ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

ANNUAL REPORT 2011

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1. INTRODUCTION

The Advisory Committee on Dangerous Pathogens (ACDP) is an expert committee of the Department of Health. The Committee comprises a Chairman and 14 members. The membership is tripartite, with scientific experts, employer and employee representatives.

The work of the ACDP cuts across a number of Government Departments, and thus the Committee is supported by a Secretariat with representatives from the Health and Safety Executive (HSE), the Health Protection Agency (HPA) on behalf of the Department of Health (DH) and the Department for Environment, Food and Rural Affairs (Defra).

In 2011 the ACDP held two main meetings (the 96th on the 8th February and the 97th on the 7th June). Agenda, papers and a summary of these meetings are available at:
http://www.hse.gov.uk/aboutus/meetings/acdp/index.htm

A number of the ACDP Working Groups met throughout the year including:

- The Transmissible Spongiform Encephalopathy Risk Management Sub Group (TSE RM SG);
- The Transmissible Spongiform Encephalopathy Risk Assessment Sub Group (TSE RA SG).

A summary of these Working Groups can be found under Item 6 of this report.

2. TERMS OF REFERENCE

The Advisory Committee on Dangerous Pathogens' terms of reference are:

"To provide as requested independent scientific advice to the Health and Safety Executive, and to Ministers through the Department of Health, the Department for Environment, Food and Rural Affairs, and their counterparts under devolution in Scotland, Wales and Northern Ireland, on all aspects of hazards and risks to workers and others from exposure to pathogens. In addition, to provide as requested independent scientific risk assessment advice on transmissible spongiform encephalopathies (TSEs) to Ministers through the Department of Health, the Department for Environment, Food and Rural Affairs, and their counterparts under devolution in Scotland, Wales and Northern Ireland and to the Food Standards Agency."

3. DANGEROUS PATHOGENS

3.1 Background

The remit of ACDP is to provide advice to workers and others on risks from exposure to dangerous pathogens (also known as biological agents and infectious agents). Workers and others can be exposed to a range of dangerous pathogens in the workplace and through workplace activities.

Certain bacteria, fungi, viruses, internal parasites, and infectious proteins (known as prions) are all defined as dangerous pathogens. Dangerous pathogens may be used intentionally at work, for example in a microbiology laboratory, but exposure can also occur that is incidental to the purpose of the work, for example when healthcare workers are exposed to infectious patients, or farmers are exposed to diseases carried by their stock. Exposure to dangerous pathogens in the workplace could lead to the development of infectious disease, disease caused by the toxins produced by the dangerous pathogen, or an allergic reaction.

3.2 Legislation

Dangerous pathogens include infectious agents that cause diseases transmissible between animals and man (zoonoses). Such agents are controlled under human health (DH/HPA remit), health and safety (HSE remit), and animal health legislation (Defra remit). The primary purpose of the latter legislation is to prevent the introduction and spread of animal diseases that affect farmed livestock and poultry.

One of ACDP's roles is to advise on worker health and safety, and much of its advice supports health and safety legislation on the control of exposure to hazardous substances such as dangerous pathogens. Health and safety legislation (principally the Control of Substances Hazardous to Health [CoSHH] Regulations 2002 (as amended)) requires employers to assess the risks from dangerous pathogens in their workplace and to prevent or control exposure. Further information can be obtained from the HSE website: http://www.hse.gov.uk/biosafety/index.htm

Defra seeks to control imports of animal pathogens and carriers from third countries under the Importation of Animal Pathogens Order 1980, and animal pathogens causing serious, predominantly exotic, diseases of farmed livestock and poultry under the Specified Animal Pathogens Order 1998 by means of licensing regimes. Further information can be obtained from Defra's website: http://www.defra.gov.uk/

There are various pieces of legislation covering public health; further information on these can be obtained from the DH website: http://www.dh.gov.uk/Home/fs/en

3.3 Role of the ACDP

The work of ACDP can be broadly divided into two areas:

- Production of guidance relating to safety at work and protection of public health;
- Provision of advice to Government on the formulation and implementation of policy and legislation, relating to specific pathogen risk issues and their impact

