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Implementation of nirsevimab in Finland in 2024-2025

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Conflicts of interest

- Advisory board, Sanofi, 2024
- Lecture, Chiesi, 2024
- Expert meeting, MSD, 2024
- Webinar, Sanofi, 2025

Background

- Massive disease burden of RSV in infants
- RSV epidemics lead to crowding of paediatric hospitals
- Effectiveness and safety of nirsevimab well documented
- Maternal vaccine is an alternative strategy for passive immunization

Decision process for including **vaccines** in the general immunization program in Finland

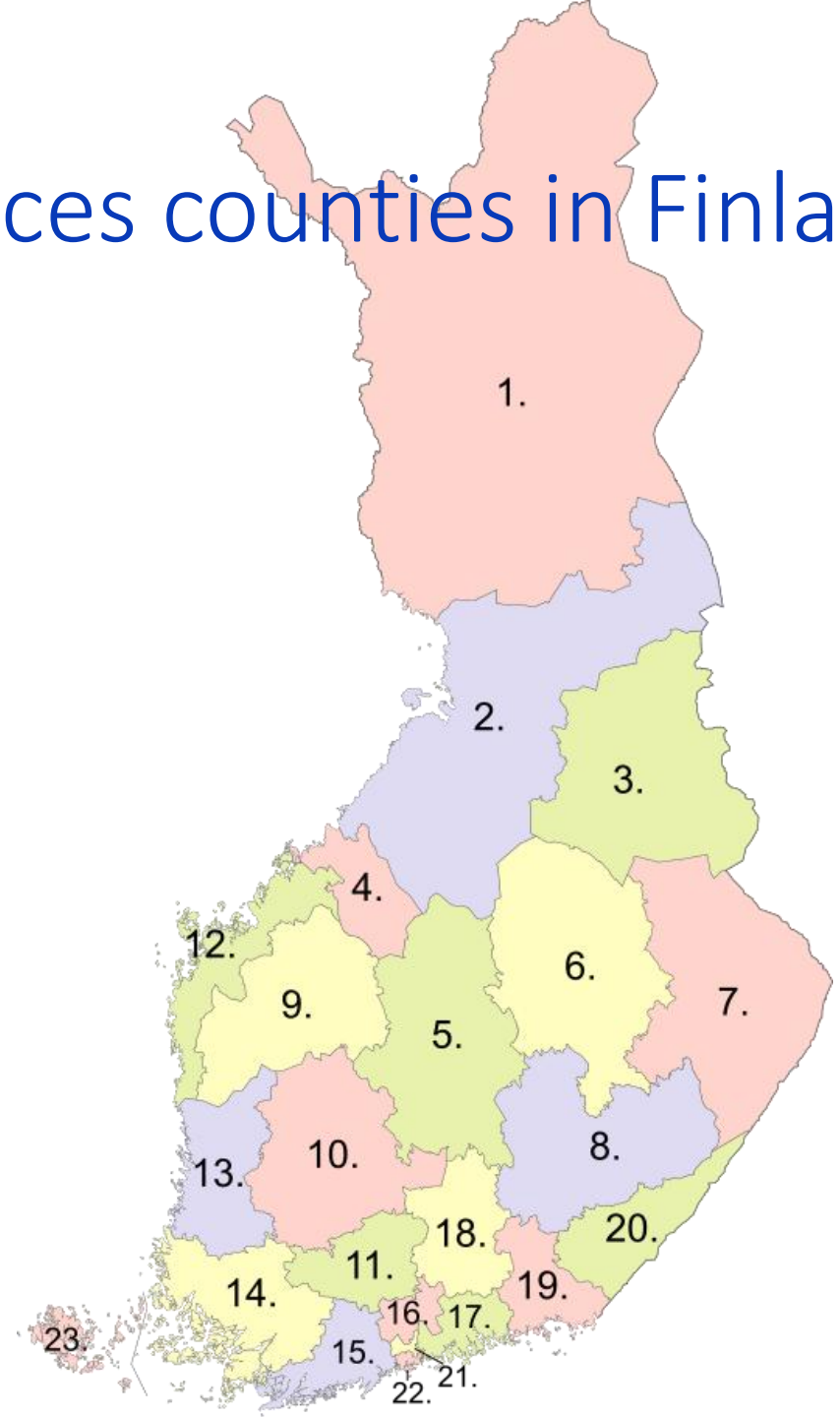
- The Finnish Institute for Health and Welfare (THL), under the Ministry of Social Affairs and Health (STM), evaluates vaccines considered for the general immunization program, with the help of the National Immunization Technical Advisory Group (KRAR)
- STM purchases the recommended vaccines, usually after price competition based on conditions set by THL
- **No recommendation for maternal RSV vaccine yet**

