1) **PURPOSE**
   a) To provide guidance for medical emergencies in the Queen's COVID Mass Vaccine Clinics (sites dedicated to COVID vaccinations)
   b) To assure accurate identification and medical management of anaphylaxis related to vaccine administration.

2) **Authority**
   The following protocol is authorized under Policy 674-XX-823-B, which states that the Infection Prevention and Control Committee Chairperson is authorized to take action on behalf of the Committee to initiate appropriate control measures when deemed necessary to prevent transmission of infection…this protocol is authorized, which allows staff to follow the procedures below and place medication orders per protocol under the Medical Director.

3) **DEFINITION**
   Anaphylaxis is an acute, life-threatening systemic allergic reaction associated with different clinical presentations and severity resulting from exposure to an allergen trigger. *Refer to Appendix A*
   a) Diagnostic criteria: Anaphylaxis is highly likely when there is sudden onset (minutes to hours) of Skin/Mucosal symptoms + [Respiratory OR Cardiovascular Symptoms]:
      i) Skin/mucosal tissue symptoms: generalized hives, itching, swollen face-lips-tongue-uvula
      ii) Respiratory system: stridor (high-pitched sound while breathing), shortness of breath, wheeze, cough, hypoxemia
      iii) Cardiovascular system: hypotension (abnormally low blood pressure), dizziness, fainting, tachycardia (abnormally fast heart rate), light-headedness, incontinence
      iv) Gastrointestinal symptoms: nausea, vomiting, diarrhea, abdominal pain
   b) Clinical pearls in the management of vaccine-related medical emergencies
      i) Maintain a high clinical suspicion for an anaphylactic reaction
      ii) Cardiovascular symptoms alone (dizziness, hypotension, light-headedness, flush) may be related to a vasovagal response to needle injection
      iii) The constellation of symptoms immediately following injection may strongly suggest anaphylaxis: full body or rapidly worsening urticaria (hives), facial swelling (eyes, lips or tongue), flushing, wheezing, chest tightness, shortness of breath, fullness or "lump" in throat, light headiness, rapid pulse.
      iv) Dermatologic findings (pruritus, rash, flush, angioedema) may not be initially present as early symptoms of anaphylaxis.

4) **EQUIPMENT & Medications**
   Emergency equipment for immediate availability at all vaccination sites include:
   a) MEDICATIONS

PAR	Drug	PAR	Drug
2	Epinephrine HCl/anaphylaxis (EPIPEN)	1	Famotidine 20 mg tablet
2	Diphenhydramine 25 mg/10 mL oral solution cup	3	Prednisone 20 mg tablet
2	Epinephrine HCl/anaphylaxis JUNIOR –EPIPEN	2	Alcohol Prep Pad
2	Diphenhydramine 50 mg/1 mL injection (1 mL)	2	Hypodermic Safety Needle 25 G x1

1	Albuterol MDI with spacer device	2	3 mL Luer-Lok Tip Syringe
1	Methylprednisolone 125 mg/mL injection		

b) Equipment- For Adult and Pediatric > 5 years old

Stethoscope	Oxygen tank x2
Blood pressure monitor –	Automatic External Defibrillator
Pulse oximeter	Ambu Bag
Nasal Cannula tubing	Bag valve mask

PROCEDURE

c) **The clinic will designate one "Lead RN" to be available at all times during clinic hours**
   i) Lead RN will have documented in-service on this protocol (Vaccine Clinic Emergency Protocol)
   ii) Lead RN will be responsible for performing assessment and instituting emergency protocols
   iii) Medications will be administered by Lead RN or designee
   iv) Lead RN or designee will be responsible for documentation of encounter

d) **Rapidly perform assessment**
   i) Assess airway and breathing
      (1) Respiratory rate
      (2) Respiratory effort
      (3) Presence of wheezing
      (4) Oxygen saturation
   ii) Assess circulation
      (1) Palpate for pulse
      (2) Check BP and Heart Rate
   iii) Assess Level of consciousness
   iv) Assess Skin and mucosa (mouth)

e) **Notify the Medical Director + onsite physician, when onsite physician is available**
   i) Primary (01/21/21): Julius C. Pham, MD via Tigertext
   ii) Secondary (01/21/21): Matthew Ing, MD via Tigertext

