World Health Organization

Evidence Assessment: mRNA-1273 COVID-19 vaccine

FOR SAGE RECOMMENDATION

Prepared by the SAGE Working Group on COVID-19 vaccines

EVIDENCE ASSESSMENT: mRNA-1273 COVID-19 vaccine

Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Population

- Adults (18-64 years)
- Older adults (≥65 years)
- Individuals with comorbidities or health states that increase risk for severe COVID-19

Intervention

- mRNA-1273 COVID-19 vaccine (2 doses, day 0 and 28)

Comparison

- Placebo/active control

Outcomes

- Efficacy against (PCR confirmed) COVID-19 or severe COVID-19, any adverse event, serious adverse events, systemic and local adverse events

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Evidence retrieval

- Based on WHO and Cochrane living mapping and living systematic review of Covid-19 trials (www.covid-nma.com/vaccines)

Retrieved evidence

Majority of data considered for policy recommendations on mRNA-1273 COVID-19 vaccine are published in:

- Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. Baden L.R., El Sahly B., Kotloff K., et al. N Engl J Med. Dec 2020. DOI: 10.1056/NEJMoa2035389
- Vaccines and Related Biological Products Advisory Committee Meeting December 17, 2020 FDA Briefing Document Moderna COVID-19 Vaccine (www.fda.gov/media/144434/download)
- An mRNA Vaccine against SARS-CoV-2 - Preliminary Report. Jackson LA., Anderson EJ., Rouphael NG., et al. N Engl J Med 2020 Nov 12;383(20):1920-31
- Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. Anderson EJ., Rouphael NG., Widge AT., et al. N Engl J Med 2020 Dec 17;383(25):2427-38

Quality assessment

- Baden L.R., et al. N Engl J Med. Dec 2020.

Type of bias	Randomization	Deviations from intervention	Missing outcome data	Measurement of the outcome	Selection of the reported results	**Overall risk of bias**
Working Group judgment	Low	Low*	Low	Low	Low	**LOW**

* Risk assessed to be low for outcomes: Mortality. Local adverse events. Systemic adverse events. Unsolicited adverse events. Withdrawals due to adverse events. Serious adverse events.

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World Health Organization

Strategic Advisory Group of Experts (SAGE) on Immunization Evidence to recommendations framework[i]

Question: **Population:** **Intervention:** **Comparison(s):** **Outcome:**							
Background:							
	CRITERIA	**JUDGEMENTS**				**RESEARCH EVIDENCE**	**ADDITIONAL INFORMATION**
PROBLEM	Is the problem a public health priority?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies by setting* ☐		
BENEFITS & HARMS OF THE OPTIONS	Benefits of the intervention Are the desirable anticipated effects large?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies* ☐		

Questions which were considered in SAGE evidence-to-recommendation tables:

1. Should mRNA-1273 vaccine be administered to adults (18-64 years) to prevent COVID-19?

2. Should mRNA-1273 vaccine be administered to older adults (≥65 years) to prevent COVID-19?

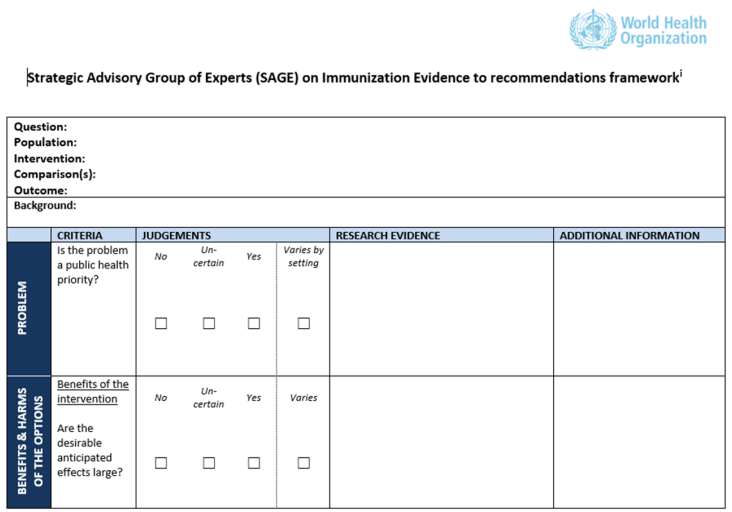
3. Should mRNA-1273 vaccine be administered to individuals with comorbidities or health states that increase risk for severe COVID-19 to prevent COVID-19?

EVIDENCE ASSESSMENT: mRNA-1273 COVID-19 vaccine

Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Criteria the SAGE Working Group on COVID-19 vaccines considered:

- Problem statement
- Benefits and Harms
- Values and Preferences
- Resource use
- Equity
- Acceptability
- Feasibility



World Health Organization

Strategic Advisory Group of Experts (SAGE) on Immunization Evidence to recommendations framework[i]

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Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

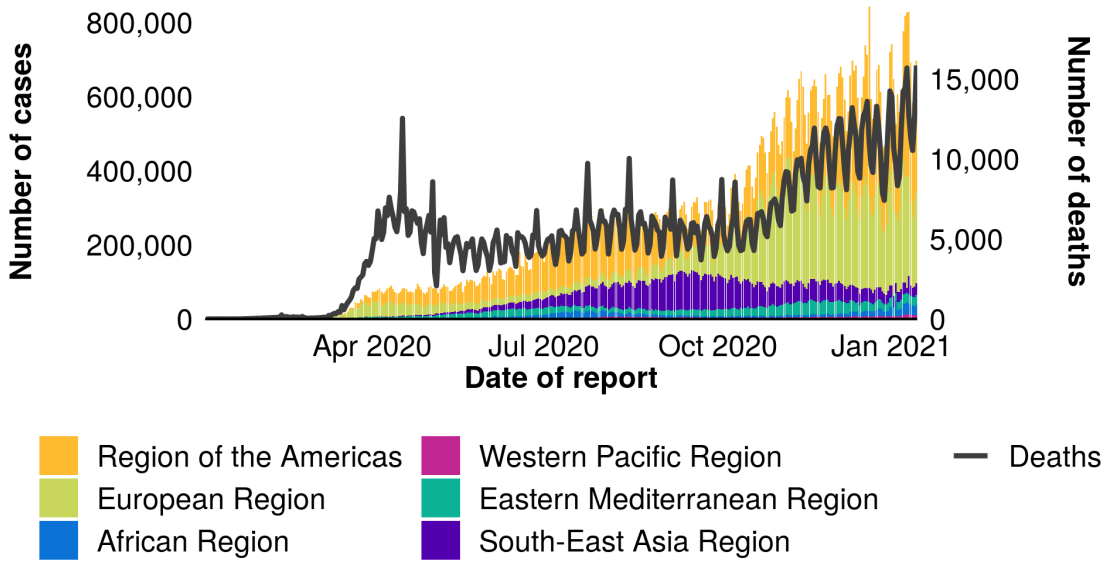
Is the problem of public health importance?

Previous 24 hours:

- 696,454 new confirmed cases.
- 15,828 new deaths.

Cumulative:

- 91,061,079 confirmed cases.
- 1,970,741 deaths.



