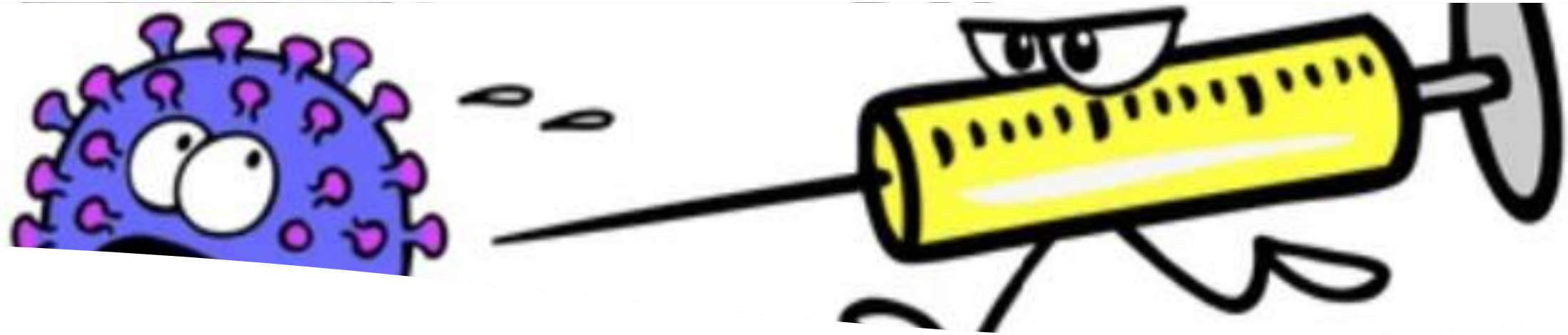


The Science of Vaccines

Dr. Manish Sadarangani

Director, Vaccine Evaluation Center, BC Children's Hospital Research Institute

Associate Professor, Division of Infectious Diseases, Department of Pediatrics, UBC

Physician Lead, Family Immunization Clinic, BC Children's Hospital

30 May, 2023

UBC

Vaccine Evaluation Center

BC Children's Hospital Research Institute

Land acknowledgement

BC Children's Hospital Research Institute operates on the traditional, ancestral, and unceded territory of the Coast Salish peoples — xʷməθkʷəy̓əm (Musqueam), Sḵwx̱wú7mesh (Squamish), and Sə́l̓ílwətaʔ/Selilwitulh (Tsleil-Waututh) Nations.

Disclosures

- Salary awards
  - BC Children's Hospital Foundation
  - Michael Smith Foundation for Health Research

- Research/Project Funding
  - Merck, Moderna, VBI Vaccines, GlaxoSmithKline, Pfizer, Sanofi-Pasteur, Seqirus, Symvivo

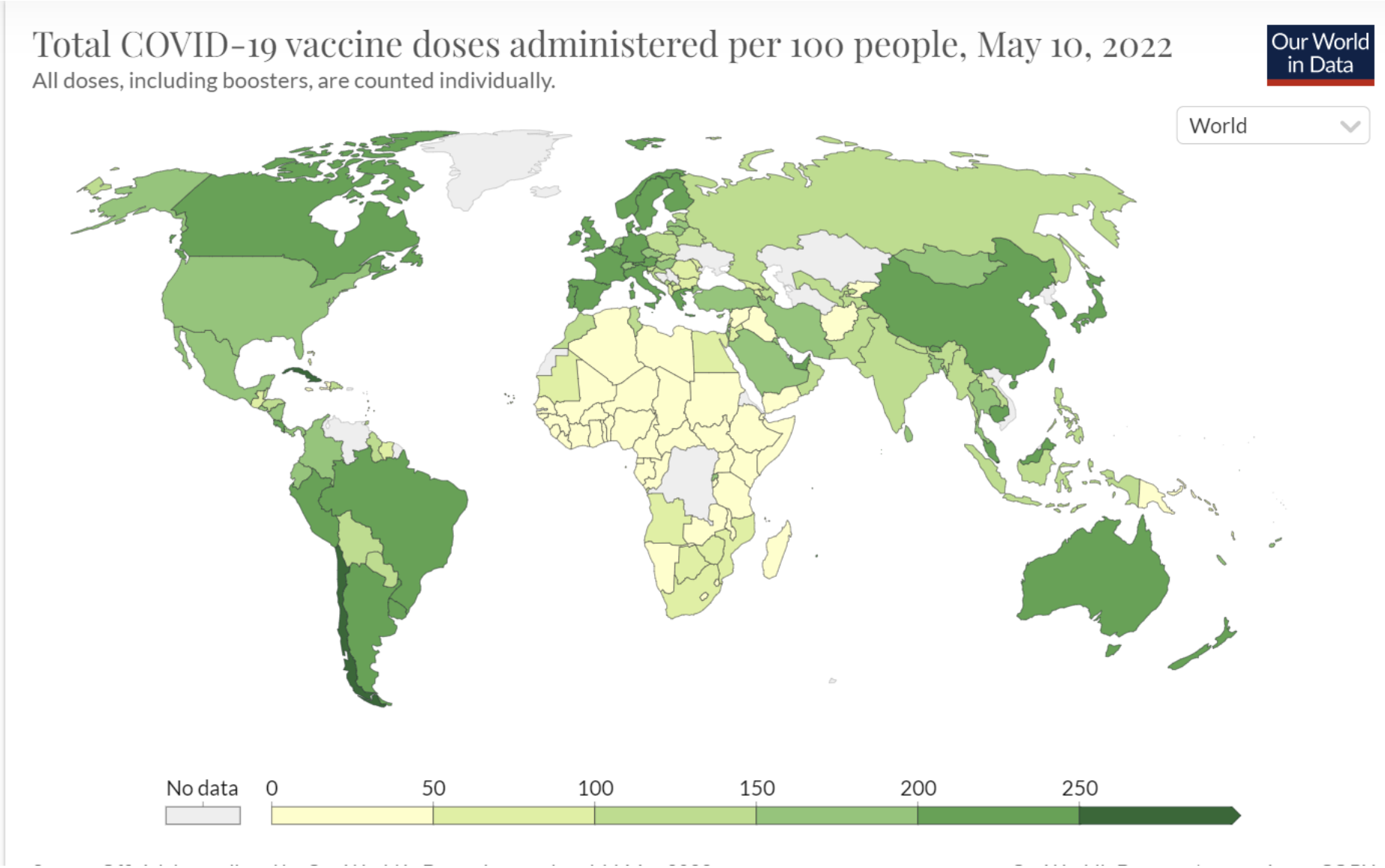
- All funds have been paid to my institute
- I have not received any personal payments

My Brief

- Advances in vaccine technology to improve vaccine delivery and efficacy
  - Reflections from COVID-19 vaccines
- New vaccines on the horizon for chronic and emerging infections
  - Respiratory infections: COVID-19, influenza, RSV
  - Antimicrobial resistance
  - Controlled human infection models (CHIMs)
- Novel strategies for addressing the challenge of vaccine hesitancy
  - The importance of your role

Vaccine technologies

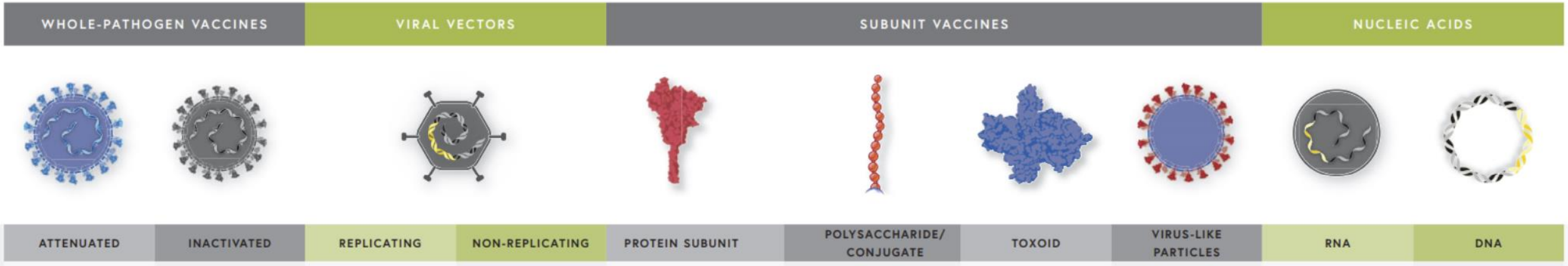
The global vaccination system has been stress-tested!



Some of the major ongoing challenges – game-changers?

- Vaccine platforms
  - Flexible, adaptable
  - Large scale manufacturing
  - Low cost
- Non-injectable administration
- Fewer doses – ideally single dose
  - Needs better understanding of how vaccines work
- Thermostable
  - In particular heat-stable

Current vaccine approaches

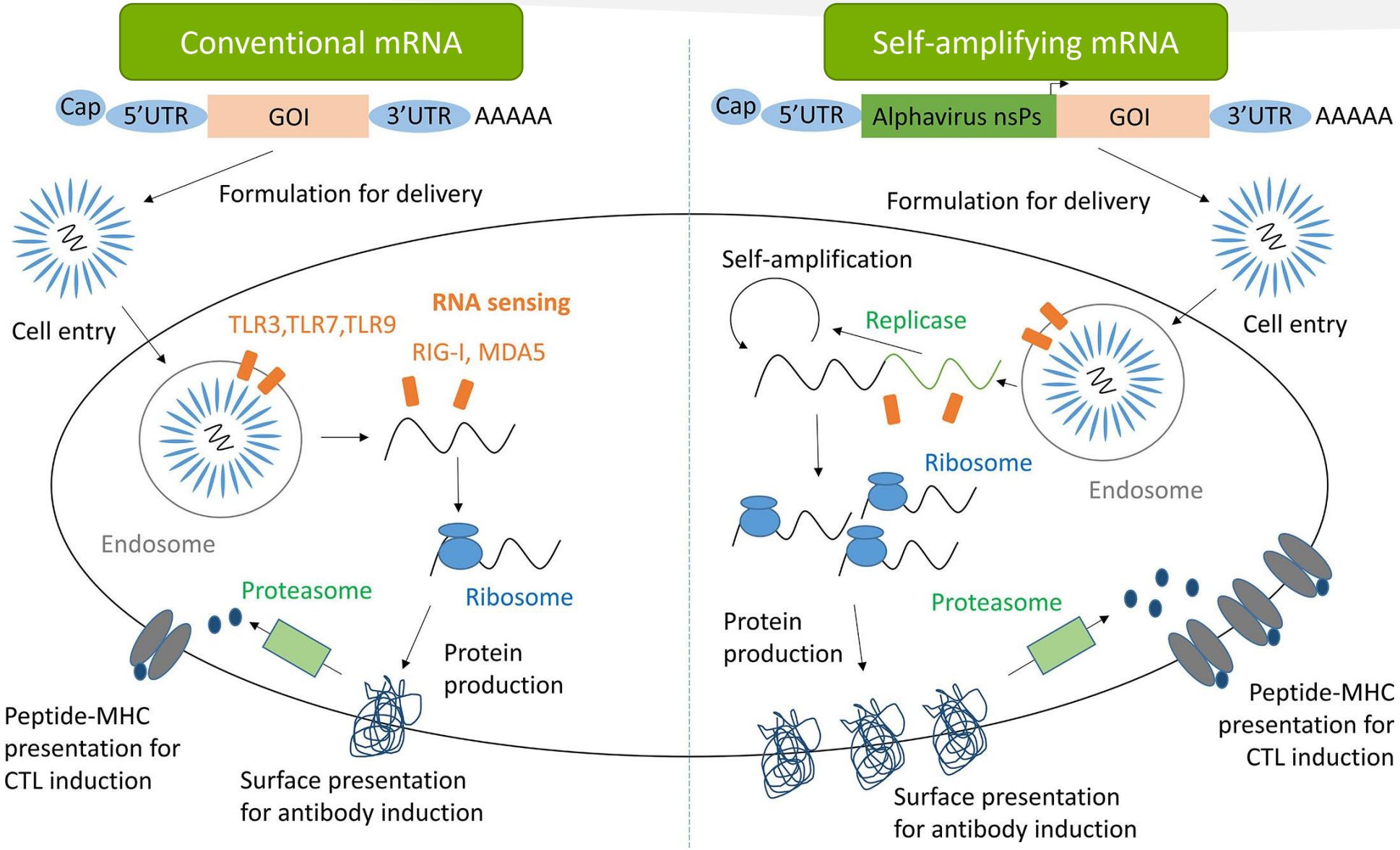


Intra-nasal influenza	Inactivated influenza	rVSV-ZEBOV (Ebola)	ChAdOx1-S Ad26CoV2S (COVID-19)	Acellular pertussis	MenC, MenACWY	Tetanus	HPV	BNT162b2, mRNA1273 (COVID-19)	ZyCoV-D (COVID-19)
Rotavirus	Polio			Hepatitis B	PCV	Diphtheria	Hepatitis B		

