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Association of Facility Type With Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions

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1Association of abortion facility type with procedural-related
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36**Key points**

37**Question:** Is there an association between the type of facility in which an
38abortion is performed and abortion-related morbidities and adverse events?

39**Findings:** In this retrospective cohort study of 50311 induced abortions
40among 49287 women with private health insurance, performance of the
41abortion in an ambulatory surgery center, compared with an office-based
42setting, was not associated with a significant difference in abortion-related
43morbidities and adverse events (adjusted odds ratio, 0.97).

44**Meaning:** Rates of abortion-related morbidities and adverse events did not
45significantly differ by whether the abortion was performed in an ambulatory
46surgery center vs. an office-based setting.

47

48**Abstract**

49**Importance**

50Multiple states have laws that require abortion facilities to meet standards of
51ambulatory surgery centers (ASCs). There is limited evidence regarding the
52occurrence of abortion-related morbidities and adverse events following
53abortions performed at ASCs compared with office-based settings.

54**Objective**

55To compare abortion-related morbidities and adverse events at ASCs versus
56office-based settings.

57**Design, Setting, and Participants**

58Retrospective cohort study of 49287 women continuously enrolled in US
59private health insurance who had 50311 induced abortions in an ASC or
60office-based setting January 1, 2011 - December 31, 2014. Outcomes were
61ascertained during the six weeks subsequent to the abortion using claims
62data from a large national private insurance claims database. The final
63follow-up date was February 11, 2015. Analyses were adjusted for age,
64abortion type, diabetes, hypertension, previous health care visits, year, and
65region.

66**Exposure**

67Facility type (ASCs vs. office-based settings, including facilities such as
68abortion clinics, non-specialized clinics, and physician offices) in which the
69abortion was performed. Facility type was based on the standardized place-
70of-service code variable used for health care billing purposes.

71 **Main Outcomes and Measures**

72 The primary outcome was any abortion-related morbidity or adverse event
73 (such as retained products of conception, abortion-related infection,
74 hemorrhage, and uterine perforation) that received an abortion-related
75 diagnosis or treatment code from any source of health care within six weeks
76 of the abortion. The two secondary outcomes, both subsets of the primary
77 outcome, were major abortion-related morbidities and adverse events (such
78 as hemorrhages treated with a transfusion, missed ectopic pregnancies
79 treated with surgery, and abortion-related infections that resulted in an
80 overnight hospital admission) and abortion-related infections.

81 **Results**

82 Among 49287 women (mean age 28 [SD 7.31]) who had 50311 induced
83 abortions, (23891 [47%] first-trimester aspiration, 13480 [27%] first-
84 trimester medication, and 12940 [26%] second-trimester or later), 5660
85 (11%) of abortions were performed in ambulatory surgery centers and 44651
86 (89%) were performed in office-based settings. Overall, 3.33% had an
87 abortion-related morbidity or adverse event; 0.32% had a major abortion-
88 related morbidity or adverse event; and 0.74% had an abortion-related
89 infection. In adjusted analyses, there was no statistically significant
90 difference between ASCs versus office-based settings, respectively, in the
91 rates of abortion-related morbidities or adverse events [3.25% v. 3.34%,
92 difference -0.8%, 95% CI -0.58% - 0.43%; aOR 0.97, 95% CI 0.81 - 1.17],
93 major morbidities or adverse events [0.26% v. 0.33%, difference -0.06%,

9495% CI -0.18% - 0.06%; aOR 0.78, 95% CI 0.45 – 1.37], or infections [0.58%
95v. 0.77%, difference -0.16%, 95% CI -0.35% - 0.03%; aOR 0.75, 95% CI 0.52 –
961.09].

97**Conclusions and Relevance**

98Among women with private health insurance who had an induced abortion,
99performance of the abortion in an ambulatory surgery center, compared with
100an office-based setting, was not associated with a significant difference in
101abortion-related morbidities and adverse events. These findings, in addition
102to individual patient and individual facility factors, may inform decisions
103about the type of facility in which induced abortions are performed.

104**Introduction**

105 In June 2016, the U.S. Supreme Court ruled in *Whole Woman’s Health*
106vs. *Hellerstedt* that Texas’s law requiring abortion facilities to meet
107ambulatory surgery center (ASC) standards was unconstitutional.¹~~Despite~~
108~~this ruling,~~ Thirteen~~eight~~ states currently enforce~~have~~ laws that require
109~~licensing standards for~~ abortions facilities that are comparable to the state’s
110~~licensing standards for~~ to be performed in ASCs.² These laws include such
111requirements as specified hall and door widths or separate procedure and
112recovery rooms.² Many of these apply only at a specific gestational week (or
113gestational duration), typically in the second-trimester.² Supporters of ASC
114laws have argued that ASC requirements make abortion safer.¹

115 Limited published peer-reviewed research has directly compared
116abortion-related morbidities and adverse events across facility types. One

117study found fewer abortion-related events in clinics than hospitals³ and a
118recent review found similar rates of abortion-related events after first
119trimester abortion procedures across study populations in different facility
120types, including hospitals, ASCs, and office-based settings.⁴

