



HHS Public Access

Author manuscript

J Public Health Manag Pract. Author manuscript; available in PMC 2022 January 01.

Published in final edited form as:

J Public Health Manag Pract. 2021 ; 27(4): E177–E182. doi:10.1097/PHH.0000000000001031.

Mitigating Ethical Risks in Public-Private Partnerships in Public Health

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Abstract

Context: Partnerships between the public and private sectors are necessary in public health and health care. Each partner provides skills, resources, and capabilities. When the public sector, including government, enters into a partnership with a nongovernmental or corporate entity, it is important to determine in advance whether there are real or perceived ethical, financial, or programmatic risks to the organization that might need mitigation.

Program: This article describes how the Centers for Disease Control and Prevention has approached assessing ethical considerations of public-private partnerships, especially those involving monetary or in-kind gifts.

Implementation: There are practices that can be applied no matter the size or structure of the organization that can lead to transparency and accountability for a potential partnership.

Discussion: Examples in this article include a list of practical considerations to review before entering into a new partnership, as well as illustrative anecdotes.

Keywords

conflicts of interest; ethics; partnerships; private-sector

Context

This article explores ethical considerations when forming public-private partnerships for projects or interventions and offers example standardized vetting processes and practices that maintain organizational integrity. The Centers for Disease Control and Prevention (CDC) recognizes it has an obligation to vet all potential public-private partnerships, especially when the partnership involves monetary gifts. The CDC defines private sector

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Publisher's Disclaimer: Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry.

Human Participant Compliance Statement: This work did not involve research involving human subjects. The authors have indicated they have no potential conflicts of interest to disclose.

partners as including for-profit businesses, professional organizations that represent businesses, philanthropies, and private individuals/groups.¹ Partnerships are formed to address specific public health needs and are thus limited in scope.

The following 2 examples illustrate how the CDC partners with private sector entities for rapid and targeted scaling of specific public health interventions.

The public health response to the 2016 Zika outbreak in the United States and Insular Areas (eg, Puerto Rico and the US Virgin Islands) included partnerships between governmental agencies and the private sector. Pharmacies became an early partner for ensuring affected populations had access to health information and products for preventing virus transmission. This virus is transmitted by mosquitoes to humans, from an infected mother to her fetus, through sex, and while not confirmed, likely through blood transfusions.² Through pharmacy partnerships, Zika prevention information was placed next to scientifically proven effective mosquito repellent, larvacide dunks for standing water, repellent-treated bed nets, and family planning products in stores within areas of high Zika virus transmission. Pharmacists were trained to discuss Zika prevention methods with pregnant women. Large pharmacy chains also worked with mosquito repellent manufacturers to ensure that repellent products were available where they were needed most.

The CDC Sickle Cell Data Collection (SCDC) program works with stakeholders to appropriately document health information of patients with sickle cell disease, to identify gaps in diagnosis, treatment, and health care access, and to inform policy changes, improve health care practices, and develop new medications.³ Some partners have provided funding for the SCDC program, including a few diagnostic and pharmaceutical companies. Each donor has gone through the vetting processes described in this article to weigh the benefits to public health against benefits to the donor or industry.

Private sector groups can play a unique role in a multisector approach to public health. For example, biotechnology and pharmaceutical companies can spur innovation and life-improving products such as the development of microneedle patches to administer vaccines.⁴ Food companies, nonprofits, foundations, and governments have collaborated to fortify grains with important vitamins and minerals.^{5,6} Large employers amplify public health chronic disease prevention messages and practices such as offering healthy choices in cafeterias, providing on-site health screenings and occupational health clinics, maintaining tobacco-free campuses, and implementing robust family leave policies. When private sector organizations partner with public sector organizations and/or utilize public health messaging in these contexts, public health benefits.

Approach

CDC's structures for public-private partnership development and support

Most partnership activities are initiated at the program level within the CDC's centers, institutes, and offices, whereas the Public-Private Partnerships team, in the Office of the Director, Office of the Chief of Staff, provides overarching guidance and support. The team

also helps private sector organizations locate appropriate points of contact, maintains connections between partners and CDC leadership, manages the CDC's internal gift review process, provides support to CDC staff when developing scalable partnership strategies, and serves as the liaison to the National Foundation for the Centers for Disease Control and Prevention (CDC Foundation), an independent, private, nonprofit organization chartered by Congress in 1995 and classified as a 501(c)(3) public charity.¹

To build internal trust and organizational consistency, the Public-Private Partnerships team promotes collaboration among CDC staff engaged in partnership work through the sharing of anecdotes and broader networking. While the CDC has approximately 12 000 staff members, there is a subset of self-identified public-private partnership practitioners who have developed working relationships. These include staff with roles in policy, communications, research, leadership, or administration. A cohesive internal partnership network is important in large organizations that are often siloed. Working across those perceived boundaries, especially regarding partnership engagement activities, is the first step to building a strong culture for partnership development.

