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JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

Minute of the meeting on Wednesday 3 October 2012
151 Buckingham Palace Road, Victoria, London, SW1W 9SZ
10.30 am – 4.00 pm

Members

Prof Andy Hall (Chair)
Dr Syed Ahmed
Prof Ray Borrow
Prof Judith Breuer
Dr Anthony Harnden
Dr Jennifer Harries
Dr Gabrielle Laing
Mrs Pauline MacDonald
Mrs Anne McGowan
Dr Andrew Riordan
Dr Peter Baxter
Dr Maggie Wearmouth
Mr Chris Liffen

Invited observers from Devolved Administrations and MHRA

Dr Nicola Steedman (Scottish Government)
Dr Elizabeth Reaney (DHSSNI)
Mr David Vardy (Welsh Assembly Government)

Invited observers and presenters

Dr Mary Ramsay (HPA)
Ms Joanne White (HPA)
Lt Col Peter Hennessey (MoD)
Wg Cdr Andy Green (MoD)
Dr Darina O'Flanagan (Eire)
Mr John Henderson (DH)
Dr Peter Grove (DH)
Mr Guy Walker (DH)
Mt Moritz Wagner (DH)
Sarah Hopwood (DH)
Gayatri Amirthalingam (HPA)
Prof Martin Buxton (Brunel Uni) for item 5
Dr Chaam Klinger (HPA) for item 1
Dr Lianne Vardy (Public Health Agency of Canada)

DH immunisation team

Professor David Salisbury
Mrs Carolyn Heaney
Dr Tom Barlow
Mr Andrew Earnshaw
Mr Chris Lucas

MHRA

Dr Phil Bryan (MHRA)
Dr Bridget King (MHRA)
Miss Catherine King (MHRA)

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I. Smallpox vaccination

1. The Chair explained that this issue would be considered in a restricted session. The committee was informed that Smallpox Management and Response Teams (SMARTs) consisting of cohorts of vaccinated frontline healthcare workers had been established in the UK, following advice from JCVI in 2002. JCVI was now asked to review that advice and consider options for SMARTs particularly in light of the risks associated with smallpox vaccination and the changed current and future risk of a smallpox outbreak. Details of the emergency response arrangements and how SMARTS might be convened and deployed would be for UK health departments to develop.

2. JCVI noted that data on the duration of protection of smallpox vaccination are lacking but considered that immunity is unlikely to be life-long. Whilst the risk of smallpox outbreak may have reduced there may still be a need for SMARTs. However, given the risks associated with vaccination and revaccination with smallpox vaccine, a more appropriate and proportionate option would be to convene SMARTs consisting of a registered cohort of unvaccinated or previously vaccinated healthcare workers who are willing to be (re-)vaccinated quickly in the event of an emergency. However, rigorous maintenance of the SMARTs would be very important (particularly over the period of NHS reorganisation), should be resourced adequately and audited regularly to ensure that they remain viable and can be vaccinated quickly.

II. Welcome

3. The Chair welcomed all to the meeting and explained that the first item had been restricted to members of the committee and a small number of officials. Attendees were reminded that papers provided for the meeting included information provided in confidence and should not be circulated more widely nor discussed with others outside of the meeting. Apologies for absence had been received from Professors Jonathan Friedland, Matt Keeling and Claire-Anne Siegrist.

III. Draft minutes of previous meeting and teleconference

4. The minutes were accepted as an accurate record of the meeting following the following amendments (in bold or strikethrough):
    - Page 3: Green Book guidance on the MMR vaccination of egg allergic individuals had been revised **but not yet published**
    - Page 10: Action: DH to consider pertussis vaccination of certain healthcare workers and HPA to consider **modifying current guidance to include pertussis immunisation**
    - Page 10: Only Menveo® should be used in children under one year of age as there are some data on its use in that age group (there are no published data on use of Nimenrix® in this age group).

- Page 14 corrections to some of the declaration of interests.

