Best Practice - I

COMPREHENSIVE QUALITY WORK WHILE FACING THE CHALLENGE OF THE COVID19 PANDEMIC

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7.2 Best Practice

November 2020 to November 2021

"COMPREHENSIVE QUALITY WORK WHILE FACING THE CHALLENGE OF THE COVID19 PANDEMIC"

Objectives of the Practice

1) To share responsibility as a medical college in National Calamity for treating **Coronavirus Disease 2019** (COVID-19) patients.
2) Empowering HCP (Health care Providers) at all levels to face this new pandemic in best possible way without affecting own health.
3) Providing testing facilities.
4) Preventive practices for protection of Non-Covid patients while load of Covid patients is increasing
5) Providing training to HCP from other institutes & community health workers.
6) Educating community to avoid fear, myths & to follow scientific methods
7) Modifying ways of undergraduate teaching as these students are off campus
8) Modifying ways of Postgraduate training in such a way that they are available for Covid / Non - Covid duty without affecting their schedule of training
9) Contributing to research on Covid
10) Participating in policy making as a part of district task force
11) Providing trained manpower for govt. Programs of community testing, Serosurveillance

Motto – to respond to the challenge with kindness and quality care to patients with a must that no HCP succumbs to the illness while doing so, WIPE TEAR FROM EVERY EYE
Resilience, leadership, empowerment, team work, vision to serve

The Context

COVID – 19 was a Novel Virus, there was fear of unknown amongst all. There were no definite answers to questions like, what would be best measures to protect one, to manage

patients & many more. Health care workers have to learn & evolve while working. The work involved physical mental stress and risk to not only their life but life of their families

Being a training institute and serving hospital we had dual challenge

First case was reported in Aurangabad in 1st week of March, & we geared up to face the challenge.

There was need for improvisation & modification in infrastructure to separate COVID & non COVID facilities, to treat COVID patients with any complication

There was need to have inhouse testing to reduce load on government machinery & to have faster results to help in management

There was need to train the health care workers at different level, in house & if need arises for outside hospitals being a training institute

There was challenge to be resolved about undergraduate training which needs to be practice based in medical field. It was necessary to conduct examinations so that their progress is not affected.

While postgraduate students worked in rotation in COVID area irrespective of their speciality it was necessary to ensure their subject related training

It was our duty to help government in COVID care, training & community awareness without affecting quality of training of undergraduates & postgraduate

The Practice

1) Separation of COVID and Non-COVID area from casualty- wards to ICUS. Addition of Oxygen Lines, Procuring Ventilators, HFO, NIV, Protective gadgets was done.
2) We volunteered for 100 COVID beds & 17 ICU beds which was increased to 550 beds & 105 ICUS beds & 85 ventilators as need increased.
3) Through brainstorming of specialist & experience of senior faculties various modules for training were prepared **(Annexure 1)**
4) Training sessions conducted for faculties of all Specialities ,Residents, Interns, Nursing Staff, Administrative Staff, Supporting Staff, with aim “Protect yourself & help others” 07 Intensivist, 25 Specialist, 100 Faculties, 200 Residents, 700 Nurses & 1700 Support staff worked in COVID area. **(Annexure 2)**
5) In house RTPCR testing (NABL accredited & ICMR Approved) was started in August 2020 Rapid Antigen Test was also available inhouse for fast results & action whoever needed. **(Annexure 3)**
6) College provided building & housekeeping staff to Municipal Corporation to start 52 beded COVID care centre.

7) Training was provided to HCP of other institutes as per demand
8) Our social workers and interns participated in community testing, contact tracing & serosurveillence. **(Annexure 4)**
9) Taking into consideration the unique situation where patient is not accompanied by relatives special provision made to make required medicine & food available & counselling, yoga & meditation
10) Hospital is approved by MJYPJAY so the benefit was extended to patients to reduce their economical burden. **(Annexure 5)**
11) Special staying facility food & transportation provided to HCP, to alliavate stress
12) Home isolation facility under supervision of trained doctors was provided to needy patients
13) Ambulance service was provided to patients in need of hospitalization to solve their problem of transportation.
14) SOPs prepared modifying existing protocols to protect non COVID vulnerable population
15) Awareness campaign was conducted for community though radio talks, articles in papers, lecture series on social media. **(Annexure 6)**
16) Providing healthcare in this situation was additional stress To take care of this yoga, mindfulness based meditation, music & other relaxation methods were adopted, for HCP & changes.
17) Monitoring & review of all this work was done by team of Administrators made as per need.
18) Undergraduate students were off campus To continue their teaching, blended mode was used. Theory part was dealt in online mode while hands on training was planned in small batches whenever students will join back
19) Their internal examinations were conducted in online mode
20) The menters kept in touch with their mentees to boost their moral, to solve any difficulty.
21) Postgraduate students were doing double work, It was not possible to follow routine postgraduate training schedule so various platforms were used like whatspp group Google classroom, zoom mails for self paced learning of subject speciality & one to one interaction in small group whenever possible
22) The postgraduate university exam was conducted face to face following norms given by NMC

23) Faculties & residents were encouraged to conduct research on available data & participated in experimental research. **(Annexure 7 & 8)**

24) The COVID worriers were appreciated by institute in various ways- giving certificates, sweets during Diwali & Mango's distribution

Evidence of Success

1) Details about patients

	Apr 2020 to Oct 2021	**Nov 2020 to Oct 2021**	**Total**
Admitted Patients	3490	4468	7958
Discharge	2987	4217	7204
Death	252	442	694

2) Tests **(Annexure 3)**

	Test Done (July to Oct 2020)	**Nov 2020 to Oct 2021**	**Total**
RTPCR Test	764	7704	8468
Rapid Antigen Test	1974	1590	3564

Only private teaching hospital in region to start this facility.

3) **233 staff members** were infected all recovered out of around 2700 HCP
4) Number of Training Programs **20 (Annexure 2)**
5) **157 interns** participated in community testing, awareness, contact tracing & serosurveillence **(Annexure 4)**
6) **Dr. Pravin Suryawanshi**, Deputy Dean was Member of District Task Force. **(Annexure 9)**
7) The work of institute appreciated by **Collector**. **(Annexure 5)**
8) Booklet of SOP & Best Practices was published **(Annexure 1)**
9) **Twelve (12)** Research Papers and **One (01)** Paper/ Poster Presentations on COVID **(Annexure 7)**
10) **Five** clinical trials including BCG Vaccine for COVID, sputnik vaccine for COVID were conducted. **(Annexure 8)**

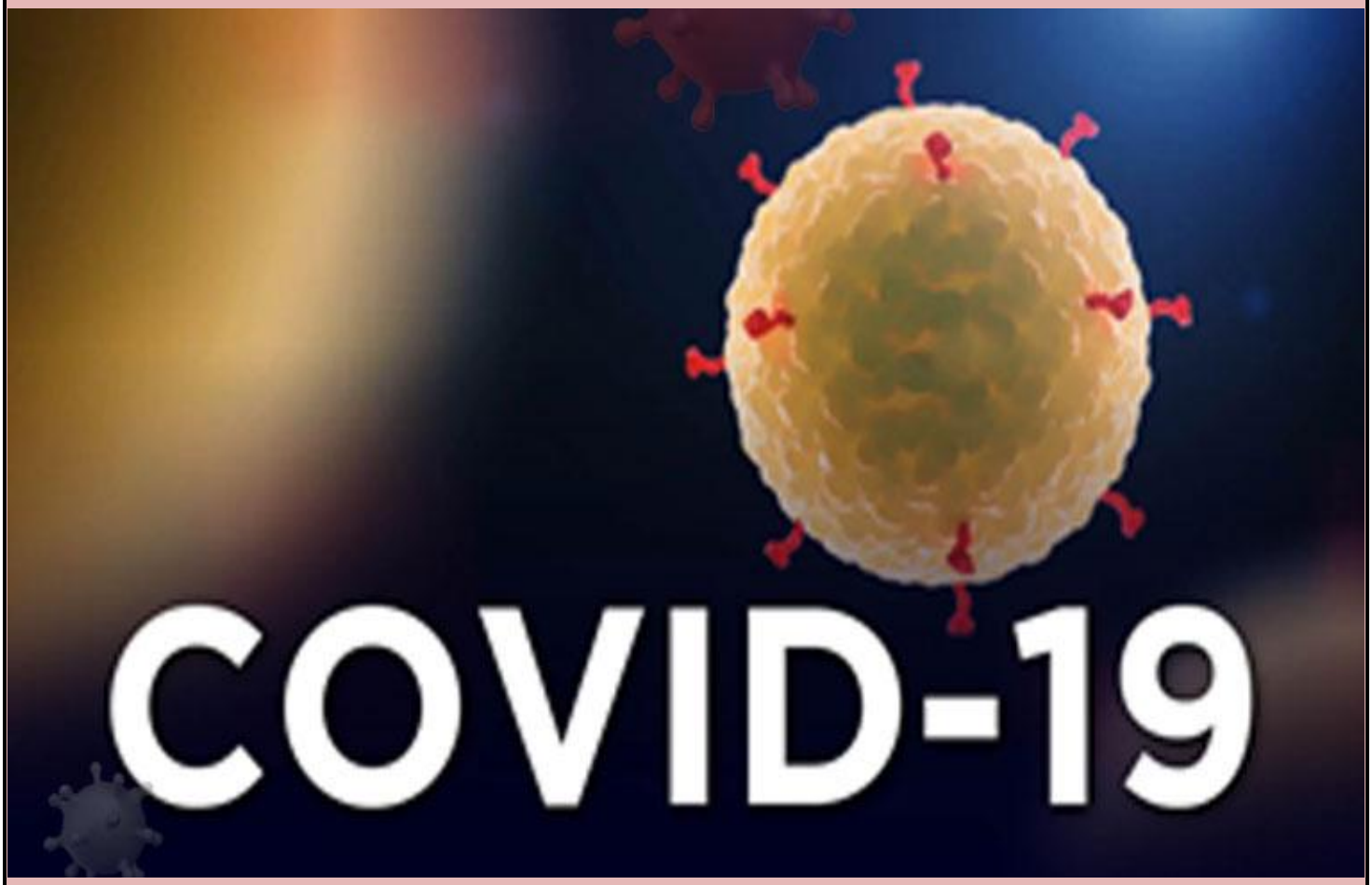
Annexure 1

MGM MEDICAL COLLEGE HOSPITAL AND MCRI

N-6, CIDCO, AURANGABAD, MAHARASHTRA

STANDARD OPERATING PROCEDURES

MANAGEMENT OF COVID-19



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INDEX

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❖ Screening and Admission

Case Definitions

SARI with history of fever or measured temperature ≥38 C° and cough; onset within the last ~10 Days; and requiring hospitalization

Surveillance case definitions of SARI

1. SARI in a person, with history of fever and cough requiring admission to hospital, with no other etiology that fully explains the clinical presentation

AND

Any of the following:

a) History of international **travel** in 14 days prior to symptom onset or

b) The disease occurs in a **health care worker** who has been working in an environment where patients with severe acute respiratory infections are being cared for, without regard to place of residence or history of travel **or**

c) The person develops an unusual or **unexpected clinical course**, especially sudden deterioration despite appropriate treatment, without regard to place of residence or history of travel, even if another etiology has been identified that fully explains the clinical presentation.

2. A person with acute respiratory illness of any degree of severity who, within 14 days before onset of illness,
had any of the following exposures

a) **Close physical contact** with a confirmed case of COVID - 19 infection, while that patient was symptomatic or

b) Healthcare facility in a country where **hospital-associated** COVID - 19 infections have been reported.

CLOSE CONTACT

Defined As:

- **Health care associated exposure**, including providing direct care for COVID – 19 patients, working with health care workers infected with COVID – 19**,** visiting patients or staying in the same close environment of a COVID - 19 patient.
- Working together in close proximity or sharing the same classroom environment with a COVID – 19 patient
- Travelling together with COVID - 19 patients in any kind of conveyance.
- Living in the same **household** as a COVID – 19 patients.

Screening Protocol

1. Screening of patient and visitors entering to hospital premises shall be screened as per the case definition.
2. All suspect patients as per the case definition shall be directed towards COVID OPD.
3. Suspect patient shall be accompanied by supportive worker whereas patient and relative shall be provided with mask immediately if not worn already. Patient shall be taken to COVID OPD from outer passage of hospital to minimize the risk of transmission in other clinical area.
4. Record of all patients screened & referred to COVID OPD shall be maintained which shall include patient name, complaints, address and contact number.
5. Screening counter shall be placed at Casualty and Hospital entrance which shall function 24X7 where as screening counter for OPD entrance shall function during OPD timings.
6. Faculty and Staff of Dept of Preventive and Social Medicine along with one Resident and Interns of MBBS shall function on screening counter where as at night time counter shall be manned by staff nurses along with resident posted.
7. Non touch Thermal sensor shall be used for measurement of temperature.
8. All required PPE such as Gloves, Masks, Caps, and Gowns shall be made available.
9. Provision of appropriate distance (1 meter) shall be maintained at all locations of screening.
10. Provision of hand washing and alcohol based hand rub shall be made available.

Screening Protocol for Patient Requiring Admission

1. All the patients requiring admission due to various clinical conditions shall compulsorily seek COVID screening consultation by being referred to COVID OPD .
2. All the patients referred to COVID OPD shall be screened as per COVID screening score.
3. All the patients should undergo chest X-ray as part of COVID screening before admission.
4. All the patients shall be categorized in two categories as per COVID screening score i.e “COVID Suspect” and “Non COVID suspect” and same shall be stamped on the OPD paper of the patient.
5. All the patients in category of “COVID suspect” shall be primarily admitted in COVID Isolation ICU or ward for further management and swab collection. Whereas all patient in “Non COVID suspect” category shall be admitted in clinical area of respective specialty.

6. If result of the report is negative then patient will be shifted to respective clinical area where as positive patients shall be treated in Isolation ICU or shall be treated as per govt. guidelines issued from time to time.
7. If 1st Test report negative then repeat sample testing is considered on following grounds:
   a. Strong clinical suspicion
   b. Primary diagnosis is Community acquired pneumonia
   c. Unable to establish etiology other than CAP or Covid 19 infection
8. Patients seeking chemotherapy and dialysis on day care basis shall be screened on day 1 and on every fourth day thereafter. COVID score of Subsequent visit shall be marked in score sheet given along with patient case sheet.

Note-Any patient requiring admission after MGM or MCRI OPD consultation, shall be referred to COVID OPD for consultation and remark along with ward attender with appropriate transport arrangement.

Annexure: Scoring form for Screening of COVID-19 Suspect

FM/MGM/AAC-55

MGM Medical College Hospital, Aurangabad

Scoring form for Screening of COVID-19 Suspect

Sr. no	Parameter	Score	Patient Score	Special Remark if any
1	Fever > 99 ˚F	1		
2	Cough	2		
3	Shortness of breath/ difficulty in breathing	2		
4	Oxygen saturation on room air <95%	2		
5	X ray Chest abnormal	3		
6	History of travel from outside city	1		
7	Contact with COVID 19 patients	2		
8	Any family member suffering from cough, fever, cold, breathing difficulty	1		
9	Whether asked to be quarantined	3		
	Total	**15**		

- **O.P.D. Screening:** Score ≥**3**, refer patient to COVID OPD.
- **Admitted patient: Score ≥ 3** Shift the patient to MICU or Isolation ward after informing chief coordinator, Nodal officer, Intensivist on call
- If score is ≤ 2, Consider patient as Non COVID

Name of Doctor: **Signature:**

COVID OPD management:

1. Any patient with suspected flu like symptoms should be immediately referred to COVID OPD of the hospital.
2. Patients and visitors entering from main hospital entrance (Gate no-9) shall be directed as per their complaints eg; patient with cough, cold, fever and shortness of breath shall be directed towards COVID OPD and all other complaints shall be directed towards Casualty or OPD for further treatment.
3. Detailed case history will be taken on OPD paper as per the application of case definition.
4. The entire patient referred to COVID OPD shall be screened as per COVID screening score.
5. All the patients should undergo chest X-ray as part of COVID screening.
6. All the patients shall be categorized in two categories as per COVID screening score i.e "COVID Suspect" and "Non COVID suspect" and the same shall be stamped on the OPD paper of the patient.
7. If required suspect cases shall be referred to Govt medical college for further treatment.
8. All referred patients shall be given referral note which shall include History, Clinical details of patient and reason for referral. Record of all the referred patients shall be maintained.
9. Patient shall be given appropriate personal protective equipments (Mask) and shall be taken outside the hospital from external route to prevent transmission of infection to other clinical areas.
10. Patient shall be transported in Hospital Ambulance.
11. All the transport medium used such as Wheelchair, Stretcher and Ambulance shall be sanitized by appropriate method (1% Hypo chloride) after the each use.
12. All required PPE such as Water Repellant Suit, Surgical scrub suit, Gloves, Masks, Caps, and Gowns shall be made available.
13. Provision of hand washing and Alcohol based hand rub shall be made available.
14. Faculty and residents of Department of medicine, Pulmonary medicine and Pediatrics shall be posted 24X7 at COVID OPD.
15. Provision of male and female changing room, dining room shall be made available.
16. Food coupon for Tea, Breakfast, Lunch, Dinner shall be made available at time office.

