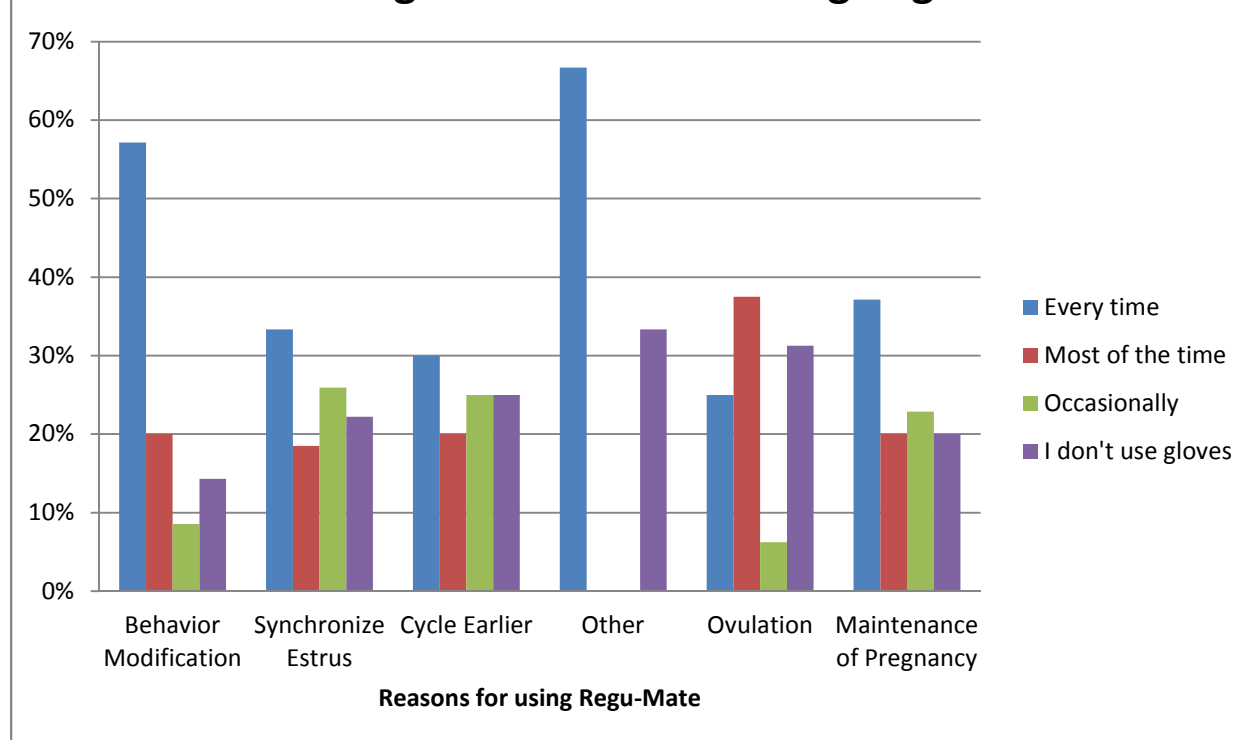
Reason for Using Regu-Mate				
Values	Column Labels			
	1 year or less	2 to 4 years	5 or more years	Grand Total
Behavior Modification	37%	17%	46%	100%
Synchronize Estrus	22%	26%	52%	100%
Cycle Earlier	20%	15%	65%	100%
Other	67%	0%	33%	100%
Ovulation	19%	25%	56%	100%
Maintenance of Pregnancy	23%	17%	60%	100%



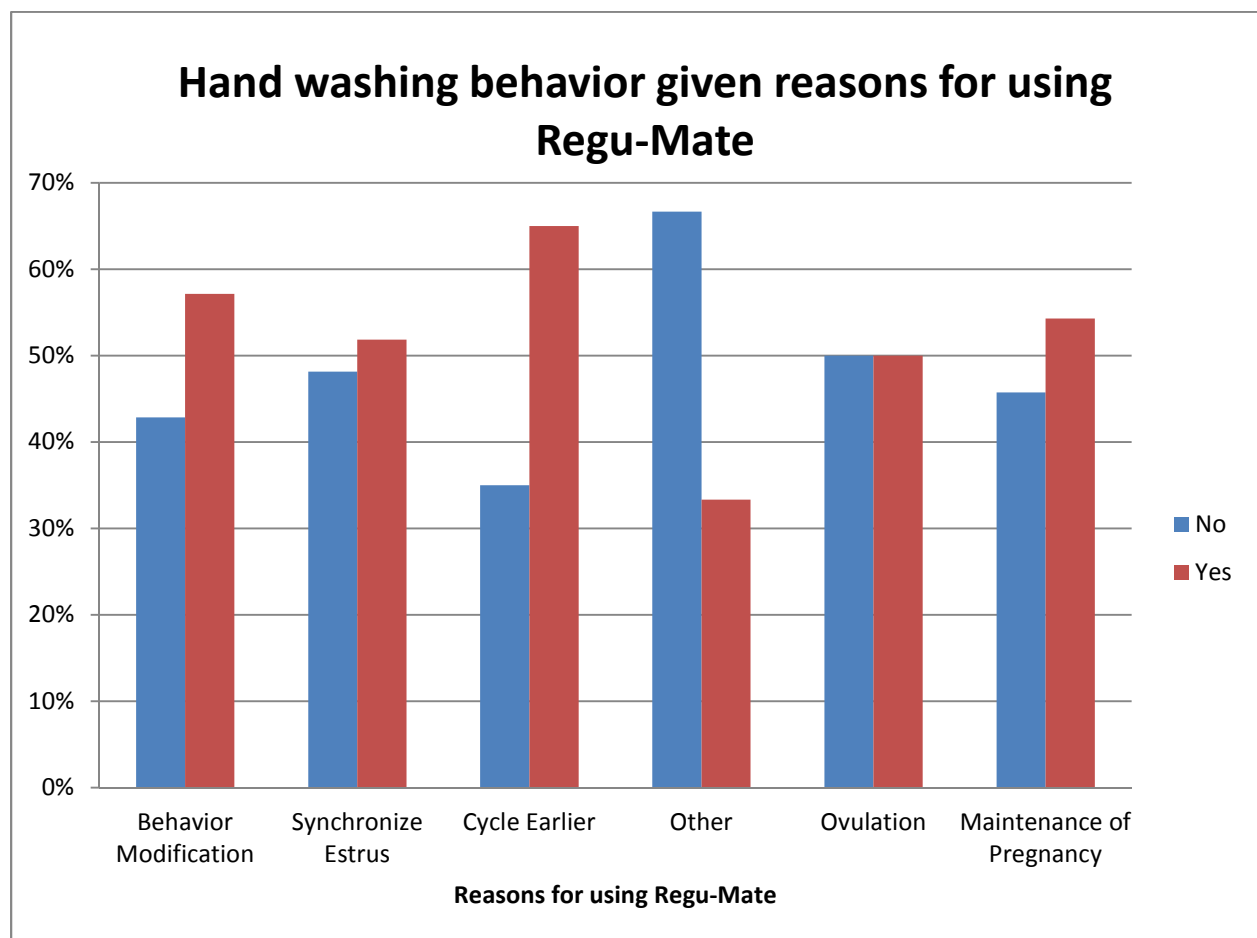
Reason for Using Regu-Mate

Values	Column Labels				Grand Total
	Every time	Most of the time	Occasionally	I don't use gloves	
Behavior Modification	57%	20%	9%	14%	100%
Synchronize Estrus	33%	19%	26%	22%	100%
Cycle Earlier	30%	20%	25%	25%	100%
Other	67%	0%	0%	33%	100%
Ovulation	25%	38%	6%	31%	100%
Maintenance of Pregnancy	37%	20%	23%	20%	100%

Glove use given reasons for using Regu-Mate



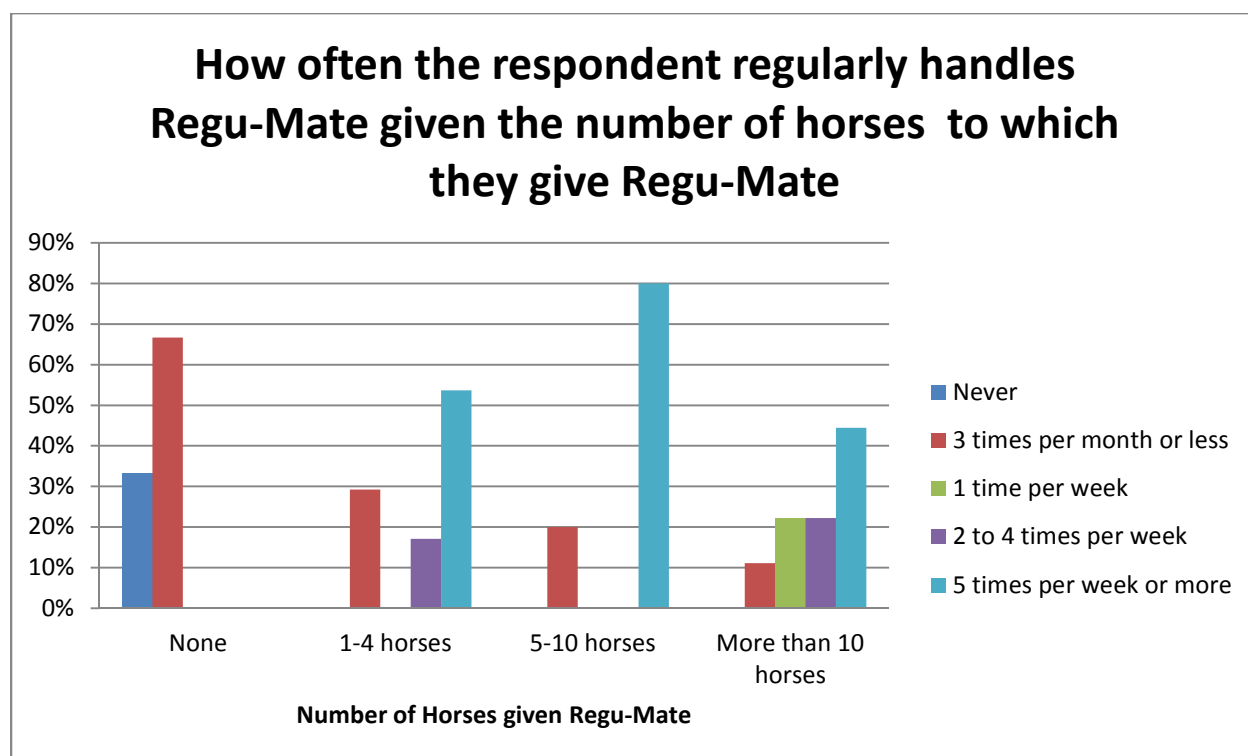
Reason for Using Regu-Mate			
	Column Labels		
Values	No	Yes	Grand Total
Behavior Modification	43%	57%	100%
Synchronize Estrus	48%	52%	100%
Cycle Earlier	35%	65%	100%
Other	67%	33%	100%
Ovulation	50%	50%	100%
Maintenance of Pregnancy	46%	54%	100%



NUMBER OF HORSES

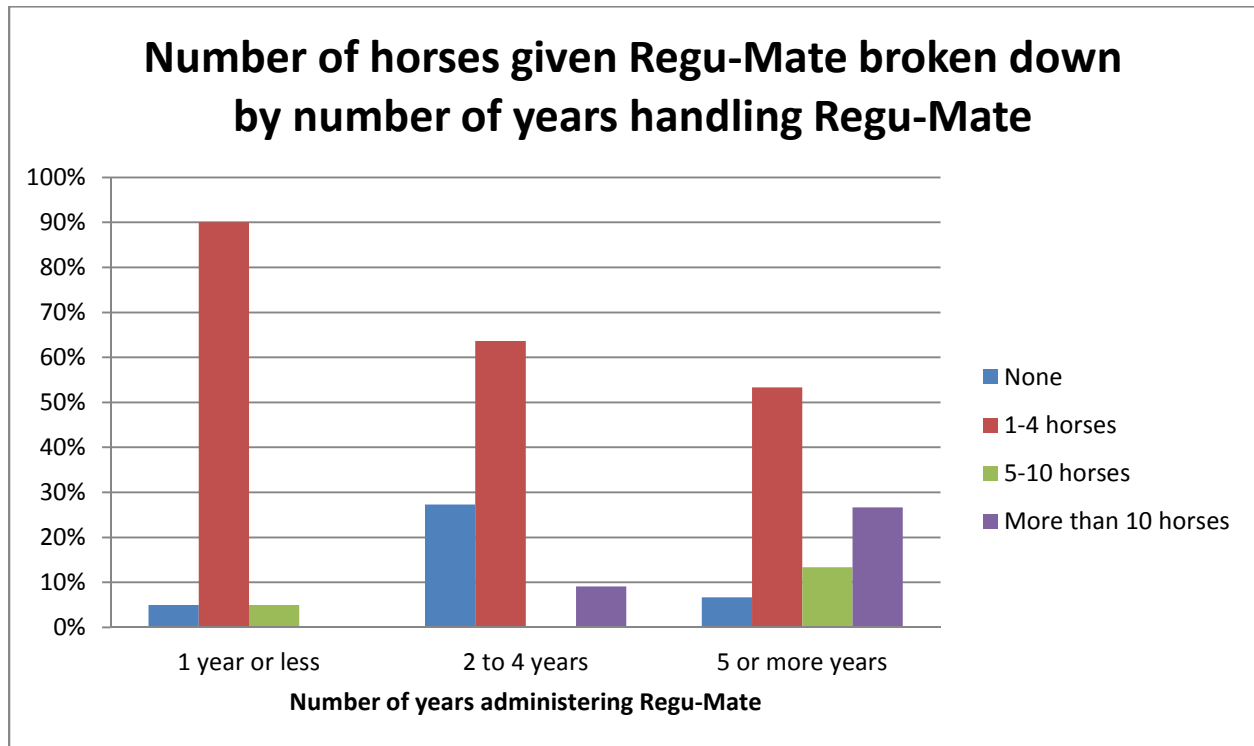
How many horses do you regularly give Regu-Mate

Count of number_horses	Column Labels					
Row Labels	Never	3 times per month or less	1 time per week	2 to 4 times per week	5 times per week or more	Grand Total
None	33%	67%	0%	0%	0%	100%
1-4 horses	0%	29%	0%	17%	54%	100%
5-10 horses	0%	20%	0%	0%	80%	100%
More than 10 horses	0%	11%	22%	22%	44%	100%
Grand Total	3%	30%	3%	15%	49%	100%



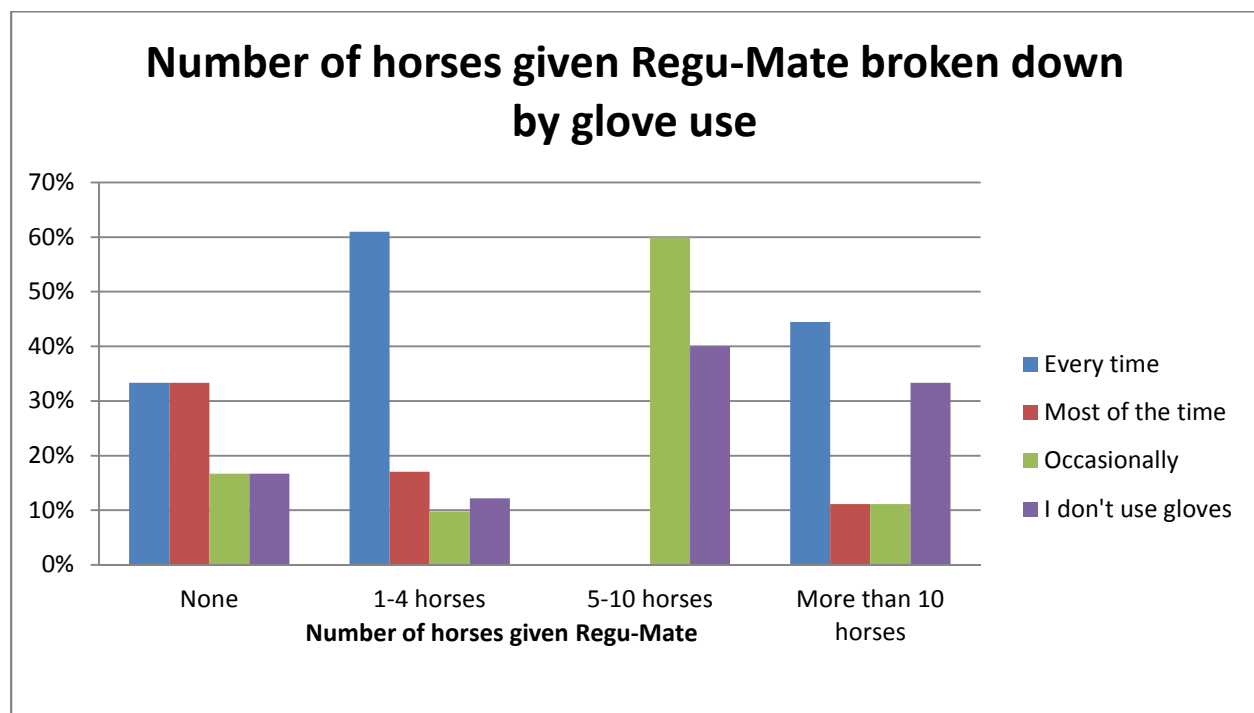
How many horses do you regularly give Regu-Mate

Count of number_horses	Column Labels					
Row Labels	None	1-4 horses	5-10 horses	More than 10 horses	Grand Total	
1 year or less	5%	90%	5%	0%	100%	
2 to 4 years	27%	64%	0%	9%	100%	
5 or more years	7%	53%	13%	27%	100%	
Grand Total	10%	67%	8%	15%	100%	



How many horses do you regularly give Regu-Mate

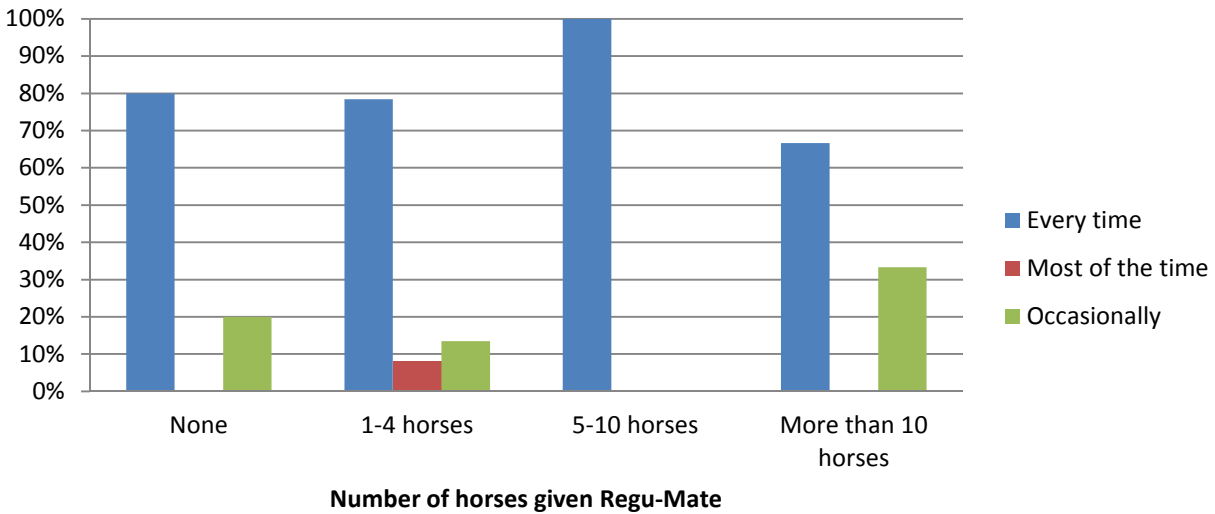
Count of number_horses	Column Labels					
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total	
None	33%	33%	17%	17%	100%	
1-4 horses	61%	17%	10%	12%	100%	
5-10 horses	0%	0%	60%	40%	100%	
More than 10 horses	44%	11%	11%	33%	100%	
Grand Total	51%	16%	15%	18%	100%	



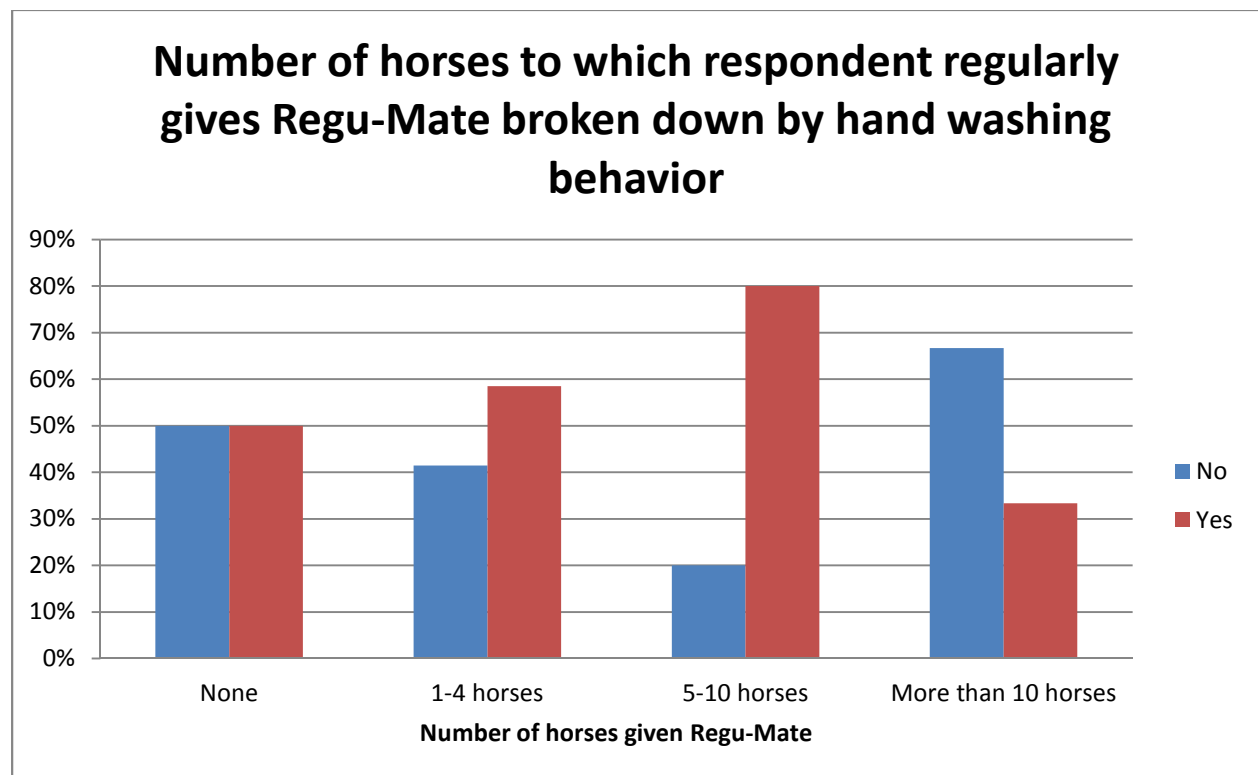
How many horses do you regularly give Regu-Mate

Count of number_horses	Column Labels			
Row Labels	Every time	Most of the time	Occasionally	Grand Total
None	80%	0%	20%	100%
1-4 horses	78%	8%	14%	100%
5-10 horses	100%	0%	0%	100%
More than 10 horses	67%	0%	33%	100%
Grand Total	78%	6%	16%	100%

