



## Brief report

## Sources of information for assessing human papillomavirus vaccination history among young women

Linda M. Niccolai\*, Vanessa McBride, Pamela R. Julian, the Connecticut HPV-IMPACT Working Group<sup>1</sup>

Yale School of Public Health and Connecticut Emerging Infections Program, 60 College Street, New Haven, CT 06520, USA

## ARTICLE INFO

## Article history:

Received 17 July 2013

Received in revised form 3 October 2013

Accepted 19 March 2014

Available online 5 April 2014

## Keywords:

Human papillomavirus virus (HPV)

Vaccination

Vaccine effectiveness

Vaccine impact

Surveillance

Medical records

## ABSTRACT

Assessing history of human papillomavirus (HPV) vaccination is important for monitoring vaccine uptake, impact, and effectiveness. Based on data collected from 1720 women with high-grade cervical lesions reported to a statewide surveillance system in Connecticut, we found that available medical records did not contain HPV vaccination information for 34% of women, and 43% of women could not be reached for interview. When both were used for data collection, concordance of vaccination history (83%) and sensitivity of self-report (96%) were both high. Reviewing medical records based on self-reported information about vaccine providers increased confirmation of vaccination histories in this sample by 18%. The vaccine registry in Connecticut is not currently utilized for HPV vaccinations, but efforts to increase use for adolescent vaccines could be useful in the future to overcome limitations of other sources.

© 2014 Elsevier Ltd. All rights reserved.

## 1. Introduction

Vaccines that protect against infection with human papillomavirus (HPV) have been available since 2006 and are currently recommended for routine administration to females and males ages 11 and 12 years along with catch-up or permissive recommendations to age 26 years. Assessing history of HPV vaccination is important for monitoring vaccine uptake, impact, and effectiveness [1]. A major challenge to assessing HPV vaccination histories is the lack of systematic and centralized collection of this information. Although state-based vaccine registries are available in the United States, they were established primarily for collecting childhood vaccine data. Other challenges include the broad range of clinical specialties including pediatrics, family medicine, internal medicine, obstetrics and gynecology that may provide vaccine due to the current recommendations for routine vaccination of adolescents and catch-up vaccination for young adults [2,3]. Young adults also tend to be highly mobile, making location of relevant

medical records potentially difficult. Therefore, we sought to evaluate sources of vaccination information among women diagnosed with high-grade cervical lesions including medical records, patient interviews, and vaccine registries in the first several years of vaccine availability (2008–2012). This evaluation was conducted as part of the HPV-IMPACT monitoring system that was established in 2008 as a collaboration between the Centers for Disease Control and Prevention (CDC) and five sites of the Emerging Infections Program (EIP) network [4,5]. A goal of the EIP network is to assess the public health impact of emerging and re-emerging infections and to evaluate methods for their control and prevention. Specifically, the purpose of HPV-IMPACT is to conduct population-based surveillance for monitoring HPV vaccine impact on trends in high-grade cervical lesions and HPV genotype distribution.

## 2. Materials and methods

In Connecticut, the EIP is a partnership between the state Department of Public Health and Yale School of Public Health. Connecticut is the only HPV-IMPACT site conducting patient interviews and thus was selected for this analysis. Site-specific methods have been previously described [6]. Briefly, in Connecticut, statewide reporting of high-grade cervical lesions including cervical intraepithelial neoplasia grade 2, 2/3, 3 and adenocarcinoma in situ was mandated by the state health department for public health surveillance in 2008 [7]. These diagnoses were selected because they are

\* Corresponding author. Tel.: +1 203 785 7834.

E-mail address: [linda.niccolai@yale.edu](mailto:linda.niccolai@yale.edu) (L.M. Niccolai).

<sup>1</sup> Members of the Connecticut HPV-IMPACT Working Group include James Meek MPH and James Hadler MD MPH at Yale School of Public Health and Connecticut Emerging Infections Program, Lynn Sosa MD at the Connecticut Department of Public Health, and Susan Hariri PhD and Lauri Markowitz MD at Centers for Disease Control and Prevention.

known to be caused by HPV infections and therefore potentially preventable by current vaccines and they are important precursors to cervical cancer. All 34 pathology laboratories that process biopsy specimens from Connecticut residents are currently in compliance with this requirement. Reports that include diagnostic and patient demographic information are sent to the Yale office of the CT EIP who is authorized to conduct the surveillance on behalf of the state health department. For women aged 18–39 years residing in New Haven County, enhanced surveillance activities include medical record reviews and patient interviews to collect HPV vaccination histories and demographic and other health history information. This age range was chosen because it is the group most affected by high-grade cervical lesions. This project has been deemed public health surveillance by university, state, and federal institutional review boards and thus exempt from the need for human subjects approval.