Transportation of Patients

A) Intra Hospital Transport

1. Information about intra hospital transfer of patients should be communicated to respective clinical area well in advance (at least 30 min prior in case of planned transfer).
2. Dedicated lift shall be used for such transfer (lift Number 4 for wheelchair and lift Number 1 for stretcher) lift men shall be informed in advance. Social distancing shall be maintained during transportation.
3. Security Personnel should clear the traffic in advance.
4. Staff involved in such transportation should use all related PPE.
5. In case patient on ventilator/NIV cuff pressure should be maintained to prevent air leak and aerosol generation. Staff should wear full PPE (water repellent suite, N 95 mask, Gloves, Eye protection etc.)
6. In case of transfer for CT/MRI, prior information shall be provided. Health worker should wear all required PPE & CT/MRI shall be cleaned with 1% of hypochlorite solution after use.
7. CT/MRI machines shall not be used till one hour after such procedure for confirmed or suspect patient.
8. Post transport, clean the trolley / chair immediately with 1% hypochlorite solution. Remove gloves, mask, gown (Doffing).Perform hand hygiene.

B) Inter Hospital

1. Communicate in advance with hospital where patient is getting transferred.
2. Patient shall be transferred through predefined designated path only.
3. Security personnel should clear the traffic in advance.
4. Staff involved in such transportation should use all related PPE (Medical mask, Cap, Gown etc)
5. In case patient on ventilator/NIV cuff pressure should be maintained to prevent air leak and aerosol generation. Staff should wear full PPE (Water Repellent Suite, N 95 mask, Gloves, Eye protection etc.)
6. Ambulance driver also shall wear Cap, at least Medical Mask, Gloves. Patient relative should seat along with patient. No relatives will be allowed to sit in the driver cabin.
7. In case of requirement of support for lifting and shifting of patient, staff accompanying or ambulance driver should hold at foot end and not at head end of patient to prevent possibility of transmission.
8. One ambulance shall be designated to transfer such patient to outside hospital.
9. Post Transport; clean the Trolley / Wheel chair/Ambulance immediately with 1% hypochlorite solution. Remove gloves, mask, gown (Doffing).Perform hand hygiene.

Management of Isolation Area

(Includes observation ward area, isolation wards, and isolation ICU area)

- Suspected and confirmed patients shall be separated in different ward areas.
- Suspected patients shall be isolated in separated cubical.
- When separate rooms are not available cohorting may be done and keep distance of 1m.
- The suspected patients must wear mask all the times and do frequent hand hygiene
- Confirmed patients can be arranged in the same room with bed spacing of not less than 1.2 meters (appx. 4feet)

COVID -19 MANAGEMENT PROTOCOL
(As per approval of DMER Mumbai)

FOR COVID -19 ADULT PATIENTS

Group	Clinical Criteria	Treatment	Remarks
A)Asymptomatic			
1. Without co morbidity	**No H/O Fever, cough, running nose, shortness of breath**	**Tab Hydroxychloroquine 400 mg BD on day 1 then 200mg BD for 4 days.**	
2. With Comorbidity Any of the following – >60 years Diabetes, HTN/IHD/COPD, Immunocompromised state	**No H/O Fever, cough, running nose, shortness of breath**	**Tab Hydroxychloroquine 400 mg BD on day 1 then 200mg BD for 4 days. + Cap Oseltamivir 75 mg BD for 5 days**	
B) Symptomatic / URTI WITHOUT CO MORBIDITY	**H/O Fever, cough, running nose without shortness of breath RR </24 / min SpO_2 > 94 % Normal Chest on auscultation**	**Tab Hydroxychloroquine 400 mg BD on day 1 then 200mg BD for 4 days. + Cap Oseltamivir 75 mg BD for 5 days + Tab Azithromycin 500 mg OD for 5 Days**	
C)) Symptomatic / URTI WITHOUT CO MORBIDITY	**H/O Fever, cough, running nose without shortness of breath RR </24 / min SpO_2 > 94 % Normal Chest on auscultation**	**Tab Hydroxychloroquine 400 mg BD on day 1 then 200mg BD for 4 days. + Cap Oseltamivir 75 mg BD for 5 days + Tab Azithromycin 500 mg OD for 5 Days Or Lopinavir / Ritonavir 200 mg + 50 mg. 2 tab BD for 5 days LOPINAVIR / RITONAVIR TO BE CONSIDERED IN 1. Symptomatic patients with any one of the following a) Hypoxia as defined as requirement of supplement O_2**	

		saturation to more than 90% **b) Hypotension as defined as systolic BP <90 mm hg or need for vasopressure or inotropic support** **c) New onset organ dysfunction increase in creatinine by 50% from baseline or urine output less than 0.5 ml /kg for 6 hours** **2. Reduction of GCS by 2 or more** **3. Any other organ dysfunction**	
D) SYMPTOMATIC WITH PNEUMONIA WITHOUT RESPIRATORY FAILURE / MODS	**No signs os severe pneumonia**	**Tab Hydroxychloroquine 400 mg BD on day 1 then 200mg BD for 9 days.** **+** **Tab Azithromycin 500 mg OD for 5 Days** **+** **Cap Oseltamivir 75 mg BD for 5 days** **Or** **Lopinavir / Ritonavir 200 mg + 50 mg.** **2 tab BD for 5 days** **LOPINAVIR / RITONAVIR TO BE CONSIDERED IN** **1) Symptomatic patients with any one of the following** **d) Hypoxia as defined as requirement of supplement O_2 saturation to more than 90%** **e) Hypotension as defined as systolic BP <90 mm hg or need for vasopressure or inotropic support** **f) New onset organ dysfunction increase in**	

		creatinine by 50% from baseline or urine output less than 0.5 ml /kg for 6 hours **2) Reduction of GCS by 2 or more** **3) Any other organ dysfunction**	
E) SYMPTOMATIC WITH SEVERE PNEUMONIA WITHOUT RESPIRATORY FAILURE / MODS	**Any one of:** **1. RR - >24/min** **2. SpO_2 -< 94% on room air** **3. Confusion drowsiness** **4. Systolic BP < 90 mm of Hg or diastolic BP < 60mm of Hg**	**Tab Hydroxychloroquine 400 mg BD on day 1 then 200mg BD for 9 days.** **+** **Lopinavir / Ritonavir 200 mg + 50 mg.** **2 tab BD for 10 days** **+** **Tab Azithromycin 500 mg OD for 10 Days** **+** **Additional antibiotics** **+** **Fluid management** **+** **Ventilatory management as per ARDS protocol** **CLOSED SUCTIONING AND USE OF HME FILTER** **CORTICOSTEROIDS TO BE AVOIDED** **AVOID AEROSOL PRODUCING PROCEDURES**	

FOR COVID -19 PAEDIATRIC PATIENTS

COVID -19 suspect case

Any patients with acute respiratory illness (fever with at least one of the following – cough or shortness of breath) with:

- History of travel to high risk COVID -19 affected countries in the last 14 days or
- Close contact with a laboratory confirmed case of COVID -19 in the 14 days.

Asymptomatic traveler / close contact

- ✓ Home quarantine
- ✓ Temperature monitoring twice
- ✓ Contact & droplet precautions
- ✓ Don't need admission

On developing symptoms

- CBC , ECG to be done or not to be decided by pediatrician
- Oseltamivir to be used in high risk influenza suspects
- Do not combine Hydroxychloroquine with lopinavir

MILD CASE

Low grade fever, cough, malaise , rhinorrhea, sore throat without shortness of breath

MODERATE TO SEVERE CASES

TEST NEGATIVE

Symptomatic Management

TREATMENT

- Captablet oseltamivir (For high risk influenza suspects) according to age / weight band
- Antibiotics if needed
- Azithromycin – amox /clave)
- Syp Tab Paracetamol @mg /kg/dose SOS

TEST POSITIVE

- Home isolation (if > 72 hours afebrile or 7 days after symptom onset whichever is longer) / two negative samples 24 hours apart.
- Monitoring of temperature
- Paracetamol & symptomatic Rx
- Contact & droplet precautions
- Danger signs explained
- High – risk individuals may be considered for admission based on clinical judgment

MODERATE TO SEVERE CASES

Patient having any one of the following

- Tachypnea (as per age group < 2 months > 60, 2-11 months >50, 1-5 yrs > 40)
- SpO_2 < 94% in room air
- Confusion / Drowsiness
- Hypotension (BP < 5th percentile or > 2 SD below normal for age)

→ TEST NEGATIVE

Treat as per clinical condition

↓

TEST POSITIVE

- Oxygen supplement to maintain SpO_2 > 94 %
- Antipyretics , antitussives, antibiotics indicated
- MDI/nebulisation
- Hydroxychloroquine (as per pediatric dose)
- Lopinavir /ritonavir (as per pediatric dose) may be considered on case to case basis (within 10 days of symptom – onset)
- Corticosteroids to be avoided

Azithromycin

@10mg /kg / dose for 5 days can be considered in confirmed cases

IF WORSENING

Respiratory failure
Hypotension
Worsening mental status \ S
MODS

↓

SHIFT TO PICU

- NIV/HFNC to be used carefully in view of risk of aerosol generation
- Ventilator management as per ARDS protocol
- Conservative fluid management (if not in shock)
- Standard care for ventilated patient
- Prone ventilation, ECMO for refractory hypoxemia
- Avoid disconnecting patients from ventilators as if results in loss of PEEP
- In line catheter for suction and clamp , endotracheal tube when disconnection required

→

DISCHARGE

If two negative sample at least 24 hours apart after clinical and radiological improvement

PEDIATRIC DOSES OF DRUGS USED FOR TREATMENT OF COVID – 19

1. Oseltamivir

- **Age< 1 year**

< 3 months: 12 mg (per dose) PO 12 hrly x 5 days

3-5 months: 20 mg (per dose) PO 12 hrly x 5 days

6-11 months: 25 mg (per dose) PO 12 hrly x 5 days

- **Age > 1 Year**

<15 kg : 30mg (per dose) PO 12 hrly x 5 days

15-23 kg: 45 mg (per dose) PO 12 hrly x 5 days

23-40 kg 60 mg (per dose) PO 12 hrly x 5 days

>40 kg : Administer as in adults Cap. Oseltamivir 75 mg (per dose) 12 hrly for 5 days

2. HYDROXYCHLOROQUINE

10 mg /kg/dose orally 12 hrly (max: 600 mg/ dose) x 2 days

Followed by

3mg / kg/ dose TID (max: 200 mg/dose) x 3 days

3. LOPINAVIR / ROTONAVIR COMBINATION

14 days to 6 months old: LPV / r: calculate dose as per lopinavir component 16 mg/kg/dose/PO 12 hrly

6 months to 18 years age: weight wise:

- 15-25 kg : LPV/r (200mg/50 mg) per dose PO 12 hrly
- 26-35 kg: LPV/r (300mg/75 mg) per dose PO 12 hrly
- 35 kg : LPV/r (400mg/ 100 mg) per dose PO 12 hrly

Endotracheal Intubation and Mechanical Ventilation

1. Airborne precautions with all PPE (N95 masks) are indicated along with face shield and full contact precautions.
2. Minimize personnel during intubation.
3. Endotracheal intubation, should only be attempted by an airway competent doctor.
4. Perform rapid sequence induction to minimize contact time with the patient.
5. Pre oxygenate with tight fitting face mask / two handed grip to minimize leak. Avoid bagging to reduce aerosalisation .
6. Use the video laryngoscope and conventional laryngoscope shall be avoided. Avoid placing the operator's face close to the patient.
7. Attach a viral filter to the bag-valve mask before the procedure, if possible. This should reduce the spread of viral particles out of the endotracheal tube following intubation (or during bag-mask ventilation if that is required)
8. Attach to the ventilator immediately post intubation and do not use positive pressure until cuff inflated.
9. Use caprnography or predetermined length to decide the placement of ET tube to avoid the need for clinical examination.
10. Ensure meticulous removal, placement and discard of equipment used and PPEs.
11. Lung protective mechanical ventilator strategy and ventilator care bundle (head end elevated, sub-glotic suction, daily sedation interval, spontaneous breathing trials, gastric ulcer prophylaxis and VTE prophylaxis) should be applied to minimize the complications of invasive ventilation.
12. Timely invasive mechanical ventilation may benefit both the patient and the health care staff.

Role of NIV and High Flow Nasal Oxygen

NIV and high flow nasal oxygen therapy is controversial due to high risk of aerosolisation.

1. Non-invasive ventilation; If NIV is applied in case if invasive ventilation is not available; non-vented NIV mask (oro-nasal interface) with dual limb circuit should be used with minimal leak around the mask.
2. High flow oxygen device and single limb NIV with vented mask is discouraged to minimize aerosolisation. However, low flows 15-30 L/min may be considered.

Personal Protective Equipments:

a) All doctors should have N-95 masks if doing close examination (e.g. Ophthalmoscopy, otoscopy, auscultation of lung fields)

b) Security staff and other staff to wear surgical mask

c) If doing any aerosol generating procedure – Full PPE (Cap, N95 mask, goggles, gloves, gown).

COVID-19 RELATED PERSONAL PROTECTION MANAGEMENT

Protection Level	Protective Equipment	Scope of Application
Level I Protection	• Disposable surgical cap • Disposable surgical mask • Work uniform • Disposable gloves or/and disposable isolation clothing, if necessary	• Pre-examination triage (Flu centre) • General outpatient department
Level II Protection	• Disposable surgical cap • Medical protective mask(N95) • Work uniform • Medical protective uniform/gown • Disposable latex gloves • Goggles	• Fever out patient department • Isolation ward area (including isolated intensive ICU) • Non-respiratory specimen examination of suspected/confirmed patients • Imaging examination of suspected/ confirmed patients • Cleaning of surgical instruments used with suspected/confirmed patients
Level III Protection	• Disposable surgical cap • Medical protective mask(N95) • Work uniform • Disposable medical protective uniform (Water repellant suite) • Disposable latex gloves • Full-face respiratory protective devices or powered air-purifying respirator	• When the staff performs procedures such as tracheal intubation, tracheotomy, bronchofibroscopy, GI endoscopy, etc., during which, the suspected/ confirmed patients may spray or splash respiratory secretions or body fluids/blood • When the staff performs surgery and autopsy for confirmed/suspected patients • When the staff carries out NAT for COVID-19

Recommended PPE during the outbreak of COVID-19 outbreak, according to the setting, personnel, and type of activity

Setting	Target personnel or patients	Activity	Type of PPE or procedure
Health care facilities			
Inpatient facilities			
Screening Clinical triage for prioritization of care according to severity (e.g. Manchester classification) should be performed in separate area for individuals with symptoms and signs	Health care workers	Preliminary screening not involving direct contact.	• Maintain physical distance of at least 1 meter. • Ideally, build glass/plastic screens to create a barrier between health care workers and patients • No PPE required. • When physical distance is not feasible and yet no patient contact, use mask and eye protection.
	Patients with symptoms suggestive of COVID-19	Any	• Maintain physical distance of at least 1 meter. • Provide medical mask if tolerated by patient. • Immediately move the patient to an isolation room or separate area away from others; if this is not feasible, ensure spatial distance of at least 1 meter from other patients. • Perform hand hygiene and have the patient perform hand hygiene
	Patients without symptoms suggestive of COVID-19	Any	• No PPE required • Perform hand hygiene and have the patient perform hand hygiene
Patient room /ward	Health care workers	Providing direct care to COVID-19 patients, in the absence of aerosol-generating procedures	• Medical mask • Gown • Gloves • Eye protection (goggles or face shield) Perform hand hygiene
	Health care workers	Providing direct care to COVID-19 patients in settings where aerosol-generating	• Respirator N95 or FFP2 or FFP3 standard, or equivalent. • Gown • Gloves • Eye protection • Apron

		procedures are frequently in place	• Perform hand hygiene
	Cleaners	Entering the room of COVID-19 patients	• Medical mask • Gown • Heavy-duty gloves • Eye protection (if risk of splash from organic material or chemicals is anticipated) • Closed work shoes • Perform hand hygiene
	Visitors	Entering the room of a COVID-19 patient	• Maintain physical distance of at least 1 meter • Medical mask • Gown • Gloves • Perform hand hygiene
Areas of transit where patients are not allowed (e.g. cafeteria, corridors)	All staff, including health care workers.	Any activity that does not involve contact with COVID-19 patients	• Maintain physical distance of at least 1 metre • No PPE required • Perform hand hygiene
Laboratory	Lab technician	Manipulation of respiratory samples Specimen handling for molecular testing would require BSL-2 or equivalent facilities. Handling and processing of specimens from cases with suspected or confirmed COVID-19 infection that are intended for additional laboratory tests,	• Maintain physical distance of at least 1 metre • Medical mask • Eye protection • Gown • Gloves • Perform hand hygiene

		such as haematology or blood gas analysis, should apply standard precautions[9]	
Administrative areas	All staff, including health care workers.	Administrative tasks that do not involve contact with COVID-19 patients.	• Maintain physical distance of at least 1 metre • No PPE required • Perform hand hygiene

