



ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

Secretariat Report for the 93rd meeting of the ACDP, and matters arising from previous meetings

1. This paper includes reports on progress made with matters arising from the last meeting, reports from ACDP Working Groups and other relevant advisory committees as well as other items that may be of interest to members.

Matters Arising from the 92nd meeting:

Advice on working with A/H1N1 pandemic influenza virus

2. At the ACDP meeting in June 2009, it was agreed that once the novel A/H1N1 influenza virus is routinely circulating in the UK and there are sustained levels of transmission, all work with the virus, including handling, concentration and propagation, may occur at Containment Level 2, subject to a suitable and sufficient risk assessment, with use of an Microbiological Safety Cabinet (MSC) until inactivation of the virus. It was agreed that this should be contingent on the situation in the UK, not the situation globally.
3. On the 7th August 2009, the Secretariat received a letter from the Chairmen of SAGE, Professor John Beddington and Professor Sir Gordon Duff, confirming that the threshold at which the virus can be said to be widely circulating in the UK, with sustained levels of transmission, had been reached. Given this confirmation from SAGE, Members confirmed that the containment advice relating to A/H1N1 influenza could be changed, as agreed at ACDP in June.
4. As a result, on Friday 25th September the following statement was published on the HSE website:

Revision of laboratory containment requirements for work with novel A/H1N1 strains of influenza

“At the June 2009 meeting of the Advisory Committee on Dangerous Pathogens (ACDP), the committee discussed laboratory containment of novel A/H1N1. It was agreed that once this strain of influenza virus was routinely circulating in the UK and there were sustained levels of transmission, all laboratory based work with the virus, including handling, concentration and propagation, could take place at Containment Level 2, subject to a suitable and sufficient risk assessment, with use of an Microbiological Safety Cabinet (MSC) until inactivation of the virus.

The Special Advisory Group on Emergencies (SAGE) has confirmed that the threshold at which the virus can be said to be widely circulating in the UK, with sustained levels of transmission, has been reached.

On the basis of the ACDP and SAGE advice, HSE recommends the above revision of laboratory containment measures subject to suitable risk assessment for laboratory based work. Furthermore, this position is contingent on the situation in the UK, not the situation globally.

Further advice can be obtained from HSE”

A/H1N1 pandemic influenza virus in pigs in Northern Ireland

5. The A/H1N1 pandemic influenza virus currently circulating in the human population has been confirmed in pigs in Northern Ireland. Given the current human flu pandemic, these findings are not unexpected. The Department of Health, Social Services and Public Safety (DHSSPS) in Northern Ireland have been informed. Their advice is that the findings do not pose any increased risk to the general public. DARDNI have published various documents on their website <http://www.dardni.gov.uk/index/animal-health/animal-diseases/swine-influenza-2> which include:
 - a Q&A sheet
 - advice to pig keepers with open farms and petting zoos
 - guidance for poultry keepers in relation to A/H1N1

A/H1N1 pandemic influenza in pigs – Worker protection

General issues

6. Further to the agreement reached at the last ACDP meeting, a cross-government group was convened in July 2009 to consider whether any additional guidance on worker protection was necessary for pig workers and abattoir workers, in the event that A/H1N1 pandemic influenza enters the GB pig herd. Current standard guidance available to pig farmers and workers (<http://www.hse.gov.uk/pubns/ais2.pdf>) contains information relating to zoonotic risk protection, highlighting examples of good farm practice and professional hygiene, which is applicable to all zoonoses, including A/H1N1 influenza virus.
7. HSE was asked to consider the need for more specific advice on appropriate personal protective equipment for workers on pig farms in the event of a confirmed or suspected outbreak of A/H1N1 pandemic influenza in the animals. Since that meeting, A/H1N1 pandemic influenza has been declared to be widely circulating in the community and therefore the risk of exposure to A/H1N1 pandemic influenza via community contact is greater than from contact with pigs in GB, given that the virus does not appear to be widely circulating in the GB pig herd.
8. HSE is considering its position on the need for additional advice to pig farmers, and is planning to meet representatives from the pig industry in the near future to determine the practical implications and reach an agreement. Advice from HSE is awaited.

