

# Chapter 15

## The Role of Public Health Ethics in Vaccine Decision Making: Insights from the Centers for Disease Control and Prevention

Leonard Ortmann and John Iskander

### Introduction

The ethics of vaccination involves a broad range of issues, in part because vaccination overlaps the fields of public health with its focus on populations and clinical medicine with its focus on individuals. This overlap means, for example, that individual vaccine decisions, through their impact on herd immunity, become votes on community solidarity [1]. This obligation to protect community health often places public health at odds with the high value democratic societies place on individual autonomy. Thus, policies which have implications for individual autonomy generate lively debate, such as vaccine mandates, exemptions, or allocations [2, 3]. Research ethics issues involving clinical trials have drawn attention as well, in particular those involving children in developing countries [4, 5]. But vaccination raises a host of ethical issues, primarily because from the beginning safety concerns about vaccines have generated controversy. The resultant ethical tensions have grown as the scope of vaccination has grown. This chapter touches on these issues but focuses on the growing yet underappreciated role ethics plays in the decision making that sets vaccine policies. Getting buy-in for policies typically requires incorporating stakeholder concerns into policy decisions. In crafting vaccine policy, the overarching ethical challenge is to balance the competing values of diverse stakeholders: public health scientists and practitioners, care providers and

---

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

L. Ortmann, Ph.D. (✉)

Office of Scientific Integrity, Centers for Disease Control and Prevention,  
1600 Clifton Rd. NE, Mailstop D-74, Atlanta, GA 30333, USA  
e-mail: [hsq3@cdc.gov](mailto:hsq3@cdc.gov)

J. Iskander, M.D., M.P.H.

Office of the Associate Director for Science, Centers for Disease Control and Prevention,  
1600 Clifton Rd. NE, Mailstop D-50, Atlanta, GA 30333, USA

organizations, and the public. To get buy-in from a public with safety concerns increasingly requires transparency on the part of policy makers. The magnitude of the problem that lack of transparency causes is difficult to gauge. It is clear, however, that controversy strains, while transparency fosters, the trust that programs involving public cooperation require. The ethical challenge of transparency is the unifying theme of this chapter, linking safety concerns to building a social consensus on vaccine policy. In particular, the chapter considers how, in the light of two recent proposals to increase transparency in the process of evaluating evidence, the Advisory Committee on Immunization Practices (ACIP) employs expert judgment informed by stakeholder values to translate evidence into vaccine policy [6–8]. In addressing these topics, we adopt a public health ethics perspective.

Public health ethics prioritizes protecting the public from harm, preventing diseases at the population level, and promoting the health of the entire community. This population or community orientation distinguishes public health ethics from the individual orientation of clinical ethics [9]. The field of public health ethics has established a set of ethical principles and values that apply specifically to public health practice rather than research [10, 11]. These specific principles and values differ from the four well-known principles of beneficence, non-maleficence, autonomy, and justice central to bioethics, clinical ethics, and research ethics. A fair statement of these public health ethics principles can be found in the Public Health Leadership Society's 2002 Principles of the Ethical Practice of Public Health [12]. A lynchpin of these principles is the recognition of the interdependence of people, which creates obligations toward others and sets limits on individual liberty. So, while public health needs to respect individual values and social norms in formulating evidence-based vaccine policy, the public needs to appreciate the trade-offs between individual rights and public obligations involved in crafting that policy. Only in this way can individual vaccine decisions be properly informed and a social consensus on vaccines reached.

The Lancet's 2010 retraction of Andrew Wakefield's 1998 article linking vaccines and autism may signal the end of a specific episode in the history of vaccination, yet attitudes antithetical to vaccination persist [13]. The status quo to which we have returned displays increasing levels of both vaccine refusal and disease outbreaks linked to them [14]. Some current attitudes mirror the long history of vaccine hesitancy, distrust of vaccine safety assurances, and divergence between scientific risk management and the public's approach to risks. Other attitudes represent perceptions linked to social trends that work counter to vaccine acceptance. First, science and government policy based on scientific evidence increasingly are being challenged [15, 16]. Second, there is concern that the pharmaceutical industry unduly influences government policy and the agenda of government-sponsored scientific research [17]. Third, a series of notorious abuses of vulnerable human research subjects has sowed a general mistrust of biomedical research and government health programs [18]. An undercurrent of this mistrust of research remains, that diffuses over to vaccination, despite all the efforts of bioethicists to address these abuses [19]. A central outcome of their efforts in individual health care, heightened respect for individual autonomy, resonates with a fourth social trend, libertarianism [20]. Libertarian opposition to collective decisions that limit

individual autonomy has been viewed as antithetical to the very idea of public health intervention [21, 22]. To the extent that vaccination programs are promoted, let alone mandated, by government, or perceived as experimental or unduly influenced by industry, vaccine hesitancy can be reinforced. Given these trends and the vaccine status quo, vaccine promotion faces a daunting communications and community engagement challenge.