An example of the trust built through communication and collaboration between staff can be drawn from the CDC's Zika outbreak response. The partnership practitioners within the CDC relied on one another to help make introductions to various pharmacy groups and pharmacy distribution companies that already were engaged in collaborative work in other parts of the agency. As a result, pharmacist education for Zika prevention doubled in a matter of days. These nonmonetary partnerships were valuable in addressing the Zika outbreak, highlighting the ability of existing partnerships to seed new ones.

Vetting projects with the private sector

In any organization, navigating processes to establish research, project, or partnership activities and/or initiatives can be daunting. As a federal agency, the CDC is no different. These collaborations are vetted through multiple stages of checks and balances. While undertaking multiple levels of review can be perceived as time consuming at the onset, there is value in addressing potential risks proactively rather than addressing problems reactively. The primary responsibility for establishing a sound partnership rests with the programmatic project lead or principal investigator (PI).

The CDC allows partnerships with the private sector as long as guidelines for mitigating real and perceived risks are followed. The CDC's practices build upon existing literature on public-private partnerships. For example, Rowe and colleagues⁷ provide a list of 12 principles for partnerships, such as "articulating a clear statement of work, rules, and partner roles, responsibilities, and accountability, to build in trust, transparency, and mutual respect as core operating principles," acknowledging there may be "deal breakers precluding the formation of an effective partnership in the first place."

CDC Director-level offices also provide guidance on a range of ethics themes that can arise in public-private partnerships. CDC staff who work on legal issues, public health ethics, individual ethics, governmental affairs, budget, policy compliance, and technical agreements are available to provide input to PIs who are considering developing a partnership. The CDC

developed a structure to provide staff with support and resources to protect against undue influence, conflicts of interest, and reputational risks for all parties involved in the partnership. The structure includes a panel of subject matter experts representing the CDC offices described earlier that conduct systematic reviews of gifts to ensure adherence to the CDC “Administration of Gifts to CDC” policy.⁸

Guiding ethical principles for public-private partnerships

In April 2015, through its Advisory Committee to the Director (ACD), the CDC initiated an effort to identify ethical considerations that should serve as guiding principles for its public-private partnerships. The ACD, representing academia, health care, nonprofit organizations, and private industry, was tasked with reviewing the CDC’s existing policies and practices related to partnerships with private industry and making recommendations regarding needed improvements. The effort focused on identifying ethical considerations in establishing financial partnerships in the form of monetary and in-kind gifts, from private industry to the CDC. However, the ethical considerations identified by the ACD provide useful general guidance for public health officials who are considering entering into any type of public-private partnership.⁹

The ACD report made specific clarifying terminology suggestions about donors, including helping CDC staff understand how a “prohibited source” is defined and adding a new “excluded source” category.¹⁰ The ACD recommended that the CDC should never accept gifts from excluded sources. Excluded sources include the following:

- Private entities involved in products or services that directly conflict with the CDC’s mission and cause unequivocal harm to the public’s health;
- Any entity seeking investigation into its own conduct and practices; and
- Any entity seeking to exercise undue influence over the design, management, reporting of results, or the dissemination of findings and will not agree to modifications that permit the CDC to maintain control of all phases of a project.

The ACD report specifically referred to the tobacco industry as an excluded source, but the agency can classify other entities as excluded sources. Other potential donors are assessed for appropriateness through the application of comprehensive definitions of prohibited and excluded sources.

The ACD identified the following 4 general principles that should guide public agencies’ partnerships with private industry:

1. The partnership should not negatively impact the public’s trust in the public agency.
2. Transparency should be maximized.
3. Partnerships should support the public agency’s core mission.
4. All agency staff members should be accountable for following partnership guidelines and principles.

