Policy and science of FMD control: the stakeholders’ contribution to decision making. A call for Integrated Animal Disease Management

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Abstract
Effective control of foot-and-mouth disease (FMD) - prevention, surveillance and response - requires integrated animal disease management as a cooperative effort between stakeholders, scientists and decision makers, at all levels: local, national, regional and international. This paper suggests a process and outlines specific critical issues that need to be addressed in order to best use the science and technology that is available now and to develop new technologies that will lead to significant improvements. The overall objective is not to allow the disease or the disease control measures to damage, violate or destroy public health, the environment, or the economy, or to allow politics to drive disease control policies at the expense of the ethical relationship between man and animals. Critical issues of prevention, surveillance and response policies are examined, and specific recommendations are made to reduce the risk or effect of natural and deliberate introductions. For prevention: a) rapid portable diagnostics and provision of vaccines to control and eradicate the reservoirs of disease and b) alerts, leading to increased controls at borders, animal movement restrictions and biosecurity on farms. For surveillance: a) reporting of unusual symptoms, rapid diagnostics and identification of patterns, b) enhanced role of GIS linked to an IT system, and c) collection, storage and sharing of disease information. For response policies: a) the role and implementation of stamping out and of vaccination, and b) simulation exercises with stakeholder participation. For all aspects of FMD control, consideration should be given to: a) the composition, responsibilities and role of the balanced, permanently operational Expert Group in EU member states as specified in the EU FMD Directive, b) establishment of a balanced, permanently operational European Expert Group, and c) establishment of both a European and an International FMD Task Force. Stakeholders need access to accurate, up-to-date, unbiased information about the science of disease control, how the technologies work and can be used, and an assurance that the technologies best fit for the required purpose will be used. Researchers need to work together to avoid duplications and gaps in their research and to recognize the benefit of new, and sometimes innovative, technologies. They also need feedback from stakeholders on the acceptability and best use of the technologies. A process to achieve these goals through an EU funded collaborative research project will be described.

Introduction
Stakeholders are defined as all those who have a direct or indirect interest in FMD due to the impact of the disease on their or their animals’ lives. This involves a cross-section of the population, ranging from those with extensive knowledge of livestock to those who have little or no knowledge or education concerning the complexity of the issues. The recommendations in this paper are based on information gathered from open meetings, private consultations and extensive internet communications, with a wide and geographically dispersed range of stakeholders, scientists and policy makers that began in February 2001 when FMD was identified in the UK. The views of stakeholders must be taken seriously because their cooperation is essential in the implementation of an effective and ethical scientific disease control process and because they represent large and diverse political pressure groups. They are increasingly vocal, often with little consensus amongst the varying interests they represent, and need to be persuaded that the control measures are appropriate, proportionate and necessary. If they say that certain measures are unacceptable, the policy makers must take their concerns into account. In order for control policies to be undertaken in a cooperative manner, it is imperative that stakeholders have access to the most objective and accurate information about the underlying science and that the implications are clearly explained and open to effective consultations and debate. Consultation exercises must be easy to access, genuine and transparent.

The role of scientists is central in the process to determine:
- How we can use the science and technology that is available now in rapid, effective, proportionate and acceptable control.
- How we can develop new technologies and new approaches using these technologies to improve control.

The overall objective is not to allow the disease or the disease control measures to:
- Damage, violate or destroy public health, the environment, or the economy, or
• Allow politics or trade issues to drive disease control policies at the expense of the ethical relationship between man and animals.

The desired objectives should be subject to examination and agreement well before an outbreak: “Control strategies might seek to minimize various quantities, such as total animal loss, duration of the epidemic (which is currently the main objective in England and Wales [DEFRA, 2004]), regional spread, financial loss (to several economic sectors), or animal suffering.” (Haydon, Kao and Kitching, 2004). Furthermore, control measures and associated regulations must be planned and implemented with sensitivity to local and regional traditions and practices (Crispin, Roger, O’Hare et al., 2001).

