Monitoring the impact of human papillomavirus vaccines on high-grade pre-invasive cervical lesions: Designing a framework of linked immunization information system and cancer registry data in Michigan

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Abstract

State immunization and cancer registries contain data that, if linked, could be used to monitor the impact of human papillomavirus (HPV) vaccine on cervical cancer and precancer. Michigan is uniquely positioned to examine these outcomes using two population-based resources: the state-wide cancer registry and immunization information system (IIS).

We assessed the feasibility of identifying females in the IIS who had continuous Michigan residence and linking them to the cancer registry. We considered continuous residence necessary for future studies of vaccine impact to avoid misclassifying those who may have been immunized while residing out-of-state and whose immunization therefore may not have been reported in Michigan.

We identified females with 1976–1996 birthdates in the IIS and used probabilistic linkage software to match them with Michigan birth records. A stratified random sample of IIS-birth matches was provided to a commercial locator service to identify females with continuous Michigan residence. Cervical carcinoma *in situ* cases diagnosed in 2006 among females aged 10 through 30 years were also matched with the birth records; cancer registry-birth matches were merged with the IIS-birth matches using the birth record identifier.

Overall, 68% of the 1274,282 IIS and 61% of the 1358 cancer registry records could be matched with birth records. Among the sample of IIS-birth matches, most (86%) were continuous residents.

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Seventy percent or more of cancer registry-birth matches merged with IIS-birth matches for cases born after 1984.

This is the first effort in the U.S. to show that linking records across IIS and cancer registries is practical and reasonably efficient. The increasing proportion of matches between the registries and live birth file with birth year, and the use of population-based data, strengthen the utility of this approach. Future steps include use of this method to examine incidence of cervical cancer precursors in HPV immunization-eligible females.

Keywords

Human papillomavirus (HPV); HPV vaccine; Cervical cancer; Immunization information system (IIS); Cancer registry

1. Introduction

Monitoring human papillomavirus (HPV) vaccines post-licensure to assess immunization programs, evaluate policies, and demonstrate population impact is essential [1–5]. Cervical cancer, an outcome of HPV infection, may take several decades to develop [6]. Monitoring the incidence of high-grade pre-invasive cervical lesions is an attractive surrogate outcome because a decline in these lesions would be an early, reliable predictor of future declines in invasive disease [3,7]. Several surveillance networks monitor immunization impact on cervical cancer precursors; however, determining the immunization status of cases can be resource-intensive [3,8].

A 2014 report on accelerating HPV vaccine uptake by the President's Cancer Panel indicates linking immunization and cancer registries would "enable study of the impact of HPV vaccination, including differences in rates of HPV-associated precancers and cancers between vaccinated and unvaccinated individuals" [9]. Michigan is well-positioned to monitor the population-level impact of HPV immunization on cervical lesions. The state's immunization information system (IIS) includes HPV vaccine administration information and the statewide cancer registry conducts routine surveillance for invasive and *in situ* cervical cancers.

Our objectives were to assess the feasibility of identifying females in the IIS who resided in Michigan continuously from birth through 2006 and to develop a method to link their records to Michigan's cancer registry. This method could be used in future studies to examine differences in the incidence of high-grade pre-invasive cervical lesions by HPV immunization status.

2. Methods

This study was approved by the Michigan Department of Community Health (MDCH) Institutional Review Board.

The three statewide population-based data sources used are described below.

Immunization information system: The state's IIS, the Michigan Care Improvement Registry, was created in 1998 as an electronic resource for confidential immunization data [10]. Through a linkage with Michigan's Vital Records, the IIS has been continually populated with data, including a birth identifier number, for all Michigan live births after 1993; therefore, the IIS contains a record for all Michigan-born residents born after 1993, regardless of immunization history. Providers can create records in the IIS for patients born out-of-state or before 1994. From its creation, providers were required to report all school-exclusionary immunizations administered to persons born after December 31, 1993 and aged <20 years. Since August 2012, providers have been required to report all immunizations (including HPV and other immunizations not required for school entry) administered to this group. Providers have been able to electively report immunizations administered to persons aged 20 years since June 2006.

