



In the name of god

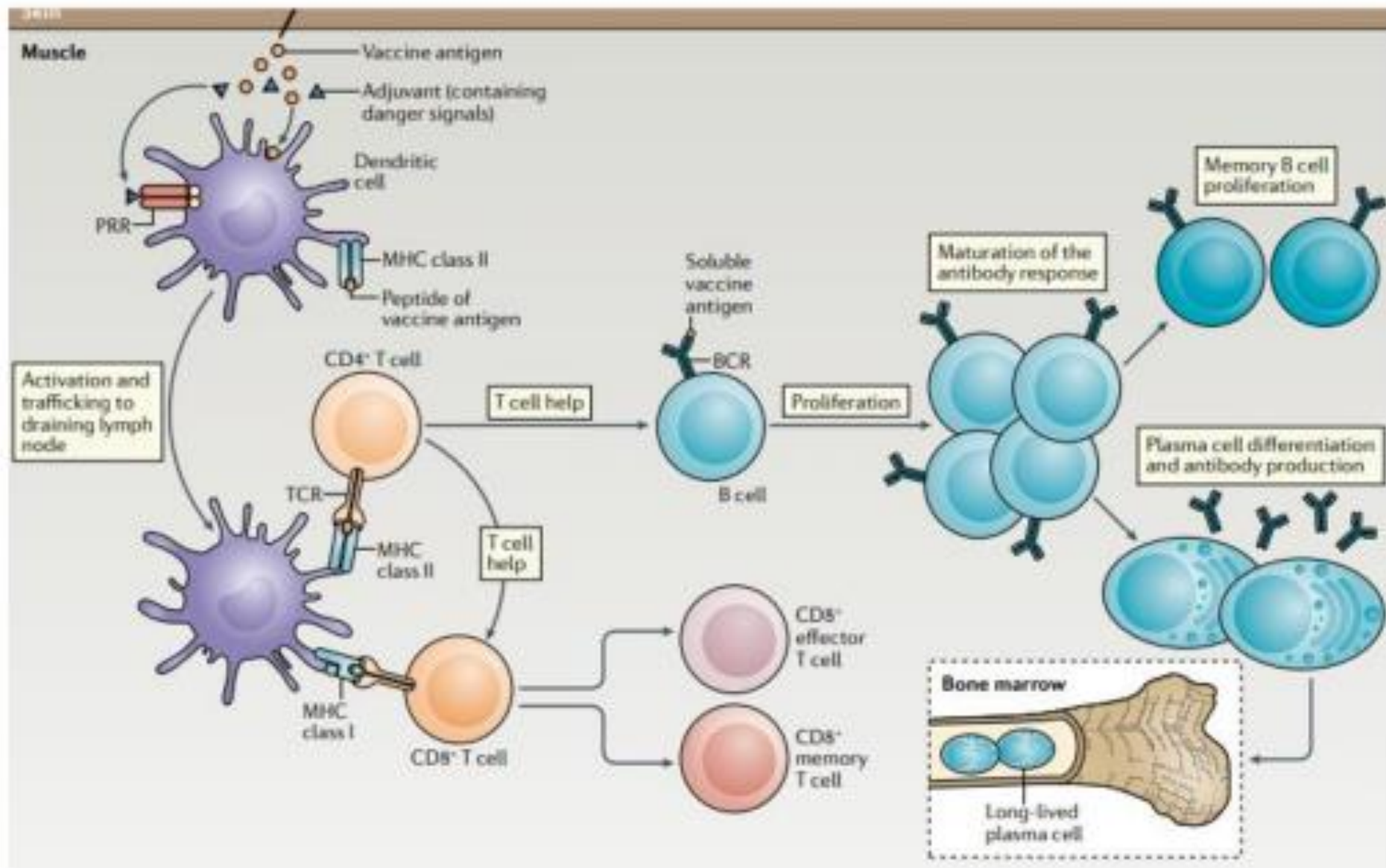
***Risk Assessment for
Covid -19 Vaccination***