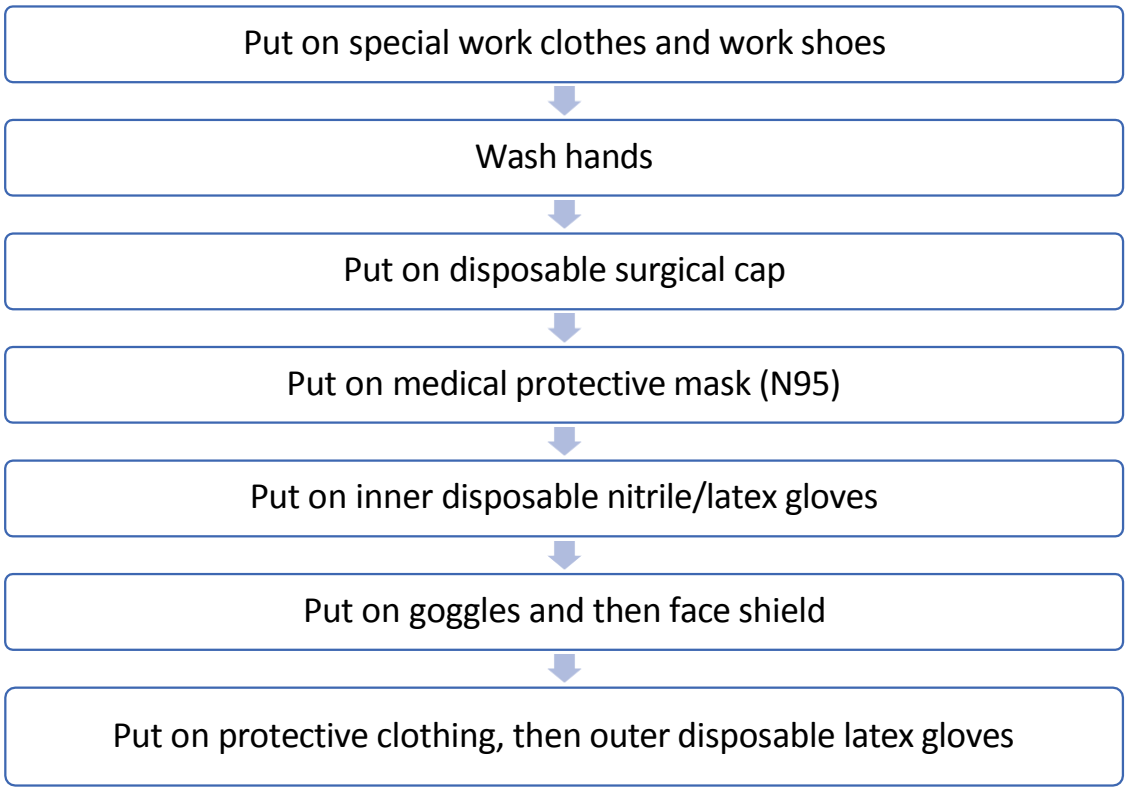
Out Patient Facilities			
Screening/triage	Health care workers	Preliminary screening not involving direct contact[c].	• Maintain physical distance of at least 1 metre. • Ideally, build a glass/plastic screen to create a barrier between health care workers and patients • No PPE required • When physical distance is not feasible and yet no patient contact, use mask and eye protection. • Perform hand hygiene
	Patients with symptoms suggestive of COVID-19	Any	• Maintain spatial distance of at least 1 metre. • Provide medical mask if tolerated. • Perform hand hygiene
	Patients without symptoms suggestive of COVID-19	Any	• No PPE required • Perform hand hygiene
Waiting room	Patients with symptoms suggestive of COVID-19	Any	• Provide medical mask if tolerated. • Immediately move the patient to an isolation room or separate area away from others; if this is not feasible, ensure spatial distance of at least 1 meter from other patients. • Have the patient perform hand hygiene
	Patients without respiratory symptoms	Any	• No PPE required • Have the patient perform hand hygiene
	Health care workers	Physical examination of patient with symptoms suggestive of COVID-19	• Medical mask • Gown • Gloves • Eye protection • Perform hand hygiene

Consultation room	Health care workers	Physical examination of patients without symptoms suggestive of COVID-19	• PPE according to standard precautions and risk assessment. • Perform hand hygiene
	Patients with symptoms suggestive of COVID-19	Any	• Provide medical mask if tolerated. • Hand hygiene and respiratory etiquette
	Patients without symptoms suggestive of COVID-19	Any	• No PPE required • Have the patient perform hand hygiene
	Cleaners	After and between consultations with patients with respiratory symptoms.	• Medical mask • Gown • Heavy-duty gloves • Eye protection (if risk of splash from organic material or chemicals). • Closed work shoes • Perform hand hygiene
Administrative areas	All staff, including health care workers	Administrative tasks	• Maintain physical distance of at least 1 metre between staff • No PPE required • Perform hand hygiene
Home care			
Home	Patients with symptoms suggestive of COVID-19	Any	• Maintain physical distance of at least 1 meter. • Provide medical mask if tolerated, except when sleeping. • Hand and respiratory hygiene
	Caregiver	Entering the patient's room, but not providing direct care or assistance	• Maintain physical distance of at least 1 meter • Medical mask • Perform hand hygiene

	Caregiver	Providing direct care or when handling stool, urine, or waste from COVID-19 patient being cared for at home	• Gloves • Medical mask • Apron (if risk of splash is anticipated) • Perform hand hygiene
	Health care workers	Providing direct care or assistance to a COVID-19 patient at home	• Medical mask • Gown • Gloves • Eye protection
Ambulance or transfer vehicle	Health care workers	Transporting suspected COVID-19 patients to the referral health care facility	• Medical mask • Gowns • Gloves • Eye protection • Perform hand hygiene
	Driver	Involved only in driving the patient with suspected COVID-19 disease and the driver's compartment is separated from the COVID-19 patient	• Maintain physical distance of at least 1 meter. • No PPE required • Perform hand hygiene
		Assisting with loading or unloading patient with suspected COVID-19	• Medical mask • Gowns • Gloves • Eye protection • Perform hand hygiene
		No direct contact with patient with suspected COVID-19, but no separation between driver's and patient's Compartments	• Medical mask • Perform hand hygiene
	Patient with suspected COVID-19.	Transport to the referral health care facility.	• Medical mask if tolerated • Have the patient perform hand hygiene

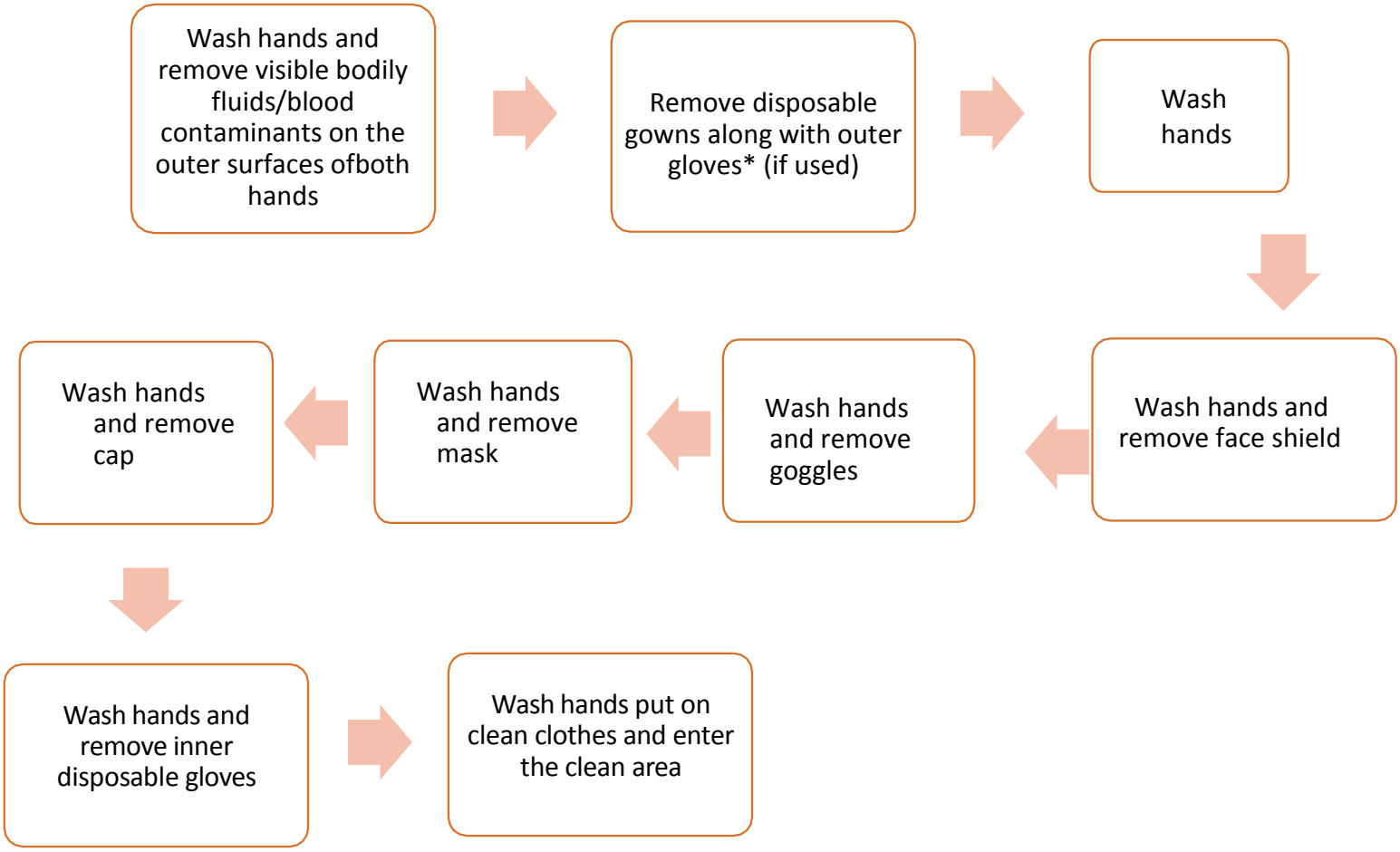
	Cleaners	Cleaning after and between transports of patients with suspected COVID-19 to the referral health care facility.	• Medical mask • Gown • Heavy duty gloves • Eye protection (if risk of splash from organic material or chemicals). • Boots or closed work shoes • Perform hand hygiene
Special considerations for rapid-response teams assisting with public health investigations			
Anywhere	Rapid-response team investigators	Remote interview of suspected or confirmed COVID-19 patients or their contacts.	• No PPE if done remotely (e.g. by telephone or video conference). • Remote interview is the preferred method.
		In-person interview of suspected or confirmed COVID-19 patients or contacts without direct contact	• Medical mask • Maintain physical distance of at least 1 metre. • The interview should be conducted outside the house or outdoors, and confirmed or suspected COVID-19 patients should wear a medical mask if tolerated. • Perform hand hygiene

Guidance on donning PPE



(If wearing protective clothing without foot covers, please also put on separate waterproof boot covers), put on a disposable isolation gown (if required in the specific work zone) and face shield/powered air-purifying respirator(if required in the specific work zone).

Guidance of removing PPE



* For gloves and protective clothing, turn inside out, while rolling them down (Note : If used , remove the waterproof boot covers with clothing)

Masks management

1. Place mask carefully to cover mouth and nose and tie securely to minimize any gaps between the face and the mask
2. While in use, avoid touching the mask
3. Remove the mask by using appropriate technique - i.e. do not touch the front but remove the lace from behind
4. After removal or whenever you inadvertently touch a used mask, clean hands by using an alcohol-based hand rub or soap and water if visibly soiled
5. Replace masks with a new clean, dry mask as soon as they become damp/humid
6. Do not re-use single-use masks
7. Discard single-use masks after each use and dispose-off them immediately upon removal

Laboratory Testing

Whom to Test?

- All symptomatic persons (fever, cough, difficulty in breathing) within 14 days of international travel
- All symptomatic contacts of confirmed cases
- All symptomatic health care workers
- All hospitalized patients with Severe Acute Respiratory Illness (Fever AND cough and/or shortness of breath)
- Asymptomatic direct and high risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact. Direct and high risk contact include:
    - Those who live in the same household of a confirmed case and
    - Healthcare workers who examined a confirmed case without adequate PPE as per recommendations.

Who will collect the sample?

- Doctor or nurse on floor will collect the sample after wearing appropriate PPE
- Specimens should be collected as soon as possible once a suspected case is identified regardless of time of symptom onset
- Label each specimen container with the patient's IPD/UIN number, name, ward, specimen type and the date of collection
- Fill the requisition form completely (As recommended by ICMR/ NIV, Pune)

Samples to be collected

Essential Samples:

- Oropharyngeal swab
- Nasopharyngeal swab

Other preferred samples:

- Bronchoalveolarlavage
- Trachealaspirate
- Sputum

} Wide mouth sterile plastic containers

In lab confirmed patients:

- Blood
- Stool and urine - Wide mouth sterile plastic containers

In deceased patients:

- Autopsy material including lung tissue
- Collection of OP and NP swabs

Optimal timing:

- Within 3 days of symptom onset and no later than 7days.
- Preferably prior to initiation of antimicrobial chemoprophylaxis or therapy.

Respiratory Specimen collection - Materials required

Personal Protective Equipment (PPE)

1. Water repellant scrub suite
2. N 95 masks
3. Goggles
4. Face shield
5. Cap
6. Shoe covers
7. Hand gloves

Specimen collection material

- **Specimen Collection**

- Nylon/Dacron flockedswabs-2
- Sterile container with viral Transport medium(VTM)

- **Specimen packing**
  - Cotton
  - Tissue papers
  - Parafilm roll
  - Scissors
  - Cello tape
  - Zip lock pouches
  - Plastic container with seal
  - Thermocol box
  - Icepacks

- **Specimen Transport**
  - Labels
  - Hard cardboard box

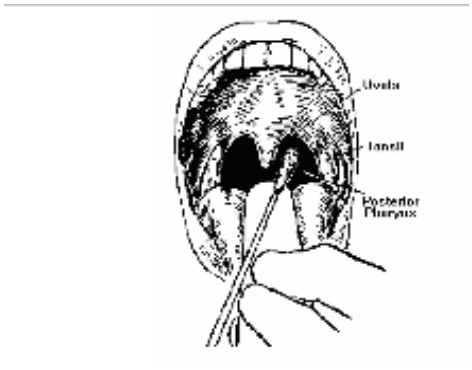
General considerations

- Combined nasal and oral swabs to be collected in viral transport medium
- All uninoculated VTM to be kept at room temperature
- Turbid VTM must be discarded
- All respiratory specimens collected in VTM must be stored in dedicated refrigerator before packing and transport.

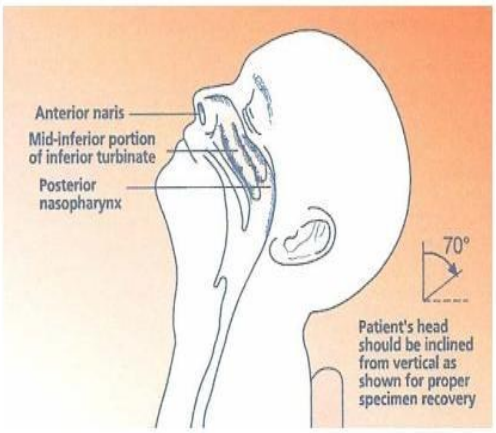
Collection of Oropharyngeal swab

Procedure:

1. Hold the tongue out of the way with a tongue depressor.
2. Use a sweeping motion to swab posterior pharyngeal wall and tonsillar pillars
3. Have the subject say "aahh" to elevate theuvula.
4. Avoid swabbing soft palate and do not touch the tongue with swab tip.
5. Put the swab in VTM



Collection of Nasopharyngeal Swabs



Procedure:

1. Tilt patient's head back 70degree
2. Insert swab into nostril (swab should reach depth to distance from nostrils to outer opening of the ear.
3. Leave swab in place in place for several seconds to absorb secretions.
4. Slowly remove swab while rotating it.
5. Place tip of swab into VTM and snap / cut off the applicator stick.

Transport of Routine Laboratory samples (e.g. Biochemistry, Hematology and Microbiology tests)

- Well labeled samples for investigations shall be sent in double transparent zip lock pouches.
- Sample requisition form shall be placed inside the pouch in a way so that patient details are clearly visible from outside without opening the pouch or requisition can be placed in software wherever possible.
- Mention the “Suspect of COVID-19” or “COVID-19” in case of confirm case on top of the requisition form in red ink with bold letters.
- All laboratories shall maintain separate register and enter the patient and specimen details without removing the requisition form from the pouch.
- Standard precautions as per HIV specimens (NACO guidelines) to be followed.
- In case of suspected exposure, COVID exposure protocol mentioned elsewhere to be followed.

Disinfection and Sanitation Procedures

- **OPD Area**

➢ Deep cleaning

- At least twice in a day
- Spray all areas with 0.5-1% Na hypochlorite/lyzol
- Mopping all high touch surfaces with 1% Sodium hypochlorite
- Flooring cleaning with soap and water

➢ Periodic cleaning

- Mopping all high touch surfaces at least every 2-4hrs with 0.5-1% Sodium hypochlorite
- Repeat the procedure at any time when there is contamination.

