

MASTER OF PUBLIC HEALTH FIELD EXPERIENCE REPORT

Policy in the Making: Establishing Public Policy for Complex Animal Diseases

By

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MASTER OF PUBLIC HEALTH

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Abstract

The goal of this review is to provide an overview of the process by which policy is developed for complex animal diseases. There is no one size fits all approach to policy. Policy making for a disease is complex, often a bit disorderly, and like medicine not an exact science. The current mission behind the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (USDA, APHIS-VS) and its role in the One Health partnership is to adequately contribute to the animal health component. One Health is a crucial component behind the response to any emerging disease because of the interrelatedness of animal, human, and environmental health. The following document strives to further support the advancement of the One Health concept as it relates to complex animal diseases.

This review also illustrates just what can happen when a student becomes an integrated part of One Health and public policy. Throughout the development of this paper, I found myself diving right into the very concepts that I had previously only seen and heard in the classroom. This paper serves not only as an APHIS training document, but as substantial evidence of how a field experience can turn an array of concepts into a workable puzzle by which one builds a career dedicated to One Health.

Keywords: policy, health, emerging, infectious, veterinary, disease

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List of Abbreviations

AHPA	Animal Health Protection Act
AI	Avian Influenza
AMA	American Medical Association
APHIS	Animal and Plant Health Inspection Service
AVMA	American Veterinary Medical Association
CEAH	Center for Epidemiology and Animal Health
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
EID	Emerging Infectious Disease
FAD	Foreign Animal Disease
FMD	Foot and Mouth Disease
FSIS	Food Safety and Inspection Service
HPAI	Highly pathogenic avian influenza
HSPD-6	Homeland Security Presidential Directive-6
MERS-CoV	Middle Eastern Respiratory Syndrome
MOU	Memorandum of Understanding
OH	One Health
OHCC	One Health Coordination Center
OIE	World Organization for Animal Health
PEDv	Porcine Epidemic Disease virus
SARS	Sudden Acute Respiratory Syndrome
Sit-Rep	Situation Report
SES	USDA HPAI Secure Egg Supply Plan
SOP	Standard Operating Procedure
USAHA	United States Animal Health Association
USDA	United States Department of Agriculture
WHO	World Health Organization
VS	Veterinary Services

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There are several people worth recognizing for their contributions throughout my six week experience and the development of this document. The first person I would like to thank is my fellow Iowa State colleague, Tai Ogg. It was through her guidance and contacts that I was able to meet Dr. Anelli. Next, it seems most appropriate to thank Dr. Joe Anelli for agreeing to take me under his wing during this six week experience and for his mentorship. I have acquired more than I ever thought possible and am sincerely grateful.

I would also like to personally recognize Maria Romano, for her support and guidance during my time with the One Health Coordination Center, and also for her valuable contributions to the review and final product of this document. Ryan Freed, whose input and feedback, was also important in the development of the final product should also be recognized.

It seems appropriate to further extend gratitude and thanks to each and every member of the APHIS, VS community in Riverdale and the other locations that helped make this document a reality. It was through my ability to interact on conference calls, emails, personal conversations, teleconferences, etc. that I was able to fully bring the idea of, “how policy is made” to full realization. Thank you all!

I am also thankful for the chance to interact with the veterinarians and professionals within APHIS and the other Federal agencies. It was through these interactions that I was able to fully recognize the impact veterinary medicine can have on the One Health concept and animal health, and the level of expertise and skill present was inspiring to a soon-to-be graduate of veterinary medicine.

Thanks are also in order to Dr. Nagaraja, my MPH graduate committee, and Dr. Cates for their patience and continual support. The challenge of completing two degrees has seemed unbearable at times, but it has become clearer than ever that this was an endeavor worth pursuing. My experience with the OHCC alone has demonstrated the value that an MPH provides not only for my future as a veterinarian but the future of One Health.

Finally, I would like to also thank the faculty and staff at the Iowa State University College of Veterinary Medicine for giving me the necessary skills and knowledge required to become a valuable asset to the veterinary profession. I would also like to specially thank Dr. Paul Plummer for his contributions to the background research investigation of MERS-CoV.

Chapter 1: What is One Health?

The One Health Experience

The One Health Coordination Center (OHCC) as part of the USDA, APHIS- Veterinary Services Surveillance, Preparedness, and Response Services (SPRS) unit in Riverdale, Maryland was the primary location for my six-week field experience. My main mentor and supervisor throughout this experience was, Dr. Joseph Anelli, the Director of the One Health Coordination Center. Maria Romano, a current third year veterinary student at Virginia-Maryland College of Veterinary Medicine and Saul T. Wilson Jr. scholar as well as Ryan Freed, a third year veterinary student from the University of Illinois, were also major collaborators during my six week experience.

One Health (OH) - what is it and what does it mean?

“Between animal and human medicine there is no dividing line –nor should there be. The object is different but the experience constitutes the basis of all medicine.” –Rudolf Virchow, German scholar (1800s)

The idea that the health of animals, humans, and the environment are synergistically linked is the driving force behind the current practice of One Health (OH). Over time, the unifying goal of controlling and preventing disease and improving health at the level of the human, animal, environmental interface has brought public and private organizations from different disciplines together. In the last three decades, the need for an OH approach has increased in importance (25). This increase is due to changing global dynamics; for example, population growth, ecological changes, and globalization. In a globalized society, as the population continues to grow, the movement of animals and humans will inevitably increase. Increased movement presents an opportunity for an increased risk of disease transmission, especially new or emerging diseases, many of which are zoonotic diseases.

One Health and Veterinary Services (VS) – the role VS plays in the One Health partnership

Since the mid-1900s, with the initiation of the Bovine Tuberculosis and Brucellosis programs, VS has played a crucial role in impacting public health with the control of several zoonotic diseases (25). Since then, the need and involvement of VS has grown. The emergence of diseases like the 2006 highly pathogenic avian influenza (HPAI) H5N1 epizootic, have not only affirmed a need for VS involvement, but has illustrated the importance of a collaborative effort among many different disciplines and organizations. As a result, the OH component of VS has continued to evolve to meet the demands of animal health and enhance the ability to address human and environmental problems.

The current mission or focus of the OH group of VS is to build on new and existing collaborations while also enhancing communication and outreach. APHIS strives to increase the APHIS-VS stakeholders and adequately contribute to the animal health component of the OH partnership (24). In partial fulfillment of this mission the OHCC was

created. The OHCC is an organizational structure established to facilitate incorporation of OH into every aspect of the VS community. Additionally, the creation of the OHCC also illustrates to the outside community and OH partners how VS is incorporating OH into its infrastructure (22).

Chapter 2: Introduction to Public Policy

What are the criteria for animal health public policy development?

The decision of what constitutes the need for regulations or policies is not clearly defined and involves a unique process that varies based on the situation. Veterinary Service's role in policy historically has been to manage issues concerning livestock and poultry health and issues related to trade. The current animal health mission goes further to indicate that the VS role in policy will embrace all aspects of animal health, including wildlife. APHIS, VS recognizes that human health is impacted by the health of animals and as defined by the current mission, stated by John Clifford, APHIS Deputy Administrator for VS, "APHIS Veterinary Services is committed to providing all of our stakeholders and partners with superior customer service and effective partnerships. VS' reorganization is designed to better align our organization with our animal health mission allowing VS to continue to deliver our services efficiently and effectively (22)."

Similar to medicine, the principles behind animal and OH policy are not an exact science. The inner complexity of public policy is intricate and dependent on a variety of factors leading to a need for balance. These factors can range from political to social to economic and everything in between. There is no one right answer to the formulation of public policy. Instead, the answer lies in finding a solution that minimizes the impacts on animal, human, and environmental health. The process can take months to years depending on the situation, and some policies never come to fruition because more benefit can come from enacting other measures.

When does VS act?

