From ethics guidelines to implementation: lessons from the Norwegian covid-19 response

Jasper Littmann

08.12.2022

Covid-19 roles and responsibility

Government

Government decides vaccination strategy and other measures based on advuce from the Norwegian Directorate of Health, the National Institute of Public Health, and The Norwegian Medicines Agency

Ministry of Health and Care Services

Responsibility for steering committee for the covid vaccinatiion programme, requests analyses and assessments related to vaccination from the Directorate of Health, the National Public Health Institute and the Norwegian Medicines Agency

Helsedirektoratet

Provides expert advice to government and munisipalities, resposnsible for vaccination equipment

FHI Folkehelseinstituttet

In charge of the covid-vaccination programme, incl. recommendations of vaccines, purchase, distribution, prioritisation, surveillance. Advice to the public and the health care sector.

Statens legemiddelverk Norwegian Medicines Agency

Approves covid-19 vaccines and is in charge of surveillance of vaccine-related side effects that are reported by the public

Municipalities

Carry out vaccination in line with FHI's recommedations and guidelines.

The covid-19 immunisation programme

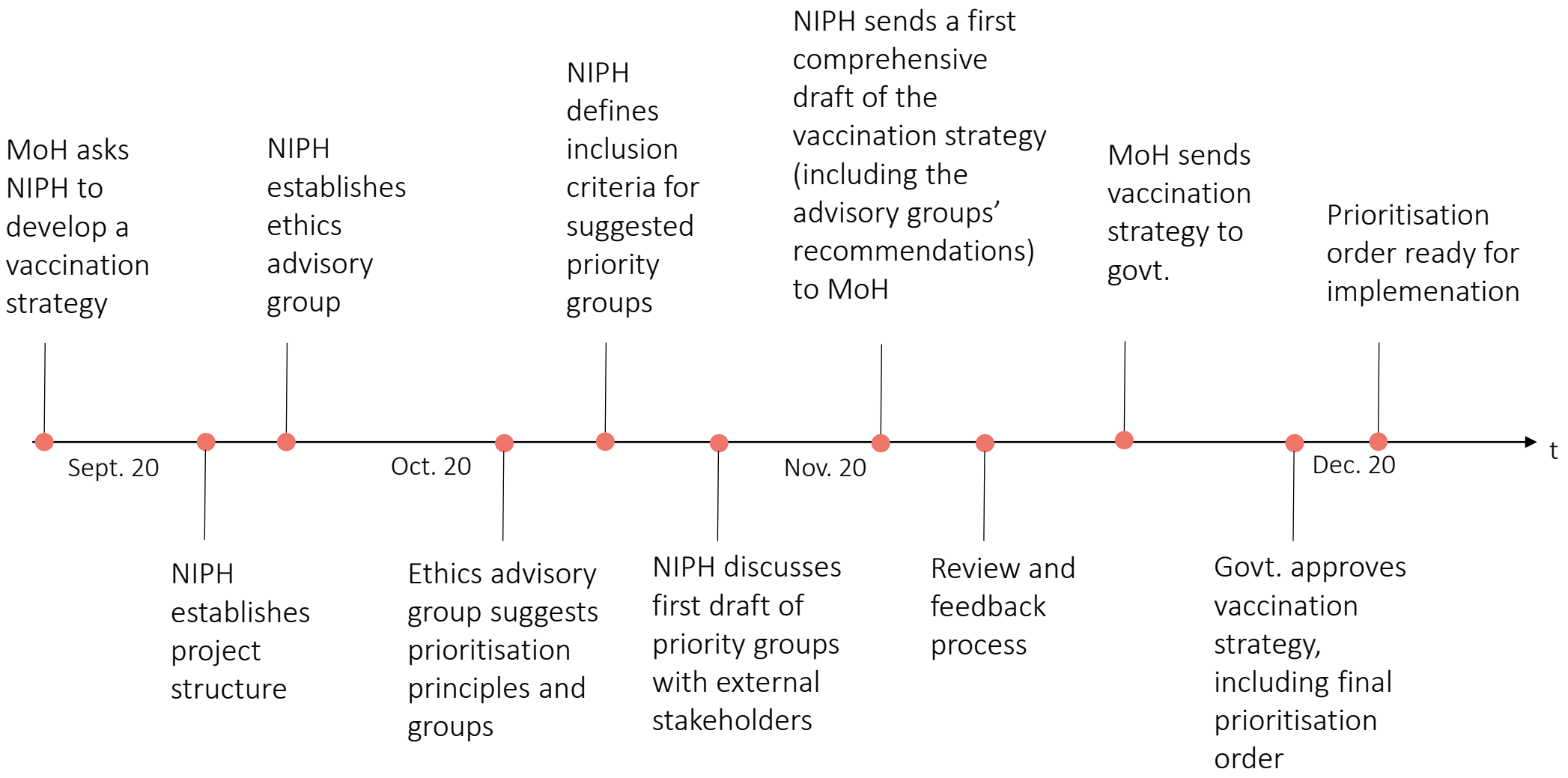
Ministry of Health and Care Services

National Institute of Public Health

