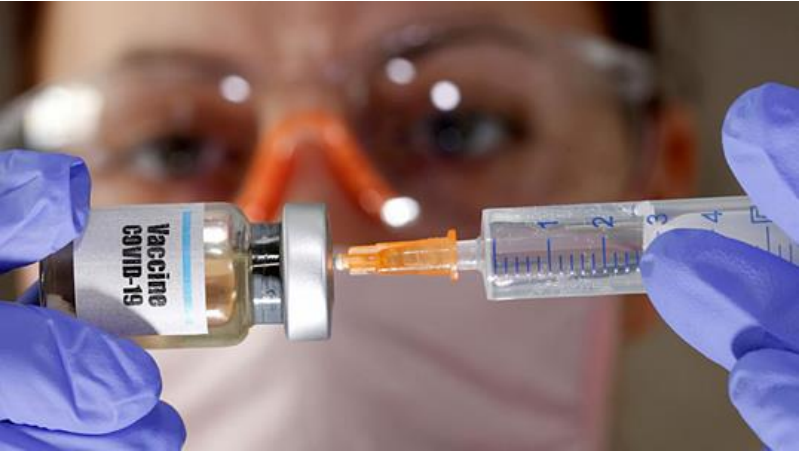


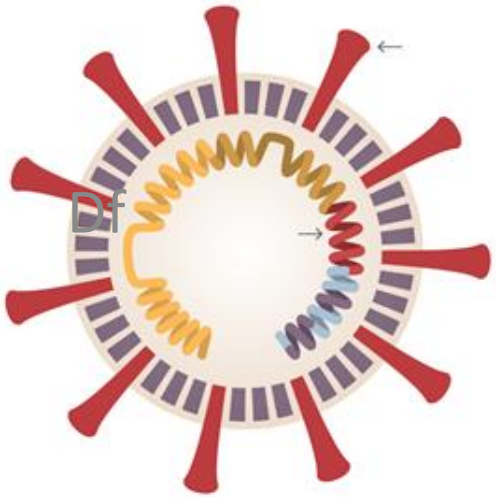
COVID-19 Vaccination Among High risk Groups

Mohsen Shati MD. MPH. PhD.