(as of 14 January 10H CET)

Countries with the highest number of new cases in previous 24 hours

Country	New Cases	Total Cases	New Deaths	Total Deaths
United States of America	217,166	22,645,757	4,117	377,446
Brazil	64,025	8,195,637	1,110	204,690
United Kingdom	47,525	3,211,580	1,564	84,767
Germany	25,164	1,978,590	1,244	43,881
Russian Federation	24,763	3,495,816	570	63,940
France	23,649	2,783,908	229	68,648
South Africa	18,555	1,278,303	806	35,140
India	16,946	10,512,093	198	151,727
Spain	16,033	2,176,089	40	52,878
Italy	15,773	2,319,036	507	80,326

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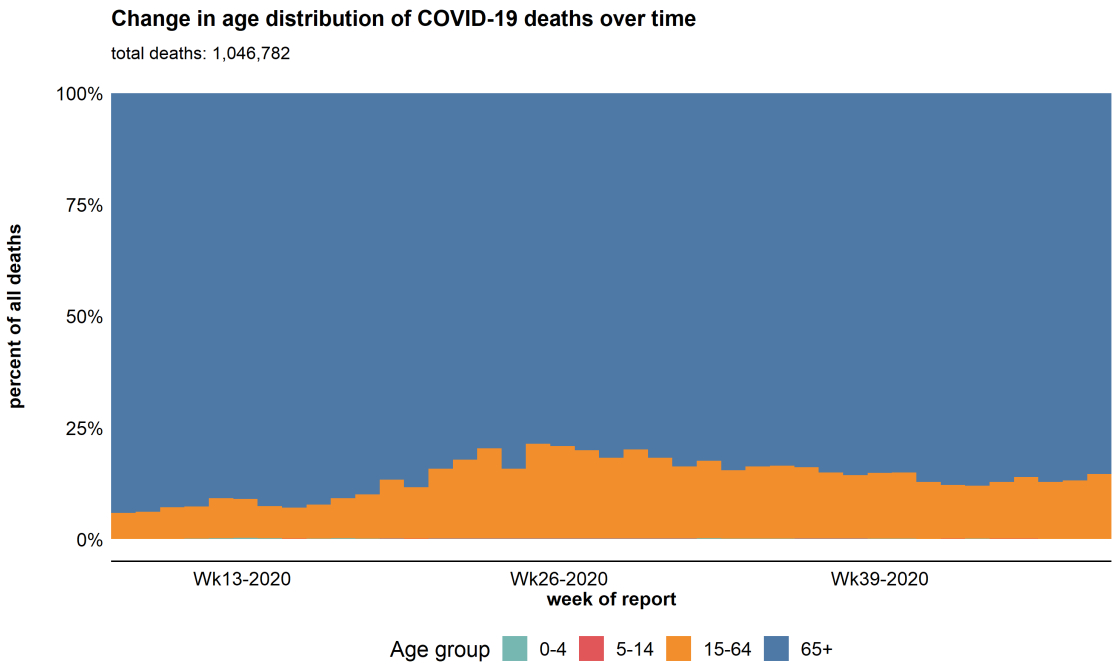
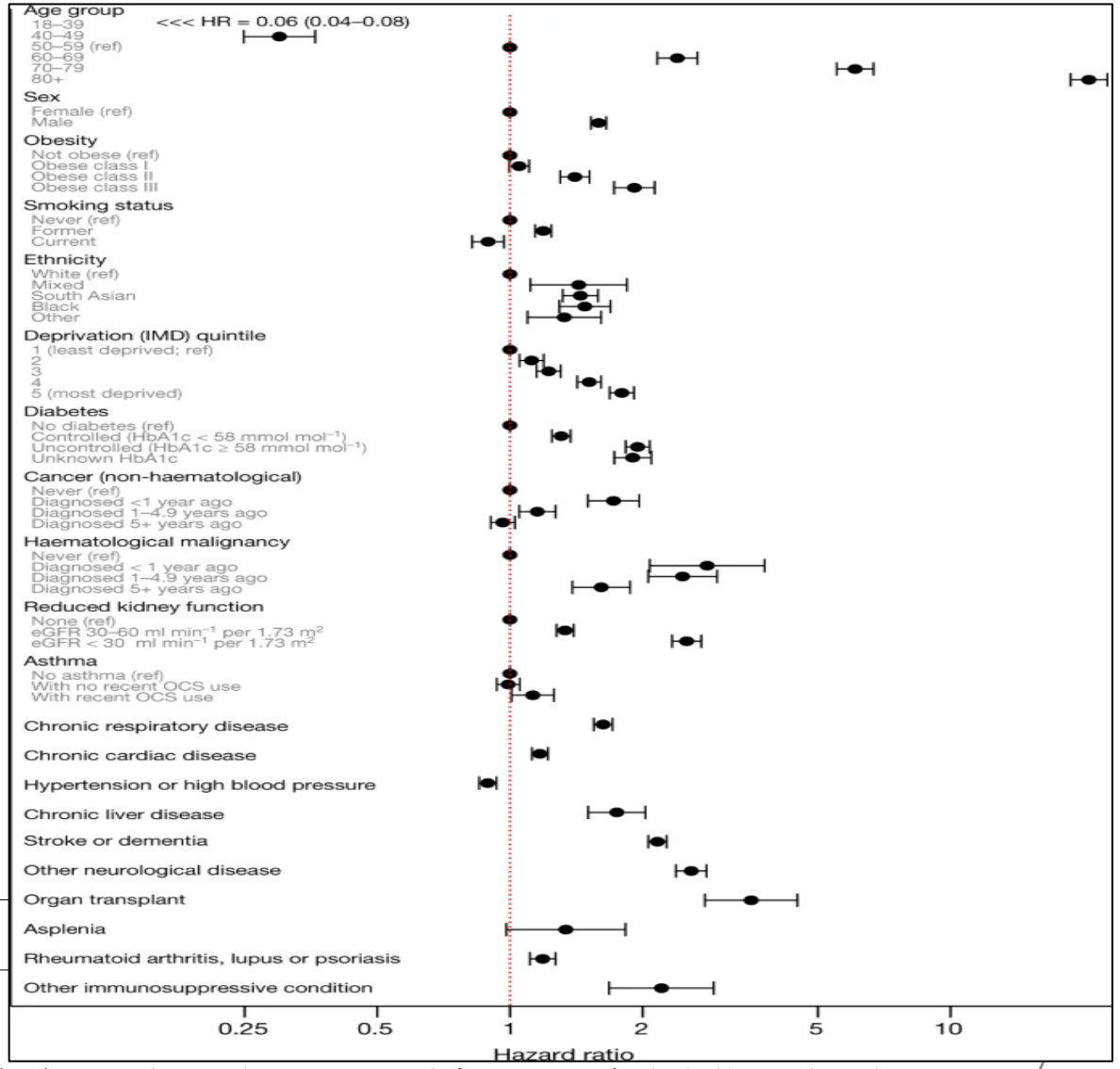
Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Is the problem of public health importance?



