



Chelsea Elizabeth

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Good morning. I finally received a response from CDPHE regarding some of your questions. I hope you find the information helpful. The Q and A are below.

-Chelsea Brentzel, KRDO

From Facebook: Thur, Apr 22, 2021

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Q: "When a Pfizer or Moderna vaccine is no longer valid, what happens to those chemicals? Should I be afraid of what was administered into my body? Can a vaccine that was not handled per the temperature guidelines become dangerous when administered to a patient?"

CDPHE: The current data show that there is no risk for the patient to become sick from an invalid vaccine. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease.

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Q: "My Dr. Moma vaccine shot is 100% potent. It was handled with correct temperature controls throughout the supply chain. However, I am still being told to restart the vaccine process."

CDPHE: There is no documentation supporting that the Dr. Moma clinic maintained the required cold chain of the vaccines. The most important thing to know is that it's ultimately up to the patient to decide what to do about revaccination. CDPHE's revaccination guidance is based on consultation with medical experts at the CDC.

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Q: "Over a nine week period, I will have received three total vaccines, all of which are 100% potent and viable. What are the risks of this situation? Is there such a thing as "vaccine overdose?" Can my body overproduce antibodies? Can my side effects from the 3rd shot be extreme? What are the short and long-term consequences I should consider?"

CDPHE: CDPHE consulted with the CDC and released guidance for patients who were vaccinated at Dr. Moma's clinic. We believe this is the best guidance to ensure patients are protected. If you have specific questions about receiving a third dose, we encourage you to also speak with your healthcare provider.

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Q: "We, the FB group seeing conflicting info about advice on 3 shots, some local docs say no, some yes. I am getting 3rd shot next week, following CDC guidelines, can they CDPHE provide anything in writing, like a study, defending that decision. So far, all the studies we've seen have the 3rd shot given 6 months from later, not 21 days"

CDPHE: Both Pfizer and Moderna are currently studying the safety and effectiveness of booster doses. There is a difference between receiving a booster dose 6 months after a valid two-dose series, and receiving additional doses as part of revaccination following invalid previous doses. CDPHE consulted with the CDC and released guidance for patients who were vaccinated at Dr. Moma's clinic. We believe this is the best guidance to ensure patients are protected.

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Q: "Biggest worry is if manufacturers got mixed together. I had two shots, my card pre-filled out at reception, then I could take my pick of injection rooms, and apparently both shots given out in each room. 1st shot 3/20, 2nd 4/9, about an hour before shut down"

CDPHE: Patients should have received two doses of the same vaccine. If someone did receive one of each, they should plan to receive one additional dose of the same type of vaccine as their most recent dose. If their second dose was Moderna, they should receive another Moderna dose at least 28 days after your second dose. If their second dose was Pfizer, they should receive another Pfizer vaccine at least 21 days after your second dose.

The safety and efficacy of a mixed-product vaccine series have not been evaluated, and should be approached cautiously. In exceptional situations in which the vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If, for some exceptional reason, you receive a different product for your second dose, you do not need to repeat the vaccination again with additional doses.

In the event individuals receive a different second dose under exceptional circumstances, no additional precautions are necessary.

In the case of the Dr. Moma clinic, if individuals do not know what vaccine they received, they can receive either mRNA vaccine as part of revaccination.

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Q: "What do we do with vax cards? Mine shows two shots, by next week 3...can we get guidance from CDPHE on if/how these will be accepted by industry, like airlines?"

CDPHE: We expect vaccine cards will still be valid with three doses shown on the card.

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Q: "Has anyone seen her cold storage, and are there really logs"

CDPHE: CDPHE has obtained a copy of the clinic's paper temperature logs and received photos of the clinic's vaccine storage unit. At the on site visit, they did not have a digital data logger for recording the vaccine storage unit's temperatures, as required.