No apologies are made for concentrating on FMD in the UK in 2001, since this epidemic was the largest emergency exercise for FMD in a developed country. Lessons must be learned so that there is no repetition of the errors that were made (Royal Society, 2002). In particular, there is a consensus amongst stakeholders that:
• We will not carry out the mass slaughter of healthy animals.
• We will not incur the financial and social costs to the livestock industry, tourism and the rural economy, or cause unnecessary loss of genetic diversity.

This might also reduce the risk of a deliberate introduction. F.P. Horn and R.G. Breeze (2004): “Deliberate attack is not about dead cows, swine or sheep; it is about economic harm …. and terrorizing the public…. The public will not accept mass slaughter … nor is such slaughter necessary any longer. Our starting point must be that we will not get into a situation in which slaughter of millions of animals is necessary: this is what terrorists want to see.”

Discussion
How should we control foot and mouth disease? There are key questions and recommendations related to the three main areas of control: prevention, surveillance and response that need to be addressed.

Prevention
It is the responsibility of national governments to take all reasonable steps to prevent entry of disease, including:
• Rapid portable diagnostics, especially to identify countries and regions posing a risk.
• Vaccines to control/eradicate reservoirs of disease
• Increased continual import surveillance and controls
• Development of an alert system at borders and to inform livestock keepers
• Animal movement restrictions based on sound science
• Biosecurity, particularly at farm level, based on sound science

Proposal: The establishment of an International Task Force for surveillance and for vaccination (on request), with funding for the purchase of vaccine, especially in developing countries. Since the reagents for real-time RT PCR assays have a shelf life of only about 12 months, the creation of diagnostic test kit banks should be considered. International good-will and cooperation is needed to identify, control and eradicate reservoirs of disease.

Proposal: Nationally and regionally, we need inter-agency cooperation to reduce risk of entry of disease at borders, and a higher level of international cooperation to reduce illegal meat imports. The measures must be appropriate to the source of risk, whether from innocent tourists, criminal meat trade, or deliberate introduction. In the case of tourism and trade, when entry is from a country or region with FMD, then passengers and cargo must be subject to increased inspection. Using modern technology, such risks can be identified before the plane or cargo ship has landed.

To further reduce the risk from tourists innocently introducing disease by importing meat products, all persons entering the EU should sign a declaration that they have no meat products in their possession. Further measures are often taken, but is there scientific evidence to support their effectiveness? It is often recommended that a sufficient number of sniffer dogs should circulate at all ports of entry, including all terminals. This should be regarded as a means of preventing illegal entry of meat and meat products, but it is not an effective means of detecting pathogens.

In some countries, arriving passengers must declare whether they have been in contact with farm animals in the previous week. If the answer is affirmative, sometimes they are required to sign a declaration that they will not be in contact with farm animals for at least three days, and they are often separated for customs officials to inspect, clean and disinfect shoes. Is this separation from livestock
necessary? Is FMD virus really transmitted on the soles of shoes? It should be a simple experiment to take washings from muddy shoes that have been on FMD infected premises at varying intervals, and then test for the presence of the virus. Bartley, Donnelly and Anderson (2002) have reviewed FMD virus survival in animal excretions and on fomites.

General measures recommended to reduce the risk of introduction from all causes:
- Up-to-date detection technology, including air sampling, should be operating in cargo holds and at baggage inspection, and possibly on aircraft traveling from FMD infected countries and regions. Depending on the level required, this might involve technology to detect aromatics which identify putrescence that would indicate the presence of meat products and/or technology to detection pathogens, including FMDV.
- Amnesty bins should be provided at all ports of entry for disposal of animal products.
- Penalties must be sufficiently severe to act as a deterrent.

