A retrospective comparison of the impact of industry payments on assisted reproductive technology practice and outcomes

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Objective: To determine whether industry payments to physicians are associated with a difference in assisted reproductive technology practices and outcomes.
Design: Retrospective cohort.
Patient(s): Patients undergoing asissted reproduction.
Intervention(s): Industry payments reported to the Open Payments 2020 database.
Main Outcome Measure(s): The live birth rate, frozen embryo transfer (FET) rate, intracytoplasmic sperm injection (ICSI) rate, preimplantation genetic testing (PGT) rate, and percentage of patients aged >40 years were obtained from the Centers for Disease Control and Prevention 2020 database. Linear regression analysis was performed comparing the percentage of physicians per center receiving industry payments to clinic-level outcomes.
Result(s): A total of 873 reproductive endocrinology and infertility physicians received payments in the 2020 database. At least one physician received a payment in 80.5% (437/543) of in vitro fertilization centers. Of 1,724 reproductive endocrinology and infertility physicians, 873 (50.6%) received at least one payment in 2020. The live birth, ICSI, FET, and PGT rates and percentage of patients aged >40 years did not significantly differ between centers by percentage of physicians receiving industry payments. However, in the subanalysis of 99 large centers (defined as ≥ 5 physicians), each increase in the percentage of physicians receiving industry payments was associated with increases of 0.20% (95% confidence interval, 0.02–0.39) and 0.14% (95% confidence interval, 0.05–0.24) in the PGT and FET rates, respectively. The live birth, ICSI rates and percentage of patients aged >40 years were not associated with increased industry payment rates to physicians.
Conclusion(s): Industry payments were not associated with differences in in vitro fertilization center outcomes overall. However, large centers with more physicians receiving industry payments may be more likely to use additional procedures such as PGT and FET, without improvement in the final outcomes such as the live birth rate. Further research is needed to determine whether these differences reflect the industry payment influence vs. individual center/provider practice habits in larger practices. (Fertil Steril® 2025;123:115–20. ©2024 by American Society for Reproductive Medicine.)
El resumen está disponible en Español al final del artículo.

Key Words: Industry payments, ART, live birth rate, affordable care act

Open Payments is a federally mandated database administered through the Centers for Medicare & Medicaid Services through which medical device and pharmaceutical companies should report payments >$10 made to healthcare providers (1). Payments reported range from entertainment, food/beverage payments, promotional gifts, lodging, and charitable donations. This program, enacted under the Physician Payments Sunshine Act in 2010, aims at improving transparency of financial relationships between industry and physicians that may affect patient care.

Such reporting became mandatory because of concern that physician practices were being influenced by these payments. Although no studies to date have demonstrated differences in

Received March 1, 2024; revised July 30, 2024; accepted July 31, 2024; published online August 3, 2024.
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Fertil Steril® Vol. 123, No. 1, January 2025 0015-0282/$36.00

https://doi.org/10.1016/j.fertnstert.2024.07.998

patient outcomes, previous research has demonstrated differences in clinical practices. For example, providers who received pharmaceutical gifts prescribed significantly more branded medications than those that did not receive pharmaceutical gifts (2,3).

One descriptive study among obstetrician/gynecologists who received industry payments in 2014 found that obstetrician/gynecologists ranked 20th of 35 specialties for median value of industry payments received (4). Various other medical subspecialties, such as orthopedic surgery and gastroenterology, have also investigated the prevalence of industry payments in their fields, although they have not examined how patient outcomes have been affected by these payments (5, 6). Potential conflicts of interest are found even among the upper tier of academic practitioners. One study found that investigators of dermatology clinical practice guidelines routinely received pharmaceutical payments from companies with products related to their guideline publications, although an influence of these payments on the guidelines was not examined (7).

