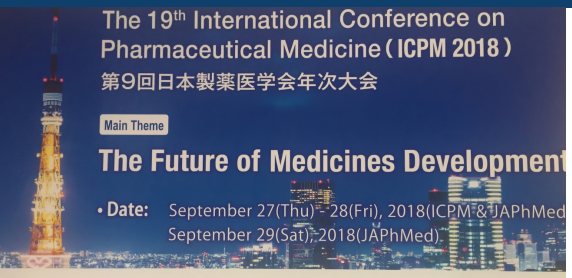

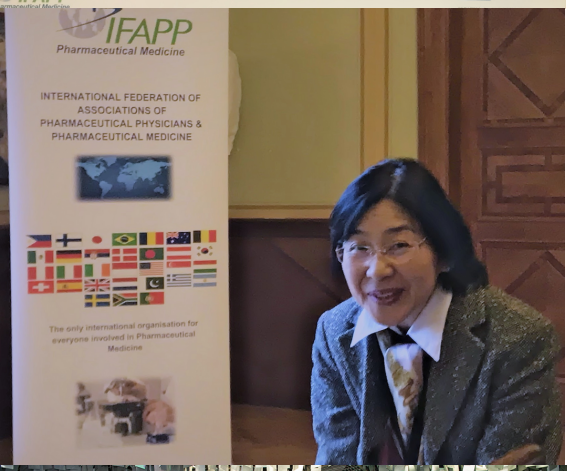

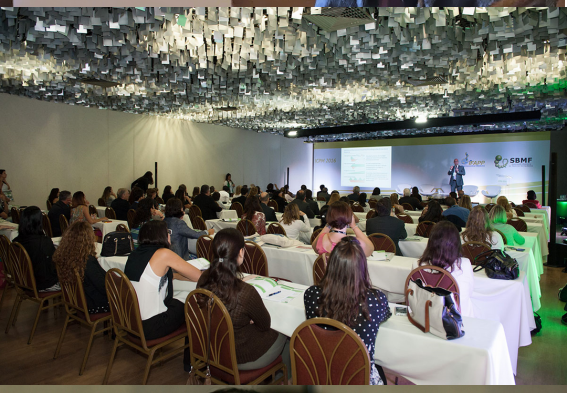

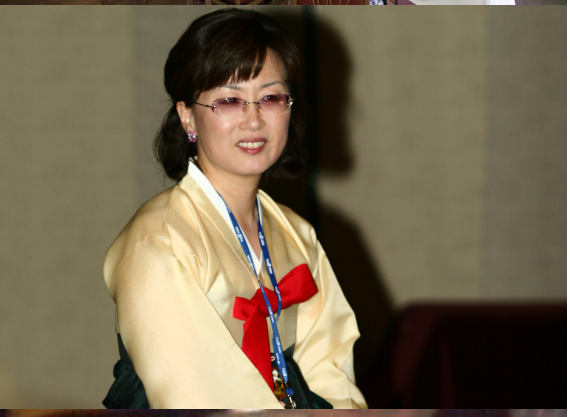

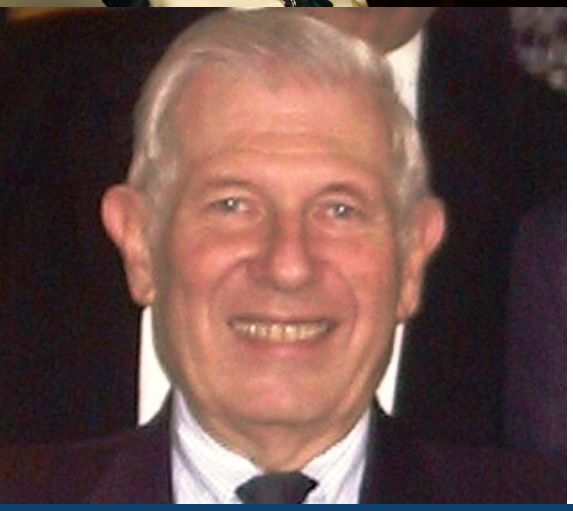

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THIS ISSUE

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5. Israeli Study Offers First Real-World Glimpse of COVID-19 Vaccines in Action

