

# Triggers for foot and mouth disease vaccination in the United States

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## Summary

In the United States, the national policy for foot and mouth disease (FMD) vaccination lacks clarity. To better understand what potential Incident Commanders see as important 'triggers' or factors to consider for implementing vaccination as a control strategy, the authors presented seven such individuals with an FMD outbreak scenario that started in north-western Illinois and spread across state lines by the end of the fifth week. The scenario had four infected premises at the end of week one, 13 at the end of week two, and 60 (including both infected and previously depopulated premises) by the end of week five. Two individuals favoured vaccination the first week of the outbreak scenario, one did not want to vaccinate during the scenario, and the remainder wanted vaccination at some time during the scenario. Respondents ranked nine specific factors to take into consideration when deciding whether or not to vaccinate. Of these, the capability to manage the outbreak by stamping out ranked first. Many of the issues raised in this report are applicable to other countries that are currently FMD-free without vaccination.

## Keywords

Animal disease – Control – Foot and mouth disease – United States – Vaccination – Veterinary Services.

## Introduction

Foot and mouth disease (FMD) may be the most economically devastating foreign animal disease (FAD) of modern times (9). During the United Kingdom (UK) outbreak of FMD in 2001 an estimated six to ten million animals had to be destroyed before the disease was eradicated (2). Total direct costs to industry and government were estimated to be over £8 billion (11). The options for controlling future outbreaks of FMD in previously FMD-free countries include emergency vaccination, movement restrictions on infected animals and animal products, biosecurity measures, and culling of infected animals. Ultimately, countries wishing to regain FMD-free status will be required to show the absence of virus circulation and animal infection (13). Vaccination-to-cull (all vaccinated animals are culled after the outbreak has ceased) is not considered as economical or as ethical as

a vaccinate-to-slaughter (vaccinated animals enter the food chain) or vaccinate-to-live policy (13). In the 2001 UK outbreak, no vaccination was used. Since this outbreak, vaccination-to-live, using high-potency emergency vaccines (minimum potency of 6 mean protective doses [PD<sub>50</sub>]) in and around infected farms, has become a more likely response strategy (13). Vaccination strategies in the United States have been examined using spatial stochastic simulation modelling (6). Results showed that the number of infected herds was significantly smaller and the median duration of epidemic outbreaks was significantly shorter when vaccination was used.

For certain outbreaks, FMD eradication without vaccination may produce problems separate from the impact on international trade. Not vaccinating rapidly and effectively in large outbreaks makes it more likely that a traditional stamping-out approach will cause more animals

to be destroyed because of disease or animal welfare considerations. This is a significant waste of animal protein and leads to serious environmental issues related to the disposal of large numbers of carcasses (buried carcasses have the potential to contaminate ground water). Vaccination was not used during the UK FMD outbreak in 2001 and millions of animals were slaughtered over the course of the outbreak: 1.3 million from infected premises, 1.2 million from dangerous contact or contiguous premises, and 1.5 million from dangerous contact but non-contiguous premises. A further 125,000 animals were slaughtered because of a suspicion of FMD, and the largest number, 2.3 million, were slaughtered for welfare reasons (11). An additional unknown number of newborn and unborn lambs and calves were slaughtered, but were not accounted for in the official total of six million.

There are no assurances, even after the required post-vaccination period has passed and serological screening has been completed, that foreign trading partners would accept exports from the United States, regardless of World Organisation for Animal Health (OIE) standards and recommendations. At least 44 countries banned poultry exports from the United States when a highly pathogenic avian influenza (HPAI) outbreak involved only the index farm and two live bird markets in Texas in 2004 (16) until after August 2005' even though the outbreak was very short (initial diagnosis on 16 February 2004, and the three infected premises identified were depopulated within six days of the first confirmed case; the subsequent four-week intensive surveillance programme found all samples collected to be negative). Given the small size and short duration of the Texas HPAI outbreak, during which no vaccination was used, and trading partner response, it seems highly likely that world response to an outbreak of FMD in the United States would result in an extensive period when the country would be excluded from markets in countries requiring 'FMD-free status without vaccination', whether or not vaccination was used in the outbreak response.