Guidance for pregnant women

9. Draft guidance for pregnant women who work with pigs has been produced by DH, HSE, Defra and HPA as follows:

"There is a very low risk of becoming infected with the pandemic A/H1N1 strain of influenza from pigs infected with this strain. Although pregnant women are not at any higher risk of becoming infected with pandemic influenza strain A/H1N1 from contact with infected pigs, they are at higher risk of suffering more severe health effects as a consequence. Pregnant women are therefore advised to avoid contact with confirmed infected pigs until six weeks after the

birth of their baby. Pregnant women are also advised to avoid contact with pigs exhibiting signs of influenza until A/H1N1 infection has been ruled out.

The new pandemic strain has now been identified in pigs in Northern Ireland. Transmission of influenza from pigs to humans is not common. Though it is known that certain strains (H1 and H3) of human influenza have circulated in the UK pig herd, the risk of re-assortment of pandemic H1N1 strain with swine or human influenza viruses in pigs, resulting in the emergence of a new human pandemic strain, is considered to be low but not negligible."

Vaccination of pig workers

10. At the last meeting when A/H1N1 was not yet circulating widely in the community in the UK, had not been found in the GB pig herd and there was not yet a licensed pandemic influenza vaccine available, Members agreed to keep a watching brief on the potential for using vaccine for pig workers.
11. The situation regarding A/H1N1 pandemic influenza virus has moved on considerably since June. Since the 7th August 2009, the virus has been declared to be widely circulating in the human population in the UK, with sustained levels of transmission. Thus pig workers are at greater risk of infection from contact in the community than contact with pigs at work. The issue of pig worker vaccination does not therefore need to be considered again as those at particular risk from flu will be captured as part of the risk groups in the community for both A/H1N1 and seasonal flu vaccine.

Fit testing of masks – Northern Ireland experience

12. At the meeting in June it was agreed that Dr Skan would provide some feedback on the experiences in Northern Ireland regarding fit testing of masks in healthcare, as the failure rates were believed to be high.
13. In Northern Ireland, fit testing fail rates have fluctuated between 10% and 30%. It would appear that the 3M FFP3 mask is likely to have a 10% failure rate. The methods are associated with different rates of failures, with a qualitative method being associated with a 30%, and the quantitative 10-15%.
14. Northern Ireland has been tracking developments in Scotland where the Alpha mask is reported as having a negligible fail rate.

Q fever vaccination

15. JCVI will be considering the issue of Q fever vaccination safety and the burden of disease in the UK at their meeting on October 14th 2009. The outcomes of this meeting will be reported back to ACDP in due course.

Update on SAPO classification of Highly Pathogenic Porcine Reproductive and Respiratory Syndrome Virus (HP-PRRSv)

16. At the last ACDP meeting Defra updated the committee on progress to classify HP-PRRSv which is not currently classified under SAPO. Defra are currently carrying out a consultation exercise to add Porcine Reproductive and Respiratory Syndrome virus Genotype 2 (PRRSv2) to Part 1 of Schedule 1 to the Specified Animal Pathogens Order 2008 by means of an Amendment Order, which ends on 16 October 2009. The effect of this amendment would be to prohibit any person from possessing this pathogen, or carriers containing it, without having a licence authorising them to do so under SAPO. The introduction of the pathogen into any animals or birds would also be prohibited, except under licence. The intention is to lay the legislation in November with it coming into effect in December, in line with the action being taken in parallel in Scotland and Wales.
17. Following consideration of this issue by Members at the last ACDP meeting, Defra vets, in consultation with HSE, concluded that PRRSv2 must be handled under Category 3 containment conditions as set out in Defra's classification of Specified Animal Pathogens. If a genotype 2 PRRS virus is known to be of low pathogenicity, a laboratory may produce evidence to Defra and the HSE to support handling the virus under Defra's Category 2 containment conditions.
18. PRRS viruses considered not to be of low pathogenicity will include those containing a molecular signature of a 1+29 aa deletion in the nsp2 region of the genome (as described by Lv *et al*¹) and those known to result in morbidity and mortality greater than that expected with infection with genotype 1 PRRS viruses endemic in UK.