For enhanced surveillance, medical record reviews were attempted for all women at the offices of providers who performed the biopsy that resulted in the CIN2/3/AIS diagnoses ('biopsy provider'). EIP staff contacted these providers to verify basic reporting elements, obtain up-to-date patient contact information, and review patients' medical records to ascertain HPV vaccination history. When the information was available, number of doses and dates of vaccination were abstracted. If there was no mention of HPV vaccination in the record, it was recorded as missing. For the subset of women for whom there was a note that she received vaccine elsewhere and the provider was mentioned ('vaccine provider'), she was recorded as having receiving vaccine and EIP staff contacted the vaccine provider in the note to confirm status and dates. Similarly, EIP staff attempted telephone interviews with all patients to collect vaccination histories. Women who were reached were asked if they had received HPV vaccine, number of doses, dates of vaccination (month and year), and where they received vaccine. Six attempts are made to reach each case before classifying them as unreachable. For the subset of women who reported a different vaccine provider from the biopsy provider, EIP staff contacted those providers and reviewed those charts to verify history and dates of vaccination.

For the present analyses, we defined history of vaccination as having received at least one dose. Statistical analyses included estimation of vaccination histories by each source separately and comparison of the two sources with concordance, sensitivity, and specificity estimates. Because medical records are often considered the gold standard for assessing vaccination histories, we estimated the sensitivity and specificity of self-report for this measure. Sensitivity was estimated as the percentage of women who had a history of vaccination by medical record review that also self-reported vaccination history, and specificity was estimated as the percentage of women who did not have a history of vaccination by medical record review that also did not self-report vaccination history.

### 3. Results

This analysis was restricted to all women reported to the statewide surveillance system for whom medical records had been reviewed and/or patient interviews had been conducted between January 1, 2008 and June 30, 2012 ( $n = 1720$ , 63% of all reported cases). The mean age of the women was  $26.9 \pm 5.1$  years and the median was 26 years. The majority of women had a diagnosis of CIN 2 (65%), followed by CIN 3 (22%), CIN 2/3 (12%), and AIS (1%). Similar information was obtained by medical record review and interview regarding the percentage who had a history of HPV vaccination with at least one dose (19% by medical record, 15% by interview) and who did not have a history of HPV vaccination (46% by medical record, 41% by interview) (Table 1). Differences emerged for 'unknown'

**Table 1**  
Vaccination history in medical records and patients interviews ( $n = 1720$ ).

Vaccination history	Biopsy or vaccine provider record <i>n</i> (% of total)	Patient interview <i>n</i> (% of total)
Yes, at least 1 dose	330 (19%)	266 (15%)
No	795 (46%)	703 (41%)
Missing/unknown	581 (34%)	22 (1%)
Data collection not done: record not available or patient not reachable	14 (1%)	729 (43%)
TOTAL	1720	1720

**Table 2**  
Vaccination history<sup>a</sup> concordance between medical records and patient interviews ( $n = 991$  of 1720 women for whom data collection was completed by both sources).

Patient interview	Biopsy or vaccine provider record review			
	Yes	No	Unknown	Total
Yes	219	14	33	266
No	7	601	95	703
Missing/do not know	1	5	16	22
TOTAL	227	620	144	991

<sup>a</sup> At least one dose.

and 'missing' categories. Vaccination history was often missing in the medical records (34%) but rarely missing when women were interviewed (1%). However, many women could not be reached for an interview (43%) in contrast to the small number of charts that could not be reviewed (1%). Of the women with vaccination histories confirmed in medical records ( $n = 330$ ), a majority ( $n = 280$ , 85%) were obtained from biopsy provider records and the remainder ( $n = 50$ , 15%) were obtained from a different vaccine provider identified by the patient during the interview. A majority of vaccinating provider locations were obstetric/gynecology offices (73%). Other vaccination locations included public/walk-in clinics (7%), college or university health centers (7%), reproductive health centers (5%), and pediatric offices (3%).

Concordance between medical records and patient interviews is presented in Table 2. Among the 991 women for whom data collection had been completed by both sources, results show that 22% ( $n = 219$ ) were concordant for vaccination history, 61% ( $n = 601$ ) were concordant for no vaccination history (overall concordance 83%), 2% ( $n = 21$ ) were discordant, and 15% ( $n = 150$ ) were unknown or missing from one or both sources. When interviews are completed, the sensitivity of self-report was 96% (219/227) and specificity was 97% (601/620). Including women for whom interviews could not be completed, the sensitivity of self-report was 66% (219/330) and specificity was 76% (601/795).

Discussions with Connecticut Department of Public Health staff in the Immunization Program revealed that the vaccine registry is set up to accept adolescent vaccines but not populated or verified for children over 2 years of age because of language in statute that authorizes the registry. Therefore, it does not currently contain adolescent vaccines and no HPV vaccinations were recorded in the state registry.

