An Analysis of Patient Safety Events Submitted by Abortion Facilities in Pennsylvania 2017–2019

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DOI: 10.33940/data/2020.12.5

Disclosure: The author declares that they have no relevant or material financial interests.
Induced abortion, also called elective abortion, therapeutic abortion, and termination of pregnancy, is widely considered a safe procedure, but complications are known to occur. In Pennsylvania, an induced abortion may be performed at an abortion facility as an outpatient procedure, and these facilities are required to report patient safety events to the Pennsylvania Patient Safety Reporting System (PA-PSRS). We extracted 736 events submitted to PA-PSRS by abortion facilities from 2017 through 2019 and analyzed these events in order to better understand patient safety concerns at abortion facilities in particular. All patients were female, and they ranged in age from 14 to 47 years, with a median patient age of 27 years (interquartile range = 23 to 31 years). Complications related to an induced abortion included failed abortions (i.e., a continuing intrauterine pregnancy following an abortion; n=103), infections (e.g., endometritis and pelvic inflammatory disease [PID]; n=45), and surgical complications (e.g., hematometra, uterine perforation, and cervical lacerations; n=66). The remainder of events (14.5%; n=107) described other patient safety events that occurred at abortion facilities, such as documentation failures and medica-
tion-related events.

Keywords: abortion complication, incomplete abortion, failed abortion, hematometra, endometritis, uterine perforation, patient safety

Introduction
Induced abortion, also called elective abortion, therapeutic abortion, and termi-
nation of pregnancy, is the removal of pregnancy tissue (i.e., an embryo or fetus) from the uterus. Induced abortion is accomplished through the use of medications (termed medical abortion or medication abortion) or surgical tech-
niques (termed surgical abortion), or some combination of the two. Medical abortions are offered up to 10 weeks esti-
mated gestational age (EGA); surgical abortions are more common for abor-
tions at nine weeks EGA and beyond. In the United States, the most common medication regimen utilized for medical abortion is a combination of mifepristo-
tone 200 mg followed 24 to 48 hours later by misoprostol 800 mcg (typically adminis-
tered vaginally or buccally). The most common surgical abortion proce-
dures are vacuum aspiration, dilation and curettage (D&C), and dilation and evacuation (D&E).

Although induced abortion is widely con-
sidered a safe procedure, complications are known to occur. Many patients hav-
ing a medical abortion will experience pain and bleeding during or after the pro-
cess as the pregnancy passes; pain is also common for patients undergoing surgical abortion. The most common complica-
tions associated with induced abortion is an incomplete abortion; other complica-
tions include failed abortion, infections (e.g., endometritis and pelvic inflammatory disease [PID]), and surgical complica-
tions (e.g., hematometra, uterine perforation, and cervical lacerations). Medications, procedures, and potential complications related to induced abortion are detailed in Table 1.

In Pennsylvania, abortions may be per-
formed at licensed abortion facilities, and any abortion facility that performs more than 100 abortions per calendar year is required to report patient safety events to the Pennsylvania Patient Safety Reporting System (PA-PSRS). The Pennsylvania Department of Health (PA DOH) has been monitoring and reporting data related to abortions since 1975, but the patient safety report forms used by PA-PSRS are typically more detailed than the information included in the annual reports published yearly by the PA DOH and may therefore provide greater insight into abortion complications and other patient safety events that occur at abortion facilities. For this reason, we performed an analy-
sis of all patient safety events submitted to PA-PSRS by abortion facilities over a three-year period to better understand associated patient safety concerns that arise at abortion facilities.

We extracted all event reports submitted to PA-PSRS by abortion facilities from January 1, 2017, through December 31, 2019. All event reports were included in this analysis.

A descriptive analysis was performed to evaluate trends among information specified by the reporting facility, including patient age, event classification and outcome, event type, and event type sub-
(s). An in-depth qualitative analysis of free-text fields (i.e., event detail, event comments, event recommendation, and event type sub-
type(s)) was performed to collect pertinent information (if specified) that would allow better characterization of patient safety event events. For event reports that included details about an abortion complication, the following information was coded (if specified):

- Abortion type (i.e., medical or surgical)
- Estimated gestational age (EGA)
- Abortion complication(s)
- Treatment modalities, including medications, used to manage abortion complication(s)

Relationships between key variables, such as abortion complication, abortion type, and treatment modalities, were also explored.