**Surveillance**

It is the responsibility of national governments to participate in an international surveillance system that can identify patterns of disease in time and space and anticipate hazards and threats. The purpose of surveillance, and a measure of its success, is its ability to provide answers to these five questions:

1. **Where is FMD in the world?** We need a comprehensive international surveillance system that will catalog historical events, and identify endemic and new outbreaks, with mapping and virus typing information. To achieve this goal, attention needs to be given to how disease information is obtained and how it is handled:
   - What information needs to be gathered, and how detailed should it be?
   - Is the information up to the minute, as recent as possible?
   - Who reports disease? CVOs, military, private diagnostic labs, private companies (e.g. those involved in agribusiness)?
   - Who keeps the information? Regional or international centres? Most acceptable is a neutral, international organization (OIE/FAO).
   - Who has access to the information and how is the information distributed? How are issues of confidentiality, trade, and prevention of panic, addressed? Should there be varying levels of distribution and varying levels of detail of information?
   - What information do stakeholders, scientists and policy makers, need to know? As an example, R.G. Breeze (personal communication, 2004) suggests: "we need to know the complete genetic sequence of every FMD virus (including vaccine viruses) circulating in the world today and to keep these data current (we also need to go back historically in the archives to sequence past viruses). ... We should link the sequences to geography in an attempt to map distribution of fingerprinted viruses..."

2. **Is it coming here?** The international surveillance system must have the capability to identify emerging patterns in time and space, and act as a warning system to inform decisions at regional, national and local levels that can be taken to prevent entry and spread of disease. Regional and global commercial flows, as well as travel patterns, must be taken into account, and used to consider preparation of appropriate vaccines, as well as if and when to raise the levels of surveillance at borders. Possible responses need to be agreed, for example if an incoming aircraft has been identified as contaminated with FMDV or other pathogens, should it be held in quarantine for inspection?

There is an urgent need for active liaison between the national and international veterinary agencies with their counterparts in the police, Interpol, and trade to actively monitor and share information on the illegal trades in meat and bush-meat, which present major diseases risks.

3. **Is it here now?** The rapid identification of disease requires both the cooperation of the livestock sector and the effective use of a continuous real time active national surveillance programme, including the use of appropriate permanent, targeted (e.g. milk collection, livestock markets) and portable rapid diagnostic devices.

A formal, active FMD surveillance methodology is described by Bates, Thurmond, Hietala et al. (2003), including:
- New technology for use in cost-effective mass screening and environmental testing;
- Embedding FMD surveillance in existing mass-screening systems for endemic diseases;
- Strategic targeting of high-risk animals and locations; and
• Strategic use of specimens submitted for routine diagnostic testing. It is essential that the data is not skewed or artificially unbalanced in its collection, especially if the data will be used to determine current and future control measures.

4. If it is here now, where will it be next? Geographic information systems coupled with knowledge of meteorological conditions, of individual animal identification, and of animal movement or nomadic patterns can be used in conjunction with satellite tracking systems to enable models of disease to be more accurately predicted in real time. These should remain under veterinary control to ensure that control systems are realistic and to avoid some of the misconceptions that may arise from modellers unfamiliar with animal disease patterns (Taylor, 2003; Honhold, Taylor, Wingfield et al., 2004; Kitching 2004).

M.E. Hugh-Jones (personal communication, 2004) explains: “GIS have a definite place in modelling and prediction and accurate situation reports, but their most important function is to accurately plot where cases have occurred, where field diagnostic kits have confirmed cases, and where suspect cases have been found not to be affected. When GPS chips are incorporated into handheld data loggers, these sites can be recorded automatically without the risk of error. Too many farms in 2001 were identified by map reference numbers and slaughter initiated, or attempted, in spite of owner claims that the stock were not affected; in each case the slaughter team had the right map reference but the wrong map, or vice versa. Nobody needs such lethal and expensive mistakes.”

F.P. Horn and R.G. Breeze (2004): “Once the presence of FMD is confirmed, as part of an Internet-based Command and Control system, continuous real-time surveillance must be employed to define the extent of the problem around the initial detection and to predict and track the progress of infection through the national agricultural commerce streams.”