f) **Patients meeting criteria for anaphylaxis**
   i) Initiate emergency protocols as below while awaiting provider leadership. Do not delay anaphylaxis treatment
   ii) Place patient in a supine position (face up), with feet elevated, unless upper airway obstruction is present, or the patient is vomiting
   iii) **Administer epinephrine 0.3 ml of the 1 mg/ml or epinephrine autoinjector (EPIPEN, or EPIPEN Junior intramuscularly at the upper lateral thigh**. May repeat dosing every 5-15 minutes (or more often) as needed to control symptoms. (There are NO absolute contraindications to epinephrine in the setting of anaphylaxis)
   iv) Administer solumedrol 125mg IM or prednisone 60mg PO if patient is able to swallow
   v) Administer oxygen 6L via nasal cannula
   vi) If patient has wheezing/bronchospasm: administer albuterol 4-8 puffs every 20 minutes through a spacer device
   vii) If patient has hives, rash, or pruritus: administer diphenhydramine 50mg IM or PO if patient is able to swallow

g) Patients experiencing non-anaphylactic allergic reactions (limited to dermatologic symptoms)

i) Consider diphenhydramine 25mg PO, famotidine 20mg PO, or prednisone 60mg PO depending on clinical assessment by physician
ii) Please refer to Pediatric weight based liquid Benadryl: Refer to bottle for concentration.

Weight	**Children's Liquid Suspension Benadryl (25mg/10ml)**
27lb 8 oz. to 32 lb. 15 oz.	6.25 ml
33 lb. to 37 lb. 7 oz.	7.5 ml
38 lb. 8 oz. to 43 lb. 15 oz.	8.75 ml
44 lb. to 54 lb. 15 oz.	10 ml
55 lb. to 65 lb. 15 oz.	12.5 ml
66 lb to 76 lb. 15 oz.	15 ml
77 lb to 87 lb. 5 oz.	17.5 ml
87 lb. +	20 ml

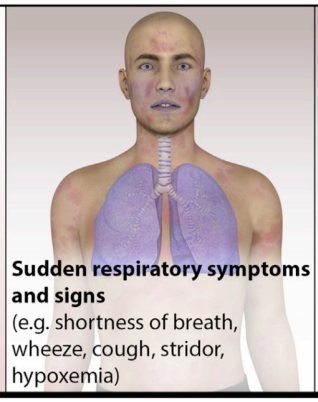
h) All other medical emergencies shall be transported to the ED for management
i) **Activate Emergency Management System (EMS) to facilitate transfer to the Emergency Department**
   i) If Emergency Medical Technician (EMT) is available on-site, notify EMT
   ii) If EMT is not available on-site, call 9-1-1
   iii) All patients receiving treatment shall be transferred to the Emergency Department

APPENDIX A- Anaphylaxis diagram

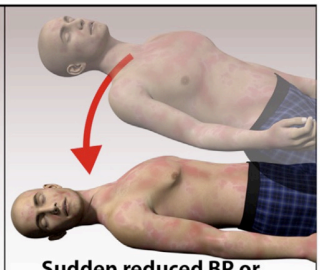
Anaphylaxis is highly likely when any one of the following three criteria is fulfilled

1 Sudden onset of an illness (minutes to several hours), with involvement of the skin, mucosal tissue, or both (e.g. generalized hives, itching or flushing, swollen lips-tongue-uvula)

AND AT LEAST ONE OF THE FOLLOWING:

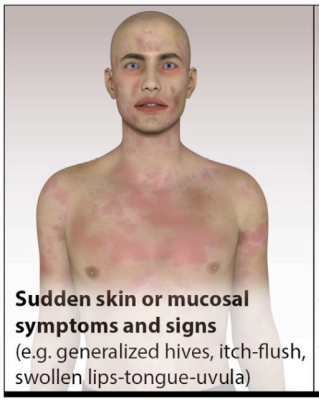


Sudden respiratory symptoms and signs
(e.g. shortness of breath, wheeze, cough, stridor, hypoxemia)

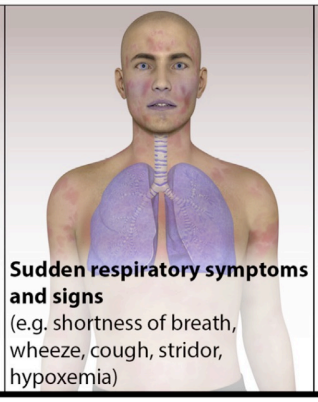


Sudden reduced BP or symptoms of end-organ dysfunction
(e.g. hypotonia [collapse], incontinence)

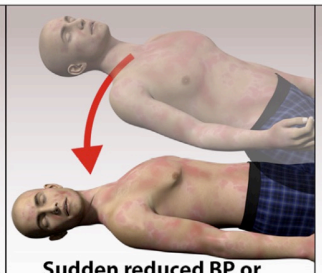
OR 2 Two or more of the following that occur suddenly after exposure to a *likely allergen or other trigger* for that patient* (minutes to several hours)