The question remains as to when the government should get involved and if a policy is necessary to achieve an outcome. Again, this is not clear and a variety of contributing factors must be considered.

The members of VS have proposed a clever way to decide whether engagement or response is required for a particular emerging infectious disease. They have established a decision matrix for this purpose. The matrix is a simple table with several criteria that are compared to four different columns along a continuum. This framework gives decision makers an additional tool to use when deciding appropriate involvement and response (23). The tool is also something that could be re-visited occasionally, especially as new information is learned about a particular disease (Appendix I, II).

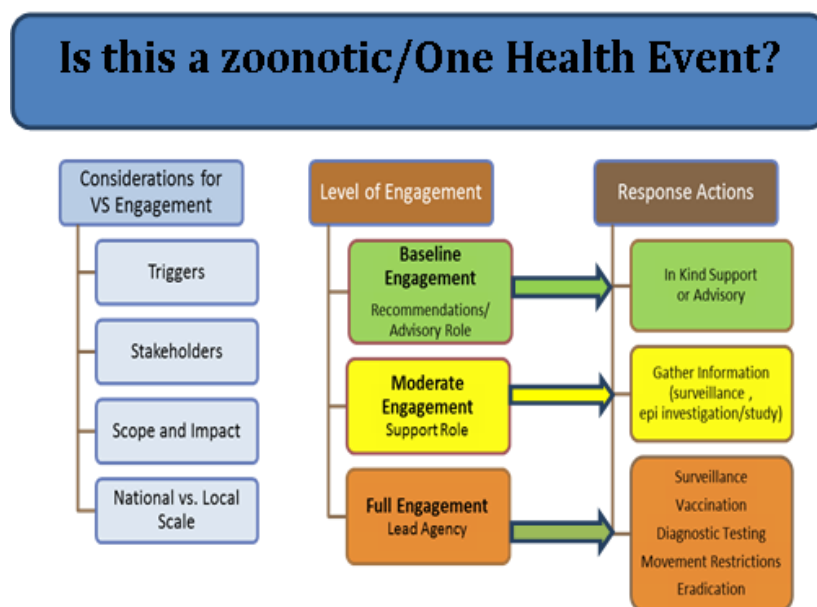


Figure 1: One Health engagement flowchart, created by APHIS, VS

Regardless of the framework used to establish when and if action should be taken, it is important to consider the various ‘triggers’ that might overrule any scientific-based decisions (23). A trigger is anything that has an overwhelming impact on the personal or public viewpoint of a particular issue. An example of a trigger to action can be described using the Accelerated Pseudorabies Eradication Program. The severe economic losses incurred by the United States (U.S.) swine industry acted as a trigger aiding in the decision to respond. In other cases, the decision is simply a political statement inciting a need for policy in a particular area. Situations, such as the consideration of which zoonotic diseases should be a priority, depends on triggers, science, and other influencing factors to decide just what should be a main focus (28). This focus, like many things, is subject to change with time as new diseases emerge, re-emerge, or as new information is acquired.

While it is often true that triggers and other influencing factors impact whether VS takes action on a particular area, there is one more area that requires consideration. More often than not, it is Congress that makes the decision by passing a bill, delegating funds to be spent on a specific program or area of interest. This is true for many of the U.S. program diseases, which includes the Accelerated Pseudorabies Eradication Program, discussed earlier. The delegation of financial support from Congress is often the most significant factor in the decision making process. Historically, financial support was primarily designated towards those diseases with an established program. The recent reorganization of the federal agencies has allowed for the allotment of funds to be directed towards program diseases and any disease of OH concern. This is an important change as it provides VS with the ability to reach farther towards the prevention and control of diseases of OH significance.

Emerging Disease vs. Foreign Animal Disease – Is there a difference?

To demonstrate the continuous work being done to provide a more coordinated and concise approach to the management of complex animal diseases, a recent VS guidance has been constructed to formally define both foreign and emerging animal diseases. As defined by the VS guidance, a foreign animal disease (FAD) is a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories (6).

To further refine this definition, an FAD is considered to be one of forty diseases recognized by the Committee on Foreign and Emerging Diseases. This committee, as part of the U.S. Animal Health Association (USAHA), meets annually to discuss the current list of foreign animal diseases. A disease previously not identified as an FAD can be added to the list as the committee deems appropriate. Animal health officials formally define a disease worthy of consideration for the FAD list as, “an important transmissible livestock or poultry disease believed to be absent from the U.S. and its territories that has a significant health or economic impact.” Historically, this list includes all FAD’s considered to be of the greatest threat to the livestock and poultry industries in the U.S (30).

In comparison, the VS guidance further defines an emerging infectious disease (EID), as any terrestrial animal, aquatic animal, or zoonotic disease not yet known or characterized, or any known or characterized terrestrial animal or aquatic animal disease

in the United States or its territories that changes or mutates in pathogenicity, communicability, or zoonotic potential to become a threat to terrestrial animals, aquatic animals, or humans (6).

To summarize, an EID is any animal disease of novel or evolving nature that is either known or not known to exist in the United States. A “foreign” animal disease which has not previously been identified as an FAD and is currently a threat to animals or humans is considered an EID. For example, Porcine Epidemic Disease virus (PEDv) is currently considered an EID. Prior to its introduction to the U.S., PEDv was only known to exist outside the U.S., but it was never considered of importance to be included on the list of FAD’s. Overtime, this might change if either the USAHA or the World Organization for Animal Health (OIE) deems PEDv worthy of an upgrade from EID to FAD. An example of a case where this has occurred can be described using HPAI-H5N1. Initially, HPAI-H5N1 was considered to be an EID, but overtime as the threat became global the OIE deemed it appropriate to upgrade HPAI-H5N1 to FAD status.

The dividing line between an FAD and EID is not really all that clear outside of personal opinions. The distinction between an EID and FAD is not based completely on science-based principles, and the same goes for the principles behind policy development. Sometimes all it takes is a group of people meeting around a round table to agree that a disease in question is an FAD or EID. Decision making and policy development are highly variable and depend on a variety of factors. All decisions are likely to change as new information is gathered about a disease. Therefore, a successful response requires that a sense of flexibility be present throughout every aspect of the process from creating definitions to the disease program implementation.

Birds, Policy, and the OH approach

A perfect example of how policy has been formulated around an emerging infectious disease can be described using the evolution of the National Avian Influenza Surveillance Plan. The initial HPAI-H5N1 epizootic promoted the development of a national surveillance program as countries worldwide scrambled to understand the virus. In September 2005, President George W. Bush created the International Partnership on Avian and Pandemic Influenza. This partnership was formed to make Avian Influenza (AI) the focal point on national agendas. Following this induction, the United States hosted the first international conference in October 2005. Since then, several conferences have been held worldwide. The conference brought an emerging issue into plain sight. It helped coordinate and mobilize resources needed to improve containment, response, and prevention of future pandemic threats (26). Additionally, President Bush established the National Strategy for Pandemic Influenza and assigned the lead role to the Department of State. In support of both the National Strategy and Department of State Pandemic Influenza plans, the Under Secretary for Democracy and Global Affairs established the AI action group. This action group was designed to serve as a collaborative effort between several government agencies allowing for efficient maintenance and coordination of U.S. information on AI and the ongoing epizootic (8).

Since 2005, there have been several outbreaks in Asia, Europe, and Africa. HPAI-H5N1 has transitioned from an emerging disease to being classified as a foreign animal disease by the OIE. Part of this is due to the economic and social impact of the disease, but much of it is also due to its evolving nature and ability to infect birds and mammals, including humans. The initial regulatory framework has set the stage. However, as we embark farther into the future, it is clear that there is a need for constant improvement (26).

Due to its success, the AI regulatory framework has served as a basis for the regulatory framework of other emerging and re-emerging infectious diseases. These beginning steps have in many ways strengthened our ability to respond and brought together disciplines and organizations across continents. All these factors demonstrate how policy can impact the course of emerging disease within the United States and abroad. With recent emergence of diseases, such as avian influenza H7N9, it is clear that our fight has only just begun.

