

Embryo transfer practices and perinatal outcomes by insurance mandate status

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Objective: To use linked assisted reproductive technology (ART) surveillance and birth certificate data to compare ET practices and perinatal outcomes for a state with a comprehensive mandate requiring coverage of IVF services versus states without a mandate.

Design: Retrospective cohort study.

Setting: Not applicable.

Patient(s): Live-birth deliveries ascertained from linked 2007–2009 National ART Surveillance System and birth certificate data for a state with an insurance mandate (Massachusetts) and two states without a mandate (Florida and Michigan).

Intervention(s): None.

Main Outcome Measure(s): Number of embryos transferred, multiple births, low birth weight, preterm delivery.

Result(s): Of the 230,038 deliveries in the mandate state and 1,026,804 deliveries in the nonmandate states, 6,651 (2.9%) and 8,417 (0.8%), respectively, were conceived by ART. Transfer of three or more embryos was more common in nonmandate states, although the effect was attenuated for women 35 years or older (33.6% vs. 39.7%; adjusted relative risk [RR], 1.46; 95% confidence interval [CI], 1.17–1.81) versus women younger than 35 (7.0% vs. 26.9%; adjusted RR, 4.18; 95% CI, 2.74–6.36). Lack of an insurance mandate was positively associated with triplet/higher order deliveries (1.0% vs. 2.3%; adjusted RR, 2.44; 95% CI, 1.81–3.28), preterm delivery (22.6% vs. 30.7%; adjusted RR, 1.31; 95% CI, 1.20–1.42), and low birth weight (22.3% vs. 29.5%; adjusted RR, 1.28; 95% CI, 1.17–1.40). **Conclusion(s):** Compared with nonmandate states, the mandate state had higher overall rates of ART use. Among ART births, lack of an

infertility insurance mandate was associated with increased risk for adverse perinatal outcomes. (Fertil Steril® 2015;104:403–9. ©2015 by American Society for Reproductive Medicine.)

Key Words: Assisted reproductive technology, embryo transfer, insurance coverage, multiple hirth

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n the United States, insurance coverage for infertility treatments is limited, with many patients incurring substantial out-of-pocket costs for medications and medical procedures (1). To increase access to services and

reduce financial burden, 15 states have adopted insurance mandates requiring that private insurers provide coverage for infertility treatments (2–5). However, the scope of the mandates is variable with respect to

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the type of services covered, patient requirements, and exceptions (3–6). As such, infertility insurance mandates are often broadly categorized into three groups according to number and types of services covered and type of plans affected by the policy (2, 7). "Comprehensive" mandates require that insurers cover the costs associated with the diagnosis and treatment of inclusive infertility assisted reproductive technology (ART) services for at least four oocyte retrievals. "Limited" mandates specify that only certain types of insurers, such as health maintenance organizations, must cover ART or impose limits on the amount of

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ART coverage to be provided. Finally, "offer" mandates require insurers to make available policies that include coverage for infertility treatments and do not require coverage of ART (2). Currently, eight states have mandates that cover at least one ART cycle (3).

In addition to expanding access to infertility services, mandated coverage of ART may lessen the financial pressure to conceive in one cycle, thereby leading to a reduction in the number of embryos transferred per cycle and a consequent decline in multiple births (1, 2, 8). Studies of insurance coverage and fertility outcomes using clinic data showed increased use of infertility services in states with comprehensive or limited mandates compared with states with no coverage (2, 9). Analyses of population-level fertility effects also demonstrated increases in the use of fertility services (7, 10) and birth rates (4) in states with comprehensive mandates compared with states without mandates; however, the effects were largely concentrated among a subgroup of older, more educated women.

It has been noted that states with comprehensive mandates transfer fewer embryos per cycle than those without mandates (2, 3, 7, 9, 11), although variations by age have been observed (12). The association between mandate status and multiple births (twins, triplets, and higher order births) is inconsistent, with some studies showing lower rates of multiple birth in states with comprehensive mandates compared with nonmandate states (2, 3) and others indicating an effect for triplet or higher order gestations only (7, 9, 11). Furthermore, the reductions in multiple birth rates appear to be heterogeneous across age groups (12) and other factors such as race and education (13).

