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# **Research Article**

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# Sars-CoV2 vaccines in Breastfeeding with different doses and types of vaccines and risk of new Sars-CoV variants

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#### Introduction

In literature, we have done a control of PubMed articles of this period, and there are many articles about SARS Covid 2019 with hypothetical vertical transition of breastfeeding for direct contact with mother or artificial milk for management during preparation of meals for babies. We analyze these recent studies and we decide to draw a new study about mother in breastfeeding or not. During emergency Sars-Covid-vaccine period (18th February – 18th August, 2022) for contrast pandemic event spread in all world, from China to Italy involving also the rest of world.

#### Aim of Study

The study wants to understand if there is a significant difference correlation both mother with Sars-Covid-vaccine with the same three doses or with one shift between first and last dose, as in case of mRNA spike vaccine or Adenovirus vector vaccine. Otherwise, we have cases with two shifts between three vaccines, according ministerial indications of Sars-Covid-2 vaccine. The distribution starts on 31th December, 2020 – with sponsor event of "Vaccine Day" on 27th December, 2020 [1]. We have some periodic "Open Day" of Covid Center in Lombardy and other regions. The incident of Sars-Covid vaccine in mother with a good cover is significant respect control patients, without Covid vaccine adherence or with immediately artificial milk feeding of their baby at the birth. Considered the real exposition of these mothers and babies to have covid infection during pregnancy medical practices, deliver of baby and hospitalization. We have a database with the dates of their first infection in same cases of family, father or/and mother and baby, and in rare cases other data of a second covid infection during final 2021 and the first half 2022.

#### **Material and Methods**

We have a total of 530 mothers and their babies treated with Sars-Cov2-2019 vaccine [2] with a number of 445 (84%) mothers and without Sars-Covid vaccine 85 (16%). Before, childhood's vaccinations, we present the study to family and we give mother an information document, in these months, in our Vaccine Center of Treviglio Hospital with a number of 530 / 1467 patients, 36,12% of babies (1 months – 3 years of life), and respective mothers, in these seven months. We gave the document to ask the mother's signature, after a short and direct questionary about vaccine: doses, label of doses and symptomatic reaction, time

of breastfeeding (BF) or artificial feeding (AF) from birth. Otherwise, the eventually postponement of dose after gynecological indications at the beginning of vaccine safety events. In other case some mothers are disagreement towards all vaccines. So, we can share this sample of 1060 subjects in two groups: of 530 total babies (mean, 7 months of life) with completed data there are 486 mothers in BF 346 (71,2%) and AF 140 (28,8%) in two different groups of mothers (mean, 33.7 years of old). Another little group of mothers, about 1.13%, that accepted the idea of this study but two of them were underage and one not completed all data in questionary, and just 3 mothers that refused to sign our consensus information for study.

# Data Management and Satistical Analysis

Database of SIAVR [14] (Regional-Vaccination Registry Information System) give us possible to control data wrote down by mother or physician with verbal communicate during anamnestic time before during periodic childhood vaccine plan of the baby. This National System Vaccine Record permit to have information about Sars-Covid vaccines and infections considering that some mother communicated a sure infection in case of positive nasopharyngeal swabs or only symptomatic events without specific swabs, after family pediatrician indication, for strict contact with positive mother or other members of family.

#### **Conclusions**

Our study's data evidences a significant correlation both female adult patients with their babies in breastfeeding immunity protection respect to controls with babies in artificial feeding. For this reason, we can analyze the incident of mRNA Sars Covid and Adenovirus types of vaccines: the numbers of doses were constancy or were shifted for different indications, according to needs. It's very important to analyze the distance among doses of vaccine and the infection of new variants covid, in these months, Sars-Covid 2019-2022 [3]. In fact, on September 3, 2022 the Ministerial Communication gave us indication of a new vaccine "Original/Omicron BA/1" to fight, in special way, this variant in population to reduce Omicron Covid's spreading in Italy and other European countries. Because we have some cases, with a second infection in the same family or also in little patients; with long quarantines of these patients in these last spring and summer days.

**Key words:** Sars-Covid Vaccine, Breastfeeding, Artificial feeding, pregnancy, mRNA covid vaccines, Adenovirus vaccine and new variants of Sars-CoV virus.

#### Introduction

In literature, recent studies have put in evidence different argues about the risk of breastfeeding or in other publishes discussions related to the importance of immunological protection. We analyze these recent studies, and we decide to draw this new study about mother in breastfeeding or not; before and after Sars-CoV2 vaccines.

During emergency vaccine period (18th February – 18th August, 2022) for contrast pandemic event spread in all world, from China to Italy involving also the rest of world. We have done a control of PubMed articles of this period, and found out that there are many articles about SARS Covid 2019 [2] and new variants [3] with hypothetical vertical transition of breastfeeding for direct contact with mother or artificial milk during management preparation of meals for babies.

These studies, likely, provide specific immunological benefits to infant respect to the artificial feeding, which could not permit breastfeeding (BF) protection; without considering severe case of mother in reanimation in which the breastfeeding is impossible and dangerous. The first studies, presented some evidence to support the potential of congenital, intrapartum, and postnatal maternal-fetal-neonatal SARS-COV-2 infections during COVID-19 pandemic [4]. In some articles, they found that milk produced by infected mothers is a source of Antibody Sars-Cov-2 IgA and IgG and neutralize Sars-Cov-2 activity. These last results, in literature, support recommendations to continue breastfeeding in a period of mild or moderate maternal Covid illness respect to artificial feeding [5].

