

PUBLIC HEALTH AND SWINE PRODUCTION MEDICINE ASPECTS OF VH1N1
INFLUENZA VIRUS

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A Report

Submitted in partial fulfillment of the requirements for the degree

MASTER OF PUBLIC HEALTH

Department of Diagnostic Medicine and Pathobiology
College of Veterinary Medicine

KANSAS STATE UNIVERSITY
Manhattan, Kansas

2012

Approved by:

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Abstract

Variant H1N1 influenza (vH1N1) virus is an issue both in swine production medicine and in the arena of public health. Influenza viruses can infect but not always produce disease) in avian, humans and swine. Swine are unique among the three previously mentioned species in that their respiratory epithelium possesses three receptor sites for the virus types common to each of the three mentioned species. Swine influenza virus (SI) is common and widespread in nearly all Midwestern swine herds and can be transmitted by both direct contact and aerosolization.

All of the three previously mentioned species have the potential to re-assort (produce virions containing genetic material of different virions to produce a unique influenza virus (IV). Because of their three specific receptor sites, swine have the greatest re-assortment capability.

This re-assortment has the potential is a low mortality/high morbidity disease that is a substantial cost to the swine industry due to its negative effect on production parameters such as average daily gain (ADG) and feed efficiency (FE). It is a public health concern due to its potential to produce different virus types which may have increased mortality/morbidity in humans. Avian are the IV reservoir and have the ability to introduce virus types that are foreign to specific populations in all venues on the planet.

It is in the mutual best interest of public health and swine production to mitigate the introduction of different virus types in swine and to control existing infections in swine populations with a goal of establishing SI-free herds. Mitigation for swine populations can occur through vaccination, diagnosis/isolation, and Biosecurity procedures designed to reduce/eliminate IV introduction into swine production facilities. In addition, preventing the interaction of infected humans with swine is another component of swine population Biosecurity.

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Chapter 1 - Background

H1N1 Background

H1N1 influenza virus or swine influenza virus (SI) belongs to the type A group of influenza viruses. It is a single strand, enveloped RNA virus of the family Orthomyxoviridae. ^(1,24) The current non-variant swine H1N1 can be documented to have been originally detected in Illinois in August, 1918 following the spring wave of human Spanish flu, suggesting an initial human-to swine transmission of H1N1. ^(1, 28) It now has an altered genome and is known as classic swine influenza.

The standardized nomenclatures used to name a specific influenza are as follows: (1) antigenic type; (2) host animal from which the virus is isolated; (3) geographic origin; (4) unique laboratory or other reference identification; (5) year of isolation; (6) the specific haemmagglutinin (HA) and neuraminidase (NA) components located on the surface glycoproteins. In addition, the level of pathogenicity is described by the terms High Pathogenicity (HP) and Low Pathogenicity (LP). ⁽³¹⁾

SI infection is considered to be common and widespread and nearly all swine herds in the Midwestern United States have SI antibody titers. ⁽³⁰⁾ Clinical cases of SI produce fever, lethargy, sneezing, coughing, dyspnea, and decreased feed consumption. ⁽³⁾ Morbidity in affected herds approaches 100% with less than 1% mortality. ⁽²⁸⁾ There is no specific therapy for SI. Antimicrobials can be used to prevent secondary bacterial infections. Anti-inflammatory agents may be administered to reduce fever and improve feed/water consumption. ⁽²⁹⁾ The economic impact of SI is derived from its association with decreased production and increased treatment; because it is a low mortality disease, death loss has minimal contribution to economic loss. ⁽²⁹⁾ A series of baseline production parameters was established pre- and post-SI elimination from a three site, 1200 sow herd ⁽¹²⁶⁾. The difference in production parameters are listed in Table 1.1. A reduction of \$600.00 in treatment was noted between the groups with and without SI. Production parameters were calculated, averaged, and presented in the table but no statistical analysis of the difference in parameters was presented.

Table 1.1: Production Medicine. SI Production Losses

Parameter	SI Present	SI absent	Difference
Age at weaning (days)	23.6	20.0	+18.0%
Avg. weaning wt. (kg)	5.7	6.5	-12.31%
Mortality risk (%)	3.2.	1.0	+220%
Avg. daily gain (kg)	0.405	0.528	-23.3%
Feed efficiency (kg feed/Kg gain)	1.34	1.6	+19.4%

The virus is transmitted via direct pig-to-pig contact and aerosolization. The basic reproductive rate (R_0) has not been calculated for swine. The high morbidity rate and explosive nature of outbreaks suggests that R_0 would be high. Based on data from the 2009 vH1N1 outbreak R_0 in humans was estimated to be 1.0-1.4. This is below the seasonal flu's R_0 of 1.5-3.0.⁽⁴⁵⁾

The incubation period for SI is 1-3 days. Recovery begins 5-7 days after onset.⁽²⁹⁾ Humans and swine are considered to be capable of transmitting virus for a period of 7 days after the appearance of clinical signs for 24 hours after cessation of clinical signs.⁽¹¹⁾ Antibody positive animals can have detectable levels of antibodies lasting for 8-10 weeks post exposure.⁽³¹⁾ These animals can be virus carriers for up to 3 months post infection, and these carriers are responsible for SI introduction into previously uninfected herds. This virus is unlikely to survive outside living cells for >2 weeks except in cold conditions, but it is readily inactivated by disinfectants.⁽²⁹⁾

Zoonotic/Public Health Aspects of SI

In 1918, a respiratory disease outbreak in swine located in the North-Central United States coincided with and had similar clinical signs to the 1918 "Spanish flu" influenza pandemic that killed an estimated 20-50 million people worldwide. In more recent times, genetic analyses have confirmed that the 1918 swine and human influenza viruses were closely related to each

other. Therefore it appears that a progenitor virus was transmitted from pigs to people or from people to pigs.⁽²⁷⁾

Zoonotic infections (including fatal infections) with influenza viruses have been reported in the U.S., Asia, and Europe. The virus serotypes involved classical H1N1, wholly avian H1N1, re-assortment H3N2 with avian internal protein genes, re-assortment H1N1, and H5N1^(33, 34, 35, 129) Non variant H1N1 (SI) has been definitively diagnosed in 50 human cases from 1958 to the present, with 6 deaths (4 of which had preexisting medical conditions).⁽⁵⁾ The majority of zoonotic SI infections have involved individuals in direct contact with pigs. European and U.S. serologic studies have documented increased risk of SI exposure in people in close contact with swine.^(6, 132, 68) One serological study found that people living on a swine farm or entering a swine barn four or more days per week (17 positive/74 in rural cohort) were statistically more likely to have an SI titer compared to regional urban control subjects.(1 positive/114 in urban cohort. $p < .001$)⁽³⁵⁾

A 1976 influenza outbreak at Fort Dix, N.J. resulted in 13 clinical cases and 1 death. Virus was successfully isolated from 5 of the surviving cases and serological evidence that some 500 other Fort Dix personnel were, or had been, infected with the same influenza virus, subsequently identified as H1N1.^(132, 6,) The outbreak was not defined as a zoonosis, because there was no history of swine exposure between the clinical cases, virus isolation cases, or serological positive individuals.⁽¹³²⁾With the exception of the Fort Dix outbreak, there is little evidence for spread of swine viruses from person to person.⁽³⁶⁾

In order to test whether SI could be passed from swine to humans via consumption of edible pork products from infected animals, The National Animal Disease Center conducted a trial in which four five-week pigs were inoculated with H1N1 influenza virus A. Five days post inoculation the animals were humanely euthanized, and the investigators reported that the virus could only be isolated from the respiratory tract. The virus was not isolated from any edible tissue. This finding supports the current World Health Organization recommendation that pork harvested from pandemic influenza H1N1 swine is safe to consume when following standard meat hygiene practices.⁽²⁴⁾

In addition to swine influenza viruses having the ability to infect humans, human influenza viruses can infect swine. Studies in 1969 showed human H2N2 influenza virus could infect swine, and in 1976 SI was isolated from both pigs and their caretaker on a Wisconsin

farm.⁽³³⁾ Older lineages of human H3N2 viruses have demonstrated ability to be maintained by circulation in pigs beyond the time of their circulation among humans.⁽³²⁾ Avian influenza viruses are also able to infect swine. Experimental and natural infections of a wide range of avian influenza viruses (AI), including re-assortment H3N2, H1N2, H1N1, and H1N7 have been reported in swine worldwide.^(7, 32) While swine have the potential to be mixing vessels to produce a pandemic virus strain, recent human outbreaks of H5N1, H9N2, H7N7, and H7N3 showed that exposure to infected poultry, not pork products and swine, exposure was the main risk factor for infection.⁽³¹⁾ Re-assortment can occur in other animals besides swine, which include humans and ferrets. Ferrets are used as animal models for the study of human re-assortment.^(22, 37) It is possible for humans to re-assort two influenza viruses into a variant virus without the need of other species.⁽¹¹⁷⁾

SI and Re-Assortment

The segmented nature of the influenza genome allows two influenza viruses that co-infect a single host to exchange RNA segments during viral replication. Re-assortment is defined as two viruses with a segmented genome infecting a single host containing cell receptors for both viruses and the subsequent replication producing virions containing RNA from both the infecting viruses.⁽²⁸⁾ A critical observation is that swine respiratory tract epithelial cells possess receptor sites for avian, swine, and human influenza virus.⁽⁸⁾ Different forms of re-assortment viruses have been isolated from pigs world-wide including re-assortment H3N2, H1N2, H1N1, and H1N7.⁽³¹⁾

Influenza A viruses typically do not easily jump between host species. They require long periods of time (years to decades) to infect, circulate and adapt to a new host species. Once re-assortment has developed in swine, the pathway for transmission and subsequent disease development would be similar to what is seen with non-variant H1N1 in swine. To date, the mixing vessel effect has been confirmed relatively rarely and is most likely to occur where there are many small farms with poultry and pigs in close association. (Asia)⁽²⁾

Swine and Avian Influenza

Avian influenza viruses (AI) have been transmitted between swine and poultry when both species have been raised on the same farm or on nearby farms. The wildlife reservoir for AI is in aquatic birds and they have infected poultry and swine by direct contact. It has been

suggested that influenza an A strain originating in wild ducks was responsible for an outbreak of influenza in pigs in Belgium.⁽¹⁰⁹⁾ A review of migratory waterfowl flyways and the 2007 Census of Agriculture map showing U.S. swine demographics at the county level reveal that almost all counties with high swine production lie beneath major flyways.⁽¹²⁴⁾

Historical outbreaks of HPAI have been linked to strains circulating in ducks.⁽¹¹³⁾ It has been postulated that wild birds have transmitted low pathogenic avian influenza (LPAI) to domestic poultry. This infection of poultry with LPAI may sometimes result in development of high-pathogenic avian influenza (HPAI) with industry wide outbreaks in the domestic poultry industry and/or potential human health events.⁽¹¹⁰⁾ During July and August 2005, several HPAI H5N1 outbreaks were reported in Russia and Kazakhstan in domestic poultry. By October, 2005, H5N1 was found in wild fowl and poultry in Turkey, Romania, and Croatia. By December 2005, H5N1 was detected in the Ukraine⁽¹¹⁶⁾. This outbreak was consistent with the spatial and temporal pattern of Anatidae family (ducks, swans, and geese), migration from the Western Siberian Lowlands. This is the first documented that wild aquatic fowl can transmit HPAI directly to domestic poultry.

