

A National Strategy for Clinical Virology in the UK



The Formation of The UK Clinical Virology Network



Summary

Issues

Clinical virology is becoming increasingly complex, rapidly developing in areas such as nucleic acid technology, antiviral chemotherapy, new viral vaccines, identification of new human viruses, and management of infection control problems in both the hospital and local community.

- There is an increasing need for specialist virological advice, surveillance and diagnostic tests to support, for example:
 - the DH sexual health strategy, which includes the control of bloodborne and sexually transmitted infections;
 - tertiary referral services for immunocompromised patients in cancer centres, bone marrow transplant and solid organ transplant units, which have increased substantially over the last 10 years;
 - rapid testing in primary care to manage community infectious illness in a more cost effective and evidence-based manner.
- Specialist routine clinical virology services in the United Kingdom are provided by 33.5 (plus 2 unfilled posts) whole time equivalent consultant medical virologists and 14 grade C scientists. There are a few additional scientists who do not carry out clinical work. This equates to one medical consultant per 1.5 million population. There are 4 additional medical consultant staff working in reference facilities. There are only 6 BMS (MLSO) grade 4 virology posts in the UK. Across the country, there is an unequal clinical and diagnostic service provision and problems with all levels of staff recruitment and retention. The distribution of consultant clinical virologists today reflects past patterns of investment and difficulties in filling posts, rather than current clinical need. The result is a speciality group mostly carrying very large clinical workloads, maldistributed geographically, and with a significant proportion of consultants practising in isolation with clinical governance implications.
- The proposal in the new strategy for infectious disease and health protection is that the Health Protection Agency will take on many of the functions of the Public Health Laboratory Service. The strategy identifies the important role of virology in public health and the need to introduce standard operating procedures, modern diagnostics and to improve reporting to national surveillance bodies. This, together with the challenge of emerging/new virus infections and the need to respond to potential bioterrorist threats, argues for a co-ordinated provision of virology sources.
- In most district general hospitals, provision of virology advice falls largely to consultant medical microbiologists, few of whom have received specialist training in this area, and amongst whom a recent survey indicates there is considerable demand for input and updates in both clinical and laboratory aspects of diagnostic virology.
- Managing individuals with chronic viral infections increasingly requires close interaction between virologists and clinical teams, especially with the need to monitor individuals on therapy by measuring the viral burden and development of antiviral resistance. Antiretrovirals cost approximately £8,400 per annum per patient. The antiviral therapy cost of managing a patient with hepatitis C infection receiving ribavirin and interferon is £5,100 over a six month treatment course. Identifying patients who can, and those who cannot, benefit from such treatment will enable appropriate targeting of expensive treatments.

Solutions

Reorganise the speciality into a Network of 20 Specialist Virology Centres, providing the full range of modern laboratory techniques and clinical service provision, and about 10 Specialist Virology Units. This will enable comprehensive and equal service provision across the population and facilitate best practice.

- Centres will be based with academic and public health units, recognising the value of close interaction between PHLS/HPA, NHS and universities;
- each Centre would be staffed by three consultant clinical virologists, one of whom could be a Grade C Clinical Scientist with substantial clinical experience;
- there will be one additional grade C Clinical Scientist, supported by at least one grade B clinical scientist, to co-ordinate research and development and technology transfer to Units;
- each centre should have a BMS 4 in virology in accordance with the IBMS Code of Professional Conduct and Code of Practice for Biomedical Scientists. The Healthcare Scientist strategy will be supported by the introduction of the Advanced Biomedical Scientist practitioner grade in virology;
- support will be given to single-handed consultant virologists in the short term, and in the medium term there will be a redistribution of consultant clinical virology posts so that single-handed practice is phased out;



- Units will normally be based at DGH settings and will provide a less comprehensive service. Area virology service committees with shared protocols will be formed to incorporate services from DGH laboratories;
- the current VRL of the CPHL will become the Clinical Virology Network Reference Laboratory (CVNRL). Diagnostic and reference work across the Network will be co-ordinated;
- a central core of active researchers will develop and compare assays for the Network, probably based at the CVNRL;
- a sufficient number of training centres and training posts will be created to safeguard succession planning for future generations of medical, scientific and technical staff;
- Service Level Agreements will be agreed nationally between the HPA and the Network to provide public health information and epidemiology for the HPA. This will ensure geographical equality of data and identify unusual clusters of disease (which could result from deliberate release);
- The proposals will be compatible with the Pathology Modernisation Programme as they will be population and service based.

Progress to date

Within the last 18 months, there have been three well-attended meetings with up to 90% attendance of senior virologists, including both medical and scientist staff throughout the nation, to discuss the problems facing the profession and to seek ways to address them. A representative committee has been appointed, a constitution agreed and Professor Paul Griffiths has been elected as the Chief Executive Officer of the Clinical Virology Network representing the UK and Ireland. A website (www.clinical-virology.org), with educational, practical and interactive elements will be live by June 2002. A working group has begun to prioritise and commission a wide range of activities for the benefit of the Network and the practice of clinical and public health virology.

Outputs and response to 'Getting Ahead of the Curve'

The formation of a comprehensive clinical virology Network of accredited laboratories will deliver several key objectives including those identified in the DH strategy for combating infectious diseases, by:

- developing and adopting agreed Standard Operating Procedures, clinical guidelines and disease management policies. We will ensure participation in a wide range of quality assessment schemes;
- providing timely, high quality and accurate surveillance reports to national public health bodies such as CDSC and SCIEH. This will include coverage, amongst others, of a range of viral infections including respiratory, sexually transmitted, blood-borne and the vaccine-preventable infections such as measles, mumps, rubella, hepatitis A and B;
- establishing a co-ordinated system for evaluating and managing the introduction of new technologies. For example, the use of near patient tests will require careful evaluation and quality assurance support from accredited laboratories;
- providing a framework for clinical governance, which will include providing updates for microbiologists and carrying out clinical and laboratory audits;
- centralising confirmation of all notifiable virus infections;
- contributing to HPA/DH rapid risk assessment and providing technical and scientific expertise to respond to natural outbreaks or deliberate releases of virus infections. For example, the Network is currently preparing a response to the potential deliberate release of smallpox virus including a rollout of rapid assays for the detection of viruses associated with vesicular rash;
- the development of a continually updated UK Clinical Virology Network website (www.clinical-virology.org) for sharing reliable, robust and accurate information on virology amongst virologists, microbiologists, epidemiologists and public health teams;
- rapid and co-ordinated deployment of nucleic acid diagnostics, quantitation and typing nationally;
- the provision of a stable, high quality national virology service, working to common standards, responsive to local needs, with equity of access across the country;
- provision of clinical support, and regular training and updates to microbiologists working in district general hospitals;
- a centralised point of contact for virology for Workforce Development Confederations to discuss the case for an increase in the numbers of consultant medical virologists, clinical scientists and healthcare scientists.



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Terms and abbreviations

BMS	Biomedical scientist
CDSC	Communicable Disease Surveillance Centre
CsCDC	Consultants in Communicable Disease Control
CMO	Chief Medical Officer
CPHL	Central Public Health Laboratory
CVNRL	Clinical Virology Network Reference Laboratories
DGH	District General Hospital
DH	Department of Health
HPA	Health Protection Agency
NAT	Nucleic acid test (also termed "molecular assay")
NTN	National Training Number
PHLS	Public Health Laboratory Service
SCIEH	Scottish Centre for Infection and Environmental Health
SOP	Standard Operating Procedure
SVC	Specialist Virology Centre – a major virology laboratory providing a comprehensive clinical and public health function in a tertiary care and academic environment
SVU	Specialist Virology Unit - smaller virology laboratory with a less comprehensive range of services and fewer senior staff
UKCVN	UK Clinical Virology Network, including Eire
VRL	Virus Reference Laboratory