Number of horses given Regu-Mate broken down by glove replacement

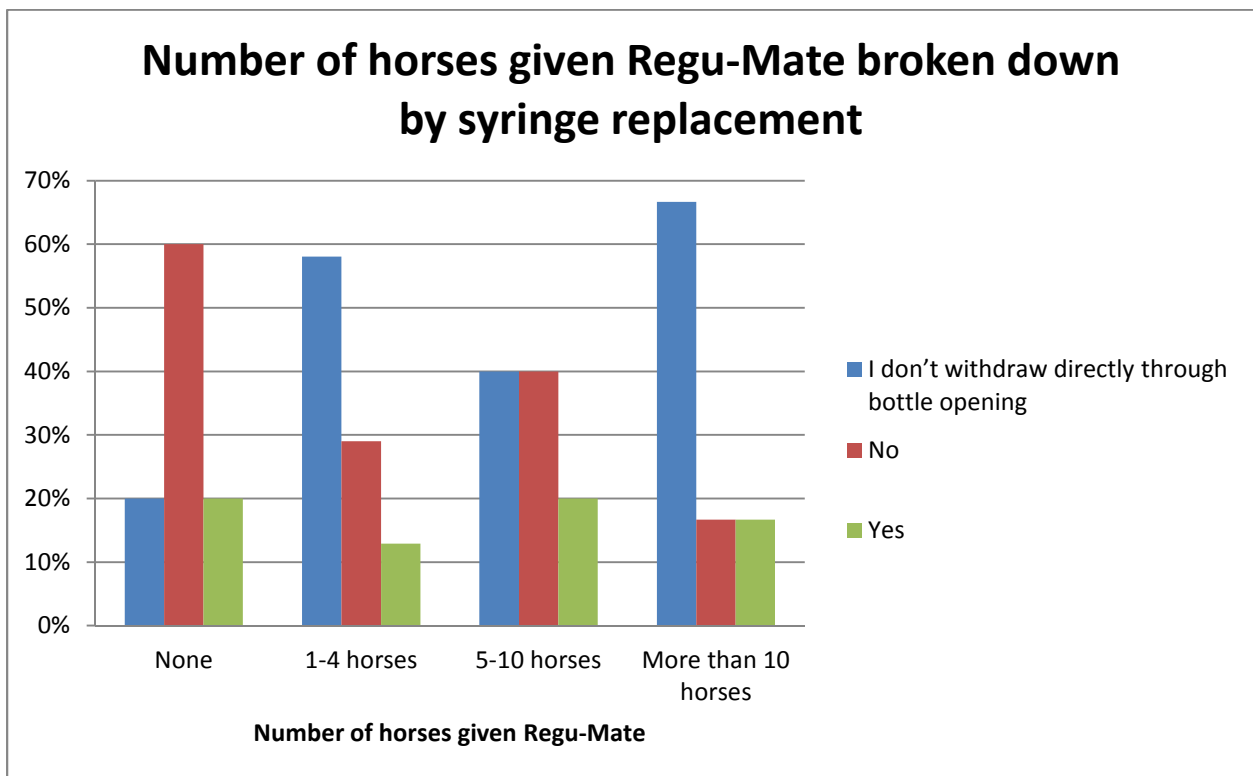


How many horses do you regularly give Regu-Mate				
Count of number_horses	Column Labels			
Row Labels	No	Yes	Grand Total	
None	50%	50%	100%	
1-4 horses	41%	59%	100%	
5-10 horses	20%	80%	100%	
More than 10 horses	67%	33%	100%	
Grand Total	44%	56%	100%	

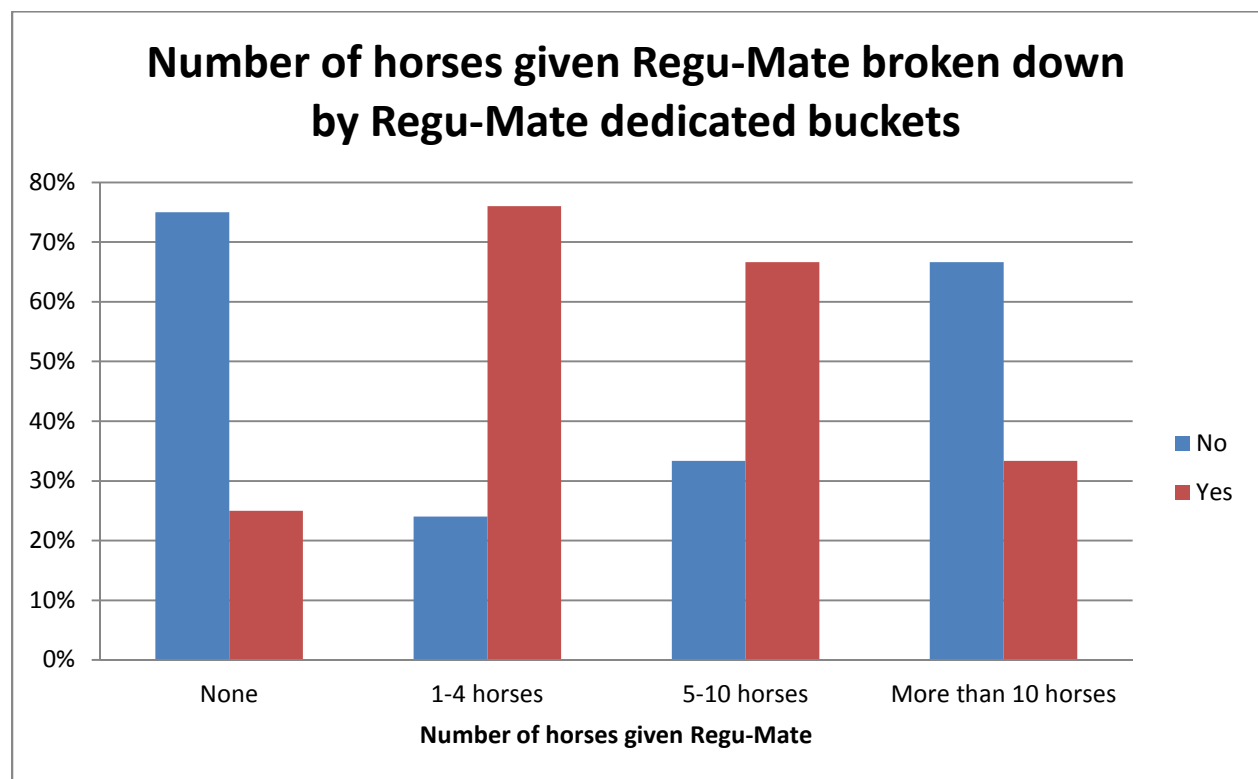


Tool (Multiple Items)

Count of number_horses	Column Labels			
Row Labels	I don't withdraw directly through bottle opening	No	Yes	Grand Total
None	20%	60%	20%	100%
1-4 horses	58%	29%	13%	100%
5-10 horses	40%	40%	20%	100%
More than 10 horses	67%	17%	17%	100%
Grand Total	53%	32%	15%	100%



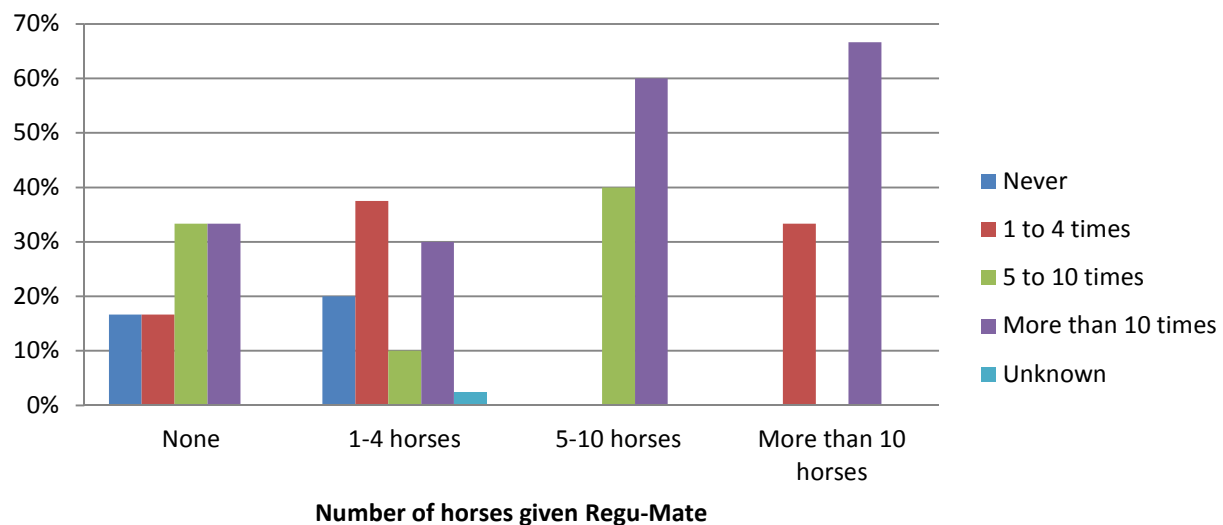
How many horses do you regularly give Regu-Mate				
Count of number_horses	Column Labels			
Row Labels	No	Yes	Grand Total	
None	75%	25%	100%	
1-4 horses	24%	76%	100%	
5-10 horses	33%	67%	100%	
More than 10 horses	67%	33%	100%	
Grand Total	34%	66%	100%	



How many horses do you regularly give Regu-Mate

Count of Contact	Column Labels					
Row Labels	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total
None	17%	17%	33%	33%	0%	100%
1-4 horses	20%	38%	10%	30%	3%	100%
5-10 horses	0%	0%	40%	60%	0%	100%
More than 10 horses	0%	33%	0%	67%	0%	100%
Grand Total	15%	32%	13%	38%	2%	100%

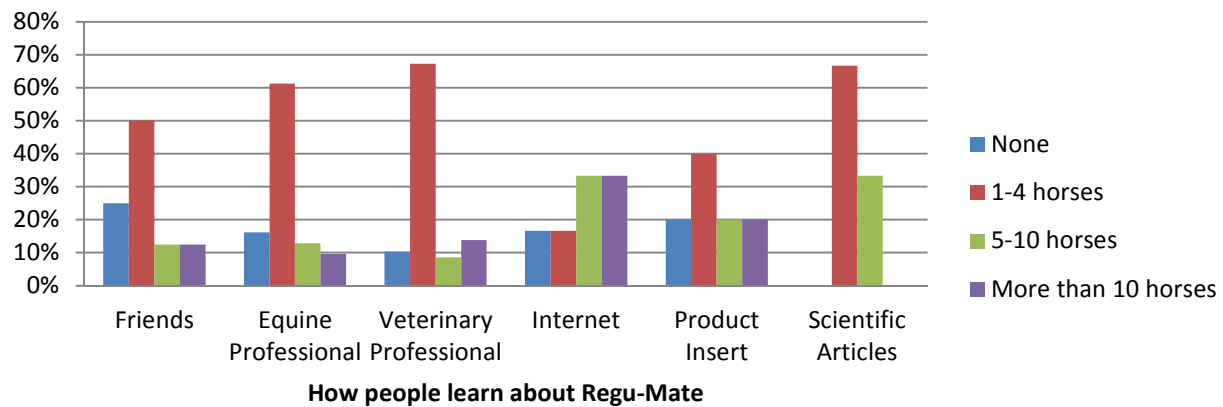
Number of horses given Regu-Mate broken down by reported skin contact with Regu-Mate



How many horses do you regularly give Regu-Mate

	Column Labels				
Values	None	1-4 horses	5-10 horses	More than 10 horses	Grand Total
Friends	25%	50%	13%	13%	100%
Equine Professional	16%	61%	13%	10%	100%
Veterinary Professional	10%	67%	9%	14%	100%
Internet	17%	17%	33%	33%	100%
Product Insert	20%	40%	20%	20%	100%
Scientific Articles	0%	67%	33%	0%	100%

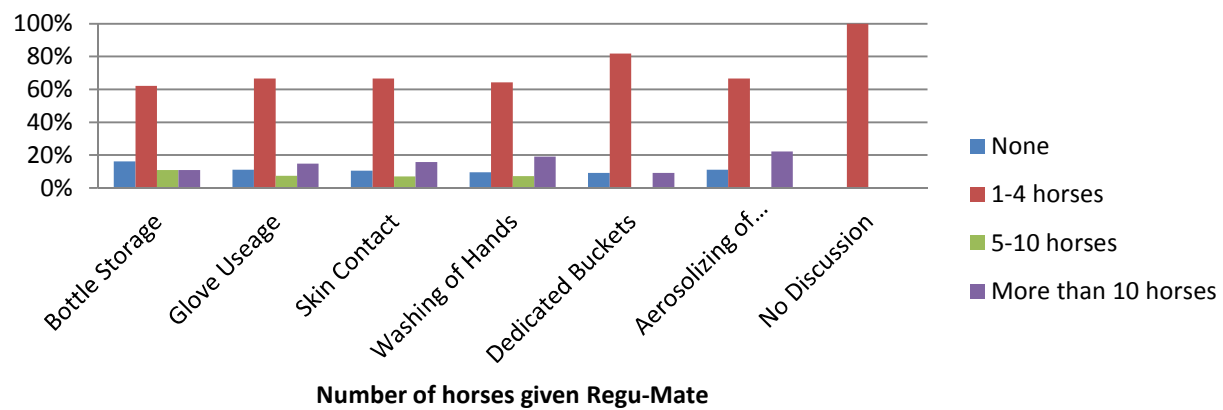
Number of horses given Regu-Mate broken down by where the respondent learned about Regu-Mate precautions



How many horses do you regularly give Regu-Mate

Values	Column Labels				Grand Total
	None	1-4 horses	5-10 horses	More than 10 horses	
Bottle Storage	16%	62%	11%	11%	100%
Glove Usage	11%	67%	7%	15%	100%
Skin Contact	11%	67%	7%	16%	100%
Washing of Hands	10%	64%	7%	19%	100%
Dedicated Buckets	9%	82%	0%	9%	100%
Aerosolizing of Drug	11%	67%	0%	22%	100%
No Discussion	0%	100%	0%	0%	100%

What veterinary professionals discussed about Regu-Mate precautions broken down by the number of horses given Regu-Mate



LEARN ABOUT REGU-MATE

Where Learned about Regu-Mate

Behavior Modification

Row Labels	Count of Learn_Friends	Count of Learn_Profession al	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInse rt	Count of Learn_scientific articles
TRUE	10	15	32	2	5	
Grand Total	10	15	32	2	5	

Synchronization of Estrus

Row Labels	Count of Learn_Friends	Count of Learn_Profession al	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInse rt	Count of Learn_scientific articles
TRUE	8	15	26	4	10	1
Grand Total	8	15	26	4	10	1

Cycle Earlier

Row Labels	Count of Learn_Friends	Count of Learn_Profession al	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInse rt	Count of Learn_scientific articles
TRUE	4	11	20	4	8	1
Grand Total	4	11	20	4	8	1

Ovulation

Row Labels	Count of Learn_Friends	Count of Learn_Professional	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInsert	Count of Learn_scientific articles
TRUE	4	6	16	2	5	1
Grand Total	4	6	16	2	5	1

Maintenance

Row Labels	Count of Learn_Friends	Count of Learn_Professional	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInsert	Count of Learn_scientific articles
TRUE	8	22	34	5	11	2
Grand Total	8	22	34	5	11	2

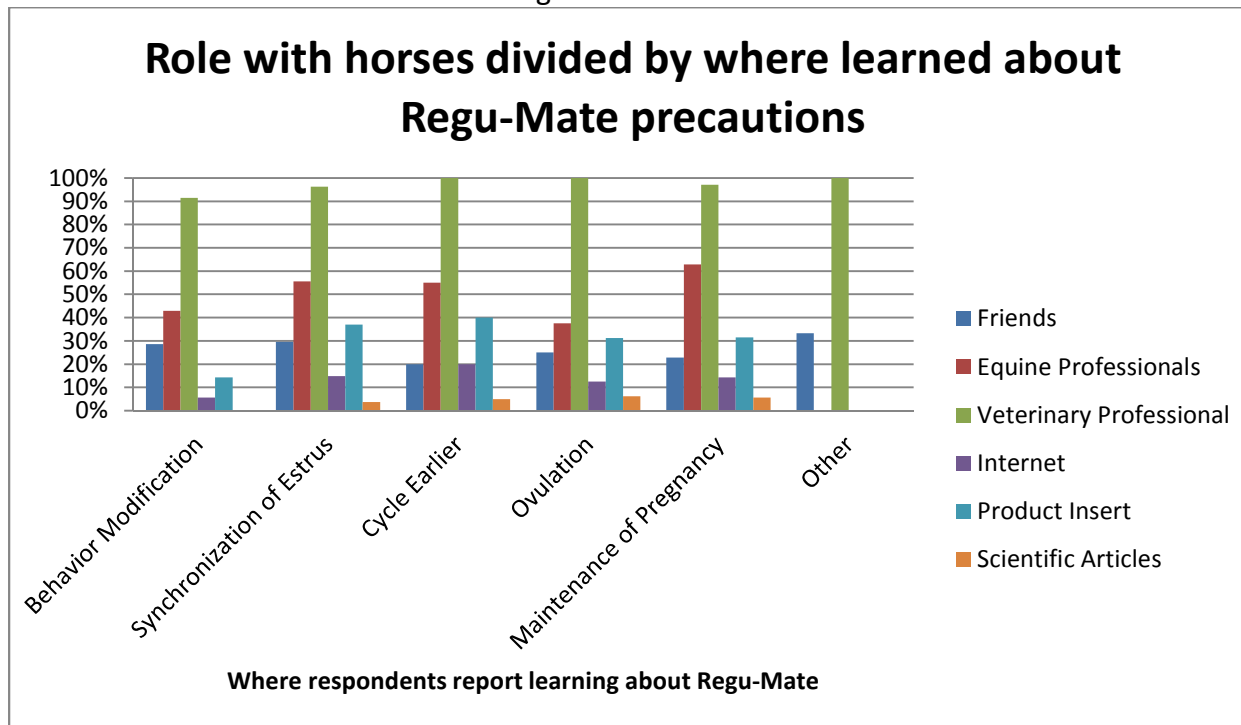
Other

Row Labels	Count of Learn_Friends	Count of Learn_Professional	Count of Learn_Vet	Count of Learn_Internet	Count of Learn_ProductInsert	Count of Learn_scientific articles
TRUE	1		3			
Grand Total	1		3			

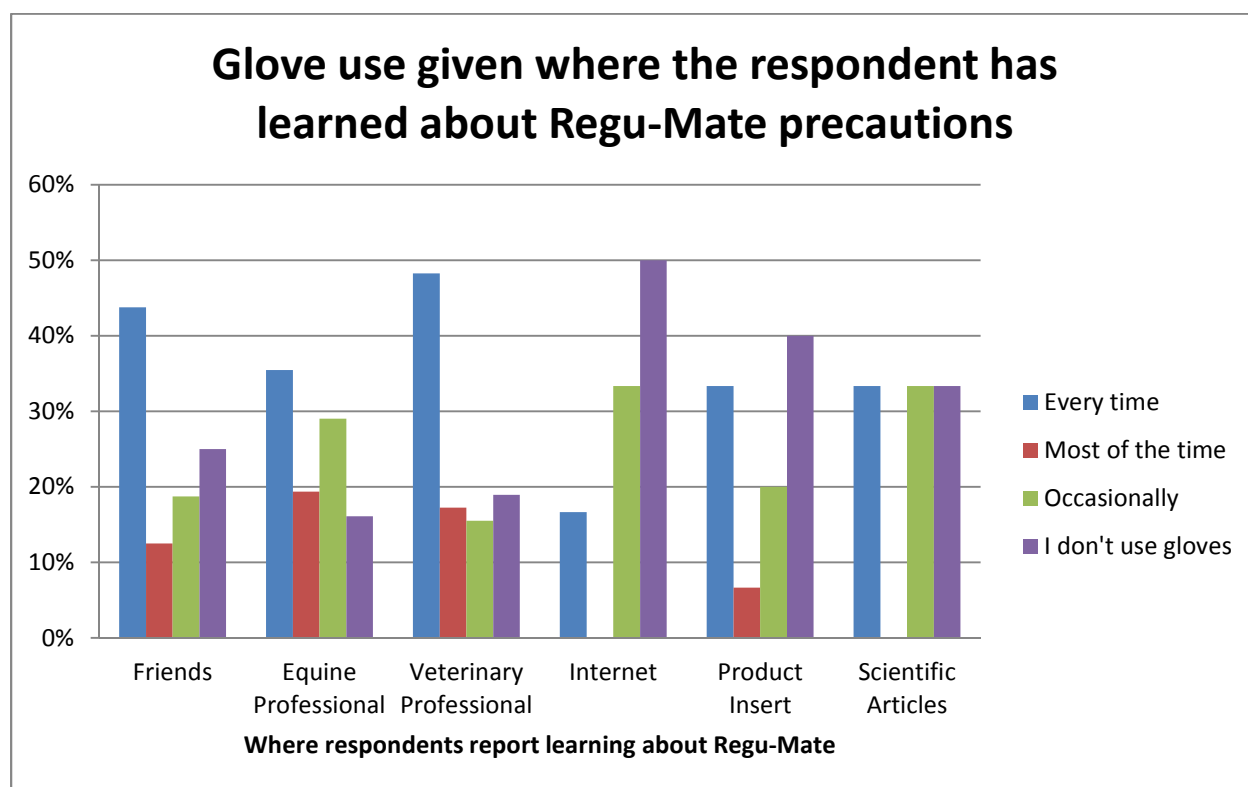
	Behavior Modification	Synchronization of Estrus	Cycle Earlier	Ovulation	Maintenance of Pregnancy	Other
Friends	29%	30%	20%	25%	23%	33%
Equine						
Professionals	43%	56%	55%	38%	63%	0%
Veterinary						
Professional	91%	96%	100%	100%	97%	100%
Internet	6%	15%	20%	13%	14%	0%

Product Insert	14%	37%	40%	31%	31%	0%
Scientific Articles	0%	4%	5%	6%	6%	0%

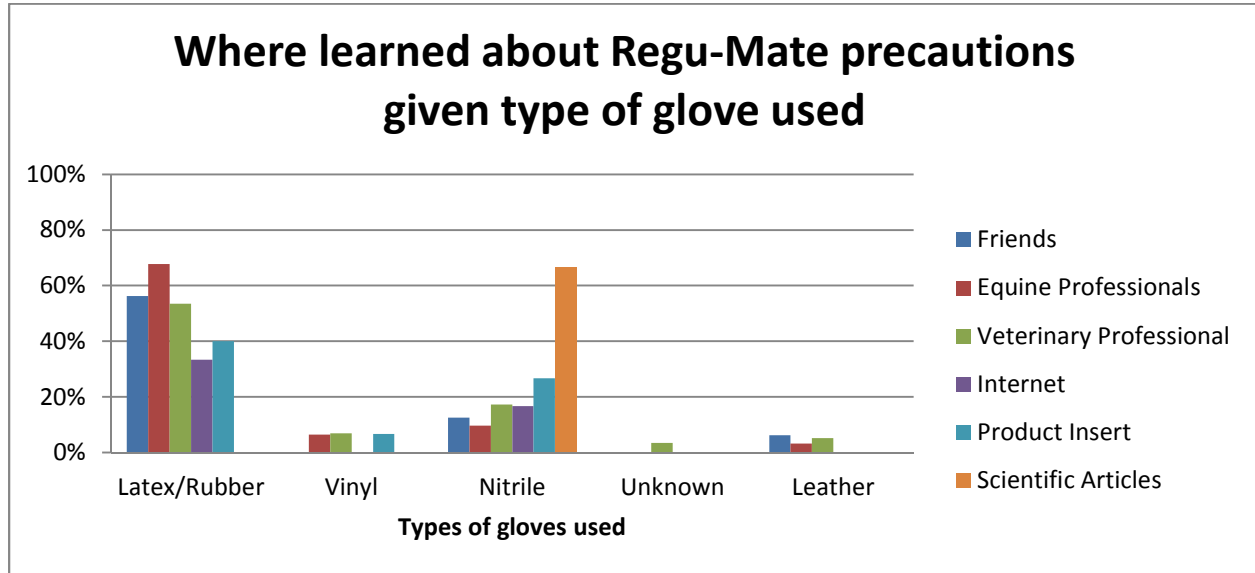
Percent of those using for a specific reason that learn from the following categories



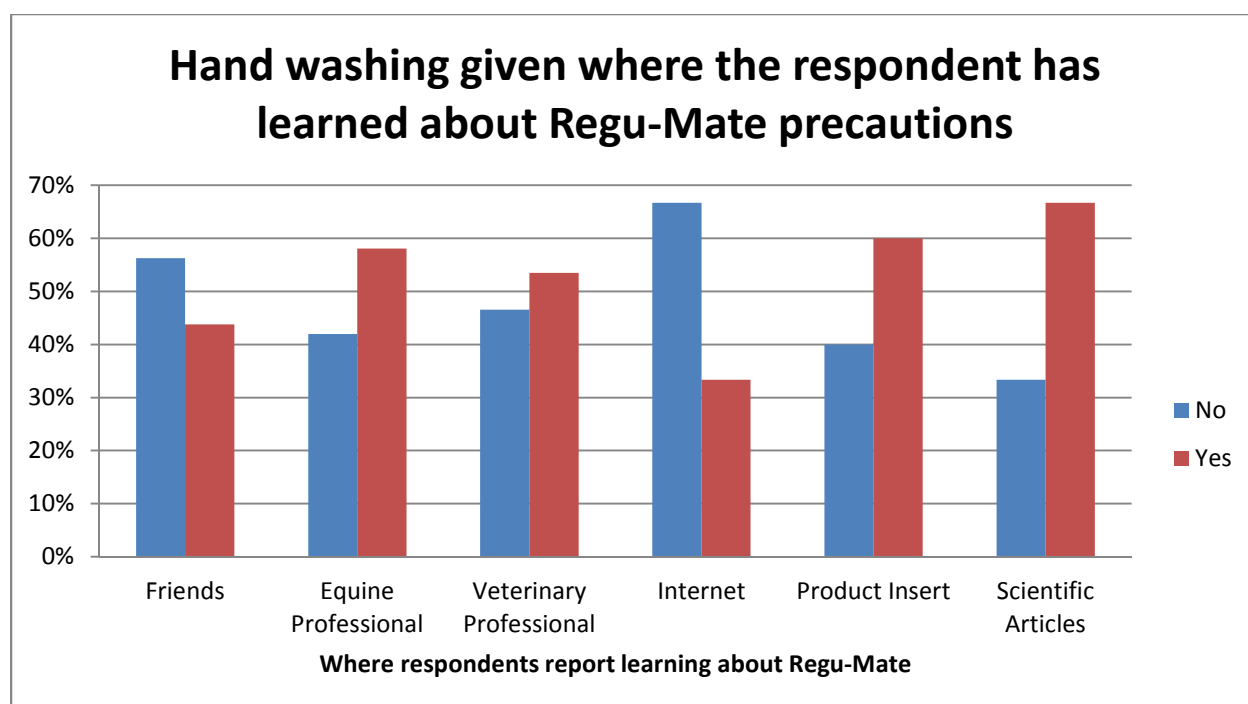
	Column Labels					
Values	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total	
Friends	44%	13%	19%	25%	100%	
Equine Professional	35%	19%	29%	16%	100%	
Veterinary Professional	48%	17%	16%	19%	100%	
Internet	17%	0%	33%	50%	100%	
Product Insert	33%	7%	20%	40%	100%	
Scientific Articles	33%	0%	33%	33%	100%	



