OPTIONS FOR DECENTRALIZED TESTING OF SUSPECTED SECONDARY OUTBREAKS OF FMD

Executive summary

This paper reviews the options for decentralised use of virus detection techniques on samples from suspected secondary outbreaks of Foot-and-Mouth Disease (FMD). These options have been expanded by the advent of new tests including disposable lateral flow devices (LFD) for the detection of viral proteins and reusable after disinfection portable RT-PCR equipment for the detection of viral RNA. LFDs have been developed to achieve a similar sensitivity as the antigen detection ELISA, but with the ability to provide a result within less than 30 minutes following the addition of epithelium or vesicular fluid. Portable RT-PCR devices are being developed that can detect FMD viral RNA in blood, epithelium or other materials with minimal sample processing and with high sensitivity within 150 minutes. These devices may be used on infected farms as pen-side tests, in regional, local or mobile laboratories, or in National Reference Laboratories (NRL). Advantages and disadvantages of different testing options are considered to facilitate informed decisions on the optimal strategies for different national circumstances. Issues include validation and quality control, containment needs, availability of test devices and reagents, the decision tree for declaring an outbreak, training issues, and provision of samples for subsequent viral characterisation. Tests to confirm the diagnosis of the index case of an outbreak of FMD should continue to be carried out in the NRL.

Recommendations

1. National veterinary authorities should review their contingency plans and operational manuals and consider if the currently available decentralised tests offer advantages for decision making in the case of secondary outbreaks;
2. An EU or EuFMD diagnostic reagents bank should be established for emergency supply of lateral flow devices (LFD);
3. Further research and product development efforts are encouraged towards type specific tests;
4. Guidelines on test usage should be developed by the Research Group in close collaboration with the Community Reference Laboratory for FMD, after performance testing of the devices for the diagnosis of the infection with the FMD virus (FMDV) in convalescent and persistently infected animals;
5. Training in the use of the tests as part of outbreak investigation should be included in the field based training programmes organised by the EuFMD Commission.

Introduction

When Foot-and-Mouth Disease (FMD) occurs in a country previously recognised as free from the disease, huge emphasis is placed on the accuracy of diagnosis of the first case of the disease in any outbreak and this diagnosis should always be confirmed by a national reference laboratory (NRL) or an internationally recognised reference laboratory for FMD. Once the primary outbreak...
has been confirmed, secondary outbreaks should be rapidly identified in order to support the measures implemented to prevent further spread of the disease. However, confirming suspect cases at an NRL may delay implementation of control measures irrespective of all efforts made to minimise the time required for transport of specimens to the NRL. Alternatively, test systems could be deployed outside of the NRL (i.e. decentralised testing), moving the confirmatory diagnostic process closer to the location of affected animals in any future outbreak. This paper attempts to summarise options that are currently available to detect FMDV in samples from secondary outbreaks of FMD and to address some of the issues that arise if these tests are performed outside of specialised high containment laboratory facilities.

A confusing multiplicity of terminologies has been used to describe the concept of testing for FMD outside of a NRL; the terms “rapid testing”, “penside testing”, “on-farm testing”, “on-site testing”, “field testing”, “devolved testing” and “decentralised testing” have all been used synonymously. Assuming that NRLs are the centres designated for testing within their respective national territories, the term “decentralised testing” will be used throughout this paper to refer to all testing outside these laboratories, including that performed in regional laboratories.

Used with the necessary care, decentralised testing could assist in setting priorities for pre-emptive culling or emergency vaccination and could support the decision to withdraw a restriction on a holding.

**Potential benefits of decentralised testing**

The drive for decentralised testing followed recognition that the delay in testing samples from suspected outbreaks of FMD caused by lengthy transport times to the NRL could potentially have a considerably negative impact on disease control. The main benefit of decentralised testing, whether on farm or in a regional or local laboratory, is to shorten the time from sampling to test result. This would enable a quicker implementation of the chosen control strategies. The relative speed of decentralised testing systems mean they could also be used to give an early indication of the likely outcome when investigating primary cases, although final confirmation would require full testing in an NRL.

