National Immunisation Advisory Committee

RECOMMENDATIONS FOR THE USE OF COVID-19 VACCINE ASTRAZENECA® IN IRELAND

1. IN OLDER PEOPLE
2. DOSING SCHEDULE

NIAC | 01.02.2021

Query for the National Immunisation Advisory Committee (NIAC)

The National Immunisation Advisory Committee (NIAC) was asked to consider the data published by the European Medicines Agency (EMA) in relation to the authorisation of the COVID-19 Vaccine AstraZeneca® and to provide any advice it may deem appropriate to the ongoing delivery of the COVID-19 vaccination programme, in respect of the following issues:

- the use of the COVID-19 Vaccine AstraZeneca® in older adults; and
- the COVID-19 Vaccine AstraZeneca® dosing schedule.

Background

The recommendation of the European Medicines Agency (EMA) for a conditional marketing authorisation for the COVID-19 Vaccine AstraZeneca® in those 18 years and older is welcome news. In Ireland, as we approach the new milestone of 200,000 cases of SARS-CoV-2 infection, of whom over 3,000 have died, each new weapon to fight SARS-CoV-2 is a welcome addition.

The main objectives of the COVID-19 vaccination strategy are to prevent serious illness and death.

The EMA accepted the efficacy of the COVID-19 Vaccine AstraZeneca® as 60%, based on data from two of four studies submitted, with 64/5258 cases of COVID-19 in vaccine recipients compared with 154/5210 cases in those who received a control injection.

Regarding those aged 55 and older, there was insufficient clinical data to allow reliable calculation of COVID-19 Vaccine AstraZeneca® efficacy. However, as a similar immune response was shown in all age groups, it is expected that reduction in COVID-19 disease will be achieved in this age group. The EMA stated that the vaccine can be used in older adults.

Epidemiology

In Ireland, hospitalisations and deaths related to COVID-19 have occurred in all adult age groups, however the risk of severe outcome is correlated with age. In the analysis of hospitalisation and mortality data, those aged 70 and older are at significantly greater risk.

Table 1 Percentage of cases hospitalised and age-specific hospitalisation rates

Percentage of cases hospitalised and age-specific hospitalisation rates						
Age (Years)	Mar – June 2020		July -Nov 2020		Nov 20- Jan 2021	
	% of cases	Rate per 100,000	% of cases	Rate per 100,000	% of cases	Rate per 100,000
50 - 54	7.11%	80.02	6.52%	44.34	6.09%	110.69
55-59	6.9%	86.26	6.38%	48.13	6.67%	134.76
60-64	7.88%	111.36	6.92%	59.03	6.73%	153.65
65-69	7.43%	118.82	7.36%	71.01	7.64%	197.41
70-84	32.61%	306.88	32.12%	182.57	32.00%	486.65
85+	14.63%	731.26	12.21%	368.59	15.12%	1221.23

Source: HPSC CIDR extract 28.01.2021

Table 2 Percentage of cases of death and age-specific death rates

Percentage of cases of deaths and age-specific death rates						
Age (Years)	Mar – June 2020		July -Nov 2020		Nov 20 – Jan 2021	
	% of cases	Deaths per 100,000	% of cases	Deaths per 100,000	% of cases	Deaths per 100,000
50-54	0.83%	6	0.06%	0.67	0.1%	3.00
55-59	1.96%	13.7	0.27%	2.59	0.27%	8.52
60-64	2.66%	15.49	0.62%	5.02	0.41%	10.47
65-69	10.34%	41.66	1.42%	8.99	1.49%	27.46
70-84	22.72%	214.06	7.65%	51.84	6.05%	127.38
85+	32.02%	1188.66	18.27%	227.96	12.65%	609.87