In 2007, a combined effort from the American Veterinary Medical Association (AVMA) and American Medical Association (AMA) set into motion the development of a One Health Initiative task force that further supports the vision of the OH concept (25). This task force created a bridge for veterinarians, physicians, and U.S. animal and human health agencies to communicate and collaborate effectively on matters related to the human, animal, and environmental interface. The OH initiative task force combined with the global effects of the National Strategy for Pandemic Influenza and its Implementation plan promoted further growth and adoption of the OH concept at home and abroad.

Chapter 3: Background information

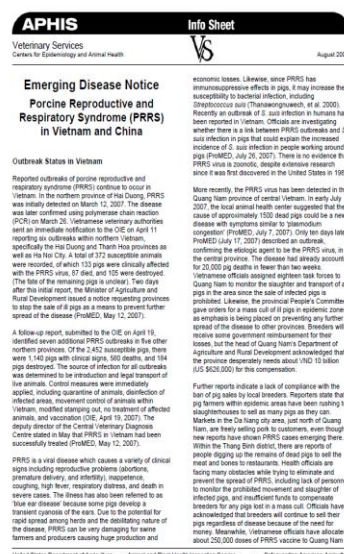
Background Research and Communication

For many diseases, exploring what is known can become quite expansive. The amount of research depends on the novelty or nature of the disease or how much is already known about it. In the case of a novel virus that has recently emerged, very little information will be known. Typically, there is need for extensive study to determine the epidemiologic characteristics of the disease.

A current example of this is the emergence of Middle Eastern Respiratory Syndrome, which is caused by a coronavirus (MERS-CoV). MERS-CoV is reported to be of camel origin and the cause of severe respiratory illness in humans. To date, only mild illness has been reported in camels with most showing no clinical signs. MERS-CoV is most closely related to Sudden Acute Respiratory Syndrome (SARS) another coronavirus of historical significance. The impact on the human population amongst the Middle Eastern countries, risk to travelers, and relation to a historical pandemic tags MERS-CoV as a significant disease for further investigation. While there is evidence of zoonotic transmission through close contact with camels there is simply not enough information known about the modes of transmission to extrapolate the source of human exposure. This illustrates the limitations arising from incomplete data due to novelty of a disease.

The background research on a particular interest area or disease usually strives to cover the basic epidemiology of the disease, but it can involve investigation of other factors. Other factors may include but are not limited to: cultural aspects, regional differences, climate, etc. For example, a cultural difference between the U.S. and Asia that has an impact on the transmissibility of AI is related to the importance of live poultry markets in Asia, and the difference in care and management of the birds. Generally, birds live in much closer proximity to people throughout Asia and there is also less knowledge of biosecurity. It is also harder to completely depopulate flocks in communities throughout Asia due to economic circumstances and cultural beliefs. Therefore, it is important that our background research is thorough as there is much that can be learned from just taking the time to understand the culture and life style of the affected population.

While much of the background research on an area can be collected through an internal review of the existing literature there is a need for subject matter experts. To illustrate this idea and its usefulness, MERS-CoV will be used as another example. During the investigation of the virus, it became necessary to understand more about camelids, the U.S. camelid industry, and the cultural differences between the U.S. and Middle East in regards to camelid health. To help fill these voids,



Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV)

Situation Report
Friday, July 11, 2014

Goals and Objectives:

1. Ensure worker safety in handling the MERS CoV or testing of animals
2. Monitor international and domestic occurrences of MERS CoV and assess their impact on US animal populations (if any)
3. Ensure the US Agriculture Sector is prepared to "respond" appropriately to an incursion of MERS CoV in the domestic animal population
4. Provide periodic reports in a timely manner to leadership on activities and risk level

Summary:

International (as of 1800 on Wednesday, July 2):

- For events before July 4, 2014 please reference previously published Sit Reps.
- (7 July) - WHO - Globally - 827 laboratory-confirmed cases of MERS-CoV, including at least 287 related deaths have officially been reported.

Domestic or Western Hemisphere (as of 1800 on Wednesday, July 2):

- For events before July 4, 2014 please reference previously published Sit Reps.
- No events to report

Resources

1. World Health Organization. 2014. Global Alert and Response: Middle East respiratory syndrome coronavirus (MERS-CoV) - update. Retrieved from: http://www.who.int/csr/don/2014_04_mers-cov/

Figure 2: Emerging Disease Notice (left) and Situation Report (Right); taken from APHIS website and APHIS-VS Microsoft SharePoint

a list of camelid experts was developed. The list consisted of several experts that could be consulted to answer questions and serve as future resources. The information acquired at this stage promotes a working knowledge of a disease and enhances the ability to discuss risk assessment.

Situation Reports and Emerging Disease Notifications

Part of what should be included in the background information about an emerging disease is information to improve the awareness of the issue and enhance a stakeholder's ability to stay informed as new information arises. Situation reports and emerging disease notices have been used by VS to achieve situational awareness of a particular EID. A situation report (Sit-Rep) can be updated as often as necessary and is distributed as determined by VS.

For example, a situation report was developed for MERS-CoV to increase situational awareness related to the recent outbreak. A Sit-Rep includes information such as, cases reported, U.S. and international activities, notices from the World Health Organization (WHO), and the socioeconomic impact of the EID. The logistics behind the distribution of a Sit-Rep requires a lot of coordination amongst federal agencies to ensure that reporting occurs seamlessly with minimal conflicts. In terms of the MERS-CoV Sit-Rep, the decision was made to distribute updates weekly due to the novelty and high volume of data reported. Since then the acquisition of new information on MERS-CoV has decreased. This has led to the decision to decrease the frequency of distribution to as needed.

The Center for Epidemiology and Animal Health (CEAH) has also contributed to the situational and scientific awareness of an EID through the development of emerging disease notices. The difference between an emerging disease notice and a situation report is the audience and format. An emerging disease notice is formatted like a technical fact sheet. It contains a summary of the outbreak and describes the current knowledge and epidemiology of the disease. It is often distributed at the public level to raise awareness and knowledge on an emerging issue. In comparison, a Sit-Rep is often restricted to distribution amongst the federal agencies and stakeholders. While, a Sit-Rep serves a valuable purpose, it is primarily a report of the activities related to the disease outbreak or situation. The emerging disease notices provide a more concise and readable description of the disease situation.

Chapter 4: Risk Assessment and Analysis

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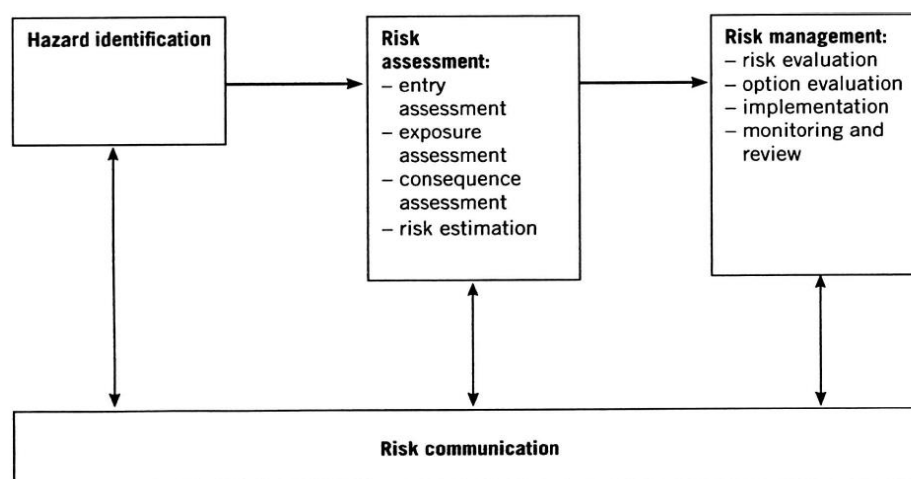
S. J. Voss *et al.*

Fig. 1. Structure of the O.I.E. risk analysis process (adapted from O.I.E. [12]).