Sudden skin or mucosal symptoms and signs
(e.g. generalized hives, itch-flush, swollen lips-tongue-uvula)



Sudden respiratory symptoms and signs
(e.g. shortness of breath, wheeze, cough, stridor, hypoxemia)



Sudden reduced BP or symptoms of end-organ dysfunction
(e.g. hypotonia [collapse], incontinence)

Sudden gastrointestinal symptoms
(e.g. crampy abdominal pain, vomiting)

OR 3 Reduced blood pressure (BP) after exposure to a *known allergen** for that patient* (minutes to several hours)

Infants and children: low systolic BP (age specific) or greater than 30% decrease in systolic BP ***

Adults: systolic BP of less than 90 mm Hg or greater than 30% decrease from that person's baseline

Appendix B: Rapid overview: Emergency management of anaphylaxis in adults

Diagnosis is made clinically:	The most common signs and symptoms are cutaneous (e.g., sudden onset of generalized urticaria, angioedema, flushing, pruritus). However, 10 to 20% of patients have no skin findings.
	Danger signs: Rapid progression of symptoms, respiratory distress (e.g., stridor, wheezing, dyspnea, increased work of breathing, persistent cough, cyanosis), vomiting, abdominal pain, hypotension, dysrhythmia, chest pain, collapse.
	The first and most important treatment in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
	Airway: Immediate intubation if evidence of impending airway obstruction from angioedema. Delay may lead to complete obstruction. Intubation can be difficult and should be performed by the most experienced clinician available. Cricothyrotomy may be necessary.
Promptly and simultaneously, give:	IM epinephrine (1 mg/mL preparation): Give epinephrine 0.3 to 0.5 mg intramuscularly, preferably in the mid-outer thigh. Can repeat every 5 to 15 minutes (or more frequently), as needed. If epinephrine is injected promptly IM, most patients respond to one, two, or at most, three doses. If symptoms are not responding to epinephrine injections, prepare IV epinephrine for infusion (see below). For the pediatric population • Use EpiPen Junior for patients under 65 lbs. • Use EpiPen adult dose for patients $\leq$ 65
	Place patient in recumbent position, if tolerated, and elevate lower extremities.
	Oxygen: Give 8 to 10 L/minute via facemask or up to 100% oxygen, as needed.
	Normal saline rapid bolus: Treat hypotension with rapid infusion of 1 to 2 liters IV. Repeat, as needed. Massive fluid shifts with severe loss of intravascular volume can occur.
	Albuterol (salbutamol): For bronchospasm resistant to IM epinephrine, give 2.5 to 5 mg in 3 mL saline via nebulizer. Repeat, as needed.
Adjunctive therapies:	H1 antihistamine:[(a)] Consider giving cetirizine 10 mg IV (given over 2 minutes) or diphenhydramine 25 to 50 mg IV (given over 5 minutes) or IM (for relief of urticaria and itching only)
	H2 antihistamine:[(a)] Consider giving famotidine 20 mg IV (given over 2 minutes).
	Glucocorticoid:[(a)] Consider giving methylprednisolone 125 mg IM once
	Monitoring: Continuous noninvasive hemodynamic monitoring and pulse oximetry monitoring should be performed. Urine output should be monitored in patients receiving IV fluid resuscitation for severe hypotension or shock.
Treatment of refractory symptoms:	Epinephrine infusion:[(b)] For patients with inadequate response to IM epinephrine and IV saline, give epinephrine continuous infusion, beginning at 0.1 mcg/kg/minute by infusion pump[(c)]. Titrate the dose continuously according to blood pressure, cardiac rate and function, and oxygenation.
	Vasopressors:[(b)] Some patients may require a second vasopressor (in addition to epinephrine). All vasopressors should be given by infusion pump, with the doses titrated continuously according to blood pressure and cardiac rate/function and oxygenation monitored by pulse oximetry.

	Glucagon: Patients on beta blockers may not respond to epinephrine and can be given glucagon 1 to 5 mg IV over 5 minutes, followed by infusion of 5 to 15 mcg/minute. Rapid administration of glucagon can cause vomiting.

REFERENCE:

- Shaker MS, et al. "Anaphylaxis-a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis." Journal of Allergy and Clinical Immunology 2020;145(4):1082-1123. doi: 10.1016/j.jaci.2020.01.017.
- Brown JC et al. "Epinephrine in the Management of Anaphylaxis" J All Clin Immunol 2020 Apr;8(4):1186-1195
- ACIP Rapid Overview: Emergent Management of Anaphylaxis in Adults. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html#t-02
- Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html