Although reproductive endocrinology and infertility (REI) specialists guide patients through lengthy and often costly fertility treatments, many of which are not covered by insurance, no such analysis has yet been conducted on the effects of industry payments to REI providers. One previous descriptive Australian study found that pharmaceutical companies spent $A522,263 on fertility-related events for healthcare professionals and scientists from 2011 to 2018 (8). However, they did not assess the clinical impact of these payments (8). Given the mandate to report assisted reproductive technology (ART) outcomes to the Centers for Disease Control and Prevention (CDC) in accordance with the Fertility Clinic Success Rate and Certification Act, the field of reproductive medicine is particularly well poised to assess the effect of industry payments on clinical outcomes (9).

In this study, we aimed to assess whether the proportion of physicians at in vitro fertilization (IVF) centers receiving industry payments was associated with ART practices and outcomes. We assessed the live birth rate as our primary outcome. We hypothesized that IVF centers with a higher percentage of physicians receiving industry payments would translate into lower live birth rates, reflecting profit-driven practices adversely impacting patient outcomes. We investigated intracytoplasmic sperm injection (ICSI) rates, preimplantation genetic testing (PGT) rates, and percentage of patients aged >40 years as the secondary outcomes. We hypothesized that IVF centers with a higher percentage of physicians receiving industry payments would be more likely to use high-profit procedures such as ICSI and PGT, possibly beyond their usual indications and with a theoretical risk of iatrogenic harm. We also hypothesized that fertility centers with a higher percentage of physicians receiving industry payments would have a higher proportion of patients aged >40 years, possibly reflecting a higher tolerance to take poor candidates through ART cycles. We hypothesized that these effects would be more pronounced in centers with physicians receiving the highest percentile of payments. Lastly, we hypothesized that these effects would be more pronounced in the largest centers, where industries may focus more attention because of higher profit potential.

MATERIALS AND METHODS

A retrospective cohort study of all IVF centers in the United States reporting to the CDC was performed. Reproductive endocrinology and infertility physicians at these centers receiving industry gifts, such as entertainment, food/beverage payments, promotional gifts, and lodging, were identified using the Open Payments database, which is publicly available online through the Centers for Medicare & Medicaid Services website. All REI physicians who received reported payments in 2020 were included. Payments for royalties/shares were excluded because these payments do not reflect industry gifts.

A list of all REI centers reporting data to CDC in 2020 was created. Each center's website was queried in 2022, the year of data collection, to obtain a comprehensive of list of all REI physicians employed at each center. Physicians reported as receiving payments in the Open Payments system were then matched to a center on the basis of the address reported to the Open Payments system in 2020; physicians who moved centers between 2020 and 2022 were counted in their 2020 center only and were removed from the denominator of their 2022 center. The proportion of physicians in each center receiving industry payments was calculated as the number of all physicians in the center reported in the Open Payments system divided by the total number of physicians in the center as of 2022.

ART outcome data by IVF center were extracted from the CDC 2020 National ART Surveillance System (NASS), also publicly available online. The 2020 Open Payments database and CDC NASS were the most recent data available at time of data collection. The following variables were collected: live birth rate; frozen embryo transfer (FET) rate; ICSI rate; PGT rate; cycle cancellation rate; and percentage of patients aged >40 years. Institutional Review Board approval was not obtained because all data collected were publicly available.

Statistical analysis

Linear regression analysis was performed comparing the percentage of physicians per center receiving industry payments to center-level outcomes. Linear regression analysis was also performed comparing the total dollar amount to physicians given per center to center-level outcomes. Subanalysis was performed specifically investigating IVF center outcomes on the basis of the percentage of physicians per center who were receiving top 10% of individual payments by the total dollar amount. Additionally, a subanalysis of large and small IVF centers (defined as ≥ 5 physicians vs. <5 physicians) was also performed. Both of these analyses were also performed with linear regression. All analyses were adjusted for number of physicians and total number of cycles.

RESULTS

A total of 1,724 REI physicians were identified while mapping physicians via IVF center websites. There were 4,546 individual industry payments reported in 2020. Of 1,724 REI physicians,

TABLE 1

Characteristics of 543 assisted reproductive technology clinics in 2020.