Cancer registry: The Michigan Cancer Surveillance Program participates in the Centers for Disease Control and Prevention (CDC) National Program for Cancer Registries and began tabulating cancer incidence reports statewide in 1985. All *in situ* cervical cancers (squamous carcinoma *in situ* [CIS] and glandular adenocarcinoma *in situ* [AIS]) have been reportable since 1985 [11]. Cervical intraepithelial neoplasia grade 3 (CIN3) cases were not reportable until 2009, and were therefore not included in this feasibility study. Both CIS and CIN3 lesions are consistently recognized by pathologists and, because they rarely regress and are at highest risk for progression to invasion, are considered true cancer precursors [12].

Birth file: Birthing facilities and attendants have been required to report each Michigan-born infant to the MDCH since 1906. These reports comprise the Michigan birth file and include a unique birth identifier number with additional demographic information on the child and her parents.

For the purposes of this study, conducted in 2009, we identified (1) IIS records for all females aged 10 through 30 years as of December 31, 2006 and (2) cancer registry records for *in situ* cervical cancer cases diagnosed in 2006 among females aged 10 through 30 years. We considered a minimum age of 10 years to be sufficient for this feasibility study, because there were no *in situ* cervical cancer cases aged <15 years in the cancer registry. The most complete cancer registry data available at the time of the study were cases diagnosed in 2006. Because HPV vaccine was not licensed until mid-2006, determination of HPV vaccine status was not a goal of this feasibility study.

2.1. IIS-birth file matching and cancer registry-birth file matching

Both IIS and cancer registry records can be linked to birth file records to obtain the birth identifier number, which can be used to link records across the IIS and cancer registry. The birth file is the only source of identifying information on the female's parents, which is necessary to determine continuous Michigan residence, as described below. We considered continuous residence necessary for future studies of vaccine impact to avoid misclassifying those who may have been immunized while residing out-of-state and whose immunization therefore may not have been reported in Michigan.

We established Michigan birth by separately matching the selected IIS records and the selected *in situ* cervical cancer records to those of females born between 1976 and 1996 (*i.e.* those aged 10–30 years in 2006) in the birth file using Registry Plus™ Link Plus version 2.0, a no-cost probabilistic matching software package developed by the Centers for Disease Control and Prevention (CDC) [13]. In each set of matched files, records were first grouped, or blocked, by first name and birth year (*i.e.*, these variables required an exact match). Variables probabilistically compared within blocks were last name, birth month and day, and address.

The matching software assigned a weighted match score to each potential record match. We reviewed potential matches to identify the score above which all matches should be considered conclusive and the score below which all matches should be considered invalid. We first sorted the result file in order of weighted match score. Then, starting with the highest matched score, when the reviewer (GC) identified the first record pair that, in his opinion, was a probable mismatch, the weighted match score for that record pair was used as the lower cut-off score for conclusive matches. Then, starting with the lowest matched score, when the reviewer identified the first record pair that was an acceptable match, the weighted match score for that record pair was used as the upper cut-off score for invalid matches. Matches between these two scores were considered potentially matched. For the IIS-birth file match, all record pairs with a match score of 14.8 were considered conclusive and those with a match score of 4.2 were considered invalid. For the cancer registry-birth file match, all record pairs with a match score of 2.0 were considered invalid. An upper score for the cancer registry-birth file match was not set because the small number of cases permitted manual review of all potentially matched pairs.

The final step was an intensive manual review of potentially matched record pairs with scores between the specified cut-off values to determine which matches should, in fact, be considered conclusive. Our review assessed the likelihood of a probable match based on fields that matched and degree of similarity between fields that did not match exactly, identifying minor misspellings, spacing differences, and other factors that caused two values to be deterministically different but judged a likely match.

To identify additional conclusive matches between cancer registry and birth file records, we manually evaluated all the potential matches with a score 2.0. Identifying additional conclusive matches between the IIS and birth file required an extra review step because reviewing all potential matches (>1 million record pairs) was too resource-intensive for our feasibility study. Instead, we manually examined a sample of 300 potential matches (4.2 score 14.8). To validate the matching process, we also manually examined 150 invalid and 150 conclusive matches. As an additional validation, we conducted an assessment of direct IIS-birth file record linkages using the birth identifier number, available in IIS records of children born after 1993, by evaluating the percentage with a conclusive match score.