121 More than 95% of induced abortions are provided in outpatient, non-
122hospital-based settings – in abortion clinics, non-specialized clinics, or
123physician offices.⁵ Abortions have been performed in office-based settings,
124including abortion clinics, non-specialized clinics, and physician offices, for
125more than forty-five years.⁶ ASCs developed in the 1980s to move some
126surgeries and procedures from hospitals to non-hospital-based outpatient
127settings.⁷ In the 2000s, some states began passing laws that required
128abortions to be provided in ASCs, and some abortion clinics that had been
129office-based settings became licensed as ASCs to continue to perform
130abortions.⁸ There are no published national estimates of the proportion of
131abortions performed in ASCs v. office-based settings; state-specific data
132indicate that the minority of outpatient abortion facilities are ASCs.^{9,10} The
133present study used a private insurance claims database to compare
134abortion-related morbidities and adverse events at ASCs versus office-based
135settings.

136**Methods**

137Study design

138 This retrospective cohort study used 2011-2014 data from the Truven
139Health MarketScan® Commercial Claims and Encounters database to

140compare abortion-related morbidities and adverse events across two facility
141types, ASCs and office-based settings. The University of California, San
142Francisco Institutional Review Board considered this study exempt and thus
143informed consent was not required. The Penn State Institutional Review
144Board considered this study not human subjects research.

145Data source

146 The Truven Health MarketScan Commercial Claims and Encounters
147database is a commercially available health insurance claims database. It
148includes claims data for a sample of privately-insured people in all 50 U.S.
149states, including demographic characteristics (i.e., age and sex), health care
150utilization, dates of service, diagnosis codes, procedure codes, and facility
151type. The data represent claims from clinicians, hospitals, and pharmacies
152that have been adjudicated for payment and are obtained directly from a
153convenience sample of large employers and health plans that agree to
154participate in MarketScan. While no attempts are made to correct or change
155information received from the participating employers and health plans,
156Truven Health has a quality control process to verify that the data meet
157criteria for quality and completeness.¹¹ The database only includes data from
158fully paid and adjudicated claims and the diagnosis and procedure codes are
159compared to codes in effect when raw data were collected, and edited as
160necessary.¹¹ This database has been used in other studies examining
161complications and follow-up care after health care procedures.^{12,13}

162Study population

163 The study population included all beneficiaries in this database who
164 were 11 years and older who had an induced abortion between January 1,
165 2011 and December 31, 2014 in an ASC or office-based setting and who
166 were enrolled in their insurance plan for at least one year prior to the index
167 abortion and at least six weeks after the abortion. Current Procedural
168 Terminology (CPT) codes used to identify abortions are listed in eTable 1.
169 Ectopic pregnancies diagnosed and/or treated within 7 days of the abortion
170 and molar pregnancies were excluded, as ectopic pregnancies and molar
171 pregnancies receive different treatments than abortions and have different
172 expected potential morbidities and adverse events.

173 Exposure

174 Facility type was identified based on the standardized place-of-service
175 code variable, which indicates the setting where the service occurred.
176 Settings in the standardized place-of-service code variable are defined by
177 the Centers for Medicare and Medicaid Services and used across health care
178 billing.¹⁴ There are 50 different possible settings that include settings such as
179 schools, homeless shelters, inpatient hospital, skilled nursing facilities, and
180 others.¹⁵ Facility type was classified as ASC when the standardized place-of-
181 service code variable (stdplac) equaled 24 (“Ambulatory Surgery Center”)
182 and office-based setting when the place-of-service code variable equaled 11
183 (“Office”), which includes most office-based settings.¹⁵ These settings
184 included facilities such as abortion clinics, non-specialized clinics, and
185 physician offices. Abortions performed in other settings were excluded.

186 Outcomes

187 The primary outcome was abortion-related morbidities and adverse
188 events occurring within six weeks of the abortion. Secondary outcomes,
189 which were both subsets of the primary outcome, were major abortion-
190 related morbidities and adverse events and abortion-related infections.

191 Per methods published in a recent study of abortion-related events
192 using billing data, abortion-related events were estimated by examining and
193 evaluating all diagnoses and treatments at all health care encounters on the
194 day of and within six weeks of the abortion.³ Each index abortion was coded
195 as to whether an abortion-related morbidity or adverse event occurred within
196 the six weeks subsequent to the abortion. Events were defined as any
197 abortion-related morbidity or adverse event that received an abortion-
198 related diagnosis or treatment code at any care location, including
199 emergency departments (EDs), the original abortion facility, other health
200 care sites, or pharmacy within six weeks of an abortion. Events included
201 those that occurred during, on the day of, or up to six weeks after the index
202 abortion. Potential events were identified through an examination of
203 International Classification of Diseases, 9th Revision (ICD-9) codes in either
204 primary or secondary positions, Health Care Common Procedure Coding
205 System (HCPCS) codes, CPT codes, and medication codes for each health
206 care encounter within six weeks of the abortion. The PAIRS Framework ¹⁶
207 which was originally developed for first trimester aspiration abortions, was
208 used to classify specific events into one or more specific diagnoses: retained

209products of conception, failed abortion, hemorrhage, infection, uterine
210perforation, anesthesia reaction, symptomatic intrauterine material, post-
211abortal hematometra, cervical injury, disseminated intravascular
212coagulation, missed ectopic pregnancy, and other/undetermined. Retained
213placenta was added to the definition of retained products of conception and
214disseminated intravascular coagulation was added to account for additional
215types of events that could occur for second-trimester or later abortions.
216Events were classified as major if they required overnight hospital admission,
217additional surgery, or blood transfusion. All others were classified as minor.

