ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

ANNUAL REPORT 2013

CONTENTS

1. INTRODUCTION

1.1 The Advisory Committee on Dangerous Pathogens (ACDP) is an expert committee of the Department of Health. The Committee comprises a Chairman and has had between 9 and 16 members during the reporting period. The membership is tripartite involving scientific experts representing a range of disciplines.

1.2 The ACDP is a resource for a number of Government Departments, and thus the Committee is supported by a Secretariat with representatives from the Health and Safety Executive (HSE), Public Health England (PHE) on behalf of the Department of Health (DH) and the Department for Environment, Food and Rural Affairs (Defra).

1.3 In 2013 the ACDP held three main meetings (the 100th on the 14th February, the 101st on the 20th June and the 102nd on the 22nd October).

1.4 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);
- The Transmissible Spongiform Encephalopathy Risk Assessment Sub Group (TSE RA SG) together with the PWG;

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

2. TERMS OF REFERENCE

2.1 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

3.1.1 The remit of ACDP is to provide advice to workers and a wider public 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 as well as more generally.

3.1.2 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

3.2.1 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. This UK legislation is often also the vehicle by which European Union legislation is brought into force in the UK.

3.2.2 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

3.2.3 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:
https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs

3.3 Role of the ACDP

3.3.1 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

3.3.2 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:

https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

http://www.hse.gov.uk/biosafety/hseandinfection.htm

4. MEMBERSHIP IN 2013

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 (to 14th February 2013)	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 (to 14th February 2013)	Expert in clinical virology	University of Nottingham
Ms Karen Jones	Lay Member	Air Support International, Crawley
Dr John Keddie (to 14th February 2013)	Employer representative	GlaxoSmithKline
Professor Dominic James Mellor	Expert in veterinary microbiology, epidemiology and/or population medicine	University of Glasgow

Dr Phil Minor (to 14th February 2013)	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 (to 14th February 2013)	Expert in laboratory health and safety	Addenbrooke's Hospital
NR	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, University of Edinburgh
Professor Jean Manson	Expert in prion science and prion disease	Roslin Institute, University of Edinburgh
Professor Peter Chiodini (from 1st October 2013)	Parasitologist/Infectious diseases specialist	Hospital for Tropical Diseases, University College London Hospitals NHS Foundation Trust
Dr / Lt Col Tiffany Hemming (from 1st October 2013)	Epidemiologist/veterinarian	MOD - Defence Medical Services
Dr Malcolm Holliday (from 1st October 2013)	Biomedical Scientist with experience of working at high containment levels	Newcastle Hospitals NHS Foundation Trust/PHE
Dr Michael Jacobs (from 1st October 2013)	Infectious Diseases specialist	Royal Free London NHS Foundation Trust
Dr Michael Kidd (from 1st October 2013)	Clinical Virologist specialising in respiratory viruses	University College London Hospitals
Dr Robert Shorten (from 1st October 2013)	Biomedical Scientist with experience of working at high containment levels	Royal Free London NHS Foundation Trust and University College London
Dr Anne Tunbridge (from 1st October 2013)	Infectious diseases specialist	Sheffield Teaching Hospitals NHS Foundation Trust

Secretariat	Representing
NR	Department for Environment Food and Rural Affairs
NR	Department for Environment Food and Rural Affairs
NR (to January 2013)	DH Secretariat - Public Health England
NR (from April 2013)	DH Secretariat - Public Health England
Mr Lee Wilson	Health and Safety Executive

In addition there were representatives from the following organisations:
Department for Environment Food and Rural Affairs
Department of Health
Food Standards Agency
Health and Safety Executive
Health and Safety Laboratory
Northern Ireland
Public Health England
Scottish Government
Welsh Government

Five Members stood down from the Committee and seven new Members joined the Committee in 2013.

There were changes to the Secretariat during 2013. Dr Julia Granerod stood down as DH Secretariat and was replaced by Dr Ginny Belson.

