COVID-19 Vaccine Webinar

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Declaration of Interests

- PAHO/WHO Regional Certification Commission for Polio Endgame in the Region of the Americas (AMR-RCC) - Member
- Caribbean Immunization Technical Advisory Group (CITAG) - Member
- No financial interests

Acknowledgement

- Professor Peter Figueroa
- Dr. Karen Lewis-Bell

Outline

- Definition of immunization
- Caribbean Achievements in Immunization
- The pandemic
- Vaccine development
- The COVID 19 Vaccine Candidates
- The COVAX Mechanism
- Challenges
- Conclusion

Immunization

- Immunization, one of the most important public health success in history has resulted in significant decreases in many diseases
- The purpose of immunization is to induce protection (immunity) from subsequent disease with the use of vaccines
- Vaccines are complex biological products designed to induce a protective immune response effectively and safely
- Therefore vaccines train the immune system to recognize the pathogen when it is encountered naturally
- Immunity following vaccination lasts for months to years, depending on the type of vaccine as well as host factors

Immunization Cont'd

- When most persons in a community are vaccinated against a disease, the ability of the pathogen to spread is limited
  (herd immunity)

- When many persons have immunity, this also indirectly protects others who cannot be vaccinated, such as very young babies and those who have compromised immune systems

Achievements of the Countries of the Caribbean Community

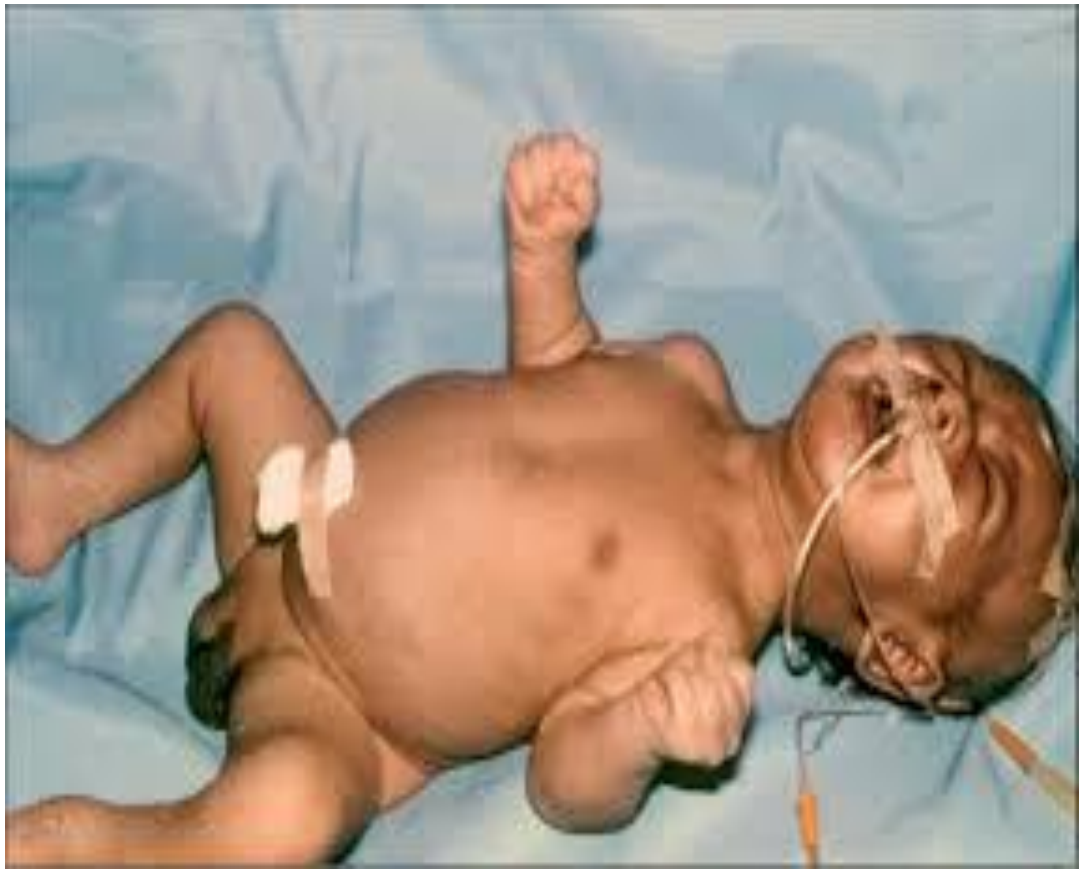
The Caribbean has led the world with immunization and was the first sub-region to achieve elimination of polio, measles, rubella and congenital rubella syndrome with almost 100% national funding

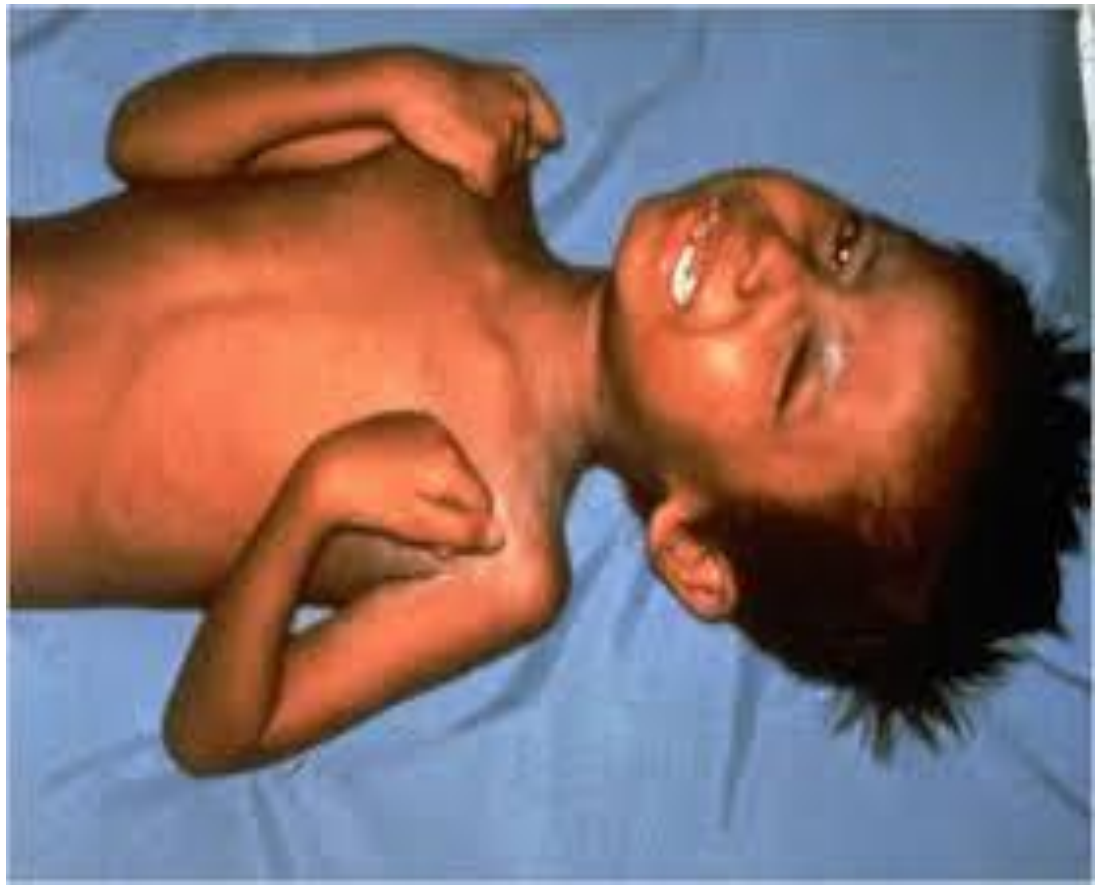
Last indigenous cases:

- Yellow Fever - 1978
- Poliomyelitis - 1982
- Measles - 1991;
- Diphtheria - 1994
- Congenital rubella syndrome -1999
- Neonatal tetanus - 2000
- Rubella - 2002