- Future vaccine “platforms”
  - RNA
  - Viral vector
  - Others in development

https://asm.org/resource-pages/vaccine-resources

RNA vaccines

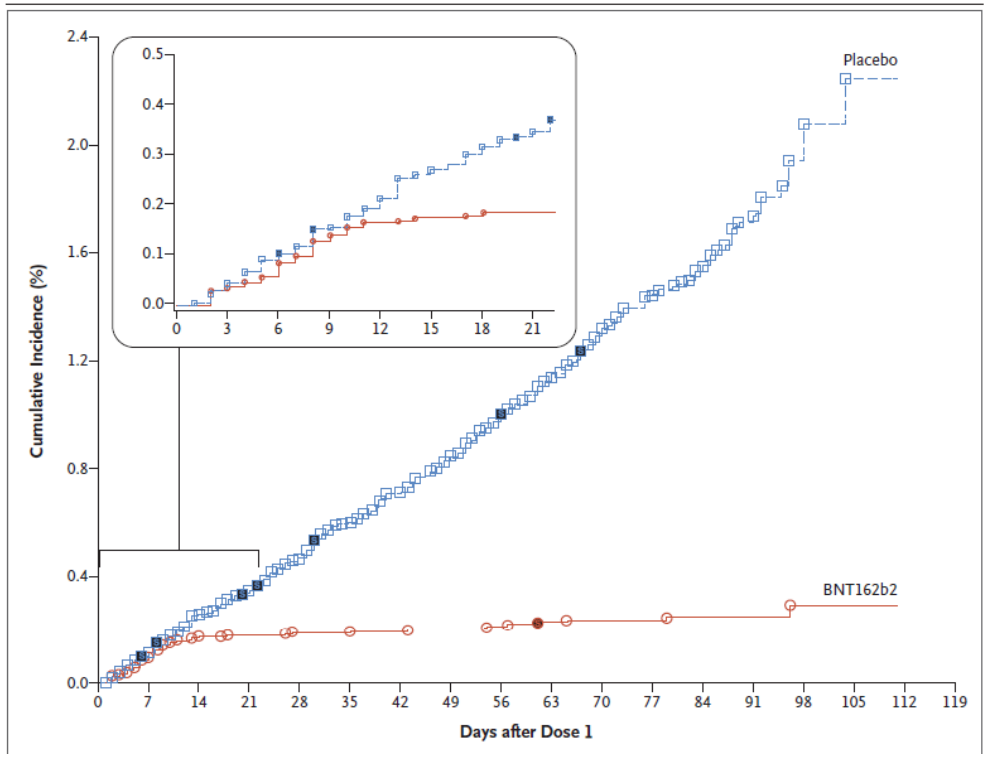


Sandbrink and Shattock. Frontiers in Immunology 2020

COVID-19 mRNA vaccines: THE GOOD

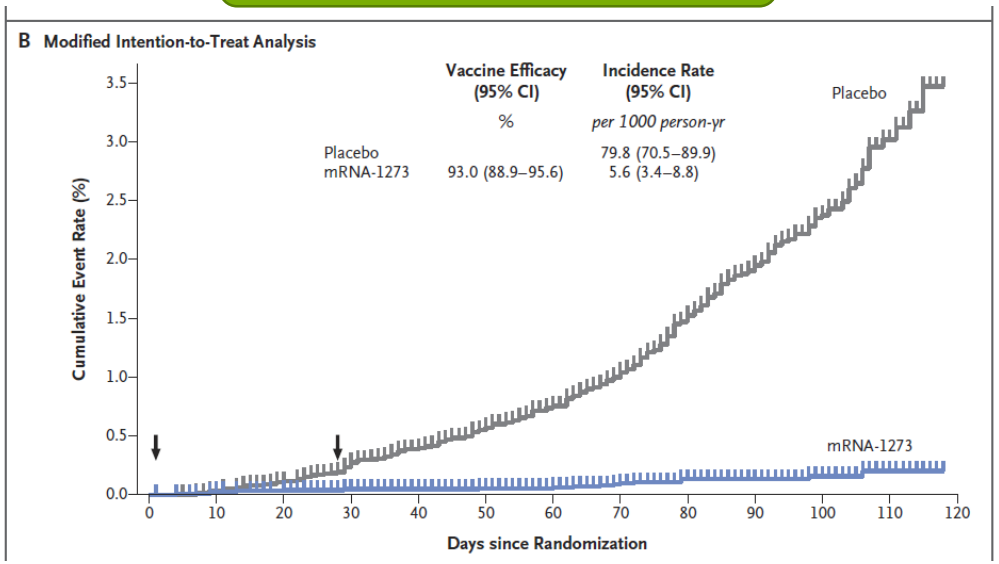
- High vaccine efficacy

BNT162b2



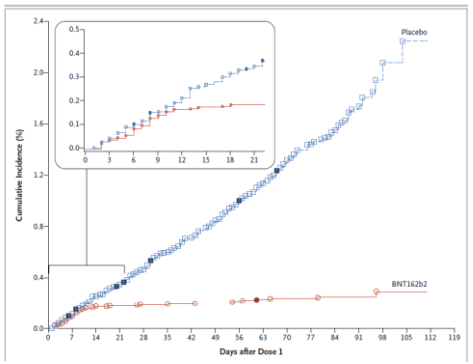
Polack et al. NEJM 2020; Baden et al. NEJM 2020

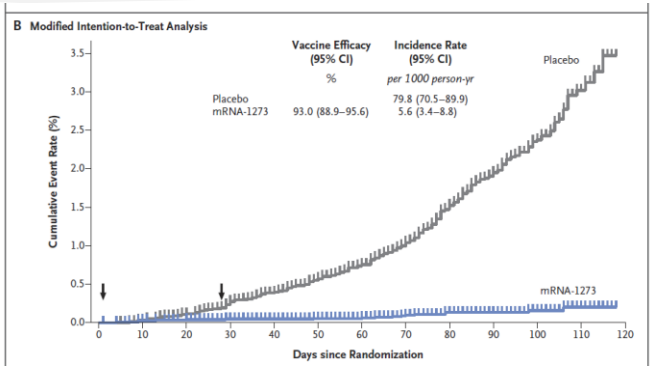
mRNA-1273



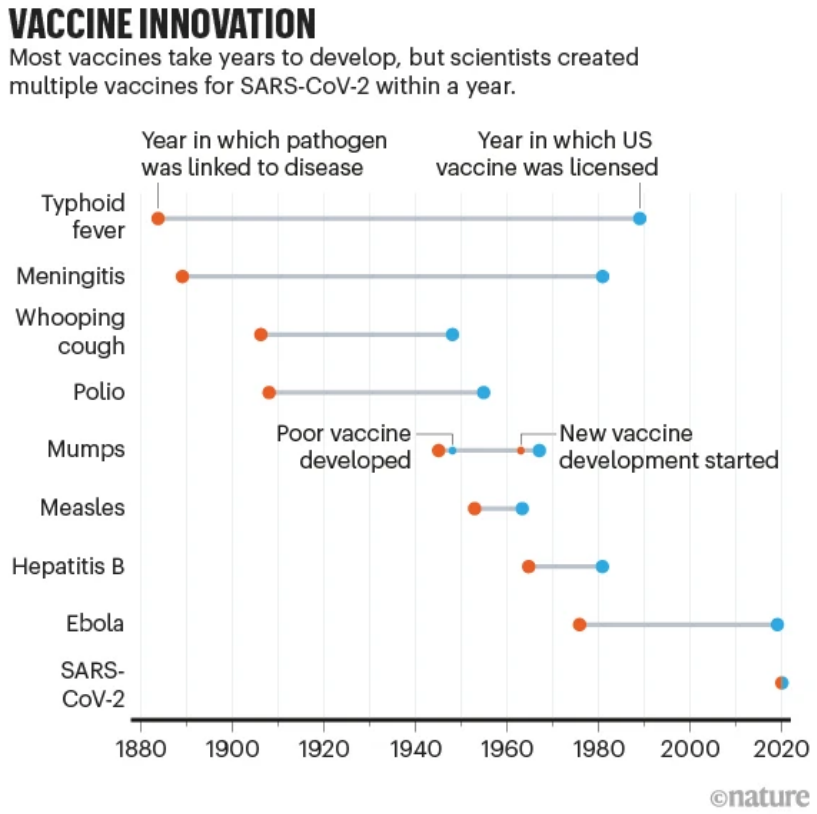
COVID-19 mRNA vaccines: THE GOOD

- High vaccine efficacy
- Rapid development





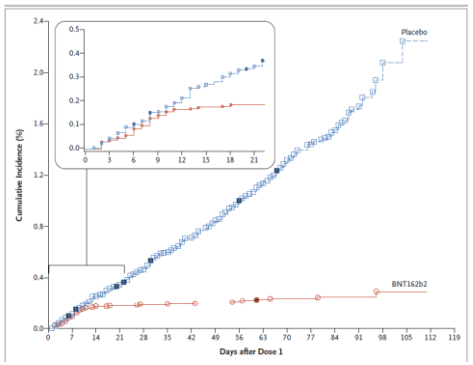
Polack et al. NEJM 2020; Baden et al. NEJM 2020

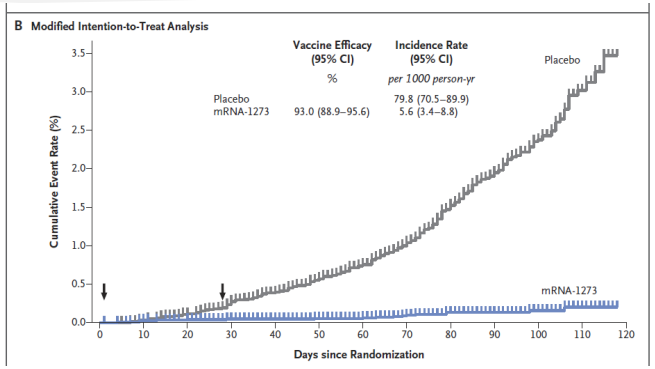


Ball. Nature 2020

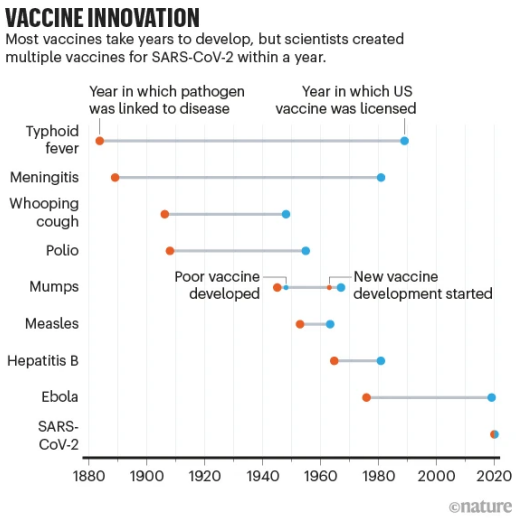
COVID-19 mRNA vaccines: THE GOOD

- High vaccine efficacy
- Rapid development
- Adapt to variants

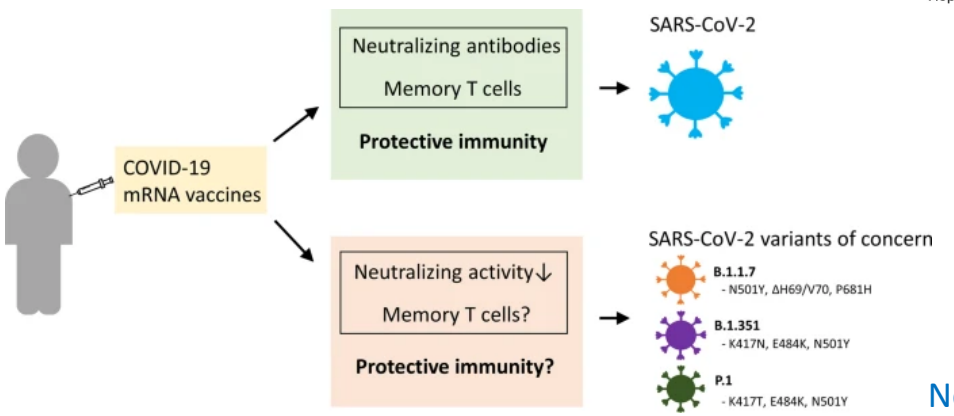




Polack et al. NEJM 2020; Baden et al. NEJM 2020



Ball. Nature 2020



Noh et al. Nature 2021

COVID-19 mRNA vaccines: THE BAD

- Adverse events
  - Very frequent local and systemic reactions
  - Rare, severe events
    - Myocarditis, pericarditis
      - Young adults, adolescents
      - Males > Females
    - Bell's palsy (facial paralysis)
- Cold chain
  - BNT162b2: -90°C to -50°C
  - mRNA-1273: -50°C to -15°C
- Need for boosters

COVID-19 mRNA vaccines: THE BAD

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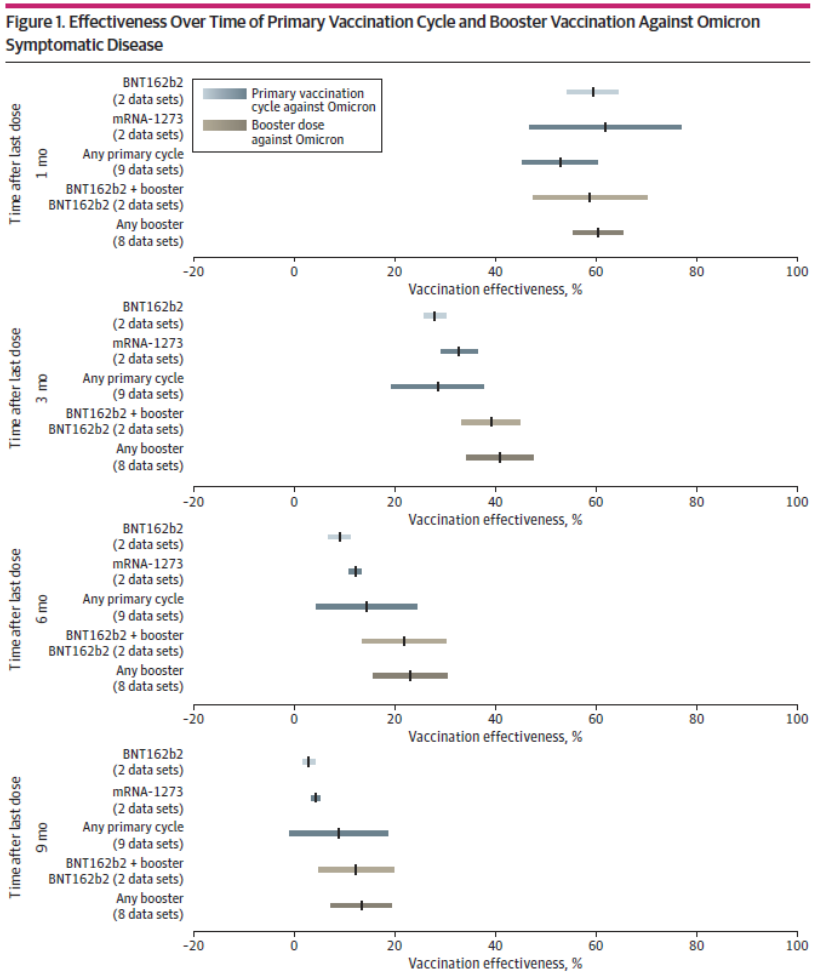


Menegale. JAMA Network Open 2023

COVID-19 mRNA vaccines: THE UGLY

- Poor global coverage

- High cost

Potential Total Cost Scenarios for One Dose of a COVID-19 Vaccine/Booster per Adult

Type of Purchase	Price/Dose ($)
Federal (Bivalent)	$29
Commercial (Low)	$96
Commercial (High)	$115

https://www.kff.org/coronavirus-covid-19/press-release/covid-19-vaccines-could-cost-billions-of-dollars-more-each-year-if-the-federal-government-ends-its-bulk-purchasing-program/

COVID-19 self-amplifying RNA vaccine

Safety and immunogenicity of a self-amplifying RNA vaccine against COVID-19: COVAC1, a phase I, dose-ranging trial

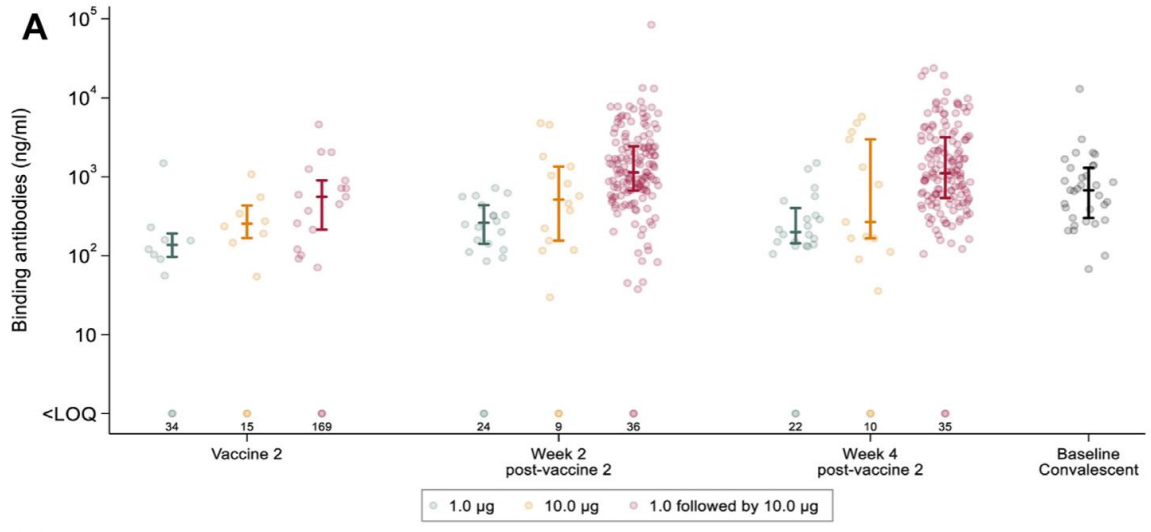
Seroconversion rate (%)

Vaccine dose	Week 2	Week 4	Week 6	Week 8
0.1 mcg	5	3	8	8
0.3 mcg	0	13	26	26
1.0 mcg	7	19	43	48
2.5 mcg	0	17	39	43
5.0 mcg	4	26	39	35
10.0 mcg	0	35	61	57

Note: conventional mRNA vaccine dose 30-100 mcg (adult)

COVAC1 phase 2a expanded safety and immunogenicity study of a self-amplifying RNA vaccine against SARS-CoV-2

Vaccine dose	Week 2	Week 4
1.0 mcg + 10 mcg	80	80



Pollock et al. eClinicalMedicine 2023 ; Szubert et al. eClinicalMedicine 2023

mRNA vaccines for other pathogens?