1 Current situation and problems

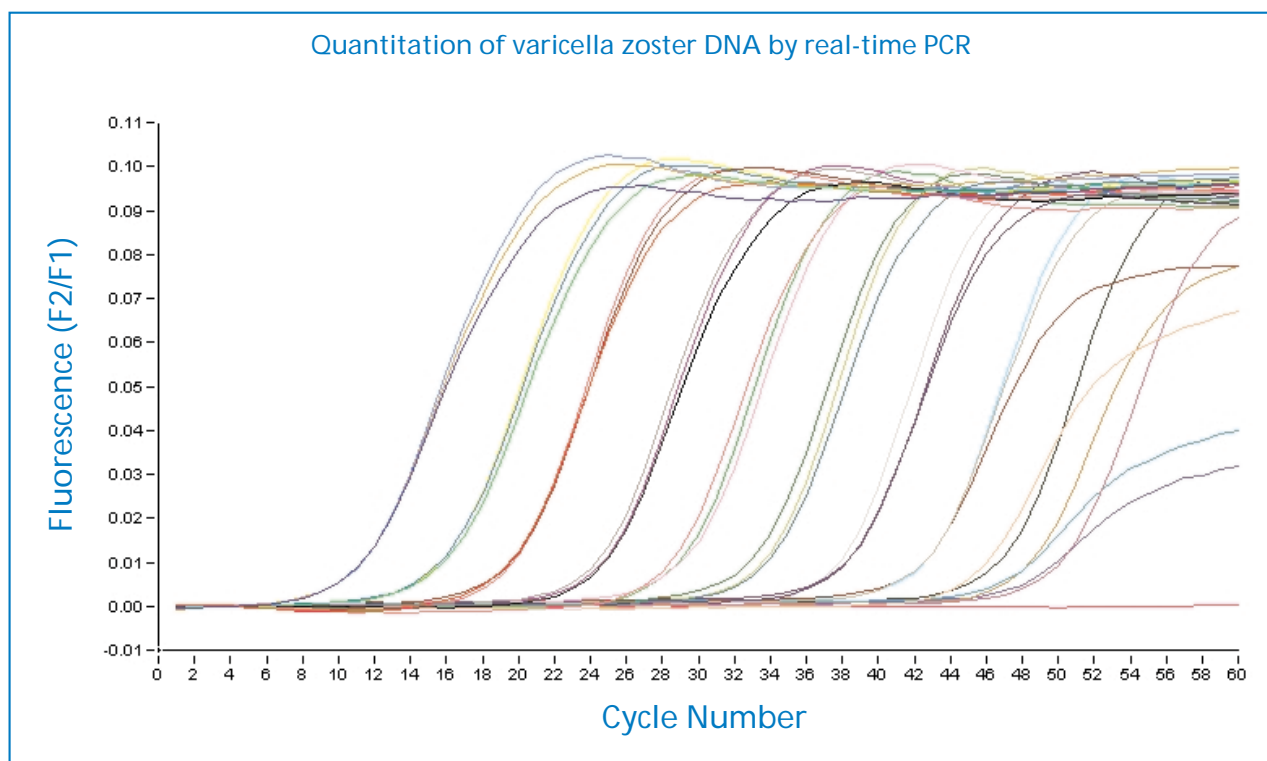
- 1.1 Specialist virology laboratories within NHS Trusts, the Public Health Laboratory Service (PHLS), and university departments, as well as microbiology laboratories in district general hospitals (DGHs) and private laboratories, currently provide virological services. Amalgamation of NHS and PHLS laboratories in England and Wales, together with the formation of eight groups of PHLS laboratories, made a start towards rationalisation of virology services.
- 1.2 Virological services can be divided into clinical, reference and public health work. The majority of virologists, either medical, grade B and C clinical scientists or biomedical scientists (BMS) are employed by the PHLS in England and Wales and by other employers in Scotland, Northern Ireland and Eire. The recent publication of the CMO for England's Communicable Disease Strategy includes the formation of a Health Protection Agency (HPA), which will replace the PHLS. It is likely that similar, interleaving, strategies will be developed in the rest of the UK. As a result, some PHLS laboratories may still continue providing diagnostic microbiology services to host Trusts, but the majority of the may be providing a service under new management. The UK Clinical Virology Network proposes to be a key player in this new management structure.
- 1.3 The type and diversity of clinical work will depend on the composition of the local patient population. DGHs provide general microbiology services for populations with different ranges of immunosuppressive and other conditions and will require specialist virology input in some cases. In general, a core set of virology tests is carried out in all hospitals, with more complex and technologically advanced tests carried out by specialist virology laboratories.
- 1.4 Audit Commission data confirm steady workload growth in microbiology laboratories from the 1970s onwards as measured by requests for investigations, and this applies equally to virology workload. Thirty new antiviral agents have been introduced including sixteen antiretroviral drugs, three drugs with activity against hepatitis B, two active against hepatitis C, two active against influenza A and B, and nine agents active against a number of herpesviruses. Nucleic acid tests (NAT) are becoming the standard of care for surveillance, early diagnosis, monitoring response to treatment and development of resistance. The requirement for more specialist clinical virology services parallels the development of cancer and transplant centres and increasing numbers of immunosuppressed patients. Specialist advice concerning immunisation, pre- and post-exposure prophylaxis to infectious agents, molecular based technology, antiviral agents, interpretation of test results and infection control issues in the hospital and community is requested regularly by a variety of health care professionals.

Licensed antivirals 2002		
Abacavir	Ganciclovir	Ritonavir
Acyclovir	Idoxuridine	Saquinavir
Amantadine	Indinavir	Stavudine
Amprenavir	Lamivudine	Tenofovir
Cidofovir	Nelfinavir	Valaciclovir
Delavirdine	Nevirapine	Valganciclovir
Didanosine	Oseltamivir	Vidarabine
Efavirenz	Penciclovir	Zalcitabine
Famciclovir	Ribavirin	Zanamivir
Foscarnet	Rimantadine	Zidovudine



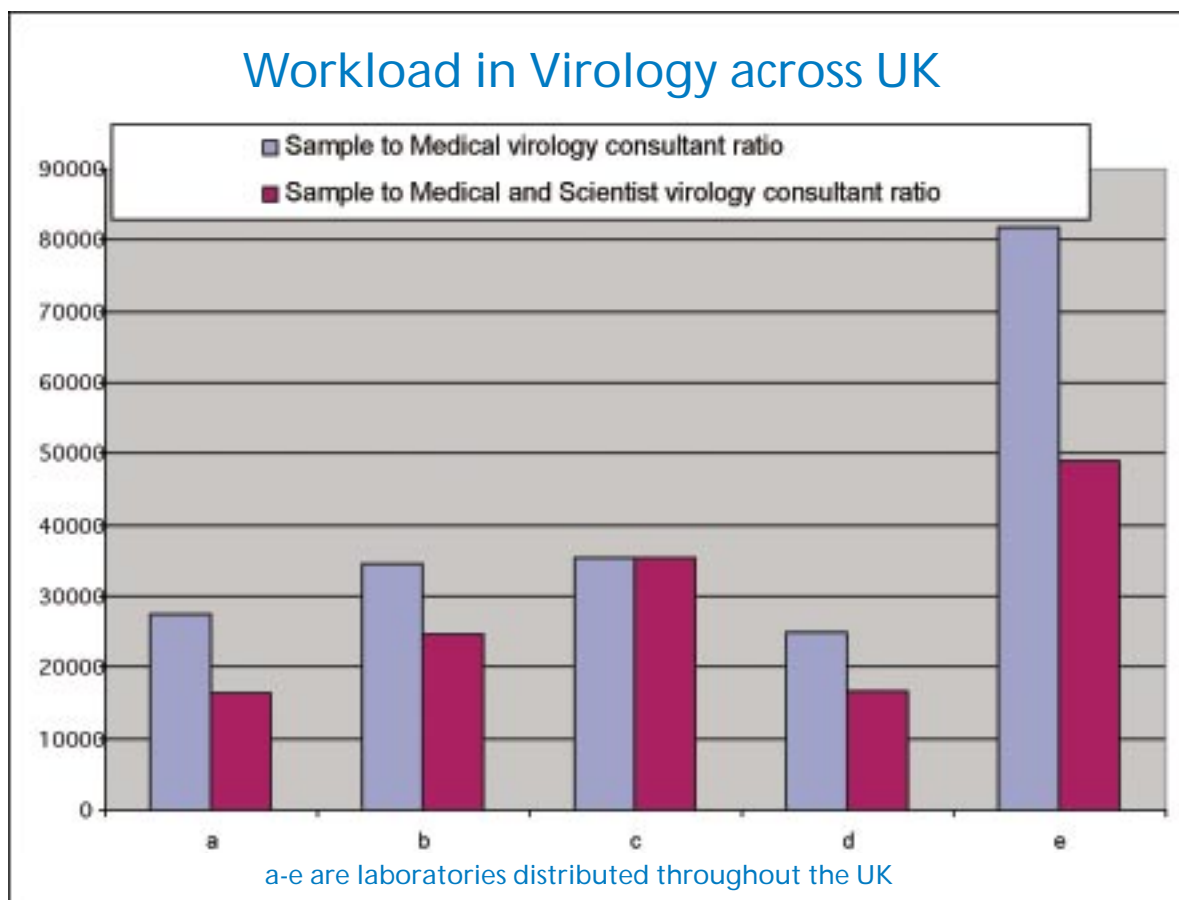
1.5 The increase in workload can be largely attributed to the following factors.

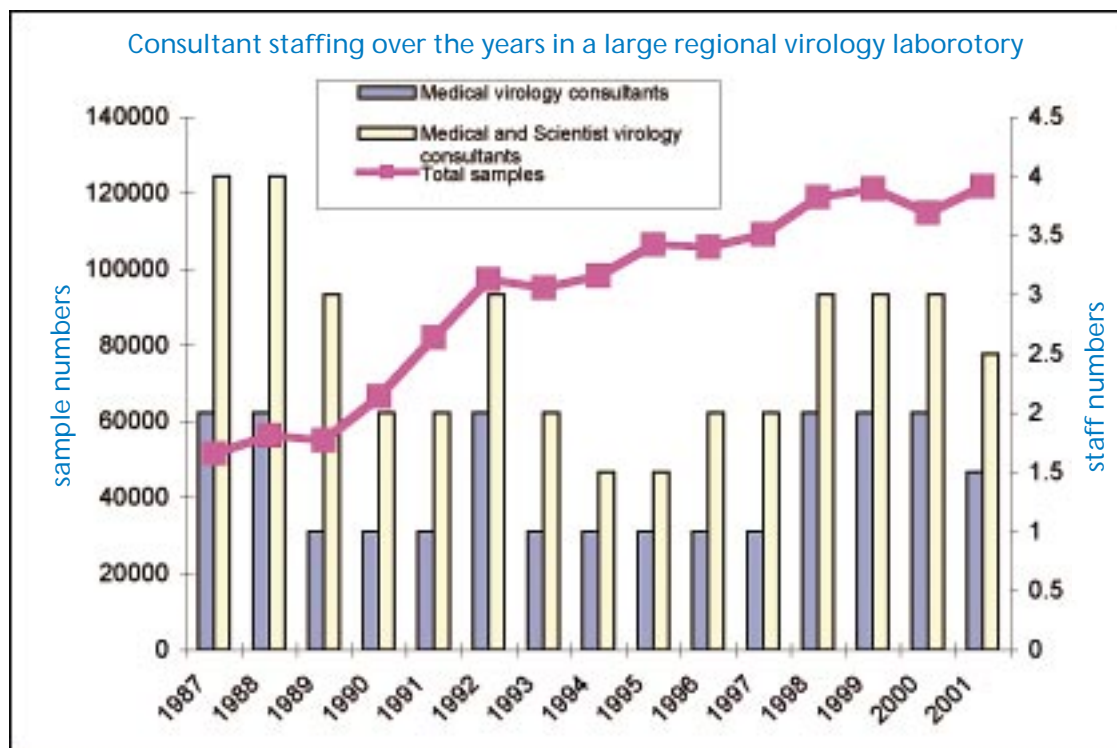
- 1.5.1 In the UK, 3,551 new HIV diagnoses were made in 2000 taking the total of HIV diagnoses to 44,744 by the end of June 2001. This will result in increased HIV load and antiretroviral susceptibility testing. These tests are critical in monitoring treatment response in individuals who are receiving a triple antiretroviral drug regime costing £8,400 per annum.
- 1.5.2 Overall, 2,839 individuals with acute hepatitis B infection in England and Wales were notified to the PHLS Communicable Disease Surveillance Centre (CDSC) between 1997 and 2000. The number of hepatitis B carriers is unknown. This figure will be needed when considering new antiviral therapies for hepatitis B treatment. 0.5% of the population in England and Wales have been infected by hepatitis C virus (HCV); 80% are carriers. The cost of receiving ribavirin and interferon is £10,200 over a twelve month treatment course. Identifying patients who can, and those who cannot, benefit from such treatment has cost-saving implications. Viral load and genotype analysis are part of patient care for these infected individuals.
- 1.5.3 Respiratory viruses are one of the commonest reasons for GP visits. There have been bird and horse influenza scares in the Far East and agents such as parainfluenza and respiratory syncytial virus are causes of fatal hospital outbreaks. The availability of new antiviral has heightened awareness and urgent diagnostic requests for these viruses.
- 1.5.4 Reduction in sexually transmitted diseases and improvement in cancer services are key targets for the NHS. Screening for papillomavirus has been proposed as integral to the strategy for reducing the incidence of cervical carcinoma. The prevalence of herpes and chlamydia is rising, especially in teenagers. Rapid diagnosis aids management.
- 1.5.5 Outbreaks of gastroenteritis are at epidemic level in hospitals and nursing homes. Rapid diagnosis allows sensible decisions about ward and even hospital closure. More than 50% of all gastroenteritis in children is due to viruses.
- 1.5.6 Demand on NHS clinical virology services for provision of epidemiological information is set to continue its upward trend, especially with the formation of the HPA and the need to formulate public health policy which is evidence based.
- 1.5.7 Virology is a fast moving field and the last twenty years has seen the identification of HIV types 1 and 2, new subtypes of HIV, human T-cell lymphotropic viruses (HTLV) types 1 and 2, hepatitis C virus, HHV 6, HHV 7, HHV 8, HEV, Bornaviruses, TTV, HGV, SEN virus, numerous arboviruses and haemorrhagic fever viruses, Sin Nombre virus and human metapneumovirus.
- 1.5.8 The rise of NAT tests has been inexorable and is accelerating with a clinical requirement for rapid results. It is expected that viral typing and routine quantification will become the standard of care over the next 5-10 years.