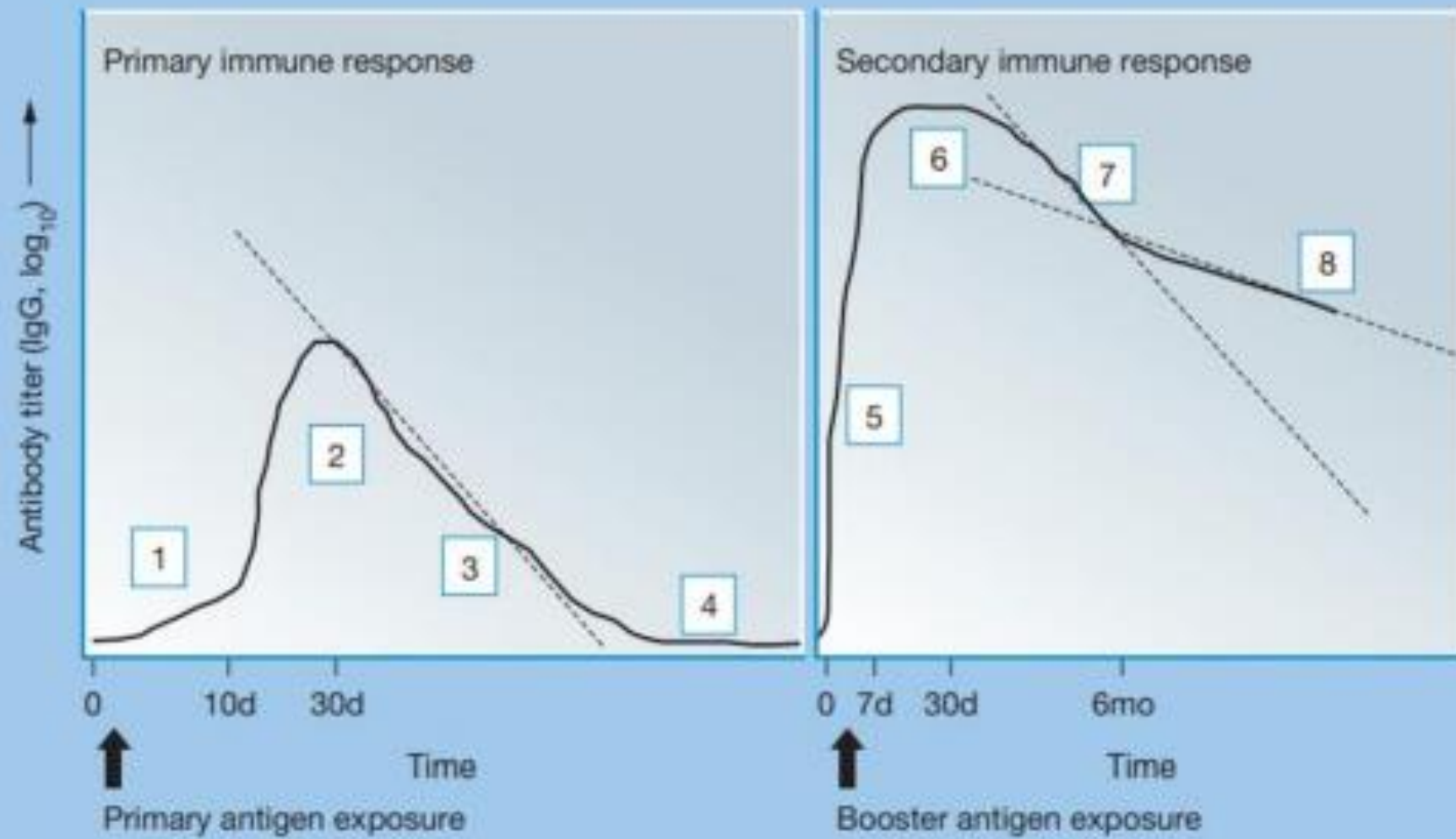
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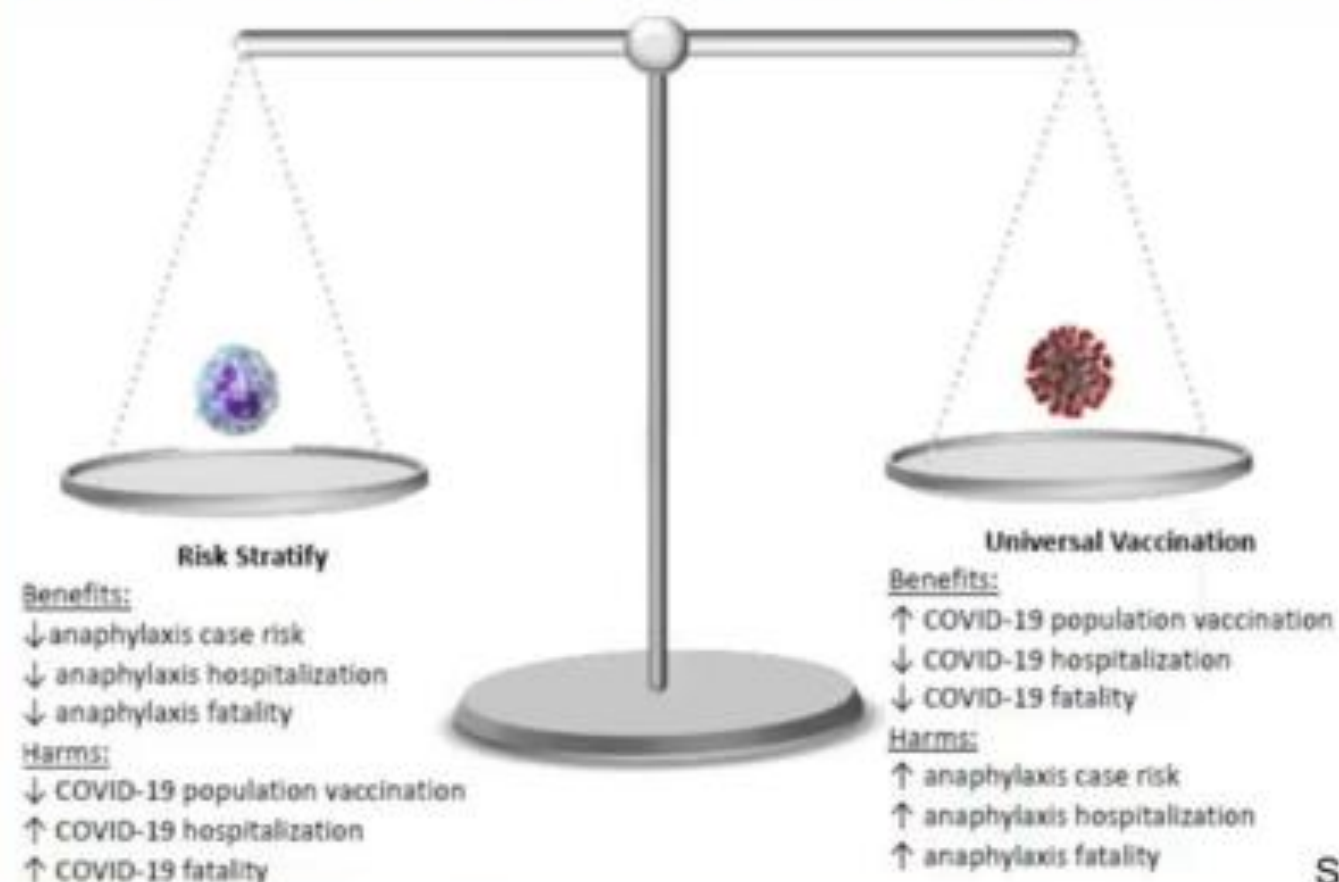
Arak medical university

