Covid-19 Vaccination in India: Challenges and Strategies

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ABSTRACT

India, a union of states, is a Sovereign, Secular, and Democratic Republic with a Parliamentary system of Government. 28 States and 8 Union territories. Healthcare percolates to the last mile (villages) through a hierarchical structure arrangement i.e. Community Health Centre, Public Health Centre and Sub-Centres. A combination of Government and private health care facilities caters to Urban and rural population in a highly diversified social fabric across the country. With 1.3 billion populations, extremely high density and limited healthcare resources India is fighting battle to containing COVID-19 spread at multiple fronts. Rigorous efforts are being made to contain this deadly virus at all levels in Government hierarchy while scientists across the world are racing to develop a vaccine that can bring the novel coronavirus pandemic to an end. There are nearly 50 vaccine candidates currently under human trials with 11 of them in phase III (typically the last stage of vaccine research) testing around the world. Storage and handling requirements attached with two front runner vaccine technologies i.e. mRNA and viral vector, will influence vaccine candidate selection process in India.

Toughest task will be planning priority groups in a Phased vaccination programme and planner would need to improvise custom criteria befitting to local conditions and healthcare system in India. Data on committed or anticipated access to number of doses of specific vaccine type (technology) on a given timeframe will be the starting point for setting-up priority groups and planning end-to-end procedure for storage, handling, distribution and inoculation. Prevention of fraudulent activities and cyber crime in COVID-19 vaccination procurement and management process is another challenge for authorities in India and would need to be suitably addressed in the National Plan.

COVID-19 is an opportunity for overhauling public healthcare system in India. Author discusses key challenges and strategies in vaccinating whole country against COVID-19.The focus of discussion is more on vaccine administration strategy for rural India which accommodates about 72 % of country's 1.3 billion populations.

Keywords*:* *COVID-19 vaccination, Public Healthcare system in India, Primary Health Canter, Immunisation in India, vaccine storage, cold chain, immunisation, immunisation Logistics*

INTRODUCTION

Decision-makers are looking for a framework to ensure that everyone throughout the world can be vaccinated, so that we can stop the spread of this virus. But each country will need to customise National COVID-19 Vaccination plan based on their access to the type of vaccine and number of doses as supplies will be constrained during initial 3-6 months once multiple vaccine candidates gets approval for use. Vaccination plan essentially will partition whole population into 3 or 4 specific groups with priority assigned to each. Data collection for ascertaining number of population in each group will follow stringent criteria defined.

UK is the first country in the world to approve use of Pfizer-BioNTech vaccine based on the recommendation made by Medicines and Healthcare products Regulatory Agency (MHRA). MHRA has concluded that the Pfizer-BioNTech vaccine has met its "strict standards of safety, quality and effectiveness" after months of rigorous clinical trials and a thorough analysis of the data by experts. Government has announced its plan to commence targeted vaccinations for frontline healthcare workers, nursing home patients and those with underlying health conditions as early as December 12. This targeted

approach is aimed at protecting those most vulnerable to severe or critical COVID-19 (the elderly and those with potential comorbidities) as well as those most likely to become infected (healthcare workers) and transmit to others. Pfizer's vaccination process requires two jabs, within 21 days of each other. It is expected to roll out vaccines to care homes and GP surgeries within a fortnight, after regulators confirmed that doses can be transported in refrigerated bags. GPs have been 10 days notice to prepare to receive stocks of the vaccine in order to begin the process of injecting elderly and vulnerable people. In the week starting December 14, with care homes expected to receive the vaccine in the same week. In UK - a particular group of patients may be managed in the GP's (General Practice) surgery by a nurse or midwife in a particular timeslot during the week.

Moscow has began distributing the Sputnik V Covid-19 shot via 70 clinics on 5th Dec. 2020 for inoculating high risk group including - doctors and other medical workers, teachers and social workers. The age for those receiving shots is capped at 60. People with certain underlying health conditions, pregnant women and those who have had a respiratory illness for the past two weeks are barred from vaccination. The Sputnik V vaccine is administered in two injections, with the second dose to be given 21 days after the first.

In United States - Food and Drug Administration's (FDA's) Canter for Biologics Evaluation and Research external icon (CBER) is responsible for regulating vaccines in the United States. Moderna Inc. and Pfizer has applied for Emergency use authorizations, known as EUAs, formal approvals by the FDA for a previously unapproved or undeveloped medical product to be used during a national disaster. FDA is expected to issue EUA by 10th Dec 2020.

Meanwhile - Canters for Disease Control (CDC), in anticipation that COVID-19 vaccine's commercial use starts by 15th Dec 2020, has recommended to vaccinate health care workers and long-term care facility residents first .Initial phase of the COVID-19 vaccination program (phase 1a) should be offered to both 1) health care personnel and 2) residents of long-term care facilities. Advisory Committee for Immunization Practice (ACIP) defined health care personnel as "paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials," and long-term care facility residents as "adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently. As per ACIP's recommendation, governors would be left to decide which segments of their state's population would be given priority. In United States - about 40 million vaccines doses — enough for 20 million people — are expected to be available by end of December. And, according to ACIP, most jurisdictions expect to be able to vaccinate all of their healthcare workers in just three weeks. Some healthcare facilities will need to stagger distribution of the vaccine among personnel in order to protect against possible adverse reactions affecting an entire workforce.

Nineteen global health experts from around the world have proposed a new, three-phase plan for vaccine distribution -- called the Fair Priority Model is the best embodiment of the ethical values of limiting harms, benefiting the disadvantaged, and recognizing equal concern for all people. But implementing "proposed fair priority model" is a challenge for any country due to variations ground conditions. As far as planning COVID-19 vaccination is concern - each country will need to improvise best suited model commensurating with critical healthcare resources, front line workers, most vulnerable group of population, access to the type of vaccine, number of doses available on a given time line, vaccine storage and handling infrastructures.

In India, the central government has formed a special taskforce to oversee administration of Covid-19 vaccine(s), whenever it is ready for public use. Vaccine candidates i.e. Pfizer and Serum Institute of India (Oxford Uni.- AstraZeneca candidate) have applied to Drugs Controller General of India (DCGI) for EUA (Emergency use authorisation) for their respective vaccine. Ministry of Health and Family Welfare has started preparatory work on war footing in anticipation of access to vaccine starting from January 2021. India plans to vaccinate about 25-30 crore (250-300 million) people by Aug 2021.