The effect of infertility insurance mandates on perinatal outcomes such as low birth weight and preterm birth has not been well documented. Moreover, most studies of mandate effects were limited by lack of patient-level data and were unable to control for demographic and clinical factors related to potential differences in patient selection between ART users in a mandate state and those in a state without a mandate. The aim of the current study was to use ART surveillance data that have been linked to birth certificate information for a state with a mandate (Massachusetts) and two states without mandates (Michigan and Florida) to compare ET practices and perinatal outcomes by mandate status.

MATERIALS AND METHODS

The data used for this analysis were derived from linked ART surveillance and birth certificate data for three states: Massachusetts, Michigan, and Florida. The linkage methodology has been described elsewhere (14, 15). Briefly, data from the Centers for Disease Control and Prevention's National ART Surveillance System (NASS) were linked with vital records information provided by members of the States Monitoring ART Collaborative. To date, data have been linked only for the three aforementioned states. Data from additional states may be added in the future but were not available for the current analysis. The linkage was constructed using LinkPlus software and used a probabilistic method with maternal and infant date of birth, plurality, maternal

residence zip code, and gravidity as primary linkage variables. Duplicate links were resolved using zip code, gravidity, and ancillary information such as maternal race, infant gender, and infant birth weight. Additional selection priorities were used to reconcile near exact matches on the primary linkage variables. Specifically, priority was given when both records matched on gravidity; when there was a single-digit difference in day or month or when day and month were swapped; or when both records matched on maternal race, infant gender, and birth weight or for first deliveries for mothers 35 years of age or older and multiple births. For all three states, this methodology resulted in an overall linkage rate of 90.2% for 2007–2009.

We included all resident live births in Massachusetts, Michigan, and Florida during 2007–2009 that successfully linked with NASS data or those live births identified to have occurred as the result of ART as determined by the linkage process. The unit of analysis was a delivery; infant records for multiple births were aggregated to a single delivery record. Deliveries with missing information on plurality or maternal age were excluded (<0.01% for each state).

Massachusetts adopted an infertility insurance mandate in 1987 requiring that private insurers provide coverage for medically necessary treatments related to the diagnosis and treatment of infertility, which is defined as an inability to conceive during 1 year for women younger than 35 years of age or during 6 months for women 35 years or older (16). Infertility-related services are covered to the same extent as pregnancy-related services, and there is no limit on the number of treatment cycles and no lifetime cap on coverage. Employers that self-insure are not required to provide statemandated benefits because the federal Employee Retirement Income Security Act preempts the state law (17). Currently, Michigan and Florida have no mandate.

For ART and non-ART live-birth deliveries, we compared sociodemographic factors (maternal age, parity, education, race/ethnicity, and insurance at delivery) for women living in the mandate state with those of women living in the nonmandate states. Among ART deliveries, we examined infertility type (tubal factor, ovulatory dysfunction, diminished ovarian reserve, endometriosis, uterine factor, male factor, other factor, or unexplained infertility), type of ART (fresh nondonor, fresh donor, frozen-thawed nondonor, or frozenthawed donor embryos), use of intracytoplasmic sperm injection (ICSI), use of assisted hatching, number of supernumerary embryos cryopreserved, embryo stage at transfer (days 2-3, days 5-6, or other), and number of previous ART cycles according to residency in the mandate or nonmandate states. Next, we compared the use of elective single ET (eSET), mean number of embryos transferred, transfer of three or more embryos, and perinatal outcomes (twin or triplet/higher order birth, preterm birth, low birth weight [in any infant for multiple births], and delivery of a term, normal birth weight singleton, i.e., singleton infant with birth weight $\geq 2,500$ g and gestational age \geq 37 weeks) for ART deliveries in a mandate state with those in nonmandate states. All sociodemographic characteristics and infant outcomes were derived from birth certificate information. ART treatment characteristics were obtained from NASS data. ESET was defined as

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