- ❖ How vaccine act?
- ❖ Adverse reaction to vaccine
- ❖ Etiology reaction to vaccine
- ❖ Excipients of vaccine used in Iran
- ❖ Which allergic patients are at risk to get vaccine?



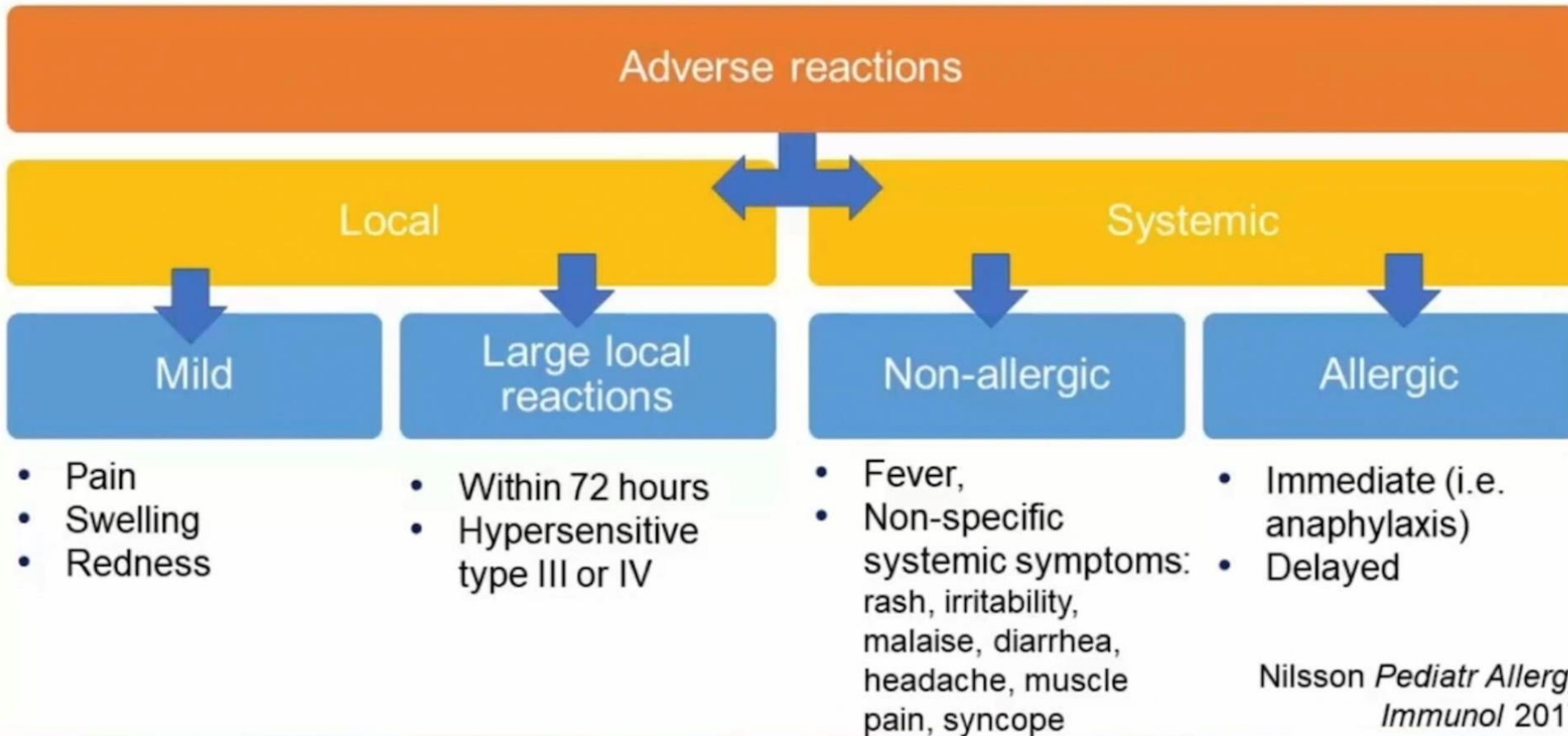


Vaccinate everyone or stratify by risk?