In Italy, there is a mass immunization campaign that started on 27 December 2020, together with most countries in the European Union. In the first months of the vaccination campaign, the governmental agencies targeted to be validated, with urgent, the health of medical and administrative personnel, together with the longtime elder and disables guests and personnel of nursing homes [6]. In the second phase of the campaign, elderly people and public service personnel should receive the vaccine [7]. After this first around, we participated to vaccine campaign of all people like teachers, educator, professors for they direct contact with children at home for Ministerial Indication on 5 March, 2020 [8].

In international studies, we have data about women with Covid-19 diagnosis that present maternal mortality ratio of 1,6 (159/10.000 births) for preeclampsia, respiratory failure in mechanical ventilation and pulmonary embolism and others dies later despite intensive respiratory support. Overall, women with covid-19 diagnosis had a lower rate of spontaneous initiation of labor but higher cesarean delivery rate, reflecting the higher rates of pregnancy complication about preterm birth with ratio of 1.59 and fetal distress with ratio of 1.70 [9].

Other authors decided to include in their analysis all women exposed to COVID-19 mRNA that were exposed to vaccine during pregnancy and who had the chance to complete their pregnancy

with live birth respect to spontaneous abortion or ectopic pregnancy. These articles data show very reassuring results when evaluating SARS-CoV2 vaccination safety among pregnant women-fetal-newborns [10]. This is of paramount importance as pregnant women are considered a vulnerable population for SARS-CoV-2 infection [11]. In our vaccine office, we decided to include only healthy mothers and baby participants with clinical control disease, in a randomize study with both genders and different ethnic origins of families. On the other hand, we have second-generation immigrant families or just one member of parents is foreigners. In Italy we have characteristics mixed families.

The virological diagnosis could be confirmed by detection of Sars-CoV-2 samples in a clinical and pharmacy laboratory to a follow transmission of daily nasopharyngeal swabs to regional vaccine system of SIAVR [12]. All participants included after signed the voluntary informed Consent Form and we confirm all exclusion and inclusion criterions like: age of mother (over of 18 years old), minor legal guardian of baby or adoptive parents. Our clinical dates are localized in Pediatric Vaccine Center of Treviglio-Caravaggio Hospital, Lombardy - Italy.

The global health crisis of our time is this pandemic infection generated by Sars-CoV-2 virus, that as rapidly immobilized the world and the expertise researchers, clinicians, and public health officials. Although our understanding of biology, clinical implications, and strategies for control travels mitigation. This pandemic also in pregnancy mothers and infant feeding practices continue to evolve. American Academy of Pediatrician (AEP), Centers for Disease Control and Prevention (CDC) and United National Children Found (UNICEF) recommend breastfeeding (BF) within 1 hour of births and an exclusive BF continued for six months of life or until two years of age. They suggest to use of appropriate respiratory hygiene and environment cleaning precaution like masks, wash hands, wear gloves and social distance. The novel coronavirus Sars-CoV-2 was named Sars-CoV due to its shared sequence homology and similar clinical characteristics: respiratory infection are principals causes of morbidity in a pregnancy and newborn [13].

#### Aim of Study

is to collect directly among our patients focus data that we observe in these months in our Vaccine Center. Parents give us clear feedback about first or second infection of Sars-Covid in their family and mothers in her newborn or baby.

This report in anamnestic data of patients has given us an input to find an answer. So, we have requested data in questionary and consensus documents of mothers that, freely, have decide to give us data about: number doses of Sars-Covid vaccine, types of vaccines, timing of breastfeeding (BF) during all vaccine childhood appointment to known if they maintain it or change in artificial feeding (AF) or the next Covid vaccine dose.

All these data suggest us to analyze the real situation that these mothers faced up in their life in these months of pandemic with spreading of new variant Sars Covid "Omicron" in all part of world like second pandemic event. The study wants to understand if there is a significant difference correlation both mother with Sars-Covid vaccine with the same three doses or with one shift both first and last, as in case of mRNA spike vaccines or Adenovirus vector vaccines.

For this motivation, we have focused the questions about numbers of vaccine doses, with controls of correct data and type of dose in Italian SIAVR (or RVRIS, Regional-Vaccination Registry Information System [12]) with mother permission.

In fact, we have cases with one or two shifts between three vaccines, according ministerial guidelines of Sars-Covid vaccine 14th June, 2021[16] with a "mixed vaccine cycle" both mRNA-Sars-Covid vaccines and also these like second dose after Adenovirus Sars-Covid vaccine dose.

The vaccination campaign in Italy had a distribution, that started on 31th December, 2020 – open with sponsor event of "Vaccine Day" on 27th December, 2020[1]. So, we have some periodic open day of Covid Center in Lombardy and others region. The incident of Sars-Covid vaccine in mother with a good cover is significant respect control patients, without vaccine adherence or with immediately artificial milk feeding of their baby.