218 Identifying abortion-related events involved the following steps. First,
219each abortion with a subsequent ED visit, a diagnosis code indicating an
220abortion or miscarriage complication on the day of the index abortion, a
221subsequent health care encounter with a diagnosis code indicating an
222abortion or miscarriage complication, or a subsequent inpatient visit was
223individually coded by a clinically-trained reviewer who evaluated all available
224billing data (ICD-9 and CPT codes, laboratory tests, and medications) for
225encounters that occurred within six weeks subsequent to these abortions,
226including on the day of the abortion. Diagnosis codes for miscarriage
227complications were included because they seemed unlikely to be separate
228pregnancies and, instead, were likely billing coding errors as the ICD-9 codes
229for miscarriage complications and abortion complications only differ in one
230number. The reviewer, blinded to abortion facility type, classified each index
231abortion with a subsequent ED visit, a complication diagnosis code, or a

subsequent inpatient visit as having an abortion-related event or not and then classified each case with an abortion-related event into one or more of the 12 possible types of diagnoses. Missed ectopic pregnancies were identified through searching all encounters within six weeks and ectopic pregnancies not diagnosed or treated within seven days after the index abortion were classified as missed ectopic pregnancies.

All encounters that were not individually coded within six weeks were searched to identify injection and IV antibiotics commonly used to treat abortion-related infections. All encounters within six weeks that were not individually coded were searched to identify repeat procedures (abortion, miscarriage, or dilation and curettage procedures, or additional doses of misoprostol). These repeat procedures were further classified as incomplete, failed, or other/undetermined based on diagnosis codes [See eTable 1]. Abortions that were incomplete, failed, or other/undetermined were coded as events. The injection and IV antibiotics and repeat procedures were added to the individually-coded dataset.

Control variables

Variables controlled for in the adjusted analyses included: abortion type (first-trimester aspiration abortion performed through 12 to 14 weeks, first-trimester medication abortion typically provided through nine weeks at the time abortions in this study were provided,¹⁷ and second-trimester and later abortion performed after 12 to 14 weeks), diabetes, hypertension, age, number of previous-year outpatient health care visits, one or more inpatient

visits in the previous year (as proxies for underlying health conditions), U.S. census region, and year. In order to have more complete data on chronic health condition and health care utilization variables, only women insured for at least one year before their abortion were included.

Power analysis and sample size

When planning the study, 3530 induced abortions in ASCs and 15444 induced abortions in office-based settings in 2012 were identified in the Truven Marketscan dataset. Based on assumptions that there would be a similar number of abortions in each year from 2012-2014 and that about one half of the abortions would meet eligibility criteria, a sample size calculation for a difference in proportions indicated that there would be sufficient power to detect up to a .06/100 difference (assuming 0.80 power) between the 2.1/100 events expected based on prior published research³ versus a possible 1.5/100 in ASCs. Based on Cohen's H, this would translate to a small effect size.¹⁸ Even when controlling for potential confounders in logistic regression, this sample size would have 0.80 power to detect small effects, i.e. an Odds Ratio of 0.7 to 0.74 for ASCs v. office-based settings.¹⁹ Upon extracting the data for 2012 through 2014 and identifying the abortions that met other eligibility criteria, the ratio of abortions in ASCs to office-based settings was closer to 1:7 than the 1:5 originally estimated. Prior to analyzing data, an updated sample size calculation was conducted and indicated that an additional year of data (2011) was needed to have sufficient power to

277detect a 0.5% difference. The final dataset had 0.80 power to detect a 0.5%
278difference in events in ASCs v. offices, assuming 2.1/100 events in offices.

279Statistical analysis

280 Analysis was conducted in Stata 14.2. In regression models, any
281abortion-related event was the main outcome and facility type the main
282exposure variable. The first model specified for each outcome included only
283facility type and the outcome. Then, adjusted models that simultaneously
284added all of the potential confounders were estimated. Analysis included
285generalized estimating equations with exchangeable correlation structure,
286logit link, binomial distribution, and robust standard errors to account for
287possible clustering by individuals who had more than one abortion during the
288study. The QIC program was used to select the correlation structure.²⁰ Per *a-*
289*priori* study plans, these analyses were repeated for major events and for
290infections (as infections could be an event type where there might be
291variation across procedure facility type). Then, per *a-priori* study plans,
292subgroup analyses were conducted for any event by abortion type using
293interaction terms, as rate of abortion-related morbidities and adverse events
294varies by abortion type³ and some laws regarding ASC requirements apply
295specifically to second-trimester and later abortions.² Subgroup analyses were
296re-ran with first trimester medication abortions as the reference group and
297then with second trimester and later abortions as the reference group to get
298interpretable odds ratios for these abortion types. Analyses for the
299secondary outcomes and the subgroup analyses were exploratory. The post-