Coordination
international partners
National partners

Development and adjustment of vaccination plan	Recommendations & prioritisation	Surveillance	Communication	Analysis and research coordination
	Ethical considerations			
	Risk groups			
	Vaccine intelligence			
	Epidemiological scenarios			
	Economic analyses			

Time line


MoH asks NIPH to develop a vaccination strategy
NIPH establishes project structure
NIPH establishes ethics advisory group
Ethics advisory group suggests prioritisation principles and groups
NIPH defines inclusion criteria for suggested priority groups
NIPH discusses first draft of priority groups with external stakeholders
NIPH sends a first comprehensive draft of the vaccination strategy (including the advisory groups' recommendations) to MoH
Review and feedback process
MoH sends vaccination strategy to govt.
Govt. approves vaccination strategy, including final prioritisation order
Prioritisation order ready for implemenation
Sept. 20
Oct. 20
Nov. 20
Dec. 20
t

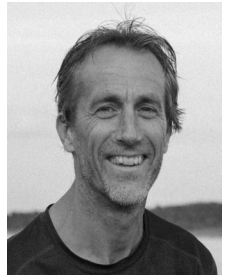
Independent ethics review


Eli Feiring


Ole F Norheim


Gry Wester


Søren Holm


Berge Solberg


Reidun Førde

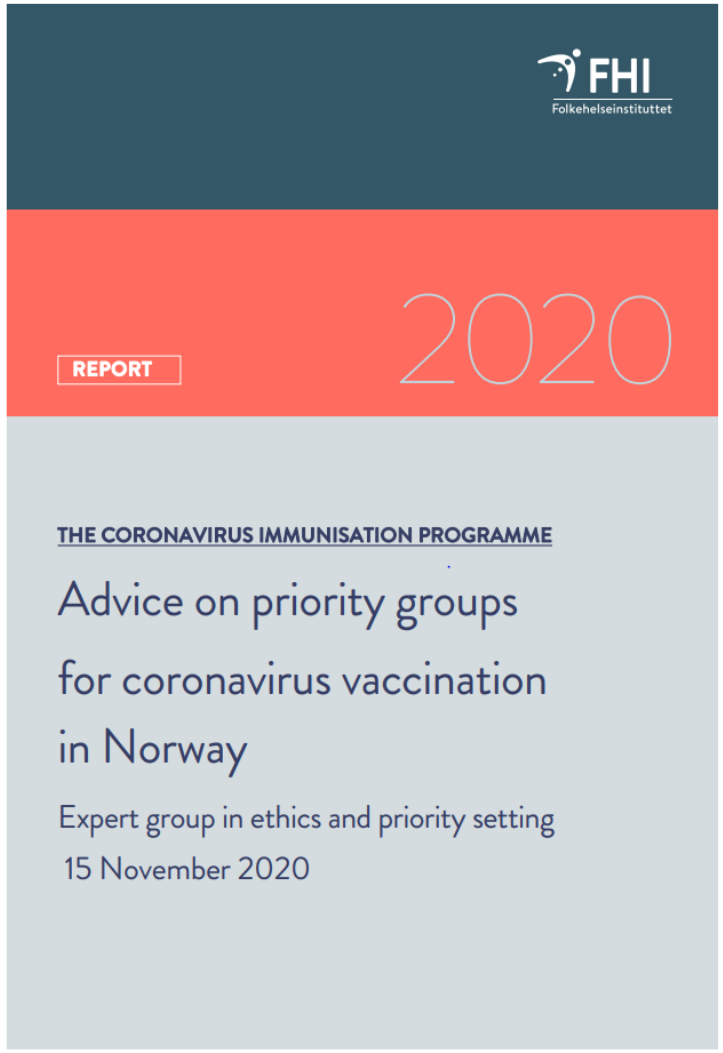
- Independent report, commissioned by NIPH
- Report was the foundation for NIPH's recommendation to the government
- Report's main recommendations were all followed