Additionally, the loss of confidence in vaccines in some communities may reflect inherent features of the life cycle of a vaccine program [23–25]. Initially, high disease burden creates public support for implementing a vaccine program. Over time, if herd immunity is achieved, the number of vaccine adverse events can approximate the number of cases of the targeted vaccine-preventable disease. As memory of the disease fades, the public becomes more acutely aware of adverse events. In this mature phase, support wanes for the vaccine program, and vaccine refusal in the context of herd immunity, so-called free riding, becomes more attractive from an individual risk perspective. The current vaccine challenge for national immunization programs of industrial nations may reflect this “paradox of success,” compounded by social attitudes and exacerbated by incidents like the Wakefield controversy.

Even if periodic losses of confidence are inevitable, building a social consensus on vaccination could reduce their incidence and duration. Moreover, such a consensus might also be the best long-term solution to addressing persistent social attitudes at odds with vaccine policy. Because building such a consensus requires educating and engaging the public, a return to an earlier era where scientific expertise in isolation set vaccine policy would be out of place. Fortunately, the approach to setting vaccine policy has progressed to an outlook that is both more flexible and more comprehensive. Better communication and greater transparency are complementing enhancements to vaccinology and vaccine safety. Focusing on the ethical values and assumptions that inform policy decisions, this chapter makes the case for greater transparency and a more comprehensive vaccine policy as steps toward achieving a social consensus on vaccine policy.

## **A Glance at Science and Risk Communication**

Effectively implementing vaccine policies requires public cooperation, making communication critical for their success. Developments in risk communication, while not our focus, are important for building a social consensus on vaccine policy. To make informed decisions and give consent to policies, communities need information from public health officials. Accuracy of information is critical, but to insure the effectiveness of communication, public health also needs to build and maintain public trust. Gaining this trust often requires engaging with the community in ways that take community values into account. Such flexible approaches are both requirements for better communication and professional obligations of public health [12].

Besides taking community values and beliefs into account, a more flexible approach would appreciate the role emotion and values play in the acceptance of messages.

Such thinking aligns with both classical rhetoric and modern research. Aristotle favored rational, scientific discourse, but acknowledged that appealing to emotions and values more effectively persuades the public [26]. Messages that appeal to community values or ones delivered by respected community leaders can help practitioners reach individuals for whom alignment with beliefs and values is paramount to receiving a message. A growing body of literature suggests that outreach and education efforts can be improved if promoted through religious and faith-based venues [27]. The World Health Organization's Global Polio Eradication Initiative, for example, recognizes the importance of directly involving religious leaders in Pakistan and Nigeria in order to secure community engagement [28]. Similar lessons apply at the clinical level. Vaccine information from a trusted provider improves confidence in the immunization process. Such trust, however, develops best from a long-standing relationship where not only communication content but also communication styles play key roles. The lesson is that providers need to provide information adapted to the way parents want to receive it [29].

Communicating risk effectively becomes all the more important in the mature phase of an immunization program when herd immunity has been achieved for a number of diseases, because providers cannot depend on the presence of disease to motivate parents. Many of the outbreaks occurring today are the result of failures of communication and confidence. Regarding risk perception, modern psychological research has shown that people solve complex problems by relying on heuristics [30]. These evolutionarily evolved rules of thumb generally help us assess complex situations, but sometimes create problematic cognitive biases. For example, people perceive familiar risks like childhood measles as less dangerous than unfamiliar risks like an adverse vaccine reaction. Strategies informed by heuristics may be better received than messages that scientifically compare disease risk to risk of adverse reactions and use academic jargon [31]. As one expert on vaccine controversies puts it, "scientific evidence, no matter how clear it seems to be to the people who produce it and vouch for it, does not have magical power to change minds" [32]. Public health needs to find compelling ways of complementing the scientific message, which is a legitimate approach as long as it neither falsifies facts nor diverts attention away from critical issues [26]. Outbreaks, unfortunately, are the most compelling persuaders, but a more flexible approach can help ensure that they are not the result of communication failures.

## **Two Proposals for a Just and Transparent Vaccine Policy**

The two proposals alluded to earlier call for crafting vaccine policies in a manner that transparently incorporates ethical values. Achieving the proposed degree of transparency would entail a broader notion of communication to work in tandem with policy decision making regarding immunizations.

Poland and Marcuse (PM) propose a "holistic policy-making paradigm" based on "the essential tenets of 'just' immunization policy" [7]. These tenets include familiar principles of public health practice such as reasonable, timely policies

based on disease morbidity/mortality and vaccine risks/benefits. To evaluate benefits and distribute them equitably, they call for both individual and public perspectives as well as for shared governance between individuals and government. Key elements of their just policy include transparency regarding the evidence base used in decisions, a standardized framework for decision making that involves a spectrum of subject matter expertise, and broad dissemination of policy decisions. These tenets are operationalized by means of a just policy template composed of ethical and evidential elements, including evidence of cost–benefit analyses. The template distills the information, the data set, and the explicit assumptions and values on which the policy discussion rested. Because the template indicates how trade-offs between different elements were made in designing and implementing policy, it can serve later to explain policy decisions or to educate and engage the public.

The PM paradigm is holistic in three key aspects. First, the template formalizes procedures and yields a comprehensive policy record or master document. Second, it incorporates ethics into evidence-based decision making (EBDM). Third, its notion of social dissemination goes beyond transparently communicating information and sharing policy decisions. It also involves creating and sustaining a social consensus regarding just policy. Arguably, their ambitious proposal is proportioned to the dimensions of the current vaccine challenge.

