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Highlights:

- A 43-country survey reports an average of 60 days delay (range 0-228) for IVF during the COVID-19 pandemic
- Clinics were more likely to follow restrictions rather than advice
- We found a lack of guidelines for prioritising fertility patients needing care more urgently

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

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

RESULTS: We obtained 43 individual country responses from Asia (13), Africa (3), Europe (17), North America (3), Oceania (2) and South America (5). In 9 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/ICSI and FET treatments had an average delay of 59 days (IVF/ICSI) and 60 days (FET) (minimum 0, maximum 228 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, 20 countries did not report any COVID-19 testing in their clinic. Additional support counselling was offered in 28 countries, partner restrictions to clinics were reported in 41 countries and time between patients' appointments was increased in 39 countries.

CONCLUSION: 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.

Key words; Patient care, global, COVID-19, infertility services, ART

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 the 11th of March 2020, the World Health Organization declared a global pandemic (WHO, 2020). As of 17th September 2021, there has been 226,844,344 confirmed cases recorded of SARS-CoV-2, of which 4,666,334 people have died (WHO, 2021).
As the strain of the virus was new, limited information was available for its effects on pregnancy and fertility (Ory et al., 2020, Anifandis et al., 2020). The knowledge available 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 *et al* in August 2020 found 10% of women attending or admitted to hospital for any reason were diagnosed with COVID-19 or suspected of COVID-19 (SCOVID) (Allotey et al., 2020). The high incidence could be however 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 to 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 not only due to the uncertainty of the new strain, but also due to the need to reduce the burden of non-essential medical treatments in hospitals and to allow as many clinical staff and resources available, to help 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 March 17, 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 the 19th of March, 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 March 19, 2020, The Fertility Society Australia (FSA) also suggested 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 (in vitro fertilisation) and other treatments from the 1st of April until the 27th of April 2020. The adjustment was guided by recommendations from the Fertility Society of Australia (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 on the management of fertility patients and the variation of clinical practice in different countries around the world.

METHODS

We performed a prospective observational cohort study using a questionnaire approved by Monash Health Human Research Ethics Committee (Reference: 65223). We surveyed fertility clinics with an online questionnaire developed through the platform RedCap (HELIX) (Paul A. Harris, April 2009). All study data was collected and managed using REDCap electronic data capture tools hosted and managed by HELIX (Monash University). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing; an intuitive interface for validated data entry, audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages and procedures for importing data from external sources (Paul A. Harris, April 2009).

The questionnaire contained a total of 33 questions (Supplementary Figure 1) in relation to the country's first response to COVID-19 and focused on the differences of country responses to different body guidelines. We contacted fertility clinic associates around the world using a known contact list comprising scientific directors, medical directors and lab managers. Emails were sent to contacts in rounds, if no response, a new contact was used for that country. Each survey was only identified by country name, allowing participant and clinics to remain anonymous. The survey consisted of questions relating to patient load pre/post lockdown regarding insemination in vitro (IVF), intra-cytoplasmic sperm injection (ICSI), frozen embryo transfer (FET), inter uterine insemination (IUI), oocyte freezing and ovulation induction (OI). The survey also contained a separate section that included questions in relation 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 13th October 2020 until 15th 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 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 also used to compare the relationship between IVF/ICSI and FET loads. Crosstabulation 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 through the program SPSS (statistical package for the social sciences) (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp).

RESULTS

We contacted 125 participants from 75 different countries (Figure 1). After two email reminders were sent, there were 43 individual country responses [(Asia (13), Africa (3), Europe (17), North America (3), Oceania (2) and 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. ASRM (6) and ESHRE (12) were the two most common guidelines

followed. Additional professional body groups also followed included; Argentine 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 59 days (standard deviation; SD: 52.58). The median delay was 50 days, with a minimum of 0 days and a maximum of 228 days. For FET treatment a mean delay of 60 days (SD; 53.6) was reported. The median delay was 54 days for FET, with a minimum of 0 days and a maximum of 228 days.
In terms of type of treatments, couples undergoing timed intercourse experienced the least delay in treatment (19 countries, mean delay of 34 days, SD: 55.35). IUI/OI patients had delayed treatment in 32 out of 43 countries (mean delay of 55 days, SD: 56.19) with fertility consultations being delayed in 26 out of 43 countries (mean delay of 42 days, SD: 54.53).

