

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

Code of Practice June 2013

Contents

	Introduction	3
	Terms of Reference	3
	Statutory basis of JCVI	4
	JCVI advice and recommendations	6
	Appointment of JCVI members	7
	Secretariat	9
	Medical Advisor	10
	Observers	10
	JCVI Sub-committees	11
	Responsibilities of JCVI and Sub-committee members	12
	Conflicts of interest	13
	Declarations of Interest	14
	Confidentiality	16
	Accountability	17
	Development of JCVI advice and recommendations	18
	Communications with PHE and UK health departments	25
	Publication Scheme	25
	The Green Book	27

	Expenses	28
Annexes		
1	Indemnity letter	29
2	Declaration of agreement to Code of Practice, including confidentiality provisions	30
3	Handling documents with protective markings	31
4	Department of Health standard rates for member expenses	32
5	Report from the Working Group on Uncertainty in Vaccine Evaluation and Procurement	34

Introduction

1. The Joint Committee on Vaccination and Immunisation (JCVI, the Committee) is an independent Departmental Expert Committee and a statutory body.
2. This Code of Practice gives information on the status, role, responsibilities and procedures of the JCVI, and its Sub-committees; the terms of appointment of members of the Committee and its Sub-committees; and the roles and responsibilities of the members of the Committee and Sub-committees. It is based on the legislation concerning JCVI and also the Government Office for Science Code of Practice for Scientific Advisory Committees¹. The JCVI Code of Practice will be reviewed as appropriate.
3. The JCVI Code of Practice does not have legal force, but all members and prospective members of the Committee and Sub-committees as well as those attending meetings to inform the Committee's or Sub-committee's discussions are required to confirm their acceptance of the provisions set out in this Code of Practice by signing the Declaration (Annex 2) as indicated.
4. JCVI can be contacted at:

JCVI Secretariat,
Public Health England,
Wellington House,
133-155 Waterloo Road.
London, SE1 8UG

e-mail: jcvi@phe.gov.uk

Terms of reference

5. As a Standing Advisory Committee established under the NHS (Standing Advisory Committees) Order 1981 (SI 1981/597), JCVI is a statutory advisory committee. That order specified that the Committee is constituted for the purpose of advising the

¹ Government Office for Science (2011) Code of Practice for Scientific Advisory Committees
<http://www.bis.gov.uk/assets/goscience/docs/c/11-1382-code-of-practice-scientific-advisory-committees.pdf>

Secretary of State on *“The provision of vaccination and immunisation services being facilities for the prevention of illness.”*

6. The JCVI's terms of reference as agreed by the UK health departments² are:

“To advise UK health departments on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies. To consider and identify factors for the successful and effective implementation of immunisation strategies. To identify important knowledge gaps relating to immunisations or immunisation programmes where further research and/or surveillance should be considered.”

History and statutory basis of JCVI

7. The Committee was originally an advisory board for polio immunisation that became JCVI in 1963. It was put on a statutory footing when it became a Standing Advisory Committee, established in England and Wales under the NHS Act 1977. It sat under the Central Health Services Council until 1980. The NHS (Standing Advisory Committees) Order 1981 (SI 1981/597) established the JCVI in its current form as the Standing Advisory Committee on Vaccination and Immunisation.
8. Under the NHS (Standing Advisory Committee) Order 1981, which was prior to the devolution settlement, the Committee provided advice to the Secretary of State in

² Prior to JCVI's reconstitution as an Departmental Expert Committee in 2013, the committee's terms of reference were:

“To advise the Secretary of State for Health and Welsh Ministers on matters relating to the provision of vaccination and immunisation services, being facilities for the prevention of illness. The Committee must advise the Secretary of State for Health and Welsh Ministers on matters relating to vaccination and immunisation as the Committee considers appropriate and on any questions referred to it by the Secretary of State or Welsh Ministers. In particular under the provisions of the Health Protection (Vaccination) Regulations 2009 which implements the NHS Constitution in England, upon request of the Secretary of State, the JCVI must make recommendations relating to new provision for vaccination (other than vaccination relating to travel or occupational health) under a national vaccination programme or to changes to existing provision under such a programme, that are based on an assessment which demonstrates cost-effectiveness.”

relation to Wales as well as England. Under the National Assembly for Wales (Transfer of Functions) Order 1999 the functions of the Secretary of State set out in section 6 of the NHS Act 1977 (which gave the Secretary of State the power to establish standing advisory committees by order) exercisable in relation to Wales, transferred to the National Assembly for Wales. Section 6 was repealed and replaced by section 250 of the NHS Act 2006 as regards England and section 189 of the NHS (Wales) Act 2006 for Wales. Paragraph 1 of Schedule 2 to the NHS (Consequential Provisions) Act 2006 provides that any subordinate legislation made under provisions in the 1977 Act has effect as if made or done under or for the purposes of the corresponding provision in the 2006 Act. By operation of this paragraph, the 1981 Order is to be treated as an order made under section 189 as well as section 250. Functions of the National Assembly subsequently transferred to Welsh Ministers under the Government of Wales Act 2006. Section 250 of the NHS Act 2006 (which provided the power for the Secretary of State to establish standing advisory committees by order) and Schedule 19 to that Act (which made further provision about the membership and procedures of such committees) were repealed by section 283 of the Health and Social Care Act 2012. However, section 283(3) provided that the repeal did not affect the continuing effect of the NHS (Standing Advisory Committees) Order 1981, meaning that the JCVI remains a standing advisory committee. However, with the repeal of Schedule 19 to the NHS Act 2006, its membership and procedures are no longer prescribed by statute. Following the Government's review of public bodies that completed in 2012³, JCVI was reconstituted as a Departmental Expert Committee and ceased to be an Advisory Non-Departmental Public Body, although its statutory status was retained as explained above.

9. JCVI has no statutory basis for providing advice to Ministers in Scotland or Northern Ireland. However, health departments from these countries may choose to accept the Committee's advice or recommendations. Specific advice given by JCVI in response to a request from any one UK health department or Minister is not binding on any of the other Ministers of the Devolved Administrations or UK Government. UK health departments are made aware of all JCVI advice through their designated observers who attend JCVI and Sub-committee meetings and receive committee papers.

³ Cabinet Office (2012) Public Bodies 2012
<http://www.cabinetoffice.gov.uk/sites/default/files/resources/public-bodies-2012.pdf>

10. The Secretary of State is accountable to Parliament for JCVI as a public body. The Minister for Health and Social Services of the Welsh Assembly Government has equivalent accountability to the National Assembly for Wales.

11. The Committee has no budget.

JCVI advice and recommendations

12. JCVI provides advice and recommendations as described in the terms of reference (see earlier) based on consideration of scientific and other evidence (see later) that is used by Government to inform, develop and make policy. JCVI is not a policy maker in its own right and has no regulatory function.

13. Since 1 April 2009 the Health Protection (Vaccination) Regulations 2009 place a duty on the Secretary of State for Health in England to ensure, so far as is reasonably practicable, that the recommendations of JCVI are implemented, where those recommendations:

- a) relate to new provision for vaccination under a national vaccination programme⁴ or to changes to existing provision under such a programme and
- b) are made by JCVI (and not therefore a Sub-committee of JCVI) and
- c) are in response to a question referred to the JCVI by the Secretary of State and
- d) are based on an assessment which demonstrates cost-effectiveness and
- e) do not relate to vaccination in respect of travel or occupational health.

This duty ceases to apply in relation to a recommendation where JCVI withdraws that recommendation.

14. JCVI can provide advice on travel vaccinations or occupational health vaccinations, as well as advice on vaccines, or the vaccination of certain clinical risk groups, that while clinically appropriate cannot be shown to be cost effective (due to an insufficiency of data). In these situations, the Secretary of State is not bound by the advice of the Committee under the Health Protection (Vaccination) Regulations 2009 but can choose to accept and implement the advice.

⁴ A national vaccination programme is any programme implemented nationally in England that does not relate to travel vaccination or occupational health vaccination. National vaccination programmes include universal programmes as well as targeted programmes.

15. In order to assess whether a national NHS-provided vaccination programme can be considered cost effective (or not), JCVI uses the methodology and criteria of the National Institute for Health and Clinical Excellence (NICE). Using the NICE approach, a vaccination programme can be considered to be cost effective if the health benefits (both the direct health benefits to those vaccinated and the indirect health benefits to the unvaccinated population) are greater than the opportunity costs measured in terms of the health benefits associated with programmes that may be displaced to fund the new vaccination programme. In other words, the general consequences for the wider group of patients in the NHS are considered alongside the effects for those patients who may directly benefit from the vaccination programme of interest⁵. The Committee also takes account of the advice and recommendations of the Working Group on Uncertainty in Vaccine Evaluation and Procurement when assessing cost effectiveness. The report of this group is appended at Annex 5.