Considerate the real exposition of these mothers and babies to have covid infection during pregnancy medical practices, deliver of baby and hospitalization. We have collected data on the database of their first infection in some cases of all family, father or/and mother and baby and in rare cases other data of a second covid infection during final 2021 and the first half 2022.

The principal causes of morbidity and mortality are in mothers and her children during the first year of life, respiratory infection transmitted with delivery and cesarean in a vertical transmission during pregnancy. If the mother was positive before hospitalization or with breastfeeding at birth. Some authors say that breastfeeding provides protection from Sars-CoV infection but depends on its durations, because colostrum has an abundant glycoprotein and lactoferrin with a lympho-stimulatory [18].

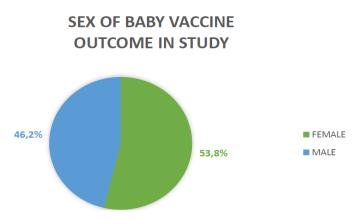
The Health Ministerial Developing Guidance in the Covid 2019 Pandemic and others infection Covid Disease with a new variants' outbreaks need to appropriately consider the importance of skin-to-skin contact for dyed both mother and her baby with early initiation of breastfeeding, rooming in. Considering the value of recommendation at beginning of Sars-CoV-2 infection 2019 were against maternal proximity and breastfeeding (BF). Recent literature had detected in BF sample and the infant blood sample a significant diagnosis of Cov19 virus. Its remained unclear if this disease is transmitted with breastfeeding or direct contact with mother or through deliver.

Author's hypothesis are that the viral antibodies could pass to newborn passively through breast milk of Covid19 positive mothers and to give immunity to child. Based on the current available limited evidence and recognizing the benefits of BF are significant also in mother positive for Sars-Covid infection or its

variants. The extraction of Sars-CoV virus in breast milk should be encouraged by healthcare provided after a careful discussion of vertical transmission of risk to the mother and new infant [19]. While in Italy, we continued to do nasal pharyngeal swabs (NP-swabs) in all mothers at access to hospital for labor and in symptomatic conditions, but we have just a rare NP-swabs of babies for parents decisions with family pediatrician in case the symptoms of infant are evident for direct contact with mother positive and the fever is on the control of paracetamol treatment, as suggested in medical prescription with postpone of 1 month of childhood vaccine plan after a parents call to communicate the change of appointment in our Central Vaccine Childhood in office hospital.

#### **Material and Methods**

We have a total number of 1060 mothers and their babies with regular Sars-Covid vaccine with 530 mothers mean of age 33.8 (range 19.9-50.9 years old) and babies mean of months 0.70 (range; 0.1-3.2 months of life). Of these, we have mothers that had not completed the questionnaire: 2 underage, 3 no signature and 1 signeted but no completed; with 6 cases of exclusion by analysis study (1.13%).



**Figure 1:** This sample included 286 Female and 244 Male for a total of 530 Babies.

By mother group of 445 (84%) mothers with and without Sars-Covid vaccine 85 (16%), we have noted that the principle Sars-COV-19 vaccine was of Pfizer "Comirnaty" with a 49.8% (50%) of our total patients. In this study, we have one dose of AstraZeneca "Vaxzevria" and one dose of Johnson&Johnson "Janssen" either Adenovirus vaccines. After the government's guidelines of 14th June, 2021[14] Health Ministry gave the possibility to shift both Pfizer to Moderna "Spikevax" (mRNA Sars-CoV-2 vaccine), this last is presented only in 15.6% (numbers of 83 mothers), and with one shift between Pfizer and Moderna and vice versa of 14.1% (numbers of 75). We have other cases that consist of a one shift between AstraZeneca "Vaxzevria" to Pfizer and/or Moderna labels; respective labels of Sars-CoV-2 spike vaccines of 2.6% (14 mothers). Eventually, we have 5 rare cases of two shifts both Adenovirus vaccines with mRNA-Sars-CoV2 vaccines for a total of three doses of vaccine; according to Italian government recommendation with further booster dose.

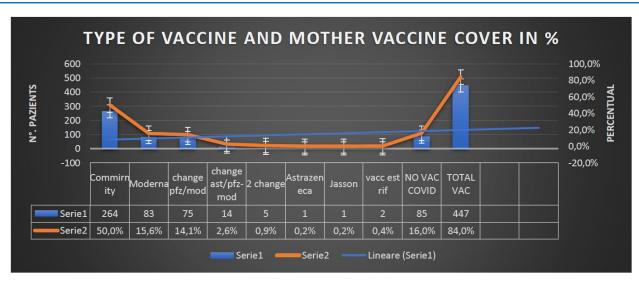


Figure 2: The first sample consist in mother vaccine for Sars-Cov2-2019 and mixed vaccine cycle or no vaccine covid groups.

In this graphic, we consider the no vaccine covid group mothers that represents 16% (85 adults), who denied consensus.

Our database shows the risk of this decision and the incidence of Sars-Covid 2019 infections were 41,13% of sample in 218

family infected and with compliance for Covid Vaccination and 213 only mothers in pregnancy (40,18%), and 189 also babies (35,66%) by SIAVR System and Anamnestic data during child-hood vaccine plan of the first years of age. In last seven months, we have collected data of recurrence of infections of 3,58%.