- **Emergency / Casualty area/IPD area**

➢ Deep Cleaning

- At least twice in a day
- Spray all areas with 0.5-1% Sodium hypochlorite
- Mopping all high touch surfaces with 1% Sodium hypochlorite
- Flooring cleaning with soap and water

➢ Periodic cleaning

- Mopping all high touch surfaces at least every 2-4hrs with 1% Sodium hypochlorite
- Repeat the procedure at any time when there is contamination

- **Isolation Area (Ward/ICU)**
  - Clean the floors and surfaces for every 4 hourly with 1% hypochlorite
  - Mopping all high touch surfaces with 1% Sodium hypochlorite at every 2 hourly
  - Repeat the procedure at any time when there is contamination

Disinfection for Floor and Walls

1. Visible dust shall be completely removed before disinfection and handled in accordance with disposal procedures of blood and bodily fluid spills
2. Disinfect the floor and walls with 0.5-1% hypochlorite through floor mopping, spraying or wiping
3. Make sure that disinfection is conducted for at least 30minutes
4. Carry out disinfection at least once per shift and repeat the procedure at any time when there is contamination

Disinfection of Object Surfaces

1. Same as above
2. Wipe cleaner regions first, then more contaminated regions: first wipe the object surfaces that are not frequently touched, and then wipe the object surfaces that are frequently touched

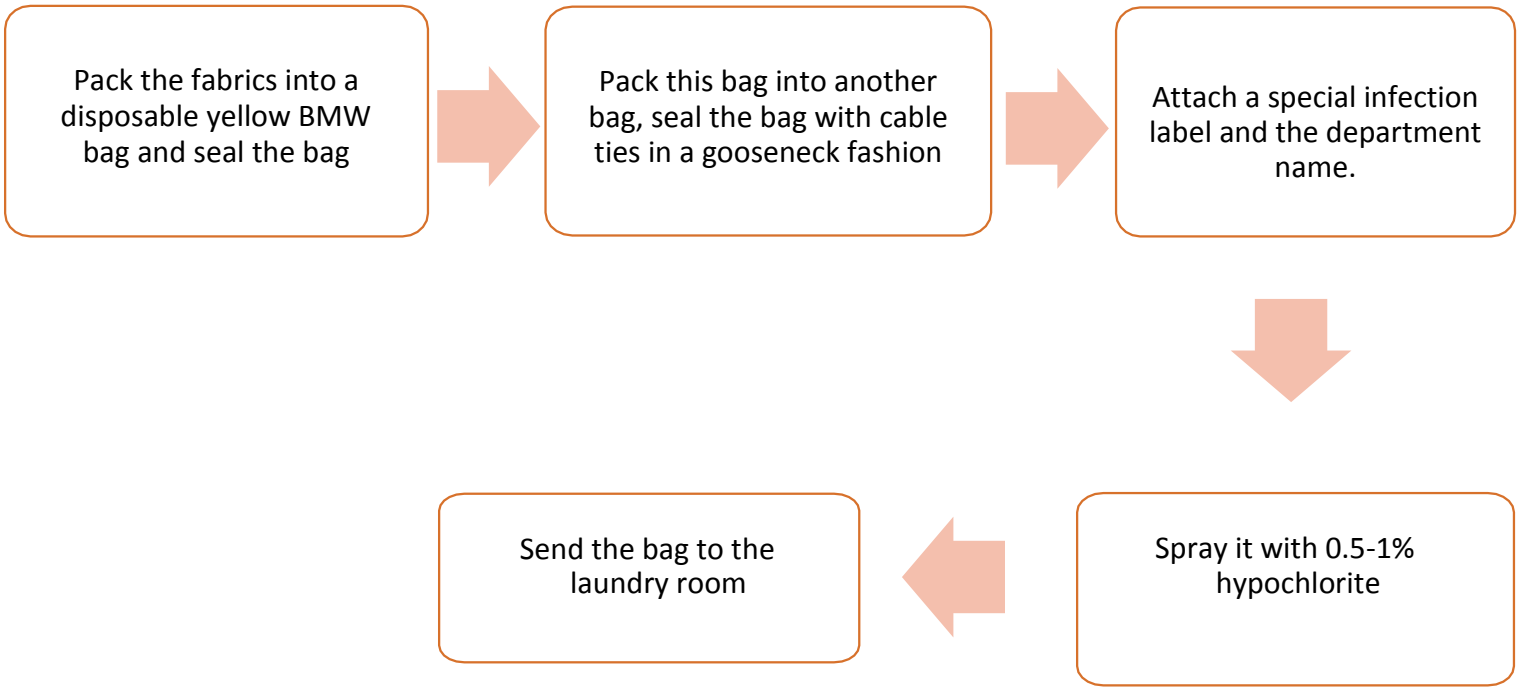
Decontamination of ambulance

- Decontamination of ambulance needs to be performed every time a suspect/confirmed case is transported in the ambulance. The following procedure must be followed while decontaminating the ambulance
- Gloves and N-95 masks are recommended for sanitation staff cleaning the ambulance.
- Disinfect (damp wipe) all horizontal, vertical and contact surfaces with a cotton cloth saturated (or microfiber) with a 1% sodium hypochlorite solution. These surfaces include, but are not limited to: stretcher, Bed rails, Infusion pumps, IV poles/Hanging IV poles, Monitor cables, telephone, Countertops, sharps container. Spot clean walls (when visually soiled) with disinfectant-detergent and windows with glass cleaner. Allow contact time of 30 minutes and allow air dry.
- Damp mop floor with 1% sodium hypochlorite disinfectant.
- Discard disposable items and Infectious waste in a Bio/Hazard bag. The interior is sprayed with 1% sodium hypochlorite. The bag is tied and exterior is also decontaminated with 1% sodium hypochlorite and should be given to the hospitals to dispose of according to their policy.
- Change cotton mop water containing disinfectant after each cleaning cycle.
- Do not place cleaning cloth back into the disinfectant solution after using it to wipe a surface.
- Remove gloves and wash hands.

Disinfection Procedures for Infectious laundry of Suspected or Confirmed Patients

- **Infectious fabrics:**
    1. Bed sheets, and pillow covers used by patients
    2. Floor towels used for environmental cleaning
    3. Hospital cloths of patients
    4. No curtains should be there in COVID management areas

Disinfection Procedures for Infectious laundry of Suspected or Confirmed Patients - Collection method



Storage and washing:

1. Person handling the infectious fabric at linen dept shall wear all required PPE such as (Water resistance suite, mask, cap, goggles, and long heavy duty gloves and Gum boots).
2. Infectious fabrics should be separated from other linen (non-COVID-19) and washed during pre fix timings to prevent mix of the infectious linen with non infectious linen.
3. All infectious linen (Cotton material) shall be kept in 1 % hypochlorite for 30 min before washing.
4. Wash these fabrics with Detergent powder preferably using warm water for 30 min cycle. Dry the linen in dryer machine for 30 min or dry in sunlight.

Washing and Disinfection Procedure for Water repellent suites

1. Dip it in to antibacterial solution like Dettol for 15 min
2. Wash it gently and do not use brush, Avoid vigorous washing
3. Dry it for 12 hours or Dry it in dryer machine for 30 min
4. Autoclave at 100^0 for 15 min

Disinfection of transport trolleys:

- Trolleys shall be disinfected immediately each time after being used for transporting infectious fabrics.
- Transport Trolleys should be wiped with chlorine-containing disinfectant 0.5-1% sodium hypochlorite.
- Leave disinfectant for 30 minutes before wiping the tools clean with clean water

Biomedical Medical Waste Management

5. All the waste generated in COVID patient care units is BMW
6. Put the medical waste into a double-layer yellow BMW bag
7. Seal the bag with cable ties in a gooseneck fashion
8. Spray the bag with 0.5-1% hypochlorite
9. Affix a special infection label and transfer it

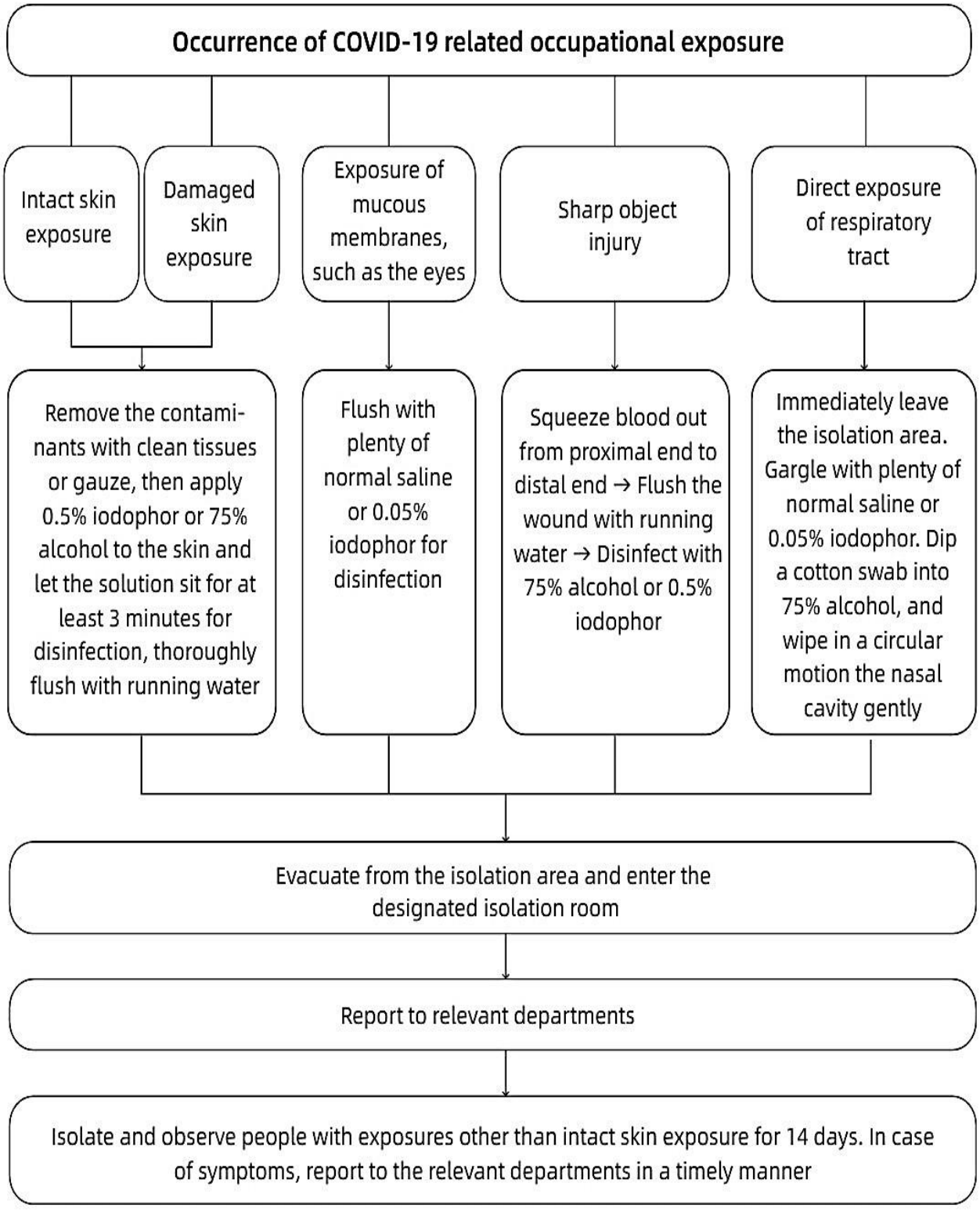
- **Sharps Containers**

- Put sharp objects into a sharps container, seal the box and spray the box with 0.5-1% hypochlorite
- Put the bagged waste into a medical waste transfer box
- Affix a special infection label, fully enclose the box and transfer it
- Transfer the waste to a BMW storage area along a specified route at a fixed time point, microwave it and store the waste separately at a fixed location

Disposal Procedures for Spills of Blood/Fluids

- Spills of a **small volume (< 10 mL)** of blood/bodily fluids
    - Carefully remove the spills with disposable absorbent materials such as gauze, wipes, etc., which have been soaked in 0.5-1% hypochlorite disinfecting solution
- Spills of a **large volume (> 10 mL)** of blood and bodily fluids
    - First, place signs to indicate the presence of as pill
    - Completely cover the spill with disinfectant powder or bleach powder containing water-absorbing ingredients or completely cover it with disposable water-absorbing materials and then pour a sufficient amount of 1-2% hypochlorite disinfectant onto the water-absorbing material (or cover with a dry towel which will be subjected to high-level disinfection). Leave for at least 30 minutes before carefully removing the spill.
- Fecal matter, secretions, vomit, etc. from patients shall be collected into special containers and disinfected for 2 hours by a 4-5% hypochlorite disinfectant at a spill-to-disinfectant ratio of1:2
- After removing the spills, disinfect the surfaces of the polluted environment or objects
- Containers that hold the contaminants can be soaked and disinfected with 1% hypochlorite for 30 minutes and then cleaned
- All waste collected should be disposed of as medical waste
- Used items should be put into double-layer medical waste bags and disposed of as medical waste

Procedures for Taking Remedial Actions against Occupational Exposure toCOVID-19



Guidelines for use of hydroxy-chloroquine as prophylaxis for SARS CoV-2 infection

Eligible individuals:

- Healthcare workers involved in care of suspected or confirmed cases of COVID patients
- Healthcare workers involved in care of asymptomatic household contacts of laboratory confirmed cases
- Household contacts of suspected symptomatic health care worker

Procedure

1. Health care worker should draw OPD registration paper
2. Health care worker shall be assessed with detailed health history
3. ECG Examination is must before final prescription
4. Chief coordinator/Authorized consultant only shall review the ECG and other assessment details
5. Health care worker shall produce written consent for willingness for prophylaxis treatment
6. Chief coordinator/Authorized consultant only shall generate the prescription in duplicate form by following all ideal prescription guidelines. Only one dose shall be prescribed at one time.
7. On obtaining prescription medical store keeper shall issue the prophylactic medication.
8. Overwriting on prescription shall not be accepted in any case.
9. Health care workers shall maintain the record of OPD case paper and ECG for subsequent doses.
10. New prescription will be generated at each dose (Weekly)

Dose:

- Asymptomatic health care workers involved in care of suspected or confirmed cases of COVID patients – 400mg 12hourly on day 1, followed by 400mg once weekly for next 7 weeks; to be taken with meals
- Asymptomatic household contacts of lab confirmed cases - 400mg BD on day 1, followed by 400mg once weekly for next 3 weeks; to be taken with meals

Exclusion/Contraindications–

- Drug not recommended for prophylaxis in children under 15 years of age
- Contraindicated in known cases of retinopathy, known hypersensitivity to hydroxy chloroquine, 4-aminoquinolonecompounds

Key considerations–

- Drug has to be given only on the prescription of a registered medical practitioner
- Advised to consult a physician for any adverse event or potential drug interaction before any initiation of medication

Note-

- ***Drug shall be provided as per duty roster of the health care worker***
- ***Those not involved in patient care and COVID testing should not initiate prophylaxis.***

Dietary Management – COVID Patients

- All diets shall be served in disposable containers
- All labeled diets must reach the designated patient care unit
- In special wards (Single room occupancy) designated food shall be placed by hospital attendant wearing full PPE
- Patients will then be informed to collect their food from outside their rooms
- All leftovers/disposables shall be discarded as BMW infected waste category (Yellow)

Hospital authorities should immediately inform to local Govt. authorities for further needful.

If COVID report is awaited dead body should not be given to relative till the report gets available.

Care of dead body and wrapping

1. The health worker attending to the dead body should perform hand hygiene, ensure proper use of PPE.
2. All tubes, drains and catheters on the dead body should be removed.
3. Any puncture holes or wounds should be disinfected with 1% hypochlorite and dressed with impermeable material.
4. Apply caution while handling sharps .
5. Plug Oral, nasal orifices of the dead body to prevent leakage of body fluids.
6. Place the dead body in leak-proof plastic body bag. The exterior of the body bag can be decontaminated with 1% hypochlorite.
7. The body bag can be wrapped with a mortuary sheet or sheet provided by the family members

Disinfection

1. All used/ soiled linen should be handled with standard precautions, put in biohazard bag and the outer surface of the bag disinfected with 1% hypochlorite solution.
2. Used equipment should be autoclaved or decontaminated with disinfectant solutions in accordance with established infection prevention control practices.
3. The health staff who handled the body will remove personal protective equipment and will perform hand hygiene
4. All surfaces of the isolation area (floors, bed, railings, side tables, IV stand, etc.) should be wiped with 1% Sodium Hypochlorite solution; allow a contact time of 30 minutes, and then allowed to air dry.

Handling in Mortuary

1. Mortuary staff handling COVID 19 dead body should follow standard precautions.
2. Dead bodies should be stored in dedicated cold chambers for COVID Patients at temperature of approximately 4°C.
3. Environmental surfaces, instruments and transport trolleys should be properly disinfected with 1% Hypochlorite solution.
4. After removing the body, the chamber door, handles and floor should be cleaned with sodium hypochlorite 1% solution.

Transportation of dead body

1. The body, secured in a body bag, exterior of which is decontaminated poses no additional risk to the staff transporting the dead body. The personnel handling the body may follow standard precautions (surgical mask, gloves).
2. The vehicle, after the transfer of the body to cremation/ burial , will be decontaminated with 1% Sodium Hypochlorite.

At the Crematorium

1. The Crematorium staff will practice standard precautions of hand hygiene, use of masks and gloves.
2. Viewing of the dead body by unzipping the face end of the body bag (by the staff using standard precautions) may be allowed, for the relatives to see the body for one last time.
3. Religious rituals such as reading from religious scripts, sprinkling holy water and any other last rites that does not require touching of the body can be allowed.
4. The funeral/ burial staff and family members should perform hand hygiene after cremation.
5. The ash does not pose any risk and can be collected to perform the last rites.
6. No more than five to ten people gathering are allowed at the crematorium.

Note- Policy on Management of dead body shall change time to time as per directions of local Govt. Authorities.

Upkeep of Medical Records

- No records to be collected by MRD personnel
- All records to be retained at COVID patient care units
- Final disposal/transport process to be updated soon

Engineering controls

At the minimum following should be ensured:

- Adequate power back must be ensured with response time log for power backup
- Ventilation should be provided through dedicated HVAC system for each patient care unit (separate AHU for patient care areas and non-clinical areas)with
    - Temperature range of18-24degrees
    - Humidity55-60%
    - ACH of 10-12ACH/hr
    - All re-circulated air must come through HEPA filters (will be reviewed as per the latest guidelines issued time to time)
    - All pre-filters to be checked weekly and logged
- Uninterrupted potable water supply to be available
- Medical Gas Pipe line System
    - All patient care units must have piped supply of Medical oxygen, Medical Air and Vacuum
    - Portable cylinders are hazardous, can carry infections - must be avoided.