COVID-19 VACCINE TECHNOLOGIES:

Cold chain storage and handling requirement for vaccines under development will commensurate with the technology used like – mRNA, viral vector etc. As per Canter for Disease Control and Prevention (CDC) guidelines - MMRV (Measles, Mumps, Rubella, and Varicella), Zoster vaccines are stored at temperatures between -58 degrees Fahrenheit and +5 degrees Fahrenheit (-50°C and -15°C), other traditional vaccines like

BCG are usually kept between 35°F and 46°F (2°C and 8°C). But storage and handling requirement for some of the leading Covid-19 vaccines under testing and approval would be more stringent. According to WHO, Covid-19 vaccines under development can be categorised in three storage temperature requirements: 2 - 8C, -20C and -70C.

How some of the Covid-19 vaccines compare

Company	Type	Doses	How effective*	Storage	Cost per dose
Oxford Uni-AstraZeneca	Viral vector (genetically modified virus)	x2	62-90%	Regular fridge temperature	£3 ($4)
Moderna	RNA (part of virus genetic code)	x2	95%	-20C up to 6 months	£25 ($33)
Pfizer-BioNTech	RNA	x2	95%	-70C	£15 ($20)
Gamaleya (Sputnik V)	Viral vector	x2	92%	Regular fridge temperature (in dry form)	£7.50 ($10)

*preliminary phase three results, not yet peer-reviewed

Source: Respective companies, WHO

Figure 1: COVID-19 VACCINE COMPARATIVE WITH TENTAIVE COSTING

The COVID-19 vaccine candidates being developed by Moderna Inc. and BioNTech and Pfizer Inc. will require stringent standards for refrigeration. mRNA-1273, which is Moderna's coronavirus vaccine candidate, requires a storage temperature of negative 4 degrees Fahrenheit (-20 degree C). BioNTech and Pfizer's candidates, BN1162b2 and BNT162b2, need to be stored in negative 94 degrees Fahrenheit (-70 degree C).

Pfizer will need to use ultralow temperature freezers and thermal shipper storage for its COVID-19 vaccine candidates. As per Sean Marett, chief commercial officer at BioNTech and responsible for distribution - stability studies on BioNTech vaccine provide evidence that their vaccine will supports handling by transport up to six hours at 2 to 8 degrees. Pfizer's vaccine is also expected to lead to high demand for dry ice, which can be used by hospitals or clinics to maintain the vaccine's subzero temperatures in temporary storage boxes for up to 15 days before being administered. If the vaccines are removed from the boxes and placed in a regular freezer, then they need to be used within five days.

The vaccine being developed by AstraZeneca AZN, -2.13% AZN, -2.50% and the University of Oxford is a recombinant viral vector vaccine. AstraZeneca-Oxford's ChAdOx1 vaccine (also christened AZD1222 and Covishield in India), will have to be refrigerated at 2-8 degrees Celsius. Johnson & Johnson's JNJ-78436735 single-shot vaccine is expected to be shipped commercially at standard refrigeration, while Russia's Sputnik V vaccine stipulates storage at a temperature not higher than –18 degrees Celsius (-0.4 degree F).

India's indigenous COVID-19 vaccine development efforts include – Covaxin from Bharat Biotech + Indian Council for Medical Research, and ZyCoV-D. The Serum Institute of India has been permitted for conduct Phase 2 and 3 human clinical trials of the third vaccine candidate from Oxford University-Astra Zeneca.

Most of the Covid-19 vaccines under development, according to the World Health Organisation (WHO), will need to be refrigerated at temperatures well below 0 degree C, the freezing point of water. Establishing robust cold chain would be essential as vaccines can easily lose potency when exposed to higher temperatures, and have to be protected against accidental freezing during transport, as well as breaks in the cold chain due to exposure to high heat.

PUBLIC HEALTHCARE SYSTEM IN INDIA:

India's Ministry of Health was established with independence from Britain in 1947. The government has made health a priority in its series of five-year plans, each of which determines state spending priorities for the coming five years. The health care system in India is primarily administered by the states. India's Constitution tasks each state with providing health care for its people. State governments provide healthcare services and health education, while the central government offers administrative and technical services. The public system is essentially free for all Indian residents except for small, often symbolic co-payments in some services. In 2019, the total net government spending on healthcare was $ 36 billion or 1.23 % of its GDP.

The Indian Constitution makes the provision of healthcare in India the responsibility of the state governments, rather than the central federal government. There are 28 states and 8 union territories in India with 640 districts. It makes every state responsible for "raising the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties. In addition to wide spread Public Health Care system, India has a matured private medical and health care sector. With socio-economic developments, more and more people opt for private heath care (as per a survey private health care attends to about 70% of households in urban areas and 63% of households in rural areas).

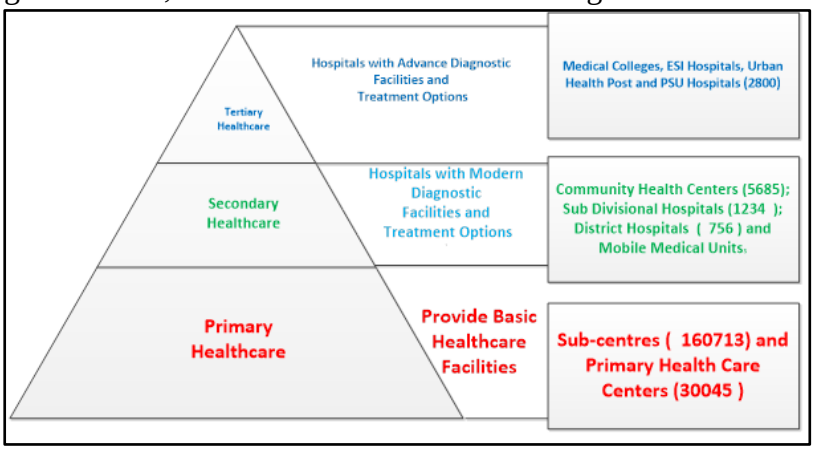

Figure 2 THREE TIER HEALTH DELIVERY SYSTEM IN INDIA

Healthcare delivery system in India is classified under three categories – primary, secondary and tertiary care as shown in figure 2. Outreach and availability of healthcare infrastructure and resources varies under each category. In each State, the Public healthcare system is organised into primary, secondary, and tertiary levels. At the primary level are Sub Centres and Primary Health Centres (PHCs). At the secondary level there are Community Health Centres (CHCs) and smaller Sub-District hospitals. Finally, the top level of public care provided by the government is the tertiary level, which consists of Medical Colleges and District/General Hospitals. In the primary health-care system in India, community health centres (CHC) provide specialist services for population groups of 100 000, while primary health centres (PHC) provide health-care services for disease prevention and cure and health-care promotion to population groups of 30 000.

