Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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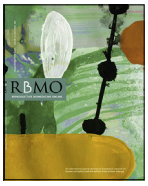

ARTICLE

The impact of COVID-19 mitigation measures on fertility patients and clinics around the world

BIOGRAPHY

Elizabeth Cutting is a PhD candidate who is passionate about helping infertility patients, specifically patients with unexplained infertility. She believes that fertility is a taboo subject within our society, which leads to miscommunication. Her research aim is to educate younger generations on their bodies, with the hope of prevention over cure.

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KEY MESSAGE

The implications of responses to COVID-19 caused most fertility clinics worldwide to suspend treatment. With advice from their governmental societies to take a cautionary approach, clinics implemented new policies to reduce virus transmission. This survey proved the need for a protocol that includes increased counselling and prioritizing of urgent cases.

ABSTRACT

Research question: What is the impact of the response to COVID-19 on the management of fertility treatments and clinical practice around the world?

Design: Fertility clinic associates around the world were approached. They completed an online survey containing 33 questions focused on the country's response to the COVID-19 pandemic. Known fertility clinic associates that were contacted comprised scientific directors, medical directors and laboratory managers.

Results: There were 43 individual country responses from Asia (13), Africa (3), Europe (17), North America (3), Oceania (2) and South America (5). In nine countries, clinics followed their government body recommendations, in 22 countries there was a combination of recommendations, in 3 countries changes were made by clinic initiative, and 9 countries did not specify. In 34 countries IVF/intracytoplasmic sperm injection (ICSI) and frozen embryo transfer (FET) treatments had an average delay of 56 days (IVF/ICSI) (minimum 0, maximum 160) and 57 days (FET) (minimum 0, maximum 166 days). During the shutdown, the number of freeze-all cycles increased in 22 countries. Only 23 countries reported patients having to undergo a SARS-CoV-2 test, and 20 countries did not report any COVID-19 testing in their clinic. Additional support counselling was offered in 28 countries, partner restrictions at clinics were reported in 41 countries and time between patients' appointments was increased in 39 countries.

Conclusions: The implications of COVID-19 mitigation measures proved the need for government societies to introduce a set protocol that includes requirements such as increased patient counselling and additional guidelines for prioritizing couples who need care most urgently.

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KEY WORDS

Assisted reproductive technology
COVID-19
Global
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Patient care

INTRODUCTION

The initial months of 2020 experienced a rapid spread of a new coronavirus named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the World Health Organization declared a global pandemic (*WHO, 2020*). As of 17 September 2021, 226,844,344 confirmed cases of SARS-CoV-2 had been recorded, of which 4,666,334 people had died (*WHO, 2021*).

As the strain of the virus was new, limited information was available for its effects on pregnancy and fertility (*Anifandis et al., 2020*; *Ory et al., 2020*). The available knowledge regarding the effect the virus may have on fertility or pregnancy was based on very limited data (*Madjunkov et al., 2020*; *Requena et al., 2020*). A meta-analysis performed by Allotey and colleagues in August 2020 found that 10% of women attending or admitted to hospital for any reason were diagnosed with COVID-19 or suspected as having COVID-19 (*Allotey et al., 2020*). The high incidence could, however, be due to the increased screening in pregnant and newly pregnant women (*Madjunkov et al., 2020*).

With the limited knowledge known regarding COVID-19 and its effects on fertility and pregnancy, a cautionary approach was advised for fertility clinics. Living with the uncertainty of the virus, most countries cancelled or delayed assisted reproductive technology (ART) treatment in the initial months of the pandemic (*Blumenfeld, 2020*). Most clinics opted for telehealth consultations for the purpose of continuing communication with fertility patients (*Karavani et al., 2021*). The advice given to fertility clinics from professional societies was to stop or delay treatment (*Boivin et al., 2020*). The cessation of treatment was guided by not only the uncertainty of the new strain, but also the need to reduce the burden of non-essential medical treatments in hospitals and to allow as many of the clinical staff and resources available to be directed towards helping with the COVID-19-related health pandemic (*Bhattacharya et al., 2021*). The delay in treatment also gave embryology laboratories the time to set up policies to adjust to the transmission of the virus (*Maggiulli et al., 2020*). It was suggested that clinics go through three phases: 'shutdown preparation, maintenance during shutdown and restart' (*Hickman et al., 2020*).

