Not immune:
UK vaccination policy in a changing world

Mark Weston

A 2020health discussion paper
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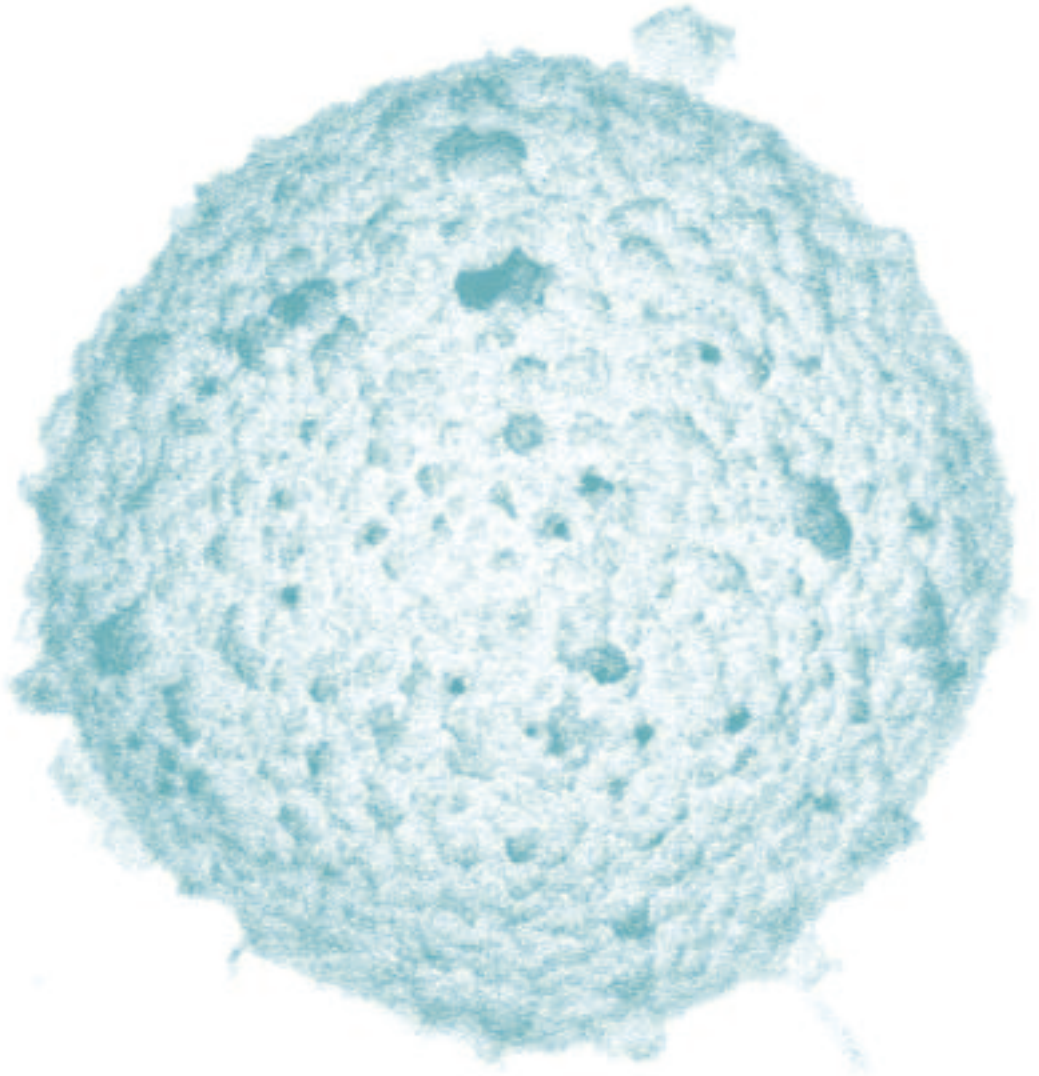

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About This Publication

This publication was inspired by the suggestion that the vaccines decision making body the JCVI should merge with NICE, the body that appraises health technologies and treatments. We wanted to look at the pros and cons of such a merger, the strengths and weaknesses of the respective bodies and make suggestions for the way forward. At the outset it was clear that there has been extensive work already on appraising NICE, so rather than repeat that work here, we focused on evaluating how the JCVI works and what the differences are in the decision making process between the two bodies. We then went on to make recommendations for improvements.

We are very grateful to everyone who agreed to be interviewed for this study and who gave their time so generously, making this report possible. A list of participants can be found at the end of the document.

We are indebted to all our sponsors for their unrestricted funding, on which we depend. As well as enabling our ongoing work of involving frontline professionals in policy ideas and development, sponsorship enables us communicate with and involve officials and policy makers in the work that we do. Involvement in the work of 2020health.org is never conditional on being a sponsor.

Julia Manning, Chief Executive

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www.2020health.org

2020health.org
PO Box 53659
London
SE5 5FL

T/F 020 7708 0683
E info@2020health.org

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About The Authors

Mark Weston
Author
Mark Weston is an independent policy consultant, researcher and writer, specialising in international development and public health. He has close links with the Harvard School of Public Health, UK policy consultancy River Path Associates, and UCLA's David Geffen School of Medicine, and is a contributor to Global Dashboard, the foreign affairs blog.

He has produced a series of reports for the World Economic Forum on how businesses can strengthen their response to AIDS, tuberculosis and malaria, and his paper on 'The Value of Vaccination', which showed how vaccination can boost economies, was recently published in World Economics.

Julia Manning
Series Editor
Julia Manning studied Visual Science at City University, graduating in 1990, and became a member of the College of Optometrists in 1991. She was a founder member of the British Association of Behavioural Optometrists, a visiting lecturer at City University and visiting clinician at the Royal Free Hospital, London and Director of the Institute of Optometry.

Julia is a founder and Executive Director of 2020health.org which launched at the end of 2006. She has written on many health and technology issues and the history of her profession in *'60 years of the NHS'* [St. James's House].

Executive Summary

Background

The Joint Committee on Vaccination and Immunisation (JCVI) is the body responsible for decision-making on vaccines in the UK. In November 2008, the Conservative Party suggested that the JCVI should be merged with the National Institute for Health and Clinical Excellence (NICE), which issues guidance on therapeutic interventions and public health. This discussion paper assesses the pros and cons of such a merger, examines the JCVI's performance, and makes recommendations for the future of vaccine policy-making in the UK. It is based on a review of the academic literature and the websites of the JCVI, NICE and their overseas equivalents, and on twenty in-depth interviews with senior stakeholders from the JCVI, Department of Health, professional health care bodies, patient groups, the vaccine industry and the media.

Roles and responsibilities

We find that the JCVI is a highly regarded expert body, whose decisions are respected by all stakeholder groups and successfully implemented by the Department of Health (DOH). The committee is comprised of many of the leading experts in the vaccine field, and the UK's high vaccine prevalence rates are testament to the esteem in which its recommendations are held. The new NHS Constitution states that people have a right to receive those vaccinations recommended by the JCVI.[i]

There are areas for improvement, however. Although the JCVI is generally seen as making independent decisions, the recent recommendation on human papillomavirus immunisation, where the vaccine introduced by the Department of Health was different from that favoured by the JCVI, led some stakeholders to question the DOH's influence on decision-making. The latter's role in meetings and recommendations should be clarified. The breadth of stakeholders consulted by the JCVI is a further concern. Several organisations whose members are key to the implementation of immunisation programmes are not included in decision-making nor allowed to attend meetings. These include the Royal College of General Practitioners and the Royal College of Nursing. The public also has only limited representation, with just one lay member and no representation by patient groups. Several of those interviewed for this study see the JCVI as a remote, somewhat secretive body, which in an era where transparency is expected may pose problems during a future vaccine controversy.

NICE and the JCVI's overseas equivalents consult a much wider range of stakeholders, which makes them appear more transparent and makes it more likely that they will identify potential problems with decisions at an early stage. The JCVI's compactness, on the other hand, leaves it little margin for error. It relies heavily on the knowledge of a small number of experts, so that if it makes a bad decision, it will not have the defence that it consulted widely and gave others the chance to comment on decisions. In an environment such as public health, which is characterised by great uncertainty, wide consultation gives policy-makers a more robust safeguard against shocks. We recommend expanding stakeholder involvement by increasing the number of lay members on the committee and the number of ex officio or liaison representatives who can attend meetings.

The decision-making process

Although the JCVI's recommendations are well respected, there are five key areas where the process of decision-making could be strengthened.

Horizon scanning

The first relates to horizon scanning. Unlike NICE, which works with the National Horizon Scanning Centre at the University of Birmingham, the JCVI does not have a systematic process for identifying upcoming issues. The vaccine industry therefore lacks a clear idea of the government's immunisation priorities. Manufacturers have to plan the research and development of vaccines up to fifteen years in advance of licensing, and investment will be wasted if products do not meet the UK's health needs. Moreover, the JCVI's appraisal process will be more efficient if industry keeps it apprised of future manufacturing developments. A formal horizon scanning process that includes consultation with industry, professional bodies and patient groups will help ensure that the right vaccines reach the public more quickly.

Speed

The second area for improvement is in the speed of decision-making. Currently, there is little consistency over when a new vaccine is reviewed, resulting in some vaccines being introduced shortly after licensing and others many years later. Bringing forward the appraisal process for all vaccines would allow the committee a similar length of time to deliberate but mean recommended vaccines could be delivered to the public sooner. A formal, consistent appraisal schedule, developed in consultation with manufacturers, would also help the DOH and industry with long-term planning.

Transparency

The third challenge is transparency. Unlike those of NICE and the JCVI's American equivalent, the Advisory Committee on Immunisation Practices, JCVI meetings are not open to the public. Issues of commercial and academic confidence and the fear that the public may disrupt proceedings have so far outweighed considerations of openness. The pressure to become more transparent is increasing, however, particularly in the light of recent health scares over bovine spongiform encephalopathy (BSE) and the measles, mumps and rubella (MMR) vaccine. These crises have weakened public trust in scientific decision-making bodies, and there are growing demands for lay participation in policy development. Public trust in the JCVI's decisions is critical for successful implementation of its recommendations, and if it is to continue to be a respected voice in the field it must guard against perceptions that it has something to hide. Allowing public participation, moreover, will enable the JCVI to anticipate challenges to its recommendations, rather

than having to defend them after they have been implemented. We recommend that meetings of the main committee be opened to the public, except where matters of national security are being discussed, and that some public participation in meetings should be encouraged.

Relations with the vaccine industry

Fourthly, relations with the vaccine industry could be improved if companies were given clearer guidelines on when to submit information to the committee, what information should be included, and when decisions will be made. The current process is opaque, and industry representatives interviewed for this study yearn for more clarity.

