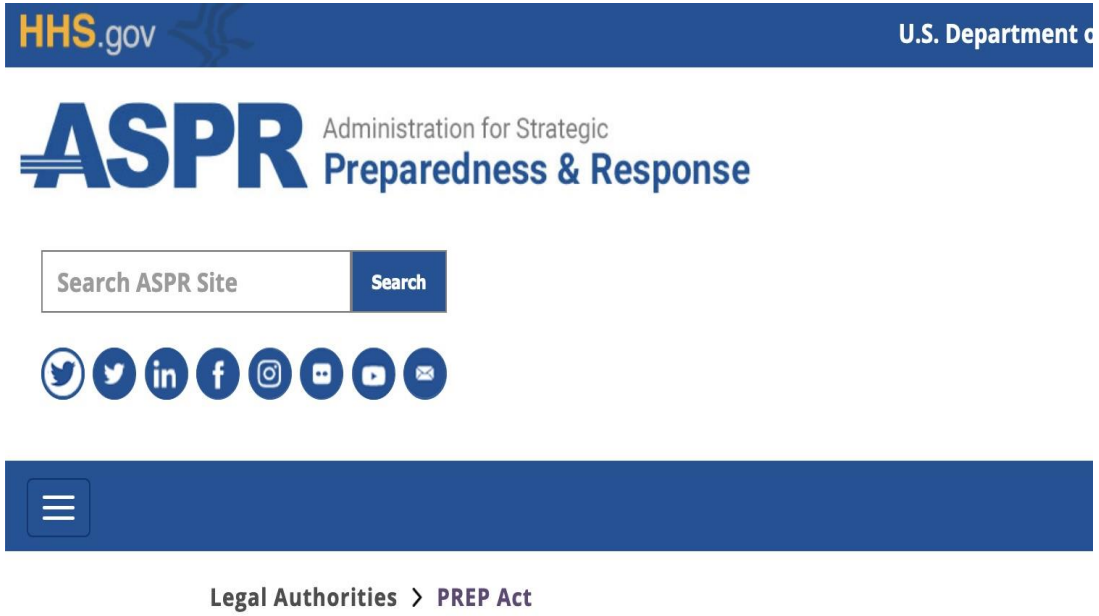
PREP Act declarations apply to active or *potential* emergencies



Other Current PREP Act Declarations

- Smallpox, Mpox, and Other Orthopox +
- Marburgvirus and Marburg Disease +
- Ebola +
- Nerve Agents and Insecticides +
- Zika Virus +
- Pandemic Influenza +
- Anthrax +
- Acute Radiation Syndrome +
- Botulinum Toxin +

What is RSV?

- RSV stands for **Respiratory Syncytial Virus**
- "In adults and older, healthy children, respiratory syncytial virus (RSV) symptoms are mild and mimic the **common cold**." *Mayo Clinic*
- By age two, 97% of babies have been infected with RSV
- Most people recover in 1-2 weeks
- We don't know how common it is, since it only causes a cold in the vast majority of people.
- Occasionally babies get a severe infection, especially in their first six months

Some babies require hospitalization for RSV

- But fluids and oxygen are usually all that they need
- 26 babies die yearly *with* RSV in the US, according to the CDC; 17 *from* RSV
- Twelve years of death certificate data were reviewed by CDC, which is considered the best information we have
- Once babies recover, there are almost never any persisting problems

Received: 24 June 2021 | Revised: 20 September 2021 | Accepted: 27 September 2021

DOI: 10.1002/hsr2.428

Health Science Reports Open Access WILEY

RESEARCH ARTICLE

Respiratory syncytial virus-associated deaths in the United States according to death certificate data, 2005 to 2016

Mila M. Prill | Gayle E. Langley | Amber Winn | Susan I. Gerber

Division of Viral Diseases, Respiratory Viruses Branch, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