4.2 Membership of the ACDP TSE Risk Management Sub Group

Independent member	Employer
Dr Roland Salmon (Chair)	Public Health Wales
Professor Colin Howard	Royal Veterinary College
Professor James Ironside	NCJDR&SU, University of Edinburgh
Professor Jean Manson	Neuropathogenesis Unit, Roslin Institute, University of Edinburgh
Dr Phil Minor	National Institute of Biological Standards and Control, Medicines Health Regulatory Agency
Dr Geoff Ridgway	Consultant Microbiologist (retired)
Dr Patricia Hewitt	NHS Blood and Transplant
Dr Gerry Bryant	General Practice (retired)
Dr Stella Barnass	West Middlesex University Hospital

Officials and Observers	Representing
NR	Department of Health, Head of Health Protection Analysis
NR	Department for Environment Food and Rural Affairs
Dr Nicola Steedman	Scottish Government
NR (to October 2013)	Department of Health, Research and Development Directorate, Senior Programme Manager
NR (from October 2013)	Department of Health, Research and Development Directorate, Senior Programme Manager
Dr Irene Hill (to October 2013)	Food Standards Agency
Dr Darren Cutts (from October 2013)	Food Standards Agency
NR	Department of Health, CJD Policy & Secretariat to the Advisory Committee on the Safety of Blood, Tissues and Organs
Mr David Pryer (until March 2013)	Chair of CJD Incidents Panel
Dr Neil Ebenezer (until October 2013)	Medicines and Healthcare Products Regulatory Agency
Dr Katy Sinka	Public Health England
NR	Public Health England
NR	Department of Health, Emerging Infections and Zoonoses
Dr Yvonne Spencer	Animal Health and Veterinary Laboratories Agency
Dr Hugh Simmons	Animal Health and Veterinary Laboratories Agency

Invited experts	Employer
Karen Madgwick	Haemoglobinopathy Nurse, North Middlesex University Hospital

Secretariat	Representing
NR (until January 2013)	Public Health England
NR (from May 2013)	Public Health England

In addition there were representatives from the following organisations:
Animal Health and Veterinary Laboratories Agency
CJD Incidents Panel
Department for Environment Food and Rural Affairs
Department of Health
Food Standards Agency
Medicines and Healthcare Products Regulatory Agency
Public Health England
Scottish Government

There were some changes to the TSE Risk Management Sub Group in 2013:

- Dr Darren Cutts replaced Dr Irene Hill as FSA observer;
- Dr Alison Daykin replaced Dr Heather Elliot as the Research and Development representative from the Department of Health;
- Mr David Pryer – Chair of the CJD IP left in March 2013 following the dissolution of the CJDIP;
- There were changes to the Secretariat during 2013. NR stood down as DH Secretariat and was replaced by NR

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
NR	Health Protection Agency
Dr Yvonne Spencer	Animal Health and Veterinary Laboratories Agency
Dr Marion Simmons	Animal Health and Veterinary Laboratories Agency

Secretariat	Representing
NR (until January 2013)	Public Health England
NR (from May 2013)	Public Health England

In addition there were representatives from the following organisations:
Department for Environment Food and Rural Affairs
Department of Health
Food Standards Agency
Health and Safety Executive
Northern Ireland
Public Health England
Scottish Government
Welsh Government

There were some changes to the TSE Risk Assessment Sub Group in 2013:

- Dr Darren Cutts replaced Dr Irene Hill as FSA observer;
- Dr Alison Daykin replaced Dr Heather Elliot as the Research and Development representative from the Department of Health;
- There were changes to the Secretariat during 2013. NR stood down as DH Secretariat and was replaced by NR
- Mr Richard Drummond replaced Mrs Julie Hitchcock as Defra sponsor.

5. KEY ISSUES DISCUSSED BY ACDP IN 2013

5.0.1 In 2013 the ACDP held three main meetings: the 100th on 14th February 2013, the 101st on 20th June 2013 and 102nd on 22nd October 2013.

5.0.2 Members discussed the work of the ACDP Working Groups under the Secretariat Report at each meeting. The ACDP Working Group reports for 2013 are in section 6 of this document.

