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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 ²morbidities and adverse events among patients undergoing induced ³abortions

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35 36**Key points**

37**Question:** Is there an association between the type of facility in which an38abortion 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.

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.

57Design, 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.

71Main Outcomes and Measures

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

81Results

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

104Introduction

In June 2016, the U.S. Supreme Court ruled in *Whole Woman's Health* 106*vs. Hellerstedt* that Texas's law requiring abortion facilities to meet 107ambulatory surgery center (ASC) standards was unconstitutional.¹-Despite-108this ruling, <u>Thirteeneight</u> states currently <u>enforce have</u> laws that require 109licensing standards for abortion<u>s</u> facilities that are comparable to the state's-110licensing standards forto 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.

136Methods

137<u>Study design</u>

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.

145<u>Data source</u>

146 The Truven Health MarketScan Commercial Claims and Encounters 147database is a commercially available health insurance claims database. It 148 includes 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 158 fully 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} 162*Study population*

The study population included all beneficiaries in this database who 164were 11 years and older who had an induced abortion between January 1, 1652011 and December 31, 2014 in an ASC or office-based setting and who 166were enrolled in their insurance plan for at least one year prior to the index 167abortion and at least six weeks after the abortion. Current Procedural 168Terminology (CPT) codes used to identify abortions are listed in eTable 1. 169Ectopic pregnancies diagnosed and/or treated within 7 days of the abortion 170and molar pregnancies were excluded, as ectopic pregnancies and molar 171pregnancies receive different treatments than abortions and have different 172expected potential morbidities and adverse events.

173<u>Exposure</u>

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

186<u>Outcomes</u>

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

191 Per methods published in a recent study of abortion-related events 192using billing data, abortion-related events were estimated by examining and 193evaluating all diagnoses and treatments at all health care encounters on the 194day of and within six weeks of the abortion.³ Each index abortion was coded 195as to whether an abortion-related morbidity or adverse event occurred within 196the six weeks subsequent to the abortion. Events were defined as any 197abortion-related morbidity or adverse event that received an abortion-198 related diagnosis or treatment code at any care location, including 199emergency departments (EDs), the original abortion facility, other health 200care sites, or pharmacy within six weeks of an abortion. Events included 201those that occurred during, on the day of, or up to six weeks after the index 202abortion. Potential events were identified through an examination of 203International Classification of Diseases, 9th Revision (ICD-9) codes in either 204 primary or secondary positions, Health Care Common Procedure Coding 205System (HCPCS) codes, CPT codes, and medication codes for each health 206care encounter within six weeks of the abortion. The PAIRS Framework ¹⁶ 207which was originally developed for first trimester aspiration abortions, was 208used 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 214 disseminated 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 223 individually coded by a clinically-trained reviewer who evaluated all available 224billing data (ICD-9 and CPT codes, laboratory tests, and medications) for 225 encounters that occurred within six weeks subsequent to these abortions, 226 including on the day of the abortion. Diagnosis codes for miscarriage 227 complications were included because they seemed unlikely to be separate 228pregnancies and, instead, were likely billing coding errors as the ICD-9 codes 229 for 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

232subsequent inpatient visit as having an abortion-related event or not and 233then classified each case with an abortion-related event into one or more of 234the 12 possible types of diagnoses. Missed ectopic pregnancies were 235identified through searching all encounters within six weeks and ectopic 236pregnancies not diagnosed or treated within seven days after the index 237abortion were classified as missed ectopic pregnancies.

All encounters that were not individually coded within six weeks were All encounters that were not individually coded within six weeks were assessment of the identify injection and IV antibiotics commonly used to treat weeks that were not common related infections. All encounters within six weeks that were not attindividually coded were searched to identify repeat procedures (abortion, all encounters are procedures, or additional doses of additional doses of additional doses of attinisoprostol). These repeat procedures were further classified as incomplete, attined, or other/undetermined based on diagnosis codes [See eTable 1]. attined, or other/undetermined based on diagnosis codes [See eTable 1]. attine that were incomplete, failed, or other/undetermined were coded as attinets. The injection and IV antibiotics and repeat procedures were added to attine individually-coded dataset.