- When the risk of anaphylaxis exceeded **0.8%**, the risk-stratified approach to vaccination was the most cost-effective strategy

Adverse reactions to vaccines



Anaphylaxis is rare but large local reaction is common

large local reactions

- Begin **hours** after the vaccination or even the **next day**
- The skin at the site of vaccination can become sore, swollen, red, and painful.
- The symptoms can last several days.
- **Not an allergic reaction** to the vaccine, there is **no risk** of an allergic reaction with the next vaccination, and an allergist consultation is not necessary

- **Atopic** individuals also appear to be over-represented in those suffering anaphylaxes to the COVID mRNA vaccines
- **Stress** : *Corticotropin releasing hormone (CRH)* and *neurotensin* are secreted by neurons in response to acute and chronic stress and they lower the threshold for mast cell degranulation. Substance P is also released by neurons adjacent to mast cells and leads to degranulation during a stress response
- use of **opiates or non-steroidal anti inflammatory drugs** may enhance mast cell activation and/or vascular responsiveness

ETIOLOGY OF ALLERGIC REACTIONS TO VACCINES

- polyethylene glycol (PEG) and polysorbate are used to improve *water solubility* in drugs and vaccines
- PEG itself has *not* previously been used in a vaccine
- polysorbate has been identified as a *rare cause* of allergic reactions to vaccines
- First-dose reactions to vaccines containing polysorbates may have occurred because of previous sensitization from polysorbate 80.

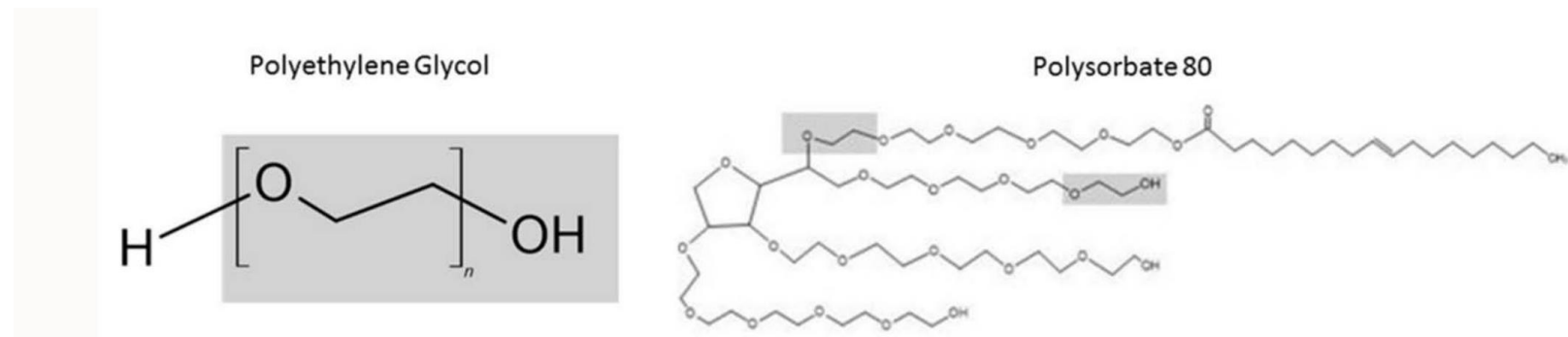


FIGURE 1. Chemical structure and similarities between PEG and polysorbate 80.

Polyethylene Glycol (PEG)

Water-soluble ingredient in a wide variety of commercial products including some vaccines and more than 1000 FDA approved medications

The primary ingredient in commonly used

- Colonoscopy preparations (Golytely)
- Constipation treatment (Miralax)
- Intravenous medications such as PEGylated medications

- Also used in ultrasound gel and injectable steroid injections such as methylprednisolone acetate

- Reactions to PEG are exceedingly **rare**, but anaphylaxis has been reported

Polysorbate

Structurally similar to PEG with polyether domains

- **Clinical cross-reactivity**
- Excipient in a multitude of medical preparations (eg, vitamin oils, vaccines, and anticancer agents), creams, ointments, lotions, and medication tablets
- At least 70% of *injectable biological agents and mAb* treatments contain a polysorbate, most typically polysorbate 80

AstraZeneca and Johnson & Johnson COVID-19 vaccines contain the excipient polysorbate 80

Vaccine used in IRAN and their excipients

AstraZeneca
vaccine

EDTA, L-histine, magnesium chloride hexahydrate, polysorbate80, sodium chloride, sucrose, ethanol

Sputnik v
vaccine

_Hydroxymethyl aminomethan, sodium chloride, disodium EDTA, polysorbate80, ethanol

Sino pharm
vaccine

Disodium hydrogen phosphate, sodium chloride, sodium dihydrogen phosphate, aluminum hydroxide

Covo
barekat
vaccine

Aluminium hydroxide, phosphate

Which medications have PEG and polysorbate?