Appointment of JCVI members

16. The Committee consists of such number of members as the Secretary of State and Welsh Ministers determine from time to time. Since the JCVI has been reconstituted as a Departmental Expert Committee, appointments of the Chair and members are made by the Secretary of State, via the Department of Health (DH) Senior Responsible Officer (SRO) in consultation with senior officials in the PHE Public Health Directorate and with the DH public appointments team.

17. Appointments to the Committee are made on merit and in accordance with the principles of the Code of Practice for Scientific Advisory Committees and the Code of Practice issued by the Commissioner for Public Appointments. The Chair and Members are appointed as individuals to fulfil the terms of reference of the Committee, not as representatives of their particular profession, or of their employer or any interest group. Membership is not determined on a geographical basis but on suitability for the role, based on an assessment against criteria specified at the time of the recruitment of new Members. New appointments are made through an open competition following advertisement of the roles in, for example, medical journals and with relevant Professional Bodies or Networks informed about roles that may interest their members.

⁵ NICE (2008) Guide to the methods of technology appraisal.
<http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf>

Criteria for candidates are set out in an application pack sent to those who express an interest in the posts. Candidates are short-listed against the criteria and then invited for interview with the most suitable candidate for a particular role selected by an appointments panel based on the candidate's application and interview.

18. The Chair and members of JCVI play a critical role in ensuring its continued standing as an internationally recognised leading body in the field of immunisation. They bring relevant knowledge, skills and experience to the Committee and contribute to the provision of high quality and well considered advice to UK health departments.
19. In practice, the Chair and members are usually appointed for a term of up to three years with expiry at a defined date that may or may not be 31 March. Reappointment of members is not automatic. Subject to conditions including satisfactory appraisal and attendance at meetings, members are usually offered reappointment for a second, or exceptionally a third, term without the post being advertised. This is desirable to retain the expertise and experience of the Committee. However, in accordance with the Code of Practice issued by the Commissioner for Public Appointment, members cannot serve on the Committee for more than 10 years⁶.
20. If the Chair is absent or otherwise unavailable to chair a meeting then the members present shall decide which member will temporarily deputise for the Chair. The Chair and/or UK health departments may indicate a preference.
21. All members including the Chair must go through an appraisal process once every 12 months. The Chair appraises members and a senior official signs off the appraisal of the Chair on behalf of PHE, in consultation with senior officials from the UK health departments.
22. Appointments may be suspended or terminated by PHE in consultation with UK health departments, without compensation, in the event that a member fails to fulfil his or her obligations or for conduct which renders the member unfit to remain in office. Members may also resign from their office, if they wish.

⁶ The Commissioner for Public Appointments' Code of Practice
www.publicappointmentscommissioner.org/Code_of_Practice/

23. The Committee membership will normally include individuals from academia and practising clinicians who have expertise in one or more of the following areas:

- infectious diseases
- epidemiology
- virology
- bacteriology
- immunology
- vaccinology
- neurology
- public health
- mathematical modelling
- health economics
- general practice
- nursing
- paediatrics
- management of immunisation programmes

24. The Committee membership will normally include at least one but preferably two lay members to provide the committee with a wider lay perspective on issues. Vacancies in the membership or absences of members from Committee meetings do not invalidate the advice provided by the Committee unless the Chair considers there is insufficient expertise for the Committee to formulate sound advice. The range of expertise of Sub-committees may differ.

25. New members of JCVI are provided with an induction programme that covers the roles and responsibilities of membership, the function, operation and practices of JCVI and its Sub-committees, the support that the secretariat provides, the type of evidence reviewed by JCVI, how the Committee interacts with its stakeholders and all the various aspects covered in this Code of Practice.

Secretariat

26. The Secretariat to JCVI is provided by officials from Public Health England, an

Executive Agency of the Department of Health.

Medical Advisor

27. The DH Director of Immunisation is Medical Advisor to the Committee.

Observers

28. A number of designated representatives (“observers”) of government departments and health or public health bodies routinely attend Committee meetings and may also attend Sub-committee meetings. The following organisations are usually represented at Committee meetings:

- Department of Health (DH)
- Scottish Government
- Welsh Assembly Government
- Department of Health, Social Services and Public Safety, Northern Ireland
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Public Health England (PHE)
- Health Protection Scotland
- Public Health Wales
- Public Health Agency, Northern Ireland
- Public Health Directorate, Isle of Man
- Public Health Department, Jersey
- Health and Social Services, Guernsey
- National Health Service (NHS) England
- National Institute for Biological Standards and Control
- Ministry of Defence
- Health Service Executive, Ireland
- National Travel Health Centre and Network
- Medical Research Council
- UK Teratology Information Service

29. Observers are provided with access to all the Committee papers (with the exception of some restricted papers) and may, as directed by the Chair, contribute to the Committee discussions to, for example, clarify points of fact, provide additional information or offer

an interpretation of data. However, observers cannot vote on Committee decisions and must at all times respect the independence of the Committee in formulating its advice. In addition, observers are expected to inform the Committee about any potential conflicts of interest they may have when providing comments or information to the Committee in accordance with the guidance described later in this Code. Observers from UK health departments are also party to all communications between the secretariat and the whole Committee and Sub-Committees and receive without restriction all committee papers. All observers are expected to abide by this Code of Practice and sign the declaration at Annex 2.

30. Other organisations and individuals may be invited to meetings by exception, for example, to present data to the Committee and may be provided with relevant papers as appropriate.

JCVI Sub-committees

31. JCVI and PHE may agree to convene Sub-committees to delegate initial consideration of specific issues which require more detailed consideration that would be possible by the Committee and that may need substantial input from additional experts who are not JCVI members. These Sub-committees will usually include individuals who are not members of JCVI. The Chair of each Sub-committee is a member of JCVI and can be the Chair of JCVI. In circumstances where a Sub-committee has been established with a Sub-committee Chair who subsequently completes his/her term of office on JCVI, that individual may, with agreement from the JCVI Chair, continue as Chair of that Sub-committee in order for the work of that Sub-committee to be completed. Sub-committee Chairs are expected to report back to the Committee on the work of the Sub-committees following each Sub-committee meeting. Members of JCVI Sub-committees are appointed by invitation following discussions between the secretariat and the JCVI Chair and Sub-committee Chair as well as the Committee and, if already established, the Sub-committee to identify suitable invitees. The secretariat will also consult with PHE and the UK health departments when drawing up a list of potential invitees.
32. Exceptionally, JCVI may consider information and evidence jointly with another body for the purpose of providing advice. In such cases, the responsibilities of JCVI members and Sub-committee members will be as described in this Code of Practice.

33. All JCVI members and members of a Sub-committee are required to signal their acceptance of the provisions set out in this Code of Practice by signing the declaration (Annex 2) as indicated.

Responsibilities of Committee and Sub-committee Members

34. All members of the Committee and its Sub-committees must demonstrate high standards of conduct.

35. In exercising their duties, members must observe the 'Seven Principles of Public Life' set out by the Committee on Standards in Public Life (the Nolan Committee, the http://www.public-standards.org.uk/About/The_7_Principles.html)

Selflessness: Holders of public office should act solely in the public interest. They should not do so in order to gain financial or other benefits for themselves, their family or their friends.

Integrity: Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.

Objectivity: In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability: Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness: Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty: Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership: Holders of public office should promote and support these principles by leadership and example.

36. The Chair should provide effective leadership, in particular:

- ensuring that the committee carries out its functions effectively and does not exceed its powers or functions
- ensuring that the minutes of meetings and any reports accurately record the views of the committee
- ensuring that views of the committee are accurately represented when providing information to the general public and press
- providing performance management of committee members
- ensuring that the committee manages appropriately any conflicts of interest that members and the Chair may have.

37. The Chair will also under usual circumstances be involved in assessing applicants during the appointment of new members to the Committee and ensuring that new Committee members receive appropriate induction.

Conflicts of interest

38. There must be no perception of conflict between a member's private interests and his/her responsibilities as a member of JCVI or a JCVI Sub-committee. All members of the JCVI and its Sub-committees must therefore follow the rules set out in this document regarding Declarations of Interests (see later).

39. Members must declare all their interests at the time of their appointment and must promptly notify the secretariat of any changes. Before or at the start of every meeting members will be asked to declare any changes to their interests and the minutes of each meeting will include interests that are declared and how they have been handled. In addition, it is the responsibility of each member to indicate if they have an interest in

any item of business on the agenda of a meeting of JCVI or a JCVI Sub-committee at the appropriate time. Where this happens, in accordance with the provisions below, the Chair will determine whether a member should take part in any discussion or decision on an issue.