ACDP makes a significant contribution to the assessment of risks to employees and the general public from infectious agents, and to ensuring that appropriate controls are in place. It has produced several guidance documents that give practical advice on the application of health and safety measures for a range of occupational groups and on a range of public health issues. These can be found at:
http://www.dh.gov.uk/ab/ACDP/DH_087526

4. MEMBERSHIP IN 2011

4.1 Membership of the Advisory Committee on Dangerous Pathogens (ACDP)

Independent member	Expert/Employer/ Employee representative/Lay Member	Employer
Professor George Griffin (Chair)	Expert in clinical and research microbiology and infectious diseases	St George's Hospital Medical School,
Professor Colin Howard	Expert in veterinary microbiology/parasitology	The Royal Veterinary College
Dr Judith Hilton	Expert in risk assessment and management	Medicines and Healthcare products Regulatory Agency
Professor Will Irving	Expert in clinical virology	University of Nottingham
Ms Karen Jones	Lay Member	Air Support International, Crawley
Dr John Keddie	Employer representative	GlaxoSmithKline
Professor Dominic James Mellor	Expert in veterinary microbiology, epidemiology and/or population medicine	University of Glasgow
Dr Phil Minor	Expert in research virology	National Institute of Biological Standards and Control
Professor Armine Sefton	Expert in medical microbiology	Bart's and The London
Mr Gordon Sutehall	Expert in laboratory health and safety	Addenbrooke's Hospital
Professor Richard Tedder	Expert in Clinical Virology	Health Protection Agency
Dr Roland Salmon	Expert in epidemiology/public health	Public Health Wales
Professor Malcolm Bennett	Expert in environmental/ veterinary microbiology	University of Liverpool
Professor Richard Knight	Expert in pathology/ clinical neurology	National CJD Surveillance Unit
Professor Jean Manson	Expert in prion science and prion disease	Roslin Institute

Assessors and observers	Representing
Dr David Brown	Health Protection Agency, Microbiology Services
Mr Richard Drummond	Department for Environment Food and Rural Affairs
Mr John Newbold	Health and Safety Executive
Dr Malcolm McWhirter	Scottish Government

Dr Andrew Riley	Scottish Government
Dr Delia Skan	Employment Medical Advisory Service, Northern Ireland
Ms Maggie Tomlinson	Department of Health
Dr Andrew Paterson	Department for Environment Food and Rural Affairs
Dr Sara Hayes	Wales Assembly Government
Mr Stephen Willie	Department for Environment Food and Rural Affairs
Mr Graeme Walker	Health and Safety Executive
Mr David Coackley	Health and Safety Executive
Dr Irene Hill	Food Standards Agency
Ms Catherine Makison	Health and Safety Laboratory
Mrs Charlie Flynn	Department of Health

Secretariat	**Representing**
Ms Tess Murray	Department for Environment Food and Rural Affairs
Dr Fay Voller (for February 2011 meeting only)	Department for Environment Food and Rural Affairs
Ms Tracy Brand (from October 2011)	Department for Environment Food and Rural Affairs
Dr Julia Granerod	Health Protection Agency
Mr Lee Wilson	Health and Safety Executive

Four new Members joined the Committee in 2011, Dr Roland Salmon, from Public Health Wales, Professor Malcolm Bennett, from the University of Liverpool, Professor Richard Knight of the National CJD Surveillance Unit, and Professor Jean Manson, from the Roslin Institute.

Mrs Ruth Lysons left as ACDP Defra Sponsor in March 2011 and was replaced by Mr Richard Drummond.

There were a number of changes to the Secretariat during 2011. Ms Tess Murray stepped down as Defra Secretariat and was replaced by Ms Tracy Brand.