This article describes some of the factors and considerations that a select group of individuals (potential Incident Commanders during an FMD outbreak response in the United States) regarded as important for implementing vaccination during an FMD outbreak. The individuals were queried using a structured approach to probe their attitudes about using FMD vaccination and to identify the factors that would prompt them to recommend vaccination for a specific FMD outbreak scenario.

## Materials and methods

Seven individuals were chosen based on input from the Director of the National Veterinary Stockpile, Dr Glen Garris, and the Director of the Preparedness and

Incident Coordination, Dr Jon Zack (both from the Veterinary Services of the Animal and Plant Health Inspection Service of the United States Department of Agriculture [USDA]). The seven individuals, hereafter referred to as respondents, were contacted to confirm their willingness to participate. A time and date were set to talk with them over the phone. The developed scenario was shared with the respondents by email within 48 hours of the phone call.

A plausible outbreak scenario (Table I and Fig. 1) was developed with the purpose of evoking a variety of responses and ensuring that respondents were unlikely to make the same recommendations regarding the timing of vaccination. A transcript (available upon request) was developed to ensure that respondents were handled in a standardised fashion. Two other individuals beta-tested the transcript and were handled in the same fashion as respondents; small changes were subsequently made to the questions and the scenario prior to contacting the respondents. None of the beta-test data is presented here.

**Table I**  
**Animals affected, by week of the outbreak**

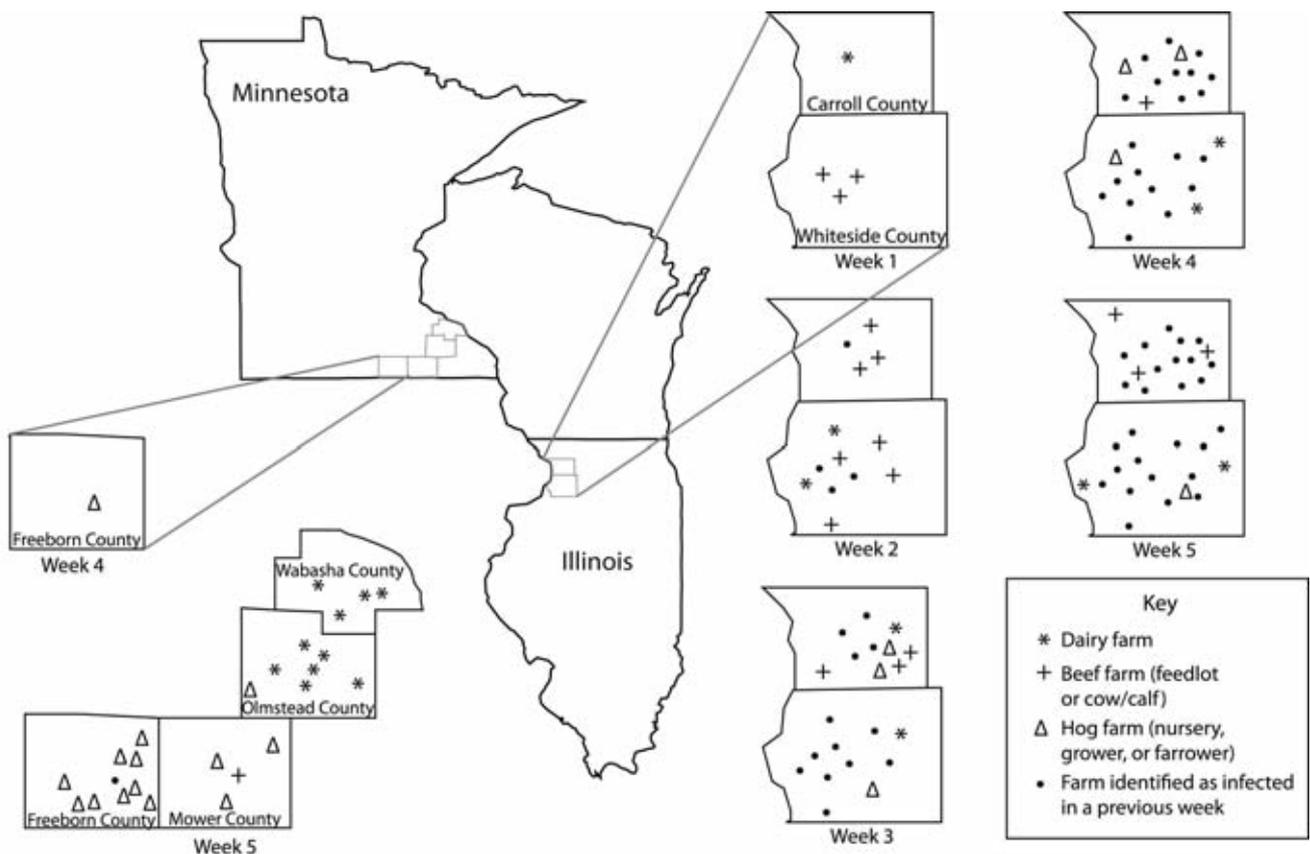
Week	Description of scenario
1	Index case: 350 steer feedlot in Whiteside County (north-western Illinois). 465 animals in total on four infected premises
2	There are 4,315 animals in total on nine newly infected premises
3	There are 4,540 animals in total on nine newly infected premises
4	There are 6,873 animals in total on eight newly infected premises
5	There are 18,185 animals in total on 30 newly infected premises

