# Are Indicators of Difficult Insertion Among Women with Intrauterine Devices Associated with Uterine **Perforation and Expulsion?**

Mary E Ritchey,1\* Susan Reed,2 Amy Alabaster,3 Darios Getahun,4 Jennifer Gatz,5 Catherine Saltus,6 Mary Anne Armstrong,<sup>3</sup> Fagen Xie,<sup>4</sup> Jinyi Wang,<sup>1</sup> Michael Fassett,<sup>7</sup> Giulia Chillemi,<sup>3</sup> Jeffrey F. Peipert,<sup>8</sup> Shannon Hunter,<sup>1</sup> Laura Ichikawa,<sup>9</sup> Alex Asiimwe,<sup>10</sup> Mary Anthony<sup>1</sup>

RTI Health Solutions





Department of Research & Evaluation Southern California



Kaiser Permanente Washington Health Research Institute



<sup>1</sup>RTI Health Solutions, Research Triangle Park, NC, United States; <sup>2</sup>Kaiser Permanente Washington, University of Washington, Seattle,

Oakland, CA, United States; 4Kaiser Permanente Southern California, Pasadena, CA, United States; 5Regenstrief Institute, Indianapolis, IN,

United States; 6RTI Health Solutions, Waltham, MA, United States; <sup>7</sup>Kaiser Permanente Southern California, Los Angeles, CA, United States; 8Indiana University School of Medicine, Indianapolis, IN,

United States; 9Kaiser Permanente Washington, Seattle, WA, United

WA, United States; <sup>3</sup>Kaiser Permanente Northern California,

**DIVISION OF RESEARCH** Northern California



#### **DISCLOSURES**

RTI Health Solutions, Kaiser Permanente Northern California, Kaiser Permanente Southern California, Kaiser Permanente Washington, and Regenstrief Institute received funding from Bayer AG to conduct this research. The contracts between the research sites and Bayer AG include independent publication rights. The authors had the final decision on the content of this poster.

### **BACKGROUND**

- Approximately 16% of women who use contraception in the United States use long-acting reversible contraceptives such as an intrauterine device (IUD).
- Outcomes such as uterine perforation and IUD expulsion may be associated with difficulty in IUD insertion.

#### **OBJECTIVE**

 To assess difficult IUD insertion as a potential risk factor for uterine perforation and IUD expulsion.

## **METHODS**

- Women aged ≤ 50 years receiving IUDs were identified in each of four sites (three Kaiser Permanente sites—Northern California [KPNC], Southern California [KPSC], and Washington [KPWA]—and Regenstrief Institute [RI], Indiana) in 2001-2018 for a larger study on IUD outcomes.
- Uterine perforation, IUD expulsion, and five indicators of difficult IUD insertion were identified via structured data (National Drug Codes, International Classification of Diseases, Ninth Revision – and Tenth Revision – Clinical Modifications, and Current Procedural Terminology) and/or unstructured data (clinical notes via natural language processing) through June 2018.
- The United States Food and Drug Administration suggested indications of difficult insertion, and study clinicians identified procedures and a medication that might be used if the IUD insertion was difficult. We were unable to determine whether the procedures/medication were used preventatively because of difficulty during the IUD insertion, because other procedures requiring these methods were performed within the same visit, due to a history of difficult insertion, or due to a routine part of clinical practice for some providers.

#### Figure 1. Indicators of Difficult Insertion

Mechanical cervical dilation

Ultrasound use

States; 10Bayer AG, Berlin, Germany

Paracervical block

Misoprostol use for cervical dilation

Provider noted difficult insertion

- The proportion of women experiencing these potential indicators of difficult insertion pooled across sites was assessed overall and separately for women with a uterine perforation or IUD expulsion.
- Univariate (unadjusted) hazard ratios (HR) for difficult insertion indicators were assessed in association with each outcome.

## **RESULTS**

- · Among 326,658 women with IUD insertions, 9% had at least one indicator for a difficult insertion.
- Having any indicator of difficult IUD insertion ranged from 3.5% to 16.3% across study sites.
- The frequency of each indicator of difficult IUD insertion varied across study sites (Table 1).
- Women who experienced uterine perforation (Table 2) and IUD expulsion (Table 3) experienced increased proportions of difficult insertion than the average (Table 1).
- Among women experiencing uterine perforation, having any indicator of difficult IUD insertion ranged from 4.6% to 25.3% across study sites (Table 2).
- Among women experiencing IUD expulsion, having any indicator of difficult IUD insertion ranged from 3.8% to 20.3% across study sites (Table 3).
- Women who had indicators of a difficult insertion had a higher risk for both uterine perforation (HR, 1.38 [95% confidence interval, 1.14-1.68]) and IUD expulsion (HR, 1.16 [95% confidence interval, 1.08-1.24]).
- This slightly higher rate of uterine perforation and IUD expulsion among women with potential difficult insertions was seen across all sites, though there was variability in the specific indicators both across outcomes and by site.