Species from the Anatidae family, particularly ducks, represent the highest risk for spread of AI^(111, 112) Antids harbor the most diverse and highest prevalence of AI.⁽¹¹¹⁾ Wild ducks can excrete large amounts of HPAI H5N1 virus while remaining relatively healthy and thus can move the virus across long distances.⁽¹¹⁴⁾ Direct contact between wild Antids and domestic poultry are believed to be relatively more common than with other groups of wild birds.⁽¹¹⁵⁾

Transmission of avian influenza pathogenic to swine was not reported. Instead it is postulated that avian influenza strains have to pass through domestic poultry and be altered from LPAI to HPAI before being pathogenic to swine.⁽¹¹⁵⁾

2009 vH1N1 Pandemic

The virus associated with the 2009 pandemic has been designated as variant H1N1 (vH1N1), as well as: North American influenza, novel H1N1, and Mexican swine origin influenza A (H1N1).⁽³⁾ In April, 2009 a vH1N1 virus was isolated from swine at a farm in Alberta, Canada that contained genetic material from four different influenza viruses; North

American swine influenza, human influenza, and swine influenza typically found in Asia and Europe. ⁽⁸⁾It is not known in what species the re-assortment that produced the variant H1N1 associated with the 2009 pandemic originally occurred. This vH1N1 could be transmitted to humans via aerosol to produce clinical disease. ⁽⁹⁾To date, the variant has been found in one swine herd in North America (Canada). Clinical influenza in humans via transmission of vH1N1 from swine has been established. ⁽⁹⁾Epidemiological information from Canada, Argentina, and Australia suggests that infected people and swine can transmit and cause infection within and between species ⁽¹⁰⁾The world health Organization (WHO) declared a pandemic alert for vH1N1 at Phase 6, the highest WHO level, on June 11, 2009. WHO declared that the outbreak was in the post pandemic phase on August 11, 2009.

Economic Impact of vH1N1 on Swine Markets in 2009

The United States exported more than 25% of its 2008 pork production. Out of this 25%, 15% of total exports, or 3.75% of total U.S. pork production, went to China and Russia. ⁽⁷⁵⁾China and Russia subsequently restricted U.S. pork imports due to reports of U.S. cases of vH1N1. This occurred despite World Trade Organization (WTO) rules to ensure that restricting imports for health and safety reasons must be supported by scientific evidence. The OIE (World Organization for Animal Health) asserts that bans based on incidence of vH1N1 do not comply with standards set by OIE and other competent standard-setting international bodies for animal health/food safety. It is speculated that vH1N1 infections in North America were used as a cover for trade restrictions that were politically motivated or intended to protect pork producers in other countries. ⁽⁷⁴⁾

In early May, 2009 swine futures contracts declined about 8% in value. This decline was attributed to media coverage of “Swine flu”. Cash hogs prices in spot markets declined almost \$20.00/Hd, which translates to an \$8 million/day loss to producers in the early days of the epidemic. Investors bid lower prices for food stocks with involvement in the pork industry such as Smithfield and Tyson based on anticipation of reduced pork demand. Industry losses were projected to be in the range of \$25-30 million/week for the remainder of 2009. ⁽⁷⁴⁾

Economic Impact of vH1N1 on Non-Agricultural Sectors

The World Health Organization (WHO) on April 27, 2009 came out against closing borders/restricting international travel as these restrictions would have detrimental economic effects without meaningful preventative value. The OIE stated that vH1N1 was being transmitted among humans with no evidence of infection in pigs or humans acquiring infection directly from pigs at that time, and that culling pigs would not help guard against human or animal risks and was inappropriate. Despite these statements the Egyptian government undertook a plan to depopulate the entire national swine herd to prevent transmission of vH1N1 to people without any evidence vH1N1 has been isolated in the country.⁽⁷⁶⁾

Table 1.2 shows the vH1N1 pandemic case fatality rate.

Table 1.2: vH1N1 2009 Pandemic Mortality Rates

Country	Cases	Deaths	% Fatal
Columbia	72	2	2.78
Dominican Republic	108	2	1.85
Argentina	1391	21	1.51
Mexico	8,279	116	1.40
Honduras	118	1	0.85
Guatemala	254	1	0.79
Costa Rica	222	1	0.45
USA	21,449	87	0.41
All others	27,860	31	0.11

vH1N1 and the Name “Swine Flu”

The actions and responses in markets, trade, and movement restrictions suggests that the descriptive term “Swine flu” which is taxonomically and epidemiologically inaccurate (in that only persons with intense contact are at risk of acquiring the virus from swine) was associated with the subsequent negative impacts to the U.S. pork industry after the emergence of

H1N1 in 2009. It is more appropriate and accurate to describe the virus by its less equivocal name H1N1 virus.⁽⁷⁷⁾

vH1N1 and External Risk Communication

At the outset of the vH1N1 outbreak the news media dubbed the disease “Swine flu”. This never was completely replaced another more accurate description, despite the best efforts, of agricultural, public health official, and the swine industry. This a specific example of external risk communication (communication of risk to individuals outside the entity directly affected) One critique of the way the swine industry handled this situation made the criticism the swine industry ran a 20th century public relations campaign by failing to utilize new social media such as Facebook, my space twitter, and blogging which would have reached more people much faster. Another criticism was using corporate spokespersons instead of individual industry employees whose perception of credibility would be higher.⁽¹³²⁾

Prevalence of vH1N1 in Swine

From August to December 2009, the National Veterinary Services Laboratory (NVSL) confirmed by virus isolation vH1N1 virus in 21 swine from the following states: MN (7), IN (4), IL (5), and NC (1).⁽²⁵⁾ Other species infected were domestic cats, ferrets, cheetahs, and turkeys.⁽²⁵⁾ A more detailed listing of the species infected and their location can be found in the appendix.

vH1N1 Regulatory Status

Currently no SIV are listed as reportable in the United States, and federal and state animal health agencies have no requirements concerning SI. However, vH1N1 is defined as an emerging disease and is reportable to the World Organization for Animal Health (OIE).⁽¹⁶⁾

vH1N1 Public Health Aspect

At this writing SI is not a reportable disease in human/veterinary medicine. The appendix contains model letters to inform the employees’ physicians and local health officials describing zoonotic diseases, including SI that employees can be potentially exposed to and management’s policies and procedures to reduce employee risk

Laboratory Diagnostics

It is not possible to make a definitive diagnosis of SI based on clinical signs alone, much less identify a specific serotype. Laboratory diagnosis is required.⁽²⁸⁾ Diagnostic samples/techniques for SI include :⁽²⁸⁾

1. Samples
 - A. Swabs for virus isolation. Swabs should be taken of the nasal passages or pharynx for mucus. Polyester, not cotton swabs, should be used. Swab temperature should be 5 degrees C. up to 48 hours or -70 degrees C. for long term storage. SI is unstable at -20 degrees C.
 - B. Trachea or lung tissue from necropsy samples can also be used for virus isolation. Tissue samples should be held under the same conditions as swabs for shipment.
2. Test Procedures
 - A. Serology: hemagglutinin and neuraminidase subtypes have historically been determined by hemagglutinin inhibition (HI) and neuraminidase inhibition (NI) tests. There are nonspecific inhibitors and agglutinins in swine serum that may interfere with the HI test. Sera should be treated to reduce/destroy such activity at the risk of lowering specific antibody levels. Paired sera are needed for diagnosis of living clinical cases.⁽¹³¹⁾
 - B. Enzyme-linked immunoabsorbant assay of serum and tissue samples⁽¹⁰⁾ (ELISA)
 - C. Polymerase chain reaction (PCR) both traditional and real time reverse transcription-polymerase chain reaction. (RT-PCR) This system offers both high sensitivity and high speed/high volume output, but may have limitations in detecting heterogenous virus populations.⁽¹⁰⁾
 - D. Immunoflourscence techniques applied to lung tissue.⁽¹⁰⁾
 - E. Immunohistochemistry in fixed tissues.⁽¹⁰⁾
 - F. Rapid cell culture assay using immunoperodidase staining.⁽¹⁰⁾
 - G. Enzyme immunoassay membrane test (Directigen FLU-A) to detect influenza A antigen in clinical specimens.⁽³⁹⁾

There is considerable antigenic heterogeneity in viruses of the same subtype circulating in pigs because of antigenic drift and lineage variation in different geographic areas. Virus strains used as antigens should be well matched to the current regional viruses.⁽⁴⁰⁾ The multiple

serotypes of SI require sub typing by PCR, genetic sequencing, or serology to identify the specific serotype of SI. Specific serotype of SI evaluation acquired during the diagnostic process is ancillary to its use in evaluating vaccine homogeneity and potential location of infection origin.

