

C E P I



Challenges of vaccinating pregnant and lactating women during the COVID-19 pandemic

A COVAX Maternal Immunization Working Group Webinar

April 13th 2021

Meeting Norms and Recording Disclaimer

Throughout the workshop, please ask any questions in the “**Chat**” function.

During the discussion sessions, please “**Raise Your Hand**” if you want to say something. If called on by the moderator, **you will be unmuted to intervene**. Please **turn on the camera on during your intervention**

For any technology issue please contact Dane Ichimura at Dane.Ichimura@gatesfoundation.org

Or reach out via direct message in Zoom

For any logistical issue please contact amanda.berzins@gatesfoundation.org

This workshop will be **recorded**. Recording might be shared after the webinar.

Please be mindful of the diverse audience attending the meeting when participating in open discussions.

Agenda

Time (PDT)	Session	Speaker
(7:30 am PT)	Tech check	
(7:45 am PT)	Attendees start to arrive	
(7:45 am PT)	Platform and webinar dynamics slide & instructions	
8:00 am PT(5 min)	Workshop Introduction	
8:05 am PT (45 min)	Session 1 - Data sources for policy and recommendations	
8:05 am PT (15 min)	COVID-19 disease burden in pregnancy and the newborn in LMIC	Ibukun Abejirinde (WHO) Sami Gottlieb (WHO)
8:20 am PT (15 min)	COVID-19 vaccine constructs and platforms suitable for pregnant women	Barney Graham (NIH)
8:35 am PT (15 min)	Studies of COVID-19 vaccines in pregnancy – safety and efficacy – are RCT still feasible or necessary?	Geeta Swamy (Duke Medical Center; ACOG)
8:50 am PT (10 min)	Q&A	
9:00 am PT (30 min)	Panel Discussion 1	
	Panelists: 1. Alejandro Cravioto (WHO SAGE) 2. Judy Absalon (Pfizer) 3. Ushma Mehta (Cape Town University)	Moderator: Ajoke Sobanjo-ter Meulen (BMGF)
9:30 am PT	Break (5 min)	

Agenda

Time (PDT)	Session	Speaker
9:35 am PT (40 min)	Session 2 - COVID-19 vaccine distribution – administration – uptake in pregnant women	
9:35 am PT (10 min)	US Country case study 1	Denise Jamieson (Emory University)
9:45 am PT (10 min)	UK Country case study 2	Asma Khalil (St. George's University)
9:55 am PT (10 min)	Israel Country case study 3	Orna Diav-Citrin (Ministry of Health, Israel)
10:05 am PT (10 min)	India Country case study 4	Narendra Arora (Inclen, Chair WHO COVID-19 vaccine pregnancy implementation/surveillance manual)
10:15 am PT (10 min)	Q&A	
10:25 am PT	Break (5 min)	
10:30 am PT (30 min)	Panel Discussion 2	
	Panelists: 1. Yodi Alakija (COVID-19 African Vaccine Delivery Alliance-AVDA) 2. Esperanza Sevene (Ministry of Health, Mozambique) 3. Heidi Larson (LSHTM Vaccine Confidence Project)	Moderator: Flor Munoz (Baylor College of Medicine)
11:00 am PT (5 min)	Concluding remarks	Ajoke Sobanjo-ter Meulen Flor Munoz



Workshop Introduction



Dr Sami Gottlieb

Medical Officer
Dept of Sexual and
Reproductive Health and
Research
World Health Organization



Dr. Ibukun Abejirinde

Consultant
Dept of Sexual and
Reproductive Health and
Research
World Health Organization

COVID-19 disease burden in pregnancy & the newborn in LMIC



**Barney S. Graham,
MD, PhD**

Deputy Director
Vaccine Research Center,
NIAID, NIH

COVID-19 vaccine constructs and platforms suitable for pregnant women



Geeta Swamy

(Duke Medical Center;
ACOG)

**Studies of COVID-19 vaccines in pregnancy – safety and efficacy.
Are RCT still feasible or necessary?**

Q&A

Panel discussion 1



Alejandro Cravioto,
Professor, Facultad de Medicina
Universidad Nacional Autónoma de México



Judith Absalon, MD, MPH, FIDSA
Senior Medical Director, Pfizer, Inc.



Ushma C. Mehta
Senior Researcher, Centre for Infectious Disease Epidemiology and Research
School of Public Health and Family Medicine, University of Cape Town

Break



Denise J. Jamieson, MD MPH,

James Robert McCord Professor &
Chair, Department of Gynecology &
Obstetrics, Emory University School
of Medicine

US Country case study 1



Asma Khalil

Professor of Maternal fetal
Medicine
St George's Hospital
University of London

UK Country case study 2

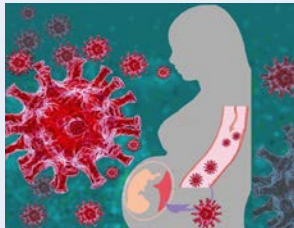


Orna Diav-Citrin

Chief physician of the
Israeli Teratology
Information Service,
Ministry of Health