40. The role of the Chair necessitates that he/she cannot have any interests that may conflict with his or her responsibilities to JCVI, and the same applies for the Chairs of Sub-committees. Therefore, the JCVI Chair and Sub-committee Chairs cannot have interests that could conflict with the issues under consideration by the JCVI or Sub-committee, respectively.
41. If, exceptionally, the JCVI Chair or Sub-committee Chair has an unresolved conflict of interest then he/she shall step aside until that is resolved. He/she may still take part in the proceedings of the Committee according to the rules set out below. In the case of JCVI, members present at the meeting shall decide which member will temporarily deputise for the Chair. In the case of a Sub-committee, the JCVI Chair may either chair the Sub-committee in the absence of its Chair or ask another Sub-committee member to do so.

Declarations of Interest

42. JCVI members and Sub-committee members must abide by the following rules when deciding whether to declare an interest.

Personal pecuniary (financial payment or other benefit) interest

If a member has in the last 12 months received, or plans to receive a financial payment or other benefit from a business or representative body relating to vaccines or any other product or service that could be under consideration by JCVI or a Sub-committee including:

- holding a directorship, or other paid position
- carrying out consultancy or fee paid work
- having shareholdings or other beneficial interests
- receiving expenses (e.g. travel to, or registration for, conferences) and hospitality

the member must declare this interest.

If this interest is specific to an agenda item and the payment or other benefit is connected specifically with the product under consideration, the member will be required to absent him/herself from the discussion and any subsequent vote.

If this interest is not specific to the agenda item (i.e. if the payment relates wholly to other products), the member will be able to participate in the discussion but not in any subsequent vote.

Personal family interest

In the last 12 months, if one of a member's family received, or plans to receive, a financial payment or other benefit from a business or representative body relating to vaccines or any other product or service that could be under consideration by JCVI or a Sub-committee including:

- holding a directorship, or other paid position
- carrying out consultancy or fee paid work
- having shareholdings or other beneficial interests
- receiving expenses and hospitality over and above the equivalent level provided by PHE to JCVI members for travel and subsistence (see section on expenses) then the member must declare this interest.

If the payment is connected with a product or service under consideration, the member will be required to absent him/herself from the discussion and any subsequent vote.

If this interest is not specific to the agenda item (i.e. if the payment relates wholly to other products), the member will be able to participate in the discussion but not in any subsequent vote.

Non-personal pecuniary interest

If a member has senior responsibility for a department or organisation that has received or plans to receive a financial payment, or other benefit in the last 12 months from a business or representative body relating to a product or service under consideration, including:

- a grant or fellowship or other payment to sponsor a post, or contribute to the running costs of the department
- commissioning of research or other work

then the member must declare this interest.

If the payment or benefit is connected with a product under consideration, the member will still be able to participate in the discussion, unless the Chair rules otherwise, but not any subsequent vote.

If the payment or benefit relates wholly to other products, the member will be able to participate in the discussion and any subsequent vote.

Personal non-pecuniary interest

If a member has acted in a way such that the public might reasonably believe that he or she will not consider evidence in a fair and unbiased manner, such as active advocacy, in the last 12 months, on behalf of an organisation with a clear opinion on the matter under consideration then the Member must declare this interest. The member will be able to participate in the discussion and decision according to the Chair's ruling.

43. As noted above, the Chair and Sub-committee Chairs will not normally have any interests to be declared. If the Chair or Sub-committee Chair has any unresolved conflict of interest of any kind then he must stand aside until that matter is resolved. This may require another member to temporarily deputise for the Chair (as set out above).

44. In accordance with the Code of Practice for Scientific Advisory Committees, the Secretariat will review and maintain a register of members' relevant interests annually, publishing details as part of an annual report or similar routine progress update.

Confidentiality

45. JCVI and its Sub-committees deal with confidential information and meetings are not open to the public. Procedures to provide strict confidentiality are required, although JCVI aims to publish as soon as practicable the information and evidence considered in the development of its advice and recommendations. Members are asked to take

particular care to avoid premature or selective disclosure of the Committee's deliberations. All JCVI and Sub-committee members are required to confirm their agreement to the confidentiality provisions of this Code of Practice (by the declaration attached at Annex 2).

46. Members must not, without authority, disclose any information which has been communicated in confidence to them in their capacity as a member of JCVI or a Sub-committee.
47. Members may receive documents with protective markings applied by the secretariat in accordance with the Government Protective Marking System. Such markings may include "PROTECT" and "RESTRICTED". Instructions for the handling of such documents are given in Annex 3 and must be adhered to strictly. Information about the criteria used for Government protective markings is available at www.cabinetoffice.gov.uk/spf.aspx
48. A member who misuses information gained by virtue of his or her office may be liable for breach of confidence under common law and / or may commit a criminal offence under insider dealing legislation.

Accountability

49. Members are free to maintain associations with trade unions, co-operative societies, trade associations etc. to the extent that such associations do not conflict directly with the interests of the Committee. If members have any doubt about any of these matters, advice should be sought from the Secretariat.
50. Any legal proceedings initiated by a third party are likely to be brought against the Committee as a whole, although in exceptional cases proceedings (civil or, in certain cases, criminal) may be brought against the Chair or other individual Committee members.
51. In response to a recommendation in the Neill Committee's report on "Public liability in public service organisations" (published in 1998) the Treasury reviewed the means of

legal protection available to appointees in Non-Departmental Public Bodies (NDPBs). It was required to “*ensure that, if such protection continues to be provided in the form of a standard indemnity, its terms accord with the protection which would be afforded under a commercial insurance policy*”.

52. As a result of the review, Treasury Ministers have agreed that wider indemnity than that previously provided should be offered to Committee members in the following terms:

“The Government has indicated that an individual Committee member who has acted honestly and in good faith will not have to meet out of his or her personal resources any personal civil liability which is incurred in the execution or the purported execution of his or her Committee functions, save where the person has acted recklessly.”

53. On 19 January 1999, Departmental Accounting Officers were asked by HM Treasury to issue suitable indemnities to their Committee members consistent with the text above. In line with this request a copy of the indemnity offered to JCVI members is attached at Annex 1. Each new member is asked to sign acceptance of the indemnity on appointment to the Committee. The indemnity is also offered to members of JCVI Sub-committees covered by this Code of Practice.

54. If a Member is at any time unclear whether or not an action in contemplation would be classified as duties as members of JCVI or its Sub-committees he or she should clarify this with the secretariat.

55. As JCVI advice may be used by UK health departments or public health bodies, any legal challenge to any action taken on the advice or recommendations of the Committee will be the responsibility of that department or body rather than the JCVI.

Development of JCVI advice and recommendations

56. Topics for consideration by JCVI are identified by PHE or the UK health departments following requests for advice, by Members themselves, health professionals, the public or through the Committee’s annual horizon scanning of vaccine developments. The agenda of meetings are developed by the secretariat in consultation with the JCVI Chair and with input from PHE and the UK health departments.

57. JCVI formulates advice and recommendations based on appraisal of the best scientific and other evidence available and reflecting current good practice and/or expert opinion. The process involves a robust, transparent, and comprehensive appraisal of the available evidence from a wide range of sources that includes:

- relevant published literature;
- unpublished data provided by, for example, vaccine manufacturers on the safety, immunogenicity and efficacy of vaccines (usually on request);
- advice from international and national bodies (e.g. WHO, ACIP, IoM, NICE, professional bodies, patient groups, charities);
- correspondence with key experts;
- commissioned clinical research to examine, for example, the safety and immunogenicity of specific modifications to the immunisation schedule;
- commissioned epidemiological analyses of the incidence of disease or population susceptibility to disease;
- commissioned operational analyses to assess, for example, aspects of the possible implementation of immunisation programmes;
- commissioned attitudinal research to assess public and healthcare professional perceptions about vaccine preventable diseases and immunisations against them and the likely acceptance of immunisation programmes;
- commissioned bespoke mathematical modelling studies of the impact and cost effectiveness of immunisations strategies;
- horizon scanning of vaccine developments that seeks information from groups/organisations developing vaccines on what new vaccines may become available or whether there may be major changes to the indications for existing vaccines;
- calls for evidence from interested parties to request from, and provide an opportunity for, stakeholders to provide unpublished data or evidence. Specific groups/organisations believed to have an interest in the call for evidence will be notified but the call is open to any group/organisation with an interest in the issue.

