



RSV vaccines in development for pediatric population

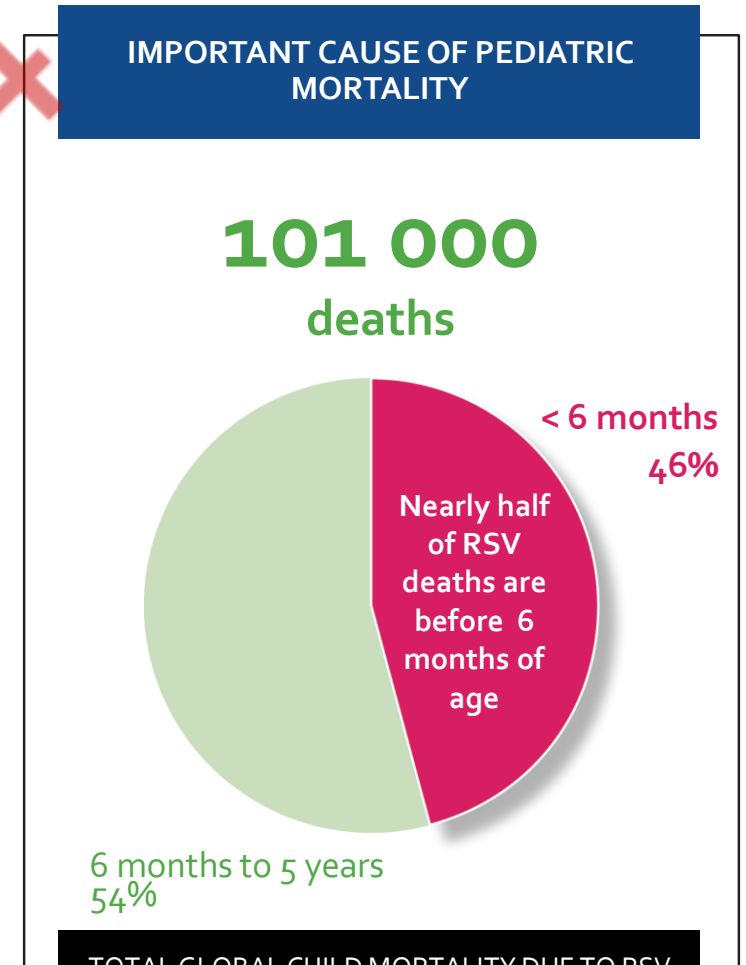