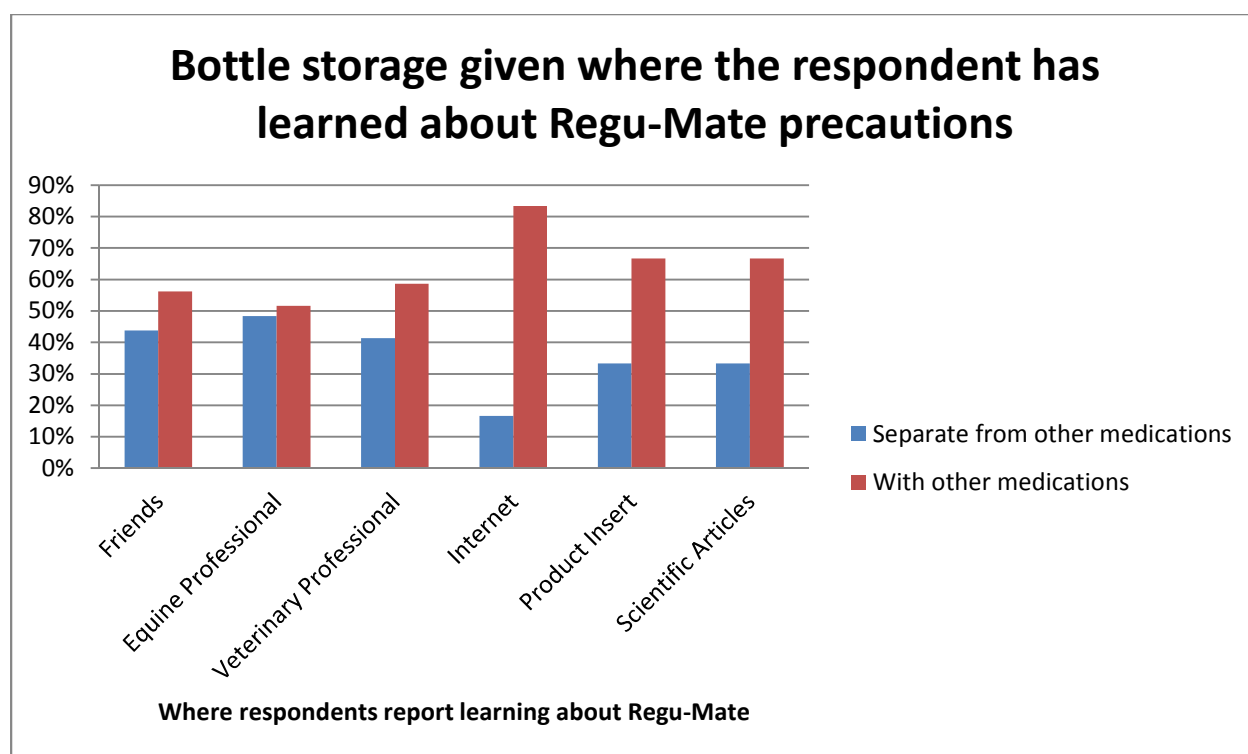
	Latex/Rubber	Vinyl	Nitrile	Unknown	Leather
Friends	56%	0%	13%	0%	6%
Equine Professionals	68%	6%	10%	0%	3%
Veterinary Professional	53%	7%	17%	3%	5%
Internet	33%	0%	17%	0%	0%
Product Insert	40%	7%	27%	0%	0%
Scientific Articles	0%	0%	67%	0%	0%



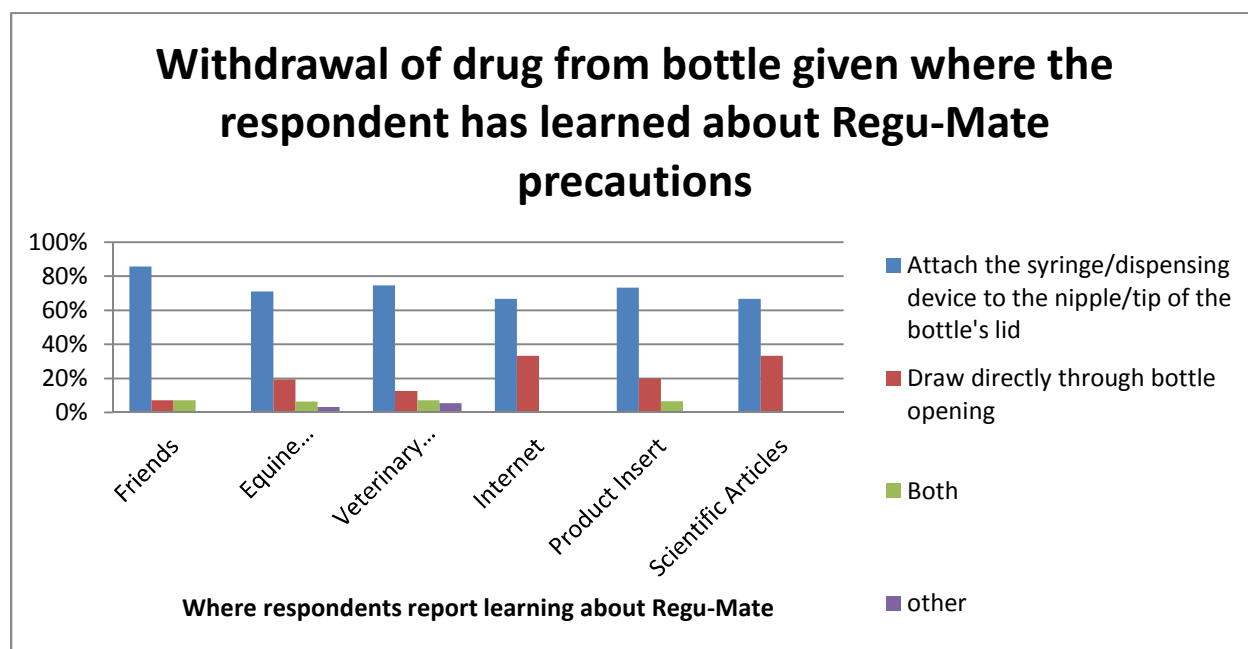
Values	Column Labels		Grand Total
	No	Yes	
Friends	56%	44%	100%
Equine Professional	42%	58%	100%
Veterinary Professional	47%	53%	100%
Internet	67%	33%	100%
Product Insert	40%	60%	100%
Scientific Articles	33%	67%	100%



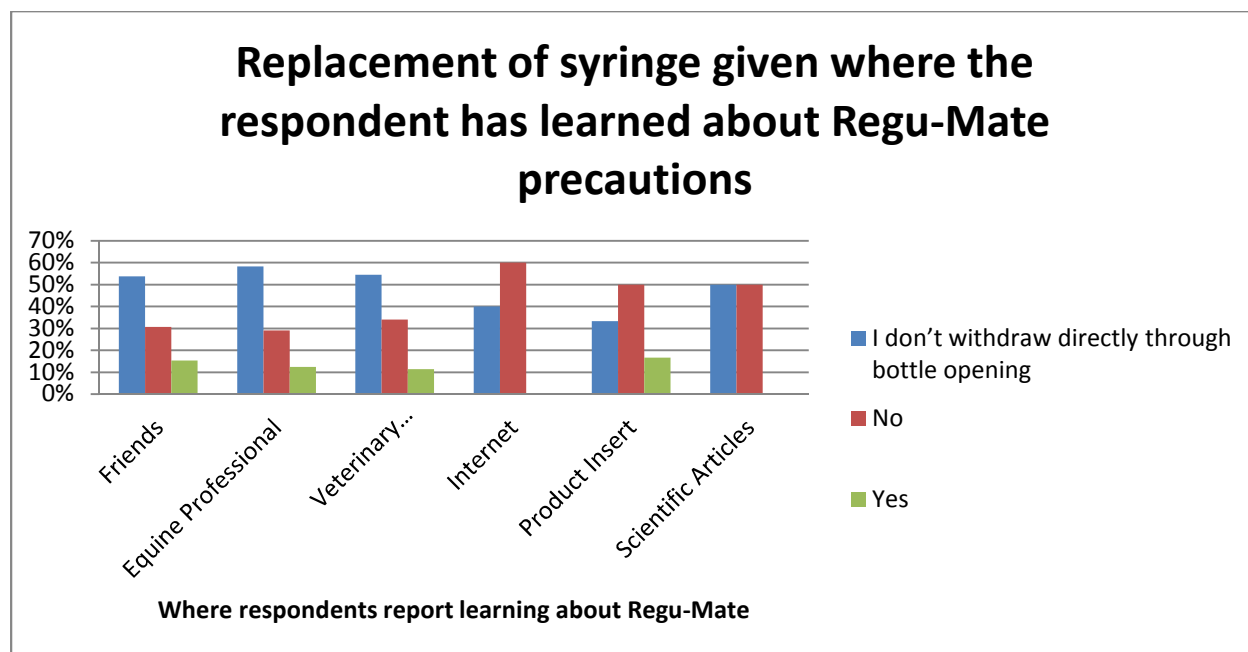
Values	Column Labels		
	Separate from other medications	With other medications	Grand Total
Friends	44%	56%	100%
Equine Professional	48%	52%	100%
Veterinary Professional	41%	59%	100%
Internet	17%	83%	100%
Product Insert	33%	67%	100%
Scientific Articles	33%	67%	100%



Column Labels					
Values	Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	Draw directly through bottle opening	Both	Other	Grand Total
			7		
Friends	86%	7%	%	0%	100%
Equine			6		
Professional	71%	19%	%	3%	100%
Veterinary			7		
Professional	75%	13%	%	5%	100%
			0		
Internet	67%	33%	%	0%	100%
Product			7		
Insert	73%	20%	%	0%	100%
Scientific			0		
Articles	67%	33%	%	0%	100%



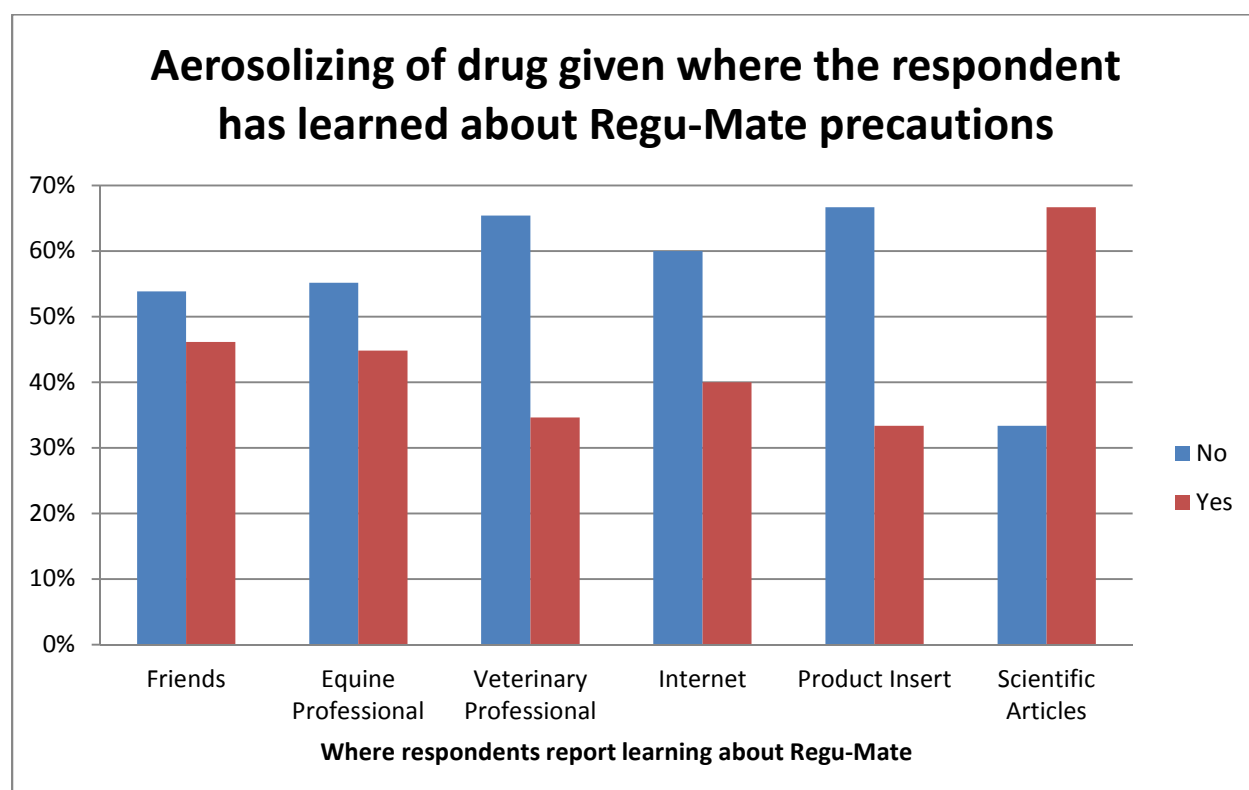
Tool		(Multiple Items)			
How many occasions has Regu-Mate come in direct contact with your skin?					
Values	Column Labels	I don't withdraw directly through bottle opening	N	Ye	Grand
			o	s	Total
Friends	54%		31	15	100%
			%	%	
Equine Professional	58%		29	13	100%
			%	%	
Veterinary Professional	55%		34	11	100%
			%	%	
Internet	40%		60	0	100%
			%	%	
Product Insert	33%		50	17	100%
			%	%	
Scientific Articles	50%		50	0	100%
			%	%	



Tool	(Multiple Items)
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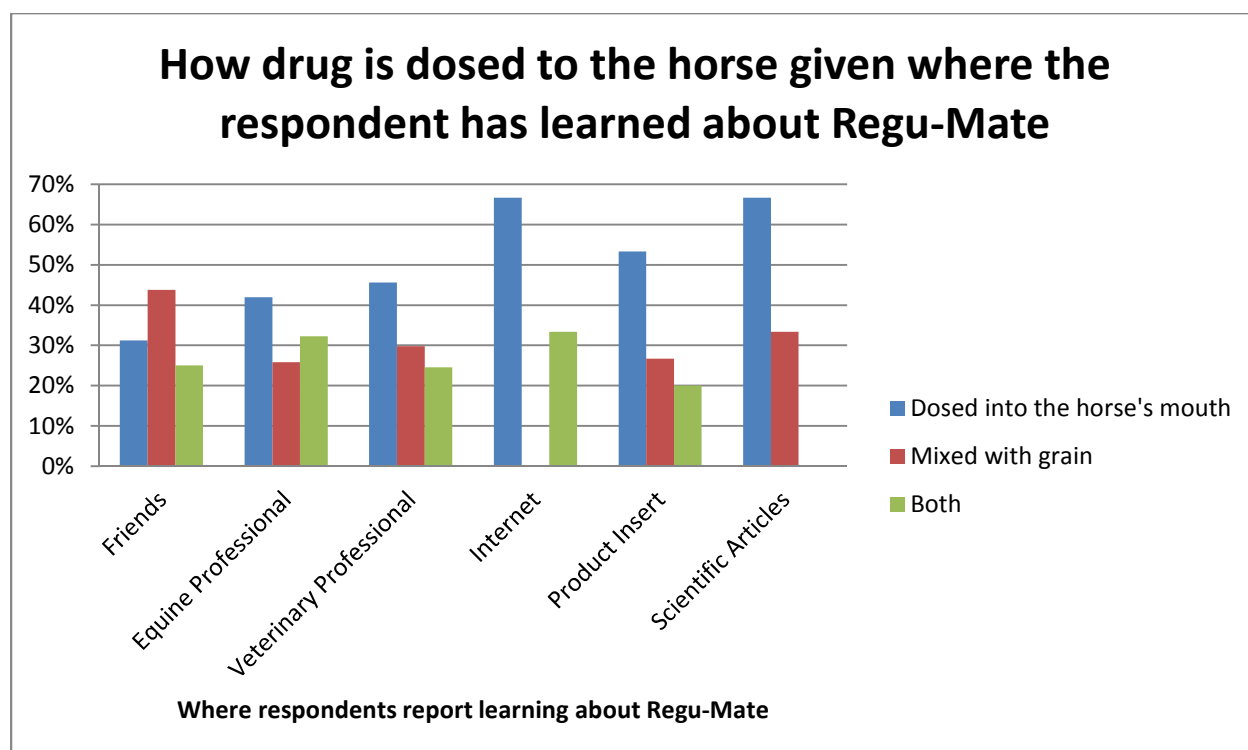
How many occasions has Regu-Mate come in direct contact with your skin?

	Column Labels		
Values	No	Yes	Grand Total
Friends	54%	46%	100%
Equine Professional	55%	45%	100%
Veterinary Professional	65%	35%	100%
Internet	60%	40%	100%
Product Insert	67%	33%	100%
Scientific Articles	33%	67%	100%



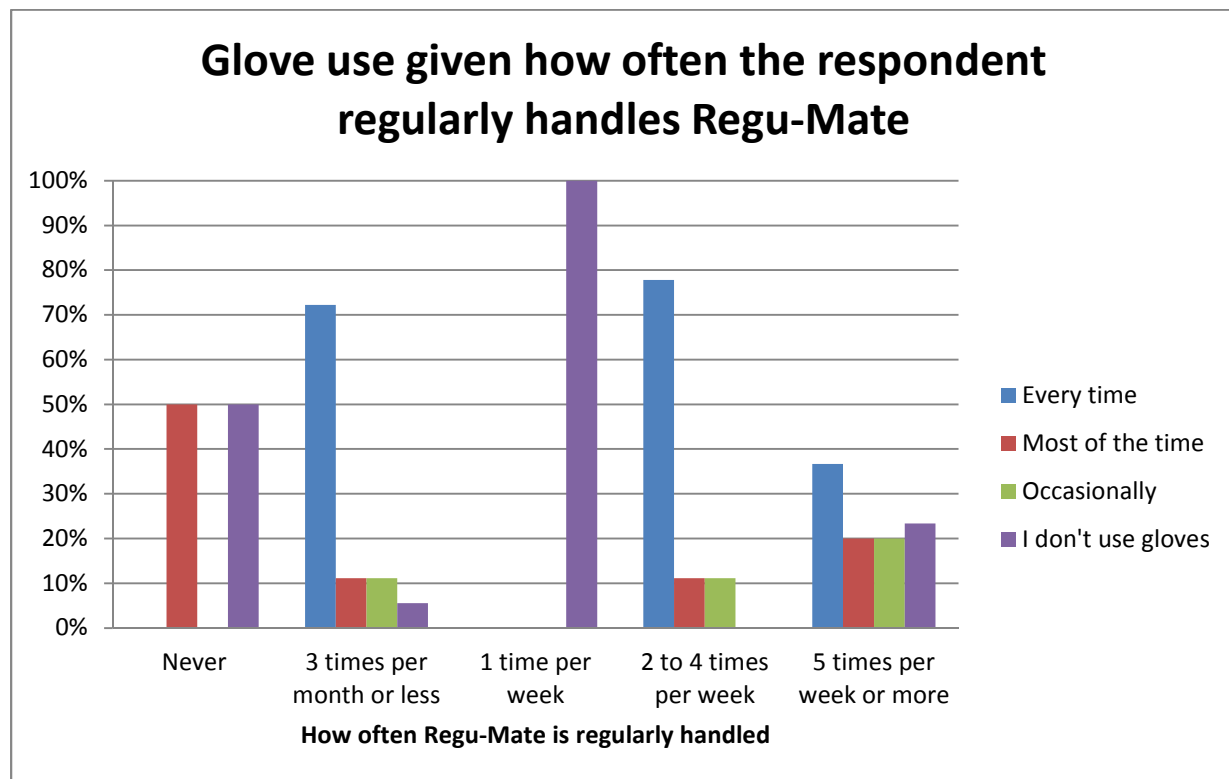
How many occasions has Regu-Mate come in direct contact with your skin?

Values	Column Labels Dosed into the horse's mouth	Mixed with grain	Both	Grand Total
Friends	31%	44%	25%	100%
Equine Professional	42%	26%	32%	100%
Veterinary Professional	46%	30%	25%	100%
Internet	67%	0%	33%	100%
Product Insert	53%	27%	20%	100%
Scientific Articles	67%	33%	0%	100%

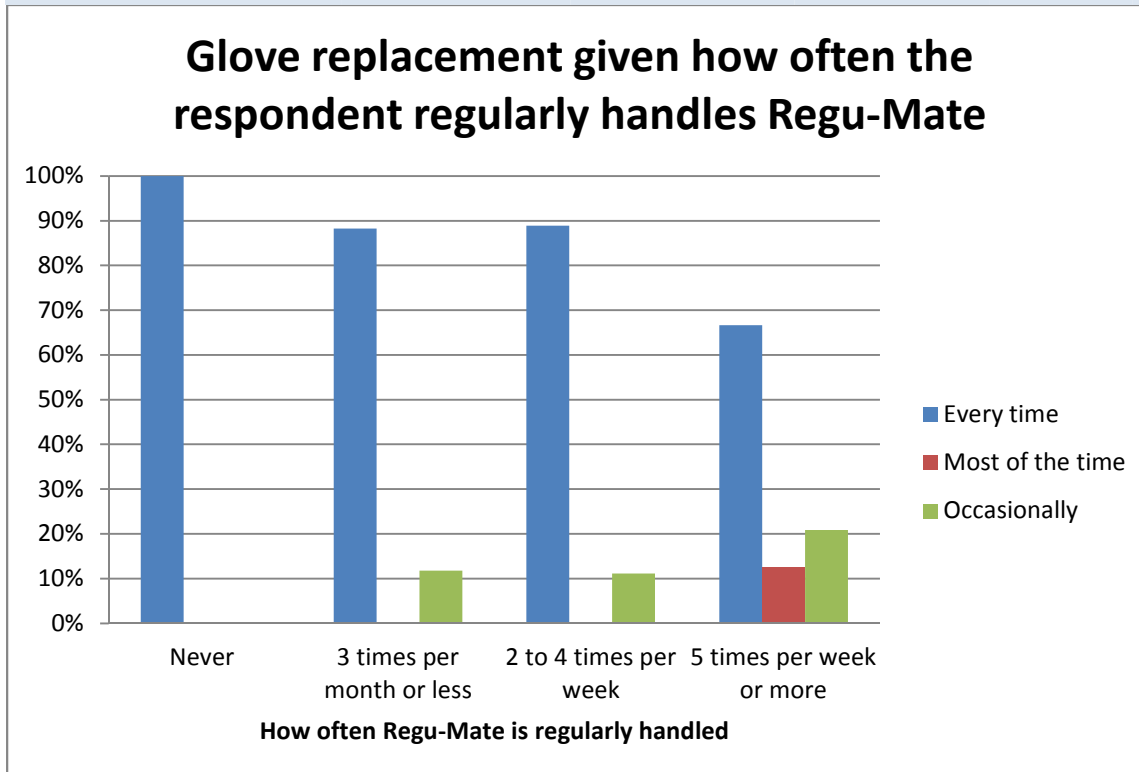


HOW OFTEN HANDLED

Count of Often_Handle	Column Labels				Grand Total
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	
Never	0%	50%	0%	50%	100%
1 time per week	0%	0%	0%	100%	100%
2 to 4 times per week	78%	11%	11%	0%	100%
3 times per month or less	72%	11%	11%	6%	100%
5 times per week or more	37%	20%	20%	23%	100%
Grand Total	51%	16%	15%	18%	100%