2.2. Merging cancer registry-birth file matches with IIS-birth file matches

Having matched records from both sources to the birth file, we used the birth identifier number to merge the records of Michigan-born *in situ* cervical cancer cases with the Michigan-born age-eligible females in the IIS (Fig. 1).

2.3. Identification of continuous Michigan residence

Michigan residence since at least age 10 years will be necessary in future studies to assure that HPV immunizations and *in situ* cervical cancer cases would have been reported to both registries. The Lexis-Nexis® Accurint® record locator service [14] was used to determine continuous Michigan residence for a stratified random sample of the age-eligible females in the IIS whose records conclusively matched to the birth file. Accurint® data are derived from legal and financial transactions; access to these data are federally regulated and safeguarded by stringent privacy and security protections (www.lexisnexis.com/privacy). Records for 810 females were sampled from each of seven 3-year birth intervals (1976–1978, 1979–1981, 1982–1984, 1985–1987, 1988–1990, 1991–1993, 1994–1996), for a total sample of 5670 females. Data submitted to Accurint included one record for each female, two records for her mother (one with name at the time of the birth, and one with maiden name), and a record for her father. Each record included first, middle, and last name, date of birth, and social security number (for the records of the mother and, if available, the father). For all record types, the mother's address at the time of delivery was included. In total, we submitted four records for each female in the sample (with exceptions for births with no registered father and occasional records that did not provide the mother's maiden name).

3. Results

3.1. IIS-birth file matching

Of the 1274,282 females aged 10–30 years as of December 31, 2006 in the IIS, we identified 863,880 (67.8%) conclusive matches to the birth file; another 278,233 (21.8%) record pairs were possible matches (Table 1). Based on the sample of 150 invalid, 300 possible, and 150 conclusive matches selected for manual review, all invalid matches were confirmed as non-matches, and all conclusive matches were confirmed to be correctly matched. We determined that 103 of the 300 (34%) possible matches were correct, indicating a full manual review of all possible matches would have resulted in an additional 94,599 correct matches and increased the total correct matches to an estimated 958,479 (75%).

The proportion of conclusive matches increased with birth year. Whereas <50% of IIS records for females born from 1976 to 1978 matched to the birth file, >70% of records for females born after 1992 matched to the birth file. Ninety-eight percent of the age-eligible IIS records already containing the birth identifier number were conclusively matched with the birth file.

3.2. Cancer registry-birth file matching

Of the 1358 *in situ* cervical cancer cases, we identified 830 conclusive matches (61.1%) to the birth file (Table 1). Matching rates increased with year of birth, rising from <50% for females born before 1979 to 70% for birth years after 1983. The highest matching rate was 78.6% for females born in 1989. There were few *in situ* cervical cancer cases with birth years in 1990 and 1991 (*i.e.*, ages 15–16) and no cases were born after 1991.

3.3. Merging cancer registry-birth file matches with IIS-birth file matches

Overall, 452 (54.5%) of the 830 cancer registry-birth file matches merged with an IIS-birth file match using the birth identifier number (Table 1). This percentage increased with birth year; overall, for cases born after 1984 >80% of cancer registry-birth file records merged with IIS-birth file records (70% for those born in 1985, increasing to 100% for those born after 1989).

3.4. Identification of continuous Michigan residence

In total, 21,542 records were submitted to Accurint containing demographic data for the random sample of 5670 age-eligible Michigan-born females from the IIS-birth file match (Fig. 1). For each female, we submitted one record with her own name and another record with the name of her mother at the time of birth. Additional records containing the mother's maiden name were submitted for 5240 (92.4%) females, and records with the birth father's name were submitted for 4962 (87.5%). Returned address histories contained up to 16 separate addresses for mother, father, and child.

The ability to identify continuously resident females using Accurint varied by record type and birth year. The percentage of continuous residents found by only using the sampled female's name was poor (14.1%). Using the mother's name at the time of birth increased the continuous residency identification rates, ranging from 89.2% for females born 1976–1978 to 99.1% for those born 1994–1996. Comparable identification rates were found when the father's name (range: 89.6–98.2%) or mother's maiden name (range: 81.9–98.1%) was used. Identification rates based on parental name increased with birth year of the sampled female. Overall, 4870 (85.9%) of the sampled Michigan-born females had an address history that indicated neither they, nor their mother or father, resided outside of Michigan during the female's life.