These general principles led to a number of specific recommendations for clarifying decision making about entering into partnerships with private industry. The following points summarize the major recommendations:

- To ensure transparency, there should be full public disclosure of policies, procedures, and guidelines governing partnerships with private industry. This should include public posting of information about all projects funded by private entities and how the relationship supports agency priorities and the core mission.
- The benefits to the public should be clear and measurable and outweigh the risks. The partnership should not adversely affect the public's trust in the agency or create a reputational risk for the agency.
- The partnership policies should be communicated to all agency staff members. There should be no questions about what constitutes an acceptable source of financial support in relation to a partnership. Decision making about entering into a partnership should be assessed through a formal comprehensive review process that is guided by clear criteria and a systematic consideration of agency priorities, risks and benefits, and impact upon all partners.
- Public agencies should determine whether there are private entities that should be excluded from partnerships. A decision to exclude a private entity should be made if it is determined that the activities of the private entity directly conflict with the mission of the public agency, if the private entity is seeking to exercise undue influence over the public agency, or if the private entity is seeking to use the public agency to advance its products or services.

The ACD encouraged the CDC to create a culture of thoughtful partnering across the organization and to offer resources for staff and the private sector for developing and maintaining appropriate partnerships.

Hypothetical scenarios of ethical considerations for public-private partnerships

We present 2 hypothetical scenarios to illustrate consideration of the ethical concepts described by the ACD.

Example 1: Domestic partnership—The first scenario is from the CDC's 2017 public health ethics training manual—*Good Decision Making in Real Time: Public Health Ethics Training for Local Health Departments*.¹¹ When government funding for public health decreases, state and local health departments must make difficult decisions. This hypothetical scenario involves a local health department that has had a significant cut in its funding that is jeopardizing a community initiative on childhood obesity. A national private company that produces diet food products, including some that promote extreme diets, has offered to provide financial support to the health department to conduct community health promotion activities in exchange for placement of its company logo on all educational materials distributed to the community.

The scenario includes a number of questions that help illuminate the ethical considerations.

- Are there any legal constraints that would prohibit this type of collaboration?

- Who are the relevant stakeholders and how should their values, perspectives, and conflicts be considered during the decision-making process?
- What are the risks and benefits of the partnership?
- Is it appropriate to display the company logo on the educational materials? What will be the impacts of displaying the company logo on educational materials?
- What is the impact if the health department is not able to meet its obligations to protect the community?
- Are there any steps that can be taken to increase benefits and decrease risks?

Example 2: International partnership—This second scenario illustrates some ethical considerations for partnerships that might arise in global public health fieldwork. For example, a middle-income country has a high prevalence of an infectious disease among its working-age population, though it does not have good data on the exact prevalence of the disease in specific subpopulations or geographic areas. Many people are not aware that they are infected. The disease can be cured through a pharmaceutical intervention, but it is cost-prohibitive for most citizens of this country. A pharmaceutical company that makes this intervention has offered a donation to help develop a more robust surveillance system in this country, build a laboratory testing network, and implement a health care provider communication campaign to educate providers about the importance of testing for this disease. The company will not be involved in any decision making about the design of the surveillance system, the laboratory network, or the communication campaign but has offered scientific and technical assistance if needed. Government-based experts from other countries also have offered scientific and technical assistance. The laboratory network and communication campaign will help identify more people who are infected. The surveillance system will help the country collect timely and accurate data on the burden and distribution of this disease in its population. Data from the surveillance system would be made available publicly.

This second hypothetical scenario raises a number of questions that may be important considerations for deciding whether a partnership should be established:

- What ethical concerns are there with identifying more people with the disease when the treatment is cost-prohibitive for most people?
- Will the data allow the company providing the donation, as well as other companies, to gain a better understanding of the potential market for the pharmaceutical intervention in this country? Recognizing that this is a potential benefit to the company, does the public health benefit for the citizens of this country justify the acceptance of the funds?
- Because of the donation from the pharmaceutical company, will the government feel pressured to purchase the pharmaceutical intervention from this company? Is that a concern if more people ultimately are diagnosed and treated? Is the company the only manufacturer of the medical intervention for this disease?

- Will a reasonable person assume that there was some quid pro quo between the company and the government with regard to this donation and future purchases of the pharmaceutical intervention?
- Could acceptance of the donation lead people being tested for the disease to question the government's intentions?
- If people are treated for this disease and lead healthier lives, can concerns about the donation be justified?