Israel Country case study 3

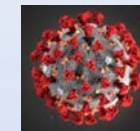
Israel Country Case Study: Challenges of Vaccinating Pregnant and Lactating Women During the COVID-19 Pandemic



COVAX Maternal Immunization Webinar
April 13th 2021



Prof. Orna Diav-Citrin



**The Israeli Teratology Information Service
Jerusalem**

Background: Demographics of Israel

- Population of more than 9 million inhabitants, children ~3rd
- Annual population growth rate 2.0% (OECD average 0.6%)
- With an average of three children per woman
- Highest fertility rate in the OECD
- ~180,000 annual live births

National Health Insurance Law

Membership in 1 of 4 'HMOs' is compulsory for all residents

1. Clalit - the largest covering ~half of the population



2. Maccabi



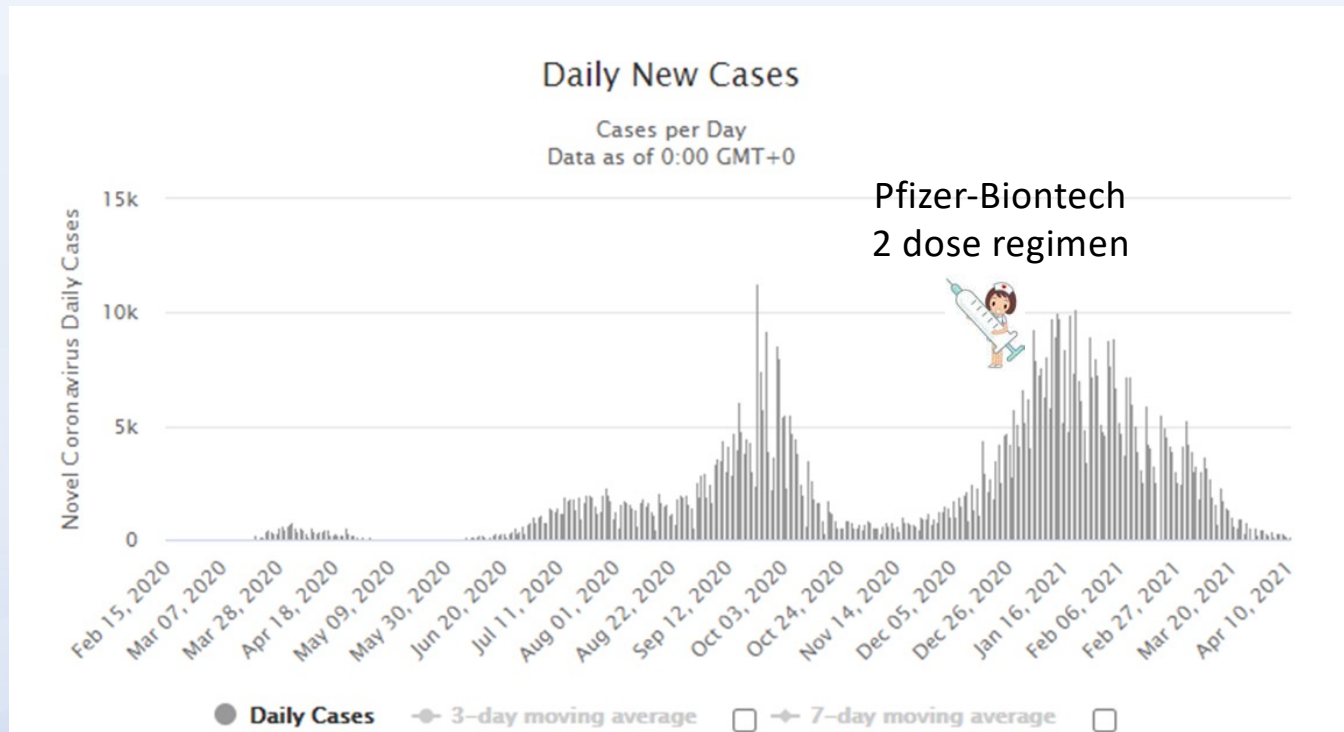
3. Meuhedet



4. Leumit



Israel's Novel Coronavirus Daily New Cases



<https://www.worldometers.info/coronavirus/country/israel/> accessed on April 4th 2021

Advisory Committee for COVID-19 Vaccine Discussion on December 19th 2020 (1st administered dose) with the following recommendations regarding the vaccine:

Women Planning a pregnancy

- Should not be withheld from women who wish to receive it
- Recommended for women at increased risk for severe disease



Pregnant women

- Should not be withheld from women who wish to receive it, especially if they are exposed to COVID patients at work



Lactating women

- Recommended for breastfeeding women



Arguments

- mRNA vaccines are non-live vaccines, while live-vaccines are generally contraindicated in pregnancy
- There is evidence that pregnant women are at increased risk for severe COVID-19, ICU admission, mechanical ventilation and preterm delivery compared to women with similar characteristics who are not pregnant, especially the in third trimester
- Without evidence of risk most participants thought it unethical to deny access to vaccination at times of raging pandemic that puts them at increased risk
- Such a risk is not anticipated based on the biology of mRNA vaccines nor on its mechanism of action

