

REGIONAL MICROBIOLOGY NETWORK



Health Protection Agency
Executive Director
Regional Microbiology Network

HPA Central Office
7th Floor
Holborn Gate
330 High Holborn
London
WC1V 7BA

1st December 2009

Tel +44 (0)20 7759
Fax +44 (0)20 7759
www.hpa.org.uk

Dear Colleague,

Consultation on proposals for strengthening the Health Protection Agency Regional Microbiology Network Public Health Microbiology Services

You may be aware that the Health Protection Agency (HPA) provides public health microbiology services from its Regional Laboratories and through a series of Collaborating Laboratories throughout England. The laboratories support public health investigations, surveillance, and research work undertaken for the NHS and Local Authorities. In addition the laboratories also support public health investigations initiated by the Local and Regional Services (LaRS) division of the HPA.

There is now a compelling case that we should modernise our arrangements and create a strengthened public health microbiology service function for England. This enclosed document highlights the background to why such change is needed and explores the options for change. The current provision of public health microbiology services are not universally accessible, are fragmented across England and delivered through a wide range of different providers with challenging priorities and pressures. This is in part due to the current service delivery model being based on historical locations many of which are commissioned from the NHS. The aim of these proposed changes is:

- to guarantee equality of access to a high quality health protection microbiology service with clear performance characteristics:
- to provide an authoritative source of expert advice on health protection microbiology and infection
- to support the NHS and LaRS Health Protection Units locally

- to support local and national surveillance with a range of partners
- to perform leading edge research and development.

Against the background of fragmented service provision the HPA is proposing to develop a modernised, network of regional laboratories with commissioned support from selected centres that will deliver a robust and resilient quality service to our key stakeholders on a consistent basis.

Attached is the consultation paper produced by the HPA. We invite and welcome your responses to this consultation by **1 March 2010**. Thereafter, a definitive plan will be published by 31 March 2010 having taken into consideration the responses received.

Implementation of this plan is scheduled from 1 April 2011. In the interim it is the intent of the HPA that the public health microbiology services will continue to be delivered through the existing Service Level Agreements.

Please send your comments to rmnconsult@hpa.org.uk. If you have any questions on any of this please contact Andrew Mumford on 0207 759 2766.

Yours sincerely

Dr Christine McCartney
Director
Regional Microbiology Network
HPA Central Office
7th floor, Holborn Gate
330 High Holborn
London, WC1V 7PP

Strengthening HPA Regional Microbiology Network Public Health Microbiology Services

CONTENTS

- 1 Executive Summary
- 2 Background to public health microbiology services
- 3 The need for change
- 4 What we want to achieve
- 5 Options for change
- 6 Implementation and consultation
- 7 Conclusions and recommendations

1.0 EXECUTIVE SUMMARY

- 1.1 The Health Protection Agency's Regional Microbiology Network (RMN) faces a number of challenges. There is likely to be a period of major change and financial stringency within the National Health Service as a whole with pathology services subject to particular scrutiny following Lord Carter's review and also targeted scrutiny within the NHS. This coincides with unprecedented technological change within microbiology driven by developments in molecular biology and genomics that provide great opportunities for new powerful tools for public health.

This review comes after the successful consultation and reconfiguration of the Food Water and Environmental (FW&E) service. It focuses on the delivery of the remaining services that are critical to the mission of the RMN and are intended to make best use of the financial resources available. The review is focussed on the RMN clinical microbiology laboratories in England. It should be noted that this network is available to work with those in the devolved administrations as has been required recently in the swine influenza pandemic.

At present, more than half of the HPA funding available for the delivery of public health laboratory services is distributed in small portions to a wide range of Collaborating Laboratories. These laboratories emerged from the dissolution of the network of former Public Health Laboratory Service Laboratories. Following the separation of the Regional Microbiology Network from Local and Regional Services (LaRS) the Agency returned a quantum of funding that was associated with NHS work within these laboratories. Since then, considerable efforts have been put into the performance management of the remaining health protection funding stream with commissioned Service Level Agreements. It has been shown that the management cost of this activity is high, the outputs and value for money vary considerably between laboratories, also the surge capacity available from these laboratories during the current swine 'flu pandemic has not matched expectations. It was, therefore, considered timely to address the investment in the Collaborating Laboratories and ensure the RMN is fit for purpose for the next ten years. To this end, the Executive Director, supported by the Regional Microbiology Network Executive appointed an internal review group to undertake the options appraisal reported in this document and then to consult stakeholders on their conclusions.

- 1.2 The review group identified that the RMN service needs:
- to guarantee equality of access to a high quality health protection microbiology service with clear performance characteristics:

- to provide an authoritative source of expert advice on health protection microbiology and infection
- to support the NHS and LaRS Health Protection Units locally
- to support local and national surveillance with a range of partners
- to perform leading edge research and development

1.3 A total of six options (see Section 5) were reviewed ranging from no change in the current arrangements to providing the full service from a single site. The group concluded that there was a need to increase investment in Regional Laboratory centres to ensure there are sufficient resources in place to create a modern and responsive microbiological testing service for each region. This testing service would need to be complemented with staff who are the authoritative source of specialist advice. Guaranteeing equality of access to service and advice was also seen as a key priority which means that it is necessary to ensure that the historical geographic imbalances inherent in the current network must be addressed. To ensure resilience in the face of future threats, research and development would need to be at the centre of our activities and be achieved by forming partnerships with the major centres of infectious diseases research nationally.

1.4 For these reasons the review group concluded that the option (Option 6) to strengthen the HPA Regional Laboratory centres and supplement them with a small number of commissioned services in key academic institutions should be recommended. Flexibility will also need to be maintained to commission additional expertise and support where necessary.