4. Discussion

To our knowledge, this is the first U.S. study to assess the feasibility of creating a linkage between individual records in immunization and cancer registries. The feasibility of using cancer registry data to follow HPV vaccine cohorts has been demonstrated in Finland [15], and an HPV Vaccination Program Register with potential linkages to Papanicolaou screening test registry data has been developed in Australia [8,16]. Both Norway and Denmark have established linkages between their immunization registries and HPV-related clinical outcome data based on the presence of unique personal identification numbers that are assigned to every citizen and used across health registries [17,18]. Our work is the first to demonstrate a practical and reasonably straightforward methodology for linking existing IIS and cancer registry data in the absence of such an identifier, which is a much more common occurrence. The linkages across these data sources utilized freely available matching software (LinkPlus). This methodology will provide future opportunities for assessing the impact of HPV immunization on incidence of high-grade pre-invasive cervical lesions in a large, population-based cohort of Michigan residents.

Data from the birth file were used to establish continuous Michigan residence among a sample of IIS-birth file matched records. Forty-six percent of Michigan-born *in situ* cervical cancer cases did not have corresponding records among the IIS-birth file matches. However, the percentage of Michigan-born *in situ* cases with corresponding records among the IIS-birth file matches increased for younger cases, possibly due to increasing quality and completeness of information in the IIS over time commensurate with the implementation of the birth file linkage, permissive reporting for adults, and expanded reporting requirements for children. Overall, 86% of sampled IIS-birth file matches resided continuously in Michigan, indicating that we could expect a large proportion to be eligible for inclusion in a future study of vaccine impact.

There were limitations to these methods which have implications for future studies. First, our methodology will limit the analytic file to age-eligible females with records in the IIS that have resided continuously in Michigan since birth, in an effort to ensure that the cohort created is restricted to females with known HPV-immunization history. Females not born in Michigan, but who resided in the state continuously since they were age-eligible for HPV immunization, thus will be excluded, reducing statistical power to detect HPV immunization impact. In addition, females born before 1994 with no immunizations of any kind would not be included in the IIS because it was not populated with birth data before that year, which also would reduce the power of future studies. Third, because HPV immunization is not school-required (but, consistent with national guidance, is recommended for children age 11 through 12 years, and may be given starting at age 9 years through age 26 years [19]) and may be administered to adults (for whom there is no reporting requirement), it may be under-reported in the IIS. Michigan's public health code was recently revised to require all vaccines administered to those aged <20 years are reported to the IIS, not just those required for school; this change is very likely to increase HPV immunization reporting. Recent efforts to accept electronic immunization messages through health information exchanges should also improve completeness of reporting [20].

The effect of these limitations could be examined and addressed in future studies of vaccine impact. For example, samples of records that could not be linked to the birth file would be evaluated to determine the proportions that can be explained by birthplace. The encroachment of non-Michigan births into both datasets does follow an expected pattern of increasing with age, however.

Michigan is uniquely positioned to examine the impact of HPV vaccine on cervical cancer and precancer through linking state immunization and cancer registry data. The large sample sizes should provide sufficient power to detect differences in incidence of cervical cancer precursors for future studies, particularly given the high percentage of IIS-cancer registry linkages for females born after 1984. While most state cancer registries discontinued collection of *in situ* cervical cancers in 1996, Michigan remained the only state-wide population-based registry that continuously collected these data [11]; Kentucky and Louisiana re-instituted surveillance for cervical cancer precursors in 2010 [21]. The Michigan cancer registry has met the North American Association of Central Cancer Registries (NAACR) Gold Standard annually since 2002 (1999 data) [22]—the highest standard for completeness (>95%), accuracy, and timeliness [23]. In 2009, Michigan

