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Hall, AJ (2010) The United Kingdom Joint Committee on Vaccination and Immunisation. *Vaccine*, 28S1. A54-A57. ISSN 0264-410X
DOI: <https://doi.org/10.1016/j.vaccine.2010.02.034>

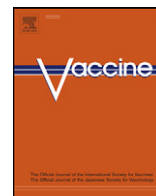
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DOI: [10.1016/j.vaccine.2010.02.034](https://doi.org/10.1016/j.vaccine.2010.02.034)

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The United Kingdom Joint Committee on Vaccination and Immunisation

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ARTICLE INFO

Keywords:

Immunisation
Decision making
Health policy
United Kingdom

ABSTRACT

The United Kingdom Joint Committee on Vaccination and Immunisation provides advice to the Ministers of Health on all aspects of vaccination. Under recent legislation a recommendation from the Committee confers the right to the vaccine concerned to the population of England Wales. A critical aspect of both advice and recommendations is that the vaccination is shown to reach a cost-effectiveness threshold. This usually requires sophisticated mathematical modelling and economics.

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1. Description and background

The Joint Committee on Vaccination and Immunisation (JCVI) is a Standing Advisory Committee. It was originally an advisory board for polio immunisation that became the JCVI in 1963. The JCVI in its current statutory form was established by the National Health Service (NHS) (Standing Advisory Committees) Order 1981 (SI 1981/597) made under what are now provisions of the NHS Act 2006 and the NHS (Wales) Act 2006. Statutory functions of the JCVI extend to England and Wales.

The committee currently consists of 17 members with each member representing a different professional discipline although all professional members must have specific knowledge of vaccination. Thus there are a general hospital paediatrician, a paediatric neurologist, an adult infectious disease physician, a paediatrician with interest in infectious disease, a community paediatrician, a nurse (currently two), a public health physician, a general practitioner, an epidemiologist, an immunologist, a bacteriologist, a virologist and a lay person plus a member from each of Scotland (a public health physician), Wales (a public health physician) and Northern Ireland (a paediatrician). An economist is currently being recruited because of the increasing importance of economic evaluation. Members are recruited through national advertisement and the selection made by an independent body, the Appointments Commission. The Chairman is selected by committee members from amongst themselves. The lengths of appointments are deter-

Abbreviations: HPA, Health Protection Agency; JCVI, Joint Committee on Vaccination and Immunisation; MHRA, Medicines and Health Care Regulatory Agency; NHS, National Health Service; NIBSC, National Institute of Biological Standards and Control; QALY, Quality Adjusted Life Year; UK, United Kingdom.

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mined using the Code of Practice from the Commissioner for Public Appointments. The Chairman and members are not remunerated but payment of expenses is made for attendance at meetings. The Committee meets three times per year under normal circumstances although two additional meetings to discuss pandemic influenza have been necessary this year (2009).

The secretariat to the committee is provided by the Immunisation section of the Department of Health. The Agenda is agreed between the Chairman and the secretariat and includes issues raised by members, through letters to the committee and by the Ministers of Health.

2. Role of the committee in policy formulation

Until recently the advice that the committee provided to Ministers was just that advice. However, relevant provisions of the NHS Constitution were enacted via Regulations which came into force on 1st April 2009. The Regulations specify that the public in England have the right to receive vaccinations as specified in any "Recommendation" of the committee that relates to a new national vaccination programme or to changes to an existing national vaccination programme. The Recommendation must be on a question specifically referred by the Secretary of State, be based on an assessment which demonstrates cost-effectiveness and not relate to travel or occupational health. All other decisions of the JCVI are merely advisory.

3. Terms of reference and processes of meetings

The JCVI adopted new terms of reference at their meeting on 17th June 2009. They are (in part): "To advise the Secretary of State for Health and Welsh Ministers on matters relating to communicable diseases, preventable and potentially preventable through

vaccination and immunisation". The JCVI's statutory functions do not relate to Scotland or Northern Ireland although their Ministers may choose to accept its advice. The role of the committee in ultimate decision making is discussed further below.