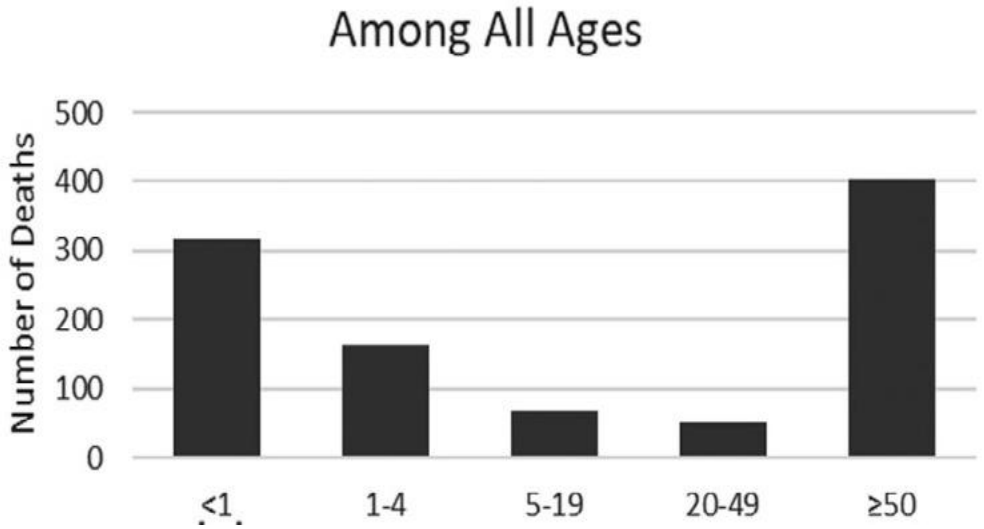
Abstract

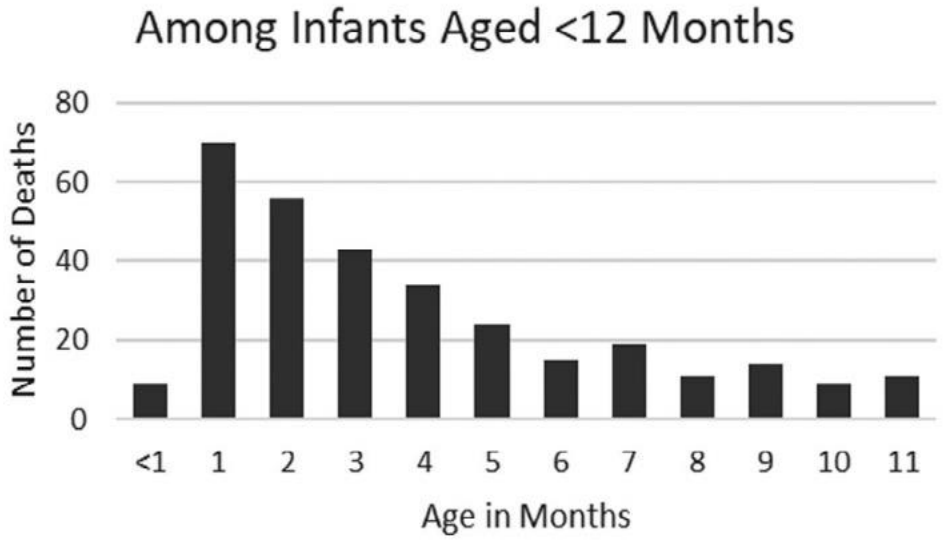
Background and Aims: In the United States, respiratory infections due to respiratory

CDC found a total of 1001 RSV-associated deaths during 12 years (2005-2016)

- Among all ages, 468 (46.8%) had an RSV-associated code listed as the primary underlying CoD
- 468 people over a 12 year span had RSV listed as the underlying cause of death
- 314 of the RSV-associated deaths were under one year old, or an average of 26 babies per year.
- 17 babies/year under age 1 had RSV listed as the underlying cause of death.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8562311/pdf/HSR2-4-e428.pdf





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Suddenly a multitude of RSV products have sprouted

An *old* monoclonal antibody given monthly to high risk, chronically ill babies (palivizumab by Medimmune)

A new monoclonal antibody to be given to all babies up to 8 months of age ***on the first day of life*** (nirsevimab=Beyfortus by Sanofi)

A vaccine for pregnant women intended to protect their newborns is pending FDA approval (the expert advisors approved it in May, then did FDA get cold feet?) Pfizer

Two vaccines for elders to protect (briefly) against RSV-licensed in May (Arexvy by GSK and Abrysvo by Pfizer)

Another vaccine for elders awaiting licensure for RSV (mRNA 1345 by Moderna)

