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## Another Look at the Human Papillomavirus Vaccine Experience in Canada

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Policy debates about immunization frequently focus on classic trade-offs between individual versus collective well-being. Publicly funded immunization programs are usually justified on the basis of widespread public benefit with minimal individual risk.

We discuss the example of the policy process surrounding the adoption of the human papillomavirus (HPV) vaccine in Canada to consider whether public good arguments continue to dominate immunization policymaking.

Specifically, we show how a range of stakeholders framed HPV vaccination as a personal—rather than a public—matter, despite the absence of a controversy over mandatory immunization as was the case in the United States. Our findings suggest an erosion of the persuasiveness of public good arguments around collective immunization programs in the policy discourse. (*Am J Public Health*. 2011;101:1850–1857. doi:10.2105/AJPH.2011.300205)

### ONE OF THE TRIUMPHS OF

public health has been the ability to prevent communicable diseases with a corresponding impact on population health through immunization.<sup>1,2</sup> This success has led to many governments enacting policies for the public administration, public financing and sometimes, public delivery of immunization programs to ensure that necessary vaccines are made available.<sup>2</sup> Collective action is usually justified on the basis of the phenomenon of herd immunity, which can halt person-to-person disease transmission via attainment of a threshold proportion of immune persons in a community.<sup>3</sup> Yet, immunization is also a highly personal matter. A biological pharmaceutical agent (the vaccine) is administered to an individual, who makes a choice to assume the vaccine's benefits as well as any potential risks, and the overall benefit of herd immunity is threatened without sufficient buy-in by individual participants. Mandatory immunization, which is usually established on the grounds of herd immunity, further heightens the

tension between the individual and the collective: through regulation, governing authorities compel individuals to take on personal risk, as a current investment for their own and for others' future benefit.

We examined the state of public good arguments in immunization policy processes through a qualitative analysis of the Canadian experience with the world's first vaccine against human papillomavirus (HPV), Merck's Gardasil. We demonstrate how arguments for the public health benefits of collective immunization programs can dissipate in the presence of policy framing that emphasizes the personal, rather than the public, dimensions of immunization.

### HUMAN PAPILLOMAVIRUS DISEASE AND VACCINE CHARACTERISTICS

HPV is a highly common sexually transmitted infection of public health significance. Depending on age and other factors, the prevalence of HPV of all types is upwards of 44%

globally,<sup>4</sup> with the highest burden of disease in those younger than 25 years.<sup>5</sup> HPV affects both males and females, and although most infections are transient and asymptomatic, HPV can cause a range of benign to malignant head-and-neck and anogenital lesions. Two high-risk strains of HPV (16 and 18) in particular have been implicated in 70% of cervical cancer cases worldwide.<sup>4</sup> Cervical cancer is the second most common cancer affecting women, and the Centers for Disease Control and Prevention has estimated that each year, 10 800 women in the United States (all age groups included) are newly diagnosed with HPV-associated cervical cancer.<sup>6</sup>

The Gardasil vaccine contains 4 types of HPV, including high-risk types (6, 11, 16, and 18). Gardasil was originally licensed in Canada and the United States in 2006 for use by females aged 9 to 26 years on the basis of Phase II and III clinical trials determining the vaccine's safety and efficacy in females aged 16 to 26 years and immunogenicity studies in younger individuals aged 9 to 15



years.<sup>7,8</sup> Gardasil was recently approved for males in the same age range.<sup>9,10</sup> Cervarix, a competing bivalent vaccine (types 16 and 18) produced by GlaxoSmithKline, was also recently licensed in Canada<sup>11</sup> and the United States.<sup>12</sup> Although the expanded indications for HPV vaccines will certainly modulate the policy debate, our analysis focused on the policy process in its early stages—that is, for Gardasil for females only. In this way, we hope to offer lessons for policy debates surrounding the adoption of new vaccines.