Cost-effectiveness analysis

The final area of concern relates to cost-effectiveness analysis (CEA) of vaccines. Such analysis is critical for ensuring efficient allocation of the UK's health care budget, but although the committee takes it into account it is not yet part of the its official remit. Immunisation is often a very high value investment, and for vaccines to be assessed on a level playing field with therapeutic interventions, robust CEA that is consistent with NICE's analysis is essential.

The JCVI and NICE should be more open about the importance of CEA, which is widely distrusted by health professionals, patient groups and the media. Several respondents to this review believe both bodies should be more proactive in explaining why CEA is needed and in outlining its benefits. They should also release cost-effectiveness models for use by external stakeholders - a recent court ruling forcing NICE to make its models available is likely to set a precedent in this area, and allowing others to examine the models will help refine them and make their use less controversial in the long-term. And the two bodies should consult with the public to develop a clear cost-effectiveness threshold for recommendations. The current threshold has not been debated in public and is widely criticised for being random and out of line with the national health budget.

Cost-effectiveness analysis by NICE and the JCVI currently only considers the direct costs to the National Health Service of treatment and averted illness. There is a strong case for broadening the analysis to include social and economic impacts. The benefits of vaccines can be profound, with effects on school performance, productivity in the workplace, and the quality of life of carers. Given that the UK vaccine programme is publicly funded and that immunisation has benefits for those who are not vaccinated as well as those who are, adopting a societal perspective would provide a fuller picture of its impacts.

Should the JCVI and NICE merge?

The Conservative Party's suggestion for a merger of the JCVI and NICE is based on the belief that it would improve consistency and transparency in health policy. As currently constituted, however, NICE is ill-equipped to take complex decisions on immunisation. Only two of the twenty stakeholders interviewed for this study supported a merger, and there was a strong sense that the JCVI could make improvements to its decision-making processes without having to be subsumed into NICE. Indeed, the changes that would be required for a merger are likely to weaken the UK's successful vaccination programme and imperil the nation's health, without any significant cost savings.

There are three main reasons why the risks of merging might outweigh the benefits. First, decisions on vaccines are more complex than decisions on therapeutic drugs. Since vaccines are generally given to healthy children for diseases they may never have contracted, the premium on safety is higher than that for treatments for the sick. Political considerations about the risks of side effects and of overloading children with vaccines require a subtlety and knowledge that is not demanded of NICE. The JCVI, moreover, has to consider how new vaccines might fit into the overall immunisation schedule - introducing one vaccine may influence the effectiveness of another. NICE, on the other hand, generally considers drugs in isolation. Herd immunity further complicates matters, and analysis of its effects requires sophisticated modelling skills which NICE lacks. Specialist expertise is needed for robust examination of these issues, but NICE deliberately excludes experts from its appraisal committees, for fear of bias. Diluting the JCVI's expertise by merging it with NICE is likely to weaken the quality of immunisation decisions.

Second, the Conservative Party's recommendation that implementation of immunisation should be transferred from the Department of Health to NICE could threaten the effectiveness of the programme. JCVI recommendations cover England, Scotland, Wales and Northern Ireland, whereas NICE guidance only applies to England and Wales. Moving vaccination policy to NICE might result in immunisation schedules that differ by country, leading to arguments about inequalities in vaccine distribution and health risks if children moving between countries with different schedules miss doses. Implementation of NICE's guidance, moreover, is patchy, with large geographical disparities for some treatments. Decentralising the immunisation programme might result in similar problems. Since it is important for herd immunity and the elimination of disease that vaccines reach all children, centralised funding and delivery, which has hitherto proved highly effective, should continue.

Third, although NICE is widely respected internationally and in the scientific press, its reputation among the mainstream media and the public has taken a battering in recent months. The JCVI, on the other hand, is trusted by a broad spectrum of stakeholders. There is a risk that if vaccine decisions were made by NICE, they would be viewed more sceptically and parents would be less likely to comply with recommendations.

Executive Summary

Although a merger appears unlikely to bring great benefits, there is a strong case for greater collaboration between the JCVI and NICE. There are currently no formal channels between the two bodies, which means work may be duplicated and policy-making inconsistent. Improved lines of communication are needed to identify when appraisals may overlap, how best to approach cost-effectiveness analysis, and how to ensure coherent decision-making, among other issues. A more systematic relationship will strengthen both organisations.

Introduction

Immunisation is one of science's greatest discoveries. It saves millions of lives worldwide each year and averts millions more episodes of illness. It has made crippling diseases like smallpox and polio a thing of the past. In the UK, measles notifications in England and Wales have fallen from over 300,000 per year before a vaccine was introduced in 1968 to less than 5,000 today. The number of annual measles deaths, which averaged eighty-six in the decade before the vaccine, is now close to zero.[ii] After the introduction of meningococcal C vaccine in 1999, the number of deaths from group C meningococcal infection in England slumped from 47 to 3 within two years and the number of confirmed cases from 551 to 79.[iii]

There is no room for complacency, however. Infections cause 70,000 deaths per year in England.[iv] In the wake of the recent controversy over the measles, mumps and rubella (MMR) vaccine, immunisation rates fell sharply, resulting in a resurgence of measles cases and, in 2006, the UK's first death from the disease for fourteen years. Other vaccine-preventable threats like tuberculosis have also made a comeback, while MRSA and avian flu are among thirty previously unknown infectious diseases that have emerged in the last four decades.[v] In the years to come, globalisation and climate change may present the UK with new communicable disease challenges, while the anthrax scare in the US in 2001 highlighted the danger that terrorists may use deadly, but vaccine-preventable viruses to achieve their goals.

The vaccine industry is responding to many of these challenges and developing new drugs to counter them. Immunisation against tuberculosis, meningitis B, clostridium difficile, malaria and staphylococcus aureus may be available within the next decade, and jabs for varicella (chicken pox) and zoster (shingles) have already been licensed.

As they grow more sophisticated, however, vaccines are becoming increasingly expensive. In the United States, for example, the cost of vaccinating a child fully in the public sector increased from $34 to $410 between 1979 and 2004.[vi] (The 1979 sum of $34 is equivalent to $89 in 2004 using the consumer price index.[vii]) Vaccines have to compete with each other and with drugs and other health technologies for their share of the country's limited health budget. Decisions on whether to introduce new vaccines have to consider both clinical and cost-effectiveness, therefore, as well as complex questions of vaccine safety, delivery and public acceptability.

The body responsible for making these decisions in the UK is the Joint Committee on Vaccination and Immunisation (JCVI). Its remit is to provide advice to ministers on vaccine-preventable diseases, and it works with the Department of Health to monitor implementation of immunisation programmes and to keep track of the wax and wane of infectious disease among the UK population.

Introduction

In November 2008, the Conservative Party suggested that the JCVI should be merged with the National Institute for Health and Clinical Excellence (NICE), which provides guidance to the National Health Service on health technologies and treatments, interventional procedures, and public health measures. Combining the two bodies it was argued would increase consistency and transparency in health care decision-making.

This discussion paper assesses the pros and cons of such a merger. It also reviews how the JCVI works and examines the strengths and weaknesses of its decision-making process. It makes recommendations on how to improve this process and on how a closer relationship with NICE might be developed. These recommendations are intended to contribute to discussions over the future of UK vaccination policy.

The study was funded by an unrestricted educational grant from Novartis Vaccines, Wyeth and Sanofi-Pasteur MSD. 2020health had full independence in the design of the study and the writing of the report. The methodology involved an extensive review of the academic literature on immunisation policy (see bibliography), a review of the websites of the JCVI, NICE and their overseas equivalents in the United States, Germany, New Zealand and Australia, and twenty in-depth telephone interviews with stakeholders and experts from the health care field. Interviewees included members of the JCVI, senior representatives from the Department of Health, professional health care bodies, patient groups and the vaccine industry, practising physicians, and health journalists (see end for list of interviewees). In both the literature review and the interviews, NICE was used as a comparator.[1]

The paper is structured as follows.

Part One looks at how the JCVI is constituted and at its relationship with the Department of Health.

Part Two examines the strengths and weaknesses of its decision-making process.

Part Three discusses the case for a merger with NICE. In each section, we have made recommendations for how processes might be improved.

Some of these recommendations have already been considered by the JCVI but not yet implemented, while others have not been discussed. In both cases, it is hoped that the suggestions will spark debate on how the JCVI should move forward in what is an increasingly complex and challenging environment for health care decision-makers.

1. Fifteen of those interviewed answered questions primarily about the JCVI and five primarily about NICE.

One Roles and Responsibilities

What is the JCVI?

Established in 1963, the Joint Committee on Vaccination and Immunisation is an independent expert advisory committee whose role, according to its terms of reference, is "to advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation." It has no executive function; Secretaries of State decide whether and how to implement its recommendations. Unlike the National Institute for Health and Clinical Excellence (NICE), whose role is limited to England and Wales, the JCVI covers all four countries of the United Kingdom.

As well as assessing the likely benefits and costs of new vaccines, the JCVI also monitors the ongoing impacts of existing vaccines, including their safety and efficacy; keeps track of emerging and re-emerging communicable disease threats; and addresses inequalities in vaccination uptake. In recent years, for example, it has responded to increasing measles incidence with a campaign to expand immunisation with the measles, mumps and rubella (MMR) vaccine among hard to reach communities such as travellers. And when it detected a rise in Hib disease (type 'b' *h. Influenzae* that can cause meningitis) it recommended a vaccine catch-up programme.

The JCVI has fifteen members under the Chairmanship of Professor Andrew Hall. Members are appointed by the Parliamentary Under-Secretary for Public Health for four-year terms, and include academics, practitioners in relevant fields, public health experts and senior National Health Service (NHS) managers. There is one lay member, and the four home countries each provide a member. Although members are experts in the vaccination field, they are required to declare possible or perceived conflicts of interest when their responsibilities as JCVI members may overlap with current or previous positions, and are expected to abstain from discussions on such matters.

In addition to the main committee members, the JCVI also has four ex-officio members who represent their organisations, including the Medical Research Council, Health Protection Scotland, the National Institute for Biological Standards and Control, and the National Travel Health Network & Centre. The committee's secretariat is composed of Department of Health staff. While NICE has an annual budget of £31 million,[viii] JCVI members are unsalaried - the only costs aside from the secretariat are members' expenses.

Strengths and weaknesses

Expertise

While NICE excludes those with direct experience of a drug or technology from decisions on whether to recommend it in case of bias, the JCVI makes full use of experts in its decision-making. Members are experts in the immunisation field, and the sub-groups it convenes to consider particular vaccines comprise specialists in the disease or type of vaccine being assessed.