Table 1a: Induced Abortion: Medications and Procedures

| Medications | Dosage Form | Route of Administration | Mechanism of Action |
|-------------|-------------|-------------------------|---------------------|
| Mifepristone (Mifepristone) | Tablet | Oral | Blocks the production of reduced folate, which is necessary for cell reproduction and DNA synthesis |
| Misoprostol (Cytotec) | Tablet | Oral | Causes uterine contractions and cervical dilation |
| Methotrexate (Trexall) | Tablet | Oral | Causes a failed or incomplete abortion |

Potential Complications of Induced Abortion

- Failed abortion
- Complication that results when an induced abortion fails to terminate the pregnancy and an ongoing pregnancy is identified in the uterus
- May also be termed retained pregnancy, retained products of conception (RPC), or intrauterine debris

Table 1b: Induced Abortion: Complications

| Complication | Description |
|--------------|-------------|
| Hematometra | Blood accumulation in the broad ligament, which is a peritoneal fold that attaches the uterus, fallopian tubes, and ovaries to the pelvis |
| Pelvic inflammatory disease (PID) | Pelvic infection that is usually a sexually transmitted disease |
| Uterine perforation | Tear or cut in the uterus that may result from a surgical abortion |
| Cervical laceration | Tear or cut in the cervix that may result from a surgical abortion |
| Ovarian vein thrombosis | Blood clot that forms in the ovarian vein and obstructs blood flow |
| Uterine rupture | Failure of the uterine wall to rupture during the delivery of the fetus |
| Vaginal laceration | Tear or cut in the vagina that may result from a surgical abortion |
| Vasovaginal reaction | Type of reflex syncope that results from a failure of blood pressure autoregulation |

In the setting of surgical abortion, this may be caused by the use of somatic dilators for cervical dilation.
Results

Descriptive Analysis

We analyzed 736 events submitted by abortion facilities in Pennsylvania from January 1, 2017, through December 31, 2019. Most events were classified by the reporting facility as a complication of a procedure, treatment, or test (84.2%; 620 of 736); within this category, events were most often specified as “other complication following surgery or invasive procedure” (59.3%; 344 of 620) or simply as “other” (36.1%; 224 of 620). Event classification (incident versus serious event) and harm score for all events are detailed in Figure 1; the vast majority of events were classified as incidents (86.8%; 639 of 736) with an assigned harm score of D (75.8%; 558 of 736), which indicates that the patient did not sustain harm as a result of the event. No events resulted in patient death. All patients were female, and they ranged in age from 14 to 47 years, with a median patient age of 27 years (interquartile range=23 to 31 years).

All events except 1 were in some way related to an induced abortion (either stated directly or implied); the 1 remaining event described an expelled contraceptive implant. About three-quarters (71.7%; 527 of 736) of events described a patient who experienced one or more complications related to an abortion, and 102 events (13.9%) described a patient who had an immediate unplanned transfer to the emergency department (ED) following an induced abortion, or later unplanned acute visit to the abortion facility or an ED following an induced abortion. The remaining 106 events (14.4%) were unrelated to an abortion complication and described procedural or administrative issues surrounding an induced abortion performed at the abortion facility, such as documentation failures or medication-related events.

In-Depth Qualitative Analysis of Abortion Complications

Among 527 events that described at least one abortion complication, patients more often had undergone a medical abortion (69.1%; n=364) than a surgical abortion (30.4%; n=163); 3 events did not specify the type of abortion. EGA was specified for 380 of these events and ranged from 4 to 23 weeks.

Events were categorized into three groups of abortion complications: retained pregnancy or pregnancy tissue (84.3%; 444 of 527), surgical complications (12.5%; 66 of 527), and infections (8.5%; 45 of 527). Complication groups were not mutually exclusive, and 28 patients experienced complications in two of the three groups, e.g., a surgical complication and an infection (see Figure 2); Abortion complications categorized by complication type and year are summarized in Table 2.

Retained Pregnancy or Pregnancy Tissue

Among 444 events involving a retained pregnancy or pregnancy tissue, incomplete abortions (77.3%; n=343) were far more common than failed abortions (22.7%; n=101). Overall, among 426 events that specified one or more treatments for a failed or incomplete abortion, the most common treatment was a D&C; treatments for failed and incomplete abortions grouped by abortion type are detailed in Table 3.

Among 350 events in which a patient was diagnosed with a failed or incomplete medical abortion, the patient received an additional dose of misoprostol as second-line treatment in 94 events (26.9%). In nearly one-third (33.9%; 31 of 94) of these events the patient required third-line treatment, and the most common third-line treatment was a D&C (37.8%; 27 of 31).