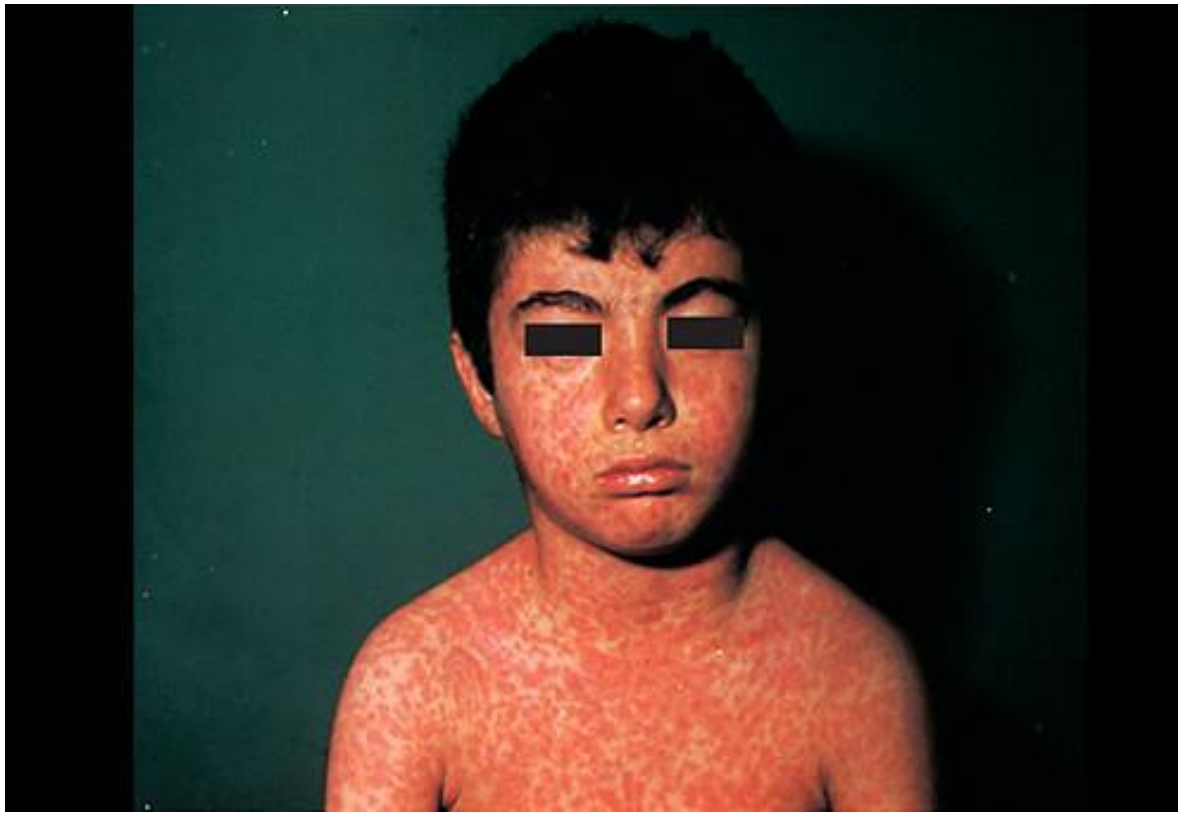
Poliomyelitis

Neonatal Tetanus and Tetanus

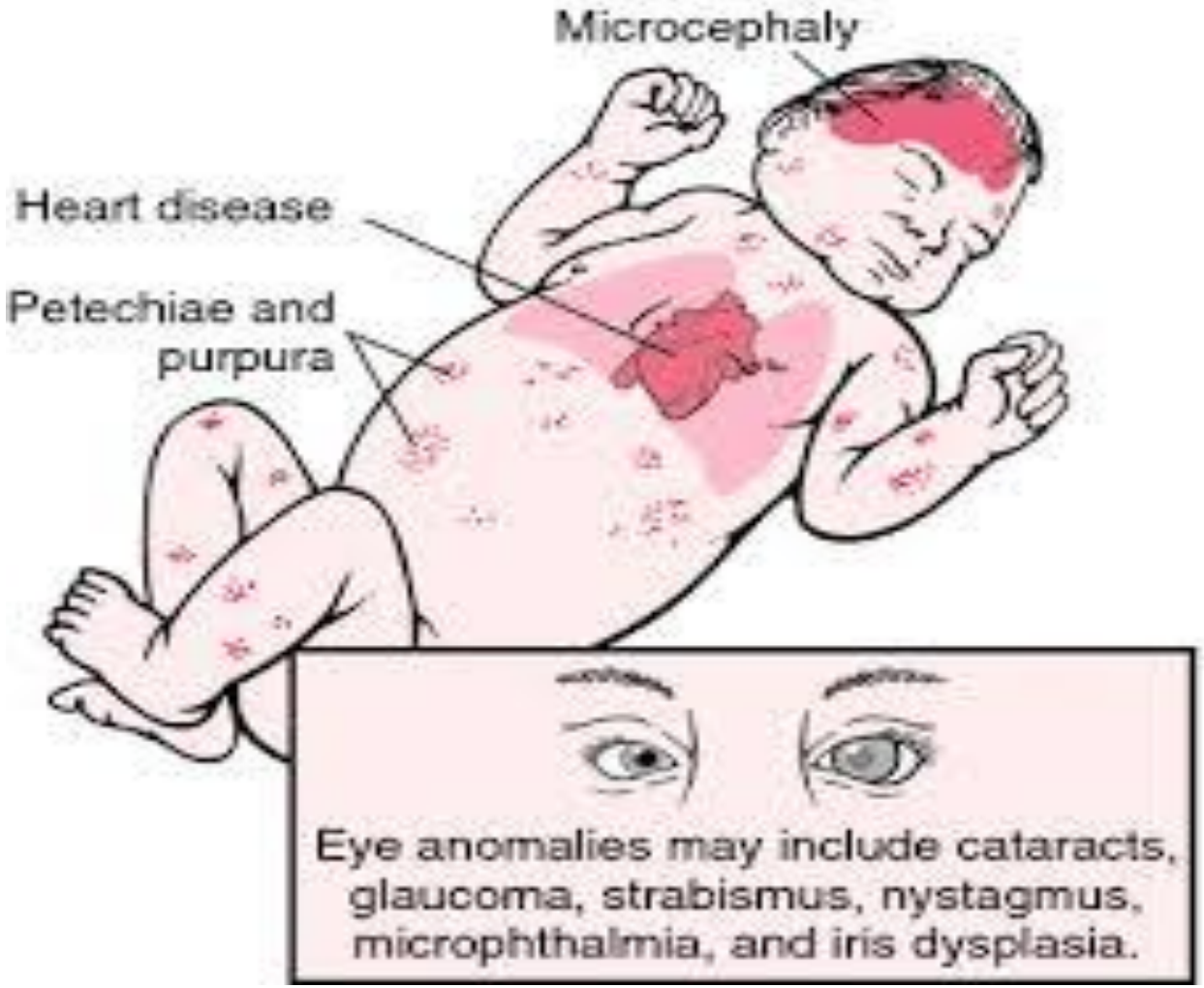




Measles



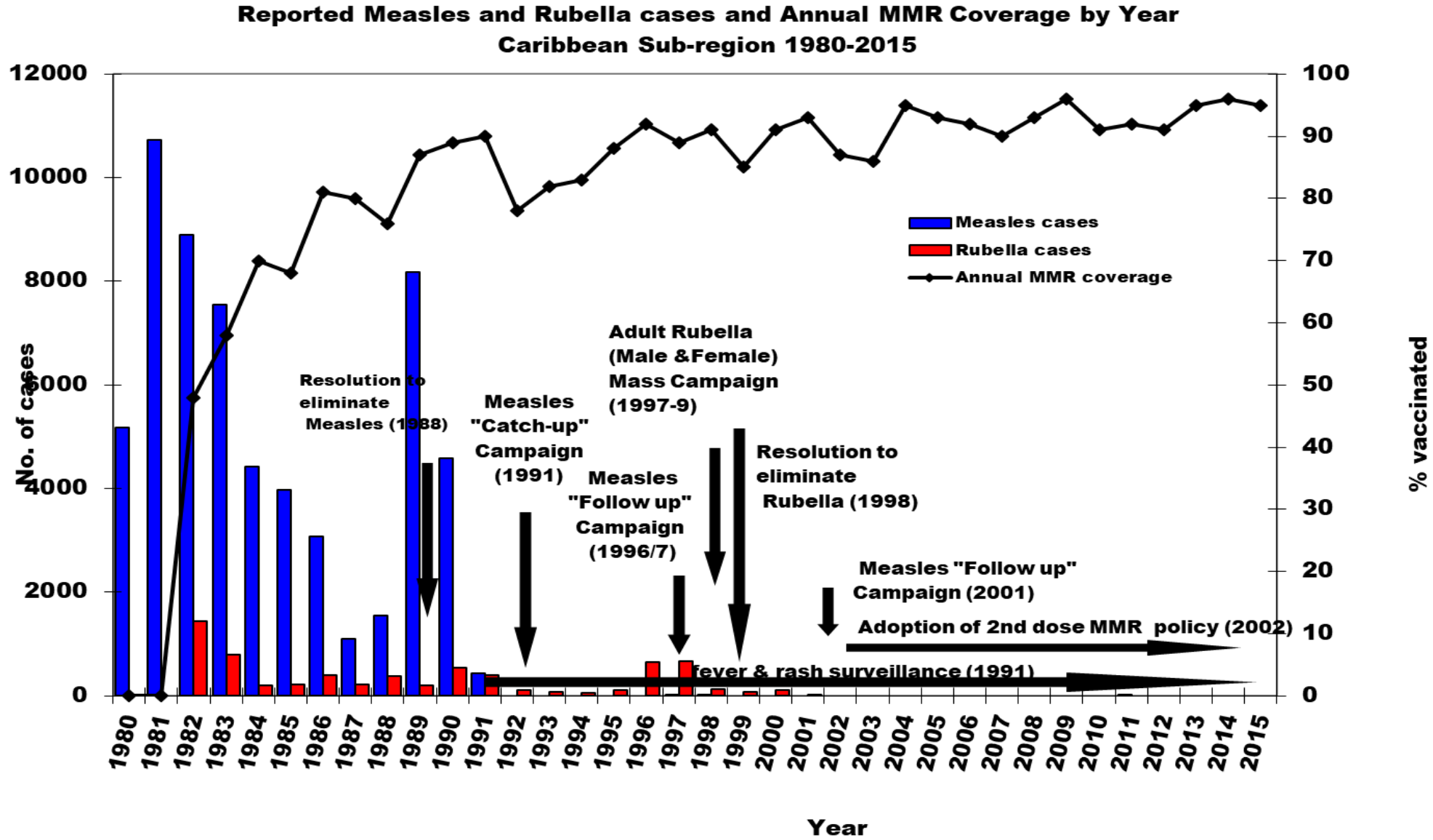
Congenital Rubella Syndrome (CRS)



Achievements of the Countries of the Caribbean Community

- The Caribbean has been remarkably successful in preventing reintroduction of measles virus into one of the countries
- This success has come despite 40 million persons visiting the Caribbean, many coming from areas, such as Europe and Africa, where the virus continues to circulate

The reason – well vaccinated population in the countries



Source: Rubella and Measles cases reported to EPI-CAREC and Country WHO/UNICEF Joint Reporting Forms.

Reason for the Success

- Concerted effort of Governments (CARICOM), commitment of health care professionals and the population, and technical expertise and guidance from PAHO/WHO resulted in the elimination of the diseases

- Well vaccinated Population in countries!

Why are we discussing Vaccine Preventable Diseases in the midst of COVID-19 Pandemic?

COVID-19 Pandemic has transformed 2020

- 65 million confirmed cases
- 1.5 million deaths
- Crippled economies
- Disrupted social life

The Pandemic and Vaccination

