

years), time period (1995-2019), and cohort (birth years 1950-2005) on the temporal trends of infertility, we used generalized estimating equations within the framework of an age-period-cohort (APC) analysis among participants with complete data, adjusted for race/ethnicity and socioeconomic status. We further stratified the APC models by self-reported body mass index (BMI).

**RESULTS:** The prevalence of reported infertility increased over time, from 2.5% in 1980-1984 to 5.3% in 2015-2019. The increase over time was observed across all age groups. The prevalence mostly increased with age (1.6%, 3.8%, 5.7%, 7.3%, 7.5%, and 7.1% among ages 20-24, 25-29, 30-34, 35-39, 40-44, and 45-49, respectively). The increase over age was observed across all periods. APC analysis further revealed independent age and cohort main effects and cohort deviations: (1) period 2015-2019 showed highest reported infertility prevalence (1.09-times higher [95% CI: 1.04-1.14] than overall average); (2) age 40-44 showed highest reported infertility prevalence (1.53-times higher [95% CI: 1.47-1.60] than overall average); (3) birth cohort 1985-1989 showed 1.07-times higher (95% CI: 1.00-1.16) reported infertility prevalence than the expectation based on age and period main effects, while birth cohort 1995-1999 exhibited 0.86-times lower (95% CI: 0.77-0.97) prevalence than the expectation. The prevalence of reported PCOS-Inf showed similar increase over time, with period 2010-2014 exhibiting the highest prevalence (1.20-times higher [95% CI: 1.12-1.29] than the overall average) and birth cohorts 1975-1984 exhibiting higher than expected prevalence. When stratified by BMI, those with BMI  $\geq 25$  kg/m<sup>2</sup> showed steeper increase in reported infertility (and PCOS-Inf) over time, while those with BMI  $< 25$  kg/m<sup>2</sup> had relative stable prevalence over time.

**CONCLUSIONS:** Among females from a US digital cohort, self-reported physician diagnosed infertility increased over time, with notable variations by age and birth cohorts. Steeper increase was observed among those with higher BMI.

**IMPACT STATEMENT:** The rising reported infertility over time and among certain birth cohorts, especially among those with higher BMI, calls for the importance of lifestyle modifications to address the growing complexity of fertility challenges in the US. Future work is needed to further investigate timing of childbearing preferences.

**SUPPORT:** This study received funding from Apple Inc. The funding source provided platforms and software for data collection and participated in review of the abstract. It played no role in the analysis of data, or in the decision to submit.

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### IDENTIFICATION OF SUPERIOR QUALITY EJACULATES THAT PRODUCE HIGHER RATES OF DAY-5 BLASTOCYSTS BY USE OF THE KINETIX SPERM FCR BINDING ASSAY.



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**OBJECTIVE:** Development of a sperm surface proteomic assay for functional FcR, run multiple times on an ejaculate at 30min intervals over time, identified several distinct temporal patterns of protein expression<sup>1,2</sup>. These distinct patterns were hypothesized to reflect the sequence of protein expression changes that occur as groups of short-lived capacitating sperm arise, mature and senesce, as described by Cohen-Dayag (1995). These patterns were evaluated to determine if a new assay could be leveraged to identify better quality sperm samples and possibly improve ART outcomes.

**MATERIALS AND METHODS:** The Kinetix Sperm FcR Binding Assay that detects levels of an Fc receptor (FcR) over time was performed on semen samples during ICSI procedures (n=162) in a prospective observational study. Briefly, 5uL aliquots of semen were analyzed at 30-min intervals to determine the proportion of sperm expressing FcR over time. Semen samples were categorized as “poor”, “medium” or “good.” Fertilization rate, production of Day 5 good quality blastocysts (QGB) with standard criteria ( $\geq 3$ BB) and formation of Day 3 good quality embryos with 8 cells were evaluated.

**RESULTS:** Similar fertilization rates were observed across all cycles independent of the Kinetix assay measured ejaculate quality, being 76% (poor quality, n=19), 69% (medium quality, n= 84) and 72% (good quality, n= 59). In contrast, the percentage of cycles at Day 3 that produced good quality embryos was limited to ejaculates of good and medium quality (76% and 82%, respectively). Only 47% of poor quality ejaculates produced good quality Day 3 embryos. At Day 5 the percentage of cycles that produced good

quality blastocysts was limited to ejaculates of good and medium quality (73% and 63%, respectively). Only 37% of poor quality ejaculates produced good quality Day 5 blastocysts.

**CONCLUSIONS:** A novel sperm FcR binding assay (Kinetix) that characterizes expression patterns of Fc Receptors on sperm during capacitation identified superior quality ejaculates which produced higher rates of Day 3 embryos and Day 5 blastocysts and distinguished these from poor quality ejaculates associated with elevated risk of cycle failure. The function measured by the Kinetix Assay appears capable of reflecting issues—not with fertilization—but with functional deficits adversely impacting embryo development after successful fertilization but preceding Day 5 and may improve ART outcomes.

**IMPACT STATEMENT:** The Kinetix Sperm FcR Binding Assay identified ejaculates associated with embryo failures at Day 3 and cycle failures at Day 5, providing a means to qualify ejaculates to improve ART outcomes.

**SUPPORT:** Arex Life Sciences, LLC

**REFERENCES:** 1. Librach et al., *Human Sperm “Cycle” Between States of Fertility and Infertility, the Knowledge of Which Can Predict IUI Success.* ASA Mtg May 2022.

2. Yazdkhasti, et al., *A Sperm Function Assay Identifies Previously-undiagnosable Male Factor in ART,* Fertil Steril., Vol 120, No. 4. 2023.

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### INVOCELL VERSUS IVF: A COST-EFFECTIVENESS ANALYSIS.



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**OBJECTIVE:** INVOcell, an intravaginal culture (IVC) system, is currently marketed as a more cost-effective in vitro fertilization (IVF) alternative for the treatment of infertility. However, no formal cost-effectiveness analysis has been done to date. Our objective was to determine the cost-effectiveness of INVOcell compared to traditional IVF and embryo transfer without PGT-A to achieve a live birth (LB).

**MATERIALS AND METHODS:** We compared the cost of INVOcell versus IVF with embryo transfer without PGT-A to achieve a LB in good prognosis patients using a decision analytic model. LB rates per IVC and IVF cycles were obtained from the literature. Cost estimates were obtained using an average of estimates published on clinic websites and from published literature. All costs were adjusted for inflation to 2025 \$USD using the Consumer Price Index. The model analyzed a hypothetical single INVOcell cycle with cost including range of minimal to conventional stimulation protocol versus IVF with a conventional stimulation protocol, with both groups undergoing a standard transfer of an untested embryo. A willingness to pay (WTP) threshold of \$10,000 was assumed.

ART	Live birth rate per cycle (SD)	Source	Cost per cycle	Source
INVOcell	0.3 (0.06)	Jellerette-Nolan et al, 2020	\$6,500-12,000	Multiple US fertility clinic websites with SD of \$3000
IVF	0.43 (0.05)	CDC’s National ART Summary, 2022	\$15,000-25,000	ASRM, 2020; adjusted for inflation to 2025 with SD of \$5000

**RESULTS:** IVC is cost-effective compared to IVF in good prognosis patients, with an incremental cost-effectiveness ratio (ICER) of \$88,137 per live birth. On average, IVF results in a 13% higher live birth rate for an