- Influenza

Moderna announces mixed results for influenza mRNA vaccine candidate

By **Rachel Arthur**
20-Feb-2023 - Last updated on 20-Feb-2023

Phase 3 interim data showed the mRNA vaccine candidate generated a strong immune response against Influenza A; but failed to demonstrate it was at least as effective as an existing vaccine against Influenza B.

The Phase 3 study looked at the safety and immunogenicity of a single dose of mRNA-1010 during the Southern Hemisphere influenza season: enrolling 6,102 adults across Argentina, Australia, Colombia, Panama and the Philippines.

- RSV

NEWS | 15 February 2023

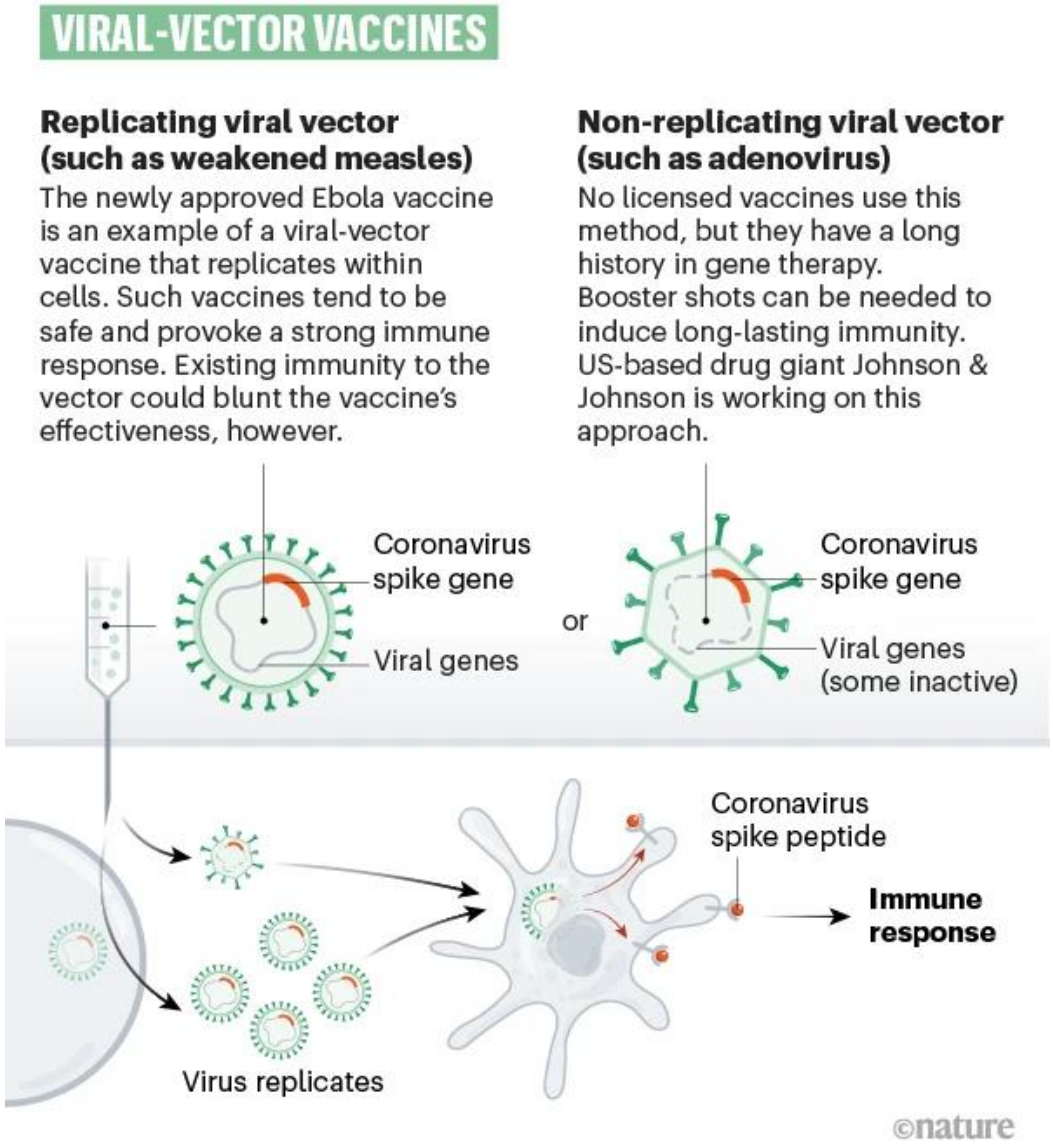
mRNA vaccine effective against RSV respiratory disease

Nature Medicine **explores the latest translational and clinical research news, with Moderna's clinical trial of a vaccine against respiratory syncytial virus in older adults.**

Moderna has announced topline results for its mRNA-based vaccine against respiratory syncytial virus (RSV) infection in adults 60 years of age and older. mRNA-1345 targets the RSV fusion (F) glycoprotein and, according to the press release, is 83.7% effective at preventing lower-respiratory-tract disease. It is the latest in a string of positive results from

https://www.biopharma-reporter.com/Article/2023/02/20/moderna-announces-mixed-results-for-influenza-mrna-vaccine-candidate;
https://www.nature.com/articles/d41591-023-00017-7

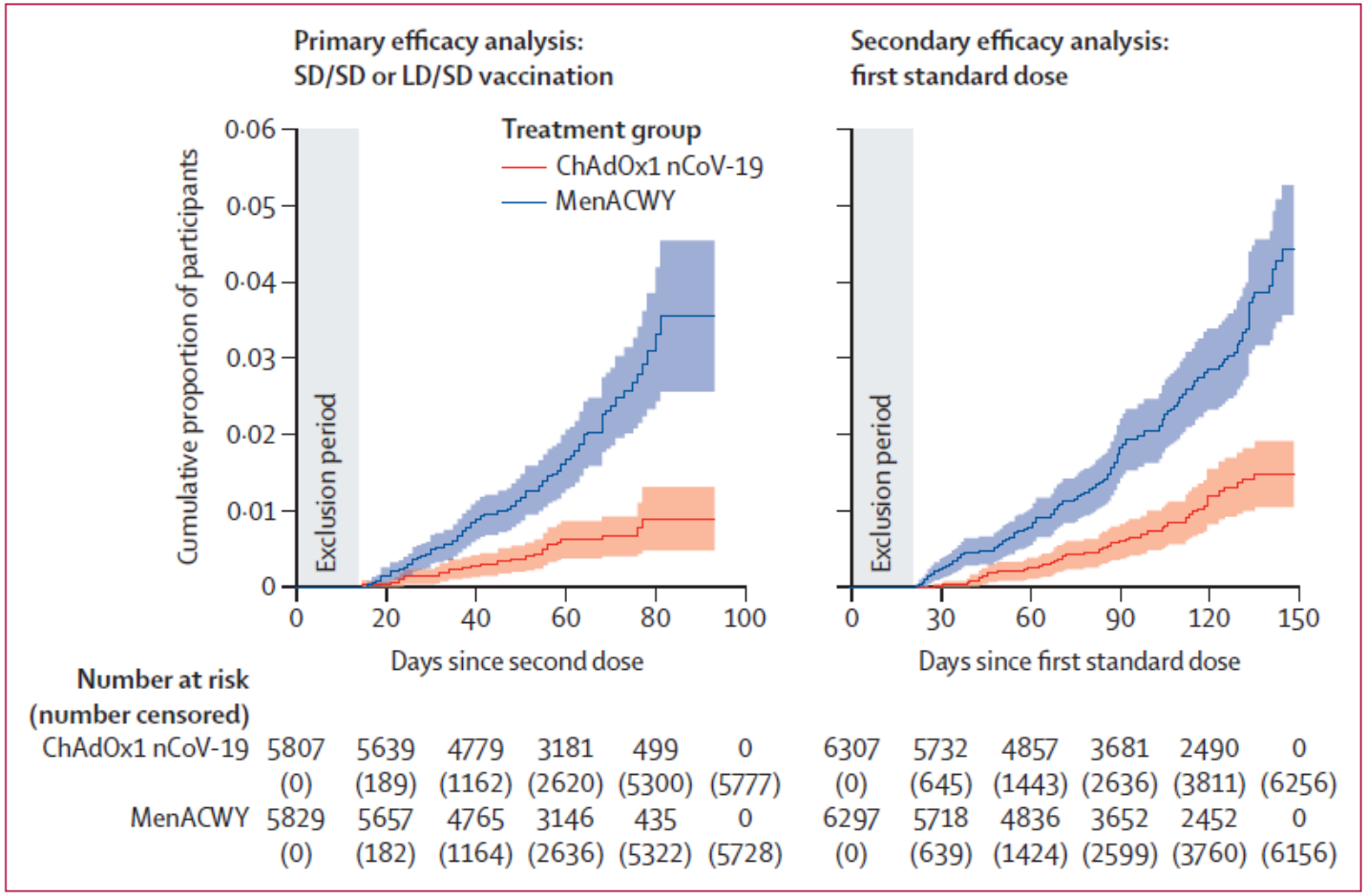
Viral vector vaccines



Callaway. Nature 2020

COVID-19 Viral vector vaccines: THE GOOD

- High efficacy
- Rapid development
- Adapt to variants



Voysey et al. Lancet 2020

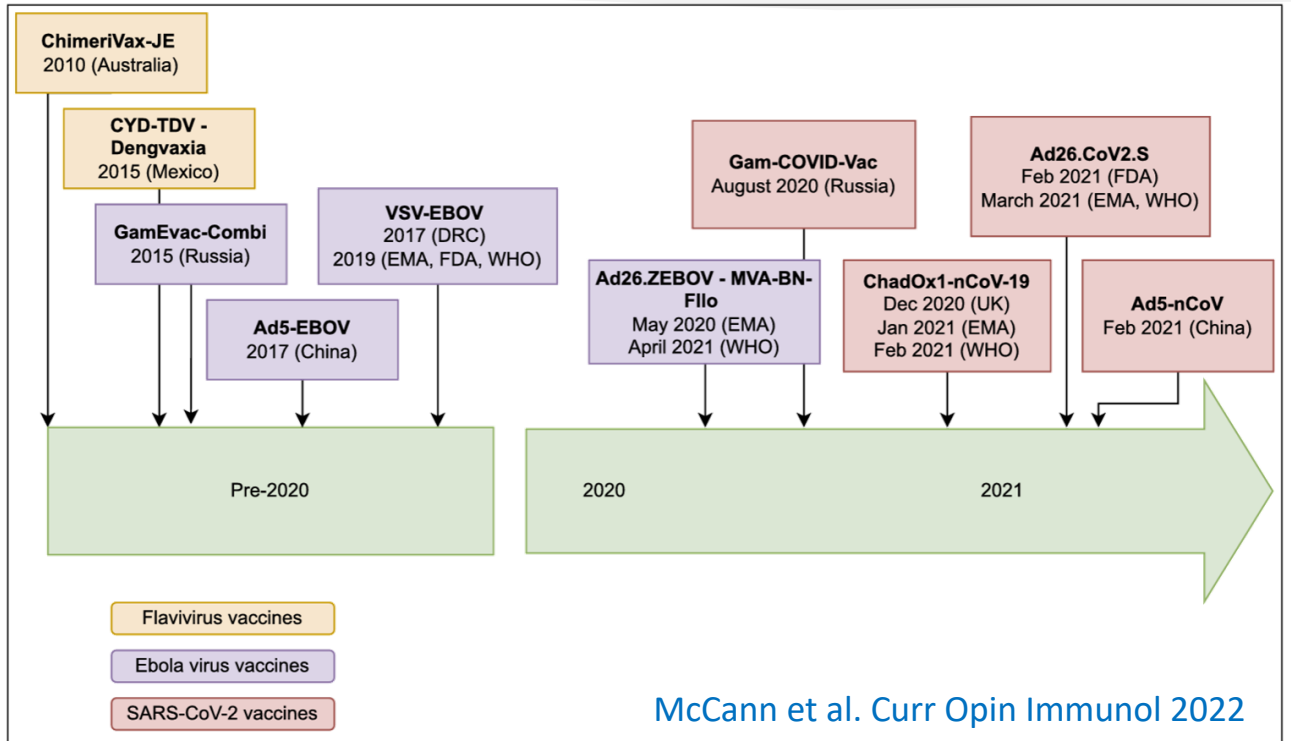
COVID-19 Viral vector vaccines: THE BAD

- Adverse events
  - Very frequent local and systemic reactions
  - Rare, severe events
    - Thrombosis with thrombocytopenia (TTS)
    - Vaccine-induced immune thrombotic thrombocytopenia (VITT)
    - Capillary leak syndrome
    - Guillain-Barré syndrome
- Cold chain
- Need for boosters

COVID-19 Viral vector vaccines: THE UGLY

- Anti-viral immunity
- High cost

Future of viral vector vaccines



McCann et al. Curr Opin Immunol 2022

- Avoiding anti-viral immunity
- Use of different vectors/platforms for priming and booster doses?
  - 'Heterologous prime-boost'
- Adjuvants
- Mucosal administration

Non-injectable administration

- Mucosal immunity

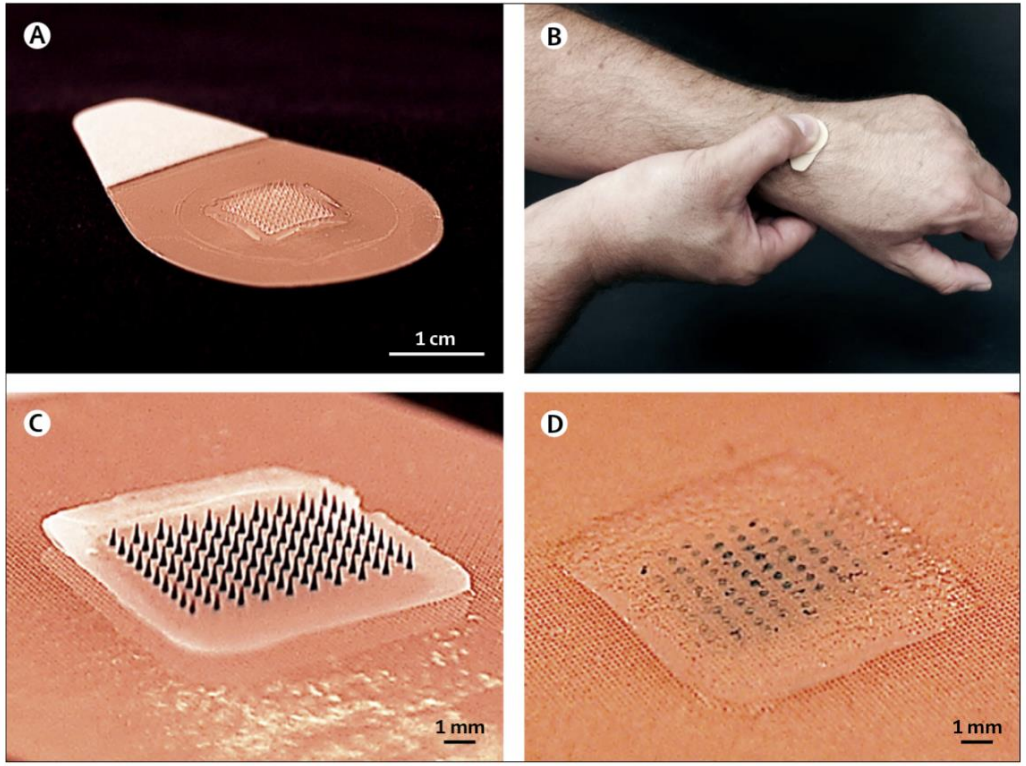
- Current
  - Oral rotavirus vaccine
  - Oral polio vaccine (plan to phase out as part of global eradication plan)
  - Live attenuated influenza vaccine