TABLE II. Polysorbate and PEG excipients in select vaccines¹²

Excipient	Vaccine type	Vaccine	Amount per
Polysorbate 20	Influenza	Flublok&Flublock quad	≤27.5 µg (Twee
Polysorbate 20	Hepatitis A	Havrix	0.05 mg/mL
Polysorbate 20	Hepatitis A&B	Twinrix	Unknown
Polysorbate 20*	SARS-CoV-2 (Sanofi)		
Polysorbate 80	Tdap	Boostrix	≤100 µg (Twee
Polysorbate 80	Influenza	Fluad	1.175 mg
Polysorbate 80	Influenza	Fluarix quad	≤0.055 mg (Tw
Polysorbate 80	Influenza	Flucelvax quad	≤1500 µg (Twe
Polysorbate 80	Influenza	Flulaval Quad	≤887 µg
Polysorbate 80	HPV	Gardasil and Gardasil -9	50 µg
Polysorbate 80	Hepatitis B	Heplisav-B	0.1 mg/mL
Polysorbate 80	DTaP	Infanrix	≤100 µg (Twee
Polysorbate 80	Japanese encephalitis	JE-Vax	<0.0007%
Polysorbate 80	DTaP + IPV	Kinrix	≤100 µg (Twee
Polysorbate 80	DTaP + HepB + IPV	Pediarix	≤100 µg (Twee
Polysorbate 80	Pneumococcal 13-valent	Prevnar 13	100 µg
Polysorbate 80	DTaP + IPV	Quadracel	10 ppm
Polysorbate 80	Rotavirus	RotaTeq	?
Polysorbate 80	Zoster	Shingrix	0.08 mg
Polysorbate 80	Meningococcal group B	Trumenba	0.018 mg
Polysorbate 80	DTaP + IPV + HepB + Hib	Vaxelis	<0.0056%
Polysorbate 80*	SARS-CoV-2 (AstraZeneca)		
	SARS-CoV-2 (Johnson & Johnson)		
PEG2000	SARS-CoV-2 (Moderna)		
	SARS-CoV-2 (Pfizer)		

vaccines

TABLE IV. Common injectable medications containing polysorbate

Drug class	Generic name (brand name)	Polysorbate
Antiarrhythmic	Amiodarone hydrochloride (generics only)	Polysorbate 80
Antidiabetic	Exenatide (Bydureon Bcise)	Polysorbate 20
	Insuline glargine (Lantus, Semglee)	Polysorbate 20
	→ Insuline glulisine (Apidra)	Polysorbate 20
	Dulaglutide (Trulicity)	Polysorbate 80
Antidote	Hyaluronidase (Hylenex Recombinant)	Polysorbate 80
Antifungal	Anidulafungin (Eraxis)	Polysorbate 80
Anti-inflammatory	Interferon beta 1a (Avonex, Plegridy)	Polysorbate 20
	→ Omalizumab (Xolair)	Polysorbate 20
Antineoplastic	Ofatumumab (Kesimpta)	Polysorbate 80
	Siltuximab (Sylvant)	Polysorbate 80
Antipsychotic	Paliperidone palmitate (Invega Trinza, Invega Sustenna)	Polysorbate 20
	Aripiprazole lauroxil (Aristada)	Polysorbate 20
Antiretroviral	Ibalizumab (Trogarzo)	Polysorbate 80
Antipsoriatic	Adalimumab (Humira, Imraldi)	Polysorbate 20 (Imraldi)/ Polysorbate 80 (Humira)
	Golimumab (Simponi)	Polysorbate 80
	Guselkumab (Tremfya)	Polysorbate 80
	Infliximab - dyyb (Inflectra, Remicade, Renflexis)	Polysorbate 80
	Ustekinumab (Stelara)	Polysorbate 80
Antiviral	Interferon alfa-2b (Intron A)	Polysorbate 80
Biological response modifier	Interferon gamma-1b (Actimmune)	Polysorbate 20
Cancer treatment	Ado-trastuzumab emtansine (Kadcyla)	Polysorbate 20
	Atezolizumab (Tecentriq)	Polysorbate 20
	Avelumab (Bavencio)	Polysorbate 20
	Bevacizumab (Avastin, Zirabev)	Polysorbate 20

