

# Perspectives: COVID Vaccine

14<sup>th</sup> September, 2020

# Contents

1. Horizon scan
2. Target groups for prioritization
3. Safety & efficacy
4. Implementation Framework
5. Resources required
6. Regulator's role
7. Indigenous production/trials
8. Risk Communication
9. Options for Pakistan
10. Recommendation

# Composition & Process of development

- **Members**

- *Dr. Asad Ali*, infectious Disease Pediatrics Specialist, AKU
  - *Dr. Salma Abbas*, Infectious Disease Specialist, SKMCH
  - *Dr. Amjad Mahboob*, Infectious Disease Specialist, Gajju Khan Medical College
  - *Ms. Ghazala Parveen*, Chief Biological Production Division, NIH.
  - *Mr. Naeem Asghar*, Deputy Director Operation Federal EPI
  - *Dr. Assad Hafeez*, Public Health Specialist, Health Services Academy
- 
- Consultations (formal & informal)
  - Development of first draft
  - Review and inputs
  - Draft report/recommendation for National Vaccine Committee/NCOC

# Vaccine and Horizon Scanning

Vaccine	Company	Country	Stage	Comments
Adenovirus Vected vaccine	Oxford-AstraZeneca	UK	Phase-3 Trials paused	Leading but may not provide full protection
Adenovirus Vected vaccine	Jansen &Jansen	USA	Phase-3 About to start	Not in phase III Strong prospects
Adenovirus Vected	CanSino	China	Phase 3	Leading but vector issues
mRNA-1273	Moderna, NIH	USA	Phase 3	Cost, better technology
3LNP-mRNAs	Pfizer	Germany	Phase 3	Cost, better technology
Perfusion Protein	Novavax	Australia	Phase-3	Promising
Inactivated Vaccine Verocell	SinoPharm	China	Phase 3	Low cost, safety
Inactivated Vaccine	Sinovac	China	Phase 1/2	Low cost, safety

# Priority Groups for targeting

- **Factors**
  - *Health perspective*
  - *Supply of vaccine*
  - *Cost of vaccine*
  - *Functionality of state Machinery*
  - *Economics perspective*
- Frontline workers (prioritized by age and exposure risk)
  - Health
  - Non Health (LEAs, other essential)
- Older persons (prioritized by co morbidities)
- Individuals with Co morbidities
- Education sector (prioritized by age and exposure risk)
- Immunocompromised persons/Death from COVID in family
- Economic machinery (Shop keepers/lawyers/Bankers)
- Airline/Rail/Transport
- Prisoners

# Safety & Efficacy

- **Importance of Phase III trials**
  - Safety
  - Degree of protection
  - Rare side effects
  - Virus shedding
  - Antibody mediated Disease Enhancement (ADEs)
- **Phase 4 trials/mechanism**
- **WHO pre qualifications**

# Implementation Framework

- Dosage, Schedule, mode of delivery
- Operation Planning (including phasing as per guidelines)
  - Macro
  - Micro
- Cold Chain
- Other Logistics
- Support entities (UN & partners, Professional associations, Academia)
- **Options**
  - Existing structure
  - New structure
  - Hybrid mechanism

# Resources/Finances

- **Evolving situation**
- **Cost Components**
  - Vaccine cost (major)
  - Cold Chain
  - Operations
  - Media/Communication
  - Research/dvp
  - Others
- **Dummy tables developed for**
  - % of population
  - Cost of vaccine
  - Dosage required
  - Wastage factor
  - Cold Chain costs
  - Others



# Regulators

- Production starts during phase III trial with stockpiles ready for distribution
- Results of phase III trials are to convince regulators for allowing the use
- Regulators have a critical role in balancing pressures
- DRAP to streamline its procedures in anticipation
- Examples & issues:
  - Emergency approvals
  - Leading regulators and follow on regulators
  - Geographical spread of production sites
  - Political influences and national stakes

# Indigenous production/Clinical Trials

- **Stages of production**

- Research & Development
- Complete chain of manufacturing
- Concentrate
- Local filling
- Labeling & packing

- **Clinical trails**

- Pre clinical
- Phase-I
- Phase-II
- Phase-III
- Phase IV

- **NIH, PHRC to coordinate clinical trials & develop capacity in Pakistan**

# Pak-China Collaboration

- **Sinopharm-** Phase III
- **CanSino-**
  - Phase III
  - Use in china
- **Tianyuan-** Transfer of technology
- Best use of diplomatic and channels through M/o NHR&C, NIH, MOFA, others

# Risk Communication

- Anti-Vaxers lobby
- Prevalent conspiracy theories
- Critical to mould public opinion
- Messages in media/press with a mature & robust communication strategy in place.

# Pakistan's Options

- **Bilateral Contracts**
  - Proactive approach to book in advance a couple of million doses
  - Risk management
- **COVAX Window**
  - 20% of Population will be covered for each country
  - Still in evolution, needs close monitoring
  - Threats
- **Chinese Collaboration**
- **Private sector**
  
- Timing is important

Thank You

S. NO	Recommendations	Responsibility
8	Continuous engagement with COVAX facility	MNHSR&C
9	Allocation of USD 20 millions as assured resource for Phase I activity	MNHSRC to move case for M/o Finance
10	Initiate Engagement with 2 lead manufacturers – 1 million individuals covered with each	Develop a framework for prioritization MNHSRC
11	Collaboration with China for indigenous manufacturing (Filling) and technology transfer	<i>NIH keeping MNHSRC &amp; MoFA in loop</i>
12	Clinical Trials on vaccine efficacy	<i>NIH/PHRC</i>
13	Regularity framework to be more responsive <ul style="list-style-type: none"> <li>a) Constitution of separate Board for covid related approvals</li> <li>b) Development of fast track protocols</li> <li>c) Assurance of safety and efficacy of candidate vaccine.</li> </ul>	DRAP
14	Public messaging be embedded in existing campaigns to include mentions of “Vaccine” at this stage	<i>Expert opinion of health communication team</i>
15	Review of National Vaccine strategy & Recommendations at 6 weekly interval	NCVC