Generally, individual primary health centres (PHC) are associated with six sub-centres, each of which covers a population group of 5000. In these sub-centres, basic medical care for minor illnesses and disease prevention and health-care promotion activities are provided by male and female multipurpose health workers. In order to promote preventive care, the Union government has announced the conversion of primary health care centres (PHC) into Health and Wellness Canters (HWCs). These HWCs will act as the pillar of preventive care and 'gateway' for access to secondary and tertiary health services.

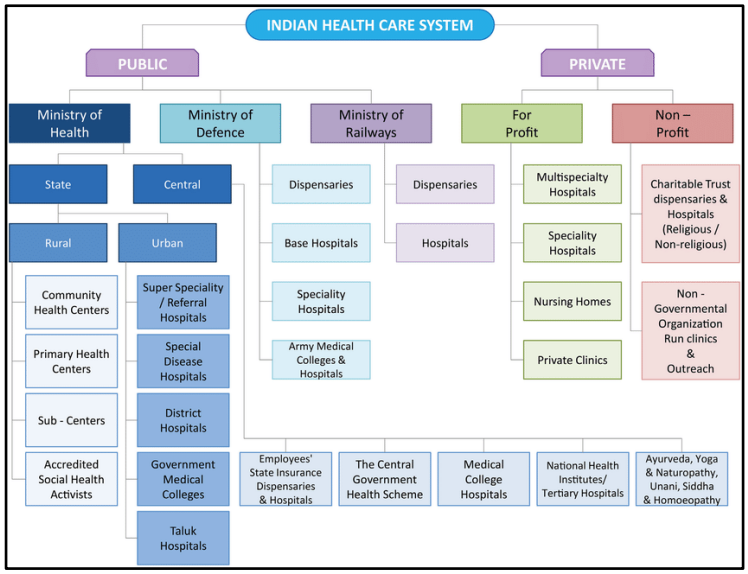

Figure 3 HEALTHCARE SYSTEM IN INDIA

SUB-CENTRE:

The Sub Centre is the most peripheral and is point of first contact between the primary healthcare system and the rural community. The

Sub Centres are assigned the task relating to Interpersonal communication in order to bring about behavioural change, Provide services in relation to maternal and child health, Family welfare, Nutrition, Immunization and Control of Communicable diseases. As per data available in document published by Ministry of Health and Family Welfare (Government of India) - there are 160713 sub-centres (SC) with 157411 in rural and 3302 Urban in Urban area as on 31st march 2019. Out of 157411 SCs in rural area 7821 SCs has been converted into Health and Wellness Centre (HWC) and out of 3302 SCs in Urban area 98 SCs have been converted in HWC.

PUBLIC HEALTH CENTRE (PHC):

PHC is the first contact point between village community and the Medical Officer. These are the first point where the rural people can directly report or can be referred from Sub Centres to qualified doctors for curative, preventive and promotive healthcare. There are 30045 functional PHC (24855 rural + 5190 Urban) across India. Manpower in PHC includes a Medical Officer supported by paramedical and other staff. Out of 24855 rural and 5190 Urban PHCs, 8242 and 1734 have been converted into HWC respectively.

Table below gives data on population average coverage and area covered at each level in healthcare system hierarchy along with allocation of skilled human resources.

Table 1 POPULATION, AREA COVERAGE AND HUMAN RESOURCES AT CSC, PHC AND SUB CENTRE [i]

(Source: Rural Health Statics 2018-19 Govt. of India)

Healthcare location/ Unit	Total Number	Population Coverage	Av. Population Covered	Av. Area Coverage (Sq. Km)	Av. Radial distance coverage	Av. No. of Villages covered	No. of HW (F)/ ANM	No of Allopath Drs	Specialist+ General Duty Medic-al officer
Sub-Centre+ HWC-SC	160713	3000-5000	5616	18.98	2.46	4	234220	-	-
PHC+HWC-PHC	30045	20000-30000	35567	120.19	6.18	26	-	29799	-
CSC	5685	800000-120000	165702	559.96	13.35	120	-	-	"3881+ 15395

COMMUNIYT HEALTH CENTRE (CHC):

CHCs serves as a referral centre for PHC and also provides facilities for obstetric and specialist consultation. The Community Health Centres provide specialized medical care of surgeons, obstetricians & gynaecologists, physicians and paediatricians. As 31st march 2019, there were 5685 CHCs with 5335 CHCs in rural and 350 CHCs in Urban area.

SUB DIVISIONAL HOSPITAL:

Sub-district (Sub-divisional) hospitals are below the district and above the block level (CHC) hospitals and act as First Referral Units for the Tehsil / Toluca /block population in which they are geographically located on one end and District Hospitals on other end. It also saves the travel time for the cases needing emergency care and reduces the workload of the district hospital. A subdivision hospital caters to about 5-6 lakh people. There are 1234 sub divisional hospitals in India.

DISTRICT HOSPITAL:

The District Hospital (DH) serves at the secondary referral level. Its objective is to provide comprehensive secondary health care services to the people in the district at an acceptable level of quality and to be responsive and sensitive to the needs of people and referring centres. There are 756 DHs across India providing crucial services to the population.

The existing healthcare system for preventive healthcare in India is supported by a team of more then four million doctors and nurses experienced in immunisation.

VACCINATION IN INDIA: CURREN PRACTICES

In India, PHCs are grassroots-level government-run health centres that are responsible for providing last-mile health services and carrying out immunisation drives. They are the nearest health facility for the people and effectively serve as the first point-of-contact between the government and society, especially in rural areas, for any public health intervention. The role of PHCs is critical in India's immunisation programme. Once a vaccine is manufactured, it is transported from the manufacturer/supplier to the state or regional vaccine store. From there, the vaccine is distributed to districts, which in turn send them to community health centres (CHCs) and primary health centres (PHCs).

