



The role of economic information in decision-making by the Advisory Committee on Immunization Practices

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ABSTRACT

With cost of vaccines steadily increasing, recommendations of the Advisory Committee on Immunization Practices (ACIP) have growing economic implications for the public. We used semi-structured telephone interviews to assess the knowledge, attitudes, and practices of the 15 voting members of the 2006–2007 ACIP regarding the use of economic information by the committee in their deliberations about new vaccine recommendations. These interviews demonstrated the importance of economic information in ACIP deliberations, but also revealed that many members felt economic information should not be outweighed by the more important issues of vaccine efficacy, disease burden, and safety. In addition, though members had variable levels of expertise in analyzing economic data, there was a general concern that assumptions inherent in the development of cost-effectiveness models made interpretation of the data resulting from these models difficult. To counteract this concern, several ACIP members suggested standardizing the process of how economic data are presented to the committee so that a more uniform consideration of consequential information might be undertaken by the ACIP in their deliberations.

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1. Introduction

Over the last several years the United States child and adolescent immunization schedule has become increasingly complex and costly [1]. In 2001, vaccines protecting against 12 antigens were recommended for routine use in children <18 years of age [2] at a per-child cost in the public sector of ~\$400 (using federal contract prices expressed in 2001 dollars) [1]. Compare this to the 2008 schedule, with vaccines against 14 antigens recommended by the age of 6, and an additional 2–3 recommended vaccine series for young adults [3] (differences due to gender-specific recommendations for human papillomavirus vaccine). Consistent with this increased number of vaccines, the public-sector cost of immunizing today's children has risen dramatically to \$950 for males and \$1250 for females [4]. Though immunizing children is generally considered a cost-effective health intervention [5], the increased total cost of vaccines has placed a substantial financial burden on individuals, private insurers, and public vaccine financing programs [6–8].

National policies regarding vaccine administration and utilization are determined by the Advisory Committee on Immunization Practices (ACIP) which serves to advise the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases in the civilian population [9]. The ACIP is a federal advisory committee comprised of 15 voting members with expertise in the fields of infectious diseases, immunization practices and public health, vaccine research, or community aspects of immunization programs [9]. The ACIP also includes 8 non-voting ex-officio members from different government agencies with an interest in vaccine-preventable diseases (e.g., Department of Veterans Affairs), and several non-voting liaison representatives from 25 medical organizations (e.g., American Academy of Pediatrics). These non-voting members provide additional opinions and information during the deliberation process.

One of the main tasks of the ACIP is to develop recommendations on population groups and/or circumstances where vaccines should be given. Vaccines that are recommended by the ACIP for routine use in children under the age of 18 years typically become incorporated into the vaccines for children (VFC) program through a separate ACIP voting process. VFC is a federal entitlement program that serves as a vital financing mechanism to provide government-purchased vaccine for more than 70 million eligible children and

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adolescents through 18 years of age. It is estimated that as much as 55% of all childhood vaccine doses are purchased through this program [6,7,10].

Because the actions of the ACIP are integrally tied to public vaccine financing programs, and because many health plan coverage patterns are aligned with ACIP recommendations [11], actions of the ACIP can have far-reaching economic influences in both the public and private sectors. Unlike many other westernized countries, the ACIP charter is unique in that it explicitly allows for cost-effectiveness information (though not vaccine price) to be considered when the committee deliberates about new vaccine recommendations [12,13]. However, the extent to which ACIP members understand and/or incorporate economic information into their discussions and decisions about new vaccine recommendations is unknown.

The goal of this study was to describe the knowledge, attitudes, and current and preferred practices of the 15 voting members of the 2006 ACIP regarding the use of economic information in their deliberations about new vaccine recommendations. Specifically, we sought to understand how ACIP members incorporate available economic data in their decision-making as individuals and as a committee, and preferences for presentation of economic data. We intended that study findings would illuminate possible opportunities to enhance the ACIP decision-making process about new vaccine recommendations.