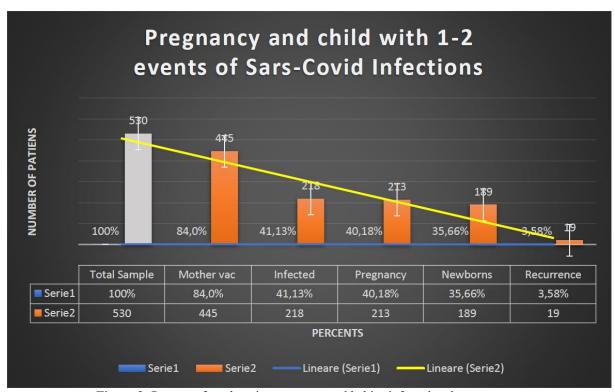


Figure 3: Percent of mothers in pregnancy and babies infected and recurrences.

Now, we need to put in consideration also these aspects, aforesaid, when we analyze vaccine and not vaccine groups with Sars-CoV2-vaccinations, like suggested by physicians of Territorial Vaccine Center within a radius of 50 kilometers from home, with different adhesion to partial or total vaccine cycle, before of ministerial disposition modified in summer, to permit in vacation to continue the following doses [17].

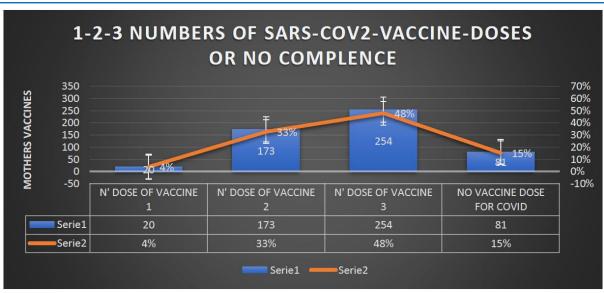


Figure 4: Numbers of doses Sars-Cov2-vaccine 2019 and booster dose or no vaccine covid.

The total or partial compliance to vaccine doses (minimum 1-maximum 3 doses) need to be in correlation both types of vaccines and number of dose vaccine. Once they have done, we can control in SIAVR System with consensus and for a correct controls of registration data also in Regional Vaccination Registry Information System [14].

During the first appointment for childhood plan vaccine, we have noted if baby had a good baby birth with regular cursus and if the mother had SARS-Covid-infections in pregnancy with/out baby by link "Info Covid" and the opportunity to control in time, if breastfeeding mothers had transmitted the Sars-Covid infection to child during "skin to skin contact" or for symptomatic mother's conditions.

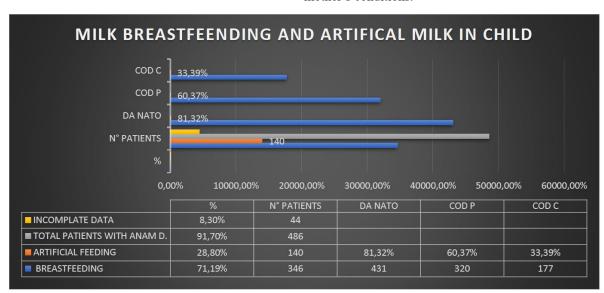


Figure 5: Patients and controls in base of BF and AF.

These graphics and tables show us the importance to study the health of babies and mothers with vaccine and breastfeeding and indicate to understand the level of correlation and the significant data; according to medical practices in Vaccine Centers for Covid Vaccination Campaign and in all HUBs Covid Center in Italy.

Before the appointment for childhood's vaccinations, we present the study to family and we give mother an information document, in these months, in our Vaccine Center of Treviglio-Hospital with a number of 530 / 1467 babies (36,12% was analysis with 1 month - 3 years of life), in these seven months.

We have given the document to have the mother's signature, after a short and direct questionary about vaccine: doses, label of doses and symptomatic reaction, time of breastfeeding (BF) or artificial feeding (AF) from birth, otherwise the eventually postpone of Covid vaccine dose; after gynecological indications at the beginning of vaccine safety campaign. In other cases, mothers are disagreement towards all vaccines.

So, we can share this sample of 1060 subjects in two groups of 530 total babies (mean, 7 months of life): with completed data are 486 mothers: in BF 346 (71,2%) and AF 140 (28,8%) and two different groups of mothers (mean, 33.7 years of age) with Sars-Covid-2 vaccine 445 (84%) and no Covid vaccine 85 (16%).

In a group of mothers, we have found only 2 mothers (under 18 years old) without requisite for enrollment on 532 adhesions, at the beginning, but 1 mother, that accepted the idea of this study, not completed all data in questionary and just 3 mothers that give us all information when they read consensus inform refused to sign our informative for study because afraid, we can oblige them to vaccine their children.

We explain them that it was impossible and they were excluded by our research, because this review constitutes human subject, and ethical approval was required with a collaboration of Ethical Commission of Bergamo in Lombardy region of Italy.

The authors declare also that the research was conducted in absence of any commercial or financial relationships that be constituted as a potential conflict interest.