1. Lv, Zhang, Sun et al. An infectious cDNA clone is a highly pathogenic porcine reproductive and respiratory syndrome virus variant associated with porcine high fever syndrome. J Gen Virol 2008;89:2075-2079

19. If members wish to participate in the consultation exercise the consultation documents may be accessed via this link:
<http://www.defra.gov.uk/corporate/consult/pathogens/index.htm>

ACDP guidance on blood-borne viruses

20. Key members of the Working Group met during August to discuss the most recent comments from ACDP at the last meeting. It was evident that some further amendments to the BBV guidance were required. These included removal of some of the infection-related Figures from Part 1 of the guidance with appropriate adjustment of text to compliment those changes; some text amendments to Tables within Part 1 and Part 3; additional legal confirmation on some of the content of Table 2.2 (Part 2) was also required.
21. Amendments to the text, where appropriate, have now been completed and a request for legal clarifications on Part 2 has been requested of HSE's legal team. Final editing to the guidance text will take place shortly and we anticipate that, within October, all aspects of the guidance will have been amended in response to the earlier consultation, ACDP and legal comments received. The document will then go forward for publication.

Needlestick injuries and the use of safe devices

22. Members will recall a discussion at the last meeting when the subject of needlestick 'safe devices' was raised. This was highlighted in connection with the HPA report "Eye of the needle", the reported increase in needlestick injuries within that report and the use of 'safe devices' as a means of using engineering controls as a hierarchical measure, as advocated under the COSHH regulations. The Secretariat are seeking legal advice on the application of COSHH to 'safe systems' for preventing needlestick injuries and will report back to the next meeting.

Reports from ACDP Working Groups

Containment Working Group

23. Progress made by this Working Group will be reported as a main item at the October meeting.

ACDP TSE Working Group

24. The TSE Working Group has met once since the June ACDP meeting, on the 17th September 2009.

Annex L – Guidance on ophthalmology

25. Following approval by ACDP at the June meeting, and some final small editorial changes, the new guidance on managing CJD/vCJD risk in ophthalmology was published on 4th September 2009 at: <http://www.dh.gov.uk/ab/acdp/tseguidance/index.htm>

Urology alert

26. The Working Group have issued an alert to urological surgeons, in collaboration with Dr David Pryer, Chairman of the CJD Incidents Panel and Dr Miles Allison, gastroenterology representative on the CJD Incidents Panel. The alert is included as Annex A.

Annex C – Decontamination and waste disposal

27. Following a decontamination and waste disposal subgroup meeting last year, Annex C has been revised to include up-to-date information on the general principles of decontamination and waste disposal for TSEs in healthcare and laboratories. More specific information, for example on surface decontamination, will be included in Parts 3 and 4 of the guidance. The new Annex C will be published in October 2009.

Annex H – After death

28. The Association of Anatomical Technologists wrote to the Working Group earlier this year with suggestions for revisions to Annex H which deals with what to do when a patient with CJD or vCJD dies. The Working Group will be revising Annex H shortly to take into account some of these recommendations.

Revision of the 1996 ACDP guidance on the Management and Control of Viral Haemorrhagic Fevers

29. The Secretariat met in September to discuss progress with the revision of this guidance. It is hoped that a full draft version will be presented to Members at the February 2010 meeting.

30. At the last meeting it was reported that clinical colleagues on the ACDP VHF Clinical Management subgroup had produced a patient risk assessment algorithm for use by primary care, accident and emergency, acute medical units and admitting physicians. This algorithm was included for Members' information. The algorithm has since been circulated widely in the medical community for comment, and the Secretariat will be meeting clinical colleagues in October to finalise it and discuss the pathways. This will inform the next iteration of the guidance as the framework and structure of the guidance will be based on the flow of the algorithm.
31. Representatives from HSE and DH visited the existing High Security Infectious Disease Unit in Newcastle in September, in order to discuss with clinicians the use of PPE and RPE in an intensive care setting that may be required for VHF patients in the future. The visit was extremely useful, and a similar visit to the Royal Free is proposed, to discuss control options including PPE.
32. It is anticipated that a revised draft of the guidance will be presented to ACDP at their February 2010 meeting.