1.5 The recommendation for reconfiguring the HPA Regional Microbiology Network microbiology service is Option Six - to develop a reconfigured national RMN within two years (by 31 March 2012). This will strengthen the HPA Regional Laboratory centres and will be achieved by reducing the number of Collaborating Laboratories and Collaborating Centres in a phased approach in order to consolidate expertise and HPA funding in specialist Regional microbiology laboratories and through selected additional collaborations.

2.0 BACKGROUND TO PUBLIC HEALTH MICROBIOLOGY SERVICES

2.1 The RMN laboratory structure still has its roots in the Emergency Public Health Laboratory Service of 70 years ago. This model is wholly inappropriate to the modern health service environment and is incapable of delivering the current resource flexibly to achieve HPA public health microbiology goals.

2.2 Currently, there are eight HPA Regional Laboratories, seven under direct HPA management, a commissioned Regional Laboratory, 36 Collaborating Laboratories and four Collaborating Centres in London. One region does not currently have a regional laboratory centre. This is illustrated at Appendix 1.

2.3 The Regional Microbiology Network (RMN) has been established for three years. In that time, many lessons have been identified which could contribute to improving the public health microbiology provision in England. As the first step, the RMN Food, Water and Environmental Services has been reconfigured successfully. Thus, Food Water and Environmental services will not be considered further in this paper. The next priority identified is to revise the provision of HPA RMN laboratory services currently provided by the RMN Regional Laboratories and their collaborating NHS Laboratories

2.4 **Relationship to NHS**

It is axiomatic that the HPA RMN does not operate in a vacuum and it can only deliver its specialist health protection microbiology function in collaboration with colleagues in the NHS and Local Authorities as well as those from other parts of the Agency. All NHS microbiology laboratories have 'core' health protection functions and responsibilities, whilst those funded by the HPA should be providing additional services and outputs. These core functions were clearly defined in 'The Health Protection Functions of NHS Diagnostic Microbiology Laboratories' (Department of Health 2006)¹ and the Service Specification document prepared by the Association of Medical Microbiologists.² These are summarised in the section below.

2.5 **The functions of NHS laboratories in Health Protection Microbiology**

The expected functions of NHS laboratories with regard to health protection microbiology have been described fully in the paper referred above.

2.5.1 The expected outputs from NHS laboratories include:

- Contributing to surveillance of infectious diseases (including mandatory and voluntary reporting)
- Providing support for the investigation of local outbreaks
- Providing specialist advice to clinicians on antimicrobial prescribing and infection control in primary care and community settings
- Contributing to the development of local policies and publications

- Contributing to training in microbiology and infection as relevant to public health
- Representation on the District Control of Infection Committee or equivalent
- Maintaining vigilance for, and reporting of, new phenomena with potential public health implications
- Participating in formal and informal networks and working with the Regional Microbiologist
- Contributing to national Department of Health Action Plans subject to availability of resources
- Using National Standard Operating Procedures (SOPs) wherever possible and contributing to their development
- Seeking, obtaining and maintaining accreditation by CPA or other recognised scheme
- Participating in NEQAS schemes for all tests provided where available
- Complying with relevant recommendations regarding biosecurity

2.5.2 More recently there has been a consultation exercise on proposals to re-enforce and strengthen the Health Protection (Notification) Regulations. These will update the current list of notifiable infectious diseases to capture new and emerging infectious better and place a new statutory obligation on laboratories to notify identification of specified infections, with clear time limits for notification to the HPA.

2.6 **The functions of the Regional Microbiology Network**

2.6.1 *Leadership and standard setting in Public Health Microbiology*

- Providing access to sources of specialist advice on all aspects of public health microbiology and infectious diseases. This is provided by members of HPA staff within the national network formed by the RMN, LaRS and by referral to HPA centres
- To be a centre of excellence for research in public health microbiology. This is delivered from solely RMN managed facilities in collaboration with colleagues in other HPA divisions, or in collaboration with University or other national or international research groups
- To develop and introduce improved diagnostics for infectious diseases
- Advocate the development of effective diagnostic pathways to improve infectious disease diagnosis

- Undertake development and testing of clinical and public health related SOPs and the field evaluation of media, reagents, kits and equipment as part of an HPA programme of R&D
- Representing the HPA at relevant policy forming meetings within regions and nationally

2.6.2 *Surveillance: enhancing coverage and quality*

- Support for early identification and control of major community outbreaks of e.g. respiratory, gastrointestinal or sexually transmitted diseases caused by known or novel agents
- Contributing to national enhanced surveillance and fostering contribution from NHS laboratories. Providing timely feedback and information for action to contributors and customers alike
- Capturing and collecting samples of public health importance for testing for surveillance and referral to national reference facilities for public health need
- Working with Centre for Infections (CfI) and LaRS to organise and deliver sentinel surveillance within regions

2.6.3 *Provision of specialist diagnostics for timely patient management*

- Provision of small volume reference/ referred tests which need to be delivered close to the patient in a clinically appropriate time frame and which it is uneconomic for NHS laboratories to provide for reasons of cost, volume and continuing quality assurance
- Provision of typing services for infections where high volume and the need for proximity to the patient preclude an approach based on transport to a central laboratory approach
- Providing a responsive typing service for the timely management of community outbreaks and providing discriminatory typing to NHS trusts for effective prevention and control of healthcare associated infections (HCAIs)

2.6.4 *Provision of Capacity to manage large scale outbreak testing*

- Supporting the NHS in large-scale look back exercises providing specialist testing or the capacity to process large numbers in short time frames

- Testing of samples from outbreaks at the request of CfI or LaRS colleagues (for designated outbreak in collaboration of an outbreak control committee), or where the scale of the outbreak exceeds the capacity of local NHS laboratories
- Providing microbiological expertise to LaRS and NHS colleagues in the investigation of outbreaks
- Commissioning of public health microbiology testing/services that cannot be delivered by RMN managed laboratories