Figure 3: OIE risk analysis process (taken from Voss, 2012)

Risk assessment is a valuable tool in deciding whether there is a need for policy. The definition of risk can be described formally as anything that is likely to cause injury, damage or loss. The goal of the assessment is to examine each of the environmental factors affecting animal and human health. This evaluation produces a consequence or estimates the likelihood of a disastrous event. The quality of the risk assessment is dependent on the nature of the disease.

In terms of a newly emerging disease, a risk assessment can have important limitations and challenges while trying to adequately assess risk. Consequently, it is these cases that strengthen the argument for further review and analysis of the associated risks as new information arises.

Risk Identification and Assessment of an EID

In terms of an emerging infectious disease, a risk can be anything that impacts or threatens the viability of animal, human, or environmental health. To properly assess these risks and potential threats, a risk assessment framework is required. Figure 4, is a generalized template of the Risk Identification and Assessment process used by APHIS-VS. This outline was extrapolated from a preliminary risk assessment of Schmallenberg virus by CEAH (21). While the framework is

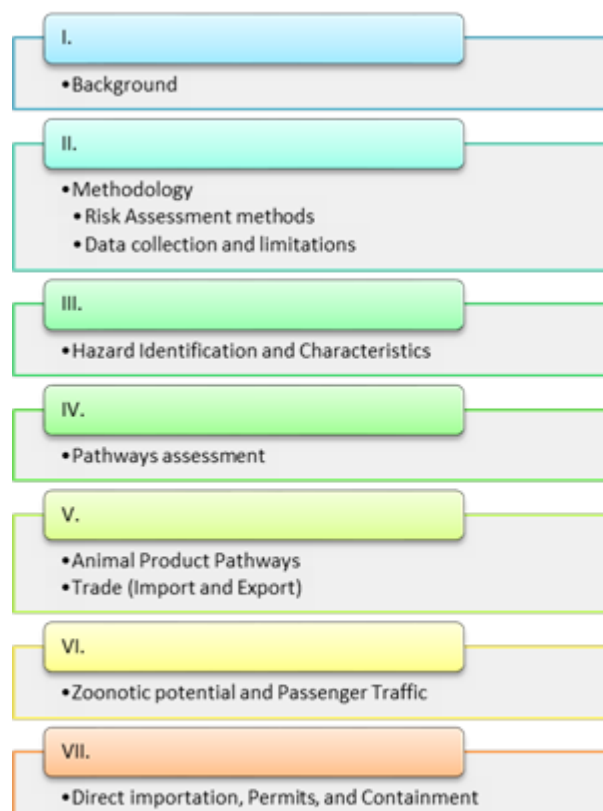


Figure 4: Generalized template of the Risk Identification and Assessment Process, APHIS-VS

likely to vary from disease to disease, VS strives to follow the OIE framework to the extent possible for all emerging diseases (18). Figure 3 briefly outlines the OIE risk analysis process.

The Schmallenberg virus is a perfect example of a case where at the time of assessment the amount of detail known about the emerging disease was limited. However, the assessment was qualitative and categorized likelihoods using a list of terms. These terms ranged from negligible to very high potential of an event occurring (21). Risk assessment is a systematic process that strives to address all critical areas that may impact animal, human, and environmental health. Several groups of individuals across disciplines and agencies are often used to effectively collect and analyze the information required to fully elaborate on these areas of interest.

Once the risk assessment process has been completed for a particular emerging issue, the assessment is made available to other health professionals, producers, and decision makers for public comment. If implemented appropriately, communication provides further insight into the issues and concerns that may require further consideration (27). However, the entire risk assessment process needs to be flexible and dynamic. The assessment is not fixed and should be subject to change at any time based on different sources of information. Different sources can include additional concerns brought forth by external sources or from the acquisition of new information; developing a need for analysis and review of the current assessment. The product of the risk assessment and analysis process is heavily weighted in the decision making process and can consume a great deal of time and energy. A comprehensive risk assessment is imperative in building the foundation of sound policy.

The Importance of Risk Communication

The USDA Highly Pathogenic Avian Influenza Secure Egg Supply (SES) plan is a great example of how sound policy can be created as a result of a successful risk analysis. In 2004, a private, public, and academic partnership was formed. This partnership was devised to address the U.S. Egg Industry's concerns related to the current AI preparedness and response policy. The U.S. Egg Industry practices a "just in time" approach, meaning that eggs laid by hens, are processed and shipped within eight to twelve hours of being laid. This rapid turnover does not require a lot of storage space, thus a delay in shipment associated with movement restrictions to control a disease outbreak would quickly overwhelm available storage capacity (27).

A proactive risk assessment, consisting of input from the Egg Sector working group (including egg processors and producers), two universities (Iowa State University and the University of

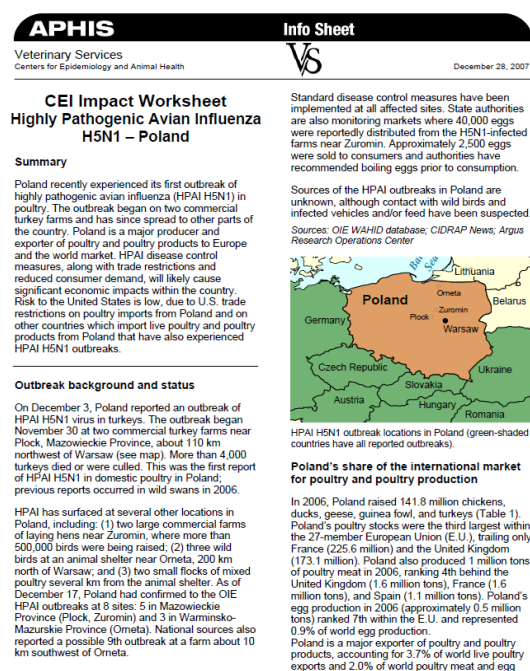


Figure 5: APHIS-VS Impact Worksheet for the H5N1 outbreak in Poland, December 2007 (taken from APHIS website)

Minnesota), and state and federal regulators, was created to address the concerns of the industry by assessing the actual risks associated with egg and egg product movement. The SES plan laid a solid foundation for risk management and helped strengthen the response by providing a more comprehensive preparedness plan. It also kept stakeholders actively involved throughout the entire process inciting a new level of trust which helps ensure a seamless response in the face of an AI outbreak. Additionally, it also kept stakeholders from becoming complacent (27).

The SES plan has set the stage, by illustrating the impact that good risk communication can have on the success of a response plan, while also demonstrating the value of good working relationships. The concept of a unified, team based approach is an idea that is becoming more widely accepted, and can vastly improve the way to which future disease response plans are developed and implemented.

Impact Assessments

An impact assessment is another assessment that is performed by the APHIS-VS community. The assessment is a preliminary assessment of an emerging disease that is drafted and released within 72 hours of its introduction (18). For example, an impact assessment was drafted and released in response to the 2007 outbreak of HPAI-H5N1 in Poland. This particular assessment is designed to raise awareness of the social and economic impacts of an outbreak, specifically as they relate to international trade. In this case, the risk to the U.S. was low due to import restrictions of poultry or poultry products from Poland, but to Europe and other countries the impact was significant. Poland exports a large percentage of its poultry and poultry products to Europe and much of the world market. The impact of trade restrictions and extensive disease control methods were estimated to cause significant economic losses for Poland. In addition, those countries that import poultry and poultry products from Poland were also at risk of introducing HPAI-H5N1 into their country (19).

The impact assessment defines a different component of disease risk, the risk to international trade, and the impact it can have on the economic and social structure of an affected country and the world market. The benefit of understanding the potential economic impacts early on in an outbreak helps raise awareness of an issue, and identifies the necessity of rapid, effective control measures.