There is a JCVI code of practice for members which is published on the committee website (<http://www.dh.gov.uk/ab/JCVI/index.htm>), however a revised Code of Practice and JCVI Protocol are in development. At each meeting all members must declare any potential conflicts of interest and a register of such interests is maintained and published on the website. These potential conflicts are classified as personal or non-personal. Personal conflicts arise where the individual has themselves received money for consultancies with industry, fee paid work where industry pays the member in cash or kind or where the members holds shares in a company (actual sums of money are not given in the declaration). Industry here refers to companies, partnerships of individuals who are involved with the manufacture, promotion or supply of vaccines, trade associations representing such companies or similar bodies engaged in research and development or marketing of products under consideration by the committee. Non-personal conflicts are those where payment benefits a department for which a member is responsible but is not received by the member personally. The usual examples are industry funded grants and fellowships, payments of salaries for staff or sponsorship of research by industry. These are all considered relevant if they occurred in the 12 months prior to the meeting or are planned to occur in the future.

These potential conflicts of interest are further divided into those that are specific to the vaccine or product under discussion and non-specific where they relate to a different vaccine or product made by the relevant company.

During the meeting members with a personal specific interest are asked to leave the room during discussion and decision making. Those with a personal non-specific interest take part in the discussion but not in the decision making. Those with non-personal specific interests can participate in the discussion, unless the chairman rules otherwise but do not take part in decision making and those members with non-personal, non-specific interests take part in the discussion and decision making.

The committee carries out horizon scanning—mainly aimed at identifying vaccines which are likely to be licensed in the next 3–5 years. This allows them to advise on the development of appropriate surveillance in advance of licensure and any research which may be needed to facilitate decision making. For example if costs of a potentially vaccine preventable illness need to be collected or the current burden of disease to be estimated.

The committee frequently has to consider changes to the vaccination schedules—for example where new evidence suggests a change in dose interval or timing would be beneficial. Similarly there may be changes in indications for vaccines due to new evidence and the committee provides advice on this. As part of its work the committee considers data on vaccine coverage and may provide advice in relation to this. However the committee has no role in running the immunisation programmes.

In addition the committee reviews information on potential vaccine adverse events including published studies from the global literature, reports of studies specifically carried out in the United Kingdom (UK), the routine surveillance of adverse reactions carried out by the Health Protection Agency (HPA) and reports from the surveillance system of the Medicines and Healthcare Regulatory Agency (MHRA). The committee uses this information to weigh risks and benefits in its decision making but has no regulatory role in relation to vaccines (see case study on the Hib booster campaign in Table 1).

The work of the committee which attracts the most attention is related to newly licensed vaccines. This is discussed in the next two sections.

Table 1
Haemophilus influenzae type b (Hib) booster campaign 2007.

1. Routine surveillance showed an increase in Hib disease greater than expected in children aged 3–4 years and over
2. The committee considered adding a booster dose to the pre-school Diphtheria-Pertussis-Tetanus (DPT) dose
3. It was estimated that 50 cases of disease and 2 deaths could be prevented but the cost-effectiveness exceeded the threshold
4. Nevertheless the committee advised that a booster campaign should be conducted
5. This advice was accepted by the Government
6. However it necessitated that for the period of the campaign the vaccine used was changed from Diphtheria-Tetanus-acellular Pertussis (DTaP)/inactivated polio vaccine (IPV) or reduced dose diphtheria-Tetanus-acellular Pertussis (dTaP)/IPV to DTaP/IPV/Hib or for older children Hib-Meningococcal C vaccine
7. This required the "off-label" use of these vaccines (i.e. outside the ages that they are licensed for)
8. On the basis of evidence the committee recommended this and that the evidence was published on the website (http://www.dh.gov.uk/prod_consum_dh/groups/dh.digitalassets/@dh/@ab/documents/digitalasset/dh_094741.pdf)