AMIFE, Born to Promote and Give Visibility to the Value of Pharmaceutical Medicine

The Spanish Association of Pharmaceutical Medicine (AMIFE) was founded in February 1975 where a reduced group of physicians working in the Pharmaceutical Industry in Spain gathered to discuss the possibility of creating an association similar to those existing in other countries, with the aim not only to maintain their identity but also to achieve a better and more coherent education, based on common criteria, aimed at developing the profession of Pharmaceutical Medicine.

The Executive Committee started the genesis of AMIFE and its objectives – mainly the representation of the pharmaceutical medicine profession at Public Administration and the Industry, training physicians in this profession and collaborating in the establishment of regulations related to the development of medicines. Once the by-laws were approved, the first Working Groups (WG) were created: Clinical Trials, Pharmacovigilance, Clinical Pharmacology and Spanish and European Legislation.

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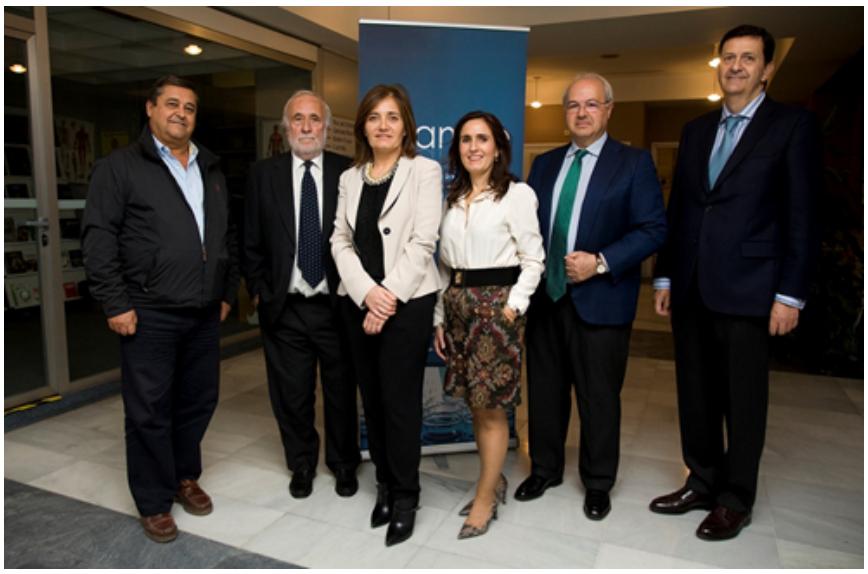
From its beginnings, AMIFE established close relationships with AEFI, the Spanish Association of Pharmacologists, and with the Spanish Society of Hospital Clinical Pharmacy; at international level, AMIFE officially joined IFAPP in 1978. The first joint meeting was celebrated in September 1990 in Madrid: the VII International Conference on Pharmaceutical Medicine (ICPM).

Some ex-Presidents of AMIFE who participated in the 40th anniversary of its foundation.



From left to right: Manuel Martin, Alvaro Bartlett (deceased), Ana Perez Dominguez, Belen Sopesen, Julian Ruiz Ferran (deceased), Jorge González Esteban.

Now, AMIFE has a large number of members from Pharmaceutical Companies, CROs, Academia, Hospitals, Training Entities, Ethics Committees and others. Seven Working Groups develop relevant and interesting events, seminars, conferences, thus giving AMIFE a wide visibility on national and even international level.
The Clinical Research WG is mainly focused on new regulations in clinical trials, e-consent, remote monitoring, pediatric studies, RWE and others.

The Pharmacovigilance WG works on updates of regulations, runs training activities for new pharmacovigilance specialists, and recently is preparing a webinar on COVID-19.
The Medical Information WG is one of the most active ones, with several local and international publications, seminars, shared learning events: its 35 members are strongly and enthusiastically involved in all the activities.