The CHCs and PHCs are generally equipped with cold chain facilities to store vaccines before they are used on ground. On the day of immunisation, the auxiliary nurse midwife (ANM) of each sub-health centre (SHC) or Sub-Centre (SC) under a PHC is issued vaccines in kits that are specially designed to ensure vaccines' temperature is maintained right to the point of usage. Under this system, PHCs play a vital role in ensuring last-mile temperature requirements for vaccines to remain safe. Figure below shows vaccine supply and cold chain network and flow in India. As a general practice - the planning, implementation and monitoring of immunization services in a district is decentralized to the primary health centres (PHC). Vaccines are stored 3 months at district headquarters, from where supplies are sent to the community health centre and to primary health centre that

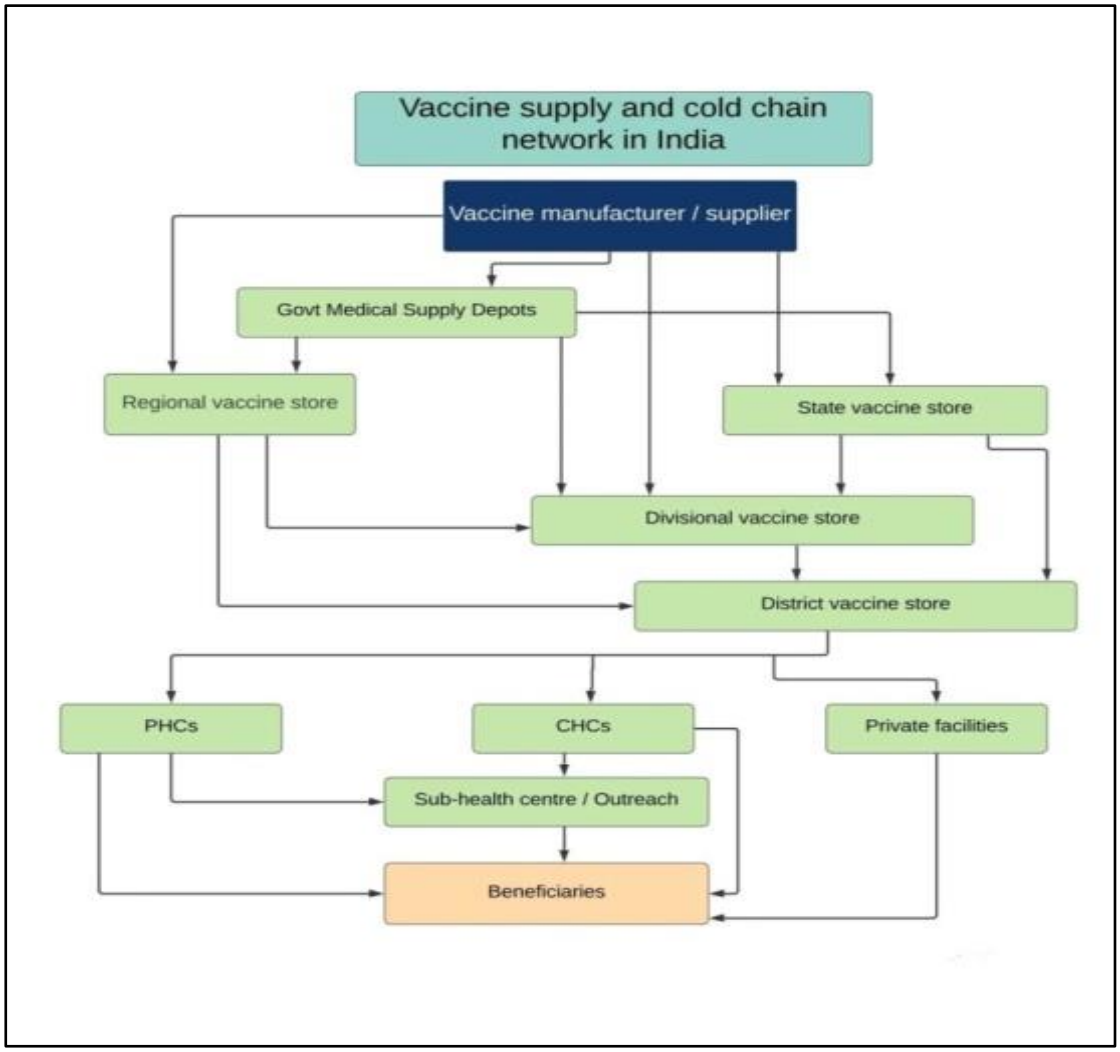

Figure 4 Existing for of Vaccine Logistics

have facilities for storing vaccine for up to 1 month. Each sub-centre holds an outreach session once a week, traditionally on a Wednesday, at anganwadis in the villages where vaccine storage facilities are not available.

India has long experience in managing vaccines which have to be stored at temperatures -20 Deg. (polio vaccine are stored at -20 Deg. C) and 2 to 8C. As per a report existing state-owned cold storages are capable of providing doses to more than eight million locations across the country.

PLANNING CONSIDERATIONS: COVID-19 VACCINATION IN INDIA

Considering strengths and weaknesses of Public Healthcare system, extreme diversities (socio-political-cultural-economic- geographic-climatic), and urgency to contain COVID-19 spread, India would need a National Strategic Plan for COVID-19 vaccination management. States and UTs will implement the National Strategic Plan for COVID-19 Vaccination Management (NSPCVM).

Vaccine doses will be very limited in number at the beginning once emergency use authorisation (EUA) is issued to manufacturer. Whatever the reason, if you don't have required number of vaccine doses to inoculate all citizens during a pandemic, it is a good idea to plan vaccination under multiple phases by dividing whole population into priority groups. Of course, this process will vary based on how many people you are inoculating under each phase. In supply oriented environment, like COVID-19 vaccines, Unified plan for all States is only option available in front of National Government for ensuring equitable and transparent distribution of vaccine doses which will be very limited with limited supplies.

COVID-19 is a National Disaster and National Government under provisions of National Disaster Management Act (2005) is competent to plan and take mitigation measure for safety of lives. The planning process should be completed through consultation with stakeholders in mission mode so as systemic preparedness can commence across the country as soon as possible. Foundation of planning process should rest on Principal of "equity in vaccine access and benefit for groups experiencing greater burdens" from the COVID-19 pandemic like health workers, diagnostic labs, heath emergency responders including ambulance workers etc.

National COVID vaccination plan will not only address preparedness measures but also enlist priority groups, criteria for selection into each group, numbers falling under each group, public communication, receiving and handling of vaccines, storage and distribution, record keeping, monitoring and evaluation of vaccination on real time basis. National plan would include SOPs for functioning at District Hospital / Municipal Hospitals / Govt. dispensaries/ CSC / PHC and other outlets selected for vaccine administration. Estimation of expected number doses, on a time scale, would be provided to State authority so as required resources can be mobilised.

National plan will also address priority vaccination group scheme which has become mandatory as number doses assessable to Indian administration will be limited and supplies will be distributed over a period of time (may be quarterly for1-2 years).