These 2 hypothetical scenarios illustrate the process for considering the risks and benefits of partnerships with the private sector. If there is a lack of transparency in how decisions about partnerships are made, there could be a negative impact upon the public's trust in public health actions and recommendations. To justify the partnership, the public agency should be able to demonstrate how the partnership will benefit the public rather than just promote the interests of the private entity and that the benefits to the public outweigh potential risks. The scenarios also illustrate how priority-setting, allocation of scarce resources, and funding decisions represent inherently ethical decisions. Decisions regarding how to allocate funds should be based on consideration of justice and fair distribution to maximize benefits.

Practical considerations for establishing public-private partnerships

During trainings for CDC staff domestically and globally, CDC trainers ask questions of staff in the preliminary stages of developing a project concept. The *Public-Private Partnerships Reference Guide*, developed by the PPP Knowledge Lab through The World Bank and contributors, also outlines legal frameworks, adherence to government policies, institutional responsibilities, and financial management approaches to guide partnership development.¹² Those factors, in consideration with concepts of public trust, accountability, core mission, and transparency described earlier in this article, are applied to create a practical set of questions staff may use to evaluate activities prior to private sector engagement. The following questions, some developed by other federal agencies,¹³ have been useful to consider in assessing the benefits and risks of partnerships and gifts offered to support the CDC's public health work:

- How does this partnership relate to the mission of your organization?
- What is the public health benefit of this partnership?
- What are the potential risks of the partnership?
- Does the public health benefit outweigh the risks?
- Has the partner been involved in any recent controversies?
- Could the partnership damage public trust in your organization?
- What will each partner contribute? For example, will contributions be in cash, in-kind (eg, technical expertise, use of a facility, or donation of a product), only information-based, or a combination of all three?

For partnerships in which a gift (ie, donation, whether monetary or in-kind) is offered, the CDC considers additional questions when reviewing the proposed gift:

- What is the practical impact of the gift within the organization?
- What would be lost if this project was delayed or not completed?
- Why is the gift being offered?
- How will the donor potentially benefit from this project (eg, increased market for a product, enhanced reputation, and/or research supporting approval of a product)?
- Does the donor alone benefit, or will multiple, related organizations benefit (ie, the donor singularly benefits vs a sector or industry as a whole)?
- Would any other entities receive benefits from or be disadvantaged by your organization accepting this gift?
- Does the donor support or manufacture any products that could benefit from the results of the project? If so, are there other comparable products either on the market or in the pipeline? Are there any competitors with similar products who will be put at a competitive disadvantage?
- What is the donor's role in the project (if any)?
- Is the donor a collaborator in the project?
- Is the donor a grantee or contractor?
- Could acceptance of the gift compromise the integrity or the appearance of the integrity of any of the employees or the organization?
- Could acceptance of the gift reflect unfavorably on the ability of any employees to carry out their duties in a fair and objective manner?
- Could the value of the gift or nature of the activity raise a significant concern in a reasonable person with knowledge of the situation?

This list of questions is not exhaustive and is not applicable to every situation, but it can help public health professionals assess whether to pursue a particular partnership. When these questions are considered at the beginning of a partnership, ethical and conflict of interest risks often can be mitigated.

Discussion and Conclusion

What makes donor-funded research permissible is under discussion within the public health ethics community, but minimizing both real and perceived risks is a constant theme throughout the literature.¹⁵ Partnerships of any kind require time, personal attention, and consistent communication. Partnerships can and should be developed for the good of public health. However, practitioners must take the time, even as a strategy is just developing, to build in checks and balances. Public-private partnerships are necessary to improve health outcomes, but each side will need to ensure they are meeting ethical and legal standards while establishing a mutual understanding. This article provides examples of successful partnerships and hypothetical scenarios that illuminate potential ethical considerations with

public-private partnerships. The questions posed earlier can be used to generate ideas about how to develop healthy partnership strategies for your own organization.

Real and perceived conflicts of interest should be mitigated similarly. Perceived conflicts of interest can be just as damaging as real risks. If science is called into question, it could damage the reputation of the researchers, the research, and each partner. Embracing checks and balances provides each partner a level of assurance that the work has been vetted and that each organization stands behind the project and the partners.

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Implications for Policy & Practice

- How the organization manages the processes of development and oversight of partnerships will depend upon the size, scope, scale, and mission of the organization.
- It is crucial that processes put in place to establish and maintain partnerships take into consideration the organizational culture and mission.¹⁴
- Project leads should take the time to determine who should be informed about a new partnership project, which offices play a role in approving or providing partnership guidance, and whether there are other practitioners within the organization already engaging with the partner.