estimation margins command was used to obtain adjusted incidence rates and adjusted differences in incidence rates. As a supplementary analysis, a series of regressions that examined the effect on the main relationship of interest of adding each covariate to the model were also conducted. Additionally, the QIC program²⁰ was used to compare nested models for the primary outcome: those that included abortion type and those that did not. Although it is not possible to determine the extent to which data are missing, the analysis assumes that missing data are rare since these are adjudicated billing claims used to determine payments to clinicians, hospitals, and pharmacies.

Two prespecified sensitivity analyses that used different definitions of abortion-related morbidities and adverse events were conducted. First, there are considerable challenges of measuring whether an ectopic pregnancy was missed based only on billing data. In particular, there is no information available in billing data about whether the clinician suspected an ectopic pregnancy at the time of the abortion visit and the timing of follow-up could be influenced by when test results came back and when the patient was able to present at a facility that provides care for ectopic pregnancies. Because, the seven-day cut-off was somewhat arbitrary and could be overly restrictive, the definition of missed ectopics was changed to those not diagnosed or treated within 14 days. Second, additional injection or IV antibiotics that are not commonly used to treat abortion-related infections were present in the dataset and were added for a sensitivity analysis. A third

sensitivity analysis was conducted *post-hoc*. This sensitivity analysis used the Elixhauser Comorbidity Index²¹ as a control variable instead of the pre-specified control variables of diabetes, hypertension, number of previous outpatient visits, and one or more previous inpatient visits. This analysis used a binary score of ≥ 1 of the 30 comorbidities in the Elixhauser index^{21,22} and, in a separate analysis, used the Elixhauser Comorbidity Index Readmission Score.²³ Statistical testing was 2-sided and used a $p < .05$ significance level.

Results

The database included 104,106 induced abortions during the study time period. 53,795 abortions were excluded due to not being in an ASC or office-based setting, patients being enrolled in their insurance plan for less than one year prior or six weeks subsequent to the abortion, or patients having an age less than 11 years old; 216 abortions involved a molar pregnancy and 765 an ectopic pregnancy diagnosed and/or treated within seven days of the index abortion and were excluded. [See Figure 1] Most of the 17,621 abortions in the database that were not performed in an ASC or office-based setting during the study time period were provided in inpatient, outpatient, or emergency department hospital-based settings ($n=16,909$). The only other type of facility in which more than 1% of the 17,621 abortions excluded due to facility type were performed was Federally Qualified Health Centers ($n=297$). The study cohort included 49,287 patients who had 50,311 abortions in an ASC or an office-based setting and who were continuously

346enrolled in their insurance plan for at least one year prior and at least six
347weeks after the abortion.

348 Multiple abortions occurred in 798 patients (1822 abortions) during the
349study time period. Of the 1822 multiple abortions, 88% of them occurred in
350the same facility type for each abortion.

351 The mean age was 28 years [range 11 – 59 years, SD 7.3]. Of the
35250311 included abortions, 23891 (47%) were first-trimester aspiration,
35313480 (27%) first-trimester medication, and 12940 (26%) second-trimester
354or later abortions. [See Table 1] 5660 (11%) of abortions were performed in
355ASCs and 44651 (89%) performed in office-based settings. The study
356population differed by facility type: patients in ASCs were slightly older (28.6
357v. 28.1 years, $p<.001$); more patients in ASCs had had a previous year
358inpatient encounter (9.8% v. 8.9%, $p=.03$); fewer medication abortions were
359in ASCs (2.6% of abortions in ASCs v. 29.9% of abortions in office-based
360settings, $p<0.001$ for comparison of abortion type by facility type); and
361abortions in ASCs were more common in the South and Midwest (25.1% of
362abortions in ASCs and 12.6% of abortions in office-based settings were in the
363South; 22.6% of abortions in ASCs and 11.5% of abortions in office-based
364settings were in the Midwest, $p<0.001$ for comparison of region by facility
365type).

366 Among the 50311 abortions, 3.33% (1674) had an abortion-related
367event; 0.32% (163) had a major event; 0.74% (374) had an abortion-related
368infection. [See Table 2] 2.52% (603/23891) of first-trimester aspiration

369abortions, 5.42% (730/13480) of first-trimester medication abortions, and
3702.64% (341/12940) of second-trimester or later abortions had an abortion-
371related event. At least 0.2% or more of abortions had one or more of the
372following types of events: retained products of conception, infection, other,
373symptomatic intrauterine material, hemorrhage, and missed ectopic
374pregnancy. The remaining types of events (failed abortion, disseminated
375intravascular coagulation, hematometra, uterine perforation, anesthesia-
376reaction, cervical injury) occurred in fewer than 0.05% of abortions or were
377not present in the dataset. [See Table 2]

