Can Electronic Health Records Be Used to Identify Medical Procedure–Related Events Indicative of Difficult Insertion of Intrauterine Devices?

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BACKGROUND

- Procedure-related information provides context for the placement of a medical device (or drug delivery system) into the human body in contrast to events related to the device itself.

- Many procedure-related events are poorly captured in claims data.

- These data are needed to provide context on product safety within a study requested by regulators.

- One method to potentially obtain meaningful procedure-related data is through electronic health record (EHR) review.

OBJECTIVES

- To assess the potential to collect procedure-related information on difficult insertion of intrauterine devices (IUDs) within 4 EHR systems.

METHODS

- The 4 collaborating sites were 3 Kaiser Permanente sites—Northern California, Southern California, and Washington—and Regenstrief Institute, Indiana.

Figure 1. Data Sources and Research Partner Sites

Kaiser Permanente Washington
Regenstrief Institute
Kaiser Permanente Northern California
Kaiser Permanente Southern California
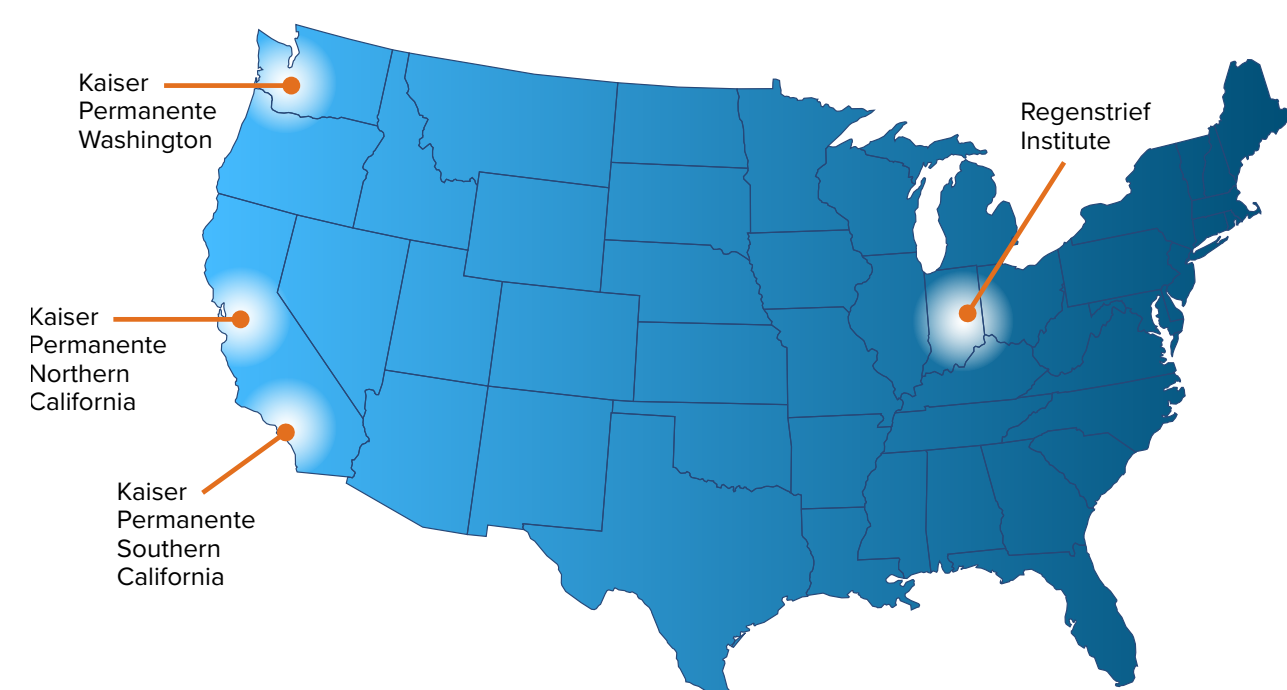
- A stratified random sample of 125 postpartum women receiving IUDs at each site formed the study population.

- Possible indicators of difficult insertion were assessed via structured (National Drug Codes, International Classification of Diseases 9–Clinical Modification [ICD-9-CM], Current Procedural Terminology [CPT]) and unstructured (chart review of clinical notes and/or natural language processing [NLP]) data (Table 1).