Partly in response to PM, Field and Caplan (FC) offer an approach for resolving “clashes” between the demands of just policy and EBDM applied to vaccination [8]. These clashes begin with efforts to quantify ethical values, for example, in estimating quality-adjusted life years (QALYs). Although setting a monetary value on life strikes some as inherently problematic, FC acknowledge the usefulness of such quantifications for comparative purposes. But because ranges for such values vary widely depending on different stakeholder assumptions, these assumptions need to be made explicit. Second, because EBDM is geared to assessing long-term population outcomes, it may obscure immediate impacts on vulnerable populations and individual values. Third, because achieving herd immunity means many vaccine recommendations apply to everyone, clashes with social norms are likely. Clashes with individual values and social norms, we might add, typify a kind of ethical tension that public health routinely faces. To the extent that EBDM favors population perspectives and the population-wide interventions associated with them, policy makers and practitioners should expect ethical tensions to arise.

To anticipate such tensions and harmonize EBDM with just policy consideration, FC broaden the range of ethical values to be taken into account and extend the ways in which various elements are quantified for comparative purposes. Their version of a just policy template operationalizes a wider range of ethical considerations: notably, impact on vulnerable populations, individual values, and social norms. They also anticipate a need to compare not only different vaccine options for a disease but also vaccine options with other prevention options and even with treatment options. For each option, template elements would be quantified with respect to not only effectiveness, safety, and cost but also ethical considerations. FC harmonize EBDM with just policy, then, by extending the notion of trade-offs between evidentiary and economic elements to include a wider range of ethical values and intervention options.

## Public Health Ethics and Vaccine Policymaking at CDC

Examining the current vaccine challenge has provided a context for considering proposals about the role ethics should play in crafting vaccine policy. Here, in order to situate the role ethics plays in ACIP deliberations at the Centers for Disease Control and Prevention (CDC) and the resources the agency has for its deliberations, we examine the broader context of public health ethics at CDC [33]. A core CDC value is integrity, especially as it relates to basing policy on the best available scientific evidence [34]. The creation of CDC ethics committees reflected recognition that scientific evidence can be unavailable or fall short of what is necessary to make timely decisions [35]. Their creation equally reflected a desire to show that proposed science-based policies not only were government mandates but also took moral considerations into account. Finally, their creation reflected appreciation of both the need and the obligation to achieve greater transparency in order to build and maintain public trust.

### CDC's Ethics Committees

Controlling infectious diseases has long been a cornerstone of CDC's public health activities. It is therefore appropriate that a national influenza vaccination campaign provided an impetus for a formal structure of public health ethics at CDC. In October, 2004, in response to an influenza vaccine shortage, CDC established a panel of outside ethicists. The creation of the panel was widely reported on in the news. The shortage had raised issues of fairness and prioritization of target groups. In CDC's public statements explaining the creation of the 2004 ethics panel, the issue of equity figured prominently [36]. In 2004, outside ethics consultation was not new at CDC. But the public notice of a standing ethics panel did signal a response to public skepticism regarding the decision-making process behind the rationing plan. With input from this panel and other ethical perspectives, the ACIP and the National Vaccine Advisory Committee (NVAC) jointly attempted the first effort at seasonal flu vaccine prioritization in 2005.

Also in 2005, CDC conducted three public engagement and stakeholder meetings in different US cities on pandemic vaccination [37]. A premise of those meetings was that formulating vaccine policies that entail consideration of values as well as science requires an understanding of the public's values. Going into the meetings, greater susceptibility to disease had led experts to prioritize the vaccine for persons over 65 years old. All three meeting groups prioritized protection for target groups as follows: critical care providers and people working to fight the pandemic, providers of community essential services, vulnerable populations, and children. A surprise was that persons over 65 years old—a quarter of meeting participants—placed a higher value on protecting children than on persons in the over-65 age group, even though it was explained that older persons are more vulnerable to severe disease and death. This unanticipated result regarding the values of the

over-65 age group underscored the importance of giving communities and the public a hearing, especially when no single best scientific answer is available. More recently, in efforts related to vaccine safety research, the Immunization Safety Office at CDC has sought broad public input that included public engagement meetings in three US cities to identify public concerns and priorities related to vaccine safety research [38]. In both the earlier and later public engagement efforts, a crucial assumption was that to build and maintain trust with the public, government must be responsive to citizens' needs, concerns, and input.

Three members of the ACIP ethics panel became members of an ethics work group convened at CDC in February 2005. By June 2005, the work group had become a subcommittee of the Advisory Committee to the Director of CDC. The Ethics Subcommittee (ES) is composed of academic and professional ethicists from outside CDC who serve up to 4 years [39]. The ES's initial charge was broader than the ethics panel: to counsel CDC on a wide range of public health ethics issues and to support CDC efforts to develop internal capacity to address ethical issues. The ES has produced ethical guidance documents on pandemic influenza response, stockpiling antivirals for pandemic influenza, ventilator usage during an influenza pandemic, and general emergency preparedness and response [40].