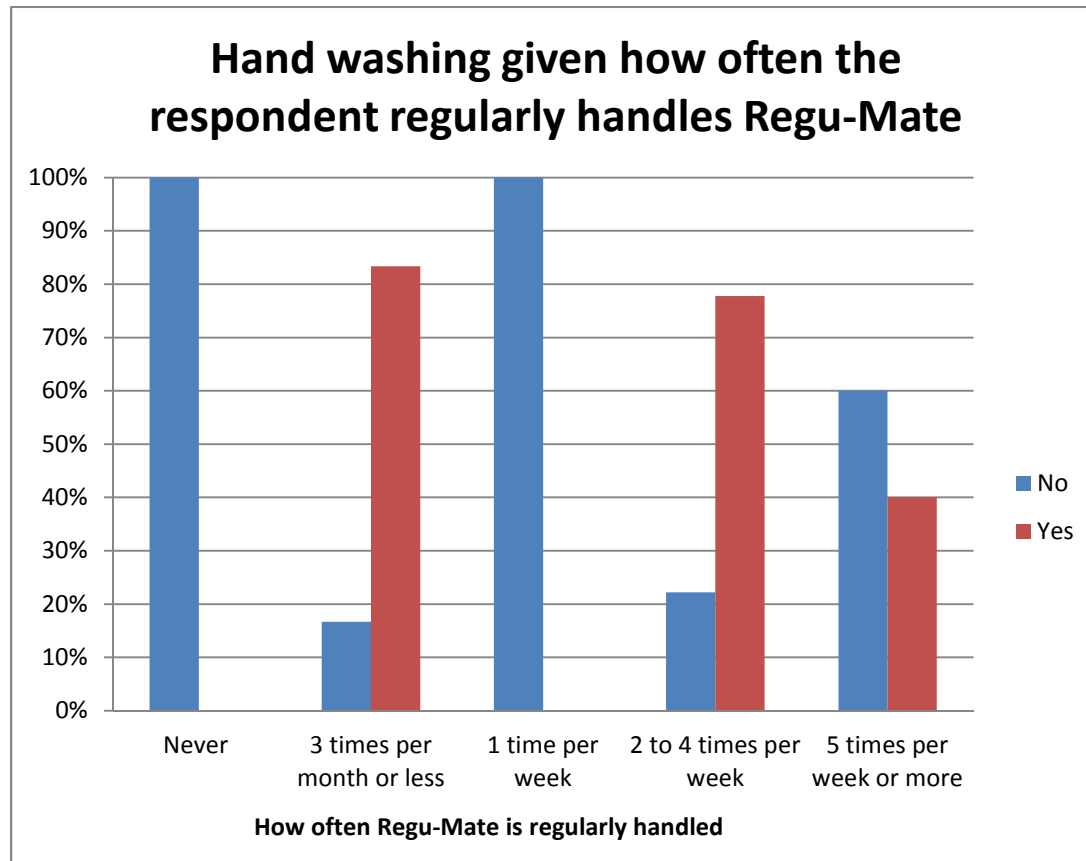


Count of Often_Handle	Column Labels			Grand Total
Row Labels	Every time	Most of the time	Occasionally	
Never	100%	0%	0%	100%
3 times per month or less	88%	0%	12%	100%
2 to 4 times per week	89%	0%	11%	100%
5 times per week or more	67%	13%	21%	100%
Grand Total	78%	6%	16%	100%

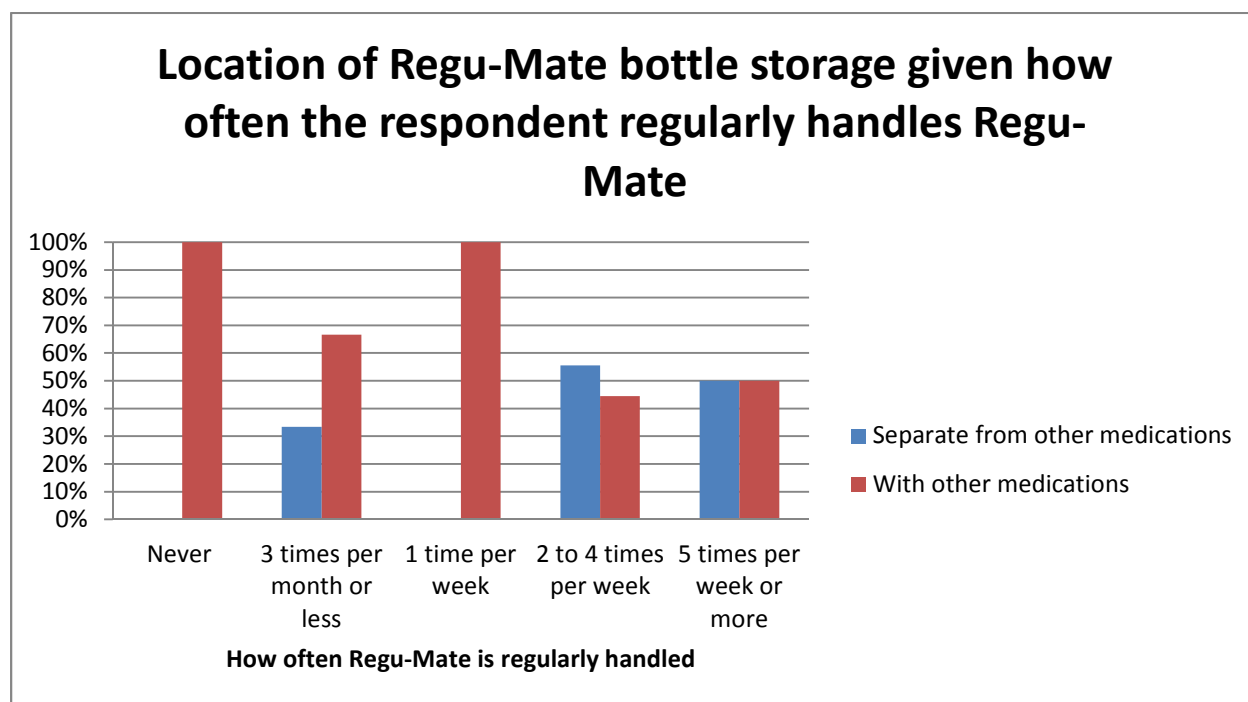


How often do you handle Regu-Mate?

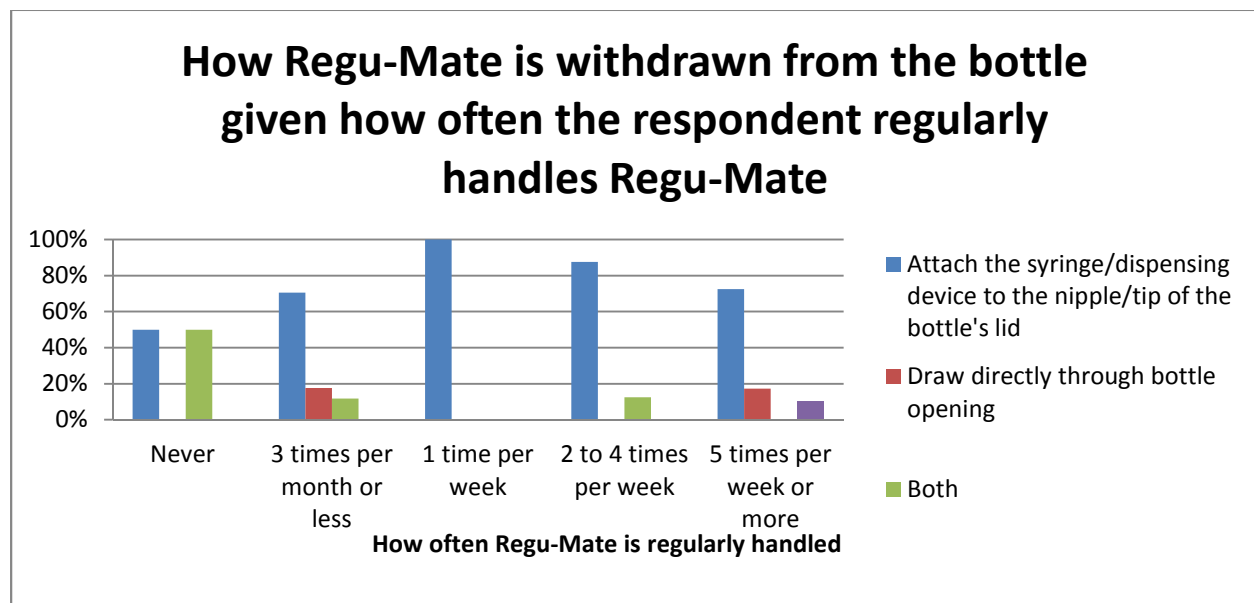
Count of Often_Handle	Column Labels		Grand Total
	No	Yes	
Never	100%	0%	100%
1 time per week	100%	0%	100%
3 times per month or less	17%	83%	100%
2 to 4 times per week	22%	78%	100%
5 times per week or more	60%	40%	100%
Grand Total	44%	56%	100%



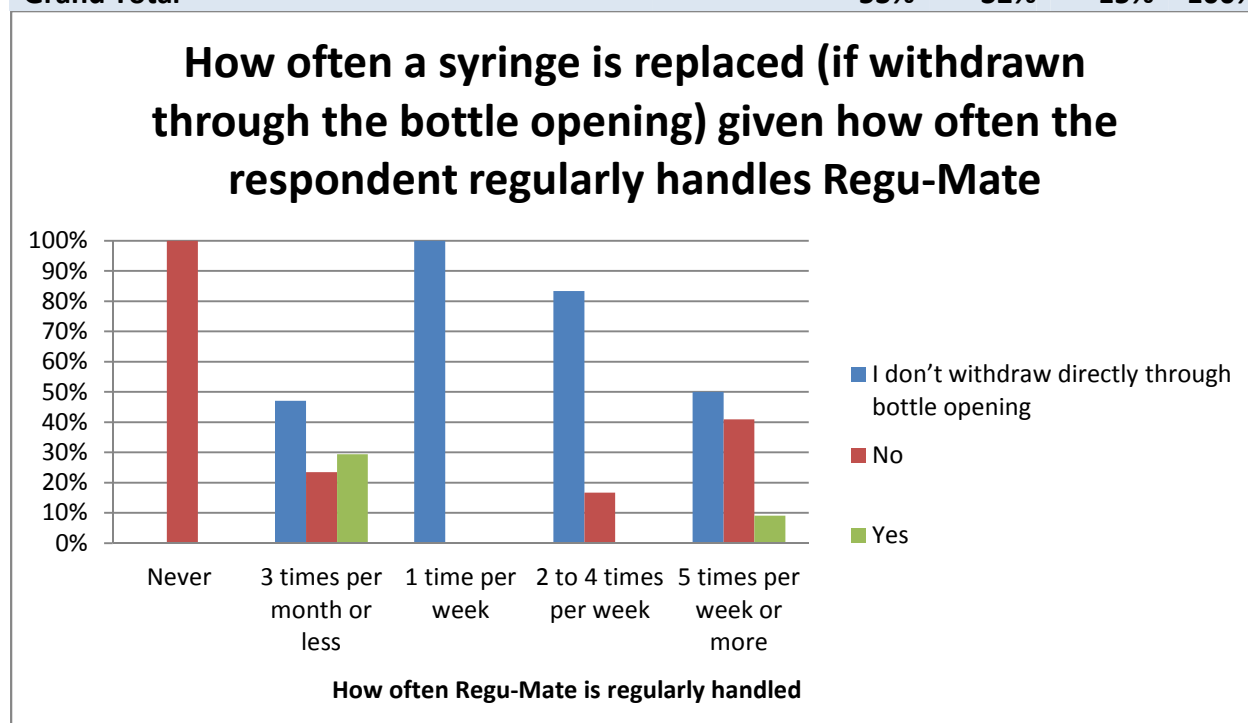
Count of Often_Handle	Column Labels		
Row Labels	Separate from other medications	With other medications	Grand Total
Never	0%	100%	100%
1 time per week	0%	100%	100%
3 times per month or less	33%	67%	100%
2 to 4 times per week	56%	44%	100%
5 times per week or more	50%	50%	100%
Grand Total	43%	57%	100%



Count of Often_Handled					
Column Labels					
Row Labels	Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	Draw directly through bottle opening	Both	Other	Grand Total
Never	50%	0%	50	0	100%
1 time per week	100%	0%	0	0	100%
3 times per month or less	71%	18%	12	0	100%
2 to 4 times per week	88%	0%	13	0	100%
5 times per week or more	72%	17%	0	10	100%
Grand Total	74%	14%	7	5	100%

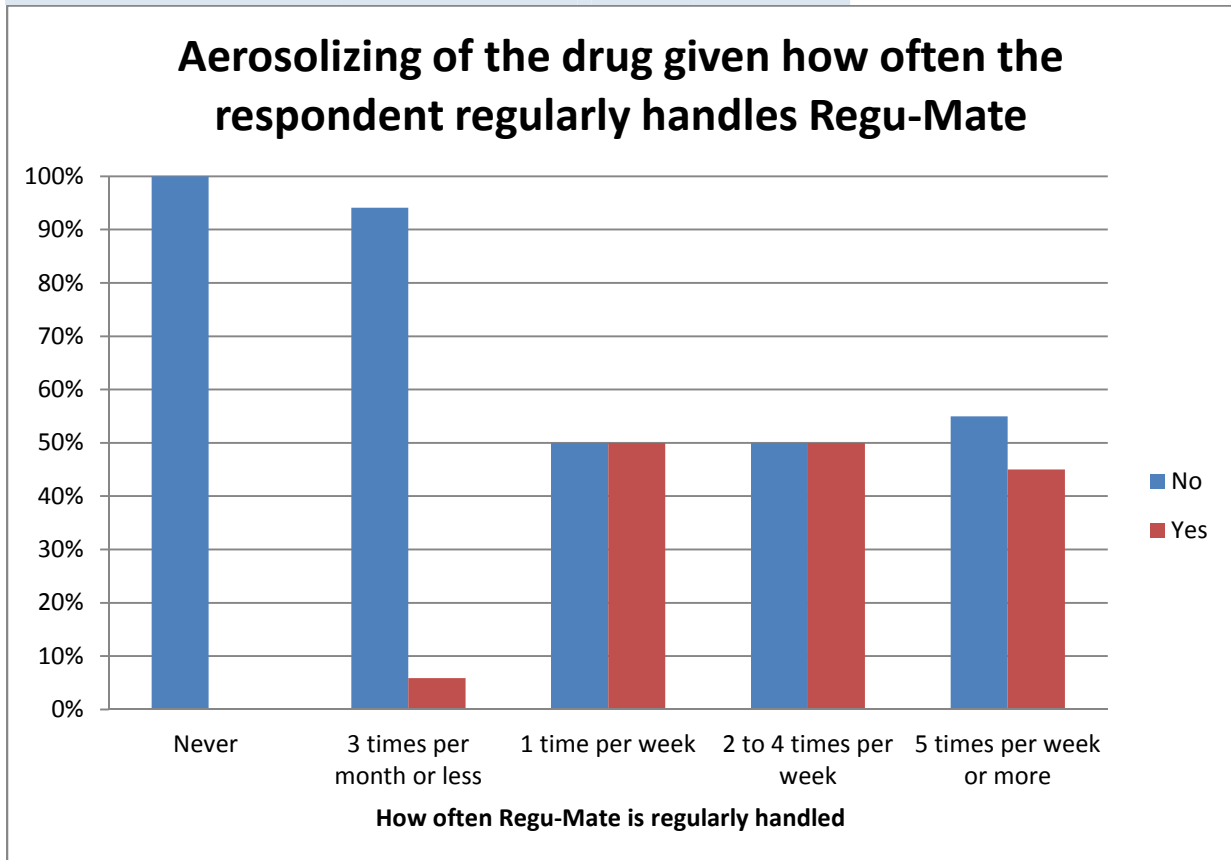


Tool	(Multiple Items)			
Count of Often_Handle	Column Labels			
Row Labels	I don't withdraw directly through bottle opening	No	Yes	Grand Total
Never	0%	100%	0%	100%
1 time per week	100%	0%	0%	100%
3 times per month or less	47%	24%	29%	100%
2 to 4 times per week	83%	17%	0%	100%
5 times per week or more	50%	41%	9%	100%
Grand Total	53%	32%	15%	100%

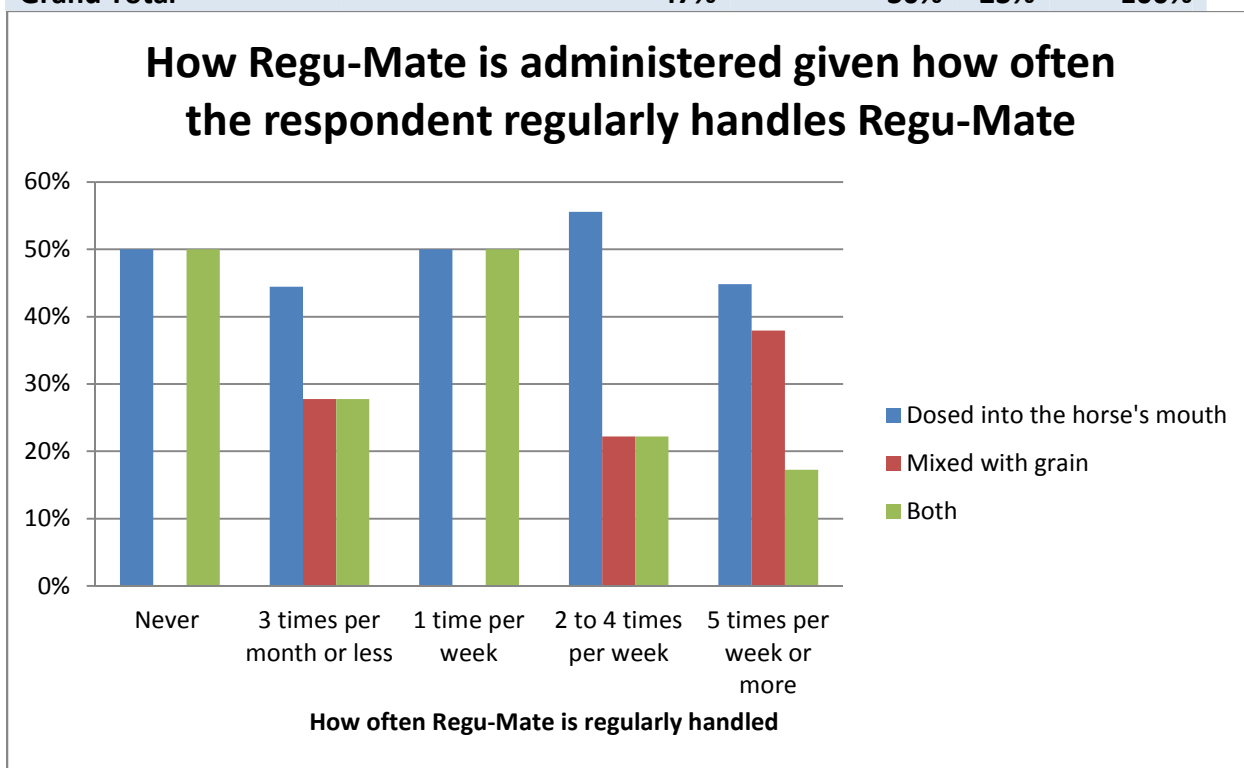


Tool (Multiple Items)

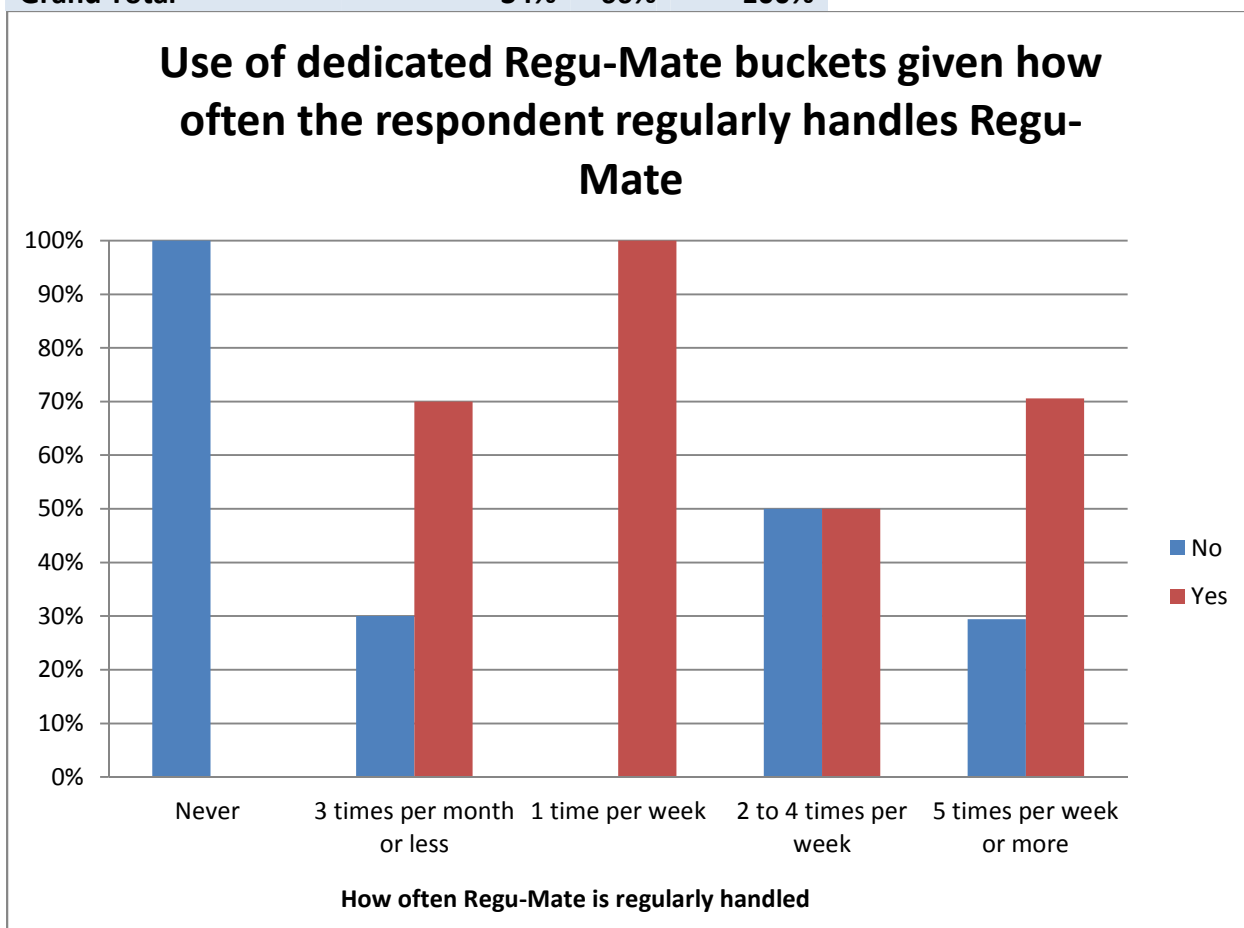
Count of Often_Handle	Column Labels		Grand Total
Row Labels	No	Yes	
Never	100%	0%	100%
1 time per week	50%	50%	100%
3 times per month or less	94%	6%	100%
2 to 4 times per week	50%	50%	100%
5 times per week or more	55%	45%	100%
Grand Total	70%	30%	100%



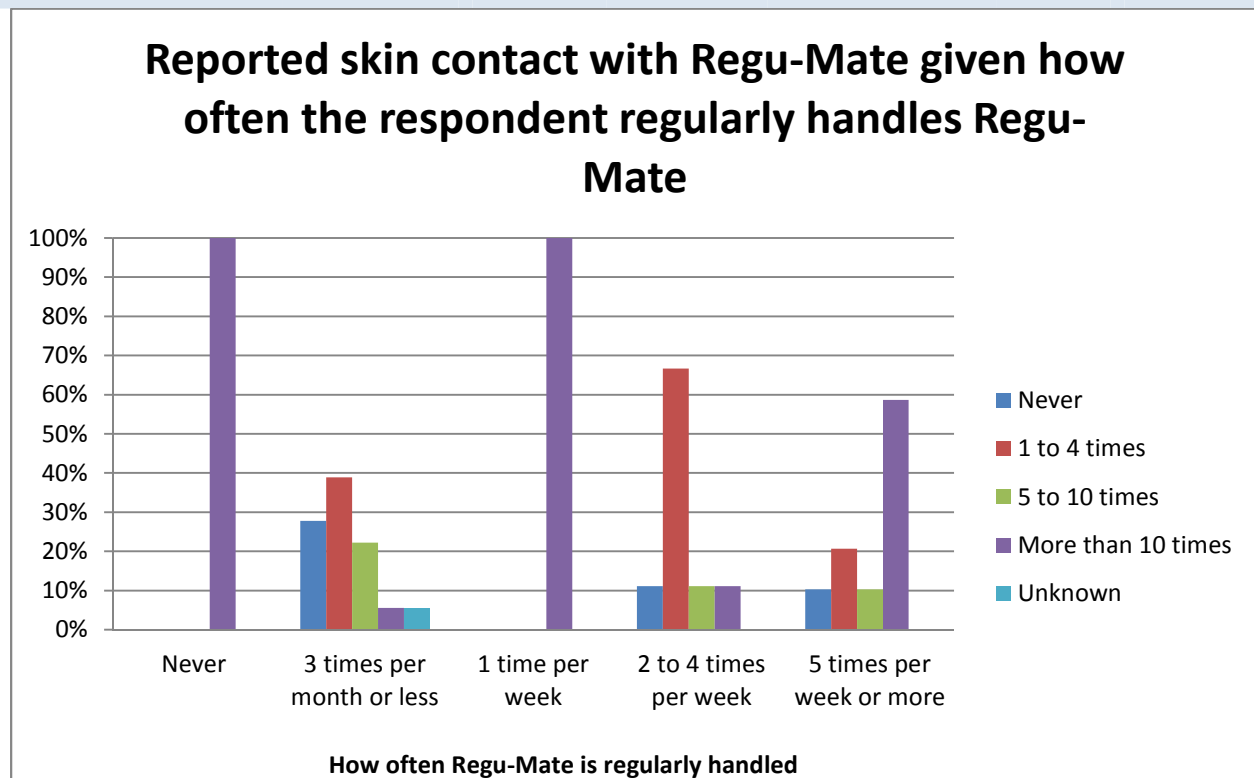
Count of Often_Handle	Column Labels				
Row Labels	Dosed into the horse's mouth	Mixed with grain	Both	Grand Total	
Never	50%	0%	50%	100%	
1 time per week	50%	0%	50%	100%	
3 times per month or less	44%	28%	28%	100%	
2 to 4 times per week	56%	22%	22%	100%	
5 times per week or more	45%	38%	17%	100%	
Grand Total	47%	30%	23%	100%	