5. If it was here, has it gone? What is role of serology? Is it really necessary to slaughter sero-positive animals, if no significant carrier state can be shown to exist? This is a good example of further information being necessary in order for a sound scientific policy to be implemented.

**Response**

**Stamping out.** It is generally accepted by stakeholders that effective control requires the slaughter of infected animals, although in some countries and regions, FMD infected animals are not slaughtered, but are kept isolated until recovered. Acceptability of the policy of stamping out would be much greater if it is accompanied by credible and scientifically sound measures to ensure that only those animals that are infected are slaughtered and that every reasonable attempt is made to prevent the spread of disease and thus minimize the number of animals slaughtered. To this end, what is required is rapid identification of disease, rapid restriction of animal movements, rapid slaughter of animals that are infected, and, if these measures are considered insufficient to control the disease, then a rapidly implemented programme of vaccination.

**Rapid identification of disease.** Rapid identification of the introduction of a foreign animal disease relies on a combined strategy: a continuous monitoring programme using state of the art detection and tracking technology, as described above, and the cooperation of livestock keepers to look for and report suspicious symptoms.

**The front line – livestock keepers and veterinary practitioners.** Arguably, the most important factor rests with livestock keepers’ ability to recognize suspicious symptoms and, once recognized, their willingness to report the suspicious symptoms. This requires a high degree of trust that the authorities will respond in a fair and proportionate manner. Following the experience of the UK FMD 2001 outbreak, it has become apparent that trust has broken down, and in some cases this lack of trust has extended from the livestock keepers to their veterinarians. Countries where this breakdown has not occurred should take care to maintain this essential trust, and countries, like the UK, where the trust has been lost, need to take the initiative to win back this trust (Crispin, Roger, O’Hare et al., 2002).

Fundamental to maintaining or winning trust is:

- An effective distribution of information
- An effective consultation process that is easy to access, genuine and transparent and confidence that:
- Local large animal veterinary expertise is available and that there is government support to enhance/maintain a strong veterinary service
• Animals will be inspected and tested rapidly and at minimal expense
• Identification of disease will not result in financial loss to the livestock keeper
• Neighbouring holdings will not be subject to unnecessary restrictions
• Livestock keepers will be kept informed of the local disease situation
• The government will respect and, not marginalize, agriculture in general, and all sectors involved in agriculture – from agribusiness to part-time farmers and the keepers of companion animals, and the large numbers of varied and important sectors in between. This is vital, since disease can appear in any animal, regardless of how it is kept.
• Consideration will be given to the characteristics of livestock management systems and of the species, which may have differing susceptibility and transmission risks (Kitching 2002; Wernery and Kaaden, 2004).
• Sound science and the best technologies will be used in all aspects of FMD control
• Regulations are necessary, proportionate, and appropriately targeted
• Stakeholder concerns will be taken into consideration by the regulatory authorities
• Systems will be put in place in “peacetime”, ready to deal effectively with an emergency.

Proposal: Stakeholders should be brought into the process of determining disease control policy. Where national governments fail to take a lead, the agriculture sector should be allowed to work jointly with government in control measures. Whether under the control of government or the livestock sector, national programmes should be established to train livestock keepers to identify disease, maintain effective biosecurity and to vaccinate. The livestock sector should consider working together to establish a system of veterinary insurance, where models from other countries should be considered.

Use of on-farm and near-farm rapid diagnostic tests. A variety of diagnostic tools can play a role in FMD control, depending on the purpose for which they will be used:

Those that are ready and available for use now, should be included in current contingency plans. What is meant by ready for use? At the October 2004 meeting of the USAHA/AAVLD Epidemiology Committee meeting on diagnostic validation, a USDA representative stated that validation only indicates that the testing procedures have complied with specific guidelines, and that validation does not refer to the quality or fitness for purpose of the test. The Smartcycler real-time RT PCR assays are considered a valuable tool and have already been distributed throughout the US National Animal Health Laboratory Network. Depending on the situation, especially to rule out false positives, confirming tests can be used.

