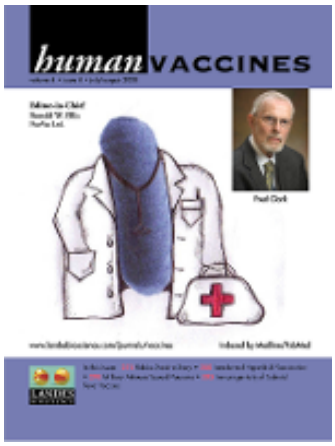

Human Vaccines
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/khvi19

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Published online: 01 Jul 2008.

To cite this article: Gary L. Freed (2008) The structure and function of immunization advisory committees in western Europe , Human Vaccines, 4:4, 292-297, DOI: 10.4161/hv.4.4.5801

To link to this article: http://dx.doi.org/10.4161/hv.4.4.5801

[Human Vaccines 4:4, 292-297; July/August 2008]; ©2008 Landes Bioscience

Research Paper

The structure and function of immunization advisory committees in Western Europe

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Abbreviations: CMO, chief medical officer; JCVI, joint committee on vaccines and immunizations; ACIP, advisory committee on immunization practices; US, united states; QALY, quality adjusted life year; STIKO, standing committee on vaccinations

Key words: vaccine, recommendations, international, government, policy

National immunization advisory committees are charged with making recommendations to either a governmental agency or the public regarding which vaccines that children and/or adults at specific ages, or with specific risk factors, should receive. However, there may be significant variability in a variety of aspects of such committees including the manner in which they are constituted, the process of their deliberations, and their authority. We explored the policies and roles of immunization advisory committees in each of ten of the largest nations in Western Europe and found significant variation among the nations. Conceptually, this variation was able to be categorized into six specific domains; committee membership, processes of meetings, basis for decision making, financial issues, authority and the role of manufacturers and insurers.

Introduction

Immunization advisory committees exist in most developed nations. Usually, they are charged with making recommendations to either a governmental agency or the public regarding which vaccines that children and/or adults at specific ages, or with specific risk factors, should receive. However, there may be significant variability in a variety of aspects of such committees including the manner in which they are constituted, the process of their deliberations, and their authority. Developing nations seeking to establish immunization advisory committees may find it useful to consider the range of possibilities that exist for their establishment. Further, developed nations may learn and improve their own systems of immunization recommendation development by examining components of the methods of other countries.

As part of a larger comprehensive study of immunization programs and policies across ten of the largest economies of Western Europe, we explored the policies and roles of immunization advisory committees in each of these nations.[1]

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Submitted: 01/22/08; Revised: 02/20/08; Accepted: 02/27/08

Previously published online as a *Human Vaccines* E-publication:
http://www.landesbioscience.com/journals/vaccines/article/5801

Results

There was significant variation regarding immunization advisory committees among the ten nations in a variety of areas. Conceptually, this variation was able to be categorized into six specific domains; committee membership, processes of meetings, basis for decision making, financial issues, authority and the role of manufacturers and insurers.

Committee membership. There is a wide range in the number of members among immunization advisory committees and whether the specific number is set by statute. For example, in England, the number of members of the committee varies according to the need for expertise but is usually around twelve. In contrast, the committee in Switzerland has 15 members who are each appointed to staggered four year terms.

Significant variability also exists in the manner in which voting members of the committees are chosen for membership. Usually decisions regarding membership are made using one of three criteria: expertise, political issues and demography. Many countries seek to include expertise from the areas of public health, infectious diseases, medical care (e.g., primary care), vaccinology and, increasingly, finance. Some countries also include a variety of politically-based appointments on these committees. For example, Austria includes a member of the Social Security Administration while other countries may include non-voting representatives from other government agencies such as those that approve pharmaceutical products as safe and effective for use. Uniquely, the advisory committee in Spain is comprised of representatives appointed from each of the 21 Autonomous Communities (states), usually physicians involved in health administration. Other considerations include some countries seeking explicitly to have a gender balance, regional representation or an individual to represent the public.