Hazard ratio for COVID-19 disease in health workers: 3·40 (95%CI:3.37-3.43)[2]

Factors associated with COVID-19-related death using OpenSAFELY[1]



[1]Williamson, E.J., Walker, A.J., Bhaskaran, K. et al. Factors associated with COVID-19-related death using OpenSAFELY. Nature 584, 430–436 (2020). [2] Compared to general community. From: Risk of COVID-19 among frontline healthcare workers and the general community: a prospective cohort study. Nguyen, L. H., Drew, D. A., Joshi, A. D., et al. (2020). medRxiv : the preprint server for health sciences, 2020.04.29.20084111. https://doi.org/10.1101/2020.04.29.20084111

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Problem statement | **Benefits and Harms** | Values and Preferences | Resource use | Equity | Acceptability | Feasibility

Benefits of the intervention

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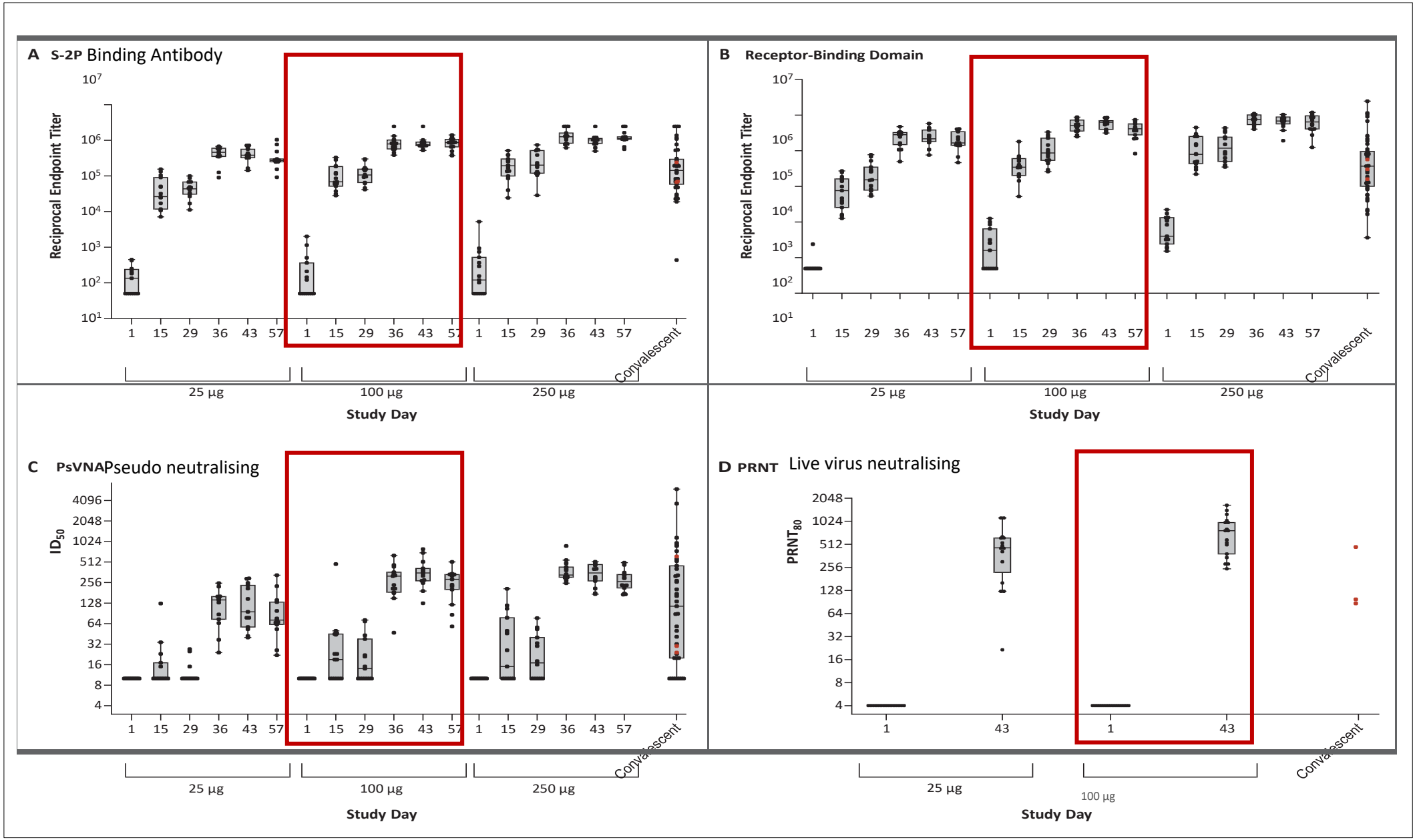
Immunogenicity



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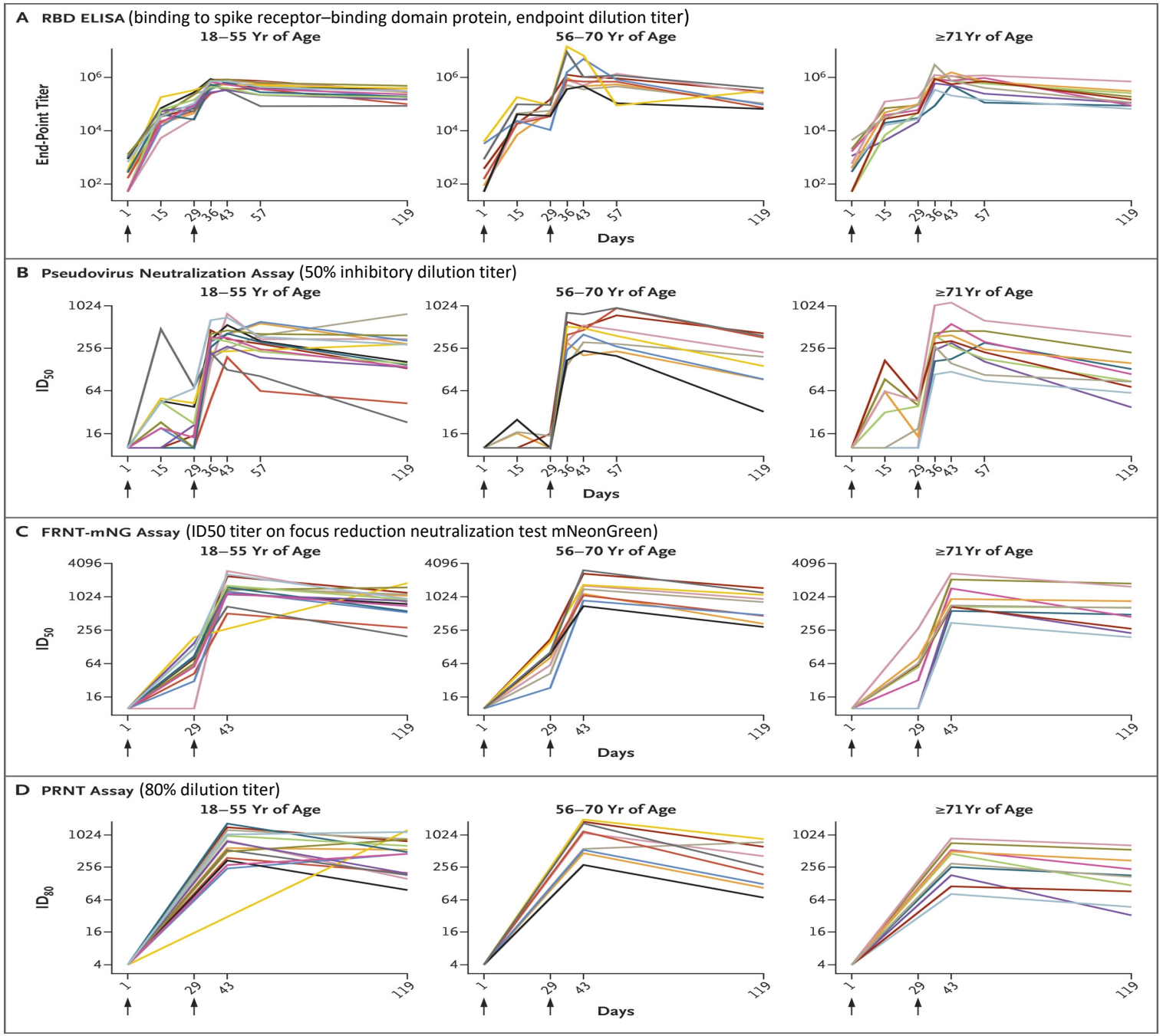