Position Paper

- The Israeli Teratology Information Service
- The national Council for Obstetrics & Gynecology, Neonatology and Genetics
- Israel Society of Obstetrics and Gynecology
- Israel Society of Maternal-Fetal Medicine

On COVID-19 Vaccination of Women Planning a Pregnancy, Pregnant, or Lactating - published on February 1st 2021

Position Paper February 1st 2021

1. There is no contraindication for vaccination at any stage of pregnancy (in line with the CDC, ACOG & WHO)
2. The vaccine is recommended for breastfeeding women
3. Women planning a pregnancy/ART: it is recommend to complete the two doses before pregnancy
4. For a woman who received the 1st dose and conceived: it is recommended to complete the second dose according to the original vaccination schedule
5. The vaccine is recommended for women at increased risk for disease (e.g. health care workers) or at increased risk for severe COVID-19 (diabetes, hypertension, BMI>30)
6. The vaccine is recommended in the 2nd or 3rd trimester

Position Paper February 1st 2021

7. The 1st trimester is more susceptible to bleeding and miscarriage and is the period of organogenesis. There is a baseline risk of malformations and miscarriages.

Women who do not belong to COVID risk groups and are in the 1st trimester, in order to avoid suspected associations, even coincidental, can defer immunization to the 2nd trimester. However, like other viral infections there is theoretical risk of placental damage even in the 1st trimester. Prior vaccination is the means to decrease risk from COVID.

8. Fever is potential adverse effect of the vaccine and should be treated according to the stage of pregnancy with antipyretics, especially in the 1st trimester

Position Paper February 1st 2021

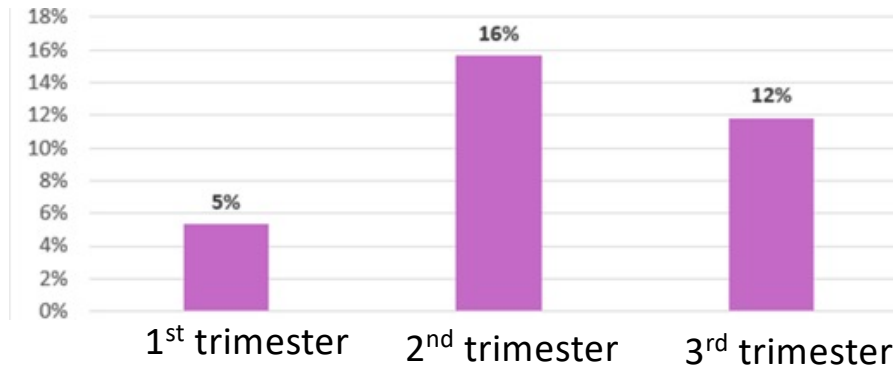
9. For women planning amniocentesis, a week interval is recommended after the procedure before vaccination to avoid fever or other complications which may be interpreted as amniocentesis complications

10. As for the general population, social distancing, use of face masks and hygiene practices, are recommended among women of childbearing age, in pregnancy and lactation, in order to minimize the risks of acquiring COVID



The largest HMO in Israel with over 4.7 million customers 53% market share

Results: Each study group included 596,618 persons. Estimated vaccine effectiveness for the study outcomes at days 14 through 20 after the first dose and at 7 or more days after the second dose was as follows: for documented infection, 46% (95% confidence interval [CI], 40 to 51) and 92% (95% CI, 88 to 95); for symptomatic Covid-19, 57% (95% CI, 50 to 63) and 94% (95% CI, 87 to 98); for hospitalization, 74% (95% CI, 56 to 86) and 87% (95% CI, 55 to 100); and for severe disease, 62% (95% CI, 39 to 80) and 92% (95% CI, 75 to 100), respectively. Estimated effectiveness in preventing death from Covid-19 was 72% (95% CI, 19 to 100) for days 14 through 20 after the first dose. Estimated effectiveness in specific subpopulations assessed for documented infection and symptomatic Covid-19 was consistent across age groups, with potentially slightly lower effectiveness in persons with multiple coexisting conditions.



Dagan et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. N Engl J Med. 2021 Feb 24. doi: 10.1056/NEJMoa2101765. Epub ahead of print. PMID: 33626250.