conducted an audit of pathology reports from 10 randomly selected facilities and identified no missed cases of pre-invasive cervical lesions [21]. Additionally, the Michigan IIS is well-populated, containing >97 million immunization records for 8.0 million individuals; >95% of Michigan children less than six years of age have two or more immunizations recorded in the IIS [24]. Michigan's IIS has been a CDC IIS Sentinel Site since 2001, with minimum requirements including 85% vaccine provider enrollment and timely reporting for 90% of administered vaccines [25]. At the time of initial HPV vaccine licensure in 2006, the IIS was already well-populated with adolescent vaccine administration data [26]; 3-dose HPV vaccine coverage for Michigan females, as measured by the IIS, has been within the confidence limits of the CDC National Immunization Survey-Teen (NIS-Teen) estimates since Michigan-specific data were first reported [27]. In the 2013 NIS-Teen, the estimated proportion of girls aged 13 through 17 years who had completed the series was 34.5% (±9.4%) and the IIS showed coverage at 32.7%. In 2010, Michigan participated in an NIS-Teen–IIS Match project. An IIS dataset for matched adolescents was compared to the vaccination data collected from immunization providers in the NIS-Teen. Weighted coverage with one or more and three or more doses of HPV vaccine for girls aged 13 through 17 years was 0.3% and 2.0% higher, respectively, using IIS data [MDCH unpublished data].

Future studies will be more easily implemented than the current feasibility study, for several reasons. First, birth data were used to populate the IIS starting in 1994, and we were able to conclusively match almost all IIS records having a numeric birth identifier to the birth file. Second, matching cases from the cancer registry to the birth file may have been hampered by name changes between birth and diagnosis; we observed higher matching rates for younger females. Beginning in 1997, social security numbers assigned to Michigan-born children became available as part of birth file data and can be used to augment the cancer registry-birth file matching. Third, the completeness and comprehensiveness of the Accurint® address histories appear to have improved over time. Another study found this source of residential history has sufficient quality to suggest its routine use [28]. Our findings indicate this resource has become more complete and extensive since the mid-1990s.

Using existing registry data to assess the impact of HPV immunization on the incidence of cervical cancer precursors is feasible. Future steps include a study using IIS-cancer registry linked records to examine incidence of cervical cancer precursors in HPV immunization-eligible females. This could include consideration of age at which the vaccine series was initiated, dose spacing, and total number of doses received. A similar methodology could be used in Michigan, or other jurisdictions with both high-quality IIS and *in situ* cervical cancer surveillance, to examine the population impact of HPV immunization on invasive cervical cancer and other HPV-associated cancers.

Acknowledgements

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| Females age 10 through 30 years as of 12/31/2006 in the Immunization Information System (IIS): 1,274,282 | Birth File: 1,439,859 | Pre-invasive cervical cancer cases diagnosed in 2006 among women age 30 years or younger in the Michigan Cancer Registry: 1,358 | **Data Sources** |

IIS-Birth File Matching and Cancer Registry-Birth File Matching

| 863,880 confirmed IIS-Birth File matches | 830 confirmed Cancer Registry-Birth File matches |

Excluded 378 Cancer Registry-Birth File matches not also matching the IIS-Birth File records