Of all of the nations included in this study, only Sweden did not have a standing external governmental advisory committee charged with making national recommendations. This country has a committee comprised of members of the National Board of Health (governmental employees from a government agency) to make recommendations.

Most countries require members to disclose potential conflicts of interest. However, this is not universal. Further, few countries

have written policies regarding the specific criteria defining required disclosure.

Process of meetings. Most nations in the study do not make the meetings of their advisory committees open to the public. For some, this was consistent with other governmental advisory committees and the nature in which the public historically had been excluded from such committee deliberation. Others expressed concerns regarding the potential for open meetings to be an opportunity for vaccine opponents to galvanize their efforts. Several believed they would have more difficulty in finding experts willing to serve on advisory committees if meetings were open while some felt that an open meeting would inhibit discussion, dissention and debate.

Although meetings may not be open to the public, most countries allow minutes of the meeting to be publicly released. However, four nations do not allow their public release and only ultimately publish approved recommendations. The most common reason given by officials in these countries is that the Ministry of Health would not want the public to be aware of decisions they might make counter to the recommendations of the advisory committee. For example, a committee may recommend a specific vaccine for use in a nation but the Ministry may not have the funds to implement the recommendation.

The advisory committees in some nations take votes to determine new recommendations while others only work through a process of consensus. Some report taking public votes only after they have privately worked through the process of consensus and ensuring that there will at least near unanimity on a particular recommendation.

Basis for decision making. Most of the committees state that the primary basis for all decision making is the public health of the nation. Attention is focused on the epidemiology of vaccine-preventable diseases and the potential for their prevention through available immunizations. However, the perception of the severity of specific diseases and the imperative for action to preserve the public health varies by nation. Further, as the underlying epidemiology of these diseases varies geographically, it is understandable that the immunizations recommended in each country would differ even if disease burden were the only criterion used.

Many nations in Europe also look to either neighboring countries or the United States to help guide the development of new immunization recommendations. Frequently, there are historic bases for these influences. For example, Ireland often takes into account the action of the Joint Committee on Vaccines and Immunizations (JCVI) from the UK in their work. Other nations, including Germany, have a rich history of expertise in the assessment of the need for new immunizations and are respected sources for other European nations. Although all of the study nations reported strong interest in the actions of the US Advisory Committee on Immunization Practices (ACIP), many felt that their own national priorities did not always coincide with those in the US and thus did not automatically adopt those recommendations in their own nations.

Political pressures also have an influence on the decision-making for immunization recommendations in many countries. For example, strong parent advocacy efforts in Spain resulted in political pressures to add specific vaccines to the immunization schedule in the face of a lack of clear epidemiological evidence or support (e.g., pneumococcal conjugate vaccine). Political pressure resulting from perceived safety concerns on the part of the public have had an influence on recommendations in some countries, including the way in which France modified recommendations regarding Hepatitis B vaccine.

Finally, of rapidly growing importance, is the role of financial considerations in the process of new immunization recommendation approval. Every nation in the study expressed that financial considerations were either a primary focus or an important factor (explicitly or implicitly) in their deliberations.

The role of financial considerations. For many nations, especially those in systems which have fixed budgeting for health care, formal or informal thresholds of cost-effectiveness are taken into account in the recommendation deliberation process. Some of the larger nations (e.g., England, France) conduct their own cost-effectiveness analyses while others choose to use studies from other countries in their own deliberations. These nations either choose not to undertake the expense of such studies or do not have the expertise within their Ministries to conduct such studies.

The nations included in this study used a variety of informal and formal thresholds in their decision-making regarding the addition of new vaccines to their immunization schedules. Informal assessments were conducted by the examination of existing economic literature from other nations surrounding a specific vaccine with rough attempts to adjust the findings to their own nation.

Most frequently, for those engaging more formal assessments, a heuristic of approximately $50,000 per quality adjusted life year (QALY) is the threshold for consideration of adding a new vaccine into a nation's immunization schedule. If a vaccine exceeds this threshold, many immunization advisory committees will not bring forward a recommendation for its use. The advisory committees in these nations either feel that the recommendation would have little or no chance of approval from the Ministry of Health or that any intervention with such a cost-benefit profile would not compete well with other potential interventions vying for addition to a national basket of services. Variation exists among nations, however, in whether both direct and indirect (e.g., parental time lost from work) benefits are taken into account in their calculations.