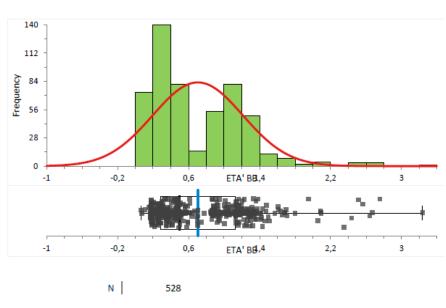
# **Data Management and Statitical Analysis**

Database of SIAVR [14] (Regional-Vaccination Registry Information System) give us possibility to control data wrote down by mothers or else verbal communicated during anamnestic session before periodic childhood vaccine plan of the baby.

This National System Vaccine Record permit to have information about Sars-Covid vaccines and infections considering that some mother communicated a sure infection in case of positive nasopharyngeal swabs or only symptomatic events without specific swabs, after family pediatrician indication, for strict contact with positive mother or other members of family and other relatives/people.

In the first descriptive analysis, we show a distribution age of our patients in months of life, with a concentration both 2-15 months as Vaccine Childhood Plan. This Gaussian curve represents the Age of Baby in our study.

# 1-Descriptive babies



	Mean	Mean SE	SD	Skewness	Kurtosis	
ETA' BB	0,704213159	0,022122698	0,508340899	1,2	2,00	
	Minimum	1st quartile	Median	3rd quartile	Maximum	
ETA' BB	0,06575342	0,282191781	0,497260274	1,127625571	3,23561644	

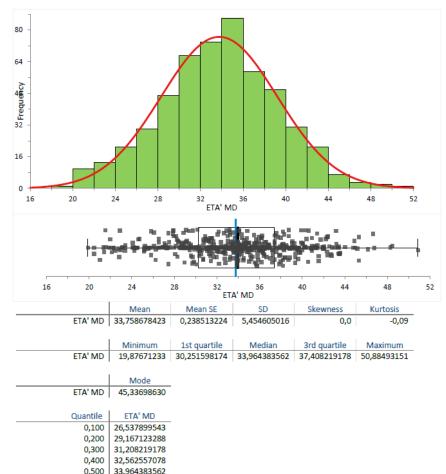
ETA' BB	0,17534247				
Quantile	ETA' BB				
0,100	0,180821918				
0,200	0,260273973 0,328310502				
0,300					
0,400	0,396347032				
0,500	0,497260274				
0,600	0,863013699				
0,700	1,011415525				
0,800	1,158904110				
0,900	1,311415525				

Mode

The second descriptive graphic is about age of mother, the Gaussian curve draws a homogenous population with large distribution between minimum age of 19 years old and maximum

51 years old in mothers with newborns and babies (1 month to 3 years age); we can see it in the previous description analysis.

# 2-Descriptives mothers



The third graphic represents the types of Sars-Cov2-2019 vaccines, considering that the first is Comirnaty that is about the half part of our sample reached in a first round of study with voluntary adhesions to analyze mothers, aforesaid, and considering to

0.600

0.700

0,800

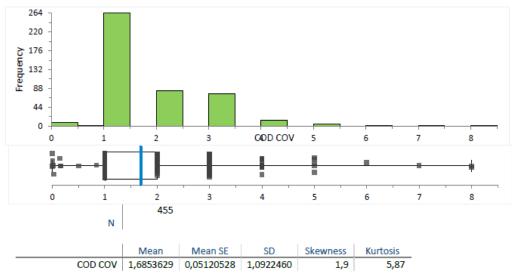
35.009132420

36,424657534

38,421917808 40,855707763

> maintain or shift doses depend on ministerial and central vaccine indications; based on simultaneous data about the adverse effects in old or young women in Italy and European countries, and in the rest of world.

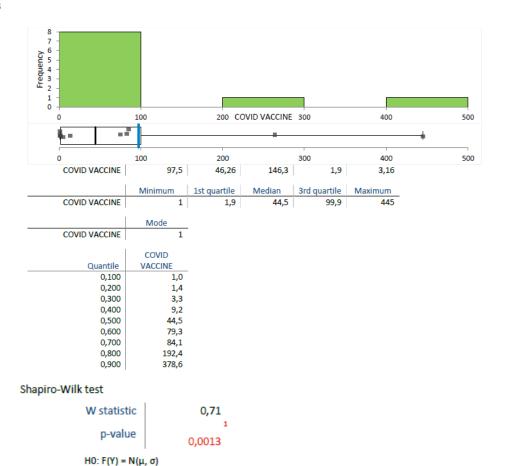
# **3-Descriptives CoVs**



Thanks to these descriptive graphics, we show the significant correlation of Sars-CoV2-types vaccines in these study groups with free compliance. The mRNA Sars-CoV2 vaccine 2019 type

1 and 2 have another very significant differences both one shift with first recalls and a second shift with booster doses; described by a p-value of 0,0013.

# 1- Analyze CoVs



The distribution of the population is normal with unspecified mean and standard deviation

H1:  $F(Y) \neq N(\mu, \sigma)$ 

The distribution of the population is not normal.