Note: PID indicates pelvic inflammatory disease.
Infections
Infections‡‡ were observed more often following a medical abortion (55.6%; 20 of 36) than a surgical abortion (42.9%; 19 of 45); the type of abortion was not specified in 1 event that involved an infectious complication. The most common infections were endometritis/PID** (66.7%; 30 of 45) and urinary tract infections (15.6%; 7 of 45); other infectious complications included sepsis and group B streptococcal infection. Endometritis/PID occurred with roughly the same frequency following a medical abortion (53.3%; 16 of 30) or a surgical abortion (46.7%; 14 of 30).

Among 45 events involving an infectious complication, 42 events (93.3%) specified that the patient received antibiotic therapy, and 13 events indicated that the patient underwent a cesarean delivery prior to the procedure. Among 26 patients who were diagnosed with endometritis, 10 patients were treated with a D&C, and 8 patients were treated with MVA. Among 23 patients who experienced a uterine perforation, 6 patients underwent laparoscopy to confirm and/or repair the perforation, and 3 patients required a hysterectomy.

Other Unplanned Transfer or Acute Visit Following Induced Abortion
Following an abortion procedure, 102 events (33.9%; N=736) involved an unplanned transfer or acute visit; among events that specified the type of abortion procedure, patients had more often undergone a medical abortion (n=84) than a surgical abortion (n=52). Eight patients were immediately transferred to an ED for evaluation of a possible complication (e.g., uterine perforation, elevated blood pressure, or excessive bleeding); these patients were treated and released following confirmation that a complication had not occurred, or the details of their visit were not specified or not known.

An additional 94 patients had an unplanned visit to a healthcare facility (i.e., the abortion facility, an urgent care clinic, or an ED) at some time after their procedure for evaluation of symptoms. Apart from bleeding, which we analyzed across all events (see below, Other Trends), the most common presenting symptoms overall were pain or cramping (n=46), dizziness or fainting (n=12), and nausea or vomiting (n=9); other complaints included fever, flu-like symptoms, dehydration, hypertension, shortness of breath, chest pain, and weakness. Among 46 patients that reported pain or cramping, 27 patients received analgesics, most of which were nonsteroidal anti-inflammatory medications, which included acetaminophen, nonsteroidal anti-inflammatory drugs, and opioids.

Brief Analysis of Other Patient Safety Events Unrelated to an Abortion Complication
The remaining 106 events (14.4%; N=736) that were not related to an abortion complication or an unplanned transfer or acute visit following an induced abortion are summarized in Figure 3. Over one-quarter (27.4%; 29 of 106) of events involved documentation errors (e.g., patient or provider did not sign consent or provider did not document procedure or monitoring), and another one-quarter (24.5%; 26 of 106) of events involved medication (e.g., patient left the facility without her prescription, patient was not given RhogAM® as indicated, or patient was dispensed the wrong medication). The other half of events (47.2%; 50 of 106) fell into one of five groups: (1) patient nonadherence (e.g., patient signed out against medical advice prior to the completion of the observation period or patient used an illicit substance prior to the procedure); (2) change in procedure from surgical abortion to medical abortion or vice versa, often related to an incorrect EGA or complicated patient anatomy; (3) patient experienced an adverse reaction following procedure while still at the facility (e.g., fall or heavy bleeding); (4) patient had a preexisting condition that precluded continuing with the induced abortion or required additional treatment following the procedure (e.g., patient had a history of ovarian vein thrombosis, broad ligament hematoma, and uterine rupture secondary to placenta increta); and (5) patient was treated and released following procedure while still at the facility (e.g., fall or heavy bleeding). Among the 94 events involving an infectious complication, 42 events (93.3%) specified that the patient received antibiotic therapy, and 13 events indicated that the patient was treated and released following confirmation that a complication had not occurred, or the details of their visit were not specified or not known.

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Discussion
To our knowledge, our analysis is the first to examine patient safety reports related to induced abortions and complications submitted solely by abortion facilities. In addition, the information available in the reports submitted to PA-PSR is more detailed than what is available in state or national abortion surveillance reports, and so our analysis is able to provide a unique perspective on the topic of abortion complications.

Recent annual reports of abortion statistics published by the PA DOH indicate that women more frequently undergo surgical abortions than medical abortions, with surgical abortions accounting for roughly 60% of procedures performed in 2017 and 2018. However, complications were observed more often following medical abortions in both our analysis and in annual reports of abortion statistics in Pennsylvania, and the most common complication we observed with medical abortion was the failure to complete an induced abortion or its follow-up.

