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# Italian and Lombardy County Art Post-Covid Pandemic Scenarios

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#### Abstract

Purpose: Aim of the present study is to report two possible scenarios, one optimistic and one cautelative, on ART activity in Italy and Lombardy County after the COVID-19 lockdown.

**Methods:** Based on historical data from the ART Italian National Register in general and Lombardy County in particular, we derived two ipothesis, on how the lockdown in Italy after Covid-19 epidemic, could affect the reduction in ART activity. The first one is considered a "cautelative" hypothesis and we modeled a substantial ART activity reduction.

**Results:** In both proposed scenarios there is data evidencing a reduction in the number of cycles and of babies born. In the cautelative hypothesis there is a reduction of the number of cycles by 55% and in the optimistic one by 35.5%. The total National loss in babies born will be between 6,719 and 5,913 and in Lombardy between 2,093 and 1,256 according to the 2 different scenarios.

**Conclusions:** The impact of Covid-19 epidemic on ART treatments will greatly reduce the number of babies born in the foreseable future. This not only to lockdown measures but also to reduced accessibility to treatments, even in a region like Lombardy carries out 30% of all the ART cycles in the country, mostly supported by public resources. Italian ART centres will face a great challenge in the management of the new policies for covid 19 containment. It will be difficult to find the right balance between maintaining enough available procedures, keeping both couples and staff safe.

Keywords: Covid-19 infection, Assisted reproductive techniques, Gamete donation, Lombardy county, ART National Register

## Introduction

On January 30, 2020 the first case of Covid-19 was detected in Italy, probably from a couple of tourists arriving from China; but it was February 22, 2020 the date when the infection spread dramatically, and a lot of cases were discovered especially in Lombardy County [1-4]. A National integrated surveillance system of Covid-19 has been created, coordinated by the Istituto Superiore di Sanità, analyzing data beginning on the 27<sup>th</sup> of February, and it suddenly showed a pattern of infection breakouts in Lombardy, and then in other northern regions [5].

The government, in a first round, decided to close only some specific municipality in Lombardy County, where most of the cases were diagnosed, calling these area "the red zone". In these territories a strict lockdown was enforced. Due to emergency regulations people could go out only for specific activities. School were closed, including universities, factories, shops, cinemas, theaters, and every activity not considered essential, like pharmacies or supermarkets, was closed. This strict lockdown procedures were implemented in Italy 4 to 6 weeks ahead of other European countries. Subsequently, from March 9<sup>th</sup>, 2020, the entire Italian territory was put under the same quarantine regimen.

Consequently, all health treatments considered not urgent were stopped, including ART procedures, in order not to overload hospitals and medical staff already engaged in the handling of covid-19 pandemic [6-13].

Many doctors working in ART units were reallocated in Covid-19 department, and spaces and facilities were quickly re adapted to create places for infected patients [14,15].

Recommendations from the major Italian Scientific Societies for Reproductive Medicine and from the Ministry of Health suggested stopping all new ART treatments and to continue only procedures for patients who had already begun ovarian stimulation. In these cases, freeze all strategy has been recommended. Only fertility preservation for cancer patients was continued [16-19].

In Italy since 2005 a National Register collecting information on Assisted Reproductive Technologies is in force by law since 2005. Data collection is mandatory, and all the 201 Centres, performing ART procedures, plus 160 performing only IUI (Intra Uterine Insemination), send data to the Register. A retrospective Data collection is made every year on a web site, <u>www.iss.it/rpma</u> with a dedicated access for each Centre and for each Region.

Comparing temporal trends of data collected from 2010 till 2018 from the Italian ART National Register [20,21], we have tried to make a reliable estimation of the impact of Covid-19 pandemic on ART procedures in Italy for the 2020 data set. All Italian ART Centers must report their activity to the Register and 100% comply with this requirement. Data were considered for all the Italian Centers and for Lombardy County, which represent around 30% of the country ART activity.