<u>Secretariat</u>
Jasper Littmann
Carl Tollef Solberg
Trygve Ottersen

Values for prioritisation

- Equal respect (non-discrimination)
- Welfare (do good; harm reduction)
- Equity (obligation not to increase social inequality)
- Trust (transparency and voluntariness)
- Legitimacy (evidence-based, with input from affected parties)
- Reciprocity (discussed but not included)

Goals for prioritisation



Goals are ranked according to priority

- Reduce the risk of death
- Reduce the risk of severe illness
- Maintain essential services and critical infrastructure
- Protect employment and the economy
- Re-open society

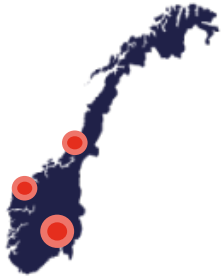
Note: departure from focus on QALY-maximisation

Criteria for prioritisation

1 Medical risk factors

- age (65+)
- underlying illness
- Diagnostic codes from electric patient files
- Code selection based on national registries and literature review
- List to be continually updated

2 Geographical differences



- Possible prioritisation of regions with presisently high incidence/prevalence
- Potential for prioritising densely populated areas

3 Professions

- 2 initial groups:
  a) Health care workers
  b) Critical infrastructure workers
- Prioritisation in line with the vaccination campaign's goals: protection of life and health

Prioritisation criteria must be adjusted to the epidemiological situatiuon and the vaccines' properties

Uncertainty during ethics review

- Which vaccines would be approved by EMA (and when)
- Delivery schedule (and packaging)
- Organisation of the national vaccine distribution network
- Storage requirements and shelf life for each vaccine
- Vaccine effectiveness in different age groups for each vaccine candidate
- Vaccine effect on transmission for each vaccine candidate
- Epidemiological situation upon arrival of vaccines

- SCENARIO-BASED DYNAMIC PRIORITISATION

Epidemic surveillance

Epidemiology

Transmission
Hospital admissions and deaths
R and projections
Immunity and vaccination

Vulnerable groups
Risk groups

Capacity

Primary and tertiary care
Testing and contact tracing
Personal protective equipment
Drugs
Vaccines

SCENARIOS AND MEASURES

FHI
Folkehelseinstituttet

1a Control

Good hygiene
Testing and isolation
Tracing and quarantine
Distancing

1b Control with clusters

Good hygiene
Testing and isolation
Tracing and quarantine
Distancing

Home office
Protecting health care facilities

2a Partial control

Good hygiene
Testing and isolation
Tracing and quarantine
Distancing

Home office
Protecting health care facilities

Avoid public transport
Avoid domestic travel
Protect risk groups

CONSIDER CLOSING
Offices and events
Restaurants and bars
High schools and universities