Early on, the ES recommended that CDC create a standing internal Public Health Ethics Committee (PHEC). PHEC's mission is to provide leadership in public health ethics and to work with CDC staff to integrate the tools of ethical analysis into day-to-day decisions and activities across CDC. PHEC consists of representatives from CDC's national centers and other organizational components within CDC, whose activities are coordinated by a Public Health Ethics Unit within the Office of the Associate Director for Science. PHEC offers public health ethics training and an ethics consult service, often in conjunction with CDC subject matter experts and current or former ES members. PHEC members also staff an ethics desk during activation of CDC's Emergency Operations Center (EOC). During its activation for the H1N1 pandemic, PHEC members provided input into deliberations about vaccine implementation strategies. An ACIP workgroup requested an ethics consult from PHEC to obtain input on ethical issues that new data raised that indicated use of the combined measles, mumps, rubella, and varicella (MMRV) vaccine increased the risk of febrile seizures compared to use of the separate MMR and varicella vaccines [41]. The consult group weighed both population and individual risks and benefits in using the combined and separate vaccines. Then-available evidence revealed no advantage for either vaccine either in regard to program implementation or in regard to efficacy, effectiveness, immunogenicity, or burden of disease prevented with the first dose. However, in children aged 12–23 months, use of the combined vaccine doubled the risk for fever and febrile seizures during the 5–12 days after the first dose compared to the separate vaccines. Although the prognosis for young children who have had febrile seizures is generally excellent, these frightening medical events can negatively affect family members and caregivers, often resulting in a visit to the emergency department. Conversely, the combined vaccine requires one less injection than the separate MMR vaccines, protects against MMRV with one injection, and may result in some children getting varicella protection at an

earlier age. The eventual ACIP recommendation acknowledged these safety concerns but placed them in ethical equilibrium with the value of individual choice, thus leaving the final decision in the hands of providers and parents.

## The ACIP

The ACIP, which has existed since 1964, has been described in detail elsewhere [42, 43]. The focus here is on transparency, a core public health value, and the relation of ethical values to evidentiary considerations, including evidence regarding cost-benefit analyses. The ACIP is a Federal Advisory Committee that complies with statutes of the Federal Advisory Committee Act (FACA) designed to ensure openness. Establishment of the ACIP grew out of recognition of the need for an expert group outside the Federal Government to develop objective national immunization policy recommendations. The 15 voting members include a consumer representative, along with experts across vaccine-relevant fields. Meetings are announced in the Federal Register and open to the public. The extensive advance preparations that policy recommendations require are the charge of ACIP Working Groups (WGs). WGs do not deliberate or vote on specific policy recommendations. They focus on fact finding and data review, which they organize for presentation in public ACIP meetings. Public comments are solicited at these open meetings and taken into account in decision making. Meeting minutes are available to the public on the ACIP Web site and final recommendations are published in the Morbidity and Mortality Weekly Report (MMWR).

Both evidentiary and ethical considerations have played a role in ACIP deliberations, though recommendations rely primarily on the evidence base concerning the disease burden, vaccine effectiveness, and vaccine safety. Health economic analyses are increasingly being factored into ACIP decision making, but no threshold value has been set for cost-effectiveness of a vaccine as this could discount other determinations of value [42, 44]. Health economic standards have been adopted by the ACIP which make value assumptions explicit [45]. Making the assumptions explicit at least can mitigate the problem that FC note in the quantifications of health economic measures, such as QALYs, namely, that the value assumptions underlying quantifications can vary widely depending on the stakeholder. Although these standards call for making the societal perspective the default, if specific population subgroups exhibit markedly higher or lower baseline risks, separate recommendations can be made for these subgroups. This option indirectly addresses equity issues by making room for considering the needs of special or vulnerable populations. Public uptake of recommendations has also been a topic of discussion relevant to ethics and social norms and attitudes. For a pressing ethical issue such as vaccine allocation, input can be provided through public engagement, an outside ethics panel, or a PHEC consult.

The ACIP has weighed ethical issues and values in relation to other evidentiary and economic factors as occasion demanded but has not developed a standardized ethics checklist. Nor did it have standardized procedures for rating the quality of the



evidence base. That changed in October 2010, when the ACIP unanimously adopted a new framework based on an internationally used EBDM model, the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach [44]. To date, GRADE reports have been published on HPV vaccine for males, hepatitis B vaccine for adults with diabetes, and two pneumococcal vaccines (PCV13 and PPSV23) for adults with immunocompromising conditions [46–48]. The intent behind the new ACIP framework is to achieve greater consistency while allowing for continuous improvement. Although meeting the demands of a just policy as proposed by PM and FC is not the intent, the goal of consistency results in standardizations that support transparency, while the flexibility implied by continuous improvement leaves open the possibility of incorporating just policy elements.