4.2 Membership of the ACDP TSE Risk Management Sub Group

Independent member	**Employer**
Professor Don Jefferies (Chair)	University of London
Dr Adam Fraise	Queen Elizabeth Hospital, Birmingham

Professor Colin Howard	Royal Veterinary College
Professor James Ironside	University of Edinburgh
Professor Jean Manson	Neuropathogenesis Unit, Roslin Institute
Dr Phil Minor	National Institute of Biological Standards and Control
Dr Michael Painter	Public Health Consultant (retired)
Dr Geoff Ridgway	Consultant Microbiologist (retired)
Dr Roland Salmon	Public Health Wales
Dr Tim Wyatt	Mater Hospital Trust, Northern Ireland

Officials and Observers	Representing
Dr Peter Bennett	Department of Health, Head of Health Protection Analysis
Mr Patrick Burke	Department for Environment Food and Rural Affairs
Dr Andrew Riley	Scottish Government
Dr Nicky Connor	CJD Incidents Panel Secretariat
Dr Heather Elliott	Department of Health, Research and Development Directorate, Senior Programme Manager
Dr Irene Hill	Food Standards Agency
Mr Mark Noterman	Department of Health, CJD Policy & Secretariat to the Advisory Committee on the Safety of Blood, Tissues and Organs
Mr David Pryer	Chair of CJD Incidents Panel
Dr Neil Ebenezer	Medicines and Healthcare Products Regulatory Agency
Mr Nigel Tomlinson	Department of Health, Estates and Facilities
Ms Victoria Hall	CJD Incidents Panel Secretariat
Dr Mark Sutton	Health Protection Agency
Professor David Perrett	University of London
Mrs Val O'Brien	Institute of Decontamination Sciences
Mr Geoff Sjogren	Institute of Decontamination Sciences
Dr Robert Spencer	Institute of Decontamination Sciences
Mr Stephen Dobra	Department of Health
Ms Helen Janecek	CJD Incidents Panel Secretariat
Ms Emma Hollis	CJD Incidents Panel Secretariat

Secretariat	Representing
Dr Julia Granerod	Health Protection Agency

Professor Don Jeffries (Chair) passed away unexpectedly in December 2011. There were some other changes to the TSE Risk Management Sub Group in 2011:

- Dr Adam Fraise and Dr Mike Painter resigned as TSE RM SG members
- Mr Patrick Burke (Defra observer) left the TSE RM SG
- Ms Victoria Hall (CJDIP Secretariat) left the TSE RM SG and was replaced by Ms Emma Hollis
- Dr Neil Ebenezer replaced Mr Allan Hidderley as MHRA observer

- Mr Nigel Tomlinson retired and thus stepped down as an observer on the TSE RM SG
- Dr Peter Grimley left the TSE RM SG with the demise of SEAC

4.3 Membership of the TSE Risk Assessment Sub Group

Independent member	Employer
Professor George Griffin (Chair)	St George's, University of London
Professor Malcolm Bennett	University of Liverpool
Professor Richard Knight	National CJD Surveillance Unit
Professor Jean Manson	Roslin Institute
Professor James Ironside	University of Edinburgh
Professor Graham Medley	University of Warwick
Dr Roland Salmon	Public Health Wales
Dr Simon Mead	National Prion Clinic
Invited experts	**Employer**
Professor Azra Ghani	Imperial College
Dr Marc Turner	Scottish National Blood Transfusion Service
Dr Patricia Hewitt	NHS Blood and Transplant
Professor Angela Mclean	University of Oxford

Officials and Observers	Representing
Dr Peter Bennett	Department of Health, Head of Health Protection Analysis
Dr Maren Daraktchiev	Department of Health, Operational Research Analyst
Dr Andrew Riley	Scottish Government
Dr Sara Hayes	Wales Assembly Government
Dr Heather Elliott	Department of Health, Research and Development Directorate, Senior Programme Manager
Dr Irene Hill	Food Standards Agency
Mr Mark Noterman	Department of Health, CJD Policy & Secretariat to the Advisory Committee on the Safety of Blood, Tissues and Organs
Dr Ailsa Wight	Department of Health, Deputy Director - Infectious Diseases and Blood Policy Branch
Dr Liz Mitchell	Department of Health Social Services and Public Safety, Northern Ireland
Mr John Newbold	Health and Safety Executive
Mr Richard Drummond	Department for Environment Food and Rural Affairs
Mrs Maggie Tomlinson	Department of Health
Professor Noel Gill	Health Protection Agency

Secretariat	Representing
Dr Julia Granerod	Health Protection Agency

5. Key issues discussed by ACDP in 2011

In 2011 the ACDP held two main meetings: the 96th on the 8th February and the 97th on the 7th June.