On 17 March 2020, the American Society for Reproductive Medicine (ASRM) announced the need to 'delay any but the most important reproductive care cases' (*ASRM, 17 March 2020*). On 19 March 2020, the European Society of Human Reproduction and Embryology (ESHRE) advocated 'a cautionary approach and recommended all infertility patients considering or planning treatment to avoid becoming pregnant at this time due to the restricted information known about COVID-19 and its effects on pregnancy' (*ESHRE, 19 March 2020*). On 19 March 2020, the Fertility Society of Australia (FSA) also suggested that patients should discuss with their specialist the appropriateness of postponing treatment (*FSA, 2020*).

In Australia, fertility clinics around the country were advised to stop IVF and other treatments from 1 April until 27 April 2020. The adjustment was guided by recommendations from the FSA and the Australian Government. The question stands as to how other countries responded to the initial shutdown and how the shutdown period affected the function of their fertility clinics. Thus, the aims of this study were to examine the effects that the initial COVID-19 mitigation measures had on the management of fertility patients and the variation of clinical practice in different countries around the world.

MATERIALS AND METHODS

A prospective observational cohort study was performed using a questionnaire approved by the Monash Health Human Research Ethics Committee (Reference: 65223, 13 August 2020). Fertility clinics were surveyed with an online questionnaire developed through the platform REDCap (Research Electronic Data Capture; *Harris et al., 2009*). All study data were collected and managed using REDCap electronic data capture tools hosted and managed by HELIX (Monash University). REDCap is a secure, web-based application designed to support data capture for research studies that provides an intuitive interface for validated data entry, audit trails to track data manipulation and export procedures, automated export procedures for seamless data downloads to commonly used statistical packages and procedures for importing data from external sources (Harris et al., 2009).

The questionnaire contained a total of 33 questions (Supplementary Figure 1) relating to the countries' first response to COVID-19 and focused on the differences in country responses to the guidelines from the different bodies. Fertility clinic associates around the world were contacted using a known contact list comprising scientific directors, medical directors and laboratory managers. E-mails were sent to contacts in rounds, and if there was no response, a new contact was used for that country. Each survey was identified only by country name, allowing participants and clinics to remain anonymous.

The survey consisted of questions relating to patient load before/after lockdown regarding IVF, intracytoplasmic sperm injection (ICSI), frozen embryo transfer (FET), intrauterine insemination (IUI), oocyte freezing and ovulation induction. There was a separate section that included questions relating to laboratory procedure responses and fertility clinic functioning responses. As the implications of the virus affected different parts of the world at different times, the questionnaire was sent to contacts from 13 October 2020 until 15 September 2021. To reduce recall bias, the survey was answered in one session and the survey questions were of a factual nature.

Analysis

Descriptive statistics were used to describe quantitative data including mean, median, standard deviation, standard error of the mean and minimums and maximums. Spearman's correlation test was conducted to explore the relationship between different outcomes, such as FET delay and IVF/ICSI delay. Pearson's t-test was used to compare the relationship between IVF/ICSI and FET loads. Cross-tabulation tests were used to compare the relationships between the IVF/ICSI and FET loads with delays and policies. A significance level of 0.05 was considered significant. The results of the survey were analysed using the program SPSS (Statistical Package for the

