

Society for Assisted Reproductive Technology advertising guidelines: How likely are member clinics to maintain compliance after resolving their violations?

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Objective: To evaluate the Society for Assisted Reproductive Technology (SART) member in vitro fertilization centers' compliance with SART's advertising guidelines after delayed correction of previous violations.

Design: Retrospective cohort study.

Setting: Internet.

Patient(s): None.

Intervention(s): None.

Main Outcome Measure(s): Clinics that were cited for noncompliance with SART advertising guidelines in 2019 and exceeded the two-week grace period in correcting their violations were studied. These clinics were rereviewed in 2020, at least 6 months after their initial citation, for violations of SART advertising guidelines in all six categories: supplemental data noncompliance, link to SART Clinical Summary Report and disclaimer statement missing, unsubstantiated claims, statements denigrating other clinics, and claims of superiority.

Result(s): In 2019, 44 (27%) of 161 of clinics reviewed by the SART advertising committee had at least one violation that was eventually resolved but not within the two-week grace period. On rereview in 2020, one clinic had not renewed its SART membership and 10 (23%) of the remaining 43 clinics were noted to have violations at the subsequent review. Improper presentation of supplemental data was the most common violation category in both the initial review, 32 (73%) of 44 clinics, and on rereview, 7 (70%) of 10 clinics cited a second time for violations.

Conclusion(s): Of the in vitro fertilization clinics with previous violations with delayed correction in 2019, 77% were subsequently compliant when reevaluated in 2020, indicating that advertising committee disciplinary and educational measures were largely effective. The most common citation for both years was maintaining consistent and transparent supplemental data on their websites. (*Fertil Steril Rep*® 2021;2:327–31. ©2021 by American Society for Reproductive Medicine.)

Key Words: Advertising, internet, in vitro fertilization, ART, SART

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In vitro fertilization (IVF) websites can be a valuable tool to both educate and attract patients to IVF

practices. However, in a competitive environment, without oversight and proper regulation, these websites may

display information that may be misleading (1). In January 2018, the Society for Assisted Reproductive Technology (SART) published revised guidelines for online advertising for its member IVF programs with the goal of maintaining transparent and ethical reporting (2). These guidelines focused on the proper reporting of IVF success rates, including prohibiting unsubstantiated claims, avoiding denigrating statements toward other clinics, and

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omitting superiority statements. The SART is the only medical organization in the United States that regulates its members through a voluntary advertising committee (AC). One of the goals of the AC is to ensure compliance with the Fertility Clinic Success Rate and Certification Act of 1992, also known as the Wyden law (3). This law mandates standardized and accurate success rate reporting by all IVF centers. Despite the organized and important supervisory role served by SART's AC, maintaining compliance with advertising guidelines is challenging for many reasons, including the following: advertising companies employed by IVF clinics are hired to promote the clinic and may not be aware of and/or disregard the SART advertising guidelines; success rate reporting may be more challenging for smaller IVF clinics or newer centers that cannot report on live birth rates, given the short time period of pregnancy outcomes and/or limited infrastructure and resources; and the competitive nature of IVF practice, which puts pressure on clinics to portray results in the most positive manner. Because of the high number of IVF programs in the United States, the SART AC reviews one third of member clinics each year, with each clinic therefore being reviewed at least once every 3 years. If deficiencies are found, the SART AC notifies the clinics and requests that all advertising violations be corrected within a two-week grace period. Violations are typically revised immediately. If an IVF clinic does not implement the requested changes, additional steps are taken in an escalating fashion, including placing a "red flag" on the clinic's SART success rate webpage, removing the clinic's data altogether, or ultimately revoking the clinic's SART membership. Our prior review of IVF program websites in 2018–2019 showed that compliance varied depending on the category violated. Most clinics followed the guidelines in avoiding superiority claims and denigrating statements but were most often out of compliance in success rate reporting (4). Our prior study showed the percentage of clinics that were adherent to the 2018 SART advertising guidelines during the single period studied. The available data and results, however, did not reflect whether the regulatory process was effective nor was there any information regarding the clinics' responses to the AC's notification of lack of compliance. Therefore, to understand how the regulatory process impacts the individual clinics' compliance, we evaluated the clinics that were cited by the AC in 2019 but took more than 2 weeks to correct their website. The goal of this study was to assess whether the clinics that were noncompliant in the past and tardy in correcting these violations were likely to be noncompliant again on rereview. Our study, in essence, was an assessment of the efficacy of the SART advertising oversight. In addition, we wanted to determine whether clinics that were noncompliant on rereview were more likely to commit these subsequent violations in the previously cited or in new categories.