In terms of specific countries, Scotland showed the largest delay in treatment with a delay of 228 days for both IVF/ICSI and FET treatments (Figure 2A-B). Six countries (Austria, China, Germany, Hong Kong, Norway, and Portugal) did not experience delays in either IVF/ICSI or FET treatments (Figure 2A/B). There was a positive correlation (0.725 – Spearman's; $p< 0.001$) between days delayed in IVF/ICSI and days delayed 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 pre and post lockdown (41 countries selected "stayed the same") with exception to an increase of ICSI in Peru and a decrease of ICSI in Iran (Table 2). Regarding patient load post lockdowns for IVF/ICSI, 44% of participants reported a decrease in patient load for IVF/ICSI and 44% of participants reported an increase in patient load (12% 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 respondent's 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 (Figure 5). Moreover, patients completed a "prior to treatment exposure questionnaire" in 34 (79%) respondent's clinics. However, only 16 (70%) of COVID-19 testing clinics reported a procedure in place for patients who test positive prior to collection or post transfer.

There was no correlation found between clinic policies and changes in patient loads (0.029 Spearman's, p= 0.856), nor between additional counselling and patient loads (0.052 Spearman's, 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 timetabling of appointments (90%) and partner policies (95%) rather than increased counselling (65%).
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 reduced number of embryologists in laboratories. 30 (70%) clinics reported an increase of time between patients for oocyte collection and transfers. Finally, only 5 (12%) of 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. This 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 the reduced patient visitation to the clinic. Furthermore, an increase of freeze all cycles was seen in clinics world-wide which may be due to the uncertainty of the virus with pregnancy and the advice of societies to delay pregnancies where possible. Additionally, clinics also showed an increased proportion of FET treatments compared to IVF/ICSI cycles, which could be due to reducing the 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, however only guidelines such as partner restrictions to the clinic, or recommendations such as counselling were suggested (ESHRE, 19 March 2020). Although the societies did give 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 prioritise patients (ESHRE, 19 March 2020, FSA, 19 March 2020, ASRM, 17 March 2020).

Furthermore, the results of this survey showed that clinics were more likely to follow guidelines rather than recommendations. This was evident by clinics implementing restrictions such as partners coming to appointments (95% clinics), more readily than the recommendation of offering additional counselling (65% clinics). Importantly, our study found increased counselling was only offered in 65% of clinics. Surveys performed throughout the pandemic such as Boivin 2020 and Haham 2021, reported patients' response to clinic changes and lockdowns as a threat to future parenthood (Boivin et al., 2020, Vaughan et al., 2020, Marom Haham et al., 2021). Boivin 2020 reported that 11.9% of respondents were not able to cope and reported intense feelings of hopelessness and deteriorating wellbeing and mental health (Boivin et al., 2020). Additionally, Haham et al. 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 *et al*, 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 65% of clinics surveyed reported increased counselling due to advice given, but 95% of clinics followed restrictions of 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 59-60 days was seen for IVF/ICSI treatments and FET cycles. ART patients usually undergo one cycle of treatment in approximately three-weeks

(21 days). With the delays shown, on average, patients missed at least two cycles of treatment. For instance, patients needing fertility preservation prior to chemotherapy, missing two cycles may be vital to their chances of parenthood. Romanski et al found that patients with a diminished ovarian reserve who were 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 et al also stated that this trend remained true for patients who were in a high-risk for poor response to ovarian stimulation (AMH <0.5 ng/ml or being above 40 years old with AMH <1.1 ng/ml). Intriguingly, a study led by Zhou 2021, found women aged 35-37 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 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 prioritise patients. However, a proposal for individualised treatment based on patient prognosis has been suggested by Alviggi et al in response to the pandemic (Alviggi et al., 2020). Alviggi 2020 proposes an ordering system, similarly to Eijkemans et al (2008), that prioritises 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 *et al* (2021) 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 may be due to the increased social distancing and the changes that fertility clinics had to make to be able to cope with staff illness (Bhattacharya et al., 2021). The addition of telehealth in a protocol, has been suggested to help patients by reducing the emotional stress of delays while also maintaining fertility care (Karavani et al., 2021, Alexander et al., 2021, Dilday et al., 2021, Berg et al., 2020, Gemmell et al., 2020). 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 our study did show a broad observation of the regulations followed world-wide, it also includes limitations. For instance, only one clinic per country was surveyed, therefore the results for that country were based solely on one clinics approach to the pandemic. This limitation was addressed by the inclusion of a question within the survey, identifying whether the clinic was following their country's regulations or deviating from their 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 United States may have varied between states. However, these countries did state they followed of national guidelines such as ASRM.

