# COVID VACCINE CLINIC ANAPHYLACTIC REACTION EMERGENCY PROTOCOL

## I. GENERAL GUIDELINES

## A. <u>PURPOSE</u>

To respond immediately and give appropriate treatment to a patient who exhibits symptoms of an anaphylactic reaction including a patient who has been administered an immunizing agent. Anaphylaxis is a serious medical emergency.

## **B.** GENERAL INFORMATION

Anaphylaxis is defined as a serious allergic or hypersensitivity reaction that is rapid in onset and may cause death. The rapid recognition and immediate management by medical and nursing personnel are critical. The goal of therapy is early recognition and treatment with epinephrine to prevent progression to life-threatening respiratory and/or cardiovascular symptoms and signs, including shock.

**Emergency care equipment must be present and available for immediate use** <u>before</u> immunizations are given. Check emergency kit to make sure epinephrine and Benadryl / Diphenhydramine are not outdated on a monthly basis or sooner as determined by the site's medical supervisor and it will be the responsibility of the medical supervisor to make sure this task is completed. Documentation of the emergency equipment supplies will occur on the table provided below. Items not applicable will be marked as "N/A".

- The Medical Director over the COVID programs is responsible for the medical supervision of the immunization program. The Medical Director, or appropriate designee, will be immediately available during the hours of immunization administration. Immunizations must be administered in an area with immediate access to a telephone.
- 2. Preventive measures
  - a. Beware of the dangers of anaphylactic reactions
  - b. Know the symptoms
    - c. Ask about previous reactions to immunizing agents and injectable medications and about history of anaphylaxis to medications, foods, pollens, bee stings, etc. before giving immunization.
- 3. Symptoms and Signs of Anaphylaxis:
  - Skin:

Feeling of warmth, flushing (erythema), itching, urticaria, angioedema, and "hair standing on end" (piloerection)

· Oral:

Itching or tingling of lips, tongue, or palate Edema of lips, tongue, uvula, metallic taste

· Respiratory:

Nose – Itching, congestion, rhinorrhea, and sneezing Laryngeal – Itching and "tightness" in the throat, dysphonia, hoarseness, stridor

## · Gastrointestinal:

Nausea, abdominal pain, vomiting, diarrhea, and dysphagia (difficulty

Page 1 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021 swallowing)

## · Cardiovascular:

Feeling of faintness or dizziness; syncope, altered mental status, chest pain, palpitations, tachycardia, bradycardia or other dysrhythmia, hypotension, tunnel vision, difficulty hearing, urinary or fecal incontinence, and cardiac arrest.

# Neurologic:

Anxiety, apprehension, sense of impending doom, seizures, headache and confusion; young children may have sudden behavioral changes (cling, cry, become irritable, cease to play)

# · Ocular:

Periorbital itching, erythema and edema, tearing, and conjunctival erythema • **Other:** 

Uterine cramps in women and girls

# C. PRECAUTIONS

- 1. Preparation for all emergencies is impossible, but pre-planning to meet the emergency is essential.
- 2. Check emergency supplies and emergency response role before each clinic.

# D. PERSONNEL

- 1. School Nurse or Nurse Practitioner
- 2. School Physician
- 3. Medical Assistant under the direct supervision of a Nurse Practitioner or Physician
- E. EQUIPMENT (available for immediate use)

All clinical areas where biologicals are to be injected will have emergency medications / equipment on site that will include the following items:

- 1. Aqueous Epinephrine Hydrochloride (Adrenaline) 1:1000 solution (or appropriate doses of Epinephrine auto-injectors 0.10 mg, 0.15 mg and 0.30 mg each per dose, dependent on patient population served)
- 2. Diphenhydramine Hydrochloride (Benadryl) injectable 50 mg/ml
- 3. Tuberculin (TB) syringe-non retractable (or appropriate available alternative)
- 4. 25 gauge 1" safety glide needle
- 5. Cold packs
- 6. Sphygmomanometer (infant, child, adult and/or large adult cuff as appropriate for population being served)
- 7. Stethoscope
- 8. Disposable vinyl gloves
- 9. Cotton balls
- 10. Alcohol or Alcohol prep pads
- 11. Sharps container

