



# Standardizing early aspiration abortion complication definitions and tracking:

## Testing an evidence-based framework

Diana Taylor, PhD, RNP, Eleanor A. Drey, MD, EdM, Richard L. Fischer, MD, Mary Gatter, MD, Melty Battistelli, Rebecca Kriz, RN, Tracy A. Weitz, PhD, MPA

#### Background

National patient safety tracking frameworks for identifying procedural complications (for non-abortion procedures) define adverse events by diagnoses (ICD codes), treatments (CPT codes) and outcomes which include uniform definitional criteria. Published data on first-trimester aspiration abortionrelated complication diagnoses and treatments range from 1.3% to 4.4% (+/- 1%) are based on data from nine peerreviewed papers with a combined sample size of 180,710 aspiration abortion procedures published between 1990-2009.1-8

Wide variation exists across these nine studies in 1) the confounding of immediate and delayed abortion complications; 2) the definition of major and minor complications;<sup>5</sup> 3) the definition of the complication type; 4) the criteria for treatment of post-abortion pain/bleeding symptoms distinct from hemorrhage or hematometra; 5) the use of "reaspiration" as a diagnosis and a treatment; 6) the lack of diagnostic criteria that includes etiology or confirmatory data to support a particular diagnosis; and 8) lack of specificity in describing patient outcomes.

### Purpose of study

The purpose of this study was to develop and evaluate a standardized method of assessing immediate and delayed abortion-related complications based on national patient safety methods for non-abortion procedures.

#### Methods

We are evaluating a systematic method for defining and tracking early aspiration abortion (<14 weeks) incidents as part of a larger IRB-approved study of early aspiration abortion provision outcomes. We evaluated a minimum dataset and standardized coding methods developed by expert clinician consensus and quality improvement experts reflecting ten patient diagnoses (abortion-related and non-abortion related), treatments (type/location) and outcomes for monitoring both abortion complications and non-abortion related incidents.

This methodology reflects a national model of adverse event reporting elements for monitoring immediate and delayed incidents associated with abortion procedures and includes post-abortion patient tracking methods (e.g., patient calls or visits and outside provider reports). Between 2007-2010, this standardized diagnosis, treatment and outcome process was used to report incidents by 107 abortion clinicians performing first-trimester aspiration abortion procedures on 7,423 patients.

#### Results

Major findings from this empirically tested model:

- Differentiation of incidents by incident type:
- Abortion-related complications include cases where there is a confirmed diagnosis of incomplete abortion, failed abortion, hemorrhage/ excessive bleeding, hematometra, infection, cervical injury, uterine perforation, symptomatic intrauterine material (SIM), anesthesia-related complication, or an "other" diagnosis determined by the study's safety monitoring board to be abortion-related (Rate = 1.3%, n=96).
- Non-abortion-related incidents include concurrent medical problems which are diagnosed and/or treated at the time of the abortion procedure (e.g., ectopic or molar pregnancy, pre-existing medical condition, infection present at the time of the procedure, and bleeding or hemorrhage secondary to anemia or uterine abnormality) (Rate = 0.3%, n=20).
- System incidents include cases in which a patient self refers to a hospital but does not receive an abortion-related diagnosis or treatment (e.g. observation only) (Rate = 0.1%, n=7).
- Specification of the timing of the abortion-related compli-
- Immediate: incident occurs during the procedure, or while the patient is recovering (0.2%, n=16 immediate complications).
- Delayed: incident occurs after the patient leaves the clinic and up to 4 weeks after the procedure (1.1%, n=80 delayed, confirmed complications).
- Specification of the definition of major abortion-related complication: Defined as those "complications requiring abortion-related surgeries, transfusion or hospitalization." None have occurred.
- Standardized complication diagnoses with etiology and confirmatory criteria for
- incomplete abortion, failed abortion, hemorrhage and hematometra;