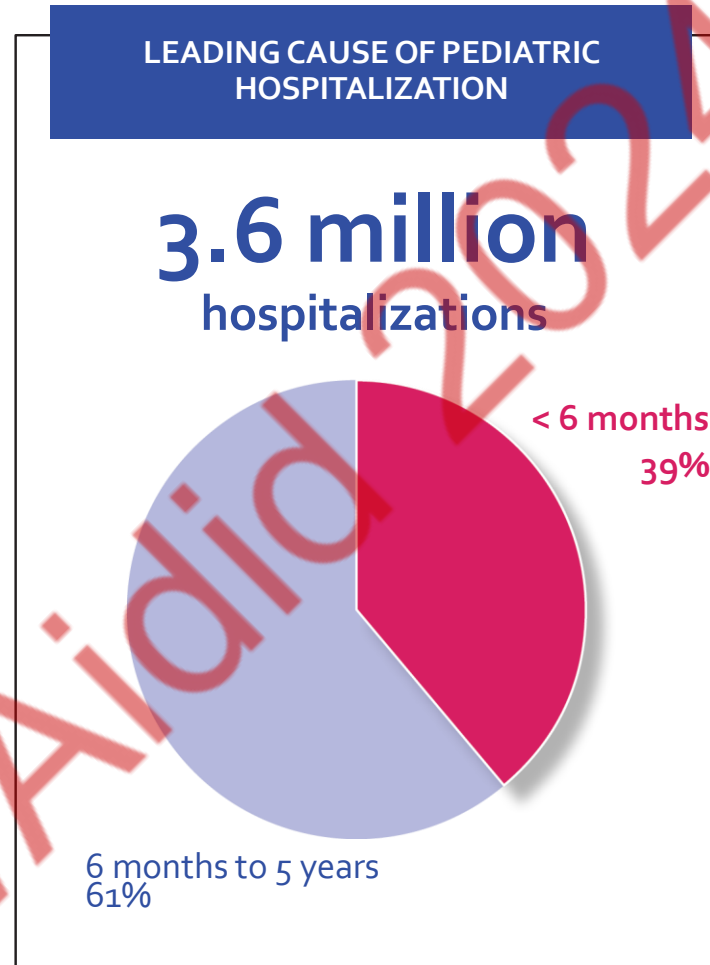
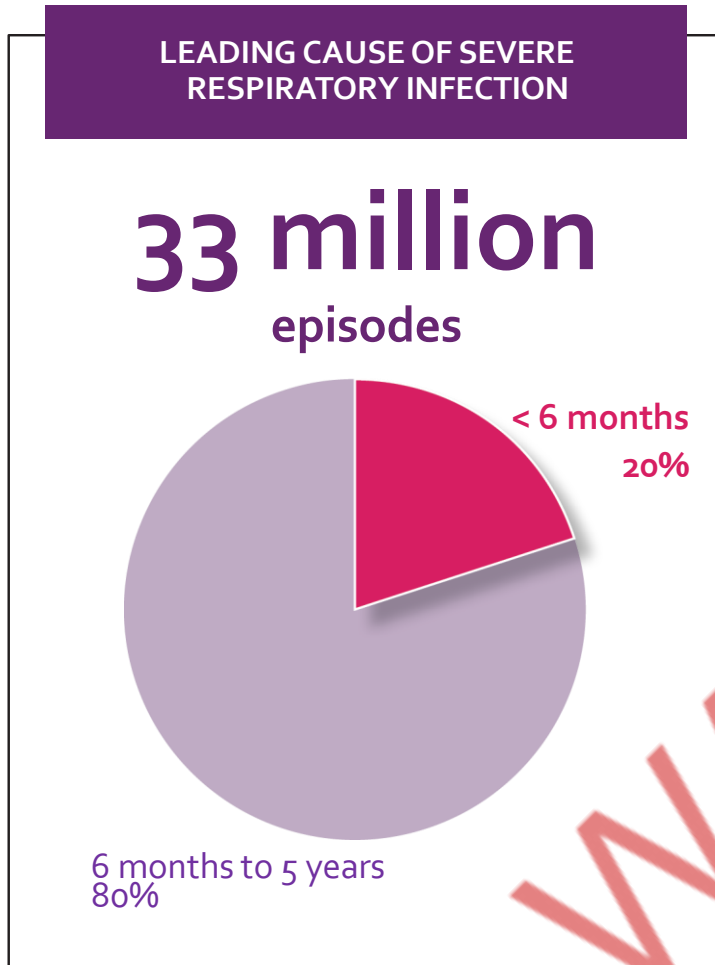
Waidid 29Nov2024