Page 2 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

II. PROCEDURE

<ol> <li>Determine that patient has symptoms of anaphylactic reaction. <u>Call "911"</u>.</li> </ol>	<ul> <li>When in doubt, treat as a serious allergic reaction. <u>CALL</u></li> <li><u>PARAMEDICS</u>. <b>AND</b></li> <li>1) the Medical Director or designee</li> <li>2) the school administrator, and</li> <li>3) parent (as appropriate)</li> <li><u>Never leave patient unattended</u></li> </ul>
2. Check, monitor and maintain the patient's airway.	Do not leave patient unattended
<ol> <li>Lay the patient flat with feet elevated. If dyspneic or vomiting, place the patient semi recumbent with lower extremities elevated.</li> </ol>	Position vomiting patient to insure patient will not aspirate
<ul> <li>4. Prepare appropriate amount**/dose*** of Epinephrine (Adrenaline 1:1000) (See table below and instructions below) or use 0.10 mg or 0.15 mg or 0.30 mg epinephrine auto-injector, follow manufacturer instructions and skip "a" and "b" below.</li> <li>a. Cleanse top of epinephrine vial with alcohol pad</li> <li>b. Attach 25 gauge 1" needle to TB syringe (or appropriate alternative)</li> <li>c. Draw up required epinephrine dose into syringe or use appropriate dose auto injector as indicated in Epinephrine Dose Chart below (also Attachment A).</li> <li>d. Inject epinephrine dose intramuscularly</li> <li>e. Assess need for second dose of epinephrine in 5 -15 minutes</li> <li>f. Draw up / administer second dose of epinephrine per Epinephrine Dose Chart below (also Attachment A) if needed.</li> </ul>	If appropriate, cleanse injection site with cotton ball soaked in alcohol or alcohol prep pad. If necessary, secure assistance to immobilize site to be injected. Administer injection INTRAMUSCULARLY, (into the mid-outer aspect of the thigh if available). Never administer by intravenous route. Patient should respond within 5 – 10 minutes. Alert patient to expected response to epinephrine (anxiety, headache, fear, palpitations, restlessness, tremor, weakness, dizziness, respiratory difficulty) A second dose of epinephrine may be given in 5- 15 minutes after the first, if symptoms have not subsided, or if response is inadequate and paramedics have not arrived. ******DO NOT ADMINISTER SECOND DOSE OF EPI IN SAME SITE AS FIRST DOSE. IT MAY CAUSE NECROSIS.

Page 3 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

ESSENTIAL STEPS	KEY POINTS AND PRECAUTIONS
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	ant. Eninembring
First-Line Treatme (recommended dose for epineph	
	Epinephrine Dose Auto-Injector
Weight	- 64
Weig	1 mg/ml injectable
	Auto-injector
Age Group Range (Ib.)	
Range	(kg)*
	(1:1000 dilution)
	(0.10 mg or 0.15 mg Intramuscular
	or 0.30 mg per dose)
	Minimum dose: 0.05 ml
Infants & Children	
1 - 6 months 9 - 19 lb. 4 - 8.5 kg 0.05 mL N/	A
7 - 36 months 20 - 32 lb. 9 - 14.5 kg 0.10 r	nL 0.10 mg 37 - 59 months 33 - 39 lb. 15 -
17.5 kg 0.15 mL 0.15 mg 5 - 7 years 40 - 56	6 lb. 18 - 25.5 kg 0.20 - 0.25 mL 0.15 mg 8
-10 years 57 - 76 lb. 26 - 34.5 kg 0.25 - 0.30	mL 0.30 mg
11 - 12 year 77 - 99 lb. 35 - 45 kg 0.35 - 0.40 13 years & older 100 + lb. 46 + kg 0.50 mL 0	•
<b>Note:</b> If body weight is known, then dosing to known or not readily available, dosing by ag *Rounded weight at the 50 <sup>th</sup> percentile for ea Maximum dose for children: Dose according min apart Maximum dose for teens/adults: 0 5-15 min apart	ie is appropriate. ach age range. to chart, max of 3 injections, 5-15
5. Place covered cold pack over vaccine injection site.	Have someone else do this if necessary. The cold pack delays absorption of vaccine
<ul><li>6. Monitor vital signs:</li><li>a. Maintain adequate airway</li><li>b. Employ CPR if needed</li></ul>	Monitor and record vital signs, including blood pressure and pulse, every 5 minutes.
7. Assess for presence of itching and hives. If present, prepare and administer Diphenhydramine (Benadryl) <b>intramuscularly</b> per Diphenhydramine Dose Chart Below (also Attachment A).	Benadryl (50 mg/mL) can be given in addition to epinephrine to relieve itching and hives. Administer once <b>INTRAMUSCULARLY</b> ( <u>at</u> <u>site other than the epinephrine</u> ) according to dosage table. <u>DO NOT REPEAT</u>