Epidemiologist

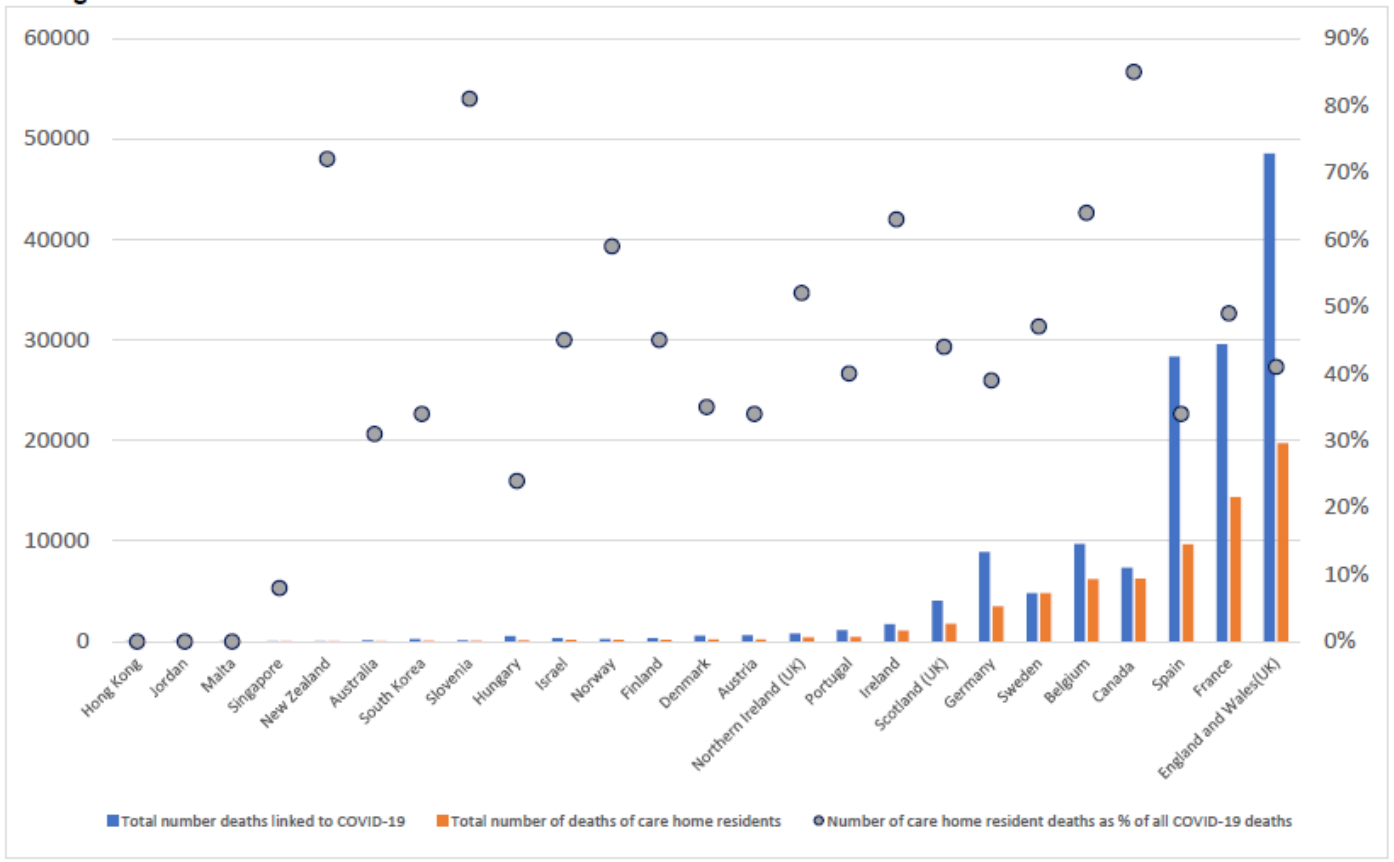
Some Statistics

COVID-19
in
High risk populations



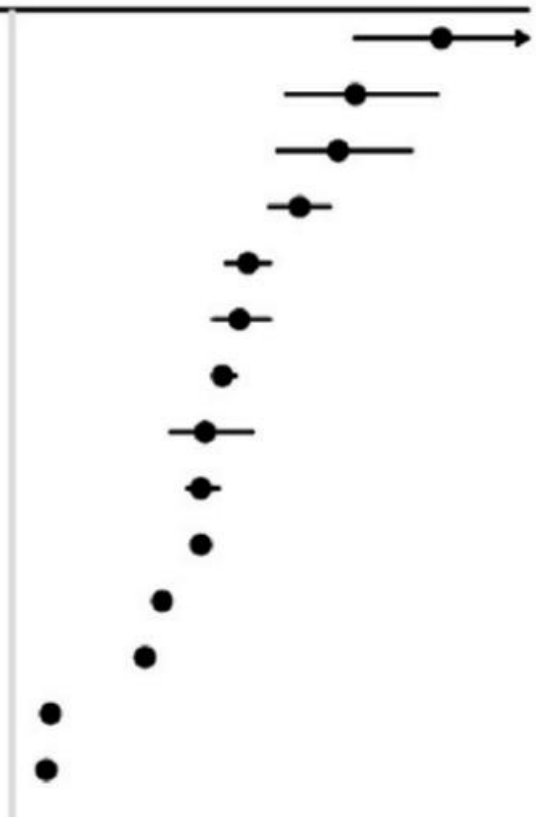
Mortality related to COVID-19 in LTCFs

Figure 4. Total number of deaths linked to COVID-19 in the total population compared to the number of deaths among care home residents