- Future
  - Epicutaneous (e.g., microneedles, microinjectors, patches)
  - Other mucosally administered
    - Intranasal, inhaled, oral

Epicutaneous vaccine administration

The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial

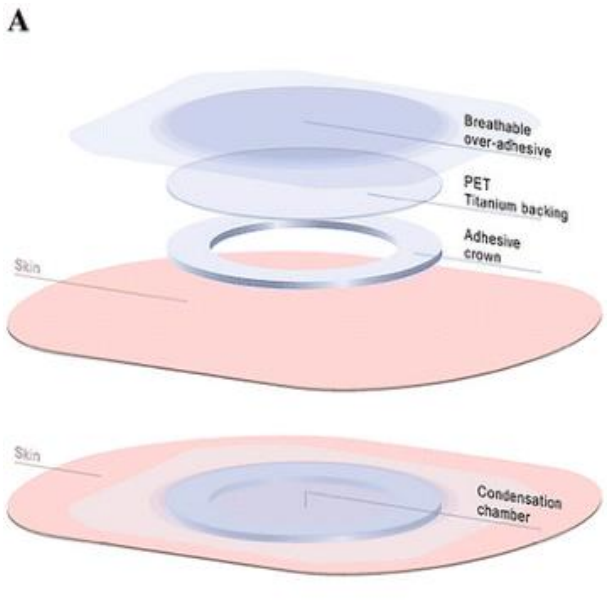
Nadine G Rouphael, Michele Paine, Regina Mosley, Sebastien Henry, Devin V McAllister, Haripriya Kalluri, Winston Pewin, Paula M Frew, Tianwei Yu, Natalie J Thornburg, Sarah Kabbani, Lilin Lai, Elena V Vassilieva, Ioanna Skountzou, Richard W Compans, Mark J Mulligan, Mark R Prausnitz*, for the TIV-MNP 2015 Study Group†*



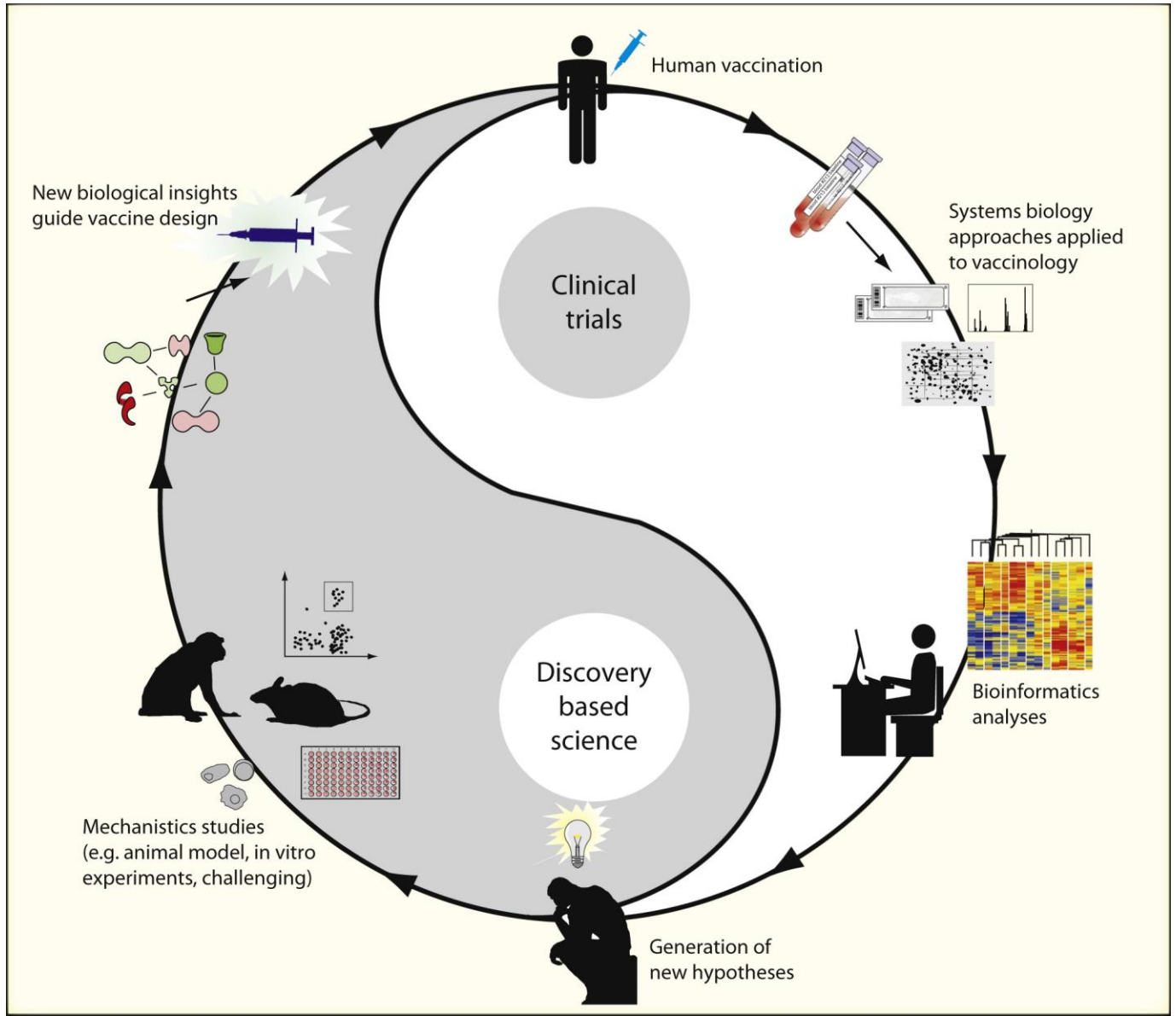
Lancet 2017; 390: 649–58

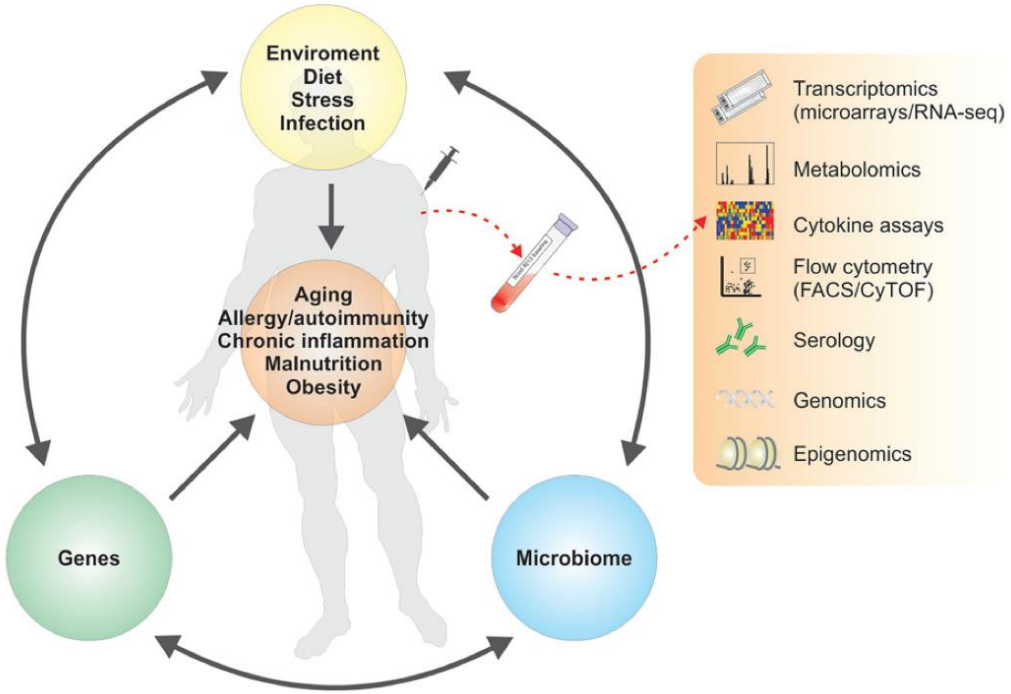
Safety and immunogenicity of the epicutaneous reactivation of pertussis toxin immunity in healthy adults: a phase I, randomized, double-blind, placebo-controlled trial Clinical Microbiology and Infection 27 (2021) 878–885

O. Chatzis [1], G. Blanchard-Rohner [1, 2], L. Mondoulet [3], B. Pelletier [3], A. De Gea-Hominal [1], M. Roux [3], A. Huttner [1, 4], P.L. Hervé [3], M. Rohr [2], A. Matthey [5], G. Gutknecht [5], B. Lemaître [6], C. Hayem [3], H.T. Pham [7], W. Wijagkanalan [7], P.H. Lambert [1], P.H. Benhamou [3], C.A. Siegrist [1, 2, *]



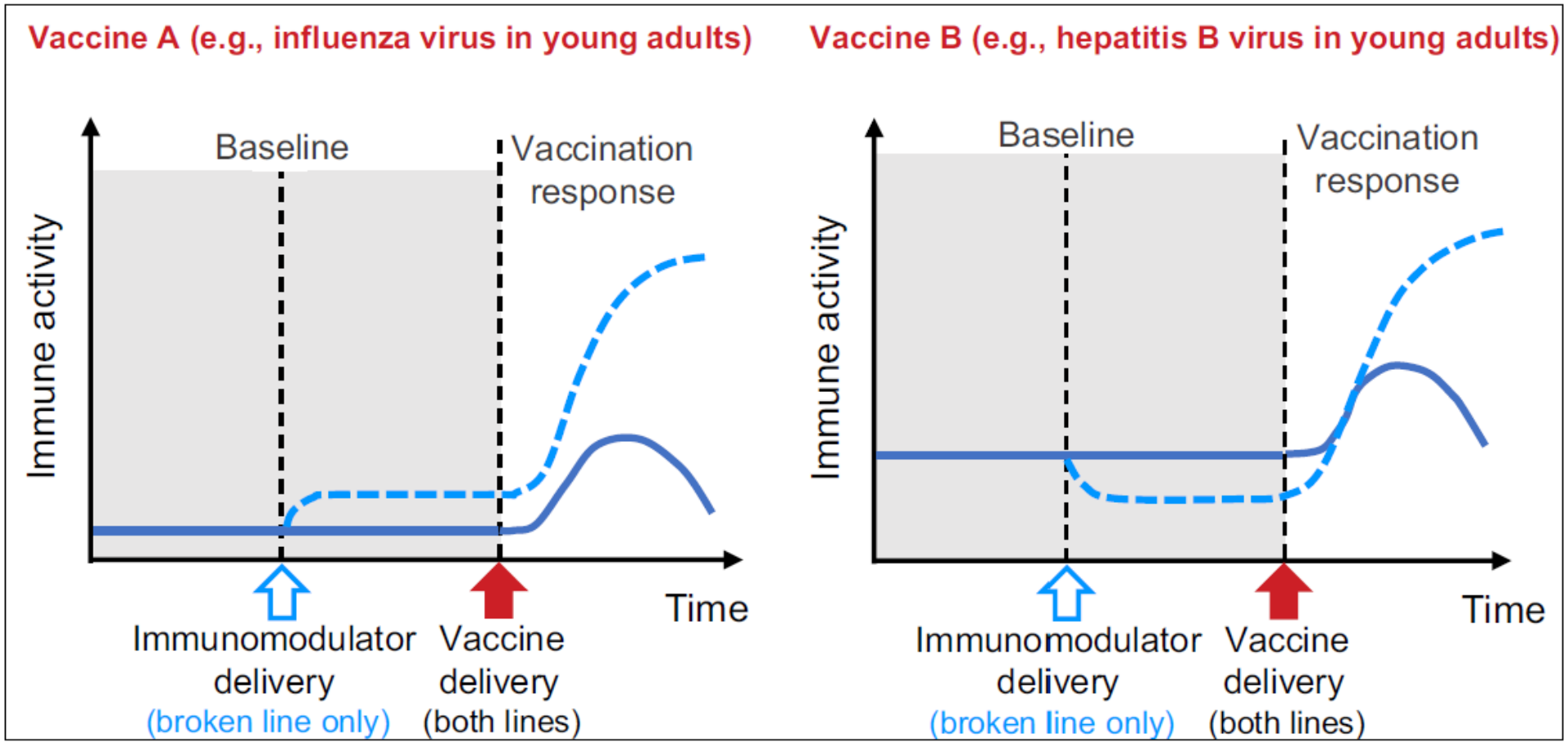
Understanding how vaccines work → Rational vaccine design





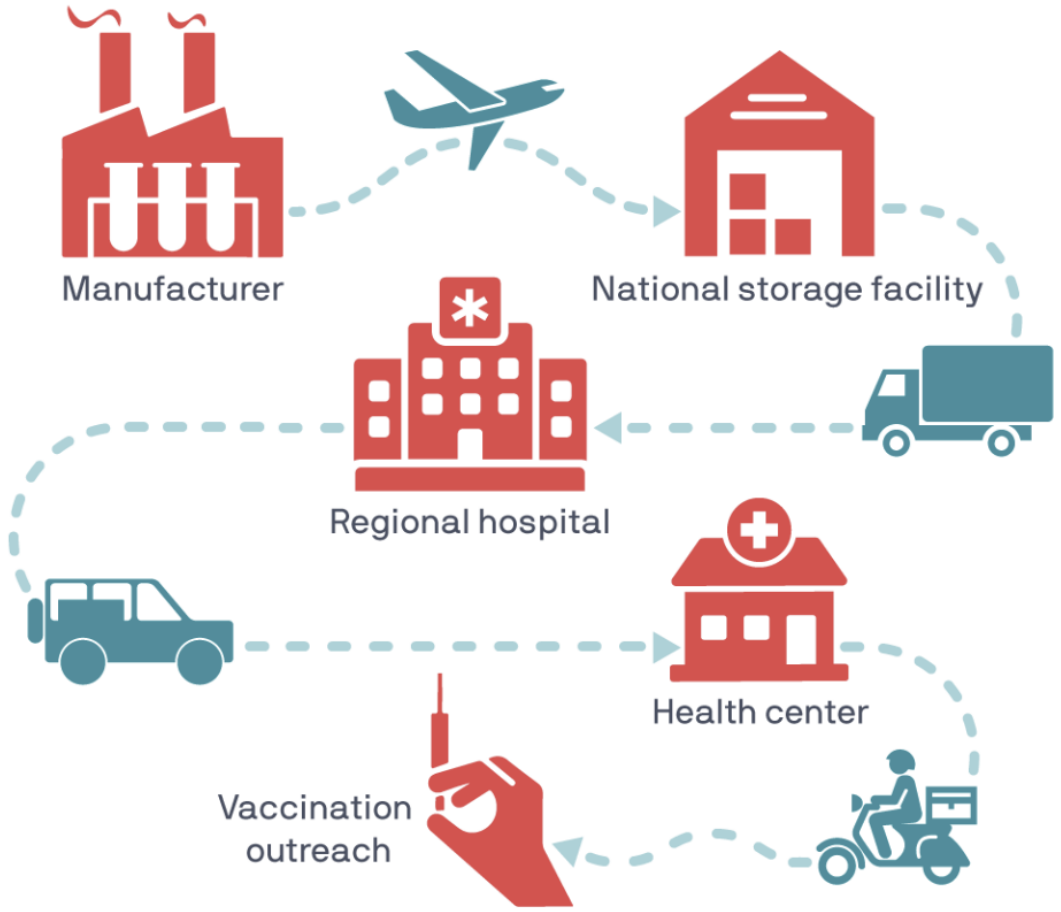
Pulendran et al. Immunity 2010
Pulendran et al. PNAS 2014

The dawn of ‘precision vaccinology’?



