AMR & Role of Novel Vaccines

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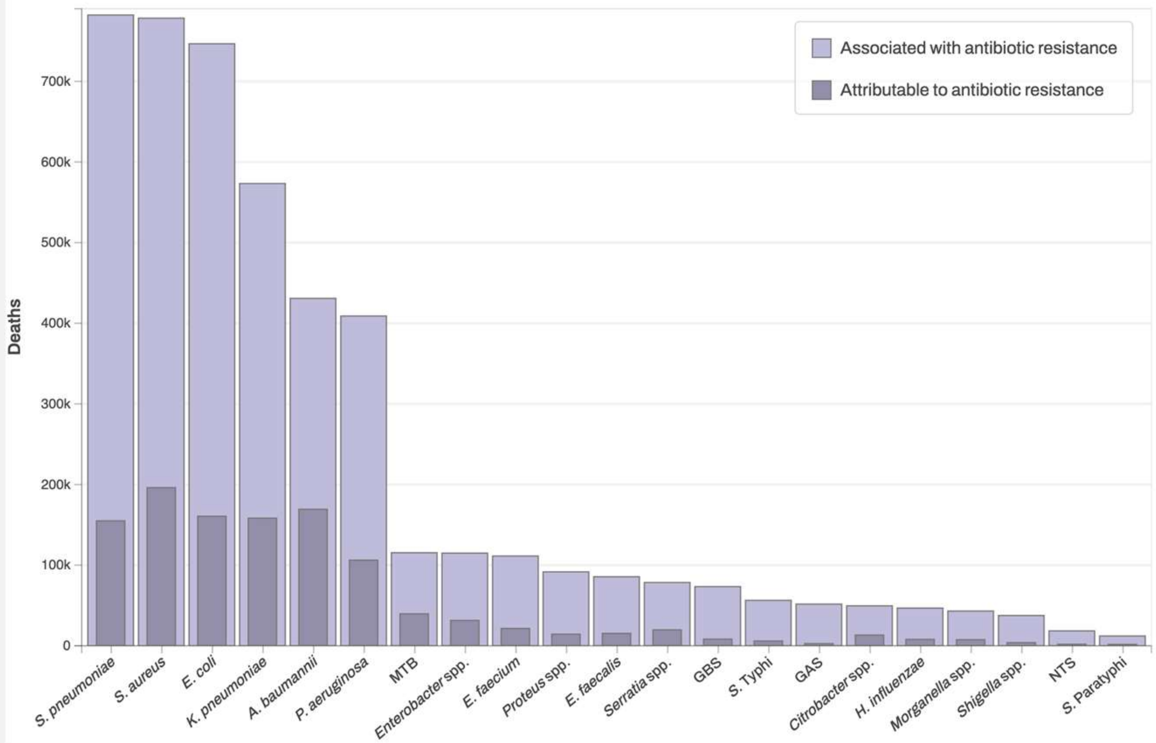
The burden of AMR

- AMR is a global health threat with **1.14 million deaths attributable** to bacterial AMR and **4.71 million deaths associated** with bacterial AMR worldwide in 2021;
- **Attributable**: deaths are the result of a progression from a drug sensitive to a drug resistant infection;
- **Associated**: deaths are the result of a progression from no infection to a drug resistant infection;

