January 2021 Supportive Supervision Tool SARS-CoV-2 Pfizer BioNTech Vaccine







PLEASE COMPLETE THIS TABLE PRIOR TO EACH VISIT	
Provider/Facility Name:	
Date of Visit:	
Site Visit Observer(s):	
Provider Staff Interviewed:	

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SUPPORTIVE SUPERVISION TOOL LEGEND

QUESTION NUMBER:	CONTENT AREA
INSTRUCTIONS	Where relevant, this section contains any instructions for completing the question.
	This section contains the text of the question. Any related subquestions appear in separate rows.
QUESTIONS	Underlined questions are directed toward the provider and meant to be asked verbatim to the provider or their staff. Questions in plain font are directed to the observer and are meant to be assessed and answered by the observer based on their observations at the time of the visit.
	Each question will be immediately followed by all the possible answer choices for that specific question or subquestion.
NOTE TO OBSERVER	The note to observer (where available) contains information necessary for properly asking the question and assessing responses. This may include definitions of terms, requirement details, and other helpful tips.
	This field provides the CDC requirement/recommendation associated with the question.
NONCOMPLIANCE	If noncompliance has been identified, the elements below must be completed.
IMMEDIATE ACTIONS	Actions that CDC requires the observer to take during the visit.

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SECTION 1: PROVIDER DETAILS

QUESTION 1.1	PROVIDER DETAILS: PROVIDER DEMOGRAPHIC INFORMATION
QUESTION:	Date of site visit * Please provide your email (Recipient filling out form):*
	Please provide your email (Necipient miling out form).
	Review all provider demographic and contact information
	Provider/Facility Name:
	Provider PIN:
	Provider Address:
	Provider City:
	Provider Zip Code:*
	Medical Director or Equivalent:
	Medical Director Email:
	Primary Vaccine Coordinator Name:
	Primary Vaccine Coordinator Phone Number:
	Primary Vaccine Coordinator Email:
	Backup Vaccine Coordinator Name:
	(please remind provider to designate a backup if this information is not readily available)
	Backup Vaccine Coordinator Phone Number:
	Backup Vaccine Coordinator Email:*
	Provider Type Hospital □ Pharmacy □
	CDT Other
	IPA/330 □

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SECTION 2: STORAGE AND HANDLING PER UNIT – ULTRA-COLD STORAGE (UNIT #1)

Does this facility have ultra-cold storage (-80 $^{\circ}$ C to -60 $^{\circ}$ C) capabilities? \square YES \square NO If the answer is YES, please answer questions in Section 2 If the answer is NO, please continue with questions in Section 3

SECTION 2	STORAGE AND HANDLING PER UNIT
DESCRIPTION	Name this unit with a description that will allow you or someone else from your program to easily identify it in the event of follow-up. We recommend using make and serial number (e.g., Thermo-Fisher-S123456789):

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QUESTION 2.1	STORAGE AND HANDLING PER UNIT: ULTRA COLD FREEZER
INSTRUCTIONS	Determine whether there is a temperature monitoring device located in this section of the storage unit and answer the questions below.
SUBQUESTION A (Choose one)	Is there a temperature monitoring device located in the ultra-cold freezer? ☐ Yes ☐ No [Complete appropriate action(s) in the "Immediate Action" section below]
NOTE TO OBSERVER	If the storage unit lacks a temperature monitoring device, immediate action is required. For temperature data (i.e., temperature readings) to be <u>useable</u> , temperatures must have been assessed using an appropriate working, temperature monitoring device. Temperature data must have been assessed and recorded within the last 72 hours to be considered recent.
SUBQUESTION B (Choose one)	Is temperature data recorded for the past 72 hours showing temperature ranges between -80°C and -60°C — Yes — No [Complete appropriate action(s) in the "Immediate Action" section below]
REVIEW REQUIREMENTS	Review recommendation with site staff: Vaccination providers should have a working, temperature monitoring device and temperature log. CDC recommends a specific type of temperature monitoring device called a "digital data logger" (DDL). A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals. Note that these are recommended practices but not required under current vaccine distribution awards/contracts.
SUBQUESTION C (Choose one)	Is a DDL used to record temperature data in this unit? □Yes □No
NONCOMPLIANCE	If noncompliance has been identified, complete the elements below.
IMMEDIATE ACTION	Note the specific action taken at the provider site based on your review of the current unit temperature and the recent available temperature data for this section of the storage unit: 1. If no recent, usable temperature data are available: suspend use of the vaccine, request that the vaccine provider contact Pfizer at 800-438-1985 for additional information and follow up. 2. If recent, usable temperature data indicate the unit temperature was out of range: suspend use of the vaccine, request that the vaccine provider contact Pfizer at 800-438-1985 for additional information and follow up.