In conclusion, during the COVID-19 pandemic most fertility services were suspended, leading to significant delays of IVF/ICSI and FET cycles world-wide. For future events of this nature, a standardised protocol may benefit outcomes for fertility patients and clinics. Professional societies such as ASRM and ESHRE advised clinics to offer additional counselling to patients, however, our results did not support 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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EC, BWM and FH designed the study. All authors (EC, SC, BV, BWM and FH) contributed and approved the final questionnaire before EC formed the questionnaire on the online database. BWM, FH and SC all contributed known contacts and email addresses for participant recruitment. EC conducted the statistical analysis and wrote the article. All authors contributed intellectually to the writing or revising of the manuscript and approval of the final version.

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Addendum

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	United States		Brazil
India		Denmark			Chile
Indonesia		Finland			Peru
Iran		France			
Israel		Germany			
Malaysia		Greece			
Nepal		Iceland			
Pakistan		Italy			
Saudi Arabia		Netherlands			
Thailand		Norway			
Vietnam		Portugal			
		Scotland			
		Spain			
		Sweden			
		United Kingdom			

Table 2: Participant Responses to patient load changes

Country	Did the amount of freeze-all cycles increased 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?	Has the 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
United Kingdom	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

FIGURES:

Figure 1: A total 125 participants were contacted from 75 different countries. The above map shows the spread of countries contacted with the difference of respondents to no-response.

Figure 2A: Number of days that in vitro fertilisation/intracytoplasmic sperm injection (IVF/ICSI) (inc. oocyte freeze) was delayed as a result of the initial COVID-19 lockdown. Black asterix symbolising countries who made changes to clinic functioning based on clinic initiative. Clinic initiative being noted as clinics that stated they did not follow any professional body guidelines but made changes based on their own initiative.

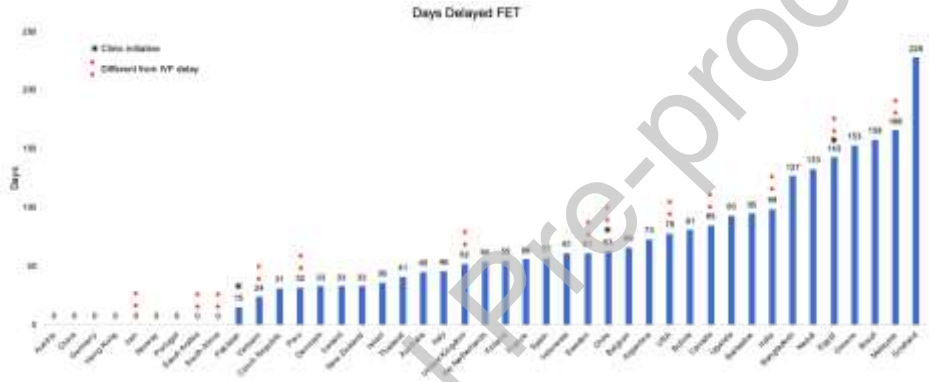

Figure 2B: Number of days that frozen embryo transfers (FETs) were delayed as a result of the initial COVID-19 lockdown. Black asterix symbolising countries who made changes to clinic functioning based on clinic initiative and two red asterix for countries who had a difference between IVF/ICSI, and FET days delayed.