A further potential advantage of a decentralised testing strategy is the surge capacity it offers during a major epidemic. In such a case, the NRL may be operating close to its capacity, with the potential for delays in sample testing. Decentralised testing may relieve some of this pressure by facilitating rapid testing of large numbers of diagnostic samples either on-farm or at various regional laboratories, although this would depend on the test system used and the overall control strategy decided by the veterinary authorities.

In order to justify decentralised testing, the significance of the time saved and, if relevant, the capacity for increased testing must outweigh the benefits of maintaining testing in the NRL. Centralised testing has the advantage of an established system, usually with quality assurance standards, and involves personnel who have expertise and experience in their field. A range of tests are usually available at an NRL, which may be employed as appropriate. The decision to use decentralised testing, therefore, should be taken with due regard to the characteristics of the outbreaks and the chosen control strategy, giving appropriate consideration to the overall situation.

**Detection of FMD virus – basic principles of currently available test methods**

The principal laboratory tests for the presence of FMDV are antigen detection ELISA (Ag-ELISA; (Have et al, 1984, Roeder and LeBlanc Smith, 1987, Ferris and Dawson, 1988), virus isolation (VI) and the reverse transcription-polymerase chain reaction test (RT-PCR; Reid et al, 2002; OIE Diagnostic Manual). Each has advantages and disadvantages. Ag-ELISA can only detect virus in samples with a high virus content such as vesicular lesion materials or cell culture supernatant fluids after prior VI. The method takes approximately 4 hours and can identify the serotype of FMDV. VI and RT-PCR methods are the most sensitive techniques and can be used to detect FMDV in many types of sample including blood, probang fluids, swabs and milk.
VI requires sensitive cell cultures to be maintained and may take up to 4 days. Ag-ELISA and RT-PCR are more easily automated than VI and more suited to dealing with a high sample throughput. Ag-ELISA and RT-PCR, but not VI, can detect the presence of FMDV regardless of whether live virus is present in samples undergoing testing. Therefore, there is potential to use these methods on samples that have been treated to inactivate FMDV at the point of collection, so that they can be tested in laboratories that do not meet the high containment standards for working with live FMDV. Methods to inactivate FMDV in clinical samples prior to RT-PCR are established, whereas the feasibility of doing this prior to Ag-ELISA is less clear.

Laboratories also undertake a range of serological tests for antibodies to FMDV and these can be helpful in identifying secondary outbreaks of FMD.

**Novel portable devices to detect FMD antigen**

A recent development in FMD diagnostics has been modification of a technology (initially commercialised in human pregnancy diagnostic kits), which is based on the diffusion of coloured, antibody-coated latex beads or colloidal gold particles through a membrane towards an immobilising band of trapping antibody. These tests are referred to as either “(immuno)-chromatographic strip tests” or “lateral flow devices” (LFDs). A prototype LFD has been shown to detect FMD virus with approximately equal sensitivity to the Ag-ELISA (Reid *et al.*, 2001) and performed satisfactorily with specimens from two suspected premises during the UK outbreak in 2001 (Ferris *et al.*, 2001). A new, commercially available LFD has been validated recently (Ferris *et al*, 2008) and was used in the laboratory as an initial rapid test during the 2007 UK FMD outbreak as well as on one farm by a veterinarian to diagnose FMD during that episode (Ryan *et al*, 2008).

If FMD viral antigen is present in sufficient concentration in the test specimen, a visible line will appear in the “test window” of the device within minutes. The test is thus rapid and easy to perform. However, current formats of this test do not serotype the virus present, although this may be considered of lesser importance in the confirmation of secondary outbreaks. Reading the device result by eye involves a degree of subjectivity; LFD readers are now available, but a requirement for their use could limit availability of the test and add to disease containment concerns. As the sensitivity of these devices is relatively low (as for the Ag-ELISA), they are only suitable for testing epithelial lesion material and vesicular fluid (which is expected to have the highest concentration of virus) and more than one affected animal within any particular group or herd of animals should be sampled and tested (on separate devices) to minimise the risk of a false negative test result.