248<u>Control variables</u>

Variables controlled for in the adjusted analyses included: abortion 250type (first-trimester aspiration abortion performed through 12 to 14 weeks, 251first-trimester medication abortion typically provided through nine weeks at 252the time abortions in this study were provided,¹⁷ and second-trimester and 253later abortion performed after 12 to 14 weeks), diabetes, hypertension, age, 254number of previous-year outpatient health care visits, one or more inpatient

255visits in the previous year (as proxies for underlying health conditions), U.S. 256census region, and year. In order to have more complete data on chronic 257health condition and health care utilization variables, only women insured for 258at least one year before their abortion were included.

259Power analysis and sample size

260 When planning the study, 3530 induced abortions in ASCs and 15444 261 induced abortions in office-based settings in 2012 were identified in the 262Truven Marketscan dataset. Based on assumptions that there would be a 263similar number of abortions in each year from 2012-2014 and that about one 264half of the abortions would meet eligibility criteria, a sample size calculation 265 for a difference in proportions indicated that there would be sufficient power 266to detect up to a .06/100 difference (assuming 0.80 power) between the 2672.1/100 events expected based on prior published research³ versus a 268possible 1.5/100 in ASCs. Based on Cohen's H, this would translate to a small 269effect size.¹⁸ Even when controlling for potential confounders in logistic 270 regression, this sample size would have 0.80 power to detect small effects, 271i.e. an Odds Ratio of 0.7 to 0.74 for ASCs v. office-based settings.¹⁹ Upon 272extracting the data for 2012 through 2014 and identifying the abortions that 273met other eligibility criteria, the ratio of abortions in ASCs to office-based 274settings was closer to 1:7 than the 1:5 originally estimated. Prior to analyzing 275data, an updated sample size calculation was conducted and indicated that 276an 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. 279*Statistical analysis*

Analysis was conducted in Stata 14.2. In regression models, any 280 281abortion-related event was the main outcome and facility type the main 282exposure variable. The first model specified for each outcome included only 283 facility 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 293 interaction 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 298 interpretable odds ratios for these abortion types. Analyses for the 299secondary outcomes and the subgroup analyses were exploratory. The post-

300estimation margins command was used to obtain adjusted incidence rates 301and adjusted differences in incidence rates. As a supplementary analysis, a 302series of regressions that examined the effect on the main relationship of 303interest of adding each covariate to the model were also conducted. 304Additionally, the QIC program²⁰ was used to compare nested models for the 305primary outcome: those that included abortion type and those that did not. 306Although it is not possible to determine the extent to which data are missing, 307the analysis assumes that missing data are rare since these are adjudicated 308billing claims used to determine payments to clinicians, hospitals, and 309pharmacies.

Two prespecified sensitivity analyses that used different definitions of 311abortion-related morbidities and adverse events were conducted. First, there 312are considerable challenges of measuring whether an ectopic pregnancy was 313missed based only on billing data. In particular, there is no information 314available in billing data about whether the clinician suspected an ectopic 315pregnancy at the time of the abortion visit and the timing of follow-up could 316be influenced by when test results came back and when the patient was able 317to present at a facility that provides care for ectopic pregnancies. Because, 318the seven-day cut-off was somewhat arbitrary and could be overly 319restrictive, the definition of missed ectopics was changed to those not 320diagnosed or treated within 14 days. Second, additional injection or IV 321antibiotics that are not commonly used to treat abortion-related infections 322were present in the dataset and were added for a sensitivity analysis. A third

323sensitivity analysis was conducted *post-hoc*. This sensitivity analysis used 324the Elixhauser Comorbidity Index²¹ as a control variable instead of the pre-325specified control variables of diabetes, hypertension, number of previous 326outpatient visits, and one or more previous inpatient visits. This analysis 327used a binary score of >=1 of the 30 comorbidities in the Elixhauser 328index^{21,22} and, in a separate analysis, used the Elixhauser Comorbidity Index 329Readmission Score.²³ Statistical testing was 2-sided and used a p<.05 330significance level.