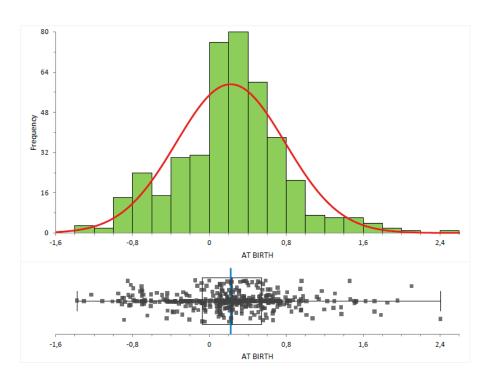
<sup>1</sup>Reject the null hypothesis in favor of the alternative hypothesis at the 10% significance level

These data explain the importance of international indication of the World Health Organization (WHO), the European Medicines Agency (EMA), the Food and Drug Administration of American Unite States and the Italian Drug Agency (AIFA). The governments of world for this pandemic emergency had united in a task force to detect first data about deaths for Sars-CoV2-Vaccines. In this way, Central Vaccine of the world could change and modulate recommendations to understand the appropriate using of specific types of Sars-Cov2-vaccines in base on woman age and mother condition before or during pregnancy.

For this reason, we share the analysis in graphics and respective tables to understand the draw of our study and our aim to discover, if our hypothesis about breastfeeding and artificial feeding influence are significant for the health of baby in a sort of immunological protection. As some recent articles ask to explain in a new study; by the point of view of Central Vaccine First Childhood, that gives us a correct incidence of this correlation.

With this Analysis we can consider the distance of different period both Covid vaccine doses since baby birth and permits to share mothers: in pregnancy and delivery, and during the first seven months of baby.

2- Analyze distance at birth to 1-2 covid vaccine: share in mother pregnancy and during the first months of life in baby.



	Minimum	1st quartile	Median	3rd quartile	Maximum
AT BIRTH	-1,37808219	0,077625571	0,227397260	0,542465753	2,40547945
	Mode				
AT BIRTH	0,11232877				
Quantile	AT BIRTH				
0,100	-0,606940639				
0,200	-0,214246575				
0,300	0,046392694				
0,400	0,146849315				
0,500	0,227397260				
0,600	0,332237443				
0,700	0,471232877				
0,800	0,610410959				
0,900	0,835799087				
Shapiro-Wilk test					
W statistic	0,98				
	1				
p-value	<0,0001				

H0:  $F(Y) = N(\mu, \sigma)$ 

The distribution of the population is normal with unspecified mean and standard deviation.

H1:  $F(Y) \neq N(\mu, \sigma)$ 

The distribution of the population is not normal.

<sup>1</sup>Reject the null hypothesis in favor of the alternative hypothesis at the 10% significance level.

# Conclusions

The Statistic Analysis of all variables, that we have considerate in these months, give us much information about correlations both periods of infections and the age of babies more than the age of mothers. While there are strict dependencies of correlations both breastfeeding and the age of mother and with/out the Sars-CoV2 infection 2019.

The variables are respectively with the first, second and third period of infections and in relations with the age of babies or their mothers during breastfeeding respect to control groups.

Our data of study evidences a significant correlation both mothers and babies ages with breastfeeding for immunity protection respects to controls without Sars-CoV2 vaccine or babies in artificial feeding. For this reason, we can analyze the incident of RNA Sars Covid types of Vaccine and Adenovirus-vaccine, if the number of doses is constancy or shift of doses for different indications according to needs.

It's very important, to analyze the distance among doses of vaccine and the infection of new variants covid, in these months, Sars-Covid 2019-2022 [3]. In fact, on September 3, 2022, the Ministerial communication gave us indications of a new vaccine

"Original/Omicron BA/1" to fight, in special way, this variant in population to reduce Omicron Covid's spreading in Italy and other European countries. Because we have some cases, with a second infection in the same family or also in little patients; with long quarantines in these last months.

The data of our research gives an answer to many articles' questions. For this reason, we have citated in references, because, we have tried to correlate much date about: the age of patient groups

and the types of Covid doses, and the compliance to Ministerial indication about booster doses.

The health minister sent many contrasts indication based on different recommendation for sanitary control of infection between mother and newborn during breastfeeding and/or artificial milk feeding and their events of infection before pregnancy, near the delivery or after.