Other financial assessments used by some nations are cost-effectiveness studies relative to other interventions, and calculations of the cost of case or specific complication prevented by a proposed vaccine specific program. Finally, some nations may model the cost of implementation of new recommendations for different ages in the population, and the relative advantage of catch-up strategies for those outside of the age range of the new recommendation being considered.

In some countries, the companies that provide the statutory insurance coverage mandated through federal legislation have a role on immunization advisory committees. Most notably in Austria, a representative of the statutory insurance companies sits on the immunization advisory committee. This representative provides information to the committee regarding the potential increase in insurance premium cost to employers and workers for the addition of each specific vaccine to the schedule.

Financial considerations may also impact the prioritization and sequence of new vaccine recommendations. Many immunization advisory committees noted their desire to add several newly approved and available vaccines to their national immunization schedule. However, they felt that the financial implications of multiple concurrent new recommendations would not be acceptable to either

government officials or insurers. As such, they were faced with the task of prioritizing a step-wise process of additions to their national recommended schedules. The factors determining the prioritization varied between nations but included such factors as disease burden and severity, and the cost of each vaccine.

Uniquely, France has a separate committee (the Transparency Committee) that examines and grades the cost-effectiveness and cost-benefit of vaccines and other pharmaceuticals once the immunization advisory committee makes its recommendations. The grading from this committee determines the extent to which the vaccine will be subsidized by the federal government.

Authority and implementation. There is significant variation among the countries studied with regard to the locus of authority for immunization policy. Nations have governments that are structured overall either with greater centralized control or with more authority granted to state and local levels for health and social welfare policy. Preventive care in general, and immunization in particular, follows the overall national framework of governmental structure for each nation. Thus, countries may have a centralized system where a national committee has federal authority from either or both a public health and financial perspective. Other nations have a decentralized system where there is greater state-level or municipal control regarding the decision to implement any recommendations.

Usually the nature of authority is tied to the governmental level at which immunization financing takes place. For example, in Germany the STIKO (Standing Committee on Vaccinations) makes national immunization recommendations. However, the financing of the implementation of these recommendations is left to the states, not the federal government. As such, the STIKO lacks authority to implement any of its recommendations. Although the German states almost always follow the recommendations, as the cost of newly added vaccines rises, it is possible that some states may delay or not implement certain recommendations due to financial issues. Delay in the implementation of new recommendations has already occurred in some Western European nations based on variable adoption among the states and localities.

In contrast, recommendations adopted by the JCVI in England are national in scope as financing of their recommendations are carried out at the national level. The same pattern is true in France and Ireland.

Many nations also require multiple layers of recommendation approval before they become accepted by the federal or state public health authorities. For example, France has five separate committees through which a new recommendation much pass before it can be presented to the Minister of Health for final approval and adoption.

Other nations attempt to build consensus among their states before any national recommendation is released. Specifically, the committee in Spain seeks to build consensus among the representatives of all of their Autonomous Communities (i.e., states) before a vote on a new recommendation would be taken.

Some countries seek to develop informal consensus among committee members, either inside or outside of formal meetings, before the committee would be asked to make an official vote. Such actions are conducted to avoid public controversy regarding new recommendations with the belief that a unified and unanimous vote would both send a stronger message to the government with regard to funding priorities, and to the public with regard to the imperative for a new recommendation. For example, in Italy, a new recommendation would not appear on the agenda of the immunization advisory committee if approval was not expected. Nations may also seek input from the Ministry of Health to determine if a recommendation is likely to be implemented if approved by the advisory committee.