- 1.6 The range and complexity of the workload of consultant virologists has been rising for many years. Those who consider that other specialists can cover virology adequately have not appreciated the pace of advance in the field over the last decade and the continuing steep rise in knowledge and application to clinical practice.
- 1.6.1 With climate change, deforestation, increasing travel and rapid urban population growth, viruses are continuously emerging. There have been unexpected emergences such as West Nile fever in the USA and a dramatic increase in Ebola virus in Africa.
- 1.6.2 Recent terrorist activities have highlighted the need for a re-think about our preparedness. New management algorithms are being written and assays developed for detecting agents which could pose a bioterrorist threat.
- 1.6.3 Virus infections are one of the dominant reasons for visiting a general practitioner. However, very few diagnoses are made, there is little ongoing education in the primary care sector, practitioners are unaware of the modern service which is potentially available and still seem to prescribe antibiotics in many cases, which leads to an increase in bacterial resistance.
- 1.6.4 Increasing numbers of chronic idiopathic conditions are being linked to virus infections. A number of viruses are oncogenic, including hepatitis B and C and certain papillomaviruses.
- 1.7 There are only 33.5 FTE consultant medical virologists (plus 2 unfilled posts) in the UK and Eire. Of these, 14 are single handed. From 1990 to 2000, there was no overall growth in the numbers of consultant medical virologists, each of whom therefore provides a consultative service for at least 1.5 million people. The Royal College of Pathologists recommends that single-handed consultant microbiological and virological practice is not acceptable because of professional isolation and unreasonable on-call commitments. Consequently, clinical virology is at a crisis point. The Figures detail the increasing workload related to consultant cover at one large regional service and shows how there are geographical inequalities.

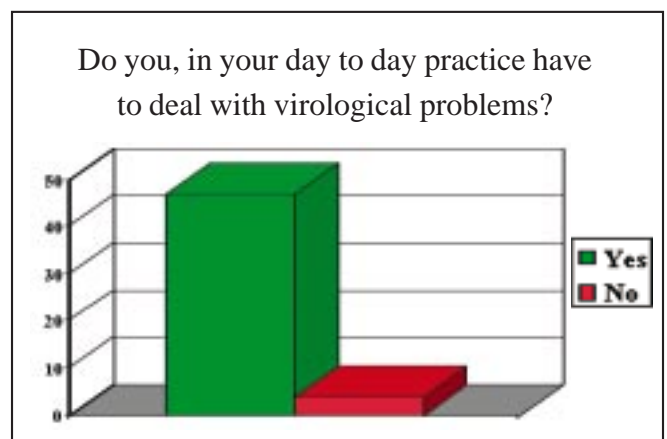
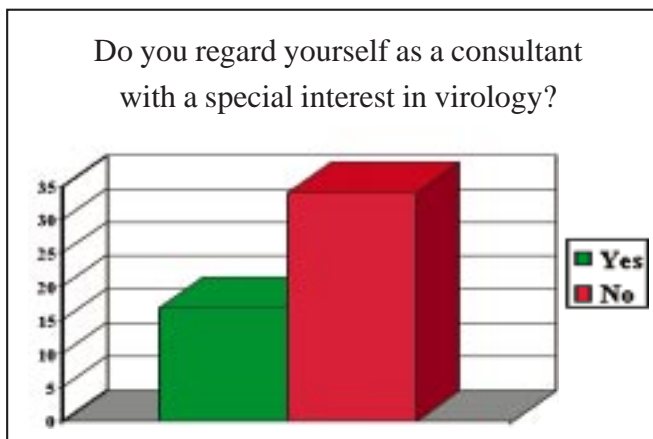




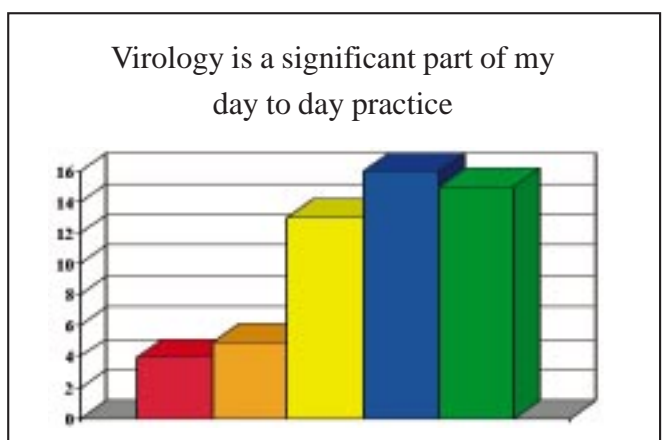
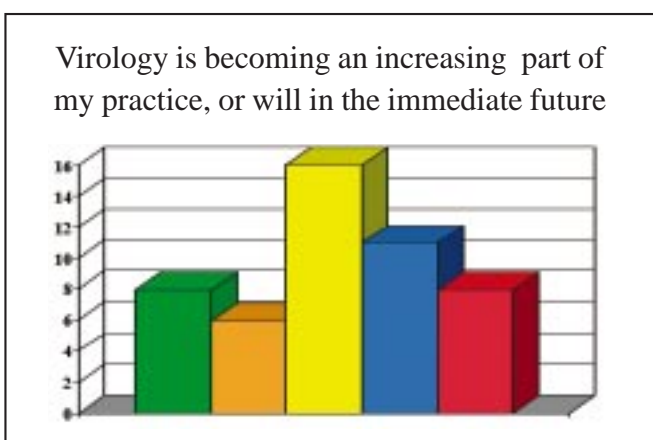
- 1.7.1 There are only 14 NTN in clinical virology in the UK. It has also become more difficult to attract good quality trainees.
- 1.7.2 Workforce planning assumptions have been disrupted by early retirements and by the loss of at least ten accredited clinical virologists to the pharmaceutical industry where their knowledge of both clinical and molecular aspects of virology is highly valued. There has been major retrenchment in academic clinical virology, with the loss of several university chairs.
- 1.7.3 Only 14 grade C clinical scientists provide routine clinical virology. A few others provide a reference or R&D function.
- 1.7.4 A major recruitment and retention problem exists nationally for BMS staff, particularly in virology, caused by poor salaries and promotional prospects. Recent structural changes have resulted in virology joining bacteriology in unified microbiology departments. This has resulted in fewer trainees and a diminishing number of skilled and experienced staff to fill vacant senior posts. The number of BMS4 posts in virology has been reduced to only 6 nationally.
- 1.7.5 The distribution of senior virologists today reflects past patterns of investment and current difficulties in filling posts, rather than current clinical need. The result is a speciality group most of whose practitioners are carrying very large clinical workloads, maldistributed geographically, and with a significant proportion of consultants practising in isolation. With so little chance of promotion, the scientist and MLSO staff are disillusioned and the skills base of the speciality has reached a nadir with serious implications for clinical governance and laboratory practice.
- 1.7.6 Due to the lack of senior staff and pressures from rising workloads, there is diminishing communication between clinical virologists. Most are unaware of what tests other laboratories provide, and there is very little sharing of protocols.
- 1.8 It is difficult to observe all aspects of Specialist Registrar/Calman training in the single-handed setting. This already has implications for training and succession planning as future clinical virologists will not be attracted to these posts.
- 1.9 Without good links to academic centres, there can be little useful translational research carried out and the skills available in the scientific community will not be available to the NHS or public health. This interaction is only likely to occur if there are sufficient consultant-level staff in clinical virology services.
- 1.10 A recent survey by the Network showed there are significant inequalities in provision of diagnostic virology across the UK.
- 1.10.1 Consequently, the NHS will not be able to access appropriate clinical virology services necessary for optimal patient care without improving resourcing for clinical virology laboratories.