## A QUESTION OF COMPULSION

Policy decisions for collective immunization programs incorporate trade-offs over whom to immunize (usually on the basis of population and disease characteristics such as prevalence, transmissibility, and individual susceptibility), how to immunize (on the basis of vaccine characteristics such as immunogenicity, safety, and efficacy), how quickly to act (on the basis of current vs future risks and benefits), and who will pay (on the basis of economics, political priorities, public trust, acceptability of the vaccine, and other ideas and values).<sup>13</sup> Although individuals must ultimately choose whether to undergo the immunization itself, acknowledgment of the social and economic constraints on individual choices and the presence of widespread public benefit (the public good argument related to herd immunity) are usually used to justify the need for the state to become involved through regulation or payment.<sup>14</sup>

In the United States, the debate over the adoption of the HPV vaccine into collective immunization programs encompassed epidemiological, technological, and programmatic issues but soon became embroiled in controversy over whether to mandate HPV vaccination as a condition of school attendance. By early 2007, 2 states had enacted provisions to make HPV vaccination compulsory, and others were considering it, resulting in a substantial backlash from a variety of stakeholders.<sup>15</sup> Although it has been argued that HPV vaccine mandates are ethical and justifiable on public health grounds,<sup>16</sup> most analysts have maintained that mandatory provisions in the case of HPV in the United States were premature. Many have held that mandatory vaccination was altogether inappropriate given that HPV was a precursor condition for which the usual herd immunity arguments did not apply and that undue political pressure from Merck in lobbying for mandates derailed what could have been a measured roll out of a promising new vaccine, with an eye to public education and continuing evaluation.<sup>15,17–20</sup>

Which prompts us to ask: in the absence of the debate over mandatory vaccination, would the roll out of HPV vaccine have met with less controversy? Can arguments about a disproportionate burden of personal risk in collective immunization programs be mitigated by avoiding policies that make vaccines compulsory?

We attempted to address these questions by looking at the HPV policy experience in Canada. Even

in the absence of a debate over mandatory immunization in Canada, the policy discourse about HPV nonetheless revolved around considerations about the individual versus the collective. This finding demonstrates that different types of trade-offs can serve to erode public good arguments around collective immunization programs. In addition, we address the literature that has characterized the central argument over HPV vaccine as “just do it” versus “what’s the hurry.”<sup>21,22</sup> Such discussion reflects ideas about current versus future benefits of immunization and the pivotal role of adequate information in individual and public health decision-making. Yet, as Gostin has emphasized, “the field of public health is as inherently political. . . as it is technological.”<sup>14(p311)</sup> Accordingly, we did not focus on the evidence for vaccine adoption (well described elsewhere)<sup>4,5</sup> but rather on policy ideas and framing in the early part of the HPV vaccine debate.

## ANALYZING POLICY IDEAS AND FRAMING

We chose a framework for analysis in which we could deliberate on the embedded assumptions in policy debates. Such an approach can be found in interpretive approaches to policy analysis and is dubbed the “search for hidden meaning” in public policy.<sup>23</sup> This type of policy analysis examines how policy ideas influence policy deliberation, design, and implementation.<sup>23–30</sup> Whereas instrumental views of policy change situate policy ideas within a set of core beliefs that direct stakeholders’

actions,<sup>31</sup> interpretive policy analyses focus on how actors use policy ideas not only for problem evaluation but also in ongoing problem construction. By studying the ideas represented in discourses, framing, and narrative story lines about policy, we can uncover how policy actors distill complex conflicts into solvable problems and reasonable courses of action. The purpose of interpretive analysis is to find out what various stakeholders “*really* think about particular events. . . independently of their publicly expressed intentions or motives.”<sup>25(p141)</sup>

We focused on the policy ideas known as frames, or the “underlying structures of belief, perception, and appreciation” on which policy positions rest.<sup>32(p23)</sup> When policymakers adopt incompatible frames, policy situations can become

resistant to resolution by appeal to facts or reasoned argumentation because the parties’ conflicting frames determine what counts as fact and what arguments are taken to be relevant and compelling.<sup>32(p23)</sup>