Tsang et al. Trends in Immunol 2020

Thermostability



Mapping the vaccine cold chain. Illustration: PATH/Thom Heileson

nature communications

Article

https://doi.org/10.1038/s41467-023-36789-2

Safety and immunogenicity of a thermo-stable ID93 + GLA-SE tuberculosis vaccine candidate in healthy adults

Received: 23 December 2022

Accepted: 16 February 2023

Published online: 06 March 2023

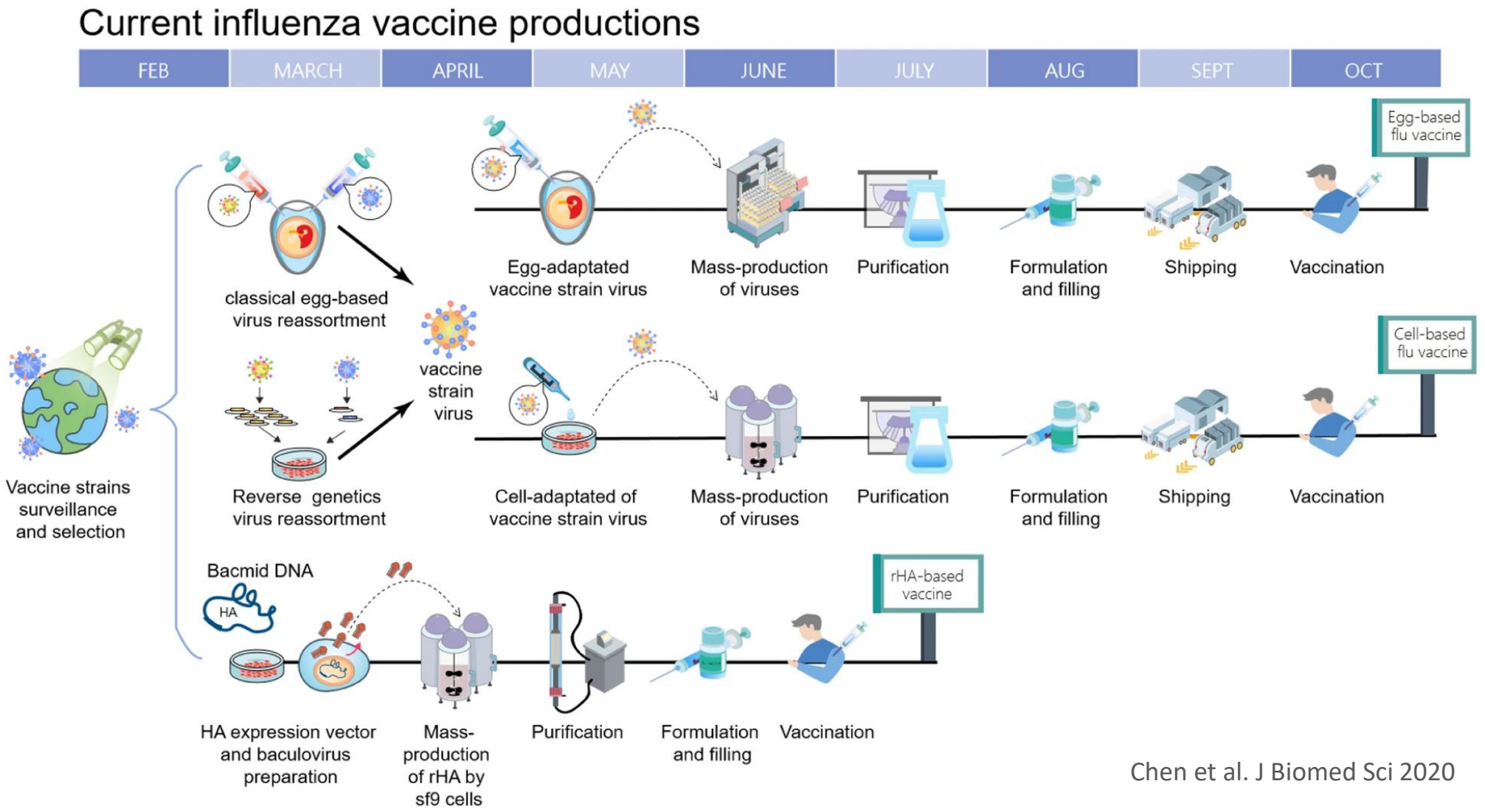
Check for updates

Zachary K. Sagawa[1], Cristina Goman[1], Aude Frevol[1,8], Azra Blazevic[2], Janice Tennant[2], Bridget Fisher[1,9], Tracey Day[1,10], Stephen Jackson[3], Franck Lemiale[3], Leon Toussaint[3], Irene Kalisz[3], Joe Jiang[4], Lisa Ondrejcek[4], Raodoh Mohamath[1], Julie Vergara[1,11], Alan Lew[1], Anna Marie Beckmann[1], Corey Casper[1,5,6,7], Daniel F. Hoft[2] & Christopher B. Fox[1,5]

Gerhardt et al. bioRxiv 2021

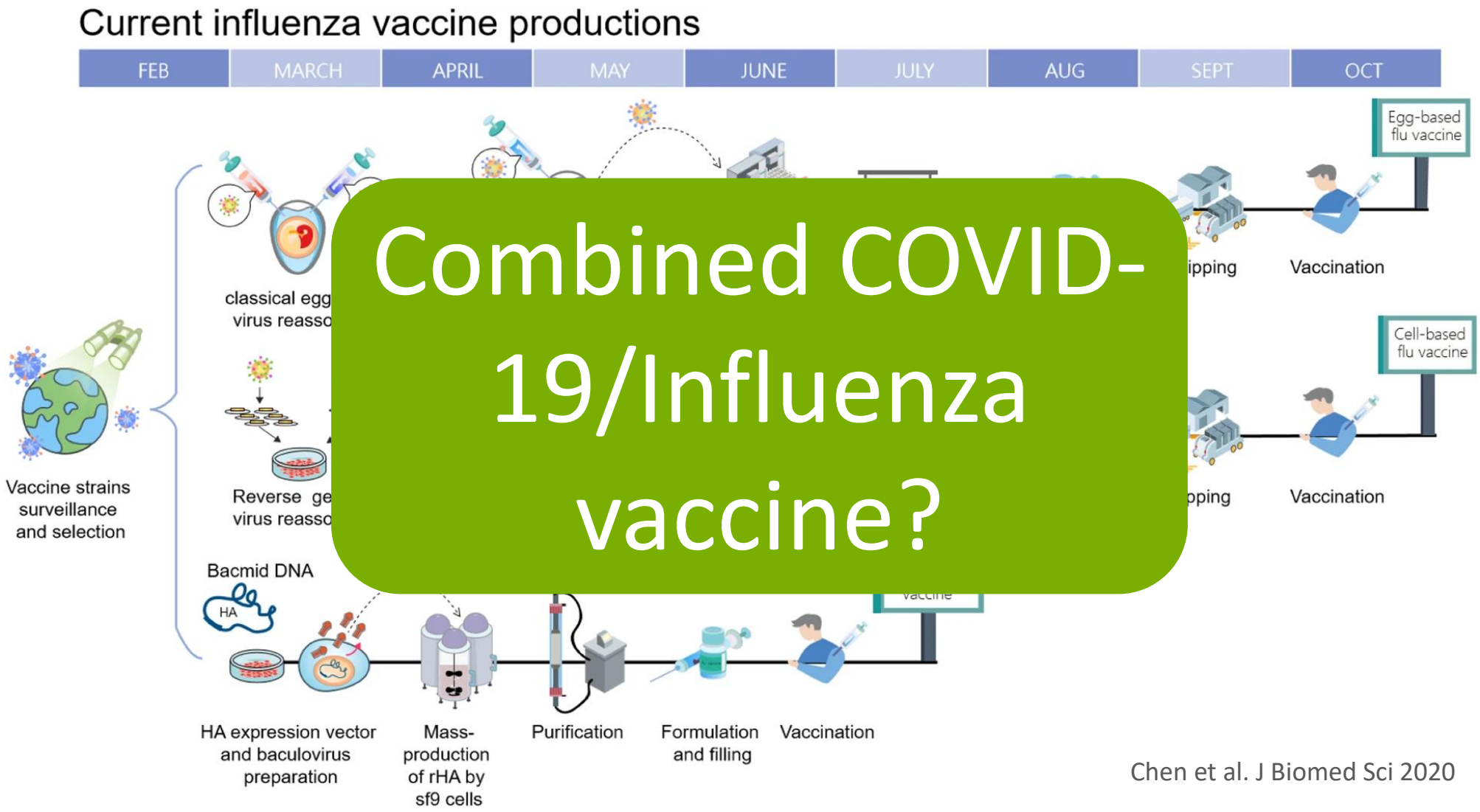
New vaccines

Seasonal influenza vaccine pathway



Chen et al. J Biomed Sci 2020

Seasonal influenza vaccine pathway



Combined COVID-19/Influenza vaccine?

Chen et al. J Biomed Sci 2020

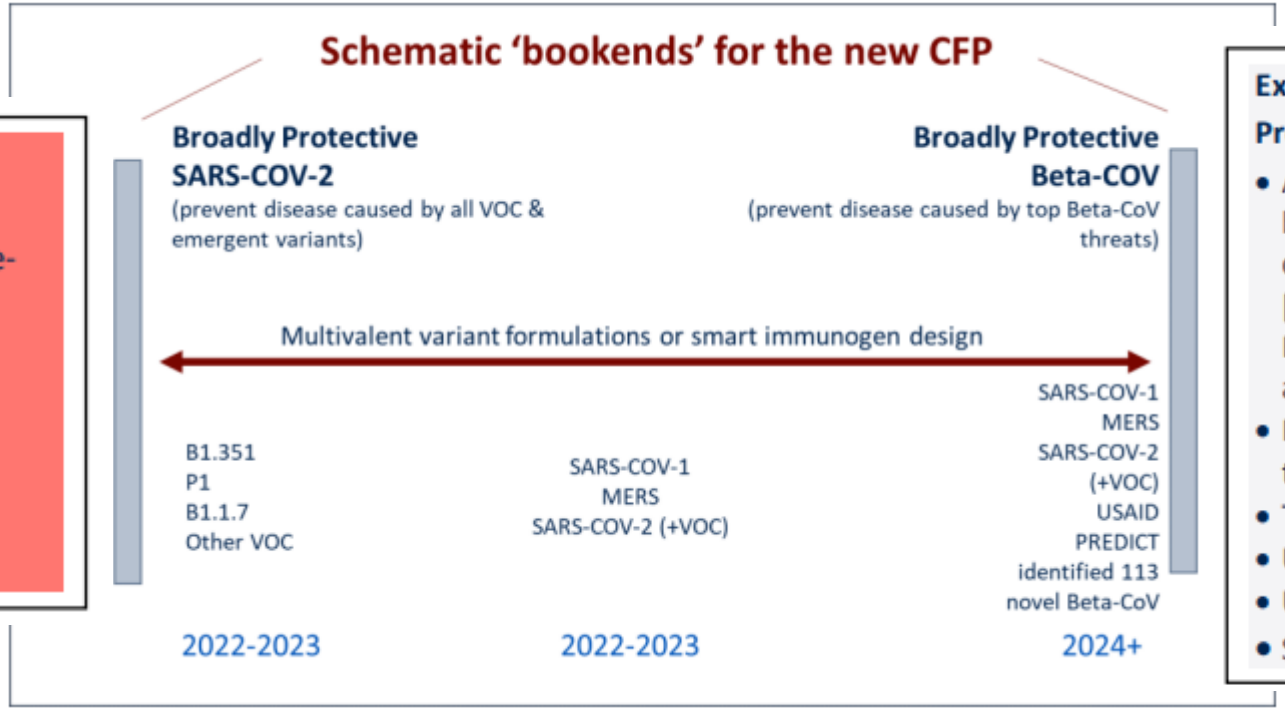
Broadly-protective beta coronavirus vaccine?

Coalition for Epidemic Preparedness Innovations

CEPI

Example BPCoV2 ideal Target Product Profile:

- 80% or more efficacy against moderate-to-severe disease caused by variants;
- Prevention of viral infection and transmission
- Thermostable at 4-8° C
- Use in all ages and pregnant women
- Use in the immunocompromised
- Potential as booster vaccine



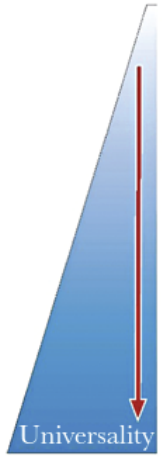
Example of a BPBC ideal Target Product Profile:

- Active immunization of at-risk individuals, based on specific risk factors, to prevent disease and mortality (proxy - robust [80%] neutralization against a panel of Betacoronaviuses predictive of protection against disease).
- Prevention of virus infection and transmission
- Thermostable at 4-8° C
- Use in all age groups and pregnant women
- Use in the immunocompromised
- Suitable for use in outbreak situation

UBC

BC Children's Hospital Research Institute

Universal influenza vaccine



Vaccine	Coverage
Strain specific	Current circulating strains
Subtype specific	All strains within a single HA subtype (eg, H1)
Multisubtype	Multiple HA subtypes within single group (eg, H1/H5/H9)
Pan-group	Covering all group 1 or 2 influenza A viruses
Universal	All influenza A viruses (with or without influenza B viruses)

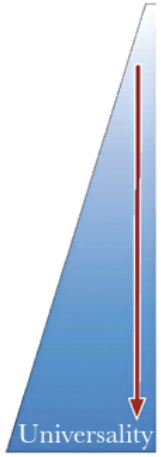
Courtesy Gary Nabel

A universal influenza vaccine should:

- Be at least 75% effective against symptomatic influenza virus infection;
- Protect against group I and group II influenza A viruses (influenza B virus would be a secondary target)
- Have durable protection that lasts at least 1 year and preferably through multiple seasons
- Be suitable for all age groups