New WGs such as Rare Diseases, Patient Centricity, Market Access and Precision Medicine gather specialists from different areas, such as practicing physicians, members of patients' associations, medical societies and foundations.

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Finally, during the first wave of the pandemic, several Medical Directors from pharmaceutical companies suggested the creation of a Forum for discussions on challenges and opportunities for their companies during these difficult times. Meetings were organized every two to three weeks and hot topics were discussed and solutions were shared among all participants.

Anna Jurczynska, MD, member of AMIFE Board.

Medical Directors at one of the regular meetings of the Forum.

A Message from the IFAPP President - Marco Romano

Dear IFAPP National Member Associations Delegates and Individual Affiliates,

Further to my March communication, the next meeting of the House of Delegates will occur on June 28th, 2021, and your presence will be critical as we will have to elect or to re-elect the Board members who are also Chairs of the Working Groups as well as the Treasurer and the Secretary.
As you all know, we were obliged, due to the COVID-19 pandemic, to cancel the ICPM2020 that should have taken place in Rome and therefore elections did not occur. I would like to remind you that, according to our Constitution, elections should occur every two to three years and the last time they happened at the ICPM2018 in Tokyo.

Candidates for any position on the Board of Officers should be nominated by the National Member Associations to the IFAPP Board Secretary at least four weeks before the election.
The General Assembly and the House of Delegates meeting will be held together this time.
Another extremely important topic is the amendment of our Constitution, which requires an update. However, the new version of the Constitution will be proposed for your vote at the subsequent House of Delegate meeting that will take place next October 2021.

Each Delegate or deputy Delegate has one vote on matters relating to changes in the Constitution. For any other matters the number of votes held by the Delegates depends on the number of members of the respective National Member Association.

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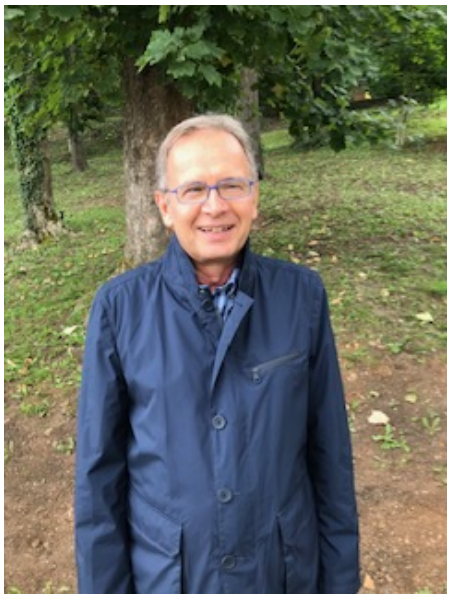

- National Member Associations with 50 or fewer members have one vote
- those with 51 – 100 members have two votes
- those with 101 – 1000 members have three votes
- those with 1000 or more members have four votes.

In the event of neither a Delegate nor a deputy Delegate being able to attend the House of Delegates meeting, the respective National Member Associations may vote on a known proposal in writing to the Board Secretary (this can be done by email).

The announcement of the meeting of the House of Delegates is dispatched in writing by email by the Secretary of the Board at least 60 calendar days before the meeting date and includes the provisional agenda. Any motion that you, as national member organizations, wish to have addressed by the House of Delegates are to be submitted by email to the President at the latest 30 calendar days before the date set for the meeting.

The invitation to the House of Delegates meeting together with the final agenda (including motion of members) is dispatched electronically by the Secretary 20 calendar days before the meeting.

I wanted to remind you of the above as I believe it is important for you to be aware of these regulations set out in the Constitution.

Thank you very much for your attention and I look forward to meeting you virtually at the next House of Delegate meeting and the General Assembly on June 28th, 2021.

Marco Romano MD GFMD
IFAPP President

95% Efficacy Rate: What Does that Mean for an Evening at the Opera?