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QUESTION 2.2	STORAGE AND HANDLING PER UNIT: VACCINE PLACEMENT
INSTRUCTIONS	Review the below questions visually if it can be done without temperature excursions of the ultra-cold freezer. If not possible or using a thermal shipper, confirm verbally
SUBQUESTION A (Choose one)	Are vaccines stored in their original packaging (wrapped trays)? ☐ Yes ☐ No
REVIEW CDC RECOMMENDATION	Review recommendation with site staff: Vaccines should be stored in their original manufacturer (or CDC centralized distributor) packaging - vaccines should only be unwrapped from their original trays immediately prior to being thawed and should be out of ultracold storage for no more than 3 minutes before it is considered thawed. It is recommended to only store vaccines in a unit, however, if other biologics must be kept in the unit the vaccines should be on a separate shelf above the biologics. Note that these are recommended practices but not required under current vaccine distribution awards/contracts.
ADDING FREEZER REMINDER	Is there another freezer? If so, please use another copy of this section to add another freezer.

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SECTION 3: STORAGE AND HANDLING – VACCINE FRIDGE (UNIT #1)

	STORAGE AND HANDLING PER UNIT
DESCRIPTION	Name this unit with a description that will allow you or someone else from your program to easily identify it in the event of follow-up. We recommend using make and serial number (e.g., Thermo-Fisher-S123456789):
QUESTION 3.3	STORAGE AND HANDLING PER UNIT: VACCINE FRIDGE
INSTRUCTIONS	Determine whether there is a temperature monitoring device located in this section of the storage unit and answer the questions below.
SUBQUESTION A (Choose one)	Is there a temperature monitoring device located in the fridge? ☐ Yes ☐ No [Complete appropriate action(s) in the "Immediate Action" section below]
NOTE TO OBSERVER	If the storage unit lacks a temperature monitoring device, immediate action is required. For temperature data (i.e., temperature readings) to be <u>useable</u> , temperatures must have been assessed using an appropriate working, temperature monitoring device. Temperature data must have been assessed and recorded within the last 72 hours to be considered recent.
SUBQUESTION B (Choose one)	Is temperature data recorded for the past 72 hours showing temperature ranges between 2°C and 8°C □ Yes □ No [Complete appropriate action(s) in the "Immediate Action" section below]
REVIEW REQUIREMENTS	Review recommendation with site staff: Vaccination providers should have a working, temperature monitoring device and temperature log. CDC recommends a specific type of temperature monitoring device called a "digital data logger" (DDL). A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals. Note that these are recommended practices but not required under current vaccine distribution awards/contracts.

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SUBQUESTION C (Choose one)	Is a DDL used to record temperature data in this unit? □Yes □No
NONCOMPLIANCE	If noncompliance has been identified, complete the elements below.
IMMEDIATE ACTION	Note the specific action taken at the provider site based on your review of the current unit temperature and the recent available temperature data for this section of the storage unit: 1. If no recent, usable temperature data are available: suspend use of the vaccine, request that the vaccine provider contact Pfizer at 800-438-1985 for additional information and follow up. 2. If recent, usable temperature data indicate the unit temperature was out of range: suspend use of the vaccine, request that the vaccine provider contact Pfizer at 800-438-1985 for additional information and follow up.
SUBQUESTION D (Choose one)	Are vaccine vials stored upright? ☐ Yes ☐ No
ADDING FRIDGE REMINDER	Is there another fridge? If so, please use another copy of this section to add another fridge.