Fertility center characteristics	10th	25th	50th	75th	90th
No. of physicians	1	1	2	4	7
No. of paid physicians	0	1	1	2	4
Total amount paid ($)	0	18	84.4	375.9	3,177.3
No. of payments	0	1	4	10	25

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873 (50.6%) received at least one payment in that year. A total of 543 centers reported ART practice and outcome data to the CDC. A median of 2 REI physicians were employed per IVF center, with the 90th percentile in size employing seven physicians (Table 1). There were 99 large IVF centers (defined as ≥5 physicians), each performing a median cycle number of 447 (interquartile range, 354–712.5). Large IVF centers comprised 18% of all clinics included. In contrast, the 444 IVF centers with <5 physicians performed a median cycle number of 122.5 (interquartile range, 60–203.75). At least one physician received a payment in 80.5% (437/543) of IVF centers. Payment value distribution was right-skewed, with a median payment of $84.40 but the 90th percentile payment being $3,177 (Table 1). The sources of payment were largely from pharmaceutical, medical device, and surgical device companies. Eighty-five percent (3,864) of payments were from pharmaceutical companies, 15% (681) were from medical/surgical device companies, and 0.24% (11) were from diagnostic genetic testing companies.

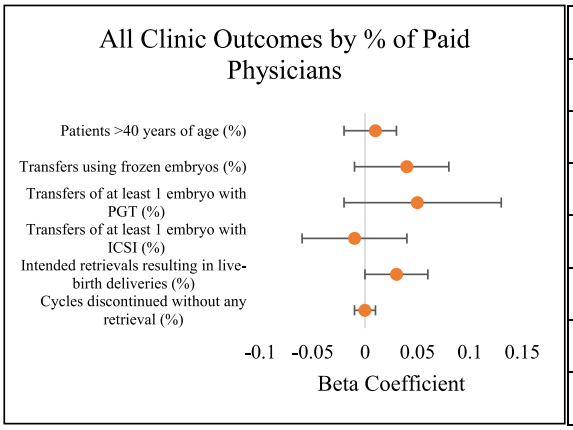
The live birth rate did not significantly differ on the basis of the percentage of physicians receiving industry payments; with each increase in the percentage of physicians per clinic receiving industry payments, the live birth rates increased by 0.06% (95% confidence interval [CI], −0.004 to 0.12; P=.07; Fig. 1). Patients aged >40 years and the FET, PGT, ICSI, and cycle cancellation rates also did not significantly differ between IVF centers by percentage of physicians receiving industry payments (Fig. 1). They also did not differ by the total dollar amount given to physicians per center (Supplemental Table 1, available online). This was maintained in the subanalysis of centers with higher percentages of physicians receiving top 10% of payments by payment value (Fig. 2).

In the subanalysis of 99 large IVF centers, significant differences were noted in the PGT and FET rates. With each increase in the percentage of physicians receiving industry payments, the PGT rate increased by 0.20% (95% CI, 0.02–0.39; P=.03), and the FET rate increased by 0.14% (95% CI, 0.05–0.24; P<.001). The live birth and ICSI rates and percentage of patients aged >40 years were not associated with increased industry payment rates to physicians in these large centers (Fig. 3). When analysis was restricted to IVF centers with <5 physicians, no significant differences were noted (Supplemental Table 2).