injectable

Drug class	Generic name (brand name)	Polysorbate
	Ramucirumab (Cyramza)	Polysorbate 80
	Rituximab (Truxima, Rituxan, Ruxience)	Polysorbate 80
	Rituximab and hyaluronidase (Rituxan Hycela)	Polysorbate 80
	Temsirolimus (Torisel)	Polysorbate 80
	Temozolomide (Temodar)	Polysorbate 80
Contraceptive	Medroxyprogesterone acetate (Depo-Provera, Depo-Provera CI, Depo-subQ provera 104)	Polysorbate 80
Corticosteroid	Methylprednisolone acetate (Depo-Medrol)	Polysorbate 80
	Triamcinolone acetonide (Aristocort Forte, Aristospan, Kenalog-40, Kenalog-10, Protherix, Triesence, Triloan Suik, Triloan II Suik, Zilretta)	Polysorbate 80
Diagnostic	Sincalide (Kinevac)	Polysorbate 20
	Tuberculin purified protein derivative (Aplisol, Tubersol)	Polysorbate 80
Disease-modifying antirheumatic drug	Anakinra (Kineret)	Polysorbate 80
	Tocilizumab (Actemra)	Polysorbate 80
Enzyme	Velaglucerase alfa (Vpriv)	Polysorbate 20
	Imiglucerase (Cerezyme)	Polysorbate 80
	Taliglucerase alfa (Elelyso)	Polysorbate 80
Erythoid maturation agent	Luspatercept (Reblozyl)	Polysorbate 80
Factor Xa inhibitor antidote	Coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa)	Polysorbate 80
Gonadotropin	Follitropin (Menopur, Follistim)	Polysorbate 20
Growth hormone analog	Somatropin (Nutropin AQ Nuspin 5)	Polysorbate 20
Hematopoietic growth factor	Erythropoietin (Retacrit)	Polysorbate 20
	Pegfilgrastim (Fulphila, Neulasta, Nyvepria, Udenyca)	Polysorbate 20
	Romiplostim (Nplate)	Polysorbate 20
	Darbepoetin alfa (Aranesp)	Polysorbate 80
	Filgrastim (Neupogen, Nivestym, Granix, Zarxio)	Polysorbate 80
Hepatitis B/Hepatitis C agent	Peginterferon (Pegasys Pegintron)	Polysorbate 80

Hemostatic	Vitamin K (Phytonadione)	Polysorbate 80
Immune globulin	Hepatitis B immune globulin (HepaGam B, Nabi-HB)	Polysorbate 80
	Rho (d) immune globulin (WinRho)	Polysorbate 80
Immunomodulator	Interferon beta-1a (Avonex, Avonex Pen)	Polysorbate 20
	Emapalumab (Gamifant)	Polysorbate 80
Immunosuppressant	Mycophenolate mofetil (Cellcept IV)	Polysorbate 80
Inflammatory bowel disease agent	Vedolizumab (Entyvio)	Polysorbate 80
Interleukin inhibitor	Sarilumab (Kevzara)	Polysorbate 20
	Dupilumab (Dupixent)	Polysorbate 80
	Mepolizumab (Nucala)	Polysorbate 80
	Secukinumab (Cosentyx)	Polysorbate 80
	Tildrakizumab -asmn (Ilumya)	Polysorbate 80
	Lanadelumab (Takhzyro)	Polysorbate 80
Kallikrein inhibitor	Lanadelumab (Takhzyro)	Polysorbate 80
Leptin analog	Metreleptin (Myalept)	Polysorbate 20
Macular degeneration agent	Aflibercept (Eylea)	Polysorbate 20
	Ranibizumab (Lucentis)	Polysorbate 20
	Brolucizumab (Beovu)	Polysorbate 80
mAb treatment	Ocrelizumab (Ocrevus)	Polysorbate 20
	Remdesivir (Veklury)	Polysorbate 20
	Romosozumab (Evenity)	Polysorbate 20
	Teprotumumab (Tepezza)	Polysorbate 20
	Atoltivimab/maftivimab/odesivimab-ebgn (Inmazole)	Polysorbate 80
	Bamlanivimab	Polysorbate 80
	Burosumab (Crysvita)	Polysorbate 80
	Canakinumab (Ilaris)	Polysorbate 80

Drug class	Generic name (brand name)	Polysorb
	Casirivimab/Imdevimab	Polysorbate 80
	Eptinezumab (Vyapti)	Polysorbate 80
	Fremanezumab (Ajovy)	Polysorbate 80
	Inebilizumab (Uplizna)	Polysorbate 80
	Raxibacumab	Polysorbate 80
Multiple sclerosis treatment	Natalizumab (Tysabri)	Polysorbate 80
Muscle relaxant	Dantrolene sodium (Dantrium, Ryanodex)	Polysorbate 80
P-selectin inhibitor	Crizanlizumab (Adakveo)	Polysorbate 80
Proprotein convertase subtilisin kexin type 9 inhibitor	Alirocumab (Praluent)	Polysorbate 20
	Evolocumab (Repatha)	Polysorbate 80
Rheumatologic	Belimumab (Benlysta)	Polysorbate 80
Thrombolytic	Tenecteplase (Tnkase)	Polysorbate 20
	Alteplase (Cathflo Activase)	Polysorbate 80
	Retepase (Retavase)	Polysorbate 80
Vitamin infusion	Calcitriol (Calcijex, Rocaltrol)	Polysorbate 20
	Doxercalciferol (Hectorol)	Polysorbate 20
	Vitamins A, B1, B2, B6, C, D3, E, K (Infuvite)	Polysorbate 80

EAACI statement: prescreening

Questions to ask patients ...