References

1. https://ncdc.gov.in/WriteReadData/l892s/89568514191583491940.pdf
2. https://www.mohfw.gov.in/pdf/GuidelinesfornotifyingCOVID-19affectedpersonsbyPrivateInstitutions.pdf
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5. https://www.who.int/publications-detail/rational-use-of-personal-protective-equipment-for-coronavirus- disease-(covid-19)-and-considerations-during-severe-shortages.
6. https://www.mohfw.gov.in/pdf/Guidelinesondisinfectionofcommonpublicplacesincludingoffices.pdf
7. https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf
8. https://www.mohfw.gov.in/pdf/StandardOperatingProcedureSOPfortransportingasuspectorconfirmedcaseofCOVID19.pdf
9. https://icmr.nic.in/node/39071
10. https://www.mohfw.gov.in

Annexure 2

MGM Medical College, Auragabad			
Covid - 19 Pandemic Management Trainings			
Sr No	**Particuar**	**No of Training Sessions**	**No of Participants**
1	Doctors & Residents	13	462
2	Nursing Staff	18	956
3	Drivers	1	12
4	Canteen Staff	1	4
5	Ward Borys & Aya	15	361
6	Doctors & Other staff From Other Hospital of the City	1	105

MGM Medical College & Hospital IQAC Aurangabad

Annexure 3

Mahatma Gandhi Mission's
Medical College & Hospital
N-6 CIDCO, Aurangabad - 431 003. Maharashtra
Tel.: 0240-6482000 E-mail: mgmmca@themgmgroup.com Website: www.mgmmcha.org

Virology Service Laboratory
Data of Covid – 19 RT PCR & Antigen Testing

	Antigen Testing			RT-PCR Testing		
Month & Year	Total Testing	Positive Report	Negative Reports	Total Testing	Positive Report	Negative Reports
10.09.2020 to 04.10.2021	3564	528	3036	8468	611	7828

Dr V P Bansal
In-charge virology Section
Central Pathology laboratory Molecular testing & Research facility
MGM Medical College & hospital, Aurangabad

DR. V. P. BANSAL
INCHARGE (VIROLOGY SECTION)
CENTRAL PATHOLOGY LABORATORY
Molecular Testing and Research Facility,
MGM Medical College and Hospital,
Aurangabad.

Annexure 4

MGM Medical College, Aurangabad

Interns List for the Year 2021

SR NO	ROLL NO	NAME OF STUDENT
1	16001	Rashi Manoj Abrol
2	16002	Agrawal Shiwali Sandeep
3	16003	Nasir Jamal
4	16004	Lavesh Aswani
5	16005	Babar Sonal Nagnath
6	16006	Badadare Ajinkya Ganesh
7	16007	Bagal Indrajit Vitthal
8	16008	Bahekar Jitesh Chandrakant
9	16009	Baheti Shivani Jaikishan
10	16010	Nidhi Barot
11	16011	Barve Parth Milind
12	16012	Bedmutha Abhilasha Suresh
13	16013	Bedmutha Swarrda Sunil
14	16014	Bedre Snehal Anil
15	16015	Berbanshi Lokesh Suresh
16	16016	Bhalani Niel Rajesh
17	16017	Bhosale Nupur Arun
18	16018	Bhosale Snehal Sanjay
19	16019	Biradar Shrinivas Govindrao
20	16020	Zeeshan Butt
21	16021	Rajika Chandra
22	16022	Kundan Singh Charan
23	16023	Chaturvedi Shubham Dinkar
24	16024	Chaudhari Saurabh Radheshyam
25	16025	Chheda Anooj Pravin
26	16026	Dahiphale Saurabh Changdev
27	16027	Dama Shivani Pramod
28	16028	Damkondwar Abhijit Chandrakant
29	16029	Pranav Datta
30	16030	Dawle Anushree Bhushan
31	16031	Debabrata Pradhan
32	16032	Desai Dhanashree Sunil
33	16033	Deshmukh Pratit Kalpak
34	16034	Deshmukh Ravikant Dattatray
35	16035	Tanya Dixit
36	16036	Emani Sashreek Aditya
37	16037	Gade Sakshi Yashwant
38	16038	Gaikar Ishita Arun
39	16039	Gaikwad Dnyaneshwar Sanjeev

SR NO	ROLL NO	NAME OF STUDENT
40	16040	Gaikwad Rushikesh Karbhari
41	16041	Game Dhanraj Prabhakr
42	16042	Gawali Gopal Ashok
43	16043	Giratkar Shivani Ramnandeshwar
44	16044	Muskaan Goenka
45	16045	Gohad Rutuja Vivek
46	16046	Gorde Rutuja Dnyaneshwar
47	16047	Anmol Gulati
48	16048	Gupta Sangam Kedarnath
49	16049	Ingle Pratik Ravindra
50	16050	Jadhav Dhananjay Suresh
51	16051	Jadhav Mrunalini Hanmant
52	16052	Jadhav Ritesh Rajendra
53	16053	Jadhav Vrushali Deepak
54	16054	Jain Aayushi Kiranraj
55	16055	Yash Jain
56	16056	Jaiswal Parag Suresh
57	16057	Shrika Jaiswal
58	16058	Piyush Jannu
59	16059	Jawanjal Prajwal Dnyaneshvar
60	16060	Priyansh Jesani
61	16061	Jhaveri Arushi Dhiren
62	16062	Kabra Snehal Venkatesh
63	16063	Kadam Aishwarya Arun
64	16064	Kadam Pranita Pradeep
65	16065	Kakde Shradha Pandurang
66	16066	Abhay Kamra
67	16067	Kaneez Fatema Mushtaque Ahmed
68	16068	Kanke Nisha Kalyanrao
69	16069	Karad Pravin Avinash
70	16070	Karnawat Rutuja Rajanish
71	16071	Karnawat Vishal
72	16072	Katruwar Vidhi Harish
73	16073	Khan Irshad Imtiyaz Firdos
74	16074	Khan Shefali Sarfaraz
75	16075	Khan Yahaya Azam Qurram Ahmed
76	16076	Khandelwal Abhay Pravinbhai
77	16077	Kirkire Padmakshi Abhiman
78	16078	Kohar Veenit Ramujagir
79	16079	Ajinkya Kulkarni
80	16080	Manisha Kumari
81	16081	Kunde Mohammed Irshad
82	16082	Kunturkar Neha Ashok
83	16083	Lagdive Shivani Suresh

SR NO	ROLL NO	NAME OF STUDENT
84	16084	Landge Sagar Uddhav
85	16085	Laturkar Gautami Ramesh
86	16086	Lomte Rucha Dhananjay
87	16087	Magar Shivdhan Balasaheb
88	16088	Mahajan Riya Atul
89	16090	Mandhane Amruta Rajesh
90	16091	Akriti D/O Harendra Kumar
91	16092	Merwana Jatan Uday
92	16093	Yukta Minocha
93	16094	Modani Shalvi Satish
94	16095	Mohd Ubaidullah Khan Asadullah Khan
95	16096	Juilee Shashikant More
96	16097	Mundhra Abhishek Santosh
97	16098	Nayak Reeta Ajay
98	16099	Pal Anupam Kamalaprasad
99	16100	Pande Namrata Purushottam
100	16101	Pandit Mahima Shyam
101	16102	Patel Mayankkumar Ramjibhai
102	16103	Patil Kalyani Surendra
103	16104	Patil Prachi Suhas
104	16105	Patil Sumit Arun
105	16106	Patil Taral Prafulla
106	16107	Patki Renuka Makarand
107	16108	Patra Arpita Chinmay
108	16109	Patre Pooja Milind
109	16110	Pawde Gayatri Balasaheb
110	16111	Sohangi Amol Pendse
111	16112	Petkar Smruti Sudhakar
112	16113	Phad Aditya Nathrao
113	16114	Phad Rahul Ramrao
114	16115	Prabhu Akanksha Sanjeev
115	16116	Mehak Preet
116	16117	Anoop Puri
117	16118	Rai Archita Narendra
118	16119	Sable Gautami Suryakant
119	16120	Saboo Bhumika Jagdish
120	16121	Shreya Saha
121	16122	Sapate Suraj Arvind
122	16123	Sathe Shweta Annasaheb
123	16124	Sayyad Alisha Ashpak
124	16125	Shaikh Madiha Tariq Mohd Tariq Iqbal
125	16126	Shinde Kunal Sanjayrao
126	16127	Shrirao Tejaswini Rajesh
127	16128	Shrivastav Shivani Ayodhyakant

SR NO	ROLL NO	NAME OF STUDENT
128	16129	Siddarth Khattar
129	16130	Deeksha Singh
130	16131	Rohan Singh
131	16132	Suyash Singh
132	16133	Utkarsha Singh
133	16134	Pratik Sinha
134	16135	Solanke Vyankatesh Avinash
135	16136	Utkarsh Harendrasinh Solanki
136	16137	Sorathiya Zikra Idris
137	16138	Suranje Rutuja Gajanan
138	16139	Surase Prajakta Popatrao
139	16140	Tariq Aziz
140	16141	Taur Ajay Sakharam
141	16142	Thakkar Kamya Uday
142	16143	Thorat Manasi Deepak
143	16144	Tupe Suraj Kalyan
144	16145	Uttarwar Avantika Arvind
145	16146	Vaghani Dhwani Suresh
146	16147	Vare Yash Anil
147	16148	Vishe Gargi Rajendra
148	16149	Wadgaonkar Ruturaj Sharad
149	16150	Wankhede Umeshkumar Sudhakar
150	07073	Divya Prakash
151	11148	Wankhede Priyanka Madhukar
152	12100	Anurag Roushan
153	14028	Vishwajeet Deshpande
154	14148	Vishwajyothi R
155	15039	Jonnalagadda Jacob Sougandh
156	15078	Padwal Harshad Pramod
157	15133	Devesh Raaj Srivastav

Dean,
MGM Medical College,
Aurangabad.

Annexure 5

Certificate of Appreciation

This certificate is awarded to

Mahatma Gandhi Mission Hospital

for exemplary performance under Ayushman Bharat
Pradhan Mantri Jan Aroyga Yojana (AB PM-JAY).
& Mahatma Jyotirao Phule Jan Aryoga Yojna (MJ-PJAY)

COLLECTOR OFFICE AURANGABAD

Date 26th Jan 2021

District Collector, Dist. Aurangabad, Maharashtra

Annexure 6

Mahatma Gandhi Mission's
Medical College & Hospital
N-6 CIDCO, Aurangabad - 431 003. Maharashtra
Tel.: 0240-6482000 E-mail: mgmmca@themgmgroup.com Website: www.mgmmcha.org

Radio Talks Related to Covid-19 Pandemic Awareness

Time Duration :June 2020 to ~~July~~ Nov 2021

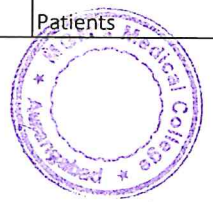
Sr. No.	Name of Faculty	Department	Name of Topic
1	Dr. Swati Mahajan	Community Medicine	Masks, its types and usage for COVID-19
2	Dr. Swati Mahajan	Community Medicine	Isolation, home quarantine, institutional quarantine with reference to COVID-19
3	Dr. Pravin Suryawanshi	General Surgery	MGM's Corona Home Care Package
4	Dr. Anupama Wyawahare	Microbiology	Corona Virus-Transmission and spread
5	Dr. Shobha Salve	Community Medicine	COVID-19 Sero Survey in Aurangabad
6	Dr. Satyajeet Shirale	General Medicine	Nutrition week – Diet in COVID patient
7	Dr. Gaurav Murambikar	Psychiatry	Psychosis and COVID pandemic
8	Dr. Shraddha Jadhav	Psychiatry	Anxiety and COVID pandemic
9	Dr. Deepanjali Deshmukh	Psychiatry	Depression and COVID pandemic
10	Dr. Arun Marwale	Psychiatry	Addiction and COVID pandemic
11	Dr. Nishant Agrawal	General Medicine	Post COVID Medical Issues and Care
12	Dr. Anand Soni	General Medicine	Post COVID Medical Issues and Care
13	Dr. Shraddha Jadhav	Psychiatry	Home Isolation for COVID-19
14	Dr. Dhananjay Bhale	Biochemistry	COVID awareness poem
15	Dr. Avinash Sangle	Paediatric	COVID in Paediatric age group
16	Dr. Rohan Gundre	General Medicine	Care at home isolation for COVID-19

MGM Medical College & Hospital IQAC Aurangabad

Annexure 7

Research Publication - 2020

Sr. No.	Publication Year	Department	Title Of The Paper	Authors	Name Of Journal	National/ International	Valume Issue
1	2020	Community Medicine	Seropevalance of Covid 19 In Aurangabad District	Dr.J.V.Dixit Et Al	International Journal Of Creative Research Thoughts	International	
2	2020	Community Medicine	Conventional V/S Online Teaching During The Covid-19 Pandemic: Perception of Undergraduate Medical Students of India	Adchitre Sangita Arunkumar1, Adchitre Piyush Arunkumar2 And Dase Rajesh Keshav3	International Journal Of Advanced Research	International	Vol.8, No.9
3	2020	Medicine	Covid - 19 Presenting As Acute Viral Encephalitis: A Rare Occurrence	Rohit Jacob*, Manjiri Naik	American Journal Of Medical Case Reports	International	Vol.8, No.11
4	2020	Medicine	Structure,Pathway Prediction For Functional Elements of E2 Glycoprotein Precursor In Sars-Cov-2 To Analyze It'S Role In Covid-19 Desease	Subodh Choukidar2*, Talib Yusuf1, Talib S.H.3 And Sanjay Harke2	World Journal Of Pharmaceutical And Medical Research	International	Vol.6, No.8
5	2020	Medicine	Covid-19: An Enigma Beyond Doubts!	Dr Rohit Jacob, Dr Nikunj Gokani	International Journal Of Scientific Reasearch	International	
6	2020	Dermatology	Dermatosurgery Practice and Implications of Covid-19 Pandemic: Recommendations By Iadvl Sig Dermatosurgery (Iadvl Academy) - 9Th Author	Anup K.Lahiry1, Chander Grover2, Syed Mubashir3, Karalikkattil T.Ashique4, C Madura5, Nilesh Goyal6, Ankur Talwar7,	Indian Dermatology Online Journal	National	Vol.11, No.3
7	2020	Psychiatry	Covid-19 Pandemic Highlights The Need To Reconsider Psychiatry Training of Indian Medical Graduate	M Kishor, Vikas Menon1, H R Vinay2, Manik C Bhise3, Mohan Isaac4, Suhas Chandran5, Ajay Kumar6, Naresh	International Journal Of Health & Allied Sciences	International	Vol.9, No.1
8	2020	Psychiatry	Stress Free Business Management: Amid Covid-19 Pandemic	Dr Manik C Bhise	Udyog Samvad- Massia Newsletter	National	
9	2020	Surgery	Elective Tracheostromy In A Covid Patient With Carcinoma Palatein Covid Intensive Care Unit-Clinical Dilemma of A Surgeon	1*Bhaskar Musande, 2Neemesha Mhatre, 1Soorya Sekar And 2Dr. Palak Bohra	International Journal Of Current Research	International	Vol.12, No.10
10	2020	Radiology	Corona Virus Outbreak and Radiology Department : Workplace Preparedness, Evidence Based Measures To Limit Transmission and How Radiologist Can Help Reduce The Spread.	Dr. Amol Lahoti, Dr. Kavita Makasare	Journal Of Dr. Ntr University Of Health Sciences	National	Vol.9, No.2
11	2021	Radiology	CT chest interpretation of novel coronavirus disease (COVID-19): our experience with the first 60 patients at MGM Medical College, Aurangabad, India	Bano Nikhat, Meghana Deshmukh, Devidas B. Dahiphale, P. S. Mishrikotkar, Saurabh Joshi	MGM Journal of Medical Sciences	National	8:9-14.
12	2020	Radiology	Role of CT Pulmonary Angiography in Evaluation of COVID-19 Patients	Nikita Mantri1, P.S. Mishrikotkar2, D.B. Dahiphale3, Kavita Makasare4	International Journal of Contemporary Medicine Surgery and Radiology	International	Volume 5 | Issue 4 | October-December 2020



MGM Medical College, Aurangabad

MD/MS students have presented their Paper, Poster & Publication in COVID-19

Sr.No.	Name of Students	Course	Paper	Poster	Publication	Other
1	Dr.Meghana Deshmukh	MD.Radiology	-	-	Yes	
2	Dr.Mantri Nikita Kailash	MD.Radiology	-	-	Yes	
3	Dr. Praveen Godara	MD.Psychiatry				Delegate
4	Dr.Gokani Nikunj Satish	MD.Psychiatry				Delegate
5	Dr. Tripathy Srabani D.	MD.Medicine				Thesis Work

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Certificate of Appreciation

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for exemplary performance under Ayushman Bharat
Pradhan Mantri Jan Aroyga Yojana (AB PM-JAY).
& Mahatma Jyotirao Phule Jan Aryoga Yojna (MJ-PJAY)

Date 26th Jan 2021

District Collector, Dist. Aurangabad, Maharashtra

INDIAN PSYCHIATRIC SOCIETY TASKFORCE FOR COVID-19 MENTAL HEALTH CARE

Webinar: Strengthening Our Soldiers
Date: 22nd May 2020

Certificate of Participation

This is to certify that

Dr. Praveen Godara

has participated in the Webinar Online on 22nd May, 2020

as Delegate /~~Faculty.~~

DR. P K DALAL	DR. GAUTAM SAHA	DR. TSS RAO	DR. ROOP SIDANA
PRESIDENT, IPS	PRESIDENT ELECT, IPS	HON. GEN. SECRETARY	CHAIR PERSON - TASKFORCE FOR COVID-19 MENTAL HEALTH CARE

MGM's Medical College Aurangabad

iagmh

Indian Association for Geriatric Mental Health

National Midterm CME of IAGMH (Webinar)

Theme : Issues and challenges in Geriatric patients with Mental Illness amid COVID-19

Certificate of Participation

This is to certify that

Dr. Praveen Godara

has participated in the Webinar Online on 15th August, 2020 as Delegate.