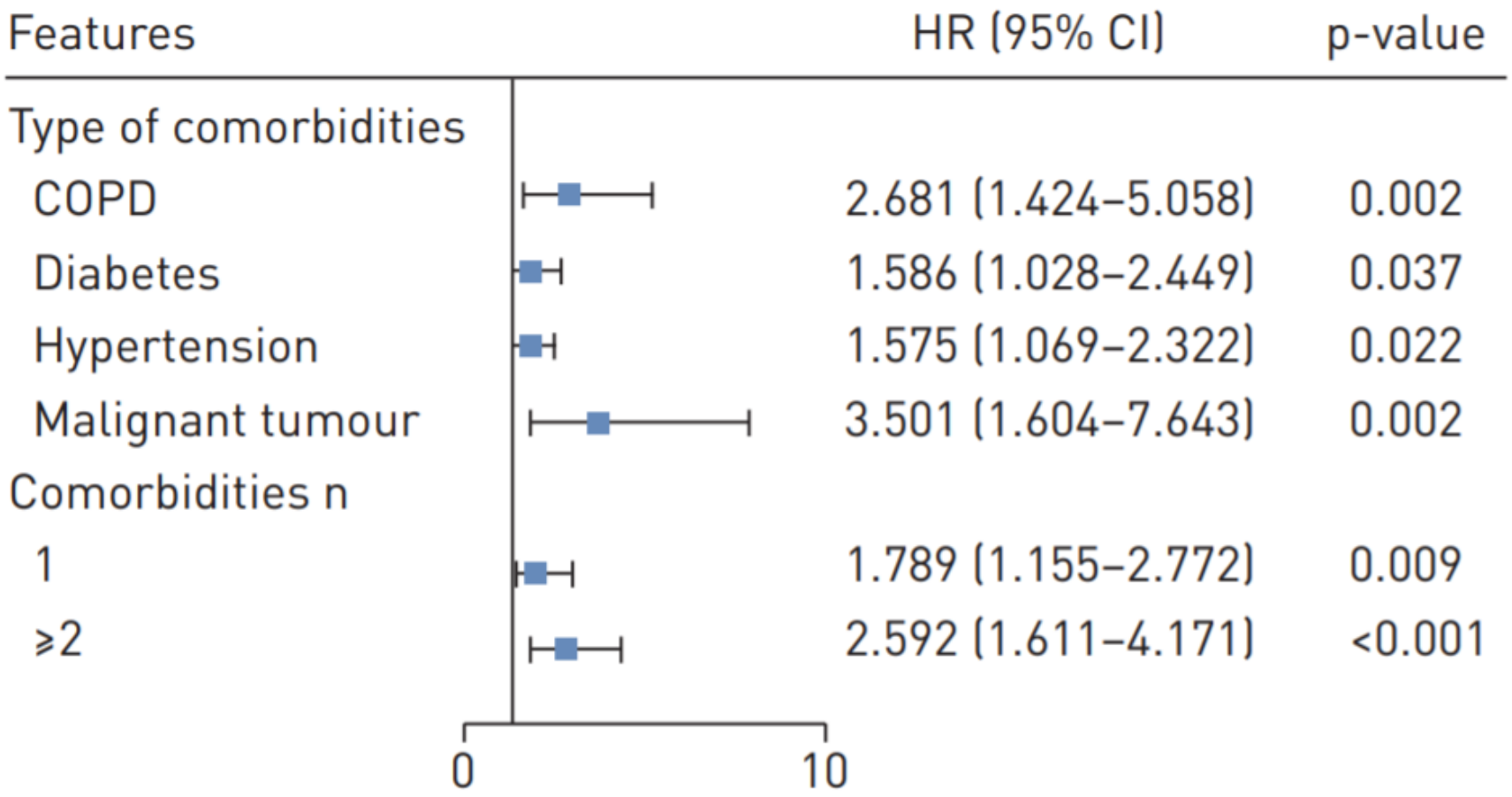


- Two countries reported that over 80% of all the COVID-19 were deaths are among long-term care residents
- 11 countries report 50% or more of all deaths from COVID-19 are from long-term care facility residents