### 4. Discussion

Neither medical records, patient interviews, nor vaccine registries is a currently optimal method of obtaining HPV vaccination histories because each has important limitations. Though concordance of HPV vaccination history among young women is high for medical records and patient interviews, use of these methods is challenged by the high frequency of missing data. Medical records that were readily available to review were often missing

vaccination information (34%), and many patients were not reached for interview (43%). However, when both were used for data collection, concordance was relatively high at 83%, and sensitivity of interview data (vs. record reviews as gold standard) was 96%. Using patient interviews to ask about vaccine providers and subsequent verification in those medical records provided 50 additional vaccination confirmations increasing the total number by 18%, from 280 to 330. The vaccine registry in CT currently does not include adolescent vaccinations for HPV.

Obtaining vaccination histories from young women requires different resources depending on the method. Reviewing medical records requires the cooperation of medical practices and providers. Interviews can be resource-intensive and time-consuming but the process can be streamlined by asking only the minimal set of necessary questions. The process can be further streamlined if both sources can be used and interviews are only conducted for women when data cannot be obtained from available records. For this particular project in which all women had been diagnosed with high-grade cervical lesions, conducting interviews soon after diagnosis may further increase yield. Post hoc analyses revealed that interviews were conducted on average 20 months after the diagnosis and that interviews attempted within 6–12 months following diagnosis date resulted in the highest completion (68%) compared to those attempted >12 months following diagnosis (50%). Of note, these data were collected as part of statewide surveillance and mandatory reporting of high-grade cervical lesions [7]; this likely increased our ability to collect information from both sources.

The relative utility of medical records, patient interviews, and vaccine registries may change over time. Available medical records of young adult women, likely to be obstetric or gynecology records, may become less useful as more adolescents are vaccinated by pediatricians. It is also worth noting that collecting data about young men who are now also recommended to receive HPV vaccination may be even more difficult due the lower frequency with which they seek reproductive health care or have a medical home. Interview data may become less reliable as time since vaccination increases for young adults who may have been vaccinated during adolescence.

The use of vaccine registries that do not depend on knowing the vaccination provider or patient recall could mitigate these potential problems but are currently not available in many areas including Connecticut. Though some registries have been expanded beyond children and these may become more complete over time, the quality and completeness of reporting face many current challenges. First, not all states have legal authorization for registries to collect data on children once they are of school age. In addition to

challenges with legal authorization, registries would need to be populated; for HPV vaccination, birth registries that are typically used may not be a useful source for adolescents. Finally, once populated, providers need to report to the registry. While pediatricians are accustomed to this process, other providers who may administer HPV vaccinations (e.g., gynecologists) may be less so. Implementation of comprehensive school-based vaccination programs as has been done in some countries (e.g., Australia) could also help with assessing vaccination histories but this is not currently being considered in the US on a broad scale.

## 5. Conclusion

The ability to assess HPV vaccination histories will become increasingly important as impact and effectiveness studies are done to evaluate vaccine policy and programs. This analysis addresses some issues in the early years of vaccine availability in the United States. Efforts to improve registries for adolescent vaccines will be useful to overcome significant limitations of missing data from other sources of vaccine history.

## Acknowledgments

We gratefully acknowledge the support and cooperation of participating pathology laboratories and provider practices and the willingness of patients to participate in interviews.

## References

- [1] Markowitz LE, Hariri S, Unger ER, Saraiya M, Datta SD, Dunne EF. Post-licensure monitoring of HPV vaccine in the United States. *Vaccine* 2010;28:4731–7.
- [2] Centers for Disease Control and Prevention. Recommendations on the use of quadrivalent human papillomavirus vaccine in males – Advisory Committee on Immunization Practices (ACIP), 2011. *MMWR* 2011;60:1705–8.
- [3] Centers for Disease Control and Prevention. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010;59:626–9.
- [4] Niccolai LM, Julian PJ, Bilinski A, Mehta NR, Meek JI, Zelterman D, et al. Area-based poverty, racial, and ethnic disparities in cervical cancer precursor rates in Connecticut, 2008–2009. *Am J Public Health* 2013;103:156–63.
- [5] Hariri S, Unger ER, Powell SE, Bauer HM, Bennett NM, Bloch KC, et al. The HPV vaccine impact monitoring project (HPV-IMPACT): assessing early evidence of vaccination impact on HPV-associated cervical cancer precursor lesions. *Cancer Causes Control* 2012;23:281–8.
- [6] Mehta NR, Julian PJ, Meek JI, Sosa LE, Bilinski A, Hariri S, et al. Human papillomavirus vaccination history among women with precancerous cervical lesions: disparities and barriers. *Obstet Gynecol* 2012;119:575–81.
- [7] Connecticut Department of Public and Health. Reportable diseases and laboratory reportable significant findings: changes for 2008. *Conn Epidemiol* 2008;28:1–3.