Erbelding et al. JID 2018

Universal influenza vaccine



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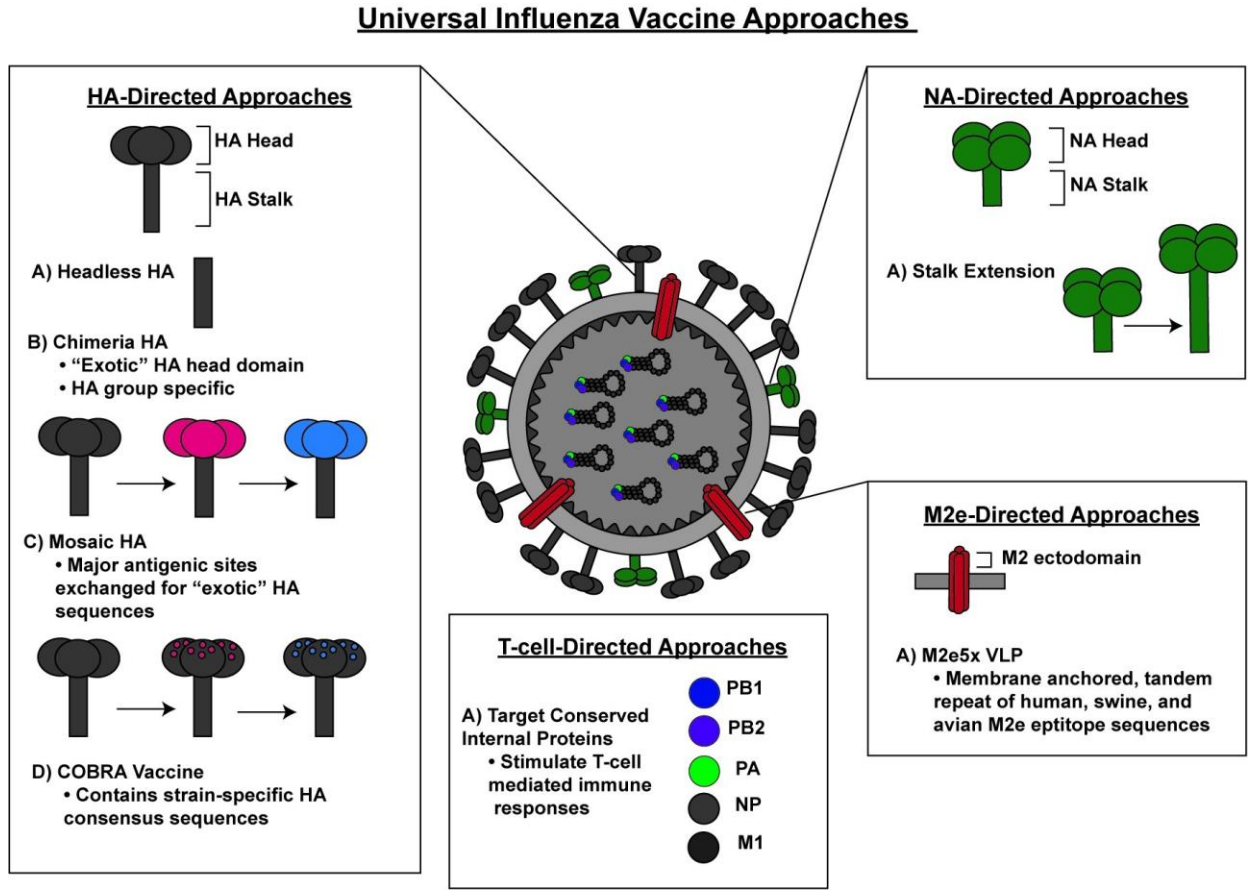
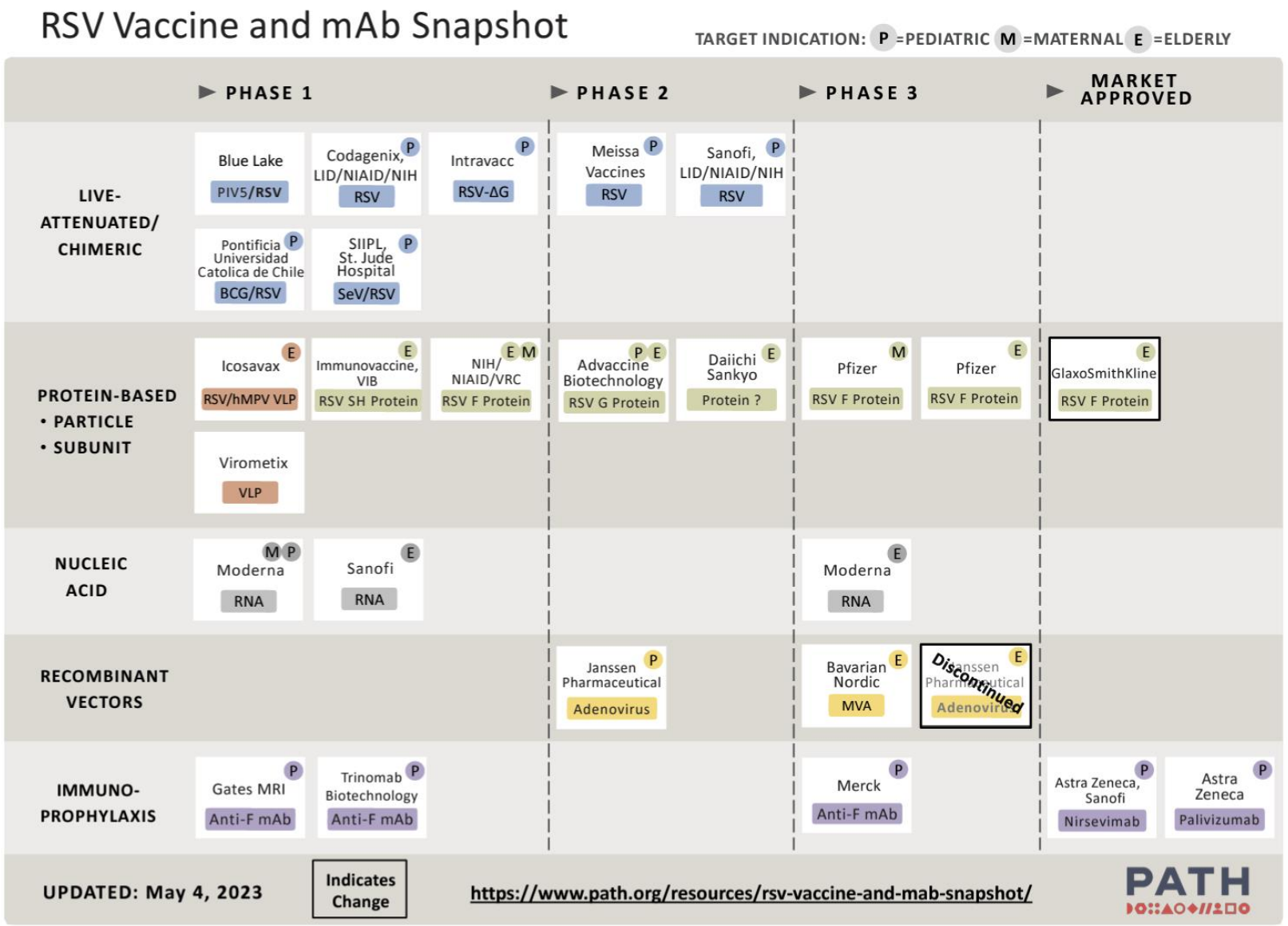


Erbelding et al. JID 2018; Vogel and Manicassamy. Front Microbiol 2020

Universal influenza vaccine

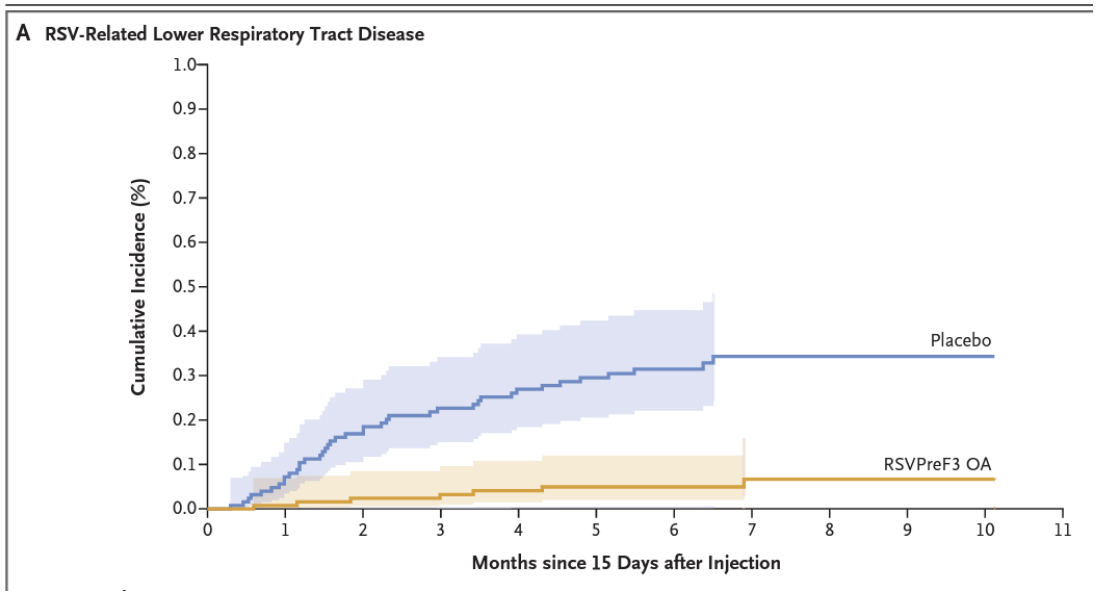
Erbelding et al. JID 2018; Vogel and Manicassamy. Front Microbiol 2020; https://www.nih.gov/news-events/news-releases/clinical-trial-mrna-universal-influenza-vaccine-candidate-begins

Respiratory syncytial virus (RSV)

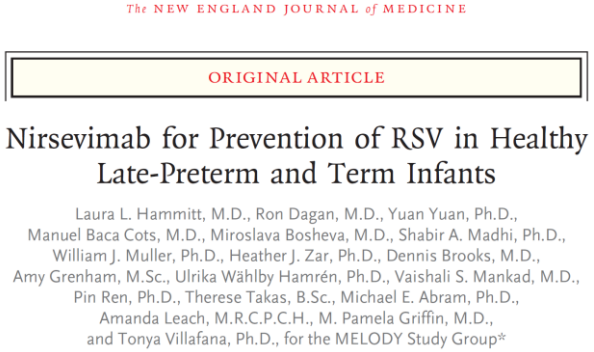


RSV – recent successes

- Vaccine efficacy 83% in adults aged 60y+



- Immunoprophylaxis – nirsevimab – efficacy ~60-80%


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

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Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants

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RSV – work in progress

- Pregnancy

Berlin

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NEWS ANALYSIS

Maternal RSV vaccine: Further analysis is urged on preterm births

A "safety signal" in a similar respiratory syncytial virus (RSV) vaccine has led to trials being stopped and prompted calls for a cautious approach to using the vaccine in pregnant women, reports **Hristio Boytchev**

Hristio Boytchev

Experts have called for further analysis of trial data and post-approval monitoring of Pfizer's maternal RSV vaccine candidate after GSK's trials of a similar product were halted over a rise in preterm births and neonatal deaths.

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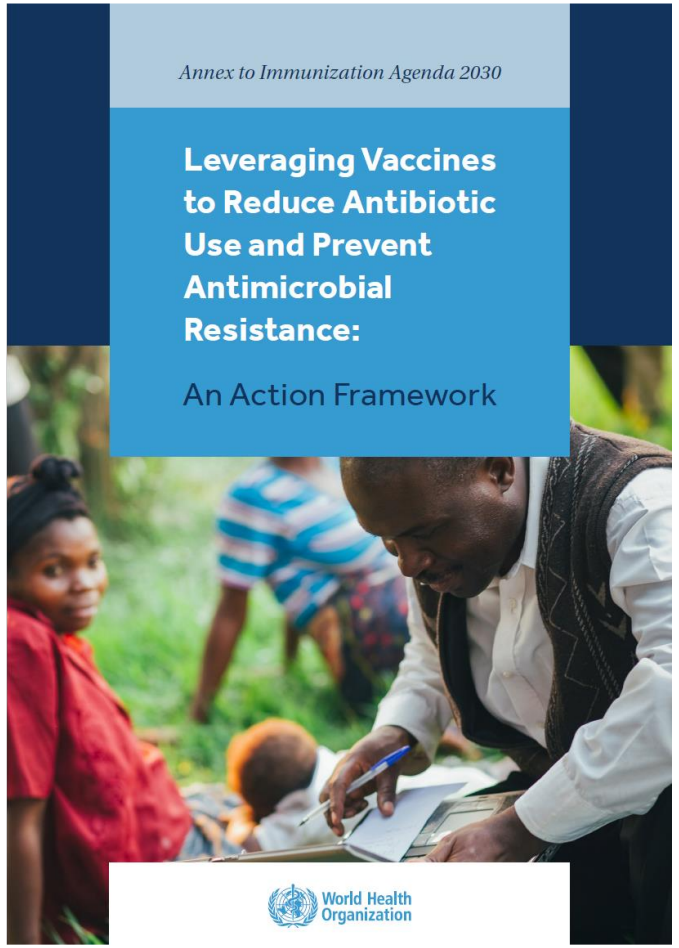
Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

B. Kampmann, S.A. Madhi, I. Munjal, E.A.F. Simões, B.A. Pahud, C. Llapur, J. Baker, G. Pérez Marc, D. Radley, E. Shittu, J. Glanternik, H. Snaggs, J. Baber, P. Zachariah, S.L. Barnabas, M. Fausett, T. Adam, N. Perreras, M.A. Van Houten, A. Kantele, L.-M. Huang, L.J. Bont, T. Otsuki, S.L. Vargas, J. Gullam, B. Tapiero, R.T. Stein, F.P. Polack, H.J. Zar, N.B. Staerke, M. Duron Padilla, P.C. Richmond, K. Koury, K. Schneider, E.V. Kalinina, D. Cooper, K.U. Jansen, A.S. Anderson, K.A. Swanson, W.C. Gruber, and A. Gurtman, for the MATISSE Study Group*

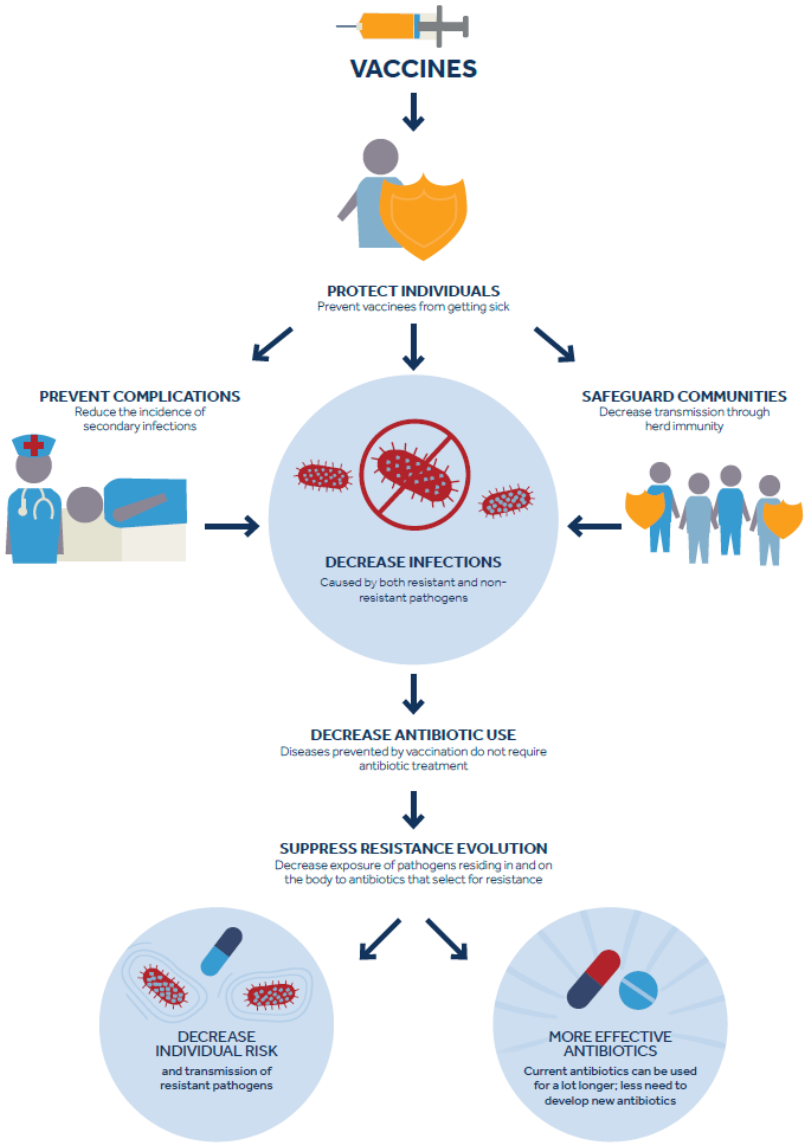
Vaccines against antimicrobial resistance