378 In unadjusted analyses examining the primary outcome, abortion-
379related events were less common in ASCs than office-based settings (2.60%,
38095% CI 2.21 – 3.05 in ASCs v. 3.42%, 95% CI 3.26 – 3.59 in office-based
381settings, $p=0.001$). In unadjusted analyses examining secondary outcomes,
382there were not significant differences in major events (0.25%, 95% CI 0.15 –
3830.42 in ASCs v. 0.33%, 95% CI 0.28 – 0.39 in office-based settings) or in
384abortion-related infections (0.58%, 95% CI 0.41 – 0.82 in ASCs v. 0.76%, 95%
385CI 0.69 – 0.85 in office-based settings) [See Table 2]. Unadjusted
386associations between variables controlled for in adjusted analyses and study
387outcomes are in eTable 2.

388 The QIC indicated that the exchangeable correlation structure was a
389better fit for the data than the independent correlation structure (QIC of
390307274.59 for exchangeable v. 307277.23 for independent). In adjusted
391analyses, there were not significant differences in abortion-related events

392(the primary outcome) [aOR 0.97, 95% CI 0.81 – 1.17, adjusted incidence
393rate 3.25% v. 3.33%, adjusted difference -0.08%, 95% CI -0.58% - 0.43%]
394between ASCs and office-based settings [See Table 3]. Full regression results
395including 95% CIs for adjusted incidence rates are in eTable 3. Abortion-type
396was the only variable controlled for in the adjusted analyses that affected the
397main association of interest between facility type and events. The model with
398only facility type had an OR of 0.75, p-value 0.001; models with all control
399variables other than abortion type had ORs of 0.74 or 0.75, p-value 0.001.
400The model that included abortion type had an OR of 0.97, p-value 0.77. [See
401eTable 4]. The QIC indicated that the model that included abortion type was
402a better fit for the data than the model that did not include abortion type
403(QIC of 307274.59 for model with versus 310114.09 for model without
404abortion type).

405 There were also not significant differences in the secondary outcomes
406of major abortion-related events [aOR 0.78, 95% CI 0.45 – 1.37, adjusted
407incidence rate 0.26% v. 0.33%, adjusted difference -0.06%, 95% CI -0.18% -
4080.06%] or infections by facility type [aOR 0.75, 95% CI 0.52- 1.09, adjusted
409incidence rate 0.58% v. 0.77%, adjusted difference -0.16%, 95% CI -0.35% -
4100.03%]. [See Table 3]

411 In unadjusted subgroup analyses by abortion type, there were not
412significant differences across facility type in abortion-related events among
413first-trimester aspiration abortions (events occurred in 78 out of 3630 or
4142.15% [95% CI 1.72 – 2.68] of abortions performed in ASCs vs 525 of 20261

415 or 2.59% [95% CI 2.38 – 2.81] of abortions performed in office-based
 416 settings) or second-trimester abortions (events occurred in 53 of 1883 or
 417 2.81% [95% CI 2.16 – 3.67] of abortions performed in ASCs vs 288 of 11057
 418 or 2.60% [95% CI 2.32 – 2.92] of abortions performed in office-based
 419 settings). Among first-trimester medication abortions, the rate of abortion-
 420 related adverse events was significantly greater at ASCs, with events
 421 occurring in 16 of 147 or 10.88% [95% CI 6.74 – 17.12] of abortions
 422 performed in ASCs vs 714 of 13333 or 5.36% [95% CI 4.99 – 5.75] of
 423 abortions performed in office-based settings, $p=0.003$). [See Table 2]
 424 In adjusted subgroup analyses, there were not significant differences
 425 between ASCs and offices in abortion-related events for first-trimester
 426 aspiration abortion [aOR 0.84, 95% CI 0.66 – 1.07, adjusted incidence rate
 427 2.19% v. 2.59%, adjusted difference -0.38%, 95% CI -0.88% - 0.12%]. The
 428 interaction term for second-trimester and later abortion x facility type was
 429 not significant, indicating that there also was no statistical difference in
 430 events in ASCs v. offices for second trimester and later abortions, [aOR from
 431 model with second trimester and later as reference group, 1.01, 95% CI 0.75
 432 – 1.37, adjusted incidence rate 2.62% v. 2.59%, adjusted difference 0.03%,
 433 95% CI -0.70 – 0.76]. There were significant differences in odds of abortion-
 434 related events in ASCs versus office-based settings for medication abortions,
 435 p -value for interaction term was 0.001, [aOR from model with first-trimester
 436 medication abortion as reference group, 2.23, 95% CI 1.30 – 3.80, adjusted

437 incidence rate 11.22% v. 5.42%, adjusted difference 5.54%, 95% CI 5.12% -
438 10.56%]. [See Table 3]

439 There were no substantive differences in the sensitivity analyses using
440 different definitions of abortion-related morbidities and adverse events and
441 adjusting for comorbidities using the Elixhauser Comorbidity Index. [See
442 eTables 5, 6, 7, 8 and 9]