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SECTION 4: ANCILLARY SUPPLIES AND VACCINE ADMINISTRATION

QUESTION 4.1	NEEDLES, SYRINGES, and DILUANTS
INSTRUCTIONS	Confirm with provider staff that supplies are present in sufficient quantities to match the amount of vaccines ordered.
NOTE TO OBSERVER	You do not have to physically count and audit the quantity of the supplies, but please verbally confirm with the provider staff that supplies are on site and in sufficient amounts.
	Does the provider have sufficient syringes to mix the vaccine with?
SUBQUESTION A (Choose one)	Each vaccine vial needs its own syringe. Syringes must be able to accurately measure 1.8 ml. □ Yes □ No
	Does the provider have individual vials of normal saline to mix the vaccine with?
SUBQUESTION B (Choose one)	Each vaccine vial needs its own vial of saline - 0.9% sodium chloride, must be preservative free. □ Yes □ No
SUBQUESTION C (Choose one)	The diluent used is ONLY the one in the individual vials that come in the ancillary kits? □ Yes □ No
SUBQUESTION D (Choose one)	When mixing the vaccine, the vial is gently inverted/swirled 10 times, but NOT shaken? ☐ Yes ☐ No
	Does the provider have sufficient needles to administer vaccines with?
SUBQUESTION E (Choose one)	Each vial of vaccine requires at least 5 needles, 22-25 gauge, 1-1.5". ☐ Yes ☐ No
	Does the provider have sufficient syringes to administer vaccines with?
SUBQUESTION F (Choose one)	Each vial of vaccine requires at least 5 syringes. Syringes must be able to accurately measure 0.3 ml. □ Yes □ No
	How many doses have you been typically withdrawing from each mixed vial?
SUBQUESTION G (Choose one)	Note that changes to the FDA guidance now allow for more than 5 doses of vaccines to be withdrawn from each vial as long as each dose is 0.3 ml. □ 5 does □ 6 doses □ 7 doses

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SUBQUESTION H (Choose one)	Any vaccine not used after 6 hours of mixed , is discarded? □ Yes □ No
SUBQUESTION I (Choose one)	Does the provider intend on using all of the needles and syringes provided in the ancillary kit for mixing and administering the vaccine? ☐ Yes ☐ No
SUBQUESTION J	If the provider is not planning to use all of the supplied needles and syringes, please describe why not (e.g. different brand preferred, not trained in vanishing-point needles). Response:
SUBQUESTION K (Choose one)	If the provider is planning to use needles and syringes beyond what is available in the ancillary kit, where will these supplies come from? Note that changes to the FDA guidance now allow for more than 5 doses of vaccines to be withdrawn from each vial. □ From pre-existing stockpiles within the institution □ From additional needles and syringes already ordered □ From additional needles and syringes to-be-ordered □ Unknown at the time of survey
SUBQUESTION L	Please describe any challenges encountered procuring needles and syringes for your vaccination needs Response:

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QUESTION 4.2	LABELS
INSTRUCTIONS	Confirm with provider staff that labels (or alternate record keeping plan) are available to ensure vaccines are used or discarded after being thawed and after being diluted.
	Does the provider have labels (or alternate record keeping plan) for marking the thaw time and "use by" time for the vaccine after it is moved from the ultra-cold storage (maintained between -80°C and -60°C) to the refrigerator (maintained between 2°C and 8°C).
SUBQUESTION A (Choose one)	(Or, if the provider receives the vaccine thawed, does the provider have labels for marking the time the vaccine was moved from the ultra-cold storage? This information is available in the vaccine delivery form)
	□ Yes □ No
SUBQUESTION B (Choose one)	Does the provider have labels (or alternate record keeping plan) for marking the "use by" time for the vaccine after it is mixed with diluent? ☐ Yes ☐ No
	Review recommendation with site staff:
REVIEW REQUIREMENTS	The Pfizer-BioNTech vaccine can be kept in ultra-cold storage (maintained between -80°C and -60°C) until its expiry date. Once the vaccines are moved from ultra-cold storage to refrigeration (maintained between 2°C and 8°C), it must be used within 5 days (120 hours)
	Vaccines must be mixed with normal saline before use. Once mixed, it must be used within 6 hours from the time of dilution. After mixing with diluent, vaccines can be returned to the refrigerator but must be used within 6 hours after dilution.
SUBQUESTION C (Choose one)	Are thawed vaccines outside fridge maintained at room temperature between 2 °C and 25 °C? — Yes — No