## Materials and Methods

We analyzed the temporal trend of all the data collected on ART cycles, from the Italian ART National Register from year 2010 till 2018, to compare them with estimated projections on the percentages of ART activity reduction that will occur during 2020, according to 2 different scenarios: a cautelative hypothesis (a) and an optimistic one (b). First, we analyzed the all National data, then specifically for the Lombardy County. Donation cycles were excluded and in line with the 2019 total number of ART procedures, our prediction models were taking in consideration already a reduced number of fresh cycles and a higher number of frozen ones. We considered various scenarios and after observing the ongoing situations in public and private centers and different opening policy in different regions of the country, we formulated what could be the most suitable hypothesis. Assuming that the activity for the first two months of 2020, January and February has remained quite stable, then, for March that the activities were reduced by the 40% than the 2019 number, due to a progressive amount of interrupted procedures, and that in April and May all the activity has been suspended with a residual 10% of procedures performed due to different closing policy, then from June on, we hypotise an activity resumption with different reductions scenarios. We have speculated for the residual seven months, (June/December 2020) that in a 2020 precautionary scenario (a), there will be a 40% recovery in activity compared to 2019, while in a 2020 optimistic scenario (b), we consider a 70% recovery in activity. Considering the different steps of ART treatments, from the number of started cycles to the oocyte retrieval, fresh and frozen embryo transfer, pregnancies, deliveries obtained, and babies born, we calculated the delta value of the variables examined according to the two-different hypothesis for the different techniques categories, fresh cycles and frozen cycles.

Some measures such as comulative pregnancy rate and pregnancy lost to follow up rate were tested with a z-test to find difference. A p-value of 0.05 was considered significant. The statistical analysis was performed with IBM SPSS Statistics 26.

### Results

We considered first the National data and then the Lombardy County performance. The Lombardy region, due probably to higher reimbursement than other regions of the country has an over 99% of the cycles covered by public resources, most of the larger volume centers concentrated in this area and in the 2018, even with all the bias of aggregated data analysis, a significantly higher (p<0.01) cumulative pregnancy rate per retrieval (34.1% with IC95% 33.4-35.0) than the overall rest of the country (31.3% IC95% 30.9-31.7) with a significantly lower (p<0.01) lost to follow up rate (3.4% IC95% 2.9-4.0) versus a general higher national percentage (9.1% IC95% 8.6-9.5). Public reimbursement is important in our country since few or no insurances cover ART procedures [22].

Therefore, many infertile couples in Italy, (27% of all the cycles are applied on couples coming from another County report ISS) move from their County to another one, to achieve reimbursed ART treatments [23].

Comparing the 2019 data set with the two scenarios, the conservative with a 40% recovery in activity, and the optimistic with 70% recovery, we have calculated the delta value for each step of the treatments: number of cycles, retrievals, and transfer for fresh plus frozen cycles, and for each technique alone, we have considered the number of pregnancies obtained and the number of babies born [24].

We estimated that the total number of ART cycles, fresh plus frozen in 2019 will be 71,991 (the final data is not available yet), and that in 2020 we will have 32,396 cycles for the worst hypothesis and 44,994 for a more favorable scenario, with a delta value respectively of 39,595 and 26,997, considering all Italian cycles (Table 1).

Considering the transfers, we estimated 50,636 for 2019 and 22,786 for scenario a, and 31,648 for scenario b, with delta values

Table 1: Number of procedures performed in Italy in the period 2018-2019 and according to a cautelative (- 55%) and optimistic (- 37.5%) and optimistic hypothesis calculation the possible loss in the 2 described scenarios.