The initial step in testing epithelial lesion material by any antigen detection method requires disruption of the tissue to release viral antigen, a process performed in the laboratory by grinding the tissue with sterile sand, pestle and mortar. To facilitate field use of LFDs, a simple extraction kit has been developed. The sample is added to a tube for mixing and grinding with sand, buffer and a disposable pestle. Thereafter, the liquid phase can be added directly to the test device. Vesicular fluid, or a swab which has absorbed vesicular fluid, can also be added to the buffer prior to applying to the device.

As for Ag-ELISA, methods to enable clinical samples to be treated at the point of collection so as to inactivate FMDV, without affecting subsequent LFD testing are not established. Work is ongoing to evaluate the possibility of recovering viral RNA or live virus for RT-PCR or VI from used LFDs.

**Novel portable devices to perform RT-PCR**

Several different companies have developed portable PCR equipment in recent years. These platforms are robust and easy to use, having been designed for use by the military (to detect infectious agents such as *Bacillus anthracis*, spurred on by fears of bio-terrorism). Combined with mobile robotic RNA extraction equipment (or simple mechanical shaking devices), this machinery is currently being evaluated for decentralised diagnosis of FMD (King *et al.*, 2008).
Pre-packaged PCR reagents, validated for FMD virus detection, are also commercially available and in future it will be possible to perform the entire RT-PCR process within disposable sealed tubes considerably reducing the risk of cross-contamination, although most systems currently on the market do not perform the nucleic acid extraction step. Unlike laboratory-based RT-PCR methods, only a small number of samples can be processed at once, but results are obtained more quickly.

Alternative methods of nucleic acid amplification have been developed which are isothermal (i.e. do not require thermal cycling and such precise instruments) and some of these processes can be formatted to produce a visible colour change if positive, allowing the test to be read without sophisticated equipment (Dukes et al., 2006; Lau et al., 2008). This could form the basis of a disposable decentralised testing kit; but none of these methods are yet routinely applied in FMD diagnosis.

Current genome detection methods are not typically designed to serotype FMD viruses. Use of a combined testing strategy involving both rapid antigen detection and rapid genome detection provides separate lines of evidence for the presence of infection and hence greater confidence in the diagnosis. However, in practice, this may not always be feasible (e.g. samples such as blood cannot be tested directly by antigen ELISA) and judgement must be used as to the level of certainty required from laboratory confirmation, according to the strength of the available field evidence (i.e. the clinical basis for suspecting FMD) and the consequences of the diagnosis.

Possible rapid testing options for diagnosis of secondary cases

**OPTION 1:** Retain all testing for FMD at the NRL and take steps to expedite transfer of samples to the laboratory. LFDs and rapid, low-throughput RT-PCR stations can be deployed to enable preliminary results to be obtained quickly for selected urgent cases. Advantages of this approach are that testing is performed within specialised (QA-accredited) containment facilities by skilled staff experienced in performance characteristics of the test methods and in the interpretation of the test results. Redundancy in test options allows back-up testing in case of equivocal preliminary results. Automated processes and availability of trained staff means that a high throughput of samples is possible (such as that required for active surveillance programmes). The principal disadvantage is the delay in getting specimens to the laboratory, a problem that may be exacerbated by long journey distances and difficult transport conditions.

**OPTION 2:** Perform real-time RT-PCR in a local, regional or mobile laboratory using RNA extraction and PCR equipment or using a modularised portable PCR unit. Equipment similar to that used at NRLs could be used for this purpose, although this would be expensive, require highly trained personnel and take a considerable time to establish. The approach might be facilitated if such equipment was used for diagnosis of other diseases between FMD outbreaks and some regional laboratories may already have capacity for this type of testing for endemic diseases. Alternatively, portable/simplified RT-PCR test equipment could be used to provide a low throughput of rapid testing.

