# Shifts in ART clinical practice – navigating cycle definitions and potential implication on fertility treatment coverage in the United States

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- Assisted reproductive technology (ART) is defined as all treatments that include the handling of gametes/embryos
- In vitro fertilization (IVF) is the most common type of ART and, at its inception, simply included ovarian stimulation to oocyte retrieval (OR), sperm insemination of oocytes, and early developed embryo(s) transfer (ET)
- Contemporary ART now involves additional clinical procedures as well as emerging laboratory technologies (extended culture, vitrification, pre-implantation genetic testing [PGT]) incorporated into the IVF cycle
- Alternative "add-ons" have also been offered to patients as an attempt to maximize chances of treatment success<sup>1</sup>
- The Society for Assisted Reproductive Technology (SART) approaches "cycles" as any initiated ORs, frozen ETs (FETs), frozen egg thawing, and canceled cycles
- Understanding how the treatment landscape shifts and how utilization differs for these different types
  of cycles, as well as their varying costs/outcomes, is crucial for employers, payer groups, and public
  policy makers



Identify clinical practice shifts over time and potential implications on fertility treatment coverage in the United States



- A descriptive review of the SART database<sup>2</sup> was conducted, including 6 years of available data (2014–2019)
- The following cycle variables were temporally compared: total number of cycles initiated including ORs (autologous/egg donor: fresh/banked, egg/embryo fertility preservation), FETs, PGT cycles (OR/ETs from biopsied embryos), and canceled cycles
- Shifting clinical practice was described by number of cycles, actual year-over-year (YOY) percent change, and average percent change per year over the 6-year period

<sup>2</sup> Society for Assisted Reproductive Technology. Available at <u>https://www.sart.org</u>.



- The total number of cycles initiated in the US increased by an average of 9.2% per year, from 189,347 to 293,672 cycles (2014–2019)
- FET cycles represented the majority of all ETs from 2017 to 2019. The percentage of canceled cycles was similar across the studied years, averaging 8.7% of the total cycles initiated per year



#### All cycles initiated

<sup>a</sup> First ET: within 1 year of OR.

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• ORs increased by an average of 5.8% per year (2014–2019), with lower YOY growth from 2018 to 2019 compared with 2017 to 2018 (2.9% vs 9.6%, respectively)



### All oocyte retrieval (OR) cycles



- PGT inclusion in ART cycles had an average utilization increase of 35.8% per year from 15,859 to 51,887 retrievals (2014–2019). The rate of increase in PGT cycles slowed for each of the five YOY timeframes, from a 70.6% increase (2014–2015) to a 14.7% increase (2018–2019)
- Similarly, FET cycle utilization increased at an average rate of 13.9% per year (2014–2019) but had a
  decrease in YOY growth, from a 20.8% increase (2014–2015) to a 3.4% increase (2018–2019)



### Additional IVF technologies



• Of note, OR autologous use, the initial type of ART OR cycle, only increased by an average of 2.8% per year; this included declines of 2.8% from 2016 to 2017 and of 1.1% from 2018 to 2019



Autologous OR cycles

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Year
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 Cycles with the largest increases: donor oocyte banking increased by an average of 31.0% per year from 2016 to 2019



## Donor OR cycles

All donor oocyte retrievals
 Banking (without recipient)
 Fresh (with recipient)



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- Cycles with the largest increases: autologous OR for fertility preservation increased by an average of 18.2% per year from 2014 to 2019
- From 2018 to 2019, large increases of 41.3% and 24.2% were seen in embryo and oocyte preservation utilization, respectively



### Autologous OR cycles for fertility preservation



- Public registry data, such as those in the SART database, can help to detect important shifts in the clinical landscape as described here
- Better understanding of the ART landscape and of the evolution of the ART cycle concept can help to guide policy discussions related to utilization management, which is important for fertility access and coverage decision making

# **Disclosures**

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# References

- 1. Farquhar C. Introduction: Add-ons for assisted reproductive technology: can we be honest here? Fertil Steril 2019;112:971–2.
- 2. Society for Assisted Reproductive Technology. Available at <u>https://www.sart.org</u>.