Chapter 5: Policy Development

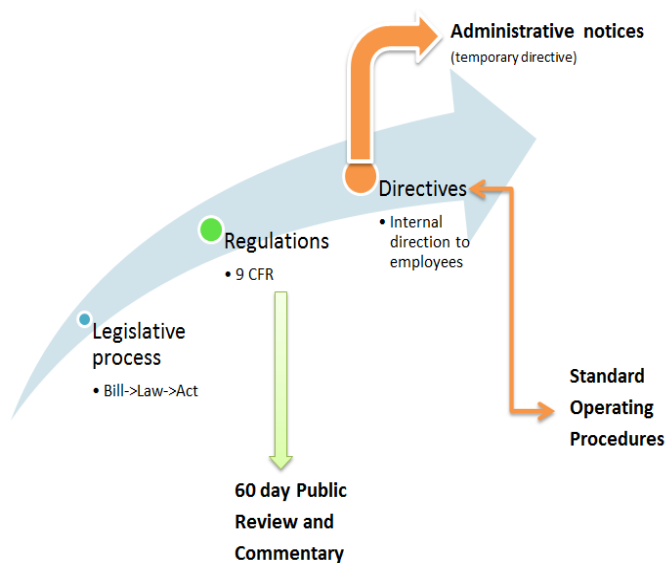


Figure 6: Diagrammatic Representation of Federal Policy Development

VS Authority

Before any action steps can occur, it must first be determined who has the authority to regulate and instigate a particular policy. The Federal government has given APHIS-VS both the statutory and regulatory authority to govern any action(s) related to the involvement of diseases or agents that impact animal health. However, the interpretation and application of this authority is less clear. Two acts have been created to grant authority to APHIS-VS. The Animal Health Protection Act (AHPA) assigns the responsibility of detection and response of animal diseases. The second act, Agro bioterrorism Protection Act – 9CFR121, designates authority in regards to biologic agents and toxins. The Homeland Security Presidential Directive-9 (HSPD-9) directs the USDA to work together with the other agencies to develop comprehensive, fully coordinated surveillance and monitoring systems (20).

Develop a clear goal and define a plan

The plan is dependent on the goal of the policy. Objectives can range from prevention to eradication and can be highly variable depending on the issue. In terms of MERS-CoV, the simple novelty and potential threat to U.S. animal and human health was enough to push for internal VS development of a standard operating procedure (SOP). This is being performed preemptively with the goal of future prevention and control of MERS-CoV in the U.S.

In other cases, the need for a plan arises after a disease outbreak is already established. PEDv is a good example of an ongoing outbreak that is currently ravaging the U.S. swine industry (16). The need for a plan related to PEDv came from many external pressures but predominately the stakeholders. The current goal for PEDv in swine herds is prevention and control of viral transmission. The option of eradication may be explored at

a later date, but not enough is known about the virus and its pathogenesis for policy makers to be able to propose any viable eradication options.

Eradication has proven effective in many areas. One of historical significance is the Accelerated Pseudorabies Eradication Program. The goal of Pseudorabies eradication was identified after the rise of severe economic loss to swine producers. The U.S. government then began to offer indemnity to producers in an effort to prompt immediate slaughter of all pigs in infected herds resulting in eradication of Pseudorabies.

These last three examples demonstrate how the policy goal was influenced by economic and social pressures. MERS-CoV is a unique example because it involved an internal decision by VS. This is certainly not an all-inclusive list and in fact many times the goal and direction that VS must go is determined by a higher official. An example of higher intervention is the National Strategy for Pandemic Influenza. In this situation President Bush outlined a strategy and assigned the lead roles to which then left it up to the government agencies to fill in the details.

How a bill becomes a law and its impact on policy development

In order to appreciate a specific policy, it's important to understand the process by which policies are made. While this is not an inclusive description, it is important to start with the initial framework. In many cases, the process begins with the introduction of a bill to Congress, and if received favorably by both houses and the president it becomes a law. These laws are the enabling authority for agencies to develop regulations. Regulations or rules provide the details about how the law will be implemented and organized under the Code of Federal Regulations (CFR). The CFR is formally defined as the compilation of general and permanent rules published in the Federal register by the executive departments and agencies of the Federal government. The CFR is further defined into fifty titles (3). Title 9 of the CFR, Animals and Animal Products, is the section of the Code that is pertinent to the authority and roles designated to APHIS-VS.

VS authority dictated by the AHPA allows VS to establish either a proposed rule or interim rule under the CFR. The only difference between the two rules is that an interim rule, once written, becomes effective immediately. One important similarity to note is both rules are subject to a sixty day comment period. It is within this sixty day comment period that the public is allowed to view and comment on the ruling. After this comment period, VS leadership reconvenes to discuss the public interpretation and comments, and then decides whether to finalize, change, or reject the rule completely. Another important component in this process is the contributions from APHIS-PPD or Policy and Program Development. This unit must also have a hand in the process to adequately analyze and assess the environmental and economic impact of the proposed policy or rule. It is in this way that we can assure that the proposed policy will benefit the economic status and not hinder environmental health (9).

If finalized, the proposed rule becomes a reality and the interim rule becomes permanent until it is replaced. At this point, VS authorities can establish a (agency) directive to internally assign direction to its employees regarding the new rule. The formal definition of a directive, as defined by APHIS, is “a permanent issuance that is in force until cancelled. Directives issue delegations of authority, basic policies, and operating instructions.” In short, a directive is a formal way for an agency to assign roles and instructions to ensure that a policy or ruling is achieved effectively. In addition to a directive, the agency may choose to establish an administrative notice which is a temporary, one-time issuance addressing a single subject or action. These are often used to address internal actions on short term programs, interim procedures, or make announcements. An administrative rule is only effective for one year and does not require a review period (9).

While, the above description outlines the standard policy making process, it is important to keep in mind that not all policy is made through the same process. Policies are often created on a situational basis, and sometimes in unconventional ways. For example, it was brought to the attention of APHIS-VS that the Food Safety and Inspection Service (FSIS) has in place a directive instructing that all FSIS plant personnel report any identifications of bovine cysticercosis to VS. It was then realized that there were several inconsistencies in the VS response to the notifications. The inconsistencies prompted a necessary intervention by VS leadership. A directive has been drafted as an informal guidance to define a minimum list of expected responses. The guidance is not meant to be an inclusive document, but a form of guidance to ensure a coordinated response is present in every case (5).