443 **Discussion**

444 In this retrospective analysis of more than 50,000 induced abortions in
445 the U.S. between 2011 and 2014, performance of abortions in ambulatory
446 surgery centers, compared with office-based settings, was not associated
447 with a significant difference in abortion-related morbidities and adverse-
448 events. The lack of a significant association between abortions performed in
449 ASCs vs office-based settings and the rates of abortion-related morbidities
450 and adverse events is consistent with the small body of literature that
451 compares the safety of other outpatient procedures across ASCs and office-
452 based settings.²⁴

453 This study reinforced that there are low rates of abortion-related
454 morbidities and adverse events after abortion, with major events occurring in
455 only one-third of one percent of cases. This study also confirmed that there
456 are low rates of abortion-related morbidities and adverse events in both
457 ASCs and office-based settings. Although the estimate of the overall
458 abortion-related event rate was higher than a previous estimate using claims
459 data, the estimate of major events was similar³. The estimates for events

460after first-trimester aspiration abortions were higher than previous estimates
461using claims data, but were within the range of estimates in other published
462studies,^{3,4} as were the estimates for second-trimester and later abortions.²⁵⁻²⁷
463The estimates for events after medication abortions are within the range of
464previous published estimates of events after medication abortions using
465claims data.³

466 The study was powered to detect a 0.5% difference in any abortion-
467related morbidities and adverse events. This difference is smaller than the
468predetermined acceptable risk difference of 2% used in a large noninferiority
469study comparing events after abortions performed by advance practice
470clinicians and physicians.²⁸ In that study, the acceptable risk difference was
471determined before the start of the study by a panel of researchers and
472clinicians.²⁸ The upper bound of the 95% CI around the 0.1% observed
473difference in this study was 0.6%, which is within the 2% specified as
474clinically insignificant in that previous study. The upper bound of the 95% CIs
475for observed differences for first-trimester aspiration and second trimester
476and later abortions were less than 1%, which is within the 2% threshold for
477any events. The upper bound of the 95% CI for the 0.1% observed difference
478in major events was 0.2%, which is slightly smaller than the 0.3% difference
479in major events defined as clinically important in a recent study.²⁹ The upper
480bound of the 95% CI for the 0.2% observed difference in infections was 0.4%,
481which is also not clinically important.

482 Abortion-related morbidities and adverse events appear more common
483 among women having first-trimester medication abortions in ASCs than
484 office-based settings. The upper bound of the difference (11%) may be
485 clinically important. As medication abortions in ASCs were rare (only 2.6% of
486 abortions in ASCs and 0.3% of all abortions in the sample), the significant
487 association between facility type and abortion-related morbidities and
488 adverse events for first trimester medication abortions should be interpreted
489 with caution. It is possible, given that medication abortions are rarely
490 performed in ASCs, that women who have medication abortions in ASCs may
491 travel a long distance and may receive follow-up care at sites that may be
492 more likely to provide an additional treatment.

493 Observational studies include the risk of unbalanced study groups,
494 where differences are not adequately controlled in analyses. While there
495 were some significant differences in the measured covariates across ASCs
496 and office-based settings, the patient-level differences identified in this study
497 were small (i.e., half a year of age, less than one percent difference in
498 proportion with one or more inpatient encounters in the previous year). Only
499 one of the observed covariates – abortion type – confounded the relationship
500 between facility type and incidents [See eTable 4]. This confounding was due
501 to first-trimester medication abortions being much more common in office-
502 based settings and, similar to previous research,³ having more incidents
503 (more than 5%) than first-trimester aspiration and second trimester and later
504 abortions (which had closer to 2.5%).

505 This study has strengths. First, the study used a national sample of
506claims data from a database that is often used to examine safety of health
507care procedures.^{12,13} Using an insurance claims database that includes a
508national sample allows direct comparison of abortion-related morbidities and
509adverse events across ASCs vs. office-based settings and provides a
510sufficiently large sample to detect differences, avoid biases associated with
511focusing on a few facilities where practice could be unrepresentative, and
512control for potential confounders. Second, there was little loss to follow up
513because of the use of claims data. Claims databases are useful for examining
514morbidities and adverse events after health care procedures (including
515abortion) because they routinely capture health care visits and treatments
516that occur subsequent to the procedure,³ thereby increasing chances that
517most post-procedure events will be captured in the dataset and limiting
518biases from loss to follow-up that have been noted in other studies
519examining abortion-related morbidities and adverse events.²⁸ Third, there
520was a large sample of second-trimester and later abortions, which allowed
521assessment of whether overall findings held among this subset of abortions.