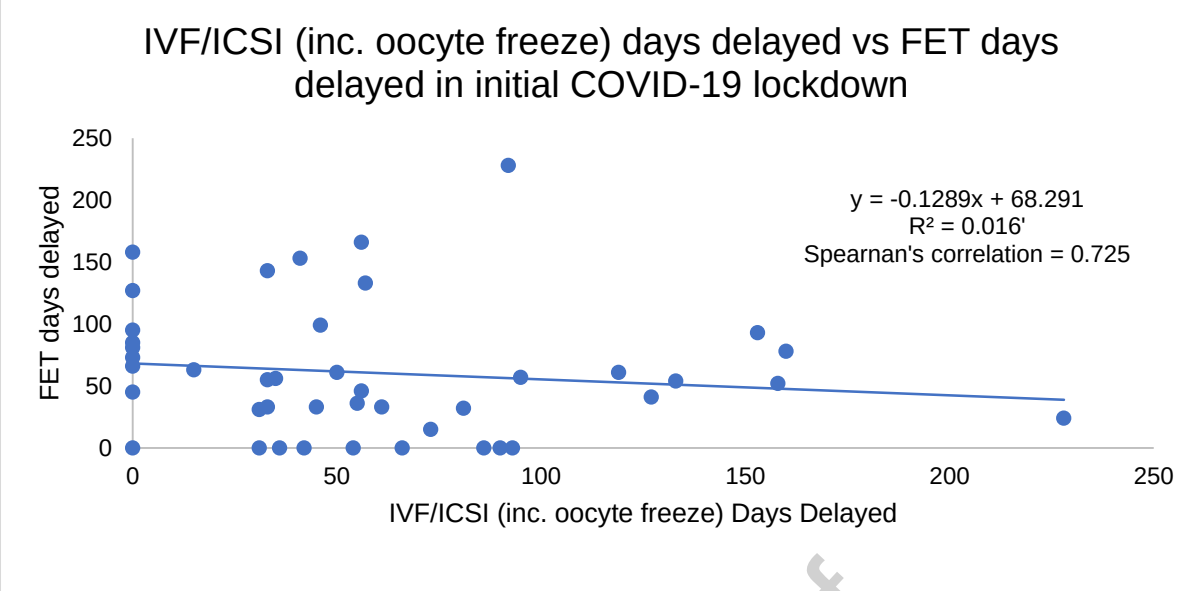

Figure 3: IVF/ICSI (inc. oocyte freeze) days delayed versus FET days delayed in initial COVID-19 lockdown. This plot indicates the relationship between days delayed for IVF/ICSI treatment versus FET treatment.