5.1 100th Meeting – 14th February 2013

At the 100th meeting, members discussed:

National Risk Scenarios

The UK's systematic approach to the process of assessing the risk of emergencies, and planning appropriate responses was outlined to Members. The Cabinet Office holds the risk register and had asked ACDP to advise with regard to potential infectious diseases risks, particularly the identification of different potential risks, their likelihood within different timescales and their potential impact. An ACDP Working Group consisting of five members, co-opted experts and DH sponsors had developed three infectious disease risk scenarios. The Committee were now asked to review the scenarios and to suggest the likelihood and impact of the presented "reasonable worst case scenarios" in the next five years, as developed by the Working Group.

VHF Guidance Review

A number of papers were presented describing the recent case of Crimean Congo Haemorrhagic Fever in a patient admitted to hospital in Glasgow, on return from a visit to Afghanistan, and subsequently transferred to the Royal Free Hospital High Security Infectious Diseases Unit. The intention was to consider the lessons learned from the experiences of managing a VHF patient in light of the new guidance, to consider the robustness of the document and necessary any changes that may be required.

Potential tensions that can arise between the requirements for the conflicts between clinical management of individual patients and wider infection control processes needed to be resolved.

The Glasgow case highlighted a need to review the training of port health and special branch officers in respect of the potential for clinical conditions (including VHF) to affect individual behaviour. Officers should not rely on controls by the carrier necessarily to exclude sick passengers from a flight.

Horizon Scanning

ACDP took on a horizon-scanning role on the dissolution of NEPNEI [in full] in December 2012. Dilys Morgan described the role of the new Human and Animal Infections and Risk Surveillance group (HAIRS) in relation to the Terms of Reference for NEPNEI. It is UK focused and recognises that many infection threats are zoonotic. Public health and animal health from across the four countries was considered. HAIRS produce a monthly summary and annual report, which will be sent to ACDP members, and where necessary, such as where there are important implications for changes in policy or practice, HAIRS will refer significant issues to ACDP for consideration.

ACDP Guidance Review

A review of the existing containment measures in line with current legislation (COSHH, GMCU and SAPO) would commence.

Advisory Committee on Dangerous Pathogens - The Approved List of biological agents

The final draft was approved and was expected to be published during the second week of March 2013.

Legionnaire's disease

In 2011 HSE conducted a review of legionnaire's disease outbreaks in the UK covering the previous 10 year period. The review reveals common failings in the control of legionella bacteria across a range of industries and a potential risk of further outbreaks, such as those in Edinburgh and Stoke in 2012.

As a result of the review, HSE had organised a range of interventions for 2013/14, focusing on securing compliance with the legislation and on promoting good practice. Premises notified as having a cooling tower or evaporative condenser, which pose the highest risk, will be sent a questionnaire, and results from the returns will be used to prioritise inspections.

On lower risks systems such as spa pools and hot and cold water systems, HSE was concentrating its efforts on raising awareness and promoting compliance through its contacts with trade associations and other industry stakeholders.

5.2 101st Meeting – 20th June 2013

At the 101st meeting Members discussed:

Human Animal Infections and Risk Surveillance (HAIRS)

Members were provided with an overview of the major topics discussed at HAIRS since the last ACDP meeting. Gratitude was expressed for the monthly summary produced and circulated by HAIRS on Emerging Infections.

Topics discussed at HAIRS included recent developments with Hydatid disease in the UK; Hantavirus in the UK; Hantavirus and pet rats; *Toxocara vitulorum*; Bovine TB notifications and *Mycobacterium bovis* infections in non-bovines; Illegally imported puppies and rabies risk for the UKMERS-CoV and H7N9.

CJD Incidents Panel

Members were informed that the CJD Incidents Panel had been formally dissolved on 31st March 2013. Responsibility for investigating, assessing and managing CJD incidents now rests with local trusts, health boards and health protection teams.

Advisory Committee on Dangerous Pathogens - The Approved List of biological agents

Pending some final small editorial changes, the "Approved List of biological agents 2013" would be published at the end of June.