National COVID-19 vaccination plan would pave way to all States and UTs in getting prepared by building required capacities. A condition assessment of "existing resources and infrastructures" would be necessary for identification and bridging resource gaps. An indicative list of key components of National Covid-19 vaccination plan is given below:-

1. COVID-19 spread foot prints in India
2. COVID-19 risk identification, understanding and mitigation measure
3. Covid-19 vaccine doses required for immunising whole population and under each group which is a sub-set of the total population.
4. Planning Priority Groups for vaccination in phases based on committed doses to be received from manufacturers
5. Planning National Healthcare Integrated Decision Support System
6. Planning mandatory pre-registration for vaccination for all citizens / residents in India. Key inputs required to be provided by individual must include his/her address with PIN code, age (Date of birth) and identity (Aaadhar number). Number of population registered under specific PIN code will determine number of doses to be allocated to respective vaccination station.

7. Planning and marking jurisdiction for vaccination station based on pre-registered population.
8. Time-line for vaccination at vaccination station.
9. Planning Priority groups and data-set
10. Vaccination plan for different phases based on committed doses available at time-interval
11. Vaccination plan when number doses available equal demand
12. Vaccination plan when number of doses available exceed demand
13. Public health communication plan for each level involved in COVID-19 vaccination in Urban as well as rural area
14. India's Access to COVID-19 vaccine: Type of vaccine (technology), availability of number of doses on time scale.
15. Planning augmentation of cold chain storage. (Planning new augmentation / overhauling existing state-owned resources including cold storage infrastructure to match capacity and hygiene conditions requirements posed by chosen COVID-19 vaccination technology for India).
16. Planning COVID-19 vaccine logistic chain (overall process of managing how resources are acquired, stored, and transported to their final destination). Minimum number of hops between point of origin and point of use would form the basis for revising supply chain architecture. IoT / Supervisory Control and Data Acquisition (SCADA) system will be used for monitoring and management of functioning of supply chain.
17. Mutual aid plan for sharing medical and other resources from
    a. Indian army
    b. Indian air force
    c. Indian Railways
    d. CGHS
    e. Private healthcare agencies / providers
18. Planning and mobilisation of ancillary medical supplies i.e. vials, stoppers, gauze, alcohol swabs, syringes required
19. Developing a training and exercise plan for vaccine distribution. A series of operational exercises should be scheduled ASAP January 2021. These drills will be utilized to validate the plan, including any policies associated with the plan, any agreements and procedures, and to clarify roles and responsibilities, plus identify resource gaps in an operational environment. This portion of plan implementation will likely be achieved by designing a drill to test a single, specific operation or function
    within a single entity.
20. Organisation structure for vaccine administration
21. SOP for vaccinating special group consisting of personnel from Defence organisation (Army, Navy and Air-force)
22. SOP for mobilisation and augmentation of required Healthcare resources, especially for servicing rural area (CSC / PHC and Sub Centre).
23. SOP for management of essential support services at vaccination canter including reliable electricity, water and sanitation.
24. SOP for mobilising and augmenting required Healthcare resources in urban area serviced by local bodies / municipal corporations, state government and private healthcare system.
25. SOP for establishing COVID-19 vaccination monitoring centre at District HQ, State HQ and National HQ.
26. Roles and responsibilities in COVID-19 vaccination administration procedure and record keeping and reporting at various levels including (a) National HQ (b) State HQ (c) District HQ (d) Sub Divisional HQ (e) Community Health Centre (CSC) (f) Public Health Centre (PHC) (g) Sub Centre
27. Mock drill on functioning of COVId-19 distribution monitoring centres – Allocation of doses, dispatch time, movement tracking, management of road blockage / cargo accident, delivery time stamping, temperature of cargo while on road, temperature of cold storage at receiving centre etc..
28. Special mock drill on COVID vaccine storage at Dist. HQ, CSC, PHC and Sub-centre with GPS enabled freezer thermometers and electricity supply (monitoring all three phases)
29. Mock drill and Exercise on COVID-19 vaccine administration at CSC, PHC and Sub Centre
30. Monitoring, reporting and Evaluation system

PHASED VACCINATION AND PRIORITY GROUPS:

When a vaccine is ready to be administered, there won't be enough doses to vaccinate the entire Indian population and vaccination will need to be spitted into several phases. Decision makers and subject matter experts will have to figure out who will be first, second, third in line based on the committed supply of number doses on a time-line / time interval and COVID-19 exposure coefficient attached with each individual. Some of common factors for grouping people include - people at high risk: frontline workers in healthcare facilities along with people who have underlying health conditions greatly increasing their risk of COVID-19 complications and mortality, Older adults living in crowded settings, such as nursing homes or old age homes etc.

Availability of relevant statistics / data including health records in electronic form is the key for segregating population into groups. India has no electronic health record system and will need to improvise customised solution for dividing population into several groups. Once broad categories of groups are concluded - rigorous preparatory efforts would be required for collection of statics / data with Aadhar as a common connecter for identification, authentication / validation and monitoring. Based on understanding on vaccine supply, storage and Governance constraints – author suggest following approach for planning and establishing groups and their priorities.

Group Priority 1: This category should include – (a) Paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. (b) Emergency Service worker / First responders.

Sub-Group Priority 1 (a): Paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials is broad heading. But a clear definition of "Health worker" and "emergency service workers" would be necessary for identifying and delineating persons eligible for inclusion in this category / group. People under this group would include doctors, nurses, attendants, lab technicians, ambulance staff, sweepers and cleaners working or attached with Government healthcare facilities at district level, CSCs, PHCs, Sub Centres, ANM, Ambulance operators, staff at incinerator, staff at crematorium, etc.

Private and Charitable Hospitals:

The role of private and charity healthcare sector has been to support incoming patients and referring the patients to public hospitals for treatment of any cases relating to Covid-19. Some of the private hospital allocated limited beds for admitting and treating COVID-19 patients on chargeable basis on Government directives. Healthcare worker belonging to private healthcare facilities participating in COVID-19 management should be included under group with priority 1. It will be Government's prerogative to put certain conditions while allocating vaccine doses to healthcare facilities out of Government's domain like – supporting National vaccination programme by sharing their resources under a committed agreement.

Sub-Group Priority 1(b): This group should include - Emergency service workers / first responder i.e. fire services and first responders during disasters (NDRF / SDRF etc.). Separate sub-group can also be formed for Fire service personnel, SDRF and NDRF. Only workers / officials deployed in filed should be enlisted for priority vaccination.

Sub-Group Priority 1(C): This group should include – Defence forces (Army, Navy and Air-force), and BSF. There role is not confined to National security but their resources supplements response and mitigation operation during sever disasters and emergencies. Logistics management experience and expertise of Army and Air Force will help in mass COVID-19 vaccination in India.