**OPTION 3a:** Use LFDs on the suspect premises. The official veterinarian who will have examined and sampled the suspect animals could perform this method and a test result could be available within 30 minutes providing that a high concentration of antigen is present in the test sample. Where an unexpected result is obtained a repeat test could be done immediately, on the same or additional animals. The low cost of the individual LFDs would facilitate their local distribution in “peacetime”, thus ensuring that devices would be quickly available for suspect cases. They could, for instance, be routinely included in the FMD field investigation kit. The official veterinarian would therefore have them immediately available while on the suspect farm.

**OPTION 3b:** Use a modularised portable PCR unit on the suspect premises. Following notification of a suspect case, this would require transport of the device to the farm, where it could be used to detect viral genome in blood, epithelium, OP fluid or other samples. A result would be available 150 minutes later. The advantage of this approach is that it would be more sensitive than the LFD, while still enabling on-farm testing. A disadvantage is that, due to the
cost of these devices, they are likely to be stored in some regional depot rather than one being issued to each official vet. Therefore the device would have to be transported to the suspect farm following a request by the investigating vet. This time delay may be insignificant in some circumstances, but in other instances it may be just as quick to simply transport the samples to a regional or local laboratory (as discussed in option 2 above), or perhaps even the NRL. In the event of a major epidemic, this option would not be as efficient as using portable PCR in a regional/local/mobile laboratory (option 2). This option depends on such devices becoming available for field use in the future.

Factors influencing the use of decentralised testing

There is a trade-off or compromise between proximity of the testing process to the affected animal (allowing for speed of diagnosis) and performing the test in ideal laboratory conditions (ensuring reliability or accuracy of diagnosis). This compromise is summarised in Table 1. Of course, there is nothing to stop the national veterinary authority from applying these various options in series until satisfied that there is sufficient evidence to deem a herd to be infected or free from infection. A potential hierarchy of testing options is illustrated diagrammatically in Figure 1. One crucial point in support of this scheme, which may not be readily apparent from Figure 1, is that the animals which pose greatest risk (because they are likely to be shedding the most virus) would most probably be rapidly identified as positive using on-site tests (Options 3a or 3b) whilst the infected animals that pose least risk (as they are shedding the least amount of virus) should eventually be identified as positive by the combination of more sensitive test methods which are employed at NRLs (Option 1).

An issue that is sometimes overlooked is that if samples are not submitted to a NRL they may not become available for subsequent analysis; for example for genome sequencing to trace routes of transmission. A possible way of overcoming this problem would be to ensure that either original or prepared samples are sent on to the NRL immediately after local testing.

Alternatively, options 1, 2 and 3a might be conducted in parallel and this would probably provide the optimum balance of speed and reliability but would be unrealistic (overwhelm the NRL), costly and probably unnecessary in a major epidemic, but clearly feasible in smaller clusters of outbreaks such as e.g. the UK 2007 outbreaks.
### Table 1: Relative ranking of different options for diagnosis of secondary cases of FMD during an outbreak (1 = best; adapted from Reid et al., 2006).

<table>
<thead>
<tr>
<th>Option</th>
<th>Location</th>
<th>Method</th>
<th>Relative ranking of testing process</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Speed</td>
</tr>
<tr>
<td>1</td>
<td>NRL</td>
<td>Ag-ELISA and/or rtRT-PCR (Delivery + 1.5 to 5 hrs)§</td>
<td>2-3</td>
</tr>
<tr>
<td>2</td>
<td>Regional or mobile lab.</td>
<td>RT-PCR (Delivery + 1.5 - 5 hrs)*</td>
<td>2</td>
</tr>
<tr>
<td>3a</td>
<td>Suspect premises</td>
<td>LFD (30 minutes)</td>
<td>1</td>
</tr>
<tr>
<td>3b</td>
<td>“</td>
<td>Portable RT-PCR (2.5 hrs)</td>
<td>1-2</td>
</tr>
</tbody>
</table>