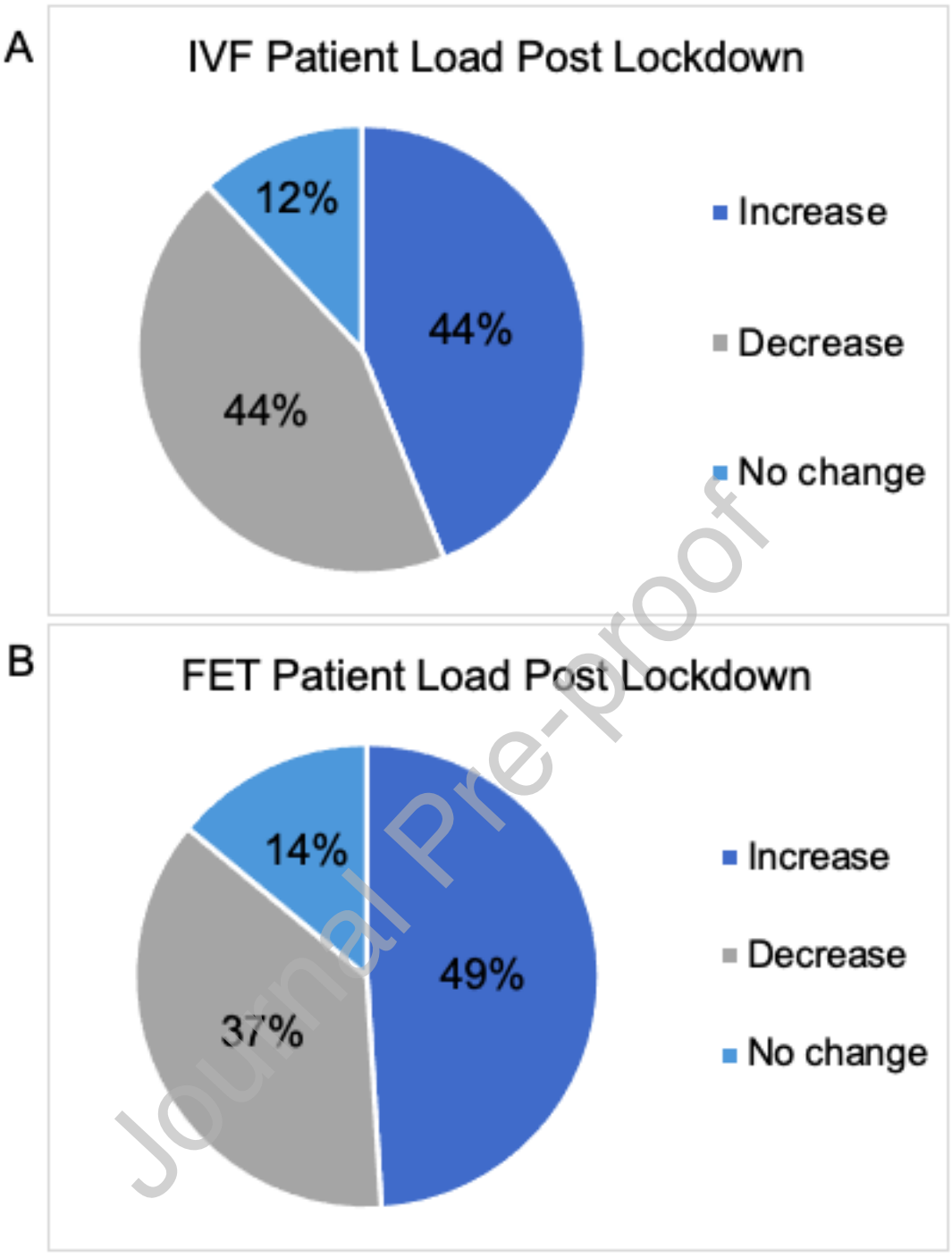

Figure 4. IVF/ICSI and FET patient loads post lockdown. The two pie charts reflect the participants answers of how the patient load changed as a result of county lockdowns. A) Did your patient load for ICSI/IVF treatment increase/decrease/no change after the lockdown period? B) Did your patient load for FET treatment increase/decrease/no change after the lockdown period?

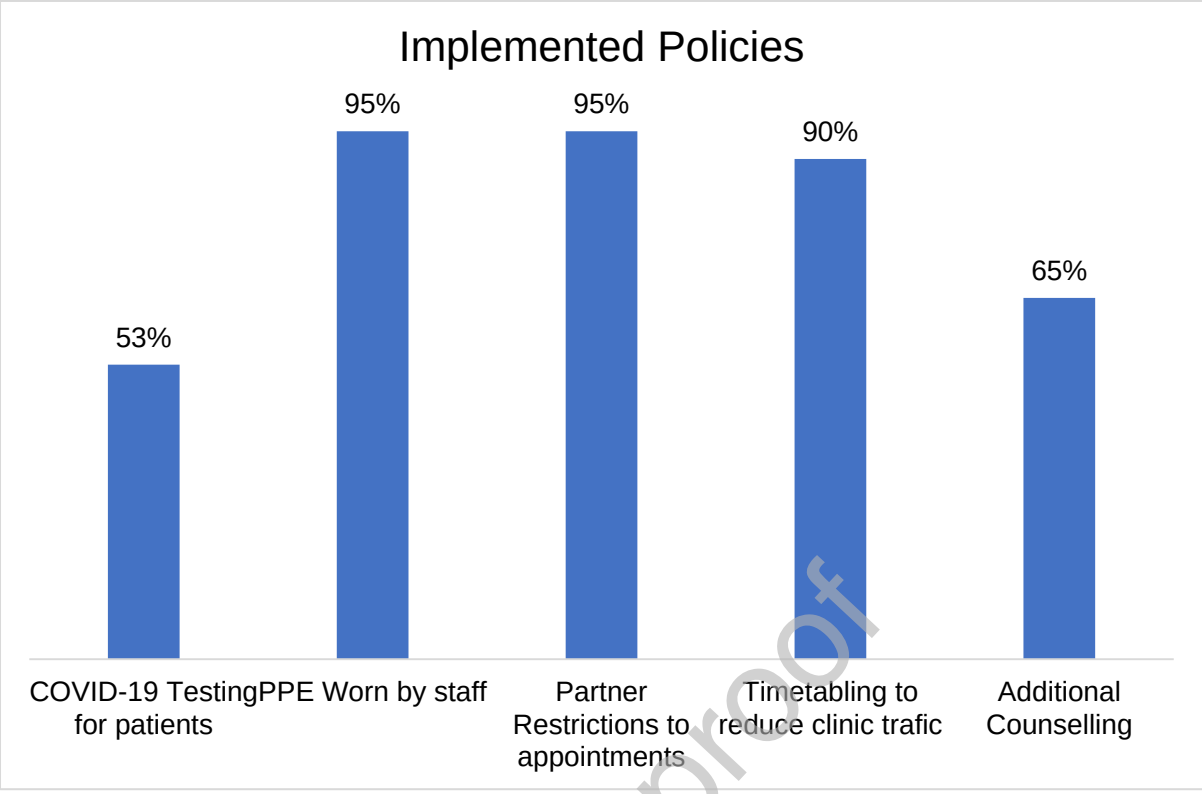

Figure 5: Implemented clinical policies as recommended by professional bodies such as ESHRE, ASRM and FSA.

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Elizabeth Cutting is a PhD candidate who is passionate about helping infertility patients, specifically patients with unexplained infertility. Elizabeth 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.

KEY MESSAGE:

Implications of the response to COVD-19 caused majority of fertility clinics worldwide to suspend fertility treatment. With advice to take a cautionary approach by their governmental societies, clinics implemented new policies such as SARS-CoV-2 testing and partner restrictions to appointments. A protocol that includes requirements such as increased patient counselling and additional guidelines for prioritizing couples who need care most urgently.