2b Widespread transmission

Good hygiene
Testing and isolation
Tracing and quarantine
Distancing

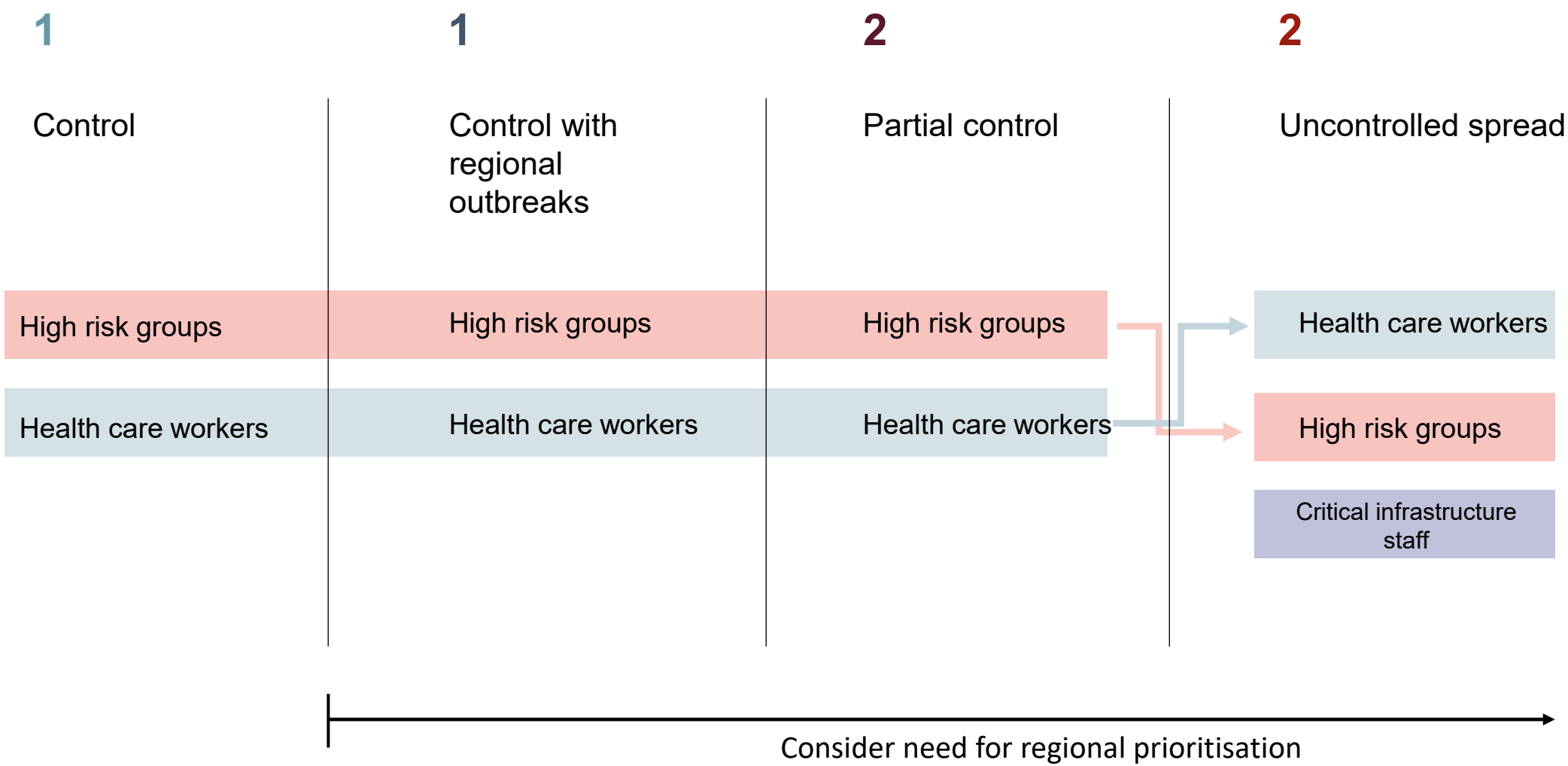
Home office
Protecting health care facilities