IV. Matters arising

5. The Chair noted that:
   - A call for evidence to inform future considerations about the HPV vaccination programme had been issued in August 2012, and interested parties had until 9 November 2012 to respond;
   - DH and HPA had met to consider modelling of pertussis and pertussis immunisation strategies. It had been agreed that it was important to develop a model to understand better the current epidemiological situation and population immunity and to look at different vaccination strategies. Such a model could take possibly up to two years to develop;
   - HPA had provided data on the vaccination status of infant pertussis cases during the current outbreak that had informed a JCVI teleconference on pertussis in August 2012;
   - JCVI had agreed at the August 2012 teleconference that immunisation of pregnant women against pertussis should be the priority when using available vaccine, and noted that the immunisation of healthcare workers would be considered by Ministers in due course.

<u>Introduction of temporary pertussis immunisation programme for pregnant women</u>

6. The committee noted that a temporary programme of vaccinating pregnant women had been launched on 1 October 2012, following JCVI advice provided at the August 2012 teleconference. Over a short period, much work had been undertaken to put this programme in place quickly including:
   - development of a contract to provide the immunisations to pregnant women;
   - development of communications materials, including a poster, leaflet, video, electronic communications and clinical guidance;
   - briefing of royal colleges, professional bodies and other stakeholders as well as journalists.

7. Some members were aware of a number of issues around the implementation of the temporary pertussis immunisation programme for pregnant women and suggested that further information be issued to:
   - indicate that Repevax® should be used in pregnant women, not Infanrix-IPV®;
   - clarify the contraindications and precautions for use for Repevax® in pregnant women as the clinical advice in the CMO letter differed from that in the Green Book;
   - emphasise that Repevax® supplied for use in children or pregnant women should not be offered to healthcare workers in order to ensure continued availability of vaccine for children and pregnant women.

Action: DH to communicate these clarifications.

Letter from GSK about JCVI advice on use of meningococcal ACWY conjugate vaccines

8. The committee noted that GlaxoSmithKline (GSK) had written to JCVI about advice set out in the draft minute of the June 2012 JCVI meeting in relation to use of meningococcal ACWY vaccines. Data had been provided on use of Nimenrix® in children from nine months of age.

9. The committee noted that data are available on the use of Menveo® in those aged from 2 months, whereas data on Nimenrix are available in those aged from 9 months. The committee agreed there is no scientific reason to reverse existing advice on the use of Menveo® despite the differing age ranges indicated in the Summaries of Product Characteristics for Nimenrix® and Menveo®. The committee would be interested in receiving immunogenicity and safety data from use of Nimenrix® in those under 9 months of age, including, if available, with concomitant use of vaccines in the routine infant immunisation schedule.
Action: the secretariat to contact GSK for immunogenicity and safety data on use of Nimenrix® in those under 9 months of age, including, if available, concomitant use of vaccines in the routine infant immunisation schedule.

V. Report from the working group on uncertainty in vaccine evaluation and procurement

10. The committee were reminded that an expert working group had been convened to consider how uncertainty in cost effectiveness analyses of immunisation programmes might best be handled. The group had provided a report, to DH and to JCVI to inform future considerations of analyses of the cost effectiveness of immunisation programmes.

11. The chair of the working group summarised the report and the recommendations. Several case studies were presented on how the recommendations would work in practice when considering a cost effectiveness study.

12. The committee welcomed the report and thanked all those involved in its production. The committee agreed that, whilst the approach to cost effectiveness assessment did not substantially differ from the approach currently used, the recommendations would enhance the committee's approach to reviewing cost effectiveness studies and the manner in which it makes judgements about the cost effectiveness of immunisation programmes. The committee agreed to trial the recommended approach when assessing the next cost effectiveness study under consideration.

13. The committee agreed it would continue to be important for the authors of cost effectiveness studies to clearly define and explain all key assumptions and parameters and the sources for them to aid review of the studies.

14. The committee suggested that it may be valuable for NICE to receive the report for consideration.

VI. Report from the meningococcal sub-committee

15. The chair of the JCVI meningococcal sub-committee summarised the conclusions of the sub-committee meeting on 13 July 2012.

16. The committee accepted the advice of the sub-committee and agreed that a booster dose of meningococcal C conjugate vaccine should be offered to adolescents at the same time as the Td/IPV booster vaccination age 13-14 years (equivalent to school year nine in England). School-based vaccination was felt likely to be the most effective setting.