Did you have a severe reaction (dyspnea, dizziness, loss of consciousness) after vaccination, drugs, insect stings, or foods?

Have you been prescribed an epinephrine autoinjector?

Do you suffer from any allergies or allergy-like diseases?

Do you have asthma? Which medications are you using? When did you last have symptoms? When did you last see a doctor?

Which medications are you on?

Consider ...

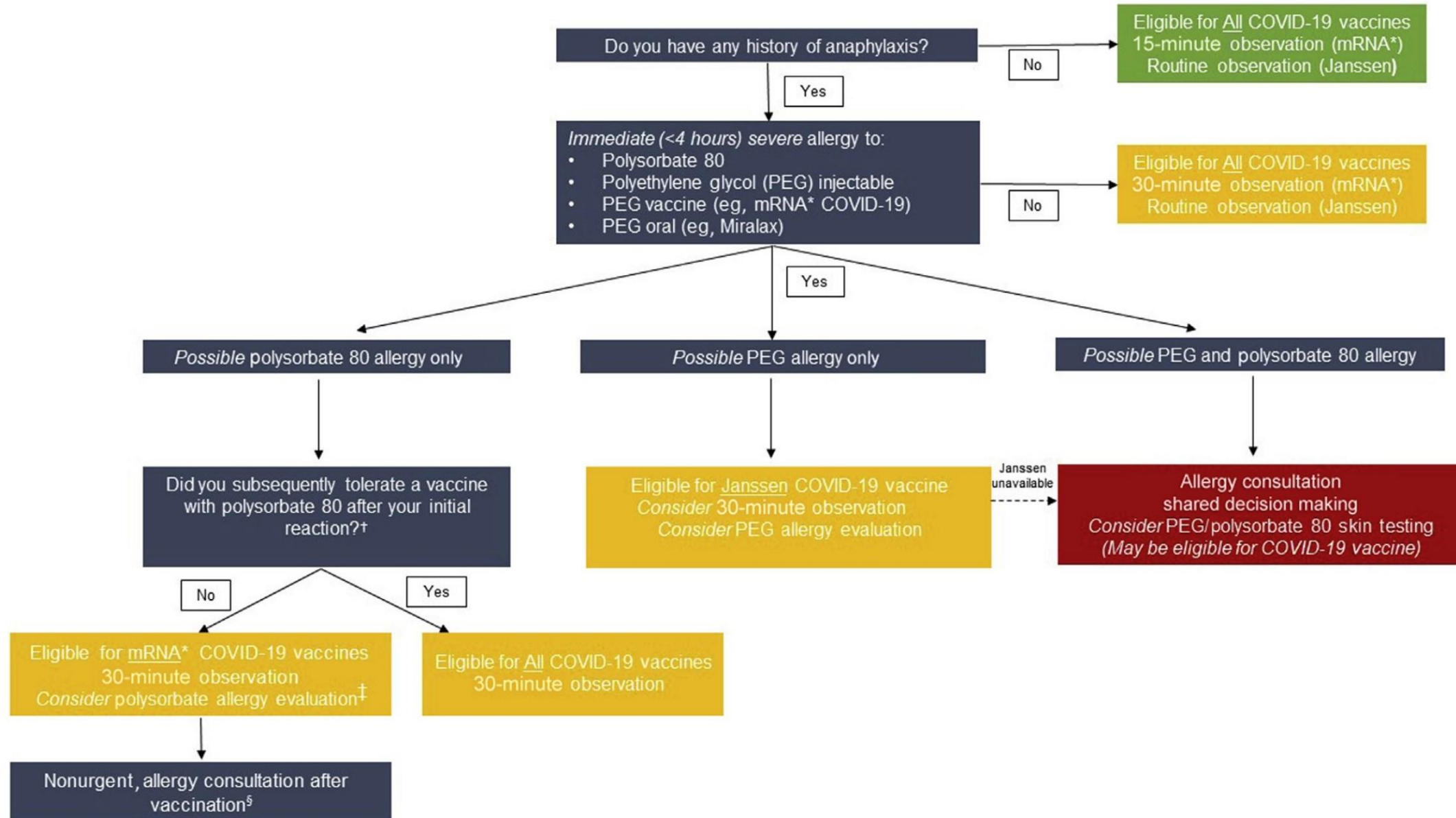
Observe 30 minutes

Observe 30 minutes

If latex: use latex free gloves
If component of vaccine: allergist referral
If mast cell disorders: hospital setting
vaccination

