Validation of Uterine Perforation and Intrauterine Device Expulsion in Electronic Health Records

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DISCLOSURES

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BACKGROUND

- Health care system databases are increasingly used for medication and device safety studies.
- Health care systems with electronic health records (EHRs) have many advantages over administrative claims databases to capture complex health outcomes; among them, clinical notes in EHRs that provide additional insight into medical encounters, medical events, lifestyle factors, and health-related behaviors.
- Methods to utilize these richer data sources must be developed and validated before use.

OBJECTIVE

- To develop and validate automated algorithms using both structured and unstructured data from health care systems with EHRs to identify intrauterine device (IUD)-related uterine perforations and IUD expulsions.

METHODS

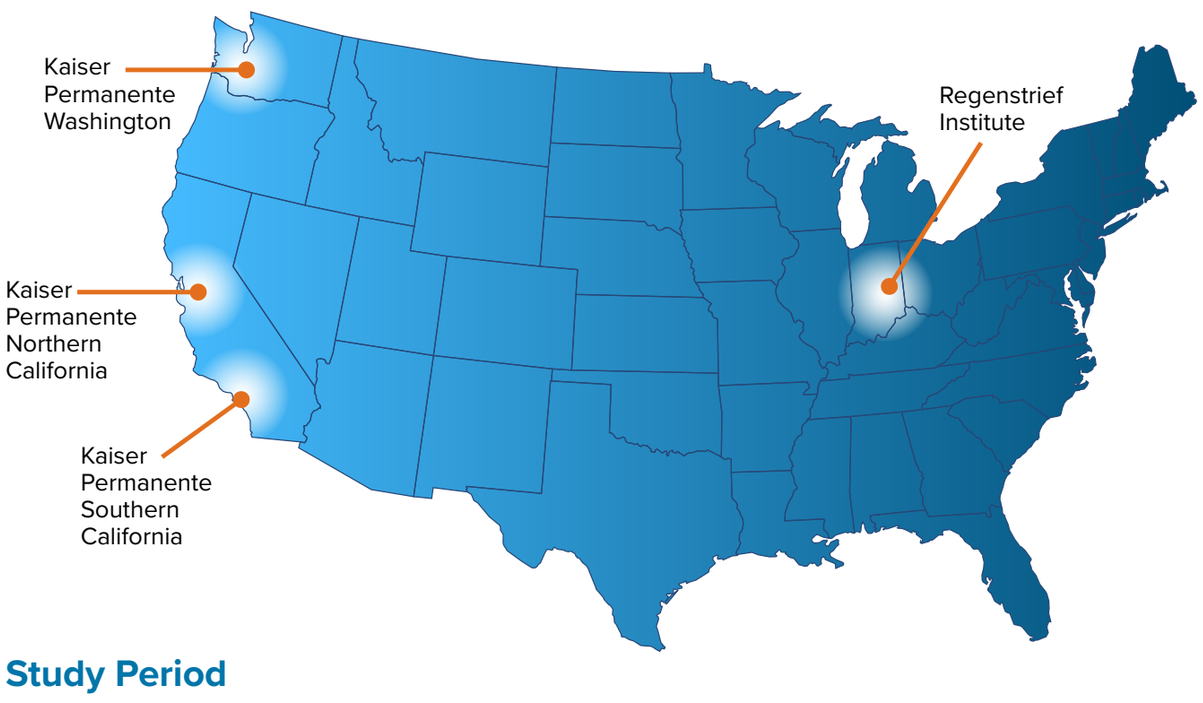
Study Design

- Cross-sectional study to validate algorithms for clinical outcome by manual review of EHRs.

Data Sources

- Four sites with access to EHRs in the United States participated: 3 Kaiser Permanente sites—Northern California, Southern California, Washington—and Regenstrief Institute in Indiana. Figure 1 shows the site locations and approximate catchment areas.