MATERIALS AND METHODS

The AC reevaluated all clinics with violations in the calendar year 2019 that were not corrected within the two-week grace period. These reevaluations took place at least 6 months from the initial citation, assessing the six categories summarized

TABLE 1

2018 SART violation categories.^a

| Category | Description/examples |
|---|---|
| Supplemental data not compliant | <ol style="list-style-type: none"> 1. Inaccurate data not congruent with SART CSR data 2. Lack of denominators (cycle, retrieval, transfer) 3. Lack of live births per cycle start (intended retrieval) 4. Combined data from several years without latest current data (e.g., 2006–2016 combined data without 2017 data); old data (i.e., 2015 data) 5. Data lacking live births (i.e., only clinical pregnancies or positive HCG level) except for most current data for which live births have not been tallied |
| Link to SART CSR missing | The link to SART's CSR on www.SART.org is required if any presentation of supplemental data are present |
| SART "disclaimer statement" missing | The disclaimer statement "A comparison of clinic success rates may not be meaningful because patient medical characteristics, treatment approaches, and entry criteria for ART may vary from clinic to clinic" is required if any presentation of supplemental data are present |
| Unsubstantiated claims Yes | Statements regarding a clinic being the best in the field or having the best physicians without verifiable published data |
| Statements denigrating other clinics Yes | Denigrating statements (i.e., "Unlike other clinics, we report true success statistics honestly") |
| Claims of superiority Yes | Ranking IVF centers (i.e., "Our success places us as better than clinic X.") |

Note: CSR = Clinical Summary Report; HCG = human chorionic gonadotropin; SART = Society for Assisted Reproductive Technology.
^a Adapted from Society for Assisted Reproductive Technology (SART) policy for advertising by ART programs (2).

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from the 2018 SART advertising guidelines (Table 1, and Supplemental Table 1, available online) (2). The category of supplemental data was considered noncompliant for the following reasons: inaccurate data not congruent with SART Clinical Summary Report (CSR) data; lack of denominators (number of cycle starts, retrievals, or transfers); lack of live births per cycle start (intended retrieval); combined data from several years without latest current data (e.g., 2006–2016 combined data without 2017 data); old data (e.g., 2015 data); and data lacking live births (e.g., only clinical pregnancies or positive human chorionic gonadotropin levels) except for the most current data for which the live births have not been tallied. The link to SART's CSR along with inclusion of SART's disclaimer statement "A comparison of clinic success rates may not be meaningful because patient medical characteristics, treatment approaches, and entry criteria for ART may vary from clinic to clinic" was only required if supplemental success rate data was present on the center's website. Examples of unsubstantiated claims

included statements regarding a clinic being the best in the field or having the best physicians without verifiable published data. Statements denigrating other clinics or claims of superiority included statements disparaging other programs (e.g., “unlike other competitors, we are fully transparent to our patients”) or any claims of superiority (e.g., “best program in the state”, “most advanced lab in the state”). Ranking programs was considered a violation of the superiority category as it implied superiority of one program over another, disregarding variances in demographics and case difficulty.

Only the clinics with initial violations in 2019 that were not corrected within a two-week grace period were included in this analysis, and the remaining clinics (without violations or with violations immediately corrected within the two-week grace period) were not rereviewed on an accelerated schedule. The number of violation categories and not the number of actual violations in each category were recorded because of the heterogeneity in how advertising committee members documented separate violations. The time period from the initial violations to rereview of new violations in 2020 was assessed. The number of violation categories at the initial evaluation in 2019 was compared with that of the subsequent evaluation.

Only members of the AC had access to clinic-identifying information, and the other investigators in this study were only provided raw, deidentified data concerning violations. A nonhuman subject research exemption was obtained from the institutional review board before this study was conducted.