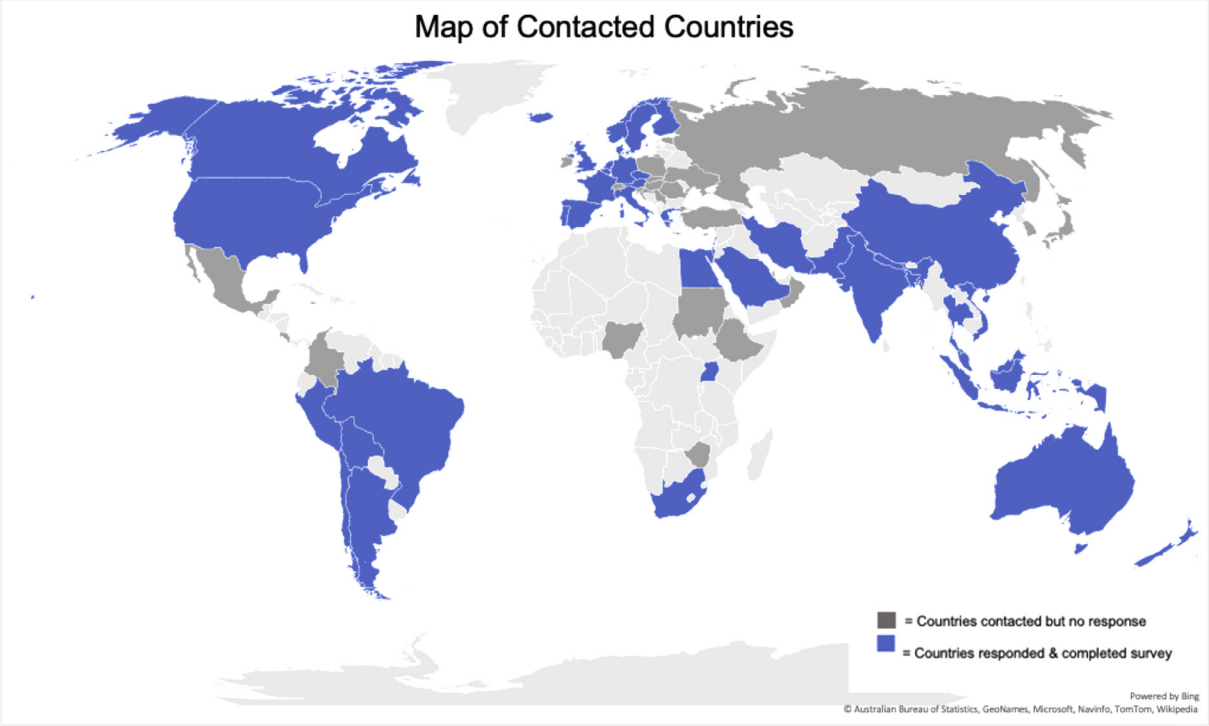

FIGURE 1 A total of 125 participants from 75 different countries were contacted. The map shows the spread of countries contacted, identifying which countries did and did not respond.

Social Sciences; IBM SPSS Statistics for Windows, Version 27.0, IBM, USA).

RESULTS

A total of 125 participants from 75 different countries were contacted (FIGURE 1). After two e-mail reminders had been sent, there were 43 individual country responses (Asia, 13; Africa, 3; Europe, 17; North America, 3; Oceania, 2; South America, 5; TABLE 1).

Professional bodies

Of the 43 countries, 9 countries followed their government body recommendations, 22 countries followed a combination of recommendations, 3 countries made changes by clinic initiative, and 9 countries did not specify. The ASRM (6) and ESHRE (12) guidelines were the two most commonly followed. Additional professional body groups also followed included the Argentine

TABLE 1 LIST OF COUNTRIES WITH PARTICIPANT RESPONSES

Asia	Africa	Europe	North America	Oceania	South America
Bangladesh	Egypt	Austria	Barbados	Australia	Argentina
China	South Africa	Belgium	Canada	New Zealand	Bolivia
Hong Kong	Uganda	Czech Republic	USA		Brazil
India		Denmark			Chile
Indonesia		Finland			Peru
Iran		France			
Israel		Germany			
Malaysia		Greece			
Nepal		Iceland			
Pakistan		Italy			
Saudi Arabia		The Netherlands			
Thailand		Norway			
Vietnam		Portugal			
		Scotland			
		Spain			
		Sweden			
		England			

Society for Reproductive Medicine (SAMER), Brazilian Society of Assisted Reproduction (SBRA), Finnish Fertility Society, Greek National Authority of Assisted Reproduction, Indian Society for Assisted Reproduction (ISAR), Indonesian In Vitro Fertilisation (PERFITRI), Israel Fertility Society, British Fertility Society (BFS), Spanish Fertility Society, Dutch Society of Obstetrics and Gynaecology (NVOG) and Fertility Society Australia and New Zealand (FSANZ).

Delay in ART treatments

IVF/ICSI treatment had a mean delay of 56 days (standard deviation [SD] 45.6) days. The median delay was 50 days, with a minimum of 0 days and a maximum of 160 days. For FET treatment a mean delay of 57 (SD 46.9) days was reported. The median delay was 54 days for FET, with a minimum of 0 days and a maximum of 166 days.

In terms of type of treatment, couples undergoing timed intercourse experienced the least delay in treatment (19 countries, mean delay of 30 [SD 47] days). Women undergoing IUI/ovulation induction had their treatment delayed in 32 out of 43 countries (mean delay of 46 [SD 43] days) with fertility consultations being delayed in 26 out of 43 countries (mean delay of 39 [SD 46] days).

In terms of specific countries, Egypt had the largest delays for IVF/ICSI treatment with a delay of 160 days (FIGURE 2A). For FET treatment, Malaysia had the longest delay with 166 days. There was a positive correlation (0.709 by Spearman's test; $P < 0.001$) between number of days delay in IVF/ICSI and the number of days delay in FET treatment (FIGURE 3).