17. The committee noted that school-aged adolescents beyond the age for the "teenage booster" at the start of the programme may be sub-optimally protected against meningococcal C disease. Therefore, the committee agreed that individuals in these relevant birth cohorts should be offered meningococcal C conjugate vaccine on, or just before, first entry to higher education establishments where they are likely to be at increased risk due to the increased risk of transmission in some settings (e.g. university halls of residence).

18. The committee noted the progress made by the sub-committee in evaluating a potential meningococcal B immunisation programme but that further data are required from the vaccine manufacturers and more work would be needed before the sub-committee is in a position to give final advice.

VII. Pneumococcal vaccination statement

19. The committee provided comments on the draft statement on the use of pneumococcal conjugate vaccine in clinical risk groups based on the considerations by the JCVI pneumococcal sub-committee in May 2012 and by JCVI in June 2012. It was suggested that the statement include schedules when PPV23 and PCV13 should be considered for certain groups. It was also noted that advisory bodies had provided advice on use of PCV in certain clinical risk groups (i.e. those with HIV infection) and that the statement should refer to that guidance.
    Action: Secretariat to circulate revised draft statement to the committee and sub-committee for comment.

20. The committee considered a submission from Pfizer highlighting concerns that other countries may interpret JCVI advice on use of pneumococcal vaccines as being directly applicable to their situation. The committee expressed surprise given JCVI's status as a UK advisory committee and that its advice is based on analysis of data on UK epidemiology and immunisation coverage. However, it was agreed that in future JCVI advice would very clearly state that it is based on circumstances in the UK and that the advice cannot necessarily be directly extrapolated to the situation in other countries. The submission had also questioned aspects around the wording of the committee's advice and interpretation of evidence. Following consideration of the points raised in the submission, the committee was content with the advice as stated in the minutes.

VIII. Update on pertussis outbreak

21. The committee was updated on the latest UK pertussis epidemiology, noting that:
    - the outbreak was continuing with month on month increases in confirmed cases with a total of 5610 confirmed cases in 2012 and 1234 cases in August 2012 alone;
    - infection rates continued to be highest in those under 3 months of age, at more than double the usual for a peak year;
    - the number of deaths in the UK had reached 10, all in those under 3 months of age with none vaccinated.

22. The committee noted that if the UK follows the pattern of disease seen in the US, then levels may not return to those seen before this outbreak.

23. The committee agreed it would review data on the evaluation of the programme at its February 2013 meeting, if data are available.

IX. Vaccine safety reports

24. The committee reviewed a report on vaccine safety from the MHRA based on the Yellow Card reporting system. It noted that a review of the use of Cervarix® following administration of over six million doses, found no significant issues regarding safety, including no increase in risk of chronic fatigue disorders.

25. The committee noted that studies were ongoing to understand the possible underlying mechanism in the development of narcolepsy following administration of Pandemrix®, but agreed that any studies undertaken would be challenging, as the aetiology of narcolepsy is poorly understood.

X. NICE immunisation guidance consultation

26. The committee agreed with the proposal in the consultation document that there is limited new evidence to point to revision of the recommendations in the guidance and that the main revisions would be in relation changes to the health care system. It was suggested that it would be important to consider in revised guidance improving uptake of immunisations by adolescents and to consider schools-based programmes as potentially the most effective delivery setting.

XI. Management of polio outbreaks

27. The Chair noted that JCVI advice in February 2011 had led to revision of the UK Standards for Microbiology Investigations: Surveillance of Polio in the UK around the public health response to potential wild poliovirus infection. Additionally the section on the "Management of suspected cases and outbreaks" in the Green Book chapter on Poliomyelitis had been redrafted.

28. The JCVI members agreed to provide comments by correspondence on the UK Standards and agreed the text of the Green Book with modification so that it related to use of IPV-containing vaccines in the initial stage of an outbreak.