Although the choice of induced abortion is dictated in part by the EGA, patients often do have clear preferences for one procedure type over another that may include considerations other than success rates. In a study of women’s preferences regarding induced abortion, women who were eligible for either a medical or surgical abortion based on EGA selected a medical abortion 68% of the time. Medical abortion offers a

Table 3: Treatments for Incomplete and Failed Abortions by Abortion Type, N=426

| Procedure                        | Surgical | Medical | Total |
|----------------------------------|----------|---------|-------|
| Dilation and Curettage           | 1        | 41      | 42    |
| Misoprostol                      | 1        | 19      | 20    |
| Aspiration                       | 1        | 11      | 12    |
| Expected Management              | 0        | 4       | 4     |
| Dilatation and Evacuation        | 2        | 6       | 8     |
| Unscheduled Surgical Procedure   | 3        | 0       | 3     |
| Other                            | 1        | 6       | 7     |

Note: “Other” includes sutures, hysterectomy, salpingectomy, and laparoscopy.

6Failure of a pregnancy that goes beyond the scope of this analysis, as the Patient Safety Authority does not have access to patient-specific clinical data related to event reports. Events were coded as infections if the facility reported them as such.
7Endometritis and PID were grouped together because endometritis is a diagnosis that falls under the umbrella of PID, and treatment of the two infections is similar.
8Placenta increta is a complication of pregnancy in which placental tissue invades the myometrium.
Bleeding is an anticipated complication of any induced abortion and was frequently reported in our study across all procedures. In the absence of infection, post-abortion bleeding may be a signal that the procedure has failed and further intervention may be required.1

Worldwide, infectious complications are associated with approximately 2% of induced abortions and mortality following induced abortion, especially in areas where access is limited or induced abortions are illegal.2 In the United States, infections following induced abortion are rare, and we do not assess patient safety at this specific abortion type here. Uterine perforation was the second most common surgical complication observed in our study, and variation in treatment depended on the clinic management system. Uterine perforation in the first trimester of pregnancy is low risk and may be managed with conservative observation.3 In contrast, perforation following a D&E may result in more severe complications (e.g., bowel injuries) and may require more invasive exploration and intervention (e.g., laparoscopy, laparotomy, hysterectomy).4 Notably, uterine perforation is the most common complication of a surgical intervention that necessitates a hysterectomy.5

In contrast to the low risk category, some surgical complications may cause a severe threat to a patient's health. Uterine rupture, the latter of which involved a hysterectomy and may require more invasive exploration and intervention (e.g., laparoscopy, laparotomy, hysterectomy).4 Notably, uterine perforation is the most common complication of a surgical intervention that necessitates a hysterectomy.5

Although it may be desirable to assess the safety of induced abortions by calculating rates of abortion complications in the state of Pennsylvania, this is beyond the scope of our study. Although the PA DHMH publishes an annual report of abortion statistics, they do not specify where procedures were performed.10,11 For our study, we only extracted patient safety events submitted to PA FRB by abortion facilities, as our objective was to broadly assess patient safety at this specific subset of facilities rather than to further detail the complications associated with induced abortion at all types of facilities. In order to further investigate this, we submitted by hospitals and physician practices as well as events that may have taken place at abortion facilities that provide fewer than 100 abortions per year, and this may also limit the generalizability of our findings to other clinical settings.

Despite mandatory event-reporting laws in Pennsylvania, our data are subject to the limitations of self-reporting. Because the data included in each event report are left up to the discretion of the reporter, some information was missing or incomplete for some events, such as EGA, abortion type, and infection type. Standard criteria for what constitutes an abortion complication have not been established, and the definitions we found were varied, so we attempted to design a framework for classification based on our available data and the most recent literature, which may also limit comparison of our findings with other studies.

Conclusion
Current data and research regarding induced abortions in the United States have demonstrated their safety. In our study, we observed that the vast majority of patient safety events reported by abortion facilities in Pennsylvania did not result in patient harm, although some may require interventions to ensure a successful outcome. Incomplete abortion was the most common surgical complication observed in our study and in the literature, and these were observed more often following medical abortions. The most common infectious complication of an induced abortion was endometritis/PID, which was typically treated with antibiotics. The most common surgical complications were hematometra and uterine perforation/rupture, the latter of which involved more severe and invasive treatments, up to and including hysterectomy. In the future, we recommend the development of a clinical audit to help ensure consistent documentation of abortion complications prospectively in order to collect specific data that may allow researchers to more definitively connect patient-specific factors, such as patient age and EGA, with specific induced abortions and associated complications.

Notes
This analysis was exempted from review by the Advarra Institutional Review Board.

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