Table 1. Example Codes and Terms to Identify Indicators of a Difficult IUD Insertion

Type of Code	Code	Description
Procedure Codes		
CPT	58300 With 22 modifiers	Insertion of IUD, complex or with complication
Diagnosis/Visit Codes		
ICD-9-CM	625.9	Pain and other symptoms associated with female genital organs–unspecified symptom
	996.32	Mechanical complication of genitourinary device, implant, and graft due to intrauterine contraceptive device
	622.4	Stricture or stenosis of cervix
NLP Terms		
Complicated, difficult, challenging, ultrasound guidance, cervical stenosis, consulted, severe *flexion, tight cervical os, misoprostol		

* = Used as wild card.

- Study clinicians recommended criteria that indicate difficult insertion (Table 2), although some of these indicators may reflect clinical circumstances that are different from difficult insertion.

- Additionally, the number of IUDs the provider had inserted in the prior 12-month period was calculated as a possible indicator of clinician experience.

- Descriptive statistics for prevalence were calculated for each site.

RESULTS

- Prevalence of indicators of difficult IUD insertion across sites is listed in Table 3.

- If all indicator categories were considered mutually exclusive, then difficult insertions constitute 4.8%-8.8% of all insertions across sites.

- No site consistently reported the highest or lowest proportion across indicators.

Table 3. Indicators of a Difficult IUD Insertion and Provider Experience

Indicator	Site 1 Sample (N = 125)	Site 2 Sample (N = 125)	Site 3 Sample (N = 125)	Site 4 Sample (N = 125)
Provider notes indicating a "difficult insertion" or "complicated procedure," n (%)	2 (1.6%)	0 (0.0%)	2 (1.6%)	1 (0.8%)
Need for cervical dilation, n (%)	2 (1.6%)	1 (0.8%)	2 (1.6%)	0 (0.0%)
Need for ultrasound guidance, n (%)	1 (0.8%)	4 (3.2%)	1 (0.8%)	2 (1.6%)
Insertion of a second IUD within 30 days, n (%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	1 (0.8%)
Misoprostol dispensed around the time of the IUD insertion, n (%)	0 (0.0%)	1 (0.8%)	2 (1.6%)	2 (1.6%)
Paracervical block procedure used during the IUD insertion, n (%)	1 (0.8%)	0 (0.0%)	2 (1.6%)	0 (0.0%)
Provider IUD insertion experience in the year prior to the index date				
Number of IUD insertions in the past year				
Mean (SD)	41.6 (23.4)	43.4 (31.8)	16.1 (13.4)	N/A
Median	39.0	37.0	14.5	N/A
Q1, Q3	26, 56	22, 53	4, 26	N/A
Min, Max	0, 109	1, 158	0, 63	N/A
< 50 insertions in the previous year, n (%)	83 (66.4%)	87 (69.6%)	122 (98.4%)	N/A

Q1 and Q3 = first and third quartiles; SD = standard deviation.

CONCLUSIONS

- The overall prevalence of indicators of difficult IUD insertion was slightly lower than has been published (8%-9%[1,2]).

- The prevalence of some indicators (e.g., dilation) was lower than previously published, while the prevalence of other indicators (e.g., misoprostol) was similar to previous reports.

- Substantial effort was needed to capture specific, procedure-related information for occasional events.

- We were able to identify indicators of difficult insertion using structured and unstructured EHR data. However, we cannot determine the proportion of the possible indictors that represent true difficult insertions because these indicators may represent other events.

Table 2. Criteria Indicating a Difficult IUD Insertion

Possible Predictors of Difficult IUD Insertion	Methods to Determine	Alternative Explanations (i.e., Not Difficult Insertion)
Second insertion procedure within 30 days	(1) IUD insertion procedure codes (2) Chart review	Possible expulsion of first IUD
Ultrasound guidance during IUD insertion	(1) Ultrasound procedure codes (2) NLP	Ultrasound performed post IUD insertion as standard practice for safe placement
Misoprostol dispensed within 7 days before IUD insertion	(1) Medication dispensing codes (2) NLP	Misoprostol used routinely in subgroups of women (e.g., nulliparous)
Paracervical block	(1) Procedure codes (2) NLP	Paracervical block used routinely by some physicians
Cervical dilation	(1) Procedure codes (2) NLP	Cervical dilation used routinely in subgroups of women (e.g., nulliparous)
Clinician experience	Automated data, number of IUD insertions annually	Number of insertions may not reflect experience level (e.g., fewer difficult insertions may confer more experience than an increased number of easy insertions)
Difficult insertion noted by clinician	NLP	N/A

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Presented at: 34th International Conference on Pharmacoepidemiology & Therapeutic Risk Management; August 22-26, 2018; Prague, Czech Republic