Rate of pregnant women receiving first COVID vaccine

Received 1 st dose in pregnancy	Infected in pregnancy	Total pregnant women	Rate of vaccination in pregnancy	Vaccinated + infected
19,727	7,072	60,222	33%	40%

The NEW ENGLAND JOURNAL of MEDICINE

Data provided on February 22nd 2021

Table 1. Demographic and Clinical Characteristics of Vaccinated Persons and Unvaccinated Controls at Baseline.*

Characteristics	Unvaccinated Controls (N=596,618)	Vaccinated Persons (N=596,618)
Pregnancy	1,508 (0.3)	1,508 (0.3)

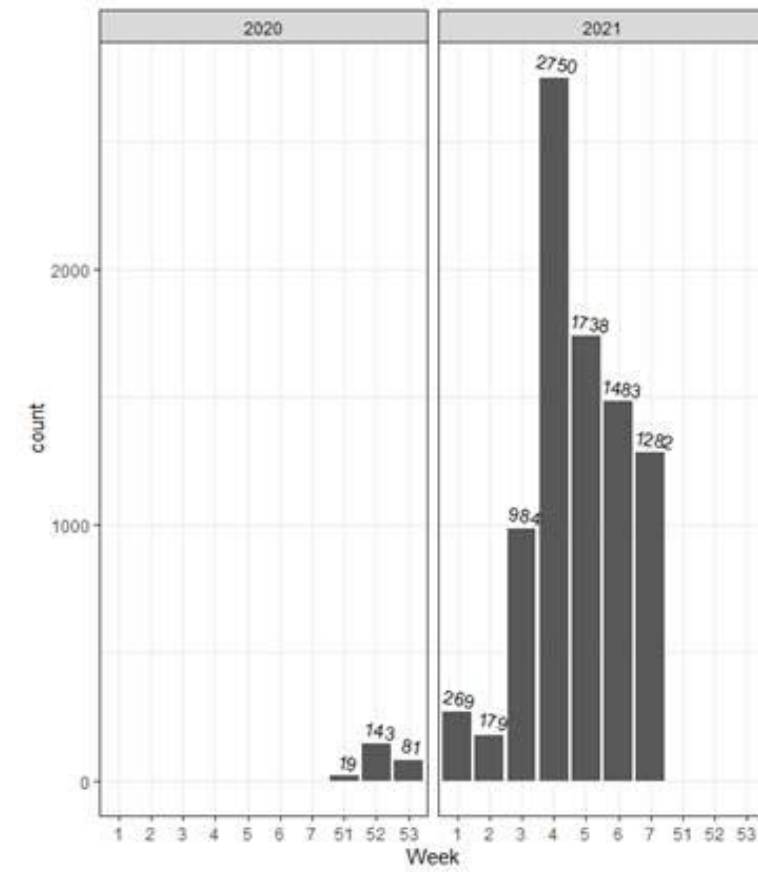




2nd largest HMO with almost 2.4 million members

7.2.21

- Members received COVID-19 vaccine during pregnancy ~8,900 women.
- Some already delivered.
- On February 7th:
- >28,441 pregnant
- 8,700 received first dose, ~30%
- A minority of ~12% in the first trimester, of the remainder half in the second and half in the third trimester
- Median+mean gestational age at first vaccination week 24