Patient load changes

During the quarantine period, the number of freeze-all cycles increased in half of the countries (22 out of 43; TABLE 2). The ratio of IVF to ICSI remained mostly constant before and after lockdown (41 countries selected 'stayed the same') with the exception of an increase in ICSI in Peru and a decrease in ICSI in Iran (TABLE 2). Regarding patient load for IVF/ICSI after the lockdowns, 44% of participants reported a decrease in patient load for

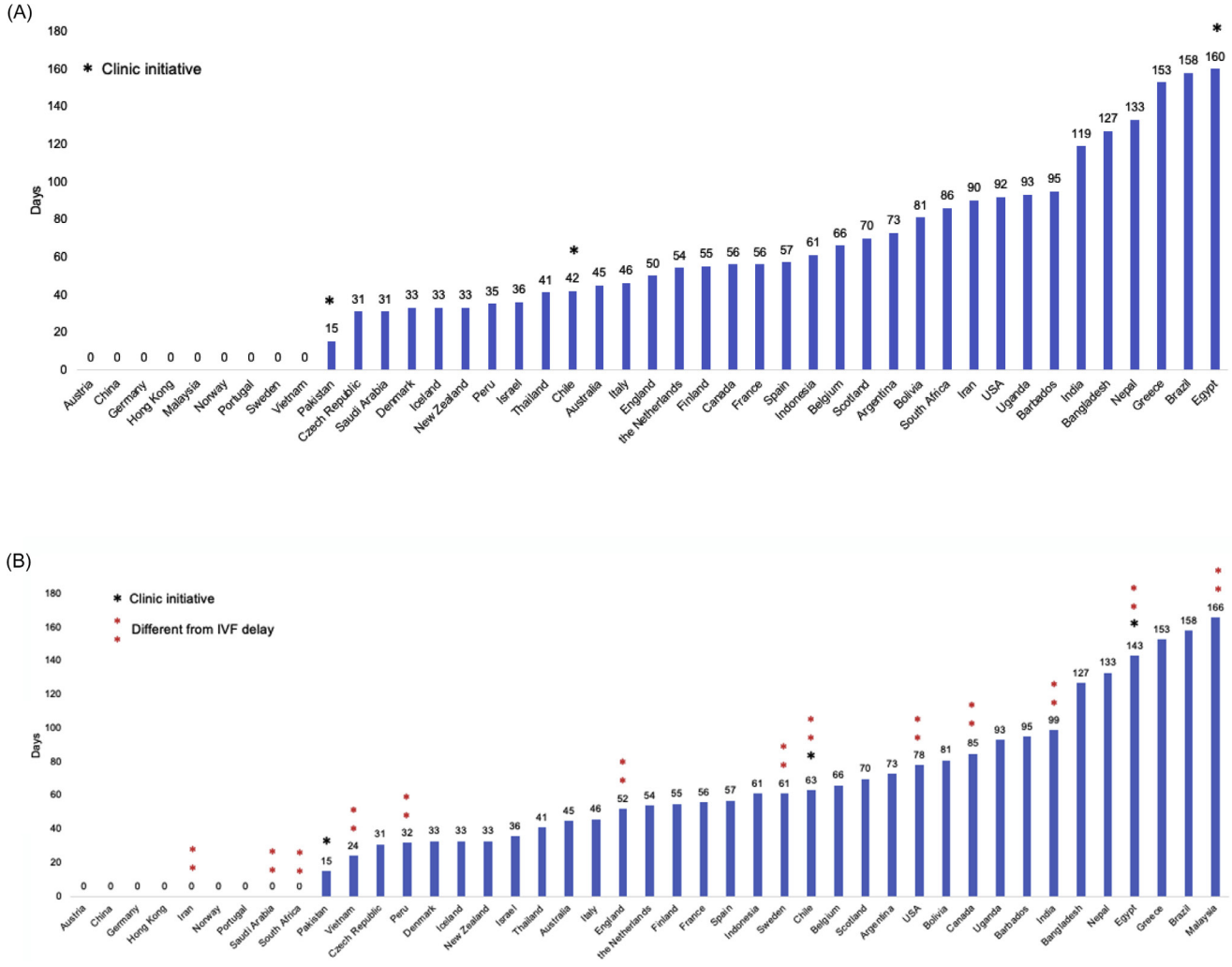

FIGURE 2 (A) Number of days that IVF/intracytoplasmic sperm injection (ICSI) (including oocyte freezing) was delayed as a result of the initial COVID-19 lockdown. The black asterisks symbolize countries that made changes to clinic functioning based on the clinic's initiative. Clinic initiatives were defined as clinics stating that they did not follow any professional body guidelines but made changes based on their own initiative. (B) The number of days that frozen embryo transfers (FET) were delayed as a result of the initial COVID-19 lockdown. The black asterisks symbolize countries that made changes to clinic functioning based on the clinic's initiative. The pairs of red asterisks represent countries that had a difference between the number of days delay for IVF/ICSI and for FET.