Stakeholders interviewed for this study expressed strong support both for the JCVI's use of experts per se and for the quality of the experts involved. An interviewee from a non-governmental research foundation argued that "NICE thinks of experts as biased, but you need experts who are passionate about the topic. They are scientists and the process of debate can persuade them - they're not close-minded. Having expert advisers is a distinct advantage of JCVI." Times health editor Nigel Hawkes agrees, claiming that excluding experts "almost guarantees that any negative decision will be opposed. A politically astute system would seek to incorporate these experts - to make use of their judgement and to implicate them with the decisions reached, however unpalatable."[ix] As for the risk of bias, John Oxford (Professor of Virology at Barts and the London School of Medicine and Dentistry) was among several interview respondents who believe NICE overstates the danger. "All academics are funded by someone," he explained. "As long as they declare their interests and grants and consultancies, there shouldn't be a problem."

The committee's expertise means that there are few complaints with the quality of its decisions. Richard Stubbins, CEO of vaccine supplier Sanofi Pasteur MSD (SPMSD) and Chairman of the UK Vaccine Industry Group, believes the JCVI's members are "the right people, from a broad range of disciplines." Freelance medical journalist and former Sun health editor Jacqui Thornton described the members as "very authoritative - at the top of their game." Another vaccine industry interviewee concurred: "They have some very good people on there, and that's evidenced by the willingness of professionals, the NHS and the public to accept their guidance."

Respect for JCVI decisions makes it more likely that they will be implemented. NICE was set up in part to eliminate "postcode prescribing," where the availability of drugs and technologies depends on where an individual lives rather than on patient need. The JCVI also aims to reduce health inequalities, and is seen as having been more successful at doing so than NICE. Vaccine coverage in the UK is strong, and George Kassianos, immunisation spokesman for the Royal College of General Practitioners, reported that those working at the frontlines have much more faith in JCVI's decisions than those of NICE. "We implement JCVI recommendations straight away," he said. "They are much better than NICE. There is not much trust in NICE decisions. We do what we think is clinically appropriate."

The JCVI's use of experts, then, is one of its great strengths. Because its decisions are respected by health practitioners, the public and the vaccine industry, they are promptly and broadly implemented. NICE, on the other hand, suffers to some extent from excluding experts. As we discuss in part three, were the two organisations to merge, their different approaches to using experts may pose a threat to the UK's childhood immunisation programme.

Inclusiveness

Although the committee itself is widely respected, there are some concerns about the breadth of stakeholders it consults. There are only four ex officio members and the committee contains only one lay member. Organisations whose members are crucial to the implementation of vaccine programmes, including the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN), are not represented at committee meetings. The vaccine industry, too, is absent, as are patient groups, the media and the public.

Until now, implementation of JCVI recommendations has not been greatly impeded by the narrow range of stakeholders it consults. However, implementation of NICE guidelines has been held back by practitioners' lack of trust in its decisions. George Kassianos believes the JCVI may face similar problems if it does not become more inclusive: "It's a bit of an ivory tower," he said. "They should engage a lot more. They need much greater representation from the organisations working at the coalface." Simon Blake, meanwhile, told us that his sexual health charity, Brook Advisory Centres, which sees 200,000 clients a year, was not consulted by the JCVI or Department of Health immunisation unit during the HPV vaccine decision-making process. "I would have thought they'd be contacting us as a major provider of sexual health services, asking what we're going to be doing to get the vaccine to people outside of schools," he commented, "but we haven't had that."

As well as the trust of health practitioners, public confidence in decisions is a further key element in an immunisation programme. If the public sees the JCVI as secretive and distant, this could create problems if a vaccine controversy arises. Several of those interviewed see the JCVI as somewhat remote, with one former member describing it as "a bit of a black box." Laws and regulations on science decision-making are increasingly leaning towards openness and informed choice, and media attention to science is also growing rapidly. Modern decision-making bodies such as NICE, which consults widely on decisions, recognise the importance of engaging with the public.[x]

The JCVI is lagging behind in this area. Committee meetings are not open to the public, and the committee's sole lay member, Vivienne Parry, is a trained scientist who writes on medical issues for the Times; as a few interviewees pointed out, whether this makes her a representative member of the public is open to question. Of course, finding one person to represent the entire UK population is impossible, but increasing the proportion of lay members can help address the problem and improve perceptions of an organisation's openness. The House of Lords Select Committee on Science and Technology has recommended that one in five members of scientific decision-making bodies should be lay members.[xi] This would mean increasing the number on the JCVI from one to three.

Andy Hall, the Chairman of JCVI, reported that the main barrier to wider involvement is that "committees work better if they are a sensible size." However, similar organisations in the UK and overseas tend to have a broader range of consultees. NICE identifies stakeholders at the beginning of an appraisal process. These stakeholders may come from patient and carer organisations, industry, research institutions and other professional bodies. Each group is consulted regularly throughout the decision-making process, and clinicians and representatives of patient groups (but not pharmaceutical companies) may attend appraisal committee meetings. In Scotland, two members of the Association of the British Pharmaceutical Industry (ABPI) sit on the committee that evaluates drugs, while in the United States, the Advisory Committee on Immunisation Practices (ACIP) has ten ex-officio members as well as 28 non-voting "liaison representatives," who serve as a two-way conduit between ACIP and their organisations.

It is appropriate that industry does not provide members of the JCVI. Independence from the involvement of manufacturers is crucial to maintaining public trust in vaccines - a point acknowledged by those industry representatives interviewed for this study. Scotland is unusual in allowing the latter to take part in decision-making on drugs, and with vaccines, which unlike therapeutic treatments require parents to allow a drug to be given to a healthy rather than a sick child, public sensitivities are more fragile. As Andy Hall explained, "the public would lose all confidence if they felt the manufacturer decided which vaccines they would get."

However, there is scope for broader stakeholder involvement at an ex officio or liaison level. As an interviewee from a research foundation suggested, "the JCVI should have a formal process whereby they try to identify and engage with key stakeholders." Excluding organisations such as the RCGP and the RCN from any representation at meetings has the potential to cause problems with implementation of recommendations, and therefore with the public's health. Excluding patient groups may exacerbate controversies over immunisation decisions. And although excluding industry from decision-making is appropriate, there may be a case for including a vaccine expert from the ABPI as a non-voting liaison representative.

Including more stakeholders is not just about improving perceptions of openness. The JCVI works in an environment characterised by great uncertainty. Few foresaw the scare over the whooping cough vaccine in the 1970s, for example, or the MMR crisis of the 1990s. America's Advisory Committee on Immunisation Practices did not predict the harmful side effects of the Rotashield vaccine. The need to reassess stocks of smallpox vaccine in the light of the terrorist threat also came as a surprise to many. Future surprises may include a new pandemic flu or another new but devastating disease, the sudden but not widely publicised discovery of a new vaccine or vaccine delivery method, or some other completely unforeseen event.

It is unlikely that fifteen individuals, even individuals of very high calibre, can have a monopoly of knowledge of the vaccine and infectious disease fields. It is even less likely that they will ask all the potential questions that could be asked, or raise all the issues that may appear on the immunisation radar screen in future. Expanding the range of stakeholders consulted will give the JCVI ballast against potential shocks, making it less likely that it will overlook new threats, challenges and opportunities. Organisations like the RCGP and RCN will provide knowledge on vaccine implementation issues; patient groups and other stakeholders may provide information on public attitudes, unforeseen side effects of vaccines, or emerging disease threats. By consulting widely and enlisting a broad range of stakeholders in appraisal processes, organisations like NICE recognise the need to allow for uncertainty and insure themselves against its effects. They will still miss things, but by consulting more widely they will miss less.

The JCVI should therefore strongly consider broadening its stakeholder base. Expanding the list of ex officio members is one option, and creating a category of liaison members, along the lines of ACIP, another. ACIP liaison representatives can attend meetings, participate in discussions, comment on draft documents and serve on working groups. The JCVI's commitment to independence would preclude liaison representatives serving on working groups, but the latter's participation in discussions and comments on documents could enhance the quality and robustness of decision-making, at the same time as strengthening perceptions of the JCVI as a transparent, open organisation. This broader involvement does not appear to have harmed ACIP, which like the JCVI is seen as one of the global leaders in the vaccine policy field.

Recommendation:
Consider increasing the proportion of lay members on the JCVI to one in five, in accordance with House of Commons Science and Technology Committee guidelines.

Recommendation:
Expand stakeholder involvement in committee meetings and sub-group meetings, by increasing the number of ex officio members or creating a new group of liaison representatives, or both. Organisations representing physicians, nurses, and key patient groups should be invited to become stakeholders and provided with clear guidelines on their roles and on what they can expect from the process. The benefits and risks of inviting the Association of the British Pharmaceutical Industry should also be assessed.

Independence

The JCVI is independent of the UK Government and the Devolved Administrations. Independence from government is important both to the quality of JCVI decisions (short-term political priorities may not always be aligned with the country's long-term health needs) and to ensuring public trust. As a House of Lords Select Committee on Science and Society study found, "people place more trust in science that is seen as independent."[xii]

In general, the JCVI is seen as more independent than NICE. According to David Elliman, of Great Ormond Street Hospital for Children, "JCVI has very strongly resisted political pressures, whereas NICE has been less successful in doing so." A House of Commons Health Committee report echoed these thoughts, noting examples of political interference in NICE decision-making. These included pressure put on the organisation by health ministers over controversial treatments such as Herceptin, which "made it almost impossible for NICE not to approve the drug, once licensed, regardless of cost."[xiii]

Although most of those interviewed believe the JCVI lives up to its claim to independence, a small number were unclear as to the Department of Health's role. As well as providing the secretariat to the JCVI, senior DOH officials attend meetings, including the director of immunisation, David Salisbury. Professor Salisbury reported that DOH staff "take no part whatsoever in decision-making," and Andy Hall explained that, while those who attend meetings may be asked to comment, "the actual discussion is among the committee."

The role of non-committee participants is not made clear either in minutes of meetings or on the JCVI website. George Kassianos wondered if they might "influence the discussion," and David Elliman saw the recent decision to use Cervarix rather than Gardasil for the human papillomavirus (HPV) vaccination programme as the "only slight blot on the copybook" in terms of the JCVI's independence. The JCVI had favoured Gardasil in its recommendation to ministers, as it protects against anogenital warts as well as cervical cancer. However, the Department of Health ultimately chose Cervarix, and a few respondents were unclear why. David Elliman was concerned about "the secrecy around how they chose the particular brand. They published the criteria they used but not the marks they attributed to each vaccine under those criteria." Other interviewees also believed the decision raised questions over the JCVI's relationship with the DOH. Clarification of the latter's role will help avoid future confusion and, potentially, controversy over the JCVI's independence.