Figure 1. Study Population Catchment Areas



Study Period

- The study period at each site was from either the time the EHR was fully implemented at that site or 2001 (corresponding to the approximate approval date of Mirena), whichever was later, through September 30, 2015 (see Table 1, inclusion dates).

Study Population

- The study population included 282,028 unique women aged ≤ 50 years at the time of IUD insertion. Among those women, there were a total of 325,582 IUD insertions documented in EHR systems at 4 sites over 7-15 years (see Table 1).

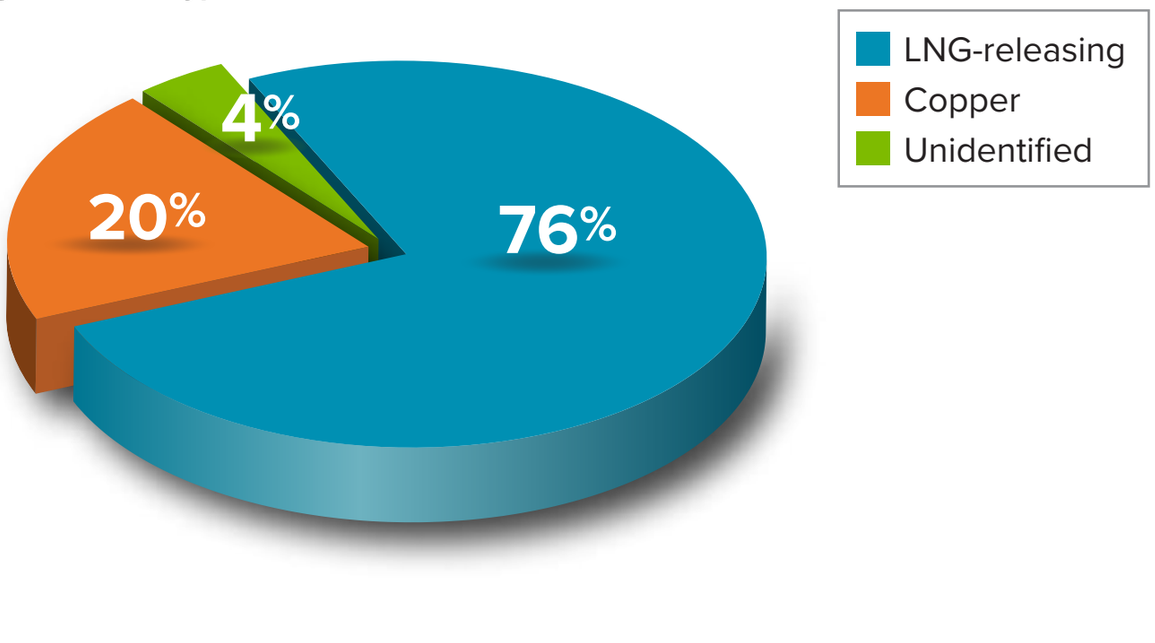
Table 1. Characteristics of the Population With One or More IUD Insertions

Characteristic	Site 1	Site 2	Site 3	Site 4	All Sites
Number of women	145,004	107,148	22,683	7,193	282,028
Number of IUD insertions	168,744	122,743	26,315	7,780	325,582
Inclusion dates	2009-2015	2008-2015	2006-2015	2001-2015	–
Age in years, median (Q1, Q3)	32 (26, 38)	31 (26, 38)	31 (25, 37)	29 (24, 35)	–

Q = quartile.

- Approximately three-quarters of the insertions were levonorgestrel (LNG)-releasing IUDs; 20% were copper IUDs, and 4% were not identified (see Figure 2).

Figure 2. IUD Type



- Structured (e.g., International Classification of Diseases codes, Current Procedural Terminology codes, National Drug Codes) and unstructured (Natural Language Processing terms) data were used to develop algorithms.
- Site-specific algorithms for uterine perforation and IUD expulsion were developed and validated by study personnel via EHR review of a random sample of one-third of the identified possible cases (up to 100).
  - If sites further refined their algorithm, a second random sample of one-third of the possible cases was selected for review.