Location Countries	Percentage of population <65 years in the general population (%)	Relative risk of COVID−19 death for those >=65 years versus those <65 years	95% CI lower	95% CI upper
Canada	82.35%	100	80	122
Switzerland	81.16%	80	64	99
Ireland	85.78%	76	62	93
Netherlands	80.39%	67	60	74
Belgium	80.99%	55	50	60
Sweden	79.80%	53	47	60
Spain	80.35%	49	47	52
Portugal	77.64%	45	37	56
Germany	78.44%	44	41	48
Italy	76.99%	44	42	46
UK	81.49%	35	34	36
France	79.61%	31	29	32
India	93.62% (90.13%)	9	9	10
Mexico	92.58%	8	7	8



Hazard ratio for the risk factors associated with admission to ICU, invasive ventilation or death




VACCINE
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VACCINE
COVID-19
VACCINE

Name of vaccine	Company/organization of origin	Type	Trial phase	Efficacy[a]	Safety	Representation of participants with DM
BNT162b2 [21]	Pfizer-BioNTech USA, Germany	Lipid nanoparticle—formulated, nucleoside-mRNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 spike glycoprotein.	2/3	95%	Short-term, mild-to-moderate pain at the injection site, fatigue, and headache. Incidence of serious adverse events low and similar in vaccine and placebo groups.	Not mentioned
mRNA-1273 [22]	Moderna and the Vaccine Research Center at NIAID USA	Lipid-nanoparticle-encapsulated mRNA vaccine expressing the prefusion-stabilized SARS-CoV-2 spike glycoprotein	3	94.1%	Transient local and systemic reactions, incidence of serious adverse events low and similar in vaccine and placebo groups.	Yes (n = 2875)
AZD1222 (ChAdOx1) [23]	Oxford-AstraZeneca Jenner Institute, University of Oxford England	Recombinant, replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 spike glycoprotein antigen.	1/2/3	70.4%	Good safety profile with serious adverse events and adverse events of special interest balanced across the study arms.	Yes (n = 270)
Sputnik V vaccine (Gam-COVID-Vac) [24]	Gamaleya Research Institute of Epidemiology and Microbiology Russia	Combined vector vaccine, based on recombinant adenovirus (rAd) type 26 and rAd type 5—both of which carry the gene for SARS-CoV-2 spike glycoprotein.	3	91.6%	Common adverse events were flu-like illness, injection site reactions, headache, and asthenia. None of the serious adverse events were considered associated with vaccination.	Yes (n = 4922) [b]
NVX-CoV2373 [25]	Novavax, Inc. USA	Matrix-M1 adjuvant and recombinant SARS-CoV-2 nanoparticle vaccine, constructed from the full-length, wild-type SARS-CoV-2 spike glycoprotein	3	89.3%	Severe, serious, and medically attended adverse events occurred at low levels and balanced between vaccine and placebo groups.	NA

Name of vaccine	Company/organization of origin	Type	Trial phase	Efficacy[a]	Safety	Representation of participants with DM
CoronaVac [26]	Sinovac Biotech China	Inactivated vaccine candidate against COVID-19	3	50.65%–91.25%	NA	NA
JNJ-78436735 or Ad26.COV2.S [27]	Johnson & Johnson (Janssen Biotech, Inc.) USA	Recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector encoding a full-length and stabilized SARS-CoV-2 spike protein.	3	66%	No report of significant safety concerns. Overall fever rates were 9% and Grade 3 fever 0.2%. Overall serious adverse events reported were higher in participants who received placebo as compared to the active vaccine candidate.	Yes (n = 2764)
COVAXIN (BBV152) [c] [28]	Bharat Biotech India	Whole-virion inactivated SARS-CoV-2 vaccine formulated with a toll-like receptor 7/8 agonist molecule adsorbed to alum (Algel-IMDG) or alum (Algel).	1 [d]	NA	Common solicited adverse events were injection site pain, headache, fatigue, fever, and nausea or vomiting. All adverse events were mild or moderate. No significant differences were observed between the vaccinated and control groups.	NA
COVISHIELD (ChAdOx1) [c] [29]	Serum Institute India	Recombinant, replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARS-CoV-2 spike glycoprotein antigen with *technology transfer from Oxford/AstraZeneca.*	NA [e]	NA [e]	NA [e]	NA [e]

