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State law requiring FDA protocol for medication abortion associated with increased need for additional interventions

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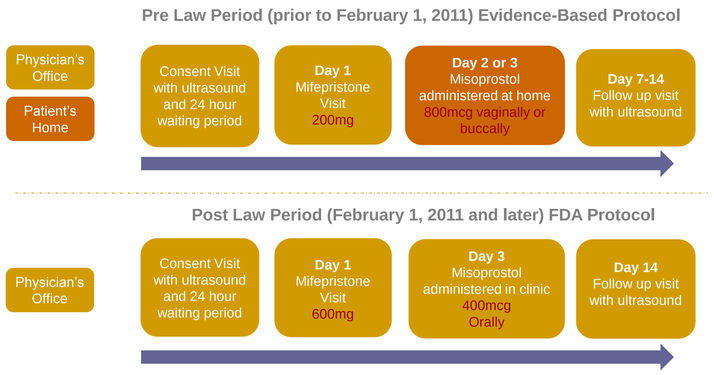
Background

- In 2011, Ohio law took effect mandating use of the FDA-approved protocol for Mifeprex™.[1]
- Current evidence-based regimens have higher completion rates (95–99%)[2,3] than the regimen in the original FDA-approved protocol (88–92%).[4,5]
- Evidence-based regimen is routinely used throughout the U.S. and the world.
- Evidence-based regimen is recommended by ACOG, NAF & WHO.

Comparison of MAB Protocols



Study aims

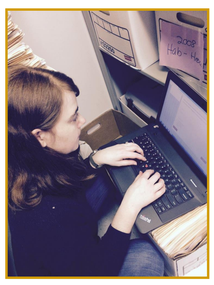
We sought to examine whether the change in 2011 from an evidence-based regimen to the FDA-approved regimen for medication abortion had impacts on:

1. Need for any additional intervention(s) following medication abortion
2. Number of visits needed to complete abortion care
3. Overall sociodemographic composition of women obtaining medication abortion

Methods

Data abstraction

- Abstracted medication abortion charts
- All obtainable charts from one year before the law's implementation (2010) and up to 3 years post-implementation (2011 –2014)
- Four abortion-providing facilities in Ohio
- September 2014 – April 2015



Key outcome

Need for subsequent intervention, which included:

- Repeat misoprostol
- Aspiration
- Blood transfusion
- Hospitalization
- Other abortion-related treatments following medication abortion

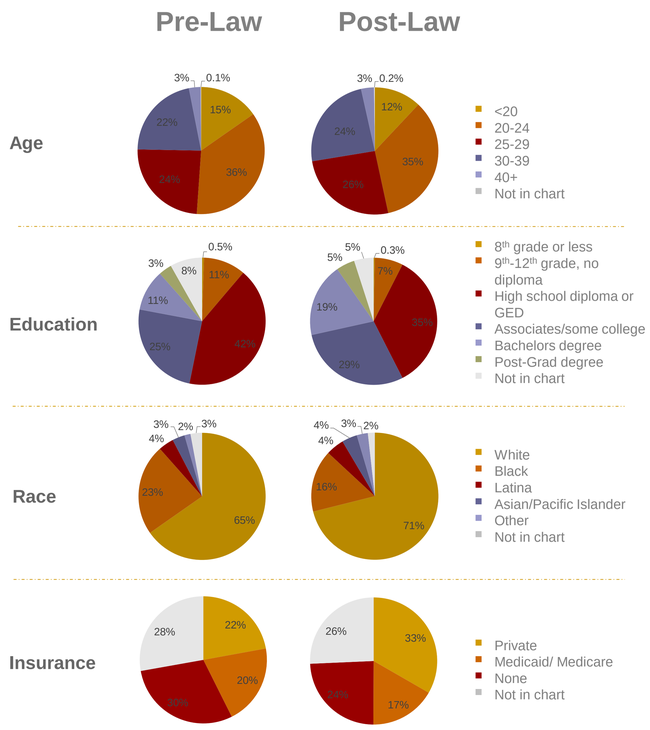
Data analysis

- Used multivariable logistic regression to model the adjusted odds of requiring an intervention and paired t-tests for comparisons of demographic characteristics
- Included only a woman's first abortion if she had more than one during the study period
- Included only gestations ≤49 days LMP to analyze change in need for subsequent intervention
- Included medication abortions at all gestations to analyze change in sociodemographics

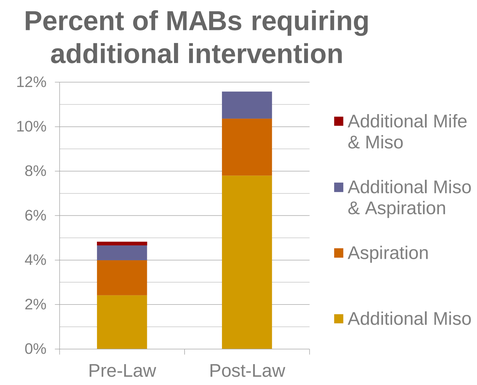
Results

3,667 charts abstracted, 2,079 from pre-law period and 1,588 from post-law period.

- The sociodemographic composition of women obtaining medication abortion changed after the law went into effect (Age p<0.05; all others p<0.001)



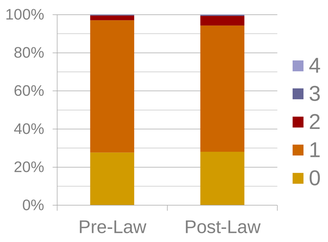
- A larger proportion of medication abortion patients required additional intervention in the post-law period (11.7%) than in the pre-law period (4.8%) (p<0.001)



Adjusted odds ratio **2.44**

- AOR controlled for age, race, education, BMI, health insurance status, weeks gestation, number of previous births, and facility.

Twice as many women in the post-law period had 2 or more follow-up visits (6% vs 3%, p<0.001)



Conclusion

- Current Ohio law requires use of a medication abortion protocol that is less effective than the current evidence-based standard of care.
- The change in Ohio law results in greater need for additional intervention and more clinical visits.
- The law may affect the ability of vulnerable populations (lower SES, non-white, younger women) to obtain medication abortion.
- Similar laws have been:
  - Enacted in North Dakota and Texas
  - Approved but currently enjoined by court order in Arizona and Oklahoma
  - Proposed in Iowa and South Carolina
- Additional states are likely to include such regulation in new legislation.[6]

[1]Cordray v. Planned Parenthood Cincinnati Region. Ohio Supreme Court; 2009:2972.

[2]American College of Obstetricians and Gynecologists. Practice bulletin no. 143: medical management of first-trimester abortion. Obstet Gynecol 2014;123:676-92.

[3]Winikoff B, Dzuba IG, Creinin MD, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstet Gynecol 2008;112:1303-10.

[4]World Health Organisation Task Force on Post-ovulatory Methods of Fertility Regulation. Comparison of two doses of mifepristone in combination with misoprostol for early medical abortion: a randomised trial. BJOG 2000;107:524-30.

[5]Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med 1998;338:1241-7.

[6]Guttmacher Institute. State Policies in Brief: Medication Abortion. 2015.

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