- 1.10.2 Many laboratories still perform a large number of serological tests, although molecular techniques for directly targeting pathogens have been available for some time. Perhaps most striking is the proportion of diagnostic samples across the UK, tested by a molecular assay, which ranges from 0 to 0.45. These assays will be required for early detection and possible intervention with antiviral agents. This is not due to a lack of awareness, commitment or enthusiasm, this can only be achieved by research and development of techniques, sharing protocols, increases in equipment/consumable budgets, dedicated training time for laboratory staff and an increase in staff establishment.
- 1.10.3 Virology is currently associated with turnaround times which are not ideal for interventive patient management. These have been improving, but wide scale electronic and transport links are required to make the service optimally clinically useful.
- 1.10.4 It may become increasingly difficult to collate epidemiological information on incidence and prevalence of a number of viral and other infections in the current setting.
- 1.11 Clinical virology and microbiology are interleaved and there are common interests, but they are distinct subjects. The clinical presentations of some infections are similar but the issues for diagnosis, and management are distinct and the state of technology is significantly different. Virologists are also particularly focused on R&D and epidemiological aspects and the paradigm of preventing antibacterial resistance does not apply to viruses. Strong clinical virology services will facilitate, rather than hinder, better information and technology dispersal to all infection-related services.
- 1.11.1 A postal survey of consultant microbiologists and public health specialists in the PHLs was carried out to find out how much of their routine workload involved virological practice, and whether there were any clinical governance issues for these groups. The following details those responses.



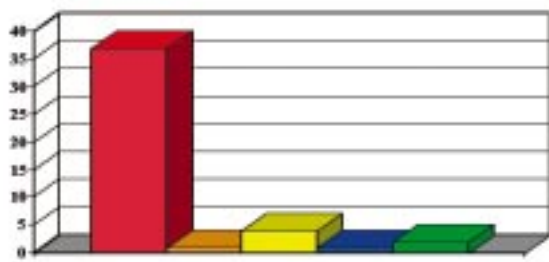
Disagree → Agree



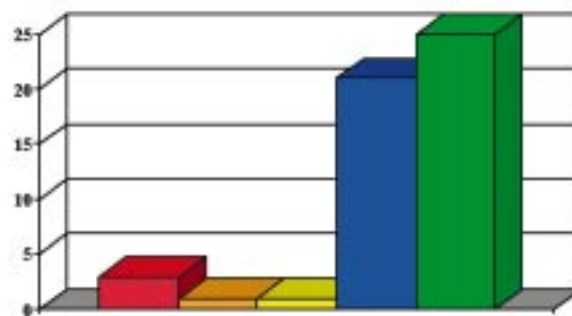


Disagree → Agree

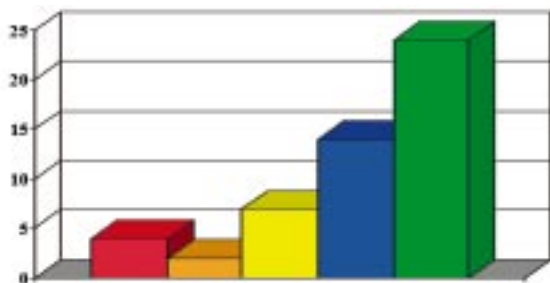
I have been officially asked to take over the virological aspects of our service



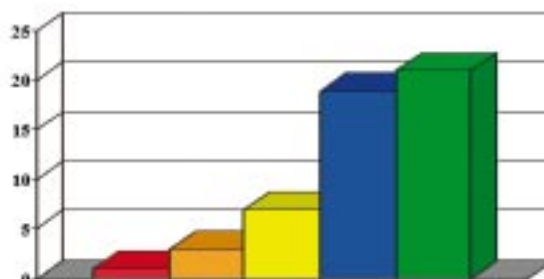
Virology is becoming more complex



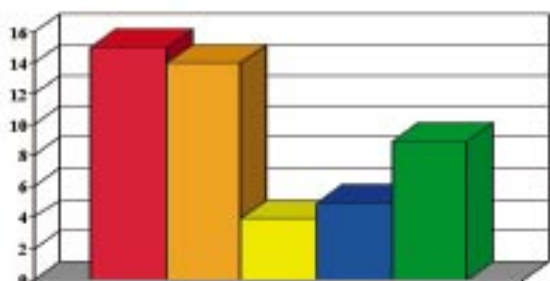
I need regularly updated protocols and guidelines for common everyday virological problems



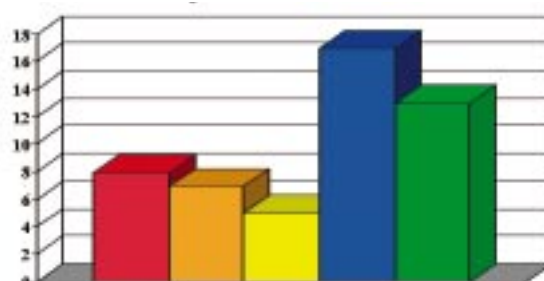
I see updated protocols and guidelines as an important component of my overall CPD/CME



Secondment - brief but regular



Specialist virologist(s) will visit my local laboratory or a venue close to it





2. The current role of the PHLS

- 2.1 The PHLS consists of the Central Public Health Laboratory (CPHL), the CDSC, the Headquarters at Colindale, North London and 52 centrally co-ordinated laboratories, including collaborating centres, organised in eight groups distributed throughout England and Wales. Reference and special laboratories or units are mostly located in CPHL.
- 2.2 PHLS strategy has resulted in around fifteen sites providing virology, excluding reference laboratories. Approximately 19 medical virologists and 9 grade C clinical scientists are based in these laboratories, excluding CPHL. They are generally in, or closely associated with, district general or teaching hospitals. They also serve general practitioners, Consultants in Communicable Disease Control, Directors in Public Health, Regional Epidemiologists and Environmental Health Officers.
- 2.3 The PHLS virology advisory committee and other working groups and fora advance development of good clinical standards of practice, standards for support for cancer services, production of SOPs and algorithms and training programmes. There are 6 PHLS virology specialist registrar posts with NTN.
- 2.4 Through its CDSC, the PHLS collates, analyses and reports information on the prevalence of infection. The regular reports received at CDSC from PHLS and hospital laboratories and other sources form a continuously changing and updated picture of communicable disease throughout the country. This is published weekly in the Communicable Disease Report, which is issued to microbiologists, community physicians and others concerned with disease control.
- 2.5 Microbiologists in peripheral and reference laboratories, together with the added epidemiological expertise of CDSC prevent, investigate and control outbreaks of infections in the community and in hospitals. Most PHLS laboratory Directors or consultants act as the hospital Control of Infection Officer. Evaluation of the effectiveness and safety of many of the immunisation programmes in current use falls to the PHLS Immunisation Division in CDSC, which also investigates new immunisation procedures.
- 2.6 CPHL is the major national centre for reference and specialist microbiology in the UK, providing a significant proportion of such services for Scotland and Northern Ireland. These services are underpinned by a strong research and development base, national resource collections and a continuing education and personal development programme. We propose that the virology component becomes The Clinical Virology Network Reference Laboratory.
- 2.7 The PHLS is often asked to advise central and local government and the NHS on aspects of infection and communicable diseases. The PHLS maintains close contact with veterinary organisations in areas of mutual interest, and collaborates with the World Health Organisation and with national laboratory and epidemiological services overseas.
- 2.8 The HPA will take on the functions of the PHLS in 2003. This will create a period of uncertainty, as the detection of infection and infectious agents, and resulting epidemiological analysis, investigation of outbreaks, development of strategies for prevention and control, and the provision of advice, may be compromised. The UK virologists are concerned that these facilities and the expertise built up over decades may be compromised if they are not integrated, in an enhanced manner, into a national Network. The added advantage is that NHS and other laboratories will be included, thus their strengths will be added to those of the current PHLS.





3. The role of a clinical virologist

Over the past decade the clinical virologist has evolved from the laboratory test-focused pathologist undertaking non-urgent clinical investigations and epidemiology studies, to a patient-focused laboratory medicine specialist delivering disease-specific investigations rapidly, reliably, with quality assured results. They provide management strategies and clinical opinions which facilitate optimum treatment, aiding patient recovery and early discharge. Laboratory-based grade C clinical scientists supervise quality assurance programmes, provide the expertise for the development of clinically relevant new diagnostic assays, and provide specialist reference tests and advice. These roles are complementary. The table lists the roles of clinical virologists as a sessional commitment

3.1 Clinical work

Clinical virology is concerned with diagnosis, interpretation of tests, clinical advice on management including treatment, and the prevention of viral infections. These will remain core daily functions of the clinical virologist, increasingly complicated by newly recognised infections or old ones re-emerging, and rapidly expanding diagnostic, therapeutic or preventive options. Those with accredited specialist training and experience will perform these tasks best.

3.1.1 Today's clinical virologist is a member of multidisciplinary clinical teams – infectious diseases, HIV, hepatitis, solid organ, peripheral blood stem cell and bone marrow transplantation, sexual health/genitourinary medicine, obstetrics, paediatrics, oncology and occupational health. Clinical virologists have individual consultant referrals in the hospital and outpatient clinics.

Many virologists have clinical sessions, a common example being the HIV/GU Medicine Clinic. Clinical virologists provide HIV diagnosis, viral load measurements and virus sequencing data, together with knowledge of antiviral pharmacokinetics and treatment efficacy data for the effective use of these agents. The clinical virologist is now required to provide expert guidance on new antiviral drug combinations in conjunction with antiviral resistance monitoring from the expanding arsenal available. This is best done in a team setting between the HIV physician, clinical virologist, pharmacist and HIV nurse/health advisor.

This role is also critical in parallel clinical settings such as viral hepatitis, bone marrow and solid organ transplantation. The use of the antiviral agents aciclovir, valaciclovir, famciclovir, ganciclovir, foscarnet and cidofovir for the herpes group of viruses (HSV, VZV, CMV, HHV 6), cidofovir/ribavirin for adenovirus infection, zanamivir/oseltamivir/amantadine for influenza, pleconaril for enterovirus infections and interferon/ribavirin/lamivudine for hepatitis infection, can significantly improve clinical outcome for the most vulnerable patient. These agents are most effective when the infection can be monitored for antiviral efficacy and the development of resistance. This requires active collaboration between physicians and virologist.

3.1.2 Each day brings consultations from general practitioners, nurse practitioners, clinic sisters, community nurses and midwives on a wide range of issues, regarding the investigation and management of infection-related diseases, infections in pregnancy, needle/sharps injuries, vaccine administration, tropical diseases and public health outbreak control. The increased frequency of overseas travel brings daily consultations on the use of vaccines and immunoglobulins before departure, and the investigation and management of fever in the returning traveller. This role is expanding as nurses take up a more clinically responsible role in patient care and improve the follow-up management of patients. Despite this, Trusts and their funding agencies, although expanding the clinical services through new appointments, do not always recognise the need to support this with adequate resource in virology services.