Italy	2018-2019	2020 Cautelative hypothesis	2020 Optimistic hypothesis	Delta Cautelative hypothesis loss	Delta Optimistic hypothesis loss
Fresh + Frozen Cycles	71.991	32.396	44.994	39.595	26.997
Fresh + Frozen Transfers	50.636	22.786	31.648	27.850	18.989
Fresh Cycles	51.086	22.989	31.929	28.097	19.157
Oocytes Retrievals	46.387	20.874	28.992	25.513	17.395
Fresh Transfers	30.584	13.763	19.115	16.821	11.469
Frozen Transfers	20.052	9.023	12.533	11.029	7.520
Pregnancies (fresh + frozen)	14.525	6.536	9.078	7.989	5.447
Babies Born	10.751	4.838	6.719	5.913	4.032

of 27,850 and 18,989 for the two models, respectively. For fresh cycles the estimated 2019 number was 51,086, while 22,989 in the 2020 first scenario, and 31,929 in the second one, delta values of 28,097 and 19,157, respectively. Transfers in 2019 fresh cycles were 30,584, compared with 13,763 for 2020 (hypothesis a) and 19,115 for 2020 (hypothesis b). Delta values will be 16,821 and 11,469, respectively. Oocyte retrievals will be 46,387 in 2019 versus 20,874 and 28,992 for the cautelative and the optimistic model of 2020 with a delta value of 25,513 and 17,395, respectively. The number of frozen transfers was 20,052 in 2019 compared with 9,023 for 2020 hypothesis and 12,533 for hypothesis b, delta values of 11,029 and 7,520 respectively.

The activity performed in 2020 will be then reduced by 45%, compared to the one of the previous year, with a loss of 55% of total activity in the cautelative hypothesis, and of the 62.5% of 2019 total with a loss of 37.5% in the optimistic scenario (Table 1).

Concerning pregnancies, we had 14,525 pregnancies in 2019 with a reduction to 6,536 in the precautionary scenario and 9,078 in the optimistic for the year 2020. Delta values will be 7,989 and 5,447 respectively. The number of babies born for year 2019 is expected to

be (most of pregnancies still ongoing) 10,751 with a prevision for the 2020 hypothesis of only 4,838 newborns and of 6,719 for the 2020 hypothesis b; relative delta values will be 5.913 and 4.032 (Figure 1).

Analyzing in more details the number of babies born we observed a mean reduction of newborns of 896 per month, specifically we will have 1,792 newborns in January/February, only 358 in March, 179 for April/May, and 4,390 from June to December 2020 for the optimistic scenario.

Lombardy county data 2019, always estimating 2018 comparable data, had 21,367 fresh + frozen cycles, 13,658 retrievals, 16,169 fresh + frozen transfers (9,770 fresh and 6,399 frozen). The general yearly loss will be of 11,752 cycles in the cautelative hypothesis and of 8,013 in the opstimistic option (Table 2).

Considering the 2019 estimates of 4,665 pregnancies and 3,348 babies born, the two 2020 models will project 2,099 pregnancies and 1,507 born babies according to the cautelative hypothesis and 2,916 pregnancies and 2,093 born babies according to the 2020 optimistic prevision. In 2020 there will be a loss of 2,566 pregnancies and 1,841 born babies in the cautelative and 1,749 and 1,256 in the optimistic prevision (Figure 2).

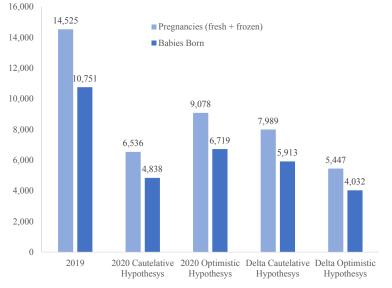


Figure 1: In Italy Post Covid 2020 cautelative and optimistic hypothesis loss in pregnancies and babies born.

Table 2: Number of procedures performed in Lombardy in the period 2018-2019 and according to a cautelative (-55%) and optimistic (- 37.5%) hypothesis calculation the possible lost in the 2 described scenarios.