Accordingly, whereas certain policy conflicts can be resolved through an appeal to a reasoned weighting of evidence (e.g., certain epidemiological preconditions as mentioned previously) many dilemmas in public health can appear to be irreconcilable, a situation based on the coexistence of divergent frames that are usually tacit.<sup>33</sup>

This analysis was part of a larger project that examined immunization policy processes and governance at the federal-provincial interface in Canada over the past decade. Our



qualitative analysis of HPV vaccine policy was an embedded case study to examine the policy process and hurdles associated with the adoption of new vaccines. This analysis used data sources from a systematized review of publicly available policy and legal documents on immunization policy-making processes, including government records (for example, legislative debate transcripts, committee reports, and federal financial reports), supplemented with participant observation in the policy community at 2 successive biennial national immunization conferences, review of mass media articles and peer-reviewed literature, and a set of validation interviews with key senior public health decision-makers.

## AN OVERVIEW OF POLICY DEVELOPMENTS IN CANADA

Immunization is primarily a local and regional responsibility in Canada, with the provinces taking the lead on the financing, delivery, and organization of immunization programs, informed by national-level expert advice. From time to time, the federal government has provided fiscal and administrative support for local activities, but there is no national immunization schedule, and the policy instruments wielded by federal departments responsible for immunization are primarily regulatory (dealing with vaccines as biological pharmaceutical products) or information-based (immunization education and promotion). Since the mid 1960s, the primary source of national-level,

expert immunization recommendations has been the National Advisory Committee on Immunization (NACI), a group of specialists in infectious disease.<sup>34</sup> NACI reports directly to the federal health ministry. NACI does not have legislative or financial levers at its disposal; its recommendations are not legally binding in any way.

The range of conditions under which vaccination is compulsory in Canada is highly limited.<sup>35</sup> School-entry regulations exist in only 2 provinces (Ontario and Manitoba) for just 6 older vaccines (measles, mumps, rubella, diphtheria, polio, tetanus). As far as we are aware, there are no indications of any intent on a policy level for expanding these indications.

A broad process of public health renewal in Canada in the late 1990s made more urgent by the outbreaks of severe acute respiratory syndrome (SARS) prompted structural changes intended to improve federal coordination of public health and immunization.<sup>36</sup> Canada adopted a National Immunization Strategy in 2003,<sup>37</sup> which was formalized through the 2003 and 2004 federal budgets, that allotted new monies for specific immunization programs.<sup>38,39</sup> The 2004 budget, in particular, included a 3-year federal-provincial transfer payment directed toward subsidizing the incorporation of 4 recent higher-priced vaccines into provincial publicly funded immunization programs (pneumococcal conjugate vaccine, meningococcal conjugate vaccine, varicella vaccine, and acellular pertussis vaccine for adolescents and adults).<sup>39</sup>

In late 2004, a reorganization of federal public health moved immunization-related activities out of the main federal health department (Health Canada) into a new agency responsible for public health matters, the Public Health Agency of Canada. By 2005, an intergovernmental body had also been established for collaborative public health decision-making: the Pan-Canadian Public Health Network, the governing council of which would report directly to provincial governments. A Canadian Immunization Committee was established within the Network to share responsibility with NACI for national-level immunization expert advice.