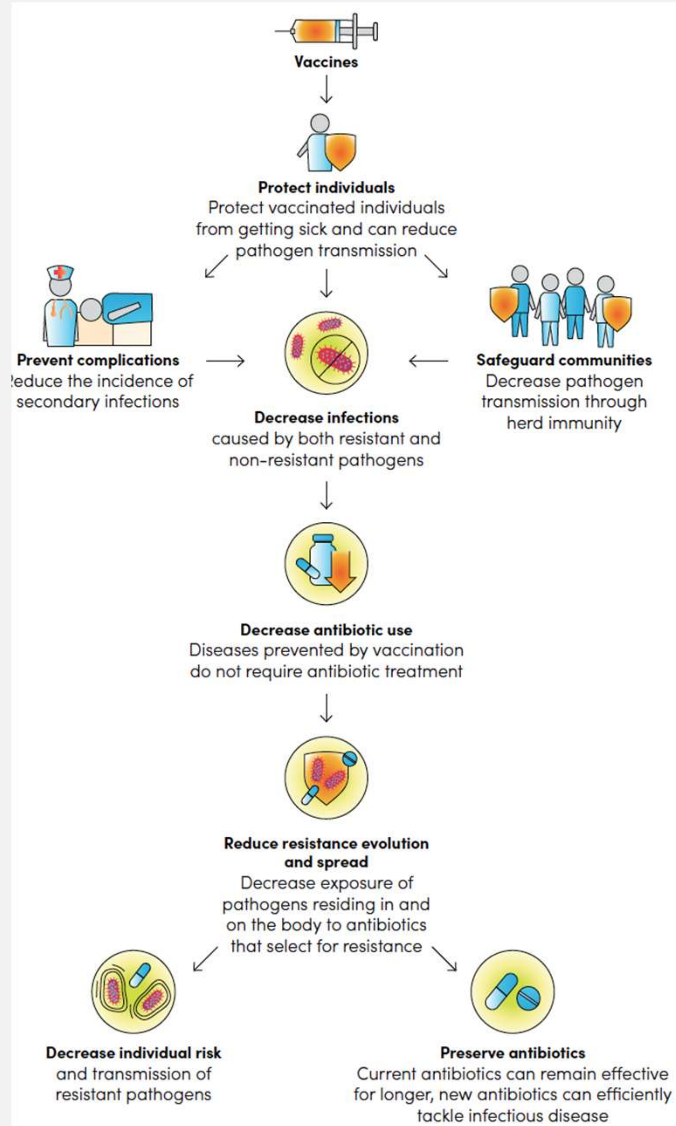
The number of deaths associated and attributable to resistance by pathogen, in 2021



https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01867-1/fulltext

How do vaccines reduce AMR?

- Vaccines prevent infections with drug-susceptible and resistant pathogens
- Vaccines prevent individuals and communities from getting sick
- Decrease antibiotic use (causal chain)
- Suppress resistance evolution and decrease transmission of resistant pathogens (causal chain)



https://www.who.int/publications/m/item/leveraging-vaccines-to-reduce-antibiotic-use-and-prevent-antimicrobial-resistance

WHO report: Estimating the impact of vaccines in reducing antimicrobial resistance and use

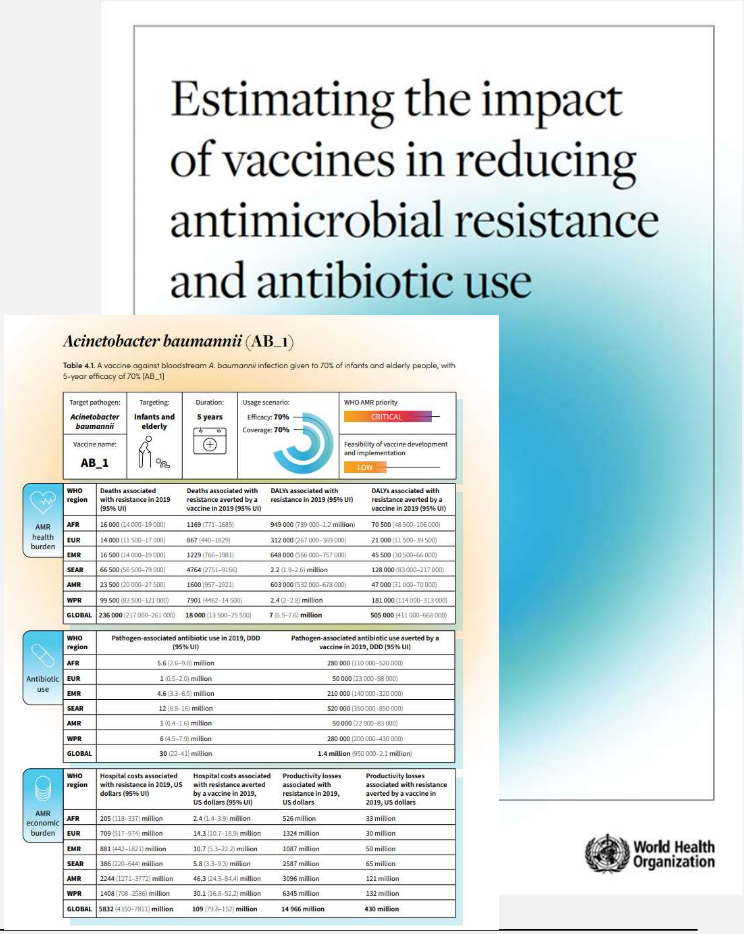
The role of vaccines in reducing AMR has been underrecognised, yet they play a vital role in protecting against pathogens and preventing infection-related complications