- COVID-19 is now a vaccine preventable disease and the commitment, dedication and strategies used for the elimination of other diseases have to be utilized to decrease the number of cases, with the ensuing morbidity and mortality

What are the Actions taken to Develop a Vaccine to ensure that it is safe and works well?

- Pre-clinical studies:
  Vaccine is tested in animal studies for efficacy and safety
- Phase I clinical trial:
  Small groups of healthy adult volunteers receive the vaccine to test for safety
- Phase II clinical trial:
  Vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended

What are the Actions taken to Develop a Vaccine to ensure that it is safe and works well? Cont'd

- Phase III clinical trial:
  Vaccine is given to thousands of people and tested for efficacy and safety

- Phase IV post marketing surveillance:
  Ongoing studies after the vaccine is approved and licensed:
  - to monitor adverse events and
  - to study long-term effects of the vaccine in the population

COVAX MECHANISM AND ACCESS TO COVID-19 VACCINE

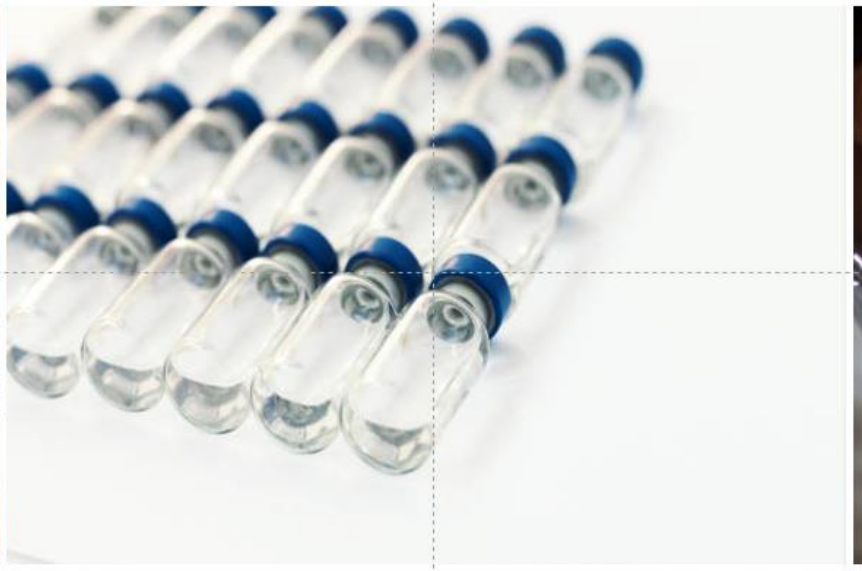
Dr. Karen Broome

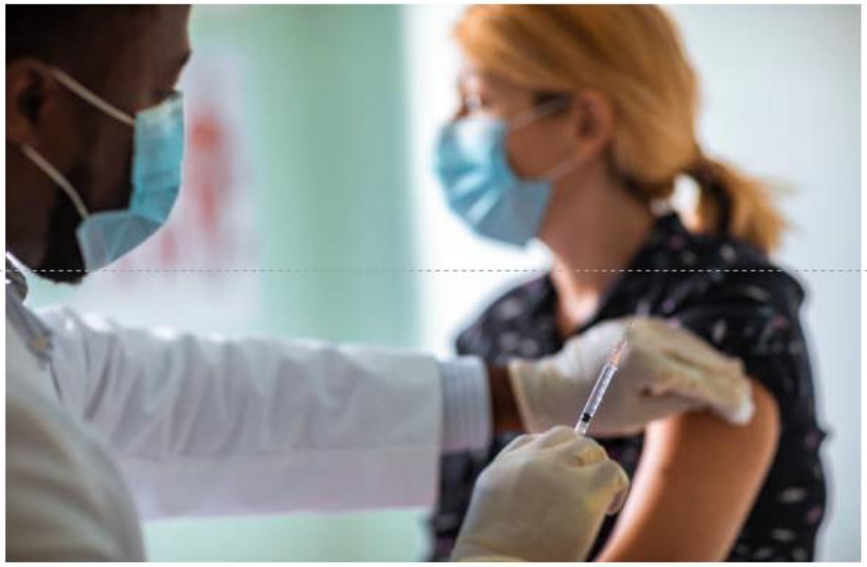
COVAX Facility

Pools purchasing power to invest in a broad portfolio of vaccine candidates

Deliver 2 billion doses by the end of 2021 and guarantees fair and equitable access

Candidates are assessed on several dimensions (e.g. safety, efficacy, availability of supply, etc.)