## **The Ethical Dimension of the ACIP's New Framework**

In discussing the new framework, features that pertain to ethical issues will be highlighted. The entire approach of the framework is to maximize net health benefits for populations and is thus utilitarian in outlook. Besides rating the strength of the evidence base, other factors explicitly recognized in developing recommendations include the balance of harms and benefits, values and preferences, and economic costs. The range of factors and values involved in crafting policy recommendations require that methodological elements be stated explicitly and with sufficient transparency to merit the confidence of stakeholders. That requirement extends to values and pointedly includes values of individual stakeholders such as parents and clinicians. In establishing that requirement, the ACIP Evidence Based Recommendation Work Group (EBRWG) explicitly refers to the MMRV Report for which PHEC conducted an ethics consult [44]. Along with the provisions for specific population subgroups, this last requirement can mitigate concerns that EBDM's long-range population emphasis overlooks individual values and effects on vulnerable populations.

Within ACIP's adoption of the GRADE framework, values are defined as the relative importance of outcomes related to benefits, harms, and costs. But it is acknowledged that judgments involved in weighing the strength of evidence and prioritizing values cannot guarantee reproducible results [44]. This is an implicit acknowledgement that evidence informs action and defines parameters for it, but ethics and values determine how we use evidence. Because ethical values are most subject to different weightings by individuals or stakeholder groups, being transparent and explicit about ethical values is all the more important. Judgments depend on those who make the evaluation and reflect their value perspectives. To resolve disagreements—or simply understand them—judgments and the assumptions behind them as well as the decision-making process need to be made transparent. Because values can offset each other, some combination of high economic costs and ethical controversy theoretically could offset effectiveness and safety values sufficiently to lower a vaccine's recommendation level. In public discourse, major ethical value conflicts often preclude reaching consensus on substantive ethical issues. When

substantive agreement is unattainable, parties must rest content with a fair and open deliberative, democratic process. In ACIP vaccine deliberations, sufficiently high variability or uncertainty in values or preferences provides a basis for lowering a vaccine's recommendation level.

GRADE operationalizes procedures for determining the recommendation of a vaccine based on four key factors: net balance of benefits and harms, quality of evidence, values and preferences, and health economic analyses. It applies specific criteria to its evidence base in order to rate it. Evidence can be downgraded because of risk of bias, inconsistency, indirectness, imprecision, and publication bias. The evidence base is categorized into four types that represent a general hierarchy reflecting the confidence in the estimated effect of vaccinations on health outcomes. The procedure methodically condenses a wealth of complex information into clear, direct rating terms that are transparent to those who will make the recommendation. The end result is a summary comparison in tabular form of the relevant factors: a statement of whether benefits outweigh harms, a rating of the quality of evidence, a description of any values that figured prominently in the recommendation, and a statement of general cost-effectiveness qualified if necessary for subgroups. GRADE reports are posted online, while detailed information about GRADE is available on CDC's Web site [49]. In the GRADE reports published in *MMWR*, disease prevention, a key public health value, has been listed as an important value in determining the recommendation [50, 51]. GRADE goes a long way toward achieving transparency regarding the ACIP's process of vaccine recommendations.

## Discussion

The ACIP's use of GRADE should be viewed along the trajectory of vaccine policy deliberations that have been advancing from the world of expert opinion toward greater transparency and use of EBDM in a forum open to the public [7]. Along with health economic factors, ethical values, too, are being explicitly incorporated into vaccine decision making. Given the degree of vaccine hesitancy, some, like PM and FC, have called for a more robust incorporation of ethical considerations. Social norms and individual values do need to be taken into consideration in crafting vaccine policy, but a public health ethics perspective also needs to inform that policy. Interdependence creates shared obligations that force us to consider how far individual liberty should extend, when the public's health is at risk or when disease can be prevented. Public health ethics is better situated to articulate the trade-offs between individual values and shared obligations. Transparency helps to inform, but consent in the public health arena will also depend on building trust and creating a social consensus through proper communication and engagement.

GRADE's more transparent incorporation of values into deliberations represents a development in the spirit of a just policy document. As a possible next step, quantifying elements on a template or a checklist of ethical values and social norms would not pose a major hurdle. To develop such a checklist, CDC could draw on

ethics expertise from its standing ethics committees. CDC also has considerable experience working with tools such as a modified Delphi process that allow a decision-making body to quantify values important in choosing amongst alternatives [52]. Determining what should be on such a checklist, who should create it, and who should do the ratings pose additional but not insurmountable challenges. Nor would it pose insuperable difficulties to use GRADE to compare a vaccine to other vaccines or intervention options, along the lines that FC propose.

A more crucial consideration is whether a just policy template's added value would justify its development and implementation costs. ACIP procedures and the new framework already go a long way toward realizing the objectives behind a template. Meetings are open, minutes published, comments of the public considered, and ethics panels, consults, or public engagement utilized as occasion demands. The new ACIP framework improves transparency, acknowledges the importance of individual values, and considers a recommendation's effect on specific populations to ensure equity. GRADE explicitly includes values important to decision makers and affords an appreciation of the trade-offs between the various factors underlying recommendations.

Given the crucial role of values, the ethical sensibilities of the ACIP's voting members will play a critical role in their judgments. These judgments can be informed by values and preference estimates from population-based studies, public comments, media reports about vaccine issues, and ethics resources available at CDC. GRADE's current procedure explicitly incorporates value considerations into decision making and could be expanded to routinely factor in a spectrum of ethical values and social norms. Whether that becomes necessary will depend on a host of factors internal and external to vaccine policy deliberations. These factors include improvements in vaccine safety, GRADE's impact, trends in measured vaccine refusal and hesitancy, outbreaks of vaccine-preventable diseases, and strength of the social consensus on vaccine policy.