You may be wondering when the last time was you have been to the opera, a concert, or a theater. Vaccines are our ticket to a return to something like normalcy. Four COVID-19 vaccines are currently authorized in Europe that offer a safe and effective way to contain the pandemic. We explain how the clinical trials were conducted and what the efficacy rates mean.

Four vaccines are currently authorized in Europe: Pfizer's and BioNTech's BNT162b2, Moderna's mRNA-1273, AstraZeneca's AZD1222, and J&J's Ad26.COV2.S. The first two rely on mRNA technology, whereas the third and the fourth are based on harmless viruses that do not replicate, all containing genetic instructions for building the coronavirus spike protein. All studies were similar in design in which they were placebo-controlled trials.

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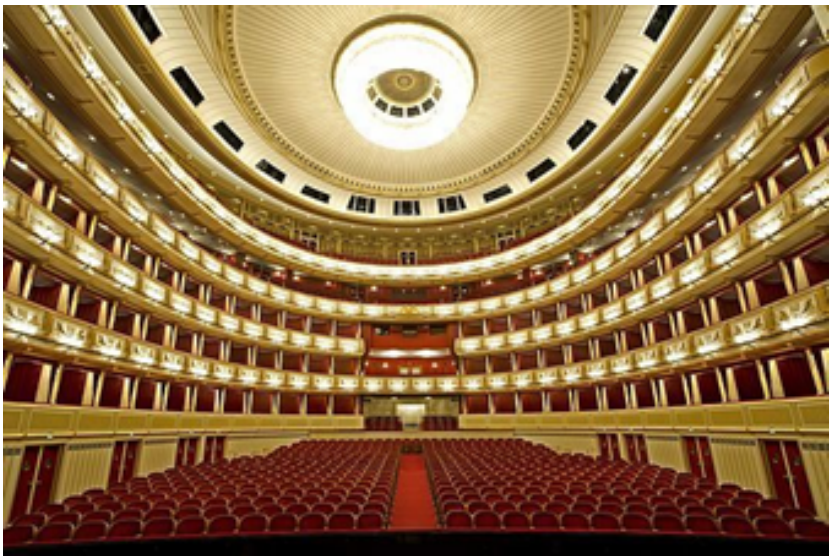
This means that half of the volunteers got the vaccine, and half got the placebo. Researchers then followed up volunteers for about 2 months, noting down any symptomatic infections and looking at what group they belonged to. A rate of 95% means that among 100 volunteers who developed COVID-19, only 5 were in the vaccinated group. The aforementioned vaccines have reached 62-95% efficacy in adults, rates that may depend on the different variants of the SARS-CoV-2 virus in circulation where the study was conducted. What is more important, vaccines spared patients from hospitalizations and death. We don't know yet if the vaccines prevent the virus from spreading or not, because asymptomatic infections were not tested in trials. That would involve routinely testing all the tens of thousands of participants enrolled in the study.

Coming back to the opera stage, the Vienna State Opera, with its 1,709 seats, could well have 15 infected people at the start of the performance (considering an active infection rate of 0.87% in the general population). Since every infected individual (symptomatic or asymptomatic) may transmit the virus to 2-3 other people (based on the assumption of basic reproduction number, R0=2.5), we could have 38 new infections by the time the Opera House's doors close. Of those, 23 people may get sick, as about 60% of people who get infected develop symptoms. Had everyone been vaccinated, the risk of getting sick from COVID-19 could be cut down by 95% at best, resulting in 1 new symptomatic infection instead of 23.

The clinical studies will continue for another two years, with regulatory agencies closely watching safety and efficacy data. We'll have to wait to find out how long the vaccines' protection lasts and how well they work against new variants. Many more vaccines are in the pipeline. In the end, any level of protection is better than no protection against COVID-19. In Austria, health care professionals have already administered the first dose to 1,181,103 people (15% of the vaccine-eligible population). Vaccination should continue as quickly and as widely as possible to slow the spread of the virus. Vaccination can liberate us to return to work and school, and not the least, to live life with gusto.