Dr. G. Prasad Rao
President

Dr. Abdul Majid
Hon. Secretary

MGM's Medical College Aurangabad

INDIAN PSYCHIATRIC SOCIETY TASKFORCE FOR COVID-19 MENTAL HEALTH CARE

Webinar: Strengthening Our Soldiers

Date: 22nd May 2020

Certificate of Participation

This is to certify that

Dr. Nikunj Gokani

has participated in the Webinar Online on 22nd May, 2020

as Delegate /~~Faculty.~~

DR. P K DALAL
PRESIDENT, IPS

DR. GAUTAM SAHA
PRESIDENT ELECT, IPS

DR. TSS RAO
HON. GEN. SECRETARY

DR. ROOP SIDANA
CHAIR PERSON - TASKFORCE FOR

3. Participation in Extension/ Outreach activity (Camps, Awareness activity etc)

Sr. No.	Date	Name of Activity	Location	Work Done
1	10/8/2020	Covid Awareness Programme	Dyotan Hall	Attended

4. Any other academic activity conducted:

_____

_____

_____

_____

PART E

1. Conference / CME / Workshop / Seminar / Symposium Attended (Attach certificates)

Sr. No.	Name of Activity	Date	Place	Certificate submitted (Yes/No)
1.	CME on critical care medicine	31/10/2020	Dyotan Hall	
2.	Covid 19 Yesterday, Today, Tomorrow	9/1/2021	virtual Meet	
3.	Approach to Congenital Heart disease	17/1/2021	Kamalnayan Bajaj Hospital	

PART C

Progress of Thesis Work

To assess the effect of Remdesivir on mortality rate, need of intubation and mechanical ventilation in covid 19 positive patients :- A retrospective observational study.

Thesis work is Reviewed & Approved by ethical committee

Thesis Guide :- Dr. Anand Nikalje

Note:-Submit Acknowledgement copy of ethics committee six months progress Report

PART D

(Activities from serial No. 1 to 5 should be rated on a scale of 0 to 10.)

1. **Case Presentations, Teaching, Recent Advances, Seminars, Journal Club,**

Sr. No.	Activity Type	Topic	Date	Guide	Marks
1	Case presentation attended	CNS Long Case	16/1/21		
2	Case presentation attended	Respiratory long case	9/2/21		
3	Case presentation attended	CNS long case attended (Hemiplegia)	13/2/21		
4	Case presentation attended	CNS long case (GBS)	16/2/21		
5	Journal presentation	RAAS inhibition & Risk of covid 19	4/2/21	Dr Namita soni	
6					
7					

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's
Ethics Committee for Research on Human Subjects
MGM campus, N-6, CIDCO, Aurangabad - 431003
Ph. No.: 0240-6601100, 6601174, Fax No.: +91-0240-2487727
Email: mgmecrhs@gmail.com
Office: Dr. Deepak Bhosle, Prof & Head dept of Pharmacology & Member Secretary MGM-ECRHS,
MGM Medical College, Aurangabad

MGM-ECRHS/2020/35

Date: 21st Dec., 2020

MGM - ECRHS APPROVAL LETTER

To,
The PI: . Dr. Srabani Tripathy
Department of General Medicine
MGM Medical College, Aurangabad

Dear Dr,

The meeting of Ethics Committee for Research on Human Subjects (ECRHS) was held on 21st Dec., 2020 at 10 AM. in the Boardroom with Dr. Manvendra Kachole as Chairperson. At the said meeting, the ECRHS approved the proposal for the clinical study entitled as **" To assess the effect of remdesivir on mortality rate, need of intubation and mechanical ventilation in COVID-19 positive patients : A Retrospective observational study."** The ECRHS **reviewed and approved** the following documents submitted for the above mentioned clinical study.

List of Documents:

1. Study Protocol
2. Informed consent form
3. Case Record form
4. Appendices/Questionnaire
5. Adverse event reporting form / Product monograph
6. Current CV of Principal Investigator
7. Principal Investigator's undertaking

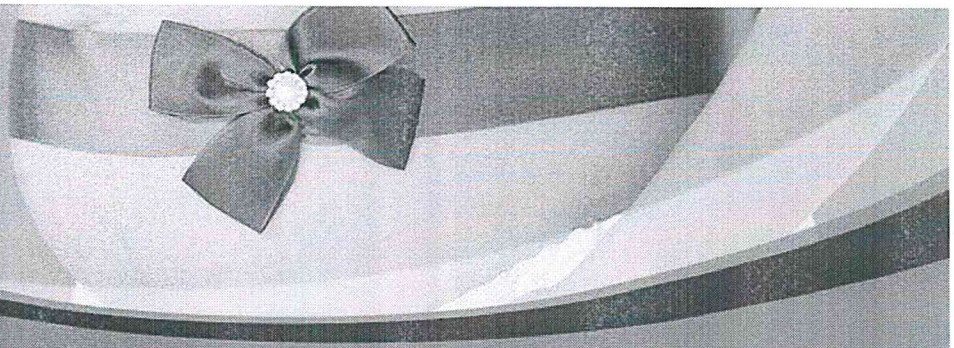
It is policy of ECRHS that, it should be informed about any serious adverse event occurring during the course of the study within seven days of the occurrence of the adverse event. The ECRHS expects to be informed about any changes in the protocol and informed Consent Document and asks to be provided a copy of the final report. The status of the study (completed/ongoing/terminated) should be reported to the ECRHS annually. 12 Members attended the meeting held on 21st Dec., 2020, fulfilling the quorum. It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

MGM's Medical College Aurangabad

MGM-ECRHS AURANGABAD

Dr. Jyoti Bobde
Member Secretary
MGM-ECRHS
Department of Pharmacology.

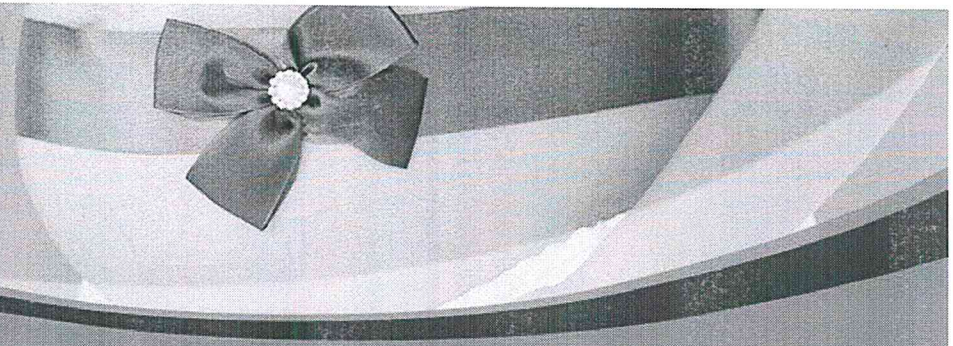
Member Secretary
MGM-ECRHS
MGM Medical College, Aurangabad



PREGNANCY OUTCOME IN COVID 19- AN EXPERIENCE AT MGM

- DR. NIDHI SHETTY
2nd YEAR PG RESIDENT IN OBGY
MGM MEDICAL COLLEGE & HOSPITAL,
AURANGABAD.

GUIDED BY DR. SWATI SHIRADKAR
PROFESSOR AND HOU.



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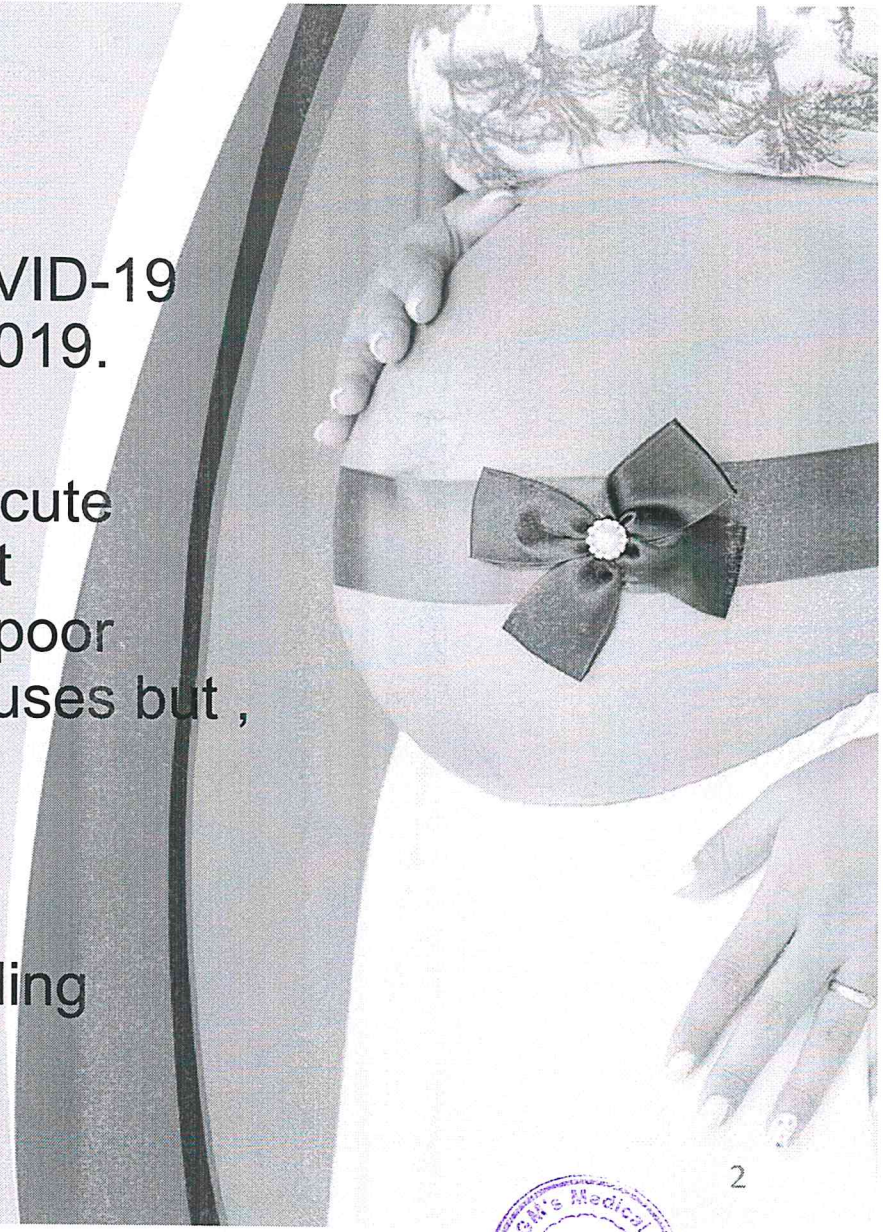
PROFESSOR AND HOU.

Introduction

- The world is currently reeling under the COVID-19 pandemic which began in the later part of 2019.

- Coronavirus infections in the past- severe acute respiratory infection (SARI) and Middle East respiratory syndrome (MERS) have shown poor outcomes for pregnant women and their fetuses but , it remains largely uncertain as to what is SARS-CoV-2' effect on mother and child.

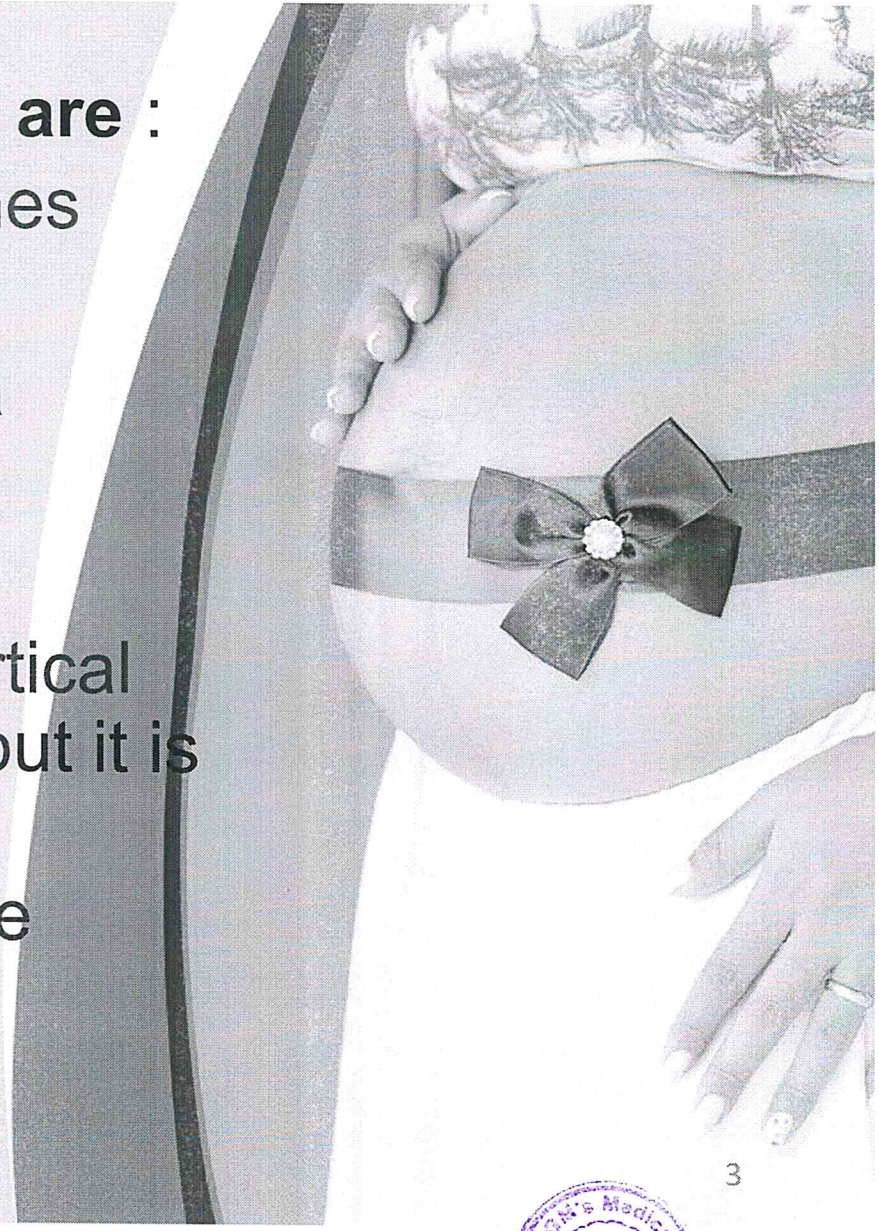
- Globally , viral pneumonia is one of the leading causes of death in pregnant women.



- **Risk factors in pregnant women are** :

✔ Reduced functional residual volumes
✔ Elevation of diaphragm
✔ Edema of respiratory tract mucosa
✔ Changes in cell immunity

- There is a potential for in-utero vertical transmission of SARS-CoV-2 too but it is still controversial.
- Neonate is at risk of contracting the infection too.



Aims and Objective

- To study the baseline characteristics of pregnant women with SARS-CoV-2 infection.

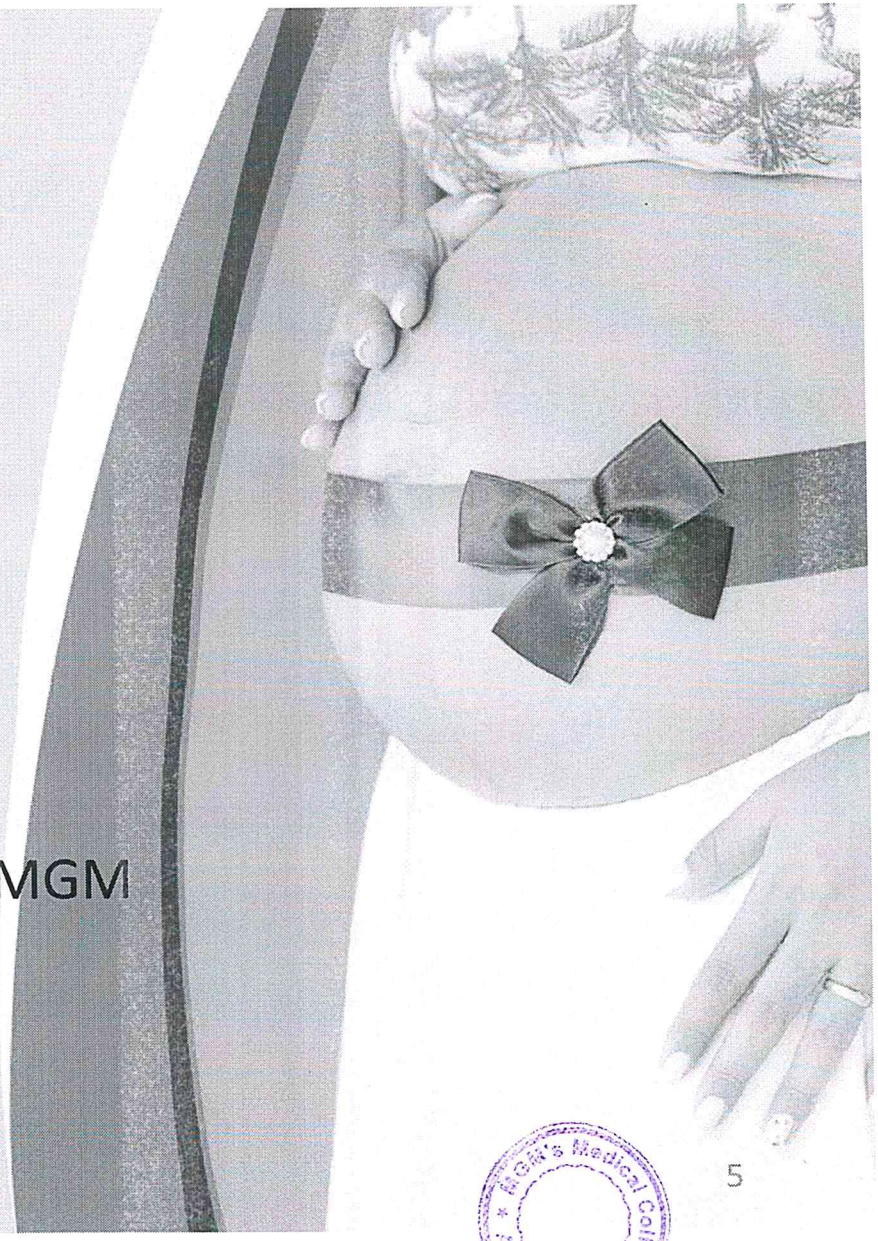
- To study the management and outcomes of pregnant women with confirmed SARS-CoV-2 infection and the neonatal outcome.