Durability of Immunological Responses after SARS-CoV-2 mRNA-1273 Vaccination

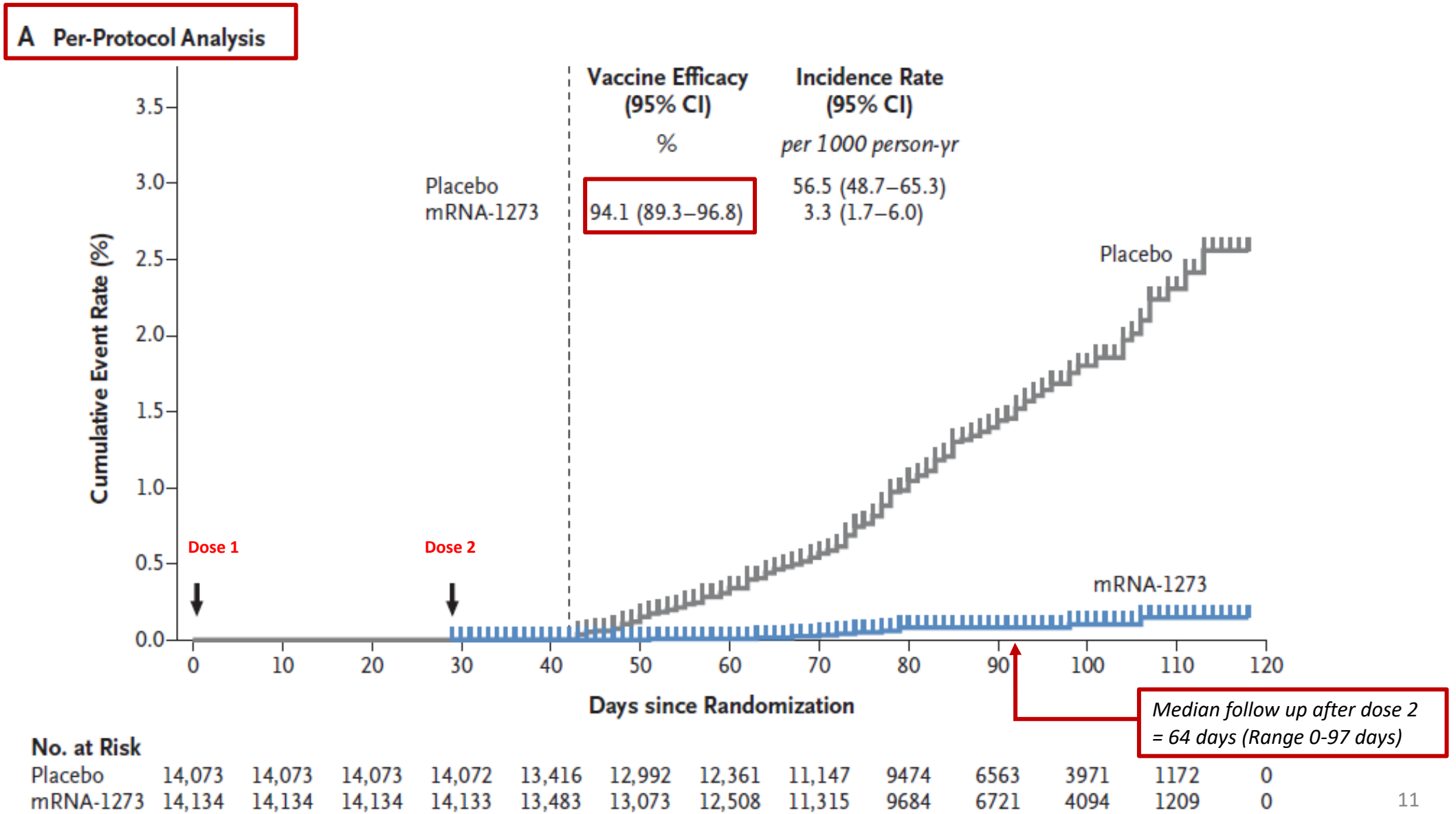
(each line is one participant)

At day 119 (90 days post dose 2), the binding and neutralizing GMTs exceeded the median GMTs in a panel of 41 controls who were convalescing from Covid-19, with a median of 34 days since diagnosis (range, 23 to 54).