Merging Cancer Registry-Birth File Matches with IIS-Birth File Matches

452 merged IIS-Cancer Registry matches

Identification of Continuous Michigan Residence

Stratified random sample of 5,670 records from IIS-Birth File matches for Accurint search
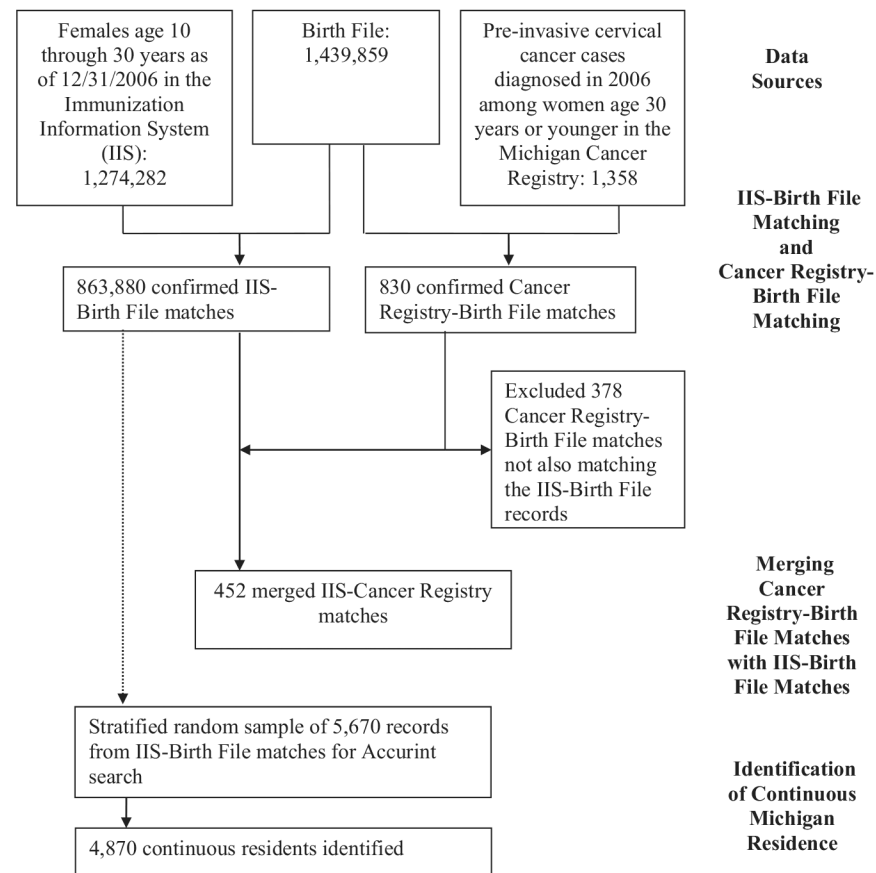
4,870 continuous residents identified

Fig. 1.
Design of a feasibility study to link cancer registry and immunization information system (IIS) records using vital records of live births, Michigan, 2006.

Table 1

Data source matching rates, by birth year/years of age, feasibility study to link cancer registry and immunization information system (IIS) records using vital records of live births, Michigan, 2006.

Birth year/years of age	Females in IIS[1]	Females in IIS Matched to Live Birth File		Cancer registry in *situ* cervical cancer cases	Cancer registry cases matched to live birth file		Cancer registry-live birth file cases merged into IIS-live birth file matches	
	N	N	(%)	N	N	(%)	N	(%)
1976/30	9982	2412	(24.2)	44	15	(34.1)	2	(13.3)
1977/29	11,031	3001	(27.2)	93	42	(45.2)	7	(16.7)
1978/28	12,769	4684	(36.7)	115	51	(44.3)	9	(17.6)
1979/27	19,703	10,023	(50.9)	115	64	(55.7)	12	(18.8)
1980/26	28,081	16,390	(58.4)	141	70	(49.6)	25	(35.7)
1981/25	34,616	21,520	(62.2)	141	81	(57.4)	27	(33.3)
1982/24	43,235	27,452	(63.5)	120	77	(64.2)	49	(63.6)
1983/23	47,465	30,858	(65.0)	134	93	(69.4)	51	(54.8)
1984/22	53,120	35,339	(66.5)	99	70	(70.7)	46	(65.7)
1985/21	58,832	39,440	(67.0)	105	76	(72.4)	53	(69.7)
1986/20	65,844	45,225	(68.7)	81	62	(76.5)	45	(72.6)
1987/19	80,851	56,674	(70.1)	79	61	(77.2)	60	(98.4)
1988/18	84,687	58,371	(68.9)	49	36	(73.5)	35	(97.2)
1989/17	90,092	62,111	(68.9)	28	22	(78.6)	21	(95.5)
1990/16	94,330	65,300	(69.2)	11	8	(72.7)	8	(100)
1991/15	93,400	64,701	(69.3)	3	2	(66.7)	2	(100)
1992/14	90,071	62,466	(69.4)	0	0	***	0	***
1993/13	87,796	61,719	(70.3)	0	0	***	0	***
1994/12	91,232	66,524	(72.9)	0	0	***	0	***
1995/11	89,004	64,984	(73.0)	0	0	***	0	***
1996/10	88,141	64,686	(73.4)	0	0	***	0	***
All Years	1274,282	863,880	(67.8)	1358	830	(61.1)	452	(54.5)

[1] Immunization information system.