GlobalData.

https://www.globaldata.com/media/pharma/preventative-measures-set-battle-rsv-market-domination-says-globaldata/

24 Jul, 2023

Preventative measures set to battle for RSV market domination, says GlobalData

Posted in Pharma

SHARE PRINT PAGE

May 2023 saw the world's first approval of two respiratory syncytial virus (RSV) vaccines, Arexvy by GSK and Abrysvo by Pfizer. However, these vaccines not the only prophylactic treatments hoping to stake a claim in the market ahead of the RSV season in September, with Moderna's mRNA-1345 and AstraZeneca's Beyfortus also on the horizon. Driven by these recent developments in preventative measures, sales of RSV drugs are estimated to surpass $9 billion by 2029, a growth of over $8 billion from 2023, according to GlobalData, a leading data and analytics company.

NIAID RESEARCH JOURNEYS: safe and effective RSV protein vaccines

Respiratory syncytial virus (RSV) is a common respiratory virus that usually causes mild, cold-like symptoms. However, RSV can cause serious illness or death in premature or very young infants and people over age 65, highlighting a critical need for vaccines in these populations.

JOURNEY TO A BETTER VACCINE

***After NIH scientists identified RSV as a human pathogen in 1957**, researchers tested multiple vaccines that proved unsuccessful, leading scientists to explore **RSV surface proteins as a vaccine target** for pregnant people (to protect the newborn) and the elderly.*

1980s

Scientists identified the RSV fusion "F" protein, a surface protein that helps the virus infect human cells.

1990s

NIAID researchers found the RSV F protein produced a **more protective immune response** compared to other RSV proteins.

2000s

Two forms of the RSV F protein were identified, later determined to be in **pre-** and **postfusion** states.

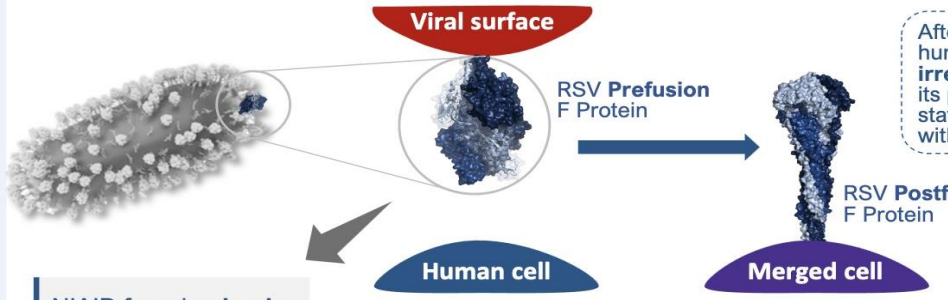
2010s

NIAID scientists **locked the RSV F protein in its prefusion state**, which was a more protective vaccine candidate.

2020s

Vaccine candidates using the locked **RSV prefusion F protein** began Phase 3 clinical trials.

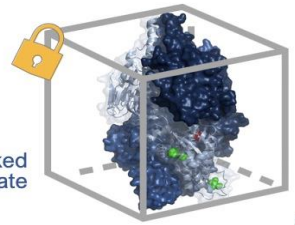
2010s: NIAID SCIENTIFIC BREAKTHROUGH
STABILIZED PREFUSION F PROTEIN



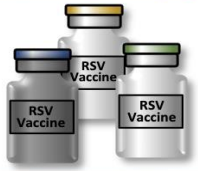
After the virus recognizes a human cell, **the F protein irreversibly transitions** from its prefusion to its postfusion state and the virus merges with the host cell.

NIAID found **animals vaccinated with prefusion F protein developed more potent immunity** than those vaccinated with postfusion F protein.

RSV F protein locked in prefusion state



2023: FDA approves the first RSV vaccine based on the locked prefusion F protein for use in special populations.



NIAID's early clinical trials with the locked prefusion F protein proved safe and induced an immune response, leading the private sector to develop similar experimental vaccines.

The locked (stabilized) prefusion F protein became a primary target for RSV vaccine development for pregnant people (to protect the newborn) and the elderly. Critical work is still needed to develop vaccines for those most affected by RSV, including infants and young children.