Decision process for nirsevimab in Finland

- The THL-KRAR-STM path could not be used for nirsevimab because it is technically not a vaccine
- Nirsevimab was evaluated similarly as certain expensive drugs
- This pathway involves evaluation by:
  The Finnish Medicines Agency (FIMEA)
  The Council for Choices in Health Care in Finland (PALKO)
  The National Health Technology Assessment Coordination Unit (FINCCHTA); National Advisory Committee on Drugs

- Price negotiations for the whole country by the Pharmacy of Helsinki University Hospital
- **Decision-making by each wellbeing services county**

Wellbeing services counties in Finland



Progress of nirsevimab evaluation in Finland

- In September 2023, the Finnish Medicines Agency (Fimea) published a Health Technology Assessment
- In May 2024, PALKO published the final recommendation supporting nirsevimab for all infants <3 months of age and certain high-risk groups, on conditions that availability is sufficient and price is markedly lower than the list price
- In 17th June 2024, the National Advisory Committee on Drugs at FINCCHTA supported PALKO's recommendation
- In 20th June 2024, HUS Group published a contract notice
- By the beginning of September 2024, all wellbeing counties had made their decision to use nirsevimab according to the recommendation during the season 2024-2025

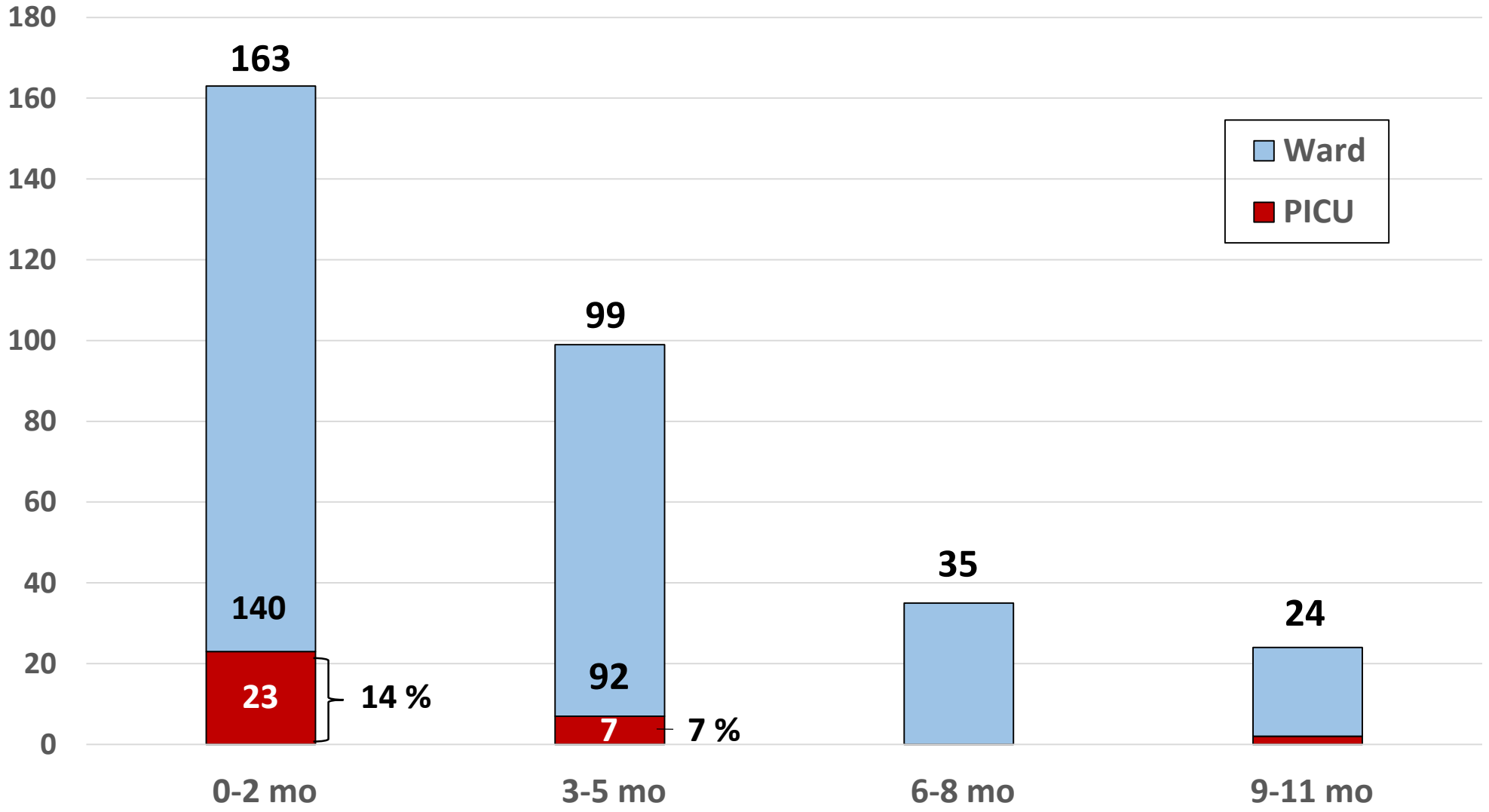
Target groups for nirsevimab in Finland

- All infants younger than 3 months of age at the start of the RSV epidemic season
- All infants born during the RSV epidemic season (estimated 1.10.24-31.3.25)
- Infants less than 1 year of age in the following risk groups:

  -Preterm birth before gestational week 29+0
  -Preterm birth at gwk 29+0 - 36+6 and an older sibling
  -Congenital heart disease requiring surgery or continuous medication
  -Severe immune deficiency
  -Bronchopulmonary dysplasia on treatment within 6 months or another comparable chronic lung disease or ventilatory insufficiency
  -Down’s syndrome
- Target groups cover about 75% of children born in a year