Diverse portfolio across technologies, geographies and characteristics (e.g. dose schedule, unique antigens)

2 vaccine candidates across 2 technology platforms are currently included in the portfolio, with many more in consideration

PAHO countries can access the COVAX Facility portfolio through the **PAHO Revolving Fund.**

Three possible modalities for how countries can gain access COVID-19 products

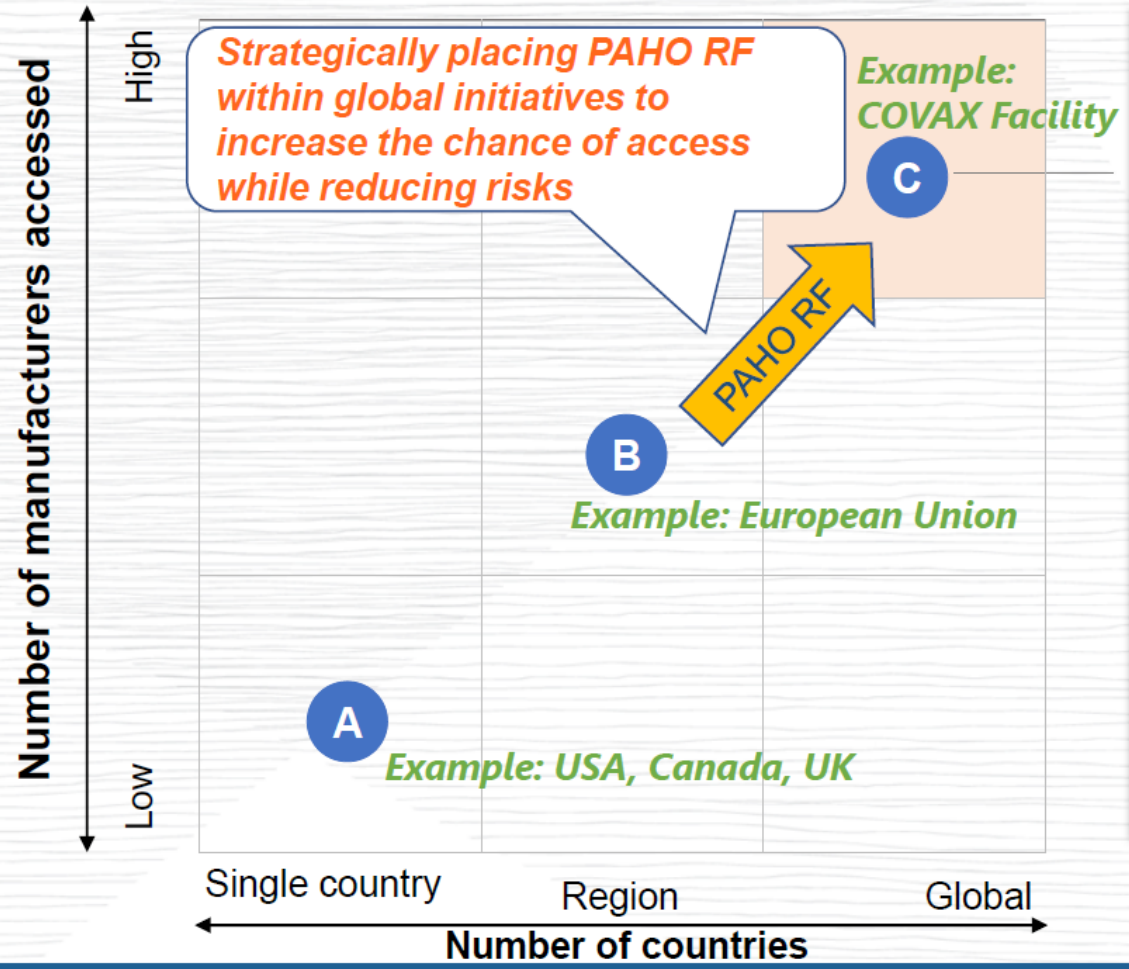
Three possible access modalities

A — National access mechanism
Countries negotiate deals with manufacturers individually (e.g., lock into supply agreements locally)

B — Grouped access mechanism
Countries form regional groups or blocks to negotiate supply agreements

C — Global access mechanism
Countries participate in a global mechanism to access products

Implications



Global access offers:

Opportunity to have equitable access through fair allocation across countries

Essential 'risk-pooling' (e.g., less risk of having no supply if certain vaccine candidates fail)

COVAX Facility focused on transparency, global access and impact

Bold ideas and brilliant innovation for the worst global health crisis in 100 years

Pooled demand

Pooled supply

Consolidates buying power and provides participants access to a broad and actively-managed portfolio

Provides manufacturers access to a massive, demand-assured market

11 August –Gavi Country Consultation Slide

Participants have the option to select between two participation arrangements upon joining the COVAX Facility

Committed Purchase Arrangement

- Lower down-payment
- Financial commitment / guarantee to purchase doses

Optional Purchase Arrangement

- Higher upfront payment
- Options to decide on purchasing doses
- Small risk-sharing guarantee

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92 COVAX AMC-eligible countries and economies

Low income: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen, Rep.,

Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Principe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, Zimbabwe

Additional IDA eligible: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu.

Gavi Board approved in July 2020, based on 2018 and 2019 World Bank GNI data

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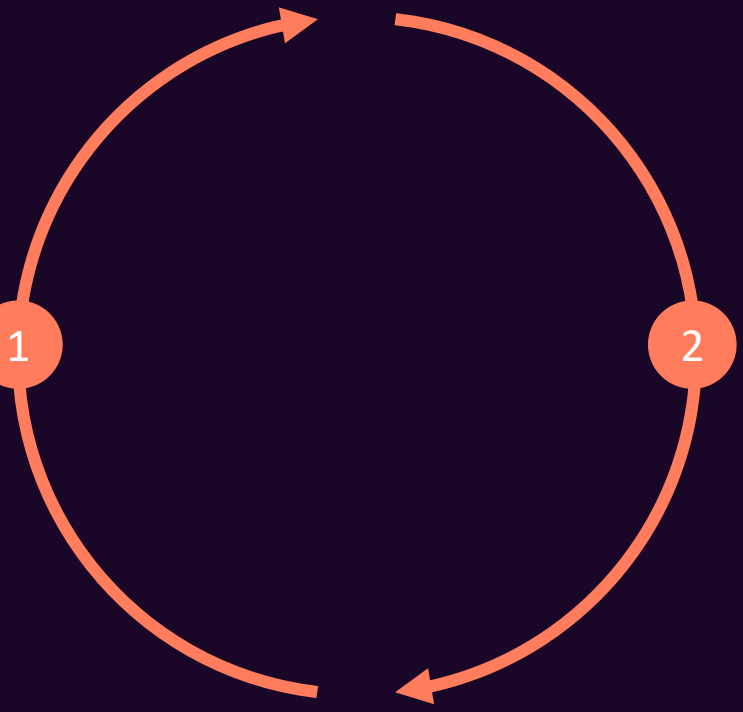
Additional Support for AMC-92 Group

Vaccine Access	• Financial support for vaccine procurement and access through the COVAX AMC
Purchase mechanisms	• Support from the Alliance through UNICEF and PAHO Revolving Fund
Delivery	• Support for cold chain equipment and technical assistance

Support may be differentiated within the group. All options explored will aim to ensure that participants do not face any significant barriers to accessing a COVID-19 vaccine

The two main goals of a vaccination program are inextricably linked

Improve individual and public health (1)



(2) **Minimize societal and economic impact**

To significantly reduce the impacts of COVID-19 in the safest, quickest and most effective way, it is not necessary to vaccinate the entire population

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Allocation Framework and Allocation Mechanism for Vaccines

Goals

Protect public health and minimize societal and economic impact by reducing COVID-19 mortality

Priorities

Health and social care workers	High-risk adults	Further priority groups
All participants receive doses to cover 3% of their population. This would be enough to cover all workers involved in health and social care work.	**All participants receive additional doses beyond the 3% to total 20% of their population (in tranches).** This could include the elderly, adults with comorbidities or others depending on locally relevant risk factors	**Participants receive doses to cover more than 20% of their population.** This would cover additional priority populations.