Descriptive statistics were used to describe the distribution of all variables. The average number of violation categories per clinic as well as violations in specific categories from the 2019 evaluations were compared using paired methods; Wilcoxon’s signed rank test for continuous variables and McNemar’s chi-squared test for categorical variables. These analyses were then repeated, restricted to only those clinics that had violations noted during the second time period in addition. Log-binomial regression models were used to examine the association between the number of violation categories for both time periods, as well as the number of months between the violations.

RESULTS

One hundred sixty-one of 383 SART member clinics were evaluated in 2019 by the SART AC members. In 2019, 44 (27%) of the 161 clinics reviewed had at least one website violation that was not resolved within the two-week grace period (Table 2). All these clinics eventually resolved their initial violations within a six-month period from the initial citation. One clinic did not renew its SART membership in 2020 and therefore only 43 clinics were reevaluated in 2020 by the AC. On rereview, 10 (23%) of the 43 clinics were noted to have violations in either the same or different categories as in the previous review. Eight (80%) of these 10 clinics that were out of compliance had a violation in the same category found in their previous review (Table 2). However, no violations were exactly the same as those during the first

TABLE 2

Overview of clinic compliance.

| | No. (%) |
|--|---------------------------|
| Percentage of clinic websites with violations in 2019 that remained noncompliant after the two-week grace period | 44/161 (27.3) |
| Percentage of these clinics that again had violations on being rereviewed in 2020 | 10/43 (23.3) ^a |
| Percentage of clinics with a second citation that had a violation in the same category as the initial violation ^b | 8/10 (80) |
| Percentage of clinics with a second citation that had a violation in at least one new category ^b | 6/10 (60) |

^a One of the 44 clinics did not renew their Society for Assisted Reproductive Technology status.

^b There were four clinics that had a second citation both in the same category as their initial citation and in a new category.

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time period, even if they were in the same category. Six (60%) of the 10 clinics with a repeat violation had a violation in at least one new category (Table 2). Increased time from the initial violation to rereview by the AC committee or a higher number of 2019 violation categories did not predict whether a clinic was going to be noncompliant in a second evaluation (Table 3).

In the clinics studied, the average number of violation categories in the 2019 evaluation was significantly greater than that in the second evaluation (mean 1.6 vs. 0.49, respectively, $P < .001$) (Table 4). The most common violation category in both reviews was noncompliance in supplemental success data with a significantly lower percentage of noncompliance on reevaluation (72.7% [32 of 44] vs. 16.3% [7 of 43], respectively, $P < .001$) (Table 4). Unsubstantiated claims and claims of superiority were in addition significantly reduced on reevaluation (Table 4). When comparing the initial with the repeat violations for the 10 clinics that were again noncompliant in 2020, there was no difference in the number and percentage of violations categories with supplemental data noncompliance being the most common violation category at both time points. (Supplemental Table 1).

DISCUSSION

The results of our study demonstrated that when noncompliant clinics that were refractory in correcting their websites were reviewed at least 6 months after their previous violations, only 23% had recurring violations with a similar distribution within the categories of violations. Supplemental data was the most common violation in both audits with 32 (73%) of 44 clinics on the first audit and 7 (70%) of 10 clinics cited a second time on rereview. This finding was consistent with the results of our previous study in which we assessed the compliance with the SART advertising guidelines of 361 member clinics and similarly found supplementary data claims was the leading cause of violations (4). Other studies have cited similar rates of noncompliance in the reporting of success rates (5, 6). Fortunately, only 7 (16.3%) of the 43 clinics had

TABLE 3

Comparison of clinics with violations noted only during the first review with those with violations found on reevaluation in addition.

| N = 43 | No reevaluation violations (n = 33) | Reevaluation violations (n = 10) | RR (95% CI) |
|---|--|-------------------------------------|-------------------|
| Number of initial violation categories, Mean (SD) | 1.5 (0.86) | 1.9 (0.88) | 1.43 (0.77, 2.66) |
| Time since first infraction (months), Mean (SD) | 10.9 (4.1) | 12.7 (4.9) | 1.09 (0.95, 1.25) |

Note: CI = confidence interval; RR = relative risk.