Avoid public transport
Avoid domestic travel
Protect risk groups

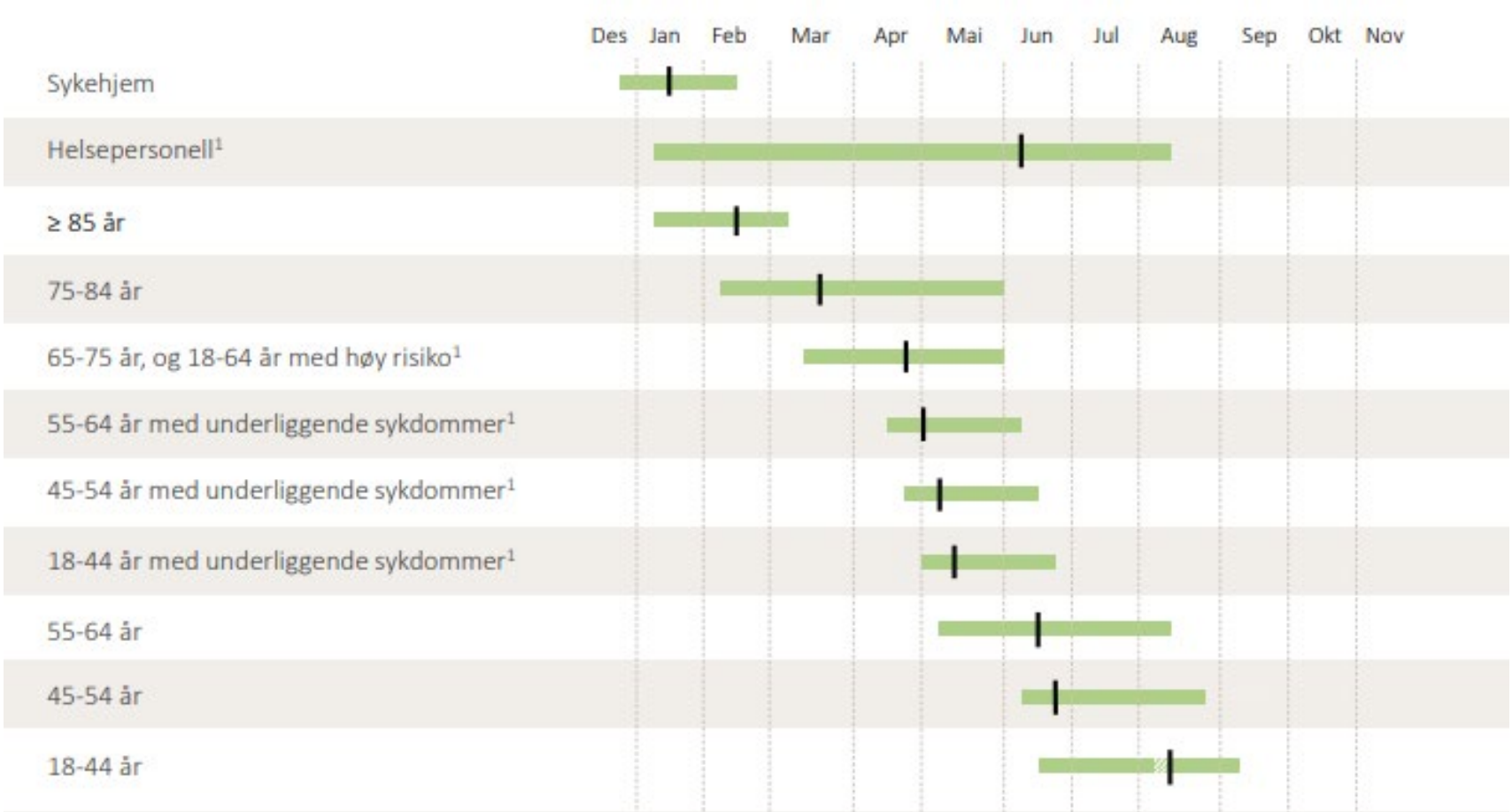
CONSIDER CLOSING
Offices and events
Restaurants and bars
High schools and universities
Other businesses
Nurseries and primary schools

IN EXTREME SITUATIONS
Curfew

Dynamic prioritisation



Order of prioritisation



ANTALL DOSER ('1000)	Levert	53	197	319*	497*	730	1 230	1 380	1 140	2 680	1 500	390	390
ANTALL DOSER ('1000)	Distribuert	2	126	400	520	710	1 210	1 380	1 020	1 970	210	-	-

Lessons learned: what went well?

- Rapid recruitment of external experts for the ethics review
- Agreement on principles for distribution before discussing individual prioritisation groups increases consistency: it makes it possible to set later decisions into context
- Publishing of guiding principles before vaccines were available, as soon as possible, and communicate them clearly.
- Be clear about the need for revision as information becomes available (dynamic prioritisation).
- Prepare for different epidemiological scenarios from the outset