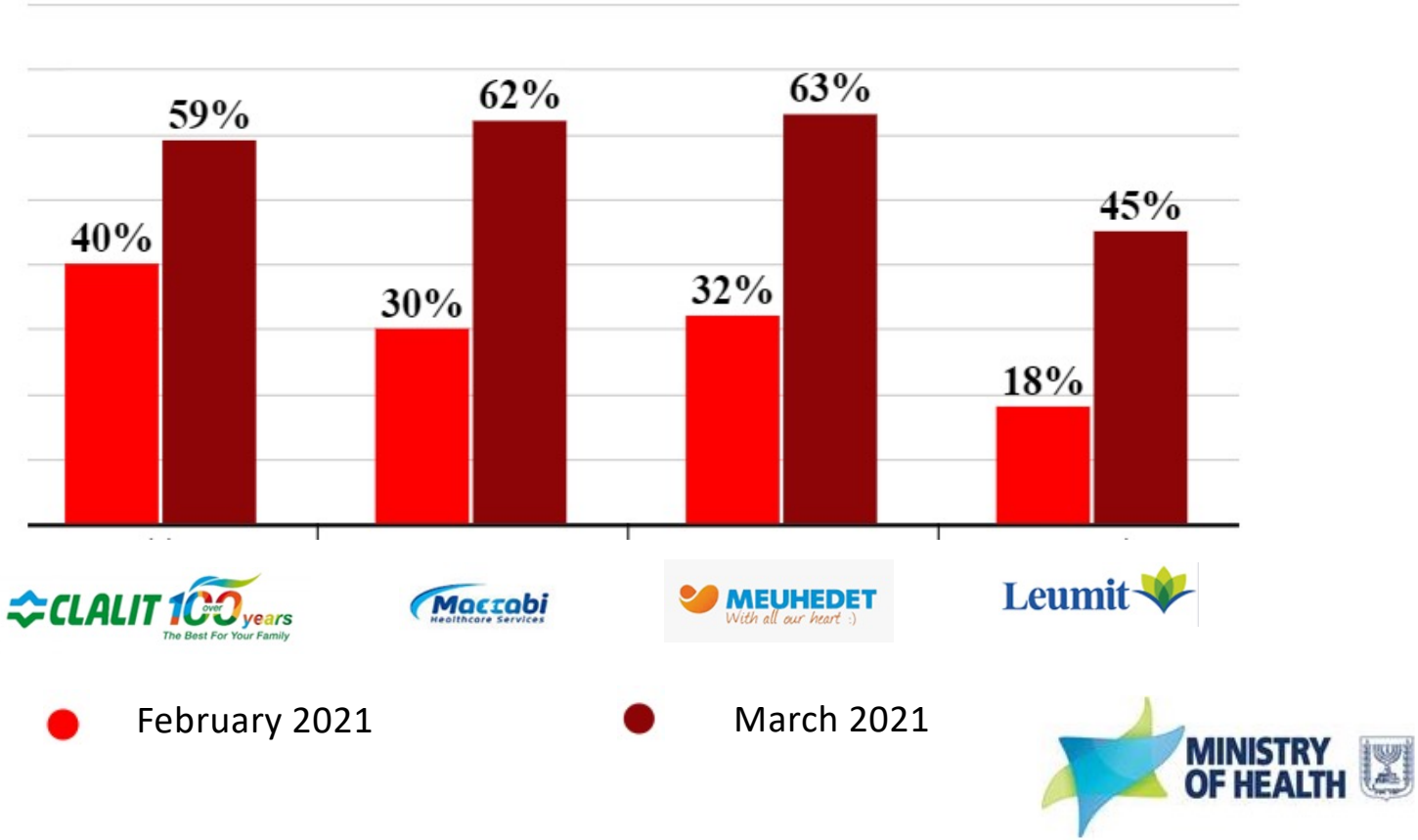




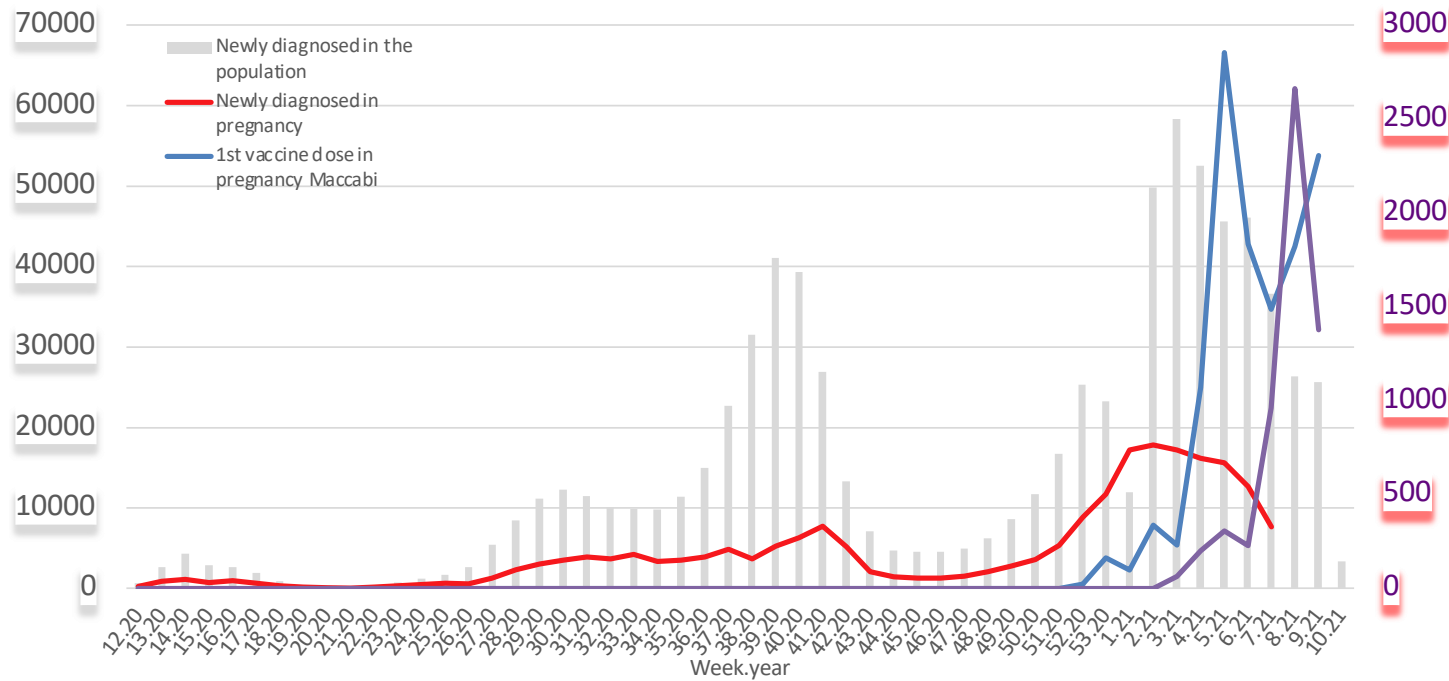
- Total of 15,000 pregnant women
- 48.3% vaccinated/recovered
 - 9% in the 1st trimester
 - 43% in the 2nd trimester
 - 48% in the 3rd trimester