Those that are in development, should be designed for specific purposes. For example, penside dipstick tests can be useful in decisions related to the lifting of isolation and movement restrictions, while portable PCR devices can be linked through wireless internet for real time remote expert management in a crisis, avoiding the difficulties that can arise from the need to transport samples rapidly to a laboratory.

Vaccination. There are a number of key issues that need to be addressed before an outbreak occurs. These include some logistical and fiscal difficulties, including the number of serotypes to consider, location of depots, time to prepare vaccine stocks, time to implement vaccine use, distribution of vaccine, etc.

R.G. Breeze (personal communication, 2004) suggests best vaccine match based on genetic sequencing, but stresses that speed of response is crucial: conventional vaccine selection may allow administration of vaccine to start at about day 8 of an outbreak, but we need to be able to respond more rapidly and to implement vaccine use if or as required by day 4 or 5 of an outbreak. However, Kitching (2002) points out that depending on the method of introduction of infection and of the species at risk, the speed of response need not always involve slaughter and/or vaccination. Kitching and Hughes (2002) observe that recovering sheep pose little threat to other animals.

Stakeholders should contribute to decisions on issues such as:
• Who provides the advice and who makes the decision to vaccinate?
• Who decides on the vaccination strategy?
• If there is disagreement, should a European Expert Group be established as the final and rapid arbiter? Such a group might also be of assistance to member states on request.
• If sufficient vaccine is not available to protect all animals, which animals will be vaccinated? Pre-registration, in a simple format, should be considered.
• What is the goal of vaccination? In a country normally free from FMD, long term immunization is not necessary. What is needed is a fast-acting vaccine that will pass through the system in about
three months. In an FMD endemic country, on the other hand, a single vaccine that can be given at birth and remain effective for a long period would be preferred.

- The livestock industry needs assurance that meat and milk products from vaccinates will be acceptable and (possibly) that live animals, subject to testing, can be exported. Consideration should be given to a new approach to export regulations based on more extensive testing; this would have the added advantage of providing more detailed international information on the geographic and temporal distribution of strains.
- Consideration should be given to the creation of an EU Task Force (working closely with EU vaccine banks) to rapidly lead a vaccination programme within the EU and, if requested, overseas.
- What is the risk from carrier animals? Can “healthy carriers” be identified by PCR tests? If carriers are not considered a significant risk, is it necessary to slaughter antibody positive animals?
- How to ensure that national governments apply regulations sensibly and do not over-regulate? (For example, in the UK, it has not been made clear that post vaccination, meat for UK consumption would not require treatment, only meat for export).

**FMD Control Measures**

*Expert Group.* FMD prevention and control is complicated, and needs a truly balanced expert group, with in-built checks and balances, to ensure that no one consideration or interest predominates (including political interests and unnecessary restrictions used as a trade barrier). Cooperation is essential, between scientists, between agencies, and at all levels, national and international. The role of the Expert Group should be clearly defined. The role of other groups that may be appointed, e.g. as the UK has done, to “challenge” the Expert Group, should be examined so that there are no conflicts which may cause serious delays in a time of emergency.

*Composition of Expert Group.* The expertise required to fulfill the responsibilities specified in Article 78.1-3 of the EU FMD Directive (D. Paton, personal communication, 2003) involves expertise in:

- FMD diagnosis
- Vaccination as a control measure
- Vaccine production
- Logistics of disease control, including military and emergency management engineers
- International developments of relevant new technologies, in diagnostics, surveillance, electronic ID, vaccines and anti-virals, and robotics (for lab tests)
- The workings of the state veterinary service
- Animal husbandry practices, including commercial and non-commercial, breeds at risk, minor breeds, companion animals and wildlife, with sensitivity to local and traditional practices
- Epidemiology of veterinary infectious diseases
- Epidemiological modelling and cost-benefit prediction
- Risk assessment and risk management
- Legal matters relating to disease control
- Environmental controls relating to carcass disposal
- General rural affairs, including tourism

This demonstrates the wide influence that control measures for diseases such as FMD have on the economy of any country and emphasizes the importance of the establishment of this Expert Group as an independent body.