Members discussed the progress of ACDP Working Groups under the Secretariat Report at each meeting. ACDP Working Group reports for 2011 are in section 6 of this document.

5.1 96th Meeting – 8th February 2011.

At the 96th meeting, members discussed:

Griffin Committee Enquiry into *E.coli* 0157 outbreak at Godstone Farm

Members were informed that a multi-agency group had been established, following publication of the Griffin Report in June 2010, to consider the recommendations made and to oversee implementation of recommendations by the relevant organisations. The outcome would be reported to the HPA Board and to ACDP.

Xenotropic murine leukemia virus-related virus

At a previous ACDP meeting members were informed that a subgroup had been convened by the National Expert Panel for New and Emerging Infections (NEPNEI) in May 2010 to review available data on XMRV. In summary, the subgroup concluded that:

- XMRV can infect humans but there was no evidence that it causes human disease;
- Development of a reliable test to accurately detect infection was required, as was further work to study the virus in more depth, investigate the possible mode of viral infection, the epidemiology of infection, whether the virus could cause disease, and thus whether there was any public health significance to XMRV infection;
- Based on the available evidence, no public health action was required at this time.

DH reported that studies published since then had not changed the conclusions of the meeting as none had provided evidence of an association with human disease. Members were informed that as a precautionary measure, the NHS Blood Service and the HPA had conducted preliminary studies on > 500 blood samples and had failed to show the presence of the virus in UK blood donors. As a further preliminary precaution, a range of further studies to develop validated diagnostic tests were underway. Members agreed that this was a research priority in order to be able to undertake any further investigative work that might be required. It was acknowledged however that although public interest remained, the scientific evidence did not indicate the need for further investigation.

Blood borne viruses

HSE reported that it expected to publish the BBV guidance on its website in March 2011. Publication would take the form of a web page with links to other documentation and references where appropriate.

The new regulatory framework – Safe work with biological agents and genetically modified pathogens

Members were updated regarding progress with the new regulatory framework. The Legislative Reform (Contained Use of Animal Pathogens) Order (LRO) would give HSE powers to regulate contained use work with animal pathogens under the Health and Safety at Work Act 1974. HSE reported that the aim was for the LRO to be in place by summer 2011, subject to parliamentary scrutiny procedures. This would enable HSE to introduce new Regulations to simplify regulatory requirements. It was expected that these would be in the form of a single set of regulations to encompass contained use work with human and animal pathogens and genetically modified microorganisms (GMMs; as previously discussed with ACDP). However, the detail was not yet finalised. Members were advised that they would be kept informed of any further developments and there would be further opportunities for stakeholders to provide comments on changes to the proposals. The earliest date that these regulations were expected to come into force was April 2012.

Pet Travel Scheme

Members were informed that an *ad hoc* meeting under the auspices of ACDP had been convened in November 2010 to bring together relevant experts to consider the public health risk from diseases other than rabies associated with pets entering the UK and whether such risks warranted the continued application of the UK's additional controls under PETS. The ad hoc group had concluded that the retention of tick controls for pets entering the UK provided a prudent and proportionate public and animal health protective measure against the risk of introduction of the brown dog tick, *Rhipicephalus sanguineus*, the vector for the *Rickettsia conorii,* the causative agent of Mediterranean Spotted Fever (MSF). The group also agreed that tapeworm controls should be retained as an important public health protection measure against a very serious health threat, and that the proposed 0-72 hour treatment window, agreed between the countries wishing to retain controls, would be acceptable on the basis that any slight but unquantifiable increase in risk would be offset by better compliance.

DH reported that the European Commission (EC) had been informed that five Member States, including the UK, together with Norway continued to want controls in place for tapeworm and that the petitioning countries had agreed a single control with a proposed 0-72 hour window for de-worming prior to entry. The EC had formally received the evidence base for seeking controls against the tapeworm *Echinococcus multilocularis*. Discussions were ongoing with the

EC about the appropriate treatment window, and the proposal from the EC was for a window of three working days, which was somewhat different to 72 hours when holidays and weekends were considered. A meeting was held with the EC in January 2011 but the outcome from this meeting was not available at the time ACDP met.