By 2006, however, there was no clear indication that immunization would continue to receive dedicated federal attention or, more importantly, funds. Meanwhile, the HPV vaccine had been licensed.<sup>7</sup> It was costlier than earlier vaccines: Can\$134.95 per dose, excluding program delivery, and a vaccine course that required 3 doses.<sup>40</sup> In comparison, provinces have purchased the measles, mumps, and rubella vaccine at Can\$8.14 per dose.<sup>41</sup> Even the newer varicella vaccine was less expensive: Can\$60 per 1-dose infant immunization course, including delivery and administration.<sup>42</sup>

In the fall of 2006, prominent public health practitioner advocates and a representative from Merck lobbied for an extension of public immunization funding in the upcoming 2007 federal budget.<sup>43-46</sup> A budget preview in December 2006 reported plans for “a dedicated fund. . . of Can\$300 million over three years for future

immunization programs” and suggested that HPV vaccine was one of several “very exciting new vaccines” that could be funded.<sup>47</sup> Soon afterward, in February 2007, NACI gave its endorsement to the HPV vaccine, advising its use for females between 9 and 26 years of age.<sup>4</sup>

When Federal Budget 2007 was released in March, however, the language of the budget previews had been altered so that the promised Can\$300 million would be earmarked for provincial HPV vaccine purchase, not the national strategy or other federally coordinated immunization activities. As is often the case for targeted federal-provincial transfers in Canada (including the immunization funds of 2003 and 2004 mentioned above), the HPV monies were offered as a lump sum in trust, providing considerable autonomy for the provinces to draw upon the funds as they saw fit.<sup>48</sup> Although the budget commented briefly on the benefits of immunization in general, it emphasized efficient integration of new technology, stating

Immunization works. . . . When effective new vaccines become available, it is in the best interest of Canadian families to receive them as quickly as possible.<sup>49(p96)</sup>

Stakeholders at the local and provincial levels admitted that the budget announcement had caught them by surprise.<sup>50,51</sup> By midsummer 2007, however, 3 provinces had formally announced publicly funded programs for HPV immunization for the fall of 2007.<sup>52-54</sup>

Negative media coverage on HPV vaccine in Canada came to a head at the end of August 2007 with a national magazine cover story entitled, “Our Children Are



Not Guinea Pigs: Is an Upcoming Inoculation of a Generation Unnecessary and Potentially Dangerous?"<sup>55</sup> The Public Health Agency of Canada issued a response stating,

The [article's approach] is inappropriate and one-sided. . . . The Chief Public Health Officer welcomes the willingness of governments to support and fund vaccine programs like this, and contends that their leadership in moving quickly should be congratulated rather than criticized.<sup>56</sup>

The *Canadian Medical Association Journal* also released a series of articles on HPV vaccine, however, including a much-cited commentary by Lippman et al. that suggested doubts about the appropriateness and effectiveness of universal, publicly funded immunization for HPV.<sup>57</sup> Negative sentiment escalated in other venues. At the end of January 2008, the House of Commons Standing Committee on Health began a study on post-market surveillance of pharmaceuticals, in which one committee member repeatedly expressed misgivings about the safety of HPV vaccine,<sup>58</sup> although no postmarket adverse events had yet been linked to the vaccine in the Canadian setting.

In early 2008, the Canadian Immunization Committee released its national advisory statement on HPV.<sup>40,59</sup> The statement had been intended to inform provincial program planning, according to the new collaborative processes put in place under the National Immunization Strategy and Pan-Canadian Public Health Network. However, 4 provinces had already gone ahead with immunizations for the 2007–2008 school year. Furthermore, whereas the Canadian

Immunization Committee statement assessed vaccine acceptability and acknowledged ethical challenges, it did not address the negative discourse that had so besieged public health advocates since the vaccine's release.

By summer 2008, 10 provinces had announced voluntary, school-based, publicly funded immunization programs for HPV.<sup>60</sup> Outside of the narrow target cohorts for publicly paid immunization<sup>61</sup> and limited catch-up provisions, however, individuals wishing to undergo vaccination would need to pay out of pocket. Alberta was the last province to announce its program in June 2008 and met with another round of negative press. The Alberta Conference of Catholic Bishops released a statement echoing earlier religious objections in the United States, advising parents to rethink the HPV vaccine on the grounds that abstinence, not vaccination, was the best way to prevent sexually transmitted infections.<sup>62</sup> The bishops also took exception to the school setting for vaccine delivery and the allocation of public funds for the vaccine.