DISCUSSION

The findings in this study suggest that industry payments are not associated with differences in the examined IVF center

FIGURE 1



	% of Paid Physicians		
	β	95% CI	p-value
Patients >40 years of age (%)	0.01	-0.02, 0.03	0.66
Transfers using frozen embryos (%)	0.04	-0.01, 0.08	0.11
Transfers of at least 1 embryo with PGT (%)	0.05	-0.02, 0.13	0.19
Transfers of at least 1 embryo with ICSI (%)	-0.01	-0.06, 0.04	0.63
Intended retrievals resulting in live-birth deliveries (%)	0.03	-0.003, 0.06	0.07
Cycles discontinued without any retrieval (%)	0.004	-0.01, 0.01	0.45

Associations of 2020 payment characteristics with 2020 clinic practice and outcomes. All models adjusted for the total number of physicians and total number of cycles. The β-coefficient represented the association of a 1% increase in the proportion of physicians receiving industry payments with clinic characteristics and outcomes. CI = confidence interval; ICSI = intracytoplasmic sperm injection; PGT = preimplantation genetic testing.

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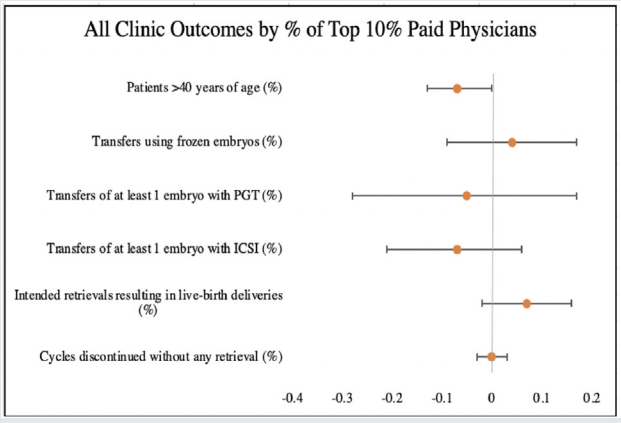
FIGURE 2



	Percentage of Physicians in Top 10%		
	β	95% CI	p-value
Patients >40 years of age (%)	-0.07	-0.13, 0.0003	0.05
Transfers using frozen embryos (%)	0.04	-0.09, 0.17	0.57
Transfers of at least 1 embryo with PGT (%)	-0.05	-0.28, 0.17	0.64
Transfers of at least 1 embryo with ICSI (%)	-0.07	-0.21, 0.06	0.29
Intended retrievals resulting in live-birth deliveries (%)	0.07	-0.02, 0.16	0.12
Cycles discontinued without any retrieval (%)	0.00	-0.03, 0.03	1.00

Association of top 10% 2020 payment characteristics with 2020 clinic practice and outcomes. All models adjusted for the total number of physicians and total number of cycles. The β-coefficient represented the association of a 1% increase in the proportion of physicians receiving industry payments with clinic characteristics and outcomes. CI = confidence interval; ICSI = intracytoplasmic sperm injection; PGT = preimplantation genetic testing.

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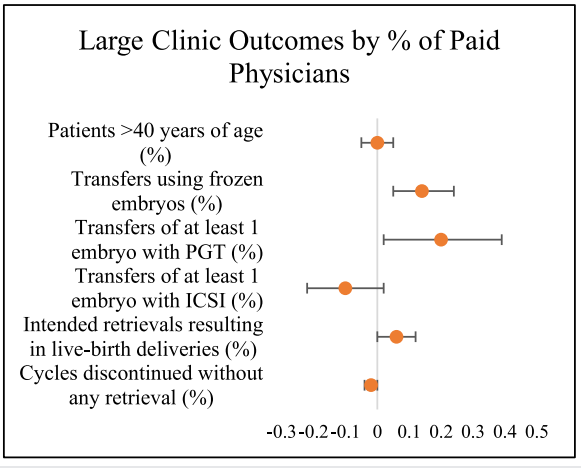
practice and outcomes overall. Industry payments were not shown to impact the live birth, ICSI, FET, PGT, cycle cancellation rates and percentage of patients aged >40 years across IVF centers nationally. This is a reassuring finding that industry payments are not associated with clear changes in clinical outcomes. However, in subanalyzes restricted to larger centers, some variations in practices are noted without an impact on clinical outcomes.