Role of manufacturers and insurers. There was significant concern expressed by study participants that the deliberations of their immunization advisory committee not appear to be influenced by vaccine manufacturers. Most of the nations participating in this study do not allow manufacturers to attend meetings of their committees. This is to prevent the appearance of bias or favoritism to a single product or company. Very few allow only highly structured participation by invitation only. Usually such presentations focus on specific questions the committee may have regarding the safety, efficacy or potential supply of a new vaccine under consideration by the committee. France invites manufacturers to present information on new products at one specific meeting per year.

Most of the countries rely on manufacturers to play a significant role in the dissemination of any new or modified recommendations. Rarely do countries invest significant resources in dissemination to either physicians or the public. The countries seem to accept the fact that the manufacturers have a proprietary interest in dissemination and thus rely on them for this function.

Countries with a statutory insurance program may invite a representative from the insurance industry to attend meetings or, in the case of Germany, to actually participate on the committee. These individuals are often called upon to provide an assessment of the cost of adding a new vaccine to the existing basket of services. Such information may be helpful to the committee to better understand the potential financial burden to the public for insurance payments if a specific new recommendation was approved.

The role of professional societies. In most countries, professional societies also have committees that issue immunization recommendations, frequently voting to endorse the same recommendations passed by the immunization advisory committee. Such support is important to add to the credibility of the recommendations in the eyes of the professional community. However, usually there is little formal coordination between the advisory committee and these organizations. An exception would be Austria where the three main physician professional societies regularly discuss any new recommendations and formally vote to support them.

Professional societies also play an important role in the dissemination of new recommendations. This can occur via presentations at official meetings of the societies or through the dissemination of brochures or other materials to members. Most commonly, these societies publish new recommendations in their professional journals.

Dissemination. National immunization advisory committees are not usually involved in the dissemination of the recommendations they develop. Dissemination strategies in most countries are not always timely and often are uncoordinated. Variation in dissemination exists between the nations in this study in several areas. The biggest differences lie in the level of government which makes the dissemination effort. Some countries attempt state-level strategies which are the responsibility of regional officials while others design national programs. This division parallels the level of government responsible for funding the recommendation.

Other efforts reported include publication in journals, letters from the Chief Medical Officer (CMO) to physicians and public

health officials, and informational meetings held in various venues around a country. Many countries now post new recommendations on a website. Some countries, such as France and England, publish public health guides which include immunization recommendations once every 1–2 years.

The Netherlands attempt to have six months of dissemination efforts before a recommendation becomes official. They also send out an annual letter from their CMO.

None of the countries conduct any type of evaluation of their dissemination efforts. As such, none of these countries have any information regarding the success of their efforts and whether they are more or less effective among different groups of health professionals or the public. They also do not have data regarding the impact of their dissemination efforts on the rate of adoption of new immunization recommendations.

Discussion

Although a perception exists that the health care systems of Western European nations are all quite similar, there are many different models of immunization advisory committees among the 10 countries in this study. These models are usually reflective of the broader style of organization of the entire health and social welfare system, with authority either vested more at the federal or the state level. There is also considerable variation in the composition of the committees across the nations.

Across all countries, the cost and financing of vaccines is playing an increasingly important role in the development and implementation of new recommendations. Although the exact nature by which financial concerns are being manifest is variable across the nations, all take the issue in account in some fashion.

A lack of emphasis on the dissemination of new recommendations was common across almost all countries. Unfortunately, this results in a lack of information regarding the timely adoption of new recommendations and the potential delay in the protective effect these new vaccines offer to the public.

Nations in other parts of the world considering the establishment of immunization advisory committees have many options in their structure and function. Examination of the efforts of other countries may help to provide models for their use. Ultimately, each nation will need to develop the recommendation system that fits with both their political and public health infrastructure. However, even within those constraints, many options exist within the six specific domains (committee membership, processes of meetings, basis for decision making, financial issues, authority and the role of manufacturers and insurers) described in this report.

Materials and Methods

The study was conducted July to December 2004. Initially, a web and printed literature review was conducted to provide background information on the health care system of each of the countries with the ten largest economies of Western Europe (England, France, Germany, Austria, Italy, Sweden, Switzerland, Netherlands, Spain and Ireland). An extensive bibliography of English language information sources was established and country profiles were prepared.