## POLICY IDEAS AND THE HPV VACCINE

In this section, we show how the HPV vaccine was framed in personal, rather than public, terms by both proponents and opponents of the vaccine.

### A Women's Health Issue

HPV vaccine was framed by vaccine advocates as a solution to a "women's health issue." In federal prebudget hearings in 2006, the representative from the

Canadian Coalition for Immunization Awareness and Promotion, an industry and professional coalition, stated

I don't really care how [a] vaccine is made accessible to kids, as long as it is. . . . It needs to be linked to a national immunization strategy and program. . . so that. . . no child in this country is lost through the cracks because of a bureaucratic set-up.<sup>45</sup>

By contrast, when asked about HPV vaccine in the same proceedings, he replied,

There's the chance of wiping out. . . cervical cancer using this vaccine and screening. That's a women's health issue and it needs to be addressed.

The representative from the Association of Obstetricians and Gynecologists of Quebec went on to state,

in our opinion, as gynecologists, [HPV vaccine] is the best thing that has happened to women since the invention of the pill.<sup>44</sup>

One parliamentarian commented,

To me, this is much bigger than a women's rights issue; this is an issue that affects families, it affects people from all walks of life,

to which the industry representative from Merck responded, "I think for women's health, it's a very important breakthrough."<sup>43</sup>

Colgrove has suggested, with regard to compulsory HPV vaccination in the United States, that

support for legal requirements is strongly influenced by the perception of HPV as a women's health issue,

arguing that such perceptions augment the policy appetite to "maximize use of the vaccine

through all policy means, including mandates."<sup>18(p2390)</sup> This assertion implies that a wider variety of policy instruments, and more coercive ones at that, becomes more palatable through the identification of HPV as a women's health issue.

Yet, central to public health is the conception that individuals, acting solely in their own interests, cannot adequately provide for the health of populations and that collective action—sometimes referred to as a justified paternalism—is required to achieve a state of public health.<sup>63</sup> The dominant framing of the HPV vaccine as a benefit to women (particularly when men can also be infected by HPV, transmit the virus, and suffer from associated cancers) created tensions with the traditional understanding of herd immunity as the broad public good resulting from collective immunization. Societal pacts about equitable allocation of resources and collective responsibility underlying universal<sup>64</sup> and school-based immunization programs<sup>20</sup> are thus potentially in conflict with the "women's issue" frame.

### The Cancer Vaccine

A second, related dimension of the framing of HPV vaccine in personal terms was as "the cancer vaccine." Although hepatitis B vaccine was the first vaccine to reduce the incidence of cancer in populations (specifically, hepatocellular carcinoma),<sup>65</sup> it was HPV vaccine that quickly gained a popular "cancer vaccine" distinction.<sup>19</sup> In Canada, the HPV vaccine presented clear synergies with the ruling Conservative Party's existing health strategy targeting cancer, and





Conservative Party legislators articulated this link regularly. By late March 2007, the term cancer vaccine had frequently replaced HPV vaccine in parliamentary parlance. Conservative Party legislators feigned surprise that opposition members “would vote against \$300 million . . . to protect women and girls against cancer of the cervix.”<sup>66</sup> Federal and provincial public education campaigns went on to predominantly emphasize prevention of cervical cancer when communicating about HPV vaccine.<sup>67</sup> (In the United States, even the Centers for Disease Control and Prevention lists “HPV vaccine = Cervical Cancer Vaccine” on its HPV Web site.<sup>68</sup>)

The emphasis on cancer in vaccine messaging was ostensibly intended to reduce the stigma of sexual transmission of HPV by focusing on a condition—cancer—to which it might be perceived that individuals are universally susceptible. Framing the vaccine so clearly as a cancer prevention measure, however, paradoxically highlighted tensions in interpreting the concept of universal susceptibility related to communicable disease; HPV is an antecedent to cancer, and cervical cancer is a condition to which not everyone in a population can succumb, even if exposed to the infective agent. Furthermore, the care of cancer in health systems has been intimately tied to personal care provision and not to public health, entailing a different range of policy instruments for health care financing and delivery. By framing the HPV vaccine as cancer prevention, the policy debate’s focus on broad public health benefits related to immunization was shifted

in favor of a perception of HPV vaccine as intended for targeted use, a shift that has been theorized to accompany the proliferation of therapeutic vaccines in the future.<sup>69</sup>