RSV hospitalizations, age <1 year

Turku University Hospital, 7/2021-6/2024 (n=321)



Heikkinen T et al

Risk factors for severe RSV infection during the first year of life: development and validation of a clinical prediction model

(Vartiainen P et al. Lancet Digital Health 2023;5:e821–30)

- Registry study of 2.72 million infants born in Finland 1997-2020 or in Sweden in 2006-2020
- 16 risk factors of RSV hospitalization were identified in a Finnish dataset
- Prediction model was validated in Finnish and Swedish datasets
- Number needed to immunize to prevent one RSV hospitalization can be estimated according to the predicted risk
- Months from birth to the next estimated epidemic peak, having older siblings younger than 4 years and gestational age at birth were the most important predictors

Implementation: Specifics of target groups

- An unofficial group of pediatric infectious diseases specialists took care of coordination of implementation
- It was decided that the epidemic season starts in 01.11.24 and continues until the end of March or April; finally administration was stopped between 30.04.25 and 15.05.25
- Infants <3 mo of age were defined as those born on 01.08.24 or later
- If mother had received an RSV vaccine >2 weeks before birth of the child, nirsevimab needed not to be given

Implementation: Administration of nirsevimab in 2024-2025

- Administration to newborns at the postnatal ward at the age of 1-2 days: started in October or at the beginning of November
- Administration to those <3 mo of age (born in August-October) in well baby clinics:
  -mostly during scheduled visits at 1, 2 or 3 mo of age during October-December
  -some areas organized separate immunization days
- Children in the risk groups with severe chronic diseases or very preterm birth were identified by hospital pediatricians
  -administration at the hospital
- Part of risk group children (birth at gwk 29+0 - 36+6 and an older sibling and those with Down's syndrome) immunized at well baby clinics