2.6.5 *Teaching and Training*

- To provide a source of training for Specialist Registrars (StRs), Healthcare Scientists, and other health professionals in public health microbiology and to contribute to the training of Specialist Registrars (StRS) in Public Health Medicine. This function includes career development, continuing professional development courses, *ad hoc* training in response to changing circumstance e.g., pandemic influenza, new infection control topics
- Inclusion of a strategy for succession planning and recruitment into public health microbiology as an integral part of business planning

2.6.6 *Emergency Response to biological events natural or malicious*

- Providing expert microbiological advice and input into policy development in the response to biological emergencies. To be a reservoir of staff trained to respond to national infectious disease emergencies and to provide surge capacity as required

3.0 THE NEED FOR CHANGE

3.1 The need for “modernised and responsive” services

3.1.1 The HPA and the NHS faces major challenges in the coming years to fulfil the expectations in public health microbiology placed on it by government. There is a pressing need to make progress on a wide range of public health problems including:

- early identification and control of major community outbreaks of respiratory infection
- improved laboratory methods for early identification and control of gastrointestinal and food related outbreaks

- more rapid diagnosis of sexually transmitted disease (caused either by known or novel agents),
- control of HCAs
- more rapid diagnosis of tuberculosis and availability of typing to support improved treatment and identification of outbreaks
- supporting infection diagnosis in the NHS.
- developing methods for detailed characterisation of microorganisms in order to track their spread and delivering these as close to patients as possible

3.1.2 These have to be achieved against a background of major changes in the environment within which the service has to be delivered including

- changes to the population (travel, culture, ethnicity & age)
- increasingly complicated industrial processes for food and water production
- increased expectations of quality, choice and governance of healthcare
- uncertainty about the security of funding to deliver the service
- reconfiguration of services and the involvement of new service providers.

3.1.3 There has been a revolution in the availability of new molecular methodologies for detection and identification of infectious agents. These provide unprecedented power to identify previously difficult to isolate organisms rapidly and powerful typing tools. This revolution provides a step change in our disease management capabilities. Many of the assays are not only extremely rapid but have either made existing single centre reference techniques obsolete or provide completely new information. The potential benefits can only be realised by co-ordinating the efforts of the RMN and working in collaboration the HPA specialist centres.

3.1.4 The laboratory methods in current use for the diagnosis of infection are varied, but have traditionally relied on growing bacteria and viruses on artificial culture media. This method is slow and relatively insensitive. To meet patient demand for improved service there is a need to bring microbiological diagnostic into line with the clinical care pathways in a more timely fashion. This can only be achieved by an increasing use of molecular biological and other methods. The HPA is a leading figure in the delivery of molecular diagnostic services for the NHS, which can give a result within hours rather than days. There are advances being made in molecular bacteriology and mycology in which we must invest if we are to continue to provide an appropriate service to the NHS and other stakeholders and to enhance opportunities for income generation.

3.2 Application of a modernised service

3.2.1 Outbreaks

3.2.1.1 Supporting the management of outbreaks is a major part of the RMN business. A modernised service will be able to provide detection and highly discriminating typing services to frontline NHS units, LARS, Primary Care Trusts based Directors of Public Health and Local Authorities supplemented by consultant level microbiological advice to support NHS laboratories. This means that the modernised service will deliver its expertise to outbreak control teams by interpreting complex microbiological data

3.2.1.2 The changing face of the NHS service indicates that there will be a growing need for “look-back” exercises. The modernised service will be able to play an increasing role providing access to archived results and specialist and confirmation testing of archived specimens using optimal techniques as these NHS (Strategic Health Authorities/Primary Care Trusts) investigations often require high throughput testing in short time frames to respond to public concern.

3.2.2 Specialist testing

3.2.2.1 The RMN believes that testing should be located as near to the patient as is practical. The location of testing will be defined by the interaction of the complexity of the testing methodology, demand for the test and the time-frame within which the result must be delivered to serve patient and public health benefit. With the increasing accessibility of molecular technology RMN are in a position to serve primary health provides with an enhanced service in specialist testing. Already the RMN is the major provider of specialist virology. Nationally, the network is integrated with other NHS specialist providers and with the Virus Reference Laboratory of Cfl and with Centre for Emergency Preparedness and Response (CEPR.) An example of this is the way in which the Agency responded to swine ‘flu pandemic. By capitalising on the previously established network of laboratories, integrated with Cfl, set up to diagnose avian influenza, we were able to provide a national service for a novel influenza virus in a matter of days.

3.2.2.2 The modernised service needs to be able to deliver the following:

- Specialised, low throughput diagnostic tests that need to be concentrated regionally in order to ensure cost effectiveness and quality assurance for NHS and other stakeholders.
- Reference tests such as identification, typing and strain characterisation of a variable range of organisms where high

throughput and need for very rapid results makes centralisation impractical e.g. *C. difficile* typing already established through the *Clostridium difficile* Ribotyping Network (CDRN).

- Support for healthcare associated infection investigation and management (e.g. norovirus detection by means of a network of laboratories which has been established).
- Confirmatory testing of samples referred from other laboratories.

3.2.3 Surveillance

3.2.3.1 Sentinel surveillance systems enable the capture of more detailed information than is achieved by routine surveillance (such as voluntary laboratory reporting) from a restricted number of sites which can then be extrapolated to provide estimates of the national picture. Examples of systems currently in existence include schemes that are managed by Cfl (e.g. Gonococcal Resistance to Antimicrobials Surveillance Programme (GRASP), Unlinked Anonymous Survey of Genitourinary Medicine Clinic Attendees (GUM Anon), whereas others are more passive, relying on self-selection by interested laboratories to submit isolates or samples for further characterisation (for example, typing of *Cryptosporidium* spp.). There are also areas in which there are several overlapping schemes (e.g. influenza).