Data provided on February 23rd 2021

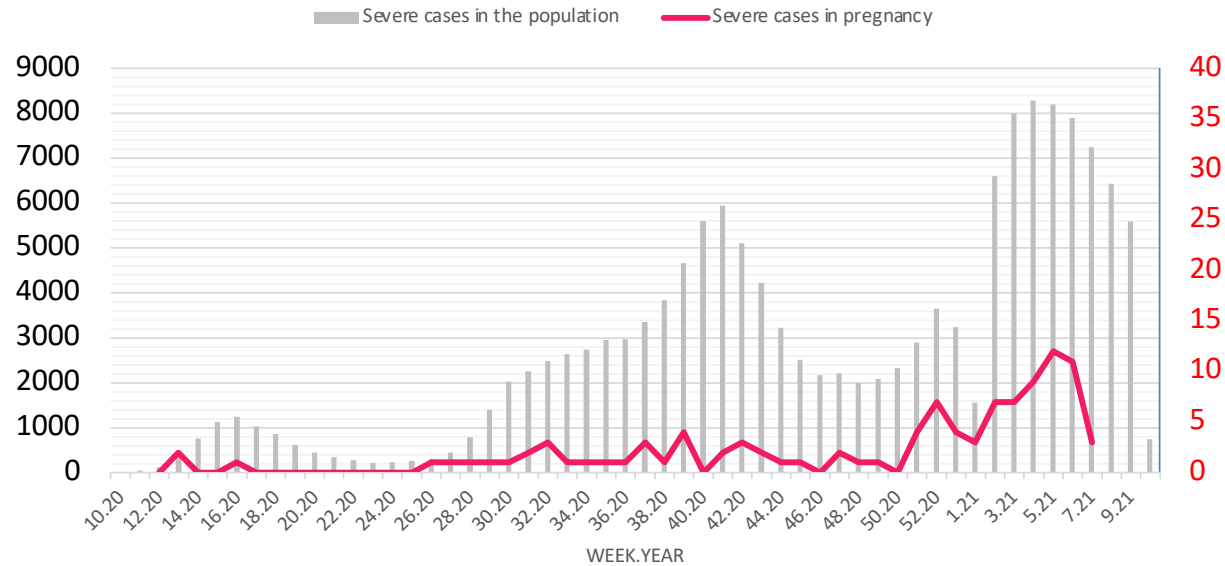
Percentage of pregnant women vaccinated in February and March 2021



Newly diagnosed in the general population, in pregnancy, 1st and 2nd dose Maccabi



Severe cases



MOH data (19.2.21):

- 9,366 Israeli women with confirmed infection in pregnancy
- ~100 with severe disease (1.1%)

MOH data update (12.4.21):

- 11,065 confirmed infection in pregnancy
- 1,178 hospitalized (10.6%)
- 148 with severe COVID (1.3%)
- 5 died

Israel: 10 Pregnant Women Critically Ill Due To COVID-19

 [theyeshivaworld.com/news/headlines-breaking-stories/1940141/israel-10-pregnant-women-critically-ill-due-to-covid-19.html](https://www.theyeshivaworld.com/news/headlines-breaking-stories/1940141/israel-10-pregnant-women-critically-ill-due-to-covid-19.html)

January 19, 2021 6:30 pm



The current coronavirus wave in Israel is striking the young and healthy, especially pregnant women. Tragically, there are currently ten Chareidi pregnant women hospitalized in critical condition due to the coronavirus, with most of them hooked up to ventilators shortly after arriving at the hospital. At least four women underwent emergency C-sections, with one baby **dying two days later** and the others in serious condition.

There are also more and more reports of young people becoming seriously ill due to the virus, including a 17-year-old **yeshivah bochor** and a two-year-old, who are currently hospitalized and receiving respiratory assistance after contracting the virus.

Chaya Rivka Pollack, a 35-year-old resident of Jerusalem with no preexisting medical conditions, contracted the virus in the 31st week of her pregnancy and is currently in critical condition in Beilinson Hospital in Petach Tikvah, sedated and ventilated. The doctors are also fighting to save the life of her baby, who was delivered by emergency C-section.

“Her condition is critical and unstable,” said Dr. Ilya Kagan, director of the coronavirus ICU unit at Beilinson. “We are fighting for her life, which is in real danger.”

Her name for tefillah is **Chaya Rivka bas Leah**. Her baby, **Tinok ben Chaya Leah**, is also in need of tefillos. (See below for full list of names for tefillos.)

Another two women were hospitalized in serious condition in Laniado Hospital in Netanya, One of them underwent an emergency C-section and is now sedated and ventilated in the coronavirus ICU unit. The second woman was transferred to Sheba Hospital in Tel HaShomer following a deterioration in her condition and is currently conscious but in serious condition and receiving respiratory assistance.



Another four women, all suffering from respiratory distress, are hospitalized in Mayanei HaYeshua Hospital in Bnei Brak.