58. The nature of JCVI advice can be separated broadly into three forms:

(i) evaluation of a new immunisation programme or major changes to, or discontinuation of, an existing immunisation programme, possibly as a recommendation under the Health Protection (Vaccination) Regulations 2009;

(ii) evaluation of a minor change to an existing programme (e.g. review of the clinical definition of clinical risk group to which an immunisation should be offered);

(iii) assessment of an emerging immunisation-related issue or new report on, for example, the coverage of vaccinations, implementation of immunisation programmes, the clinical effectiveness of an immunisation programme, a potential vaccine safety issue or horizon scanning of vaccine developments. Generally, JCVI receives a report on vaccine safety on routine immunisations annually from the MHRA, an annual report on horizon scanning of vaccine developments prepared by the secretariat and data on the coverage of routine childhood immunisations at each meeting and on other routine immunisation programmes annually from PHE and other UK health departments/public health bodies.

59. The approach taken to review the evidence necessarily differs according to the issue under consideration. However, the process for all three forms of JCVI advice generally involves identification of evidence through searching for papers using defined search criteria and information from a wide range of sources that may include analyses or reports commissioned specifically to address certain issues, although often this may not be required for (iii). The aim is to generate a comprehensive body of evidence that will allow the relevant issue(s) to be addressed authoritatively, and to highlight any important gaps in the evidence, including any that need to be addressed before final advice can be provided. This body of information can often include submissions from vaccine manufacturers that are provided to JCVI or a JCVI Sub-committee in confidence for commercial reasons. It may also include yet to be published studies from academic groups that are also provided in confidence prior to publication. The evidence considered by the Committee or Sub-committee is listed as an annex to the minute of the meeting at which it is discussed.

60. Generally consideration of (i) will follow the approach outlined in Box 1. This will include extensive evidence gathering using systematic searches of the literature (e.g. using databases such as PubMed with defined search terms) to identify as comprehensively as possible the published evidence relevant to the issue under

consideration and may also include a public call for evidence and specifically commissioned reviews or analyses. A JCVI Sub-committee may be set up to review the evidence in detail, possibly over a number of meetings, and provide advice to JCVI. JCVI will consider the advice of the Sub-committee and often also the key evidence upon which that advice is based. Depending upon the issue under consideration, once JCVI has reached a position, the Committee may decide to issue an interim statement for a short (around one month) period of consultation with those stakeholders who submitted evidence that informed the Committee's advice. Stakeholder responses would be reviewed by JCVI, and possibly the Sub-committee involved in developing the advice, before the Committee reaches a final position and makes a final statement that is subsequently published.

61. There may be occasions when on emergency public health grounds some of the steps outlined in Box 1 may be by-passed for expediency, for example, to consider a vaccination programme in the event of an influenza pandemic or evidence of another emergent disease epidemic (e.g. pertussis). Generally, in these situations, it will not be possible to include a stakeholder consultation on the advice from (ii) or (iii) on practical grounds.

62. When identifying a need for epidemiological analyses, clinical research studies or mathematical modelling studies, JCVI has historically requested these from the Health Protection Agency (now PHE) led National Vaccine Evaluation Consortium or from the HPA (now PHE) Centre for Infections. These studies are conducted to a sufficiently high standard to be publishable in the peer-reviewed scientific literature and JCVI encourages the research groups to submit the studies for publication in the peer-reviewed scientific literature. However, publication can take time and often the studies may not have been published by the time that JCVI issues advice. Prior release of the studies may prejudice their publication in the peer-reviewed scientific literature. Once the studies have been published in the peer-reviewed literature, the original study reports can be released onto the JCVI website. Operational and other analyses have been provided by the DH Health Protection Analytical Team. Attitudinal research has been commissioned by DH on a study by study basis.

63. There are established requirements for the production of mathematical modelling

studies on the impact and cost effectiveness of vaccination strategies. Development of these studies includes comprehensive evidence gathering including literature review to support the modelling that is usually supplemented by data from vaccine manufacturers. The studies follow the criteria, methodology and practice of NICE for cost effectiveness analysis and are based on the situation within the UK. The studies list all relevant assumptions and the sources; a full description of the methodology and base-case and variant scenarios, in sufficient detail for full assessment; sensitivity analyses adapted to the nature of the particular uncertainties of the disease(s) under consideration; the health impact in terms of natural measures for the particular infection (e.g. cases, GP consultations, hospitalisations, deaths); examination of the impact of different discount rates; cost effectiveness based on costs per quality adjusted life years (QALYs) and as a function of vaccine price at different cost *per* QALY thresholds. Following completion, the studies are peer-reviewed by independent experts in the epidemiology of the particular disease(s), in mathematical modelling and in health economics sometimes in conjunction with a JCVI Sub-committee at a meeting or anonymously by correspondence. The peer-review involves assessing the studies against a comprehensive set of questions⁷ to determine whether the study is scientifically and methodologically sound and is suitable and sufficiently robust to support the formulation of JCVI advice. Consideration will also be given to other cost effectiveness studies, including those provided by vaccine manufacturers, that can be used to assess the independent bespoke study but the final advice will be based on the independent study, not those provided by vaccine manufacturers. When assessing cost effectiveness, the Committee and Sub-committees take into account the advice and recommendations of the Working Group on Uncertainty in Vaccine Evaluation and Procurement when assessing cost effectiveness (report appended).

64. In future, the epidemiological and mathematical modelling studies will be provided by teams primarily within PHE and possibly also from DH commissioned programmes of research from academic groups or other independent sources. The clinical research

⁷ Questions typically include: are assumptions made about the epidemiology and burden of disease and vaccine characteristics reasonable based on the available evidence; is the approach to estimating the impact of indirect protection appropriate; are the analyses methodologically sound; are the economic analyses sound; is uncertainty adequately represented and qualitatively, and if possible quantitatively, represented and assessed by sensitivity analyses; is the base-case representative; does the study provide an adequate basis for JCVI to provide advice to decision makers and / or are additional analyses required. Variations on these questions or additional questions may be asked depending on the nature of the issue and the modelling study.

may be commissioned through NVEC or from a National Institute for Health Research Health (NIHR) Protection Unit or NIHR Public Health Research Programme. Operational and other analyses will continue to be provided by the DH Health Protection Analytical Team. PHE may commission attitudinal research.

65. The JCVI secretariat gathers the evidence to present to JCVI in the form of papers, including the reports on commissioned studies, for discussion at Committee or Sub-committee meetings. In the course of the meetings, the Committee or Sub-committee, utilising the individual and collective expertise available, assesses and interprets the evidence through consideration of its quality based on an assessment of the methods employed, the strengths and limitations (the selection of study participants and controls, the techniques used to measure the outcome(s), the statistical analyses of the findings, risk of bias, level of uncertainty in the results, strength of association, biological plausibility) and hence the validity of the results, and the relevance and strength of the findings to the issue under consideration.

66. Advice or recommendations are normally formulated during the course of meetings. If a matter requires an urgent response the secretariat, with the agreement of the JCVI Chair, may seek the relevant advice by correspondence or telephone conference with the Committee and similarly with a Sub-committee Chair for a Sub-committee.

Box 1: General schematic for the evaluation of a new immunisation programme or major changes to, or discontinuation of, an existing immunisation programme, possibly as a recommendation under the Health Protection (Vaccination) Regulations 2009

Defining the issue

Need for advice on new or expanded immunisation programme made by UK health department(s) or identified by committee horizon scanning

Evidence gathering (including on disease epidemiology, vaccine safety and effectiveness and impact and cost effectiveness of potential immunisation strategies)

Public call for evidence from interest parties issued to gather evidence from stakeholders

Systematic search of published literature identified and summarised
Impact and cost effectiveness study commissioned

Evidence analysis

JCVI Sub-committee usually (but not always) convened with specific terms of reference and meets to:

- (i) review submissions made in response to call for evidence
- (ii) review published literature
- (iii) review preliminary impact and cost effectiveness study and agree the scope and initial assumptions
- (iv) identify important data gaps
- (v) agree key data needs and commission further research and/or analysis and/or data from, e.g., vaccine manufacturers
- (vi) review further evidence gathered or reports of studies commissioned
- (vii) final impact and cost effectiveness study is peer-reviewed by Sub-committee and/or other experts
- (vi) agree report to JCVI

Advice formulated

- (i) final impact and cost effectiveness study peer-reviewed by Sub-committee and/or other experts considered by JCVI, along with any other relevant reports and the advice from the Sub-committee
- (ii) JCVI formulates advice and recommendations
- (iii) interim JCVI statement summarising the interpretation of the evidence and the Committee's conclusions prepared
- (iv) interim statement may be issued for one month stakeholder consultation with those that submitted evidence
- (v) consideration of stakeholder responses and final advice / recommendations agreed by JCVI
- (vi) finalised statement provided to PHE and UK health departments and published

Communications with PHE and UK health departments

67. Communications between the Committee and PHE and UK health departments will usually be through the senior representatives of these bodies, normally via the secretariat, with the JCVI Chair. Generally the Committee will communicate its advice to PHE and UK health departments through the published minutes of Committee and Sub-committee meetings and statements produced by the Committee. These will be provided by the secretariat when finalised by the Chair and/or Committee to the DH Director of Immunisation and senior medical officers from the other UK health departments prior to publication. The JCVI Chair may also request access to Ministers or Chief Scientific/Medical Advisors on any matter that he or she believes raises important issues relating to the advice or operation of the Committee. Ministers or Chief Scientific/Medical Advisors may request advice from the Committee directly or to meet with the JCVI Chair.