Selection of interviewees in each nation. The Director of the World Health Organization European office for immunization in Copenhagen sent letters to the Chief Medical Officer (CMO) in each of these nations requesting their assistance in finding appropriate persons to interview to gain greater insights into the vaccine policy and financing structure of each nation. A suggested roster of governmental agencies and non-governmental organizations (e.g., professional societies) was enclosed as well as a list of issues to be investigated in each country.

The CMO in each nation subsequently designated an official in their Ministry of Health to assist in both identifying individuals and arranging the interviews.

Data collection. Face to face interviews were conducted with several sources from government agencies involved in immunization policy and financing, professional societies and the practice community within each nation. Each interviewee was provided with structured interview questions prior to the meeting. In addition, each participant was given the option of having a translator present for their interview.

Handwritten notes were taken by the investigator during each interview. Within two weeks of each interview, a written summary of the interview was prepared. This was sent electronically to each individual interviewee for review, additions and/or corrections. Occasionally, follow up questions for clarification of specific interview items were sent via electronic mail. After receipt of any comments or corrections, final interview summaries were prepared and shared with the interviewee.

This project was approved by the Institutional Review Board for the Protection of Human Subjects at the University of Michigan.

Acknowledgements

Funded by a grant from the National Institute of Allergy and Infectious Diseases, Baltimore, Maryland, United States.

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Appendix

Topics for Interviews in European Nations

I. Statistics/Tracking/Data systems

(1) What are the current immunization rates by antigen? [Both for routine and high risk groups]

(a) How are they measured/calculated? Perceived accuracy?

(b) How often are they measured?

(c) How do the rates differ by segment (ethnicity, socio-economic status) of the population? What age range is considered pediatric?

(d) How do the rates differ by geographic area?

(2) What is the current incidence of vaccine preventable diseases in the country?

(a) Do these rates vary by region or high-risk group?

(b) How are these disease rates determined?

(3) Is there currently a functioning national or regional registry for childhood immunizations?

(a) If no:

(i) Has there ever been a national or regional immunization registry?

(ii) Are there plans for one in the future? If no, why not?

(b) If yes:
(i) When did it begin?
(ii) What functions does it perform?
(iii) Does it include batch numbers?
(iv) What ages of children are included?
(v) Is it electronic or another format?
(vi) What portions of the country are involved?
(vii) What portion of the population is enrolled?
(viii) Can health professionals access the information? How?
(ix) Is there a recall and reminder component?
(x) Is it linked to other health or social welfare/social welfare databases?
(xi) How is the registry funded?
(xii) What are areas of needed improvement?

(4) Electronic medical record
(a) Is there a national electronic medical record?
(b) If so, are immunizations included?
(c) How are immunization records accessed?

II. Financing/Pricing/Insurance

(1) Financing
(a) What proportion of vaccines is purchased in the public vs. private sector?
(b) For the private sector, what proportion of vaccines is paid for via private insurance vs. out of pocket (reimbursed or not)? Does it differ by vaccine? Why?
(c) What are the sources for public funding for immunization (e.g., federal, state, local)? What is the proportion of funding by each?
(d) What is the national, state or local budget for immunization purchase?
(e) How is the budget for vaccines determined? What about new recommendations?
(f) Is the funding of immunization infrastructure different from that of vaccines themselves? What is funded as a part of infrastructure (e.g., clinics, reminder recall)?
(g) How are decisions made regarding the financing of new vaccines?
(h) How are decisions made regarding the financing of vaccines for special population groups (e.g., children at risk for influenza)?

(2) Private insurance
(a) Are any vaccines covered by private insurance? If so, which ones? To what degree? Why?
(b) Is there variation in insurance plans with regard to immunization coverage?
(c) What is the process by which immunizations become covered?
(d) Are there deductibles and co-payments associated with immunization provision? Are they bundled with well child care?

(3) Pricing
(a) Who or what agency sets immunization pricing in the public and/or private sectors?
(b) How do prices differ in the public vs. private sector?
(c) How are government contracts negotiated? Does the lowest bid always win?
(d) How often are prices negotiated?
(e) Is there any plan that returns excess profits to the government?