Splitting Sub-Group:

It is anticipated that supply of vaccine doses would be very limited / scarce at the beginning and initial supplies may not be sufficient to inoculate whole healthcare community in one go. For example if we consider 20 million healthcare workers eligible and registered under first priority, they would need 30 million doses (2 dose each person at 21 days interval) for inoculation. If number of doses available is 20 million then there should be some mechanism for further dividing sub-group 1(a) to identify top 10 million most critical work forces for vaccination. Multiple vaccination plan with list of identified workers should be

readily available, tentatively assuming different scenario viz. availability of 20 million doses, 40 million doses and 80 million doses in Phase-I.

Listing of health workers with service categories like (1) COV emergency call centre, (2) COV-ambulances, (3) COV-hospital (Doctors / Nurses / attendants and other staff), (4) COV-morgue and crematorium etc. would be useful. If needed - each one of service group can be further divided in to "role based sub-group" viz. COV-hospital can be divided into – admission / discharge sub-group, general / cottage ward sub-group, ICU / emergency care sub-group, Laboratory sub-group, postpartum sub-group. Similar division would need to be worked out for each of the proposed groups (1-4) above for drawing a final priority list for COVID-19 vaccination. This is one example of how priority grouping in "patient attendance chain" could be worked out. There could be more such chain with multiple groups working in the day-to-day management and mitigation of COVID-19 pandemic and opinion of subject matter experts should prevail in decision making process.

Group Priority 2:

Sub-Group Priority 2 (a): Field workers responsible for operation and management of selected "essential services" like sanitation workers including public and private workers engaged in garbage collection and disposal, anganwadi workers, postal and telecommunication service, electric and water supply distribution, civil supplies and public transport including road and rail transport system in India. It would be useful if a relative priority standing is defined for workers under each functional category viz. list and number of sanitation and garbage management personnel, list and number of anganwadi worker, list of drivers and conductors in the state transport department, school teachers and staff etc.

Sub-Group Priority 2 (b): In many countries second priority is assigned to person with underlying conditions. As per CDC person of any age suffering from – Cancer, Chronic kidney disease, COPD (chronic obstructive pulmonary disease), Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies, Immuno-compromised state (weakened immune system) from solid organ transplant, Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2), Severe Obesity (BMI ≥ 40 kg/m2), Pregnancy, Sickle cell disease, Type 2 diabetes mellitus, Asthma (moderate-to-severe), Cerebrovascular disease (affects blood vessels and blood supply to the brain), Neurologic conditions such as dementia, Liver disease, Cystic fibrosis, Hypertension or high blood pressure are at increased risk of severe illness from the virus that causes COVID-19.

Priority Vaccination policy followed in Russia contradicts US and UK policy. The age for those receiving shots is capped at 60. People with certain underlying health conditions, pregnant women and those who have had a respiratory illness for the past two weeks are barred from Sputnik V vaccination in Russia!

The inclusion of persons with underlying condition for priority vaccination is necessary but not feasible in absence of a national electronic health record system. Government will need to improvise way for identification and validation of population with underlying condition. Due diligence must be done if Sputnik V doses are used for inoculating people with underlying condition as in Russia this group is barred from receiving vaccination.

Sub-Group Priority 2(C): All senior citizens / residents of age 65+ should be covered for COVID-19 vaccination under this sub group. Government may like to further divide this group into 50-65 and 65+ for better manageability. Sub-groups can be merged / un-merged based on vaccine supply position.

Group Priority 3:

All citizens / residents of India not included or inoculated under group 1 and 2 above will be administered vaccine in this category. Majority of India's population will fall this group. This group can be subdivided into multiple sub-groups Based on number of doses available and the aggregate handling capacity of vaccination centres. For example a sub-group with children of age upto 15 years and , a subgroup with population of age 16- 50 years. It is also possible to further divide subgroups based on gender with priority assigned to female gender for balancing supply and demand.

Sub-dividing a group is intended to bring manageability by matching vaccine doses available in a typical supply oriented system. National plan will provide enough flexibility to split or merge groups and sub-groups based on supply of vaccination (short supply, balanced supply, over supply).

CHALLENGES AND STRATEGIES

Vaccinating a huge population is always a task fraught with challenges, more so in the midst of a raging pandemic that has infected close to 1 crore people in the country and killed at least 1.37 lakh. There are multiple challenges while Government is working to stream line resources and infrastructures required for inoculating more then 1.3 billion populations. COVID-19 is curse as deadly virus is taking toll of hundreds of thousand people every day. But then every adversity has a seed of greater benefit – and Indian Government should look at how their strategies can benefit overall healthcare system in short term for fighting out COVID-19 and in long term by providing improved healthcare system to the population.

Based on in-depth review literature and personal knowledge of public healthcare system in India, author deliberates on issues / challenges and strategic interventions / measures for enabling effective PAN-India implementation of COVID-19 vaccination in short term and enhancing performance of public healthcare delivery system in long term.

Worldwide, the goals of medicine have undergone a paradigm shift from curative to preventive, preventive to social and social to community medical intervention strategies aimed at improving healthcare. The ultimate purpose is not to just to achieve a disease-free state but also to improve overall quality of life.

Distribution of Healthcare Resources between Urban and Rural India:

Performance of existing healthcare system during current pandemic COVID-19 provides enough indicators on strengths and weaknesses of public and private healthcare system across India. Majority of health resources, about 70 % are concentrated in urban area with numerous private hospitals and clinics which provide quality healthcare to 26 % of Indian population living in urban area, where as 30 % healthcare resources are allocated for attending more then 70 % population in rural area. As per a study conducted by KPMG - about 80% of doctors, 75 % of dispensaries and 60% of hospitals are present in Urban areas when 72 % of Indian population lives in rural area.[ii] This suggests that with the current status COVID-19 vaccination administration in Urban India would be far easier and faster then vaccine administration in rural India.

Recommendation:

Wide gaps between the rural and urban populations in its healthcare system are worsening the problem. There is an urgent need for private sector participation for bridging this gap as resources of Government may not suffice looking to size of country and distribution of population.

Formation of a Universal Service Obligation Fund for Rural Healthcare (USOFRH) looks worth considering here as was done in telecom sector. With an objective to promote and establish mobile telecom services in rural and inaccessible areas, Telecom Policy - 1999 (NTP'99) provided that the resources for meeting the Universal Service Obligation (USO) would be raised through a 'Universal Access Levy (UAL)', which would be a percentage of the revenue earned by the operators under various licenses. Government should also look into possibilities of establishing a Universal Service Obligation Fund (USOF) for rural healthcare in line with what is done in telecommunication sector. Large Private health provider, with turn over more then 100 crore, should either contribute to USOF for primary healthcare or do proportional investment by open satellite healthcare centres in rural area.