The interplay between some of these external factors and the overall process of vaccine policymaking constitutes an implicit dialogue between vaccine policy makers and the public that needs to become explicit [6]. The notion of consumer choice resonates with the public, but having safer choices regarding vaccines provides too narrow a basis for moving the public dialogue about national immunization policy forward. Consumer demand for safer vaccines has a psychological dimension that technical improvements do not fully address. The psychological dimension of vaccine controversy can also index the degree to which public health has to engage the public to earn trust, build consensus, and work toward shared governance regarding vaccine policies. Regarding shared governance, emerging threats of new pandemics or bioterrorism also underscore the need for society to think in a proactive, coordinated way about national immunization policy [53]. Herd immunity against vaccine-preventable childhood diseases not only is a public good but also a national asset [54]. As such, herd immunity can be framed as an issue of community resilience for public health preparedness and response (PHPR). A resilient community not only bounces back from disturbances but also withstands them without losing integrity or continuity of function [55]. If community resilience entails herd immunity and

PHPR requires community engagement, then the public must become a partner in implementing immunization programs [56, 57]. A public dialogue built around a notion of shared health governance that puts equal weight on choice and civic responsibility to protect oneself and others may provide a bridge between individual and communal values [58].

## Conclusion

The current challenges of vaccine hesitancy may not represent a deepening trend so much as a phase in the cycle of a mature vaccine program. That does not imply that the periods during which segments of the public lose confidence in a vaccine cannot be shortened or decreased. Just as a fracture becomes the occasion for the body to make a bone stronger than before, so does a vaccine-preventable disease outbreak provide an occasion to strengthen prevention. In this regard, the ACIP has significantly raised awareness of the importance of childhood immunization and has redoubled efforts to raise it for adults. These “unofficial” efforts of ACIP might seem at odds with the charge of objectively weighing evidence, but they do indicate recognition of the need to proactively create a climate of vaccine acceptance. Clear, consistent scientific messaging must form the basis on which to raise awareness, but raising awareness is not tantamount to gaining acceptance. The prevention strategy best suited to countering any vaccine refusal inherent in the mature phase of the vaccine cycle may well lie in building a durable social consensus on vaccination. But doing so will require a comprehensive effort that involves not only evidence and economics but also ethics and engagement. Engagement embraces a more flexible communication approach that creatively harnesses the power of emotion and appeals to community values. The tools of public health ethics can help to articulate the rationale behind such a comprehensive effort that creates a social consensus. Framing vaccination as a shared obligation of public health and the public can help ensure the effectiveness of vaccine programs whose success ultimately depends on public acceptance.

**Acknowledgments** We acknowledge Robert T. Chen of the CDC National Center for HIV/AIDS, Viral Hepatitis, STD and Tuberculosis Prevention and Walter Orenstein of the Emory University School of Medicine for their perspectives and expertise; Christy Cechman of the CDC Public Health Library and Information Center and Lindsay Kramer of the CDC Public Health Ethics Unit for bibliographic support; and Jane Gidudu of the CDC Office of Scientific Quality and Captain Drue Barrett of the CDC Public Health Ethics Unit for reviews of an earlier draft of this chapter.

## References

1. Dawson A. Herd protection as a public good: vaccination and our obligations to others. In: Dawson A, Verweij M, editors. *Ethics, prevention and public health*. Oxford: Oxford University Press; 2007.
2. Schwartz JL, Caplan AL. Ethics of vaccination programs. *Curr Opin Virol*. 2011;1(4):263–7.