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QUESTION 4.3	VACCINE ADMINISTRATION
INSTRUCTIONS	Observe vaccine administration and answer the following questions
SUBQUESTION A (Choose one)	A new, sterile needle is used for each vaccine recipient? ☐ Yes ☐ No
SUBQUESTION B (Choose one)	A new, sterile alcohol pad is used to clean the stopper on the vial before withdrawing a new vaccine dose? □ Yes □ No
SUBQUESTION C (Choose one)	Do the staff administering the vaccine us a face mask and eye protection to administer the vaccine? (gloves are optional) ☐ Yes ☐ No
SUBQUESTION D (Choose one)	Is the vaccine vial swirled before withdrawing a new vaccine dose? ☐ Yes ☐ No

QUESTION 4.4	PREVACCINATION SCREENING AND CONSENT
INSTRUCTIONS	Confirm with provider staff that the below information is collected before vaccine administration
SUBQUESTION A (Choose one)	Does the provider have the most updated Pre-Vaccination Questionnaire from the PRDH available for screening of people who are going to be vaccinated? ☐ Yes ☐ No
SUBQUESTION B (Choose one)	Was the questionnaire administered to all people being vaccinated at the time of your visit and reviewed by the staff before administering the vaccine? ☐ Yes ☐ No
SUBQUESTION C (Choose one)	Is the PRDH consent form for vaccine administration available and administered to all people being vaccinated? ☐ Yes ☐ No

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QUESTION 4.5	VACCINE INFORMATION SHEETS
INSTRUCTIONS	Confirm with provider staff that the below information sheets are available for distribution.
SUBQUESTION A (Choose one)	Does the provider have Emergency Use Authorization (EUA) fact sheets or Vaccine Information Statements (VISs) are made available for vaccine recipients? ☐ Yes ☐ No
SUBQUESTION B (Choose one)	Does the provider have v-safe information sheets available for distribution to vaccine recipients? ☐ Yes ☐ No

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SECTION 5: POST-IMMUNIZATION CARE

QUESTION 5.1	POST-IMMUNIZATION CARE
INSTRUCTIONS	Confirm with provider staff that the following are available at the vaccination administration sites.
SUBQUESTION A (Choose one)	Is there a socially-distanced waiting area for observation and care for after vaccine receipt? ☐ Yes ☐ No
SUBQUESTION B (Choose one)	Are the providers aware of the recommendations from the PRDH regarding the preparation for the management of potential anaphylaxis events? □ Yes □ No
SUBQUESTION C (Choose one)	Does the site have at least 3 doses of epinephrine on-site for use in case of anaphylaxis? ☐ Yes — epinephrine auto-injector available (e.g. epi-pen) ☐ Yes — epinephrine in prefilled syringes available ☐ Yes — epinephrine in another form is available ☐ No
SUBQUESTION D (Choose one)	Does the site have equipment available for to measure vitals (blood pressure, pulse, and respiratory rates) during the management of anaphylaxis? This can be as basic as a blood pressure cuff, a stethoscope, and a watch or it can be automated devices that measure these things. □ Yes □ No
SUBQUESTION E (Choose one)	Does the site have antihistamines (e.g. Benadryl, Claritin) on-site to provide as adjunctive treatment for anaphylaxis? ☐ Yes ☐ No
SUBQUESTION F (Choose one)	Does the site have a "crash-cart" containing materials for intubation, oxygen, IV fluids, etc. available? This is not a requirement - this is recommended if the facility has it readily available. □ Yes □ No
SUBQUESTION G (Choose one)	Do all people vaccinated receive a CDC vaccination card with the date and type of vaccine administered and the date for the next dose, if applicable? □ Yes □ No
SUBQUESTION H (Choose one)	Does this facility have staff trained in PREIS? ☐ Yes ☐ No

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SUBQUESTION I (Choose one)	Are the majority (95% or more) of the vaccine doses administered being entered in the PREIS system: Within 12 hours Within 24 hours Within 48 hours Mithin 72 hours
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SECTION 6: KNOWLEDGE REVIEW

SECTION 6	KNOWLEDGE REVIEW
	The section below is meant to be a learning tool, please ask the question below verbally, have the CMO or vaccine coordinator consider their response (they don't have to say it – recommend that they say it to themselves or write it down) before announcing the answer.
DESCRIPTION	SCRIPT: The following section are a series of knowledge review points covering the unique aspects of storage, handling, and administration of the Pfizer-BioNTech vaccine. After I read a question, please take a moment to consider the response internally – you don't have to tell me your answer, feel free to write it down or just think to yourself – and then I will provide the answer.