Fund Allocation:

One of the central problems has been the low levels of public spending on health and as a result the poor access to affordable and good quality healthcare for the majority of India's population. The public expenditure on health at about 1.2% of the GDP is amongst the lowest in the world. Paucity of funds is a major factor for poor status of Public health facilities, poor infrastructure and human resource inadequacies.

Recommendation:

There is an urgent need for extra allocation of resources to strengthen public healthcare system. Committed efforts are required with purposeful action, thorough planning and execution to achieve sustainable development goals for primary healthcare in India. Some of the key issues are addressed under NHP 2017 which aims to "increase health expenditure by Government as a percentage of GDP from the existing 1.2% to 2.5 % by 2025". UNDP's sustainable development goals and NHP 2017 are the right way forward. Government needs to explore possibilities for Private-Public-Partnership (PPP) for brining additional investments into primary healthcare system. Formation of Universal Service Obligation Fund for Rural Healthcare (USOFRH) as explained above would work as catalyst for enhancing quality of rural healthcare.

Public Healthcare Decision Support System (PH-DSS) and Broadband Internet Access:

India's Health Management Information System (HMIS), an online portal provides information on health indicators in India. HMIS compiles data from state- and district-level health authorities, the National Family Health Survey (NFHS), the District Level Household Survey (DLHS), and the Office of the Registrar General & Census Commissioner, among other sources. In absence of National Standards / guidelines - multiple versions of Health Information management system are procured and used in various States.

India also uses Electronic Vaccine Intelligence Network (eVIN) system, which provides real-time information on vaccine stocks and storage temperatures across all cold chain points in the country. It is an internet-based digital system to track routine immunisation, vaccine stock, and storage temperature in about 25000 dedicated cold chain storage points. The eVIN system is regularly monitored by health authorities at State and District level.

Poor, costly or non-existent broadband access limits PHCs and CHCs ability to use technology to reduce costs or enhance quality of care. Absence of broadband also makes attracting medical personnel to rural areas extremely difficult. Doctors looking to move to rural areas are more inclined to establish themselves and practice in localities where advanced technology is available to better serve their patients. Tele-health and tele-consultation has proved extremely useful during COVID-19 related wide-spread lockdown in recent days. For remote monitoring and management of cold storage, electronics attendance, HMIS and PH-DSS would need broadband internet connectivity at SC, PHC and CHCs.

Recommendation:

The goal of health information system should not be confined to collection and projection of data but to produce analytic outcome / information which can used for decision making at various level. Also irrespective of data source and location (village / Block /Taluka/ District) compatibility and convergence should be possible for visualisation at any level with authentication and control. There should be a centralised link for data acquisition and dissemination. eVIN should not work as a standalone application but should be part of health information management system connected with DSS for generating alerts and warning when parameters cross their threshold value (stock goes below set point level or when temperature exceeds set points) and suggest choice of actions.

All attempts should be made to harness potential offered by new technologies like AI (Artificial intelligence), machine learning and IoT (Internet of Things). eVIN should work not only as stand alone application but should be a part of comprehensive Public Healthcare Decision Support System (DSS).

Fundamental rule is "if you can monitor you can manage". Government of India's move toward establishing inter-operable electronic health records system and a new National health are progressive and in synch with NHP 2017. Majority of population would need to register for getting COVID-19 vaccine under various priority groups planned by Government of India. There can not be a better time for National Government to

advance implementation of planned endeavours for establishing electronic National Health Record System (NHER) integrated with unique citizen identification program s ('Aadhaar') with further linkages with insurance beneficiary databases.

Broadband internet connectivity should be included as one of the mandatory requirement under the National standards for SCs, PHCs and CHCs under directives from MoHFW. A fraction of Universal Service Obligation Fund (USOF) can be used for establishing and maintaining broadband services for rural healthcare centres. Lesson learned while establishing GSTN (Goods and Services Tax Network) and GEM (Government e-Marketplace) should be included while planning Public Healthcare DSS Network.

Skilled Human Resources: Vacant Positions and Absenteeism

The non-availability of adequate skilled human resources is one of key challenge and hindrance in efficient functioning of the Rural Health services. As per Government statistics - on 31st March, 2019 the overall shortfall (which excludes the existing surplus in some of the States) in the posts of HW(F) / ANM is 3.9% of the total requirement as per the norm of one HW(F) / ANM per Sub-Centre (SC) and PHC. Similarly, in case of HW (M), there is a shortfall of 62.3% of the requirement.

As on 31st March 2019, 9.6% PHCs are without a doctor, 33.4% are without a Lab Technician and 23.9% are without a pharmacist. The conditions are more alarming when we look at availability of specialist CHC. Government data reveal that at CHC, as on 31st March, 2019, out of the sanctioned posts, 79.9% of Surgeons, 64% of obstetricians & gynaecologists, 77.5% of physicians and 69.7% of paediatricians are vacant. A very marginal number of sub-centres and PHCs are functioning as per Indian Public Health Standards (IPHS).

Medical Worker's authorised / unauthorised absence from their work place further degrades primary healthcare service performance. Current statics on extent of absenteeism are not available but as per a research study conducted in 2011 medical providers are frequently absent from public health facilities in India. It is also important to recognize that doctor attendance is a minimum prerequisite for service delivery, and the measures of absence are therefore a lower bound on the extent of "lack of service" in the public sector. As per the study[iii] - while there were substantial variations across states, study estimates show that the national average absence rate for PHC and CHC medical providers was over 39 percent, with the absence rate for doctors exceeding 43 percent

Recommendation:

Shortage or unavailability of skilled human resources in rural healthcare is harder then in urban area. Filling skilled worker's vacant posts at CSC, PHC and Sub-centres for meeting current demand (now and 4 months down the line) for COVID-19 vaccination may not be practicable.

Options available with the Government for bridging shortfall in skilled worker for meeting current needs include (1) rotate staff from other Government departments / agencies having established healthcare system viz. Railways, CGHS, ESIS, Defence organisation and (2) Conduct crash training courses for ANMs, AWW and ASHA workers on COVID-19 vaccination procedures. There are about 208,000 ANMs, 1.2 million Anganwadi Worker (AWWs), and 857,000 ASHA workers in rural areas. CONVID-19 offers an opportunity to harness potential offered by tremendous force of health and social workers consisting of ANMs, AWW and ASHA. It is possible to ready a team of millions of social and health worker to support COVID-19 vaccination programme in next 4 months.

Absenteeism of doctors and other healthcare staff can be controlled by applying electronic attendance management system which uses biometry and aadhar number of an individual. Similar system is being used in all central Government offices in Delhi. Parole should be connected with electronics attendance register. Electronic attendance equipment's at remote location should be installed under operation and maintenance contract for 5 years. Adequate arrangements should be made for reliable broadband connection and electricity supply CHC, PHC and Sub-centres.