Timing

*Participants receive doses proportionally to their total population**

If protracted severe supply constraints remain, timing is based on participants' vulnerability and COVID-19 threat

A buffer will also be set aside for emergency deployment based on immediate needs

Note: The fundamental principle applies that all participants receive doses at the same rate to the extent possible, notwithstanding likely practical limitations to be further worked out (e.g. minimum delivery volumes)

WHO SAGE Policy development: steps and processes

Status update

1. **Values Framework** for the allocation and prioritization of COVID-19 vaccination: Principles, objectives and target groups of a COVID-19 vaccination programme → Endorsed by SAGE and published Sept 14 2020

2. **WHO SAGE Roadmap For Prioritizing Uses Of Covid-19 Vaccines** In The Context Of Limited Supply: development of use case scenarios of limited vaccine under different epidemiological settings → Published November 13

3. **Policy recommendations on the use of COVID-19 vaccines** once registered; under consideration of product-specific data and attributes, and with consideration of the regulatory approval process (emergency use or full registration) → Timeline depends on registration by countries or Emergency Use Listing/ prequalification by WHO; process iterative as products come along

Steps in vaccine development

Actions taken to ensure a new vaccine is safe and works well

- **Pre-clinical studies**
  Vaccine is tested in animal studies for efficacy and safety, including challenge studies
- **Phase I clinical trial**
  Small groups of healthy adult volunteers receive the vaccine to test for safety
- **Phase II clinical trial**
  Vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended
- **Phase III clinical trial**
  Vaccine is given to thousands of people and tested for efficacy and safety
- **Phase IV post marketing surveillance**
  Ongoing studies after the vaccine is approved and licensed, to monitor adverse events and to study long-term effects of the vaccine in the population
- **Human challenge studies**
  Studies in which a vaccine is given followed by the pathogen against which the vaccine is designed to protect. Such trials are uncommon in people as they present considerable ethical challenges

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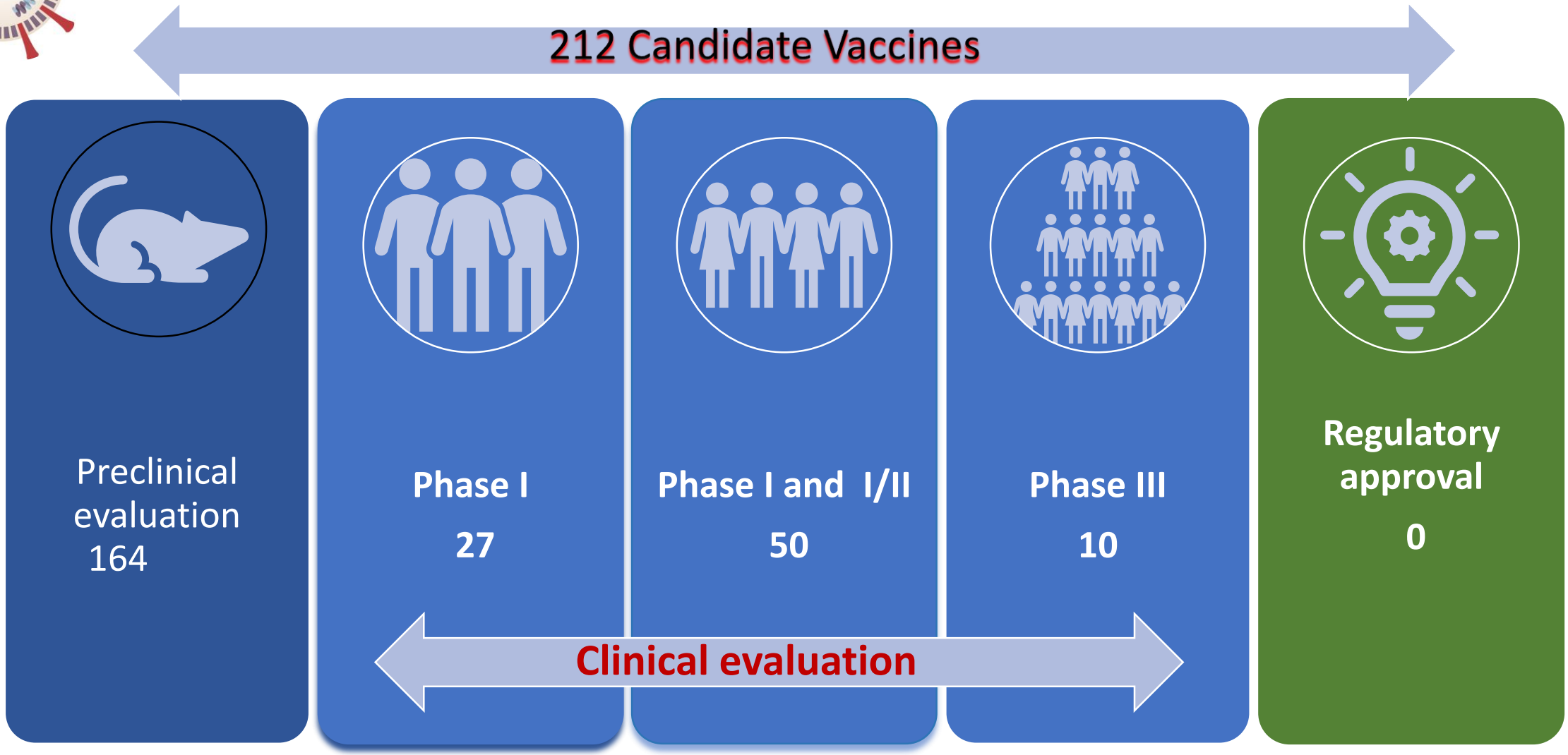
Landscape COVID-19 Candidate Vaccines
November 12, 2020

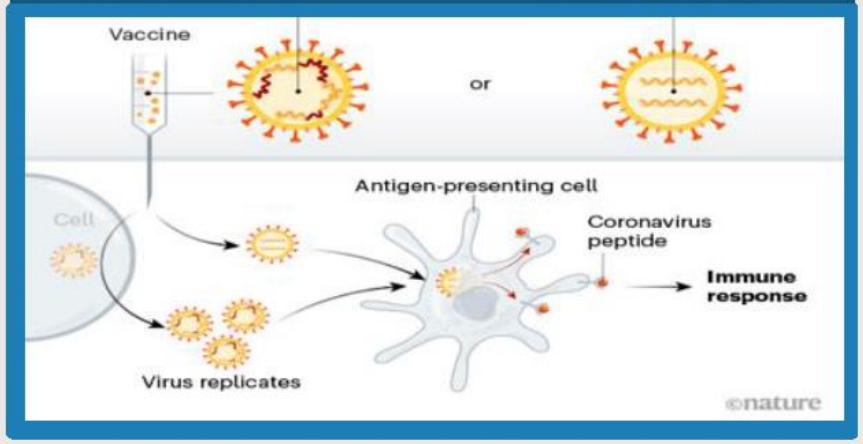


Sources: WHO. Draft landscape of COVID-19 candidate vaccines. 12 November 2020. Available at: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