Working Group to write guidance on non-circulating strains of influenza virus of known pandemic potential

33. Progress made by this Working Group will be reported as a main item at the October meeting.

Other matters

Polio

34. In a post eradication/post Oral Polio Vaccine (OPV) cessation era, those laboratories or Inactivated Polio vaccine (IPV) production facilities still holding the virus will be the only remaining sources with potential to reintroduce wild poliovirus, Vaccine Derived Polio virus (VDPV) or Sabin poliovirus into the population, resulting in potentially major health consequences. It is envisaged that laboratories serving essential international vaccine production, and control, reference and research functions, will have to meet stringent containment requirements. The latest draft of the WHO's Global Action Plan (GAP III) is intended to minimise the potential for such as a release from containment. In response to the Department of Health's UK Working Party for Containment of

Poliovirus, HSE commenced, in 2007, a programme of inspections/contacts of laboratories registered as holding 'polio materials' on the National Inventory of polio containment for the purposes of:

- assessing the adequacy of containment implemented by these laboratories (as required by COSHH);
- promoting the WHO best practice guidance for containment of polio virus;
- providing information on the upcoming changes to containment requirements for polio virus (e.g. likely re-categorisation);
- providing information on the National Polio Containment Programme and details of the coordinator; and
- encouraging duty holders to destroy unwanted stocks.

35. The National Inventory consists of 121 laboratories and was compiled through provision of voluntary information from ~3500 UK laboratories in responses to two questionnaires circulated by the Public Health Laboratory Service (Now Health Protection Agency (HPA)).
36. During the period of the programme HSE has contacted via telephone, email or site visit most of the laboratories on the National Inventory. Due to the time elapsed between the compilation of the Inventory and the HSE contact, the researchers or nominated contacts from some laboratories have moved on.
37. Confirmation was received through telephone or email and site visit from 75 laboratories that they no longer held the polio materials. Either the polio materials had been destroyed; transferred to another laboratory; or the researcher had moved on.
38. The remaining 46 laboratories confirmed that they intended to retain their polio materials. In addition, 2 more laboratories have been identified, which were not included on the National Inventory but which also hold polio materials. Of these 48, only 10 laboratories still hold wild polio virus. Of the 48 laboratories still retaining polio materials, HSE has conducted 21 site visits and plans to visit the remaining laboratories by mid-October 2009.
39. These visits have not identified any containment issues of significant concern. The predominant issue has related to the understandable fact that information

provided to the National Inventory is inaccurate in terms of materials held, their location and contact details. Other issues raised were the need to store poliovirus stocks in locked fridges and freezers; the need to vaccinate staff including cleaners entering the laboratory (based on risk assessment); and the need to maintain accurate inventory of stocks, all of which have subsequently been addressed by HSE. A full report has been forwarded to the Chair of the UK working group for consideration at the next working group meeting.

Positive Pressure Ventilation Lobby (PPVL) isolation room design

40. Members will recall that the report of the research findings on the performance of 'Positive Pressure Ventilated Lobby' patient isolation facilities was circulated to the Committee for comment. No comments were received.
41. The research findings were also sent out for peer review. The initial peer review was incomplete as the reviewers felt they lacked the necessary expertise to offer robust opinions on the aerodynamic analysis undertaken.
42. The research has therefore been subjected to a further expert peer review and the final report of that review is awaited. In the meantime, and subject to confirmation of satisfactory expert peer review, a group has been convened to revise the guidance on the provision of isolation facilities, taking account of the research findings. It is anticipated that the draft guidance will be available for consideration at the next meeting in February."