Did you know? *The stabilized prefusion protein technology was applied in **the rapid development of COVID-19 vaccines in the U.S.** and vaccines for other viruses.*

NIH National Institute of Allergy and Infectious Diseases

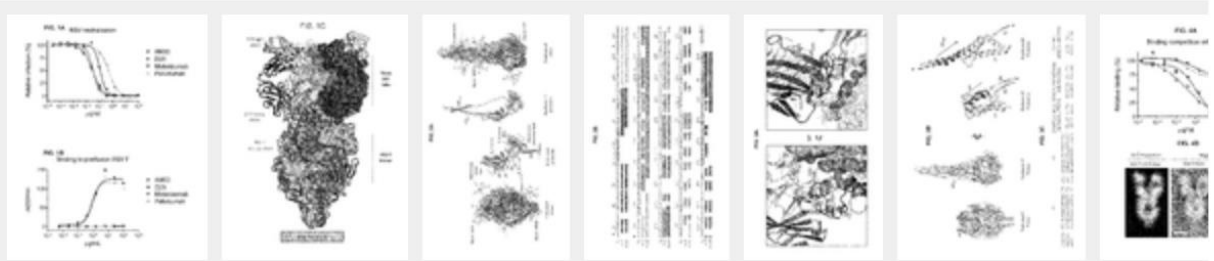
For more information, visit: https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv

Prefusion rsv f proteins and their use

Abstract

Disclosed are immunogens including a recombinant RSV F protein stabilized in a prefusion conformation. Also disclosed are nucleic acids encoding the immunogens and methods of producing the immunogens. Methods for generating an immune response in a subject are also disclosed. In some embodiments, the method is a method for treating or preventing a RSV infection in a subject by administering a therapeutically effective amount of the immunogen to the subject.

Images (20)



Classifications

C07K14/005 Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof from viruses

View 7 more classifications

US20170298101A1

United States

Download PDF | Find Prior Art | Similar

Inventor: Peter Kwong, Barney Graham, Jason McLellan, Man Chen, Baoshan Zhang, Tongqing Zhou

Current Assignee : US Department of Health and Human Services

Worldwide applications

2014 • US 2017 • US

Application US15/633,578 events

- Priority claimed from US201361780910P

2017-06-26 • Application filed by US Department of Health and Human Services

2017-06-26 • Priority to US15/633,578

2017-09-06 • Assigned to THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substitutions-modified Prefusion RSV F Proteins and their Use: Collaboration and Licensing Opportunity

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases have overcome technical obstacles to produce a homogeneous, soluble RSV F glycoprotein vaccine which is stabilized in the prefusion conformation and has improved stability and immunogenicity compared to the native protein. Additionally, several modifications were introduced to remove the requirement for furin during production, resulting in an increase in expression levels of the immunogen.

Produced by

nature research custom media

NIH National Institute of Allergy and Infectious Diseases

William B. Plowman/NBC/Getty Images

February 13, 2023

Horowitz: As FDA prepares to roll out RSV, flu shots, Fauci concedes they're not ready for prime time

Daniel Horowitz

https://www.conservativereview.com/horowitz-as-fda-prepares-to-roll-out-rsv-flu-shots-fauci-concedes-theyre-not-ready-for-prime-time-2659409502.html

Rethinking next-generation vaccines for coronaviruses, influenzaviruses, and other respiratory viruses

David M. Morens,[1] Jeffery K. Taubenberger,[2,*] and Anthony S. Fauci[1]
[1]Office of the Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD 20892, USA
[2]Viral Pathogenesis and Evolution Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD 20892, USA
*Correspondence: taubenbergerj@niaid.nih.gov
https://doi.org/10.1016/j.chom.2022.11.016

"**Past unsuccessful attempts** to elicit solid protection against mucosal respiratory viruses and to control the deadly outbreaks and pandemics they cause **have been a scientific and public health failure** that must be urgently addressed. We are excited and invigorated that many investigators and collaborative groups are rethinking, from the ground up, all of our past assumptions and approaches to preventing important respiratory viral diseases and working to find bold new paths forward."