3.2.3.2 The RMN, in collaboration with LaRS, must play a role as a bridge to HPA centres from the NHS achieving a co-ordinated approach to sentinel surveillance in high priority areas identified by the HPA nationally. The modernised service must maintain sufficient managed laboratories and develop appropriate partnerships to provide national coverage for surveillance to meet the current and emerging infectious diseases threats. The RMN is ideally placed to facilitate this, as it represents an expert group integrated within the NHS and other care providers, which is thus able to guarantee participation of its own laboratories and provide advice to the centres on the appropriate sites for surveillance and able to recruit additional sites on a commissioned basis, whose contributions can then be performance managed by Regional Microbiologists. This approach has recently been used successfully to revitalise the HPA Sero-Epidemiology Programme.

3.2.3.3 The RMN also has an important role in working with the NHS to fulfil its public health reporting responsibilities. It must also be able to work with LaRS and the HPA centres to ensure that surveillance outputs fit the needs of end-users through consultation with partners locally or working with colleagues to ensure that existing data sets are formatted and communicated in a way that is most productive for the NHS and others.

3.3 Research and Development

3.3.1 Research

The RMN has within its current full and part-time staff a considerable number of researchers of international standing. It has established research governance arrangements to manage these activities. The Network is linked with some of the leading university infectious diseases research departments in the UK. This linkage is supported by the close relationship in the HPA between RMN, LaRS, CfI and CEPR and enhances our ability to influence national policy. This places the RMN in an unrivalled position to engage in translational research in public health microbiology. This objective, for a modernised service, will generate new public health knowledge for action. It will also develop key relationships with partners and add to the quantum of funding available for public health microbiology.

3.3.2 Development

The RMN is expert at developing and implementing new diagnostic tests. The modernised service must utilise this skill set to work to develop new assays and to work with assays developed by the Centres and assist in implementing them in the Regional Laboratory centres and the NHS to provide a better service to the patient.

3.3.3 In addition to the response to new pathogens, the HPA laboratories form a national network of laboratories with expertise that means that they are ideally placed to be engaged in development and evaluation of new diagnostic tests from commercial partners.

3.4 *Training*

3.4.1 The staff of the RMN Regional Laboratories are the key resource to deliver our business. The intention to modernise the network will not be effective unless the Agency builds training into its programme. Without ensuring a succession of appropriately trained staff in a range of professional categories the change that is applied to the network will only have a transitory effect. Thus, the delivery of training in health protection microbiology is a major consideration in the options appraisal. The modernised service must ensure that whatever reconfiguration is adopted the skill mix of the staff in laboratories is appropriate for future needs. Good training and mentoring programmes are needed to ensure effective succession planning. In a rapidly changing environment with continual and fast moving technological and scientific innovation, the RMN needs to regularly review service and training needs. There are four major groups of staff which are crucial for the continued functioning of RMN laboratories:

3.4.2 Medically trained staff

Training of medical staff in public health microbiology is a key function of a modernised service. The HPA needs to provide training for its own medical trainees that equip them to be the health protection microbiology specialists of the future by ensuring that they have full exposure to the public health aspects of clinical microbiology and virology in Regional Laboratories as well as training in Health Protection Units and Cfl. It is also essential that the modernised service is able to train non-HPA funded trainees before their appointment as NHS Consultants. Training this cohort expands the range of those who may decide to pursue a career as Health Protection Consultant Medical Microbiologists and Virologists for posts in RMN Regional Laboratories but also ensures that future NHS infection specialists have a good understanding of health protection microbiology.

3.4.3 Clinical Scientists

To deliver a modernised service the RMN will need a cadre of Clinical Scientists. Future plans must develop staff that can

- perform research and development roles, closely allied to the needs of the developing clinical service
- work as Consultant Clinical Scientists performing work similar to Consultant Microbiologist and Virologist colleagues.

3.4.4 Biomedical Scientists

Biomedical scientists are essential for the delivery of a modernised service. In the future RMN laboratories must continue to provide training to State Registered Biomedical Scientists to supply our own needs but also to offer training to NHS and other laboratory staff to widen the expertise in public health microbiology. This aim should be delivered in association with local Higher Educational Institutions (HEIs) and NHS Trusts.

3.4.5 Support Staff

Support staff are also essential to the delivery of a front-line service. The modernised service needs to recognise the value of these staff and support them in developing their careers to more senior positions. In the future it will be necessary for the RMN to develop sources of funding to allow these individuals to access relevant training.

4.0 **WHAT WE WANT TO ACHIEVE**

4.1 To enable us to achieve a public health microbiology service that is fit for purpose and future proof we must:

- Develop a network that delivers appropriate public health microbiology services across England and provides an equitable access to its services from wherever support is requested
- Develop a network that is fit for purpose for the next 10 years and meets the demands of its key stakeholders
- Develop a network that is flexible and can evolve to meet the changes and new challenges that will occur in healthcare provision and public health nationally and internationally
- Be ready to support NHS clinical microbiology services with advice, specialist testing and outbreak support as it changes configuration and service requirements
- Work more closely with the Centre for Infections to develop and deliver specialist and reference functions and essential surveillance outputs for the country, together with colleagues in LaRS
- Improve and build upon existing relationships across the NHS in microbiology
- Contribute to better, speedier and more accurate diagnostic technologies for patients
- Provide relevant timely information for Public Health action to key colleagues within the HPA and to the wider health economy including Primary Care Trusts and Local Authorities.
- Provide leadership in the area of microbiology and infectious diseases
- Provide a modern skilled workforce able to be deployed flexibly to meet the public health microbiology priorities
- Support the development of a NHS laboratory workforce with a public health microbiology focus
- To work closely with colleagues in LaRS to investigate and control outbreaks locally