3. The January 2012 issue of *Virtual Mentor*, a monthly ethics journal of the American Medical Association, comprises 11 articles on the topic of "Vaccines and Ethics." <http://virtualmentor.ama-assn.org/2012/01/toc-1201.html>. Accessed 15 Nov 2012.
4. Ethical consideration in HIV preventive vaccine research. UNAIDS guidance document. [http://www.who.int/vaccine\\_research/diseases/hiv/en/JC072-EthicalCons-E.pdf](http://www.who.int/vaccine_research/diseases/hiv/en/JC072-EthicalCons-E.pdf). Accessed 13 Sep 2012.
5. Ethical considerations arising from vaccine trials conducted in paediatric populations with high disease burden in developing countries. WHO/IVR ethics meeting, 26–28 November, 2002, Accra, Ghana. [http://www.who.int/vaccine\\_research/documents/en/manu774\\_.pdf](http://www.who.int/vaccine_research/documents/en/manu774_.pdf). Accessed 13 Sep 2012.
6. Schwartz J. The first rotavirus vaccine and the politics of acceptable risk. *Milbank Q.* 2012;90(2):275–310.
7. Poland GA, Marcuse EK. Developing vaccine policy: attributes of just policy and a proposed template to guide decision and policy making. *Vaccine.* 2011;29(44):7577–8.
8. Field RI, Caplan AL. Evidence based decision making for vaccines: the need for an ethical foundation. *Vaccine.* 2012;30(6):1009–13.
9. Lee LM. Public health ethics theory: review and path to convergence. *J Law Med Ethics.* 2012;40(1):85–98.
10. Childress JF, Faden RR, Gaare RD, Gostin LO, Kahn J, Bonnie RJ, et al. Public health ethics: mapping the terrain. *J Law Med Ethics.* 2002;30(2):170–8.
11. Callahan D, Jennings B. Ethics and public health: forging a strong relationship. *Am J Public Health.* 2002;92(2):169–76.
12. Public Health Leadership Society. Principles of the ethical practice of public health. <http://www.apha.org/NR/rdonlyres/1CED3CEA-287E-4185-9CBD-BD405FC60856/0/ethicsbrochure.pdf>. (2002). Accessed 13 Sep 2012.
13. The Editors of *The Lancet*. Retraction—Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet.* 2010;375(9713):445, ISSN 0140-6736, [10.1016/S0140-6736\(10\)60175-4](http://www.sciencedirect.com/science/article/pii/S0140673610601754). <http://www.sciencedirect.com/science/article/pii/S0140673610601754>. Accessed 13 Sep 2012.
14. Omer SB, Enger KS, Moulton LH, Halsey NA, Stokley S, Salmon DA. Geographic clustering of nonmedical exemptions to school immunization requirements and associations with geographic clustering of pertussis. *Am J Epidemiol.* 2008;168(12):1389–96.
15. Michaels D. *Doubt is their product: how industry's assault on science threatens your health.* Oxford: Oxford University Press; 2008.
16. Rosenau J. Science denial: a guide for scientists. *Trends Microbiol.* 2012;20(12):567–9.
17. Washington H. *Deadly monopolies: the shocking corporate takeover of life itself—and the consequences for your health and our medical future.* New York: Random House, Inc.; 2011.
18. Washington H. *Medical apartheid: the dark history of medical experimentation on black Americans from colonial times to the present.* New York: Doubleday; 2006.
19. Quinn S, Thomas T, Kumar S. The anthrax vaccine and research: reactions from postal workers and public health professionals. *Biosecur Bioterror.* 2008;6(4):321–33.
20. Bayer R, Fairchild AL. The genesis of public health ethics. *Bioethics.* 2004;18(6):473–92.
21. Jennings B. Public health and liberty: beyond the Millian paradigm. *Public Health Ethics.* 2009;2(2):123–34.
22. Powers M, Faden R, Saghai Y. Liberty, Mill and the framework of public health ethics. *Public Health Ethics.* 2012;5(1):6–15.
23. Chen RT, DeStefano F, Pless R, Mootrey G, Kramarz P, Hibbs B. Challenges and controversies in immunization safety. *Infect Dis Clin North Am.* 2001;15(1):21–39.
24. Chen RT. Evaluation of vaccine safety after the events of 11 September 2001: role of cohort and case-control studies. *Vaccine.* 2004;22:2047–53.
25. Iskander J, Vellozzi C, Gidudu J, Chen RT. Vaccine safety. In: Morrow J, Sheikh N, Schmidt C, Davies H, editors. *Vaccinology: principles and practice.* 1st ed. Oxford: Blackwell Publishing Ltd; 2012.
26. Aristotle. *The art of rhetoric.* In: Lawson-Tancred H, editor. London: Penguin; 1991.