522Limitations

523 This study has several limitations. First, while the study differentiated
524between first and second-trimester abortions, it was not possible to know the
525weeks' gestation at which the abortion was provided, a potential limitation
526given that the risk of abortion-related events increases with each week
527gestation.^{25,26} If there were differences in timing of abortions within the first

and second-trimesters across offices and ASCs, this could be an unmeasured confounder. Second, it is not known whether the ectopic pregnancies classified as missed were suspected at the index abortion visit. The approach of including all ectopics diagnosed and/or treated after seven days as missed was conservative. Third, by virtue of the data included in the Truven Marketscan database, the study only included abortions paid for by private insurance. Only about 15% of the almost one million abortions provided each year in the U.S. are paid for by private insurance.^{5,30} Thus, findings may not be generalizable to all abortions in the U.S. Fourth, other potential confounders, including BMI, race, previous cesarean section, were not available in the database and thus could not be controlled. However, recent research has not indicated associations between obesity and abortion-related events, so this should partially address this concern.²⁵ Other indicators of health status, such as frequency of healthcare visits, were controlled for. As no anesthesia-related reactions were identified, it does not appear that not being able to control for anesthesia has biased the results. Fifth, the Truven Marketscan database did not include information on the specific type of facility (i.e. abortion clinics, non-specialized clinics, and physician offices) in which the abortions were performed. This study thus was unable to assess whether abortion-related morbidities and adverse events vary by whether the abortion was performed in an abortion clinic, non-specialized clinic, or a physician office.

Conclusions

551 Among women with private health insurance who had an induced abortion,
552 performance of the abortion in an ambulatory surgery center, compared with
553 an office-based setting, was not associated with a significant difference in
554 abortion-related morbidities and adverse events. These findings, in addition
555 to individual patient and individual facility factors, may inform decisions
556 about the type of facility in which induced abortions are performed.

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569

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571 study and take responsibility for the integrity of the data and the accuracy of
572 the data analysis.
573

574 The authors have completed and submitted ICMJE forms for Disclosure of
575 Potential Conflicts of Interest and none were reported.
576
577

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Table 1. Sample description (n=50,311 abortions)				
	Total (n=50,311)	Ambulator y surgery centers n=5,660	Office-based settings n=44,651	p-value
Number of patients ^a	49,287	5,601	43,776	
Age in single years mean (sd), range	28.1(7.3), [11-59]	28.6(7.48), [11-59]	28.1(7.29), [11-58]	<0.001
Abortion type n(%)				<0.001
First trimester aspiration	23,891 (47.5%)	3,630 (64.1%)	20,261 (45.4%)	
First trimester medication	13,480 (26.8%)	147 (2.6%)	13,333 (29.9%)	
Second trimester and later	12,940 (25.7%)	1,883 (33.3%)	11,057 (24.8%)	
Diabetes n(%)	1,109 (2.2%)	133 (2.4%)	976 (2.2%)	0.43
Hypertension n(%)	1,960 (3.9%)	228 (4.0%)	1,732 (3.9%)	0.58
1 or more previous year Inpatient visits n(%)	4,532 (9.0%)	554(9.8%)	3978(8.9%)	0.03
Previous year outpatient visits n(%)				0.42
0-6	27,634 (54.9%)	3,085(54.5 %)	24,549 (55.0%)	
7-12	12,120 (24.1%)	1,383(24.4 %)	10,737(24.1%)	
13-23	6,923 (13.8%)	758(13.4%)	6,165(13.8%)	
>=24	3,634 (7.2%)	434(7.7%)	3,200(7.2%)	
Year of abortion n(%)				<0.001
2011	13,538 (26.9%)	1,639 (29.0%)	11,899 (26.7%)	
2012	13,808 (27.5%)	1,483(26.2 %)	12,325(27.6%)	
2013	11,119 (22.1%)	1,047 (18.5%)	10,072(22.6%)	
2014	11,846 (23.6%)	1,491(26.3 %)	10,355(23.2%)	
Region of the country n(%)				<0.001
Northeast	21,633 (43.0%)	2,081 (36.8%)	19,552 (43.8%)	
South	7,029 (14.0%)	1,418 (25.1%)	5,611 (12.6%)	
Midwest	6,390 (12.7%)	1,280 (22.6%)	5,110 (11.5%)	
West	14,290 (28.4%)	849 (15.0%)	13,441 (30.1%)	
Other	969 (1.9%)	32 (0.6%)	937 (2.1%)	

666Note: p-value for table 1. is based on a chi-square test for categorical and binary variables
667and T test for continuous variable. Unit of analysis is abortions.

668^a The sum of patients in ambulatory surgery centers and office-based settings is greater
669than the total number of patients because, while most patients who had more than one

670abortion had each abortion in the same facility type, a few had a subsequent abortion in a
671different facility type.

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Table 2. Unadjusted rates of abortion-related morbidities and adverse events (n=50,311)