VHF Guidance Review

Possible amendments to ACDP guidance: 'Management of Hazard Group 4 Viral Haemorrhagic Fevers and similar human infectious diseases of high consequence'

The HSE and DH secretariat had considered all the comments and suggestions, and formulated a series of remedial actions and proposed recommendations for possible amendments to the guidance, which were tabulated and provided as an annex to the paper.

Review of published ACDP guidance

Phase I of the project was now underway with particular attention given to how the guidance is written and how relevant information is conveyed in accordance with the principals of good guidance outlined in the Governments 'Code of practice on Guidance and Regulation. It was the intention of the secretariat to bring populated sections back to the committee for review.

Update on the Single Regulatory Framework (SRF)

HSE updated members on the fate of former plans to attempt to improve the regulation of human, animal and genetically modified organisms by bringing them into a single regulatory framework rather than be the subject of three

separate frameworks, as at present. Work to enact a single regulatory framework using a Legislative Reform Order had proved insurmountable because of legal difficulties. HSE are now looking to simplify and streamline, where possible, without new legislation, in the short-term, whilst exploring longer-term possibilities. There are a number of parallel work streams that are part of this wider programme of work:

5.3 102nd Meeting – 22nd October 2013

At the 102nd meeting Members discussed:

HAIRS risk assessment of Mycobacterium bovis in cats

The HAIRS risk assessment of *M. bovis* in cats was presented. This was undertaken in response to the December 2012 and 2013 cluster of 10 reported cases from a veterinary practice in Berkshire. Seven of the reported cases were confirmed *M. bovis*.

VHF Guidance Review

The discussion identified a number of areas where further refinement would be of benefit; these included the early categorisation of VHF, which appears to be in contradiction of the text, the handling of samples and the return home of possible cases whilst awaiting laboratory diagnosis. The proposal to create two groups to discuss these issues was proposed and agreed.

Lyme disease update

This paper was to update the Board on the current work being undertaken on Lyme disease. A national Centre of Clinical Excellence for Lyme Disease in Winchester was being proposed and the dissemination and communication strategy will be important in ensuring the successful delivery of this plan. ACDP would wish to be kept abreast of developments.

Occupationally acquired Mycobaterium.bovis infection

Consideration of a recent human case of *M.bovis* identified a need for evidence based guidance, or at least a framework on which local guidance can be built for the risks and prevention of occupational bovine tuberculosis. This framework might provide a model for consideration of other zoonoses which can potentially be acquired from handling carcasses. A subgroup has been established to take this forward.

Middle East Respiratory Syndrome Coronavirus

The Respiratory Group of PHE deal with this and have produced some risk assessments

Severe Fever and Thrombocytopenia Syndrome (SFTS)

The issue of the potential for human-to-human transmission of a new Bunyavirus that is spread by ticks in Japan was raised. It was agreed there was a need to consider whether the hazard group classification of this organism needed revision.

6. ACDP WORKING GROUPS

6.1 Transmissible Spongiform Encephalopathy Risk Management Sub Group (ACDP TSE RM SG) (Until November 2013)

6.1.1 The TSE RM SG met twice in 2013 on 7th March and 2nd July before merging with the Transmissible Spongiform Encephalopathy Risk Assessment Sub Group to form one single TSE sub group.

6.1.2 At each meeting of the ACDP TSE RM SG, 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 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.

6.1.3 The following key issues were considered by the TSE RM SG at their two meetings in 2013:

Neurosurgery and 2006 Guidance from NICE re: vCJD

There had been some correspondence concerning the recommendation within the 2006 NICE guidance to protect patients born after 1st January 1997 from iatrogenic vCJD from neurosurgical exposures through the use of dedicated instrument sets reserved for these individuals born after 1997. It raised the point that reserving separate instruments for these patients going forward was going to be increasingly costly and logistically more difficult as the older patients in this group were now moving into adult services.

This issue was relevant to previous discussions that had taken place between the ACDP TSE RM SG and Society of British Neurological Surgeons (SBNS) who had expressed a willingness to draft guidance for their colleagues.

It was agreed that a further meeting should be arranged with the SBNS together with representation from the ACDP TSE RM SG

Annex F – Nasendoscopy

There were residual issues relating to the revision of Annex F that related to nasendoscopy and olfactory epithelium. It was agreed that a small group of experts should be approached to advise on this aspect.