APHIS Veterinary Services		Factsheet July 2013
Foot-and-Mouth Disease Foot-and-mouth disease (FMD) is a severe, highly contagious viral disease. The FMD virus causes illness in cows, pigs, sheep, goats, deer, and other animals with divided hooves. It does not affect horses, dogs, or cats. FMD is not a public health or food safety threat. It is also not related to hand, foot and mouth disease, a common childhood illness caused by a different virus. FMD is a worldwide concern, as it can spread quickly and cause significant economic losses. While many countries across the globe are dealing with FMD in their livestock populations, the United States eradicated the disease here in 1929. In carrying out our safeguarding mission, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) works to ensure the continued health of our Nation's livestock. These efforts include preventing FMD from reentering the country. What is FMD? Animals with FMD typically have a fever and blisters on the tongue and lips, in and around the mouth, on the mammary glands, and around the hooves. These blisters, called vesicles, pop and turn into red areas called erosions. Pain and discomfort from the vesicles and erosions lead to other symptoms such as depression, anorexia, excessive salivation, lameness, and reluctance to move or stand. Most affected animals will not die from FMD, but the disease leaves them weakened and unable to produce meat and milk the way they did before. FMD causes production losses and hardships for farmers and ranchers. It also has serious impacts on livestock trade—a single detection of FMD will likely stop international trade completely for a period of time. Since the disease can spread widely and rapidly and has grave economic consequences, FMD is one of the animal diseases livestock owners dread most. What Causes FMD? FMD is caused by a virus. After an animal is infected with the virus, the first signs of illness usually appear within 2 to 14 days. The virus survives in living tissue and in the breath, saliva, urine, and other excretions of infected animals. It can also survive in contaminated materials and		
the environment for several months under the right conditions. Time, extreme temperatures, and pH changes will inactivate (i.e., kill) the virus. There are 7 known types and more than 60 subtypes of the FMD virus. Immunity to one type does not protect an animal against other types or subtypes. How Does FMD Spread? FMD can spread when infected animals bring the virus into physical contact with susceptible animals (i.e., divided hoof animals). An outbreak can also occur when susceptible animals: • Are held in contaminated facilities; • Are moved in contaminated vehicles; • Are fed raw or improperly cooked garbage containing infected meat or animal products; • Have contact with people wearing contaminated clothes or shoes or using contaminated equipment; • Are exposed to contaminated materials such as hay, feed, hides, or biologic products; • Drink contaminated water; or • Are inseminated by semen from an infected animal. Signs of Illness The best known signs of the disease include vesicles, which are similar to blisters, that quickly pop and cause erosions in the mouth or on the feet, resulting in excessive salivation or lameness. Because they pop quickly, these blisters are not always easy to see. These signs may appear in affected animals during an FMD outbreak: • Great increase in body temperature for 2 to 3 days • Vesicles that rupture and discharge clear or cloudy fluid, leaving raw, eroded areas surrounded by ragged fragments of loose tissue • Sticky, foamy, stringy saliva • Eating less because of painful tongue and mouth blisters • Lameness with reluctance to move • Abortions • Low milk production in dairy cows • Heart disease and death, especially in newborn animals		
It will take many months for animals to regain weight lost during illness. Animals that recover seldom produce the same amount of milk as before, and conception rates may be lower. Confusion With Other Diseases Diseases involving blisters show similar signs. As a result, FMD may be confused with other vesicular but less harmful diseases, including vesicular stomatitis, bluetongue, bovine viral diarrhea, foot rot in cattle, and swine vesicular disease. The only way to tell if the vesicles are caused by the FMD virus is through laboratory testing. If you observe mouth or foot blisters or other typical disease signs in your animals, please report them immediately so that the appropriate testing can occur. Where FMD Occurs While the disease is widespread around the world, North America, Central America, Australia, New Zealand, Chile, and many countries in Europe do not have FMD. Various types of FMD virus have been identified in Africa, South America, Asia, and some parts of Europe. Prevention and Control FMD is one of the most difficult animal diseases to control. Because the disease occurs in many parts of the world, there is always a chance of its introduction into the United States. Consequently, many animals and animal byproducts from areas known to be affected with FMD are subject to import restrictions or are prohibited entry into this country. Livestock animals, including those in the United States, are highly susceptible to FMD viruses. If an FMD outbreak occurs here, the disease could spread rapidly to all regions of the country through routine livestock movements—unless we detect it early and eradicate it immediately. The economic impact of unchecked FMD spread could reach billions of dollars in the first year. Vaccines for FMD are available, but must be matched to the specific type and subtype of virus causing the outbreak. In the event of an outbreak, animal health officials will carefully consider use of vaccination. If it becomes apparent at any point that a “stamping-out” strategy will not effectively eliminate the disease, we will immediately consider alternate strategies, including vaccination. It could then be used to help slow the spread of the FMD outbreak or to protect specific animals, depending on the situation.		
How You Can Help There are many ways you can support our efforts against FMD: • Watch for excessive salivation, lameness, and other signs of FMD in your herd. • Immediately report any unusual or suspicious signs of disease to your veterinarian, State or Federal animal disease control officials, or your county agricultural agent. • When traveling outside the United States, make sure that you do not bring back prohibited animal products or other at-risk materials. If FMD appears in your animals, your report will set in motion an aggressive State and Federal eradication program to protect our Nation's livestock herd. Your participation is vital. Both the early recognition of disease signs and the prompt notification of veterinary officials are essential to a successful eradication program. Your warning could prevent FMD from becoming established in the United States, or if it does spread, reduce the time and money needed to wipe it out. Additional Information For more information about FMD, contact: Veterinary Services APHIS, USDA 4700 River Road, Unit 41 Riverdale, MD 20737-1231 Phone: (301) 851-3595 Current information on animal diseases and disease outbreaks is also available on our Web site at www.aphis.usda.gov. USDA is an equal opportunity provider and employer.		

Figure 8: APHIS Technical Fact Sheet for FMD (taken from APHIS Website)

MOUs, SOPs, and Technical Fact Sheets – what do these mean and what is their role in animal health policy?

In addition to the VS directive, it may be necessary to establish additional documents to ensure that the overall goal is being achieved. One way that this can be done is through the development of a Memorandum of Understanding (MOU). A formal definition of a MOU is a document that describes broadly, concepts of mutual understanding, goals, and plans shared by parties (9). A recent example of a MOU is the collaborative effort between APHIS and FSIS on the matter of properly assessing the root cause of foodborne illness. Previously, these duties have primarily been of FSIS responsibility, but since one of the four emphases of VS is pre-harvest food safety it seemed imperative that these two agencies join forces (4). The goal that both agencies hope to achieve from this relationship is increased marketability and reduced foodborne illnesses. This continues to illustrate the value of the OH approach and the ability of the OHCC to further open the pipelines of communication between federal agencies.

A standard operating procedure (SOP) is a more thorough explanation of the goal and actions that should be performed. This document is derived as a supportive document that defines a protocol to fulfill the overarching goals. Depending on the situation, an SOP can be developed before or after a directive. In the case of MERS-CoV, a SOP is being developed before an official directive to define a sampling and surveillance protocol that can be utilized in the event that it becomes necessary. While there is no directive for MERS-CoV, if needed, VS leadership can initiate one later. To summarize, a directive is a permanent issuance of the roles and actions to be performed, and can refer to information provided in a SOP to further provide direction on an issue (9).

Additionally, technical fact sheets can also serve a supportive role in policy development and communication. The development of such educational materials helps outline knowledge or perception of a topic, and explains the current methodology for prevention and control. For example, figure 8 provides a visual example of a technical fact sheet used by the APHIS-VS community to educate and to help enforce the prevention and control of Foot-and-Mouth disease (FMD). The technical fact sheets serve a valuable role by keeping all stakeholders or interested parties adequately informed. This education builds the foundation for sound policy by ensuring implementation is relatively seamless during a FMD outbreak.

Regulation analysis

After a regulation on a specified area of interest has been established, the next step is to determine how to assess its effectiveness. There are two separate review processes that can occur. One is a station or administrative review, which is essential but less focused on the actual program. It helps assure that the management and operations at the office level are appropriate. The other type of review is the program review, which is a review of the program at the field level. Both reviews are performed annually but not in every state. Two of the more common reasons for review of a state's program, is a state previously identified with problems or a state that has not been reviewed in a couple years. It is during

these assessments that VS can determine if the goals are being met, and if the resources and funds are adequate (9).

As a result of the VS reorganization and change in the allotment of funds for the disease programs, the analysis of programs has now expanded to include not only the program diseases but also any emerging disease issue of OH concern. This is especially important as the emergence of new diseases continue to occur within the borders of the U.S. and abroad and further enhances the role of VS in their mission to effectively control and prevent diseases of OH concern.

Social Media and its potential impact on policy development

Society is more modernized and technologically savvy than ever before. As smartphones, iPads, apps, and other electronic devices enhance the way we interact with the world, information is being shared every second. How does social media influence the policy making process?

The lines of communication between the public and politicians have become easier, as many politicians have adopted twitter accounts and use Facebook to communicate with the general public. Early in his presidency, President Obama became the first U.S. president to initiate a Facebook page with the attempt to enhance community outreach and communication. Additionally, governmental organizations have begun using GovDelivery, a multichannel distribution system, which allows them to deliver emergency notifications, build online communities, and track customer requests (33). The questions remain as to how the government can use this information in a useful way and also how it can impact our decisions both positively and negatively.