Such a shift in perception was amplified by the organization of provincial vaccine programs for HPV in Canada. As is customary given the high degree of provincial autonomy over health care decisions in Canada, provinces independently elected to offer HPV vaccine for narrow cohorts in selected school grades. This represented a clear mismatch with recent messages related to the National Immunization Strategy, which was founded on a goal of equitable access to new vaccines across jurisdictions through public funding. In Canada, where vaccine mandates are rare, parental perceptions regarding which vaccines are universally recommended for their children have been linked instead to public payment.<sup>70,71</sup> As such, the implementation of HPV vaccination in an uncoordinated and limited fashion without clear provisions for vaccination of other vulnerable individuals made the argument for universal susceptibility—the cancer vaccine frame—difficult to reconcile in the public arena.

### A Political Issue

The third dimension of the framing of the HPV vaccine in personal terms was the portrayal of the HPV vaccine as a political issue: a venture pursued for political gain by government, industry, and other self-interested stakeholders. This dimension was strongly forwarded by opponents

of the vaccine and the mass media. Yet, the politics of the HPV vaccine also represented a framing dilemma.

In the 2008 parliamentary committee hearings on postmarket surveillance of pharmaceuticals, one member singled out the HPV vaccine, portraying its adoption as a risky political venture with a reported human toll.<sup>58</sup> Strikingly, 13 expert witnesses responded by talking around or perpetuating her allegations, with one witness even raising the spectre of the MMR-autism scares over the past decade.<sup>72</sup> Clearly, even expert witnesses were at a loss as to how to respond to the media furor around the HPV vaccine. Ultimately, a representative of the Public Health Agency of Canada directly addressed the escalating debate with specific accounts of policy actions taken to ensure that reported deaths had not been attributable to the HPV vaccine,<sup>73</sup> and the committee did not comment on the relative risks or benefits of the HPV vaccine in its final report.

The mainstream media also largely framed the implementation of the HPV vaccine as a political issue. In a *Globe and Mail* article reflecting on the HPV vaccine “hoopla,” Picard outlined how the speedy adoption of the vaccine into publicly funded programs was an indication of undue political maneuvering, including capitulations by the federal Conservative government to aggressive lobbying about the vaccine by its manufacturer, Merck.<sup>74</sup>

A look at the Canadian immunization policymaking experience during the 1990s, however, reveals that a rapid adoption of

vaccines is not unprecedented and has reflected factors beyond the articulation of stakeholders’ interests. For example, the first vaccine (Pentacel) to combine routine infant vaccines for polio, diphtheria, and tetanus with ones for *Haemophilus influenzae* b and acellular pertussis was licensed in December 1996. The first publicly funded provincial programs were established in July 1997; by January 1998, all but one province had adopted the vaccine.<sup>75</sup> Later, one of the provincial health ministers remarked,

Provinces are becoming increasingly willing to ensure they are all offering similar and compatible programs. . . . It took six years . . . to implement routine hepatitis B vaccine for adolescents. The second measles dose was universally adopted in 18 months. And now . . . the pertussis vaccine within a single year.<sup>76</sup>

Indeed, the rapid provision of public funding for HPV vaccine was deemed a positive policy development in the public health community.<sup>56</sup> The framing of the HPV vaccine as a political issue conflicts deeply with the notion of immunization as a health measure with solid evidence of broad public benefit. By contrast, HPV vaccine was portrayed in personal terms, specifically, personal risk.