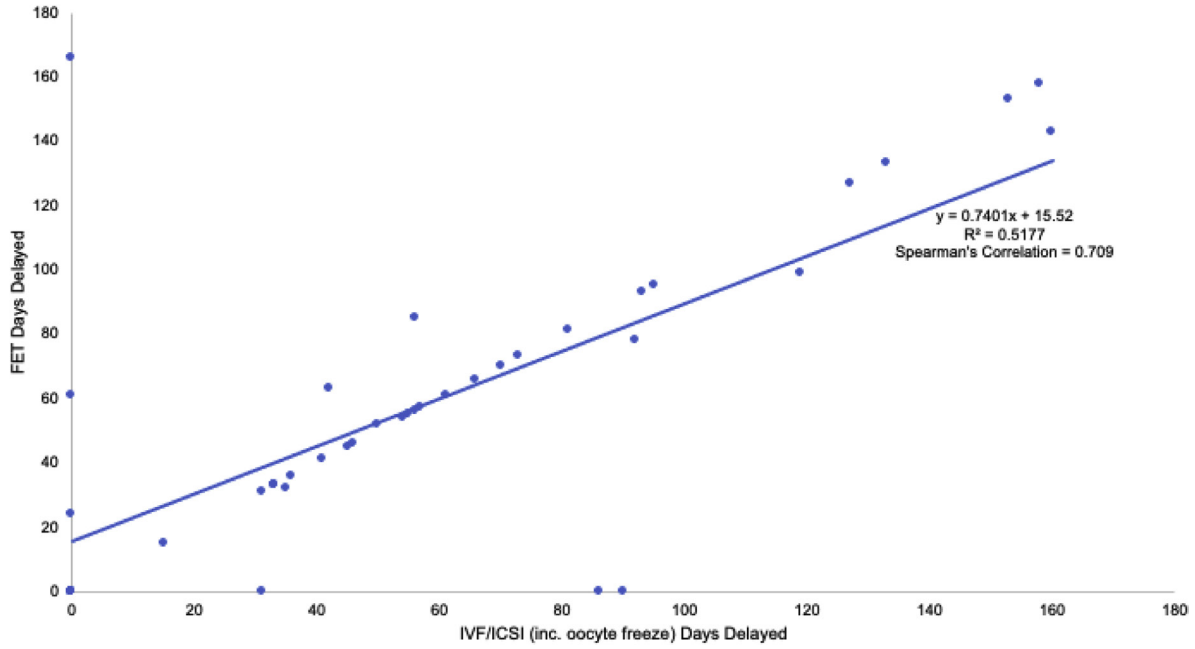

FIGURE 3 Relationship between the number of days delay for IVF/intracytoplasmic sperm injection (ICSI) ((including oocyte freezing) versus frozen embryo transfer (FET) in the initial COVID-19 lockdown.

IVF/ICSI and 44% reported an increase in patient load (12% reporting no change; TABLE 2, FIGURE 4A). For FET treatment, 37% of participants reported a decrease, 49% reported an increase and 14% reported no change (TABLE 2, FIGURE 4B).

Clinic policy changes

For clinic policies, COVID-19 testing was present in 23 (53%) of respondents' clinics (FIGURE 5). Furthermore, 21 (49%) COVID-19 testing clinics reported waiting for a negative result prior to starting treatment, 41 (95%) responses reported postponing treatment for patients who tested positive, and a procedure was in place for staff who tested positive in all 23 clinics where COVID-19 testing was implemented. Moreover, patients completed a 'prior to treatment exposure questionnaire' in 34 (79%) respondents' clinics. However, only 16 (70%) of COVID-19 testing clinics reported a procedure in place for patients who tested positive prior to collection or after transfer.

No correlation was found between clinic policies and changes in patient loads (0.029 on Spearman's testing, $P = 0.856$), nor between additional counselling and patient loads (0.052 on Spearman's testing, $P = 0.741$). Additionally, patients were not deterred from treatment due to additional policies or screening procedures. However, it was found that clinics were more likely to have a procedure in place for the timetabling of appointments (90%) and partner policies (95%) rather than increased counselling (65%) (FIGURE 5).

For clinic and laboratory changes, 33 (77%) participants reported the implementation of masks or face shields to be worn constantly when having contact with patients. Furthermore, 15 (35%) clinics reported having a reduced number of embryologists in laboratories. A total of 30 (70%) clinics reported an increase of time between patients for oocyte collection and transfers. Finally, only 5 (12%) clinics reported no changes to laboratory procedures.