Source: HPSC CIDR extract 28.01.2021

Characteristics of authorised COVID-19 vaccines

Table 3 Characteristics of authorised COVID-19 vaccines

	Comirnaty® BioNTech/Pfizer	**COVID-19 Vaccine Moderna®**	**COVID-19 Vaccine Astra Zeneca®**
Vaccine Platform	mRNA	mRNA	Simian Adenovirus vector
Storage *Freezer* *Fridge* *Room* *Opened/diluted*	 -90^{0}C to -70^{0}C: 6 months 2^{0}C to 8^{0}C: <5 days Up to 30^{0}C: 2 hours 2^{0}C to 30^{0}C: 6 hours	 -25^{0}C to -15^{0}C: 7months 2^{0}C to 8^{0}C: 30 days 8^{0}C to 25^{0}C: 12 hours 2^{0}C to 25^{0}C: 6 hours	 Not applicable 2^{0}C to 8^{0}C: 6 months 2^{0}C to 8^{0}C 48 hours* 2^{0}C to 25^{0}C: 6 hours**
Doses (days)	0, 21 - 28	0, 28	0, 28 - 84
Trial participants	43,448 >16years	30,351 >18years	23,745 >18years
Comorbidity in trial participants	46.3%	22.1%	39.3%
Safety profile	Acceptable	Acceptable	Acceptable
Efficacy overall (95%CI)	8/18,198 v 162/18,325 95% (90.-97.9)	11/14,134 v 185/14,073 94.1% (89.3-96.8)	64/5,258 v 154/5,210 59.5% (45.8-69.7)
Efficacy >55 & Older ≥65 to <75 ≥75	 93.7% (80.6 – 98.8) 92.9 (53.2 – 99.8) 100 (-12.1 – 100)	 Not available 82.4% (48.9 – 93.9) 100 (not estimable, 100)	 Data do not allow an estimate of vaccine efficacy in those aged 55 and older
Hospitalisation or severe COVID-19 disease (vaccine v control)	1/21,669 v 9/21,686	0/14,134 v 30/14,073	0/5258 v 8/5210
Time to protection after dose 2	7 days	14 days	15 days
Efficacy against variants of concern	Likely efficacy against B1.1.7 (UK variant)	Reduced but still significant neutralisation against B1.351 (South African variant)	No data

*Chemical and physical stability once vial punctured

**6 hours within the 48-hour period for punctured vials

1. Use of COVID-19 Vaccine AstraZeneca® in older adults

Each of the three authorised COVID-19 vaccines represents a remarkable achievement. All have proven to be effective in preventing COVID-19. Efficacy of the three vaccines is variable (see table 3), being higher in the mRNA vaccines. However, all are effective in preventing severe COVID-19 disease, which is the primary aim of the vaccination programme.

While there is a lack of efficacy data regarding COVID-19 Vaccine AstraZeneca® in older adults, there is nothing in the immunogenicity data indicating that it will be less effective than in the younger population.

The NIAC deliberations on the optimal use of authorised vaccines for those 70 years and older have been wide ranging, taking into account the risks of disease and the benefits afforded by the vaccines. Factors considered included disease risk, vaccine safety, immunogenicity, efficacy, age-specific vaccine data, and likely time to protection. The potential impact on confidence and trust in the vaccination programme was also discussed, and regard was taken of the ethical principles of equity, fairness and minimising harm.

The mRNA vaccines are associated with higher reported overall efficacy which makes them preferable for use in those at highest risk of adverse outcomes. However, all authorised vaccines for COVID-19 are suitable for use in all adult age groups.

There is an urgency to protect those aged 70 and older who are at most risk of a severe outcome. Because of the ongoing concern regarding rates of community COVID-19 transmission and hospitalisation, **NIAC recognises that the best vaccine anyone can receive at this time is the vaccine that can be soonest administered**. Everyone is strongly urged to accept whichever vaccine is available.

Recommendations for those aged 65-69 will be made when impending new evidence has been reviewed.

Recommendation 1

Any currently authorised COVID-19 vaccine can be given to adults of all ages, including those aged 70 and older

Recommendation 2

Vaccination of those aged 70 and older should not be delayed. Where practicable and timely, those aged 70 and older should be given an mRNA vaccine.

2. Dosing schedule

The COVID-19 Vaccine AstraZeneca® two-dose schedule was licensed for administration at an interval of 4 – 12 weeks, based on immunogenicity and efficacy data. There is evidence of a greater immune response with a longer interval between doses in those under 65 years. However, of those aged 65 and older, 90% received their vaccine with an interval of less than 6 weeks.

While longer dosing intervals may be associated with higher antibody levels, the clinical impact is not known at this time. As such, it cannot be concluded, based on clinical data, that vaccine efficacy increases within the time interval. Conversely, a shorter dosing interval, within the recommended range, allows for earlier completion of the schedule to optimise protection offered by the vaccine for those aged 65 and older.

Recommendation 3

For those aged 65 and older, a 2-dose schedule of COVID-19 Vaccine AstraZeneca® administered at an interval of 4 - 6 weeks is recommended

Recommendation 4

For those less than 65 years of age, a 2-dose schedule of COVID-19 Vaccine AstraZeneca® administered at an interval of 4 - 12 weeks is recommended

These recommendations are based on current data and are subject to ongoing review.

DOH will be informed of any changes.

References

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