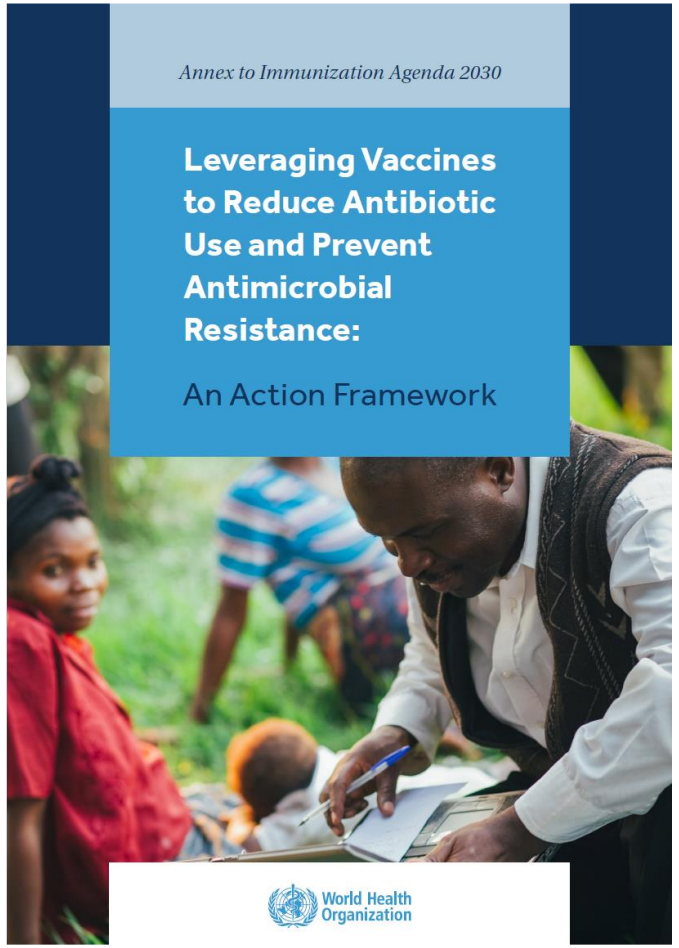
Fig. 1. Strategic objectives of the Global Action Plan on Antimicrobial Resistance



Vaccines against antimicrobial resistance

Fig. 2. Impact of vaccines on AMR: a schematic pathway





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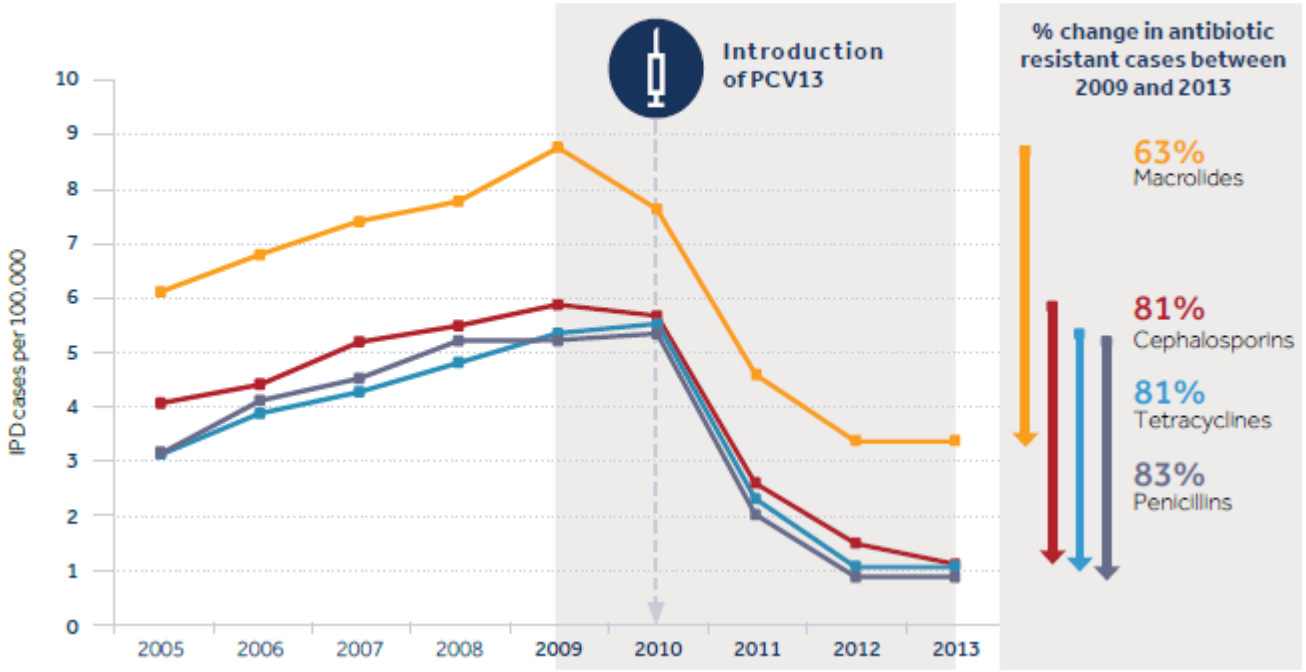
Vaccines against antimicrobial resistance

1 Expanding use of licensed vaccines to maximize impact on AMR

Fig. 3. Impact of pneumococcal vaccine on rates of drug-resistant invasive pneumococcal disease (IPD) in the United States of America[a, b]



Vaccines against antimicrobial resistance

1. Expanding use of licensed vaccines to maximize impact on AMR

2. Developing new vaccines that contribute to prevention and control of AMR

3. Expanding and sharing knowledge of vaccine impact on AMR

Pipeline Feasibility Group	Description	Pathogens
Very high Group A	AMR priority pathogens for which licensed vaccines already exist	• *Salmonella enterica* ser. Typhi • *Streptococcus pneumoniae* • *Haemophilus influenzae* type b • *Mycobacterium tuberculosis*
High Group B	AMR priority pathogens for which a vaccine candidate is in late-stage development (Phase 3) and vaccines would be suitable to target AMR infections caused be these priority pathogens in the coming years	• Extraintestinal pathogenic *Escherichia coli* (ExPEC) • *Salmonella enterica* ser. Paratyphi A • *Neisseria gonorrhoeae* • *Clostridioides difficile*
Moderate Group C	AMR priority pathogens for which a vaccine candidate has either been identified in early clinical trials or been identified as a feasible vaccine target during expert review. Vaccines may be feasible solutions to target AMR infections, with moderate feasibility of vaccine development	• Enterotoxigenic *Escherichia coli* (ETEC) • *Klebsiella pneumoniae* • Non-typhoidal *Salmonella* • *Campylobacter* spp. • *Shigella* spp.

Frost et al. Hum Vacc Immun 2022

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Controlled human infection models (CHIMs)

TABLE 38 Summary recommendations for the continued development and utilization of human challenge models for 17 infectious diseases[a]

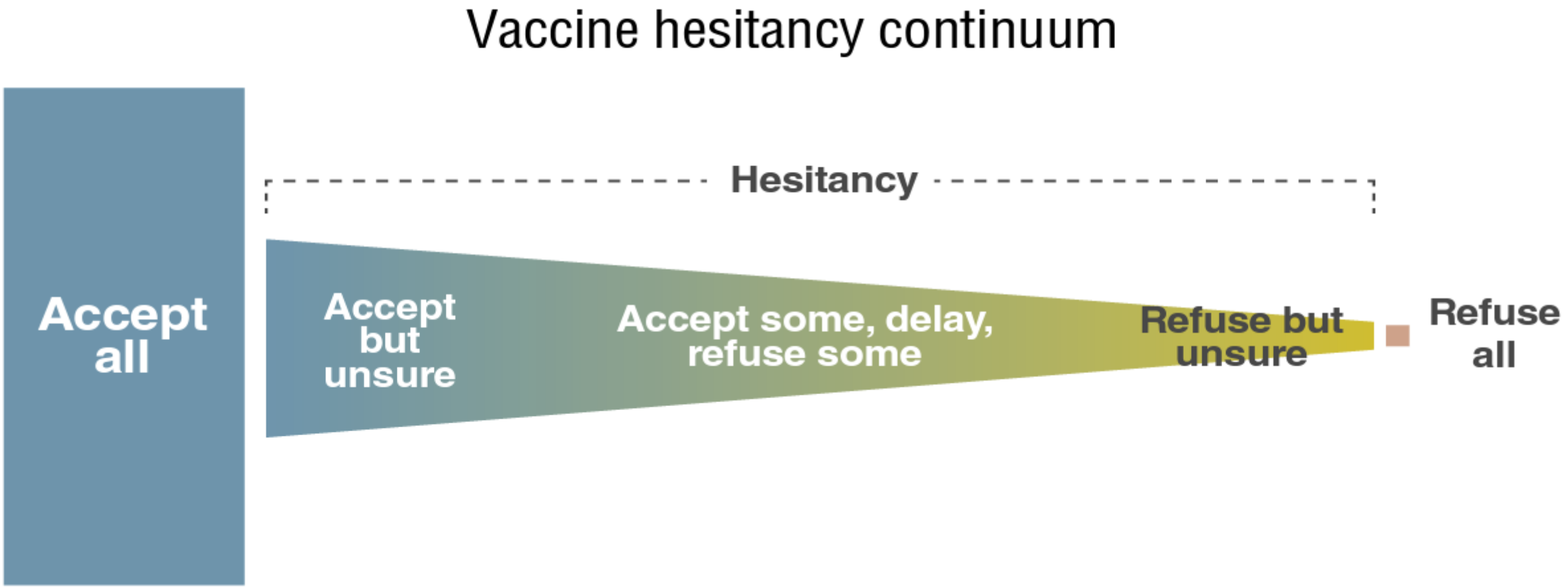
Disease	Challenge agent(s)	Recommendation from the literature review
Malaria	*Plasmodium falciparum*	Proceed. Few concerns identified, if any.
Cholera	*Vibrio cholerae*	
Pneumococcus	*Streptococcus pneumoniae*	
Rotavirus	Live oral rotavirus vaccine	
Poliomyelitis	Oral poliovirus vaccine	
Influenza	Influenza strains pertinent to the development of universal influenza vaccines	
Typhoid/Paratyphoid	*Salmonella* Typhi and *Salmonella* Paratyphi serovars	
ETEC	ETEC strains expressing selected toxins and colonization factors	Proceed with caution. Minor concerns identified.
Shigellosis	*Shigella flexneri* serotypes and *Shigella sonnei*	
Norovirus	Norovirus genogroups and genotypes	
RSV	RSV strains of genogroups A and B	
Dengue	Attenuated dengue virus serotypes 1 through 4	
Malaria	*Plasmodium vivax*	Address major concerns before proceeding.
Campylobacteriosis	*Campylobacter jejuni* serotypes	
Tuberculosis	Bacillus Calmette-Guérin	
Pertussis	*Bordetella pertussis*	
Cryptosporidiosis	*Cryptosporidium parvum* and *Cryptosporidium hominis*	
COVID-19	SARS-CoV-2	

[a]COVID-19, Coronavirus disease 2019; ETEC, enterotoxigenic *Escherichia coli*; RSV, respiratory syncytial virus; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Choy et al. Clin Micro Rev 2022

Vaccine hesitancy

What is vaccine hesitancy?

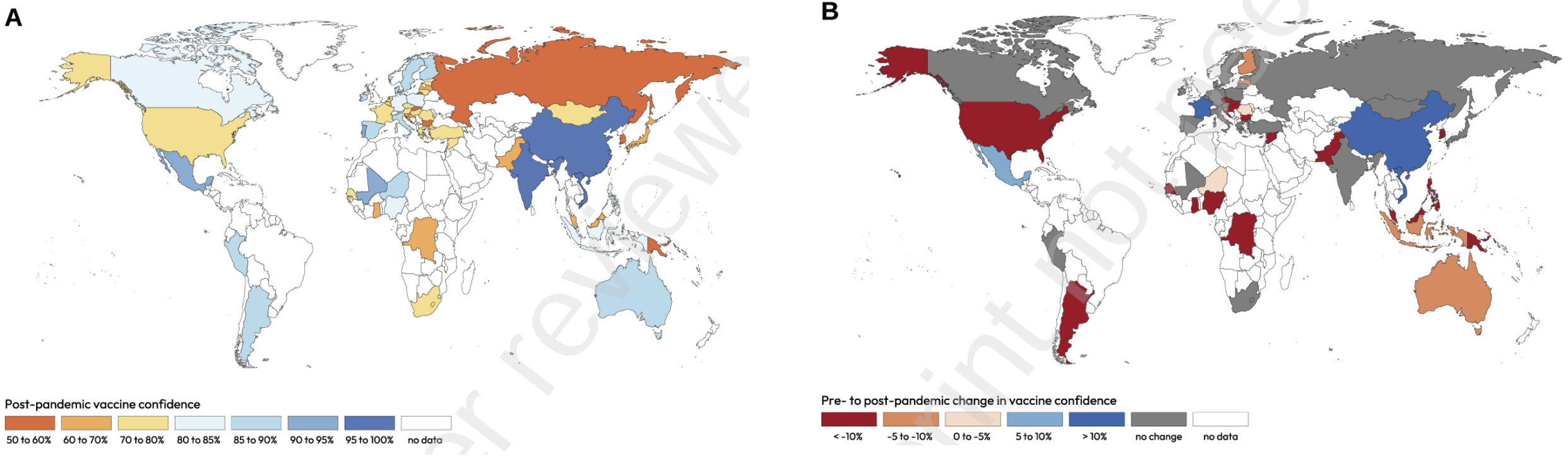


http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Immunization/Vaccine%20Safety/ICT-2021.pdf

Should we be worried about vaccine hesitancy?