Plasma Products – denotification exercise

The difficulty in balancing the need for an appropriate level of precaution with the impact on those individuals who were classified as at increased risk of CJD was acknowledged. Some members of the subgroup were unsure as to what new evidence had prompted this denotification exercise. It was explained that this was based on the conclusions that had been drawn from revised blood risk assessment exercise that had been discussed earlier in the meeting. It focussed on the conclusion that the "window of risk" had changed. In addition, when the universal notification exercise of plasma products recipients was carried out it was acknowledged that there would be different levels of exposure to risk within the group including some who could be considered to have a low risk. The RM SG was reassured that patient groups and the doctors who see and treat these patients were taking a leading role on this communication exercise.

NIBSC Research and Resources Centre

Members were informed that the Human Prion Disease Resource and Oversight Committee had funding secured for the next five years.

Annex F and J of the ACDP Infection Control Guidance

It had come to the attention of the CJD IP secretariat that the relevant clinical groups (e.g. haematologists and haemophilia doctors) were not aware of the recent changes that had been made to Annexes F and J. The Secretariat was asked to work on identifying a new approach to informing the relevant parts of the NHS of changes to the guidance.

Variably Protease-Sensitive Prionopathy

A presentation on VPSPr, a condition first identified in the US and characterised by a poorly protease-resistant abnormal prion protein was given to the subgroup. Due to its unusual biochemistry it requires a modified Western blot methodology for its detection and so has not been picked up in the past. The results of a retrospective review of cases reported to the UK National CJD Research and Surveillance Unit (NCJDRSU) were presented.

The review identified ten cases of VPSPr in the UK during the surveillance period from 1991 to the present day. These data indicate that VPSPr is a comparatively rare phenotype within human prion diseases in the UK. Detailed analysis of the abnormal prion proteins present in VPSPr and sCJD showed molecular overlaps between these two human prion diseases. It was recommended that further surveillance was required to establish more accurately the epidemiology and characteristics of VPSPr.

Several enquiries regarding VPSPr had been received by the CJD team already and the group agreed that references to this alternative form of CJD should be added to the ACDP TSE infection control guidance. It was also agreed that a look back, such as that carried out for sCJD cases, should be carried out for the VPSPr cases that had been reported to PHE even though it was still unclear at this time how transmissible this prion might be.

It was agreed that, if it was possible, the VPSPr cases should be recorded separately to sCJD when the cases were recorded.

Highly transfused notification exercise report

A brief history of the previous discussions on introducing additional vCJD public health measures for people defined as highly transfused was given. It was explained that this definition had been revised following a series of risk assessments from the Department of Health looking at vCJD transmission through blood. As a result the number of donor exposures estimated to equate to a 1% increased risk, above the risk to the general population from eating BSE infected beef, had been revised from 80 to 300. It was agreed, though not unanimously, that no patients with >300 donor exposures should be identified at this time.

SBNS/NICE meeting

A report of the meeting that had taken place on 27th June 2013 involving some Members of the ACDP TSE RM SG with neurosurgeons and a representative from NICE was provided.

Tonsillectomy instruments

A request for advice regarding a return to reusable instruments had been received. The subgroup agreed with the proposal as set out and was content for a return to reusable instruments for these procedures.

CJD risk and cardiovascular tissue

A question had been sent for consideration from a UK based heart valve bank. A charity, which performs life-saving heart valve surgery in the UK and abroad on patients that cannot afford to travel to the UK and pay for surgery, has asked the bank if they have any heart valves available to donate for free for this treatment. Most of the surgery is performed abroad as the patients are too sick to travel. Although the NHSBT and SNBTS have both decided that they will not export tissue abroad, the Human Tissue Authority has not banned exports at all.

The sub group considered the information and agreed that, in accordance with Table A1 in the ACDP guidance document "Distribution of TSE infectivity in human tissues and body fluids" (published: 2nd June 2003 updated: December 2010) where heart valves come within the category "other tissue" and as such were considered a low risk tissue. The sub group were satisfied that since the latest update of this guidance document no new information or evidence has come to light that would change that assessment or give cause for review.