4.2 It is anticipated that with these outputs we will have the potential to contribute to the following health outcomes over the next five years

- Develop new knowledge for action through research in health protection microbiology
- HCAI – reduction in the harm from healthcare associated infections and antimicrobial resistance.
- TB – reduction in the incidence and consequences of TB
- Blood Borne infections – reduction in the incidence of Hepatitis B and C.
- Sexual Health – reduction in the incidence and consequences of HIV and sexually transmitted infections
- Gastrointestinal Infection - reduction in the incidence and consequences of key bacterial infections (e.g., Salmonella, VTEC, Listeria and Campylobacter)
- Vaccine Preventable infections – reduction in the incidence of vaccine preventable diseases.

4.3 These outcomes will be achieved by:

- Developing a Regional Microbiology testing service with a standard portfolio of tests with uniform performance characteristics
- Providing comprehensive microbiology testing for public health emergencies
- Work with NHS and others to improve speed and accuracy of testing in public health microbiology
- Providing guaranteed access to specialist advice for infectious diseases and infection control advice equally across the country
- Being a national resource for public health microbiology research
- The HPA being a national resource for enhanced and sentinel surveillance independently or in collaboration with external partners

4.4 **Financial management and governance arrangements**

The aim of these proposed changes is to support the provision of services based on public health need and population through establishing appropriate levels of funding that are clearly associated with activities additional to the core health protection functions of NHS laboratories and developing a consistency of approach within a national network that assures equality of access to service.

The proposed changes will:

- strengthen the provision of public health microbiology services on an equitable basis in each region

- maximise the deployment of HPA resources to meet public health needs
- ensure that the RMN provides best value for its use of public money

4.4.1 There will be an agreed set of Key Performance Indicators implemented to monitor the effectiveness of the new health protection systems both for HPA and key external stakeholders.

4.4.2 There will be open and transparent processes for the procurement of any services that need to be commissioned under whichever option is taken forward.

4.5 Development of specialist and appropriately skilled staff

4.5.1 Implement an improved workforce plan to meet regional and national HPA microbiology staffing priorities in the medium and long term.

4.5.2 Develop opportunities for NHS staff to undertake specialist training in health protection microbiology.

4.6 Capital and other investments required to develop a robust service

4.6.1 To provide a robust network strengthened by improved IT connectivity between HPA regional laboratories and their different Laboratory Information Management Systems (LIMS) and central HPA reference laboratories.

4.6.2 To support the implementation of advances in molecular technology and automation to maintain our leading edge specialist testing across all microbiology disciplines.

4.6.3 To ensure that the network has ready access to an efficient transport system reflecting work flows within and between the local health economies in each region and into HPA central reference laboratories where appropriate.

5.0 OPTIONS FOR CHANGE

5.1 The following list of options has been considered below. These options have been developed against an assumption that the resources currently deployed within the HPA Regional Laboratories and the current Collaborating Laboratory arrangements are available to be re-invested in these new arrangements.

Option 1 - Maintain existing arrangements

Option 2 - Focus all RMN resources in the eight Regional Laboratories

Option 3 - Establish a smaller number of Supra Regional Laboratories

Option 4 - Delivery of public health microbiology services from a single centre

Option 5 - Fully Commissioned Services

Option 6 - Strengthening HPA Regional Laboratory centres and commission a small number of services from other key institutions.

5.2 **Option 1 - Maintain existing arrangements**

In this option we would retain the current configuration of eight regional laboratories, 36 collaborating laboratories and four collaborating centres together with the Food Water and Environmental network.

5.2.1 *Advantages*

- There would be minimal disruption to the current laboratories and service and continuity of service.
- The system would remain unchanged and familiar to the providers and recipients of the service.

5.2.2 *Disadvantages*

- The current HPA Collaborating Laboratory arrangements provide very variable output, the arrangements do not provide best value for money for the HPA and do not deliver a satisfactory level of service to stakeholders.
- Performance management of this arrangement has required significant senior management resource disproportionate to the outputs
- The current arrangements do not provide assurance of equality of access to a satisfactory service
- This model has also been seen not to be fully effective in providing surge capacity in response to emerging threats. For example, during the containment phase of the pandemic swine flu incident it was found that some of the commissioned laboratories, whilst working extremely

hard, were unable to deliver reliably to the same level as the HPA Regional Laboratories. Some others made only a small contribution.

- Public health microbiology is seen, inevitably, as a second priority for NHS laboratories
- Some NHS colleagues will continue to believe that the arrangements are inequitable with some laboratories with some laboratories being “subsidised” by the HPA on a purely historical basis without any measurable outputs. This is keenly felt by NHS laboratories that perform their public microbiology services as required under the Duerden and Dance paper¹ but do not receive any funding from the Agency.
- This model does not invest in the future and without a significant reconfiguration the network will not be fit for purpose in the future
- Without reconfiguration the network may not be able to make the quality improvements and efficiencies that the Agency will require in the future
- This option does not define the outputs produced adequately and, therefore, does not assure good stewardship of public money

5.2.3 *Risks*

- The current arrangements are not an optimal use of resource and if continued in the current format the network may lose funding during a period of fiscal stringency as the outputs delivered cannot be seen to justify the resource expended.
- Failure to optimise use of resource could result in loss of funding for public health microbiology

5.2.4 *Financial*

- The HPA will control the level of financial expenditure through the process of commissioning services via Service Level Agreements with agreed performance targets.
- Increased management cost of maintaining effective commissioning arrangements over time.

