Pharmacovigilance – COVID-19 vaccines – Norway:

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- NOMA member of European regulatory network ➔ Benefit Risk assessment = EU (CHMP) decision.
- National level: Norwegian Institute of Public Health - mandated to decide on how to use COVID-19 vaccines
  - option to undertake benefit-risk assessment at group level
- **Lesson Learned:** With a few exceptions our pharmacovigilance verifies the safety profile seen in clinical trials.
  - Thrombosis with Thrombocytopenia Syndrome (TTS) and myocarditis/pericarditis
- **Pharmacovigilance tools:**
- Active spontaneous ADR reporting - HCP and consumers (electronically submitted).

  ➔ near real-time monitoring of COVID-19 vaccine safety ➔ signals picked up early – e.g., TTS
- National population-based health registries incl. the vaccination registry
  - e.g., risk of myocarditis after vaccination.
- Large health survey cohorts (NIPH)
  - Enrolled on a voluntary basis (vaccinated and unvaccinated): respond to health questionnaires
  - e.g. useful when data on background incidence is limited
- Communication: Summary reports on incoming ADR reports - published weekly
  - The general public expects transparency
- **Vaccine uptake – not negatively affected: 79-96 % depending on the age group (adult population, 2 doses)**