The more obvious way that social media could impact policy development is at the public awareness stage. This stage is defined as the initial comment period where the public has the chance to voice their opinions about the proposed rule. Social media could increase the awareness on an issue and allow more individuals to provide input. A potential downside would be effectively organizing this information in a way that it is useful. For example, FSIS is currently attempting to use social media outlets to aid in data collection of foodborne illnesses. (29) The idea is promising, but may be challenging due to the logistics of data transformation into a form that can be used effectively by the agency.

Another way that social media could influence the formulation of policy is through increased awareness of the issues. Society is striving to be more informed and the overall need to be transparent across disciplines has become a requirement. Social media can help create this transparency and increase individual and public knowledge in a variety of areas. For example, through the implementation of a disease outbreak and investigation app and the 'Zombie apocalypse' preparedness and response plan, the Centers for Disease Control and Prevention (CDC) is attempting to increase social awareness and get people excited about public health preparedness (34).

Social media can also cause some challenges as increased public awareness of an ongoing issue, i.e. an emerging disease outbreak, could lead to added pressure from society

to initiate action. This would not always be a negative as it would still keep us informed of the concern and awareness of the issues, and it could make issues of social awareness a higher priority. Additionally, there is also the risk when information is distributed to large numbers of people that information will be misinterpreted or misconstrued.

The future of social media is promising and its value as a tool for policy makers and other professionals is evident. It has its downsides, but the potential benefits could outweigh the costs overtime as the use of social media is refined as a policy making tool.

Chapter 6: Regulatory Affairs

Reportable diseases – OIE vs. State

Whether a disease becomes reportable is dependent upon many factors, and the organization in charge of monitoring the disease is an important aspect. Historically, the OIE has developed a list of reportable diseases that it considers economically, politically, and socially important worldwide. This is fairly inclusive, but is subject to change as the OIE deems appropriate. For example, a conference call was hosted by APHIS-VS and included all fifty state veterinarians. During this meeting, one of the talking points consisted of an update from the OIE and its plan to remove Vesicular Stomatitis from the OIE list of reportable diseases (1). This change will become effective as of January 1, 2015 (31).

Figure 9, illustrates the 2014 listing of the diseases affecting multiple species that should be effectively reported by member countries (2). There are currently 180 member countries represented by the OIE, including the United States (32). OIE has also defined an additional list of diseases for each animal species that it deems significant to a particular class of animals.

The OIE, in addition to its list of reportable diseases, also maintains other regulations to protect its members. The OIE is currently the only organization worldwide to grant an official status of freedom from a specified animal disease.

The free status designation can describe a country as a whole or a particular zone. A couple of factors play into the designation of a member country for a specified disease status. The OIE must have a specified official recognition program for the disease and a request must be submitted from the delegate of the member country (14). For example, the United States is one of sixty four member countries recognized by the OIE as free of Foot-and-Mouth disease (35).

Not all OIE-listed diseases have an official recognition program for declaration of free status. An example of this is Avian Influenza. In cases, such as Avian Influenza, a country can self-declare freedom as defined by the criteria and standards of the OIE *Terrestrial*

Figure 9: 2014 OIE-listed multiple species diseases, infections, and infestations

Anthrax
Bluetongue
Brucellosis (B. abortus, melitensis, and suis)
Crimean Congo hemorrhagic fever
Epizootic hemorrhagic disease
Equine encephalitis, specifically Eastern
Foot and mouth disease
Heartwater
Infection with Aujeszky's disease virus
Echinococcus granulosus, multilocularis
Rabies
Rinderpest
Trichinella spp.
Japanese encephalitis
Cochliomyia hominivorax (New world screwworm)
Chrysomya bezziana (Old world screwworm)
Paratuberculosis
Coxiella burnetti
Rift valley fever
Trypanosoma evansi
Tularemia
Vesicular Stomatitis*To be removed starting Jan 1, 2015
West Nile Virus

Animal Health Code (14). This helps member countries uphold and maintain trade agreements, and protect the agricultural commodities within their country.

The OIE list is important because it helps define diseases of worldwide importance that require effective monitoring or surveillance programs. This creates more pressure for policy development to ensure that a country maintains its current disease free status and controls diseases of importance for international trade. For example, the United States is not free of *Salmonella pullorum*, but for international trade to occur proper documentation may be required (as agreed on by delegates of each country) to define measures that must be performed to satisfy a trade agreement.

The USAHA Committee on Foreign and Emerging Diseases also creates and updates a list of foreign animal diseases. The committee consists of a group of selected individuals that meet annually. Similar to the OIE, the USAHA Committee on Foreign and Emerging Diseases adds or removes diseases as they deem appropriate. The collective list is compiled into a book, which over the years, has been referred to as the, “the gray book.” “The gray book” includes the list of foreign animal diseases with clinical descriptions and pictures. Through its development and with the support of various professionals, the gray book has continued to serve as an educational resource for private, public, and corporate veterinarians, and even veterinary students (30).

In addition to the guidelines set forth by the U.S. government, each of the fifty states has the right to establish added regulations for disease reporting. This is any disease that has been deemed economically or politically significant to a particular state. The minimum national standards do not preclude the adoption of more stringent regulations, but regulations dealing with interstate movement must comply with the federal standards. For example, in the State of Nebraska there is a legal requirement to report all Trichomoniasis cases to the state veterinarian on a monthly basis. In addition, the producer, in compliance with the state law, must also notify all surrounding farms of their positive status. This regulation was instated to protect cattle herds through effective monitoring and containment of the disease (17).

The topic of regulatory medicine is similar to the other components of policy development. It is often complex and can take time to sort out all the details, especially at the international level. Regulations become increasingly complex as emerging or re-emerging diseases surface. Therefore, it is necessary to keep regulations flexible. This allows those responsible for drafting policies to adapt to fit the current economic, social, and political situation to effectively meet goals.

Stakeholders

The role of stakeholders in regulatory medicine and policy development is best described by dividing the stakeholders into two separate groups. The first group consists of stakeholders representing the interests at the state or local level (20). These members include local industry groups, producers, local and state veterinarians, public health veterinarians, and the state animal health officers. The individuals at this level are on the front lines during a disease outbreak or emerging issue. An issue generally arises from

reports of significant loss or illness in animal or human health. The focus is small scale with concern directed to the health of individual animals, herds, or humans within a state or community. The second group consists of the stakeholders representing the interests of the entire country (20). The national stakeholders include federal agencies and public organizations. The focus at this level is more broad and directed to the large scale effects of the emerging issue on animal, human, and environmental health.

A formal request for action on an area can arise from stakeholders at either level. For example, the current outbreak of PEDv in U.S. swine herds led to a request from local stakeholders for VS services. In comparison, the Pseudorabies program was initiated by national stakeholders to eradicate Pseudorabies and enhance the health status of U.S. swine herds. Both of these examples describe situations where the decision to initiate action directly benefited the animal health status. In contrast, a disease of OH concern may result in action being initiated by stakeholders for the benefit of human health. For example, the incidence of foodborne outbreaks associated with animal products, and the goal to reduce foodborne illnesses in humans.

Stakeholder interest plays a significant role in both influencing decisions and in the regulatory process. The goal of all stakeholders is the same, to maintain the health of animals, humans, and the environment. However, issues can arise due to communication failures and conflicts of interest. To alleviate these potential challenges, it is important that the lines of communication are open between stakeholders. The OHCC was created in partial fulfillment of this goal. The OHCC strives to further open and maintain these pipelines and enhance the relationship between stakeholders.

Chapter 7: Conclusion

Final Thoughts

The past six chapters have provided a generalized overview and understanding of the policy making process, especially as it relates to complex animal diseases. The main take home point from this review is that there is no one size fits all approach to policy. Policy making is complex and a dynamic process. It could be said that policies are like Influenza viruses, evolving and changing, as a result of a variety of different factors, pressures, and situations.