Existing vaccines and candidates in early and late-stage clinical development for 24 pathogens have the potential to annually avert up to:

- **515,000 deaths**
- **28 million DALYs**
- **US $30 billion in hospital costs**
- **US $20 billion in productivity losses**

Which are all associated with AMR

These vaccines could also help to reduce antibiotic use by **2.5 billion doses**



Acinetobacter baumannii (AB_1)

Table 4.1. A vaccine against bloodstream *A. baumannii* infection given to 70% of infants and elderly people, with 5-year efficacy of 70% [AB_1]

Target pathogen:	Targeting:	Duration:	Usage scenario:	WHO AMR priority
Acinetobacter baumannii	Infants and elderly	5 years	Efficacy: 70% Coverage: 70%	CRITICAL
Vaccine name: AB_1				Feasibility of vaccine development and implementation: LOW

AMR health burden

WHO region	Deaths associated with resistance in 2019 (95% UI)	Deaths associated with resistance averted by a vaccine in 2019 (95% UI)	DALYs associated with resistance in 2019 (95% UI)	DALYs associated with resistance averted by a vaccine in 2019 (95% UI)
AFR	16 000 (14 000–19 000)	1169 (771–1685)	949 000 (789 000–1.2 million)	70 500 (48 500–106 000)
EUR	14 000 (11 500–17 000)	867 (440–1829)	312 000 (267 000–369 000)	21 000 (11 500–39 500)
EMR	16 500 (14 000–19 000)	1229 (766–1981)	648 000 (566 000–757 000)	45 500 (30 500–66 000)
SEAR	66 500 (56 500–79 000)	4764 (2751–9166)	2.2 (1.9–2.6) million	128 000 (83 000–217 000)
AMR	23 500 (20 000–27 500)	1600 (957–2921)	603 000 (532 000–678 000)	47 000 (31 000–70 000)
WPR	99 500 (83 500–121 000)	7901 (4462–14 500)	2.4 (2–2.8) million	181 000 (114 000–313 000)
GLOBAL	236 000 (217 000–261 000)	18 000 (13 500–25 500)	7 (6.5–7.6) million	505 000 (411 000–668 000)

Antibiotic use

WHO region	Pathogen-associated antibiotic use in 2019, DDD (95% UI)	Pathogen-associated antibiotic use averted by a vaccine in 2019, DDD (95% UI)
AFR	5.6 (2.6–9.8) million	280 000 (110 000–520 000)
EUR	1 (0.5–2.0) million	50 000 (23 000–98 000)
EMR	4.6 (3.3–6.5) million	210 000 (140 000–320 000)
SEAR	12 (8.8–16) million	520 000 (350 000–850 000)
AMR	1 (0.4–1.6) million	50 000 (22 000–83 000)
WPR	6 (4.5–7.9) million	280 000 (200 000–430 000)
GLOBAL	30 (22–41) million	1.4 million (950 000–2.1 million)