Prof Hanna Nohynek
MD PhD

Terveyden ja
hyvinvoinnin laitos
8.1.2025

RSV is a global disease, causing disease in children worldwide

Almost every child is infected with RSV by their second birthday.



TOTAL GLOBAL CHILD MORTALITY DUE TO RSV

3.6%
< 6 MONTHS

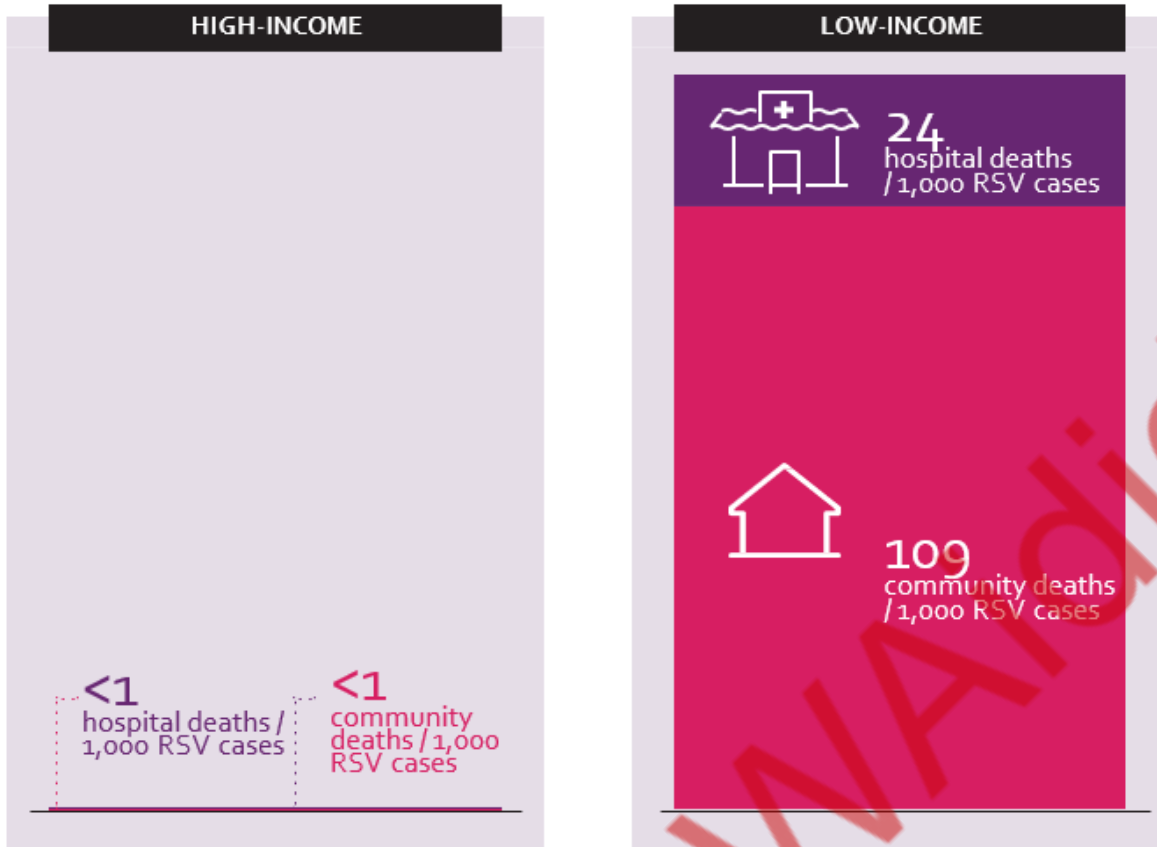
2.3%
< 5 YEARS

Reference: Li Y, et al. *Lancet* 2022.

Original slide developed by the World Health Organization and PATH. June 2024.

97% of paediatric mortality occurs in low- and middle-income countries

In children < 6 months of age, RSV is responsible for:



Many children in low-income economies never make it to a hospital.²

4X
as many children die from RSV in the **community** than in the **hospital**

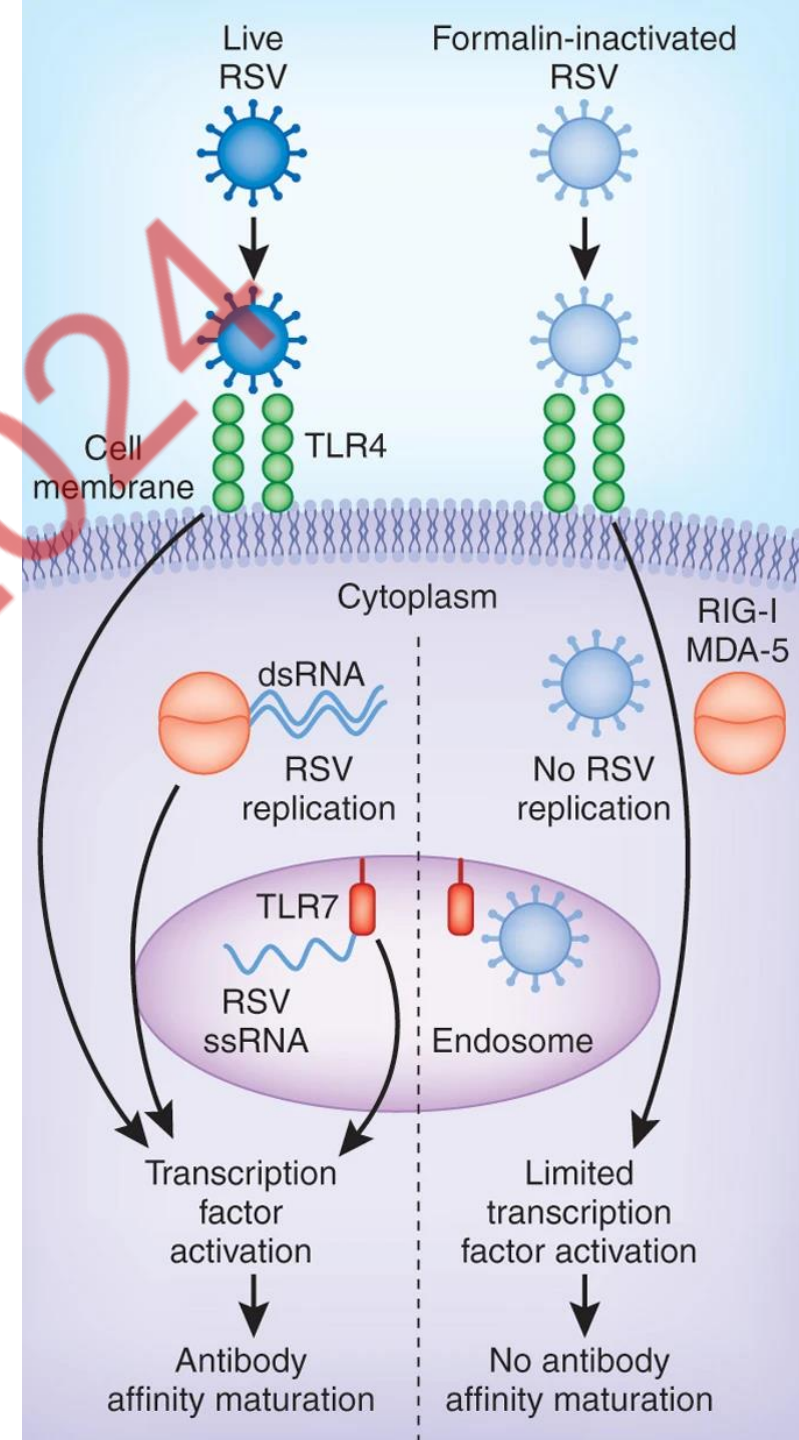
The disparity in RSV mortality between low- and high-income contexts is substantial.

¹ Li Y, et al. *Lancet*. 2022; ² Srikantiah P, et al. *Clin Infect Dis*. 2021.

Original slide developed by the World Health Organization and PATH. June 2024.

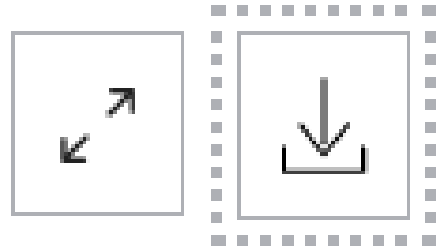
Memory of the 1960's incidence

- In 1966, children in Washington, DC received a formalin inactivated RSV vaccine.
- 80% of vaccinated children were hospitalized with severe respiratory disease; 2 died.
- Many scientists had thought the formalin was responsible for the vaccine's problems, but it has been used safely in other vaccines.
- Polack et al Nature Medicine 2008: the problem = affinity maturation. The children's antibodies were not binding strongly enough to the inactivated virus to produce a protective immune response. Instead, the antibodies were dragging the dead virus with them, triggering a massive attack by other arms of the immune system.