- 3.1.3
- The advent of rapid diagnostic tests such as the direct detection of viral antigens in samples of respiratory secretions (e.g. influenza), skin rashes (e.g. VZV), stool samples (e.g. Norwalk virus), urine samples (e.g. adenovirus) and blood (e.g. hepatitis B virus) has led to prompt diagnosis, treatment and infection control.
 - The wider use of NAT for qualitative detection or quantitative (viral load) evaluation e.g. hepatitis C, hepatitis B, HIV, CMV, HSV, VZV, enterovirus, HHV 6, adenovirus and EBV, has provided new levels of service provision in respect of sensitivity, specificity and turn-around times bringing virology into the fold of 'urgent' and necessary investigations. These initiatives have enabled a reduction in unnecessary antibiotic and other medical treatments.
 - The availability of a choice of antiviral treatments and a range of immunoglobulins and vaccines, all of which provides enhanced virus targeting when applied with professional skill and application.
 - Many treatments or diseases render the patient immunocompromised allowing the reactivation of endogenous viruses with more serious disease. As the number of these units increase, there is a need to increase the investigative and management support units associated with their work. Clinical virology is one of these associated healthcare units.



Consequently there is a requirement for

- a) Laboratory-based clinical duty sessions.
- b) Sessions for rounds or liaison on the wards or at clinics, which include attendance of varying length in different places, depending on the patients, type of units and number of acute hospitals to be covered.
- c) Out-patient clinics, for example for hepatitis or HIV.

3.2 Links with District General Hospital Microbiology laboratories

As more virology kits for automated analysers are introduced at DGH microbiology laboratories, managers will appoint microbiologists with additional training in virology. This will impose an extra burden of training on virology consultants. Specialist Virology Centres will continue to be the referral point for clinical virology advice and specialised virological investigations for the DGH. Regular interaction facilitates equal and up to date clinical virology service provision across the country. Regional audit, dissemination of guidelines and good practice facilitates clinical networking within the speciality of infection.

3.3 Clinical governance

Sessions for infection control, audit and clinical effectiveness and occupational health matters are required with some flexibility required for peaks of activity.

3.4 Research, development and reference

Clinical virologists have been and will remain active in research and development. Individual expertise has led to specialist services that were not considered appropriate for every regional laboratory until they became feasible common practice, as with HIV viral load tests.

Current reference functions include antiretroviral susceptibility assays, hepatitis C genotyping, and hepatitis B virus quantitation for occupational health. The next five years will see other services becoming available on a referred basis such as papillomavirus detection in cervical screening, and genotyping of newly-diagnosed HIV.

Sessions for R&D will vary as to the extent of medical staff involvement; they are seen to be a significant part of clinical scientist time, as are sessions for laboratory quality assurance supervision.

3.5 Public Health

The clinical virologist is the major source of clinical advice to local, regional and national professional and public enquirers on virus-related issues. They have an integrated part in the local infection control team, managing high-risk exposures to patients and staff, liaise with Consultants in Communicable Disease Control and Regional Epidemiologists, advising them of the current trends in virus endemicity, management of cases, contracts and outbreaks of infection. They are involved in the reporting of notifiable diseases to local CCDCs and to CDSC and the investigation of infections of public health importance, particularly when there is local laboratory expertise in reference laboratories.

3.6 Teaching and training

Teaching medical, dental, biomedical sciences and nursing undergraduates

Most virologists work in cities with medical schools and they will be expected to contribute regularly to teach the students. This is going to be particularly important as the number of clinical academic virology posts has fallen dramatically. The new curriculum features much more small group teaching, problem-based learning and early clinical correlation, all requiring considerable staff-student contact time. Sessions for university undergraduate teaching are timetabled, and so fixed.

Trainee SpRs in virology, microbiology, infectious diseases, sexual health

The training of these juniors and some from other specialties is a substantial undertaking in any regional virology laboratory, where there may also be clinical scientists in training. The commitment to training microbiologists in virology will increase, as additional virology experience is required.

There are teaching duties in relation to postgraduate staff, infection control nurses, midwives and occupational health staff, but these have to be absorbed within daily duties. There is a growing pressure from clinical microbiologists in local DGHs for regional virologists to establish more educational links for protocol development and quality assurance.

3.7 Professional

The experienced or specialised clinical virologist is asked to contribute at regional or national level in an advisory capacity. This can be in regard to training, examining for MRCPATH, appointments in the speciality, assessment of new technologies or developing guidelines, providing a referral service, or advice to broader NHS management. These senior committees take time in preparation and responding to consultative papers as well as attendance. The proportion of time varies for any individual over the years, but will entail absence on professional leave of a senior staff member many days in any year. The developments related to assessment of professional competence and stricter accreditation standards will also have an impact. Some of the unallocated sessions will be required to cover for such duties.



Sessions for four Consultant Clinical Virologists in a regional tertiary care centre ¹	
Type of duty	Sessions per week
Lab based clinical duty – advice / test selection/result authorising	10
Ward liason/rounds	4
Out-patient clinics	3
Infection control and outbreak management	2
Audit/clinical effectiveness	2
Occupational Health	0.5
Research and development ²	4
Laboratory QC ²	0.5
Teaching and Training	4
CPD	3
DGH microbiology liason	2
Administration/management	5
Total available for 4 FTE excluding on-call	40
<p>1 Based on a Specialist Virology Centre serving two or more acute teaching hospitals with several tertiary referral units, occupational health unit, a medical school, and specialist virology from regional DGHs. There are 3 consultant clinical virologists (which may include 1 grade C clinical scientist with appropriate experience and written MRCPATH in Virology) at each SVC;</p> <p>2 Responsibilities predominantly of Grade C clinical scientist without a significant commitment to provision of clinical services;</p> <p>Note: leave entitlement per annum / consultant:- annual leave (6 weeks) = 60 sessions; public holidays (10 days) = 20 sessions; study leave (10 days) = 20 sessions. Total sessions in working week, excluding on-call, are 10 per full time consultant; 40 in week for 4 equivalents.</p>	

3.8 Management

Some consultant virologists will take on management of a laboratory service; a few progress to senior management roles in Trusts. All consultant virologists are responsible for the consensus element of management in their laboratory and play a lead in maintaining the visibility of the virology service, ensuring it is in a position to contribute to maintaining and improving performance standards of the organisation.

Sessions are allocated for virology service administration for one consultant, excluding annual leave. This would include work relating to special services funded from central government.

3.9 Continuing professional development

Clinical virologists in the UK meet with scientists to learn about and discuss a wide range of virology issues in the Clinical Virology and Virus Groups of the Society for General Microbiology. The European Society for Clinical Virology has over 80 UK members. This link with European colleagues has been of great benefit in progressing rapid virus diagnosis and establishing quality assessment programmes for molecular diagnostic work. There are an ever rising number of single-subject meetings, for example, on management of hepatitis or HIV, on infections in oncology, or on issues relating to transplant patients.

4. Workload and distribution of work between Specialist Virology Centres/Units and DGH microbiology laboratories

4.1 The complexity and range of tests carried out in a diagnostic laboratory will depend on the patient population and presence of specialist units such as cancer centres, solid organ transplantation, bone marrow transplantation, renal dialysis, genitourinary medicine and HIV, infectious diseases, paediatric ITU, obstetrics with attached fetal medicine unit, occupational health service and regional neurology. There is a need for 'out of hours' work, especially in transplantation centres.

4.2 The specialist virology laboratory workload consists of virus isolation, electron microscopy, immunofluorescence, NAT and serological analysis. The range of these activities in different virology laboratories may be wide and include testing for Chlamydia, which can be a substantial workload, in addition to a full range of other bacteriological, mycological and parasitological serology, some of which will be sent to appropriate reference facilities. Most virology laboratories will carry out a range of NAT assays, which require technical expertise, dedicated laboratory space and a degree of clinical interpretation



depending on the assay. Over the last 5 years, qualitative and quantitative detection of viral genomic material has increased enormously together with the advent of antiretroviral resistance testing by genotypic analysis.

- 4.3 In most DGHs, core virology testing is carried out under the direction of medical microbiologists, some of whom have a special interest in virology. The core tests may include immunofluorescence based assays for respiratory virus antigen detection, HIV antibody, hepatitis B surface antigen, anti-HB surface, hepatitis C antibody, rubella IgG, varicella zoster virus IgG and EBV monospot assays. Depending on the patient population, a wider portfolio of tests may be carried out.
- 4.4 The issue of specialist and core virology has been examined by the CPA. Their guidance includes criteria for the requirement of specialist virology CPA assessors. Presence of one or more of the major criteria is sufficient to require specialist virology inspection. The presence of a number of minor criteria and an exclusion category are included to help distinguish those microbiology laboratories providing a fairly comprehensive repertoire of virology tests from those performing a number of screening assays.
5. **Response to the crisis in clinical virology and to the CMO of England's strategy for infectious disease – a model to provide specialised virology services with equal and improved outputs across the UK and Eire**
- 5.1 Meetings were held in September 2000, September 2001 and April 2002, at which attendance of senior medical and scientist virologists was high, to identify more clearly the problems facing the profession and to seek ways to address them. It was decided to re-organise the speciality into Specialist Virology Centres (SVC) and Units (SVU) with strong links to DGH Microbiology Services and Public Health Laboratories under the umbrella of a UK Clinical Virology Network (UKCVN).

Achievements of UK Clinical Virology Network Mid 2002

In the short time since its creation, the UK CVN has:

- Reached agreement with Virologists nationally on the principles of establishing a managed network.
- Agreed a Mission Statement and a constitution
- Elected a representative Network Committee, Working Group and Chief Executive Officer (Professor Paul Griffiths) to take forward the Mission Statement. The Working Group will meet four times a year and the full UKCVN committee twice a year.
- Defined the criteria for Specialist Virology Centre and Specialist Virology Unit, ensuring that these are compatible with the needs of national quality CPA standards.
- Prepared draft job descriptions and business plans to help colleagues seeking to address the problem of single-handed clinical practice.
- Established electronic links among members for dissemination of information
- Established a dedicated website (www.clinical-virology.org) to allow two-way communication, including feedback on initiatives and revisions of proposals.
- Begun to roll-out best practice across the UK by disseminating standard operating procedures, protocols and clinical trial information to all members. The working group has begun to prioritise and commission a wide range of activities for the benefit of the Network and the practice of clinical and public health virology.
- Entered into negotiation with the Department of Health to transform the vision of a managed network into reality.