Botulism vaccine supply issue

Defra reported on a supply problem with a botulism vaccine for veterinary use in the UK. Due to the animal health and welfare risks associated with the disease and as there are no animal vaccines against botulism authorised for use in the UK or EU, the VMD had permitted the importation of Singvac from Australia for use under the VMD's Special Treatment Certificate (STC) Scheme. The manufacturer, Pfizer Animal Health, had recently advised that this vaccine was no longer available for supply to the UK.

To ensure there was no significant gap in supply, the feasibility of sourcing an alternative product was being investigated. Members were informed that Defra had pending applications to import two alternate vaccines and subject to receipt of some additional data relating to safety it was hoped to be able to approve the import of these vaccines through the STC scheme into the UK market soon. The VMD would advise stakeholders once an alternative vaccine had been assessed as suitable for importation. Veterinary surgeons had already been advised that it was possible to submit STC applications for alternative suitable vaccines to the VMD with each application being assessed on merit to ensure its safe use in the UK. The vaccines would not be stocked in the UK and therefore there would be a shipping delay unless a wholesaler wished to import a bulk purchase.

The Advisory Committee for Microbiological Safety of Food (ACMSF) recently considered the potential public health risk associated with botulism in cattle, sheep and goats. The Committee concluded that the risk to consumers was negligible and there was, therefore, no reason to prevent the sale of meat or milk from clinically healthy animals from farms where there have been clinically suspected cases of botulism in animals. Thus, any temporary non-availability of a vaccine for veterinary use should be regarded principally as an animal health and welfare problem, rather than a public health issue.

Charges for HSE's regulatory activities

Members were informed that HSE had been asked to review all areas for which they currently charge for their activities and those areas for which charging may be introduced. As part of the consultation for the single regulatory framework HSE indicated that a cost recovery scheme would be introduced for work to review notifications, inspect laboratories and carry out investigations.

New structure of ACDP

Members were advised of the new structure of ACDP. The Government's review of Advisory Non-Departmental Public Bodies (ANDPBs) concluded that ACDP would lose its ANDPB status and become an expert committee of DH. ACDP would continue its functions of providing advice through officials to DH, Defra and HSE, and would in future also provide advice for FSA on TSE issues, following the abolition of the Spongiform Encephalopathy Advisory Committee (SEAC). It was recognised that TSE issues remain of high importance and it would be necessary to take independent expert scientific advice on both risk assessment and risk management. The proposal for the transfer of SEAC's functions to DH and the delivery of these by ACDP was outlined.

Revision of Agriculture Information Sheet AIS 23

Members were provided with revised guidance published by the HSE for those who open their farms to the public on how to control and prevent infection risks ("Avoiding ill health at open farms - Advice to farmers" [AIS(rev)]). Subject to members' comments HSE proposed to publish the revised guidance before the end of March 2011, in advance of the commencement of the visitor farm attractions' spring/summer season. Members were asked to consider and comment on the changes to AIS23 in the context of the conclusions and recommendations of the Griffin Investigation Committee's Review of the major outbreak of *E.coli* O157 in Surrey, 2009.

Members discussed how and to whom this guidance would be applied, the difficulty to expect people to change their behaviour if most of the time there are no adverse consequences from their current practices, when information will be made available to the public, the difficulty of conveying the message of risk whilst not deterring parents from taking their children to open farms, and the practicality of the recommended hand-washing time of two minutes. Following these discussions, members agreed the revised guidance and were content with the presentation and inclusion of photographs to promote good practice.

Contained Use Approved List

At a previous meeting of ACDP, Members had commented on a draft of the Contained Use Approved List. Since then, the layout of the List had been restructured for clarity and ease of use for those assessing the risk of handling biological agents in contained use. Additionally, consultation with relevant experts had been undertaken to ensure that taxonomic nomenclature reflected current convention and advice had been sought from reference laboratories within the HPA Microbiology Services, the Veterinary Laboratories Agency, University of Liverpool, and the TSE Risk Management Sub Group.