Recommendation:
The role of Department of Health staff in JCVI meetings and recommendations should be clarified and explained on the JCVI website.

Two The Decision-Making Process

How does the JCVI take decisions?

The JCVI meets every four months to discuss immunisation policy. Suggestions for the agenda may come from the medical and scientific community, the government, non-governmental organisations, the pharmaceutical industry, international health agencies such as the World Health Organisation, or the Health Protection Agency (a non-departmental public body specialising in vaccine research and surveillance, which works closely with and is funded by the Department of Health).

In making decisions, the Committee must consider "the need for and impact of vaccines, the quality of vaccines and the strategies to ensure that the greatest benefit to the public health can be obtained from appropriate use of vaccines."[xiv]

The JCVI decision-making process involves the following steps:[xv]

- Identifying evidence, including searching for papers and information and identifying gaps in the evidence base.
- Systematic literature review.
- Commissioning work, including, where required, studies on cost-effectiveness and qualitative research among the public and professionals on the appropriateness of a new vaccine for the UK.
- Review of evidence by the JCVI or an expert sub-group. The sub-groups include JCVI members with expertise in the relevant field as well as other experts identified by the JCVI and the Department of Health. Papers and other research evidence are graded for their quality, validity, results and relevance.
- The committee and its sub-groups can consider unpublished as well as published work (unlike NICE, which only considers published materials), data provided by manufacturers, and ongoing research by academics and vaccine companies. The JCVI may write to experts not included in sub-groups for additional information and opinions.
- The JCVI also considers attitudinal research, to assess the likely ease of implementation. On HPV vaccines, for example, it reviewed a DOH survey of parents' attitudes to cervical cancer and to the vaccine, and consulted parents on when the vaccine should be given to children (NICE does not consider such research).
- The JCVI is presented with papers summarising the evidence base, and uses these to make a recommendation. A statement explaining the recommendation is placed on the JCVI website and provided to the Secretary of State.

- The JCVI "aims to ensure that its information and advice is made public in a clear, understandable manner."[xvi] Minutes and agendas of meetings are published on the website, within four months of main committee meetings, with sub-group outputs published within a month of the main committee meeting. An annual report is also placed on the website, although the latest currently available report dates from 2005-2006.

Strengths and weaknesses

The JCVI's decision-making is widely respected in the UK and internationally. Among those we interviewed, all believe the quality of its recommendations is strong. However, if the JCVI is to confront a more complex future with confidence, there are areas for improvement in some aspects of the decision-making process.

Horizon scanning

The first area of concern is horizon scanning - the process of identifying upcoming issues in the immunisation field. While NICE has a formal process, conducted by the National Horizon Scanning Centre at the University of Birmingham, horizon scanning for the JCVI is less systematic. The secretariat at the Department of Health provides papers to the committee roughly every two years summarising new developments, but it is not clear how issues are identified and there does not appear to be a defined schedule for when the papers will be presented to the committee.

Respondents to this study from the vaccine industry are concerned about the lack of clarity. Research and development investment will be wasted if vaccine companies are not informed about the long-term immunisation needs of the UK public. Richard Stubbins, CEO of SPMSD and Chairman of the UK Vaccine Industry Group, commented that "it's not clear how JCVI does horizon scanning. There's not the same clear and transparent process that exists for horizon scanning of [non-vaccine] pharmaceuticals." Another vaccine industry representative reported that "NICE horizon scanning is very open and involves industry by eliciting information on licensing, clinical trial status and future planned trials. With JCVI it's very informal."

Stubbins also pointed out that 'Ahead of the Curve,' a 2002 publication by the Chief Medical Officer that set out UK vaccination priorities, has not been updated. "Manufacturers," he explained, "are looking 10, 12, 14 years ahead in development terms, and they need a clearer idea of what the government has as its priorities and what it is telling the JCVI to review."

A formal and clear horizon scanning process would benefit the public as well as vaccine companies. Keeping companies apprised of future health priorities will allow firms to focus on vaccines that meet society's needs and to develop and deliver those vaccines more quickly. Involving companies formally in the horizon scanning process and eliciting

information from them on future developments, moreover, will allow the JCVI to assess vaccines promptly and speed up the appraisal process.

Consultation on horizon scanning should not just be limited to the vaccine industry. As noted in part 1, professional bodies and patient and carer groups may have information about future vaccine needs, opportunities and problems of which the JCVI is unaware. If the committee expands its audience of ex officio members or liaison representatives, the latter should be consulted during horizon scanning. Making the process more inclusive is more likely to ensure that important emerging issues are identified at an early stage.

Recommendation:
The JCVI's horizon scanning process should be clarified and published on the website. Vaccine companies and other key stakeholder groups should be consulted on how best to develop the process, so that it provides information to stakeholders in a timely way and allows for input from those who may have useful information on emerging issues.

Recommendation:
During horizon scanning, strong consideration should be given to consulting formally with vaccine companies and other key stakeholder groups.

Speed

The speed of JCVI decision-making varies. For some vaccines, recommendation follows very soon after licensing. For others, there are long delays. With the HPV vaccine, for example, the JCVI sub-group first met in May 2006. The vaccine was licensed in Europe in September 2007, and the JCVI made its final recommendation in July the following year. Immunisation of 12-13 year old girls began just two months later. Meningitis C vaccine, according to an interview respondent from a research foundation, was introduced "faster than anyone hoped." And the committee has already asked the Health Protection Agency for burden of disease information for meningitis B, even though a vaccine for the disease has not yet been licensed.

On the other hand, the JCVI varicella sub-group was set up in 2001 but did not meet until six years later. Pneumococcal conjugate vaccine, meanwhile, was licensed in February 2001 but was not introduced into the UK immunisation programme until September 2006. According to the UK Vaccine Industry Group, earlier introduction could have averted 1,500 cases of pneumonia, meningitis and septicaemia, and over eighty deaths.[xvii]

There are risks associated with speed, of course. In the US, ACIP made a relatively quick decision to recommend introduction of the Rotashield vaccine for rotavirus, but the vaccine had to be withdrawn when it was found to cause intussusception (a potentially fatal intestinal blockage) in some children. As David Elliman argued, "you can justify its slowness in comparison with drugs for treatment because we are giving something to healthy people, so you have to be much more certain about the risks. With terminal cancer, for example, you're going to accept large risks, but if you're giving something to healthy people you have to be that much clearer that it's safe."

Accelerating the decision-making process, however, need not mean sacrificing thoroughness. If the appraisal process began earlier, the committee would have a similar length of time to study a vaccine, but that vaccine could be introduced more promptly. "If they streamlined the [decision-making] process," noted Richard Stubbins, "this would provide a better environment for planning by everyone and could enable the public to get earlier access to vaccines." The Chief Medical Officer concurs with this suggestion, recommending in his 2007 annual report that "as new vaccines get close to being available for implementation, there should be a streamlined process for bringing their benefits to the population."[xviii]

Vaccine manufacturers often plan the research and development of new vaccines up to fifteen years in advance.[xix] A number of potentially important immunisations have already reached phase three of clinical trials, including vaccines for genital herpes and the H5N1 strain of avian flu, meaning they are likely to be ready for launch within five years. Many others (for tuberculosis, malaria and HPV vaccines with broader coverage) are in phase two trials and could be ready within ten years.

In some cases, as noted above, the JCVI is quick to begin its appraisal process, but consistency is lacking. NICE has faced similar criticisms of the speed of its decision-making. The House of Commons Health Committee has recommended pilot schemes to assess the benefits of earlier appraisals by NICE, with the pharmaceutical industry involved in identifying emerging technologies that could be assessed early.[xx] The Cooksey review of UK health research funding also recommended earlier engagement between NICE and manufacturers.[xxi]

Such engagement could also help speed up and make more consistent the vaccine assessment process. As well as a formal horizon scanning process conducted with input from manufacturers, the JCVI could benefit from consulting with industry to establish when the appraisal process can start. A formal schedule for assessing new vaccines would allow for more efficient long-term planning by manufacturers and help the Department of Health plan the allocation of resources for immunisation programmes.

Recommendation:
The JCVI should aim to formalise early commencement of the appraisal process, so that assessment of each vaccine begins as soon as possible and the timing of appraisals is consistent. The committee should consult with manufacturers to identify when appraisals can begin.

Transparency

The JCVI's meetings are not open to the public. All papers submitted to the committee (including those submitted by manufacturers) are confidential. The committee occasionally consults the public, for example on attitudes to cervical cancer and the HPV vaccine, but aside from a biannual Department of Health survey of mothers' attitudes towards immunisation and the publication of minutes from meetings on the JCVI website, there is no regular interaction with those being asked to take their children to be immunised.

Those close to the JCVI put forward two reasons for its distance from the public. The first is that the data the committee receives from industry is often commercially sensitive, while academic papers it reviews are sometimes unpublished. Holding meetings in public might make companies and researchers more reluctant to share information, for fear that rivals may use it. As a former JCVI member argued, "if the meeting was held in public, there wouldn't be the same spirit of sharing information."

The second reason is the risk that meetings will be disrupted by public participation. The JCVI's American equivalent, ACIP, allows people in the audience to make comments during the proceedings. According to JCVI Chairman Andy Hall, this causes an "enormous hoo-ha because you have all these mothers of young children damaged by autism who come along and make a great fuss. I don't think that's a way to make sensible decisions."

Current and former members of the JCVI interviewed for this review acknowledged that some observers perceive the committee as a black box. Andy Hall admitted, "we've been accused of being secretive," and that this may harm public perceptions of the committee. Others agreed. "I'm sure if you asked most people," opined Jacqui Thornton, "they wouldn't know what the JCVI was." She pointed out that even on the NHS Choices website, which aims to provide the public with comprehensive healthcare information, a search under "JCVI" brings up just four links, compared to over 500 for "NICE."

The JCVI has for some time been considering holding its meetings in public, but has not yet reached a decision. Raising its head above the parapet may of course expose the committee to greater scrutiny. NICE, whose proceedings are much more transparent, has received a barrage of media criticism in recent months, with a 2008 review finding that nearly all of over 200 stories on NICE between August and October were negative, with "some stretching the boundaries of reasonable comment to breaking point."[xxii] The JCVI's role is to provide advice to ministers, with any legal challenges and media enquiries currently fielded by the Department of Health. Given the JCVI's small size and limited budget (NICE has a press office but its budget is much larger and it has hundreds of full-time staff), it is appropriate that the DOH should be responsible for communicating with the media on immunisation issues.

