

萬佛聖城新冠疫苗安全論壇記要

CTTB Forum on COVID-19 Vaccines and Their Safety

王楊端文/譯

Written and translated by David Wang

自新冠疫情爆發以來，萬佛聖城附近的護法居士王存林博士與王恒冰醫師，每月輪流在線上說明新冠疫情的最新狀況與疫苗前景。萬佛聖城住眾開始接受新冠疫苗注射後，王存林與王恒冰再度於2021年2月7日應邀說明新冠疫苗的安全性與有效性；兩位醫護士余禾與當娜·法摩也分享了她們為人注射新冠疫苗的經驗。



王存林博士

王存林為約翰霍普金斯大學「流行病學與全球衛生」博士，並獲該校公共衛生學院的疫苗科學證書。在2017年搬到加州瑜伽市之前，他任職於美國聯邦食品藥物管理局流行病學部門主任，目前在一家全球醫藥公司擔任安全與藥物警戒副總裁。以下為他的發言：

目前美國已有兩款疫苗獲得聯邦食品藥物管理局的緊急使用授權，分別是輝瑞疫苗和莫德納疫苗；另外嬌生疫苗和諾華疫苗也預計在近月內問世（註：嬌生疫苗於2021年2月27日獲食藥局緊急使用授權）。疫苗的研

Since the outbreak of Covid-19, Dr. Cunlin Wang, Ph.D, and Dr. Hengbing Wang, who both live near the City of Ten Thousand Buddhas (CTTB,) have given monthly updates on the pandemic and prospects of vaccines via online forums. After the initial vaccination on CTTB residents, they were again invited to share their observations on efficacy and safety of those vaccines on February 7, 2021. Two nurse practitioners, Ms. He Yu and Ms. Donna Farmer, also shared their experiences in administering the vaccines.

Dr. Cunlin Wang

Dr. Cunlin Wang earned both his Ph.D in Epidemiology and Global Health, and Certificate of Vaccine Science, from

Johns Hopkins University. Before moving to California, he worked at the US Food and Drug Administration as Division Director of Epidemiology. He is currently a Vice President of Safety and Pharmacovigilance at Acentage Group Pharma. The following are his remarks at the forum.

Two vaccines have been approved under the FDA Emergency Use Authorization. They are Pfizer BNT162b2 and Moderna mRNA-1273. Johnson&Johnson and Novavax are expected to gain EUA in the next few months. (Note: Johnson & Johnson vaccine was approved under EUA on 2/27/2021).

New vaccines usually take 5-10 years to develop. Safety and efficacy are the foremost concern for FDA. Any breach of these standards will typically call for suspension, or termination of the trials. US companies, under the Operation Warp Speed, have developed two highly effective vaccines in less than a year without

發一般需時5-10年，食品藥物管理局在安全性及有效性的把關極為謹慎，任何安全疑慮都可能暫停臨床試驗或取消計劃。這次卻以前所未有的「快速通關」計劃，一年有成，安全也不打折扣。主要有幾個因素：

1. 基礎研究及臨床試驗上的跨國合作。
2. 臨床試驗與疫苗量產同步進行，各國政府透過注資預購等方式分擔廠商的財務風險。
3. 核酸疫苗使用的技術能縮短量產時程，並透過跨國授權生產方式，大大提高產能。
4. 食藥局、疾管中心在行政、審批程序上的優先與簡化。

臨床試驗結果

輝瑞和莫德納疫苗的效力都令人振奮。輝瑞疫苗施打第一劑後就有52%的保護，隔三週打第二劑後，更能達到近95%的保護。莫德納疫苗也有幾乎相同的高效。值得一提的是，它們對於重症（住院、加護病房、死亡）的保護幾達百分之百。這意味著雖然沒有對付新冠的特定療法，但疫苗的普遍施用也能讓新冠肺炎「流感化」，就算染病，也如一般感冒不會有太大問題。而參與的受試者按年紀、種族、性別、基線健康狀況等，按平均比例分布，結果也沒有顯著差異。

核酸疫苗的安全與副作用

基本上輝瑞和莫德納疫苗的三期臨床試驗結果，經過至少8週的追蹤都沒有嚴重安全顧慮。但還是有些一般常見的副作用：

1. 接種臂膀有一兩天的疼痛
2. 疲倦，頭疼，肌肉痛，輕微發燒。但發高燒情況很少，且一般退燒藥物如布洛芬都可有效緩解。
3. 接種第二劑後不適反應較強，且在年輕身上人更為明顯。

根據大面積接種後的數據顯示，藥物強烈過敏反應也很罕見；發生率遠低於一些已知藥物的過敏反應（例如盤尼西林）。換言之，這些副作用不能歸咎於疫苗。

compromising any safety standards or measures. We can attribute this unprecedented success to several factors:

1. Cross-industry and cross-country cooperation in research and clinical trials.
2. Phased trials and mass production of vaccines are going concurrently. Government subsidy and financial guarantee help to reduce business risks.
3. mRNA technology greatly reduces time to produce vaccine. The cross-licensing, multi-country manufacturing arrangement significantly increases production capacity.
4. FDA, CDC have simplified and accelerated the review/approval processes.