§Assumes conventional testing methods but LFDs and/or portable PCR can also be used at the NRL for occasional (i.e. low throughput) high speed testing of urgent samples;

*Depends on the method used

### Issues that will arise with decentralised testing for FMD

The veterinary authority in each country must decide whether and how they would use decentralised testing technologies in the event of any future outbreak. Clearly, the strategy chosen must be appropriate to the circumstances, and so this paper does not intend to be prescriptive, but rather seeks to clarify the issues involved. Some national authorities have already given considerable thought to how they might decentralise testing for FMD (and other OIE-listed diseases) in the event of a future disease outbreak; some examples are summarised at the end of this paper (Annex 1). If a decision is taken to opt for decentralised testing, a number of predictable issues arise; these issues are listed and briefly outlined below. Each of these issues could and should be resolved in "peacetime". Action points are suggested after each item.

1. **Comparative evaluation and field validation of rapid test systems.**

Several studies have been conducted in which one or other of the rapid test systems described above have been compared with conventional laboratory-based testing methods for FMD (Reid *et al.*, 2001; Hearps *et al.*, 2002; Callahan *et al.*, 2002, Ferris *et al*, 2008), demonstrating the efficacy of these methods. However, to the authors’ knowledge, none of the currently available test systems have been fully validated for field use. The authors recommend that the three testing options described above should be applied in parallel and their performance compared in a real "outbreak" situation. A potential opportunity for such field evaluation and validation exists in Anatolia, where FMD is endemic and where such a study could complement other work already in progress in that region to better understand and control the spread of FMD. An LFD supplied by Princeton Biomedical Corporation was employed with limited success during a pilot study on FMD outbreak investigation conducted in Erzurum in 2004 (Bulut *et al.*, 2004). Testing of the LFD device using field samples is currently underway in Turkey.

It is important to note that following a primary diagnosis of FMD in any future outbreak, the NRL must ensure that whatever test system will be applied for diagnosis of secondary outbreaks is capable of recognising the causative strain of the virus.
2. Availability of test devices, reagents and equipment
Options 3a and 3b require that sufficient LFDs or portable RT-PCR equipment are purchased and stored or that a contract for supply is agreed with a commercial source or that an EU “diagnostics bank” stockpile equipment to be used by member states as required, in advance of an outbreak. Both the shelf-life and cost of devices should be considered when making these arrangements. Option 2 requires that regional or mobile laboratories are equipped with the necessary precision instrumentation; the machinery could be provided in advance (and possibly put to other uses in peacetime) or instruments could be stored at the NRL and delivered to where they are most urgently required during an outbreak (the machines could be relocated during the outbreak as events dictate). With respect to either testing option, commercial companies need incentives to develop, validate, produce and market FMD testing systems during peacetime if such tests are to be commercially available when required during an outbreak. Planning is also required to ensure the logistical pathways to deliver materials for decentralised testing to the field during an outbreak are considered in advance.

**Action:** representatives of the national veterinary authority should decide in consultation with colleagues in the NRL; EU member states should consult with DG-SANCO on the possibility of LFDs and/or portable PCR units being included in an EU diagnostic reagents bank; the concept of a reagents bank has been the subject of a previous EuFMD position paper by Haas (2003).

3. Determine the levels of proof required to cull a herd or derestrict a herd
Who will decide to cull or derestrict a herd? On what basis will this decision be made? Thought should be given as to how decisions will be made at a herd level, and how test results and other evidence (epidemiological and clinical information) will be considered in the decision-making process. It is critical that this is discussed and agreed in advance of an outbreak whilst there is time available for debate.

**Action:** representatives of the national veterinary authority should discuss with colleagues in the NRL and should attempt to formulate a “decision tree”.