ACDP review 2010

43. It has been agreed that ACDP, its Working Groups and Sub Groups will be reviewed in 2010. This review will be 'light touch' and will include the ACDP TSE Working Group and the CJD Incidents Panel. A paper detailing the proposal for the quinquennial light touch reviews of all infectious diseases scientific advisory committees is attached as Annex B. In this, the broad questions to be asked during the review are listed. These are:
 - Does the committee meet wider objectives of Government, including links to pertinent PSA and targets, responsiveness to public concerns, ability to inform policy and identification important new issues?
 - Is the committee's remit appropriate and fit for purpose?

- How effectively does the committee operate currently, including the appraisal process for Chair and members?
- Are the governance arrangements for the committee appropriate and effective?
- Does the current membership equip the committee to meet its remit effectively?

44. Members are asked to note this for information at this stage, but may be asked to participate in the review in 2010.

Secretariat

September 2009

Alert to Urological Surgeons

TRANSRECTAL PROSTATIC BIOPSY IN MEN AT RISK OF VARIANT CJD

It has come to the attention of the Advisory Committee on Dangerous Pathogens' TSE Working Group and the CJD Incidents Panel that some transrectal prostatic biopsies are undertaken by means of single use needles passed **through the internal lumens** of reusable ultrasound probes (e.g. BK Medical Triplane, Biplane or Endfire).

The ACDP TSE Working Group categorises surgical and other invasive procedures according to their potential for onward transmission of tissue contaminated with abnormal prion protein, the putative infective agent in variant Creutzfeldt Jakob disease (vCJD)². Lymphoid aggregates occur in rectal mucosa and submucosa, and have been shown to be contaminated with abnormal prion protein in cases of vCJD. There is therefore a potential risk of vCJD cross-infection during transrectal prostatic biopsy if reusable equipment is employed for this procedure on patients at risk of vCJD, because there is no decontamination method that reliably eliminates or destroys abnormal prion protein.

It is understood that most transrectal prostatic biopsies are undertaken by means of single use needle devices guided by an **adjacent** ultrasound probe. As the biopsy instruments are single use, there is no reason why such procedures would carry a potential risk of cross-infection.

Therefore the ACDP TSE Working Group and CJD Incidents Panel advise the following:

Patients at risk of vCJD³ requiring transrectal prostatic biopsy should have the procedure performed by means of single use equipment that runs alongside (rather than through) the ultrasound probe. Where a unit does not have such equipment and intends to carry out a biopsy procedure on a patient at risk of vCJD, their options are as follows:

- **To refer the patient to a unit offering the alternative technique that does not pose a risk of contaminating the internal channels with traces of biopsy tissue**
- **To borrow the alternative equipment from another unit**
- **To undertake the procedure with equipment that has internal biopsy channels and then quarantine the reusable components of that equipment after decontamination. It must be accepted that this equipment would be unlikely to return to general use, except for dedicated re-use in the same patient.**

Dr Miles C Allison, Gastroenterology Representative, CJD Incidents Panel and ACDP TSE Working Group Endoscopy Subgroup

Professor Don Jeffries, Chairman of the ACDP TSE Working Group

Mr David Pryer, Chairman of the CJD Incidents Panel

²<http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/>

³ The following patient groups have been notified of their increased risk of subclinical vCJD infection:

- People who have received blood from someone who went on to develop vCJD
- People who have given blood to someone who went on to develop vCJD
- People who have received blood from someone who has also given blood to a patient who went on to develop vCJD
- People who have had surgery using instruments that had been used on someone who developed vCJD
- People who have had a neurosurgical procedure, or an operation for a tumour or cyst of the spine, before August 1992
- People who have received an organ or tissue from a donor infected with vCJD or at increased risk of vCJD
- People who have been treated with certain UK sourced plasma products between 1980 and 2001

It is important to note that new patient groups may be notified in the future of their increased risk of vCJD.