		_	. 1	0 1						
Variable	N	Mean	SD	Median	Maximum					
INF PERIODO I	134	-0,540870988	10,574136499	0,515068493	1,53150685					
INF PERIODO II	127	-0,683982310	10,860747069	0,435616438	1,47397260					
INF PERIODO III	130	-0,908598525	10,740999355	0,219178082	1,06027397					
ETA' BB	528	0,704213159	0,508340899	0,497260274	3,23561644					
ETA' MD	523	33,758678423	5,454605016	33,964383562	50,88493151					
DATA VAC	529	44654,4	94,2	44655,0	44791					
COD P	497	1,58465	20,87932	1,00000	466,0000					
COD LM	490	1,4	19,9	0,0	428					
COD C	499	0,57757	4,97616	0,00000	111,0000					
Correlation										
	INF PERIO DO I	INF PERIODO	INF PERIODO III	ETA' BB	ETA' MD	DATA VAC	COD P	COD LM	CODC	
INF PERIODO I	-	1,000	1,000	0,029	-0,093	-0,013	-0,059	0,057	0,053²	Pearson's r
	-	0,959	0,741	-0,073	0,044	-0,075	-0,123	-0,029	0,055	Spearman's rs
	-	0,889	0,594	-0,049	0,026	-0,052	-0,101	-0,024	0,045	Kendall's tau
PERIODO II	1,000	-	1,000	0,027	-0,097	-0,015	-0,058	0,056	0,053	
	0,959 0,889	-	0,769 0,630	-0,140 -0,094	0,059 0,043	-0,060 -0,043	-0,100 -0,082	-0,064 -0,053	0,031 0,026	
PERIODO III	1,000	1,000	-	0,032	-0,100	-0,013	-0,060	0,058	0,056	
	0,741	0,769	-	-0,125	-0,064	-0,044	-0,151	-0,022	0,073	
ETAL DD	0,594	0,630	0.000	-0,091	-0,044	-0,033	-0,124	-0,018	0,060	
ETA' BB	0,029	0,027	0,032	-	0,056	0,144	-0,002	0,004	0,005	
	-0,073 -0,049	-0,140 -0,094	-0,125 -0,091	-	0,020 0,012	0,067 0,050	-0,076 -0,062	0,038	0,084	
ETA' MD	-0,093	-0,097	-0,100	0,056	0,012	-0,005	0,000	0,001	-0,005	
LIA WID	0,044	0,059	-0,064	0,020	_	0,000	0,031	0,004	-0,042	
	0,026	0,043	-0,044	0,012	_	0,002	0,026	0,003	-0,035	
DATA VAC	-0,013	-0,015	-0,013	0,144	-0,005	-	0,038	-0,066	-0,046	
	-0,075	-0,060	-0,044	0,067	0,000	-	0,047	-0,070	-0,062	
	-0,052	-0,043	-0,033	0,050	0,002	-	0,038	-0,057	-0,051	
COD P	-0,059	-0,058	-0,060	-0,002	0,000	0,038	-	0,994	0,993	
	-0,123	-0,100	-0,151	-0,076	0,031	0,047	-	-0,531	-0,961	
	-0,101	-0,082	-0,124	-0,062	0,026	0,038	-	-0,531	-0,961	
COD LM	0,057	0,056	0,058	0,004	0,001	-0,066	0,994	-	0,996	
	-0,029	-0,064	-0,022	0,038	0,004	-0,070	-0,531	-	0,539	
	-0,024	-0,053	-0,018	0,031	0,003	-0,057	-0,531	-	0,539	
COD C	0,053	0,053	0,056	0,005	-0,005	-0,046	0,993	0,996	-	
	0,055	0,031	0,073	0,084	-0,042	-0,062	-0,961	0,539	-	
COD P, COD	0,045	<mark>0,026</mark>	0,060	0,069	-0,035	-0,051	-0,961	0,539	-	
LM COD P, COD	486	0,994	0,993	0	0,0021485	<0,0001²				
COD LM,	497	0,993	0,992	0	0,00247221	<0,0001				
COD C	487	0,996	0,995	0	0,00150465	<0,0001				

 $^2H0$  ;  $\rho$  = 0, The correlation coefficient  $\rho$  of the bivariate population is equal to 0.

H1:  $\rho \neq 0$ , The correlation coefficient  $\rho$  of the bivariate population is not equal to 0.

These data explain the importance of international indication of the World Health Organization (WHO), the European Medicines Agency (EMA), the Food and Drug Administration of American Unite States and the Italian Drug Agency (AIFA). The governments of world for this pandemic emergency had united in a task force the relevant first data about deaths for Sars-CoV2 vaccines [18]; in this way, Central Vaccine of the world could change and modulate recommendations to understand the appropriate using of specific types of Sars-Cov2 vaccines based on woman age and mother condition before or during pregnancy.

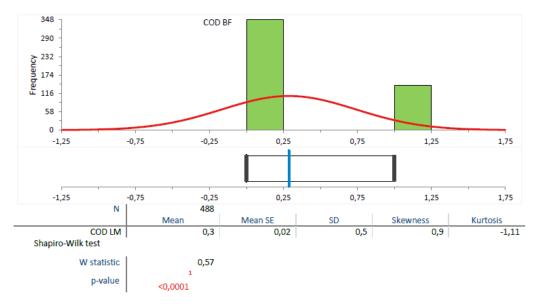
For this reason, we share the analysis in graphics and respective tables to understand the draw of our study and our aim to discover, if our hypothesis about breastfeeding and artificial feeding influence significatively the health of baby in a sort of immunological protection. As some recent articles ask to explain in a new study by the point of view of Central Vaccine First Childhood to have a correct incidence and significant correlation.

In fact, the value of correlation is significant with p-value < 0,0001 both patients breastfeeding and controls artificial feed-

ing. The age of babies shows dependent and independent correlations with Pearson's, Spearman's rs, and Kendall's tau of about 0,05 for control groups. The period of infections, generally, depends on mother and she were in pregnancy, at birth or after delivery babies in breastfeeding depend on the correlation of Pearson's 0,05 respects to artificial feeding with an independent correlation with Spearman's rs of 0.03. Whereas the age of mothers was correlated with significant value of p <0,0001 with breastfeeding and data of infections with Pearson's correlation; that has the same significant level of 0.005 ascertained with positive nasopharyngeal swabs after a time by first, second and third doses of Sars-CoV2-vaccine 2019.