2. Methods

The project team developed a semi-structured interview guide that was administered to each of the 15 voting members of the ACIP between September 2006 and January 2007. During this time, the ACIP committee was comprised of 13 physicians, 1 pediatric nurse practitioner with expertise in infectious diseases and 1 lay consumer representative. Physicians were generalists (7 pediatricians and 6 internal medicine physicians), some of who had subspecialty training in infectious diseases ($n=6$) or currently worked in the public health arena ($n=4$). All members participated. Interviews were administered by telephone after verbal informed consent was obtained. Audiotapes of these interviews were transcribed verbatim to ensure accuracy. The Institutional Review Board at the University of Michigan approved all study activities.

Each interview was comprised of case scenarios and open-ended questions. Scenarios were developed initially based on study team consensus, and further refined to incorporate feedback of pilot testing among vaccination experts who were not current members of the ACIP. The case scenarios described a hypothetical vaccine, “ChildVax”, that the ACIP was asked to consider recommending. ChildVax was described as having a favorable safety profile and efficacy, but also as the “most expensive broadly recommended childhood vaccine series to date” (in comparison to the HPV vaccine which was the most expensive recommended vaccine at the time of the study at a list price of \$120/dose) [4]. Information about disease severity and disease burden potentially prevented by ChildVax was not provided. Respondents were then presented in a stepwise manner with increasingly detailed economic information about the vaccine (price and cost-effectiveness) and asked to describe how this information affected their individual-level deliberations. This stepwise progression of information allowed differentiation between issues of efficacy and safety of a vaccine versus issues of price and cost-effectiveness. Open-ended questions queried respondents about how they used economic information in their deliberations about new vaccine recommendations, how the ACIP as a group should use this information, and preferences for how this information should be presented. Although both the case scenarios and interview questions were identical for each study

subject, because responses were open-ended, some of the issues summarized in this report were addressed by only a subset of participants.

Three authors (AC, AFD, MMD) independently reviewed the interview transcripts and generated a set of central emerging themes, as well as the perspectives of respondents that supported those themes. Themes were stimulated, in part, by the topic areas the authors presented to respondents in the interviews, but also included several issues that respondents raised on their own initiative beyond the anticipated topics. Coding discrepancies were resolved on a case by case basis and the final analysis was based on themes coded with consensus among the three reviewers. Major themes in response to the case scenarios are presented; for each theme, we characterize the ways in which members of the ACIP responded similarly or differently. Themes of responses to open-ended questions that queried participants about their views outside of case scenarios are also described.

3. Results

3.1. Responses to case scenarios

3.1.1. Influence of price and cost-effectiveness data on individual perspectives

When queried about how the price of the ChildVax vaccine series (without cost-effectiveness information) would affect their deliberations about the vaccine, members uniformly indicated that vaccine price alone would not be influential. Instead, all members indicated that additional information would need to be considered in conjunction with price, including disease burden and disease severity.

In contrast, all members indicated that cost-effectiveness data would influence their thinking about ChildVax. Cost-effectiveness data were felt to provide a sense of the “relative value” of the vaccine (i.e. the combination of reductions in morbidity/mortality and health care utilization compared to cost of vaccine) compared to other vaccines, and two members noted that this type of data provided a context for comparison with other data that the committee typically considers when deliberating about new vaccine recommendations (e.g., disease burden). As a caveat, two members indicated that the extent to which cost-effectiveness data would influence their thinking depended on the burden of the disease in question. Additionally, another member had concerns that, in general, cost-effectiveness data do not fully capture the more broadly defined “value” of a vaccine.

Most members ($n=8$) did not have a specific target cost-effectiveness threshold value for new vaccines. One member noted that \$50,000 per quality adjusted life year (QALY) is often cited as a threshold value below which the cost-effectiveness of the vaccine would be more acceptable, and another noted a range of \$50,000–150,000 as an acceptable threshold. Other members ($n=2$) indicated that disease burden and severity would need to be considered when deciding on an acceptable threshold value for vaccine cost-effectiveness.

Members were then asked about their willingness to recommend ChildVax without any economic data (price or cost-effectiveness data). While a few members ($n=3$) indicated that this lack of information would not affect their willingness to recommend the vaccine, many ($n=7$) indicated that it would, with some ($n=3$) noting that they have come to expect cost-effectiveness data to be available for all newly licensed vaccines. In fact, one member indicated that the only way the ACIP should not be presented with cost-effectiveness data was if the vaccine under consideration was so inexpensive that the question of cost-effectiveness was no longer relevant.