Allowing the public to attend JCVI meetings, however, would not impose a large cost, nor would it require committee members to learn new skills in media relations. Health scares over MMR and bovine spongiform encephalopathy (BSE) in recent years have highlighted the importance of transparency and increased the pressure on scientific bodies to open up. In its review of the BSE debacle, the House of Lords Select Committee on Science and Technology noted a "crisis of trust" in science, and found that "it is now normal for assertions of authority to be questioned…the public is in no mood to place uncritical trust in experts."[xxiii] A study of the MMR scare drew a similar conclusion, arguing that "challenge to authority, including the authority of science, should be expected in a healthy democracy."[xxiv]

A 2008 legal ruling against NICE, which forced it to release a working version of its cost-effectiveness models for appraising Alzheimer's drugs, is further evidence of the pressure for greater openness in science policy-making.

Jacqui Thornton believes that although they had a difficult task, the JCVI and Department of Health did not handle the MMR scare effectively, and that they "failed to regain public confidence." The House of Lords Select Committee argued that government bodies in general, including scientific bodies, are failing to respond to public concerns, reporting that "there is still a culture of governmental and institutional secrecy in the UK, which invites suspicion." David Elliman, meanwhile, made the pointed observation that:
"If Andrew Wakefield [the paediatrician whose study instigated the MMR scare] said, 'I believe X, Y and Z but I can't tell you the reasoning behind it because it's commercially sensitive,' you can imagine what the response would be."

Public trust in vaccination policy is crucial if parents are to bring their children to be immunised. Parents interviewed in the wake of the MMR scare wanted the government to be more open and transparent, acknowledging uncertainty and being less defensive about single dose vaccines.[xxv] Jacqui Thornton was one of several respondents to this review who believed meetings should be held in public. "There should be no place in today's government for secrecy like that," she argued. "It only breeds suspicion." A former JCVI member concurred, saying, "we do need to get away from being a shadowy committee in the dark."

As well as satisfying the growing public demand for more openness, a higher profile for the JCVI is likely to strengthen perceptions of the committee as an authoritative voice in the immunisation field. During the MMR scare, many different experts put forward conflicting views. Andrew Wakefield and his co-authors - all experts in their fields - put forward the view that MMR was unsafe. The JCVI and Department of Health argued throughout that the vaccine was safe. The government also said the vaccine was safe, but the Prime Minister, Tony Blair, did not disclose whether his son had received it. Some physicians began to waver.

If the JCVI wants its voice to be respected above all others, so that government and the public accept its recommendations, it needs to be trusted. If it is seen as having something to hide, this trust may be weakened. ACIP holds its meetings in public, except in special circumstances, and as the House of Lords Select Committee noted, "the typically adversarial nature of such processes in the USA is often looked upon with horror by British scientists; but it does not seem to have done US science any harm." NICE, too, whose culture of openness has exposed it to flak from the mainstream media, is very widely respected internationally and in the scientific press.[xxvi] Future immunisation decisions may arouse even more controversy than MMR, and in a culture where authority is challenged and the public demands to be fully informed, decision-making in secret is becoming increasingly anachronistic.

The House of Lords Select Committee recommended that "advisory and decision-making bodies in areas involving science should adopt a presumption of openness," except when there are strong reasons to keep information and discussions confidential. It recommended meetings be open to the public, "while reserving the right to meet in private when necessary." ACIP has a similar proviso. In the case of vaccines, for example, where discussions cover immunisation against biological weapons and therefore relate to matters of national security, there may be a case for holding meetings, or parts of meetings, in private. Similarly when discussing highly confidential information submitted by vaccine manufacturers or researchers. Questions over issues of commercial and academic confidentiality would require consultation with industry and research organisations, although the problem could be addressed if confidential data were considered by sub-groups rather than the main committee, with only the latter's meetings open to the public.

Questions remain over whether the public should be allowed to comment during meetings or attend only as observers. There are trade-offs to be made between the speed and serenity of decision-making and the need to give the public a genuine stake in the process. Several of those interviewed for this study felt that allowing the public to observe meetings would be sufficient, arguing that public participation might disrupt meetings. On the other hand, if the JCVI wishes to build some slack into the decision-making process and to anticipate challenges to its recommendations rather than having to deal with them after they have been implemented, allowing some public participation during or at the end of meetings may be preferable. Consultation is a major part of the NICE decision-making process, and is seen by most observers as one of the organisation's strengths. "The NICE process is very robust," explained Simon Blake of Brook Advisory Centres, a sexual health charity. "They engage with people all the way through, so whether or not you agree with the recommendations, you know you've had the opportunity to have your say and that they've considered it." Provided the JCVI clearly outlines the public's roles and responsibilities and that meeting organisers ensure that a single interest group does not dominate proceedings, allowing public involvement will help the committee fend off damaging accusations of secrecy should a controversy emerge in the future.

Recommendation:
The JCVI should open meetings to the public, while reserving the right to hold discussions in private where absolutely necessary. Some public participation in meetings should be encouraged.

Recommendation:
The Department of Health should continue to be responsible for communicating with the media on vaccine policy.

Relations with the vaccine industry

The JCVI considers submissions from the vaccine industry during the decision-making process, but companies are not allowed to present information to the committee.

Vaccine company representatives interviewed for this study report mixed experiences of the decision-making process. One respondent has been impressed with how the JCVI has dealt with his firm's latest travel vaccine. "We have an understanding of how to interact with them and when, and of what information they are looking for," he said. On the other hand, he is frustrated that his firm cannot present to or speak to the committee: "We benefit from a good dialogue during the regulatory process but we don't have the same dialogue with the JCVI," he reported.

A representative of another firm was less impressed. "It's very unclear how agendas are set," he said, "their work plans are very unclear, and it's unclear how decisions are made. You never know when your vaccine will be reviewed, and you're not involved in the process." Richard Stubbins of SPMSD agreed: "Vaccine developers need to know where they are in the process." Another industry respondent also noted the lack of milestones during the process, and the lack of a format for providing the JCVI with information. The JCVI is considering whether to allow manufacturers to present information to sub-groups. Such a move is not without risks. John Edmunds of the Health Protection Agency was one of several respondents keen for the JCVI to maintain its distance from industry:

"The decisions need to be independent and be seen to be independent of influence from industry. You need to build trust among the public - look at what happens when the public starts to lose trust, as with MMR. If they think this is being run by big pharmaceutical companies in order to make their shareholders more money that would be a serious problem for maintaining public confidence."

Industry submissions, moreover, are not always reliable. A survey of 326 drug company submissions to the Australian Department of Health and Aged Care found that two-thirds had "major problems detected by critical review."[xxvii] And a study of economic evaluations submitted to the NICE technology appraisal programme by pharmaceutical companies concluded that their cost-effectiveness estimates were generally significantly more favourable than those submitted by NICE assessment groups for the same interventions.[xxviii]

However, the JCVI already considers written industry submissions, so allowing companies to present rather than send in information would not be a giant leap. In the US, ACIP allows presentations from manufacturers and, as one industry representative argued, "if we were allowed to present information to them, this would not compromise the JCVI's decision-making in any way and it would still remain entirely their decision [whether to recommend a vaccine]. And there is an independent procurement process where there is usually more than one company supplying."

The question, then, is whether presentations by industry would strengthen decision-making. They may be of benefit if committee members or sub-groups have questions on the data. Asking such questions face to face would be faster than an e-mail exchange and would reduce the risk of misunderstandings. This could enhance both the speed and quality of decisions.

Perhaps more important than allowing industry to present data is clarity of process. Companies are currently in the dark as to how the JCVI process works, and they bemoan the inconsistency between how different vaccines are considered. As one industry representative commented, "if they are prepared to tell us exactly what they want and we have the capability to give them that, that's great, but at the moment there is not that clarity."

The Conservative Party has recommended the establishment of a steering group made up of the Association of the British Pharmaceutical Industry, DOH and NICE, which would meet periodically to discuss current and future issues and give industry a clearer idea of what they are required to produce for a NICE appraisal. A similar group could benefit the JCVI.[xxix]

In the absence of such an arrangement, templates should be developed outlining the information the committee requires from industry, along with formal timelines for when data can be submitted, when it will be considered and when decisions will be made. These would give industry a better idea of what information it is required to produce and when vaccines are likely to be needed. This would also assist long-term planning by the Department of Health.

Recommendation:
Clear timelines for decision-making should be produced in consultation with industry, along with templates outlining the information the committee requires. There is no strong case for allowing companies to present data to the committee face to face.

Cost-effectiveness analysis

The final area for improvement in the JCVI decision-making process is its consideration of the cost-effectiveness of vaccines. Cost-effectiveness analysis (CEA) allows vaccines to be compared with each other and with therapeutic drugs and other health technologies, thereby helping policy-makers choose the health interventions that provide the greatest benefits per pound spent. In a context such as that of the National Health Service, where many new and old interventions compete for limited funds, such comparisons are essential for maximising the benefits obtainable with the health care budget.

America's Advisory Committee on Immunization Practises is charged with considering cost-effectiveness, as are similar organisations in Germany, Sweden, Australia and New Zealand. NICE, too, is charged by the Department of Health to consider cost-effectiveness.[2] Although sometimes controversial - patient groups and the media often protest NICE's rejections of drugs[xxx] - the World Health Organisation believes NICE's use of CEA is "setting a new, international benchmark."[xxxi]

The JCVI's terms of reference do not currently incorporate CEA, although members report that it is an increasingly important consideration and in June 2008 the committee agreed to revise its terms of reference to include economic modelling.[xxxii] This has not yet been done, however, and there remains some confusion over the part CEA should play in decisions.

The JCVI has acknowledged the need for greater and more robust consideration of cost-effectiveness and other economic factors.[xxxiii] Compared with most of the treatments assessed by NICE, immunisation is often a high-value investment. Many vaccines are cost saving. In US studies, benefits were found to exceed costs for pertussis vaccine, MMR for young children and flu jabs for the elderly. For the DTP vaccine (which protects against diphtheria, pertussis and tetanus), the benefit to cost ratio is 6.2 to 1 for direct costs, while combining DTP and Hib vaccines was found to result in savings of over $90m a year.[xxxiv]

To ensure that immunisation receives the public investment it deserves, robust comparison of vaccines with each other and with therapeutic drugs is essential. The JCVI should not delay in incorporating cost-effectiveness into its terms of reference, and the analysis should inform each of its assessments in the same way it informs NICE appraisals.