	Total (n=50,311)	Ambulator y surgery centers n=5660	Office- based settings n=44,651	p-value
Any abortion-related morbidity or adverse event (Primary outcome)	1674 (3.33%)	147 (2.60%)	1527 (3.42%)	0.001
Major abortion-related morbidity or adverse event ^a (Secondary outcome)	163 (0.32%)	14 (0.25%)	149 (0.33%)	0.28
<i>Any abortion-related morbidity or adverse event</i>				
First trimester aspiration	603/23,891 (2.52%)	78/3,630 (2.15%)	525/20,261 (2.59%)	0.12
First trimester medication	730/13,480 (5.42%)	16/147 (10.88%)	714/13,333 (5.36%)	0.003
Second trimester or later	341/12,940 (2.64%)	53/1,883 (2.81%)	288/11,057 (2.60%)	0.60
Specific types of abortion-related morbidities and adverse events				
	n, %	n, %	n, %	
retained products of conception	743 (1.48%)	46 (0.81%)	697 (1.56%)	
abortion-related infections ^b (secondary outcome)	374 (0.74%)	33 (0.58%)	341 (0.76%)	0.14
other or undetermined ^c	316 (0.63%)	49 (0.87%)	267 (0.60%)	
symptomatic intrauterine material	301 (0.60%)	28 (0.49%)	273 (0.61%)	
hemorrhage	201 (0.40%)	19 (0.34%)	182 (0.41%)	
missed ectopic pregnancy	106 (0.21%)	4 (0.07%)	102 (0.23%)	
failed abortion	15 (0.03%)	1 (0.02%)	14 (0.03%)	
disseminated intravascular coagulation	8 (0.02%)	1 (0.02%)	7 (0.02%)	
post-abortion hematometra	5 (0.01%)	0 (0.00%)	5 (0.01%)	
uterine perforation	2 (0.00%)	0 (0.00%)	2 (0.00%)	
anesthesia-reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	
cervical injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	

Note: an abortion could have more than one type of abortion-related morbidity or adverse event (e.g. abortion-related infection & retained products of conception). Of the 163 major events, 90 had only one specific type of morbidity or adverse event. The remaining 73 had two or more specific types of events. Unit of analysis is abortions.

^a Events were classified as major if they required overnight hospital admission, additional surgery, or blood transfusion.

^b Infections were a secondary outcome of interest.

^c These are primarily repeat procedures where the diagnosis could not be determined

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Table 3. Multivariable logistic regressions of odds of events, adjusted incidence rate of events (aInc), and differences in adjusted incidence of events (aDiff) after abortion in ambulatory surgery centers vs. office-based settings among total sample and by abortion type (subgroup analyses)

Analyses among total sample						
	Adjusted Incidence		aDiff [95% CI of aDiff]		aOR [95% CI]	p-value
	Ambulatory Surgery Centers	Office-based settings				
Any abortion-related morbidity or adverse event (Primary outcome)	3.25%	3.33%	-0.08% [-0.58% - 0.43%]		0.97 [0.81 - 1.17]	0.77
Major abortion-related morbidity or adverse event (Secondary outcome)	0.26%	0.33%	-0.06% [-0.18% - 0.06%]		0.78 [0.45 - 1.37]	0.39
Abortion-related infection (Secondary outcome)	0.58%	0.77%	-0.16% [-0.35% - 0.03%]		0.75 [0.52 - 1.09]	0.13
Subgroup analyses						
	Adjusted Incidence		aDiff [95% CI of aDiff]	Variables	aOR [95% CI]	p-value
	Ambulatory Surgery Centers	Office-based settings				
				First trimester aspiration	ref	
Any abortion-related morbidity or adverse event among first trimester aspiration abortions	2.19%	2.59%	-0.38% [-0.88% - 0.12%]	First trimester aspiration X Ambulatory surgery centers	0.84 [0.66 - 1.07]	0.16
				First trimester medication	2.16 [1.93 - 2.43]	<0.001
Any abortion-related morbidity or adverse event among first trimester medication abortions	11.22%	5.42%	5.54% [5.12% - 10.56%]	First trimester medication X Ambulatory surgery centers	2.65 [1.47 - 4.76]	0.001
				Second trimester and later	1.00 [0.86 - 1.16]	0.99
Any abortion-related morbidity or adverse event among second trimester and later abortions	2.62%	2.59%	0.03% [-0.70% - 0.76%]	Second trimester and later X Ambulatory surgery centers	1.21 [0.82 - 1.77]	0.34
Interpretation of interactions is that main effect for abortion type is the aOR or adjusted probability for that abortion type in offices						

compared to first trimester procedures in offices, facility type main effect is for first trimester procedures in ambulatory surgery centers vs. in offices, and interaction terms are whether and to what extent that type of abortion in ambulatory surgery centers differs from that type of abortion in offices

Adjusted models for total sample control for age, abortion type, diabetes, hypertension, previous year outpatient health care visits, previous year inpatient health care visits, year, and region. Office-based settings are the reference group

Full regression results are available in eTable 3

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690Figure 1. Figure 1. Study flow diagram

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692Footnotes for Figure 1.

693¹ abortions could be excluded for more than one reason

694² There are 50 different possible settings that include settings such as schools, homeless shelters, inpatient hospital,
695skilled nursing facilities, and others. Facility type was classified as ASC when the place-of-service code variable
696(stdplac) equaled 24 (“Ambulatory Surgery Center”) and office-based setting when the place-of-service code
697variable equaled 11 (“Office”).

698³ events identified through individual review of cases with inpatient encounters, ED visits, and complication
699diagnosis codes were mutually exclusive.

700⁴ events identified through programming were not mutually exclusive; i.e. an abortion could have had one or more
701of the programmed events. These abortions were not individually reviewed by the clinician coder

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