The use of real time RT-PCR has many advantages. Time to results is very fast at approximately 4 hours, while sensitivity and specificity are increased compared to many other tests. In addition, the gene target can be quantified. A closed system decreases the risk of PCR cross-contamination and the methodology is well suited for high volume testing making RT-PCR potentially the most cost-effective test for surveillance testing. However, virus isolation is required to detect changes in HA and NA genes to develop new primers for RT-PCR. ⁽³¹⁾

In July 2011, a portable PCR kit was marketed. POCKETtm claims to run a maximum of 8 samples per 55 minute cycles. A kit for testing 6 specific production animal diseases, including influenza A can be purchased, or the end user can develop their own specific DNA test. ⁽⁷⁸⁾

Suspect/Confirmed case of vH1N1 in Swine

USDA/APHIS has a series of actions for implementation in case of a suspect/confirmed vH1N1 case in swine. The complete document is contained in the appendix. The plan relies on initial notification of state animal health officials of suspected/confirmed vH1N1 cases via diagnostic results from laboratories, first points of concentration, and other official investigations linking pigs to sick humans. Clinically ill/exposed animals will be isolated and diagnostic tests will be expanded. The OIE will be informed of the case and its location while maintaining confidentiality of business information. Other federal, state, and pork industry agencies will be updated by APHIS. ⁽²⁵⁾

Chapter 2 - Prevention and Control of SI

Immunity/Vaccination in SI Herd Control

A combination of vaccination and Biosecurity are used to control SI in herds.

⁽²⁸⁾Infection or vaccination exposure to SI produces both humoral and cell-mediated immune responses. Antibody responses may develop to HA, NA, M, and NP proteins. Antibodies to the globular head region of the HA block attachment of the virus to cell receptors to neutralize viral infectivity. NA, M, and NP antibodies do not prevent infection but mediate killing of infected cells. Cytotoxic T lymphocytes (CTL) may play a role in clearing virus from the lungs. ⁽²⁸⁾ The immune response is reported to clear SI from the respiratory tract in one week. Antibody titers remain high for eight to ten weeks. ⁽⁴²⁾ Antibody-secreting cells have been demonstrated in nasal mucosal tissue. ⁽⁴³⁾

After primary infection there is solid protection against reinfection with the same or similar virus strain for at least nine weeks. ⁽⁴³⁾ The duration of immunity is unknown ⁽⁴³⁾ There exists limited cross-protection from SI vaccines with different antigens in pigs. This cross-protection also interferes with activity to antibody response due to vaccination. Pigs with high passive antibody levels do not develop an immune response to infection and are susceptible to re-infection. ⁽⁸⁰⁾

Vaccination and SI Transmission

It has been demonstrated that commercial SI vaccines have failed to significantly reduce viral replication or shedding following a challenge, although the vaccines did prove to be beneficial in reducing clinical signs and lung lesions. ⁽¹¹⁷⁾ This failure could be critical in the epidemiology of swine influenza viruses, possibly increasing the risk of transmission to susceptible animals and humans. ⁽¹¹⁸⁾

Techniques to mitigate this problem include:

1. Updating commercial SI vaccines to be more genetically similar to infectious SI serotypes. ⁽¹¹⁷⁾
2. Use of vectored vaccines. ⁽¹¹⁹⁾
3. Use of autogenous vaccines. A study comparing naïve groups of pigs exposed to pigs vaccinated with an autogenous vaccine derived from the SI used for subsequent

exposure and naïve groups of pigs exposed to pigs vaccinated with a commercial vaccine showed that autogenous vaccinated pigs did not transmit SI to other pigs in the study group. The naive pigs exposed to the autogenous vaccinated pigs did not become positive and infection was not established. Variable transmission was shown for the treatment group of naïve pigs exposed to pigs vaccinated with a commercial vaccine; however, the transmission of the infective SI was slowed by commercial vaccination. Virus was also circulating among the commercially vaccinated pigs at a time when the virus would be expected to have died out if compared to the naive population exposed to SI.⁽¹²⁰⁾

Pfizer Animal Health markets a killed virus vH1N1 swine vaccine. A two dose primary series is used for immunization.⁽²²⁾ A recombinant HA vaccine has seen limited use and is a candidate for provisional licensure.⁽²³⁾ Current H1N1 vaccines for classic H1N1 have demonstrated partial cross-protection to vH1N1.⁽²⁷⁾

Swine Vaccination

The primary effort in swine vaccination has been in reproducing females.⁽²⁸⁾ This is because pigs nursing vaccinated sows have protective passive antibody titers (1:40) until 16 weeks of age.⁽⁵⁶⁾ These titers will interfere with vaccination of grower/finisher pigs.⁽²⁸⁾ After the two vaccination primary series according to manufacturer's directions, a single vaccination will be administered two weeks before farrowing to maximize passive immunity.⁽²⁸⁾ In addition to vH1N1 other SIVs that have been identified in the herd will be included in the SI vaccination program as autogenous vaccines. Grower/finishers will not be routinely vaccinated. The goal is stabilization of the virus in new additions to the breeding herd by acclimatization of new breeding stock entering the breeding herd or vaccination.⁽²⁹⁾ Modifications to the protocol will be considered in the event of a significant outbreak in grower/finisher facilities. Breeding animals from outside the herd will follow the same vaccination protocol following an appropriate isolation period and SI testing protocol. This vaccination protocol is routine in the swine industry.⁽²⁸⁾

Vaccine Efficacy

The effect of vaccination has been examined in experimental conditions. Three commercial and 1 academic trials of various SIs will be reviewed to illustrate their efficacy.

Trial 1⁽⁵⁷⁾ compared a group of pigs vaccinated twice at two week intervals against a placebo-vaccinate group. All groups were intra-tracheally challenged 27 days after the last vaccination. Clinical respiratory disease was observed in 65% of the placebo group and 10% of the vaccinates ($p=.0028$). At 5 days post challenge, 100% of the placebo group were positive for viral shedding versus 15% of the vaccinated group ($p<.0001$). Significantly less virus ($P<.003$ each day) was isolated on days 29-32 in the vaccinates (1.6-3.0 LS Mean $\text{Log}_{10}\text{TCID}_{50}$) versus the control group (.8 LS Mean $\text{Log}_{10}\text{TCID}_{50}$) ($p<.0030$ each day). Bronchioalveolar lavage (BAL) fluids demonstrated virus in 100% of the placebo group versus 0% of the vaccinated group on day 5-post challenge.⁽⁵⁷⁾

Trial 2⁽⁵⁸⁾ used four groups of pigs (2 groups of 23 for challenge and 2 groups of 17 for controls) for a trial in which the controls were vaccinated with a bivalent vaccine (H1N1 and H3N2) and each group was exposed to either H1N1 or H3N2. All animals were challenged via nebulization chamber two weeks post vaccination and observed for clinical signs for five days post vaccination and nasal swabs were also collected for five days. The vaccinated pigs had a statistically significant ($p. <05$) lower score for clinical signs, a statistically significant ($p<01$) lower score for lung lesions. However, H1N1 vaccinates had a lower, but not statistically significant reduction in mean nasal swab positive days (1.1 vaccinates Vs. 3.6 controls) and H3N2 vaccinates did not have a significant difference in reduction compared to controls (.7 vaccinates Vs. .6 controls)⁽⁵⁸⁾

In trial 3⁽⁵⁹⁾, two groups of 24 pigs were vaccinated at 7 to 10 days of age and again 21 days later. The group was challenged three weeks after the second vaccination with either H1N1 or H3N2 and compared to a group of 12 non-vaccinated controls and 6 environmental control pigs. At five days post challenge the pigs were necropsied and the vaccinated control group showed statistically significant decrease in isolation of virus from nasal swabs and lung tissue (H1N1- $p=.0001$. H3N2 $p=.0004$).⁽⁵⁹⁾

In trial 4,⁽⁶⁰⁾ a group of pigs vaccinated with a multivalent vaccine twice two weeks apart (Group A) and another group vaccinated 2 times two weeks apart with an autogenous vaccine composed of an H1N1 strain produced from the same virus strain used as the challenge,(Group B) and a non-vaccinated naive group (Group C) were exposed via an infected pig (Pig D) shedding H1N1. Virus detection in individual animals was measured over 14 days via PCR. At day 7 100% of the non-vaccinated pigs (Group C) had detectable levels of virus.

By day 14, 35% of the pigs vaccinated with the autogenous vaccine (Group B) had detectable virus. Virus transmission could not be detected in group B. The H1 isolate used in the commercial vaccine was genetically and phenotypically different from the challenge strain.⁽⁶⁰⁾

Based on these references it is plausible that vaccination with SI vaccine slows and may reduce the spread of SI within a swine production unit. While cross protection between different virus strains does exist the closer the genetic/phenotypic relationship between the vaccine and the virus circulating in the unit, the better the response in reduction of clinical signs and virus shedding. Therefore, monitoring of the virus types circulating in the herd and potential new pathogenic viruses is needed to optimize the vaccination protocol.

In conclusion, while many SI vaccines can be effective in reducing clinical disease, the greater the genetic similarity between the vaccine and infecting virus, the greater the likelihood the vaccination program will stop circulation of the virus through a herd. Virus identification in specific herds and vaccine matching, to the point of using autogenous vaccines, is important to reducing SI in a herd.

Best Practices for ON-Farm SI Control

The following concepts will be used to develop a strategy to reduce introduction of SI into a swine production unit. Concepts of bio containment (prevention of spread of existing SI and its eventual eradication) and bio security (prevention of introduction of SI) will be used.