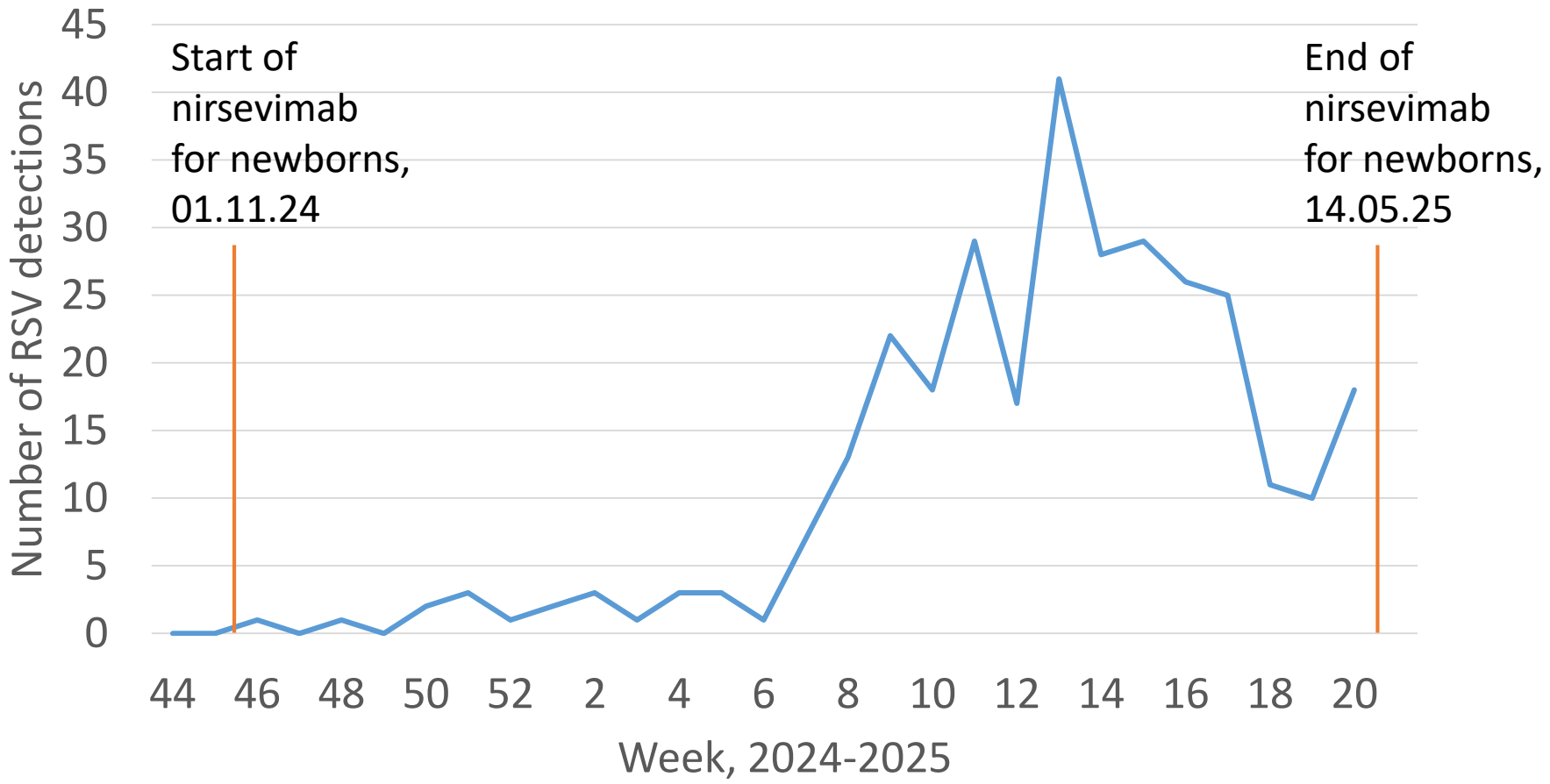
Information campaigns

- Organized locally by wellbeing counties
- Limited time frame
- Social media groups of pregnant women had an important role
- Most parents of young babies in Finland probably already knew about RSV
- Informing immigrant families was a challenge

Documenting nirsevimab use and estimating effectiveness

- Big challenges because of lack of national coordination
- THL agreed to collect the data nationally, but the vaccine registry was not compatible with nirsevimab
- Different health data systems were a problem; data was directly sent to THL only from parts of the country
- University hospitals documented their own use
- RSV hospitalizations are followed up nationally by THL

Weekly RSV detections at the Dept. of Microbiology, Turku University Hospital, season 2024-2025



Experiences

- At the newborn wards very positive attitudes by personnel and parents
- Experiences from well-baby clinics variable. 1 or 2 month visit better time than the 3 month visit because of other vaccinations.
- In some parts of the country difficulties in giving immunizations at well-baby clinics