Mission statement

The Network will consist of a linked and co-ordinated group of laboratories and clinical virologists distributed in all major centres throughout the UK and Ireland performing modern and quality assured assays. It will provide evidence-based and practical virological advice to the CMOs, Health Protection Agency and other national bodies on all aspects of viral diseases. There will be a close relationship with bacteriology laboratories. The Network will ensure there is a uniform approach to surveillance, a rapid but considered response to virological emergencies, centrally agreed protocols for the management of viral diseases and will ensure the establishment of best laboratory practice.



The following has been agreed nationally :

- 5.1.1 There should be a national UK strategy for clinical virology based on the provision of a stable, high quality service, working to common standards, responsive to local needs, and with equity of access across the country.
- 5.1.2 The senior staffing of each SVC should be: three consultant clinical virologists one of whom could be a Grade C clinical scientist with substantial clinical experience; one grade C clinical scientist (whose primary role is to drive research and development – R&D); at least one grade B clinical scientist devoted to R&D; and a BMS 4.
- 5.1.3 There is a continuing need for high quality surveillance of a range of viral infections including respiratory, sexually transmitted, blood-borne and vaccine-preventable infections.
- 5.1.4 Delivering such services from up to 20 SVC and about 10 SVU would be population and service based; this will be compatible with the Pathology Modernisation Programme and the distribution of cancer services.
- 5.1.5 There would be a Clinical Virology Network Reference Laboratory (CVNRL) service, subsuming the VRL of the PHLS which would provide quality assurance and reference facilities to the UKCVN.
- 5.1.6 One of the functions of CVNRL will be to develop new assays and compare them to commercial equivalents to decide on the best and most cost-effective assays to roll out to UKCVN members.
- 5.1.7 There is excellent potential in such a model for SVC to provide clinical support, and regular training and updates, to medical microbiologists working in DGH in their vicinity. There will be regional committees co-ordinating virology services.
- 5.1.8 There is a need to draw to the attention of Workforce Development Confederations the case for an increase in the numbers of consultant medical virologists, clinical scientists, and the issues in recruitment and retention of BMS and other staff.
- 5.1.9 There is significant added value in bringing together all clinical virologists, consisting of those currently employed by the PHLS, NHS and Universities, who would have regular meetings and agree defined outputs. These include :

development of standardised clinical, laboratory and training protocols

development of national quality standards

timely and more complete dissemination of professional and management information

regular updating of workforce planning information, ensuring timeliness and accuracy

a wider patient base for clinical and laboratory audits

improved interaction between all staff including trainees in different centres

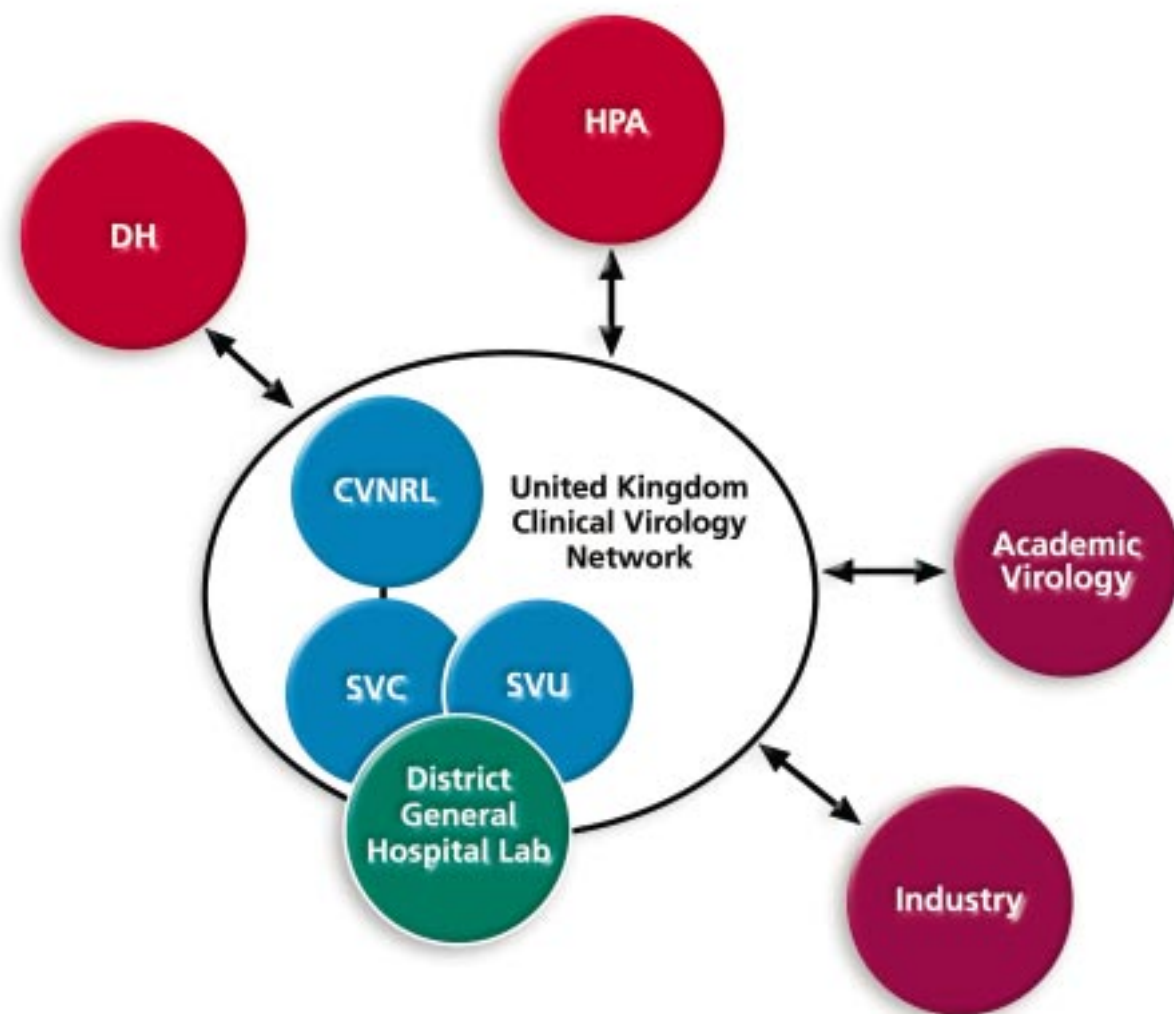
- 5.1.10 There should be improved interaction with main stakeholders including DH, universities and the HPA.
- 5.1.11 There is a need to support single-handed consultant virologists in the short term, and in the medium term to look to a redistribution of consultant clinical virology posts so that single-handed practice is phased out over time.
- 5.1.12 There is an urgent need to increase the rate of deployment of NAT over the next 5 years. Currently, overall usage is below clinical expectations and service provision is unequal across the country.
- 5.1.13 There is a need to create a sufficient number of training centres and training posts to safeguard succession planning, and in doing so, recognising the value of close interaction between PHLS/HPA, NHS and universities. This would attract sufficient numbers of good quality trainees into the profession.
- 5.1.14 There should be close links fostered with other organisations involved in clinical virology issues such as the Royal College of Pathologists, the Association of Medical Microbiologists and industry.



5.2 The proposed model

The UKCVN will be a centrally co-ordinated group of laboratories striving to work towards agreed protocols and management algorithms. Each local area virology Network would consist of a SVC based in an academic environment, liaising with SVU and/or DGH microbiology laboratories. The latter would offer a core virology service and work closely with the SVC. The Figures detail the links and interactions between the national stake holders in the proposed model of virology service provision and how a local area clinical virology network would function.

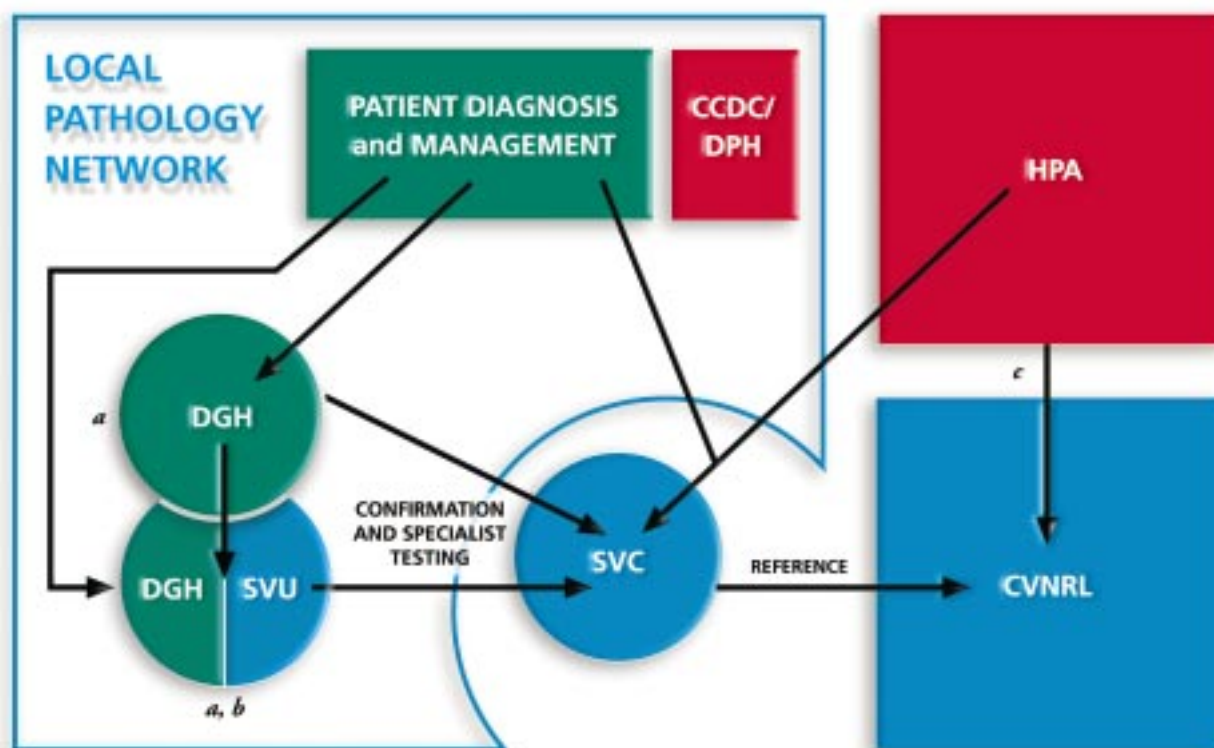
The National Structure of the UKCVN A collaborative clinical network



Colour key	Description
Blue	Specialist Clinical Virology
Green	Linked laboratories
Red	Provision of services by UKCVN
Mauve	Clinical trials and joint projects



Flow of virological samples and requests within a local pathology network



The local area virology network will be managed by a committee under the Chairmanship of the lead Consultant of the SVC.