Page 4 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

			• • · · • • • • • •
			weight) Diphenhydramine Dose
	Age Group Range of	Range of	50 mg / ml injectable (IV or IM)
lu fa u fa	Weight (lb)	Weight (kg)*	
Infants and	7 - 36 months 20 - 3	2 lb 9 - 14.5 l	kg 10 mg - 15 mg / dose (0.20 - 0.30 ml)
Children Teens /	37 - 59 months 33 - 39 lb 15 - 1 years 40 - 56 lb 18 - 25.5 kg 20 8 - 12 year 57 - 99 lb 26 - 45 kg	mg - 25 mg /	
Adults	13 years & older 100 + lb 46 + l	kg 50 mg / do	se (1.0 ml)
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eadily avai Rounded w Aaximum do *Although o Benadryl) in the consider 3. Continue the para by the	lable, dosing by age is appropriate eight at the 50 <sup>th</sup> percentile for each ose for: 1-2 mg/kg. <u><b>Do not repeat</b></u> commonly used, data supporting the in the management of anaphylaxis red only as adjunct therapy to epin to monitor the patient until amedics arrive or as advised	in age range. <u>initial dose.</u> the role or effe are limited. He ephrine. Observe <u>Send/ta</u> informa neares <u>DO NO</u> <u>PARAI</u> <u>****If pa</u>	activeness of second-line treatment options lence, these second-line treatments should re patient until transferred to hospital. ake all appropriate patient emergency ation with the patient when transported to t emergency room. <i>If you used an <u>AED</u></i> , <u>or SEND IT TO HOSPITAL WITH</u> <u>MEDICS</u> arent or guardian is not present, t personnel must accompany a
eadily avai Rounded w Aaximum de *Although o Benadryl) in be consider 3. Continue the para by the Medical	lable, dosing by age is appropriate eight at the 50 <sup>th</sup> percentile for each ose for: 1-2 mg/kg. <u><b>Do not repeat</b></u> commonly used, data supporting the in the management of anaphylaxis red only as adjunct therapy to epin to monitor the patient until amedics arrive or as advised	in age range. initial dose. ine role or effe are limited. He ephrine. Observe Send/ta informa neares DO NO PARAI ****If pa Distric minor. "Univer contam baggeo contam	activeness of second-line treatment options lence, these second-line treatments should re patient until transferred to hospital. ake all appropriate patient emergency ation with the patient when transported to t emergency room. <i>If you used an <u>AED</u></i> , <u>or SEND IT TO HOSPITAL WITH</u> <u>MEDICS</u> arent or guardian is not present, t personnel must accompany a