Count of Often_Handle	Column Labels		
Row Labels	No	Yes	Grand Total
Never	100%	0%	100%
1 time per week	0%	100%	100%
3 times per month or less	30%	70%	100%
2 to 4 times per week	50%	50%	100%
5 times per week or more	29%	71%	100%
Grand Total	34%	66%	100%

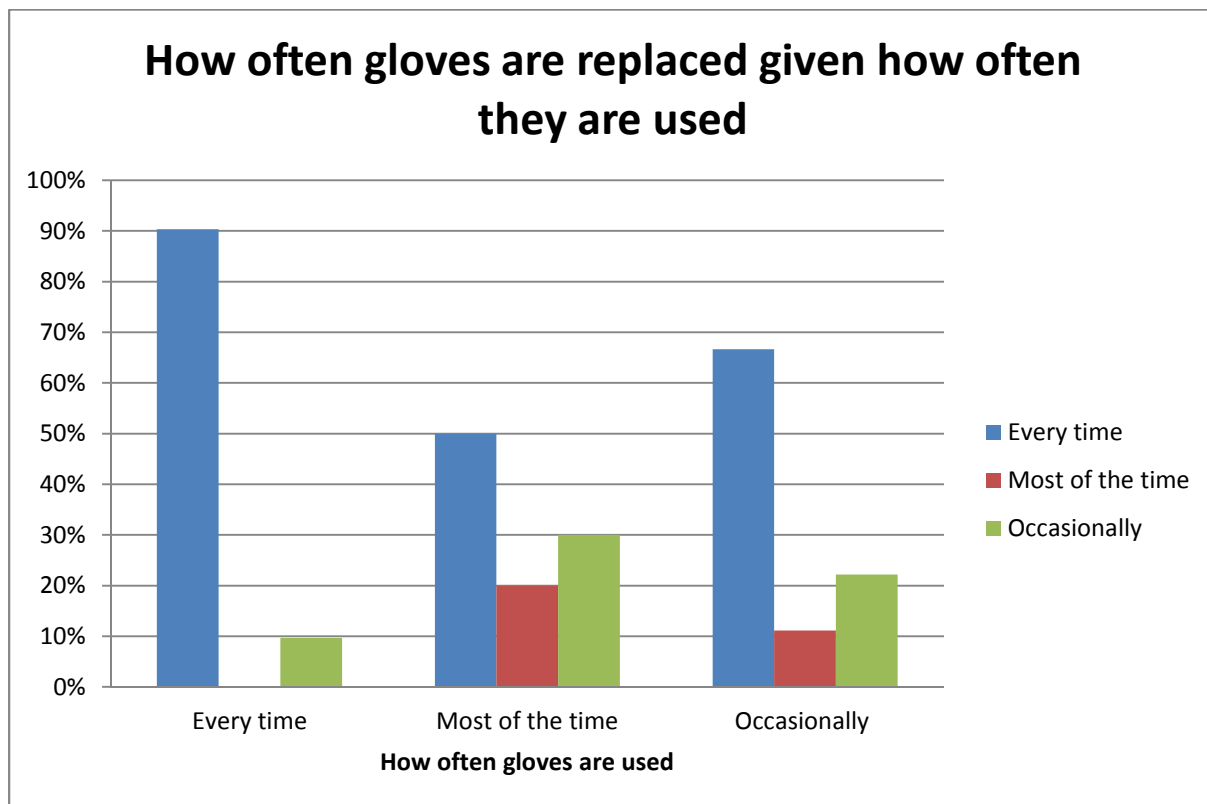


Count of Often_Handle	Column Labels					
Row Labels	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total
Never	0%	0%	0%	100%	0%	100%
3 times per month or less	28%	39%	22%	6%	6%	100%
1 time per week	0%	0%	0%	100%	0%	100%
2 to 4 times per week	11%	67%	11%	11%	0%	100%
5 times per week or more	10%	21%	10%	59%	0%	100%
Grand Total	15%	32%	13%	38%	2%	100%

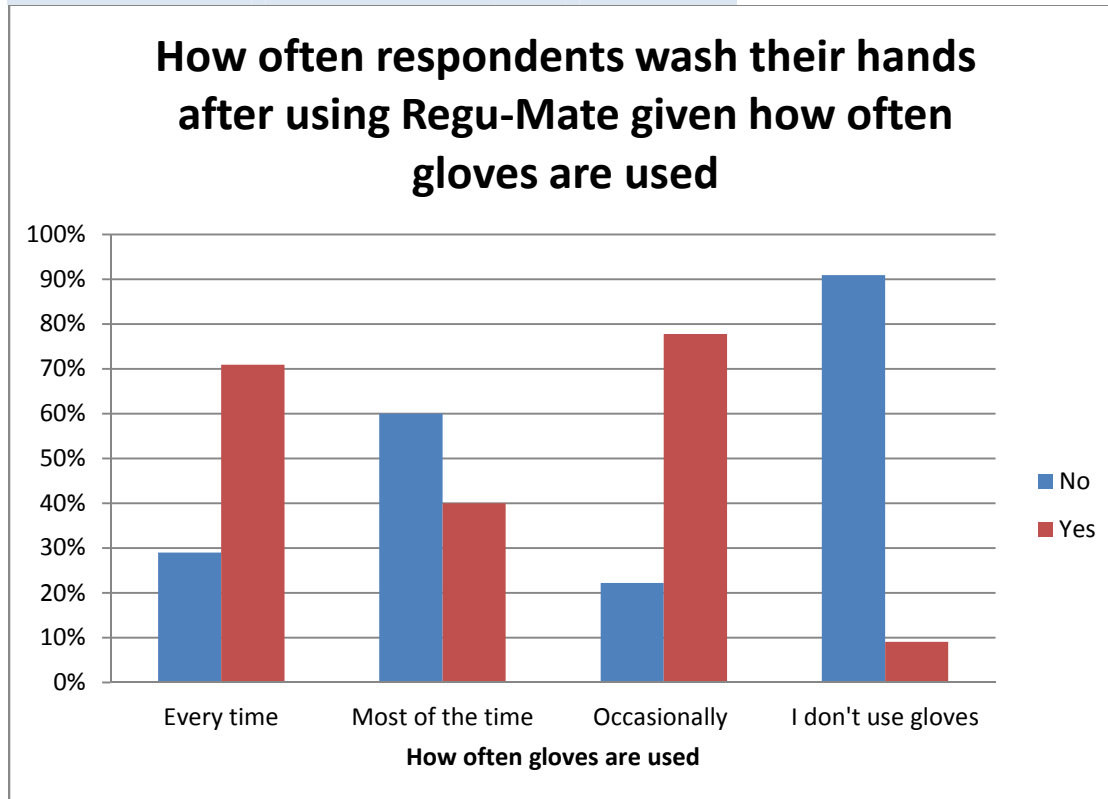


GLOVE USE

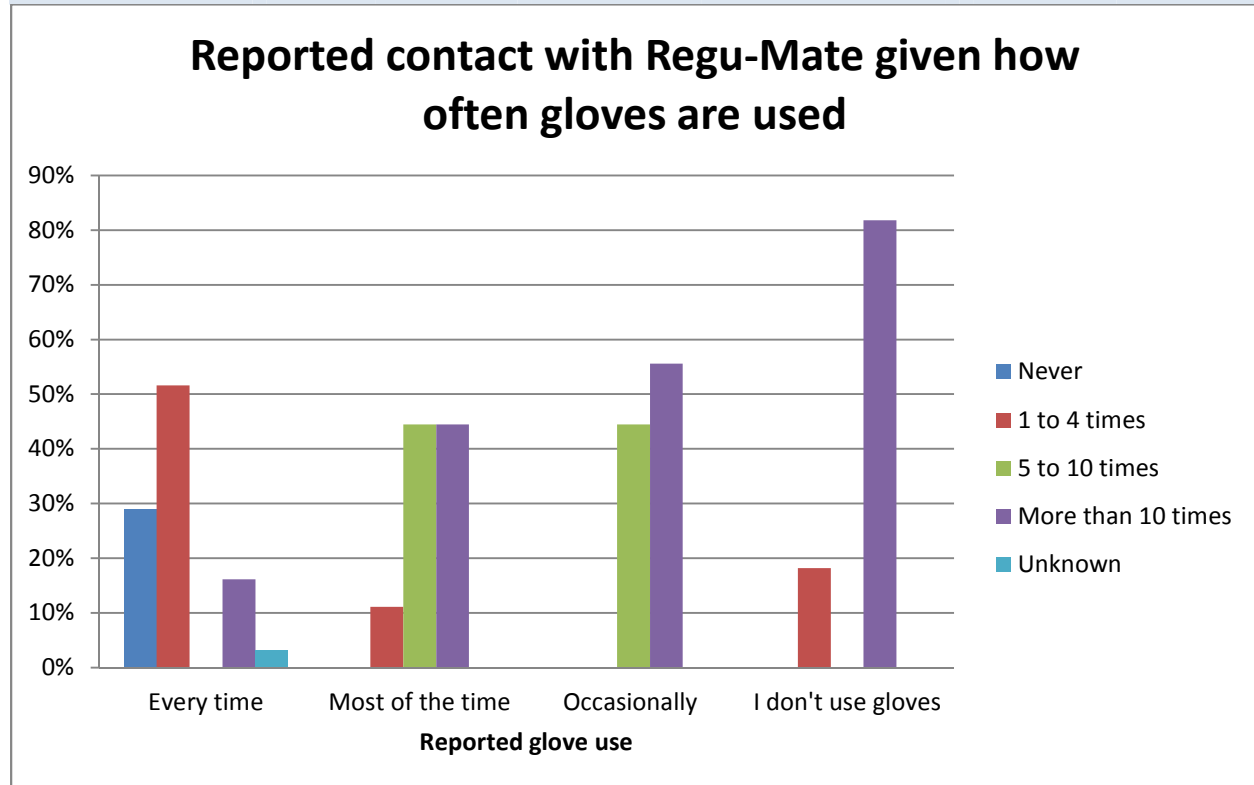
Count of Glove Use	Column Labels			
Row Labels	Every time	Most of the time	Occasionally	Grand Total
Every time	90%	0%	10%	100%
Most of the time	50%	20%	30%	100%
Occasionally	67%	11%	22%	100%
Grand Total	78%	6%	16%	100%



Count of Glove Use	Column Labels		
Row Labels	No	Yes	Grand Total
Every time	29%	71%	100%
Most of the time	60%	40%	100%
Occasionally	22%	78%	100%
I don't use gloves	91%	9%	100%
Grand Total	44%	56%	100%



Count of Glove Use	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total
Every time	29%	52%	0%	16%	3%	100%
Most of the time	0%	11%	44%	44%	0%	100%
Occasionally	0%	0%	44%	56%	0%	100%
I don't use gloves	0%	18%	0%	82%	0%	100%
Grand Total	15%	32%	13%	38%	2%	100%



Vet Discussed Glove Use vs. Actual Glove Use

Count of Glove Use	Column Labels	
Row Labels	TRUE	Grand Total
Every time	54%	54%
Most of the time	17%	17%
Occasionally	17%	17%
I don't use gloves	13%	13%
Grand Total	100%	100%

Participants whose vets did not talk about glove use

Education_NR	(blank)
Education_NoDiscussion	(blank)

Count of Glove Use	Column Labels	
Row Labels	(blank)	Grand Total
Most of the time	25%	25%
I don't use gloves	75%	75%
Grand Total	100%	100%

Vet Discussed Skin Contact Use vs. Actual Glove Use

Count of Glove Use	Column Labels	
Row Labels	TRUE	Grand Total
Every time	51%	51%
Most of the time	18%	18%
Occasionally	16%	16%
I don't use gloves	16%	16%
Grand Total	100%	100%

Participants whose vets did not talk about skin contact

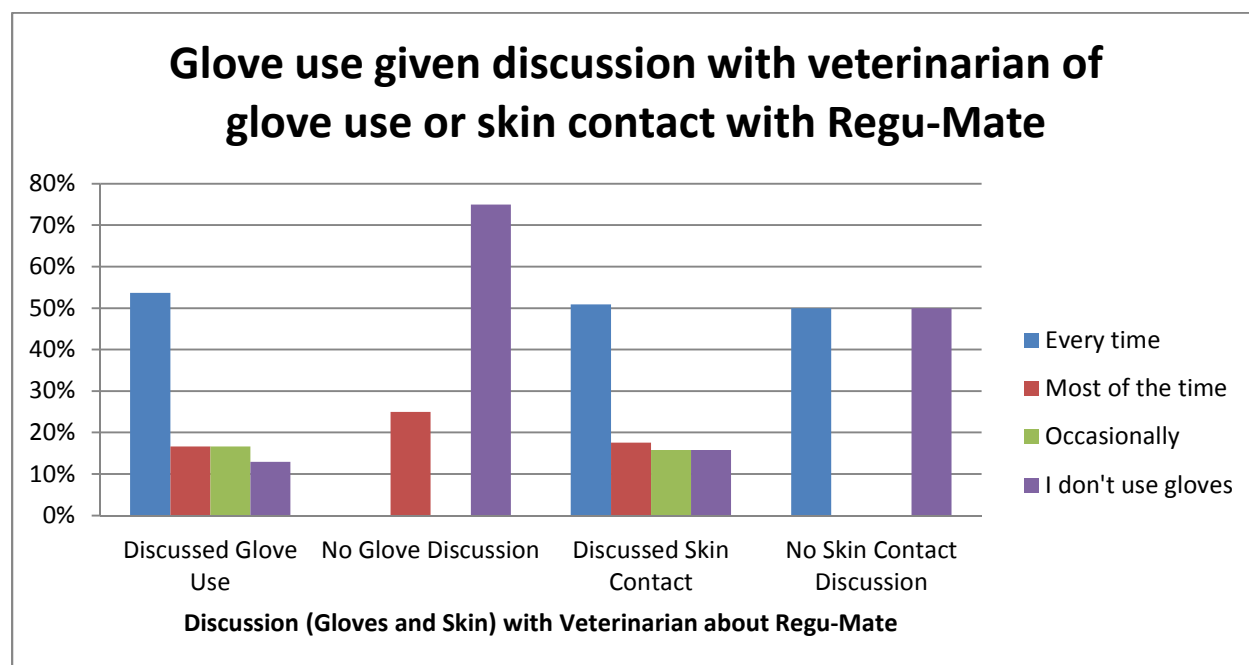
Education_NR	(blank)
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Count of Glove Use	Column Labels	
Row Labels	(blank)	Grand Total

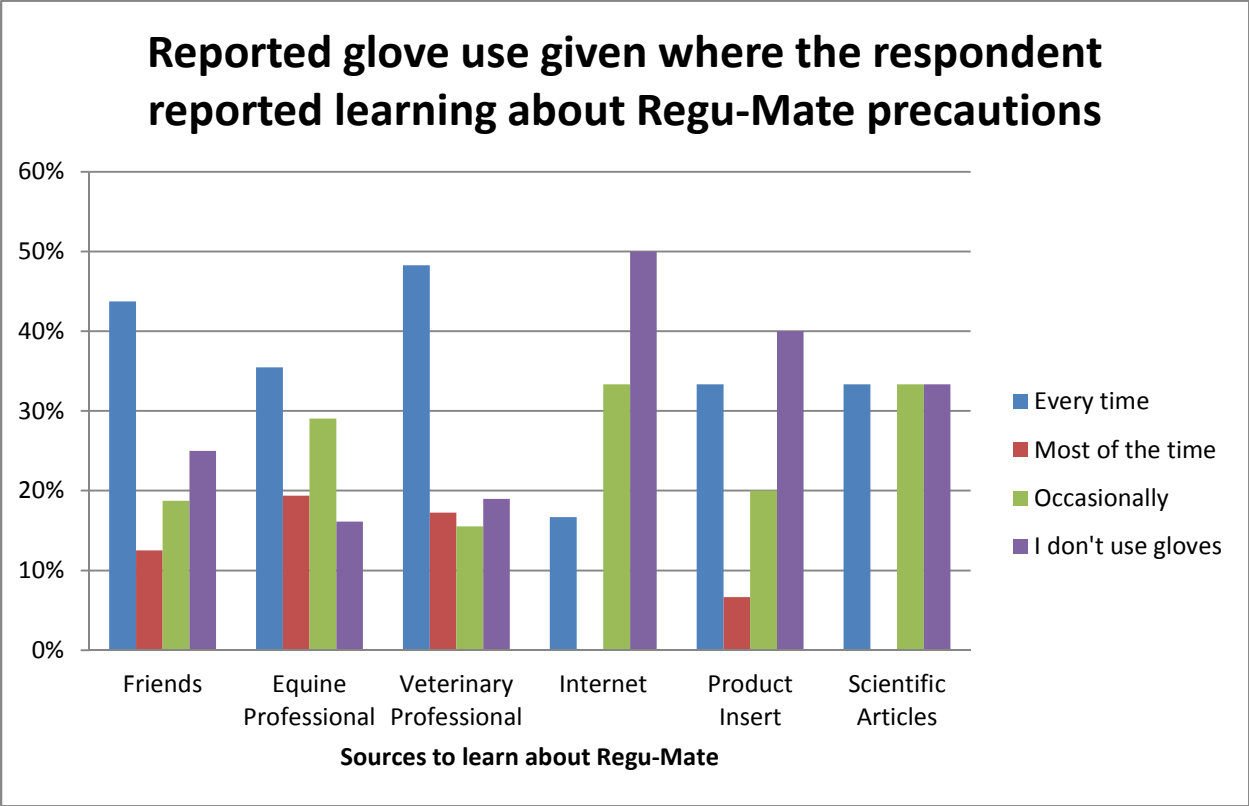
Every time	50%	50%
I don't use gloves	50%	50%
Grand Total	100%	100%

Report of Glove Use	
Row Labels	Count of Glove Use
Every time	31
Most of the time	10
Occasionally	9
I don't use gloves	11
Grand Total	61

Glove Use	Discussed Glove Use	No Glove Discussion	Discussed Skin Contact	No Skin Contact Discussion
Every time	54%	0%	51%	50%
Most of the time	17%	25%	18%	0%
Occasionally	17%	0%	16%	0
I don't use gloves	13%	75%	16%	50%



Glove use given learning about Regu-Mate						
	Column Labels					
Values	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total	
Friends	44%	13%	19%	25%	100%	
Equine Professional	35%	19%	29%	16%	100%	
Veterinary Professional	48%	17%	16%	19%	100%	
Internet	17%	0%	33%	50%	100%	
Product Insert	33%	7%	20%	40%	100%	
Scientific Articles	33%	0%	33%	33%	100%	

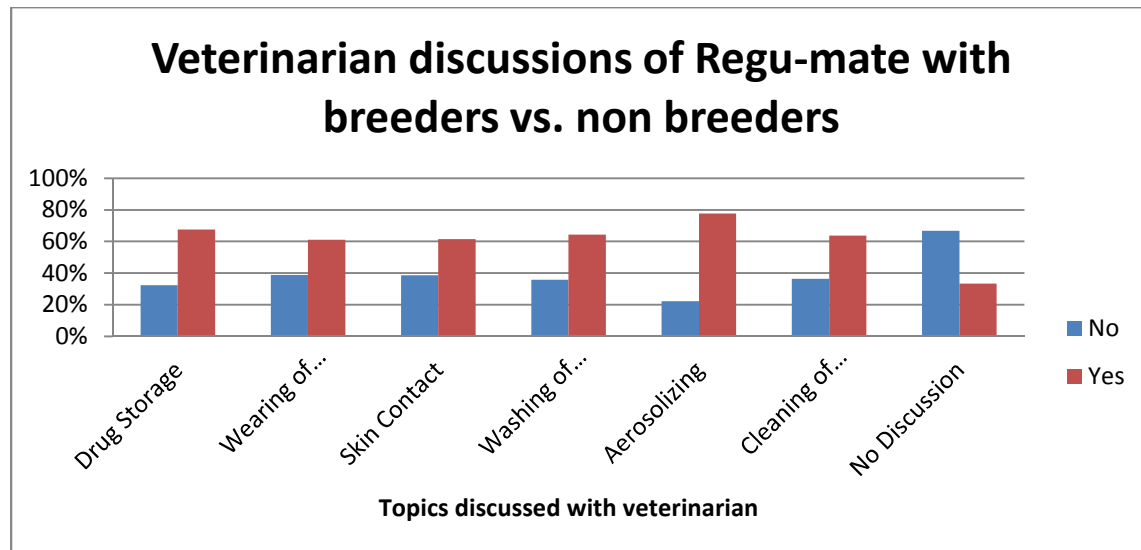


EDUCATION

Values	Column Labels		Grand Total
	No	Yes	
Drug Storage	32%	68%	100%
Wearing of Gloves	39%	61%	100%
Skin Contact	39%	61%	100%
Washing of Hands	36%	64%	100%
Aerosolizing	22%	78%	100%
Cleaning of Buckets	36%	64%	100%
No Discussion	67%	33%	100%

No	Yes
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Mean 34% Mean 66%

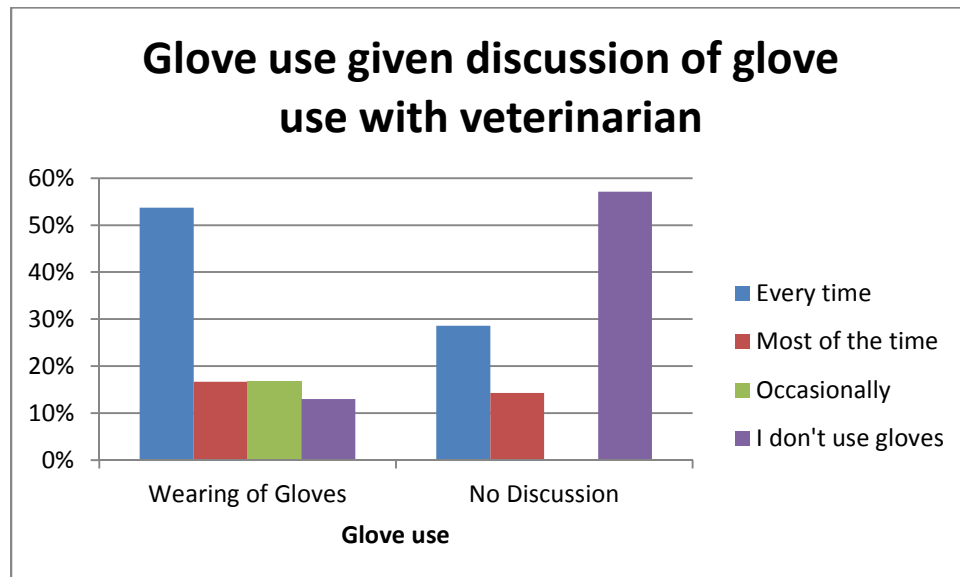


Values	Column Labels				Grand Total
	Every time	Most of the time	Occasionally	I don't use gloves	
Wearing of Gloves	54%	17%	17%	13%	100%
No Discussion	2			1	3

Education_NoDiscussion (blank)

Count of Glove Use	Column Labels				
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total
TRUE	29	9	9	7	54
(blank)		1		3	4
Grand Total	29	10	9	10	58

	Every time	Most of the time	Occasionally	I don't use gloves
Wearing of Gloves	54%	17%	17%	13%
No Discussion	29%	14%	0%	57%



	Column Labels		
Values	No	Yes	Grand Total
Skin Contact		42% 58%	100%
Washing Hands		31% 69%	100%
No Discussion		67% 33%	100%

Education_NoDiscussion (blank)