6.2 Transmissible Spongiform Encephalopathy Risk Assessment Sub Group (ACDP TSE RA SG) (Until November 2013)

The TSE RA SG met once in 2013 on the 20th May and also met that day with the UK blood services Prion Working Group (PWG).

The following key issues were considered by the TSE Risk Assessment Sub Group in 2013:

Prion disease in fish

A paper had been circulated on this issue requesting comments from the sub group. The comments received were used to inform an update that was sent to CMO by DH officials.

Members were content with the principle that had been set out in this update but were concerned that this process may not be feasible in practice. The Chairman would write to the CMO and CVO to alert them to this concern.

Appendix Prevalence Studies

Members were informed that the results of this study had been published in the Heath Protection Report on 20th July 2012 and that a manuscript had been submitted to the BMJ for publication.

The Appendix III study had been designed to address the issue of "prevalence" of abnormal PrP in populations presumed not to have been exposed to BSE. The study was designed to have two arms examining stored appendix tissues from two presumed "negative" UK populations:

- Patients who underwent appendectomy pre-1980; i.e. before it is believed that BSE had entered the UK food chain (the first cases of BSE were recorded in 1986);

- Patients born after 1996; it is presumed that after 1996 effective controls on the use of animal protein in feed and on risk materials entering the human food chain were in place.

Members were asked to consider and comment on the protocol for the Appendix III study.

The protocol set out the steps that would be taken to validate any positive samples identified in the Appendix III study. Members agreed that the method for the independent verification of positives as set out in the protocol would provide a robust system for verification.

It was agreed that the ACDP TSE RA SG would provide oversight for the study.

Following these discussions the committee agreed that the study met all peer review guidance requirements in terms of relevance, quality, strength, impact and value for money.

Members discussed a range of implications for our understanding of TSEs, for associated risk assessments and for the current and potential new risk management actions should a positive sample be found in the presumed negative control groups in the Appendix III study.

It was felt that this had been a useful discussion and would help inform a response should any positives be found.

Potential de-notification of plasma product recipient

The issue that had been raised was "what is the status of "implicated" plasma products manufactured before 1990 following the re-assessment of blood transmission risk, which considers that blood in the UK donor population would not have been significantly infective until after 1990?"

Members of the subgroup were asked to consider whether the risk status of plasma products produced from implicated batches before 1990 should be revised to be in line with the principles of the revised risk assessment agreed by ACDP which had narrowed the time period for the window of risk.

A discussion was had which considered the difference between general assumptions that were made for modelling purposes and evidence of a known link with a vCJD case. It was agreed that the known link changed the specific situation and the way it should be managed.

Highly transfused – assessment of implications of possible notification

The subgroup agreed the risk assessment exercise relating to this group had not changed and this was an issue for the risk management group to take forward with the help of haematologists involved in the management of the patients that would be affected.

6.3 A Joint meeting of the ACDP TSE Risk Assessment Sub Group and UK Blood Services Prion Working Group

This combined group met once in 2013 on 20th May to consider the ongoing issues relating to blood tests for vCJD

The group was informed that Department of Health funding for the NIBSC based Human Prion Disease Reseach and Resource centre and of the associated Human Prion Disease Resource Oversight Committee had been secured for the next five years and they would be supported by NIBSC, which was now within the MHRA. This meant there would continue to be a facility available to provide positive vCJD samples for testing the sensitivity and specificity of tests in development and a validation process for blood tests being developed. Although this route was not compulsory it was likely that

most organisations would choose to use this facility to validate their tests. Access to samples of the rare known positive vCJD blood samples would be decided upon by the Oversight Committee. In addition the group were informed that an additional resource was held within this facility which held 5000 anonymised UK blood samples and 5000 anonymised US blood samples. All the samples were available in different blood components but not whole blood.

It was noted that ovine blood from sheep inoculated with vCJD was also available but the usefulness of these samples may be limited.

It was noted that a test developed for measuring population prevalence of abnormal prion protein would not need a CE mark whereas it would if it was going to be used as a blood screening test.