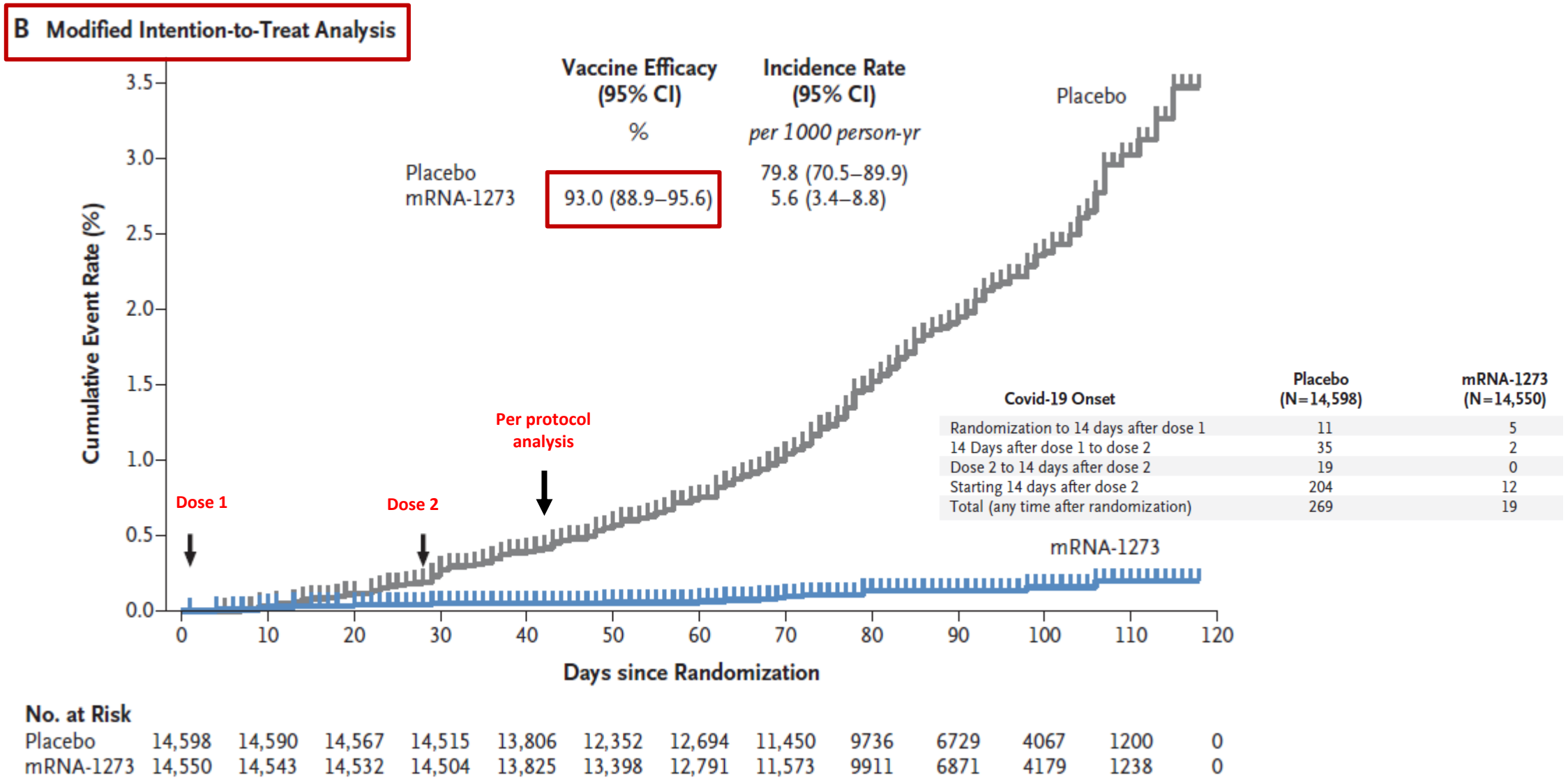
. N Engl J Med 2021; 384:80-82

Vaccine efficacy - symptomatic infection

(primary analysis among those with no evidence of previous infection at baseline)



Vaccine efficacy - symptomatic infection



Covid-19 Onset	Placebo (N=14,598)	mRNA-1273 (N=14,550)
Randomization to 14 days after dose 1	11	5
14 Days after dose 1 to dose 2	35	2
Dose 2 to 14 days after dose 2	19	0
Starting 14 days after dose 2	204	12
Total (any time after randomization)	269	19

Vaccine efficacy - symptomatic infection

(Modified intention to treat analysis)

Covid-19 Onset	Placebo (N=14,598)		mRNA-1273 (N=14,550)		VE (95%CI)
Randomization to 14 days after dose 1	11	46	5	7	85% (66%, 94%)
14 Days after dose 1 to dose 2	35		2		
Dose 2 to 14 days after dose 2	19		0		100% (79%, 100%)
Starting 14 days after dose 2	204		12		94% (89%, 97%)
Total (any time after randomization)	269		19		93% (89%, 96%)

Vaccine efficacy – Severe Covid 19

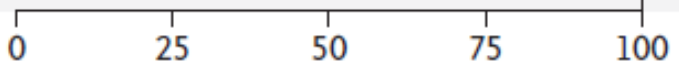
	Placebo	mRNA-1273	VE (95% CI)
Cases of severe disease based on adjudication committee assessments (≥14 days after dose 2)	30	0	100% (87%, 100%)

Characteristics of 30 severe cases: *1 death; 9 hospitalised; 2 ICU; 28 O_2 saturation ≤ 93%; 6 resp. failure or acute RDS; 17 Female; 10 ≥65y; 26 white; 20 co-morbid conditions*

Severe Covid-19 as defined by one of the following criteria: respiratory rate of 30 or more breaths per minute; heart rate at or exceeding 125 beats per minute; oxygen saturation at 93% or less while the participant was breathing ambient air at sea level or a ratio of the partial pressure of oxygen to the fraction of inspired oxygen below 300 mm Hg; respiratory failure; acute respiratory distress syndrome; evidence of shock (systolic blood pressure <90 mm Hg, diastolic blood pressure <60 mm Hg, or a need for vasopressors); clinically significant acute renal, hepatic, or neurologic dysfunction;

Vaccine efficacy - symptomatic infection – subgroup analysis

Subgroup	Placebo (N=14,073)	mRNA-1273 (N=14,134)	Vaccine Efficacy (95% CI)
	no. of events/total no.		
All patients	185/14,073	11/14,134	94.1 (89.3–96.8)
Age			
≥18 to <65 yr	156/10,521	7/10,551	95.6 (90.6–97.9)
≥65 yr	29/3552	4/3583	86.4 (61.4–95.2)
Age, risk for severe Covid-19			
18 to <65 yr, not at risk	121/8403	5/8396	95.9 (90.0–98.3)
18 to <65 yr, at risk	35/2118	2/2155	94.4 (76.9–98.7)
≥65 yr	29/3552	4/3583	86.4 (61.4–95.2)
Sex			
Male	87/7462	4/7366	95.4 (87.4–98.3)
Female	98/6611	7/6768	93.1 (85.2–96.8)
At risk for severe Covid-19			
Yes	43/3167	4/3206	90.9 (74.7–96.7)
No	142/10,906	7/10,928	95.1 (89.6–97.7)
Race and ethnic group			
White	144/8916	10/9023	93.2 (87.1–96.4)
Communities of color	41/5132	1/5088	97.5 (82.2–99.7)



Protection against asymptomatic infection

	No symptoms but nasal swab RT-PCR positive at visit for 2nd dose		
	Placebo	**mRNA-1273**	Reduction in prevalence (95% CI)
Negative for SARS-CoV-2 at baseline (by RT PCR or antibody testing)	39	14	64% (32%, 82%)

Protection among those with evidence of previous infection at baseline

Insufficient data to conclude on the efficacy of the vaccine in the 2.2% of participants who were seropositive or RT-PCR positive at baseline.

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Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Problem statement | **Benefits and Harms** | Values and Preferences | Resource use | Equity | Acceptability | Feasibility

Harms of the intervention

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BENEFITS & HARMS OF THE OPTIONS	Benefits of the intervention Are the desirable anticipated effects large?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies* ☐		

Vaccine Safety

Safety endpoint	Data
Reactogenicity and adverse events	Frequent, mostly mild to moderate , short lived Less frequency and severity in older (≥65 years) than younger adults (18 -64 years) Generally more frequent after 2nd dose compared to 1st (all ages)
Lymphadenopathy-related events (injection site lymphadenopathy, lymph node pain, lymphadenitis)	Vaccine: 1.1% (n=173), placebo: 0.63% (n=95) Occurred in the axillary region within 1 to 2 days after vaccination More frequent in younger adults after dose 2 Plausible relation to vaccination
Bell`s palsy	Vaccine n=3, placebo n=1 Occurred 22, 28, and 32 days after dose 2 (vaccine recipients) , 17 days after dose 1 (placebo recipient) Observed rate consistent with background rate in general population No clear basis upon which to conclude a causal relationship , further surveillance
Hypersensitivity-related events (injection site rash, injection site urticaria, maculo-papular rash)	Vaccine: 1.5% (n=233), placebo: 1.1% (n=166) Plausible relationship to vaccination No anaphylactic , or severe hypersensitivity reactions with close temporal relation to the vaccine

Safety – Serious Adverse Events (SAEs)

- Frequency of SAEs was low (1.0% in the vaccine, and placebo arms), with no meaningful imbalances between study arms.

- Deaths: 13 total (6 vaccine, 7 placebo)
  - No causal relationship was determined.