(4) Incentives
(a) Are there provider incentives for immunizations?
(b) Are there patient incentives for immunizations?

III. Provision/Supply/Inventory management

(1) Supply/inventory management
(a) What is the distribution system for vaccines in the public and private sectors?
(b) What processes are in place to ensure continuity of the cold chain?
(c) Have there been vaccine shortages in the recent (last 5 years) past?
(i) Public and/or private sector?
(ii) What short-term actions were taken?
(iii) What longer-term actions were taken?

IV. Administrative Processes/Regulations

(1) Venue of administration
(a) Where are vaccines given?
(b) Do children receive some vaccines in public and some in private venues?
(c) Are some vaccines only available in public or private venues?

(2) School and day care policies
(a) Are there school entry requirements regarding immunization? How often are these requirements assessed? At which ages?
(b) Same questions for public and private Day Care settings.
(c) Are there grace periods for deviations from specific required intervals between immunization doses or recommended ages of administration?
(d) Are exemptions granted? If so, by what criteria?

(3)Consent
(a) What is the process for informed consent for immunizations?
(b) Does it differ by antigen?

(4) Interactions with border countries regarding immunization

(5) Process of communication with private sector physicians

V. Safety and Monitoring

(1) Safety
(a) What have been the recent (last 2 years) vaccine safety concerns that have reached national importance?
(b) Have immunization rates decreased secondary to any general or specific safety concerns?
(c) What agencies are involved in assessing vaccine safety? Which takes the lead?
(d) What strategy does each agency/professional organization use to address safety concerns?
(e) Is there a national tracking system(s) for vaccine safety concerns?
(f) How is adverse event data captured? Passive or active monitoring? Separate from adverse drug events?
(g) Who responds to adverse event reporting?

(h) What is the liability exposure for physicians and manufacturers regarding allegations of harm done by vaccines?
(i) Is there a compensation scheme for those claiming injury from vaccines? How does it work?

(2) Anti-vaccination groups
(a) How active are anti-vaccination groups in the country?
(b) Are they localized to a specific region?
(c) Do they focus on specific vaccines or preservatives?
(d) What efforts (public and private) are undertaken to address their message and/or concerns?

VI. Licensure

(1) What is the process for licensing of new vaccines?
(a) Can a vaccine be sold or marketed without being licensed for use (can a professional prescribe unlicensed vaccines for a specific patient)?
(b) What is the process for accepting vaccines under parallel import status? Are there specific issues before a product can be sold in the domestic market (e.g., repackaging)
(c) Do licenses have to be renewed? If so, at what interval?

VII. Recommmendations

(1) What is the current government recommended immunization schedule? Are there other recommended schedules in the country?
(2) Approval and dissemination of new recommendations
(a) What is the process for new vaccine recommendation? Which agencies and/or organizations make vaccine recommendations? Who appraises the evidence and to whom are they accountable? What were the most recently approved/recommended vaccines?
(b) What are the criteria for membership on expert advisory panels?
(c) What vaccine recommendations are on the horizon?
(d) Do cost-effectiveness analyses play any role in the decision to recommend a vaccine?
(e) Does membership in the EU play any role in this process?
(f) How are new recommendations disseminated to health care providers (physicians, nurses and public health officials) and parents?

VIII. Special Groups

(1) Adolescents
(a) Are there special immunization programs for adolescents?
(b) Where do adolescents routinely receive immunizations?
(c) Have there been recent changes in the immunization schedule for adolescents?

(2) Disparities and high risk groups
(a) Are there disparities in immunization rates among
-Immigrants/travelers?
-Social classes
-Racial or ethnic groups
(b) Are there special or targeted immunization programs for such children?

(3) Viral influenza
(a) What types of viral influenza immunizations are available? Recommended?
(b) Are there specific supply issues related to viral influenza immunization?
(c) Have you applied lessons from child immunization programs to adult or high-risk viral influenza immunization?