Methodology

- Record based retrospective study.
- Duration : 6 Months (May- October)
- 30 cases studied from MGM hospital.

- Inclusion criteria :

All pregnant mothers who tested positive for SARS-CoV-2 infection and were admitted in the MGM Hospital.



- The parameters used for assessment were :

1. Gestational age
2. Symptoms
3. Requirement of ICU care
4. Severity of condition
5. Treatment
6. Comorbidities in mother
7. Mode of delivery
8. Maternal and neonatal outcome.

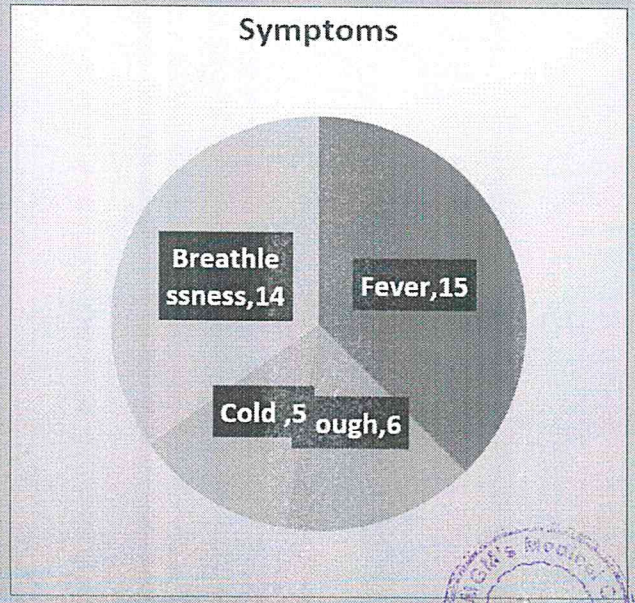
RESULTS

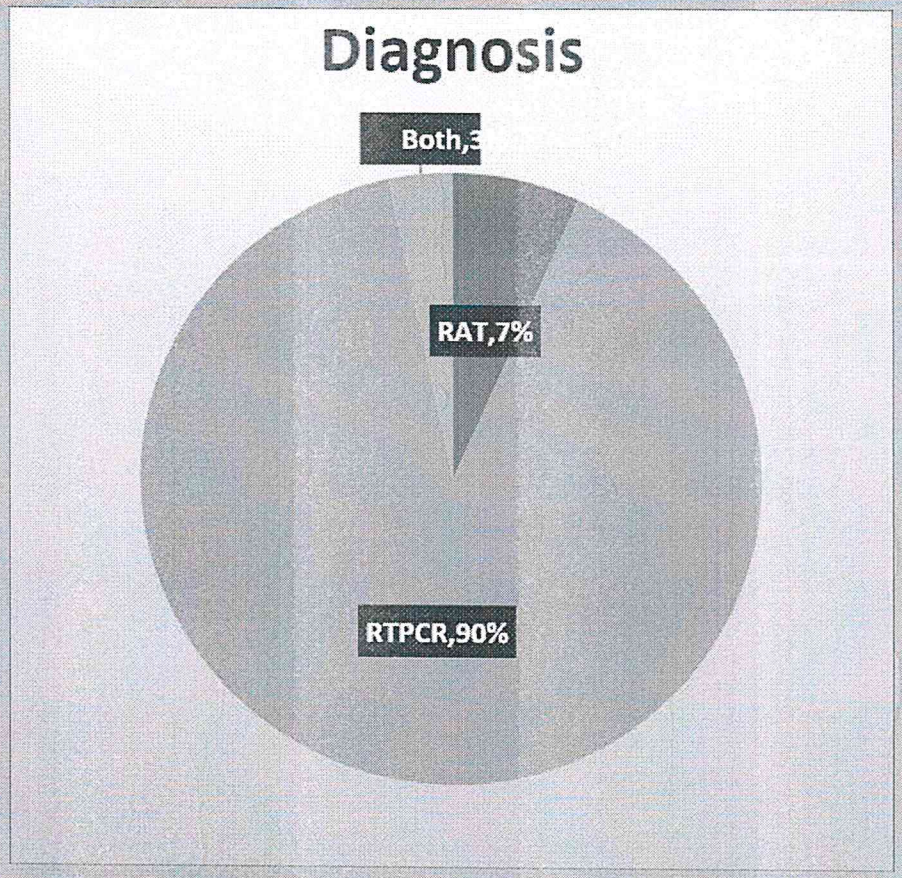
- Total COVID positive patients- 4068. Recovered- 93.8% Death- 6.19%
- All ANC patients (945) underwent covid testing as routine protocol.
- This record based study of 30 pregnancy outcomes , yielded the following results :

- **<u>Baseline characteristics of study participants</u> :**

Trimester	Frequency (N=30)	Percent
First	1	3.3
Second	9	30.0
Third	20	66.7

- Majority were asymptomatic.
- Fever (50%) & breathlessness (46.7%) were the commonest symptoms
- Three (13.3%) pregnant women required ICU care.

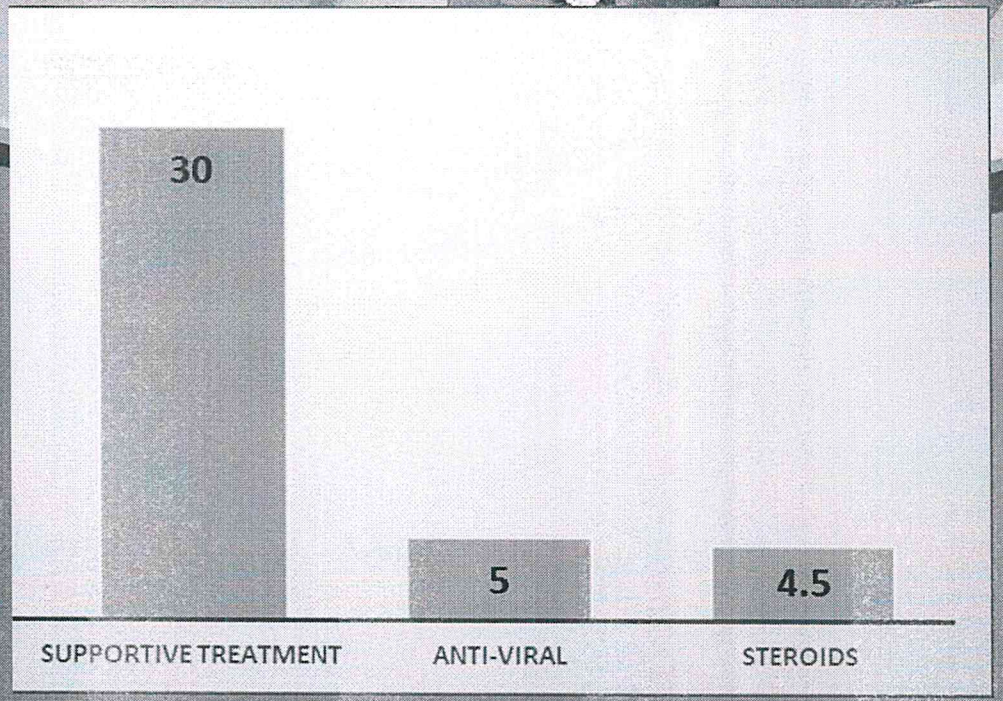




Other Lab investigations

Other investigations	Number	Percent
Lymphopenia	11	36.7
Neutropenia	16	53.3
Deranged CRP, LDH, Ferritin, ESR	21	70.0

TREATMENT

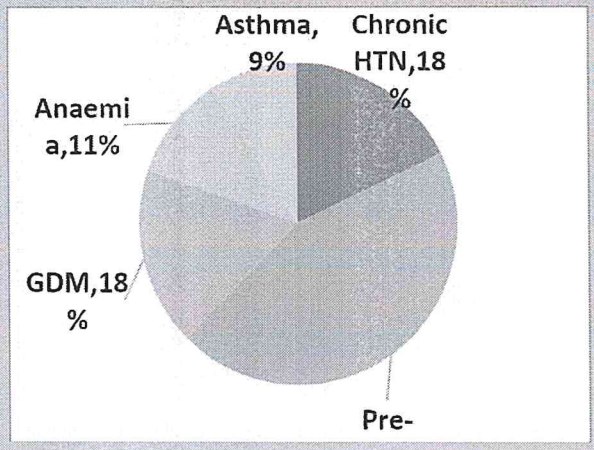


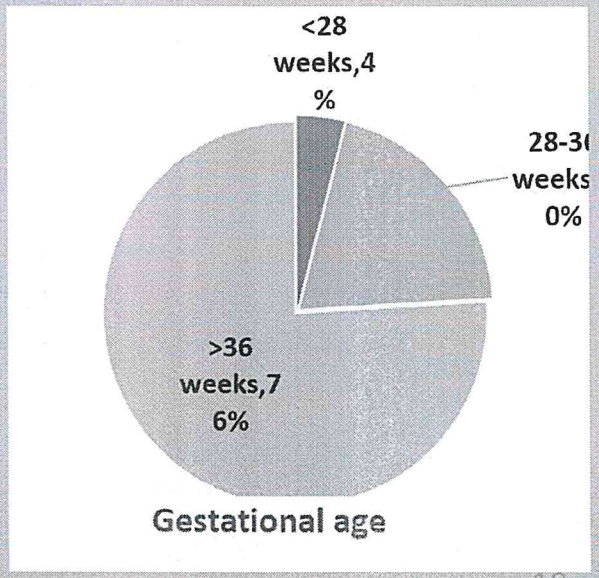
All patients received supportive treatment in form of oxygen and fluids. Anti-virals were given to 16.7% patients and steroids were administered in 26.7%.

Co-morbidities

- Pre-eclampsia was the commonest co-morbidity.
- Followed by associated co-morbidities like GDM, HTN, Anaemia, Asthma.

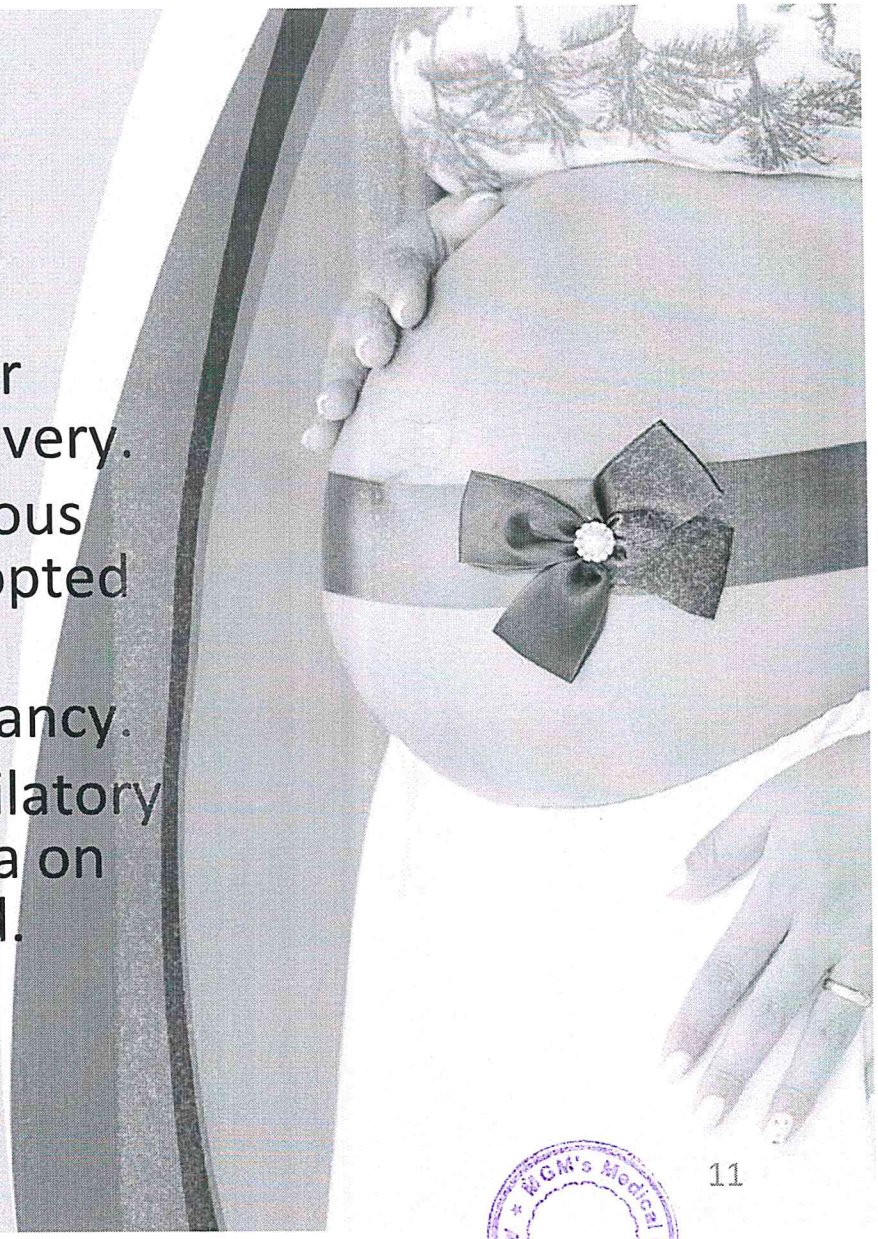
- The gestational age at the time of delivery/ termination was >36 weeks in majority of the patients. (76%)
  Preterm labour was observed in 24% of cases.



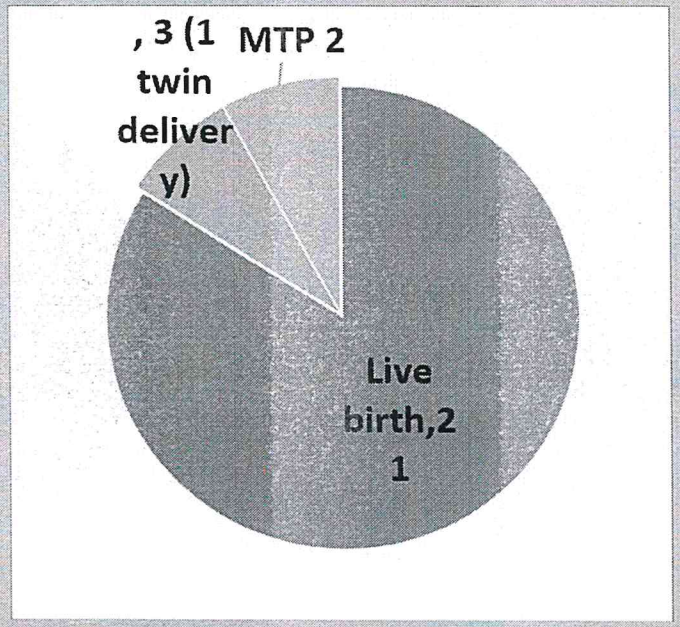


PREGNANCY OUTCOME

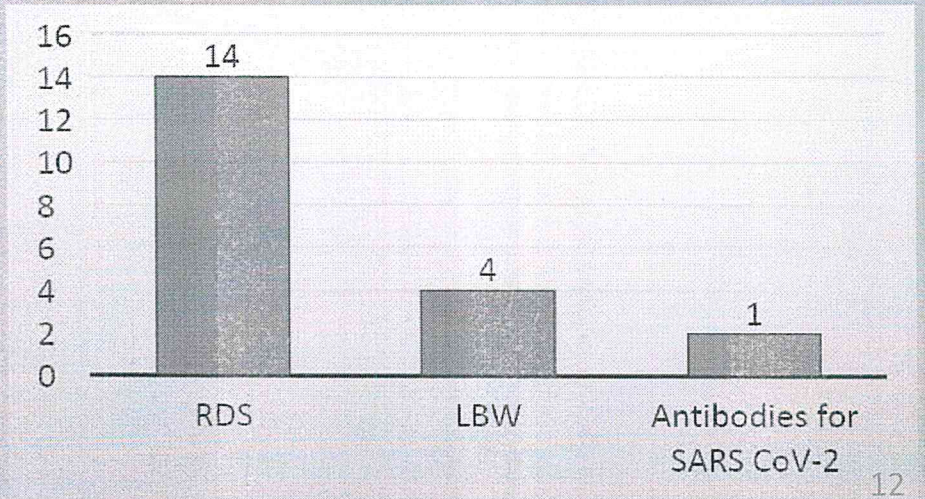
- 14 (48%) of the mothers underwent LSCS for obstetric condition, 9 (30%) had vaginal delivery.
- One patient underwent MTP due to anomalous baby while another COVID positive patient opted for MTP after 14 days of treatment.
- Five (16.7%) patients had an ongoing pregnancy.
- Total 3 patients required ICU care with ventilatory support, One patient died due to pneumonia on PND- 23 while the remaining two recovered.
- Other 27 (94.7%) patients were stable.