The goals are:

1. Reduce clinical SI in the production unit: Production medicine concern. Bio containment
2. Reduce chances of infection by new IV in the production system to reduce potential for viral re-assortment that may produce new pathogenic strains of IV that produce morbidity/mortality in swine/poultry/humans: Production medicine and public health concern. Bio security.
3. Reduce chances of swine production staff/vendors becoming infected with SI with subsequent human re-assortment and morbidity: Production medicine and public health concern. Bio security and bio containment

Strategy: Process Control Perspective

Defining the parameters for intervention in an agricultural production unit is a task that lends itself to use of an objective program. Statistical process control (SPC) will be used as a template. Two incidence density databases will be developed: 1. Mean production unit morbidity due to respiratory disease. 2: Mean production unit mortality due to respiratory disease. The incidence density period will be 12 months so subsequent data for the same time frame can be compared to the original database. While an average for other herds ⁽⁴⁷⁾ could be used while the database is being established, the highly individual nature of this specific metric makes use of data collected outside the specific production unit problematic.

Once a historical mean incidence has been established a graph is constructed (% of parameter/day) with the historical mean constructed as a straight line above the X axis. Current prevalence data is now plotted on the graph for the chosen time period (daily, weekly, monthly, Etc.) Control bars located 3 standard errors (se) above and below the historic mean are constructed. SPC defines the process as being out of control if a parameter point is greater than 3 SE above/below the historic mean, or between 2 and 3 standard deviations (SD) for three consecutive data point measurements. ⁽⁵¹⁾

A limitation of SPC is that it was designed and is used in mechanical production systems with a very narrow and specific range of parameter values. It has not been validated in biological systems with a wide range of production values. A methodology proven to evaluate quality control in the production of nuts and bolts faces major challenges when used to evaluate morbidity/mortality in production animal agriculture. This being said a chart with historical vs. current morbidity/mortality data would be an important check on the subjective skill of “clinical judgment”

Human Contact

All persons in contact with production unit swine will follow a shower in-shower out production unit specific clothing protocol. Anyone entering the facility will not have exhibited clinical signs of influenza for at least 24 hours before entry. Inputs such as feed will be off-loaded onto production unit vehicles so there will be no direct contact between vendor vehicles and animals.

There will be no direct or indirect contact between poultry and the swine production unit. A potential source of IV transmission is aquatic birds if the production unit is located in a migratory flyway. Efforts will be made to reduce the attractiveness of the production unit to migratory birds.

1. Feed will be contained to prevent bird feeding
2. State/federal animal damage control officials will be consulted on approved techniques such as use of propane noise makers and appropriate decoys to reduce the population of any migratory birds on bodies of water under the unit's control.

Physical Surroundings of Production

Previous information suggests SI from a production unit could spread via aerosol for a radius of 2 miles from the unit.⁽⁴⁹⁾ New unit site selection would favor no other swine/poultry units within a 2 mile radius of the selected site.

Serological Testing of Swine

The generalization that serologic testing for SI should begin if the virus is in close traveling distance to the production unit needs to be reevaluated considering that any point on the planet is currently within one days' international travel and attendant exposure to a wide variety of pathogens. A more pragmatic approach would be to institute serological testing immediately after confirmed cases within a radius of one day's travel by transport truck (8 HR X 50 MPH=400 miles) or if there is a confirmed case in a production unit serviced by a common vendor. Serologic testing should begin if a case of SI or AI is confirmed within the potential aerosol range (2 Mi. radius).

Because multiple pathogens produce similar clinical signs of respiratory disease the case definition of SI will be any animal displaying clinical signs of respiratory disease that also has a positive virus isolation or PCR for SI. To address vaccine selection issues positive SI tests will be subsequently expanded to identification of specific strain.

New breeding stock will be tested for SI via PCR and after receipt of a negative test held in isolation for 8 days post arrival (1 day longer than the current known infectious period). Criteria for movement into the general population will be absence of SI clinical signs and

negative PCR tests. Failure of either criteria means these animals will not be permitted to stay on the production unit site. Breeding animals raised on site with no history of SI will not go through the isolation period. These animals will be considered to be virally exposed to the herd through their previous acclimation and vaccination.

Current Rt-PCR has been described as 99% sensitive and 88-100% specific. This was determined by testing serial dilutions of various subtypes of SI for sensitivity and confirmed with a population of 900 samples from abattoir surveillance program and 62 samples submitted for diagnostic testing. The results were validated against a gold standard of virus isolation⁽⁶⁴⁾ Based on this information the testing protocol will be a single test with negative test required for herd acceptance. Positive test animals will have subsequent virus isolation for vaccination information. Finisher animals by definition will be removed from the unit at harvest and no longer present a source of SI virus, so testing of breeding stock will be adequate in the majority of cases.

Routine Surveillance

Routine testing will be done on all animals necropsied regardless of cause of death. Surveillance testing of clinically healthy/ill animals will be considered if the morbidity process has been considered to be out of control according to statistical process control standards⁽⁵¹⁾

Use of Segregation

Production segregation (breeding/nursery/feeding) is an important Biosecurity /Bio containment measure. A good vaccination program should provide good passive immunity through the nursery period. An All in-all out production stage assist in giving an optimal all animals in a specific group immune response via acclimatization/immunization. The enveloped characteristic of the virus and its short life span outside living cells makes cleaning and disinfection (C & D) highly effective in virus destruction. C & D will be routinely performed whenever a building is vacated and before introduction of a different production group.

Finishers versus Nursery Breeding Herd

The control program goal will be reduction of SI by vaccination of pre-partum sows to provide passive immunity to piglets up to 10 weeks of age with no routine vaccination of nursery/finishing phases. Control in these areas will be based on all in-all out production with (C & D) between groups. This is based on SI's short life span outside living cells and vulnerability to a wide variety of C&D agents. (A list of appropriate C&D agents is included in the appendix) SI outside the farrowing facility will be investigated as: 1: A failure of C&D. 2: Failure of all in-all out protocol. 3: Introduction via Fomite. Vaccination outside the farrowing unit will be a final option protocol.

Human Influenza Cases/Vaccination

Swine exposure to human influenza cases can be mitigated by:

1. Limiting access to the production unit
2. Monitoring of persons with access to the production for clinical signs of influenza and excluding them from the unit until a minimum of 24 hours post clinical signs or 7 days after beginning of clinical signs, whichever is longer.
3. Vaccination of staff with appropriate human influenza virus vaccines

Swine workers have the potential to: A: Participate in the generation of novel viruses. B: Serve as a bridging population between swine and human urban populations, and C, accelerate a pandemic. Despite these possibilities there is no current plan to vaccinate and train swine workers in SI mitigation.⁽⁵⁴⁾ For this plan, employees will be strongly encouraged annual vaccinations for all current forms of influenza virus. The vaccinations will be paid for by management either directly or through company insurance or by local health department programs if such exist. An exemption is allowed for those with a physician's statement that vaccine administration is against medical advice. (AMA) Immediate family members will be encouraged to be vaccinated likewise, with the above described exemption applying. Management will coordinate with the local health department for family vaccination if vaccination by other venues is not possible.

A study reported in the New England Journal of Medicine⁽⁵⁵⁾ of 239 human participants receiving two doses of vaccine 21 days apart reported no major adverse side effects. Minor adverse events: 56.3% reported at least one local adverse event (Injection site tenderness/pain). 53.8% reported at least one systemic adverse event (headache, malaise, and myalgia). No hospitalizations or deaths occurred. Using disease threshold detection in WinEpiScope a study of this size could find 1.5 serious adverse reactions in a population of 1,000,000 people. Post vaccination titers based on hem agglutination-inhibition (HI) assay were observed in 95% of the participants. The immune response observed after the first dose was sustained after the second dose. This was considered to be protective.

R_0

R_0 (R_0 naught) is an estimation of the number of secondary cases susceptible individuals that will develop from contact with an infected primary case. R_0 can be calculated via multiple techniques. A simplified formula using estimated and/or literature acquired is $R_0 = C * P * D$ (C= number of contacts the infected individual makes per day. P=probability per contact with infectious individual. D=duration in days the infected individual is infectious to others).⁽⁶¹⁾ Previous research indicates SI has an R_0 of approximately 10.⁽⁶⁰⁾ Using $R_0 = 10$ secondary cases $P = 0.9$ probability of successful infection transmission⁽⁶⁰⁾ $D = 7$ day primary contact is infectious⁽²⁸⁾ $C = 1.6$ contacts per day. R_0 would increase if C increased. The most current estimate for R_0 for the 1918 human Spanish influenza pandemic is 2-3. Mathematical models indicate that vaccination in the face of any disease outbreak is more effective with a low R_0 . This suggests that successful pre infection vaccination for any form of SI is an important control measure.⁽⁹²⁾

SI Immunization Cost

As of February, 2012 current pricing on licensed SI vaccines runs from \$.93 to \$1.66 /dose.⁽¹³³⁾

Use of Anti-Viral Drugs in Poultry and Swine

There are currently two classes of anti-viral drugs available to treat influenza in humans: Adamantane (amantadine and rimantadine) and neuraminidase inhibitors. (oseltamivir and zanamivir) These drugs do not have a label indication for any other animal species. Their use in veterinary medicine would be classified as extra-label drug use.(ELDU) The Animal Medicinal Drug Use Clarification act of 1994(AMDUCA) defines how veterinarians may use these drugs in non-human species. Drug cost would be a secondary issue. The use of anti-viral drugs is not considered common in veterinary medicine due to their effectiveness against a limited number of viral disease and few anti-viral drugs have been studied in animals.⁽³¹⁾

There is a list of drugs in AMDUCA that are prohibited by the Food and Drug Administration (FDA) for use in specific situations in non-human species. Currently adamantane and neuraminidase inhibitors are prohibited for use in turkeys, chickens, and ducks because of concerns that use in these species will accelerate the development of drug resistant strains of IV that could become pathogenic in humans.⁽¹²⁶⁾ Starting in the late 1990s Chinese avian producers have been using amantadine as a therapeutic and prophylactic drug for avian influenza in their flocks⁽¹³⁰⁾. This practice was approved and encouraged by the Chinese government⁽¹³⁰⁾. H5N1 is currently non-responsive to amantadine and rimantadine.⁽¹²⁷⁾

This use in poultry is contrary to recommendations from the WHO, Food and Agriculture Organization (FAO) and OIE.⁽¹²⁶⁾

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SI Elimination from a Swine Herd

In all in-all out (AIAO) production systems, discrete closed populations, or populations without previous levels of immunity, SI elimination may happen for certain herds. In large herds, continuous flow populations and herds this may not occur. Other approaches to virus elimination in the herd are needed. The following is a description of a virus elimination technique tried at a three-site, 1200 sow herd.⁽¹²⁶⁾

Site 1: Breeding herd. Gilt replacement in the gilt development unit was switched from monthly/bimonthly to quarterly in order to facilitate the viral infection die-out. After that gilts from an SI negative source were introduced to serve as sentinels. (>30 gilts)

Site 2: Nursery. Site 2 was depopulated since attempts to control virus spread by strict AIAO procedures were inadequate. A separate off site facility was established to accommodate the flow from site 1 while the depopulation took place. Facilities were cleaned, disinfected, and retested for at least 4 weeks. Vaccines were not used in the breeding herd or the pig moving from breeding to the nursery site or from the nursery to the finisher site.