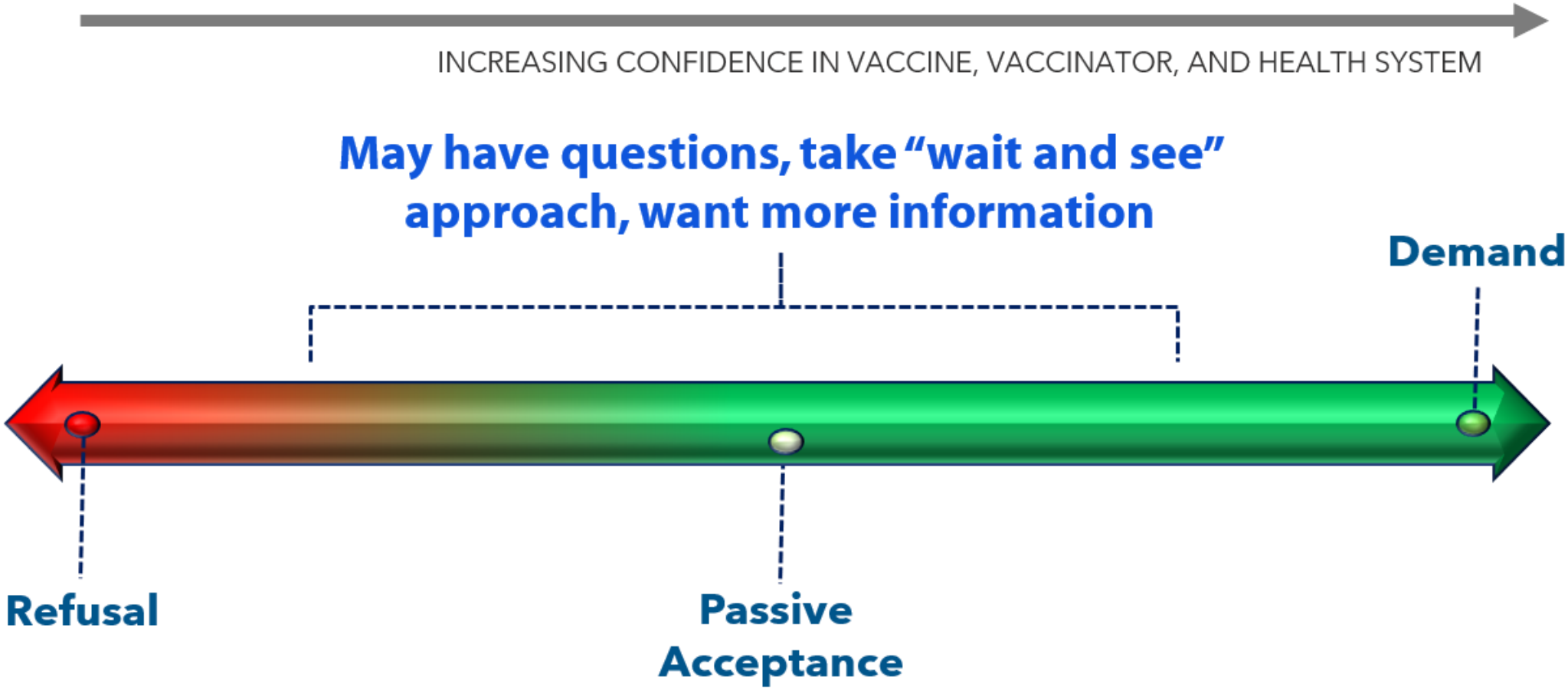
Experimental COVID-19 vaccines

Vaccine	Type	UK stockpile (doses ordered)	Main phase III inclusion criteria	Main phase III exclusion criteria	Comments
AstraZeneca AZD 1222	Modified adenovirus	100 M	Adults aged 18 or over	Significant other medical condition	Phase II trials in those aged 70-84 show good antibody response and low reactogenecity events. Phase III trial in UK and Brazil showed 70% efficacy
Novavax NVX-CoV2373	Protein adjuvant	60 M	Adults aged 18-84 yr	People aged 85+ Taking anticoagulants or anti-platelets Immunocompromised Chronic neurological diseases	Phase II trials in those aged 65-84 show good antibody response and low reactogenecity events. Phase III trial in UK ongoing—initial results expected Jan 2021
GSK/Sanofi	Protein adjuvant	60 M	Unpublished	Unpublished	Still in Phase I/II. Expected to enter Phase III in early 2021
Valneva VLA2001	Inactivated live virus	60 M	Unpublished	Unpublished	Still in Phase I/II. Expected to enter Phase III by start of 2021.
Pfizer/BioNTech BNT162	mRNA	40 M	Adults aged 18 or over at higher risk of COVID-19	Significant other medical or psychiatric illness	Phase III trial early results show >90% efficacy
Janssen Ad26.CoV2.S	Modified adenovirus	30 M	Adults aged 18 or over	Significant acute or chronic medical condition	Phase III trial ongoing—initial results expected Mar 2021
Moderna mRNA-1,273	mRNA	5 M	Adults aged 18 or over, medically stable	Immunosuppression	Phase III trial early results show 95% efficacy
Gamaleya GAM-COVID-VAC (Sputnik V)	Modified adenovirus	0	Adults aged 18 or over	Immunosuppression, neoplasms, chronic infections	Phase III trial early results on 20 positive cases suggest 92% efficacy
