

The Norwegian Covid-19 immunisation programme

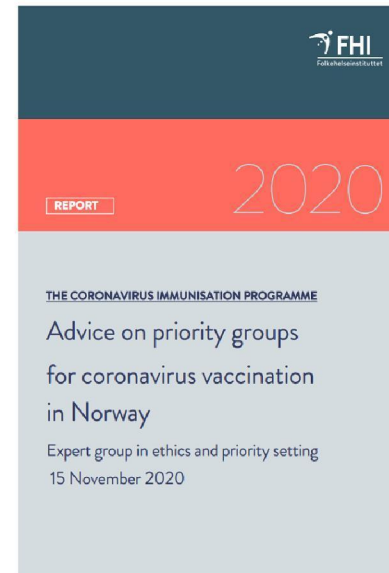
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4th February 2021

What are the goals for the immunisation programme?

- 1 Reduce the risk of death
- 2 Reduce the risk of serious disease
- 3 Maintain essential infrastructure and services
- 4 Protect employment and the economy
- 5 Re-open society



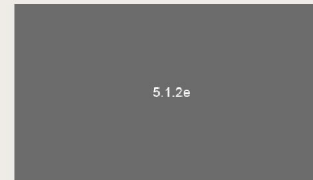
Current order of priority for covid-19 vaccine

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 these diseases/ conditions at high risk of a severe disease course
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



Norwegian setting

- High trust in national vaccination program and authorities
 - Voluntary vaccination
 - Small community of antivaxxers
 - Vaccine hesitancy ~20%
- High public interest in safety of vaccines
- Transparency important for trust
 - High demand for information
 - Openness on ADR reports
 - Prime Minister and Minister of Health and Care Services have promised full openness
- Media coverage is well-balanced - in general



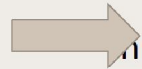
Norwegian setting II

- High degree of reporting adverse events
 - Reporter receives written feedback, incl. causality assessment
 - Transparency
- HCP: mandatory reporting of serious and/or unexpected AEFIs
 - Low threshold for reporting for new vaccines

Follow up of the program

Norwegian registries

- SYSVAK – mandatory Norwegian immunisation registry
- MSIS – Norwegian infectious diseases registry
- BIVAK (NIPH) - NorADRR (NoMA) - Adverse events following immunisations registry
- National patient registry



in a good position to follow up SAFETY and EFFICACY

Observed 5th-8th January

- Spontaneous reports of fatal events in very frail patients
 - Difficult to establish causal relation
- Reemphasis advice – more detailed guidance
 - severely frail patients or patients with a short remaining life expectancy must be assessed individually
 - Clinical frailty scale (level 8 or higher)
 - Same principle applies for decision making on provision of all medical care for this patient group
- HCP working in nursing homes
 - Protect residents against covid-19 infection vs. Toleration adverse events in frail/fragile patients

First report published by NoMA 14th January

- 13 deaths reported within 6 days of vaccination
 - Fever, nausea/vomiting, shortness of breath and cough
 - Some had symptoms of concomitant acute illness prior to vaccination
 - Several of the reports labelled «unrelated», but reported «just in case»
- No context or background information
- No explanation of findings
- Next day: English translation published
 - >44 000 individuals
 - nursing home residents with many co-morbidities
 - Fragile patients; high frailty score

Lessons learned

- Need context and background information
 - Number doses given
 - Vaccinated population/health state
 - Temporal relationship does not imply actual causal relationship
- Background rates of expected events
 - 300-400 patients die in Norwegian nursing homes every week from natural causes
- Prepare the public (before start of vaccination)
 - Media message: «On average 300-400 patients die in Norwegian nursing homes every week. Vaccinees will die following vaccination, most likely of natural causes»

Lessons learned II

- Assessment of causality – challenging to explain:
 - Reporter's causality = «unlikely»
 - Mild/moderate adverse events *might* contribute to worsening of already poor general condition and fatal outcome in very frail/fragile patients
 - PV center causality = «Possible» implies temporal relationship but not proven causality
- High impact/media coverage
 - English translation of material
 - Prepare/inform national and international partners
- Learning from others: Icelandic approach
 - NoMA are establishing expert committee for independent review of fatal cases

Status per 4th February

- Weekly report (NoMA website)
<https://legemiddelverket.no/godkjenning/koronavaksiner/meldte-mistenkte-bivirkninger-av-koronavaksiner>
- All fatal cases among elderly, frail individuals
 - Several of the cases reported *without* suspicion of causality
 - Review by independent expert group
- No statistical indication of increased risk of death

Thank You for Your
attention!