

# Recommendations for the use of virusvector vaccines in the Norwegian covid-19 vaccination program

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### Decision-making

- Norwegian Institute of Public Health is an advisory body
- The Government decides based on the advise

#### Current order of priority for covid-19 vaccine

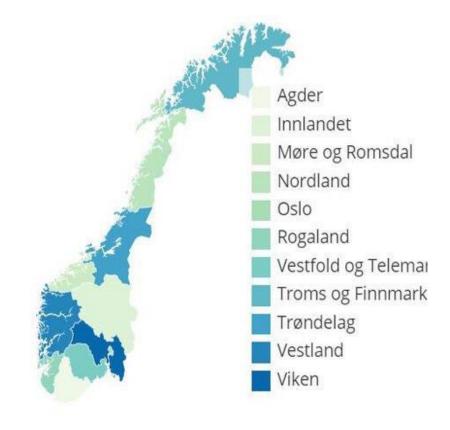
- 1. Residents in nursing homes and selected groups of healthcare personnel
- 2. Age 85 years and above and selected groups of healthcare personnel
- 3. Age 75-84 years
- 4. Age 65-74 years

  AND people between 18 and 64 years with diseases/ conditions at high risk of a severe outcome (transplantation, immunodeficency, active cancer treatment, dialysis etc)
- 5. Age 55-64 years with underlying diseases/conditions
- 6. Age 45-54 years with underlying diseases/conditions
- 7. Age 18-44 years with underlying diseases/conditions
- 8. Age 55-64 years
- 9. Age 45-54 years



#### The Norwegian Vaccination System

- The municipalities are responsible for delivering vaccines to the prioritized groups within the municipality
- 356 municipalities geographically and demographically diverse
- Advantages: brings the vaccines to where people live, good for trust and uptake
- Disadvantages: complex distribution and operationalization



#### **AZ-vaccine in Norway**

- Number of vaccinated: 135 000
- Health care personnel: 100 000
- Almost exclusively used in < 65 years of age, 80% women, average age 45 years</li>
- Paused from 11. March after report from DK and some other European countries
- Almost simultaneously national reports of severe AEFI
- In Norway 6 cases with thromobocytopenia, thromboembolism, bleedings
  - 4/6 cases fatal
  - 5/6 cases intracerebral thromboembolism (4/6 CSVT)
  - 1/6 cases portal vein thrombosis
  - 5/ 6 femalė
  - All below 60 years of age

## Recommended discontinuation of the AZ-vaccine

- Plausible and likely causal relationship
- Practical implications for the Norwegian program
- Risk-benefit considerations with Norwegian numbers
- Registry based analyses with data from DK and NO
- Considerations regarding trust
- Considerations regarding social economics

https://www.fhi.no/contentassets/3596efb4a1064c9f9c7c9e3f68ec481f/svar-pa-oppdrag-21\_sladdet.pdf

### Practical implications for not using AZ

- Fewer doses delivered than initially expected
- > 65 years will have been offered first dose by end of April
  - Not using will hence not delay the oldest age groups
- An overall delay in the total program of aprox 2 weeks (likely shorter now with increases in Comirnaty deliveries)

#### Risk benefit considerations

Death from covid-19 vs death from AZ-vaccine

Agegroup	Female	Male
45-49	79 weeks	36 weeks
50-54	63 weeks	30 weeks
55-59	29 weeks	14 weeks
60-64	15 weeks	7 weeks
65-69	11 weeks	5 weeks
70-74	8 weeks	4 weeks

#### Risk benefit considerations

#### ICU due to covid-19 vs ICU from AZ-vaccine

Agegroup	Female	Male
30-34	18 weeks	9 weeks
35-39	14 weeks	7 weeks
40-44	10 weeks	5 weeks
45-49	7 weeks	4 weeks
50-54	5 weeks	2 weeks
55-59	4 weeks	2 weeks
60-64	3 weeks	2 weeks
65-69	3 weeks	1 week
70-74	3 weeks	2 weeks

#### Registry based analyses

- Observed vs expected analysis
  - In < 65 years</li>
  - Data from NO and DK
  - 2x risk of all thromboembolic evens
  - CVST -> 1 extra case per 40 000 vaccinated
- Self-controlled case series
  - Much of the same results
  - Results not publicly available

#### Conclusions

- Only use in the older population a possibility (+65 yrs)
- But little to gain given where we are in the program
- A lot of mistrust, would require a huge effort to re-establish trust
- IMPORTANT: the recommendation only valid in the Norwegian context:
  - Relatively low transmission of the virus
  - High incidence of the severe adverse events
  - Good access to alternative vaccines
  - No gain for the overall program if given only to +65 yrs

#### Status AZ vaccine

- The Norwegian Government wanted a second opinion and NIPH recommendation is so far put on hold
- An external expert committee established without representatives from the NIPH. To report by 10. May

#### Status Janssen vaccine

- NIPH recommended to withhold introduction given the reported similar cases from USA – waiting for updated report of cases from FDA/CDC
- Waiting for preliminary results from ongoing signalprocedure in EMA
- No further recommendations given
- A problem is that when receiving large amounts of the Janssen vaccine we will be vaccinating the younger population
- Not using Janssen-vaccine could lead to 8-12 weeks delay in the program –
   likely less now as we are receiving more Comirnaty