3.2. Use of economic information by the ACIP more broadly

3.2.1. How should economic information ideally be used by the ACIP?

The majority of ACIP members ($n=10$) indicated that economic information should be an important, but not dominant, factor considered during the committee's deliberations about new vaccine recommendations. These members agreed that disease burden, vaccine safety and vaccine efficacy should be given greater weight than economic information. Individual views about the degree to which economic data should be used by the ACIP varied widely among the other members. For example, one member felt the ACIP should make recommendations irrespective of the economic impact of those recommendations, while two others recognized a need to be cognizant of cost but that this information would not necessarily influence their recommendation. Two others were ambivalent, being torn between making strictly "science-based recommendations" and including economic information as a factor in their decision.

3.2.2. How does ACIP currently use economic information in deliberations about vaccine recommendations?

There was not a uniform perception of the manner in which ACIP currently uses economic information in their deliberations. A general theme that emerged from this line of discussion was that the importance the ACIP currently gives to economic information may vary depending on the disease/vaccine in question. In general, as disease severity increased, issues of cost and cost-effectiveness were thought to become less influential. For example, the quadrivalent meningococcal conjugate vaccine (MCV4) was cited by several members ($n=4$) as a "special case" where the less favorable cost-effectiveness ratio for the vaccine was acceptable due to the severe nature of the disease. All members indicated that their perspectives on the influence of cost and cost-effectiveness data did not differ based on whether the vaccine under consideration was for children/adolescents or adults.

3.2.3. How familiar are members of the ACIP with the use of economic data?

Only four members indicated that they had prior experience with economic analyses before becoming an ACIP member. There were mixed opinions about whether providing training for members in economic analyses would be beneficial. On one hand, several ($n=5$) members suggested that training would not be a valuable use of the committee's time and that a better strategy would be to take their cues from the opinions of "experts" who were better able to assess whether an economic analysis had been well done. However, others ($n=4$) felt that some level of training would be useful, and suggested a variety of venues to achieve this, including written information, didactic educational sessions, or even a list of "minimal acceptable factors" for a well-done cost-effectiveness study.

3.2.4. What type of economic information does the ACIP want?

When queried about their preferred format for cost-effectiveness data, several members ($n=6$) were satisfied with presentation of QALYs alone. However, six members expressed a preference for a variety of measures to be presented (e.g., dollars per QALY, dollars per illness episode prevented) so that a full picture of the economic impact of new vaccine recommendations could be provided. Specific problems associated with QALYs were cited by the members and included difficulty in explaining QALYs to policy makers and the "arbitrary nature" of some of the data used to derive the QALYs.

The source and validity of data used in presentations of economic information to the ACIP was an explicit concern for the majority ($n=10$) of members of the group. There was discomfort with the wide range of the confidence intervals sometimes produced by economic analyses. Some ($n=4$) felt this uncertainty hindered the ability of the group to identify the appropriate course of action about a given vaccine. Furthermore, several ($n=5$) members expressed frustration with the variety and apparent "randomness" of some of the assumptions upon which economic models are based, and the difficulty in understanding which of these assumptions were valid. There was also concern about the perception that models could be manipulated to bias the economic picture toward a more favorable cost-effectiveness profile—this was a particular concern for models generated or sponsored by vaccine manufacturers.

3.2.5. Additional suggestions from the committee

A major theme in the interviews was concern by members of ACIP about the validity and "believability" of data derived from cost-effectiveness models. Several suggestions were offered about processes that might counter this problem. One was to perform more than one analysis for any given vaccine so that different groups, which would likely undertake the analysis with different assumptions and/or approaches, could provide a more robust view of the economics of the vaccine in question. Another was to have an independent group, unrelated to the CDC or industry, review cost-effectiveness models outside of ACIP deliberations in order to provide another opinion about the quality of the analyses performed and potential implications for vaccine policy. This idea is similar to that used for the National Health Service in the United Kingdom, which some commentators (not associated with the ACIP) have suggested should also be adopted for the US health care system more broadly [14].