Respondents were contacted over a two-week period in January 2010. Conversations were recorded and a written transcript sent to each respondent. Respondents concurred with the transcription or edited it to reflect their ideas. The results were summarised using basic descriptive statistics. For the question where respondents ranked potential factors to consider in the decision of whether or not to vaccinate, the results were ranked using the Baldwin ranking method (4).

## Results

### General attitudes about foot and mouth disease preparedness and response

Three questions were asked to elicit attitudes about USDA preparedness for an FMD outbreak, what activities USDA should undertake to improve preparedness and what the most limiting factors would be, currently, to an FMD response by the USDA. A prevailing attitude was that the USDA would be limited by financial and human resources in the case of an outbreak, but that financial



**Fig. 1**  
**Geographic representation of outbreak scenario**

resources could probably be procured if necessary (although there was some doubt that there would be political or public will to support a response). There were several ways in which respondents felt the USDA could enhance preparedness. They included: improving carcass disposal and euthanasia, improving the industry's ability to maintain operations during an outbreak, establishing formal agreements with processors/slaughter facilities so that they would accept animals during an outbreak, improving reporting of suspected FADs and reducing the associated stigma of reporting, providing more training in vesicular diseases, facilitating better communication between state and federal Veterinary Service personnel, and developing better systems of animal identification and record-keeping.

**General attitudes about foot and mouth disease vaccination**

Participants received information about the outbreak on a week-to-week basis and evaluated its development at the end of each week. Respondents fell into three general categories: those who supported vaccination at the end of week one ( $n = 2$ ), those who did not recommend vaccination at the end of week one but supported vaccination as the scenario progressed ( $n = 4$ ), and those

who did not recommend vaccination at the end of week one or at any point during the five-week scenario ( $n = 1$ ) (Table II). Reasons for supporting vaccination or not supporting vaccination at the end of the first week varied. The two individuals who were either somewhat or very likely to vaccinate after the first week of the scenario acknowledged that stamping out would be the first line of defence and the best way to manage an outbreak if possible. However, by the end of week one, the situation had progressed to the point where they were likely or very likely to vaccinate. They also said that the logistics and planning required to implement a vaccination programme would be extensive and should be started at least by the end of the first week. The four participants who changed from unlikely to likely to vaccinate during the course of the scenario did so at the end of weeks two, three, and five of the outbreak for varying reasons (Table II). The final individual was ambivalent about vaccination. He opposed using it during the scenario but felt it might be used in some cases.