Count of WashHands	Column Labels		
Row Labels	No	(blank)	Grand Total
(blank)		1	1
Grand Total		1	1

Education_NoDiscussion (blank)

Count of WashHands	Column Labels			
Row Labels	No	Yes	(blank)	Grand Total
(blank)		12 4		16
Grand Total		12 4		16

	No	Yes
Skin Contact	42%	58%
Washing Hands	31%	69%
No Discussion	74%	26%

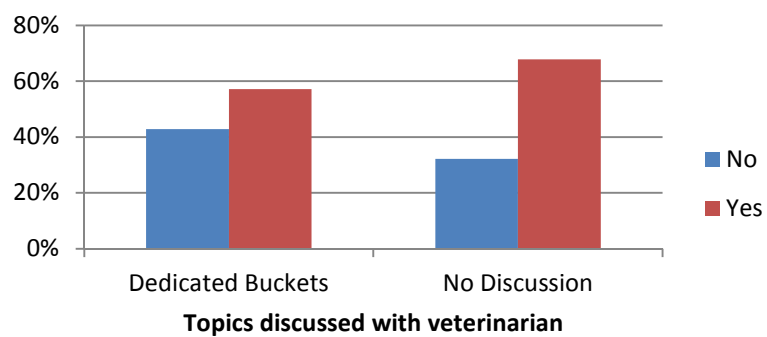


Values	Column Labels		Grand Total
	No	Yes	
		57	
Dedicated Buckets	43%	%	100%
No Discussion		3	3
Education_NoDiscussion	(blank)		

Count of Buckets	Column Labels		Grand Total
	No	Yes	
TRUE	3	4	7
(blank)	9	16	25
Grand Total	12	20	32

	No	Yes
Dedicated Buckets	43%	57%
No Discussion	32%	68%

Use of dedicated Regu-Mate buckets given discussion with veterinarian

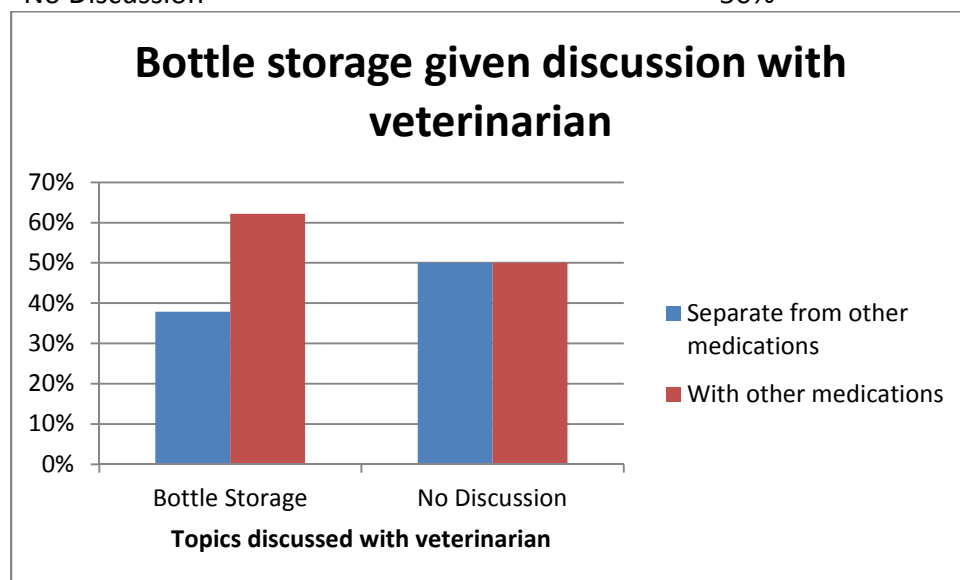


Values	Column Labels Separate from other medications	With other medications	Grand Total
Bottle Storage	38%	62%	100%
No Discussion	67%	33%	100%

Education_NoDiscussion (blank)

Count of BottleStorage	Column Labels Separate from other medications	With other medications	Grand Total
Row Labels			
(blank)	10	11	21
Grand Total	10	11	21

	Separate from other medications	With other medications
Bottle Storage	38%	62%
No Discussion	50%	50%

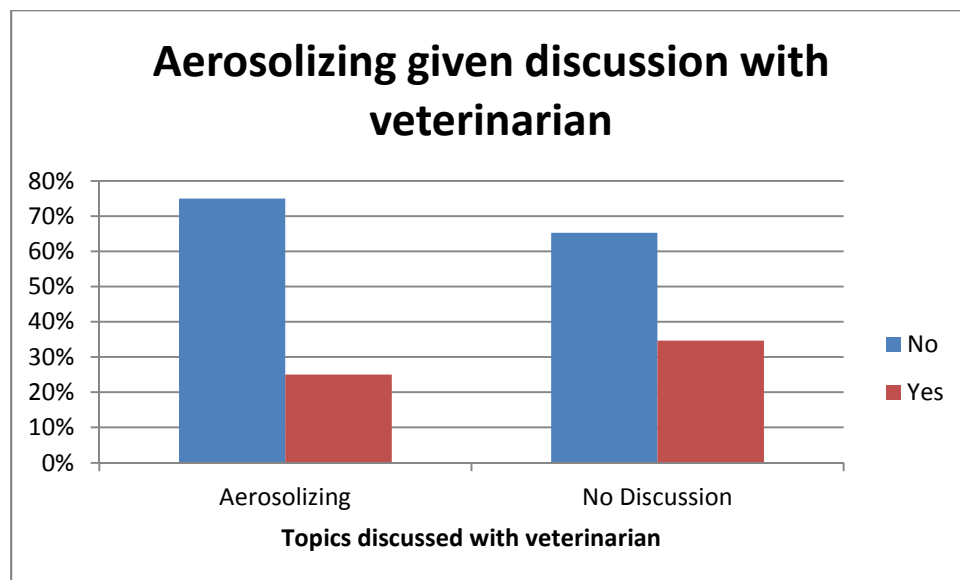


Values	Column Labels		Grand Total
	No	Yes	
Aerosolizing	75%	25%	100%
No Discussion	50%	50%	100%

Education_NoDiscussion (blank)

Count of Aerosolize	Column Labels		Grand Total
	No	Yes	
(blank)		31 16	47
Grand Total		31 16	47

	No	Yes
Aerosolizing	75%	25%
No Discussion	65%	35%

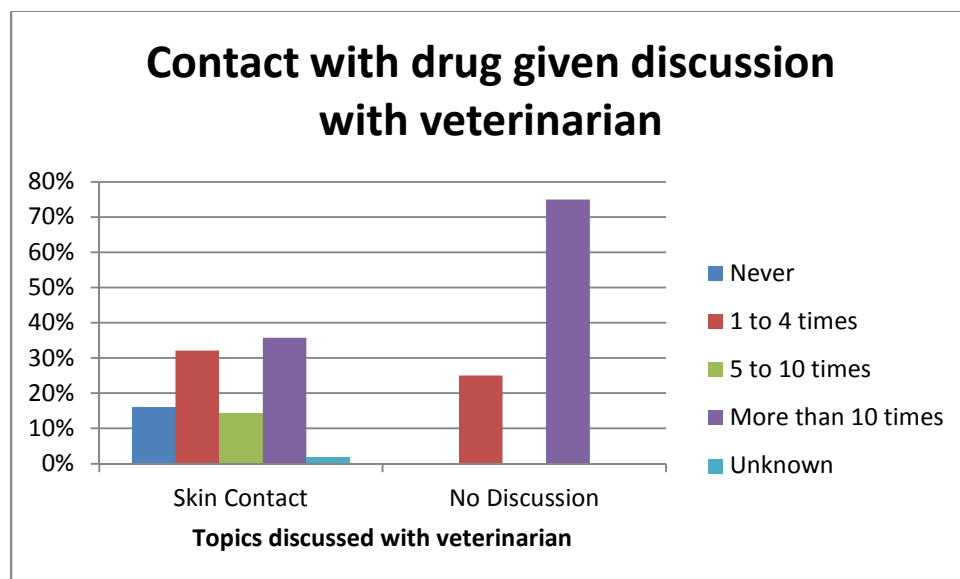


Values	Column Labels					Unknown	Grand Total
	Never	1 to 4 times	5 to 10 times	More than 10 times			
Skin Contact	16%	32%	14%	36%	2%	100%	
No Discussion	0%	33%	0%	67%	0%	100%	

Education_NoDiscussion	(blank)
------------------------	---------

Count of Contact	Column Labels	Grand Total
Row Labels	More than 10 times	
(blank)	1	1
Grand Total	1	1

	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown
Skin Contact	16%	32%	14%	36%	2%
No Discussion	0%	25%	0%	75%	0%



Actions Prior to Washing Hands (Vet Discussed Washing)			Total who were educated about washing hands	
			Column Labels	
Values	TRUE	Grand Total	% of those whose vets talked about washing hands who report the following prior to washing hands	Count of Education_Wash
Count of ActionsWash_eating	3	3	7%	
Count of ActionsWash_writing	7	7	17%	
Count of ActionsWash_feed	4	4	10%	
Count of ActionsWash_handling	17	17	40%	Total who responded to question but didn't report washing hands education
Count of ActionsWash_doors	17	17	40%	Count of Education_NR
				3

Actions Prior to Washing
Hands (Vet Did Not Discuss
Washing)

Education_NR (blank)

				Column Labels
Values				(blank)
				Grand Total

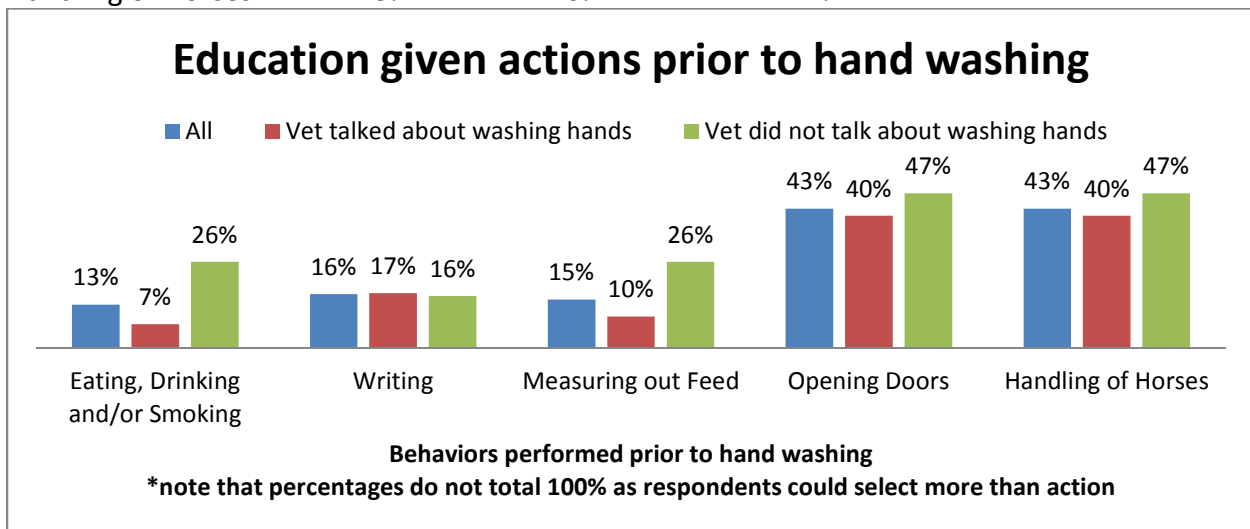
% of those whose vets talked about
washing hands who report the
following prior to washing hands

Count of				
ActionsWash_eating	5	5	26%	
Count of				
ActionsWash_writing	3	3	16%	
Count of				
ActionsWash_feed	5	5	26%	
Count of				
ActionsWash_handling	9	9	47%	
Count of				
ActionsWash_doors	9	9	47%	

Values	Column Labels			Grand Total
	TRUE	(blank)		
Count of				
ActionsWash_eating	3	5	8	13%
Count of				
ActionsWash_writing	7	3	10	16%
Count of				
ActionsWash_feed	4	5	9	15%
Count of				
ActionsWash_handling	17	9	26	43%
Count of				
ActionsWash_doors	17	9	26	43%

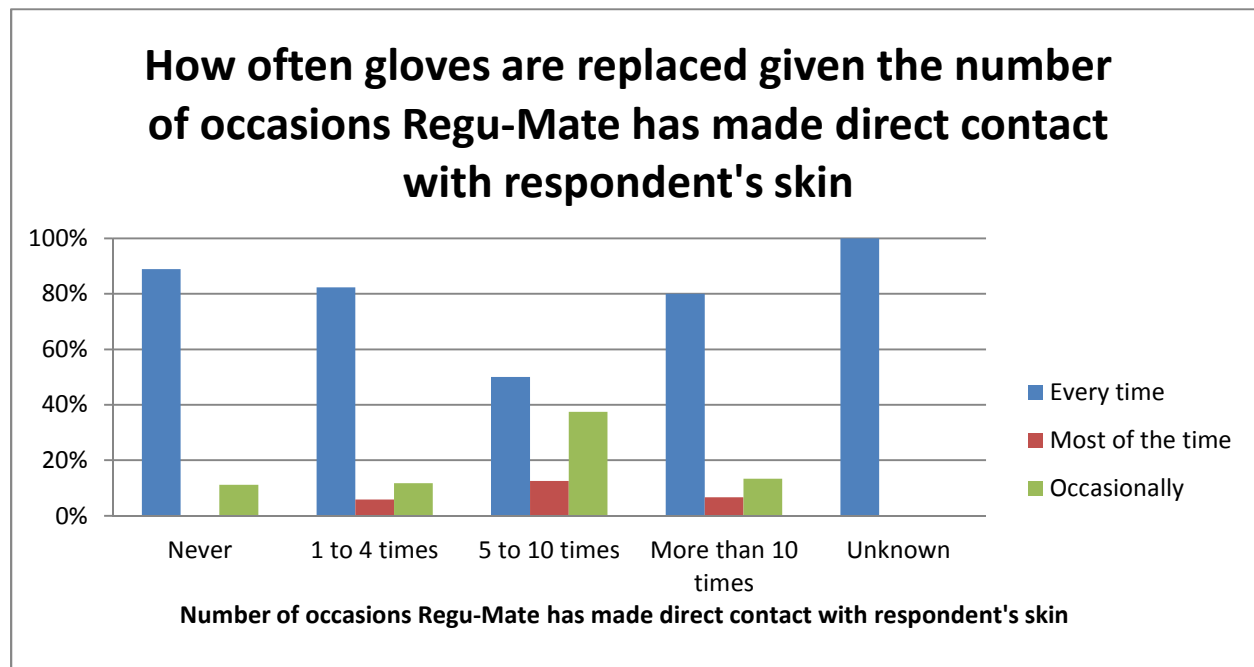
Washing Hands Actions and Education

	All	Vet talked about washing hands	Vet did not talk about washing hands
Eating, Drinking and/or Smoking	13%	7%	26%
Writing	16%	17%	16%
Measuring out Feed	15%	10%	26%
Opening Doors	43%	40%	47%
Handling of Horses	43%	40%	47%

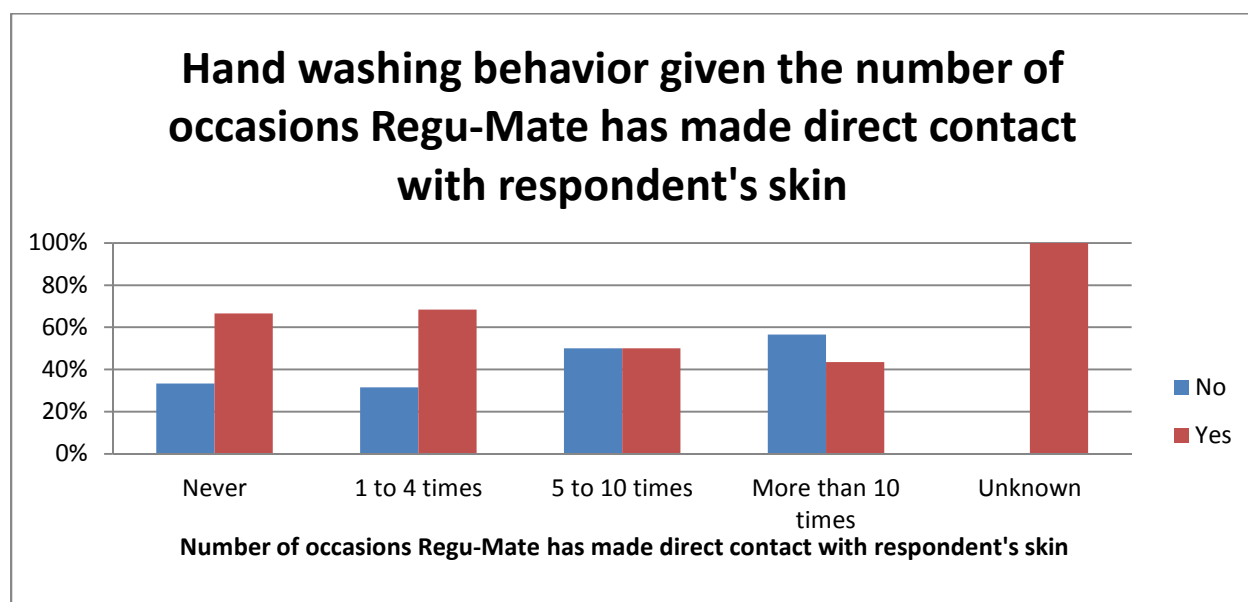


CONTACT

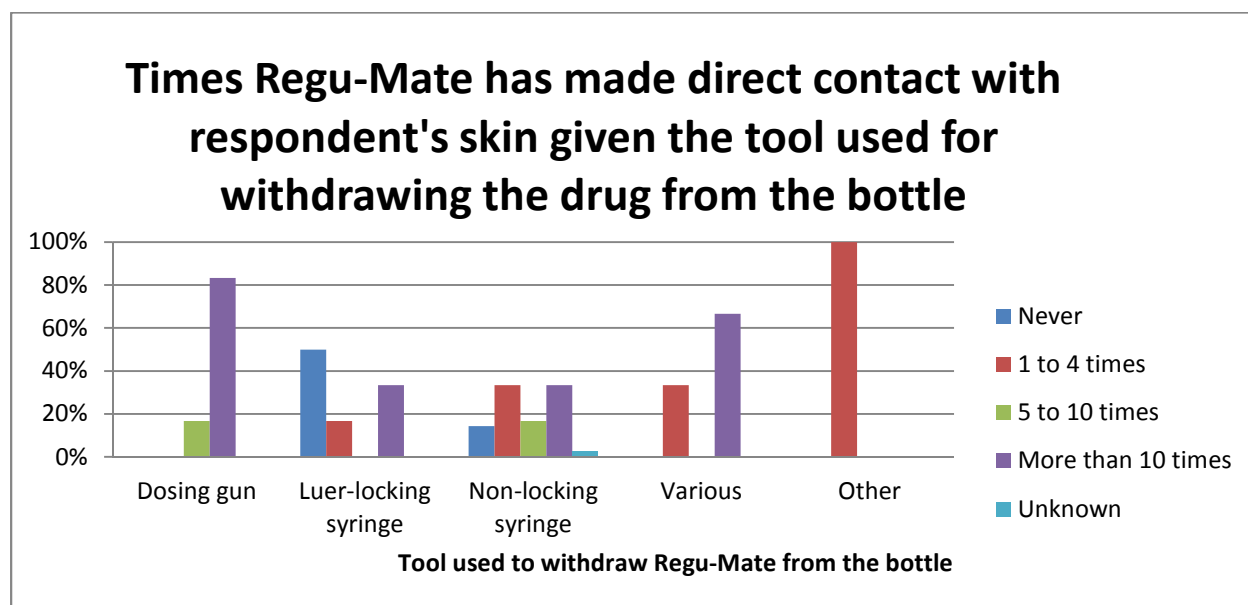
Count of Contact	Column Labels			Grand Total
Row Labels	Every time	Most of the time	Occasionally	
Never	89%	0%	11%	100%
1 to 4 times	82%	6%	12%	100%
5 to 10 times	50%	13%	38%	100%
More than 10 times	80%	7%	13%	100%
Unknown	100%	0%	0%	100%
Grand Total	78%	6%	16%	100%



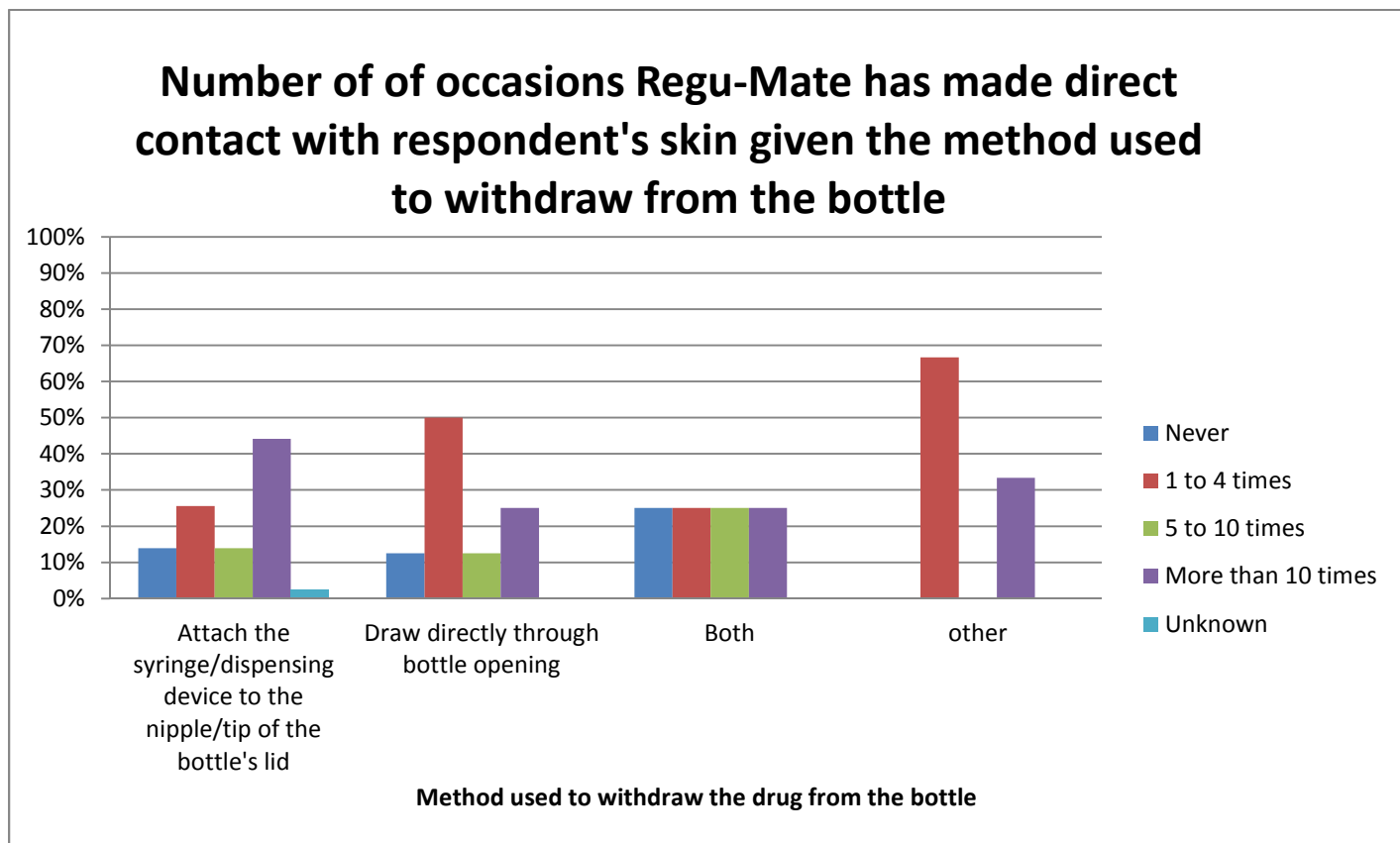
Count of Contact	Column Labels		
Row Labels	No	Yes	Grand Total
Never	33%	67%	100%
1 to 4 times	32%	68%	100%
5 to 10 times	50%	50%	100%
More than 10 times	57%	43%	100%
Unknown	0%	100%	100%
Grand Total	43%	57%	100%



Count of Contact	Column Labels						
Row Labels	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total	
Dosing gun	0%	0%	17%	83%	0%	100%	
Luer-locking syringe	50%	17%	0%	33%	0%	100%	
Non-locking syringe	14%	33%	17%	33%	2%	100%	
Various	0%	33%	0%	67%	0%	100%	
Other	0%	100%	0%	0%	0%	100%	
Grand Total	15%	32%	13%	38%	2%	100%	