5.3 **Option 2 - Focus all RMN resources in the current eight Regional Laboratories**

Concentrate all HPA resource in the existing Regional Laboratory centres and withdraw from all Collaborating Laboratory arrangements.

5.3.1 *Advantages*

- Such a concentration would simplify the management of the network allowing for economies of scale in backroom function. Streamlined supervision of public health outcomes by the executive and the regional microbiologists would be facilitated.
- The limited resources available for public health microbiology technological developments that are in turn available to the Agency would argue for a concentration of resource in a smaller number of sites than at present. This would allow the further development of centres of excellence in each of the regions all of which are aligned with major university departments with strong infectious diseases research portfolios. Regional Laboratories are already established and have a distribution that largely mirrors the population. The Regional Laboratories were highly successful in responding to the recent public health emergency of swine 'flu.
- This change would build on and simplify the established relationships within the NHS and with colleagues in LaRS and the Centre for Infections.
- This option would minimize the disruption to the core working of the microbiological service.
- It would allow a concentration of capital, staff and revenue resource which would aid the development of a continuously modernising state of the art microbiology service.
- It would facilitate workforce development
- It would facilitate the building of strong microbiology diagnostic networks based on the existing HPA Regional Laboratories and in line with the outcome of the Carter Report and many previous government reports on pathology modernisation.
- By retaining a network with a presence in each of the regions the RMN will be able to continue to support surveillance work that matches the distribution of population.

5.3.2 *Disadvantages*

- It would not be possible to give the same assurance of equality of access to service that would be available in options with more laboratories performing HPA commissioned work.
- By focusing only in Regional Laboratories it is inevitable that many key NHS partners will be geographically remote from HPA employed infection specialists.

- It would represent a major change to public health microbiology provision where, with the exception of the North East, there are a large number of microbiology laboratories with a broad geographic sweep.
- This may limit the ability of the HPA to influence infectious diseases discussion locally. It may leave a significant number of important infectious diseases diagnostic and advice centres without a significant HPA relationship.
- There is a danger that we would create centres that might be perceived by the wider NHS to have an unfair advantage, perpetuating the pernicious two-tier complaint.

5.3.3 Risks

- Loss of resource in some regions may compromise the delivery of public health microbiology services and may have a de-stabilising effect on some NHS laboratories
- Without sufficient management control and acceptance within the network, the new resources may not translate into gains in efficiency, service delivery and modernisation
- Increased ill feeling with NHS current partners may lead them cease all public health microbiology activities.

5.3.4 Financial

- Concentrating resources onto Regional Laboratory sites should provide a more efficient investment.
- There will be full control in the level of resource that is invested.

5.4 Option 3 - Establish a smaller number of Supra Regional Laboratories

This option takes the process of concentration of resource one step further by reducing the number of laboratories under direct HPA management further. In this instance the HPA RMN would manage three or four laboratories based at established Centres of Excellence. A high quality transport system would be established to ensure rapid transmission of specimens. In this option is assumed the Regional Microbiology Network would retain a Regional Microbiologist in each region.

5.4.1 Advantages

- This option concentrates HPA resources further allowing for better investment in the service. This would allow the smaller number of centres to invest in equipment, training and revenue in a most cost effective way.
- This configuration would be optimized to deliver a small number of high calibre centres where the Agency could be sure that a microbiology service using cutting edge molecular diagnostic techniques would be delivered.
- By concentrating in a small number of centres the overall management and supervision cost could be reduced allowing a better ratio of funding to be directed to the delivery of front-line services.

5.4.2 Disadvantages

- It would be impossible assure equality of access to a high quality public health microbiology service.
- A service delivered with a smaller number of laboratories will mean that there are large areas of the country that are at a considerable distance from an HPA laboratory.
- This would reduce the capacity of the RMN to provide public health microbiology advocacy and to create local networks for the delivery of health protection microbiological services.
- This would reduce the capacity for public health microbiology intelligence gathering and, thus, make us less able to provide a effective health protection service
- There would be significant logistical challenges to move labile microbiology samples around the country and provide laboratory diagnoses in a timely way
- It would pose significant challenges in the support of sentinel and other surveillance that matches the national geography.
- By limiting HPA RMN investment in just a few centres, it is inevitable that a large number of important academic and NHS centres would be left without HPA investment and engagement. There is a significant risk that this would reduce the Agency's ability to influence the infectious diseases community in a consistent way.
- This option would make the task of engagement with Primary Care Trusts, Regional Directors of Public Health and Health Protection Units more difficult.
- In the absence of a laboratory base in each region recruitment of high calibre Regional Microbiologists and other senior scientific staff may be challenging

- The combination of a small number of high volume laboratories linked to a Regional Microbiologist in each region would not be perceived as a credible service to provide health protection microbiology.

5.4.3 Risks

- This process could alienate the RMN from key stakeholders on the front-line such as Directors of Public Health, Primary Care Trust leads, Commissioners, Local Authorities and NHS partners.
- By removing geographical relationship between need and service delivery it could compromise our ability to deliver a responsive service.
- Training through a small number of centres may make succession planning and staff recruitment very challenging.
- This process may alienate key stakeholders at regional level by not having substantial readily accessible capacity within each region.

5.4.4 Financial

- Concentrating resources onto Supra Regional Laboratory sites should provide a more efficient investment if universal coverage can be achieved.
- The postulated management efficiencies may be offset by increased costs associated with centralisation and transportation.
- There would be full control in the level of resource that is invested.

5.5 **Option 4 - Delivery of public health microbiology services from a single centre.**

This option extends the concept of concentration of resources further and would make use of one of the existing HPA Centres to provide diagnostic service.

5.5.1 Advantages

- The service would be based on an HPA owned site
- This option concentrates HPA resources further thus allowing for better investment in the service. It would optimise the investment in equipment, training and revenue.
- This configuration is the simplest managerially and the Agency could be sure that a microbiology service using cutting edge molecular diagnostic techniques would be delivered.