CELL Host and Microbe, January 11, 2023

https://www.cell.com/action/showPdf?pii=S1931-3128%2822%2900572-8

CDC Recommends a Powerful New Tool to Protect Infants from the Leading Cause of Hospitalization

New immunization is the first approved and recommended in the U.S. to prevent severe RSV disease in all infants

Print

Press Release

For Immediate Release: Thursday, August 3, 2023

Contact: Media Relations
(404) 639-3286

Jabbing pregnant women

- 15-20% more preterm deliveries and low birth weight babies in vaxxed moms (Pfizer vax)
- This results in more fetal deaths and other medical problems
- There was no risk-benefit analysis performed or presented to FDA
- GSK had a very similar vaccine—it too caused preterm deliveries—and GSK shut its vaccine studies down and did not apply for a license, despite initially claiming:

"Extensive vaccine testing, including preclinical studies and phase I and II trials conducted on non-pregnant and pregnant women, demonstrated a favorable safety profile and robust immunogenicity."

https://www.ncbi.nlm.nih.gov/books/NBK594261/

- But FDA did not pull the trigger and issue a license as expected in May, possibly because its interaction with nirsevimab had not been elucidated

The monoclonal antibody for **newborns** (nirsevimab or Beyfortus)

- The only contraindication is a prior anaphylactic reaction to a vaccine component—a sick joke for a newborn
- Only side effects identified are rashes and anaphylaxis, indicating very poor safety assessment
- No monoclonal has ever been given *en masse* to babies or even adults and adverse effects remain a mystery
- Resistant strains already exist and will grow
- The cost is $400-$500 per infant

How does Pharma Funding Correlate with the Likelihood of a Drug being Approved?

Table 1 | How the regulators compare

	Australia TGA	Europe EMA	UK MHRA	Japan PMDA	USA FDA	Canada HC
Budgets and fees						
Proportion of budget derived from industry↻	96%	89%	86%	85%	65%	50.5%
Total annual budget↟	AU$170m (£95m)	€386m (£331m)	£159m	¥29.1bn (£175m)	US$6.1bn (£5bn)	C$2.7bn (£1.7bn)
Transparency, COIs, and data						
Proportion of covid-19 vaccine committee members that declared financial COIs	50%	3%	32%	75%	<10%	0%
Declared COIs available as public information	No	Yes	Yes	Yes	Yes	No
Regulator routinely receives patient level datasets*	No	No	No	Yes	Yes	No
Drug approvals						
Proportion of decisions to approve new medicines (*v* not approve)	94%	88%	98.5%	Not disclosed	69%^ 29%#	83%
Proportion of new drugs approved through expedited pathways in 2020	20%	50%	36%↟	26%	68%	16%

https://www.bmj.com/content/bmj/377/bmj.o1538.full.pdf. BMJ June 2022. Maryanne Demasi

Maybe it's just a coincidence...

https://www.bioworld.com/articles/700196-us-fda-approvals-up-20-year-over-year-average-14-a-month-in-2023

Biopharma regulatory actions and approvals July 2023

US FDA approvals up 20% year-over-year, average 14 a month in 2023

By Amanda Lanier Aug. 18, 2023

The Vaccine injury Compensation Program (VICP)

- Established by the 1986 Childhood Vaccine Injury Act
- Vaccines were established by the Supreme Court as "unavoidably unsafe"
- A 75 cent excise tax is charged to every vaccine in the program and placed in a fund to compensate those injured by covered vaccines
- Manufacturer liability is waived
- A "vaccine court" with 9 special masters adjudicate cases
- Since 1998, 10,000 claimants have received 5 billion dollars in compensation (average $500,000 each)

https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-08-01-23.pdf

The new vaccine *gold rush*: pregnancy added to the VICP

- As a consequence of the **21st Century Cures Act of 2016**, **all vaccines recommended by CDC for pregnant women** have had **all manufacturer liability waived** and are placed in the National Vaccine Injury Compensation Program.
- **This improves profitability**
- **Could it lead to mandates?**

"Warp Speed was not an anomaly. It is a new framework that requires bold new leadership to reset the Great Reset on Bodily Autonomy and Informed Consent." -- Daniel Horowitz

https://www.conservativereview.com/horowitz-cdc-committee-shockingly-approves-yet-another-rsv-shot-that-had-more-fatalities-in-trial-group-than-placebo-2663084345.html

Meryl Nass, M.D.

August 20, 2023