Because there had been delays in putting the new single regulatory framework in place, it was not possible to present the revision to the Approved List of human pathogens as though it were part of that new framework. Therefore, human pathogens and their hazard groups only were presented. Members were asked to consider and approve the revised List. Some taxonomic changes and addition of viruses were suggested to the List. There was also discussion on changing the human hazard pathogen group for some organisms. Members were advised that this would be possible; however, evidence would need to be compiled and submitted for wider consultation. It would not be possible to change the hazard group below the current European category. Members expressed concern over this as the European List is more than 10 years old and not up to date.

Work Plan 2011/12

The Secretariat invited members to comment on the proposed Work Plan for 2011/12. Members suggested adding production of annual report to the Work Plan. It was also suggested that ACDP produce new guidelines for constructing biosafety and diagnostic laboratories. ACDP sponsors were not convinced that this was an appropriate role for ACDP given that its remit is to advise on risks to human health from pathogens.

Viral Haemorrhagic Fevers

Members were updated on progress made with the drafting of the new ACDP VHF guidance. Since the last ACDP meeting, HSE and DH had further consulted with a limited group of experts and drafted all the main sections of the VHF guidance and a number of the appendices. These sections had not yet been sent out for wider external consultation to relevant clinicians and professional societies. Members were asked to consider the following issues: what should be advised regarding paediatric VHF cases; how co-infection with malaria and VHF should be managed within the algorithm; and what negative test result can be considered definitive. In addition, members had a number of general comments regarding the VHF risk assessment algorithm, which they thought was too complicated.

HSE informed members that the fundamental issue yet to be resolved was the risk of aerosol transmission, the extent to which this was likely to occur and in what circumstances. The answers to these questions would determine the design of the premises, degree of patient isolation and containment and the type and extent of personal protective equipment to be used by healthcare staff. Deciding whether or not a patient with a VHF could be cared for without being isolated within a Trexlar tented environment, with its own ventilation system, would be critical in providing guidance for the NHS.

Whilst there is sound evidence of transmission of VHFs via splashes and droplets of blood or body fluids and direct contact with blood or body fluids, evidence of proven transmission via the aerosol route within the clinical setting appears elusive. ACDP was required to provide advice as to this

potential risk. Members were informed that an ad hoc subgroup of experts in this field would be convened in March 2011 to provide risk assessment advice to underpin the ACDP guidance document.

5.2 97th Meeting – 7th June 2011.

At the 97th meeting Members discussed**:**

Airborne and aerosol transmission risks from patients with VHFs

Having considered all the available evidence, members of the ad hoc subgroup concluded that there is no circumstantial or epidemiological evidence of an aerosol transmission risk from VHF patients. Members were of the view that the theoretical risk posed, based upon results of animal studies under laboratory conditions, was not relevant in the context of the healthcare setting. This risk assessment would be used to underpin revisions to the current ACDP guidance on management of patients with VHFs and would allow greater flexibility in the way patients are cared for and patient samples are dealt with. The proposed revised guidance would be put out for wider specialist and technical consultation.

Pet Travel Scheme

Members were updated that negotiations between the UK and the European Commission were ongoing to agree the wording to support maintenance of the UK's tapeworm controls, specifically the tapeworm *Echinococcus multilocularis*. The European Commission had indicated that there would be changes to the treatment 'window' within which treatments could be administered. Subject to agreement of the EC's proposals by the European Council and Parliament, the UK would be allowed to retain its tapeworm controls under the new proposals. The UK was not pressing to retain tick controls as the risk assessment case was less strong than that for tapeworms. When the UK's current derogation on pet travel rules ended in December 2011, the UK would harmonise its pet travel rules with those of the EC with respect to rabies, though it was hoped to retain tapeworm controls subject to the above negotiations.

Cancellation of the poultry workers seasonal flu vaccination programme

Due to the low uptake of vaccine by poultry workers and the infrequency of avian influenza occurrence in wild and domestic birds in the UK, the routine seasonal vaccination programme would discontinue after the 2010/11 season. However, in the event of a future avian influenza outbreak in domestic poultry, poultry workers would be offered seasonal influenza vaccine as part of the outbreak control measures subject to assessment of the risks of infection with seasonal flu.