AMR economic burden

WHO region	Hospital costs associated with resistance in 2019, US dollars (95% UI)	Hospital costs associated with resistance averted by a vaccine in 2019, US dollars (95% UI)	Productivity losses associated with resistance in 2019, US dollars	Productivity losses associated with resistance averted by a vaccine in 2019, US dollars
AFR	205 (118–337) million	2.4 (1.4–3.9) million	526 million	33 million
EUR	709 (517–974) million	14.3 (10.7–18.9) million	1324 million	30 million
EMR	881 (442–1821) million	10.7 (5.3–22.2) million	1087 million	50 million
SEAR	386 (220–644) million	5.8 (3.3–9.3) million	2587 million	65 million
AMR	2244 (1271–3772) million	46.3 (24.3–84.4) million	3096 million	121 million
WPR	1408 (708–2586) million	30.1 (16.8–52.2) million	6345 million	132 million
GLOBAL	5832 (4350–7811) million	109 (79.8–152) million	14 966 million	430 million

AMR, antimicrobial resistance; DALY, disability-adjusted life years

Status of development of vaccines for bacteria on the WHO priority list

https://www.who.int/publications/i/item/9789240093461

Pathogen	Use case	Phase I	Phase II	Phase III
Mycobacterium tuberculosis (TB)	Prevention of active pulmonary TB disease (with or without evidence of latent infection), including in those with HIV infection	**2** SSI CanSino	**6** Bharat/IAVI, BioNTech x2 Quratis, Oxford Uni., Anhui Zhifei Longcom[2]	**3** SII Gates MRI Gamalaya Res. Centre
Shigella spp	Prevention of moderate to severe diarrhoea due to Shigella in infants from 6 months and children up to 36 months of age		**4** GVGH/Bharat Biotech LimmaTech/Valneva Eveliqure Institut Pasteur	**1** Zhifei
Salmonella (non-typhoidal)	Paediatric vaccines for prevention of invasive disease caused by non-typhoidal *Salmonella* in children aged 6 – 36 months, with and without a typhoid conjugate	**1** iNTS-TCV (GVGH)	**2** iNTS-GMMA (GVGH) TSCV (Uni. Maryland & Bharat)	
Streptococcus pyogenes (group A streptococcus)	Prevention of GAS disease: pharyngitis, impetigo and invasive disease in young children. Potential for prevention of GAS immune-mediated sequelae: acute rheumatic fever and rheumatic heart disease	**3** Dalhousie Uni. Queensl'd Inst. Med. Research Uni. of Alberta & Griffith Uni.		
Streptococcus agalactiae (group B streptococcus)	Maternal immunisation during pregnancy to prevent GBS-related stillbirth and invasive GBS disease in neonates and young infants	**1** PATH-Inventprise	**1** MinerVax	**1** Pfizer
Klebsiella pneumoniae	Vaccine administered during pregnancy to prevent neonatal sepsis caused by the major disease-causing serotypes of K pneumoniae	**1** CHO Pharma[1]		

Note: [1] The CHO Pharma Klebsiella vaccine is currently being developed as a preventive vaccine against nosocomial and community-acquired infections caused by hypervirulent Klebsiella pneumoniae K1 & K2 serotypes. It is not currently being evaluated as a maternal use vaccine.