Key inputs cold storage, stock / inventory of essential supplies, electricity and other power resources, staff register; patient register, medical supply dispensation etc. should converge into centralised decision support system (DSS) with authentication based access given to supervisory authorities at various level.

Primary Healthcare Centre: Infrastructures and Logistics

There is an acute shortage of required infrastructures at almost all level in public healthcare system. Availability, operation and maintenance of basic health infrastructures exponentially decreases / degrades as we go from top level to the lowest health service delivery point (tertiary to primary to sub-centre).

Issues related to operation and maintenance of gadgets and equipment's at CSC, PHC and Sub-centres can be remedied by injecting additional funds and establishing extended maintenance contracts with suppliers. However public healthcare facilities across the country would need to undertake a "condition assessment" of existing cold storage capacity and its status along with a detailed condition assessment of other equipment's and inventories keeping National COVID-19 vaccination plan into consideration. Cold storage requirement for central distribution hub, State hub, District Hub, CHC, PHC and Sub-centres will be different. Maintaining cold freezers at PHC and levels below is most challenging. As per a report majority of PHC are facing difficulties due to freezers not functioning due to various reasons.

Recommendation:

Preparation at all level in healthcare system hierarchy must ensure that number COVID-19 vaccines go waste. As per a report at least 25% of the vaccines go waste even before reaching the doctors and patients while many lose their efficacy by the time they are administered due to lack of quality supply chain and logistics management system. According to the Immunisation Technical Support Unit under the health ministry the supply of vaccines is computed by 25% wastage rate for all vaccines except BCG which records the maximum wastage of over 50%.

The best approach would be that under COVID-19 vaccine logistic management plan new cold storage equipment of required capacity / freezers are procured and installed at 160713 sub-centres, 30045 PHC and, 5685 CHC across the country. The existing cold storage can be used as a "back-up" arrangement. As per WHO's a recommendation - Health facility refrigerators may be powered by electricity, solar energy or gas (or kerosene). A health facility refrigerator should be chosen based on the most reliable power supply available and the combined capacity needed for vaccine and water pack storage. The new freezers should be IoT enabled (fitted with temperature and capacity sensors) and procurement should be bundled with maintenance service for five years at the location of installation. Good and services should be procured in a centralised manner using GEM (Government e-Marketplace).

Primary Healthcare Centre: Electricity Supply

Access to electricity, water supply and internet in healthcare facilities are key to the efficacy of health service delivery. It is needed for deliveries, storage of vaccines, provision of emergency services, the supply of clean water, as well as retention of skilled staff. As on March 31, 2018, nearly 39,000 sub centres in rural India were functioning without electricity supply. In Jharkhand, 66% sub centres had no power supply, while in Bihar the figure was 64%. Share of health centres without regular water source and electricity has fallen from 25% and 26% in 2010 to 15% and 21% respectively in 2018. But still over 27,000 rural health centres are without regular water supply and nearly 40,000 without electricity. While both electricity supply from the grid and the availability of electricity backup in the PHCs has improved over the years, but reliable data on continuous availability of electricity at PHC and sub-centres for planning mitigation measure, specially when distribution of COVID-19 vaccines is being planned.

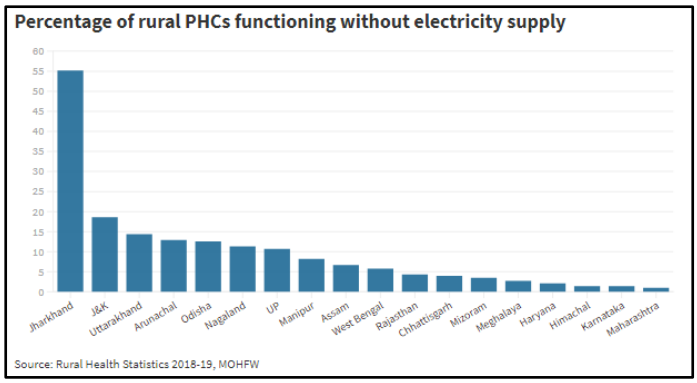

Figure 5 Electricity Supply Access in PHCs

Recommendation:

Pandemic COVID-19 provides an opportunity to streamline equipment maintenance issues and address issues related to continuous availability of electricity and water supply. A quick healthcare infrastructure condition assessment will be useful for identifying functional / non-functional essential equipment's and gadgets, including freezer, and status of electricity and water supply. New cold storage / freezer procurement

should include maintenance for five years under a service level agreement. Solar rooftop systems can effectively meet needs for lighting, refrigeration, water pumping, and provide power for advanced medical equipment in health facilities. As per research study electricity requirement at a Sub-canter, PHC and Community Health Canter can be met with 1 kW, 5 kW 8 kW PV systems respectively. However actual PV sizing should be commensurate with emergency load calculation at each location.

CONCULDIRNG REMARKS:

Indian Public healthcare system is fragile owing to paucity of resources and lack of motivation for healthcare workers in rural area, but it has a tremendous time-tested outreach. The National COVID-19 Vaccine Plan should be built on the existing Public Healthcare system with a clear understanding on its strength and weaknesses.

With precise objectives, indicators and Goals, the National COVID-19 Vaccination plan should articulate key issues like - authority, funding, priority area, inter-agency coordination, supply chain management, public communication and vaccination monitoring strategy, Immunisation Decision support System connected with interoperable health information technology, strengthening public health infrastructure for vaccine delivery and storage, disease surveillance, monitoring vaccine safety, and assessing vaccine coverage leverage the increasing ubiquity of the internet and wireless data services, personal communication devices, and social networking facilities.

COVID-19 procurement, management of logistics and administration in India is susceptible to frauds and cybercrime and cybercriminals are waiting for loopholes so as situation can be exploited for leveraging profits. Already, researchers have reported a phishing campaign spread across six countries targeted organizations associated with The Vaccine Alliance's Cold Chain Equipment Optimizations Platform (CCEOP) program. Entry of duplicate vaccines is not ruled-out. National Plan would need suitable address mitigation measure for preventing fraudulent activities and cyber related crime in the COVID-19 vaccination procurement, distribution and management.

COVID-19 is a National and Global disaster and adversity but it has seeds of greater benefit. Pandemic exposure has given a deeper understanding on the resilience (strength and weaknesses) of public health system working in each country across the world. COVID-19 has set a new bench mark and this knowledge will undoubtedly pave way for "building better public healthcare system" in India and other countries in coming years.

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