Pubmed search
With key words
RSV
vaccine
children

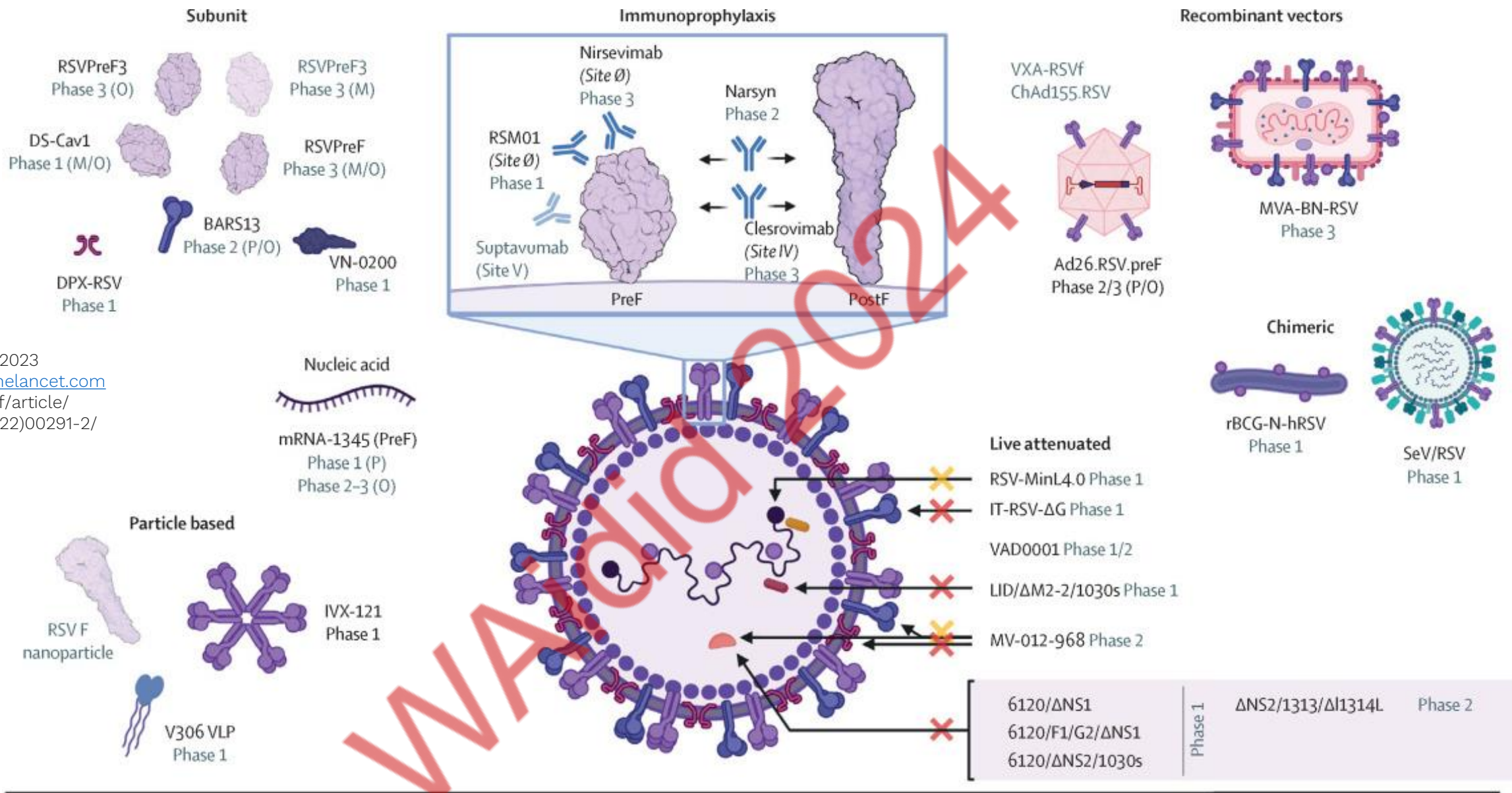
RESULTS BY YEAR



PUBLICATION DATE

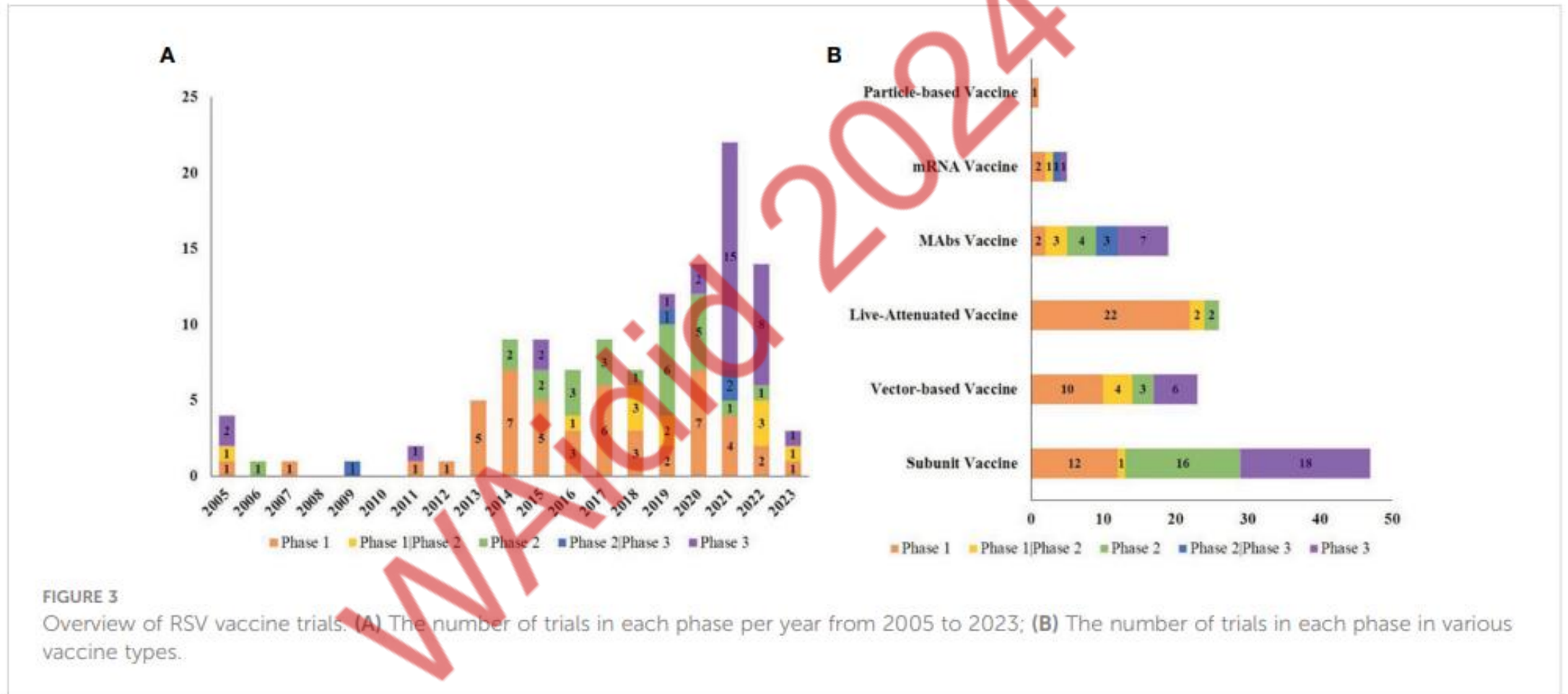


Mazur et al
 Lancet Inf Dis 2023
[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00291-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00291-2/fulltext)