4. Training and/or instruction in the use of rapid test systems
Options 3a and 3b require that clearly-written, step-by-step instructions are provided with the test devices, such as those developed by FAO for the use of LFDs in the diagnosis of rinderpest (Roeder, 2002). Option 2 will require staff training.

**Action:** In the case of commercially-available LFDs, detailed instructions are provided with the devices. Similarly clear instructions should accompany any portable PCR system. The NRL could provide further training and instructions as required.

5. Containment risks and their mitigation
It is important to emphasise that personnel entering and leaving livestock holdings, whether for the purposes of clinical surveillance or taking samples from suspect cases, must take the utmost precautions with regard to containment. If containment is insufficiently stringent, there is a risk of spreading the disease further.

Option 3 above does not pose a biosecurity risk (over and above that associated with any field investigation of suspect cases) as the testing is done on the suspect premises and the LFD devices may be discarded or sent to the NRL once the test has been performed. Portable PCR devices must either be used in a way that avoids their contamination or enables decontamination (e.g. complete submersion in disinfectant). Used LFDs and reaction cartridges may be discarded or sent to the NRL once the test has been performed.

Option 2: to avoid the prospect of live FMD virus being handled in non-high-containment laboratory facilities, samples could be treated on collection so as to destroy infectivity whilst preserving and stabilising RNA. However, this may to some degree limit the scope for subsequent characterisation of virus in samples scored as positive. However, such samples may still be subjected to sequence analysis, and work is continuing on protocols for the recovery of infectious virus by transfection of RNA into cell cultures.
As regards option 1, all NRLs for FMD should operate to the prescribed standards (Anon., 1993; Haas 2008).

**Action:** for option 2, protocols for treatment of samples should be developed and agreed that will ensure loss of infectivity without affecting viral RNA recovery.

**Use of decentralised testing systems in countries with endemic FMD**

This paper primarily examines the potential uses of decentralised testing in FMD-free developed countries. However, countries with endemic FMD may also find these devices beneficial in FMD control campaigns. Some countries may not have an FMD NRL but have good regional laboratories. In these laboratories, portable RT-PCR devices in which RNA extraction, RT and PCR are carried out within a disposable sealed tube may be useful as an alternative to stationary real time RT-PCR equipment, which can be susceptible to cross-contamination problems if the necessary infrastructure is not available. LFDs could be used in regional or local laboratories as an alternative to antigen ELISA.

LFDs and portable RT-PCR devices could be brought onto farms during FMD investigations for rapid and convenient pen-side testing. This could be particularly useful where transport of samples to a regional or national laboratory is difficult or slow. The low cost of LFDs makes them particularly suitable for this role.

A further advantage to using these devices in endemic countries is that operating them is relatively simple. This may help overcome the problem of a lack of specialist or highly-trained staff.

The various scenarios in which these devices may be used would be influenced by the above factors (lack of an NRL, quality of regional lab network, distance from outbreak to laboratory, availability of trained staff) as well as cost and the nature of the FMD control campaign.

**Conclusion**

Decentralised tests for FMDV detection offer considerable benefits for rapid confirmation of secondary outbreaks of FMD, but careful thought and planning are needed for their optimal use. LFD devices are commercially available; in the face of a future outbreak, there may be pressure to use them. In such a scenario, it would be essential to have planned for their use and considered their role in the decision making process in advance. Early recognition of the disease will remain highly dependent on the awareness, vigilance and goodwill of the farming community and practising veterinarians. Furthermore, the decision to confirm or refute a diagnosis of FMD will continue to require careful assessment of all relevant clinical and epidemiological indicators as well as test results. The services of a NRL will remain indispensable, not only to confirm the primary outbreak and characterise the virus involved, but also to oversee all subsequent testing for the presence of the disease and to co-ordinate if not perform the large-scale serological testing required to substantiate freedom from FMD after an outbreak.