4. Development of recommendations and basis for decision making

Where a new vaccine or an alteration to the routine schedule is to be discussed by the main committee the first step taken is to establish an expert sub-committee. This has a member of the main JCVI as the chairman and any additional members of the main committee who have particular expertise relevant to the vaccination being considered. Other members of this sub-committee are then recruited with relevant expertise from academia, government agencies, etc. This is done to ensure that all of the necessary disciplines are represented—e.g. laboratory science, clinical, epidemiological, modelling and economics. These sub-committee members also have to make declarations of potential conflicts of interest and the same procedures in handling these apply. The sub-committee will then meet perhaps two or three times to review the evidence available and where appropriate to provide advice on parameters for modelling and economics. It will formulate advice on a recommendation which is then passed to the main committee. In the meantime any cost-effectiveness modelling that has been necessary will go out to peer review. This review is done by national and international experts—both in economic modelling and in the disease specific area. These referee reports are then sent to the group who carried out the cost-effectiveness estimation and they respond—either with a rebuttal of the comments or with a modification of the estimates.

All of these reports then come to the main committee. It then chooses to accept or modify the sub-committee recommendation. On occasion it may require a further modification of the economic analysis or of the underlying question being addressed.

Finally the JCVI makes a recommendation or provides advice. A recommendation applies when the question has been asked of the committee specifically by the Secretary of State for Health and it applies to universal vaccination. This has specific implications as described above. Advice, rather than a recommendation, is provided when such a question has not been asked, for example where it is a change in indication or a modification of existing advice—or where the vaccination concerned is occupational or for travellers. These latter two are not funded centrally by the government—either the employer or the traveller themselves must pay for the vaccine. In these cases the advice from the JCVI is simply guidance.

Table 2
Developing Human Papilloma Virus (HPV) vaccine advice.

1. New vaccines against HPV 16 and 18 were about to become available, there were two potential vaccines: one bivalent and one quadrivalent including HPV types that cause genital warts
2. Joint Committee on Vaccination and Immunisation (JCVI) established a sub-committee of experts on HPV
3. Sub-committee reviewed published evidence, data from manufacturers and worked with Health Protection Agency (HPA) surveillance and infectious disease modellers to develop advice (3 meetings)
4. Sub-committee identified missing information
5. HPA collected data to fill gaps on age specific information on acquisition of HPV types 16 and 18 by single years of age from 12- to 25-year-old girls [1]
6. HPA collected data on costs of treatment of genital warts [2]
7. HPA developed cost-effectiveness model of HPV vaccination in the United Kingdom [3]
8. Cost-effectiveness model refereed, modified and submitted to main JCVI
9. JCVI agreed recommendation:
http://www.dh.gov.uk/prod_consum_dh/groups/dh.digitalassets/@dh/@ab/documents/digitalasset/dh_094739.pdf

5. Role played by economic evaluations and other financial issues in decision making

Cost-effectiveness is the cornerstone of decision making where universal vaccination of the population is concerned since the costs of the vaccination are borne by the Government through central procurement of vaccines. The guidelines used by the committee are that the vaccine should result in a cost of less than £20–30,000 per Quality Adjusted Life Year (QALY) gained. This is used across the health policy making field in the UK to ensure a balance in preventative and treatment options available to the public. The development of the cost-effectiveness data requires a combination of economic cost data on vaccine, vaccine delivery, illness and death and mathematical modelling to capture potential herd immunity effects. The perspective used is that of the NHS—so no societal costs are included (such as loss of parental time at work). This leads to some less serious infections, such as rotavirus and chickenpox, where the burden fall largely on the family not reaching the cost-effective threshold. The committee plays no role in procurement of vaccine. It does not know the price of vaccines offered to the UK nor what is finally agreed by the procurement process since this is commercially confidential (see case study on the HPV vaccine advice in Table 2).