NOTES

- Some DGH will be SVU
- In some areas, there will not be an SVC immediately; consequently specimens will be referred to an SVU.
- Some public health/epidemiology samples of a highly specialist nature will be referred directly to CVNRL.

5.3 Specialist Virology Centres

Large, adequately funded, laboratories have a number of advantages:

- 5.3.1 There are sufficient experienced senior staff to discuss difficult cases, to attend important meetings and keep abreast of the scientific literature in this rapidly evolving field, to represent virological issues on regional, national and international committees, to liaise with other specialist and DGH laboratories, to provide sufficient clinical cover, including on-call, and to have "quality time" to train Specialist Registrars and grade A and B clinical scientists.
- 5.3.2 There are sufficient resources to collaborate with public health and epidemiology teams to ensure timely and accurate reporting of notifiable diseases and outbreaks.
- 5.3.3 Centralisation of confirmation of all notifiable virus infections would, in particular, ensure timely and definitive reporting of blood-borne and sexually transmitted infections.
- 5.3.4 There is sufficient consumable budget to allow evaluation of new assays and technologies, to respond effectively to outbreaks, and to cope with surge demand.
- 5.3.5 The equipment budget would ensure that a local repository could be maintained to store clinical samples and isolates for future use, to purchase new molecular technology, IT hardware and software. This would allow effective communication within and outwith the laboratory.
- 5.3.6 There is a suitable environment for medical, scientific and BMS trainees, to underpin future service provision.



5.4 20 SVCs will be set up at tertiary referral centres with medical schools that will be resourced to meet the above objectives. The essential features of each of these laboratories are as follows :

An SVC would provide a clinical service for a hospital(s) which could include two or more types of transplantation (solid organ and BMT), an ID unit, sexual health department with large HIV/AIDS population, specialist neurology unit, neonatal and fetal medicine unit, and haemodialysis unit. This is in line with the DHs 'Modernisation of Pathology' document, which suggests Pathology Networks should serve populations of 1.5 to 2.5 million. They should be sited wherever there is a Medical School. There may also be an Academic Virology department.

Service level agreements will be agreed nationally between the HPA and the UKCVN to provide public health information and epidemiological data for the HPA. This will ensure geographical equality of data.

There should be 3 consultant clinical virologists with MRCPATH by examination, one of whom will be Head of Department. Some post-holders will be grade C clinical scientists with substantial experience in clinical virology and so be seen as joint and equal members of the clinical team at consultant level.

Grade C clinical scientist. The role of this additional person is primarily laboratory based with a focus on excellence in R&D and a role in quality management.

Grade B clinical scientist, dedicated to R&D and working under the supervision of the Grade C Clinical Scientist.

1 BMS 4 in virology in accordance with the recommendations of the IBMS Code of Professional Conduct and Code of Practice for Biomedical Scientists. Informed and considered workforce planning should be undertaken through local Workforce Development Confederations. The Government's Healthcare Scientist strategy will be supported by the introduction of the Advanced Biomedical Scientist practitioner grade in virology.

At least one Specialist Registrar

A quality manager.

Appropriate staffing with a mix of trained experienced staff and trainees to cope with the diagnostic workload, R&D, training requirements and CPD. This can be any mix of BMS, MLA, clerical and grade A and B clinical scientists.

The 2 year horizon, once the UKCVN is properly set-up, for the ratio of diagnostic samples tested by one or more NAT assays: 0.3.
The 5 year horizon for the ratio of diagnostic samples tested by one or more NAT assays: 0.6.

The SVC would take responsibility for the quality of the clinical virology service across its catchment area and would liaise via the Virology Committee in order to take advantage of the combined expertise.

There should be nationally agreed curricula, approved by the College, for the training of virology SpRs and Clinical Scientists. Training will be reviewed by the Royal College of Pathologists in conjunction with the UKCVN committee. It will no longer be allowed in centres where appropriate resources are not available or if the track record is poor, as decided by the UKCVN committee, with approval by the College. In this way future standards will be improved. Training of each SpR should take place in two SVCs, if geographically possible, to allow a broader experience.

5.5 Specialist Virology Units

The SVC should develop and evaluate techniques centrally, some of which may be performed in the SVUs. The SVU would be led by either a consultant medical virologist, a grade C clinical scientist with MRCPATH in virology or a microbiologist with a proven commitment to virology. The microbiologist would have the MRCPATH, a CPD portfolio ratified by the Royal College of Pathologists as demonstrating continuing virological education, be a member of the area virology committee, and have a formal working arrangement with the SVC. The UKCVN committee will approve the SVU status of a laboratory. The range of tests are listed in section 4.3

5.6 Clinical service provision across the catchment area of the SVC

5.6.1 The lead consultant at each SVC would chair an area virology committee, with members drawn from all consultant level staff involved in providing clinical virology services. This committee could define which services are provided by the SVC, SVUs and DGHs. The role of CPA would be important in this regard.

5.6.2 One of the most important functions of the SVC in this catchment area would be to enforce participation in National External Quality Assurance Scheme (NEQAS) and overseas quality assurance schemes.



Proposed Specialist Virology Centres

Belfast

Birmingham

Bristol

Cambridge

Cardiff

Dublin

Edinburgh

Glasgow

Leeds

Leicester

Liverpool

London East (Royal London/Barts)

London North (Royal Free/UCL/GOS)

London South (Dulwich and Kings/ St Thomas'/Guys/St George's)

London West (St Mary's/Chelsea and Westminster/Charing X/Hammersmith)

Manchester

Newcastle

Nottingham

Oxford

Sheffield

Proposed Specialist Virology Units

Aberdeen

Dundee

Hull

Inverness

Norwich

Plymouth

Preston

Southampton/Portsmouth

Note: we propose that there be 20 SVC and an undetermined number of SVU (around 10) throughout the UK. SVU could evolve to SVC dependent upon local needs

5.7 Liason between SVCs across the UK – the role of the UKCVN Committee and CEO

Although it may not be possible to decide which tests and protocols should be used across the UK, all SVCs should agree to achieve as much consensus as possible. The UKCVN committee has 12 elected and ex officio members, each of whom serves for 3 years. Ex officio members are: chairman of the Royal College of Pathologists Virology subcommittee; Chief Examiner in Virology, Royal College of Pathologists; a Postgraduate Dean; and a nominee from the Department of Health. The CEO will be elected and serve for 3 years. A working group will support the CEO in setting priorities, organising literature searches, rolling out suggested assays and collating information. Results of endeavours will be posted on the website (www.clinical-virology.org) and be presented at annual meetings. The CEO will be the first point of contact with the UKCVN by The NHS and government agencies, including the DH and HPA.

It is proposed that all lead consultants at the SVCs meet once a year for at least a day to discuss matters of common concern. Such interaction could, for example, pave the way for centrally co-ordinated trials of antivirals, with a lead SVC, funded by government agencies. This would greatly improve the competitiveness of UK virology and would reinforce the rationale for the pharmaceutical industry to remain in UK and Eire and use our laboratories. This would have tangible spin-offs for clinical departments with patients to enrol in trials. A co-ordinated approach would also allow new technology to be cost-effective because of the enhanced buying power.