Joana Enes (1), Vanessa Puehringer (1), Ghazaleh Gouya Lechner (1, 2)
(1) Gouya Insights Vienna, Austria; (2) GPMed Board Member



Vienna State Opera Source: https://www.wiener-staatsoper.at/en/

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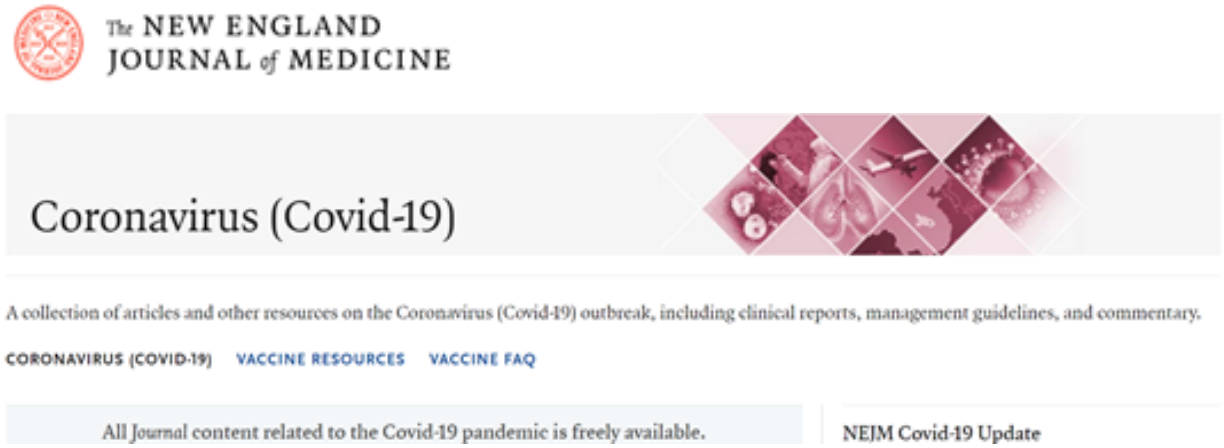
Vaccination of Patients with COVID-19 or Possible COVID-19

This informational update presents important Questions and Answers (Q&A) for immunization of people infected or possibly infected with SARS-CoV-2. It includes current available data to support confidence, communication, and uptake of the COVID-19 vaccine, with health care professionals and the groups of patients as mentioned above.
The resources used for this communication are from the NEJM COVID-19 literature and comprehensive updated Q&As accessed on March 29, 2021.



The Q&A published are free to access and are listed below for your convenience:

1. SHOULD A PATIENT WHO WAS EXPOSED TO COVID-19 RECEIVE THE VACCINE IN ORDER TO PREVENT THE DISEASE?

Currently there are no data to support use of the Covid-19 vaccines acutely to prevent disease after a known exposure to an active case. Since the incubation period for Covid-19 averages around 5 days, it is unlikely that the vaccine would elicit an immune response quickly enough to block the infection. As a result, people who have been exposed to Covid-19 should finish their 10-day quarantine before undergoing immunization. This can be shortened to 7 days after receiving a negative PCR test result (test must occur on day 5 after exposure or later). Since some vaccines for other diseases (notably varicella) are effective in preventing infection after exposure, it is possible that this will be a future recommendation for Covid-19 vaccination, but currently it is not. (Last reviewed/updated on 17 Feb 2021)

2. SHOULD PATIENTS WHO HAVE RECOVERED FROM COVID-19 RECEIVE THE VACCINE?

Yes, they should receive the vaccine. Some of the people who participated in the clinical trials had evidence of prior SARS-CoV-2 infection (based on a positive antibody test), and the vaccines were safe and effective in this group. Because re-infection after recovery from Covid-19 is rare in the first 90 days, some people may wish to defer immunization: however if they wish to be immunized sooner, there is no contraindication.