Consideration should be given to the provision of a system to create sub-groups or panels on an ad hoc basis to deal with issues that may require more in-depth consideration. An example of such a sub-group of independent scientific input might be to provide a transparent process for the selection of diagnostic assays, perhaps making more transparent the increasing role played by patent agreements. This could be an effective mechanism to broaden the input from the normally small (one person?) composition of the Expert Group on a particular issue, and might provide a better approach than the establishment of an outside group to “challenge” the Expert Group.

Proposal: The establishment of a balanced, permanently operational European Expert Group, with both the new EU FMD reference lab and EUFMD/FAO as important members, and to act as the final arbiter if there is a complaint about a national Expert Group or the control policy of a member state, and to be available to all member states for advice on request.

*Emergency simulation exercises* must include a broad range of stakeholders, including the livestock sector, military and emergency management engineers, in order to increase the levels of preparedness.
for a future outbreak. A standard platform for communication between all agencies should be in place. Control policies cut across agencies, whatever their name, that deal with: agriculture, food, rural development, tourism, environment (e.g. water supply), security, trade and international relations.

**Dissemination of information that is accurate, up-to-date, objective and comprehensive.** A major initiative in furthering this objective will be the forthcoming EU-funded FMD and CSF Coordination Action, which is scheduled to begin January 2005. Coordinated by IAH-Pirbright, the project’s objective is to avoid duplication and gaps in research, and partners include the key players: the EU reference labs, DG-Sanco, OIE, and EUFMD/FAO. The author of this paper will be the principal officer of the project’s Central Network Resource, responsible for dissemination of information amongst the partners and with stakeholders in a two-way exchange. The goal will not be to achieve a consensus, but to allow for flexible decision making based on informed discussions and effective research without stifling innovation. A long-term objective is to establish a European Animal Health Association as a forum for exchange of information leading to collaborative resolutions, amongst scientists, policy makers and stakeholders.

**Conclusions**
Integrated animal disease management enhances disease control policy by the involvement of all stakeholders in the decision making process, allowing co-ownership of policy and encouraging collaborative and acceptable strategies and applications of technologies. It requires critical issues to be addressed and the implementation of realistic, practical and often innovative scientific advances in diagnostics, epidemiology, prevention and control, as part of the continuing preparation to deal with future outbreaks of FMD. The outlines for stakeholder involvement and a command structure within the EU are suggested. The dissemination and discussion of accurate, up-to-date, objective and comprehensive scientific knowledge is described and a consultation process suggested. Review of transboundary disease continues to be an area of increasing importance, within the EU and globally, as altering disease patterns are monitored. Continued vigilance and rapid resolution are a necessary part of integrated animal disease management. A two-way flow of information should be encouraged between those who develop the control technologies and those who use them. Users need to understand what technologies are available now, what technologies are in development, and how they can be effectively used to help in disease control. Researchers need to have feedback on how their technologies will be used on the ground and what would be most useful for future development. Processes are suggested below to ensure that decisions are based on the best and most appropriate advice.

**Recommendations**
- Implementation of effective national FMD Expert Groups according to the specifications of the EU FMD Directive, and enhanced to include the creation of ad hoc sub-groups or panels as required.
- Creation of a European FMD Expert Group that is available to all member states for advice on request.
- Creation of a European and International FMD Task Force for assistance with surveillance and vaccination on request, involving both diagnostic test kit banks and vaccine banks.
- Discussions leading to the creation of a European Animal Health Association involving stakeholders, scientists and regulators, with power to propose and vote on resolutions.

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**References**