**Foot and mouth disease vaccination trigger ranking**

Respondents ranked nine factors in order of importance as factors to consider in the decision to vaccinate. Five of the

**Table II**  
**Summary of approval or disapproval of vaccination by week of scenario and reasons for opinion**

	<b>Whether respondents were in favour of vaccination at the end of Week 1 and their reasons for being so</b>	<b>Week in which previously opposed respondents became in favour of vaccination and their reasons for doing so</b>
<b>Yes</b>	Rate of spread and infected premises in adjacent county	Not applicable
<b>Yes</b>	Logistics of vaccination need to be planned as soon as possible Averse to a 'slash and burn' technique. Dense livestock region	Not applicable
<b>No</b>	Outbreak appears to be geographically limited at this point It has not spread to hogs yet so there is no aerosolised plume	<b>Week 2</b> The number of animals and premises involved
<b>No</b>	Stamping out should be attempted first in these circumstances	<b>Week 2</b> The disease is still spreading, and quarantine and stamping out appear not to be as effective as they need to be to control the disease
<b>No</b>	Stamping out would be better for the industry at this point	<b>Week 3</b> It has now spread to swine. There was an epidemiological link with a semen tank, so it could be more widely dispersed than known due to semen being shipped from infected premises
<b>No</b>	Limited number of animals and premises affected at this point	<b>Week 5</b> Geographically more widespread. Rate of spread increased
<b>No</b>	Vaccination will complicate the eradication strategy since infected animals will unknowingly be vaccinated. Vaccination lengthens time to regain export markets. Incident Commander will not have time to consider vaccination due to other time constraints during an outbreak	The remaining individual remained opposed to vaccination in this scenario

seven respondents ranked the capability to manage the outbreak with a stamping-out approach as the most important factor when considering vaccination (Box 1). Of the two respondents who did not rank this the highest, one clarified that his interpretation of stamping out was that it was a 'scorched earth' policy or 'euthanising herds and disposing of carcasses with no efforts to salvage anything'.

The effect on national security or the economic impact of the disease was ranked sixth as a trigger for vaccinating. No respondent placed it higher than fourth and one respondent ranked it last. In general, respondents did not explain the reasons for their rankings. However, one did mention that national security is important and that the economic impact from FMD will be large regardless of the response method chosen, so it would not be a major factor in the decision to vaccinate during an outbreak.

#### **Box 1**

##### **Factors to consider in the decision of whether or not to vaccinate**

1. Capability to manage the outbreak with a stamping-out approach
2. Rate of spread of outbreak
3. Size of outbreak
4. Density of animal population in outbreak area
5. Number/type of industries affected
6. National security and/or economic impact
7. Duration of outbreak
8. Type of index case
9. Infection in wildlife

## Discussion

Currently, the OIE recognises six countries with an FMD-free zone where vaccination is practised, ten countries with an FMD-free zone where vaccination is not practised, one country that is FMD-free where vaccination is practised, and 65 countries that are FMD-free where vaccination is not practised (21). Foot and mouth disease emergency vaccination programmes may be implemented with the intent either to kill and subsequently dispose of the vaccinates, to slaughter the vaccinates through normal processing channels, or to allow vaccinates to live for the duration of their normal productive lifespan. Vaccination programmes may target all or a subset of susceptible species in proximity to an outbreak. The rapidity of spread or the limited availability of vaccine may mean that not all animals in the vicinity of the outbreak can be vaccinated and a decision will have to be taken on which animals must be the priority. The desired geographical extent of the vaccination programme may depend upon many factors, including specific aspects of the outbreak (such as serotype and strain of FMD involved, rate of spread, the density and value of susceptible animals in or near affected areas), as well as the disposition of vaccinates and acceptance of animal products from vaccinated animals. All use of FMD vaccine requires USDA approval. Also important in the decision to vaccinate are the short- and long-term impacts of FMD on domestic and foreign trade.