Although the JCVI has pledged to align its cost-effectiveness analysis with that of NICE, there are some areas of concern with the approach of both bodies, particularly with regard to openness. The first relates to communication of the role of cost-effectiveness analysis. Many of NICE's critics in the media, the health professions and the public believe it places too much emphasis on cost-effectiveness rather than the clinical benefits of drugs. George Kassianos of the Royal College of General Practitioners, for example, told us that "NICE decisions are taken because of cost, not clinical need, when it should be the other way round." A former JCVI member said, "if we moved to NICE it might get more focused on issues of cost-effectiveness rather than clinical need."

In these comments and in much of the media discussion of NICE decisions, there is the implication that cost-effectiveness analysis is a bad thing. NICE has failed to communicate the importance of CEA for allocating limited health care resources. Simon Blake and others see the organisation as reactive in responding to criticism. "You normally find someone from NICE talking on the news when something's already on the front page of the Daily Mail," he said. "You don't see them going out and saying, 'we recognise these are very difficult decisions but on balance with limited resources we believe X, Y and Z.'"

Nigel Hawkes believes "they've lost the initiative, and this has contributed to the negative coverage. They don't think they can win the argument in the media so they've stopped trying. This is a mistake as they have a better story to tell than they're telling." Blake believes NICE should be "braver" and more proactive in pre-empting criticism, by explaining why cost-effectiveness is important and how it can benefit the nation's health. Richard Philips of Medtronic Ltd, who has sat on NICE committees, agreed, saying that "NICE should bring some of these arguments about resource allocation into the public sphere, even though it's a difficult conversation to have." As the JCVI focuses more on CEA, it too should pre-empt the critics by working with the DOH to outline the benefits of CEA and explain its place in the committee's decision-making.

The second area for improvement also relates to openness. In 2008, the pharmaceutical company Eisai won a high court ruling against NICE, forcing it to release a working version of the cost-effectiveness model it used to evaluate Alzheimer's drugs. Previously NICE had only made public read-only versions of the models, but the decision reflects the increasing tendency towards openness discussed above. The JCVI, too, does not release its cost-effectiveness models.

Richard Stubbins of SPMSD summed up why this is a problem:

"It would give us an idea of the benchmarks needed to pass. At present there is a duplication of work, as industry and the recommending bodies such as JCVI and NICE all build and run models on cost-effectiveness. This work is also performed across Europe. An ideal scenario would be for one model to be created for each vaccine, which could be used in the EU, such that manufacturers and decision-makers could just plug in the different costs, levels of infection, burden of disease etc, and get results based on local data. The whole process would be more transparent and could accelerate decision-making."

The Chief Medical Officer has called for the government to be "open about the information it has [on vaccination] and offer it freely for independent scientific scrutiny,"[xxxv] and the Eisai ruling is likely to increase the pressure on the JCVI to release its models. If these

2. NICE's cost-effectiveness analysis relates the net cost of an intervention (for example, distribution costs minus health care costs averted) to a desired health outcome. It uses quality-adjusted life years (QALYs) as its desired outcome. QALYs are a measure of the number of life years gained as a result of a health intervention, weighted by the quality of life experienced during those years. According to a review of the academic literature, "analysts generally agree that QALYs are closer to the fundamental concept of health benefits than are the standard physical measures used in CEA." (RE Levine (2003): Cost effectiveness of immunization: asking the right questions. In B Bloom and P-H Lambert (eds.): The Vaccine Book. San Diego, California. Academic Press: 23-36.)

models are robust and the committee has confidence in them, it should have nothing to fear from making them available. If not, opening them up to criticism should help refine them (as Richard Philips observed, CEA is a "very imprecise science") and make their use easier, faster and less controversial in future.

The third challenge relates to the cost-effectiveness threshold. NICE's threshold for recommending an intervention, which is also used by the JCVI,[xxxvi] is widely thought to be between £20,000 and £30,000 per QALY, which roughly equates to annual per capita GDP, the common benchmark for determining cost effectiveness.[xxxvii] This has never been explicitly confirmed, however, and critics see it as a random figure with no evidence base.[xxxviii] NICE argues that the figure is based on "the collective judgement of the health economic community,"[xxxix] but since the threshold has not changed since NICE's formation, despite NHS spending rising sharply, it appears the relationship between the threshold and the NHS budget is weak.[xl] Moreover, NICE has accepted some treatments whose cost effectiveness ratio is above the £30,000 limit, with £48,000 per QALY the least cost effective treatment recommended so far.[xli]

Appleby and co-authors believe the NHS should have a "threshold committee", which sets the cost per QALY benchmark independently of Department of Health and NICE interference, using criteria such as the size of the NHS budget, society's willingness to pay for health care interventions, the level of health sector inflation and the value of technologies to the NHS.[xlii] Even without such a committee, there is a strong case for both NICE and the JCVI to allow the threshold to be debated publicly. An inappropriate threshold will result in inefficient allocation of health care resources and in health outcomes that are not in line with political and societal priorities. Once a figure has been set, both bodies should use it consistently in their assessments and recommendations.

The final area of concern is the failure of both NICE and the JCVI to include the social and economic costs and benefits of health interventions in their cost-effectiveness analysis. The Department of Health instructs the two bodies to ignore these broader considerations. The benefits of a treatment or a vaccine to those caring for the sick, for example, and the economic costs of time off work for patients and carers are therefore overlooked.

This can have a significant impact on recommendations. In 2008 the JCVI decided not to recommend rotavirus vaccine because although it would reduce incidence of diarrhoea it was not considered cost-effective. However, the committee believed that the vaccine would be cost-effective "if the economic analysis were from a societal perspective," and it recommended that the potential cost-savings to society be included in the advice to ministers.[xliii] Including this proviso in a recommendation is inconsistent with the Department of Health's instructions not to consider societal costs and benefits, and means that the advice on rotavirus vaccine was not in line with advice on other vaccines and treatments where societal impacts have been ignored. As the JCVI sub-group acknowledged, "the same economic criteria are used to make decisions across the health service," so such a recommendation is likely to cause confusion.

Although somewhat muddled, however, the JCVI's decision on rotavirus highlights the potential impact of incorporating the societal and economic effects of vaccines. These extend well beyond the direct savings from not having to treat the sick. Improved health in childhood allows individuals to attend school more regularly and learn more effectively while in school. For example, episodes of pneumococcal pneumonia, by keeping children out of school for long periods, have been found to impede cognitive development.[xliv]

Pneumococcal otitis media can have a similar effect; a US study found that children who had suffered from the disease before the age of three years had weaker school performance and lower scores in tests for cognitive ability, language and speech at the age of seven years than other children.[xlv] School performance in turn is associated with productivity in adulthood - children who have avoided harmful diseases because of vaccination will contribute more to the economy when they reach working-age. Improved health in adulthood makes workers more productive and enables them to earn more, create more jobs and contribute more money in taxes. Ill health, on the other hand, can lead to social exclusion and plunge families into, or deeper into poverty, with effects not just on the exchequer but on social cohesion.[xlvi] Carers of those who are sick face similar risks.

Miller and Hinman argue that, given that immunisation programmes are often supported by governments and that benefits accrue not only to those who are vaccinated but also to those who are not vaccinated (from the reduced likelihood of exposure), it is logical to take a societal perspective when deciding whether to introduce them.[xlvii] Alexandra Wyke of Patient View, whom we interviewed for this study, believes it would be more "meaningful" to the context of everyday life to include factors such as getting back to work and leading a normal existence, rather than just measuring the direct medical costs to the NHS. In Germany, Sweden, Australia and New Zealand, societal value is part of the decision-making process for pharmaceuticals; by overlooking it in the UK, the JCVI and NICE are failing to take account of the full impacts of health interventions.

In Table 1, Barnighausen and co-authors (2008) provide a useful taxonomy of the factors that could inform a broader analysis of the economic impact of vaccines.[xlviii]

Table 1 The benefits of vaccination

Perspective		Type of benefit	Definition
Broad	Narrow	Health gains	Reduction in morbidity and mortality through vaccination
		Healthcare cost savings	Savings on medical expenditures because vaccination prevents illness episodes
		Care-related productivity gains	Savings of parents' productive time because vaccination avoids the need for taking care of a sick child
		Outcome-related productivity gains	Increased productivity because vaccination improves cognition, physical strength and school attainment
		Behaviour-related productivity gains	Benefits accruing because vaccination improves child health and survival and thereby changes household behaviour
		Community externalities	Benefits accruing because vaccination improves outcomes in unvaccinated community members

Recommendation:
The JCVI should fulfil its pledge to incorporate consideration of the cost-effectiveness of vaccines into its terms of reference.

Recommendation:
The JCVI should work with the DOH and NICE to explain to stakeholders the importance of cost-effectiveness analysis. In this way, it can pre-empt rather than react to criticism.

Recommendation:
The JCVI should strongly consider releasing working versions of its cost-effectiveness analysis models.

Recommendation:
The JCVI should work with NICE to consult the public on the cost-effectiveness threshold for health interventions. A publicly debated threshold should be clarified and used in all assessments by both bodies.

Recommendation:
The JCVI should take the social and economic impacts of vaccines into account when making its decisions. Only then will the full value of immunisation be reflected in the allocation of health care resources.

Three Should the JCVI and NICE merge?

The call for a merger

The Conservative Party suggested that the JCVI should come under the wing of NICE.[xlix] "While there is undoubted expertise in JCVI and its committees," it argued in a recent position paper, "it is essential for the future that vaccines and immunisation programmes form part of a consistent process of evaluation and advice to Ministers and NHS commissioners. For this to be the case, the evaluation of vaccines and immunisation programmes must be added to the NICE remit, with a corresponding transfer from the Department of Health. This will also ensure greater transparency in the evaluation of vaccines."

NICE also argued in favour of a merger in an April 2007 submission to the House of Commons Health Committee.[l] Its rationale was that since NICE has a public health remit, it would be sensible for it to consider immunisation - a bulwark of disease prevention - in its public health guidance.

Although it is likely that vaccination policy would be more transparent if the JCVI became part of NICE, and there may be economies of scale and more consistent decision-making if NICE assesses vaccines as well as most other health interventions (screening is also outside its current mandate), there are a number of disadvantages to a merger, which may put what is a very successful vaccination programme at risk. Even the issue of transparency could be solved if the JCVI itself became more open, while consistency could be improved if the two organisations worked more closely together.

Of the twenty stakeholders interviewed for this study, only two thought a merger would be a good idea, and both of these admitted to having little knowledge of the JCVI (two others were neutral). The remainder, including representatives from the vaccine industry, the health professions, patient groups and the media, were opposed to the proposal, often strongly. John Oxford argued that "you could end up blowing the whole thing apart if you merged them." George Kassianos said "there are no advantages to a merger. JCVI is doing a far better job than NICE." David Salisbury asked, "how does this proposal benefit the UK population or the medical community?" And David Elliman argued: "You might lose something - JCVI has a decent track record and is well respected internationally. It's not worth doing unless it would save a lot of money." Given how little the JCVI costs to run, the latter is unlikely.