DISCUSSION

The results of this survey allow reflection on which guidelines were implemented worldwide and where improvements may be warranted. The survey showed that clinics were more likely to follow guidelines such as partner restrictions than recommendations like additional counselling. Most countries experienced delays in most treatment categories. The differences between delays, such as timed intercourse, IVF/ICSI treatments and FET cycles, may be due to reduced patient visits to clinics. Furthermore, an increase in freeze-all cycles was seen in clinics worldwide, which may be due to the uncertainty of the virus in relation to pregnancy and the advice from societies to delay pregnancies where possible. Additionally, clinics also showed an increased proportion of FET treatments compared with IVF/ICSI cycles, which could be due to the reduction in clinic traffic.

Importantly, the results of this survey show that most clinics were following professional society guidelines, which left the treatment of patients in the care of professional societies. Societies advised fertility clinics to take a cautionary approach, but only guidelines such as partner restrictions to the clinic or recommendations such as counselling were suggested (ESHRE, 19 March 2020). Although the societies did provide recommendations and enforce restrictions to help reduce virus exposure and transmission, there was a lack of advice for clinics in two main areas – increasing psychological support and how to prioritize patients (ASRM, 17 March 2020; ESHRE, 19 March 2020; *FSA, 19 March 2020*).

Furthermore, the results of this survey showed that clinics were more likely to follow guidelines rather than recommendations. This was evident from clinics more readily implementing restrictions such as partners coming to appointments (95% clinics) than the recommendation of offering additional counselling (65% clinics). Importantly, the current study found that increased

TABLE 2 PARTICIPANT RESPONSES TO PATIENT LOAD CHANGES

Country	Did the amount of freeze-all cycles increase in your clinic during the quarantine period?	Did your patient load for IVF/ICSI treatment increase/decrease after the lockdown period and by how much?	How much did your patient load for FET treatment increase/decrease after the lockdown period?	Ratio of ICSI to IVF cycles
Argentina	Yes	Decrease by 50–75%	No change	Stayed the same
Australia	Yes	Increase by 25–50%	Increase by 25–50%	Stayed the same
Austria	Yes	Increase by <25%	No change	Stayed the same
Bangladesh	Yes	Decrease by 25–50%	Decrease by 50–75%	Stayed the same
Barbados	No	Decrease by 25–50%	Decrease by 25–50%	Stayed the same
Belgium	Yes	Increase by 25–50%	Increase by <25%	Stayed the same
Bolivia	No	Decrease by 50–75%	Increase by <25%	Stayed the same
Brazil	No	No change	No change	Stayed the same
Canada	No	Increase by <25%	Increase by 25–50%	Stayed the same
Chile	No	Increase by <25%	No change	Stayed the same
China	No	No change	Increase by <25%	Stayed the same
Czech Republic	Yes	No change	No change	Stayed the same
Denmark	Yes	Increase by <25%	Increase by <25%	Stayed the same
Egypt	No	Decrease by 50–75%	Decrease by 50–75%	Stayed the same
Finland	Yes	Increase by <25%	Increase by 25–50%	Stayed the same
France	No	Decrease by 50–75%	Decrease by 50–75%	Stayed the same
Germany	Yes	Increase by <25%	Increase by <25%	Stayed the same
Greece	Yes	Decrease by 25–50%	Decrease by 25–50%	Stayed the same
Hong Kong	No	No change	No change	Stayed the same
Iceland	Yes	Increase by <25%	No change	Stayed the same
India	No	Decrease by 50–75%	Decrease by 25–50%	Stayed the same
Indonesia	Yes	Increase by 25–50%	Increase by 50–75%	Stayed the same
Iran	Yes	Decrease by 25–50%	Decrease by 25–50%	Decreased
Israel	No	Increase by 25–50%	Increase by 25–50%	Stayed the same
Italy	Yes	Increase by <25%	Increase by <25%	Stayed the same
Malaysia	Yes	Decrease by 25–50%	Decrease by 25–50%	Stayed the same
Nepal	No	Increase by <25%	Increase by <25%	Stayed the same
New Zealand	Yes	Increase by <25%	Increase by <25%	Stayed the same
Norway	Yes	Increase by 25–50%	Increase by <25%	Stayed the same
Pakistan	Yes	Increase by <25%	Increase by <25%	Stayed the same
Peru	No	Decrease by 25–50%	Decrease by 25–50%	Increased
Portugal	Yes	Decrease by <25%	Increase by 25–50%	Stayed the same
Saudi Arabia	No	No change	Increase by <25%	Stayed the same
Scotland	Yes	Increase by <25%	Increase by <25%	Stayed the same
South Africa	No	Decrease by 50–75%	Decrease by <25%	Stayed the same
Spain	No	Increase by 25–50%	Increase by 25–50%	Stayed the same
Sweden	Yes	No change	Increase by 25–50%	Stayed the same
Thailand	No	Decrease by 75–100%	Decrease by 75–100%	Stayed the same
The Netherlands	No	Decrease by 25–50%	Decrease by 25–50%	Stayed the same
Uganda	No	Decrease by 25–50%	Decrease by <25%	Stayed the same
England	Yes	Decrease by 25–50%	Decrease by 25–50%	Stayed the same
USA	No	Increase by <25%	Increase by <25%	Stayed the same
Vietnam	No	Decrease by <25%	Decrease by <25%	Stayed the same