Site 3: Finishing site. The site was treated in the same manner as site 2; after depopulation pig flow was restored and the pigs monitored for the presence of clinical signs and sero-conversion using an IHA test. Performance parameters were recorded and an economic analysis was performed.

Introduced SI negative sentinel gilts remained clinically and serologically negative for 12 months. Pigs in sites 2 and 3 also remained sero-negative after repopulation. No clinical signs suggestive of SI were observed after completion of the study. Performance parameters of average daily gain (ADG), feed medication costs, and mortality improved.

In another report ⁽¹²⁸⁾ a new farm complex (Farm 3) was being created from two different health sources. Pigs from 1 had sero-converted to SIV (H1N1) without clinical signs. The growing population has serological evidence of SI but no virus isolation. H1N1 was ultimately isolated from sentinel pigs at weaning and the isolated virus was used to develop an autogenous vaccine. Pigs from farm 2 were serologically negative and no influenza had been identified in any diagnostic submissions.

The vaccination protocol at farm 1 was as follows:

1. Gestating females: 1 dose 4 weeks pre-farrow and 1 dose 2 weeks pre-farrow
2. Replacement gilts pre-breeding: 1 dose 4 weeks pre-breeding. 1 dose 2 weeks pre-breeding.
3. Subsequent booster vaccinations: 1 dose 2-3 weeks pre-farrow.

The stocking procedure was as follows: Weekly shipments of piglets 15-21 days of age were made to the farm 3 site for 34 weeks. Pigs from Farm 1 were isolated for 25 days after the arrival of pig from farm 2. Weekly a random statistical sample was collected before the group was moved to Farm 3's nursery and finishing site. Fourteen days post entry to the nursery and finishing site farm 2 piglets were serologically tested for the SI strain from Farm 1. After 4 months, serological evidence of the homologous SIV strain was detected circulating in Farm 2

pigs. This demonstrates the difficulty of creating a SI negative herd based on vaccination while using a continuous flow system.

Biosecurity Procedures

Specific Biosecurity procedures and their validation via a search of research literature will be discussed in detail under the validation of Biosecurity practices. A listing of these procedures subject to literature search and subsequent review/comment follows.

1. Fenced perimeter to control access by vendors, non-employees, wildlife, feral animals
2. Restricted vendor entrance/site specific unloading
3. Production unit dedicated veterinary equipment
4. Distance between the production unit and other swine/avian production units
5. Employee health status/vaccination program
6. Employee exposure to potential zoonotic disease sources
7. Site specific employee clothing
8. Visitor control
9. Biosecurity procedures for contract professionals
10. Employee training in zoonotic diseases

Various Biosecurity practices have been devised based on veterinary/producer experience and opinion. Scientific research to validate these practices does not always exist. The following is a summary of Biosecurity practices and evidence of their validity. The fact a specific practice has no research confirmation is not of itself a reason for deleting the procedure, but an admission that its current value may be more theoretical than proven.

Disposition of SI/vH1N1

A SI outbreak in a feeding phase would be handled by enforcing the all in-all out concept. The affected animals would be fed out under isolation/quarantine. The animals would be marketed after a 24 hour period with no clinical signs of SI/vH1N1 from any animals in the group. Staff working in the affected unit would be required to shower in-shower out and wear fresh clothing before coming in contact with other swine in the production unit. Every effort would be made to have specific staff confine their work activities to the SI/vH1N1 infected facility. Equipment would be dedicated to the infected unit only and receive D&C before being used at other units. SI/vH1N1 is a high morbidity/low mortality disease so it is expected that the finishing period would be extended with concurrent production loss but no reduction in the number of live animals marketed from the isolated unit.

There is currently no regulatory restriction against the use of swine for consumption if they are recovered from SI in general or H1N1 specifically. The only restriction is against the harvesting of animals that are morbid for any cause.

SI/vH1N1 in a nursery/ breeding unit would be isolated and handled under the same protocol as described in a finisher unit. Vaccination of pigs in the face of an outbreak will be considered. Pigs moving from this venue to finishing will be identified and finished in one group. Clinically normal sows will have virus isolation testing done before re-breeding. Sows with positive virus isolation tests will be candidates for culling. Euthanasia would be performed for animal welfare reasons only.

In a multipliers/seed stock unit the highest level of biosecurity is to be maintained. Any animals with clinical signs of SI will be removed/isolated immediately. Animals with positive virus isolation will be sold for slaughter after cessation of clinical signs.

Carcass disposal

Current evidence is that SI survives outside living cells for a short period of time and is readily deactivated by environments routinely produced by carcass disposal techniques of incineration, rendering, burial, and composting. The correct use of any of these disposal methods is acceptable.

SI Infection in Swine and the Canadian Experience⁽¹²⁷⁾

During the 2009 vH1N1 pandemic, an Alberta, Canada producer had vH1N1 isolated from his swine herd. . The infection source was determined to be an infected employee who had recently

been in Mexico where vH1N1 had occurred. This individual had been hired to work on the production unit ventilation system. The unit was placed under a precautionary quarantine by the Canadian Food Inspection Agency (CFIA) under the authority of the Canadian Health of Animals Act (CHAA). CFIA defines Highly Pathogenic Avian Influenza (HPAI) as a reportable disease but not SI.⁽⁷²⁾ The province of Alberta lists SI as a notifiable disease. Notifiable diseases are recorded for surveillance purposes but there is no government response to confirmed cases⁽¹³⁰⁾. Subsequent to the publicity surrounding vH1N1 packers refused to purchase these swine post recovery out of concern of SI infection persistence, disregarding scientific evidence SI has not been isolated from edible tissues of infected animals that are not showing signs at time of harvest. This caused overcrowding at the production unit and resulted in depopulation at the owner's request due to animal welfare issues.⁽¹²⁷⁾

In the United States state diagnostic laboratories require producer permission to forward data of non-reportable diseases such as SI to any entity beyond the producer. To date very little data has been forwarded to USDA. U.S. producers are aware of the outcome of the Canadian vH1N1 infection and have declined to give state diagnostic labs authorization to forward vH1N1 test results originally performed for diagnostic purposes. As of May 29, 2009, a total of 143 samples submitted to 17 National Animal Health Laboratory facilities and tested under the USDA monitor/surveillance program. All samples tested negative for vH1N1. All samples tested negative for vH1N1. This situation will continue until producers receive assurances laboratory samples will not be used as a reason for not purchasing their products. Efforts to ensure this have been undertaken but are not completed.⁽⁶⁷⁾ Risk communication has not been adequate to demonstrate to producers the utility of this knowledge.

There is no current mandatory SI surveillance program in the United States as a result of the vH1N1 pandemic. USDA initiated a voluntary surveillance plan which continues and has been updated.⁽⁶⁶⁾ This plan relies on data collected by diagnostic laboratories. Target populations are: swine at exhibitions and samples from clinical signs of SI. USDA has funding for testing to be performed at minimal/no cost to producers.

Swine production unit/veterinarian/physician/public health interaction

SI is a zoonotic disease that can travel from human to swine and swine to human. The swine production ownership, employees, veterinarians, private physicians, and public health officials all have a vested interest in communication of timely and accurate information regarding SI. This communication is complicated by medical professional/client confidentiality both from the disciplines of human and veterinary medicine. With the exception of reportable diseases,

specific medical information is the property of the animal owner/patient to be released only with the animal owners' patient consent. There is specific need for diagnostic investigation of influenza-like symptoms in swine unit employees to protect both employees and swine.

Human/veterinary aspect of SI

Management will inform employees about the occurrence of all zoonotic diseases discovered on the premises by veterinary professionals. This information will also be communicated to the employees' primary care physician to include zoonotic disease in the physician's differential diagnosis of employee health problems. Production unit management will be the conduit through which this information flows.

Public Health Aspect

At this writing SI is not a reportable disease in human/veterinary medicine. In the appendix there are model letters from the unit production management/veterinary professional which will be sent to local physicians/public health officials defining management's policies and procedure on SIV along with other zoonotic diseases employees can be potentially exposed to.

Herd Immunity Threshold

Herd immunity threshold (H) is the proportion of immunes in a population above which the incidence of infection decreases. The formula for calculating herd immunity threshold is $(R_0 - 1)/R_0 = (10 - 1)/10 = 9/10 = .9 = 90\%$ required immunity. Typical demographics in a farrowing facility indicates that one infectious sow will be within the two meter range of aerosol transmission of 5 other sows and 60 pigs (including the infectious sow's pigs in varying states of immunological resistance.⁽⁶³⁾

Protocol for mitigating disease introduction (including SI) into a swine production unit.

Information from the previously described information and the following checklist will be formed into the protocol below. This protocol is an effective Biosecurity plan to reduce the chances for introduction of infectious disease into a production, including all forms of SI.

Validation of Biosecurity practices.