The risks of merging

There are three key reasons why the risks of a merger might outweigh the benefits. These relate to the JCVI's use of experts, implementation of vaccine policy, and the public image of the JCVI.

The importance of experts

Decisions on whether to introduce vaccines are very different to those covering therapeutic drugs. There is a stronger emphasis on safety with vaccines, as they are generally given to healthy rather than sick individuals, and against diseases those individuals may never have contracted (thanks to the success of vaccines in reducing their prevalence). Parents bringing in their children to be immunised have valid concerns about potential side effects and about the risks of overloading their children with vaccines. Journalist Nigel Hawkes believes the JCVI's expertise enables it to address these concerns:

"JCVI has to take account of political as well as medical issues. When it's considering a new childhood vaccine, it has to think what impact this will have on our other childhood vaccines. Are we overloading mothers with taking their kids to be vaccinated every five minutes? Do we really want to save a limited number of lives with a new vaccine at the cost of deterring mothers from taking their kids for really important vaccinations? These are political questions, and NICE is not good at these soft but important decisions."

Another respondent provided the example of the hepatitis B vaccine, which has been recommended by the World Health Organisation and implemented in several other countries but which, because it might have negative effects on protection against hib meningitis, has not yet been recommended in the UK. "Even an expert committee might not take account of this," she argued, "let alone a non-expert group like NICE that does not take account of the overall programme and takes decisions in isolation." As Andy Hall observed, "you can't separate one piece of the vaccination schedule from another - if you change one part of the schedule you might have to change all the other vaccines."

The complexity of vaccination is compounded by the phenomenon of herd immunity, whereby unvaccinated people can benefit from others being immunised because of the reduced incidence of disease in the community. As Elizabeth Miller (Head of the Immunisation Division Communicable Disease Surveillance Centre of the Health Protection Agency) argued, "given that vaccines have the potential via herd immunity to have major impacts on the unvaccinated, estimating what is likely to happen when a vaccine is introduced requires sophisticated disease transmission modelling, much more sophisticated than is required for NICE assessments of therapeutic interventions. It is a very complex area that requires input from epidemiologists who understand the disease, surveillance scientists who have got the data, modellers who are used to working closely with epidemiologists and economists."

Herd immunity may also have significant effects on the cost-effectiveness of a vaccination programme. "Coming to a decision on cost per QALY gained for a vaccine is an order of magnitude more complex than for a therapeutic drug," argued Elizabeth Miller. According to John Edmunds, "the standard health economics models don't take that into account, but these knock-on effects can be very important."

These issues require specialist expertise, and the JCVI is seen as doing a good job of addressing them. NICE, on the other hand, excludes experts from its decision-making process. Unlike the JCVI, it does not undertake any primary research. And it has no experience of deciding how a technology such as a vaccine can fit into a wider set of health interventions. David Salisbury pointed out that "NICE looks at drugs in isolation, whereas the JCVI is dealing with a whole programme." Another respondent believed "NICE would have to change the way it works [in order to assess vaccines] as it only looks at published evidence and doesn't have an expert panel. This could be a real problem. Having expert advisers is a distinct advantage of the JCVI." A vaccine company representative agreed, saying, "NICE wouldn't be capable of evaluating vaccines versus each other."

The expertise necessary for decision-making on vaccines would be diluted if the JCVI became part of NICE. The quality of the JCVI's decisions is widely respected by stakeholders from the health service, industry and patient groups. Assessing the epidemiological and cost-effectiveness of vaccines would be a difficult challenge for a body like NICE that does not consult experts, and it is likely that a merger would weaken the quality of decisions, with potentially harmful effects on the entire vaccine programme and, as a consequence, on the nation's health.

Implementation of vaccine policy

The Conservative Party has called for immunisation programmes to be transferred from the Department of Health, which currently runs them and funds them centrally, to NICE, whose recommendations are implemented and funded by primary care trusts (PCTs).

This suggestion presents a number of problems. Under the current system whereby immunisation is delivered centrally by the DOH, vaccination coverage in the UK is high, and comparable with the European average. Coverage of basic childhood vaccines in the UK is above 90 per cent, with the exception of the MMR vaccine where coverage has fallen to 85 per cent.[li] Coverage of flu vaccine among the elderly is over 70 per cent, the highest rate in Europe.[lii] Stakeholders interviewed for this study were of the strong opinion that implementation of JCVI recommendations is effective and that the UK's immunisation programme is well run.

As well as delivering the immunisation programme, the DOH and JCVI also monitor its implementation and impact. They use disease surveillance data provided by the national immunisation registry, focus groups with parents, and the Health Protection Agency.[liii]

Effective surveillance helped the JCVI detect a rise in Hib disease in the early 2000s, which it countered with a vaccine catch-up programme. Rates of Hib disease fell again as a consequence.[liv] "If you look at implementation of vaccines in relation to other pharmaceuticals and the inequalities in uptake of new treatments," commented one interview respondent, "they do a pretty good job."

NICE has had less success with the implementation of its recommendations. If responsibility for the UK's immunisation programme were transferred from the JCVI and the Department of Health to NICE, it would be decentralised, with PCTs responsible for implementing NICE's guidance. However, implementation and monitoring of this guidance has so far been patchy. Nigel Hawkes told us that "NICE hasn't eliminated postcode prescribing, and there's been no proper ascertainment of the extent to which its recommendations are followed." Richard Philips of Medtronic Ltd agreed, saying "there are still huge discrepancies geographically." The Audit Commission has warned that "the implementation of NICE guidance by NHS bodies is less comprehensive and timely than desired,"[lv] while a British Medical Journal commentary argued that "none of the systems used to monitor implementation of NICE guidance have worked so far."[lvi]

According to David Salisbury, unlike the JCVI, "NICE doesn't do any programme management work. It doesn't manage and review the day to day running of a programme." Decentralising funding of the vaccination programme and moving responsibility for it from an organisation that has a good track record in both implementation and monitoring to one that has no experience of running a programme and a patchy record in ensuring its recommendations are put in place would appear a risky move. With many vaccines, it is important that every child in the country receives them. If herd immunity is to be achieved and dangerous childhood diseases eradicated, central management and funding of the programme are likely to be more effective than leaving it to the discretion of local primary care trusts. As several of the respondents to this study asked, "if it ain't broke, why fix it?"

A further implementation problem lies in the fact that JCVI recommendations cover England, Scotland, Wales and Northern Ireland, and the DOH purchases vaccines on behalf of all four countries. NICE's recommendations only apply to England and, in some cases, Wales. Merging the two would present political and public health challenges. Politically, if a vaccine decision in Scotland and Northern Ireland differed to one in England and Wales, there may be arguments about inequalities in vaccine distribution. And from a public health point of view, if immunisation schedules differed by country, there would be a risk of children who move between countries missing out on vaccines. John Edmunds explained:

"Currently, if somebody moves two miles across the border from Wales into England, there is no problem, their vaccine schedule is the same. Whereas NICE only covers England and Wales, they don't cover Scotland and there is already a difference in some of their recommendations from those in Scotland. Inevitably there would be differences in recommendations across the UK and that would be to the detriment of public health, people would inevitably miss vaccinations - not by design but by accident - if there were different vaccination schedules in different parts of the country. You might have a 2, 4, 6 month schedule in England and 2, 5, 7 in Scotland, so what happens when people move? That's what happens across Europe all the time."

The image problem

The final stumbling block to a merger is the reputation of NICE compared to that of the JCVI. As noted above, trust is very important if parents are to bring their children to be vaccinated, and it may be that if the two organisations merge, vaccination policy will suffer from the damage already done to the NICE brand.

Several interview respondents believed handing vaccine policy to NICE might pose a threat to immunisation rates. An industry representative argued that "NICE doesn't appear to have the reputation with members of the public that NICE does." John Edmunds agreed, saying that "NICE hasn't had a particularly good press - it's kind of a whipping boy - and vaccines have been outside that. I don't think the public quite have the same level of confidence in NICE - I think it would be potentially dangerous. People are generally pretty confident in decision-making in the vaccine policy field."

Even when vaccine policy has been criticised, as in the case of MMR, there is a perception that it may have been more controversial if NICE had been in charge. Nigel Hawkes explained: "JCVI has a better public image than NICE. Vaccines are a very touchy area and you don't want to start alienating people. We've seen what a disaster MMR was, you have to tread very gently and I don't think NICE does treading gently. If MMR had been a NICE recommendation, it would have been even worse."

Overall, the three problems of the potential loss of expertise, the risk of less effective vaccine implementation, and the image problems associated with NICE suggest that a merger is likely to do more harm than good. An industry respondent summed up the views of many,

saying: "When you see companies merge, you don't often see a better company coming out the other end. Both organisations should assess where improvements can be made to their existing processes before contemplating a merger."

Recommendation:
The disadvantages of a merger between the JCVI and NICE outweigh the potential advantages. Given the importance of vaccination to the UK's health, the risk of weakening a highly effective programme is not merited.

Working together

While a merger appears a risky idea, there is no doubt that increased collaboration between the JCVI and NICE would be beneficial. At present, the two bodies occasionally work together, but collaboration is far from systematic. For the JCVI's analysis of the HPV vaccine, cost-effectiveness models were peer reviewed by NICE. When NICE produced guidance on tuberculosis and needed advice on the BCG vaccination, JCVI Chairman Andy Hall sat in on the consultation. And for NICE's current study of differences in immunisation uptake among young people (a review that many feel should have been the responsibility of the JCVI), two members of the JCVI are attached to the review committee.

However, as the Department of Health's David Salisbury admits, cooperation happens "as and when." Sometimes there is no collaboration even on issues where there is obvious overlap. NICE has developed clinical guidelines for diarrhoea in children, for example. Many cases of diarrhoea are caused by rotavirus, and the JCVI has recently assessed the case for a rotavirus vaccine. Although prevention may have impacts on the need for treatment and vice versa, however, there has been no systematic communication between the two bodies on this matter.

To ensure consistency in health policy-making, formal collaboration mechanisms between the JCVI and NICE (and also the National Screening Committee) are required. We noted in part two the need for the JCVI and NICE to work together to develop robust cost-effectiveness models and a consistent cost-effectiveness threshold, but there may also be benefits in terms of epidemiological analysis and in ensuring that work is not duplicated. A former JCVI member called for "improved lines of communication between NICE and the JCVI," while David Elliman of Great Ormond Street Hospital suggested that "there may need to be closer working as a lot of what they do overlaps. We need to make sure there are more formal routes of liaison rather than a takeover. Someone has to think if this decision has an impact on what the other body is doing." Such links could take the form of members sitting on each other's committees, or regular meetings to discuss how upcoming assessments may overlap or to monitor the consistency of decision-making.