331**Results**

The database included 104,106 induced abortions during the study 333time period. 53795 abortions were excluded due to not being in an ASC or 334office-based setting, patients being enrolled in their insurance plan for less 335than one year prior or six weeks subsequent to the abortion, or patients 336having an age less than 11 years old; 216 abortions involved a molar 337pregnancy and 765 an ectopic pregnancy diagnosed and/or treated within 338seven days of the index abortion and were excluded. [See Figure 1] Most of 339the 17621 abortions in the database that were not performed in an ASC or 340office-based setting during the study time period were provided in inpatient, 341outpatient, or emergency department hospital-based settings (n=16909). 342The only other type of facility in which more than 1% of the 17621 abortions 343excluded due to facility type were performed was Federally Qualified Health 344Centers (n=297). The study cohort included 49287 patients who had 50311 345abortions 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.

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 358 inpatient 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).

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]

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% Cl 0.81 – 1.17, adjusted incidence 393rate 3.25% v. 3.33%, adjusted difference -0.08%, 95% Cl -0.58% - 0.43%] 394between ASCs and office-based settings [See Table 3]. Full regression results 395including 95% Cls 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).

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

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% Cl 1.72 – 2.68] of abortions performed in ASCs vs 525 of 20261

415or 2.59% [95% CI 2.38 – 2.81] of abortions performed in office-based 416settings) or second-trimester abortions (events occurred in 53 of 1883 or 4172.81% [95% CI 2.16 – 3.67] of abortions performed in ASCs vs 288 of 11057 418or 2.60% [95% CI 2.32 – 2.92] of abortions performed in office-based 419settings). Among first-trimester medication abortions, the rate of abortion-420related adverse events was significantly greater at ASCs, with events 421occurring in 16 of 147 or 10.88% [95% CI 6.74 – 17.12] of abortions 422performed in ASCs vs 714 of 13333 or 5.36% [95% CI 4.99 - 5.75] of 423abortions performed in office-based settings, p=0.003). [See Table 2] 424 In adjusted subgroup analyses, there were not significant differences 425between ASCs and offices in abortion-related events for first-trimester 426aspiration abortion [aOR 0.84, 95% CI 0.66 – 1.07, adjusted incidence rate 4272.19% 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 429not significant, indicating that there also was no statistical difference in 430events in ASCs v. offices for second trimester and later abortions, [aOR from 431model 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%, 43395% 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, 435p-value for interaction term was 0.001, [aOR from model with first-trimester 436medication abortion as reference group, 2.23, 95% CI 1.30 – 3.80, adjusted

437incidence rate 11.22% v. 5.42%, adjusted difference 5.54%, 95% CI 5.12% -43810.56%]. [See Table 3]

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

443 Discussion

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

This study reinforced that there are low rates of abortion-related 454morbidities and adverse events after abortion, with major events occurring in 455only one-third of one percent of cases. This study also confirmed that there 456are low rates of abortion-related morbidities and adverse events in both 457ASCs and office-based settings. Although the estimate of the overall 458abortion-related event rate was higher than a previous estimate using claims 459data, 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-467 related 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 475 for 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.

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

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

505 This study has strengths. First, the study used a national sample of 506 claims 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 511 focusing 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

528and second-trimesters across offices and ASCs, this could be an unmeasured 529confounder. Second, it is not known whether the ectopic pregnancies 530 classified as missed were suspected at the index abortion visit. The approach 531of including all ectopics diagnosed and/or treated after seven days as missed 532was conservative. Third, by virtue of the data included in the Truven 533Marketscan database, the study only included abortions paid for by private 534 insurance. Only about 15% of the almost one million abortions provided each 535year in the U.S. are paid for by private insurance.^{5,30} Thus, findings may not 536be generalizable to all abortions in the U.S. Fourth, other potential 537 confounders, including BMI, race, previous cesarean section, were not 538available in the database and thus could not be controlled. However, recent 539research has not indicated associations between obesity and abortion-540related events, so this should partially address this concern.²⁵ Other 541 indicators of health status, such as frequency of healthcare visits, were 542controlled for. As no anesthesia-related reactions were identified, it does not 543appear that not being able to control for anesthesia has biased the results. 544Fifth, the Truven Marketscan database did not include information on the 545specific type of facility (i.e. abortion clinics, non-specialized clinics, and 546physician offices) in which the aboritons were performed. This study thus 547was unable to assess whether abortion-related morbidities and adverse 548 events vary by whether the abortion was performed in an abortion clinic, 549non-specialized clinic, or a physician office.