Various Biosecurity practices have been devised based on veterinary/producer experience and opinion and have not been validated scientific research. The following is a summary of Biosecurity practices and the evidence of the validity. The fact a specific practice has no research confirmation is not of itself a reason for deleting the procedure, but an admission that its current value may be more theoretical than proven.

Aerosol

The literature suggests that *Actinobacillus pleuropneumoniae*,⁽⁹²⁾ PRRSV,⁽⁹³⁾ Hog Cholera Virus (HCV),⁽⁹⁶⁾ and Swine Vesicular Disease Virus (SWDV),⁽⁹⁴⁾ can be transmitted by Aerosol over short distances and FMD,⁽⁹⁷⁾ *Mycoplasma hyopneumoniae*,⁽⁹⁵⁾ and PRV,⁽⁹⁸⁾ can be transmitted over long distances. Field evidence exists for SI to be transmitted by the airborne route and SI has been isolated from air.⁽¹²⁵⁾

Domestic and non-porcine feral animals

Although seemingly probable, no definitive proof exists that pathogens can be naturally transmitted from domestic/non-porcine feral animals to swine.⁽⁹⁹⁾

Feed

Research has not proven that porcine pathogens can be transmitted via contaminated feed that is not based on uncooked garbage.⁽⁹⁹⁾

Vehicles

There is some evidence that *A. pleuropneumoniae*⁽¹⁰⁰⁾ and *S. suis*⁽¹⁰¹⁾ could be transmitted via contaminated vehicles.

Personnel and visitors

Transmission of pathogens between people and swine varies with the pathogen. SI infection can be transmitted between swine and humans.⁽⁹⁹⁾

Showering/hand washing

Hand washing with non-medicated soap for 10 seconds reduced the numbers of artificially inoculated bacteria tenfold: however, less than half of naturally occurring bacteria were removed.⁽¹⁰²⁾ Drying hands for 10 seconds via a towel or 20 seconds via dryer reduced the number of bacteria transferred to skin or equipment by 94-99.8%⁽¹⁰³⁾ No reports on effects of showering were found. Showering in/changing clothes does remove contaminated clothing and the procedure discourages visitors.

Cleaning disinfection and drying

Cleaning removes organic matter that can deactivate disinfectants. Disinfection reduces/eliminates contamination. Drying kills many organisms. The only porcine pathogens for disinfectant efficacy studies were reported and confirmed effective are:

African Swine Fever (ASF)⁽¹⁰⁴⁾

B. Hyodysenteriae⁽¹⁰⁵⁾

Porcine Parvo Virus⁽¹⁰⁶⁾

S. suis⁽¹⁰¹⁾

Swine Vesicular Disease Virus (SVDV)⁽¹⁰⁸⁾

Transmissible Gastroenteritis Virus (TGE)⁽¹⁰⁶⁾

Vesicular Exanthema Virus (VEV)⁽¹⁰⁷⁾

SI is an enveloped virus and because of this is considered to be susceptible to disinfectants effective against other enveloped viruses. A list of approved disinfectants is in the appendix.

Barriers to mitigate SI transmission to staff-gloves and mask.

It has been demonstrated that swine production unit staff who routinely wear gloves have no increased risk of SIV infection compared to staff who do not handle swine. Production staff who do not use gloves have an odds ratio (OR) of 30.3 of exposure to H1N1 compared to those who use gloves. Smokers have an 18.7 OR of H1N1 exposure compared to non-smokers. It is postulated that smokers expose themselves to H1N1 by exposing oral mucosa after handling infected pigs. The postulation with glove use is the gloves are a barrier to virus exposure on skin with skin-oral mucosa contact after the gloves are removed.^(68, 69) Use of the N95 respirator mask has been shown to offer no statistically significant improvement of SI infection rates over standard surgical masks. In the cited trial both groups experienced an approximately 23% infection rate. There were no unmasked controls in this trial.⁽⁷⁰⁾

Color codes of danger concept

This protocol is based on the color codes of danger concept developed during World War II by the United States Marine Corps to describe readiness levels of personnel to various threat scenarios.⁽²⁶⁾

The levels are:

Condition White: No perception of danger.

Condition Yellow: Relaxed Alertness.

Condition Orange: Unspecified Threat Detected

Condition Red: Armed Encounter /No Assault initiated

Condition Black: Assault in Progress

This concept can be used as an internal risk communication tool to staff to describe the current disease threat level in the production unit and the appropriate bio-security/bio-

containment measures for that threat level. The threat level can be unobtrusively communicated to unit staff by displaying an appropriately colored object at an area all staff enter such as a time clock location or break area. Specific procedures are to be followed for each threat level. As the threat level increases additional procedures are added to the previous threat level procedures.

Condition White: No Perception of Danger

No plans have been made concerning the appearance of disease in condition white. No preventive measures have been made, staff has no training, and no emergency supplies have been purchased. Management has not even considered the possibility of a disease outbreak. If such an outbreak occurs the production will be destroyed in the economic sense. Condition white is an unacceptable state of readiness.

Condition Yellow: Relaxed Alertness

Management recognizes the possibility of disease outbreak and its consequences. A Biosecurity plan has been developed to mitigate introduction of multiple infectious diseases and is used daily. The plan is the baseline and is enhanced by additional steps as the color code escalates.

Condition Yellow Biosecurity: Premises. To prevent vH1N1 introduction via fomite/infected wildlife/feral animals or aerosol

1. The premises have perimeter fencing to prevent wildlife/feral animal from accessing the premises.
2. Personnel and supplies enter/exit through a staffed gate that restricts access to areas based on need and records access.
3. Vendors will unload all purchased commodities at a perimeter area and unit staff will transport commodities in unit vehicles.
4. Basic veterinary equipment will be purchased by the unit and dedicated for unit use only by veterinarians who come to the unit. Any required specialized equipment will be brought in a surgically sterile condition.

No additional swine or avian units owned by the firm currently owning the existing unit will be constructed within a 2 mile radius of the unit.

Condition Yellow Biosecurity-Personnel: To prevent vH1N1 introduction via staff, to protect health of staff and their families, to prevent potential spread from the production unit to staff, and to form an infection barrier between staff and their surrounding community.

1. All staff and their immediate family will be strongly encouraged to have current immunizations necessary to their health/safety as determined by the staff's insurance provider, unit management, and veterinary staff. These immunizations will include (but not be limited to) diseases such as tetanus and appropriate strains of influenza virus. (IV)

2. Supervisors will physically observe all staff as they report to work. Anyone displaying clinical signs of disease will be subject to professional examination and may be sent home based on medical advice. Individuals diagnosed with IV will be off work 7 days post fever. This will be considered as sick leave with pay⁽²¹⁾.
3. Clinical signs that will require a management decision to continue work include a fever > 37.0 degrees C. plus any one of the following clinical signs:
 - a. Nasal discharge or congestion
 - b. Sore throat
 - c. Cough

Differentiation initially between cold and flu will be admittedly difficult but necessary considering the potential for lost production from swine infected with SI.

4. Staff is required to shower in, wear unit supplied clothing/dedicated clothing and footwear, and shower out upon leaving the unit.
5. A staff member who travels to any venues defined by the United States Department of Agriculture as subject to a Foreign Animal Disease (FAD) must not contact animals for a minimum of five days after leaving the FAD subject area.
6. Staff and their immediate family are encouraged to report any clinical signs/diagnosis of zoonotic disease.
7. Staff will be issued with appropriate gloves which will be used at all times when handling swine.
8. Job assignments will be made with the goal of minimizing staff movement between different premises within the unit.
9. Employees will be trained in hand washing as follows. Hands and forearms will be washed for 10-30 seconds using warm water and surgical scrub. Hands and forearms will be rinsed until no scrub residue remains and drying will be done by paper towels or hot air dryer.⁽¹³⁾

Condition Yellow Biosecurity-Zoonotic Diseases: To inform staff about the clinical signs of all zoonotic diseases they could potentially come in contact with.

1. Staff will receive instruction/written information on zoonotic disease from public health officials and consulting veterinary staff. The goal is for staff to recognize, prevent, and report these conditions if identified at the workplace or within the staff or their immediate families.

Condition Yellow Biosecurity-Visitors: Protect visitors who are not knowledgeable about zoonotic disease and protect animals from infection from visitors

1. Visitations/group tours will be scheduled through upper level management. Visitors will comply with steps 5-8 for staff. Visitors will be issued visible identification to be worn

while on the premises. Visitor identity and addresses will be acquired, recorded and held on file. Visitors will be under the escort of management at all times.

Condition Yellow Biosecurity-Vendors: To protect swine from zoonotic/vector transmission via vendors and their equipment.

1. Vendors will be allowed direct contact with swine only on an as required basis and will be required to comply with steps 5 through 8 for staff.

Condition Yellow Biosecurity-Animal Transportation

1. All vehicles used in animal transportation will undergo C&D before driving onto the premises.

Condition Yellow Biosecurity-New Swine Introduction:

1. Introduction of new swine to the unit shall be kept to a minimum. The maximum amount of replacement breeding stock shall come from the unit.
2. Any new breeding stock imported into the unit will undergo surveillance testing for a predetermined list of infectious diseases as determined by the consulting veterinarian.
3. Release from confinement requires negative diagnostic test and 7 consecutive days without evidence of clinical signs of disease.

Condition Yellow Biosecurity-Diagnostics: To accurately diagnosis disease in swine

1. The following types of animals shall be subject to diagnostics. .
 - A. Dead swine. All dead swine shall be necropsied. Appropriate samples shall be collected to arrive at a definitive diagnosis.
 - B. Animals that have left and returned to the unit will be subject to ante mortem serology pathogen isolation. The results will be compared to their known status before departure.
 - C. New additions to the unit as discussed above.

Condition Yellow Biosecurity-Vendor Vehicles: To prevent vector introduction.