Overview of RSV vaccine trials 2005 – 2023

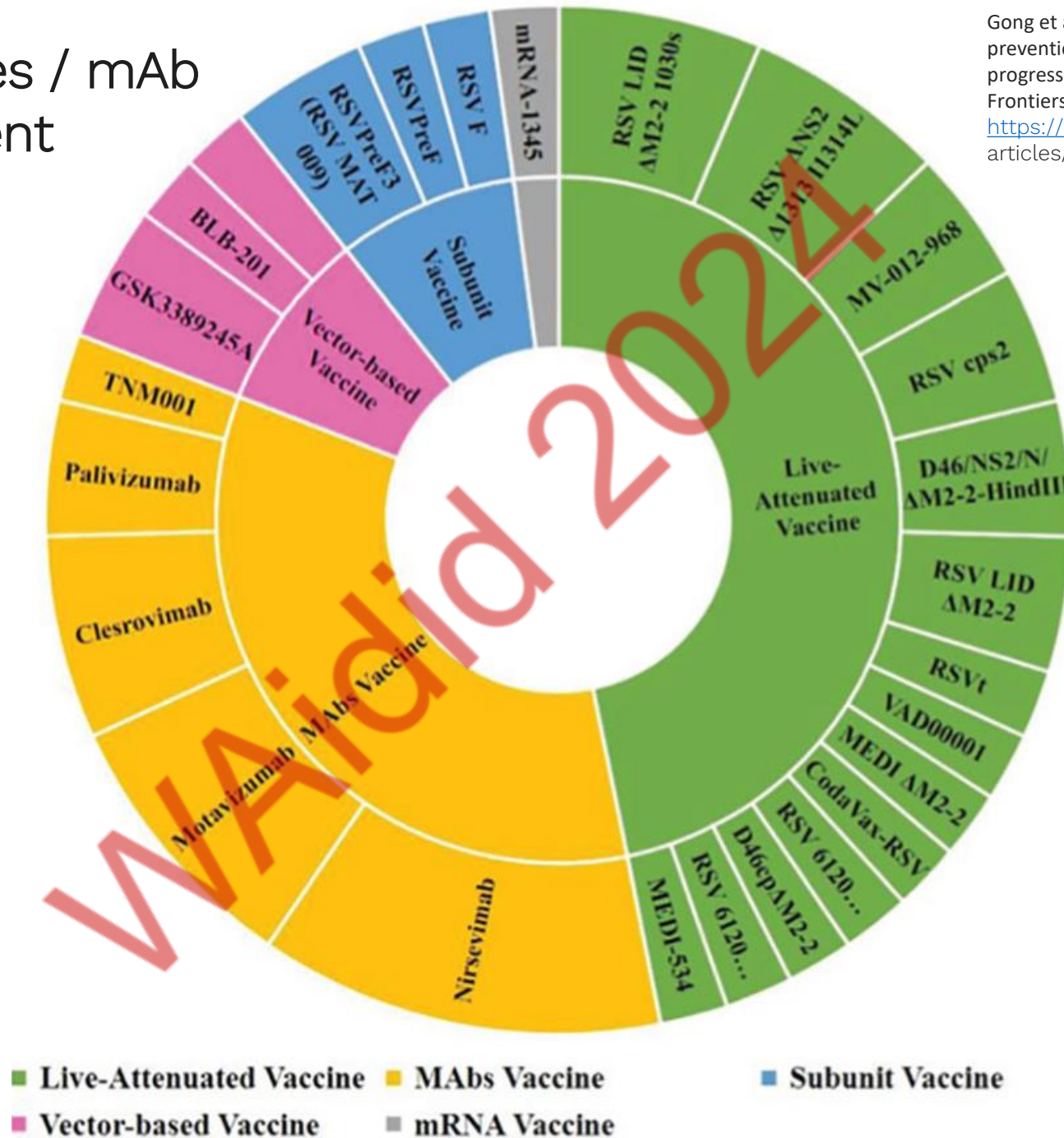
Pregnant women and children, based on info in clinicaltrials.gov



Gong et al. Clinical research on RSV prevention in children and pregnant women: progress and perspectives
Frontiers Immunology, 24 January 2024
<https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2023.1329426/full>

Types of RSV vaccines / mAb In clinical development for children

Gong et al. Clinical research on RSV prevention in children and pregnant women: progress and perspectives
Frontiers Immunology, 24 January 2024
<https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2023.1329426/full>



Gong et al: Despite recent advancements in RSV vaccines, four noteworthy concerns remain

1. the duration of the protective effect of RSV vaccines, which has been reported to last up to one year with vaccines such as MK1654, but requires further investigation to determine their **long-term efficacy**;
2. while successful outcomes have been observed with RSV vaccines for elderly individuals, maternal immunization, and infant monoclonal antibody therapy, **children aged 6 months to 5 years still require protection**;
3. the co-occurrence of RSV and multiple influenza virus epidemic seasons results in infants frequently experiencing multiple viral infections. The efficacy and safety of administering RSV and influenza **vaccines concurrently** necessitates further substantiation through additional data.
4. Although maternal-fetal immunity serves as an effective approach for safeguarding newborns, the **potential influence of prenatal vaccination on fetal development** warrants further scrutiny.



Gong et al. Clinical research on RSV prevention in children and pregnant women: progress and perspectives