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Patients who were treated with monoclonal antibodies or convalescent plasma should wait this time interval. These treatments might inactivate the vaccines, making them less effective. Deferral of immunization for 90 days after treatment with monoclonal antibodies or convalescent plasma is recommended. Since publication of the clinical trials, researchers have reported that people with prior Covid-19 who received immunization with the mRNA vaccines had more pronounced antibody responses to their first vaccine than those who were seronegative. Anecdotally, this is accompanied by more marked systemic side effects. This response suggests that recovered patients' natural immunity was the "prime" and the first vaccine was the "boost" for the hosts' SARS-CoV-2 immune response. While such a model implies that a second dose of the vaccine may not be necessary, not all immunologists agree. For now, a second vaccine is still recommended. (Last reviewed/updated on 17 Feb 2021)

3. SHOULD A PATIENT WHO IS DIAGNOSED WITH COVID-19 SHORTLY AFTER THE FIRST DOSE STILL RECEIVE THE SECOND SCHEDULED DOSE?

The vaccine begins to generate protective immunity 10 to 14 days after the first shot. As a result, it is not surprising that some people have experienced Covid-19 shortly after their first immunization, and they naturally wonder whether they should proceed with the second shot as originally scheduled. The current recommendation is that people with current infection should wait until they have recovered from the acute illness and are eligible to discontinue isolation. These recommendations apply both to those who developed Covid-19 before their first injection and to those who developed it after starting the vaccine series. On the basis of this guidance, some people in the latter group may be able to proceed with their scheduled second shot and others will need to wait. Treatment of Covid-19 with either monoclonal antibodies or convalescent plasma should delay receipt of the vaccine by 90 days, since these treatments could theoretically make the vaccine less effective. (Last reviewed/updated on 17 Feb 2021)

4. SHOULD A PATIENT WHO RECEIVED AN ANTIBODY TREATMENT, HYPERIMMUNE PLASMA, OR BOTH FOR COVID-19 RECEIVE THE VACCINE?

Eventually yes, but not right away. Monoclonal antibody treatments for Covid-19 and hyperimmune plasma might interfere with the vaccine-induced immune response, making them less effective. Deferral of immunization for 90 days is recommended. (Last reviewed/updated on 17 Feb 2021)

5. HOW DOES THE VACCINE AFFECT THE EVALUATION OF A PATIENT AND DIAGNOSTIC TESTING FOR POSSIBLE COVID-19?

The Covid-19 vaccines will not influence the results of PCR or antigen testing for the disease. The vaccines do generate antibodies to SARS-CoV-2, which are directed at the spike protein.
Note that, if you are evaluating someone for active or recent Covid-19 using antibody (not PCR or antigen) testing, then a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used. As noted above, the vaccines elicit antibodies to the SARS-CoV-2 spike protein, not the nucleocapsid. (Last reviewed/updated on 5 Mar 2021)

Readers are kindly advised to refer to their National Vaccination Committees and local Health Care System for their local guidance.

This communication was prepared by Dr Varvara Baroutsou, Consultant Internist, GFMD, EMAUD, EL.E.F.I. President and IFAPP President elect.

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Israeli Study Offers First Real-World Glimpse of COVID-19 Vaccines in Action

Posted on March 9, 2021 by Dr. Francis Collins on https://directorsblog.nih.gov/2021/03/09/israeli-study-offers-first-real-world-glimpse-of-covid-19-vaccines-in-action/

There are many reasons to be excited about the three COVID-19 vaccines that are now getting into arms across the United States. At the top of the list is their extremely high level of safety and protection against SARS-CoV-2, the coronavirus that causes COVID-19. Of course, those data come from clinical trials that were rigorously conducted under optimal research conditions. One might wonder how well those impressive clinical trial results will translate to the real world.