#### Early abortion diagnoses/treatments/outcomes (encountered vs. published rates)

		. 13123	. 3.13 1.31 1.33
Aspiration abortic	n complica	ations by dia	ignosis
Successful, uncomplicated	7,327	98.7%	95.9–99.1 <sup>3,4,7</sup>
Incomplete abortion	22	0.3%	0.2-4.4%1,2,4,5,7-9
Failed abortion (cont pg)	11	0.1%	0.4-2.3% <sup>2,4-7</sup>
Infection	10	0.1%	0.1-2.6%2-4,6-8
Post-abortal hematometra	12	0.2%	0.1-2.2%1,2,7
Uterine perforation	2	0.0%	0.2-0.7%1-4
Cervical injury	1	0.0%	0.0-1.1%1-8
Symptomatic intra-uterine material (SIM)	29	0.4%	NA
Hemorrhage >150 cc	1	0.0%	0.1-0.4%1-3,7
Anesthesia-related	0	0.0%	0.0- 0.1%4,8
Missed ectopic pregnancy	0	0.0%	0.0-0.3%
Other diagnoses	8	0.1%	N/A
Other diagnoses (no	t directly re	lated to abo	ortion)
Diagnosed ectopic pregnancy	6	0.0%	0.03-0.33%10
Diagnosed molar pregnancy	4	0.0%	0.01-0.04% 11,12
Uterine abnormality	2	0.0%	NA
Other diagnosis	8	0.1%	NA
Treatments for abortion-	related diag	gnoses/comp	olications
Reaspiration	57	0.8%	2 to 4.7% <sup>1,6</sup>
Repeat abortion	9	0.1%	0.036-2.3%6,7
Medications (non IV)	43	0.6%	NA
IV medications	1	0.0%	0.3 to 4.4%
Hospital or ER transfer	0	0.0%	0.07-0.1%1
Surgical treatment	0	0.0%	0.0-0.1%
Outcomes for abortion-r	related diag	noses/comp	lications
Diagnosis resolved	93	98.7%	NA
Unable to complete abortion	1	0.0%	0.87%
Λ οΙ, το το ο το τέσο στο σ		0.00/	NΙΛ

post-abortion pain/bleeding symptoms (SIM) distinct from hemorrhage or hematometra;

0.0%

NA

NA

Adverse outcome

Unknown outcome

- Improved precision and specificity in the estimation of abortion-related complication diagnoses.
- The most frequently reported complications were SIM (post-abortion pain/bleeding that did not meet the criteria for hemorrhage, 0.4%, n=29), hematometra (0.2%, n=12) and incomplete abortion (0.3%, n=22).
- Clarification of reaspiration as a treatment for incomplete abortion, SIM (patient or provider preference), or hematometra.

#### Conclusion

With improved precision and specificity in defining abortionrelated incidents by diagnosis, treatment and outcomes, all complication rates associated with early aspiration abortion procedures performed were lower than published rates<sup>1-8</sup>. This systematic framework for defining and tracking abortion complications across the continuum of care will allow evidence-based comparisons with national clinical effectiveness assessment standards for other common, low-risk, outpatient procedures and can be used in all settings including primary care sites.

#### References

- <sup>1</sup>Goldberg, A.B., et al., Manual versus electric vacuum aspiration for early firsttrimester abortion: a controlled study of complication rates. Obstet Gynecol, 2004. 103(1): p. 101-7.
- <sup>2</sup>Goldman, M.B., et al., *Physician assistants as providers of surgically induced* abortion services. American Journal of Public Health, 2004. 94(8): p. 1352-7.
- <sup>3</sup>Hakim-Elahi, E., H.M. Tovell, and M.S. Burnhill, Complications of firsttrimester abortion: a report of 170,000 cases. Obstet Gynecol, 1990. 76(1): p. 129-35.
- <sup>4</sup>Westfall, J.M., et al., *Manual vacuum aspiration for first-trimester abortion.* Arch Fam Med, 1998. 7(6): p. 559-62.
- <sup>5</sup>Macisaac, L. and P. Darney, *Early surgical abortion: an alternative to and* backup for medical abortion. Am J Obstet Gynecol, 2000. 183(2 Suppl): p. S76-83.
- <sup>6</sup>Paul, M.E., et al., *Early surgical abortion: efficacy and safety.* Am J Obstet Gynecol, 2002. 187(2): p. 407-11.
- <sup>7</sup>Bennett, I.M., et al., *Early abortion in family medicine: clinical outcomes.* Ann Fam Med, 2009. 7(6): p. 527-33.
- <sup>8</sup>Warriner, I.K., et al., Rates of complication in first-trimester manual vacuum aspiration abortion done by doctors and mid-level providers in South Africa and Vietnam: a randomised controlled equivalence trial. Lancet, 2006. 368(9551): p. 1965-72.
- <sup>9</sup>Healing Arts and Institutions, Sec 2 Definitions, in West's California Jurisprudence 3d. 2007, Thomson West: Danvers, MA. p. 205.
- <sup>10</sup>Lehner, R., et al., *Ectopic pregnancy*. Arch Gynecol Obstet, 2000. 263(3): p. 87-92.
- <sup>11</sup>Wulff, G.J., Jr. and S.M. Freiman, *Elective abortion. Complications seen in a* free-standing clinic. Obstet Gynecol, 1977. 49(3): p. 351-7.
- <sup>12</sup>Kiel, F.W., The medical value of examining tissue from therapeutic abortions: an analysis of 13,477 cases. Br J Obstet Gynaecol, 1986. 93(6): p. 594-6.