Cansino Ad5-nCoV	Modified adenovirus	0	Adults aged 18 or over at high risk of COVID-19	Immunosuppression, Any severe co-morbidity	Phase II data showed good antibody response after a single dose, but few over 55 s
Sinovac CoronaVac (two versions)	Inactivated live virus	0	Adults aged 18–59	Immunosuppression, poorly controlled chronic disease	Phase I/II study in older people yet to report

Estimated COVID-19 death during full cycle of the pandemic under different vaccination scenarios in Germany (NNT)

Population group	Infection Case Mortality Rate	Population 2019 Germany (million) (%)	Death according vaccine (1000)		Saved deaths (1000) (%)	Vaccine persons per saved death
			No	Yes		
Institutional frail elderly	25%	0.8 (1%)	120	30	90 (41%)	7
Other ≥75 y	2%	8.7 (10%)	104.4	26.1	78.3 (36%)	83
Other 65-74 y	1%	8.6 (10%)	51.6	12.9	38.7 (18%)	167
Upper-risk <65 y	0.2%	9.3 (11%)	11.2	2.8	8.4 (4%)	833
High-risk total	1.75%	27.4 (33%)	287.2	71.8	215.4 (99%)	95
Low-risk <65 y	0.01%	55.8 (67%)	3.3	0.8	2.5 (1%)	12,873
Total population	0.58%	83.2 (100)	290.5	72.6	217.9 (100%)	243

Willingness to accept a vaccine falls on a continuum



Most people are able to get the COVID-19 vaccine, once supplies allow for their priority group to be vaccinated. But, a few groups of people should not get the vaccine, and some others should consult with their doctor or follow special procedures.

People who should NOT get the COVID-19 vaccine

- Anyone with a previous severe or immediate allergic reaction (i.e., one that causes anaphylaxis or requires medical intervention) to a COVID-19 mRNA vaccine dose, a vaccine component, or polysorbate.
- Those younger than 18/15/12 years of age.
- People currently isolating or experiencing symptoms of COVID-19; these people can get vaccinated once they are finished isolation and their primary symptoms have resolved.