Frontiers Immunology, 24 January 2024

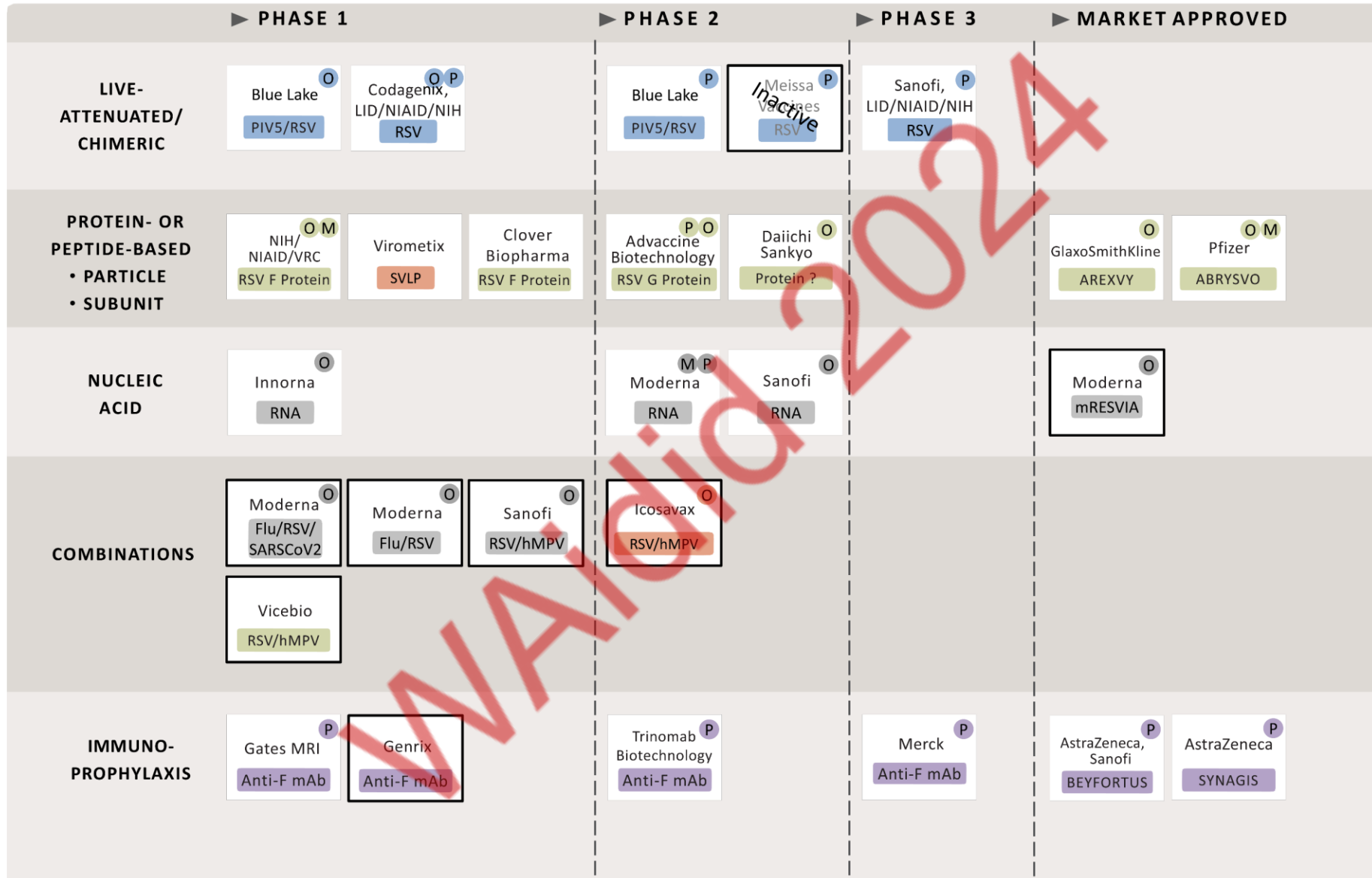
<https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2023.1329426/full>

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RSV Vaccine and mAb Snapshot

TARGET INDICATION: P = PEDIATRIC M = MATERNAL O = OLDER ADULT

PLATFORM KEY: ● = LIVE/CHIMERIC ● = PARTICLE ● = SUBUNIT
● = NUCLEIC ACID ● = mAb



UPDATED: September 18, 2024

Indicates Change

<https://www.path.org/resources/rsv-vaccine-and-mab-snapshot/>

ADVISORY COMMITTEE MEETING | VIRTUAL

Vaccines and Related Biological Products Advisory Committee December 12, 2024 Meeting Announcement

DECEMBER 12, 2024

Scheduled

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On December 12, 2024, under Topic I, the committee will meet in open session to discuss Considerations for Respiratory Syncytial Virus [RSV] Vaccine Safety in Pediatric Populations.





We are not quite there yet ...

Terveyden ja hyvinvoinnin laitos
8.1.2025



Thank you!

Questions and comments

WMAidialo 2024