550<u>Conclusions</u>

551Among women with private health insurance who had an induced abortion,

552performance of the abortion in an ambulatory surgery center, compared with

553an office-based setting, was not associated with a significant difference in

554abortion-related morbidities and adverse events. These findings, in addition

555to individual patient and individual facility factors, may inform decisions

556about the type of facility in which induced abortions are performed.

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570Dr. Sarah Roberts and Guodong Liu had full access to all the data in the 571study and take responsibility for the integrity of the data and the accuracy of 572the data analysis.

573

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

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Table 1. Sample description	Total	Ambulator	Office-based	p-value
	(n=50,311)	y surgery centers n=5,660	settings n=44,651	p-value
Number of patients ^a	49,287	5,601	43,776	
Age in single years mean	28.1(7.3),	28.6(7.48),	28.1(7.29),	<0.001
(sd), range	[11-59]	[11-59]	[11-58]	
Abortion type n(%)				<0.001
First trimester aspiration	23,891	3,630	20,261	
	(47.5%)	(64.1%)	(45.4%)	
First trimester medication	13,480	147 (2.6%)	13,333	
	(26.8%)		(29.9%)	
Second trimester and later	12,940	1,883	11,057	
	(25.7%)	(33.3%)	(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	3,085(54.5	24,549	
	(54.9%)	%)	(55.0%)	
7-12	12,120	1,383(24.4	10,737(24.1%)	
	(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	1,639	11,899	
	(26.9%)	(29.0%)	(26.7%)	
2012	13,808 (27.5%)	1,483(26.2 %)	12,325(27.6%)	
2013	11,119	1,047	10,072(22.6%)	
_010	(22.1%)	(18.5%)		
2014	11,846 (23.6%)	1,491(26.3 %)	10,355(23.2%)	
Region of the country n(%)	(,,,,,,	,		< 0.001
Northeast	21,633	2,081	19,552	
	(43.0%)	(36.8%)	(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%)	
Other	303(1.3%)	JZ (0.0%)	957 (2.170)	

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.

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

(n=50,311)				
	Total	Ambulator	Office-	p-value
	(n=50,311	y surgery	based	
)	centers	settings	
		n=5660	n=44,651	
Any abortion-related morbidity or	1674	147	1527	0.001
adverse event (Primary outcome)	(3.33%)	(2.60%)	(3.42%)	
Major abortion-related morbidity or	163	14 (0.25%)	149	0.28
adverse event ^a (Secondary outcome)	(0.32%)		(0.33%)	
Any abortion-related morbidity or				
adverse event				
First trimester aspiration	603/23,89	78/3,630	525/20,26	0.12
	1 (2.52%)	(2.15%)	1 (2.59%)	
First trimester medication	730/13,48	16/147	714/13,33	0.003
	0 (5.42%)	(10.88%)	3 (5.36%)	
Second trimester or later	341/12,94	53/1,883	288/11,05	0.60
	0 (2.64%)	(2.81%)	7 (2.60%)	
Specific types of abortion-r	-		dverse ever	nts
	n, %	n, %	n, %	
retained products of conception	743	46 (0.81%)	697	
	(1.48%)		(1.56%)	
abortion-related infections ^b (secondary	374	33 (0.58%)	341	0.14
outcome)	(0.74%)		(0.76%)	
other or undetermined ^c	316	49 (0.87%)	267	
	(0.63%)		(0.60%)	
symptomatic intrauterine material	301	28 (0.49%)	273	
	(0.60%)		(0.61%)	
hemorrhage	201	19 (0.34%)	182	
	(0.40%)		(0.41%)	
missed ectopic pregnancy	106	4 (0.07%)	102	
-	(0.21%)		(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-abortal 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: on chartier could have many them				