People who may get the vaccine after considering risks and benefits and/or consulting with their healthcare provider

- Individuals with a history of severe or immediate allergic reaction to any vaccine or injectable medication (These individuals should be observed for 30 minutes after receipt of the vaccine.)
- Pregnant women
- People with certain immune-compromising conditions
- Breastfeeding women
- People with coagulopathies or on anticoagulants
- People with some severe underlying diseases

People who should follow special procedures

- Someone with a history of severe or immediate allergic reaction (requiring medical intervention) to anything other than a vaccine or injectable medication can get the vaccine, but they should remain at the vaccination location for medical observation for 30 minutes after receipt of the vaccine.
- People who recently had COVID-19 and were treated with antibody-based therapies (e.g., monoclonal antibodies or convalescent plasma) should wait until 90 days after treatment to be vaccinated.
- People with a known COVID-19 exposure should wait until their quarantine is over before getting vaccinated
- People who got another vaccine (non-COVID-19 vaccine) should wait at least 14 days before getting COVID-19 vaccine. Likewise, if a person got the COVID-19 vaccine, they should wait at least 14 days before getting any other vaccines (non-COVID-19 vaccines).

High Risk Groups

Older adults resident in a care home

- there is clear evidence that those living in residential care homes for older adults have been disproportionately affected by COVID-19
- those living in care homes have a high risk of exposure to infection due to their close contact with staff (including bank staff) and other residents including those residents returning to the care home from hospital
- the closed setting of the care home also increases the risk of outbreaks occurring as any asymptomatic residents and staff could be potential reservoirs for on-going transmission
- given the increased risk of outbreaks, morbidity and mortality in these closed settings, older adults in care homes are considered to be at very high risk
- This group should be the highest priority for vaccination
- vaccination of residents and staff at the same time is considered to be a highly efficient strategy within a mass vaccination programme with the greatest potential impact

Older adults

- older adults are considered to be at very high risk if they develop COVID-19 infection
- current evidence strongly indicates that the single greatest risk of mortality from COVID-19 is increasing age and that the risk increases exponentially with age
- disease severity, risk of hospitalisation and mortality increase from age 50 upwards, with the highest risk in those aged 80 years and above
- data indicate that the absolute risk of mortality is higher in those over 65 years than that seen in the majority of younger adults with an underlying health condition

Groups with underlying health conditions

•As well as age, other risk factors have been identified that place individuals at risk of serious disease or death from COVID-19. These include groups with certain underlying health conditions and may include people who have:

- chronic (long-term) respiratory disease
- chronic heart disease
- chronic kidney disease
- chronic liver disease
- chronic neurological disease
- diabetes
- a weakened immune system due to disease or treatment
- asplenia or dysfunction of the spleen
- morbid obesity (defined as BMI of 40 and above)
- severe mental illness

•Detailed information giving examples of conditions in each of the clinical risk groups which would make individuals aged 16 years and over eligible for vaccination is provided in the COVID-19 Green Book chapter.

Can someone who is pregnant or breastfeeding get a COVID-19 vaccine?

Yes.

- The American College of Obstetricians and Gynecologists recommends that COVID-19 vaccines be offered to pregnant and breastfeeding individuals.

- Right now, we don’t have much data about whether the COVID-19 vaccines are safe in people who are pregnant or breastfeeding. So far, scientists haven’t found any safety concerns for pregnant people who were vaccinated, or for their babies.

- We do know that getting sick with COVID-19 during pregnancy can increase the risk of severe illness and might increase the risk of outcomes like preterm birth.

- Getting vaccinated is a personal choice for people who are pregnant or breastfeeding. A discussion with your healthcare provider might help you feel comfortable but you aren’t required to get their approval before getting vaccinated.

Are the COVID-19 vaccines safe for children?

- The Pfizer vaccine is authorized for people ages 12 and older.
- The Moderna and Johnson & Johnson vaccines are authorized for people ages 18 and older.
- Younger children and adolescents should not get the COVID-19 vaccine right now.