Communications with the media

68. Members of JCVI or JCVI Sub-committees should not speak to the media as a member or voice of the JCVI or JCVI Sub-committee. All enquiries from the press should be directed via the PHE press office to the Chair of the JCVI. Members should inform the Chair and secretariat of all relevant contacts with the media. A JCVI member or Sub-committee member may discuss with the media, an issue that has also been discussed at JCVI, but should take care to explain that he/she is discussing it in an individual professional capacity and not as a member of JCVI or on behalf of JCVI or its Sub-committees. The member should not divulge information that is only available to JCVI or JCVI Sub-committee members including the outcome of discussions. In addition, the member will need to consider whether participation in such discussions could constitute an interest (for example a personal non-pecuniary interest) for the purpose of their declaration.

Publication Scheme

69. JCVI and its Sub-committees must comply with the Freedom of Information Act 2000 (FOIA) which came into force on 1st January 2005.

70. The Committee is committed to making as much of its work open to public scrutiny as possible. However, often information discussed by JCVI is not in the public domain and the default position is that JCVI will meet in closed session. This allows members to have free and open debate before coming to any conclusions, which will be fully and explained clearly in minutes or statements when these are published.
71. JCVI advice and recommendations are published in the minutes of meetings. Where advice or recommendations relate to a new vaccination programme, or revisions to an existing vaccination programme, these are also published in a JCVI statement. Since UK health departments and Ministers may wish to consider and come to view on the advice given in JCVI statements before they are published, publication will be after statements have been considered.
72. The agenda for a JCVI meeting is published about one week before the meeting. Draft minutes are published within six weeks of the Committee meetings. Final minutes are agreed at the following meeting and these are published replacing the draft version. Sub-committees minutes are normally published following review and approval by the Sub-committee and their review by JCVI at its next meeting. Where there are items of business which are urgent and need to be dealt with through correspondence before the next scheduled JCVI or JCVI Sub-committee meeting, the minute of the subsequent JCVI meeting will note that the issue has been discussed and what the conclusions were.
73. Since 2009, the Committee's aim has been to eventually publish all papers considered. All those invited to provide papers for the Committee or Sub-committees will be made aware of this publication process. However, this does not mean that confidential papers will necessarily be published. Under the FOIA, except where an absolute exemption applies, material should be disclosed unless the public interest in maintaining the exemption in question outweighs the public interest in disclosure.
74. Summary reasons will normally be given why particular papers are being withheld from routine publication, in line with exemptions available under the FOIA. Examples are:
- 'Published' – s.32 'information accessible to applicant by other means'

- 'Pre-publication' - s.22 'information intended for future publication' or s.41 'information provided in confidence'
- 'Commercial' – s.43 'commercial interests'
- 'Policy' - s.35 'formulation of government policy, etc'

75. Further releases of information about papers considered may be made subsequently, either following a review or decisions on a specific request under the FOIA. In these circumstances, papers may be published with redactions to withhold information in line with provisions of the FOIA.

76. If papers contain commercially sensitive information or information about named individuals, the general principle of common law duty of confidentiality will apply, except in cases where the information was provided under legislation which deals specifically with disclosure and non-disclosure.

77. JCVI may be asked to comment, prior to publication, on unpublished research, draft risk assessments, draft guidelines, draft pre-publication material. Premature disclosure of unpublished research may prejudice publication in scientific or medical journals. There is a generic understanding that scientific advisory committees will treat unpublished research in confidence until it has been peer-reviewed and published in the scientific or medical literature, unless the investigators give specific permission for pre-publication release. This helps ensure that the Committee has access to as much of the relevant, but unpublished, data as possible.

78. Similarly draft assessments or cost effectiveness analyses may, in some cases, be treated as confidential until finalised and published. There may be a delay between JCVI's review of a draft assessment and publication of the committee's advice to allow the appropriate Government departments to develop risk management strategies. In these cases, relevant papers, minutes and statements (or parts thereof) may need to be temporarily withheld, pending publication.

79. JCVI may be asked to provide scientific advice early in the drafting process when Government departments revise or produce new guidelines/advice on policy issues. As

Ministers may wish to have the opportunity to consider new or revised guidelines/advice before these are finalised and placed in the public domain, the committee may be asked to provide advice on draft guidelines in confidence.

80. In addition, Government rules prevent departments discussing issues surrounding policy development in public during an election period. This is from the date a general election is announced until the election is completed.

81. In summary, JCVI aims to publish the following documents:

- JCVI Code of Practice, including Terms of Reference
- JCVI Meeting Agendas and Minutes
- JCVI Statements
- JCVI papers from 2009 (if not withheld in line with FOIA exemptions)
- JCVI Sub-committee Minutes
- JCVI Sub-committee papers from 2009 (if not withheld in line with FOIA exemptions)
- Register of JCVI members' Interests

All the documents detailed above will be made available on:

<https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>

82. The Publication Scheme is reviewed from time-to-time, and at least every two years, in line with the decisions of the Information Commissioner. Thus, this Scheme will be reviewed no later than April 2015.

The Green Book

83. *Immunisation against infectious disease* or 'the Green Book' is the joint clinical guidance of UK health departments for health professionals who administer immunisations or who provide information or advice on them. JCVI advice and recommendations inform revisions to the Green Book, and thus it can be considered a product of JCVI advice. Generally, minor changes based on advice from JCVI are cleared with the Clinical Editors of the Green Book. However, a range of other bodies may be consulted on the wording and accuracy when making major changes to existing

chapters or adding new chapters to the Green Book that may include: UK health departments and public health bodies, MHRA, vaccine manufacturers, NHS England, NaTHNaC, as well as the Clinical Editors and JCVI.

84. The updated 'Green Book' is available on the website at:

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Expenses

85. JCVI has no budget. Although members are not remunerated, they are eligible to claim expenses in accordance with Public Health England rules for travel, subsistence and overnight accommodation as set out in Annex 4. All reasonable receipted childcare and carer expenses will be reimbursed where applicable. As noted above, JCVI members will not gain financial benefit from their membership of the committee.

Annex 1 – Indemnity letter

INDEMNITY OFFERED TO MEMBERS OF JCVI INDEMNITY BY THE SECRETARY OF STATE FOR HEALTH TO MEMBERS OF THE JOINT COMMITTEE ON VACCINATION AND IMMUNISATION AND RELATED SUB-COMMITTEES.

The Secretary of State for Health hereby undertakes with each of the members of the Joint Committee on Vaccination and Immunisation and all of its Sub-committees covered by the code of practice ("the members") to indemnify them, their estates and their heirs against all personal civil liabilities in respect of any action or claim which may be brought, or threatened to be brought, against them either individually or collectively by reason of or in connection with the performance at any time of their duties as members, whether before or after the date of this indemnity, including all costs, charges and expenses which the members or any member may properly and reasonably suffer or incur in disputing any such action or claim.

The members or any member shall as soon as reasonably practicable notify the Secretary of State if any action or claim is brought or threatened to be brought against them or any of them in respect of which indemnity may be sought pursuant to paragraph 1. If any action or claim is brought the Secretary of State shall be entitled to assume the defence. The Secretary of State shall notify the members or member as soon as practicable if the Secretary of State intend to assume the defence and the members or member shall then provide such information as the Secretary of State reasonably requests, subject to the Secretary of State reimbursing all out of pocket expenses properly and reasonably incurred by members or any of them. The Secretary of State shall, where reasonable and practicable, consult with and keep the members or any of them informed of the progress of the action or claim. Where the Secretary of State does not assume the defence, members or any of them shall keep the Secretary of State fully informed on its progress and any consequent legal proceedings and consult with the Secretary of State as and when reasonably required by them or any of them concerning the action or claim.