YWN previously **reported** on yet another heartrending case of a Jerusalem mother of six hospitalized in critical condition in Beilinson Hospital.

Dr. Yael Haviv, the director of the coronavirus ICU unit at Sheba, said: "In the course of this wave, we're encountering more and more incidents of young people becoming seriously ill or even critically ill from the coronavirus. This isn't an illness of elderly people with pre-existing conditions anymore."

Coronavirus czar Prof. Nachman Ash said on *Army Radio* on Tuesday morning: "We're evaluating whether the increased morbidity among pregnant women is a new phenomenon or there is a common denominator of vulnerability among these women. We're also examining the possibility of a link to the [British] mutation."

Prof. Galia Rahav, Director of the Infectious Diseases Research Laboratory at Sheba Medical Center, told *Yediot Achronot*: "These women are having severe breathing difficulties. Some of them are from Chareidi centers. We need to consider vaccinating pregnant women in areas with high morbidity, definitely when they are in the advanced stages of pregnancy."

"We didn't see this during the previous waves. It's possible it's linked to the mutation."

Unfortunately, the infection rate in the Chareidi sector has soared and is currently five times higher than the general population.

The Israel Society of Obstetrics and Gynecology sent a letter to the Health Ministry on Monday requesting that the ministry approve vaccinations for pregnant and nursing women.

"There is no scientific basis or facts that indicate infertility as a result of the vaccine," the society wrote. "Coronavirus can be harmful during pregnancy, causing more serious illness and premature birth."

Prof. Yariv Yogev, director of the Obstetrics and Gynecology Department at Sheba Hospital, said earlier this month during the annual Puh Institute conference that pregnant women should get vaccinated, especially if they have any risk factors.

A list of women and newborn babies in need of tefillos:

- **Chaya Rivka bas Leah and her baby, Tinok ben Chaya Rivka.**
- **Rochel Naomi bas Esther Chana and Tinok ben Rochel Naomi** – A 33-year-old resident of the Ramot neighborhood of Jerusalem, mother of five.
- **Chana bas Bella Hadassah** – A 38-year-old resident of Modiin Illit, mother of five.
- **Yehudis Miriam bas Chana Gittel** – a 37-year-old resident of Bnei Brak.
- **Chedva bas Rochel**

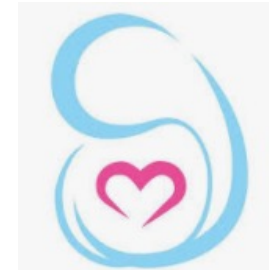


Coronavirus: 25-week-old fetus dies of COVID-19 in Israel

THE JERUSALEM POST

To date, in only between 1% and 3% of cases has a pregnant mom directly passed on the virus to her baby.

By MAAVAN JAFFE-HOFFMAN FEBRUARY 16, 2021 19:18



For the first time in Israel, a fetus has died from COVID-19.

Over the weekend, a 29-year-old woman from the South arrived at Samson Assuta Ashdod Hospital after she told her doctor she did not feel her baby moving. Dr. Josef Tovbin, head of the hospital's Labor and Delivery Ward, told The Jerusalem Post.

The hospital confirmed that the baby had no heartbeat. The woman delivered a stillborn baby, who was then tested for coronavirus and found to be positive. The hospital also tested the placenta, and coronavirus was found, as well.

According to Tovbin, the mother had felt sick for three or four days prior to visiting her doctor. She did not suspect she had coronavirus. But when they tested her, she was also found to be sick with the virus.

She had been [pregnant](#) for 25 weeks.

"The significance of getting infected is dramatic in light of my great personal loss," the mother said in an interview with the Hebrew website Ynet. She said she observed Health Ministry regulations as much as possible.

Two weeks before arriving at the hospital, she had been examined and the baby was found to be healthy.



Hadassah: 32-year-old mother and her fetus die of COVID-19

The woman entered the hospital last Tuesday when she began experiencing respiratory distress.

By MAAYAN JAFFE-HOFFMAN FEBRUARY 21, 2021 09:41



A 32-year-old woman and her fetus died of [COVID-19](#) late Saturday night after receiving treatment at Hadassah-University Medical Center, the hospital reported Sunday morning.

The woman entered the hospital last Tuesday when she began experiencing respiratory distress. Her condition quickly deteriorated until she suffered from multisystem organ failure.

A multidisciplinary medical team made efforts to treat her, the hospital said, including performing prolonged resuscitation efforts. The 30-week-old fetus was delivered via emergency C-section in an effort to save it.

Despite the mother being hooked up to an ECMO machine and the heroic work of the staff, ultimately, they both died.

Hadassah said its staff is very emotional over the loss.

“The whole Hadassah team shares in the heavy grief of the family,” a statement read.