Lombardy	2018-2019	2020 Cautelative Hypotesys	2020 Optimistic Hypotesys	Delta Cautelative Hypotesys loss	Delta Optimistic Hypotesys loss
Fresh + Frozen Cycles	21.367	9.615	13.354	11.752	8.013
Fresh + Frozen Transfers	16.169	7.276	10.106	8.893	6.063
Fresh Cycles	14.968	6.736	9.355	8.232	5.613
Oocytes Retrevals	13.658	6.146	8.536	7.512	5.122
Fresh Transfers	9.770	4.397	6.106	5.374	3.664
Frozen Transfers	6.399	2.880	3.999	3.519	2.400
Pregnancies (fresh + frozen)	4.665	2.099	2.916	2.566	1.749
Babies Born	3.348	1.507	2.093	1.841	1.256

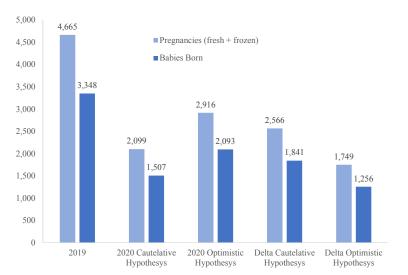


Figure 2: In Lombardy Post Covid 2020 cautelative and optimistic hypothesis loss in pregnancies and babies born.

#### Discussion

In the so-called phase 2 of the epidemic in Italy, that has started May 4th, in which ART centres could restart their activity, couples will have fewer financial resources to support the birth of a child and less resources to access ART costs on a private scheme. Even if most scientific authorities support a more widly coverage of ART treatment [22,25] this is still poorly undertood in most regions of our country. So we are offering less ART cycles to our infertile population in comparison with some northen European Countries The public and contracted facilities will have to reconvert spaces and staff now dedicated to other activities and will experience a difficult phase and a longer period for restarting even with a reduced number of cycles [16,17]. Private facilities will be more likely to resume faster, but the number of couples with available resources to afford 'out of pocket' cost will be less than previously, even if gonadotrophins are financially supported by a National regulation until 45 years of age and for an FSH level < to 30 UI/ml. In 2019 > 99% of treatments in Lombardy compared to a National average of about 69% (2018 data) were paid for by the Regional and/or National Health System. Couples moving from the Regions of the country to access to ART cycles has been always high in Italy reaching rates over 50% of performed cycles in some counties, in Lombardy it was the 33.1% only in 2018. This rate is significantly lower than the rate of out of county patients treated for other pathologies. Everyone will experience the transformation of work for the protection measures of couples and staff [26,27].

Many things are still unknown and studies on the effects of COVID 19 on reproductive cells are ongoing, even if reassuring data on pregnancy outcome have been published [13,18,28-30].

Recent real world data from the Humanitas Fertility until October 31th show a 31% of total number of 2020 performed procedures with a possibile reduction due to the probable new lockdown at least in some Italian Regions as Lombardy to over 50% of the 2019 perfomed procedures.

#### Conclusions

Whatever scenario will really appear at the end of year 2020 [14], regarding the reduction on ART activity, the impact of Covid-19 pandemic will be really strong for all the Italian ART Centers, not only because of the reduction of cycles performed and subsequently babies born, but because of the diminished availability of procedures [31], even in a Region like Lombardy that carries out 30% of all the ART cycles in the Country, mostly supported by public resources. Being compliant with new rules to protect couples and staff from the risk of infection, will determine a shortage in the number of patients treated. Only a strong willingness and a great organizing capacity of the ART Centers could partially overcome the burden of the impact of Covid-19 epidemic that will continue in the next months. In this emergency situation, in a Country with the lowest natality rate in Europe, where the Assisted reproductive techniques contribute for the 3% of the babies born annually, and plays an important role answering to the need of infertile couples, Government and Regional local authorities should encourage and support ART activity and promote access for infertile couples with dedicated actions [32,33].

Ultimately, given the ethical concerns raised by public health recommendations regarding pregnancy avoidance, strong justification for any such advice is needed and the criteria to be fulfilled during certain public health emergencies (e.g., a radiation emergency with continuing exposure), we don't believe that the risks associated with Covid-19 meet the bar [1].

## Data Availability

The datasets generated for this study are available on request to the corresponding author.

## **Conflict of Interest**

Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## **Author Contributions Statement**

PELS wrote the research project, analyzed data and prepared the final draft, RDL analyzed data, GS and MB and RDL contributed to the data, the manuscript and references preparation.

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