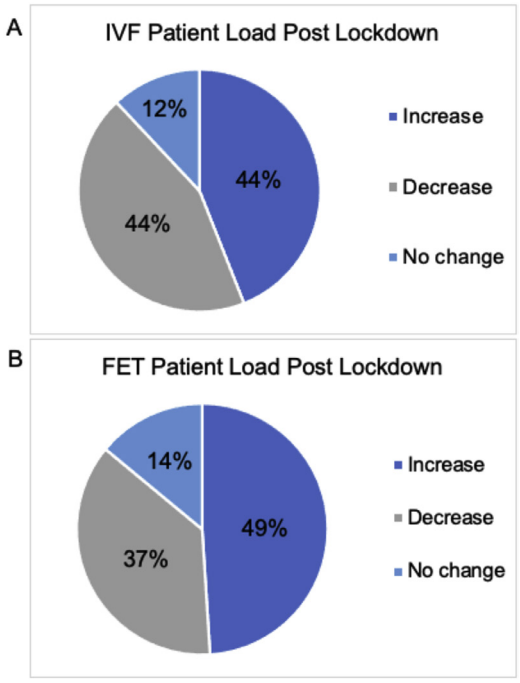

FIGURE 4 IVF/intracytoplasmic sperm injection (ICSI) and frozen embryo transfer (FET) patient loads after lockdown. The two pie charts reflect the answers of the participants for how patient load changed as a result of the country lockdowns. (A) Did your patient load for ICSI/IVF treatment increase/decrease/no change after the lockdown period? (B) Did your patient load for FET treatment increase/decrease/no change after the lockdown period?

counselling was only offered in 65% of clinics.

Surveys performed throughout the pandemic, such as those of Boivin and colleagues and Marom Haham and co-workers, reported patients' response to clinic changes and lockdowns as a threat to future parenthood (*Boivin et al., 2020*; *Marom Haham et al., 2021*; *Vaughan et al., 2020*). Boivin and colleagues reported that 11.9% of respondents were not able to cope and reported intense feelings of hopelessness and deteriorating well-being and mental health (*Boivin et al., 2020*). Additionally, Marom Haham and co-workers reported patient feelings of sadness (66%), anxiety (60%) and helplessness (60%) in response to the Canadian Fertility and Andrology Society guidelines (*Marom Haham et al., 2021*). Similarly, Samani and Nemati used a questionnaire to explore the psychological impact of COVID-19 restrictions on fertility patients, suggesting that an 'effective strategy is needed to provide psychosocial support' to infertility patients during a crisis (*Samani and Nemati, 2020*). Considering that, in the current study, 65% of clinics surveyed reported increased counselling due to advice given, but 95% of clinics followed restrictions for partners accompanying patient to appointments, it is important that a protocol includes increased counselling as a requirement.

In terms of fertility treatment, a mean delay of 56–57 days was seen for IVF/ICSI treatments and FET cycles. ART patients usually undergo one cycle of treatment in approximately 3 weeks (21 days). With the delays shown, patients on average missed at least two cycles of treatment. For instance, for those needing fertility preservation prior to chemotherapy, missing two cycles may be vital to their chances of parenthood. Romanski and colleagues found that patients with a diminished ovarian reserve whose treatment was delayed by 180 days did not have a lesser chance of live birth compared with women who started within 90 days (*Romanski et al., 2020*). Furthermore, Romanski and colleagues also stated that this trend remained true for patients who had a high risk for poor