**Recommendations:**

1. Governments should carefully consider the use of decentralised tests in advance of any outbreak. It is important that decision-making processes and any applicable protocols are decided in the framework of the contingency planning in peacetime, rather than under pressure during an outbreak;

2. If governments decide to retain the option of using decentralised tests, they should consider in advance the necessary supply chain. The options are:
   
   (a) Purchase decentralised tests (e.g. LFDs) in bulk and stockpile them;
   
   (b) An EU diagnostics bank to purchase devices in bulk and make them available to member states as necessary;
(c) Purchase small numbers of devices but with a draw-down contract whereby the supplier would provide a pre-arranged number of devices in bulk in the event of an outbreak.

3. Current field trial should be continued and their result evaluated and further field testing of the decentralised devices should be carried out.
References:

ANNEX I

Decentralised FMD testing in France

A network of five regional laboratories has been put in place in order to perform FMD serology in the event of a future outbreak. These five laboratories have to participate in an annual ring test organized by the national reference laboratory (NRL), AFSSA, Maisons-Alfort. Moreover, they must test 800 sera per year in order to maintain competence. A similar network of five regional laboratories (each with high containment facilities) is to be put in place for rtRT-PCR testing to detect FMD virus. As for serological testing, these laboratories would have to participate in ring-tests organized by the NRL; in addition regional laboratory staff would receive training from the NRL in biosafety measures that have to be followed. Suspected cases of FMD would continue to be sent to the NRL. The regional laboratories would only be authorised to perform rtRT-PCR in the event of FMD being confirmed by the NRL and only in the case of suspected secondary cases. Some of the laboratories have systems in place for collection of samples on farm. Alternatively, in the case of remote farm locations, a transport system will be put in place to ensure biosecure delivery of specimens to the nearest laboratory. Testing would be performed under the supervision of the NRL and all results would be sent electronically to the NRL for interpretation; no result would be released without NRL authorisation. The extent to which such a system would be used in any future outbreak is difficult to gauge and will depend on such factors as the number of outbreaks and the outbreak locations. Decentralised rtRT-PCR testing is already in place for both bluetongue and avian influenza and has been extensively used for both; a network of ISO-accredited laboratories has been operating under control of the relevant NRL. The requirement for NRL oversight to ensure confidence in test results, imposes an upper limit on the number of laboratories that could be included in such a network.

Decentralised FMD testing in Germany

There are three strands to either current contingency plans or applied research for decentralised FMD testing in Germany: (i) in case of an FMD epidemic - serological testing (by NSP ELISA) in laboratories of the German States (“Länder”) using reagents from a national test kit bank and testing sera derived from low risk premises in which no clinical signs of FMD have been seen; (ii) in “normal times” - screening of samples (by qRT-PCR at German State laboratories) to rule out FMD as a potential, but unlikely differential diagnosis, e.g. in suspected cases of bluetongue. (Note: Where there is a clinical suspicion of FMD, specimens would be delivered with minimum delay by special courier, e.g. police helicopter, to the national reference laboratory FLI, Insel Riems) and (iii) a research project involving the validation of portable PCR machines that might eventually be deployed for use in the field by special task forces with clinical specimens derived from experimentally-infected animals.

Decentralised FMD testing in Israel

In Israel FMD control policy consists of annual vaccination (with 150% coverage of the national herd) and quarantine in the event of an outbreak. The main problem in dealing with new outbreaks of FMD is the time interval that elapses between first appearance of clinical signs and first recognition of the disease. Rapid test methods will not necessarily ensure rapid recognition of FMD. Of much greater importance in this regard is that all persons involved with the livestock industry are aware of the disease and remain vigilant (regular training to remind key persons about FMD may be very useful in this regard). An LFD (Svanova), will be distributed this year to all regional veterinary services stations (six throughout the country) and this device will be used to support the local veterinary officer when faced with a clinical suspicion of FMD, in deciding whether or not to place the affected herd under quarantine. This new approach will be used in addition to sending samples to NRL for confirmation by conventional testing methods; the time taken to reach the NRL with samples from anywhere in the country would not exceed four hours.