The indemnity contained in paragraph 1 shall not extend to any losses, claims, damages, costs, charges, expenses or any other liabilities:

- a) in respect of which members are indemnified by or through any defence organisation or insurers; or
- b) which may result from bad faith or wilful default or recklessness on the part of the members; or
- c) which may result from any of the following circumstances (without the prior written consent of the Secretary of State having been obtained such consent not to be unreasonably withheld):

- any settlement made or compromise effected of any action or claim brought, or threatened to be brought, against them; or
- any admission by the members of any liability or responsibility in respect of any action or claim brought, or threatened to be brought, against them; or
- members taking action that they were aware, or ought reasonably to have been aware, might prejudice the successful defence of any action or claim, once the members had become aware that such an action or claim had been brought or was likely to be brought.

Annex 2 - Declaration of agreement to Code of Practice, including confidentiality provisions

This declaration is for the use of all members of the Joint Committee on Vaccination and Immunisation (JCVI, the Committee), all members of its Sub-committees and all invited observers (other than those who are subject to the Civil Service Code) in their work with JCVI or its Sub-committees.

The JCVI Code of Practice, amongst other provisions, contains:

- the Seven Principles of Public Life
- rules for the declaration of interests by JCVI members and members of JCVI Sub-committees
- a binding requirement that members must not, without authority, disclose any information which has been communicated in confidence to them in their capacity as a member of JCVI or a JCVI Sub-committee.

DECLARATION

I have read and understood the JCVI Code of Conduct, including the provisions mentioned above.

I agree that I will abide by the provisions of the JCVI Code of Conduct for
(a) the period of time I am a JCVI member / a JCVI Sub-committee member / an invited observer, and
(b) in respect of confidentiality, thereafter for such periods of time as information communicated in confidence is not disclosed by authority

SIGNED

SURNAME (BLOCK LETTERS)

FORENAME(S) (BLOCK LETTERS)

DATE

TITLE OF SUB-COMMITTEE (IF RELEVANT)

Annex 3 - Handling documents with protective markings

1. Any JCVI paper with a protective marking (for example, PROTECT or RESTRICTED) should not be shared further with others. Please contact the secretariat with any queries.
2. Protectively marked JCVI papers must be stored only in a locked container. They must not be left out on an unoccupied desk.
3. Keep protectively marked JCVI papers in your possession at all times when carrying them outside your own office or home.
4. Protectively marked JCVI papers may be disposed of by cross-cut shredding or they can be torn up small and mixed with other waste. Unwanted papers may also be returned to the secretariat for disposal.
5. All JCVI papers will be reviewed for publication. This may result in the publication in redacted form of some papers with protective markings. In that case, the original papers retain their original protective marking. If the protective marking of a complete paper is changed (ie deleted) then JCVI members will be informed of the change.

Annex 4 - Public Health England standard rates for expenses

Reimbursable day expenses

Over 5 hours - one receipted meal up to a ceiling limit of £5

Over 10 hours - two receipted meals up to a ceiling limit of £10

Over 12 hours - two receipted meals up to a ceiling limit of £15.00

Night subsistence rates

When staying at a hotel: Up to £85.00 per night of receipted cost if staying outside of London (£115.00 London only). Plus a meal allowance of up to £22.50 with receipts can be claimed for each night away.

Travel expenses

Travel by public transport.

Taxis: May be used for local journeys (less than 5 miles) and must be receipted. The use of taxis in London should only be undertaken as a real necessity, e.g. not during normal working hours or where the underground is available etc.

Private car: Business journeys in your own care are reimbursed at the single rate of 25p per mile. There is a passenger supplement of 5p per mile for one and 2p per additional passenger per mile.

Rail: Lowest cost option for travelling by rail should be the default option. Rail tickets purchased should have date and time restrictions where possible. Rail tickets should be purchased in advance of travel.

Air: Lowest cost option for air travel should be default option. All domestic air flights should be economy class without exception. All air tickets to be purchased in advance of the date of travel.

Overseas travel and subsistence: Overseas subsistence rates are set separately for each country and expressed in the currency of the country, although in some cases payments will be based on receipted actuals only. For more details contact the secretariat.

Annex 5

Report from the Working Group on Uncertainty in Vaccine Evaluation and Procurement

(18/09/2012)

1. Introduction

1. The Working Group (see Annex A) was set up to provide the Department of Health (DH) and the Joint Committee on Vaccination and Immunisation (JCVI) with technical advice and more general expert opinion on issues surrounding uncertainty in vaccine evaluation and procurement.
2. The Working Group considered the current processes for evaluation of cost-effectiveness by the JCVI and subsequent procurement process. They focussed on: the way the JCVI determined whether it viewed a particular programme as cost-effective, the way it took account of uncertainty, and the implications of this for the procurement process.
3. After discussion within the group and with DH officials, it was agreed that the aims of the Working Group could be summarised as being:
 - to provide the JCVI with guidance as to how they should determine if a vaccine programme is cost-effective, taking into account uncertainty;
 - to propose a method for the DH vaccine procurement process that ensures that procurement decisions are consistent with the JCVI determination concerning cost-effectiveness.

2. The existing process for evaluation of cost-effectiveness and subsequent procurement process

4. This section summarises the current process used for the evaluation of cost-effectiveness. It is included to provide a context for the Working Group's recommendations for how this process could change in the future, as set out in sections 3 to 6.
5. The current methods, issues and general background were set out for members of the Working Group in documentation and were discussed at the first meeting. The Working Group understood the current process to be as summarised in this section.
6. The JCVI has previously decided in principle to follow a similar methodology to National Institute of Clinical Excellence (NICE) technology appraisals¹. This ensures consistency across these programmes relating to different technologies drawing on the same National Health Service (NHS) budget (when this report refers to the NHS budget or resources, it considers a wide definition, which would include all the public expenditure

spent on health and social care). The JCVI is presented with cost-effectiveness modelling which assumes a particular price for the vaccine (usually the UK “list” price if available, or an estimate based on a price published elsewhere).

7. This cost-effectiveness modelling will often be subject to considerable uncertainty. One form of uncertainty will be that surrounding the value of each parameter in the model: for example, there will be uncertainty about the precise degree of effectiveness of the vaccine. Other uncertainty will relate to the structure of the model: there can often be uncertainty around how best to model disease progression, or there may be biologically plausible reasons to believe a vaccine may be beneficial beyond its main purpose of a vaccine, but there may only be limited evidence to support this belief.

8. In the light of the clinical evidence and modelling of cost-effectiveness, the JCVI then makes a judgement on the cost-effectiveness of the vaccine at the assumed price. The expertise within the JCVI can help it understand and make judgements about the uncertainty relating to the health benefit that a particular vaccine may offer, but inevitable uncertainty remains.

9. The JCVI may consider the vaccine(s) to be cost-effective at the assumed price. However, if there are competing vaccines available, DH still needs to decide which vaccine should be purchased.

10. If the JCVI does not consider the vaccine(s) to be cost-effective at the assumed price, but considers the vaccine(s) to be clinically effective, the DH might still be able to purchase the vaccine(s) at a lower price than that assumed, and so still need to decide whether, if offered at a lower price than had been assumed, the vaccine should be purchased.

11. Following Ministerial consideration of the JCVI's advice and recommendations, DH may issue a tender to procure a supply of a vaccine. The invitation to tender contains Evaluation Criteria explaining how each tender will be evaluated. The prices tendered are commercially confidential and not shared beyond a very few people at DH.

12. The Evaluation Criteria are operationalised as a points-based scoring system. The aim is to maximise a measure of expected Net Health Benefit (NHB) taking account of the opportunity costs of alternative uses of NHS funds. The score given to each vaccine tender represents a quantity proportional to the NHB. It is based around an assessment of the difference between the ‘cost per course of vaccine required to be cost-effective’ and the ‘tendered cost per course of vaccine’.

13. If only one manufacturer has tendered, the contract will be awarded if the score is positive. If it is a competitive tender, the manufacturer with the vaccine with the largest positive score (suggesting the largest NHB) will be awarded the contract.

14. Despite the recognised uncertainty, this definitive rule based approach still requires a single value for the “cost per course of vaccine required for cost-effectiveness”. Current DH practice is to assume that the JCVI would have considered there to be significant health benefits not captured by the cost-effectiveness modelling and, as a consequence, that they would have used a threshold of £30,000 per QALY. Remaining uncertainty is currently dealt with by the requirement that, to demonstrate cost-effectiveness, DH needs to be ‘almost sure’, that the vaccine procurement provides a positive NHB. Depending on the way the analysis has been carried out, where the uncertainty (parameter or structural) can be quantified, this might be that of the order 95% of scenarios in a Monte Carlo simulation are below a £30,000 per Quality Adjusted Life Year (QALY) threshold. Non-quantifiable structural uncertainty requires a judgement (based on JCVI discussion) of the level of health gain that can be considered ‘almost sure’.