Types of COVID-19 candidate vaccines being developed

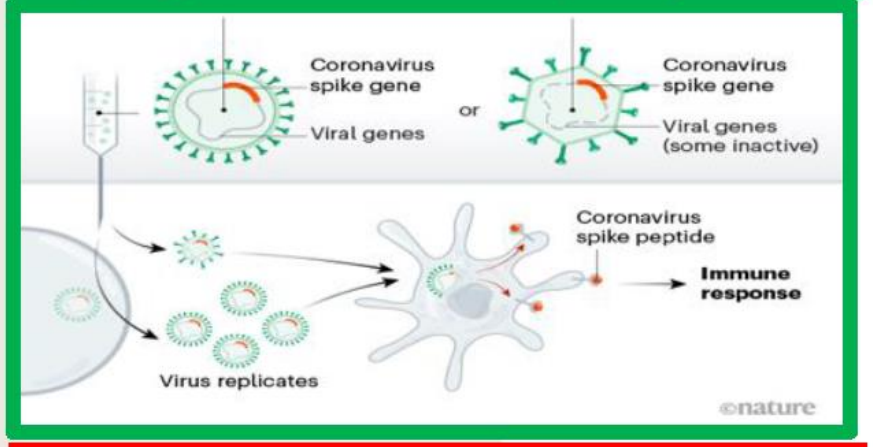
VIRUS VACCINES

Live-attenuated virus | Inactivated virus



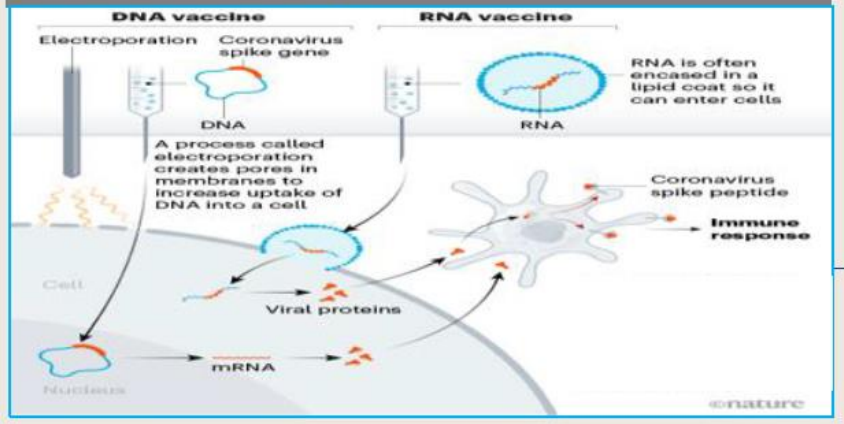
VIRAL VECTOR VACCINES

Replicating viral vector | Non-replicating viral vector



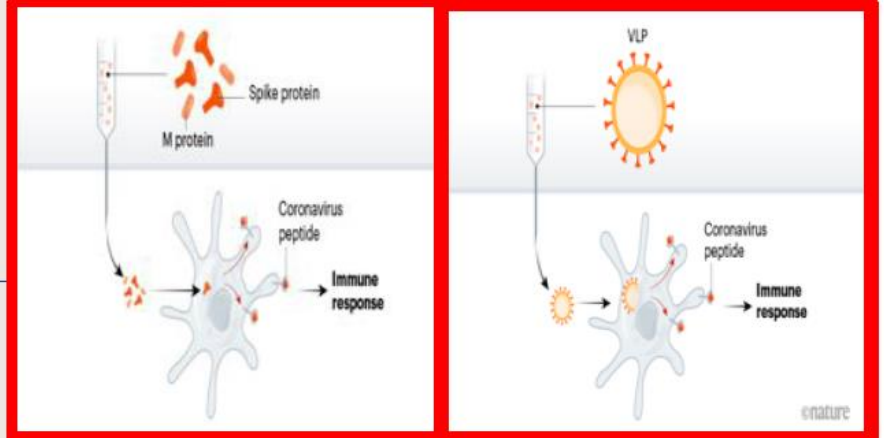
NUCLEIC ACID VACCINES

DNA and RNA vaccines



PROTEIN-BASED VACCINES

Protein subunits | Virus-like particles



Ira Longini
Univ of Florida

COVID-19 Vaccines have been decades in development

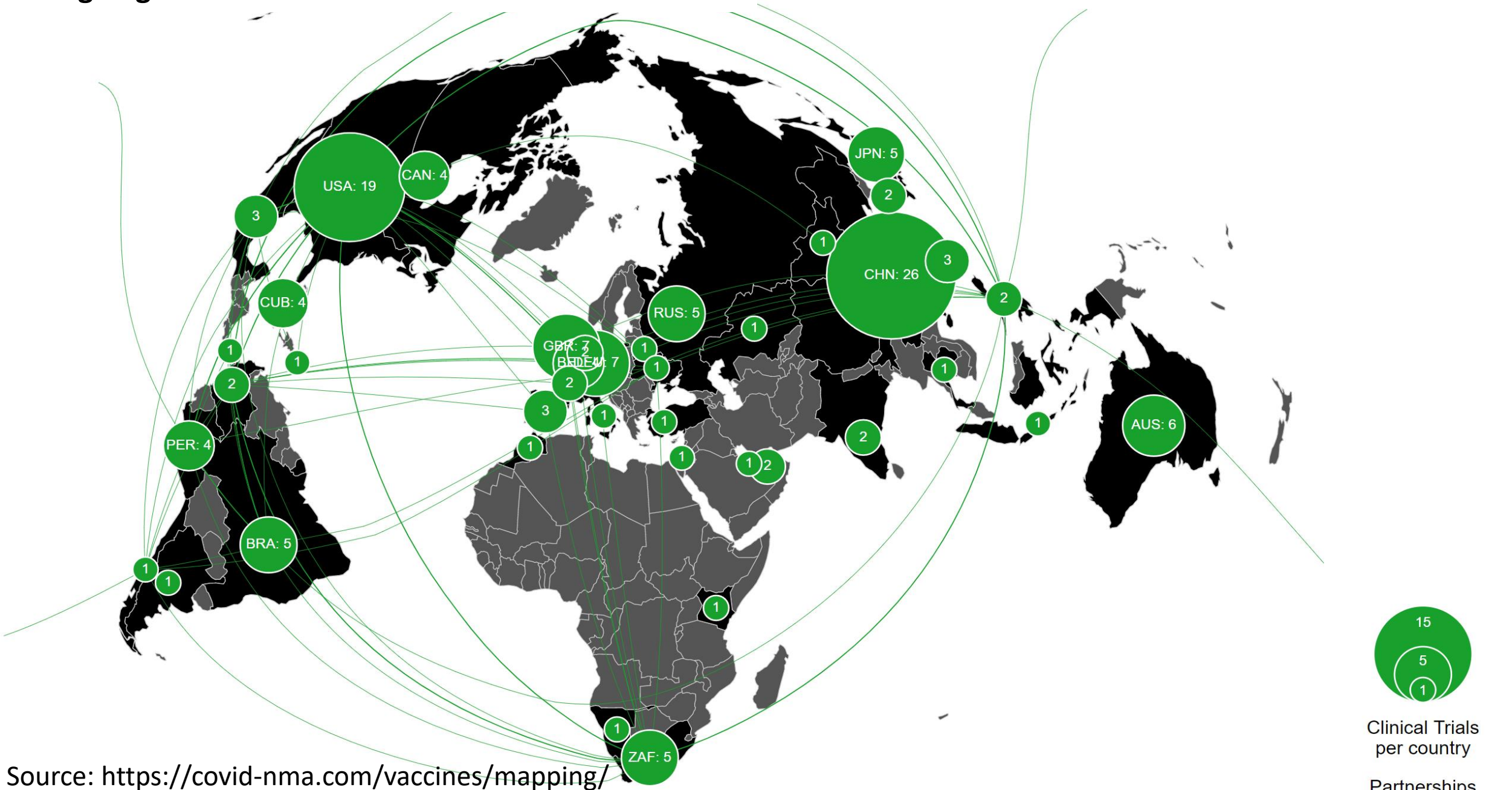
- Efforts to develop a vaccine against the common cold due to Corona viruses have been ongoing for decades
- 2005 - SARS outbreak stimulated research for a vaccine against the spike protein of the SARS Corona virus
- 2012 – MERS outbreak stimulated further research
- January 2019 - Genome of the SARS CoV2 was decoded and research to prepare a vaccine began immediately
- Highly sophisticated technology is available now that was not available when earlier vaccines were being developed

Vaccine Trials have included Thousands of Persons

- Clinical trials have been conducted in several continents with tens of thousands of participants - both sexes, diverse races & different ages:
- Pfizer BioNTech Phase 3 clinical trial – 43,500
- Moderna clinical trial – 30,000
- AstraZenica clinical trial – 30,000
- China: Sinovac > 100,000 persons vaccinated
- Russia: Sputnick vaccine > 100,000 persons vaccinated

- Initial results of the trials are very encouraging

Ongoing Clinical Trials – COVID19 vaccine candidates



Source: https://covid-nma.com/vaccines/mapping/

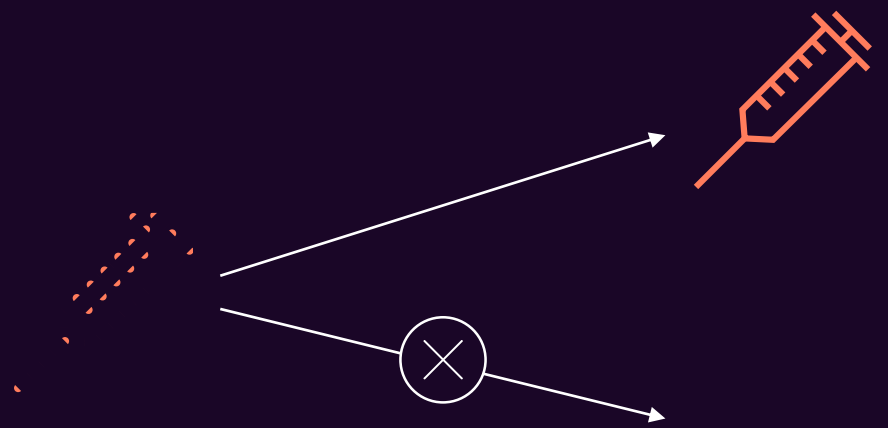
COVID-19 Candidate Vaccines in Phase III
November 16, 2020