- Related SAEs (FDA conclusion)
  - Intractable nausea and vomiting (n=1, in a 65 year old one day post dose 2).
  - Facial swelling (n-2, in 46 and 51 years old, one and two days post dose 2, both had prior dermal fillers).

- Possibility related (FDA conclusion)
  - Rheumatoid arthritis (n=1)
  - Peripheral edema/dyspnea with exertion (n=1)
  - Autonomic dysfunction (n=1)

Pregnancies

- Women were screened for pregnancy prior to each vaccination and were excluded or discontinued from vaccination if there was a positive test.
- As of December 2, 2020, 13 pregnancies (vaccine= 6, placebo=7) have been reported.
- The pregnancy outcomes in the placebo group include spontaneous abortion and an elective abortion. The other outcomes are not known to date and the pregnant women are being followed.
- A combined developmental and perinatal/postnatal reproductive toxicity study of the vaccine in rats was conducted.
- Concluded that the vaccine (at 100 µg), given prior to mating and during gestation periods, did not have any adverse effects (including on female reproduction, fetal/embryonal development, or postnatal development).

Safety – Special Considerations: PEGylation (or pegylation)

- The vaccine contains four lipids. The lipids encapsulate the mRNA in the form of a lipid nanoparticle to aid cell entry, ensure stability and have an adjuvant effect.

- Two of the lipids are commonly used in approved medicinal products (cholesterol and 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)) and two have not been commonly used in an authorised medicinal product.
  - SM-102 (proprietary to Moderna)
  - 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]

- Anaphylaxis cases reported with the Moderna vaccine.

- The potential role of the PEG in the anaphylactic reactions, and whether IgE or CARPA (complement activation-related pseudoallergy), a non-IgE-mediated pseudoallergy, related to be determined.

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Balance between benefits and harms and quality of evidence

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Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Balance between benefits and harms

- The Working Group concluded that at this point in time, the beneficial efficacy across age-groups data outweigh the limited number of reported harms.
- Further data will need to be generated, from additional studies and post-marketing surveillance.

Favours intervention	Favours comparison	Favours both	Favours neither	Unclear
☒	☐	☐	☐	☐

GRADEing of Evidence	Statement on quality of evidence	SAGE Working Group Judgement
Efficacy against PCR confirmed COVID-19 (Adults)	**High level of confidence**	We are very confident that 2 doses of mRNA-1273 vaccine are efficacious in preventing PCR confirmed COVID-19 in adults (18-64 years).
Safety-serious adverse events (Adults)	**Moderate level of confidence**	We are moderately confident that the risk of serious adverse events following one or two doses of mRNA-1273 vaccine in adults (18-64 years) is low.
Efficacy PCR confirmed COVID-19 (Older adults)	**High level of confidence**	We are confident that 2 doses of mRNA-1273 vaccine are efficacious in preventing PCR confirmed COVID-19 in older adults (≥65 years).
Safety-serious adverse events (Older adults)	**Moderate level of confidence**	We are moderately confident that the risk of serious adverse events following one or two doses of mRNA-1273 vaccine COVID-19 in older adults (≥65 years) is low.
Efficacy PCR confirmed COVID-19 (*Individuals with comorbidities or health states that increase risk for severe COVID-19*)	**Moderate level of confidence**	We are moderately confident that 2 doses of mRNA-1273 vaccine are efficacious in preventing PCR confirmed COVID-19 in individuals with comorbidities or health states that increase risk for severe COVID-19 as included in the clinical trial. No data were obtained on vaccination of pregnant or breastfeeding women, and persons who were immunocompromised.
Safety-serious adverse events (*Individuals with comorbidities or health states that increase risk for severe COVID-19*)	**Low level of confidence**	We are have low confidence in the quality of evidence that the risk of serious adverse events in individuals with comorbidities or health states that increase risk for severe COVID-19 following one or two doses of mRNA-1273 vaccine COVID-19 is low.

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Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

How certain is the relative importance of the desirable and undesirable outcomes?

There is possibly important uncertainty related to the target population's weighing of desirable and undesirable effects (i.e. the protection conferred by the vaccine weighed against the currently reported safety signals, related to COVID-19 vaccination).

Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability	No known undesirable outcomes
☐	☒	☐	☐	☐

Values and preferences of the target population: Are the desirable effects large relative to undesirable effects?

Limited evidence suggest that the target population probably attaches more weight to the desirable effects than the undesirable effects related to COVID-19 vaccination.

No	Probably No	Uncertain	Probably Yes	Yes	Varies
☐	☐	☐	☒	☐	☐

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Resource Use- is mRNA-1273 an efficient allocation of resources?

Are the resources required small?

- Considerable additional resources are required for procurement of vaccine and vaccination supplies, training, social mobilization and communication, delivery logistics, information systems, immunization safety surveillance, and planning and coordination, especially for vaccination of priority groups without existing robust immunization platforms and where surge resources will be needed to accelerate roll-out.

No	Uncertain	Yes	Varies
☒	☐	☐	☐

Cost-effectiveness

- Cost-effectiveness analyses and economic impact of vaccination will depend on:

Cost of vaccine, COVID-19 burden, timing of vaccine roll-out (at time of rise of cases versus decline), vaccination coverage levels achieved, duration of vaccine protection, vaccination implementation costs, other mitigation measures used.

No	Uncertain	Yes	Varies
☐	☐	☐	☒

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Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

- Currently vaccine only available to high income countries.
- Vaccine is not part of COVAX.
- Several factors may increase inequity: cost, logistics, cold chain storage and transportation requirements.
- Appropriate medical treatment to manage anaphylaxis must be immediately available.
- Need for 2 dose series may disadvantage homeless, nomads, persons living in remote places, and those with limited access to health care.

What would be the impact of mRNA-1273 vaccine on health inequity globally?

Increased	Uncertain	Reduced	Varies
☒	☐	☐	☐

What would be the impact of mRNA-1273 vaccine on health inequity at national programme level?

Increased	Uncertain	Reduced	Varies
☐	☐	☐	☒

EVIDENCE ASSESSMENT: mRNA-1273 COVID-19 vaccine

Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Problem statement	Benefits and Harms	Values and Preferences	Resource use	Equity	**Acceptability**	Feasibility

World Health Organization

Strategic Advisory Group of Experts (SAGE) on Immunization Evidence to recommendations framework[i]

Question:
Population:
Intervention:
Comparison(s):
Outcome:
Background:

	CRITERIA	JUDGEMENTS				RESEARCH EVIDENCE	ADDITIONAL INFORMATION
PROBLEM	Is the problem a public health priority?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies by setting* ☐		
BENEFITS & HARMS OF THE OPTIONS	Benefits of the intervention Are the desirable anticipated effects large?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies* ☐		