Adverse effects

- No reported severe adverse effects
- Reactogenicity very low even in newborns

Coverage

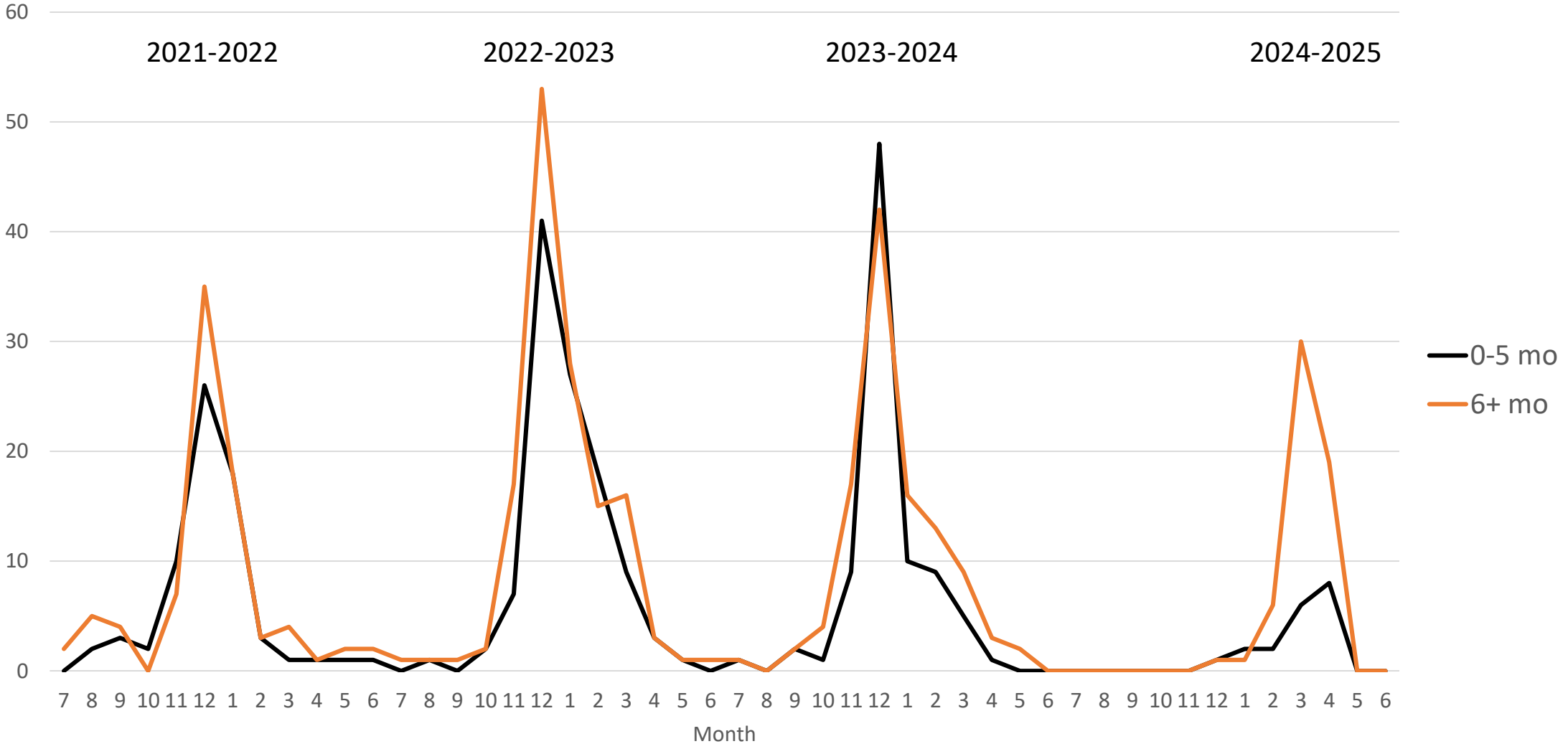
- No official national coverage data
- Council for Choices in Health Care in Finland (PALKO) coverage estimates (27.03.25): **92 % in hospitals, 89 % in well baby clinics**
- University hospitals, reported coverage in newborns:

Turku	94 %
Helsinki	90 %
Tampere	95 %
Kuopio	88 %
Oulu	80 %

- Limited data from well-baby clinics

  Data from some Varha municipalities: 77 % before 3 months of age, in total probably 80-90 % in < 4 months of age

Monthly numbers of RSV hospitalizations by age, Turku University Hospital, 7/2021 – 4/2025



Season 2025-2026 in Finland

- PALKO recommended that nirsevimab use should be continued with similar criteria in 2025-2026
- Still no recommendation for maternal RSV vaccine by THL
- All wellbeing counties decided to continue nirsevimab
- Regional differences in implementation:
  -Some regions will start newborn immunizations on 01.10.25 and give doses to those born in 01.08.-30.09. at well-baby clinics
  -Some regions do not give immunizations at well-baby clinics and have started newborn immunizations in August or September