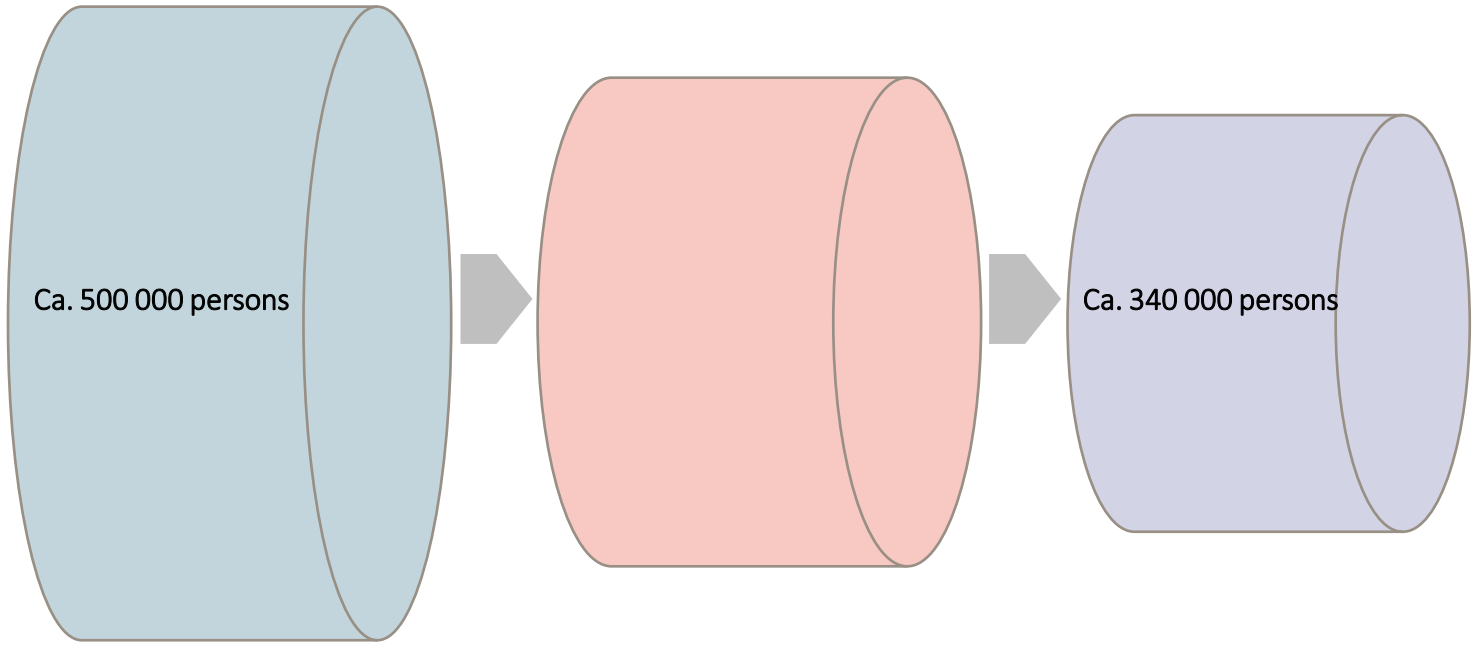
Lessons learned: what we did not fully anticipate

- Agreement on principles prior to vaccine availability does not avoid conflict once these principles become action-guiding in practice.
- Interest groups rarely take into consideration opportunity costs of their requests
- Solidarity has an expiration date (geographical prioritisation)
- There may be confusion about:
  - How to account for direct and indirect health effects of vaccination
  - the scope of a national guideline
- Definitions of prioritised groups matter, and rules will be interpreted differently, leading to local and regional differences in who is prioritised (*«Who is a health care worker?»*)

- Follow-up decisions about the interpretation of the general ethical advice had to be made by FHI, not by the expert group (weekly review of requests)

Which health care workers should be prioritised?

Criteria	Relevante profession?	Relevant institution	Direct patient contact
Data source Norwegian Labour and Welfare Administration (*NAV AA Register*)	Ca. 500 000 persons		Ca. 340 000 persons
Classification	Professional classification STRYK-08	Standard for employer SN 2007	NIPH's own assessment



Lessons learned: what we should do differently next time

- Define a clearer (government) mandate for an ethics expert group, and for the selection of its members. If not:
  - People will question how members were (not) chosen
  - Experts will be more at risk to be exposed to personal attacks.
- Be even more specific about decision-making processes: ethics is an important consideration, but one of many factors that inform the governments' decision
- Make available resources to continually review ethics recommendation throughout the pandemic
- Include ethics reviews in non-vaccine related decisions (social distancing, lock-downs, etc.)
- Prepare before the next pandemic: definitions for prioritised groups (health care workers, risk groups) can be agreed upon in advance, with input from relevant stakeholders.

B:CEPS
BERGEN CENTRE FOR ETHICS AND PRIORITY SETTING IN HEALTH

FHI
Folkehelseinstituttet

Thank you!