6. Role of manufacturers, and other private and professional interest groups

Manufacturers do not attend JCVI nor sub-committees. They are in regular contact with the secretariat in the Department of Health and have meetings to discuss developments and relationships. JCVI has recently introduced the practice of asking manufacturers for information directly when carrying out horizon scanning in order to make this as complete as possible. When sub-committees meet to discuss possible advice the industry is asked to provide written information. This often includes unpublished and commercially sensitive information. Industry has expressed a desire to have more input to the process and specifically to attend and present at sub-committee meetings. However JCVI has so far not agreed to this. Despite this situation some of the public and news media perceive the committee as too influenced by the Pharmaceutical industry. This perception arises from the fact that the publicly listed potential conflicts of interest include funding for research from commercial organisations. Although these potential conflicts of interest are carefully handled in meetings to ensure that they do not influence the advice provided.

Meetings of the JCVI and of sub-committees are closed. However observers are invited, and regularly attend, from the devolved administrations in Wales, Scotland and Northern Ireland as well as on occasion from Jersey and the Isle of Man. Also invited as observers are representatives of the HPA, Health Protection Scotland (HPS), the National Institute of Biological Standards and Control (NIBSC which since April has been part of the HPA), MHRA. The HPA is responsible for surveillance in England of vaccine preventable disease and carries out extensive work on the assessment of vaccines both through observational studies and trials. In addition HPA carries out routine surveillance of adverse reactions with specific research studies where necessary. This work is often done in conjunction with the MHRA. HPS fulfils a similar role for Scotland. NIBSC is responsible for the testing and clearance of batches of vaccine imported to the country and thus has exceptional knowledge and experience with laboratory aspects of vaccines. The MHRA is responsible for monitoring of adverse reactions to medicines including vaccines. They regularly report to the committee on these data. Members of the public or representatives of public interest groups are not admitted to JCVI or sub-committee meetings.

7. Communication activities and training practices

The agenda for JCVI meetings is placed on the public website 2 weeks in advance of each meeting. The minutes of each meeting are also placed on the website within 6 weeks of each meeting along with minutes of sub-committee meeting once ratified by the sub-committee and JCVI. All JCVI advice is collaged into a publication – Immunisation against Infectious Disease (“the Green Book”). This is edited by the Department of Health and members of the Immunisation Division of the HPA. Although it is physically published irregularly (the last edition was in 2006) every alteration to the advice is posted on the website and a “patch” is provided which can be printed and pasted into the hard copy of the book. The chairman of the committee speaks on the work of the committee at meetings of Immunisation Coordinators in England annually and when requested in Scotland, Wales and Northern Ireland.

8. Problems encountered, limitations and future developments

The committee functions well and in general has not had specific problems. A general concern has been how we ensure that the committee keeps up to date with the latest evidence. There are many vaccines involved in the programme and the committee would like to see any relevant evidence that might affect existing policy on these at each meeting. However the volume of work in carrying out rolling systematic reviews makes this impossible. Of course the committee members are themselves all involved in vaccination – either research or programme delivery – and the secretariat in Department of Health are constantly exposed to new information, therefore the committee relies on these sources to keep the committee up to date.

The committee would ideally like each cost-effectiveness analysis to be carried out by at least two groups using different methods. This has occurred with the work on modelling of influenza A/H1N1v epidemiology and vaccination. However to do this for each question facing the committee is beyond the infectious disease modelling capacity of the UK—although the UK is very well supplied with such expertise. The growth of interest in this area of science and the extensive training now ongoing should resolve this limitation in time.

A result of the changes resulting from the NHS Constitution is that we need to strengthen the committee in economics and infectious disease modelling expertise. In addition the committee has

been criticised for a lack of openness—this is a topic the committee regularly reviews and plans to take steps to improve transparency in the near future.

9. Summary and conclusions

JCVI is an independent committee which advises Ministers of Health in the UK on vaccine policy. It has been successful in that the Government has, to date, implemented the advice. However the processes of the committee are constantly being criticised (unfairly in the opinion of the committee, which is strongly protective of its independence and regards it as vital to its role) either by the vaccine industry for not allowing them sufficient access to the committee or by the public for being too influenced by the vaccine industry. In addition there is constant pressure to increase openness and transparency in the committee activities. This is likely to lead to changes

in the near future, although ensuring that any changes made are not detrimental to its role and function.

Conflict of interest statement

The authors state that they have no conflict of interest.

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