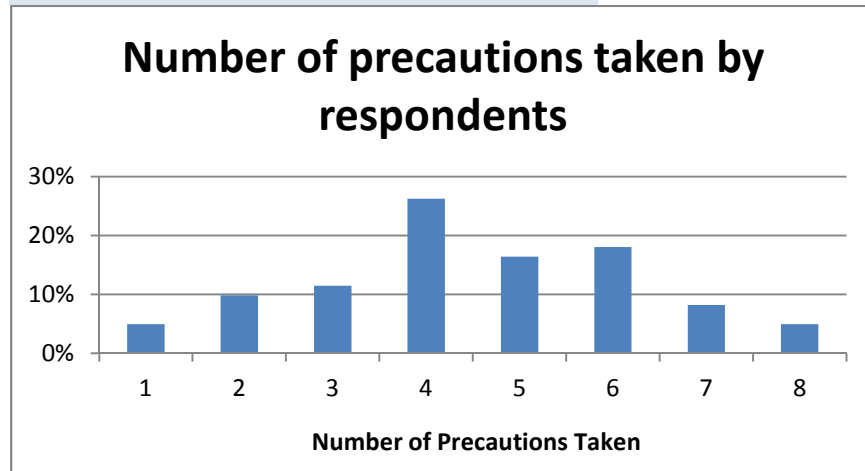


Count of Contact	Column Labels					Grand Total
	Never	1 to 4 times	5 to 10 times	More than 10 times	Unknown	
Row Labels						
Attach the syringe/dispensing device to the nipple/tip of the bottle's lid	14%	26%	14%	44%	2%	100%
Draw directly through bottle opening	13%	50%	13%	25%	0%	100%
Both	25%	25%	25%	25%	0%	100%
other	0%	67%	0%	33%	0%	100%
Grand Total	14%	31%	14%	40%	2%	100%



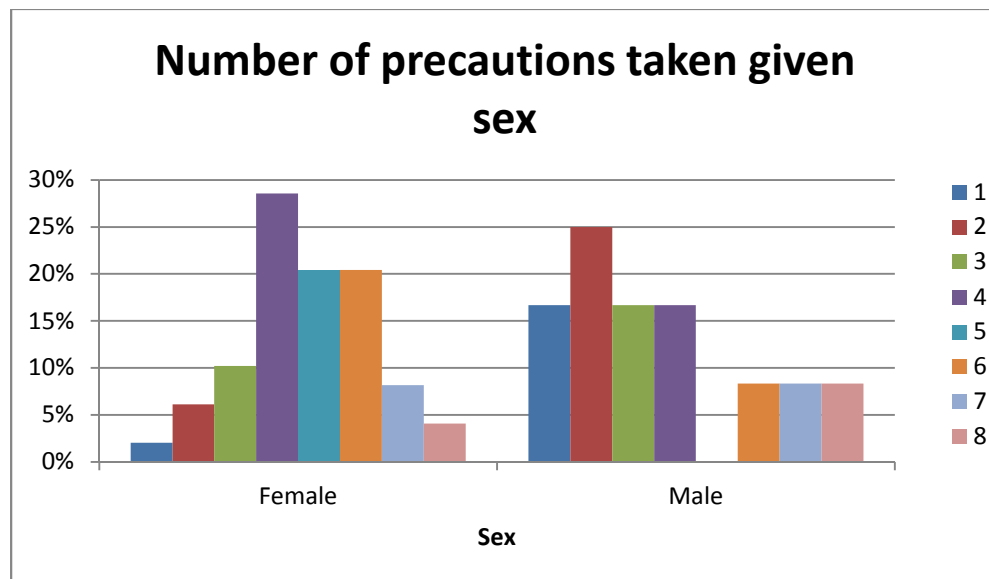
PRECAUTIONS

Row Labels	Count of Precautions
1	5%
2	10%
3	11%
4	26%
5	16%
6	18%
7	8%
8	5%
Grand Total	100%

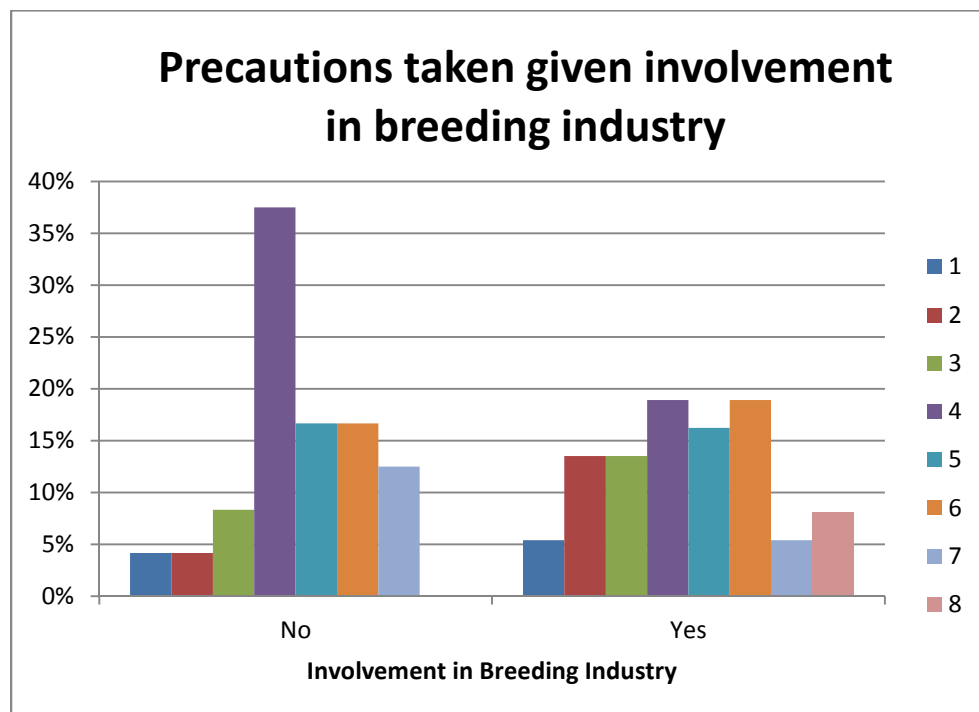


Precaution Taken	# Respondents Taken Precaution
Glove Use	50
Glove	
Replacement	40
Glove Type	15
Wash Hands	34
Bottle Storage	26
Tool	6
Withdraw	
Method	43
Aerosolize	38
Buckets	23

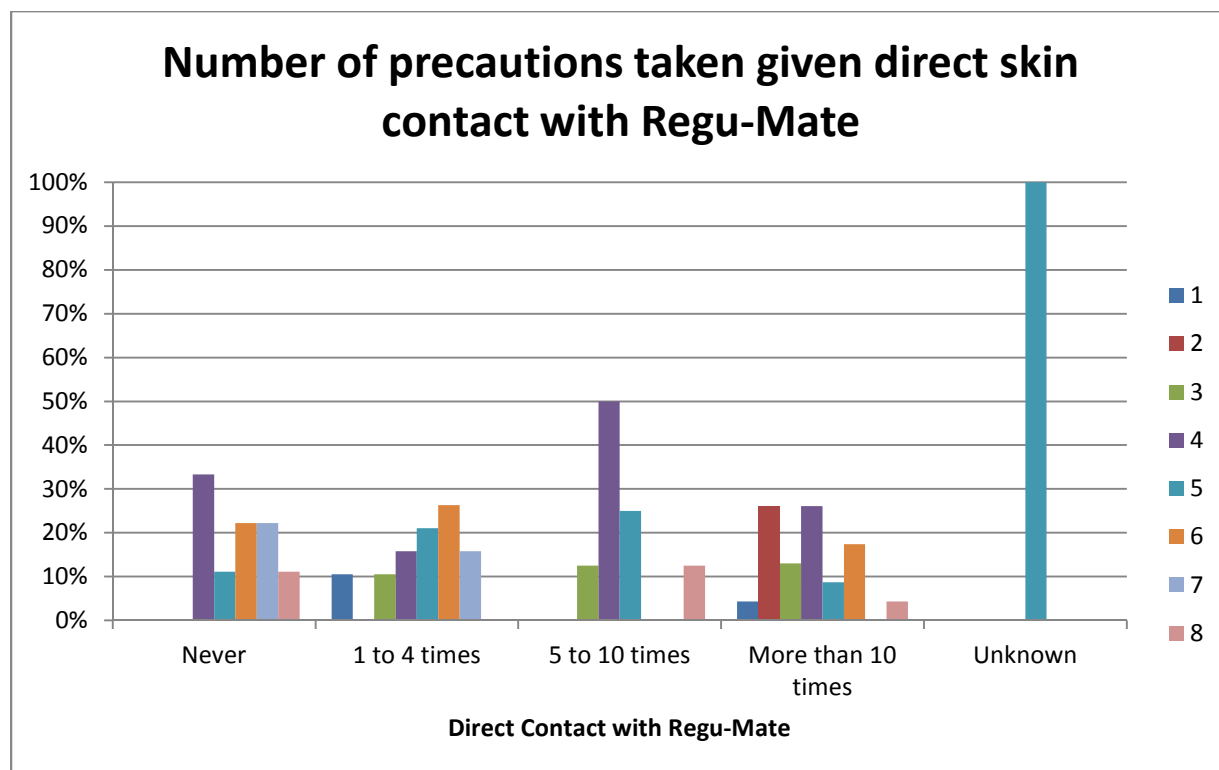
Count of Precautions	Column Labels								Grand Total
Row Labels	1	2	3	4	5	6	7	8	
Female	2%	6%	10%	29%	20%	20%	8%	4%	100%
Male	17%	25%	17%	17%	0%	8%	8%	8%	100%
Grand Total	5%	10%	11%	26%	16%	18%	8%	5%	100%



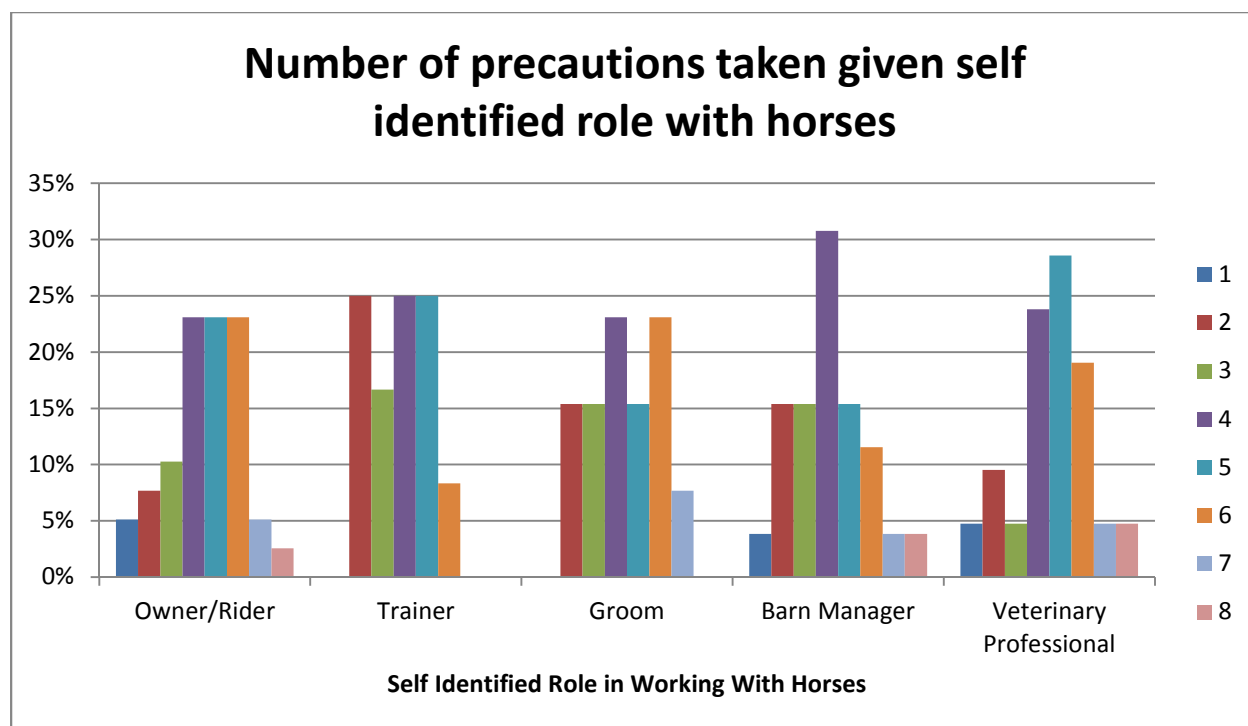
Count of Precautions	Column Labels								Grand Total
Row Labels	1	2	3	4	5	6	7	8	
No	4%	4%	8%	38%	17%	17%	13%	0%	100%
Yes	5%	14%	14%	19%	16%	19%	5%	8%	100%
Grand Total	5%	10%	11%	26%	16%	18%	8%	5%	100%



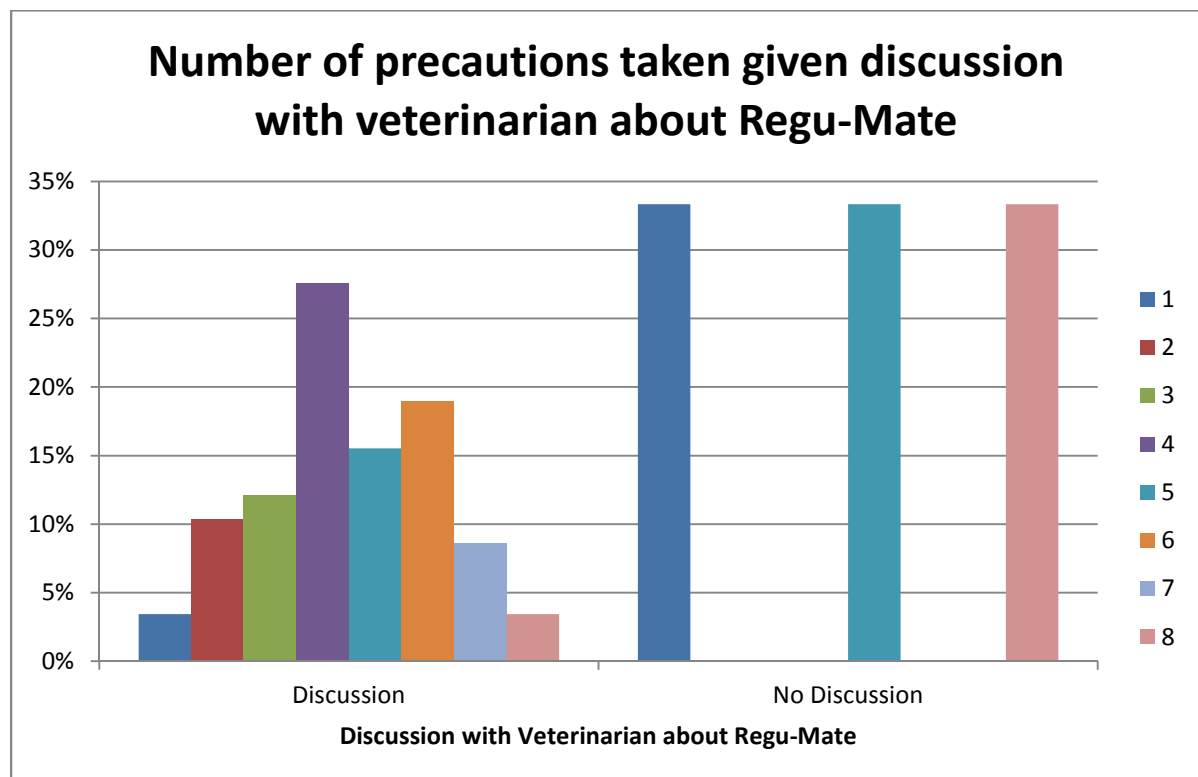
Count of Precautions	Column Labels								Grand Total
Row Labels	1	2	3	4	5	6	7	8	
Never	0%	0%	0%	33%	11%	22%	22	11	100%
1 to 4 times	11%	0%	11%	16%	21%	26%	16	0%	100%
5 to 10 times	0%	0%	13%	50%	25%	0%	0%	13	100%
More than 10 times	4%	26%	13%	26%	9%	17%	0%	4%	100%
Unknown	0%	0%	0%	0%	100	0%	0%	0%	100%
Grand Total	5%	10	10	27	18	17%	8%	5%	100%



Column Labels									
Values	1	2	3	4	5	6	7	8	Grand Total
Owner/Rider	5%	8%	10%	23%	23%	23%	5%	3%	100%
Trainer	0%	25%	17%	25%	25%	8%	0%	0%	100%
Groom	0%	15%	15%	23%	15%	23%	8%	0%	100%
Barn Manager	4%	15%	15%	31%	15%	12%	4%	4%	100%
Veterinary Professional	5%	10%	5%	24%	29%	19%	5%	5%	100%

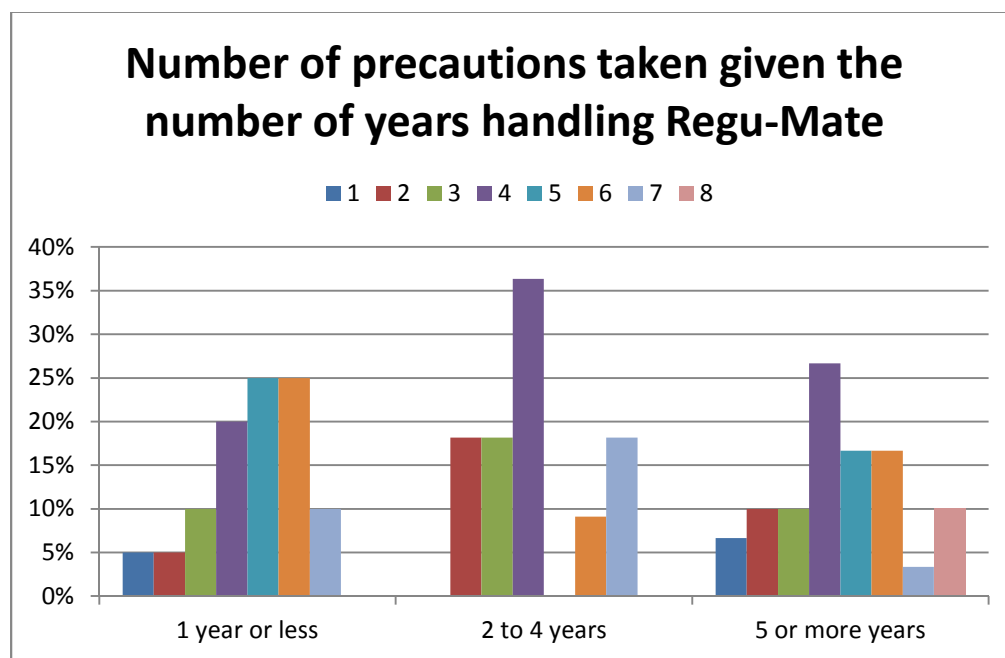


Count of Precautions	Column Labels								Grand Total
Row Labels	1	2	3	4	5	6	7	8	
Discussion	3%	10%	12%	28%	16%	19%	9%	3%	100%
No Discussion	33%	0%	0%	0%	33%	0%	0%	33%	100%
Grand Total	5%	10%	11%	26%	16%	18%	8%	5%	100%



Count of Precautions	Column Labels								
Row Labels	1	2	3	4	5	6	7	8	Grand Total
1 year or less	5%	5%	10%	20%	25%	25%	10%	0%	100%
2 to 4 years	0%	18%	18%	36%	0%	9%	18%	0%	100%
5 or more years	7%	10%	10%	27%	17%	17%	3%	10%	100%
Grand Total	5%	10%	11%	26%	16%	18%	8%	5%	100%

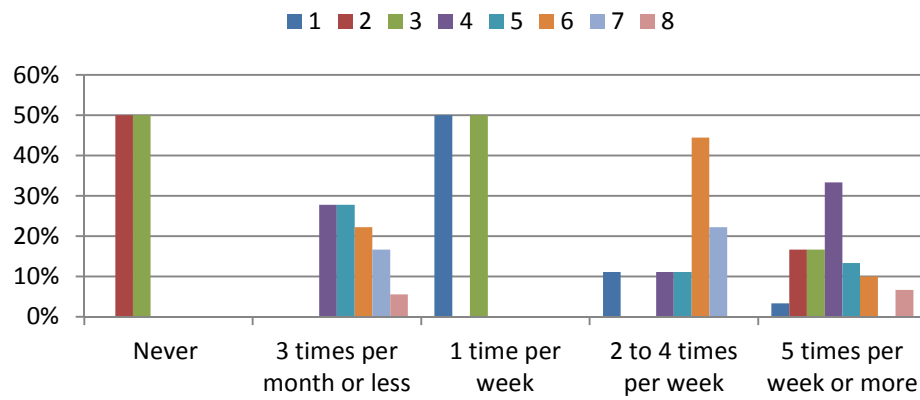
Count of Precautions	Column Labels								
Row Labels	1	2	3	4	5	6	7	8	Grand Total
1 year or less	1	1	2	4	5	5	2		20
2 to 4 years		2	2	4		1	2		11
5 or more years	2	3	3	8	5	5	1	3	30
Grand Total	3	6	7	16	10	11	5	3	61



Count of Precautions	Column Labels								Grand
Row Labels	1	2	3	4	5	6	7	8	Total
Never		1	1						2
3 times per month or less				5	5	4	3	1	18
1 time per week	1		1						2
2 to 4 times per week	1			1	1	4	2		9
5 times per week or more	1	5	5	10	4	3		2	30
Grand Total	3	6	7	16	10	11	5	3	61

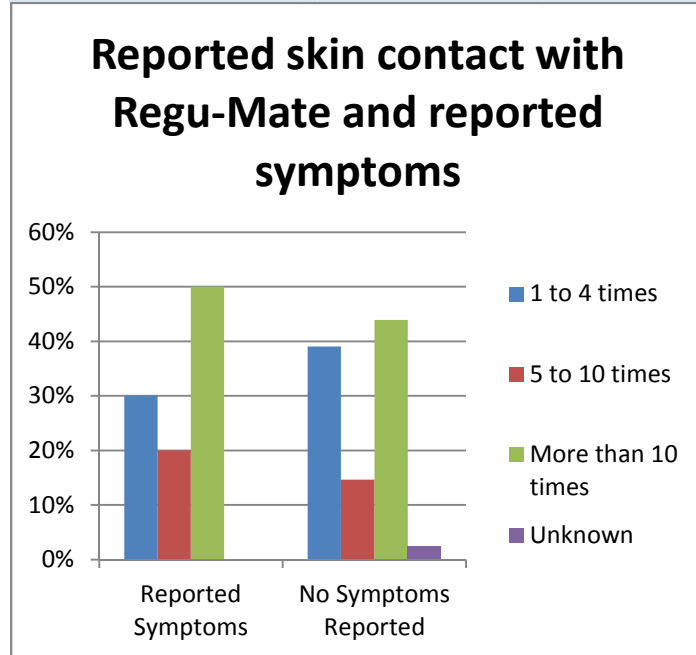
Count of Precautions	Column Labels								Grand
Row Labels	1	2	3	4	5	6	7	8	Total
Never		50							
3 times per month or less	0%	%	50%	0%	0%	0%	0%	0%	100%
1 time per week	50%	0%	50%	0%	0%	0%	0%	0%	100%
2 to 4 times per week	11%	0%	0%	%	%	%	22%	0%	100%
5 times per week or more	3%	%	17%	%	%	%	0%	7%	100%
Grand Total	5%	%	%	%	%	%	8%	5%	100%