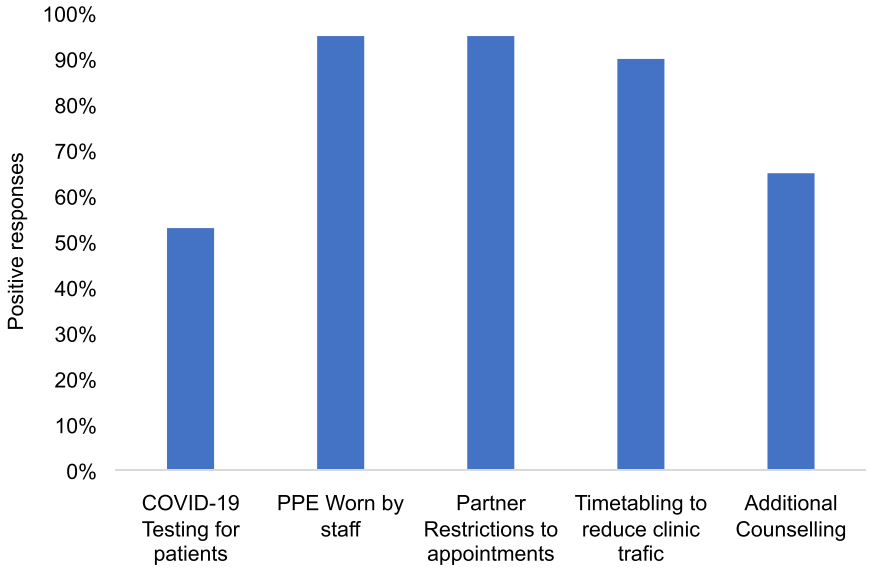

FIGURE 5 Implementation of clinical policies as recommended by professional bodies such as the European Society for Human Reproduction and Embryology, American Society for Reproductive Medicine and Fertility Society of Australia.

response to ovarian stimulation (anti-Müllerian hormone [AMH] <0.5 ng/ml or being above 40 years old with an AMH <1.1 ng/ml). Intriguingly, a study led by Zhou in 2021 found that women aged 35–37 years were returning to treatment more frequently than women over 40 years since the reopening of fertility treatment in America (*Zhou et al., 2021*). The cohort study by Romanski allows relief for patients over 40 years of age in that a short delay of treatment, although emotionally and psychologically impacting, does not affect the clinical outcome for the patient.

In the early stages of the pandemic there appeared to be a lack of guidelines on how to prioritize patients. However, a proposal for individualized treatment based on patient prognosis has been suggested by Alviggi and collaborators in response to the pandemic (*Alviggi et al., 2020*). They propose an ordering system, similar to Eijkemans and colleagues, that prioritizes patients with a poorer prognosis over patients who can withstand the delay of starting treatment, thus treating those patients with the most urgent need (*Eijkemans et al., 2008*).

Additionally, a study by Bhattacharya and co-workers (found there was a backlog of patients waiting to be treated as quickly as possible (*Bhattacharya et al., 2021*). It was suggested that the backlog might be due to the increased social distancing and the changes that fertility clinics had had to make to be able to cope with staff illness (*Bhattacharya et al., 2021*). The addition of telehealth to a protocol has been suggested to help patients by reducing the emotional stress of delays while also maintaining fertility care (*Alexander et al., 2021*; *Berg et al., 2020*; *Dilday et al., 2021*; *Gemmell et al., 2020*; *Karavani et al., 2021*). Additionally, by using a telehealth service prior to in-clinic appointments doctors would have a better understanding of patient prognosis and give them the ability to order patients by priority (*Hernández et al., 2020*).

Although the current study showed a broad observation of the regulations followed worldwide, it also includes limitations. For instance, only one clinic per country was surveyed and therefore the results for that country were based solely on one clinic's approach to the pandemic. This limitation was addressed by the inclusion of a question within the survey to identify whether the clinic was following its country's regulations or deviating from its country's stance. However, most clinics were following their country's guidelines or those of the larger societies ESHRE and ASRM. It is also important to highlight that as one clinic per country was used, larger countries such as the USA may have shown a variation between states. However, these countries reported that they followed national guidelines such as those of the ASRM.

In conclusion, during the COVID-19 pandemic most fertility services were suspended, leading to significant delays of IVF/ICSI and FET cycles worldwide. For future events of this nature, a standardized protocol may benefit outcomes for fertility patients and clinics. Professional societies such as the ASRM and ESHRE advised clinics to offer additional counselling to patients, but the results of the current study did not support the following of this advice. Thus, the implications of COVID-19 mitigation measures proved the need for government societies to introduce a set protocol that includes requirements such as increased patient counselling and additional guidelines for prioritizing couples who need care most urgently.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.rbmo.2021.12.016.

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