It was notable that none of the respondents mentioned concerns about FMD carrier status and only one respondent mentioned the need to differentiate infected

from vaccinated (DIVA) animals following the implementation of a vaccinate-to-live strategy. Perhaps one reason that these considerations were not noted is that, until recently, FMD vaccination has not been discussed broadly as an outbreak response in the United States. A carrier state in animals can occur whether or not an animal is vaccinated and carriers are defined as those animals in which virus or viral RNA can be detected for more than 28 days, including animals which may or may not shed the virus (19). Cattle, sheep, goats and water buffalo all have the potential to develop a carrier state (1, 5, 18). Some of the research suggests that the prevalence of carriers varies with FMD virus serotype and strain, and the length of time an animal may remain a carrier and the potential that carriers will result in disease transmission is debated (1, 18). To make the potential role of carriers even more complex, there is evidence that vaccination influences the development of the carrier state. Some studies indicate that it does not affect or increase the number of carriers (8) and others suggest that it decreases the number (12, 14). An explanation for these noted discrepancies could be the strain of the virus, varying routes of infection, severity and timing of challenge, antigen payload of vaccine and different vaccination protocols; it is also difficult to extrapolate results from laboratory experiments to field situations. The carrier rate in cattle is known to decline over time (20). Tenzin (20) reported that the only successful FMD transmission from a carrier animal in the published literature has been from water buffalo to other species.

An additional important consideration if vaccinating to live is having DIVA capability. If vaccines used are adequately purified of the non-structural proteins (NSPs) then tests which identify NSPs can be used to identify infected animals post vaccination because the vaccinated animals will be negative to NSP tests. There is debate about whether these tests should be used solely on a herd basis or whether they should be used selectively to address individual animals (7, 10). Arguments have been made (given estimates of carriers in vaccinated populations and optimised testing systems) that carrier detection can be increased by adopting an individual animal testing regime in which all animals in all vaccinated herds are tested and positive animals rather than herds are culled (3, 15). Evidence from the 2001 outbreak in Uruguay demonstrated that carriers did not play a role in the timely recovery of freedom from FMD with vaccination (17).

Some respondents felt that the FMD preparedness level in the United States is lower today than it has been historically in terms of personnel and training. A common reason cited was declining state and federal veterinary infrastructure and fewer personnel with technical expertise. The threat from two global influenza pandemics (H1N5 and H1N1), and the significant media attention that they attracted, may have also contributed to the

decline of resources devoted to prevention of other FADs, including FMD. With those issues becoming less pressing and a global increase in FMD activity, the USDA National Center for Animal Health and Emergency Management has worked on updating many of the FADPREP (Foreign Animal Disease Preparedness and Response Plan) documents for FMD, initiating the development of a national FMD vaccination policy, enhancing the North American FMD vaccine bank and its logistical plans, and supporting and participating in pre-event government/industry business continuity planning. Planning and policy development for FMD vaccination in the United States is ongoing. Formal agreements allowing sharing of state resources and personnel are in place. For instance, all states are now members of the Emergency Management Assistance Compact (EMAC) and EMAC has been successfully activated and used for a number of responses ([www.emacweb.org/](http://www.emacweb.org/)).