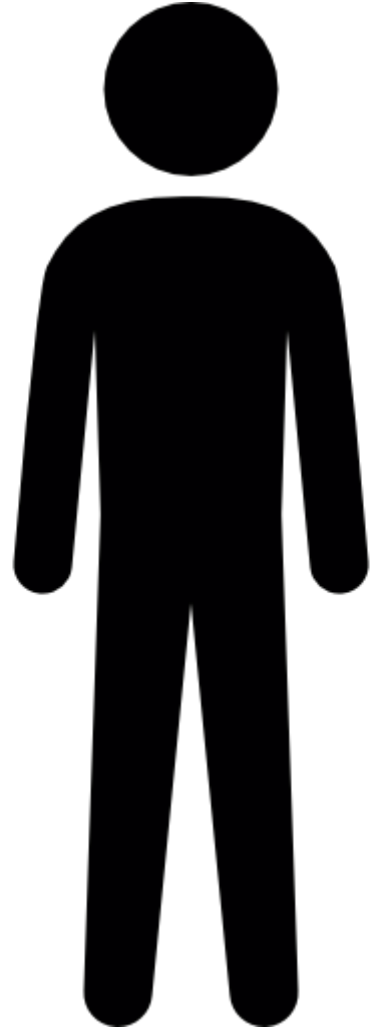
If uncontrolled asthma: hospital setting
vaccination

If beta-blockers, observe 30 minutes



Example 4

- 42 year old male
- History of anaphylactic reaction to influenza vaccine
- She is candidate for receiving Astra Zeneca vaccine
- Is it safe?



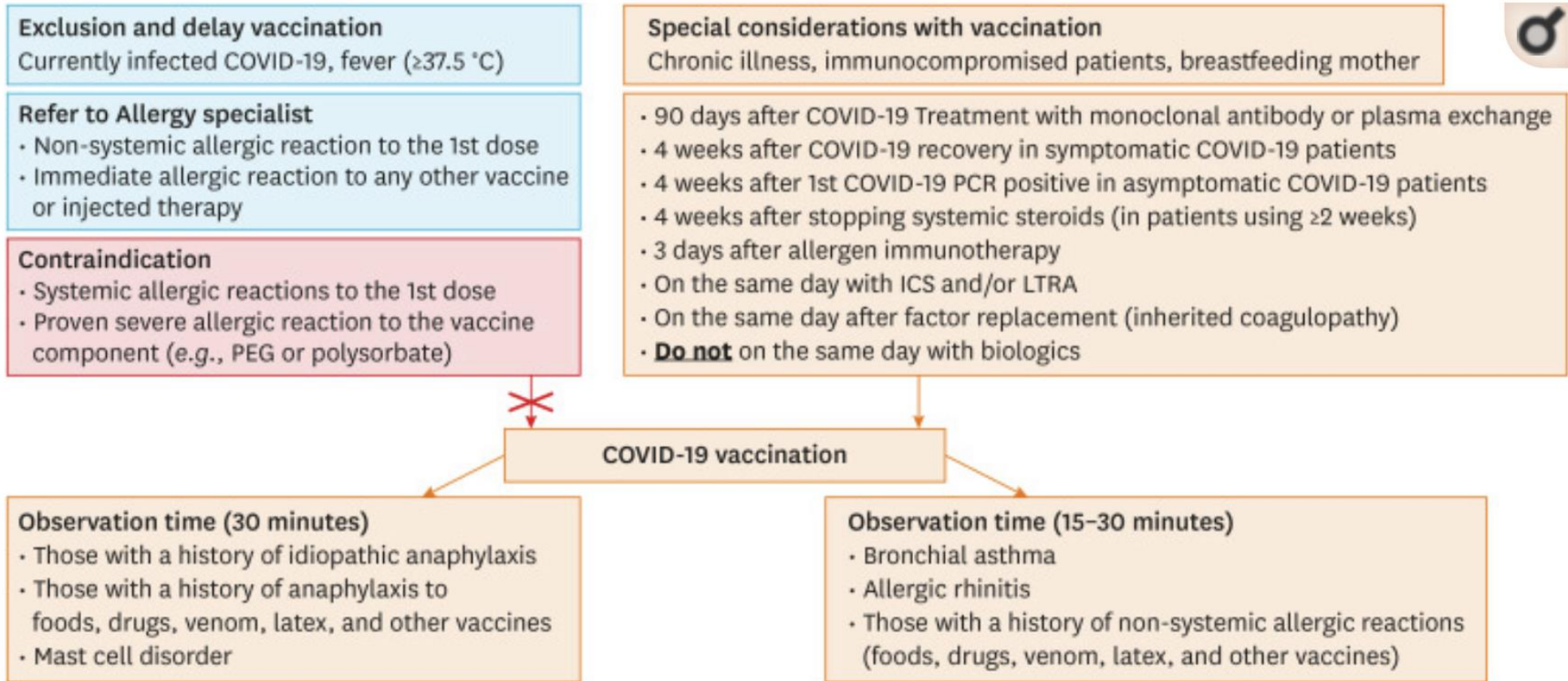


Astra Zeneca AND Spotnik V



Sinopharm AND Covo barekat

To summarise



Summary of contraindication and recommended observation time by medical history.

THANKS YOUR ATTENTION