Interestingly, in the subanalyzes, some differences in practices were noted, although notably without significantly affecting live birth rates. In large IVF centers, with ≥5 physicians on staff, the PGT and FET rates were significantly higher with higher rates of industry payments. It is unclear from this study why this trend exists. CDC NASS does not differentiate between different types of PGT, such as for aneuploidy or monogenic disorders, limiting interpretation. The CI for the PGT rate difference was also wide (95% CI, 0.02–0.39; *P*=.03). Although there was a statistical difference, it is unclear how clinically impactful this is. The FET rates were likely a consequence of the higher PGT rates in these clinics, which necessitate a frozen transfer. Payments were predominantly from pharmaceutical and medical/surgical device

FIGURE 3



	% of Paid Physicians		
	β	95% CI	p-value
Patients >40 years of age (%)	0.001	-0.05, 0.05	0.97
Transfers using frozen embryos (%)	0.14	0.05, 0.24	**0.003**
Transfers of at least 1 embryo with PGT (%)	0.20	0.02, 0.39	**0.03**
Transfers of at least 1 embryo with ICSI (%)	-0.10	-0.22, 0.02	0.09
Intended retrievals resulting in live-birth deliveries (%)	0.06	-0.004, 0.12	0.07
Cycles discontinued without any retrieval (%)	-0.02	-0.04, 0.002	0.07

Associations of 2020 payment characteristics with 2020 large clinic practice and outcomes. Large clinics defined as ≥5 physicians on staff. n = 99. All models adjusted for the total number of physicians and total number of cycles. The β-coefficient represented the association of a 1% increase in the proportion of physicians receiving industry payments with clinic characteristics and outcomes. CI = confidence interval; ICSI = intracytoplasmic sperm injection; PGT = preimplantation genetic testing.

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companies, not companies that supply genetic testing technology, and, therefore, should not have directly affected PGT, and consequent FET, usage. Thus, likely what is being seen is an association, not causation. It is possible that industries target larger IVF centers because of their higher profit potential, driving some of this difference. Conversely, perhaps, larger centers are more profit-driven and, therefore, more likely to use higher-earning procedures such as PGT as well as accept industry gifts. Alternatively, because this difference was only observed in large IVF centers, it could also reflect a difference in practices on the basis of IVF center size that is not related to industry payments or profit-based practices. For example, larger practices may have standardized protocols for performing FETs over fresh transfers.

Overall, this study is a novel investigation in industry payments within the field of REI and does provide reassurance that such payments are not significantly impacting the primary goal of achieving live births. This study, however, has several limitations. First, the data available were limited to only clinic-level outcomes, which precludes any possible analysis on how payments to individual physicians impact their specific care and outcomes. Second, physician mapping to IVF centers was performed in 2022, 2 years after the IVF center outcomes and Open Payments data. Eighteen physicians were identified as having moved during this time period. The effect of this time discrepancy was minimized by ensuring that physicians' address on the Open Payments database matched the regional location of their current job posting, and the physicians who had moved were instead matched to their 2020 location. We also were limited by our ability to track the previous employment history of physicians who were not listed in the Open Payments database but potentially relocated. Some other local job relocations may have been missed. Furthermore, this study is limited by its retrospective nature, limiting the range of individual outcomes that can be measured. The available data were only for clinic-level outcomes, not the outcomes per physician, which would likely be the most accurate measurement of industry payment effect. Additionally, there are potential IVF center characteristics, such as physician compensation model, delineation between private and academic practices, and patient population, that could not be accounted for and may be influencing outcomes. It is difficult with this study design to postulate why differences in practices are seen only in certain settings, such as large IVF centers, but not in the total cohort. Further research comparing fertility outcomes stratified by center size may be warranted.