XII. Coverage data

29. Routine childhood vaccine coverage rates for the quarter January to March 2012 were summarised for England, Scotland, Wales and Northern Ireland:

England	http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/VaccineCoverageAndCOVER/
Scotland	http://www.isdscotland.org/Health-Topics/Child-Health/publications/index.asp
Wales	http://www.wales.nhs.uk/sites3/page.cfm?orgid=457&pid=54144
Northern Ireland	http://www.publichealth.hscni.net/directorate-public-health/health-protection/vaccination-coverage

XIII. Paper for information/comment

30. The Chair noted that a paper by Lucija Tomljenovic *"The vaccination policy and the Code of Practice of the Joint Committee on Vaccination and Immunisation (JCVI): are they at odds?"* had been drawn to the committee's attention. The committee disagreed with the eight assertions made in the paper noting that the committee:
    - members are appointed as independent experts through open competition;

- had a rigorous and open process for dealing with potential conflicts of interest to ensure the objectivity of its advice;
- works entirely within its terms of reference and strongly believes it works in accordance with its Code of Practice;
- examined carefully all the available and relevant evidence including on epidemiology of disease, vaccine efficacy and vaccine safety and keeps its advice on immunisation programmes under review in order to consider new emerging important evidence;
- weighed carefully the risks and benefits of immunisation programmes;
- is an independent expert advisory committee that informs and advises on immunisation policy in the UK but is not a policy maker and is not responsible for the communication, delivery or safety monitoring of immunisation programmes which are a matter for UK health departments and their agencies.

XIV. AOB

31. The chair thanked all those present and closed the meeting.

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Annex A – Declarations of Interest

Item 1

The following members declared interests in the company that manufactures and supplies smallpox vaccine to the UK (Sanofi-Pasteur MSD).

Member	Action	Interest
Ray Borrow	Non-personal, non-specific Sanofi-Pasteur MSD,	The member is able to participate in the discussion and to vote
Judith Breuer	Non-personal, non-specific Sanofi-Pasteur MSD	The member is able to participate in the discussion and vote
Anne McGowan	Non-personal, non-specific Sanofi-Pasteur MSD	The member is able to participate in the discussion and to vote

Item 4 and item 6

The following members declared interests in the companies that manufacture and supply meningococcal vaccines (Novartis, Baxter, Pfizer and GSK)

Member	Action	Interest
Ray Borrow	Non-personal, specific Novartis, Baxter, Pfizer and GSK	The member is able to participate in the discussion but not to vote
Anne McGowan	Non-personal, non-specific GSK	The member is able to participate in the discussion and to vote
Andrew Riordan	Non-personal, non-specific GSK	The member is able to participate in the discussion and to vote

Item 7

The following members declared interests in companies that manufacture or supply pneumococcal vaccine (Pfizer, Sanofi-Pasteur MSD and GSK)

Member	Action	Interest
Ray Borrow	Non-personal, non-specific Pfizer, GSK and Sanofi-Pasteur,	The member is able to participate in the discussion and to vote
Judith Breuer	Non-personal, non-specific	The member is able to participate

	Sanofi-Pasteur MSD	in the discussion and to vote
Anne McGowan	Non-personal, non-specific Pfizer, GSK and Sanofi-Pasteur MSD	The member is able to participate in the discussion and to vote
Andrew Riordan	Non-personal, non-specific GSK	The member is able to participate in the discussion and to vote

Item 8

The following members declared interests in companies that manufacture and supply pertussis containing vaccines (GSK, Sanofi-Pasteur MSD).

Member	Action	Interest
Ray Borrow	Non-personal, non-specific GSK, Sanofi-Pasteur MSD	The member is able to participate in the discussion and to vote
Judith Breuer	Non-personal, non-specific Sanofi-Pasteur MSD	The member is able to participate in the discussion and vote
Pauline MacDonald	Personal, non-specific GSK	The member is able to participate in the discussion but not to vote
Anne McGowan	Non-personal, non-specific GSK and Sanofi-Pasteur MSD	The member is able to participate in the discussion and to vote
Andrew Riordan	Non-personal, non-specific GSK	The member is able to participate in the discussion and to vote

Item 11

The following members declared interests in companies that manufacture and supply polio vaccines (SanofiPasteur MSD and GSK).

Member	Action	Interest
Ray Borrow	Non-personal, non-specific Sanofi-Pasteur MSD, and GSK	The member is able to participate in the discussion and to vote
Judith Breuer	Non-personal, non-specific Sanofi-Pasteur MSD	The member is able to participate in the discussion and vote
Anne McGowan	Non-personal, non-specific Sanofi-Pasteur MSD and GSK	The member is able to participate in the discussion and to vote

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Andrew Riordan	Non-personal, non-specific GSK	The member is able to participate in the discussion and to vote

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Annex B – evidence considered by the committee