1. In the event of vendor vehicles requiring movement onto the premises, the vehicles will have tires/wheels washed and sprayed with an anti-bacterial/anti-viral product on arrival and departure by unit staff. Vendors required to work on premises will comply with steps 6, 7, & 8 for staff and be escorted by staff while they are at work.

Condition Yellow Biosecurity: Wildlife, feral animals, and pests.

1. Birds will be discouraged from nesting in animal housing areas by nest removal, sound (propane cannon) and artificial predator images (dummy hawks, etc.)
2. Exterminators will be employed for rodent/insect control.
3. Stray dogs/cats will be collected and turned over to local animal control.
4. Federal/state Animal Damage Control will be utilized to control wildlife found on unit property.

Condition Yellow Biosecurity-Production Practices: To reduce potential exposure to pathogens.

1. All phases of production will utilize the all in-all out concept of production.

Condition Yellow Biosecurity: Premises Disinfection.

1. Animals housed on dirt will have the top layer soil layer turned over between introduction of animals to minimize levels of pathogens.⁽²⁰⁾
2. After a premises has been emptied of animals, all organic matter will be removed and the premises will be cleaned with detergent and water and disinfected with an approved disinfectant (appendix) that is defined as being effective against influenza virus along with other pathogens of concern.⁽¹⁸⁾

Condition Yellow Biosecurity-input documentation: To trace back source of potential exposure.

1. All inputs purchased by the unit will have date of purchase and unique identifier such as lot number/invoice number recorded in case of needed future trace back.

Condition Yellow Biosecurity-Feed

1. Feed supplies will be held in rodent/bird proof containers.

Condition Orange Biosecurity Level

An event of unknown etiology has occurred that has resulted in a detectable increase in morbidity/mortality or decrease in production parameters (average daily gain, feed conversion, litter size, Etc.). This may be a short term event the etiology of which is never determined or the initial signs of a serious long term disease incident. Condition Yellow Biosecurity protocols will continue to be in force along with additional protocols designed to determine etiology and reveal new corrective measures, or at the least rule out high consequence disease of concern.

Condition orange will exist when morbidity/mortality parameters are determined to fit the SPC definition of out of control. This will be three consecutive reporting periods when the morbidity/mortality levels are at least 3 standard deviations above the mean for the unit historical average. Morbidity/mortality will be expanded to theriogenology parameters such as litter size, number of pigs born alive, abortions and stillbirths, neonatal mortality, Etc. Some of these parameters could result in out of control being defined as 3 standard deviations below the unit mean.

Condition Orange Biosecurity Level-Staff: To alert staff to potential disease event

1. Staff will be informed on condition of confidentially that an increased level of clinical signs of an as yet nonspecific disease is occurring.
2. All group tours, visitations, Etc. Will be postponed until the situation has reverted to condition yellow.
3. Staff may be dedicated to care for only diseased/exposed animals.

Condition Orange Biosecurity Level-Surveillance: To increase probability of diagnosis

1. Diagnostic testing will be expanded to any pigs showing clinical signs of interest
2. Spatial and population at risk data will be collected to begin epidemiologic analysis and isolation of specific animals and areas may begin.

Condition Orange Biosecurity Level-Therapy.

1. Therapy based on clinical signs will begin in ill swine.

Condition Red Biosecurity Level

There is a specific reason to believe the unit's risk to exposure of a specific disease has increased. (vH1N1 will be used as an example) Scenarios for this could be:

1. Confirmed human cases of vH1N1 in a spatial area readily accessible by the unit.
2. Confirmed swine cases of vH1N1 in a spatial readily accessible by the swine unit or in other swine units served by common vendors.
3. Confirmed avian cases of vH1N1 in aquatic migratory avian that could access the unit.
4. Confirmed cases of vH1N1 in another swine/avian production unit within the theoretical 2-mile radius of aerosol transmission.

Condition Red Biosecurity Level:- marketing & Commodities: To minimize probability of being in a poor marketing position as a result of a high consequence disease event.

1. Marketing plans will be re-evaluated to avoid being caught with large numbers of market ready animals during a potential stop movement order.

Condition Red Biosecurity Level-Surveillance

1. Surveillance of dead avian on the premises begins (with assistance from appropriate regulatory agencies if appropriate)

Condition Red Biosecurity Level:-Staff.

1. Staff will have refresher training on all aspects of vH1N1 that applies to their jobs.

Condition Red Biosecurity Level-Vendors. Reduce possibility of disease introduction via vector

1. Unit vendors will be referenced to see if they have serviced premises with cases of vH1N1. New vendors may be selected temporarily.

Condition Red Biosecurity Level-Animal Importation: Prevent introduction of disease via new animal importation

1. Importation of swine into the unit will be cancelled until condition yellow is reestablished.

Condition Black Biosecurity Level: Initiate bio-containment/ pathogen eradication program

A case of vH1N1 has been confirmed in unit animals or staff.

Condition Black Biosecurity Level-Staff. Minimize staff exposure.

1. Staff will be reassigned to allow staff or immediate family members showing IV signs to remain off premises for a minimum of 7 days post develop of clinical signs.

Condition Black Biosecurity Level-Premises

1. Building containing infected swine will be noted and isolated. Dedicated staff/equipment will be used on these premises to address the issue of cross-contamination.
2. Any of these premises that can be cleared of animals will be closed and undergo C&D.

Condition Black Biosecurity Level: - Regulatory Issues.

1. Although vH1N1 is not currently a reportable disease, as a professional courtesy public health/veterinary regulatory officials will be notified.

Conclusions

vH1N1 influenza virus has the ability to infect and subsequently produce clinical influenza in pigs and people. People have 2 receptor sites in their respiratory system and have the potential to produce a double re-assortment virus from 2 different influenza viruses. Pigs have three receptor sites and can potentially have a triple re-assortment. Any influenza virus that can attach to any of these sites can be part of a re-assortment. This re-assortment can produce a virus with new hosts, pathogenicity, and virulence from its progenitors.

vH1N1 is a low mortality disease of swine with the ability to produce high morbidity if infected swine have low immunity to the virus. There is limited cross protection from non vH1N1 vaccines that mitigates clinical signs of disease but does not prevent the establishment of vH1N1 in a swine production unit with subsequent economic losses. Vaccines with a genome more similar to vH1N1 mitigate clinical disease, lung lesion, and do a better job of mitigating establishment of vH1N1 in a swine production unit than virus vaccines made with less similar IV genomes.

The economic losses from having vH1N1 established in a swine herd come from decreased production parameters such as average daily gain, feed efficiency, reducing weaning

weight, more days to reach market weight and costs of treating for secondary pathogens subsequent to the initial vH1N1 infection.

It is in the interest of production medicine to prevent vH1N1 from becoming established and to eliminate it from swine production units. The current techniques for this prevention are vaccination of breeding stock with the appropriate vH1N1 genomic material to confer passive immunity to newborn pigs for the first 8-10 weeks of life and bio security/bio containment measures to prevent vH1N1 introduction to the production unit and isolate vH1N1 if it does appear in the unit and subsequently eliminate it from the unit.

Public health interest overlaps those of production medicine in that the prevention of vH1N1 in pigs reduces the chances the virus could be a source of genomic material for reassortment into a virus with different, potentially more virulent/pathogenic properties towards people.

Risk communication of the potential hazards to people of pigs being infected with vH1N1 needs improvement. Risk communication can be divided into two categories. Internal Risk Communication: This will take place among the staff of the production unit and be done by the animal health professionals working for the unit. The consequences of vH1N1 infection at the production unit will be described, along with specific procedures staff is expected to do to prevent/mitigate vH1N1 in the pig population and prevent/mitigate spread of infection from pigs to staff. External Risk Communication: An individual with specific specialized training in risk communication will be assigned the task of interacting with the community and media on events occurring at the production unit that are perceived as potential risks to the immediate community and pork consumers. New media such as twitter and Facebook will be utilized.

A Bio-security/Bio-containment protocol for the production unit has been developed for vH1N1 that can also apply to other swine diseases. The procedures used and current production unit bio-security/bio-containment status will use the "Color Codes of Danger" template previously developed by the military for assessing current threat status, level of alertness, and reactions to the current health status of the production unit. The template for Statistical Process Control (SPC) will be used to determine when health parameters outside normal parameters and the point for determining veterinary intervention is required.

A sound protocol for bios-security/bio-containment that prevents the introduction of and isolates infection of vH1N1 along with a protocol for its elimination in a swine production is important in swine production medicine from an economic standpoint as well as from the public health standpoint of reducing the potential re-assortment of vH1N1 becoming a component of a re-assort process that could potentially produce an influenza with increased virulence and pathogenicity for people.

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Appendix A - Model Letter to Local Public Health Officials

Dear Dr/Mr/Ms

XXX swine farms would like to take a moment of your time to discuss a topic of our mutual concern-the potential interaction of zoonotic disease between our staff and animals.

It is the best interest of XXX swine farms to successfully mitigate zoonotic disease in both our employees and animals. To that end we have developed an extensive Biosecurity plan for our employees that include mandatory immunization for high consequence diseases, education on zoonotic diseases, and mandatory minimum health status to be on our premises. We also have a similar Biosecurity plan for our animals developed and implemented by our consulting veterinary staff which includes a surveillance program for zoonotic and non-zoonotic diseases. These plans have been developed/implemented out of concern for the health and well-being of our staff and animals and the realization that said health/well-being of employees/animals is crucial to the long term viability of our farm individually and the swine industry as a whole.

We are concerned and wish to improve information sharing on the subject of zoonotic disease. Not all zoonotic diseases are reportable to both human and veterinary regulatory officials. We would like to be on your list of entities that receive information on the local occurrence of zoonotic/reportable disease within the legal realm of patient confidentiality. In return we will reciprocate concerning veterinary information.

Our specific disease of concern is influenza. Currently swine influenza is not a disease reportable to regulatory veterinary medicine. Our swine specific Biosecurity plan includes virus isolation/serotyping of any influenza virus detected in our animals. We are interested in human serotypes to see if any potential influenza virus infection is moving from humans to animals or animals to humans so the appropriate mitigation steps may be developed.