The new regulatory framework – Safe work with biological agents and genetically modified pathogens

The new regulatory framework would need to go out to public consultation and this was now anticipated to happen in October 2011, with the aim of introducing the new regulations by October 2012.

Blood borne viruses guidance

HSE reported that the final few chapters were currently being edited in line with corporate HSE publishing standards with the expectation that the BBV guidance would be published on the HSE website by August 2011.

Viral Haemorrhagic Fever

Members were updated on progress with the revision of the ACDP guidance "Management of Hazard Group 4 viral haemorrhagic fevers and similar human infectious diseases of high consequence". Revisions had been made to the algorithm following comments made at the last meeting. With some discussion, members endorsed the current draft and, subject to their suggested points, recommended that it go forward for consultation.

Contained Use Approved List 2011

With the delay in implementing the new single regulatory framework, Members were updated on the current situation with the Contained Use Approved list and were asked to consider;

- Withdrawing the 2004 Approved list and replacing it with a new Approved list of human pathogens 2011.
- Retaining the 2004 list and delaying further work on the new combined list, pending the implementation of the new regulatory framework.

Members agreed that having an up to date, authoritative list of human pathogens was of high importance and agreed the significance of the proposed taxonomic changes to human pathogens warranted the publication of a revised 2011 list.

6. ACDP WORKING GROUPS

6.1 Transmissible Spongiform Encephalopathy Risk Management Sub Group (TSE RM SG)

The TSE RM SG was reconfigured in 2011 with the following terms of reference:

> *"To provide ACDP as requested with practical, scientifically based advice on the management of risks from transmissible spongiform encephalopathies (TSEs), in order to limit or reduce the risks of exposure to, or transmission of, TSEs. To handle issues as referred, taking into account the work of other relevant bodies."*

The TSE RM SG met three times in 2011 on the 22nd March, 6th July, and 2nd November.

At each meeting, members received an update on the numbers and epidemiology of both CJD and BSE cases and a progress report on current research. Members also received feedback from the ACDP, and related committees such as the CJD Incidents Panel, the Advisory Committee on the Safety of Blood, Tissues and Organs and the Engineering and Science Advisory Committee on the decontamination of surgical instruments, including prion removal.

The following key issues were considered by the TSE RM SG in 2011:

Annex M

New guidance on 'Managing vCJD risk in liver transplantation and general surgery' was drafted by the TSE RM SG. This was sent out for targeted consultation, and following this would be sent to ACDP for final approval.

Protocol for incineration of surgical instrument store

Surgical instrumentation deemed to be at risk of transmitting vCJD if re-used had been collected and stored by the HPA on behalf of DH. The aims of the service were to remove them from circulation in the first instance, so they could not be re-used, and to potentially use the collected instruments for research into TSE detection and decontamination. Following review of the store function by the TSE RM SG, the HPA has been advised to cease operation of the store, make arrangements for sending stored endoscopes to University of Southampton and to dispose of the remaining instruments. Further collection of instruments has also ceased.

Members were presented with two options for disposal of the instruments originally collected. Both proposed disposal routes were based on a limited body of evidence describing the destruction of infectivity by an incineration temperature of 1000°C for 15 minutes. Members agreed that either of the proposed options were satisfactory but emphasized the importance of ensuring an audit trail and that audit records on the incinerator (e.g. temperature logs) were kept.

Options for disposal or retention of NATA samples

The TSE Unit and the CJD Section of the HPA Colindale have a large number of samples (~95,000) from the National Anonymous Tonsil Archive (NATA) project stored in -80°C freezers (residual unfixed tissue) and room temperature racks (residual formalin fixed tissue and wax-embedded tissue) at the Fisher BioServices' facility at Bishop's Stortford. The HPA proposed to keep all of the blocks of wax-embedded tissue samples, as these do not occupy that much space and so are less expensive to store. A decision however was required on the disposal or retention of the residual frozen tissue and the residual formalin fixed tissue. Members were asked to advise on the fate of these samples.

Members agreed that the blocks of wax-embedded tissue should be kept and advised that the formalin fixed tissue could be disposed of. Members agreed that more information, including a breakdown of details of specimen quality such as the number of freeze-thaw cycles, was required on the frozen samples before a recommendation regarding their fate could be made. These data were subsequently provided to Members prior to the meeting.