Vaccine developer/ manufacturer	Vaccine platform	Name of vaccine candidate	Number of doses and timing	Route of administration	Sample size, age	Location clinical trial	Status	Registry number
AstraZeneca/Oxford University	***Non-replicating viral vector***	AZD1222	1 dose	IM	2,000, ≥18 - 55 years	UK, **Brazil**	Recruiting	ISRCTN89951424
			2 doses (0, 28 days)		30,000, ≥18 years	US. Other*:South Africa, India, Bangladesh	Recruiting	NCT04516746
			2 doses (0, 28 days)		100, ≥18 years	Russia	Not yet recruiting	NCT04540393
CanSino Biological Inc./Beijing Institute of Biotechnology		Ad5-nCoV	1 dose	IM	40, 000, ≥18 years	Pakistan	Not yet recruiting	NCT04526990
					500, ≥18 -85 years	Russian. Other*: China, Canada, United Arab Emirates, **Mexico, Brazil.**	Not yet recruiting	NCT04540419
Gamaleya Research Institute		Gam-COVID-Vac	2 doses (0,21 days)	IM	40,000, ≥18 years	Russia. Other*: Kazakhstan, Belarus, **Brazil, Mexico.**	Recruiting	NCT04530396
Janssen Pharmaceutical Companies		Ad26.COV2.S1	1 dose	IM	60,000, ≥18 years	**Brazil, Chile, Colombia, Mexico, Peru**, Philippines, South Africa, Ukraine, US	Not yet recruiting	NCT04505722
Sinovac	***Inactivated***	CoronaVac	2 doses (0, 14 days)	IM	8,870, ≥ 18 years	Brazil	Recruiting	NCT04456595
					1,620, ≥18 – 59 years	Indonesia. Other*: China, Bangladesh, **Chile**, Indonesia, Turkey.		669/UN6.KEP/EC/2020
Wuhan Institute of Biological Products/Sinopharm		CNBG Wuhan	2 doses (0, 14 days or 0, 21 days)	IM	15,000, ≥ 18 years	United Arab Emirates. Other*: China, Morocco.	Recruiting	ChiCTR2000034780
Beijing Institute of Biological Products/Sinopharm		BBIBP - CorV	2 doses (0, 14 days or 0, 21 days)	IM	15,000, ≥ 18 years	United Arab Emirates.	Recruiting	ChiCTR2000034780
Moderna/NIAID	***RNA***	mRNA-1273	2 doses (0, 28 days)	IM	30,000, ≥ 18 years	US	Recruiting	NCT04470427
BioNTech/Fosun Pharma/Pfizer		BNT162b	2 doses (0, 28 days)	IM	29,481, ≥ 18-85 years	**Argentina, Brazil**, Turkey, US. Other*: **Chile,** Germany, China.	Recruiting	NCT04368728
Novavax	***Protein subunit***	NVX-CoV2373	2 doses (0,21)	IM	10,000, 18 to 84 years	United Kingdom	Not recruting yet	NCT04368988

No single vaccine is guaranteed to succeed or has enough capacity

For planning purposes, the Facility is targeting 2 B doses by the end of 2021

- Many vaccines in development – unknown how many will succeed
- No single manufacturer has the capacity to supply the global volume required



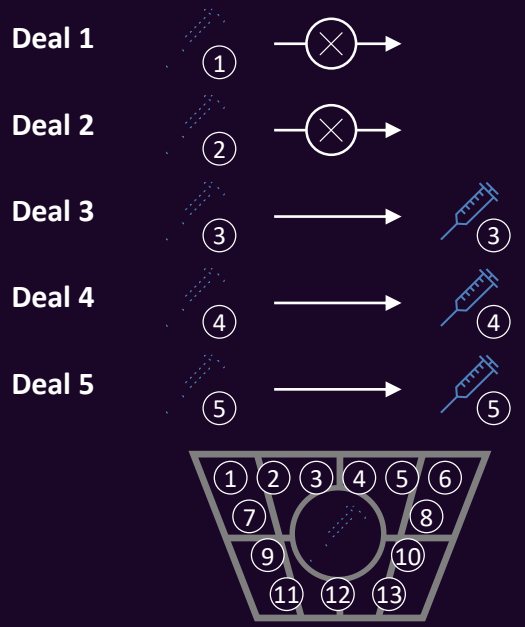
Individual deals might fail

A diversified portfolio is needed to diversify risk and create capacity to scale

COVAX thus selected a basket of vaccine candidates to mitigate these risks

- A **basket of deals is needed** to increase the chances of delivering 2B doses by end of 2021
- **Deals for more than 2 B doses are needed** to account for the risk of unsuccessful development

Deals for more than 2B doses



COVAX still has enough doses even after some vaccines fail

COVAX is creating a basket of 10-15 vaccine candidates

CEPI COVID-19 vaccine portfolio currently consists of 9 projects, 8 in clinical trials

	DNA / mRNA			Viral vector			Protein		
COVID-19	**Inovio**	**Moderna**	**CureVac**	**Merck / Themis**	**AstraZeneca / Univ. Oxford**	**University of Hong Kong**	**Novavax**	**Clover BioPharma**	**University of Queensland / CSL**
Location	USA	USA	Germany	USA / Austria	UK	China	USA	China	Australia
Platform	DNA	mRNA	mRNA	Viral Vector	Viral Vector	Viral Vector	Protein	Protein	Protein
Antigen / Adjuvant	Full-length S protein	Full-length S protein	Full-length S protein	Full-length S protein	Full-length S protein	Receptor Binding Domain / AS03	Full-length S protein / saponin-based Matrix-M	Full-length S protein/AS03 or CPG1018	Full-length S protein / MF59 or AS03 or CPG1018
Current phase	Phase I/II	Phase III	Phase I	Phase I	Phase III	Preclinical	Phase II	Phase I	Phase I

Speed **Scale** **Access**

Current BMGF portfolio being evaluated for inclusion in COVAX

	Protein						Viral vector	saRNA	Inactivated
COVID-19	**Candidate #1**	**Candidate #2**	**Candidate #3**	**Candidate #4**	**Candidate #5**	**Candidate #6**	**Candidate #7**	**Candidate #8**	**Candidate #9**
Location	South Korea	China	India	India	USA	China	USA	UK	Global (multi-manufacturer partnership)
Platform	Protein (CHO + E.coli)	Protein (Pichia)	Protein (Pichia)	Protein (Pichia)	Protein (CHO + E.coli)	Protein (CHO)	Viral vector / DNA (HEK)	saRNA	Inactivated (Eggs)
Antigen / Adjuvant	RBD-NP	RBD	RBD	RBD-VLP	RBD-NP	RBD-dimer	Full length S protein	Full length S protein	Full length S protein
Current phase	Tech Transfer	Late discovery	Discovery	Late discovery	Tech transfer	Phase I	Late discovery	Phase I	Late discovery

BMGF "Wave 2" portfolio selected based on potential for combination of attributes relative to leading SARS-CoV2 vaccine candidates:

Higher Potency

Existing Manufacturing Capacity

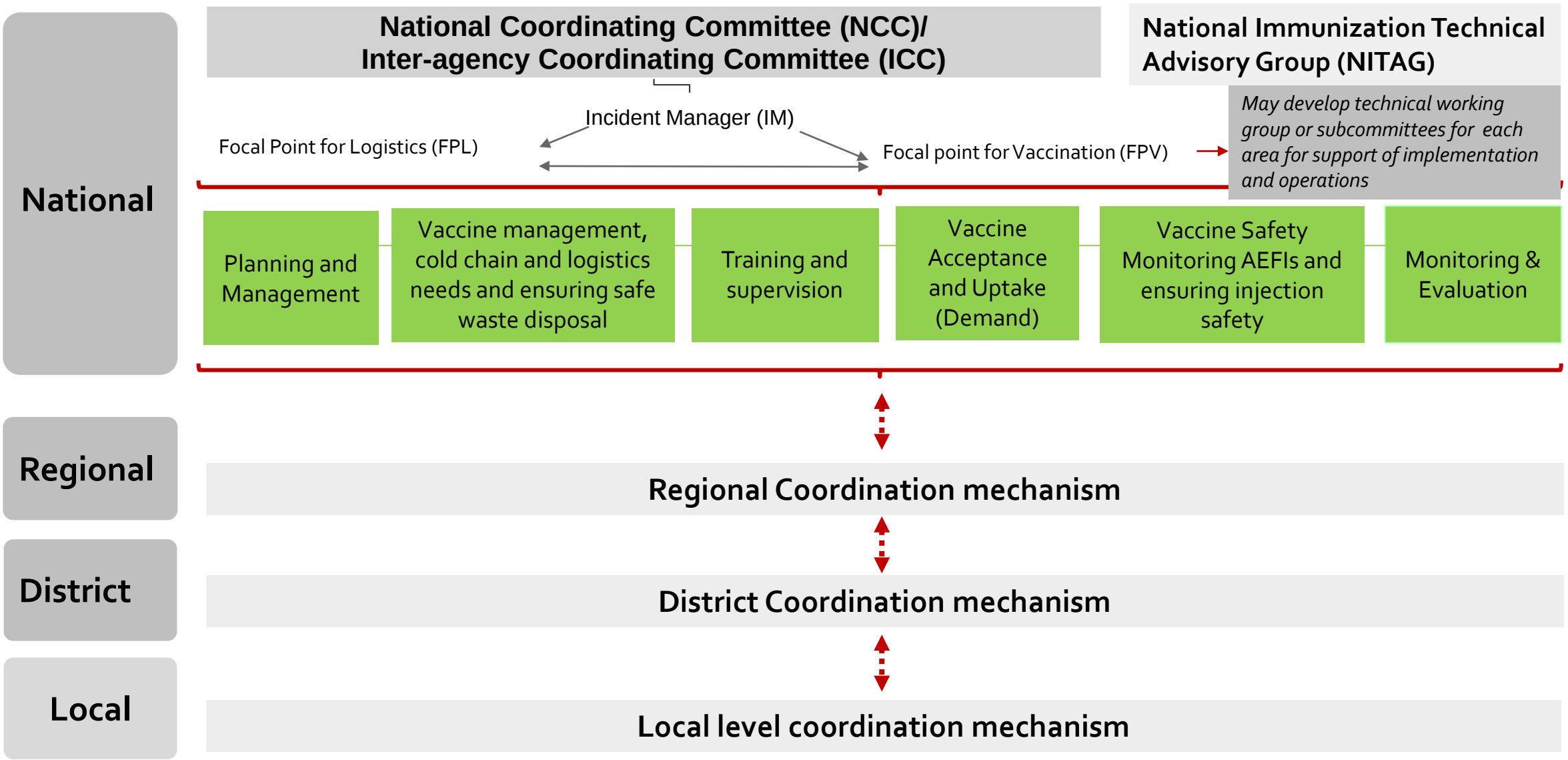
Lower Cost of Goods

Novel Approach

3 COVID-19 VACCINE CANDIDATES

Vaccine Candidate	PFIZER-BIONTECH	MODERNA	ASTRAZENECA OXFORD
Efficacy	95%	94.5%	70% (90%, 62%)
Type	mRNA	mRNA	Adenovirus vector
Shelf life	2-8^{0}C – 5 days Dry ice chest – 30 days -(60-80)^{0}C – 6 months	Room temp – 12 hours 2-8^{0}C – 30 days -(15-25)^{0}C – 6 months	2-8^{0}C – 6 months
Approximate cost per dose (US)	$20	$15-25	$4
Administration route	2 doses - 28 days apart	2 doses - 28 days apart	2 doses - 28 days apart
Regulatory status	Emergency authorization – UK → FDA	→ FDA	To seek emergency authorization from WHO
Production capacity	50 million – 2020 1.3 billion - 2021	20 million – 2020 500m –> 1b - 2021	3 billion - 2021

Chain of reporting and management structure for Vaccine Deployment and Intro



National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines

Forms the backbone of the “One operational country plan” for COVID-19 Vaccine Introduction – Guidance published - November 16, 2020 (*Joint global, regional, partners*)

1. Introduction

2. Regulatory Preparedness

3. Planning and Coordination

4. Identification of Target Populations

5. Vaccination Delivery Strategies

6. Preparation of Supply Chain Management and Health Care Waste

7. Human Resources Management and Training

8. Vaccine Acceptance and Uptake (Demand)

9. Vaccine Safety Monitoring Management of AEFIs and Injection Safety

10. Data Monitoring Systems

11. COVID-19 Surveillance

12. Evaluation of COVID-19 vaccine Introduction

Vaccine Acceptance and Challenges

Acceptance of Vaccine

- The perceptions of the public and the medical community about the disease and the vaccine are important factors in determining acceptance of vaccination and its priority
- Acceptance of vaccination is the norm in the majority of populations globally
- However, a small number refuse some vaccines, agree to others and some delay vaccination
- Adults rely on their healthcare providers to give recommendations for vaccination

Vaccine acceptance Cont'd

Several general factors have been identified that affect vaccine acceptance including:

- ❖lack of knowledge about the need for vaccine(s)
- ❖misperceptions about the vaccines and the disease
- ❖ fear of side effects after vaccination
- ❖lack of trust in the health system
- ❖history of a negative interaction with immunization providers, and
- ❖inconsistent vaccine availability

Barriers to Vaccination

- Many factors converge to create barriers to vaccination:
- the systemic level (access to health care services) and
  - the patient level (Inadequate knowledge regarding the vaccine and the benefits of the vaccine)
- Studies have also suggested that vaccine-hesitant individuals, who hold various degrees of indecision about specific vaccines or vaccination in general
  - can significantly contribute to decreases in immunization rates and slow uptake of the vaccine to be newly introduced

Vaccine Hesitancy

- The major reasons can be categorized as:
- Complacency - perceived risks of diseases are low and vaccination is not deemed a necessary preventive action or priority at that time
- Confidence - trust in the effectiveness and safety of vaccines, the system that delivers them, the reliability and competence of the health services and health professionals
- Convenience - physical availability, affordability, geographical accessibility, ability to understand (language and health literacy)

What are some of the strategies to address these issues?

Suggested Strategies

- Attempts must be made to engage community members in a meaningful manner
- Get buy-in from community leaders including those from Faith-based organizations
- Work with country communicators
- Collaboration with partners at various levels
- Concerns and rumors need to be addressed regardless if they are considered to be trivial
- Devise an approach to appeal to audience –Champion as was used for MMR mass vaccination in adults
- Processes should be participatory and multisectoral
- Build trust

Communication Channels

Use as many modalities as possible:

- Social media- know the audience and know your target group
- The newspaper “lasts longer”
- The radio “reaches more people”
- The television “has more influence”
- Web FAQ and Myth busters on COVID-19 vaccines

Conclusion

- To be successful, the COVID-19 vaccination programme should provide education and increase awareness to counter the misinformation and negative perception of the vaccine
- Health care professionals have to be champions of the programme and willing to recommend the vaccine to the target population
- Government and population support are crucial for success

Take Home Messages

- The effort to develop a vaccine against the coronaviruses has been ongoing for decades with acceleration in 2005 and 2012
- mRNA vaccines do not use live virus that causes COVID-19 and do not interfere with DNA
- Clinical trials conducted in several countries >30,000 participants of both sexes, diverse ethnicity and different ages
- Findings from the trials - the vaccines are safe and effective
- We will have to live with COVID for the foreseeable future
- Vaccine is not a silver bullet – will still need non-pharmaceutical measures
- Prepare for more change as the situation is dynamic

Suggestion:

Take the vaccine when you get the chance, I will be taking it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THANK YOU!