A new study published in the New England Journal of Medicine [1] offers an early answer for the Pfizer/BioNTech vaccine. The Pfizer product is an mRNA vaccine that was found in a large clinical trial to be up to 95 percent effective in preventing COVID-19, leading to its Emergency Use Authorization last December. The new data, which come from Israel, are really encouraging. Based on a detailed analysis of nearly 600,000 people vaccinated in that nation, a research team led by Ran Balicer, The Clalit Research Institute, Tel Aviv, found that the risk of symptomatic COVID-19 infection dropped by 94 percent a week after individuals had received both doses of the Pfizer vaccine. That is essentially the same very high level of protection that was seen in the data gathered in the earlier U.S. clinical trial. The study also found that just a single shot of the two-dose vaccine led to a 57 percent drop in the incidence of symptomatic COVID-19 infections and a 62 percent decline in the risk of severe illness after two to three weeks. Note, however, that the protection clearly got better after folks received the second dose. While it is too soon to say how many lives were saved in Israel thanks to full vaccination, the early data not surprisingly suggest a substantial reduction in mortality.

Israel, which is about as large as New Jersey with a population of around 9 million, currently has the world's highest COVID-19 vaccination rate. In addition to its relatively small size, Israel also has a national health system and one of the world's largest integrated health record databases, making it a natural choice to see how well one of the new vaccines was working in the real world. The study took place from December 20, 2020, the start of Israel's first vaccination drive, through February 1, 2021. This also coincided with Israel's third and largest wave of COVID-19 infections and illness. During this same period, the B.1.1.7 variant, which was first detected in the United Kingdom, gradually became Israel's dominant strain. That is notable because the U.K. variant spreads from person-to-person more readily and may be associated with an increased risk of death compared with other variants [2].

Balicer and his colleagues reviewed data on 596,618 fully vaccinated individuals, ages 16 and older. A little less than one third—about 170,000—of the people studied were over age 60. To see how well the vaccine worked, the researchers carefully matched each of the vaccinated individuals in the study to an unvaccinated person with similar demographics as well as risks of infection, severe illness, and other important health attributes. The results showed that the vaccine works remarkably well. In fact, the researchers determined that the Pfizer/BioNTech vaccine is similarly effective—94 percent to 96 percent—across adults in different age groups. It also appears that the vaccine works about equally well for individuals age 70 and older as it does for younger people.

Read further on page 10

Wednesday, April 14, 2021

COVID-19 PANDEMIC IN EUROPE: EXPERIENCE IN SWITZERLAND, AUSTRIA AND GERMANY

FREE REGISTRATION

- This webinar is free to everybody.
- Click here for more information and registration.

Time Schedule

08:00 - 09:30 AM EST
01:00 - 02:30 PM GMT
02:00 - 03:30 PM CET
09:00 - 10:30 PM JST

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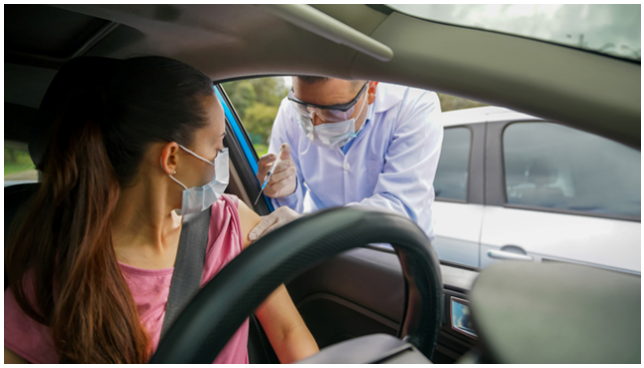
Continued from page 8

So far, more than 92 million total vaccine doses have been administered in the U.S. with the Janssen COVID-19 vaccine (also called the Johnson & Johnson vaccine) now coming online, that number will rise even faster. For those of you who have not had the opportunity just yet, these latest findings should come as added encouragement to roll up your sleeve for any one of the authorized vaccines as soon as your invitation arrives.



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[1] BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. Dagan N, Barda N, Kepten E, Miron O, Perchik S, Katz MA, Hernán MA, Lipsitch M, Reis B, Balicer RD. N Engl J Med. 2021 Feb 24.

[2] Emerging SARS-CoV-2 Variants. Centers for Disease Control and Prevention.

THE FLAG

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