

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Colgrove J, Abiola S, Mello MM. HPV vaccination mandates — lawmaking amid political and scientific controversy. *N Engl J Med* 2010;363:785-91.

HPV Vaccination Mandates— Lawmaking Amid Political and Scientific Controversy

Supplementary Online Appendix

In this Appendix, we provide more detail about our key informant interview methodology.

How were the 6 states selected?

Six states were selected for study after applying several selection criteria. First, we identified a shortlist of 10 states that had been actively deliberating about HPV immunization policy, as measured by news reports and passage of legislation. Using Lexis-Nexis, we examined 2128 online and print newspaper articles from 2006-2008 and selected the 10 states with the greatest volume of media coverage. Of these, 4 states (Texas, Virginia, New York, and Indiana) had enacted related legislation at the time of the search; these were automatically included in the sample.

From among the remaining states, we selected 2—New Hampshire and California—based on application of other selection criteria aimed at ensuring that the sample of states was diverse geographically, politically, and in terms of immunization policies. In addition to geographic region, we examined each state’s ethnic composition, purchasing policies for vaccines generally, and laws concerning vaccination mandates and exemptions. As measures of the political environment, we examined data on political ideology, religiosity, political party control of government, proportion of women legislators, and whether the year in which HPV bills were introduced was an election year in the state.

We limited our study sample size to 6 in order to maximize the depth of our research given available resources for data collection. We also determined that 6 was a sufficient number of states to reflect a diversity of policy environments and outcomes related to HPV immunization.

How were key informants identified and recruited?

We recruited at least 10 key informants in each state for interviews, in addition to several individuals who had been active in HPV policy debates at the national level. We aimed to recruit a sample of individuals in each state that was representative of all of our major stakeholder group categories and that consisted of individuals who were knowledgeable about HPV immunization policy making in their state.

To identify potential interview respondents, we first composed a list of key stakeholder groups for HPV vaccination policy decisions, based on preliminary interviews with public health experts, consultation with two national organizations of health policy makers, analysis of news coverage, and our prior work in this area (Table 1). The stakeholder groups from which we attempted to obtain the largest representation, based on their importance to policy decisions, were legislators and public health officials. We also sought to recruit from medical professional organizations, advocacy organizations focusing on cancer, women’s issues, youth issues, religious or “family” values, vaccine safety, vaccination benefits, and civil liberties; and health insurers. Additionally, we recruited representatives of Merck, the manufacturer of Gardasil, including individuals hired to work for the company as local political consultants.

We then identified individual representatives of each stakeholder group based on consultation with the national organizations, news coverage, analysis of bill sponsors, and

internet research (e.g., to identify immunization program managers). In recruiting legislators, we targeted sponsors of legislation related to HPV vaccination or cervical cancer, health committee chairs and vice chairs, and ranking minority members of health committees, and legislators identified as vocal opponents of legislation related to HPV vaccination. Finally, we identified additional respondents through snowball sampling methods, utilizing the knowledge of key informants who agreed to be interviewed. Four of the individuals added to our sample through the snowball method did not fall into the previously articulated stakeholder groups. These four individuals worked as journalists or clinical researchers.

Informants were recruited through email messages and follow-up phone calls. Recruitment scripts were approved by the institutional review boards of the Harvard School of Public Health and Columbia Mailman School of Public Health. Oral informed consent was obtained from all subjects. Participants were promised that their responses would not be reported in a way that could identify them. To protect respondents' identities, study reports attribute specific responses either to a stakeholder type (e.g., "one health official stated...") or to a respondent within a particular state (e.g., "a California respondent stated...") but not to a stakeholder type within a particular state.

How were interviews conducted?

Interviews were conducted face to face, where possible, and by telephone when an in-person meeting was not feasible. Interviews were semi-structured and followed an interview guide that was vetted with representatives of the two national policy makers' organizations. The interview guide contained a core set of questions posed to all respondents but was customized for particular types of stakeholder groups, such as legislators and advocacy organizations.

Interviews generally lasted 45-60 minutes and were conducted by two investigators. Most interviews were with one key informant, but several involved 2 to 4 informants who were interviewed as a group. Interviews were audiorecorded and transcribed in full. Occasionally, we had follow-up contact with respondents by email, usually to obtain documents that the respondent had indicated during the interview were of interest (such as meeting minutes).

How were the data analyzed?

Transcripts were analyzed using methods of thematic content analysis. Thematic content analysis is a foundational qualitative analytic process by which the common themes presented in text are identified and grouped together. In this method, themes constitute the unit of analysis and are derived from recurring patterns of speech and vocabulary.

For this study, all 3 investigators each developed an initial, hierarchical coding scheme by independently reviewing and coding a sample of 6 transcripts, identifying passages in each transcribed interview that were relevant to the study questions. The investigators then compared the themes in each coding scheme and discussed and resolved points of difference.

A detailed coding manual was developed for the final set of themes which included a definition and set of inclusion and exclusion criteria for each. Each transcript was then coded by a single investigator using the NVIVO8 software package (QSR International, Melbourne, Australia) and the coding manual. Finally, text passages coded within all themes relevant to this paper were juxtaposed and analyzed to identify overall findings as well as differences in interview responses across states and types of stakeholder groups.

In addition to interview transcripts, we reviewed documentary materials provided by interview respondents or available on the internet, such as legislative testimony, meeting minutes, position papers, and memoranda.