Members agreed that the frozen samples should be kept at present pending for example epidemiological input in order to determine what sample size would be required to give enough power for future studies and the final results of the appendix study.

Concern about processing instruments used on patients with or at increased risk of CJD for re-use on the same patient

The Secretariat was contacted by the Institute of Decontamination Sciences (IDSc) regarding concern expressed by their membership around processing of instruments from high risk patients for use on the same patient as described in Annex E. The IDSc sought further clarification and evidence to support the safety of the recommendations contained in this particular Annex of the guidance to circulate to the wider healthcare decontamination community to dispel fears around the perceived hazards.

In summary, the following recommendations/statements were endorsed by Members in response to the concerns raised by the IDSc –

- To date, there is no evidence of transmission of vCJD from instruments.
- Members caution against people going their own way in terms of the number of decontamination cycles.
- Members encouraged the IDSc to reassure colleagues that there is no evidence of occupational risk in high, medium or low risk surgical procedures.
- There are many shared uncertainties in the area of prions and the aim of the current guidance is risk reduction rather than risk elimination. There has so far been no evidence that the current guidance has got it wrong.
- Research is currently under way to address many of the issues raised.

Annex J

Issues regarding the implementation of Annex J of the TSE RM SG guidance in relation to haemoglobinopathy patients, many of whom are known to be multiply transfused, were brought to the attention of the Secretariat by a member of the UK Forum on Haemoglobinopathies. The main concern raised relates to the identification and management of patients who are known by their clinicians to be multiply transfused, but have not been formally assessed as highly transfused preceding surgery on high infectivity tissue. Some of these patients might require medium risk surgery. Following discussions, the group agreed that the most appropriate strategy would be to convene a subgroup to redraft Annex J in accordance with this discussion. This group

would consist of members of both the TSE RM SG and the CJD Incidents Panel.

6.2 Transmissible Spongiform Encephalopathy Risk Assessment Sub Group (TSE RA SG)

The TSE RA SG was formed in 2011 with the following terms of reference:

> *"To provide ACDP as requested with scientifically based assessment of risk from transmissible spongiform encephalopathies (TSEs) in relation to food safety, public and animal health issues, taking appropriate account of scientific uncertainty and assumptions in formulating advice."*

The TSE RA SG met once in 2011 on the 14th July.

The following key issues were considered by the TSE Risk Assessment Sub Group in 2011:

Blood-borne transmission of vCJD: re-examination of scenarios
DH analysts prepared a paper for consideration by the TSE RA SG. The Subgroup reviewed the evidence on transmission of vCJD via blood components. In general, the Subgroup endorsed the approach suggested. Three key conclusions reached by this independent expert group were as follows:

- Early findings from a survey of appendix tissues being conducted by the HPA confirm the previous estimates for the prevalence of prion infection within the population, and extend this finding to older age cohorts than those examined previously. This study is continuing: evidence on the existing prevalence of infection is of key importance in assessing the possible scale of onward transmission.

- Evidence suggests a much lower estimate for the level of infectivity in blood.

- It is appropriate to calibrate transmission models against observed clinical case numbers, subject to taking a precautionary approach in estimating how many vCJD infections would have shown up as clinical cases, as well as how many known cases might have been due to blood-borne infection.

Aerosol transmission of prions – new research

A recently published paper on aerosol transmission by Haybaeck *et al* concluded that aerogenic exposure to prions is efficient and can lead to direct invasion of neural pathways without an obligatory replicative phase in lymphoid organs. They also postulated that the results indicated a previously unappreciated risk for airborne prion transmission that may warrant re-thinking on prion biosafety guidelines in research and diagnostic laboratories.

Members were asked to consider whether the contents and implications of the paper warranted a formal risk assessment of airborne transmission risk being carried out. The FSA was particularly concerned with regards to risk to abattoir workers. Members concluded that this study represented a very extreme situation rather than one that reflects normal human exposures and that the results of these studies do not raise new evidence of risk of airborne prion transmission. Members were of the view that no further risk assessment was required on the basis of these results.