Page 5 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

ESSENTIAL STEPS	KEY POINTS AND PRECAUTIONS
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11. Record procedure for transfer of information onto VAERS.	Record the incident in VAERS, including, but not limited to:				
	a. Date and time of incident.				
	<ul> <li>b. Symptoms indicating need for initiating anaphylaxis procedures.</li> </ul>				
	c. Times, dosage, and site of medication given				
	<ul> <li>d. Vital signs. Include all blood pressure readings and times</li> </ul>				
	e. Patient's response				
	f. Medical Director's or designee's order/notification.				
	<ul> <li>g. Time and place patient was transported</li> <li>by paramedics and who accompanied (if</li> <li>applicable, parent, guardian, District</li> <li>personnel, etc.)</li> </ul>				
Report an Adverse Event to VAERS <u>Online</u> or Report Using a <u>PDF Form</u>	If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.				

## APPROVED: January 25, 2021 Date

Murray Lappe, MD Medical Director, COVID Vaccine Program

Page 6 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021 <u>REFERENCES</u>

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treatment?search=https:%2F%2Fwww.uptodate.com%2Fcontens%2Fimage%3FimageKe

<u>%3DEM%252F4242%26topicKey%3DALLRG%25392%26search%3Danaphylaxis%26ran</u> <u>k%3D2~150%26source%3Dsee\_link&source=search\_result&selectedTitle=1~150&usage</u> <u>type=default&display\_rank=1</u>

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Page 7 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

# Attachment A

# Medical Management of Vaccine Reactions in Children and Teens/Adults

For your convenience, approximate dosages based on weight and age are provided in the charts below. Please confirm that you are administering the correct dose for your patient.

First-L	ine Treatment: <i>E</i> µ	binephrine (reco	mmended dose f	or epinephrine is 0.01 mg/	/kg body weight)	
Infants	Age Group	Weight Range (Ib.)	Weight Range (kg)*	Epinephrine Dose	Auto-Injector	
& Childr en			1 mg/ml injectable (1:1000 dilution) Intramuscular Minimum dose: 0.05 ml	Auto-injector (0.10 mg or 0.15 mg or 0.30 mg per dose)		
	1 - 6 months	9 - 19 lb.	4 - 8.5 kg	0.05 mL	N/A	
	7 - 36 months	20 - 32 lb.	9 - 14.5 kg	0.10 mL	0.10 mg	
	37 - 59 months	33 - 39 lb.	15 - 17.5 kg	0.15 mL	0.15 mg	
	5 - 7 years	40 - 56 lb.	18 - 25.5 kg	0.20 - 0.25 mL	0.15 mg	
	8 -10 years	57 - 76 lb.	26 - 34.5 kg	0.25 - 0.30 mL	0.30 mg	
Teens/	11 - 12 year	77 - 99 lb.	35 - 45 kg	0.35 - 0.40 mL	0.30 mg	
Adults	13 years & older	100 + lb.	46 + kg	0.50 mL	0.30 mg	

**Note:** If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

\*Rounded weight at the 50<sup>th</sup> percentile for each age range.

Maximum dose for children: Dose according to chart, max of 3 injections, 5-15 min apart Maximum dose for teens/adults: 0.5ml/injection, max of 3 injections, 5-15 min apart

Secondary Treatment Option: <u>Diphenhydramine</u> (recommended dose for the diphenhydramine ( <u>Benadryl</u> ) is 1-2 mg/kg body weight)							
Infants and	Age Group	Weight Range (Ib.)	Weight Range (kg)*	Diphenhydramine Dose			
Children		Range (ib.)	Kange (kg)	50 mg/mL injectable (IV or IM)			
	7 - 36 months		9 - 14.5 kg	10 mg - 20 mg (0.20 - 0.30 ml)			
	37 - 59 months	33 - 39 lb.	15 mg - 30 mg (0.30 - 0.40 ml)				
	5 - 7 years	40 - 56 lb.	18 - 25.5 kg	20 mg - 30 mg (0.40 - 0.50 ml)			
Teens/Adult	8 - 12 year	57 - 99 lb.	26 - 45 kg	30 mg (0.50 ml)			
S	13 years & older	100 + lb.	46 + kg	50 mg (1.0 ml)			

**Note:** If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

\*Rounded weight at the 50<sup>th</sup> percentile for each age range.