3. Guidance for the JCVI when considering if a vaccine is cost-effective

15. The Working Group recommends that in future the JCVI explicitly consider the cost-effectiveness of proposed programmes in the following steps that are spelt out in more detail in the subsequent sections of this report.

- **The JCVI should determine what they consider, taking account of all the relevant evidence, to be the most plausible estimate of the incremental cost-effectiveness ratio (ICER) of the programme in question.** In determining this, they should consider whether the modelling presented to them fully captures all the health benefits, and all the associated costs. Where the modelling does not capture all such relevant health benefits or costs, the JCVI, guided by available evidence, should use their judgement to adjust the modelled estimates to reflect what they believe to be the most plausible ICER;
- **This most plausible ICER then should to be tested against the threshold value of £20,000: to be cost-effective the most plausible ICER needs to be no greater than this threshold.**
- **The JCVI should also consider how certain they are of their most plausible ICER estimate i.e. to determine the degree of uncertainty around the estimate.**
- **They should then assure themselves given the uncertainty the risk of the programme being not cost-effective is acceptable. The level of risk aversion that the committee should demonstrate is a difficult judgement, but we recommend that the JCVI should require that their estimate of the likelihood that the true ICER exceeds £30,000 per QALY is no more than 10%.**

- **With that explicit analysis from the JCVI, the DH should be able to proceed with the procurement process and make decisions consistent with the Committee's expert judgement of cost-effectiveness.**

3.1 Consistency with NICE

16. As noted, the JCVI has previously decided in principle that it wishes to use a similar methodology to that used by NICE for its technology appraisals programme, to ensure consistency in spending decisions for different technologies. The Working Group took this starting point as a given, and has attempted to define methods that, whilst in detail may be specific to the particular circumstance of the work of the JCVI and the need to guide the subsequent procurement process, are aimed at achieving a similar decision making framework to that which follows from the application of the NICE methodological guidance.

3.2 The most plausible estimate of the ICER

17. The Working Group recommends that the JCVI try to ensure that the estimated ICER, with which it is presented, adequately captures all the health benefit and relevant cost factors they consider important, and that are consistent with the perspective adopted by NICE. Currently, the perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers), and the perspective adopted on costs should be that of the NHS and Personal Social Services. (Paragraph 54 addresses the need to maintain consistency in the event of future changes).

18. Most relevant benefits and costs can be, and are already, captured in the analyses the JCVI normally receives. For example, modelling from the Health Protection Agency normally allows for the benefits of herd immunity, and cost savings to the NHS from vaccination.

19. Where all relevant benefits and costs have been incorporated in the model, the JCVI should then agree what it believes to be the most plausible estimate of the ICER. Where uncertainty, both parameter and structural, can be quantified in the model, the most plausible estimate for the ICER should be a measure of central tendency from the uncertainty highlighted by the model. In general, the Working Group recommends that the most plausible estimate is constructed by assuming the most likely set of parameter values within the model. (Particular cases may suggest other measures such as the median of a Monte Carlo type analysis.) Where, for example, structural uncertainty is shown by a number of estimated ICERs, the JCVI will need to make a judgement of the 'most likely' or use a weighted average.

20. However, specific relevant aspects of the health benefits or other cost factors may not have been directly captured in the modelled ICER. Where such factors are identified, the JCVI should request that it be presented with analyses that give an indication of the plausible magnitudes of such factors that have been omitted from the formal modelling. This additional information may make it clear that the scale of the effects in question is so small that it would be inappropriate to attempt to model them, and that they would be unlikely to affect their decisions.

21. Where, exceptionally, it is clear that in (a) specific way(s) the estimate before the committee does not allow for a significant element of expected health benefit or cost savings, the JCVI should consider how they would adjust the modelled ICER (or multiple ICERs representing say, structural uncertainty).

22. The Working Group was clear that, contrary to what had been suggested to it, the argument that 'prevention is better than cure' is not a logical rationale for a higher cost-effectiveness threshold for vaccines. To the extent that this common adage is true, any health benefits or reduced costs due to prevention would generally have been captured in the initial cost-effectiveness modelling.

23. However, the Working Group recognised that there were a number of factors that might potentially be important in the case of vaccines and which were probably not currently quantified in the analyses presented to JCVI. Examples of these might include, but will not be limited to, the following:

24. Effects that would reduce the most plausible ICER:

- the higher than average costs savings from averting a hospitalisation from an infectious disease that causes epidemics with pronounced peaks. (Though not currently considered in modelling, in principle an effect such as this could be incorporated if it were thought to be important.);
- the reassurance or peace of mind that individuals receive from their personal vaccination as well as the vaccination of the wider society;
- the public concern and unquantified social implications that would value preventing an epidemic outbreak of a disease in a local area in excess of the same health effect were it to be dispersed over time and geography;

25. Effects that would increase the most plausible ICER:

- reducing the specific health risk targeted by the vaccine may bring changes in behaviour that would increase the burden associated with other infectious diseases;
- replacement effects that may see a rise in prevalence of strains of disease not targeted by vaccine;

- in a busy vaccination schedule, in childhood for example, introducing the vaccine under consideration might disrupt or otherwise reduce the effective delivery of other vaccines in the programme.

26. The Working Group recommends that where there is good reason to believe that the modelled net costs over- or under-estimate the true costs, the particular nature and reasoning for the concern should be recorded, and a cost adjustment factor (CAF) to allow for these should be estimated. Similarly, where there is good reason to believe that the modelled health benefits over or underestimate the true benefits, the basis for the concern should be recorded and a QALY adjustment factor (QAF) should be estimated.

27. By their nature, the sorts of benefits or costs illustrated above may not always be readily measurable and there will be a degree of uncertainty around what is the appropriate adjustment to make. The adjustment factors should be commensurate with a reasonable view of the relative magnitude of the additional factors. If a factor's impact was not thought to be of a size to warrant modelling, then it should not justify an adjustment factor substantially different from 1.

28. As previously stated, **the Working Group recommends that, if in a particular appraisal the JCVI concludes that there are additional health benefits or cost implications (positive or negative) not explicitly captured by the cost-effectiveness modelling, it should explicitly state and record what these are, as well as the resulting CAF or QAF that it considers appropriate to use for the vaccination programme under consideration.**

3.3 Acceptability of this most plausible ICER.

29. **The principle of consistency with NICE guidance would suggest that, the JCVI should adopt an ICER threshold of £20,000 per QALY. This figure reflects the current estimate of the opportunity cost elsewhere in the NHS of allocating resources to the programme in question from a fixed NHS budget.** The Working Group recognised that this figure is an imperfect estimate, but also noted that research was underway to improve the evidence-base on which this estimate is based.

30. Where the price of the vaccine is uncertain the JCVI should be presented with a simple one-way sensitivity analysis to show at what price the most plausible adjusted ICER would be acceptably cost-effective.

31. Using the above approach the sort of additional considerations that according to NICE guidance permit an Appraisal Committee to recommend a technology that exceeds the £20,000 threshold (up to around £30,000) should effectively have been allowed for in JCVI's most plausible ICER.

3.4 Considering Uncertainty

32. The Working Group recommends that the JCVI continue to follow NICE practice and not simply consider the most plausible point estimate of the adjusted ICER from the modelling but they should also consider the degree of certainty in that ICER. In particular, other things being equal, they should be more cautious about recommending a vaccine for which there is significant uncertainty around the ICER.

33. If, at the assumed price, the most plausible estimate of the ICER is less than the appropriate threshold, the modelling may show that there is some chance that the vaccine will be substantially cost-ineffective. The likelihood of this should be illustrated by the modelling. The JCVI's decisions on cost-effectiveness should be influenced by the likelihood of decision error and its consequences. Therefore, the JCVI should consider the level of certainty/uncertainty and decide if the risk of decision error is acceptable before declaring a vaccine as cost-effective.

34. If a decision error is made and a substantially cost-ineffective vaccine is bought, this has the consequence that the health benefit gained from the vaccine may be substantially less than the health benefit lost from the displaced treatment. Also, since there is a general benefit of having a stable vaccination programme, this error is likely to be difficult, or even damaging, to reverse. Hence, the error could last for a long time causing a large net health loss. In addition, there are capacity constraints on the vaccination programme, and this error may increase the risk that a future cost-effective vaccine may have its implementation delayed due to lack of capacity.