27. Underwood SM, Powell RL. Religion and spirituality: influence on health/risk behavior and cancer screening behavior of African Americans. *ABNF J.* 2006;17(1):20–31.
28. World Health Organization. Global Polio Eradication Initiative: strategic plan 2010–2012. Geneva: World Health Organization; 2010. <http://www.polioeradication.org/content/publications/gpei.strategicplan.2010-2012.eng.may.2010.pdf>. Accessed 28 Jun 2012.
29. Gust D, Kennedy A, Shui I, Smith P, Nowak G, Pickering L. Parent attitudes toward immunizations and healthcare providers: the role of information. *Am J Prev Med.* 2005;29(2):105–12.
30. Gigerenzer G. *Gut feelings: the intelligence of the unconscious.* New York: Viking Penguin; 2007.
31. MacDonald NE, Smith J, Appleton M. Risk perception, risk management and safety assessment: what can governments do to increase public confidence in their vaccine system? *Biologicals.* 2012;40(5):384–8.
32. Kirkland A. Creditability battles in the autism litigation. *Soc Stud Sci.* 2012;42:237–61.
33. Barrett DH, Bernier R, Sowell A. Strengthening public health ethics at the Centers for Disease Control and Prevention. *J Public Health Manag Pract.* 2008;14(4):348–53.
34. A statement of CDC's mission and core values is available at <http://www.cdc.gov/about/organization/mission.htm>. Accessed 7 Jul 2012.
35. Briss PA, Gostin LO, Gottfried RN, Snider Jr DE. Science and public health policy makers. *J Law Med Ethics.* 2005;33(4 suppl):89–93.
36. Harris G. U.S. creates ethics panel on priority for flu shots. *New York Times.* October 28; 2004.
37. Public Engagement Pilot Project on Pandemic Influenza. Citizen voices on pandemic flu choices. (2005). <http://www.hhs.gov/nvpo/PEPPPI/PEPPPICompleteFinalReport.pdf>. Accessed 15 May 2012.
38. Centers for Disease Control and Prevention's Immunization Safety Office Scientific Agenda. Immunization Safety Office, Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases. (2011). [http://www.cdc.gov/vaccinesafety/00\\_pdf/ISO-Final-Scientific\\_Agenda-Nov-10.pdf](http://www.cdc.gov/vaccinesafety/00_pdf/ISO-Final-Scientific_Agenda-Nov-10.pdf). Accessed 30 Jul 2012.
39. Information on the Ethics Subcommittee of the Advisory Committee to the Director. <http://www.cdc.gov/od/science/integrity/phethics/EthicsSubcommittee/index.htm>. Accessed 15 Nov 2012.
40. Documents available at <http://www.cdc.gov/od/science/integrity/phethics/ESdocuments.htm>. Accessed 7 Jul 2012. Discussion of travel restrictions document available at [http://www.cdc.gov/maso/FACM/pdfs/ACDCDC/2009022526\\_ACDCDC\\_ES.pdf](http://www.cdc.gov/maso/FACM/pdfs/ACDCDC/2009022526_ACDCDC_ES.pdf). Accessed 7 Jul 2012.
41. Marin M, Broder KR, Temte JL, Snider DE, Seward JF. Use of combination measles, mumps, rubella, and varicella vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2010;59(RR-3):1–12.
42. Smith JC. The structure, role and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). *Vaccine.* 2010;285:A68–75.
43. Smith JC, Snider DE, Pickering LK. Immunization policy development in the United States: the role of the Advisory Committee on Immunization Practices. *Ann Intern Med.* 2009;150:45–9.
44. Ahmed F, Temte JL, Campos-Outcalt D, Schünemann HJ. ACIP Evidence Based Recommendation Work Group (EBRWG). Methods for developing evidence-based recommendations by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention. *Vaccine.* 2011;29(49):9171–6.
45. *ACIP Guidance for Health Economics Studies.* <http://www.cdc.gov/vaccines/recs/acip/downloads/economics-studies-guidance.pdf>. Accessed 8 Jul 2012.
46. Grading of recommendations, assessment, development and evaluation (GRADE) for HPV vaccine for males. *MMWR Morb Mortal Wkly Rep.* 2011;60(50):1705–8. <http://www.cdc.gov/vaccines/acip/recs/GRADE/hpv-vac-males.html>. Accessed 15 Nov 2012.
47. CDC recommendation for Hepatitis B vaccination among adults with diabetes: grading of scientific evidence in support of key recommendations. *MMWR Morb Mortal Wkly Rep.* 2011;60(50):1709–11. <http://www.cdc.gov/vaccines/acip/recs/GRADE/hepB-vac-adults-diabetes.html>. Accessed 15 Nov 2012.

48. Grading of recommendations, assessment, development, and evaluation (GRADE) for pneumococcal vaccines for immunocompromised adults. *MMWR Morb Mortal Wkly Rep.* 2012;61(40):816–9. <http://www.cdc.gov/vaccines/acip/recs/GRADE/pneumo-immuno-adults.html>. Accessed 18 Nov 2012.
49. Additional GRADE information is available at <http://www.cdc.gov/vaccines/acip/recs/GRADE/about-grade.html>. Accessed 15 Nov 2012.
50. CDC. Recommendations on the use of quadrivalent Human Papillomavirus Vaccine in males—Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 2011;60:1705–8.
51. CDC. Recommendation for Hepatitis B vaccination among adults with diabetes: grading of scientific evidence in support of key recommendations. *MMWR Morb Mortal Wkly Rep.* 2011;60(50):1709–11.
52. Fitch K, Bernstein SJ, Aguilar MS, et al. The RAND/UCLA Appropriateness Method User’s Manual, chapters 6–8. Available at [http://www.rand.org/pubs/monograph\\_reports/MR1269.html](http://www.rand.org/pubs/monograph_reports/MR1269.html). Accessed 13 Sep 2012.
53. Caplan AL, Schwartz JL. Ethics. In: Plotkin SA, Orenstein WA, Offit PA, editors. *Vaccines: expert consult*. 5th ed. Philadelphia, PA: Saunders; 2008. p. 1677–83.
54. Buttenheim A, Jones M, Baras Y. Exposure of California kindergartners to students with personal belief exemptions from mandated school entry vaccinations. *Am J Public Health.* 2012;102(8):e59–67.
55. Adger WN. Social and ecological resilience: are they related? *Prog Hum Geogr.* 2000;24:347–64.
56. Jennings B. Community in public health ethics. In: Ashcroft RE, Dawson A, Draper H, McMillan J, editors. *Principles of health care ethics*. West Sussex: John Wiley and Sons; 2007.
57. Jennings B. Public health and civic republicanism. In: Dawson A, Verweij M, editors. *Ethics, prevention, and public health*. Oxford: Oxford University Press; 2007.
58. Ruger J. *Health and social justice*. Oxford: Oxford University Press; 2010.