Number of precautions taken given frequency of Regu-Mate use

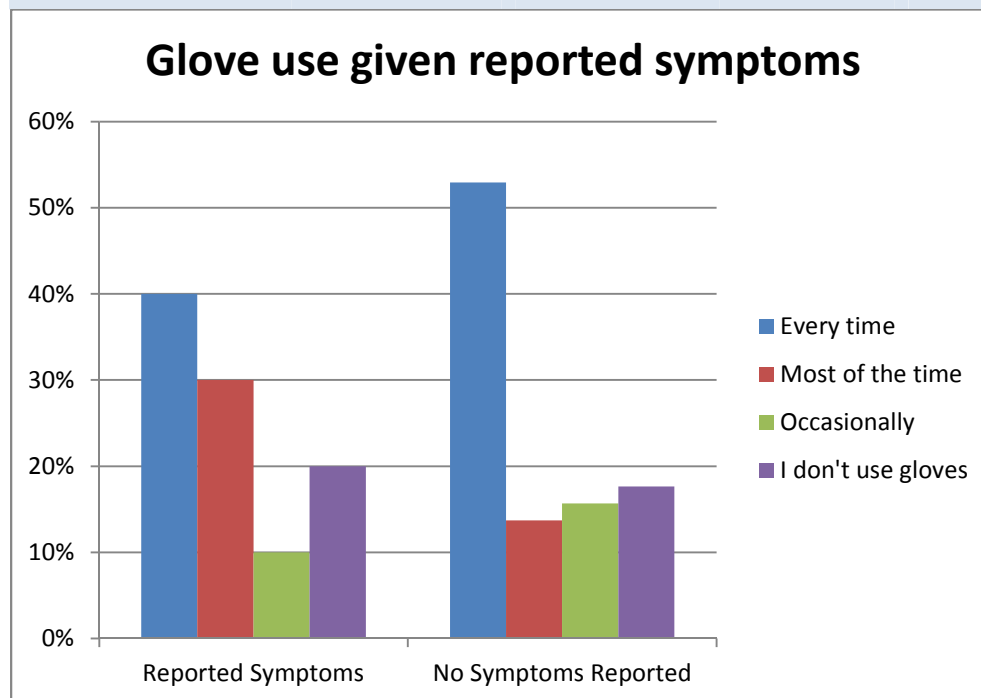


SYMPTOMS

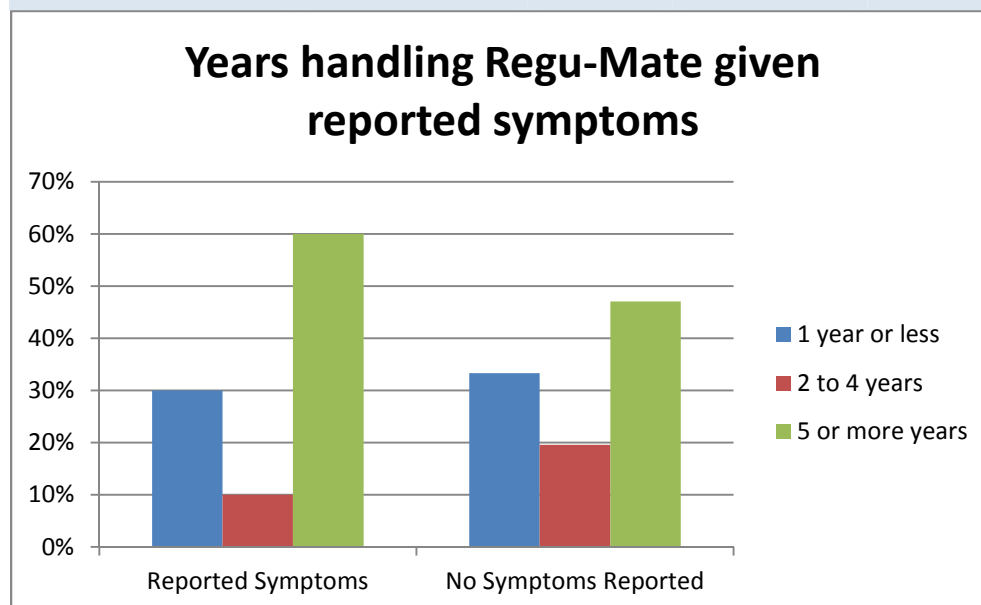
Count of Contact	Column Labels				
Row Labels	1 to 4 times	5 to 10 times	More than 10 times	Unknown	Grand Total
Reported Symptoms	30%	20%	50%	0%	100%
No Symptoms					
Reported	39%	15%	44%	2%	100%
Grand Total	37%	16%	45%	2%	100%



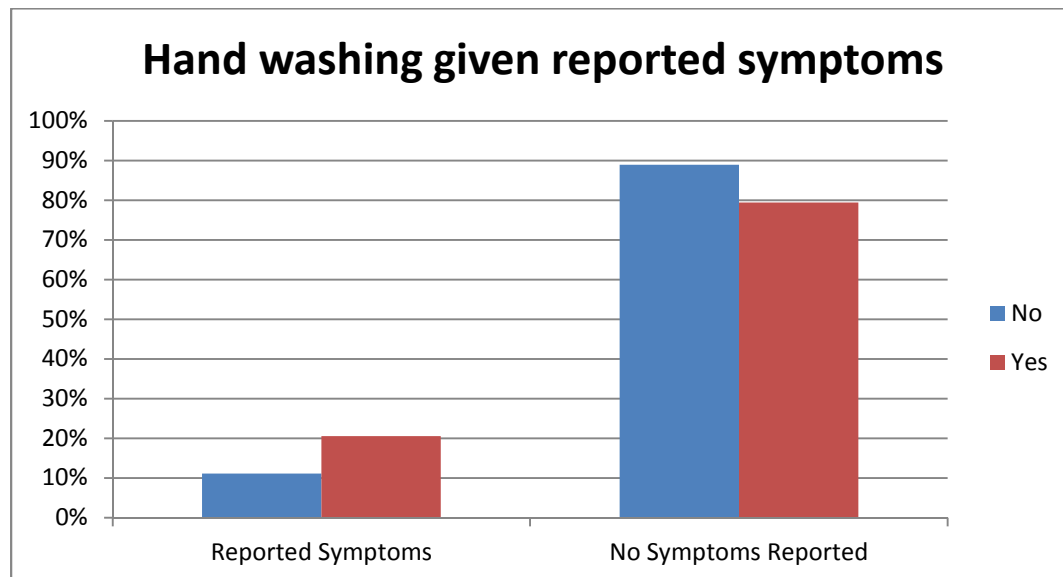
Count of Glove Use	Column Labels				
Row Labels	Every time	Most of the time	Occasionally	I don't use gloves	Grand Total
Reported Symptoms	40%	30%	10%	20%	100%
No Symptoms Reported	53%	14%	16%	18%	100%
Grand Total	51%	16%	15%	18%	100%



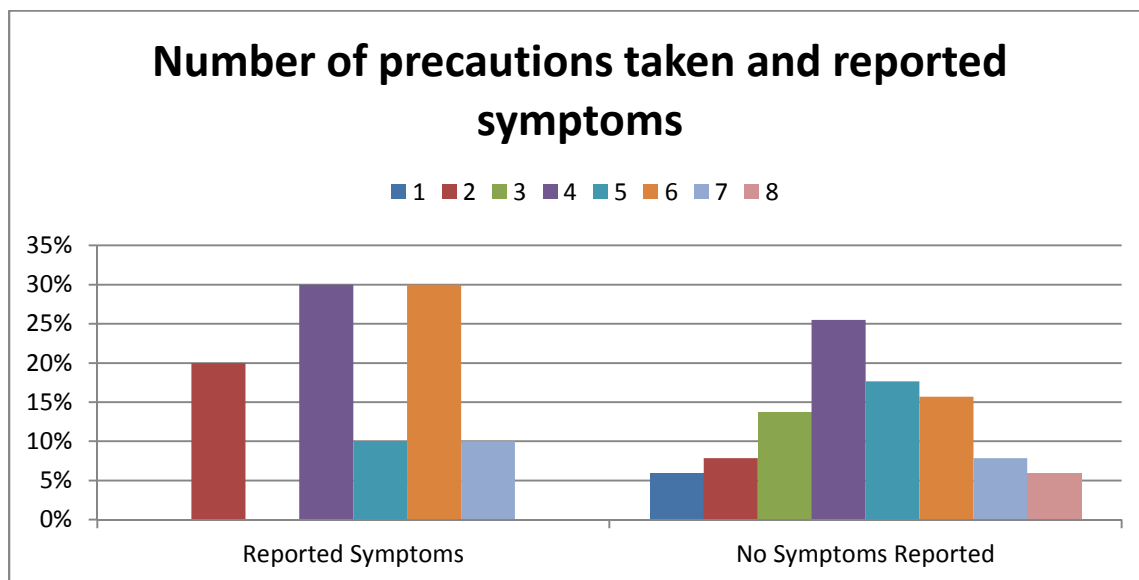
Count of YearsHandled	Column Labels			
Row Labels	1 year or less	2 to 4 years	5 or more years	Grand Total
Reported Symptoms	30%	10%	60%	100%
No Symptoms Reported	33%	20%	47%	100%
Grand Total	33%	18%	49%	100%



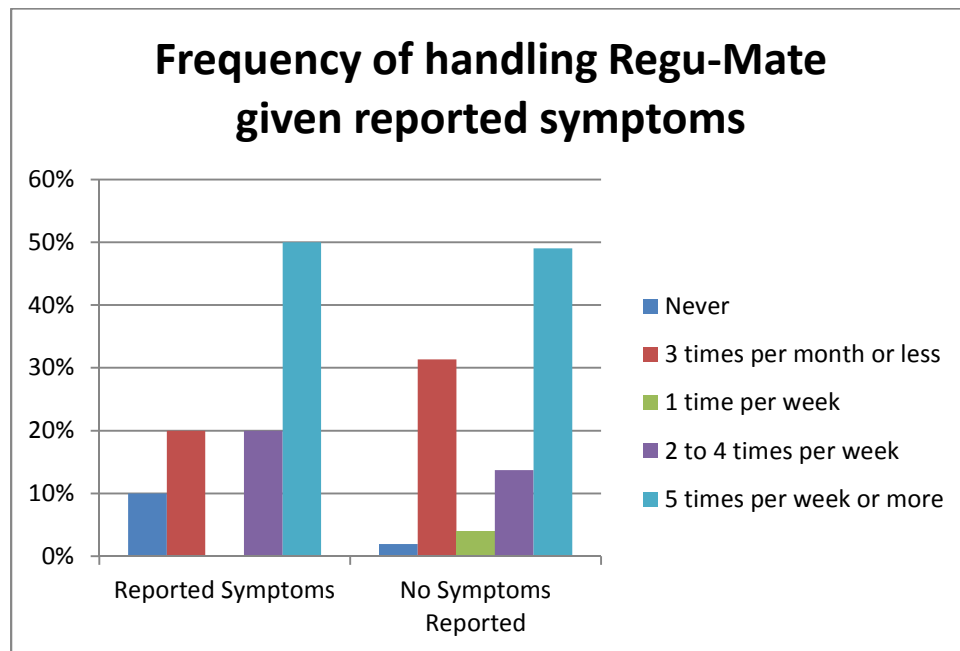
Count of WashHands	Column Labels		
Row Labels	No	Yes	Grand Total
Reported Symptoms	30%	70%	100%
No Symptoms			
Reported	47%	53%	100%
Grand Total	44%	56%	100%



Count of Precautions	Column Labels								
Row Labels	1	2	3	4	5	6	7	8	Grand Total
		20		30	10	30	10	0	
Reported Symptoms	0%	%	0%	%	%	%	%	%	100%
No Symptoms			14	25	18	16		6	
Reported	6%	8%	%	%	%	%	8%	%	100%
Grand Total	5%	10%	11%	26%	16%	18%	8%	5%	100%



Count of Often_Handle	Column Labels				
Row Labels	Never	3 times per month or less	1 time per week	2 to 4 times per week	5 times per week or more
Reported Symptoms		10%	20%	0%	20%
No Symptoms Reported		2%	31%	4%	14%
Grand Total		3%	30%	3%	15%



MISCELANEOUS

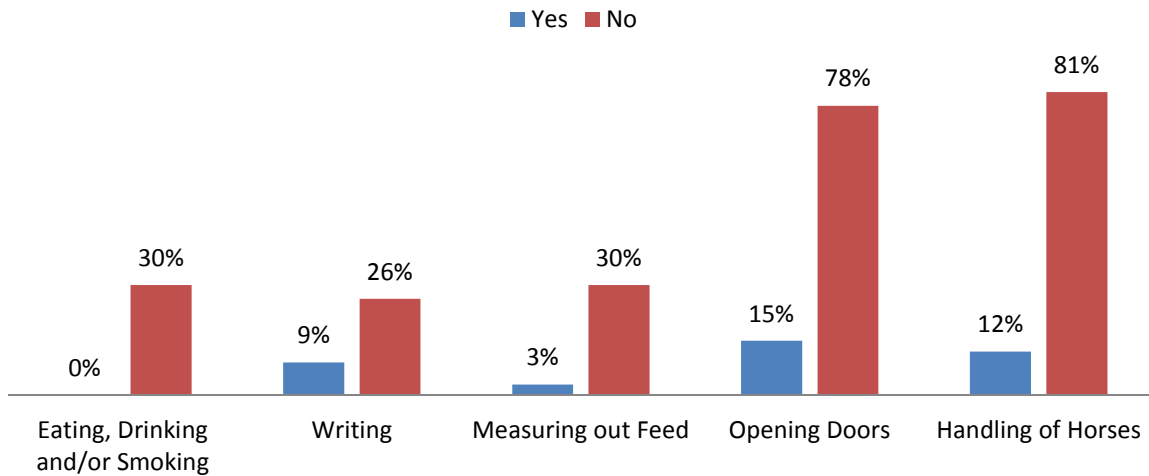
Row Labels	Count of WashHands
No	27
Yes	34
(blank)	
Grand Total	61

	Column Labels			
Values	No		Grand Total	
Count of ActionsWash_eating	8		8	30%
Count of ActionsWash_writing	7		7	26%
Count of ActionsWash_feed	8		8	30%
Count of ActionsWash_doors	21		21	78%
Count of ActionsWash_handling	22		22	81%

Values	Column Labels		Grand Total	
	Yes			
Count of ActionsWash_eating	0	0	0	0%
Count of ActionsWash_writing	3	3	3	9%
Count of ActionsWash_feed	1	1	1	3%
Count of ActionsWash_doors	5	5	5	15%
Count of ActionsWash_handling	4	4	4	12%

Actions Prior to Hand Washing Broken Up By Washing Hands Response			
	Yes	No	
Eating, Drinking and/or Smoking		0%	30%
Writing		9%	26%
Measuring out Feed		3%	30%
Opening Doors		15%	78%
Handling of Horses		12%	81%

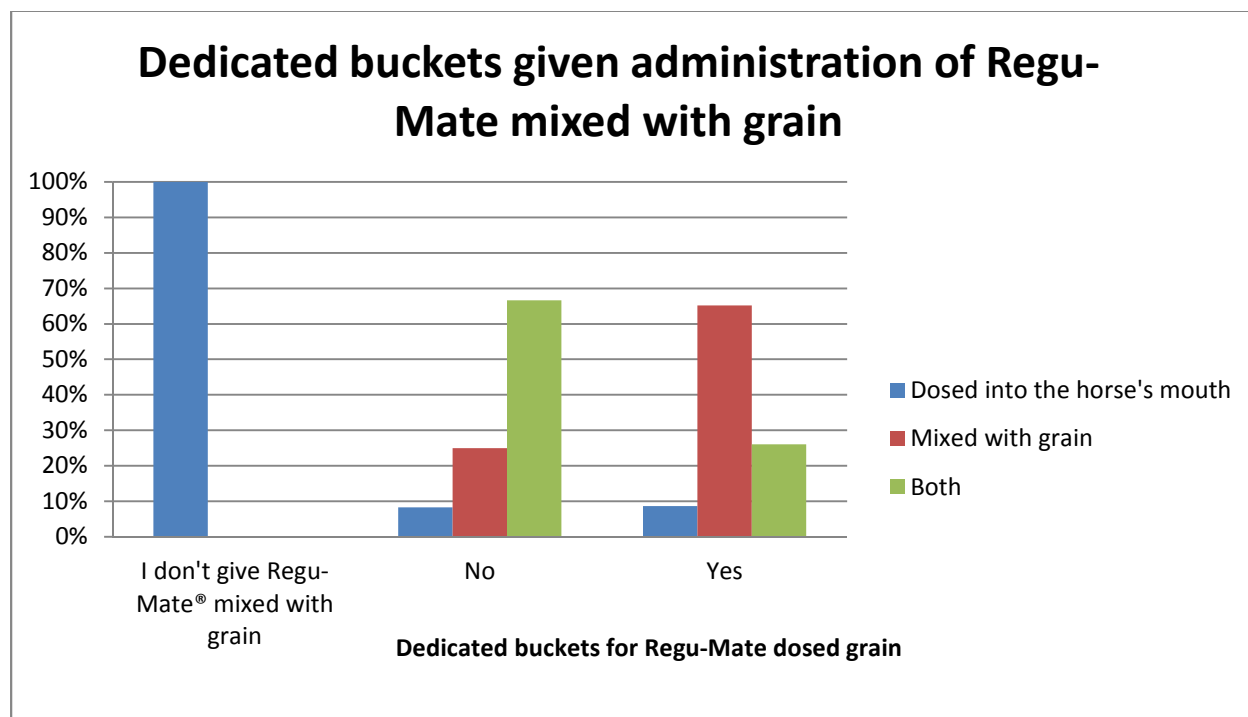
Actions performed prior to hand washing given respondent's hand washing behavior



Actions performed prior to washing hands

*note that respondents could select all actions performed prior to washing hands

Count of Buckets	Column Labels			
Row Labels	Dosed into the horse's mouth	Mixed with grain	Both	Grand Total
I don't give Regu-Mate® mixed with grain	100%	0%	0%	100%
No	8%	25%	67%	100%
Yes	9%	65%	26%	100%
Grand Total	46%	31%	24%	100%



Appendix F: Information Sheet

Regu-Mate® Safe Handling

Storage: Store Regu-Mate® separately from other medications in a leak-proof container to prevent contamination of other items and surfaces. It should be stored at or below 25° C (77°F)^{1,2}.

Skin Contact: Wear disposable nitrile or vinyl gloves when handling Regu-Mate®. After removing gloves wash hands with soap and water; small holes or tears in a glove can expose skin to Regu-Mate®. Use gloves only once and replace each day.

Care should be taken to **avoid skin contact**. If skin contact with Regu-Mate® occurs the area should be washed well with soap and water.

Avoid touching anything (writing records, cell phone, opening/closing doors, etc.) while wearing gloves after handling Regu-Mate®. Utilize a second person to assist with opening doors/holding horses/writing records or if working alone wear multiple pairs of gloves to allow for the use of a clean glove to open doors while discarding the Regu-Mate®-contaminated gloves.

Withdrawing/Dispensing: Attach the Luer-lock syringe to the nozzle tip of the bottle while it is upright. Invert the bottle and withdraw the medication. Right the bottle and remove the syringe from the nozzle tip with a twisting action. Re-cover the nozzle tip.

Administering: Regu-Mate® can be administered directly by mouth or by top-dressing the horse's grain ration. Do not aerosolize (spray into the air or forcefully eject) Regu-Mate® when emptying a syringe.

When dosing by mouth: Administer directly to the back of the tongue.

When dosing by grain: Use dedicated grain buckets for Regu-Mate® topped grain.

Potential Health Effects: Health effects from exposure may include headaches, disruption of the menstrual cycle (period coming later/earlier than normal and/or length of period being longer/shorter than normal), uterine and/or abdominal cramping, change (increase or decrease) in menstrual bleeding and prolonged pregnancy^{3,4}.

Evaluate your facility's safety protocol once a year to ensure that all equine care givers handling Regu-Mate® are safely handling the medication.

¹ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."

² CEVA Animal Health, "Altresyn® Solution 0.22% Product Label."

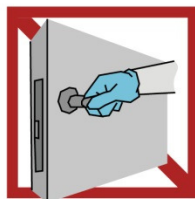
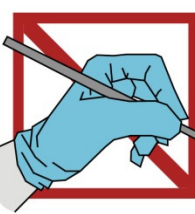
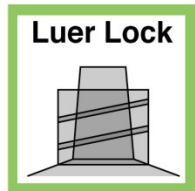
³ Ibid.

⁴ Intervet Inc, "Regu-Mate Solution 0.22% Product Label."

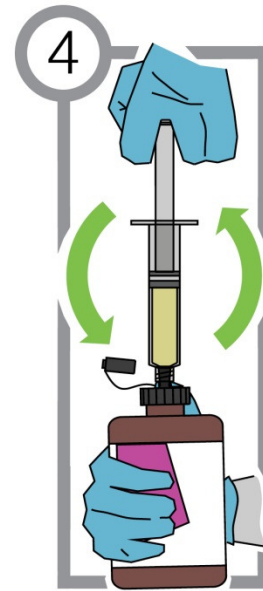
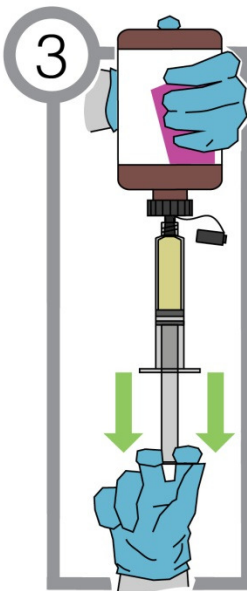
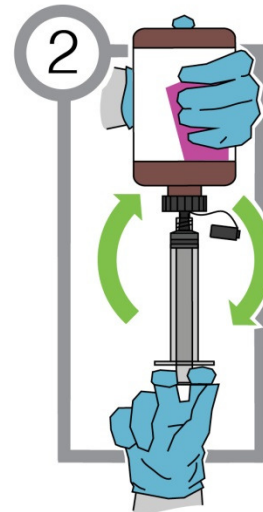
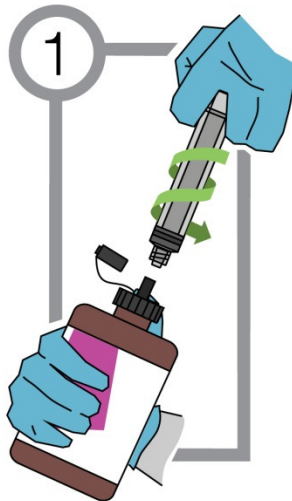
Appendix G: Instructional Placard

Regu-Mate® Equine

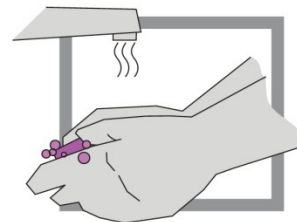
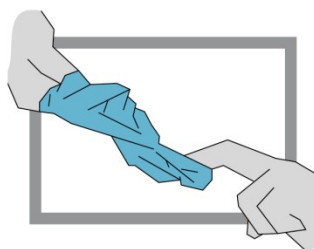
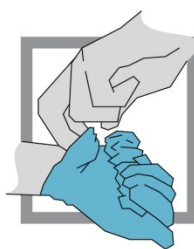
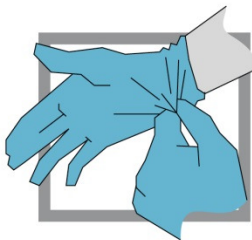
Safety Guide



Safe Withdrawal Steps

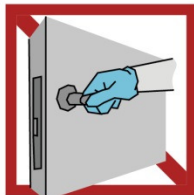


After using: remove gloves and wash hands

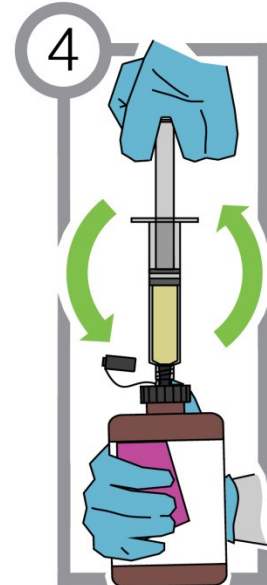
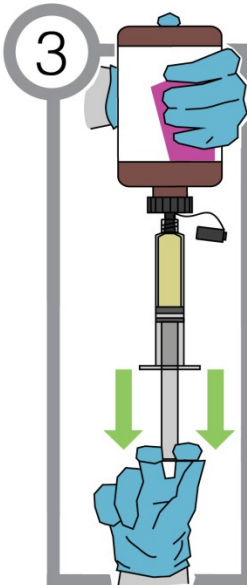
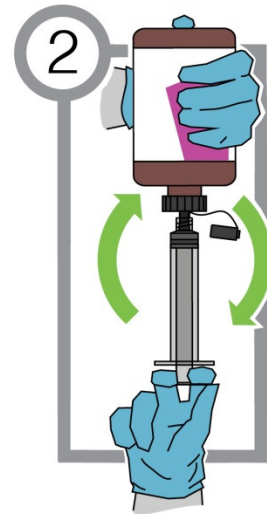
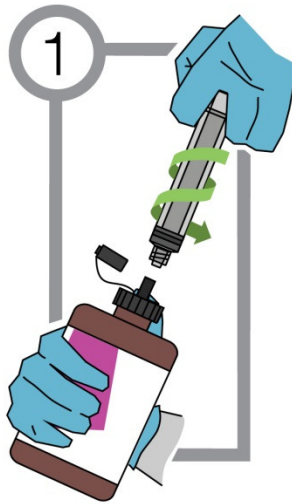


Regu-Mate® Equine

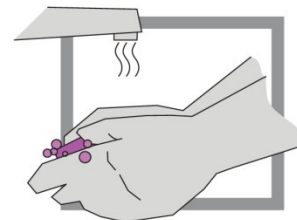
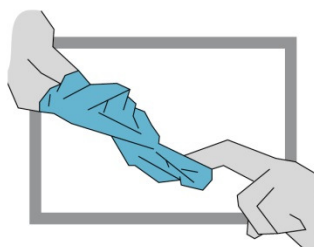
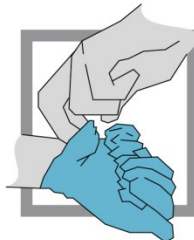
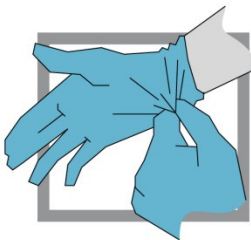
Guía de Seguridad



Safe Retirar Pasos



Después de usar: quítese los guantes y lavarse las manos



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