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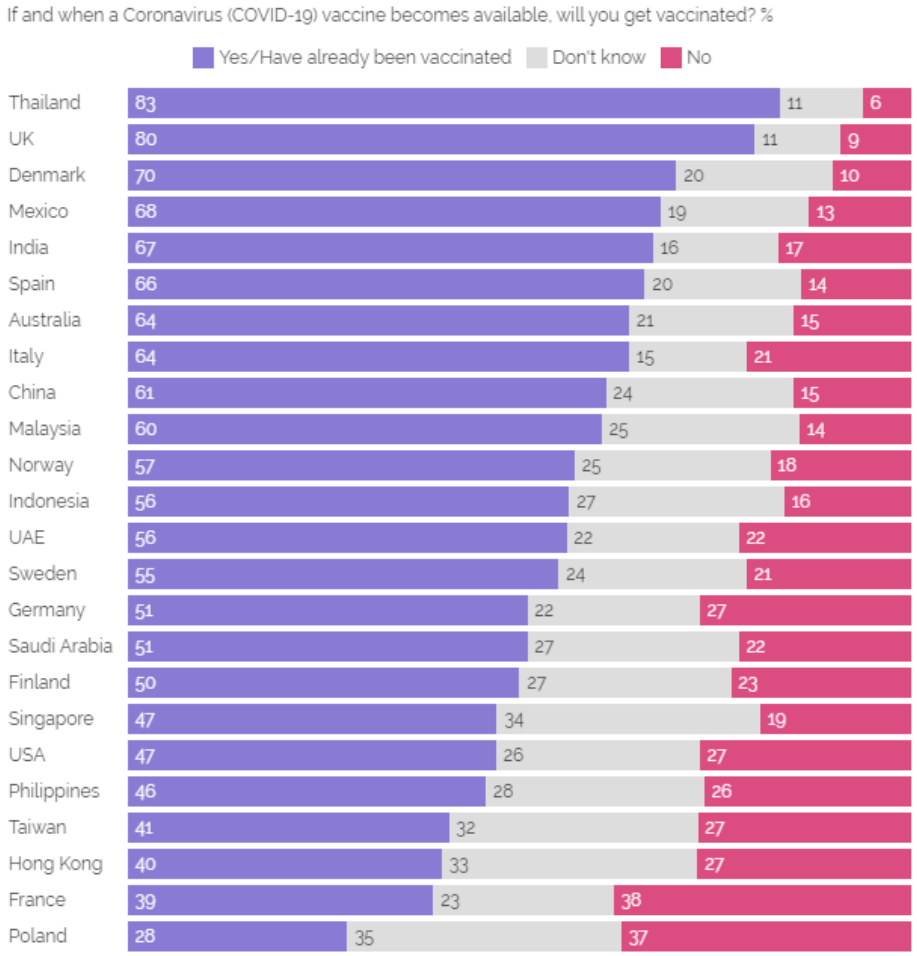
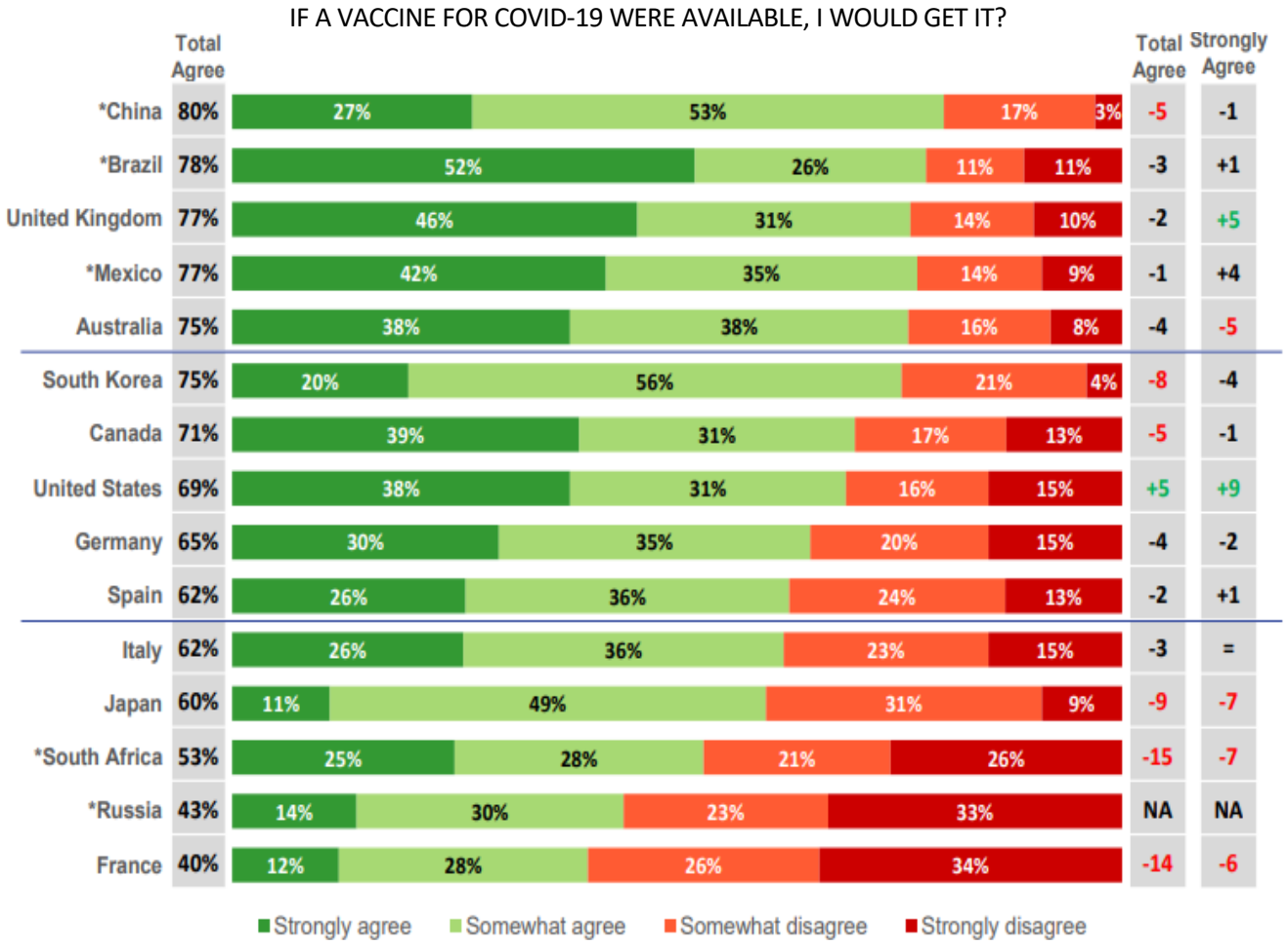
Acceptability to the target group



Source: YouGov. https://yougov.co.uk/, accessed 18 January 2021



Source: Global Attitudes on COVID-19 vaccine. Ipsos survey. https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-december-2020, accessed 18 January 2021

Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine

Acceptability to key stakeholders and the target group

Which option is acceptable to target groups?

- No vaccine-specific global data available, though it is assumed that the target population would accept mRNA-1273 vaccine.

Intervention	Comparison	Both	Neither	Unclear
☒	☐	☐	☐	☐

Which option is acceptable to key stakeholders (Ministries of Health, Immunization Managers)?

- As vaccination is an eagerly awaited tool in combatting COVID-19, it is assumed that key stakeholders, in particular Ministries of Health and Immunization Managers are strongly in favor of COVID-19 vaccination.