- By concentrating in a single centre the management and supervision cost would be reduced allowing a better ratio of funding to be directed to the delivery of front-line services.

5.5.2 *Disadvantages*

- A central service would be remote from the National Health Service and engagement with routine clinical practice
- This option would break any geographical link between the Regional Microbiology Network and their NHS and Local authority partners
- It would make advocacy roles within regions significantly more difficult
- It would pose significant challenges to move samples and results in a timely manner
- It would be more difficult to provide an assurance of equity of access to service
- It would make the task of recruiting public health microbiologists more difficult if the link between the laboratory and the population it served was broken
- In the absence of a local laboratory base recruitment of high calibre Regional Microbiologists and other senior scientific staff may be challenging
- It would reduce the opportunity for the network to support surveillance in a demographically relevant way
- It would reduce the capacity of the Agency to train health protection microbiologists
- It could duplicate the work of the HPA Centres

5.5.3 *Risks*

- By removing geographical relationship between need and service delivery it would compromise our ability to deliver a responsive service
- Training through one centre would make succession planning and staff recruitment very challenging
- This process could alienate the RMN from key stakeholders on the front-line such as Directors of Public Health, Primary Care Trusts leads, commissioners, local authorities and NHS partners and key regional partners.

- A centralised laboratory may create an “ivory tower” mentality out of tune with front-line clinical practice

5.5.4 *Financial*

- Concentrating resources onto one central Laboratory site could provide the most efficient investment if universal coverage could be achieved.
- The postulated management efficiencies may be offset by increased costs associated with centralisation and transportation
- There would be full control in the level of resource that is invested.

5.6 **Option 5 - Fully Commissioned Services**

All services to be commissioned from either the new Pathology networks or from the private sector. This would include the existing RMN Regional laboratories.

Commissioned services and HPA management are not mutually exclusive options but could be applied, in part, to all other options.

5.6.1 *Advantages*

- This option removes the appearance of a two tier microbiology service as all NHS and private providers will be able to bid for contracts.
- It could create an open and transparent process for the commissioning of microbiological services provided by the HPA.
- A tendering process would set out the key managerial parameters of the service clearly.
- Careful management of contracts could allow for improved consistency of delivery nationally but could be hard to deliver in practice.
- It would reduce the HPA RMN investment in capital but this could come at a high revenue cost.
- This could reduce the management costs associated with running laboratories as this function would be out-sourced.
- This approach would allow the RMN to concentrate its resources where the major health protection threats were located rather than base distribution of resource on the basis of history.

- It would free the RMN from the need to train large numbers of technical scientific and medical staff, producing a leaner organisation.
- It could enhance the influence of the RMN as providers compete to obtain contracts.

5.6.2 *Disadvantages*

- Overall experience of managing commissioned services on a major scale has shown that it requires significant management effort at senior level.
- It does not deliver a consistent level of service across a wide range of partners.
- It is not a reliable means of ensuring HPA priorities are delivered.
- It is difficult to modify existing services or introduce new tests urgently and in an equitable way across different regions to respond to a new public health microbiology threat (e.g. pandemic influenza).
- Experience of recent outbreaks indicate that some commissioned services respond poorly due to competition with NHS priorities
- There is a risk that, in the face of an emergency of unexpected scale or nature that insufficient testing, advice and support would be provided.
- It could reduce the ability of the RMN to contribute to the shaping of microbiology in the future as the network would be the passive recipient of whatever the market provided.
- The RMN would no longer have the facility to train and, thus, may not be able to deliver a comprehensive workforce development plan for key professional roles in health protection microbiology.
- It would reduce or remove the ability of the network to perform health protection microbiology research and would inevitably weaken the UK research capacity overall.
- The sanctions available to manage a commissioned service within the NHS are limited, in practice
- The costs of commissioning and ongoing performance management would be high and may exceed the potential savings.

5.6.3 *Risks*

- Considerable resource could be engaged in the commissioning and contract management process that distracts the network from service delivery
- Loss of public health microbiology expertise through difficulties in recruitment and by the nature of running the service remotely
- Key diagnostic services may fail during a national outbreak without the management tools and infrastructure to provide alternative solutions rapidly
- It may not be possible to rely on commissioned services being able to rapidly re-prioritise work without paying a substantial premium and it would still be difficult to guarantee continuity of service
- Providers would have different priorities therefore may not be as dependable in certain circumstances and as they would be NHS providers we may not have available the effective levers to manage the arrangement.

5.6.4 *Financial*

- The HPA would control the financial expenditure through the process of commissioning services via Service Level Agreements.
- Increased management cost of maintaining effective commissioning arrangements over time.

5.7 Option 6 - Strengthening HPA Regional Laboratory capability and commission a small number of services from other key institutions

In this option the RMN would retain its HPA Regional Laboratory centres, (establishing a regional laboratory centre in the East Midlands) and would increase the investment at these centres. In addition it would develop a small number of selected Health Protection partners to provide comprehensive geographical coverage and equitable access and to optimise links with key partnerships in leading infectious diseases centres. It would also retain the flexibility to commission additional expertise and support where gaps are identified within these arrangements.

5.7.1 *Advantages*

- This option allows the network to increase the investment in the regional laboratories allowing it to respond better to health protection emergencies and to have a sufficient concentration of resource to allow the service to modernise efficiently.