Clinical Trial Results

Both Pfizer and Moderna have produced encouraging results. Pfizer vaccine produces 52% protection after the first shot. It increases to nearly 95% efficacy after the second shot. Moderna vaccine has also achieved a very similar performance. Most notably, their protections against severe illnesses (hospitalization, ICU, death) are nearly 100%. This could mean even without targeted therapy, Covid-19 becomes a flu-like illness, and patients recover rather quickly. The trial participants cover population across age, race, gender, and baseline health condition, etc. Results show no significant difference amongst subgroups.

mRNA vaccines safety & side effect

The results from phase III clinical trial show no significant health and safety concerns for both Pfizer and Moderna vaccines, with a minimum of 8-week follow-up. But there are still some common, mild to moderate side effects:

1. Pain and swelling on the arm in which you get the shot. It usually goes away after two days.
2. Tiredness, headache, muscle pain, and fever are common, but high fever is rare. These discomforts can be relieved with over-the-counter medicines such as Ibuprofen and Tylenol.
3. Side effects are stronger typically after the second shot and it's more evident in younger adults.

Although trial data shows slightly higher occurrences in the vaccine group over the placebo group, the number is close to the baseline occurrence in the general population.

新冠病毒變種

目前所知的變種病毒有：英國變種 B.117，南非變種 B.1.351，巴西變種 P-1。初期觀察結果顯示 B.117 變種傳染力更強，致病率更高。而 B.1.351 變種，現有疫苗對它們的防護率也較低。

結語

人一旦感染新冠病毒，病毒在體內大量複製，這過程極易產生變種。疫苗的開發與施打如同在與病毒賽跑，快速全面的施打疫苗是阻斷病毒傳播與變異的最好方法。

王恒冰醫師

王恒冰醫師是瑜伽谷醫療中心血液腫瘤專科醫生。2015年搬到瑜伽市之前，擔任明尼蘇達州胡伯特韓福瑞癌症中心醫生。發言如下：

非常贊成存林的觀點，需要大面積接種疫苗，才可能將新冠病毒改造成普通的感冒病毒，比較容易對付。剛才存林講，輝瑞和莫德納疫苗對有症狀的感染和降低住院率有很大的幫助。如果我們的感染者都只有很輕微的症狀，或者沒有症狀，或者沒有什麼致死率的話，那新冠病毒就跟普通病毒差不多了。

我的預期是，新冠病毒在未來的若干年不會絕跡，唯有透過疫苗普及才能達到全體免疫。而疫苗對於重症的高效防護，也能更快地讓我們恢復正常的生活與運作。

此外，目前的疫苗也能有效降低無症狀的新冠病毒感染機率。莫德納疫苗蒐集了臨床實驗參加人群的鼻黏膜病毒狀況，疫苗組和安慰劑組各一萬五千餘人，一開始病毒檢測均為陰性。注射第二針時再檢測，安慰劑組有39人病毒檢測為陽性但無症狀；疫苗組則有15人病毒檢測為陽性而無症狀。這意味疫苗大約能降低無症狀感染達到60%。目前因為數字仍低，因此我們知道疫苗對於降低無症狀感染肯定有幫助，但是到底有多大的好處，現在還無法量化，估計三到六個月即可有此數字。

Similarly, number of anaphylactic reaction cases is much lower than with commonly-used drugs such as Penicillin. In other word, these side effects cannot be statistically attributed to the vaccine.

Covid-19 Variants

There are at least three well-known variants: UK B.117, South Africa B.1.351, and Brazil P-1. In general, these variants tend to be more contagious and transmissible. Unfortunately, current vaccines offer less protection against these new strains.

Summary

We are in a race against the virus. Once infected, the viruses replicate rapidly inside human body. The viruses have a good chance to mutate, and to form new strains in the process. The wide and fast vaccination is the most effective way to stop the spread and reduce the probability of mutation.