35. What level of risk of decision error is acceptable is fundamentally a matter of judgement that can be informed by analysis, but not answered by it. In the absence of a clear view from Ministers as to the degree of risk aversion appropriate to vaccination policy, the JCVI should take a collective decision as to whether the suggestions below, seen as consistent with NICE methodological advice, seem appropriate.

36. NICE leaves the issue of the acceptability of the uncertainty largely to the discretion of the Appraisal Committees. For the JCVI, because of the nature of the procurement process, a more explicit and consistent process is desirable.

37. Given the range of threshold values from £20,000 per QALY to £30,000 per QALY adopted by NICE, the Working Group recommends that, in general a vaccine should not be accepted as cost-effective if there is a unacceptably high chance that its ICER (adjusted as appropriate) exceeds £30,000.

38. How high that chance needs be is a non-technical judgement, but the Working Group suggests that it be seen as not cost-effective if the JCVI estimate that there is more than a 10% likelihood that the ICER might exceed £30,000. This likelihood might be illustrated by the 10% of scenarios with the highest ICER from a Monte Carlo simulation model.

39. The Working Group wish to emphasise that this 10% suggestion is not technical advice, but is a reasonable recommendation given the different value positions of its members. The 10% suggestion should be seen as a starting position for the JCVI's discussions, and decision. This value should be expected to remain constant, and not be differentially assessed with each vaccine considered.

40. When the risk of decision error is the limiting factor preventing a vaccine being deemed cost-effective, the various sources of the uncertainty and their relative contribution should be highlighted. Where possible, an assessment should be made of various actions, and their ability to reduce the uncertainty. If the uncertainty could be substantially reduced with further research the JCVI might wish to consider whether, if a decision were to be delayed, such research could be undertaken. A formal value of information analysis (VOI) could be undertaken to ascertain the value of such further research. However the Working Group recognised that in the case of vaccines much uncertainty is intrinsic to the stochastic dynamics of infectious diseases.

41. Historically, to illustrate uncertainty, cumulative curves such as the cost-effectiveness acceptability curves have been presented in the analysis. Although useful and commonly used to represent the uncertainty, they do not adequately communicate the most plausible value for the ICER. The Working Group recommends that modelling for JCVI should consider also presenting information in a form similar to a probability density function so that the eye is drawn more towards the central tendency of the model's outputs than to the upper end of the distribution.

42. The Working Group recommends that the JCVI are also presented with estimates of the NHB and the uncertainty surrounding such estimates. A value of £20,000 per QALY should be used as the opportunity cost for the NHS budget to be consistent with NICE. This should help highlight the chance that the vaccine may decrease the Nation's health (as measured by QALYs) as well as increase it.

43. These proposals should have the added benefit that there will be an incentive for manufacturers to gather and make public necessary evidence. This will help increase confidence in the benefits of the vaccine and aide the decision making process.

4. Method for the DH vaccine procurement process

44. If the guidance above is accepted by the JCVI, then the DH will know both the general risk of decision error the JCVI considers acceptable, and for each individual programme the explicitly stated and recorded appropriate CAF and QAF.

45. From the modelling, the DH should be able to estimate, or ask the modellers to estimate, the maximum cost per course for the vaccine consistent with the Committee's most plausible estimate of cost-effectiveness. From this information, the DH should be able to construct Evaluation Criteria that aim to maximise a measure of the expected NHB in a similar way to present, but with the clear focus on the most plausible estimates from the model.

46. Also, from the modelling, the DH should be able to estimate, or ask the modellers to estimate, at what cost per course the general risk of decision error is on the limit of what the JCVI consider acceptable.

47. The Working Group recommends that the Evaluation Criteria should ensure that the expected NHB (at a cost per QALY of £20K) is greater than zero, and the risk of decision error is consistent with the level agreed as acceptable by the JCVI (and suggested here as 10%). This would ensure that procurement decisions are consistent with the JCVI determination concerning cost-effectiveness.

48. The Department of Health aims to maximise the NHB of the vaccine programme. The Working Group recognises that maximising the NHB may involve trying where possible to purchase the vaccine at a cheaper price than the maximum cost-effective price.

5. Process of moving towards these recommendations

49. What is proposed here does not represent a major change from the currently used methods, although there are some detailed changes in language to better reflect NICE guidance and the need to have a formalised system for procurement. However, the Working Group recommends that some further preparatory steps be taken before moving entirely to the revised approach.

50. The JCVI and DH may wish to consider whether modelling results previously seen by JCVI, if interpreted in the way recommended now by the Working Group, would suggest that the JCVI would have given different advice regarding the cost-effectiveness of a vaccine. They may also wish to consider if the price per course for cost-effectiveness used in previous procurement Evaluation Criteria would have changed. If so, the JCVI needs to see whether it would feel comfortable with different conclusions, had they been made now.

51. The JCVI and DH may wish to consider trialling the Working Group's recommendations, or having a period of time where the historic and recommended

processes are considered in parallel (conducted in a way that prevents any legal issues). This may help highlight some of the practical implications of this advice.

52. If these preparatory analyses or trialling of methods create cause for concern, the Working Group could be consulted again.

53. There are various ways of displaying the information that is produced by the modelling. Although the Working Group has made some suggestions, they appreciate that alternative graphics could be used that still maintain the key recommendations in this report about considering uncertainty.

54. Looking forward, to maintain consistency across the NHS, the Working Group recommends that the JCVI's assessment of cost-effectiveness of vaccines should continue to reflect NICE methodological guidance and practice. This may require that the JCVI's methods, and its consideration of the evidence, evolve as, for example, NICE refines its methodology, or if Value Based Pricing changes the way in which health benefits are quantified.

6. Final remarks

55. The Working Group wish to re-iterate that there is no one "correct" way to consider the inherent uncertainty associated with cost-effectiveness modelling. Value judgements have to be made, and the modelling and thresholds are essentially heuristic devices to try to ensure that scarce NHS resources are used appropriately.

56. The Working Group believes that the recommendations made here should provide a practicable and realistic framework for considering the issues for vaccine evaluation and procurement, which are consistent with the reasoning that underpins NICE methodology. The recommendations should help the JCVI to ensure that its decisions on vaccination programmes are consistent, transparent and aligned with efforts to increase the cost-effectiveness of the NHS as a whole.

References

1. National institute for Health and Clinical Excellence, Guide to the methods of technology appraisal, Issue date: June 2008

Annex A: Membership: Working Group on Uncertainty in Vaccine Evaluation and Procurement

This report is the consensus view of the Chairman and the Members of the Working Group. The membership, as assembled by invitation from Prof. David Salisbury, is listed below. The Specialist Associate Members participated fully in the Working Group. However, the views in this report are not necessarily endorsed by the Specialist Associate Members. Declaration of interests from the Chairman and the Members are included below.

Chairman

Prof. Martin Buxton - Professor of Health Economics, Health Economics Research Group, Brunel University (*Declared a personal pecuniary interest – non-specific, relating to a number of vaccine manufacturers*)

Members

Prof. John Cairns – Professor of Health Economics, LSHTM

Prof. John Edmunds – Head of Department of Infectious Disease Epidemiology, LSHTM. (*Declared a personal family interest – non-specific, relating to one vaccine manufacturer*)

Prof. Matt Keeling – Professorship joint in both the Mathematics Institute and the Department of Biological Sciences, Warwick University

Prof. Carole Longson – Director of the Centre for Health Technology Evaluation, NICE (Represented by Meindert Boysen at the second meeting)

Prof. David Spiegelhalter –Winton Professor for the Public Understanding of Risk, Cambridge University

Prof. Martin Utley –Director of the Clinical Operational Research Unit, UCL.

Specialist Associate Members

Dr. Tom Barlow – Department of Health, Immunisation Branch, Joint Committee on Vaccination and Immunisation (JCVI) Secretariat

Dr. Peter Grove – Department of Health, Health Protection Analytical Team

John Henderson – Department of Health, Economist, Health Protection & International Healthcare

Danny Palnoch – Department of Health, Medicines, Pharmacy & Industry – Prescription and Pharmacy Analysts

Prof. David Salisbury – Department of Health, Director of Immunisation

Prof. Adrian Towse – Director of the Office of Health Economics

Secretariat

Kristin McCaugherty – Department of Health, Health Protection Analytical Team, Working Group Secretariat support

Moritz Wagner – Department of Health, Health Protection Analytical Team, Working Group Secretariat support

Guy Walker – Department of Health, Health Protection Analytical Team, Working Group Secretary