Maximum dose: 1-2 mg/kg. Do not repeat initial dose.

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Page 9 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

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City:	ity: State: County:											
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2. Date of birth: kern	idiraa) m	3. Sex: □ Male □ Fem	ale 🗆 Unknown									
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	WHI	CH VACCINES WERE GIVE	IN? WHAT HAPPEN	NED TO	THE PATIE	IT?						
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Page 10 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

### COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

### GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile[.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an
  email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the Continuation Page if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at <u>www.vaers.hhs.gov/reportable.html</u> for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who
  administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

#### SPECIFIC INSTRUCTIONS

#### Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.

- Items 4 and 5: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the
  month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or
  afternoon or evening ("PM"), please provide that information.
- Item 6: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- Item 8: If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any
  pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- Item 9: List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/ alternative medicines being taken by the patient when the vaccine(s) was given.
- Item 10: List any allergies the patient has to medications, foods, or other products.
- Item 11: List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this
  date (e.g., cold, stomach flu, ear infection, etc.). This does NOT include the adverse event you are reporting.
- Item 12: List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- Item 13: List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the
  patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically
  entered for you. Otherwise, please provide new contact information.
- Item 14: List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- Item 15: Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- Item 16: Select the option that best describes the type of facility where the vaccine(s) was given.

Page 11 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

#### ETURN TO PART

Unknown

- Item 17: Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous, · By mouth/oral · Other (specify) intradermal, jet injection, and unknown) In nose/intranasal Unknown For body site, the options include: Right arm · Right thigh Nose · Other (specify)
  - Left arm
    - Left thigh
  - Arm (side unknown) Thigh (side unknown)

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."

Mouth

- Item 18: Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred. diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- Item 19: List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- Item 20: Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- Item 21: Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- Item 22: List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- Item 23: Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- Item 24: Check all races that apply.
- Item 25: Check the single best answer for ethnicity.
- Item 26: For health department use only.
- Items 27 and 28: Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

#### GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Page 12 of 13 COVID Vaccine Clinic Anaphylactic Reaction Emergency Protocol, Rev. 01/23/2021

# O<sub>2</sub> Tank and Emergency Supplies Monthly Log

Year:

SUPPLIES & EQUIPMENT	exam ple	JUL	AUG	SEP	ост	NOV	DEC	JAN	F
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			T				<u> </u>
	12/12 /19						
Oxygen Tank - 3/4 full (PSI 1500), key, chain & regulator attached) ^	2000						
Dosage Chart in Emergency Kit +	$\checkmark$						
Epinephrine 1:1000 *	12/12/2 1						
Benadryl *	12/13/2 1						
Bag-Valve Mask (Infant) ^	1						
Bag-Valve Mask (Pediatric) ^	1						
Bag-Valve Mask (Adult) ^	1						
Suction Device (Bulb Syringe) +	$\checkmark$						
Infant O2 Face Mask & Tubing ^	1						
Pediatric O2 Face Mask & Tubing ^	1						
Adult O2 Face Mask & Tubing ^	1						
Nasal Canula (Pediatric) ^	1						
Nasal Canula (Adult) ^	1						
Nebulizer +	$\checkmark$						
Oral Airways +	$\checkmark$			 			
Tuberculin syringes with needles *	11/15/2 1						
Alcohol Wipes +	$\checkmark$						
Albuterol SOLN/MDI*	11/30/2 1						
Personal Protective Equipment (masks, goggles, gowns, gloves) +	V						
Sterile Dressings +	$\checkmark$						
Splints +	$\checkmark$						
Staff Initials	2						

\* expiration date ^ amount

Document date and appropriate symbol as you check each item.

Initials indicate the supplies have been checked, expired medication and supplies purged, properly disposed of, and the disposal is documented.