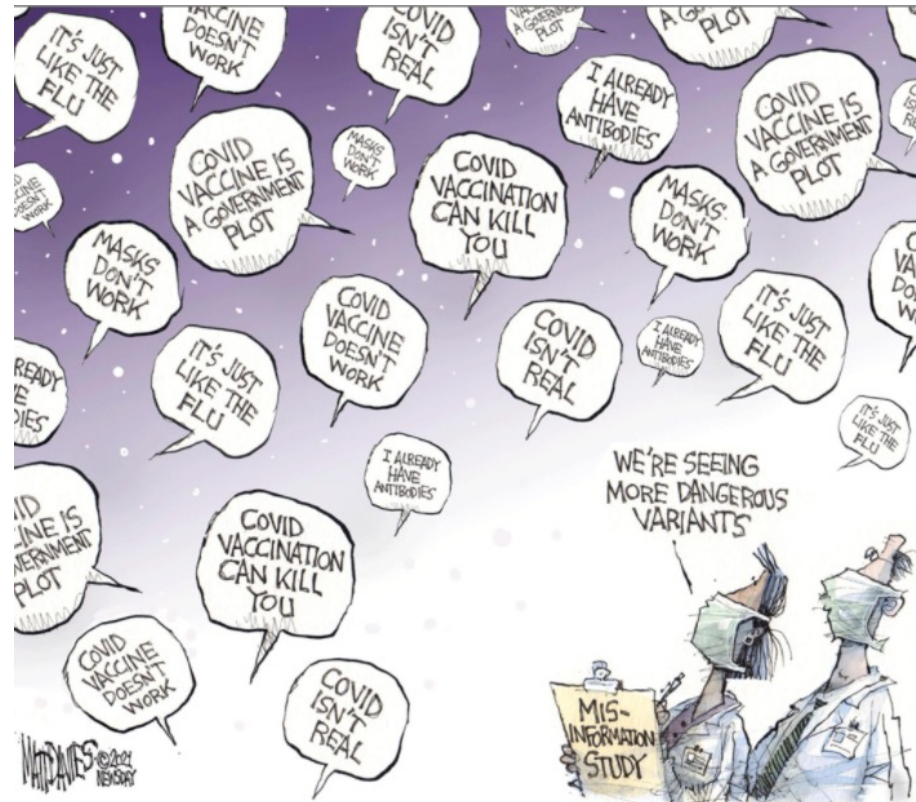
Factors associated with Israel's COVID-19 vaccination campaign success

- 1. Small size, relatively young population**
- 2. Centralized national government system**
- 3. Experience in implementing responses to national emergencies**
- 4. Logistic capacities of Israel's community-based HMOs**
- 5. Availability of community-based health care nurses/workers employed by HMOs**
- 6. Cooperation between HMOs, hospitals, and emergency care providers**
- 7. Functioning frameworks for decision making about vaccinations and support tools for assisting in the implementation of vaccination campaigns**
- 8. Mobilization of special government funding for vaccine purchase and distribution**
- 9. Timely contracting for a large amount of vaccines relative to Israel's population**
- 10. The use of simple, clear and easily implementable criteria for determining who had priority for receiving vaccines in the early phases of the distribution process**
- 11. A creative technical response that addressed the demanding cold storage requirements of the Pfizer-BioNTech COVID-19 vaccine**
- 12. Well-tailored outreach efforts to encourage the population to sign up for vaccinations**

Misinformation & disinformation regarding COVID-19 vaccine

Myths in the context of pregnancy:

- Coronavirus vaccines alter DNA
- Coronavirus vaccines affect fertility
- The vaccine is unsafe for pregnant women
- The vaccines cause adverse pregnancy outcome e.g. miscarriage
- They are unsafe because they were developed too fast
- They are unsafe because they are based on new technology
- They are unsafe because they cause hormonal changes e.g. bleeding
- They are unsafe because they cause long term effects on the offspring

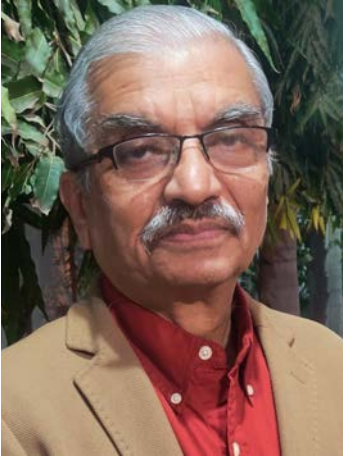


Thank you for your attention!



Special thanks to

- Dr. Eric Haas from the Epidemiology wing who helped access the MOH data on COVID in pregnancy
- Dr. Svetlana Shechtman for her support in preparing slides 14+15
- The HMO representatives who sent their data on vaccination in pregnancy



Prof (Dr) Narendra Kumar Arora

Executive Director
The INCLEN Trust International
New Delhi – India

India Country case study 4

Q&A

Break

Panel discussion 2



Yodi Alakija (COVID-19 African Vaccine Delivery Alliance-AVDA)



Esperança Sevene

Associate Professor of Clinical Pharmacology
Eduardo Mondlane University/Manhiça Health Research Centre
Member of the National Technical and Scientific Commission for COVID-19 prevention and Response



Heidi Larson (LSHTM Vaccine Confidence Project)

Concluding remarks