- This is the most flexible approach allowing the network to review the current health protection needs. By reviewing needs on a five yearly cycle, it will be possible to adjust the commissioned service partners to take account of scientific, political, academic and epidemiological changes.
- It should create an open and transparent commissioning process which should remove the current perception of a two tier service.
- This approach has already been trialled in the London Region, in part, and some of the relationships that were established previously performed well in response to the swine 'flu and other emergencies.
- This option builds relationships with opinion formers in NHS and academia and enhances the ability of the RMN to deliver collaborative translational research.
- By linking in with the key academic centres it would enhance the ability of the RMN to access to cutting edge technological development.
- This option would target the HPA investment more carefully.
- The change would deliver the change necessary to modernise the service.
- It would optimise the retention of HPA investment in NHS and academic centres allowing for the voice of the Agency to be heard.
- This option would provide assurance of a core service delivered nationally to partners in the Agency, the National Health Service and in the Universities
- Interaction with a range of NHS and University partners would facilitate workforce development for all grades of professional staff
- This optimises the use of resources to deliver advocacy in public health microbiology
- This arrangement would provide a geographical spread of HPA services and would facilitate equality of access.

5.7.2 *Disadvantages*

- It is possible that the competition for resource between the centralising theme and the collaborating centres would result in neither development receiving enough resource to allow sufficient change to modernise the service.
- There is a risk that the competition between NHS and academic partners could create ill-will that could interfere with the ability of the RMN to deliver its function to influence in the regions.

5.7.3 Risks

- The process could create a new two-tier system that is resented by some NHS partners that are excluded although they will have been afforded a fair opportunity to participate

5.7.4 Financial

- The HPA would control the financial expenditure through the process of targeted investment in Regional laboratories and commissioning services via Service Level Agreements.

6.0 IMPLEMENTATION AND CONSULTATION

6.1 Implementation group

The proposed changes to the configuration of the RMN are significant and will require careful project management. The HPA is in the process of appointing a dedicated project manager to support the management of the consultation process and the subsequent implementation. To ensure that the process is managed effectively, while considering the needs of key stakeholders, it is proposed to establish a multidisciplinary project implementation group consisting of staff within RMN, representatives from Communications, Human Resources and Finance, and colleagues from LARS and the Centres. In addition colleagues will also be invited to join the group from the DH Inspector of Microbiology and Infection Control, NHS microbiology and from a leading Academic microbiology group and from a service recipient. This group will be charged with the overseeing the overall development, managing the consultation process, responding to and adapting the proposal and implementation plan in the light of consultation and ensuring that relevant timelines are met within agreed resources.

6.2 The Consultation process

Consultation is a key aspect of this development to ensure that the modernised service delivers the objectives set out in the review. It is critical that the HPA's external partners are supportive of the general direction of development and we explain clearly what the benefits of the proposed changes will be. Similarly, it is essential that the implementation is flexible and listens to the comments and concerns of external partners who may identify potential issues and can provide advice to improve the plans and optimise the delivery of service.

It will be essential to consult with external national partners including, but not limited to, the Department of Health, through the Inspector of Microbiology and Infection Control, with other agencies such as the Veterinary Laboratory Agency, Local Authorities, and national infection associations such as the Royal College of Pathologists, Association of Medical Microbiologists (or its successor), Association of Clinical Microbiologists, and the Institute of Biomedical Scientists.

We will consult with colleagues within the Agency especially those within LaRS and the Centres especially the Centre for Infections.

Ultimately, the success of this reconfiguration will depend on matching the needs of external partners with the service available. Ensuring that the programme of modernisation achieves this objective will be delegated to the Regional Microbiologist who will consult locally through face to face meetings with NHS partners, Regional Directors of Public Health, Local Authorities and others as appropriate.

The process of consultation is expected to be complete by March 2010.

6.3 Implementation

The results of consultation will be incorporated into a modified proposal and implementation plan and it is anticipated that this process will be complete by the end of March 2010.

The outcome of this reconfiguration will depend on interlinking national and local plans. In parallel with the consultation process the implementation group will work to define a national service specification with minimum standards for the service provided and setting out development goals. The implementation group will develop a tender document setting out the requirements for the Health Protection Partner organisations envisaged in the recommended option. The tendering and selection process for the Health Protection Partner organisation will commence from **1st April 2010**.

The national plan will be integrated with the regional plan which will be created by the Regional Microbiologists in concert with local LARS, NHS and academic partners.

The recommended option requires that we give notice to the existing Collaborating Laboratories. In view of the significance of this change, this notice will be for 12 months and will be given no later than **31st March 2010**.

7.0 CONCLUSIONS AND RECOMMENDATIONS

- 7.1 The paper demonstrates that there is a clear need for change in how the arrangements for public health microbiology are delivered in order to improve the level of service provided on a consistent basis and to provide value for money.
- 7.2 There are a number of ways in which change can be achieved but the recommended option provides the best way to build on existing strengths within the current system whilst developing the service so that it meets the long term needs of health protection microbiology and is future proof.
- 7.3 The proposals outlined in this paper will represent a major change in how public health microbiology is delivered in the regions. This proposed change will require full consultation with external and internal partners, careful project management of the agreed change to ensure successful implementation, and a representative steering group to help oversee the process.
- 7.4 The recommended option for reconfiguring the HPA Regional Microbiology Network microbiology service is Option Six - to develop a reconfigured national RMN within two years (by 31 March 2012). This will strengthen the HPA Regional Laboratory centres and will be achieved by reducing the number of Collaborating Laboratories and Collaborating Centres in a phased approach in order to consolidate expertise and HPA funding in specialist regional microbiology laboratories and through selected additional collaborations.

Dr Christine McCartney
Executive Director, HPA Regional Microbiology Network
27 November 2009

¹ 'The Health Protection Functions of NHS Diagnostic Microbiology Laboratories' (Department of Health 2006)
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4136989.pdf

² 'Blue Skies Agenda for Microbiology: How do we deliver Microbiology services for the next decade and beyond' (prepared by the Association of Medical Microbiologists, September 2006)

SEE OVER