In children, Covid-19 infection are lower than in adults, in fact babies have milder symptoms. The currents policy in Covid infection consists in breastfeeding and it is contraindicated only for a limited number of viral diseases (for example: HIV and CMV). Because, breast milk with covid virus has properties, that are protective with IgA and IgG and determined by the immune response of the mother to previous infection or with Sars-CoV2 vaccinee; so the first dose is followed by the second and third dose in mRNA vaccine or in Adenovirus vaccine [17].

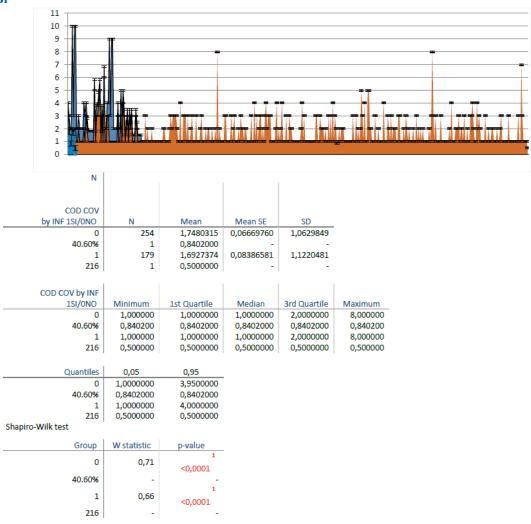
# 2- Analysis of Breastfeeding mothers (BFs)



H0:  $F(Y) = N(\mu, \sigma)$  The distribution of the population is normal with unspecified mean and standard deviation H1:  $F(Y) \neq N(\mu, \sigma)$  The distribution of the population is not normal.

<sup>&</sup>lt;sup>1</sup> Reject the null hypothesis in favor of the alternative hypothesis at the 10% significance level.

#### 3-Analyze CoBf



H0:  $F(Y_i) = N(\mu, \sigma)$ 

The distribution of the population is normal with unspecified mean and standard deviation.

 $\mathsf{H1}\colon\mathsf{F}(\mathsf{Y}_{\mathsf{i}})\neq\mathsf{N}(\mu,\sigma)$ 

The distribution of the population is not normal.

<sup>1</sup> Reject the null hypothesis in favor of the alternative hypothesis at the 10% significance level

Analyzing these data of mothers in breastfeeding, we have a significant correlation with p-value of <0.0001, that means in our group of babies there is a normal distribution of population respect to Sars-CoV2 infections detected with nasopharyngeal swabs. The single or mixed Sars-CoV2-vaccines 2019 are represented in different percentages with positive infections by nasopharyngeal swabs tested for Sars-CoV2 virus and new variants in mothers, during the second infection, affected by minor symptomatic effects in their respective infants.

The gold standard for infant with Sars-CoV2 infection or vaccine mother is the human milk, when is possible directly by breastfeeding, giving attention to measures of protection to be insert into the best practices during maternal Covid 19 infection. Analytical methods for the study of breast feeding show a very significant p-value of <0.0001 given us an explanation of importance to vaccine mothers before and not during pregnancy or after baby birth and in the first months.

This substantial and interdisciplinary research answers the protective results of breast milk and this topic is required and should

be performed rigorously and rapidly and to be included in the best inform policies regarding early feeding choices for mother affected by Sars-Covid2 infection and clinical management of breastfeeding babies [19].

The developing guidance in the COVID 19 pandemic about the correct management of mother and baby, before and after delivery, is important to give sanitary operator's specific indications to mother vaccine at baby birth with or without Sars-CoV2 infections [20]. Because the distance among the first vaccine dose, that has a W statistic 0,261, and the second CoV2 vaccine dose, that has a W statistic 0,981 is significant as the booster vaccine dose with W statistic of 0,061 and their significant correlation with a p-value of <0.00011.

At the end of this extensive work of reach data and analysis, we can be sure about the importance of covid vaccine in mother before pregnancy, at birth or during breastfeeding to reduce risk of disease Sars-CoV2 infections in the critical period of development of fetal or when colostrum is finish and also the immunological baby protection.

Completed the vaccine doses with booster is very important according to our data and this give us a relevant indication to continue to fellow ministerial ed international institute indications to reduce morbidity in mothers and babies born in this pandemic period.

With these approaches at Covid vaccine campaigns of these months we can have a minor number of diseases in mothers and child with recrudescence, during this period with a reduced preventive protection in public services.

We attend the introduction of new dose of vaccine for Sars-Covvariant virus "Omicron" specially; with the hope the compliance will be high for influence vaccine and fourth dose of Sars-CoVvaccine in European and other countries in the world.

Our analysis permit to concluded that the breast milk protection is very significant and for this reason the UNICEF recommends to maintain in this pandemic period this directive, if the mother condition consent it. In other cases, the personal physician of mother and baby that have to evaluate the risks and effects of artificial milk or breastfeeding without distress mother with her afraid or psychological problem before or after the baby birth.

For this reason, we must continue with a massive vaccination of population, for which baby can be protected during pregnancy by mother and relative vaccination for Sars-CoV2 2019 and Sars-CoV variants. So, we'll protect mothers and babies at birth in a so significant way during first months of life, to reduce their morbidity and mortality risk.

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