If the two organisations are to work in the most effective manner, the relationship between them needs to be strengthened and made systematic.

Recommendation:
Formal channels should be established between the JCVI and NICE to ensure greater consistency in decision-making.

Conclusion

The Joint Committee on Vaccination and Immunisation is an effective and much admired vaccine policy maker. It makes high quality decisions whose implementation is well managed by the Department of Health and closely monitored by the JCVI, DOH and Health Protection Agency.

Although there are a number of areas for improvement in how the JCVI works, it is unlikely that a merger with NICE would help propel these improvements. Rather, a merger may put at risk the UK's well-run vaccination programme and jeopardise aspects of the nation's health. Instead of merging, the JCVI should learn from NICE and work to expand stakeholder involvement, formalise the horizon scanning process, bring forward and clarify the appraisal schedule, and become more open to public scrutiny. It should develop formal communication channels with NICE, and work with it to strengthen the cost-effectiveness analysis used by both bodies. At present, the two organisations work well and generally receive widespread acclaim; the potential downside of merging them is far steeper than the upside.

List of recommendations

Roles and responsibilities

Recommendation:
Consider increasing the proportion of lay members on the JCVI to one in five, in accordance with House of Commons Science and Technology Committee guidelines.

Recommendation:
Expand stakeholder involvement in committee meetings and sub-group meetings, by increasing the number of ex officio members or creating a new group of liaison representatives, or both. Organisations representing physicians, nurses, and key patient groups should be invited to become stakeholders and provided with clear guidelines on their roles and on what they can expect from the process. The benefits and risks of inviting the Association of the British Pharmaceutical Industry should also be assessed.

Recommendation:
The role of Department of Health staff in JCVI meetings and recommendations should be clarified and explained on the JCVI website.

The decision-making process

Recommendation:
The JCVI's horizon scanning process should be clarified and published on the website. Vaccine companies and other key stakeholder groups should be consulted on how best to develop the process, so that it provides information to stakeholders in a timely way and allows for input from those who may have useful information on emerging issues.

Recommendation:
During horizon scanning, strong consideration should be given to consulting formally with vaccine companies and other key stakeholder groups.

Recommendation:
The JCVI should aim to formalise early commencement of the appraisal process, so that assessment of each vaccine begins as soon as possible and the timing of appraisals is consistent. The committee should consult with manufacturers to identify when appraisals can begin.

Recommendation:
The JCVI should open meetings to the public, while reserving the right to hold discussions in private where absolutely necessary. Some public participation in meetings should be encouraged.

Recommendation:
The Department of Health should continue to be responsible for communicating with the media on vaccine policy.

Recommendation:
Clear timelines for decision-making should be produced in consultation with industry, along with templates outlining the information the committee requires. There is no strong case for allowing companies to present data to the committee face to face.

Recommendation:
The JCVI should fulfil its pledge to incorporate consideration of the cost-effectiveness of vaccines into its terms of reference.

Recommendation:
The JCVI should work with the DOH and NICE to explain to stakeholders the importance of cost-effectiveness analysis. In this way, it can pre-empt rather than react to criticism.

Conclusion

Recommendation:
The JCVI should strongly consider releasing working versions of its cost-effectiveness analysis models.

Recommendation:
The JCVI should work with NICE to consult the public on the cost-effectiveness threshold for health interventions. A publicly debated threshold should be clarified and used in all assessments by both bodies.

Recommendation:
The JCVI should take the social and economic impacts of vaccines into account when making its decisions. Only then will the full value of immunisation be reflected in the allocation of health care resources.

Should the JCVI and NICE merge?

Recommendation:
The disadvantages of a merger between the JCVI and NICE outweigh the potential advantages. Given the importance of vaccination to the UK's health, the risk of weakening a highly effective programme is not merited.

Recommendation:
Formal channels should be established between the JCVI and NICE to ensure greater consistency in decision-making.

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Interviewees

Simon Blake	*Chief Executive, Brook Advisory Centres*
Dr David Elliman	*Great Ormond Street Hospital*
Professor John Edmunds	*Health Protection Agency, London School of Hygiene and Tropical Medicine*
Professor Andrew Hall	*JCVI Chairman*
Nigel Hawkes	*Health Editor, The Times*
Dr George Kassianos	*Immunisation spokesman, Royal College of General Practitioners*
Professor Elizabeth Miller	*Head of the Communicable Disease Surveillance Centre's Immunisation Department, Health Protection Agency*
Professor John Oxford	*Professor of Virology at Barts and the London School of Medicine and Dentistry*
Richard Phillips	*Public Affairs & Reimbursement Manager UK & Ireland, Medtronic Ltd.*
Professor David Salisbury	*Director of Immunisation, Department of Health*
Richard Stubbins	*Managing Director, Sanofi-Pasteur MSD and Chairman of the UK Vaccine Industry Group*
Jacqui Thornton	*Freelance medical journalist and former health editor, The Sun*
Alexandra Wyke	*CEO, Patient View*
Anonymous	*University child health institute*
Anonymous	*Patient group*
Anonymous	*Research foundation*
Anonymous	*Royal College of General Practitioners*
Anonymous	*Vaccine manufacturer*
Anonymous	*Vaccine manufacturer*
Anonymous	*Vaccine manufacturer*

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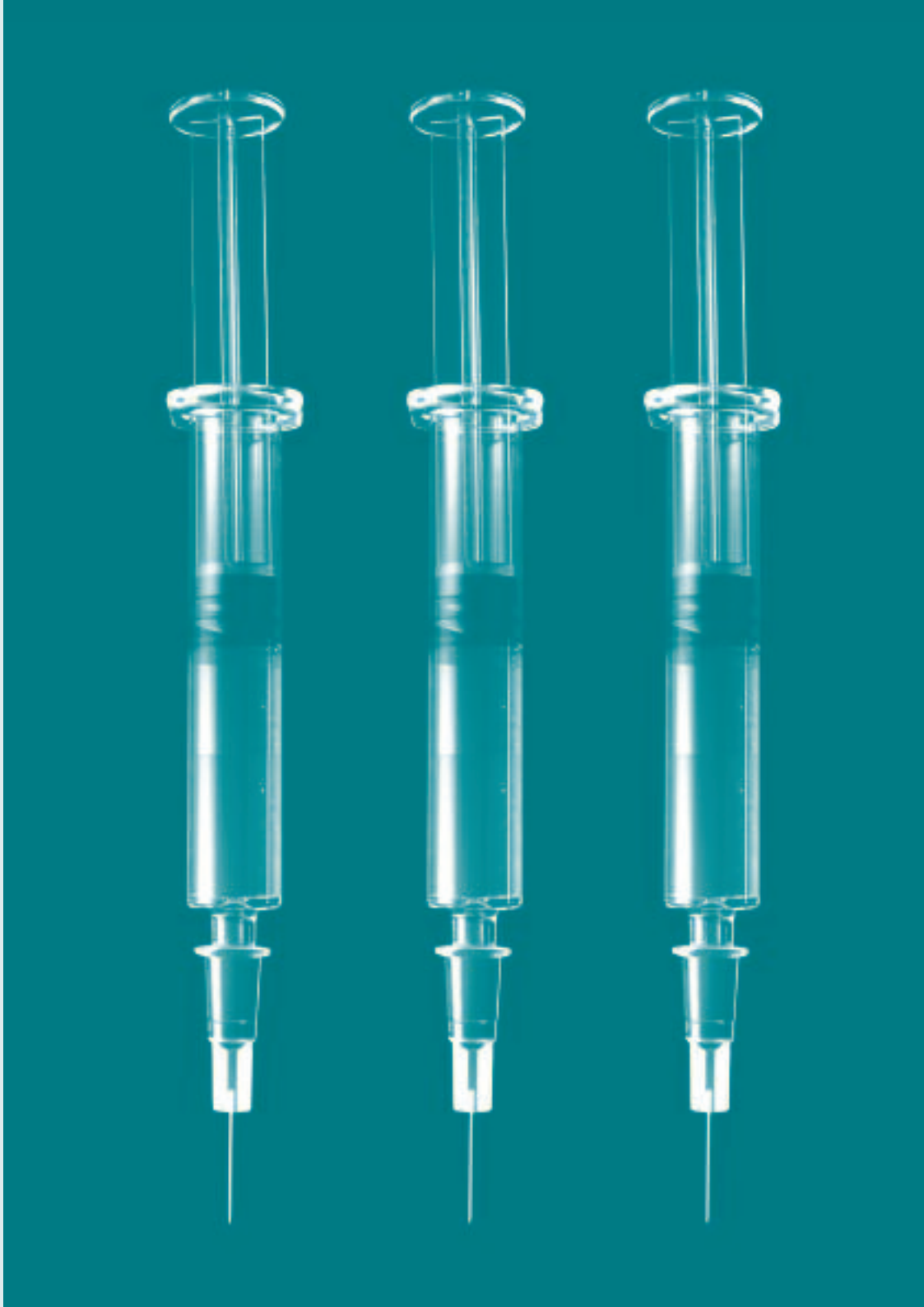

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About 2020health

2020health.org is a centre-right Think Tank for Health and Technology

Our vision

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We seek a level playing field between the public and private sector as they work to improve health outcomes.

We search for ways in which the workforce can take more responsibility in local healthcare.

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Not immune:
UK vaccination policy in a changing world

Mark Weston

A 2020health discussion paper
February 2009

The Joint Committee on Vaccination and Immunisation (JCVI) is the body responsible for decision-making on vaccines in the UK. In November 2008, the Conservative Party suggested that the JCVI to be merged with the National Institute for Health and Clinical Excellence (NICE), which issues guidance on therapeutic interventions and public health.

This discussion paper assesses the pros and cons of such a merger, examines the JCVI's performance, and makes recommendations for the future of vaccine policy-making in the UK. It is based on a review of the academic literature and the websites of the JCVI, NICE and their overseas equivalents, and on twenty in-depth interviews with senior stakeholders from the JCVI, Department of Health, professional health care bodies, patient groups, the vaccine industry and the media.

2020health exists to improve health. We aim to do this by promoting effective commissioning, competition and technology with more opportunities for responsibility in local healthcare and by analysing the impact on patients and culture.

2020health.org

2020health.org
PO Box 53659
London
SE5 5FL

T/F 020 7708 0683
E info@2020health.org

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