- Global state of vaccine confidence

Figure 2 ***Confidence in the safety of vaccines***



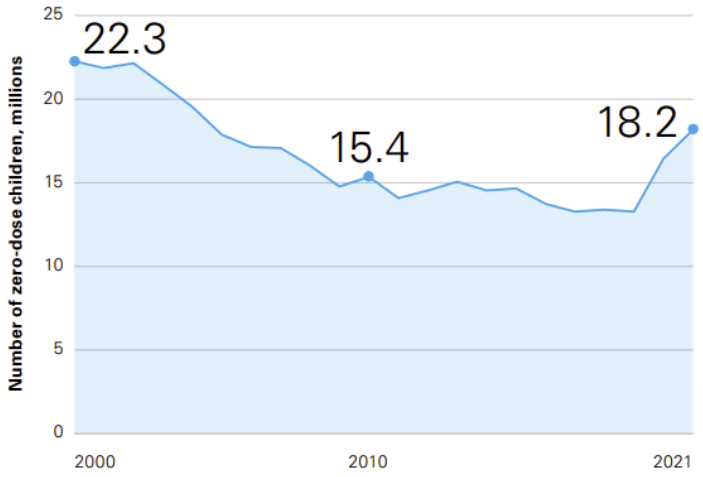
Wiegand et al. SSRN 2023

We are failing to vaccinate the world

Vaccines save lives, but far too many children in the world are not being vaccinated. The COVID-19 pandemic only added to their numbers. The children who are missing out live in the poorest, most remote and most marginalized communities. To reach them, it is vital to prioritize investment in primary health care and in the health workers – mostly women – who deliver services. It is essential, too, to build confidence in vaccines and to make the most of a host of new ideas and technologies that can boost the power of vaccines and ensure they reach every child.

Over the past decade or so, despite growing efforts to expand immunization, there has been little progress in reducing the number of zero-dose children. Reaching every child remains a challenge.

Figure 1. Zero-dose children globally, 2000–2021



Source: World Health Organization and United Nations Children's Fund, 'Estimates of National Immunization Coverage (WUENIC), 2021 revision', July 2022.

1 in 5

children are **zero-dose** (unvaccinated) and **under-vaccinated**, leaving them vulnerable to a range of vaccine-preventable diseases.

Around

1 in 5

children have no protection at all against measles, a childhood killer.

Around

7 in 8

eligible girls are not vaccinated against human papillomavirus (HPV), which can cause cervical cancer.

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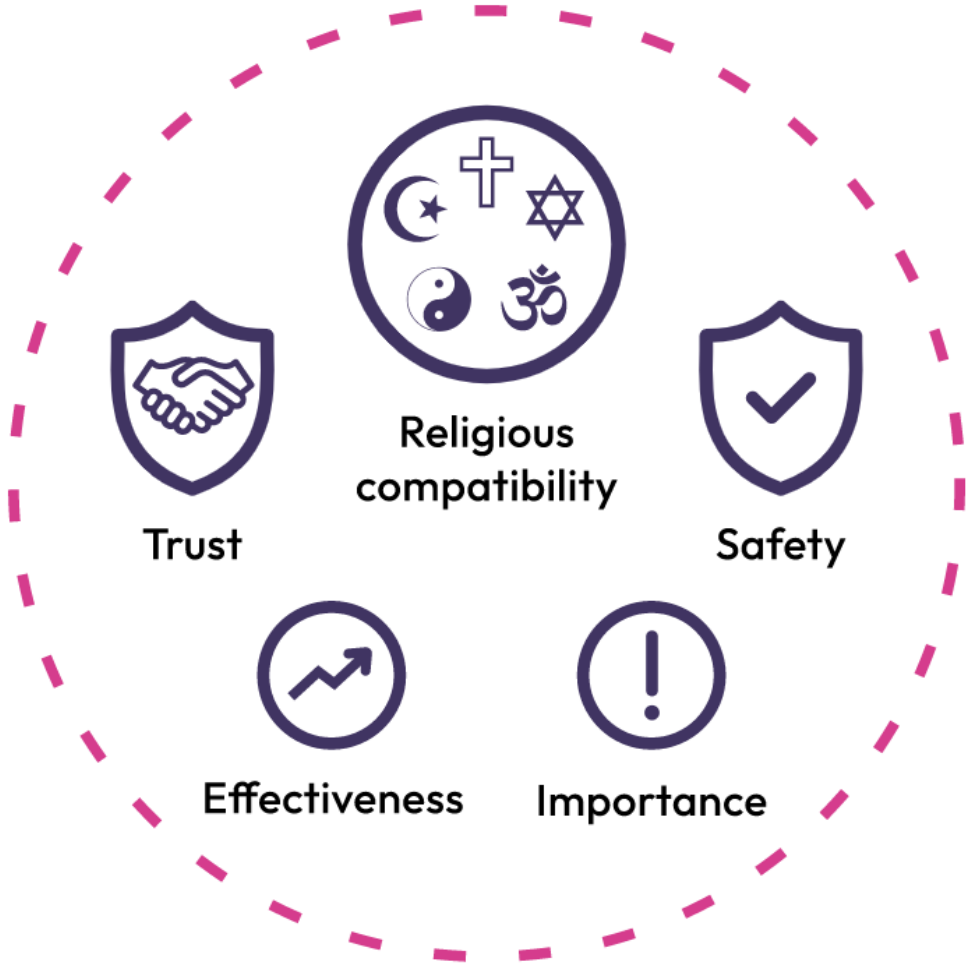
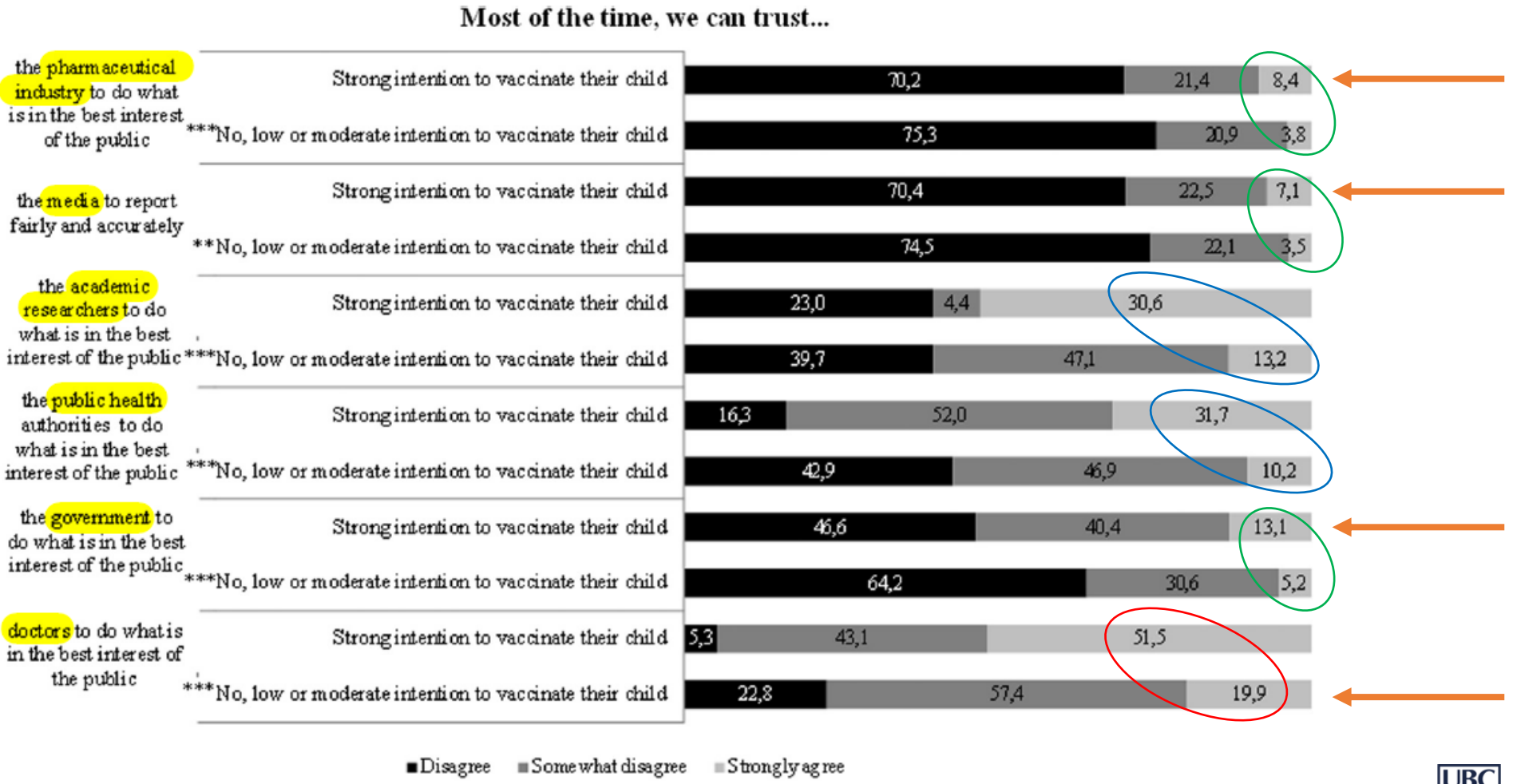
www.vaccineconfidence.org

Pillars of vaccine confidence



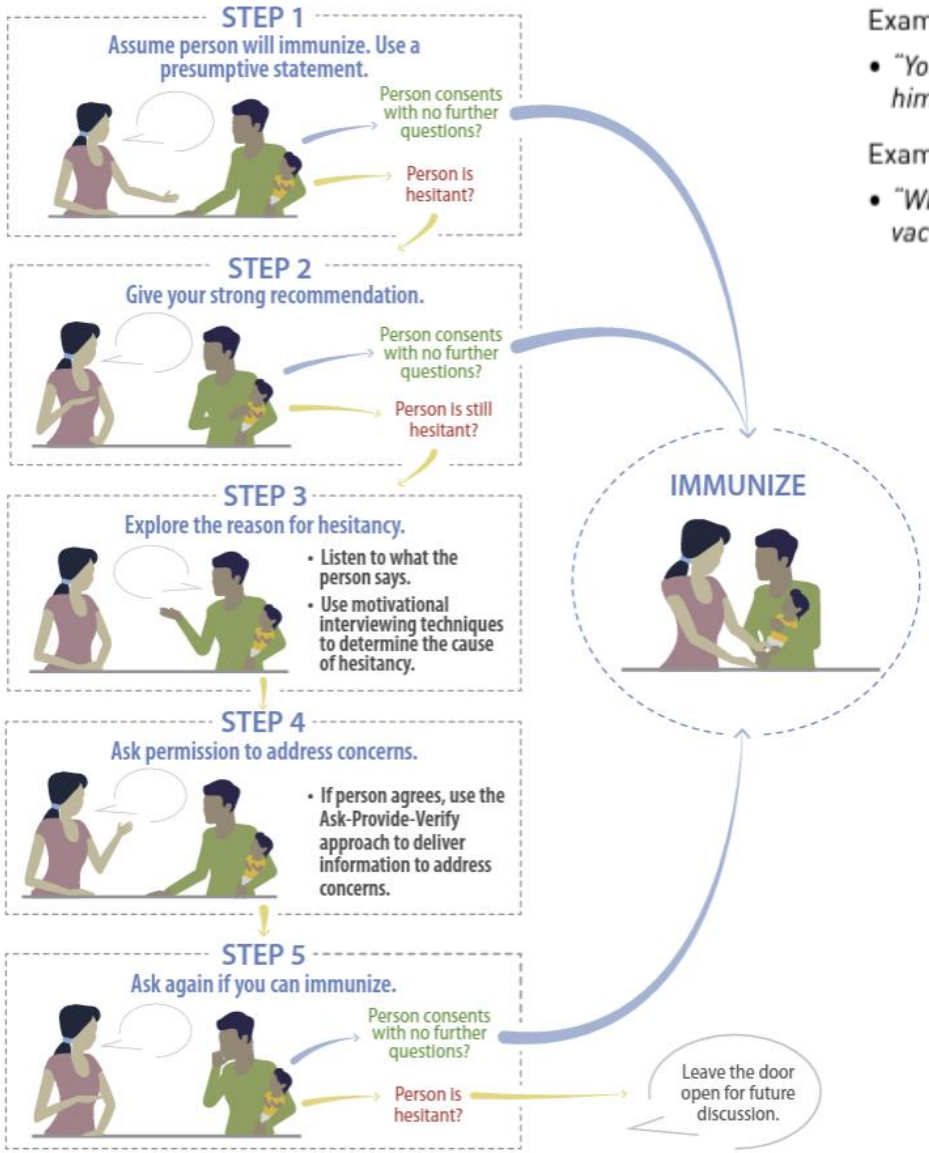
What can you do?

- You are the most trusted source of information…



Dubé et al. Vaccine 2018

You have the power to address vaccine hesitancy



Example of a presumptive statement:

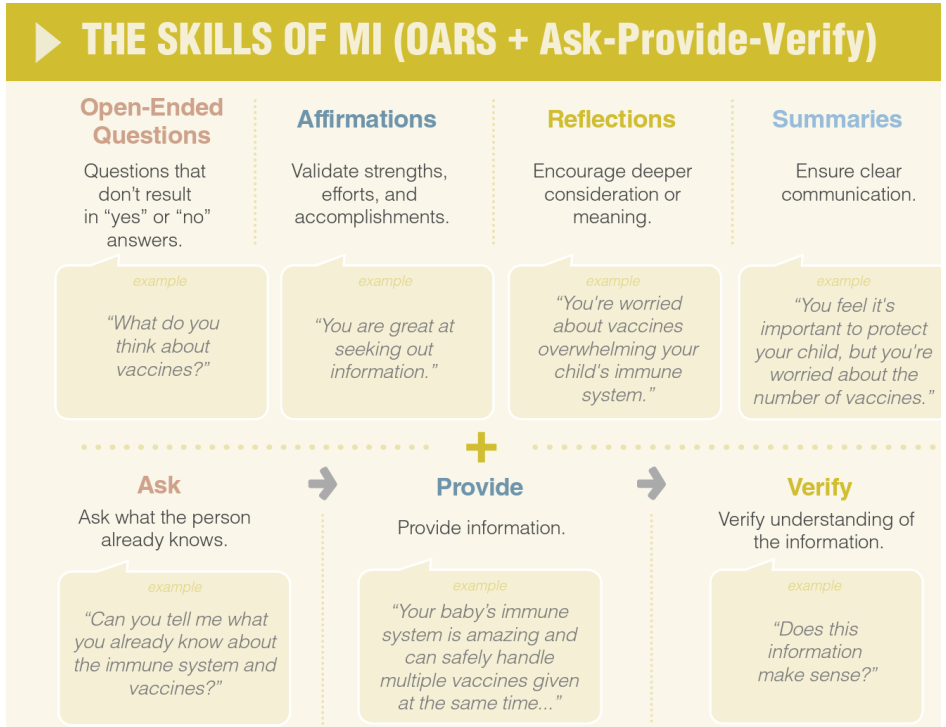
- *"Your son is due for his 4-month vaccines. We will give him these vaccines before you leave today."*

Example of a participatory ask:

- *"What would you like to do about your son's 4-month vaccines?"*

- *"I strongly recommend your child gets these vaccines today. These vaccines are very important to protect your child against serious diseases."*

http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Immunization/Vaccine%20Safety/ICT-2021.pdf



- *"I hope I was able to address your concerns regarding the safety of vaccines. I really want to ensure your daughter is protected against these diseases. Can I provide the immunizations now?"*

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Summary

- COVID-19 has enabled rapid optimization of vaccine platforms
  - RNA and viral vector potentially promising for future vaccines
  - Multiple issues that remain to be resolved
  - Other platforms also in development
- Potential game-changers would be
  - Non-injectable administration
  - Need for a single vaccine dose
  - Long-term thermostable vaccines
- Vaccines will be a vital part of our strategy against antimicrobial resistance
- New and improved vaccines against respiratory viruses are coming soon…
- Do not under-estimate your role in addressing vaccine hesitancy

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Thank you