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TABLE 4

Characteristics of the violations noted in the audits.

| | Initial evaluation 2019 (n = 44) | Second evaluation 2020 (n = 43) | P value |
|---|-------------------------------------|------------------------------------|--------------------|
| Average number of violation categories per clinic Mean (SD) | 1.6 (0.87) | 0.49 (1.1) | <.001 ^a |
| Supplemental data not compliant | 32 (72.7) | 7 (16.3) | <.001 ^b |
| Link to SART CSR missing (required if supplemental data are present) | 5 (27.8) | 3 (16.7) | .41 ^b |
| SART "disclaimer statement" missing (required if supplemental data are present) | 2 (11.1) | 4 (22.2) | .32 ^b |
| Unsubstantiated claims Yes | 15 (34.1) | 3 (6.9) | .003 ^b |
| Statements denigrating other clinics Yes | 3 (6.8) | 2 (4.7) | .65 ^b |
| Claims of superiority Yes | 15 (34.1) | 2 (4.7) | .001 ^b |

Note: Categorical data are number (percentage). Eighteen clinics had supplemental data presented in 2019 and 2020 reviews.

^a Wilcoxon's signed rank test.

^b McNemar's chi-squared test.

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subsequent supplemental data violations after they were addressed by the SART AC.

This analysis is the only study in the United States to review assistive reproductive technology (ART) advertising compliance after an intervention. In Australia, a similar study was performed with contradictory outcomes (7). Thirty-two IVF clinics were audited by the Australian Competition and Consumer Commission in 2016 and then reaudited in 2017. As measured by a scoring matrix, most noncompliant ART clinics had not improved the quality of the information about success rates after the Australian Competition and Consumer Commission investigation, which indicated that their regulatory process could be restructured. In contrast, our study revealed that of those clinics with delayed correction of website violations in 2019, 77% were in compliance when reaudited. The higher compliance in the United States may be because of SART's well-structured oversight process. SART's AC gives a clinic 2 weeks to make changes to their website, and if the necessary changes are not made 30 days after that grace period, then a red warning flag is placed on the clinic's SART CSR data. Such warnings are very

uncommon, and most of the cited clinics will correct their violations to avoid a public display that may negatively affect their reputation. If the violations are not corrected within 90 days after that, then the SART CSR data are removed altogether from the SART website. Such action is rarely undertaken by SART (SART AC internal information). Although in our prior study (4) we found that 90% of clinics were noncompliant in at least one SART AC guideline, we were not specifically evaluating their response to SART review and intervention. In this study, we noted that only 23% were noncompliant; therefore, it is likely that many corrected their violations within the two-week grace period.

The limitations of this study include the inability to assess multiple violations committed within a given category (e.g., one vs. several unsubstantiated statements were all counted as one violation). In addition, we were not able to determine how many of the 161 IVF clinics surveyed in 2019 had violations on initial review because many corrected their violations within 2 weeks and therefore were not tracked in SART's databases and did not undergo an accelerated follow-up review. In addition, we were unable to identify

the root cause of violations (i.e., public relations agency unaware of SART guidelines managing the website; medical director unaware of guidelines or of his/her website content; willful disregard). Furthermore, the AC's primary goal was to ensure the compliance of its member clinics rather than using a heavy-handed approach to embarrass colleagues or create unnecessary conflicts.

The underlying assumption by the SART AC is that most violations are committed innocently, supported by the high level of subsequent compliance, and that membership in SART is highly valued by its clinics. The SART advertising guidelines, unique to American medical organizations, were created to promote truth in advertising, not only to comply with the Wyden law but to reduce misleading information for a vulnerable patient population.

CONCLUSION

In conclusion, we found that most clinics followed the SART advertising guidelines after previous violations. Issues surrounding the presentation of supplemental data, rather than unsubstantiated claims or denigrating statements, were the most common area for lack of compliance for both initial and subsequent violations. Improvements in the education of member clinics regarding the most up-to-date advertising guidelines as well as the recent simplification of SART's

success rate reporting with an abbreviated snapshot view may further promote compliance in the future.

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