A number of issues were considered including:

- the types of sample are needed (whole blood, plasma etc)
- the number of samples needed and should each be from a different individual
- the sample volume would be needed from each individual
- in which media should the samples be stored
- should the samples be from the UK or overseas
- the anonymisation/pseudoanonymisation options
- where should such a resource be stored
- which body should control access to the resource
- the need for confirmatory tests and their funding

6.4 Transmissible Spongiform Encephalopathy Sub Group (from November 2013 onwards)

During 2013 it was agreed that the two ACDP Transmissible Spongiform Encephalopathy Sub groups should be merged to form An ACDP Transmissible Spongiform Encephalopathy Sub Group. The following Terms of Reference were agreed for this new group at their inaugural meeting on 14th November 2013:

"To provide ACDP as requested with practical, scientifically based advice on the assessment and the management of risks from transmissible spongiform encephalopathies (TSEs). This advice should be in relation to food safety, public and animal health issues, taking appropriate account of present scientific uncertainty and assumptions in formulating advice on risk. To handle issues as referred, taking into account the work of other relevant bodies."

As at each meeting of the ACDP TSE RM SG it was agreed that members of this new group should receive an update on the numbers and epidemiology of both CJD and BSE cases and a progress report on current research.

Members will also receive feedback from the ACDP, and related committees such as 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 ACDP TSE SG at their inaugural meeting:

Questions re:BSE in cattle and the persistence of born-after-the-reinforced-ban (BARB) cases

Members have several questions outstanding:

i) What is the number of cases of BSE within the rest of Europe;
ii) The persistence of BARB cases in UK cattle and the amount of passive versus active surveillance that was being carried out to detect BSE; and
iii) a view of when the first cases of BSE were detected in the UK as a marker of when it may have first been present in the UK food chain.

It was agreed a letter should go to Defra requesting a report on these topics.

Appropriate management of patients identified as highly transfused and amendments to ACDP guidance documents

The following principles were agreed:

i) Highly transfused should be included on the list of people at increased risk of vCJD contained within Paragraph J14 of Annex J, the pre-surgical assessment guidance;
ii) Surgical instruments should be managed in the same way as those used on other people at increased risk of vCJD;
iii) Patients identified as highly transfused and at increased risk of vCJD should be informed of this and be added to the follow up register managed by Public Health England.

It was acknowledged that there were Members of the group who were still concerned about the potential risk this group posed as a source of vCJD infection.

Neurosurgery – Society of British Neurosurgeons TSE guidance

Members were informed that enquiries were still being received regarding the movement of children born after 1997 from paediatric into adult neurosurgical services and the continued requirement to have separate instruments for this age group.

TSE Roadmap 2: Future Changes to EU TSE Feed

An update on the EU proposal that processed animal protein (PAP) derived from poultry would be fed to pigs and PAP derived from insects would be fed

to non-ruminant farm animals was provided. The implementation of these proposals had been delayed which was welcomed by the group as they had concerns about the changes being proposed.

Update of ACDP TSE guidance

The changes proposed were accepted and it was agreed that the revised guidance should be published. A table would be inserted at the start of each Annex setting out the changes that had been made making reference easier for users.

It was also agreed that disposal of the endoscopic equipment currently held by the NCJDRSU for known vCJD cases should be carried out.

vCJD: Occupational Health Surveillance

Members were informed that PHE and NCJDRSU had created a registry to record the occupational exposures of healthcare and laboratory workers to CJD and TSEs. The aim of this registry was to improve the national evidence base regarding exposure to CJD and TSEs by the long term follow up of healthcare and laboratory workers who have reported occupational risks. It was also reported that a retrospective lookback of potential occupational risks for patients diagnosed with CJD was planned.

For the look back the NCJDRSU is seeking to identify all CJD patients who previously worked in healthcare settings or laboratories. For CJD patients who have been healthcare workers, the NCJDRSU will identify any overlaps between their employment and all hospital procedures and inpatient stays of other CJD patients. The findings will be reported back to the ACDP TSE SG at future meetings.