QUESTION 6.1	FOR PROVIDERS WITH ULTRA COLD STORAGE CAPABILITIES KNOWLEDGE REVIEW – ULTRA-COLD STORAGE
INSTRUCTIONS	Please take a moment to review verbally with the CMO (or equivalent) and Vaccine Coordinator(s) the following critical points on ultra-cold storage procedures.
	¿Cuál es el rango de temperatura a la que se deben congelar las vacunas?
Knowledge Check 6.1.1	[PAUSE – allow the respondent to consider the question]
	Answer: -60C to -80C
	¿Se deben abrir las bandejas de vacunas cuando se almacenan en el congelador ultra-frío? Should the vaccine packs/trays be opened when being placed in the ultra-cold freezer?
Knowledge Check 6.1.2	[PAUSE – allow the respondent to consider the question]
	Answer: No – the vaccine trays should be opened only when the vaccine is about to be thawed.

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QUESTION 6.2	FOR PROVIDERS WITH ULTRA COLD STORAGE CAPABILITIES KNOWLEDGE REVIEW — VACCINE HANDLING
INSTRUCTIONS	Please take a moment to review verbally with the CMO (or equivalent) and Vaccine Coordinator(s) the following critical points on vaccine handling.
Knowledge	¿Por cuánto tiempo pueden mantenerse refrigeradas (2 a 8 C) las vacunas luego que se remueven del congelador ultra-frío? How long can the Pfizer-BioNTech stay refrigerated after it is removed from ultra-cold storage?
Check 6.2.1	[PAUSE – allow the respondent to consider the question]
	Answer: 120 hours (5 days).
	¿Los frascos de vacunas se almacenan de forma vertical o acostados?
Knowledge Check 6.2.2	[PAUSE – allow the respondent to consider the question]
	Answer: They should be stored upright
Knowledge Check 6.2.3	¿Los frascos de vacunas se pueden recongelar si se han descongelado? Once thawed, can the vaccine be refrozen?
	[PAUSE – allow the respondent to consider the question]
	Answer: No, once thawed, the vaccine cannot be refrozen.
	¿Cómo se descongela la vacuna? How should the frozen vaccine be thawed?
Knowledge Check 6.2.4	[PAUSE – allow the respondent to consider the question]
	Answer: Vaccines should be thawed in a refrigerator between 2°C and 8°C for 3 hours, or it can be thawed at room temperatures up to 25°C for 30 minutes.
	¿Qué se debe hacer con los frascos de vacuna luego de que han sido manejados sin guantes?
	How should the frozen vaccine vial be treated after it has been handled by bare hands?
Knowledge Check 6.2.5	[PAUSE – allow the respondent to consider the question]
	Answer: Individual vials handled by bare hands should be considered thawed and should not be refrozen. Thawed vials must be used within 120 hours if it stays refrigerated.
	Vials kept in trays are not considered thawed until it has been in room temperature for 30 minutes or for up to 3 hours. Vials touched briefly by dry ice gloves are not considered thawed.