We believe the maximum allowable cooperation between your department and our enterprise will improve both human and veterinary medicine and subsequently our community

Yours for one health

Appendix B - General Precautionary Measures

Y N Do you require that all individuals wash hands with soap and warm water before AND after animal contact?

Farm Entrance and Perimeter

Y N Do you limit access to your farm?

Y N Do you have only one gated entrance to the animal areas on your farm to better control and monitor visitors and vehicles?

Y N Do you keep the gate locked when not in use?

Y N Do you limit contact between your animals and others that may present a risk of disease?

Y N Do you keep cats and dogs from roaming between farms?

Y N Do you minimize visitors and traffic on your farm?

Y N Have you posted signs at the farm entrance to inform visitors to stay off your farm unless absolutely necessary?

Y N Have you posted a visitor biosecurity sign that clearly lists specific measures to follow when on your farm?

Y N Do you require visitors to follow your farm's biosecurity procedures?

Y N Do you require visitors to check-in with farm personnel upon their arrival?

Y N Do you require delivery vehicles and personnel to follow your farm biosecurity guidelines regarding parking, driving and animal contact?

Y N Do you inspect delivery vehicles for cleanliness and restrict entry to those with visible contamination on tires, wheel wells, etc?

Y N Do you require feed deliveries to your farm be the first delivery of the day?

Y N Do you require that all deliveries be left at the perimeter of your farm?

Y N Are your animal load out and delivery facilities located at the perimeter of your farm?

Employees

Y N Do you talk to your employees about the disease risks associated with owning or handling pigs outside of your operation?

Y N Do you require that employees that have contact with swine at other locations (including their own home) use strict biosecurity measures while on your farm (e.g. provide them with clean boots and coveralls to wear)?

Y N Have you educated yourself and trained your employees to recognize and report diseases?

Y N Do you maintain a written Biological Risk Management Plan and have regularly scheduled meetings to educate and update those involved?

Neighbors

Y N Do you restrict the sharing of equipment or vehicles between farms?

Y N If equipment must be shared, do you remove all manure and bedding, wash the equipment with warm water and soap, rinse, disinfect and rinse again before using it with animals from your farm?

Y N Do you always wear clean clothes or coveralls, gloves, hats, boots, etc. when coming in contact with animals?

Y N After contacting your neighbors' livestock, do you wash and disinfect boots, change gloves, hats, and clothes or coveralls before returning to your farm?

Visitors and Vehicles

Y N Have you posted warning signs telling visitors to only enter your farm with permission?

Y N Do you provide a phone number at your farm entrance for visitors to call and make an appointment?

Y N Are all visitors accompanied by someone from the farm at all times?

Y N Do you use only on-farm vehicles for transporting visitors within your operation?

Y N Do you require visitors and vehicles to park in designated areas at the entrance to your farm and away from all animal areas?

GENERAL PREVENTION PRACTICES CHECKLIST FOR SWINE PRODUCERS (CONT'D)

Y N Do you restrict visitors from animal housing areas and from contacting or handling your pigs (unless absolutely necessary)?

Y N Do you provide clean coveralls and disposable or disinfected rubber boots and require that these items be worn by all visitors at all times

while in animal areas?

Y N Do you provide facilities and equipment (pressure washers, brushes, hoses) for cleaning and disinfecting vehicles, boots, etc.?

Record Keeping

Y N Do you maintain a log sheet to record any visitors or vehicles that come onto your farm?

Y N Do you maintain thorough and accurate records of animal movement?

Y N Is each farm location treated as a separate unit?

Animals- Animal Health

Y N Do you review and update your vaccination and treatment protocols with your veterinarian at least once a year?

Y N Do you monitor and inspect animals for signs of illness at least daily?

Y N Do you investigate all animals with unusual signs or those unresponsive to treatment, especially those that die suddenly?

Y N Do you clean equipment, boots, and change clothing when between animal groups with different health status and age?

Y N Do you promptly euthanize animals that are not going to recover?

Y N Does your veterinarian necropsy animals that die from unknown causes?

Y N Do you promptly remove dead animals and dispose of the carcass (e.g. render, compost, bury or burn) according to local and state laws?

Animals- New Introductions

Y N Do you follow an all in/all out policy for pig barns to minimize disease introduction and allow for cleaning and disinfection?

GENERAL PREVENTION PRACTICES CHECKLIST

FOR SWINE PRODUCERS (CONT'D)

Y N If an all in/all out policy is not possible, do you limit the frequency and number of new introductions?

Y N Do you limit purchases to a few sources with known and trusted herd health programs?

Y N Do you obtain a complete herd health history prior to purchasing and introducing new animals?

Y N Do you request copies of vaccination and treatment records for all purchased animals?

Animals- Isolation and Quarantine

Y N Are your isolation and quarantine facilities removed from all other animal areas and separate from one another?

Y N Do you prevent the sharing of equipment (feed, treatment, restraint) between isolation and quarantine animals?

Y N If equipment must be shared, do you wash it in warm water and soap to remove visible contamination, rinse, disinfect and rinse it again before removing it from one location and moving it to another?

Y N Do you immediately isolate sick animals from the herd to minimize disease spread?

Y N Do you prevent direct contact between isolated animals and others?

Y N Do you prevent the sharing of ventilation, feed/water and equipment between isolated or quarantined animals and others?

Y N Do you use separate facilities, equipment, and staff to handle isolated livestock?

Y N If it is not possible to use separate facilities, equipment and staff, do you handle or visit the isolated animals LAST?

Y N Do you clean and disinfect all equipment, clothing, boots, etc. that comes into contact with ill and isolated animals?

Y N Do you quarantine all animals that are recent purchases or those that return to your farm?

Y N Do you prevent new additions and animals returning from sharing water, feed, facilities or bedding with your other animals?

Y N Have you determined together with your herd veterinarian the appropriate times for animals to spend in isolation and quarantine?

Y N Do you test for key diseases before taking animals out of isolation or quarantine?

GENERAL PREVENTION PRACTICES CHECKLIST

FOR SWINE PRODUCERS (CONT'D)

Animals- Wildlife, Other

Y N Do you prevent your animals from having contact with free roaming animals (e.g. wildlife, feral swine, cats, dogs, etc.)?

Y N Do you keep farm access routes, parking areas, yards and storage areas clean and tidy to avoid attraction of birds or rodents?

Y N Do you minimize bird contact and nesting in your operation?

Y N Do you maintain a rodent control program?

Y N Do you secure all feed storage areas and clean up spilled feed to minimize access by pests?

Supply Handling

Y N Do you always read and follow label directions for proper storage of vaccines and medications?

Y N Are products that do not require refrigeration properly stored in a cabinet or other enclosure to restrict access by unauthorized individuals and minimize environmental exposure?

Y N Do you monitor your supply refrigerator at least monthly to help ensure the products are adequately stored (36-46oF)?

Y N Have you worked with your veterinarian to teach proper procedures to all people who handle vaccines and medicines?

Y N Do you restrict vaccine and medicine access to only trained personnel?

Y N Does your personnel training include proper handling and administration of vaccines and medicines plus when to use them?

Cleaning and Disinfection- General Recommendations

Y N For pigs housed on dirt flooring, do you turn over the top layer of soil to reduce the buildup of pathogens and parasites?

Y N Do you thoroughly clean all objects to remove any visible debris (manure, dirt, bedding) before applying a disinfectant?

Y N Do you always use the proper concentration of any disinfectant and mix according to the product label?

GENERAL PREVENTION PRACTICES CHECKLIST FOR SWINE PRODUCERS (CONT'D)

Y N Do you always allow a disinfection solution contact time to “sit” and work?

Y N Do you refer to the disinfectant label to determine the amount of contact time that is recommended?

Conclusion

Total number of: Yes responses _____ No responses _____

If you have 1 or more No responses, you have identified areas for improvement on your farm. Not all questions are equal in their risk of disease transmission, so it is important to work with your veterinarian to develop a management plan addressing the biggest risks first.

This will help minimize the chance of diseases entering your farm. Each farm will be unique in their ability to prevent disease transmission because management styles, herd sizes and finances vary.

Appendix C - Model Letter to Individual Staff Primary Health Care Provider from Employer

Dear Dr. XXX

Mr./Ms XXX, an employee of XXX swine farms has identified your practice as their primary health care provider. We would like to take a moment of your time to discuss the unique health challenges their employment at our farm presents.

Your professional training has made you aware of the potential of zoonotic disease among individuals whose job description requiring physical contact with domestic animals. As employers we are concerned about the risk factors our staff encounters for all types of disease. We want to mitigate these risk factors for the sake of our employees' health and well-being. We are also aware of the potential for the transmission of disease from our staff to the swine under our care. We also want to mitigate these risk factors for the health and well-being of our animals.

As a professional courtesy our firm will inform your practice of any diagnosed zoonotic disease in our swine herd and steps we are undertaking regarding these diseases. This will include diagnostic information regarding pathogen type. In our submitted list of enclosures is a list of high consequence zoonotic diseases we are concerned about. Some of these diseases are reportable to both human and veterinary health regulatory officials. Our consulting veterinarian Dr. XXX has our authorization to supply your practice with any relevant information regarding zoonotic disease/public health matters as regards our farm. We are enclosing a list of employee required immunizations for diseases that could be potentially acquired in our workplace environment

We believe this type of cooperation between physicians, production agriculture and veterinary medicine will result in improved health and well-being for our employees, our community, our animals, which will in turn improve the viability of our farm individually and the swine industry collectively.

Yours for one health

XXX

CEO XXX swine Farms

Enclosures:

1. Employee recommended vaccinations/diagnostic tests

A. tetanus

B. Influenza all current serotypes

Tuberculosis ID test

High consequence zoonotic diseases

1. Leptospirosis*

2. Brucellosis*

3. Tuberculosis*

4. Anthrax*

5. Influenza

6. Trichinellosis*

7. Taeniasis*

*Reportable to human and/or veterinary regulatory officials