### PUBLIC HEALTH GETS PERSONAL

Even though the Canadian policy debate over HPV vaccine did not deal with individual compulsion, it was striking that both proponents and opponents nonetheless framed the vaccine and the establishment of publicly funded



collective immunization programs in personal terms. The trade-offs in policy discussions related to HPV vaccine adoption have thus revolved around personal benefit versus personal risk, rather than the traditional arguments around public good (for example, as in policy discussions around the National Immunization Strategy). The personal framing of HPV was at odds, therefore, with the archetypal conception of immunization as a collective action problem in public health, in which trade-offs in favor of public benefit have generally been justified on the basis of their importance over the concerns of the individual.<sup>69</sup> Thus even for immunization, an arguably classic example of the public health debate over the rights and responsibilities of the individual versus the well-being of the commons, the set of policy justifications used for state involvement on the grounds of protecting public health continue to evolve.

From a policy standpoint, the HPV vaccine experience in Canada suggests impending challenges for public health. In both Canada and the United States, the HPV vaccine experience has revealed a diminished persuasiveness of public good arguments amid more prominent debates about risks and benefits at the individual level. As vaccines become more costly and as their range of indications expands, traditional arguments for government involvement in immunization on the basis of widespread public benefit at minimal cost (or even cost savings) may become less credible to various

stakeholders. Our examination of the HPV vaccine thus illustrates evolving barriers to the promotion, regulation, and funding of new vaccines by public authorities. From a research perspective, we suggest that in this policy environment it will become increasingly important to explicitly evaluate the frames, goals, and ideas embedded in policies influencing the public's health. ■

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#### Contributors

C.L. Mah conceptualized and led the research as a doctoral candidate under the supervision of R.B. Deber and wrote the article. All authors contributed to interpretation of the data and reviewed and edited the article drafts.

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## Aligning Community Engagement With Traditional Authority Structures in Global Health Research: A Case Study From Northern Ghana

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Despite the recognition of its importance, guidance on community engagement practices for researchers remains underdeveloped, and there is little empirical evidence of what makes community engagement effective in biomedical research.

We chose to study the Navrongo Health Research Centre in northern Ghana because of its well-established community engagement practices and because of the opportunity it afforded to examine community engagement in a traditional African setting.

Our findings suggest that specific preexisting features of the community have greatly facilitated community engagement and that using traditional community engagement mechanisms limits the social disruption associated

with research conducted by outsiders. Finally, even in seemingly ideal, small, and homogeneous communities, cultural issues exist, such as gender inequities, that may not be effectively addressed by traditional practices alone. (*Am J Public Health*. 2011;101:1857-1867. doi:10.2105/AJPH.2011.300203)

There is a saying that a stranger has eyes but he cannot see. That is why it is good to see the chief to introduce you to the community. (Focus group discussions with chiefs and elders)

**WITH GROWING RECOGNITION** that communities can suffer research-related harms and exploitation, community engagement (CE) has become an important

ethical requirement for research, especially when conducted in low and middle-income countries by investigators from high-income countries.<sup>1-4</sup> Community engagement has been defined as

the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people.<sup>5</sup>

Guidance on CE practices for researchers and public health workers remains general and underdeveloped,<sup>6</sup> although 2 of us (J.V.L., P.O.T.) recently published a preliminary framework for CE in global health research that provides a general overview of the scope of relevant CE activities.<sup>7</sup>

Although there is a growing body of research on various aspects of CE,<sup>8-14</sup> little empirical evidence exists of what makes CE effective in biomedical research.<sup>15</sup> The evaluation of CE is complex and rarely involves direct measures of success or impact, in part because the precise goals in any context are rarely articulated. What constitutes a community in the context of research or public health intervention is also rarely stipulated. In longstanding initiatives, such as the Navrongo Health Research Centre (NHRC; see box on page 1858) in northern Ghana (see box on page 1859), CE practices have evolved along with the relationship between communities and research institutes. Research and interventions can affect a wide range of actors with legitimate interests in these