Development of a framework to identify Novel Combination Vaccines for Endemic Pathogens for Children Under 5 Years of Age

2025	2026

Identify and prioritize novel vaccine combinations for children under 5 that do not increase the number of injections

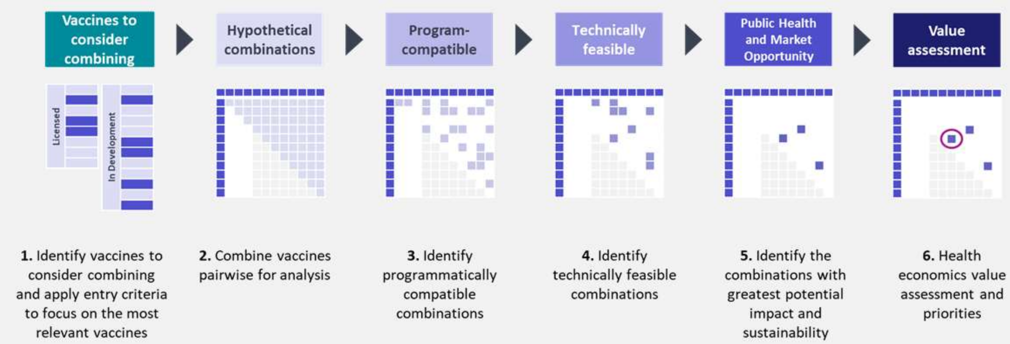
Goal

To develop a combination vaccine priority-setting framework that identifies **novel vaccine combinations** likely to be:

- Programmatically compatible
- Technically feasible
- Impactful in the long term

Combinations that have a synergistic affect on AMR?

Staged approach to prioritize combinations



Preliminary results: Programmatically compatible, technically feasible combinations (licensed + licensed)

Injectable — Licensed

Compatibility with	HepB	PCV	MenB	C19 (Pfizer)	EV71	JE (inact.)	JE (live atten.)	Men ACWY (Pfizer)	Men ACWY (GSK)	Men ACWY (Mncta)	Men ACWYX	Men ACWY (MenQ)	MR	MMR	MMRV	TCV	YF	DTwP	HepA (inact.)	HepA (live)
BCG	AR																			
Hexa aP		P	P			<5														
Hexa wP		P	P			<5														
PCV			<5																	
MenB						<5														
Malaria (GSK)				PAB																
Malaria (SIIL)				PAB																
C19 (Moderna)					PS		PS	<5	<5	<5	<5	<5	PS			PS	PS		PS	PS
C19 (Pfizer)					PS															
C19 (inact)								<5	<5	<5	<5	<5								
EV71														AB	AB					
JE (live attenuated)								PB	PB	PB	PB	PB	<2	<2	<2	PB		A		
JE (live recombinant)								PB	PB	PB	PB	PB		<2	<2	PB		A		
MenACWY (Pfizer)													PB	PB	PB	<2	PB	<5	<5	P
MenACWY (GSK)													PB	PB	PB	<2	PB	<5	<5	P
MenACWY (SP Menactra)													PB	PB	PB	<2	PB	<5	<5	P
MenACWYX													PB	PB	PB	<5	PB	<5	<5	P
MenACWY (SP MenQuadfi)													PB	PB	PB	<2	PB	<5	<5	P
MR																PB	<2	A	A	<2-B
MMR																PB	<5	A	A	<2-B
MMRV																PB	<2	A	A	<2-B
TCV																	PB	<5		
YF																		A		
DTwP																			<5	A

Legend

P1 feas. in 2 years	<2
P1 feas. in 5 years	<5
Prog Med, Low, VLow	

Oral

Compat.	Rota
bOPV	PS

DRAFT: Results currently under review

Vaccines without compatible, feasible combinations are not shown

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Overview of the session

Speakers:

- Dr. Sushant Sahastrabudhe, Dy. DG (Acting) - IVI
- Dr. Laurence Mulard, Head of Laboratory - Institut Pasteur
- Prof. Maria Elena Bottazi, Co-Director of Texas Children's Hospital Center for Vaccine Development - Baylor College of Medicine

Panelists:

- Mr. Stefano Malvolti, Managing Director - MMGH Consulting
- Dr. Michael Karl Schunk, Senior Industry Specialist-Vaccines & Biopharma - IFC
- Dr. Frauke Uekermann, Director Vaccines Market - CHAI
- Dr. Ankur Mutreja, Director of Strategy, Partnerships & Communications - PATH