#### Table 1. Indicators of Difficult Insertion: Pooled and by Study Site, First Observed IUD Insertion

	No. of Women	Cervical Dilation n (%)	Ultrasound Use n (%)	Paracervical Block n (%)	Misoprostol Use n (%)	Provider Note n (%)	Any Indicator of Difficult Insertion n (%)
All women	326,658	10,209 (3.1)	4,628 (1.4)	14,731 (4.5)	8,689 (2.7)	2,987 (0.9)	29,777 (9.1)
KPNC	161,442	8,501 (5.3)	3,620 (2.2)	12,788 (7.9)	3,827 (2.4)	1,701 (1.1)	19,685 (12.2)
KPSC	123,214	33 (0.0)	252 (0.2)	1,051 (0.9)	2,329 (1.9)	767 (0.6)	4,273 (3.5)
KPWA	20,526	102 (0.5)	194 (0.9)	654 (3.2)	1,295 (6.3)	230 (1.1)	2,324 (11.3)
RI	21,476	1,573 (7.3)	562 (2.6)	238 (1.1)	1,238 (5.8)	289 (1.3)	3,495 (16.3)

Table 2. Women With Uterine Perforation and Indicators of Difficult Insertion: Pooled and by Study Site, First Observed IUD Insertion

	No. of Women With Uterine Perforation n (%)	Cervical Dilation n (%)	Ultrasound Use n (%)	Paracervical Block n (%)	Misoprostol Use n (%)	Provider Note n (%)	Any Indicator of Difficult Insertion n (%)
All women	1,008	40 (4.0)	25 (2.5)	40 (4.0)	21 (2.1)	27 (2.7)	116 (11.5)
KPNC	529	28 (5.3)	17 (3.2)	30 (5.7)	11 (2.1)	17 (3.2)	70 (13.2)
KPSC	324	0 (0.0)	3 (0.9)	4 (1.2)	3 (0.9)	6 (1.9)	15 (4.6)
KPWA	64	1 (1.6)	4 (6.3)	2 (3.1)	1 (1.6)	1 (1.6)	8 (12.5)
RI	91	11 (12.1)	1 (1.1)	4 (4.4)	6 (6.6)	3 (3.3)	23 (25.3)

Table 3. Women With IUD Expulsion and Indicators of Difficult Insertion: Pooled and by Study Site, First Observed IUD Insertion

	No. of Women With IUD Expulsion n (%)	Cervical Dilation n (%)	Ultrasound Guidance n (%)	Paracervical Block n (%)	Use of Misoprostol n (%)	Provider Note n (%)	Any Indicator of Difficult Insertion n (%)
All women	8,943	352 (3.9)	136 (1.5)	465 (5.2)	213 (2.4)	104 (1.2)	893 (10.0)
KPNC	5,035	315 (6.3)	114 (2.3)	419 (8.3)	103 (2.0)	68 (1.4)	659 (13.1)
KPSC	3,172	4 (0.1)	9 (0.3)	34 (1.1)	56 (1.8)	20 (0.6)	119 (3.8)
KPWA	436	2 (0.5)	9 (2.1)	10 (2.3)	30 (6.9)	7 (1.6)	54 (12.4)
RI	300	31 (10.3)	4 (1.3)	2 (0.7)	24 (8.0)	9 (3.0)	61 (20.3)

# **CONCLUSIONS**

- We were able to identify indicators of difficult insertion using structured and unstructured data.
- The prevalence of difficult insertion indicators in the complete study population (9%) was similar to published data from prospective studies (8%-9%) and was higher among women with uterine perforations and IUD expulsions.
- Differences in prevalence of difficult insertion exist across study sites and may suggest differences in modes of data collection, patient characteristics, or clinician practice. However, we cannot determine the proportion of indicators that represent true difficult insertions.

# **CONTACT INFORMATION**

Mary Anthony, PhD Senior Director, Epidemiology

RTI Health Solutions 3040 Cornwallis Road Research Triangle Park, NC

Phone: +1.919.485.5509 E-mail: manthony@rti.org