Proposal for a for a “light touch” review of the Department of Health Scientific Advisory Committees (SACs) supported by the Health Protection Agency

1. MATTER FOR CONSIDERATION

- 1.1 This paper sets out a proposal and timetable for “light touch” quinquennial reviews of the infectious diseases Scientific Advisory Committees (SACs) sponsored by the Department of Health and with a Health Protection Agency (HPA) provided secretariat. It also proposes extending the review process to all the committees where the secretariat is provided by the HPA.

2. RECOMMENDATIONS

- 2.1 The first “**light touch reviews**” of the four “infectious diseases” Scientific Advisory Committees and the CMO’s Committee to be undertaken over the next three years and on a 5-yearly basis thereafter.

- 2010: Advisory Committee on Dangerous Pathogens (plus TSE Working Group and CJD Incidents Panel)
- 2011: Advisory Group on Hepatitis/Expert Advisory Group on AIDS
- 2012: Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection
- 2012: National Expert Panel on New and Emerging Infections (CMOs Committee).

- 2.2 **Methodology of the Review:** A short questionnaire to be developed in consultation with representatives of the sponsors and issued to a selection of stakeholders (to include committee Chair, members, sponsors, HPA staff, NHS staff using committee advice etc.). In parallel, a selection of stakeholders to be interviewed with a view to obtaining a broad spectrum of informed opinion on the issues set out in the questionnaire. The approach to be similar to that used in the review of another SAC (the Spongiform Encephalopathy Advisory Committee).

- 2.3 **Proposed terms of reference:** To examine the committee, its governance, methods of operation and effectiveness including its terms of reference and composition, the openness and transparency of its procedures and the

relationships between the committee and other bodies with related responsibilities.

2.4 The broad questions to be asked:

1. Does the committee meet wider objectives of Government, including links to pertinent PSA and targets, responsiveness to public concerns, ability to inform policy and identification important new issues?
2. Is the committee's remit appropriate and fit for purpose?
3. How effectively does the committee operate currently, including the appraisal process for Chair and members?
4. Are the governance arrangements for the committee appropriate and effective?
5. Does the current membership equip the committee to meet its remit effectively?

2.5 Annual appraisal of Chairs and committee members: Each committee sponsor, with advice from the secretariat and the HPA senior scientific contact or HPA observer (as appropriate), will annually appraise the committee Chair; the Chair, with advice as appropriate from the secretariat and sponsor will annually appraise members. Appraisal of members will include an assessment of the members' contributions to the committee's work and identify any skill gaps. The Chair would provide personal feedback to each member. This will supplement existing arrangements for ongoing review of the committee's work plan in the light of the sponsor's priorities and issues identified by the committee e.g. by horizon scanning..

2.6 Communication: Each Committee to be informed of this proposal at their next meeting and by prior circulation of this paper.

2.7 Extending the review to all SACs based at HPA: The secretariat and DH sponsors for the radiation and toxicology committees based at HPA Chilton to be advised of this proposal, for it to be discussed at the annual meeting of all secretariats and sponsors to be held in the autumn 2009.

3. BACKGROUND

- 3.1 All ANDPBs should be subject to a regular review process. The purpose of such a review is to question whether the Body continues to meet the wider objectives of Government and if so whether a different model of organisation might be more appropriate and whether services and functions could be provided more effectively in future.
- 3.2 The secretariat function of the four SACs referred to in 2.1 transferred to the HPA in November 2004. The committees have not been subject to any form of review since the function transferred. With the publication of the Government Office of Science (Go-Science) review of DH SACs, it is timely for such an external review to be undertaken.

4. ARGUMENT

- 4.1 In the recent Go-Science Review of DH SACs, it is stated that “there is no formal system for reviewing the portfolio of DH SACs to ensure it continues to be appropriate”. The Go-Science review recommends that “DH should monitor its portfolio of SACs to identify needs, gap and overlaps to ensure that the role and remit of each SAC is appropriate and directed where they have most impact and value”.
- 4.2 It also recommends that “DH should ensure that monitoring and evaluation is undertaken at an appropriate level and regularity for each SAC”.
- 4.3 The above proposals should support the DH in complying with these recommendations.

5. RESOURCE CONSIDERATIONS

Appropriate resources will be allocated to the review programme.