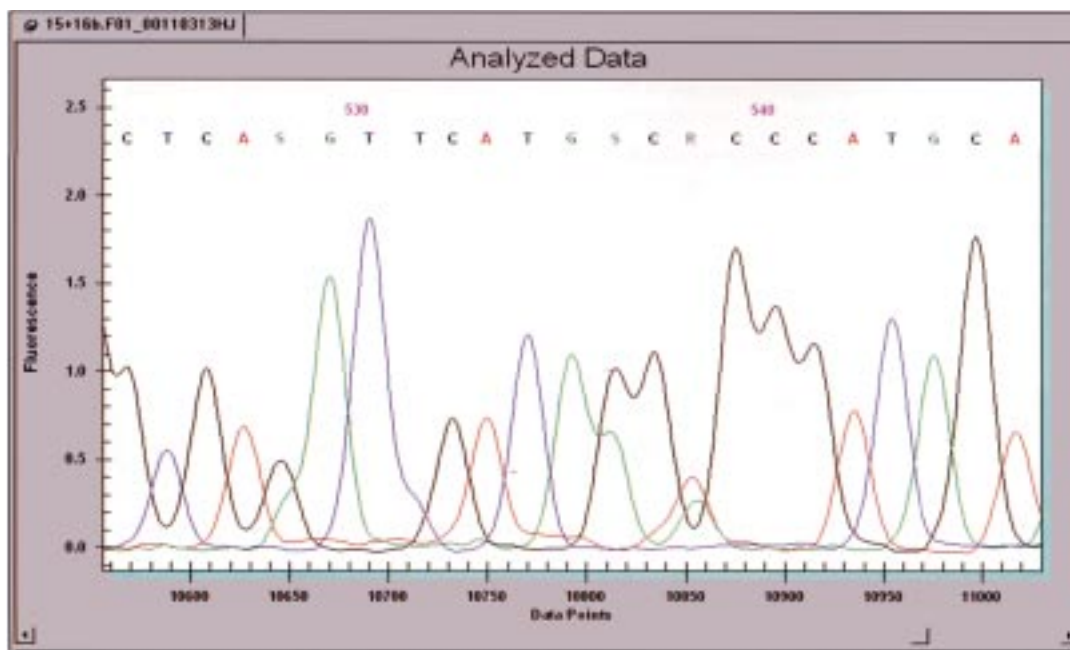


5.8 The role of the SVC in public health

- 5.8.1 SVCs will be the major contributors, by far, of viral epidemiological data to the HPA, SCIEH and other bodies. Consequently, this activity will have to be properly funded to ensure that reports are timely, using modern computer links. Clinical Virologists have traditionally been at the centre of the investigation of outbreaks due to viral infections. Many will have maintained databases of infections, particularly those due to blood-borne viruses, respiratory viruses, and infectious agents, including chlamydia, associated with sexually transmitted diseases at the local level as well as reporting to relevant regional and national epidemiological bodies. The particular expertise in the epidemiology of blood-borne viruses has been widely recognized in its importance in the protection of the blood supply and in the evaluation of risks in particular groups such as haemophiliacs, intravenous drug users, and more recently the prison population. The study of the associations of viruses such as cytomegalovirus in transplant populations has been crucial in developing strategies for monitoring and targeted therapy.
- 5.8.2 At both local and national levels, successful surveillance of virological disease and the monitoring of trends in viral infection will require SVC data and close collaboration with the regional director of public health, the public health team, and epidemiologists at, for example, CDSCs and SCIEH. Centralised reporting will ensure accurate incident infection data.
- 5.8.3 From a public health perspective, this is particularly relevant to the monitoring of the vaccine-preventable infections including measles, mumps, rubella, hepatitis A and B. The clinical reporting schemes also require the backup of robust laboratory data to ensure accuracy of reporting, particularly of childhood rashes where clinical diagnoses are notoriously unreliable. In addition, many of the SVCs and SVUs will also be involved in diagnostic work highlighted in the Sexual Health strategy. In particular, chlamydial, treponemal, and herpetic infections. Targeted surveillance schemes such as those for respiratory syncytial virus and influenza viruses will remain priorities for the SVC.
- 5.8.4 The role of the SVC is critical in the monitoring of infections that are being eradicated. The eradication of poliomyelitis is imminent, and the continuing monitoring of enteroviral isolates will be maintained through SVCs using tissue culture and molecular diagnostic technologies.
- 5.8.5 The increasing availability of antiviral drugs is leading to the need for antiviral susceptibility tests, principally for HIV, but also for the herpesviruses and, in the near future, hepatitis viruses. Testing tends to be genotypic and will be part of the SVC repertoire. Antiviral susceptibility data, generated in SVCs, should be fed into a national database.
- 5.8.6 Data collection and transmission is likely to be enhanced by having a designated individual in the SVC responsible for data management. This might be the individual responsible for information technology (IT) within the SVC, or might fit in with the responsibilities of the SVC Quality Manager. The provision of epidemiological data by the SVC is a quality issue and is part of the added value that a large laboratory can offer. To this end the SVC must be supported by the feeder laboratories of the Network or by the epidemiological agencies in terms of personnel and IT infrastructure. The sophisticated facilities in each SVC will allow the timely and meaningful investigation of outbreaks. Routine surveillance will continue to be based on routine laboratory reporting schemes. The SVC will need a substantial throughput of service work to allow fulfilment of its epidemiological roles.
- 5.8.7. To achieve this critical goal, it is proposed that Service Level Agreements are set up between the HPA, or its agencies, and other national bodies interested in obtaining epidemiological data, and the UKCVN. Another appropriate initiative would be for the HPA or its equivalents in the rest of the UK to fund consultant sessions at Network laboratories. The CEO will lead this process on behalf of the UKCVN.
- 5.8.8 A programme to audit epidemiological performance should be agreed and implemented.
- 5.8.9 The SVC should have available appropriate modern virological diagnostic and typing methods so as to offer rapid investigation and timely epidemiological typing services.



Sequencing of HCV strains from a transmission event from a health care worker to three patients



5.9 Website (www.clinical-virology.org)

This will be the primary information dispersal system of the UKCVN and will be managed by the working group and CEO of the UKCVN. Protocols and algorithms will be available to all members. Lists of current R&D, papers and newly developed guidelines will be accessible. Commonly asked questions, with responses, will be posted and continually updated. We hope this medium will become the primary source of good quality, reliable information on clinical virology in the UK, and perhaps further afield.

5.10 Research and Development

At present there is general commitment to research and development within the larger virology laboratories which will form the basis of the network of SVCs. There is a long history of substantive research from clinical virologists, both basic and applied, including the discovery of the hepatitis B surface antigen, the recognition of the clinical importance of hepatitis B mutants, the characterization of hepatitis A virus and its adaptation for vaccination, the discovery of parvovirus B19 and the use of electron microscopy in finding enteric agents including rotaviruses, adenoviruses, astroviruses, and Norwalk-like viruses. Current examples include introduction of new technologies for virus diagnosis, monitoring and typing, assessment of antiviral susceptibility, application of real-time quantitative PCR assays, continued application of sequencing, introduction of microarray technology, and investigation of Luminex and mass spectroscopy.

Thus, in the future, the SVC will have significant research and development outputs including basic research, applied research, clinical research and technology developments and evaluations. R&D will be the primary function of grade C Clinical Scientist with assistance from one grade B. However, throughout, the R&D work will be linked with the training needs of healthcare scientists and Specialist Registrars, so ensuring that these dual missions of the Network inform and reinforce each other. There will be opportunities for projects to be performed by healthcare scientists pursuing vocational projects as part of MSc training in virology. Basic research is likely to be undertaken in SVCs with close links to university departments. Such work should be encouraged within the constraints of organizational priorities and funding. Clinical or applied research is likely to be more commonly undertaken because it sits more easily with the routine commitments and ethos of most clinical virology departments. Once developed, the technology will be transferred to other laboratories within the UKCVN.

The importance of SVC R&D will be recognised by submission of progress reports to an expert panel of senior Virologists active in R&D. This panel will encourage and support R&D throughout the SVC network, will help to identify external funding opportunities, and will foster collaborative efforts among SVCs. The panel will also select R&D presentations as part of the annual meeting of the CVN.



5.11 Improved outputs

The formation of a comprehensive clinical virology Network of accredited laboratories will deliver several key objectives identified in the DH strategy for combating infectious diseases by:

Developing and adopting agreed Standard Operating Procedures, clinical guidelines and disease management policies. This will reduce “reinventing the wheel” across the UK. We will ensure participation in a wide range of national and international quality assurance schemes;

Providing timely, high quality and accurate surveillance reports to national public health bodies such as CDSC and SCIEH. This will include coverage, amongst others, of a range of viral infections including respiratory, sexually transmitted, blood-borne and the vaccine-preventable infections such as measles, mumps, rubella, hepatitis A and B. This will be provided under service level agreements with the HPA or its agents;

Establishing a co-ordinated system for evaluating and managing the introduction of new technologies. For example, the use of near patient tests will require careful evaluation and will require quality assurance support from accredited laboratories;

Providing a framework for clinical governance, which will include providing updates for microbiologists and carrying out clinical and laboratory audits;

Centralising confirmation of all notifiable virus infections ensuring timely and definitive reporting of bloodborne and sexually transmitted infections;

Contributing to HPA/DH rapid risk assessment and providing technical and scientific expertise to respond to natural outbreaks or deliberate releases of virus infections. For example, the Network is currently preparing a response to the potential deliberate release of smallpox virus including a rollout of rapid assays derived from three laboratories within the Network for the detection of vesicular rash causing pathogens.

Other measurable outputs include:

The development of a continually updated UK Clinical Virology Network website for sharing reliable, robust and accurate information on virology between members of the Network and any other interested parties such as CCDC, microbiologists, clinicians members of the public and the government;

The deployment of nucleic acid diagnostics, quantitation and typing will be rapid and co-ordinated nationally;

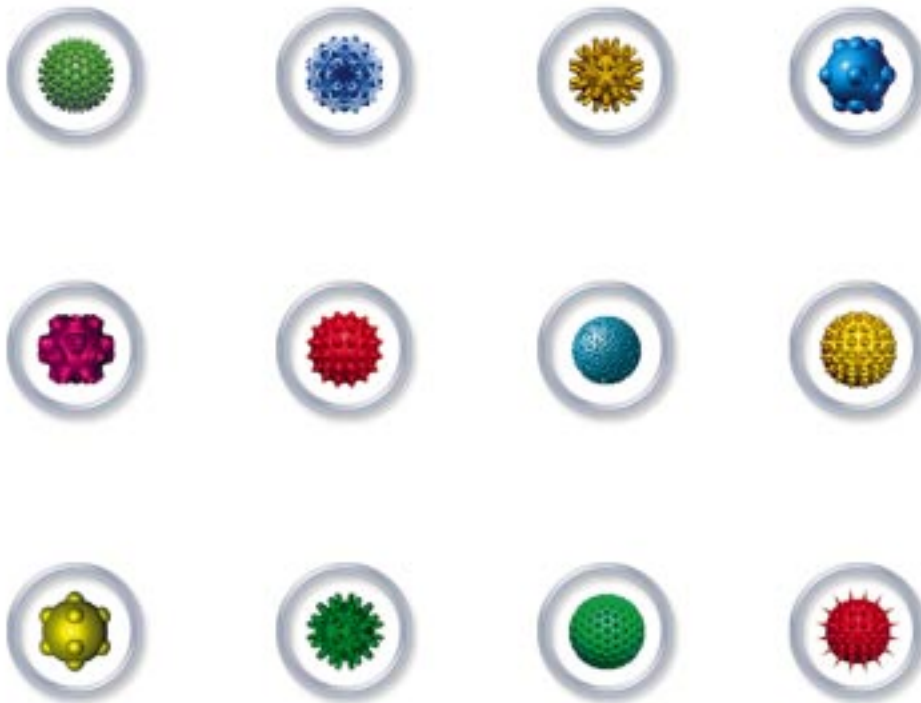
The provision of a stable, high quality national virology service, working to common standards, responsive to local needs, with equity of access across the country;

Provision of clinical support, and regular training and updates to medical microbiologists working in district general hospitals in their vicinity;

A centralised point of contact for virology for workforce development confederations to discuss the case for an increase in the numbers of consultant medical virologists and clinical scientists.

Other issues of relevance (eg: The training of clinical virologists; Medical and scientific consultant virology job plans; The role of the Specialist Virology Centre in research and development and epidemiology; Academic virology) are available at www.clinical-virology.org

This proposal was written and approved by the UKCVN in collaboration with the Royal College of Pathologists, the Institute of Biomedical Sciences and the Association of Clinical Microbiologists.



www.clinical-virology.org

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