A wise veterinary epidemiologist at Kansas State University once said, “It is not the facts or data that are most important but rather the concepts. Facts, figures, and data will inevitably change with time but it’s our conceptual understanding that is forever.” This is true for many areas but especially the OH concept. With the onset of emerging diseases coming onto the scene every minute, it is clearly evident the necessity for a team based approach. The OH concept lives through the ability of professionals, scientists, and many others within a variety of disciplines to work together towards a unified goal. In the case of OH, the goal is advancement of health at the level of the animal, human, and environmental interface.

Issues of OH concern may not always require policy, but one thing that will remain true far into the future is the need for an OH approach. The future success of all disciplines depends on this integrated, team based approach. It is only once this concept is realized by everyone that the goal of safeguarding animal, human, and environmental health can be fully optimized.

Completing the puzzle

Over the course of the five years it took to complete my degree program, I can honestly say that I was able to obtain not only a deeper understanding but really ascertain a sincere appreciation for public and One Health. This realization would not have been achievable, however, without the ability to cap off my didactic studies. Prior to arriving at the APHIS headquarters in Riverdale, Maryland my head was full of knowledge, but while I knew I had been given all the pieces to a puzzle its complexity required some assistance to complete. This assistance as I soon discovered would come with time spent in the real-world.

Early on in my field experience, I was fairly naïve to believe that I would simply be working on one project, and what I soon discovered was somewhat life and career changing. I quickly learned that working in a government setting requires a level of flexibility. Issues emerge and re-emerge frequently and often spontaneously, and in the line of federal work what becomes a priority can change amid a variety of outlets. Therefore, further requiring that you always be prepared, and just expect that you are never going to be working on just one issue.

In example of this can be described by discussing my initial project while with the OHCC. The recent emergence of MERS-CoV quickly made it an area of interest for the

APHIS-VS, SPRS Unit. To better understand the disease and epidemiology behind it part of my duties was to expand what was known. This included understanding not only camelids themselves but the cultural differences between us, the Middle East, and East Africa. The end result of this particular project was achieved through extensive literature reviews, google searches, and lengthy discussions with subject matter experts. Though, the most important lesson taken away from this particular project was the realization that my core training in public health laid the foundation by which I could start to culminate my experiences. I'll admit while in the classroom such topics as the social and behavioral sciences were not nearly as exciting as learning about infectious disease processes, however, I began to appreciate them a lot more once I was faced with situations where this information became useful.

In retrospect, it is kind of interesting to look back and see just where my field experience took me. It went far beyond the brim of just digging up background information. In addition to providing assistance on various technical documents (fact sheets, Sit-Reps, etc.) my field experience mentor saw a unique opportunity to utilize my skills even more. He had discovered early on that I carried an apparent ability to take in a lot of information and somehow sort through it in a way that made comprehensible sense on paper. With this in mind, he came to me with the idea of developing an APHIS training document that discussed the complex yet important topic of animal health policy. Thus, how the topic of this paper was born.

This challenge soon sky-rocketed my field experience in terms of what I could have possibly expected to take away. In achieving this goal, I quickly found myself diving into public policy, and to do so required going outside of the SPRS unit of APHIS-VS. I not only met individuals within each of the government agencies but also found myself spending some time on Capitol Hill. It was also during this time that I began to really integrate all that knowledge that had once just been seen as a mix of concepts, theories, and facts.

To summarize, a field or capstone experience is generally set at the end of a student's studies to help them not only synthesize but begin to integrate the knowledge they have acquired throughout their course of study. Up until the point of my field experience, I had been charged with a substantial amount of information that like most students, I didn't really know what to do with. The time I spent with the OHCC showed me the true value of the concepts that had collectively been laid before me over the past five years. It did exactly what a culminating experience should do by bringing all the pieces together, allowing me to begin to integrate, and utilize this knowledge. Finally, my puzzle was complete, but no good puzzle is without a missing piece. This piece is not anything that can be filled by a practicum, but rather represents the space required to grow and learn long into the future.

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Appendix I

Engagement Consideration and Response Alternatives Tool

Circle the appropriate parameter in each row (e.g. species involved, or zoonotic transmissibility) to determine the level of engagement for the situation. More than 3 selections in a column should guide decisions to the corresponding level of engagement for the situation.

Example: MERS-CoV receives five selections from the Baseline Engagement column supporting a low level of engagement.

	Full Engagement	Moderate Engagement	Baseline Engagement	No Involvement
Species Involved	Cattle, sheep, swine, poultry	Horses, Farmed Cervids, Farmed aquaculture	Wild cervids, feral swine, wild fish, wild horses, domestic pets, zoo animals, insects	Animals not involved
Animal Prevalence	Agent not thought to exist in susceptible population	Agent exist at low to moderate levels in population	Agent is endemic or highly prevalent in species	Agent is not found nor infectious in animal species
Animal Transmissibility	Agent highly transmissible within and between species	Moderate transmissibility within species	Animal transmission unlikely, limited or uncertain	No known animal transmission
Animal Consequences	High mortality/morbidity in species of concern	Serious illness and moderate economic loss in species of concern	Little, unknown or uncertain illness in species of concern	Animal infection unlikely
Host Species	Primary host is "farm" species	Secondary host is farm species	Host range is unknown or uncertain OR VS-covered species are unlikely hosts	Exclusive human pathogen
Zoonotic Transmissibility	Zoonotic transmission likely or common	Known zoonotic transmission of moderately transmissible agent	Zoonotic transmission unlikely, limited or uncertain	No known zoonotic transmission
Human Consequences	Agent is potentially fatal to humans	Agent causes serious illness in humans	Human illness asymptomatic or mild	Human infection unlikely
Stakeholder Interest/Concern	High pressure, interest, request expectation	Moderate level of pressure, interest, request for engagement	Little pressure, interest, request for engagement	No pressure, interest, request for engagement
Possible Actions	Surveillance Vaccination Diagnostic Testing Movement Restriction Eradication	Gather Information (surveillance, epi investigation/study) Support	In Kind Support or Advisory Subject Matter Expert	No Activities

Appendix II

Response Alternatives

If the Response Alternatives Tool suggests Moderate to Full Engagement, District Field Offices are encouraged to contact the OHCC or the Chief Epidemiologist to assist in further evaluation and routing of information to the appropriate units and leaders within VS.

Example: MERS-CoV reveals a requirement for Baseline Engagement or an advisory role by VS.

Full Engagement	Moderate Engagement	Baseline Engagement
VS as Lead Agency	VS in Supporting Role	VS in Advisory Role
VS action necessary to safeguard animal and/or human health	Event involving livestock	Event involving animals
Possible Actions: • Lead other agencies • Lead animal health aspect if multi-agency • Provide guidelines • Commit resources for disease control (e.g., surveillance, vaccination, movement restrictions) • Commit resources for surveillance design and implementation – e.g., sample collection, testing, and reporting • Possible setting and enforcing rules, regulations • Regulate testing • Facilitate vaccine approval and importation Deploy VSAT	Possible Actions: • Gather information – Situation report – Epi investigation/study – Collect information in NAHMS study – Deploy epidemiologic investigation team – Risk assessment – Cost/benefit option analyses – Surveillance analysis of existing information • Lead other agencies by setting direction – VS has information, skills, supplies, services to provide • Help implement recommendations made by VS or other stakeholders	Possible Actions: • Provide in-kind support: time, knowledge, skills, information • Monitor situation • Use expertise to make recommendations • Provide education related to VS and animal health • Conduct discussions with stakeholders – Surveillance analysis of existing information – Risk Assessment – NAHMS study – Sampling or small scale surveillance – Cost/benefit option analyses
– Varied cost—minimal to substantial – Varied resources—minimal to substantial	– Another agency is lead – Minimal resource requirements	– Limited to no resources required