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 (alnc), 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)

		yses among total sa		-	1
Adjusted Incidence		aDiff [95% CI of aDiff]		aOR [95% CI]	p-value
Ambulatory Surgery Centers	Office- based settings				
3.25%	3.33%	-0.08% [-0.58% - 0.43%]		0.97 [0.81 - 1.17]	0.77
0.26%	0.33%	-0.06% [-0.18% - 0.06%]		0.78 [0.45 - 1.37]	0.39
0.58%	0.77%	-0.16% [-0.35% - 0.03%]		0.75 [0.52 - 1.09]	0.13
	Sub	group analyses		•	
Adjusted Incidence		aDiff [95% CI of aDiff]	Variables	aOR [95% CI]	p-value
Ambulatory Surgery Centers	Office- based settings		First trimester aspiration	ref	
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
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
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
	Ambulatory Surgery Centers 3.25% 0.26% 0.58% Adjusted Incid Ambulatory Surgery Centers 2.19% 111.22%	Ambulatory Surgery CentersOffice- based settings3.25%3.33%0.26%0.33%0.26%0.77%0.58%0.77%Adjusted IncidenceAmbulatory Surgery CentersOffice- based settings2.19%2.59%11.22%5.42%2.62%2.59%	Ambulatory Surgery Centers Office- based settings aDiff] 3.25% 3.33% -0.08% [-0.58% - 0.43%] 0.26% 0.33% -0.06% [-0.18% - 0.06%] 0.58% 0.77% -0.16% [-0.35% - 0.03%] 0.58% 0.77% -0.16% [-0.35% - 0.03%] Adjusted Incidence aDiff [95% Cl of aDiff] Ambulatory Surgery Centers Office- based settings 2.19% 2.59% -0.38% [-0.88% - 0.12%] 11.22% 5.42% 5.54% [5.12% - 10.56%] 2.62% 2.59%	Ambulatory Surgery Centers Office- based settings Output 3.25% 3.33% -0.08% [-0.58% - 0.43%] Output 0.26% 0.33% -0.06% [-0.18% - 0.06%] Output 0.26% 0.33% -0.16% [-0.35% - 0.03%] Output 0.58% 0.77% -0.16% [-0.35% - 0.03%] Output Adjusted Incidence aDiff [95% CI of aDiff] Variables Ambulatory Surgery Centers Office- based settings First trimester aspiration N Ambulatory surgery centers 2.19% 2.59% -0.38% [-0.88% - 0.12%] First trimester medication X Ambulatory surgery centers 11.22% 5.42% 5.54% [5.12% - 10.56%] First trimester medication X Ambulatory surgery centers 2.62% 2.59% 0.03% [-0.70% - 0.76%] Second trimester and later	Ambulatory Surgery Centers Office- based settings Diff] Output 3.25% 3.33% -0.08% [-0.58% - 0.43%] 0.97 [0.81 - 1.17] 0.26% 0.33% -0.06% [-0.18% - 0.06%] 0.77% 0.78 [0.45 - 1.37] 0.58% 0.77% -0.16% [-0.35% - 0.03%] 0.75 [0.52 - 1.09] 0.58% 0.77% -0.16% [-0.35% - 0.03%] 0.75 [0.52 - 1.09] Subgroup analyses Adjusted Incidence aDiff [95% CI of aDiff] Variables aOR [95% CI] Ambulatory Surgery Centers Office- based -0.38% [-0.88% - 0.12%] First trimester aspiration X Ambulatory surgery centers 0.84 [0.66 - 1.07] 11.22% 5.42% 5.54% [5.12% - 10.56%] First trimester medication X Ambulatory surgery centers 2.16 [1.93 - 2.43] 11.22% 5.42% 5.54% [5.12% - 10.56%] First trimester medication X Ambulatory surgery centers 2.65 [1.47 - 4.76] 2.62% 2.59% 0.03% [-0.70% - 0.76%] Second trimester and later 1.00 [0.86 - 1.16]

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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