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Q: "Why has CDPHE been so absent in assisting us with our questions. Thankful for our local journalists, doing their job for us. CDPHE is definitely in "avoid a lawsuit" mode, and not in full disclosure mode"

CDPHE: CDPHE has communicated directly with people affected by vaccine administration at this site, providing them specific guidance for revaccination depending on how many doses they received at the Dr. Moma clinic as well as multiple options for additional vaccine appointments. We have also provided information to the statewide hotline so people can call 1-877-CO VAX CO (1-877-268-2926) to get additional answers to questions, and we will continue correspondence directly with people affected because we feel it's our obligation to make sure they feel comfortable moving forward, and we hope they choose to get re-vaccinated.

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Q: "I would like to know if the health department will consider our vaccine dose given at MOMA as valid if an antibody test demonstrates a sufficient level of antibodies. My daughter who is 16 received her vaccine there and had side effects with first shot. I do not intend to blindly give her three doses. I will be getting an antibody test as per medical advice. I do not want to later find out she needs proof of two dose regimen for school or travel and CDPHE won't consider her validly vaccinated despite antibody testing evidence. I also want to know what is the likelihood she received moderna vs Pfizer. We went on 4/7."

CDPHE: CDC has provided the following guidance regarding antibody testing: Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination because the clinical utility of post-vaccination testing has not been established. Antibody tests currently authorized under an EUA have variable sensitivity, specificity, as well as positive and negative predictive values, and are not authorized for the assessment of immune response in vaccinated people. Furthermore, the serologic correlates of protection have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection.

Finally, antibody testing against nucleocapsid will not detect immune responses resulting from vaccination, but patients may not always know what type of antibody test was used. If antibody testing was performed following vaccination, additional doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time. If antibody testing was done after the first dose of an mRNA vaccine, the vaccination series should be completed regardless of the antibody test result.

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Q: "Did Dr. Moma have the technology/appliances to properly store vaccines for an extended period? In the thread, it has come to light that we "received" the same lot as another patron 8 days before us which would have required very cold storage to even be plausibly acceptable. We find it hard to believe we were still getting that same lot 8 days later on a day when over 450 people were vaccinated in a single day."

CDPHE: "The site attested to having the equipment that is required per the CDC and the state is investigating whether they were compliant with their attestation. Part of what the state is investigating is their record management and it is possible that the records were inaccurate in terms of which lot people were given. Out of an abundance of caution, the state conferred with CDC and decided that it is prudent for anyone affected to restart their series since the vaccine may not be viable and the records are not sufficient.

Pfizer vaccine can be stored between -25°C and -15°C for up to two weeks and between 2°C and 8°C for 120 hours. Moderna vaccine can be stored between 2°C and 8°C for up to 30 days.

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Q: "Which lot number did CDPHE find records that -59 doses were purportedly given (i.e. that the records indicated administration of more than the # of doses provided)?"

CDPHE: We are still looking into this but the state suspects that multiple lots were recorded inaccurately.

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Q: "Is there any indication (other than the photo in the report where the different vaccines are being drawn up without labelling) that the vaccines may have been mixed up (i.e. Moderna given when the card said Pfizer or vice versa)? If so, will the State release the lot numbers Dr. Moma was given and on which days so that people can compare what they got when?"

CDPHE: Unfortunately, there is no way to verify if the lots on the card matched the physical lots. Upon conferring with the CDC, we believe that people should use their vaccine card to determine what vaccine to get next. If your vaccine record was inaccurate and you receive a different product when you restart your series, the CDC says you will still be protected from COVID-19. The safety and efficacy of a mixed-product vaccine series have not been evaluated, and should be approached cautiously. In exceptional situations in which the vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If, for some exceptional reason, you receive a different product for your second dose, you do not need to repeat the vaccination again with additional doses.

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KRDO: "Do you have a contact at CDPHE that we can direct concerned Dr. Moma patients to?"

CDPHE: 1-877-CO VAX CO (1-877-268-2926), available 24 hours a day, 7 days a week. Answers available in multiple languages."