Post authorisation surveillance

•On-going studies of vaccines continue after the vaccine has been authorised for use. These studies aim to assess long term efficacy and to detect any rare adverse effects because in real life administration, compared to pre-licensure trials, there will be:

- some variability in preparation of the vaccine as vaccines will come from different batches
- possible variability in stability and storage, for example the cold chain may not be as rigidly maintained in practice as it was in a clinical trial
- use of the vaccines in different groups than in pre-authorisation studies, for example they will be given to people with underlying medical conditions who would not necessarily have been included in a pre-licensure/pre-authorisation clinical trial
- mutations in the virus which may result in the vaccine being less effective

خلاصه بحث:

- با وجود گزارش ۷۱ مورد مرگ در سالمندان دریافت‌کننده واکسن Pfizer/BioNTec، شامل ۲۳ مورد در نروژ، ۱۶ مورد در انگلستان و ۱۲ مورد در آلمان، باید توجه داشت که تمامی این موارد در سالمندان بسیار پیر و مبتلا به بیماری‌های زمینه‌ای روی داده است.
- ۳۵ درصد آن‌ها بالای ۹۰ سال، ۴۶ درصد بالای ۸۰ سال و تقریبا تمامی آن‌ها بالای ۷۰ سال سن داشته‌اند.
- در سالمندان به دلیل میزان بالای Frailty، درصد قابل توجه مرگ خودبه‌خودی قابل انتظار است.
- از این رو، انتساب مستقیم این موارد مرگ به عارضه ناشی از واکسن بسیار دشوار بوده و نیاز به ارزیابی‌های تکمیلی دارد که در دست انجام است.
- نسبت وقوع DVT در افراد واکسینه با واکسن آسترازنکا نیز یک نفر در 250 هزار نفر بوده که عمدتا در سنین قبل از سالمندی و زنان بوده.

معیارهای منع مطلق واکسیناسیون بر اساس شواهد موجود :

۱- افراد دارای سابقه آلرژی شدید به سایر واکسن ها یا افرادی که سابقه شوک آنافیلاکسی یا راکسیون های دارویی شدید داشته اند.

۲- ابتلا به بیماری کرونا در طی ۱۵ روز گذشته

۳- داشتن بیماری تب دار / بیماری حاد

۳- افرادی که در انتهای زندگی هستند و امید به زندگی کمتر از چند هفته دارند.

۴- عدم رضایت فرد به انجام واکسیناسیون

موارد توصیه به احتیاط بیشتر در تصمیم گیری انجام واکسیناسیون:

۱- بیماری مزمن کبدی پیشرفته، مبتلایان به سیروز پیشرفته و دارای آسیت
۲- ابتلا به بیماریهای کلیوی انتهایی (کراتینین بالاتر از ۲ یا فرد در حال حاضر دیالیز می شود)
۳- دیابت کنترل نشده (هموگلوبین A1Cبالاتر از 8.5 ٪)
۴- اختلال عملکرد تیروئید شدید
۵- اختلالات خونی مانند هموفیلی یا اختلالات انعقادی شدید
۶- صرع کنترل نشده و سایر بیماریهای اعصاب مرکزی مثل ام اس و یا سابقه سکته مغزی در طی شش ماه اخیر
۷- بیماریهای عروق کرونر کنترل نشده (آنژین صدری پایدار و ناپایدار)، میوکاردیت، اندوکاردیت و یا پریکاردیت حاد.
۸- بیماران مبتلا به بیماریهای خودایمنی مانند بیماران مبتلا به لوپوس فعال
۹- مبتلایان به سرطان های بدخیم انتهایی (Solidو سرطان های خون)
۱۰- سالمندان Frail

با توجه به:

1. **شیوع بالای فاکتورهای خطر بروز بیماری کوید در این افراد**
2. **شیوع بالای موارد احتیاط تزریق واکسن**
3. **در دست نبودن شواهد کافی از** Safety **واکسن در این افراد بدلیل** Exclude **کردن این گروه در اکثر کارآزمائیها**

و به دلیل:

شانس بسیار بالاتر مرگ و میر در این گروه نسبت به سایرین، به نظر می‌رسد فواید مورد انتظار واکسیناسیون، به مراتب بیش از خطرات آن است.

VACCINES ARE THE ONLY WAY TO CONTROL THE COVID-19 PANDEMIC

- Everyone has to do their part and get vaccinated to get back to a normal life