Validation

- Uterine perforation included:
  - Complete (i.e., IUD was documented as located in the pelvis or abdominal cavity).
  - Partial (i.e., IUD was documented as embedded in the myometrium) identified via hysteroscopy, laparoscopy, laparotomy, or an imaging study in conjunction with evidence of a difficult IUD removal (e.g., ultrasound suggested partially embedded plus string avulsed with traction upon attempted removal).
- IUD expulsion was defined as the unintended, spontaneous expulsion of the IUD through the cervix.
  - It included both partial (e.g., IUD visibly extruding through external cervical ostium but still lodged in the cervix or lower uterus) and complete (i.e., not present in the cervix, uterus, pelvis, or abdominal cavity).
  - If the IUD was malpositioned in the uterine cavity, it was not considered an expulsion.

Analysis

- The positive predictive value (PPV) for each outcome (uterine perforation and IUD expulsion) was defined as the percentage of possible cases identified by the algorithms that were determined to be actual cases upon medical record review. PPV was calculated as (number of true positives / number sampled) × 100.
- The exact (Clopper-Pearson) 95% confidence intervals (CIs) around the estimates were used to assess the accuracy of the algorithms in identifying uterine perforation and IUD expulsion.

RESULTS

- The number of possible uterine perforations identified by algorithms at each site ranged from 67 to 444 (see Table 2), and the number of possible IUD expulsions ranged from 268 to 4,185 (see Table 3).
- Two sites refined their algorithms and selected one or two additional possible-case samples.
- PPVs for uterine perforation were 77% for site 1, 81% for site 2, 82% for site 3, and 47% for site 4 (see Table 2).
- PPVs for IUD expulsion were 77% for site 1, 87% for site 2, 68% for site 3, and 37% for site 4 (see Table 3).

Table 2. Uterine Perforation Algorithm Validation Results Within Each Study Site

Study Site	Potential Uterine Perforations Identified by Algorithm	Number Sampled for EHR Review	Case Status After EHR Review			PPV % (95% CI)
			Yes	No	Undetermined	
Site 1	444	100	77	16	7	77 (68-85)
Site 2	388	100	81	19	0	81 (72-88)
Site 3	121	28[b]	23	4	1	82 (63-94)
Site 4	67[a]	30	14	14	2	47 (29-65)

[a] Site 4 identified only the first potential uterine perforation for each woman; the total number of potential uterine perforations was not assessed.

[b] Less than one-third of the total sample because some patients were included in prior samples.

Table 3. Intrauterine Device Expulsion Algorithm Validation Results Within Each Study Site

Study Site	Potential IUD Expulsions Identified by Algorithm	Number Sampled for EHR Review	Case Status After EHR Review			PPV % (95% CI)
			Yes	No	Undetermined	
Site 1	4185	100	77	21	2	77 (68-85)
Site 2	2376	100	87	12	1	87 (79-93)
Site 3	531	103[b]	70	30	3	68 (58-77)
Site 4	268[a]	100	37	61	2	37 (28-46)

[a] Site 4 identified only the first potential IUD expulsion for each woman; the total number of potential IUD expulsions was not assessed.

[b] More than 100 possible cases included because all overlapping possible cases identified in the prior two samples were included.

DISCUSSION AND CONCLUSIONS

- These results suggest that a retrospective study using algorithms to identify the outcomes of uterine perforation and IUD expulsion can be successfully conducted in sites with EHRs.
- Review of possible cases is recommended at the one site that relied solely on unstructured data and in certain subgroups at other sites to reduce misclassification of outcomes.
- EHRs are unique among data sources in the level of detail that is available and in the opportunity they provide to query unstructured data with natural language processing to identify complex variables, such as uterine perforation and IUD expulsion, that are often not identifiable with coded diagnosis or procedure codes.

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