There is ample opportunity for further research in this area of study. First, assessing industry payment effect on individual provider practice and outcomes, as opposed to clinic-level outcomes, would provide more informative analysis. Second, assessing whether out-of-pocket costs to patients are influenced by industry payments would be pertinent to the patient experience as well. In addition, further study should be assessed looking into IVF "add-on" procedures such as intralipid therapy, intravenous immunoglobulin, and human growth hormone. Furthermore, this research would benefit from further qualitative research assessing motivations for receiving industry payments and perceived clinical impact. It would also be beneficial to assess the impact of industry gifts in IVF centers outside of the United States.

CONCLUSION

Industry payments have been demonstrated previously to impact clinical practice, necessitating the implementation of the Open Payments system. However, this study suggests that within the field of REI, industry payments are not associated with differences in fertility outcomes overall. Further research is needed to determine whether the increased PGT and FET rates in large IVF centers reflect a disproportionate impact of industry payments or are more reflective of differences in practice habits in larger IVF centers.

CRediT Authorship Contribution Statement

Meaghan Jain: Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Miranda Blanco-Briendel:** Data curation. **Haotian Wu:** Formal analysis. **Julian Gingold:** Writing – review & editing, Conceptualization, Methodology. **Harry Lieman:** Writing – review & editing, Conceptualization, Supervision.

Declaration of Interests

M.J. has nothing to disclose. M.B.-B. has nothing to disclose. H.W. has nothing to disclose. J.G. has nothing to disclose. H.L. has nothing to disclose.

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Comparación retrospectiva del impacto del pago de la industria en la práctica de la tecnología de reproducción asistida y sus resultados.

Objetivo: Determinar si los pagos de la industria a los médicos está asociado con alguna diferencia en la práctica de la tecnología de reproducción asistida y sus resultados.

Diseño: Cohorte retrospectiva

Lugar: Centros con tecnología de reproducción asistida.

Paciente(s): Pacientes sometidas a reproducción asistida.

Intervención(es): Pagos de la industria reportados en la base de datos Open Payments 2020.

Medida de Resultado(s) Principal(es): La tasa de nacido vivo, tasa de transferencias de embriones congelados (FET), tasa de inyección intracitoplasmática de espermatozoides (ICSI), tasa de testeo genética preimplantacional (PGT), y porcentaje de pacientes >40 años fueron obtenidos de la base de datos del Centro de Control de Enfermedades y Prevention del 2020. Se realizó una análisis de regresión lineal comparando el porcentje de médicos por centro que reciben pagos de la industria con resultados a nivel de clínic.

Resultado(s): Un total de 873 médicos en endocrinología reproductiva e infertilidad recibieron pagos en la base de datos del 2020. Por lo menos un médico recibió un pago en el 80.5% (437/543) de los centros de fertilización in vitro. De los 1,724 médicos en endocrinología reproductiva e infertilidad, 873 (50.6%) recibieron por lo menos un pago en el 2020. Las tasas de nacido vivo, ICSI, FET y PGT y el porcentaje de pacientes >40 años no mostro diferencias significativas entre los centros por el porcentaje de pagos de la industria a los médicos. Sin embargo, en el subanálisis de 99 centros grandes (definidos como $\geq$5 médicos), cada incremento en el porcentaje de médicos que recibieron pagos de la industria fue asociado con un incremento del 0.20% (intervalo de confianza 95%, 0.02-0.39) y de un 0.14% (intervalo de confianza 95%, 0.05-0.24) en las tasas de PGT y de FET respectivamente. Las tasas de nacido vivo, de ICSI y el porcentaje de pacientes >40 años no se asoció con el incremento de pagos de la industria a los médicos.

Conclusiones: Los pagos de la industria no se asociaron con diferencias en los resultados generales de los centros de fertilización in vitro. Sin embargo, los centros grandes con más médicos que reciben pagos de la industria, pueden tener mas probabilidades utilizar procedimientos adicionales como PGT y FET, sin una mejoría de los resultados finales como la tasa de nacido vivo. Se necesitan más investigaciones para determinar si estas diferencias refleja una influencia del los pagos de la industria frente a los hábitos de centros individuales/práctica del proveedor en centros grandes.