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QUESTION 6.3	FOR ALL PROVIDERS OF PFIZER VACCINE KNOWLEDGE REVIEW – MIXING VACCINE WITH DILUENT AND VACCINE ADMINISTRATION
INSTRUCTIONS	Please take a moment to review verbally with the CMO (or equivalent) and Vaccine Coordinator(s) the following critical points on vaccine mixing and administration.
Knowledge Check 6.3.1	Starting with a thawed vaccine vial, all required materials, and after completing universal precautions, please describe verbally (or act out accompanied by verbal descriptions) all the steps for mixing the vaccine with diluent. Check off the boxes below as they accomplish or describe each step.
	If a step is missed or not described specifically, please interrupt the review and ask for this specific step.
	 Gently invert the thawed vial 10 times (do not shake) prior to dilution. Using the needle and syringe for the diluent, draw up 1.8 ml of sodium chloride 0.9% solution for injection, then discard the diluent vial and any remaining diluent in it. Add the 1.8 ml of sodium chloride 0.9% solution to the vaccine vial. Equalize the vial pressure by removing 1.8 ml of air with the now empty diluent syringe. Discard the needle and syringe used for the diluent. Gently invert the diluted solution 10 times. Do not shake. Label the vial containing the solution with the discard tie and date (6 hours after tie of dilution). Return the vial containing the solution to the refrigerator or cool box.
Knowledge Check 6.3.2	What volume of mixed vaccine (mixed with diluent) should be administered intramuscularly at each dose?
	[PAUSE – allow the respondent to consider the question]
	Answer: 0.3 ml
	How long after diluted, should the vial be discarded?
Knowledge Check 6.3.3	PAUSE – allow the respondent to consider the question]
	Answer: 6 hours
QUESTION 6.4	KNOWLEDGE REVIEW – FEEDBACK
INSTRUCTIONS	After this review, were there any aspects of the above points that were unclear during the training you have received?
	Were there aspects of vaccine storage, handling, and administration that you think were unclear in the training materials available to you?
	Response:

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SECTION 7: FREEFORM FEEDBACK

SECTION 7	FREEFORM FEEDBACK
DESCRIPTION	Please take a moment to solicit feedback from sites on the following aspects of immunization activities, please feel free to ask follow up questions at each section to enrich the feedback.

QUESTION 7.1	FREEFORM FEEDBACK – VACCINE SHIPMENT AND TRANSPORT
	Were there any challenges in receiving and (if applicable) redistributing the Pfizer-BioNTech vaccine that you encountered? Were there aspects that you think could be improved upon?
	Response:
	□ Ninguno □ Fechas de recibo de vacuna no fueron comunicadas
	☐ Fechas de recibo de vacuna fueron comunicadas con menos de 24 h de aviso
	☐ Cantidad de vacunas recibidas no corresponde con cantidad de vacunas esperadas ☐ Más vacunas ☐ Menos vacunas
QUESTION 7.1	☐ Fecha y hora de descongelamiento no son claras en la forma de entrega
	☐ Forma de entrega no contiene todos los datos necesarios
	Otros

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QUESTION 7.2	FREEFORM FEEDBACK – VACCINE STORAGE AND HANDLING
	Were there any challenges in storing and handling the Pfizer-BioNTech vaccine that you encountered? Were there aspects that you think could be improved upon?
	Response:
	□ Ninguno
	□ No hay espacio suficiente en neveras para el proceso de descongelamiento
QUESTION 7.2	□ Limitación en equipo requerido para manejar la vacuna congelada (guantes)
	☐ Desconocimiento/no están seguros de tiempos límite para transferencia de vacuna de congelador
	Otros

QUESTION 7.3	FREEFORM FEEDBACK – VACCINE ADMINSITRATION
	Were there any challenges in administering the Pfizer-BioNTech vaccine that you encountered? Were there aspects that you think could be improved upon?
	Response:
QUESTION 7.3	□ Ninguno □ No tienen suficientes kits para el número de dosis de vacuna que pueden sacar de un frasco (más dosis que kits) □ Jeringuillas no son las que usan normalmente y tuvieron que entrenar personal □ Espacio físico para administrar la vacuna es limitado Otros

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QUESTION 7.4	FREEFORM FEEDBACK – VACCINE DOCUMENTATION
	Were there any challenges in documentation for the Pfizer-BioNTech vaccine that you encountered? Were there aspects that you think could be improved upon?
	Response:
QUESTION 7.4	□ Ninguno □ No están seguros de que documentos deben entregarse al vacunado □ No tienen suficientes copias de documentos para todos los vacunados □ No tienen suficientes copias de tarjeta de vacunación para todos los vacunados □ No tienen personal suficiente para entrar datos de vacunas en PREIS □ Dificultad para acceder al sistema PREIS Otros

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