The small number of respondents is a limiting factor in this study and makes it difficult to draw broad conclusions. However, the realistic pool of potential Incident Commanders during an FMD outbreak in the United States is fairly small, perhaps in the range of 25 to 30 people. The sponsors of the project recommended these respondents as particularly experienced individuals who would have the capacity to act as Incident Commanders in the event of an outbreak. It seems apparent from this study that there is a lack of clarity in the decision-making process and criteria for implementing an FMD vaccination campaign. State and federal animal health officials need to consider these issues further. There is a need for better definition of roles and responsibilities, empowerment of individuals involved at the local, state or regional level, and enhanced development and pre-planning for FMD vaccination strategies. This lack of clarity about FMD vaccination decisions will delay the decision to vaccinate, which will have significant impacts, because to have maximum effectiveness vaccination must be implemented quickly (6). Hence, there is a need for well-developed and exercised decision-making criteria for the development and execution of an FMD vaccination strategy. Enhanced planning, preparedness, and the development of stakeholder consensus as to the decision process and the potential strategies to be considered for various scenarios will be key in ensuring that any FMD outbreak response using vaccination will be executed in an optimal manner.

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## Éléments déterminant la décision de recourir à la vaccination pour lutter contre la fièvre aphteuse aux États-Unis

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### Résumé

Aux États-Unis, la politique nationale de vaccination contre la fièvre aphteuse manque de clarté. Afin de mieux comprendre quels sont les éléments déclenchants importants que les responsables des Services vétérinaires chargés de gérer les incidents sanitaires prennent en compte pour décider de recourir à la vaccination, les auteurs ont présenté à sept de ces responsables un scénario d'apparition de foyer de fièvre aphteuse survenant dans le nord-ouest de l'Illinois et se propageant au-delà des frontières de l'État dès la fin de la cinquième semaine. Dans ce scénario, le nombre d'exploitations atteintes était de 4 exploitations à la fin de la première semaine, 13 exploitations à la fin de la deuxième semaine et 60 exploitations (comprenant les établissements infectés et les établissements précédemment dépeuplés) à la fin de la cinquième semaine. Deux des responsables interrogés étaient favorables à pratiquer la vaccination dès la première semaine du scénario ; un autre responsable n'a envisagé de vacciner à aucun moment du scénario, tandis que les autres responsables ont choisi de vacciner à un moment ou à un autre du scénario. Dans leur réponse, les responsables ont classé par ordre d'importance les neuf éléments susceptibles de déterminer leur décision de vacciner. Parmi ces éléments, le plus important était la capacité ou non de maîtriser le foyer au moyen de l'abattage sanitaire. Nombre des questions soulevées dans ce rapport peuvent s'appliquer à d'autres pays actuellement indemnes de fièvre aphteuse sans vaccination.

### Mots-clés

États-Unis – Fièvre aphteuse – Maladie animale – Services vétérinaires – Stratégie de lutte – Vaccination.



## Factores que desencadenan la vacunación contra la fiebre aftosa en los Estados Unidos

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### Resumen

En los Estados Unidos, la política nacional de vacunaciones contra la fiebre aftosa es ambigua. A fin de aprehender con más precisión lo que los responsables de gestión de incidentes de los Servicios Veterinarios considerarían los principales factores determinantes para poner en marcha las vacunaciones como estrategia de lucha, los autores sometieron a siete de esas personas una hipotética situación de brote epidémico que empezaba en el noroeste de Illinois y se iba extendiendo hasta cruzar las fronteras del estado a finales de la quinta semana. En la hipótesis formulada había 4 explotaciones infectadas al final de la primera semana, 13 al final de la segunda y 60 al final de la quinta (contabilizando tanto las granjas infectadas como las sometidas previamente a sacrificio sanitario). Dos personas se inclinaron por empezar a vacunar desde la primera semana del brote, una juzgó preferible no hacerlo en

ningún momento y las restantes optaron por empezar en algún otro punto a lo largo del proceso. Esas personas definieron nueve factores específicos que inducirían la decisión de empezar a vacunar, de entre los cuales otorgaron preeminencia a la capacidad para contener el brote sólo con medidas de sacrificio sanitario. Muchas de las cuestiones examinadas en el estudio pueden aplicarse a otros países actualmente exentos de fiebre aftosa sin vacunación.

#### Palabras clave

Control – Enfermedad animal – Estados Unidos – Fiebre aftosa – Servicios Veterinarios – Vacunación.



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