Many members ($n=7$) explicitly expressed support for standardizing the process of performing and presenting economic information to ACIP. Making the presentation format for cost-effectiveness ratios consistent across studies was suggested by two members as a mechanism to minimize confusion, and to allow easier comparison between multiple cost-effectiveness studies for the same vaccine, or between one vaccine and another. One member suggested generating a "set of standards" that should be presented for each vaccine, enabling members to compare the vaccine in question to a "norm," and thus discern the relative value of that vaccine to other vaccines or other preventive interventions. Members unanimously indicated that they wanted analyses to be presented clearly and simply, with terms and assumptions specified, and conclusions summarized. However, this need for simplification was tempered by recognition that analyses presented too concisely could lack sufficient information to adequately understand the assumptions driving the model.

3.2.6. Vaccine recommendations versus vaccine financing

Although we did not ask specific questions about vaccine financing, more than half of the members ($n=8$) found it difficult not to consider the cost of vaccines and the impact on public spending when making recommendations. For example, one member noted that because ACIP recommendations were tied to inclusion of vaccines in the VFC program, it was difficult for this member to see how the ACIP could divorce itself completely from vaccine financing issues when considering new vaccine recommendations.

4. Discussion

This study illustrates that members of the Advisory Committee on Immunization Practices are variably comfortable in their

understanding of the methodologic details of cost-effectiveness analysis, yet are acutely aware of the need to incorporate some form of economic information into their vaccine deliberations. Responses to case scenarios demonstrated that cost-effectiveness, but not price, was an influential factor in the deliberation process. All members agreed that economic information needed to be considered in the context of disease burden and severity and vaccine safety.

There was a strong sense that the ACIP would benefit from standardizing the presentation and consideration of economic information. Standardization of information could address several important issues raised by the committee members in our study. First, if the base-case assumptions in economic model inputs were transparent, ACIP members could better understand the potential impacts of a vaccine on medical, public health, and economic outcomes. Standardization of information could also reduce the potential for bias in cost-effectiveness analyses, especially since these types of analyses rely heavily on data from the vaccine's manufacturer. In addition, standardization might allow the ACIP members to examine economic analyses earlier in the decision pipeline, thus enabling them to be better informed about conclusions from, and limitations to, the economic data at hand. Finally, standardization could facilitate comparison of information from one vaccine relative to another or between vaccines and other preventive interventions.

New guidelines have recently been developed by the CDC to standardize the way economic information is presented to the ACIP [15]. These guidelines include anonymous peer review before presentation of a report that details the economic study under consideration, and provide criteria for how economic information should be presented during ACIP meetings. These guidelines officially go into effect at the June 2008 ACIP meeting and are described in detail on the CDC/ACIP website (<http://www.cdc.gov/vaccines/recs/acip/economic-studies.htm>) [15]. This new process of standardization may counteract some of the discomfort described by the participants in our study related to the “uncertainty of assumptions” used in economic evaluations. However, our results also suggest that a “guided interpretation” of the results of these standardized analyses may also be of use given that several of the study participants voiced unfamiliarity with interpretation of economic data.

The maximum tenure as a voting member on the ACIP is 4 years, thus a limitation of our study is that the issues and views captured by our analysis could change over time as new members become appointed. However, several key opinions about the relative importance of and need for economic information was expressed by all members of the committee, appointed at different times. These opinions are therefore more likely to represent issues that are inherent to the ACIP deliberation process, rather than member-specific issues.

In summary, our study identified several key issues brought forth by the members of the ACIP regarding the incorporation of

economic information in the deliberation process for new vaccines. There was a general belief that economic information is a meaningful factor to be considered, but that this information should be regarded in the context of disease- and vaccine-specific characteristics. Furthermore, because it is difficult to determine the validity of assumptions underlying economic models, cost-effectiveness data are interpreted cautiously. Standardization in the way that economic information is gathered, presented and considered was suggested as a mechanism to improve the ACIP deliberation process. The newly developed standardization process, which was approved by the ACIP in June 2007 and will be implemented beginning with the June 2008 ACIP meeting, may provide an opportunity to evaluate how this process impacts ACIP deliberations [15].

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