Intervention	Comparison	Both	Neither	Unclear
☒	☐	☐	☐	☐

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Problem statement | Benefits and Harms | Values and Preferences | Resource use | Equity | Acceptability | **Feasibility**

World Health Organization

Strategic Advisory Group of Experts (SAGE) on Immunization Evidence to recommendations framework[i]

Question:
Population:
Intervention:
Comparison(s):
Outcome:
Background:

	CRITERIA	JUDGEMENTS				RESEARCH EVIDENCE	ADDITIONAL INFORMATION
PROBLEM	Is the problem a public health priority?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies by setting* ☐		
BENEFITS & HARMS OF THE OPTIONS	Benefits of the intervention Are the desirable anticipated effects large?	*No* ☐	*Un-certain* ☐	*Yes* ☐	*Varies* ☐		

EVIDENCE ASSESSMENT: mRNA-1273 COVID-19 vaccine

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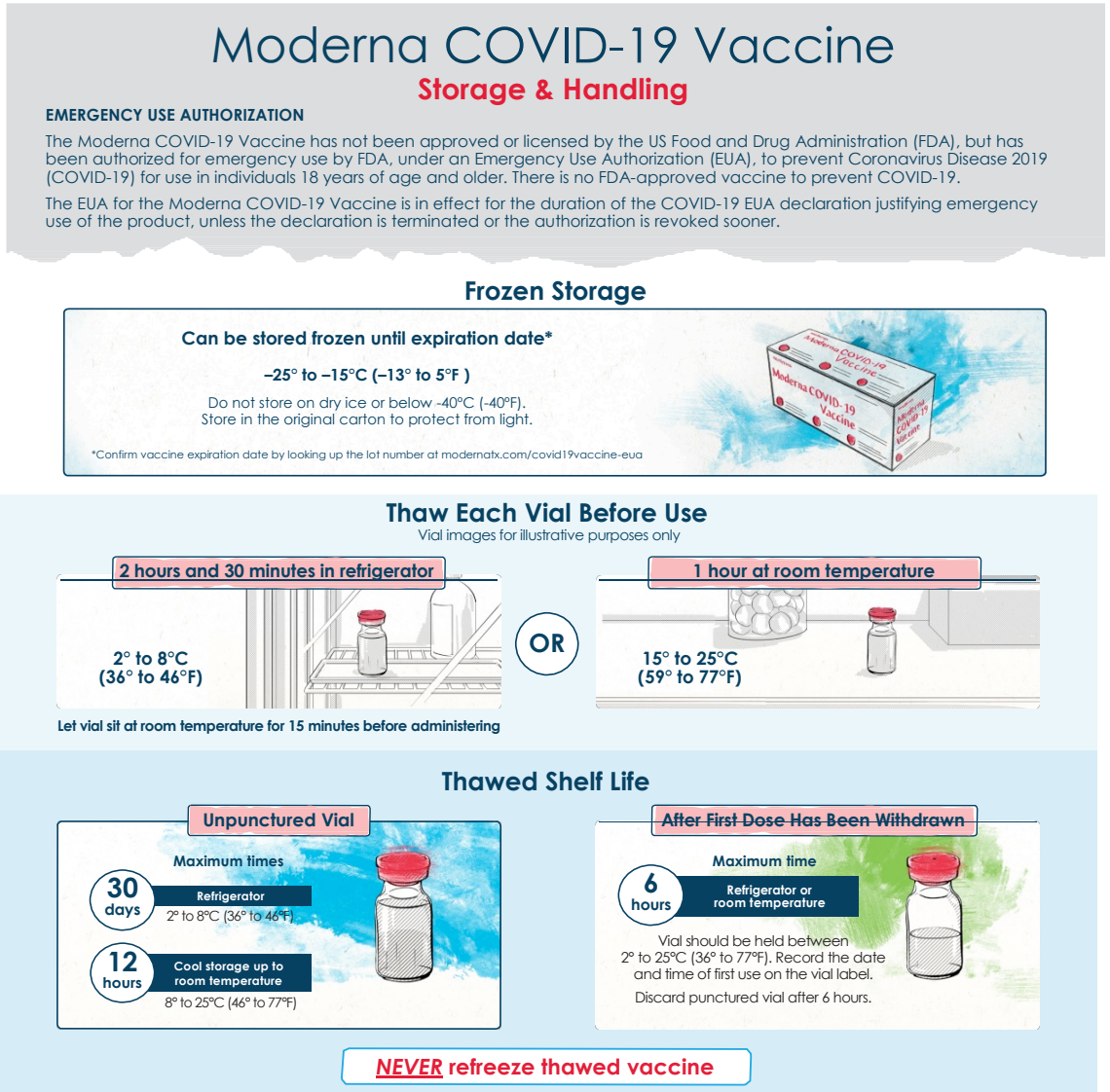
Feasibility -is the intervention feasible to implement?

- Preservative-free frozen suspension for intramuscular injection stored between -25° to -15°C.
- Multi-dose vial containing 10 doses (0.5 mL each).
- Vials can be stored refrigerated between 2° to 8°C for up to 30 days prior to first use.
- Unopened vials may be stored between 8° to 25°C for up to 12 hours.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C and discarded after 6 hours.

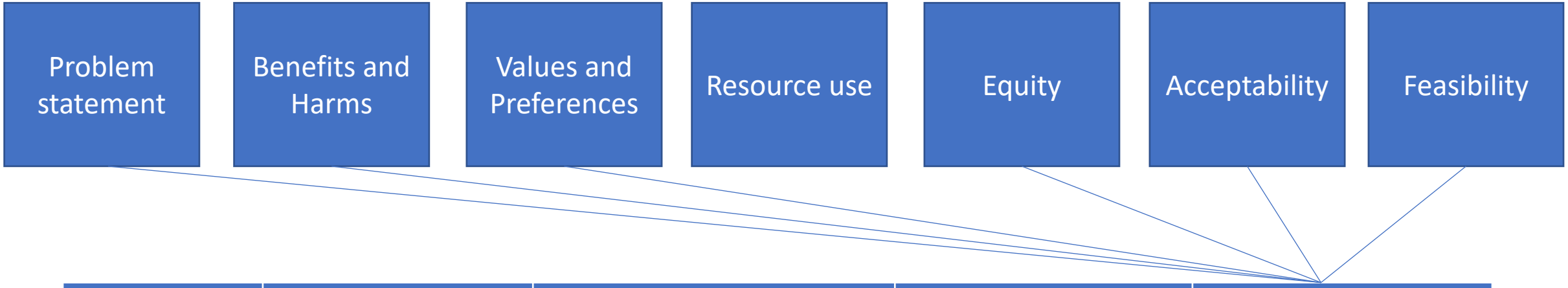
No	Probably No	Uncertain	Probably Yes	Yes	Varies
☐	☐	☐	☐	☐	☒



Reference: Moderna COVID-19 Vaccine Storage & Handling www.modernatx.com/covid19vaccine-eua/providers/storage-handling.pdf

EVIDENCE ASSESSMENT: mRNA-1273 COVID-19 vaccine

Key evidence to inform policy recommendations on the use of mRNA-1273 COVID-19 vaccine



Undesirable consequences clearly outweigh desirable consequences in most settings	Undesirable consequences probably outweigh desirable consequences in most settings	The balance between desirable and undesirable consequences is closely balanced or uncertain	Desirable consequences probably outweigh undesirable consequences in most settings	Desirable consequences clearly outweigh undesirable consequences in most settings
☐	☐	☐	☐	☒

Specific recommendations: NEXT PRESENTATION