A FMD Vaccine Bank Network: A Developing Concept

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ABSTRACT

A network of FMD Vaccine Banks has been initiated with the support of vaccine bank executors (worldwide) that participated in a workshop held at Pirbright in April 2006. Terms of Reference (TOR) for coordinated activities is under consultation. A key benefit from this network would be the formation of a virtual 'global' vaccine bank that could orchestrate additional emergency cover with vaccine or antigen from member's reserves. To realise these benefits, solutions must be found to problems of disparate standards, conflicts of interest and confidentiality issues over virus strain selection. Participation of commercial companies in this network is crucial and essential.


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INTRODUCTION

The purpose of this poster is to describe the concept of creating a FMD Vaccine Bank Network and to encourage collaborations between FMD Vaccine Bank Managers, Owners, Technical Representatives, Manufacturers and Authorised Parties.

Foot-and-mouth disease (FMD) vaccine banks are reserves of stored concentrated FMD antigen that have been established by individual countries and groups of countries for vaccination of livestock in an emergency. Each vaccine bank faces similar issues over strain selection, manufacture, storage, formulation and regulation of vaccines, which are now dealt with independently. Practical and economic benefit could be realised through collaboration between vaccine banks.

The OIE convened an *ad hoc* meeting on FMD antigen and vaccine banks in June 2004, recognizing that a virtual (International) vaccine/antigen bank network would have two main benefits:
(i) facilitating information exchange on the ability of banked vaccine strains to protect against current circulating FMD virus; and (ii) providing access for members to reduce the burden of stockpiling of all antigens by the network.

This *ad hoc* group met again in April 2005 to discuss development and operation of a potential vaccine bank Network (ToR4) noting synergies to an EU funded FMD and CSF Coordination Action (C.A.) project initiated in January the previous year. Issues relating to a network and its potential to contribute significantly to the improved control of FMD worldwide were discussed . The concept of a Network of FMD Banks was initiated following a meeting in April 2006 (Bashiruddin 2006a).

"..vaccine banks hold more than antigens.."

CONCEPT AND BENEFITS

The decision on managing what and how much to hold in a vaccine bank, is currently considered in isolation taking into account the global status of FMD. Financial implications inevitably play a role. The minimum dose holdings of vaccine strains in an emergency bank has recently been considered for Europe (Dekker and Barnett, 2007).

A coordinated approach to antigen/vaccine bank activities around the world through a Network could be a better approach facilitating the harmonisation of standards for vaccine bank antigens, ensuring better control of FMD in the event of an outbreak, and reducing some of the costs arising from the maintenance of such reserves.

Such a Network could aim to:

1. Increase co-operative effort, mutual support and back-up for vaccine bank Network members in order to improve international control of FMD by vaccination.
2. Consider common vaccine bank issues such as vaccine dose requirements, virus strain selection, manufacture, formulation, testing and regulatory control, storage, security, maintenance, monitoring and disposal, to:
   a. share information and best practices;
   b. avoid duplication of effort and realise economies;
   c. harmonise approaches and define standards where appropriate;
   d. promote rationalisation and sharing of bank reagents;
   e. investigate possibilities for the sharing of banked antigens, working towards a virtual international bank for FMD vaccines;
3. Identify routes for independent testing and assessment of FMD antigens/vaccines.
4. Improve the availability of emergency vaccines and access to a wider range of vaccine types and quantities.
5. Monitor progress and technical developments relating to emergency FMD vaccines.
6. Identify and promote areas of research that could lead to improvements in emergency FMD vaccine banks.
7. Increase the efficiency of vaccine banks and the proficiency of vaccine bank staff.
8. Offer expertise to member countries and to international disease control agencies such as OIE and FAO to assist in the control of FMD by vaccination.
9. Identify and propose solutions to any constraints in the functioning of the Network.


Canada 1952


UK 2001


UK 1967


UK 2001


Canada 1952


UK 2001


UK 2001

NETWORK PRINCIPLES

The Network will act through its members financially independent and supported by their own resources. A secretariat will be provided by one of the members determined at the time of the annual meeting. The secretariat will organise the annual meeting and disseminate minutes or reports, to establish and maintain the web-based network tool and to facilitate the implementation of the agreed plan of work. The network will:

1. Meet annually to appoint a secretariat, review progress, identify priorities and agree plans for the network.
2. Produce an annual network report.
3. Operate initially for 3-5 years, with a review of the value of continued interaction thereafter.
4. Agree a Terms of Reference to identify strategic objectives and facilitate exchange of materials/ information.
5. Develop processes based on best practice to achieve equivalence in FMD vaccine bank standards in compliance to OIE recommendations and guidelines of the EU Committee on Veterinary Medicinal Products.
6. Address by risk analyses, the appropriate types and the optimal amounts of antigens/vaccines in reserves.
7. Promote the development of *in vitro* tests that provide improved correlation with protection against challenge and ultimately reduce reliance on animal testing.
8. Consider practical uses of emergency antigens/vaccines no longer required in banks or that have or are about to have exceeded their holding period.
9. Identify research requirements and where appropriate develop joint research projects.
10. Develop guidelines for successful implementation of emergency vaccination.
11. Develop a web-based tool for the network to share and make available laboratory information such as vaccine strain matching results, as close to real time as possible.
12. Maintain a database of FMD vaccine bank managers and their field of expertise.

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FMD and CSF Coordination Action

PROGRESS TOWARDS A NETWORK

The Workshop that was held at Pirbright in April 2006 established contact between personnel involved in different banks and provided the first forum for discussion of a range of technical problems. The challenges of disparate standards, conflicts of interest between manufacturers and bank managers, and confidentiality requirements over virus strain selection were recognised, leading to a decision to develop a Memorandum of Understanding (MOU) to guide member interactions. In follow-up teleconference unanimous support was given to the creation of an international FMD vaccine Bank Network (Bashiruddin 2006b). A secure web based data entry and repository for this Network was seen as a priority following ratification of the Terms of Reference that has replaced the MOU.

In order to develop a Network there are considerable benefits in starting with a relatively small group of individuals with closely shared aspirations and the current Network membership is centred around countries that meet the standards of vaccine production and testing laid down in the European Pharmacopoeia. It is however, recognised that the current membership of the Network is not comprehensive and that there will be room for expansion into the future.

"…shared knowledge is power.."

THE WAY FORWARD

To move forward, it is important that coordinated activity on global antigen/vaccine banks retains momentum and support in order to develop standards for vaccine bank antigens, ensure better control of FMD in the event of an outbreak and reduce the cost of individual membership. The rather complex administration of many individual banks does not lend itself to rapid decision making and clearly, it will be some time before this concept will be ratified and have all the necessary signatories.

Additional financial support would be welcomed, possibly from a new EU collaborative project, to continue the progress that has already been achieved and to develop this goal further. This will provide an endorsement of the Network, the infrastructure and process to hold routine meetings, support its web based reporting system to allow the exchange of information or reagents and incorporate participation of commercial companies which will undoubtedly be a valuable step toward efficient control of FMD outbreaks.

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Canadian Food Inspection Agency

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Questions

See: Dorothy Geale  or David Paton