Dr. Hengbing Wang

Dr. Hengbing Wang is a Hematologist/Oncologist at Ukiah Valley Medical Center. Before moving to the city of Ukiah in 2015, he worked as an Oncologist at Hubert Humphrey Cancer Center – North Memorial Hospital in Minneapolis, Minnesota. The following are his remarks at the forum:

“I echo Dr. Cunlin Wang’s point that large-scale vaccination can effectively reduce the severity of Covid-19 to a more flu-like illness. Both Pfizer and Moderna vaccines are proven to be highly effective to prevent severe symptoms and hospitalization. Thus all infections become either mild or asymptomatic; Covid-19 could be not much different from a common virus. My prediction is that Covid-19 will not disappear in years to come. Broad vaccination is the only way to achieve “herd immunity” and restore our normal life.

Besides, vaccines can also significantly reduce asymptomatic infections. For example, the Moderna study analyzes the nasal swap data of trial participants, with 15,000 participants each in the vaccine and the placebo group. They are all tested negative at the onset (baseline). After the second shot, the placebo group had 39 cases of asymptomatic positives, while the vaccine group had only 15. This means a 60% reduction of asymptomatic infections. Based on preliminary data, we know vaccination helps. We expect the final and definitive results be available in 3-6 months.

今年二月的第一個星期五為止，（萬佛城所在的）曼都西諾縣已有20%的人群接種新冠疫苗，還沒有人出現嚴重副作用，也沒有人因此住院。估計全縣近九萬人如果都打了新冠疫苗，大約會有一例到二例出現嚴重反應。

余禾醫護士

余禾醫護士2016年和同修郭清源博士帶著兩個兒子從美東馬里蘭州搬到瑜伽市萬佛城附近定居。她的發言如下：

為人注射新冠疫苗須先接受訓練，注射前會先詢問對方是否有過敏歷史，注射時會準備腎上腺素，以及減輕過敏反應的針劑，以防萬一。

平日照顧的病患從59歲到100歲都有，但到二月第一週為止，只為88歲至99歲的老人家注射第一劑新冠疫苗，至今沒有人出現任何嚴重的反應，甚至連臂膀痠痛都沒有。正如王存林博士和王恒冰醫生所說，老年人確實對新冠疫苗的反應不及年輕人強烈。

當娜·法摩醫護士

當娜·法摩醫護士，2011年起在萬佛城擔任駐城護士。

她說，我們和曼都西諾縣衛生局保持密切聯繫，因此縣衛生局也關注到我們對疫苗的需要。目前已為萬佛城所有75歲以上的住眾注射疫苗，除了兩位年近百歲的高齡長者，因家人反對，因此未給他們注射。另外，注射當天，在接種第一劑疫苗的百位住眾當中，只有一位年輕的照護人員出現輕微的噁心、嘔吐現象，但休息幾個小時後已經好了。

輝瑞疫苗是非常有效的疫苗。鑑於時間和遞送的問題，輝瑞疫苗需要很小心地處理。因為輝瑞疫苗的可使用劑量有限，並且從公共衛生部收到後要盡量在一到兩天內完成接種。我希望長遠的話，在未來，能有更多的疫苗選擇。❀

Also, through first Friday of February, 20% of adult populations in Mendocino County received the first vaccine. And we have not seen any case of severe side effect or hospitalization. In my estimate, there might be only one or two cases of severe reaction when we vaccinate nearly 90,000 residents.”

Ms. He Yu

Ms. He Yu is a nurse practitioner with a specialization in gerontology. She and her husband, Dr. Cheng Guan Koay, and their two sons, moved to Ukiah from Maryland. They live near the City of Ten Thousand Buddhas. During the series of panel discussions, she remarked:

“All nurses receive training in administering vaccine shots. Prior to vaccination, we ask patients about their history of allergic reaction and make a general assessment on health conditions. We also have Diphenhydramine and Epi-pen available just in case.

I have people from 59 to 100 years of age under my care. During the first week of February, we gave the first shot to 88 to 99 year-old age group. There were no incidents of a strong reaction, and some didn't even experience any pain on their arms (while receiving the shot.) As both of the Dr. Wangs commented, elders tend to have less of a reaction to the vaccine than younger individuals.”

Donna Farmer, Nurse Practitioner

Donna Farmer, Nurse Practitioner, has been the resident nurse practitioner for the City of Ten Thousand Buddhas since 2011.

She mentioned that we are in close contact with Mendocino County's Public Health Department, and they are fully aware of and supportive of our vaccination needs. As of today, except for two elders in their late nineties, all residents 75 years or older have been vaccinated. After the first shot, only one young caregiver had a mild reaction of nausea, but was fine after a few hours of rest.

The Pfizer vaccine is a very effective vaccine, but distributing it requires careful coordination with regard to timing and delivery, because the doses are limited in availability and must be administered immediately within a short window of time (less than two days) once received from the Public Health Department. I hope that in the long-term, there will also be more shelf-stable options available. ❀