Neonatal Outcome



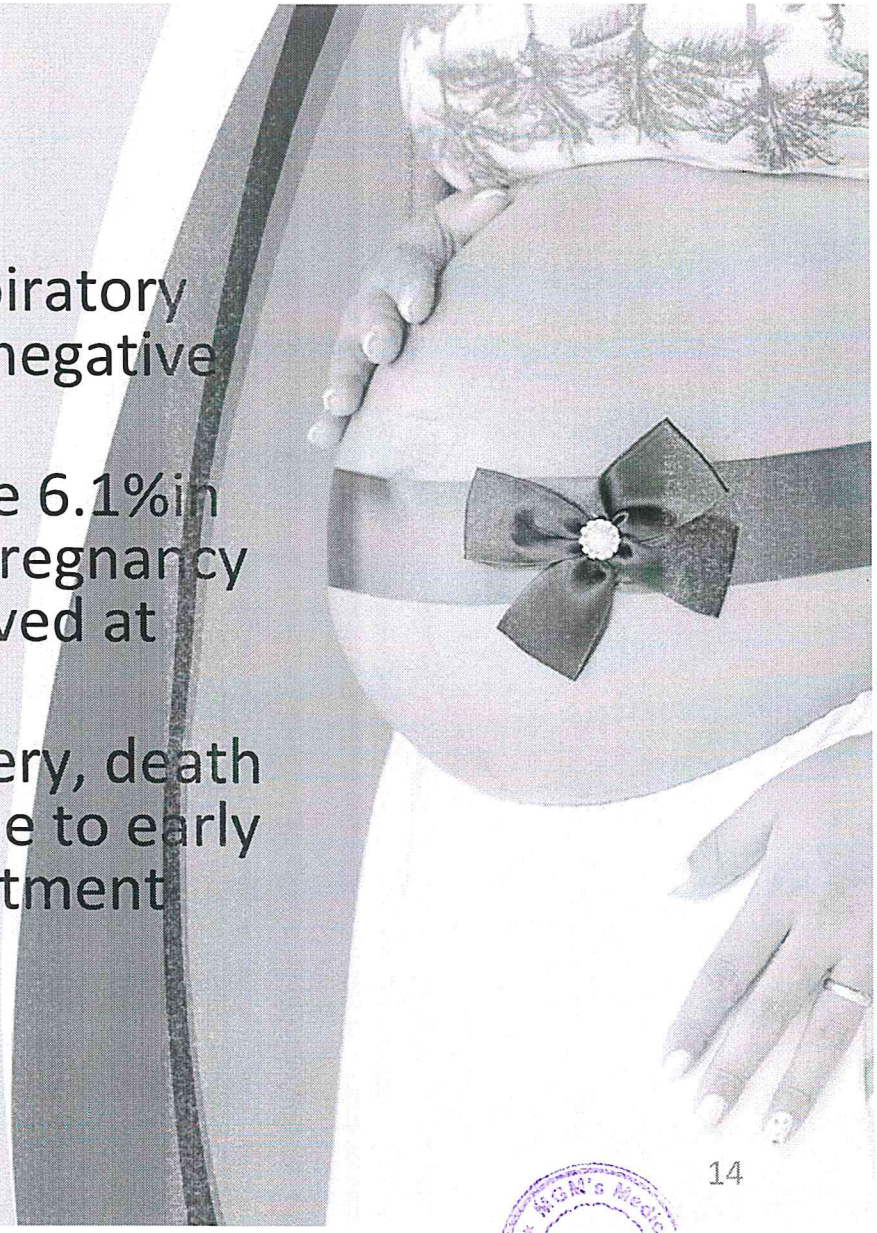
Respiratory distress syndrome (14) was the commonest cause for NICU admission in full term pregnancies. Prematurity in pre term babies (4) required NICU care. Rest babies had no co-morbidities and were isolated (5). RT-PCR testing in all neonates was negative.



Conclusion

- Most of the pregnant woman detected with covid 19 were asymptomatic.
- Fever and breathlessness were the commonest symptoms.
- About 13.3% pregnant women required ICU admission.
- One case of Maternal mortality due to COVID pneumonia reported

- Around 40.6% neonates developed respiratory distress at birth but all neonates tested negative for COVID 19
- Incidence of deaths due to covid 19 were 6.1%in general population while death rate in pregnancy and post partum period was 0.3% observed at MGM.
- Covid 19 has not affected mode of delivery, death rate and the neonate at birth. Maybe due to early detection, 100% testing, supportive treatment and team work.



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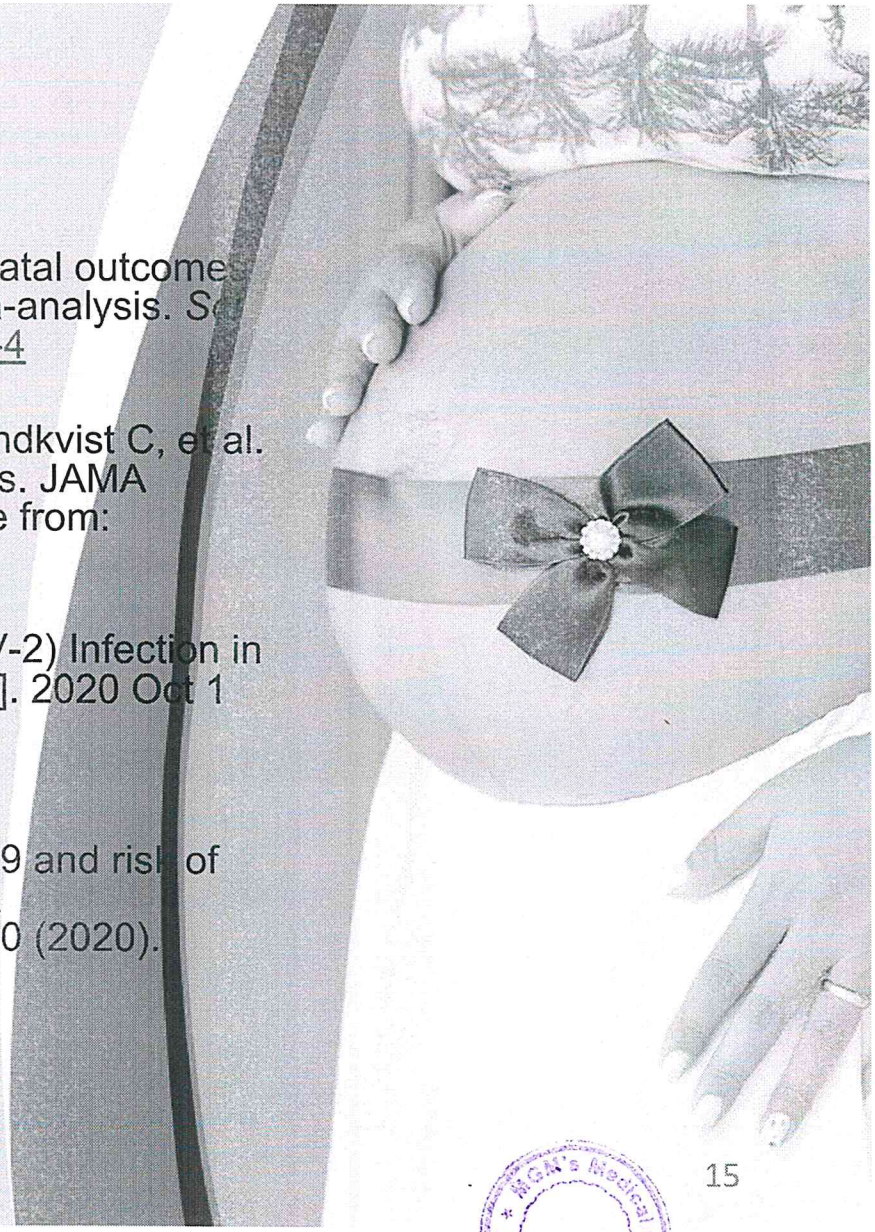


THANK YOU

Annexure 8

भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2020 ◑ AY 043234

21 AUG 2020 500/-

नं. 11629 दि. ..... मु.शु.रक्कम .....

दस्ताचा प्रकार ..... Agreement .....

दस्त नोंदणी करणार आहेत का ? होय/नाही.

मिळकतीचे वर्णन .....

मुद्रांक विकत घेणाऱ्याचे नांव ..... For Serum Institute of India Pvt. Ltd.

पत्ता .....

दुसऱ्या पक्षकाराचे नांव .....

हस्ते व्यक्तीचे नांव व पत्ता .....

किरण देवराम लडकत

परवाना क्र. २२०११२५

मुद्रांक विकत घेणाऱ्याची सही जि.प. अंडर ग्राऊंड, मंगळवार पेठ, पुणे-११

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला, त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासुन ६ महिन्यात वापरणे बंधनकारक आहे.

14 AUG 2020

This stamp paper forms an integral part vide sectio
24-H of the Clinical Trial Agreement by and amongs
Serum Institute of India Private Limited, Diagno
Search Life sciences Pvt. Ltd., Dr. Tayade Deepa
Narayan and MGM Medical College and Hospit
dated 2nd May, 2020.

X SIIPL

X CRO

X PI

X Institution

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of 2nd day of May 2020 (hereinafter "Effective Date") by and between:

Serum Institute of India Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter **"Sponsor"**);

DiagnoSearch Life Sciences Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter **"CRO"**), acting on behalf of **Serum Institute of India Pvt. Ltd. / the Sponsor;**

Dr. Tayade Deepak Narayan, MGM Medical College and Hospital,N-6, CIDCO, Aurangabad 431 003,Maharashtra, India :hereinafter referred to as **Investigator;**

MGM Medical College and Hospital, a deemed university having its office at N-6, CIDCO, Aurangabad 431 003, Maharashtra, India an unit of Mahatma Gandhi Mission (a Charitable Trust registered Societies Registration Act and Bombay Public Trust Act) hereinafter referred to as **Institution.**

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical Study entitled:

A Multicenter, Phase III, Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subject under Protocol no. – SII-rBCG/COVID-19/IN-01, Version 3.0 Dated: 11 April 2020 ("the Protocol") and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;

AND WHEREAS Sponsor intends to appoint Investigator relating to the said **SII-rBCG/COVID-19/IN-01,** Clinical Study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.

AND WHEREAS Institution and Investigator have each reviewed sufficient information regarding Sponsor's vaccine viz. SII-rBCG VPM1002 (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth CRO, Investigator and Institution agree as follows.

The Sponsor, CRO, Investigator and Institution are sometimes hereinafter individually referred to as a Party and collectively as Parties.

Article 1 – The Study

1.1 The Institution and the Investigator undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) (f) Sponsor's Standard Operating Procedure (SOP)s, if required; Institution's own SOP, the Protocol which is approved by Sponsor, Investigator and the IRB and a copy of which is attached hereto as Schedule A (g) such other guidelines as may be issued by Indian Council of Medical Research and Ministry of Health and Family Welfare and (h) data privacy laws as may be applicable and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time (hereinafter "Regulatory Requirements"). It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

1.2 The Investigator hereby certifies and undertakes that s/he is not and has not been debarred under the Drugs and Cosmetics Acts 1940, Drugs and Cosmetics Rules, 1945, and any legislation in connection with any of the services or work provided hereunder as amended, or any other similar legislation, or excluded by a regulatory authority from participating in the development or approval of a drug or biological or disqualified by a regulatory authority as a clinical investigator, and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. Furthermore, the Institution and Investigator hereby certify and undertake that they will not use the services of a person so debarred, and that such certification can be similarly relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Institution and Investigator to notify the CRO/Sponsor of any change in the truth of this certification.

1.3 The Investigator acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Investigator were instrumental in the Sponsor's / CRO's selection of the Investigator for the conduct of the Study. Consequently, it is agreed that the Investigator may not in any way transfer, cede or assign, directly or indirectly, the rights granted herein to any third party. If Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the CRO regarding the appointment of a new principal investigator. In such an event, CRO shall supervise the services / activities undertaken by new principal investigator relating to the Study along with the services provided by CRO to Sponsor. If both Parties cannot agree on a substitute, all further enrolment of subjects into the Study shall immediately cease and decision on the continuation of subjects already recruited in the Study will be taken jointly by CRO & Sponsor on a case to case basis. However, it is agreed between the Parties that,

the outgoing Investigator shall be liable and responsible for all his acts, deeds, actions, omissions, and liabilities arising there from, during the period he / she acts as a Principle Investigator.

1.4 The Institution and the Investigator undertake to conduct the Study in an efficient and professional manner under the provisions of this Agreement and will use their best efforts to complete the Study within the time period agreed between the Parties.

1.5 Parties agree to coordinate the day-to-day management of the Study with each other and to comply with and perform their respective responsibilities and activities as set forth in this agreement.

1.6 CRO will act as a contact point for the Investigator, Institution and Sponsor, regarding any issue which may arise in the implementation of the Study.

1.7 Before commencing the Study, within seven (7) business days the Investigator will seek approval to conduct the Study from the IRB and shall obtain consent as per applicable local regulations of all Study Subjects (or, if permitted their legal representative) who participate in the Study, including consent to allow Sponsor and its Affiliates (hereinafter defined) to access personal and medical information as necessary to monitor the Study or to receive and use Study data. Investigator must deliver to the Sponsor/CRO the written approval for the conduct of the Study, the approved informed consent form and the terms of the Protocol from the IRB. Sponsor may terminate this Agreement under Article 9 (**Term and Termination; Effect of Termination**) upon the failure of the Investigator to seek the aforementioned approval from IRB. In this Agreement "Affiliate" means any entity that controls, is controlled by, or is under common control with the party being referred to. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise;

1.8 The Sponsor/CRO is under no obligation to release Study Vaccine or any other related supplies as defined in Protocol to the Investigator unless and until satisfactory proof of IRB approval is submitted to the CRO.

1.9 The Investigator and Institution hereby warrants that they:

(a) shall use Study Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, ship and dispose of Study Vaccine with appropriate care and in compliance with manufacturer's instructions in writing or over an email and all applicable local, state and federal laws, rules and regulations, including, but not limited to, those governing hazardous substances.

(b) shall not charge any Study subject or third-party payer for Study procedures required by the Protocol that are paid for by CRO/Sponsor under this Agreement or for any Study Vaccine that is provided or paid for by CRO/Sponsor.

(c) received a copy of the Investigator Brochure and has read and understood its contents.

(d) shall prepare, document and maintain records and case histories on the case report form supplied by the CRO, retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter "Subjects").

(e) shall administer the preparation of laboratory tests for shipment (e.g., centrifuge, freezing, packing, labeling) and arrange for courier services with respect to the shipment of biological samples (e.g., completion of shipment forms, ensure the relevant shipment procedure and safe delivery of the shipment);

(f) shall report adverse events and serious adverse events as required by the regulation in force and amended from time to time. The definition of 'Adverse Events' and 'Serious Adverse Events' and the reporting procedure are included in the Protocol, which shall be followed for such reporting.

(g) agree to inform Sponsor / CRO promptly if they become aware of material non-compliance with the Protocol, ICH Good Clinical Practices, or any applicable laws, rules or regulations; incomplete or inaccurate recording of data; or any significant misconduct or other matters of concern relating to the performance of the Study at Institution.

1.10 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by all Parties. Provided however those changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) with the agreement of the Investigator, Institution and Sponsor. Any changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by applicable law and/or the Protocol. The Institution and the Investigator shall not consent to any change in the Protocol requested by the relevant IRB without the prior written consent of CRO or SPONSOR.

1.11 The Investigator may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as sub-investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "Sub-investigators"). All such Sub-investigators must be approved by CRO / Sponsor and copies of their curriculum vitae and other regulatory documentation as required (such as financial disclosure forms) forwarded to CRO/ Sponsor. The Investigator shall be responsible for leading any such team of Sub-investigators, and shall ensure that such Sub-investigators are properly qualified and licensed.

1.12 The Institution and the Investigator shall keep appropriate records of Study Vaccine received, dispensed, used, and returned to pharmacy/storage (and returned to CRO/Sponsor) in accordance with Regulatory Requirements.

1.13 Institution and Investigator agree that Sponsor / CRO may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to

Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Vaccine or that otherwise relates to Sponsor, Investigator will disclose that he/she was an investigator for the Study.

1.14 The CRO/ Sponsor shall provide, without cost, sufficient amounts of the Study Vaccine to conduct the Study. The Institution and Investigator may not use or dispose of the Study Vaccine in any way other than as specified in the Protocol.

1.15 Institution agrees that any nationally-licensed medicinal products that are not the subject of the Study but are required for the routine care of a Study subject during and after the Study for the disease or condition to which the Study relates are expected to be available to the Study subject and funded through the usual operations of the local healthcare system independently from the Study and without expectation of support from CRO and/or Sponsor.

1.16 Institution/Investigator agree to record all side effects including laboratory abnormalities, whether serious or not, of which they may become aware in the appropriate Case Report Forms (CRFs) and in medical files of the subjects in accordance with the requirement set out in the Protocol.

1.17 Upon reasonable notice and at reasonable times, Institution and the Investigator shall permit representatives of the CRO and/or the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements. CRO/Sponsor representative should also be permitted to review the relevant financial documents related to the Study including but not limited to quotations, invoices, employee agreement, salary slips, attendance records, subject compensation logs, annual maintenance contract (applicable for instruments, equipments being used in the Study) agreements, physical verification of assets.

Article 2 – Compensation

2.1 All payments will be made by CRO/Sponsor as per payment schedule provided in schedule B hereto and assumptions provided thereunder.

2.2 The Parties hereby agree and covenant that Investigator / Institution will directly issue invoices to Sponsor which will be certified by CRO. The Parties agree that CRO shall act as a pure agent of Sponsor and facilitate payments to be made to the Investigator / Institution. Invoices shall be addressed to CRO and be sent at the following addresses:

DiagnoSearch Life Sciences Pvt. Ltd.
702, Dosti Pinnacle, Wagle Estate
Thane – 400 604, India

2.3 All amounts payable to the Investigator / Institution will be subject to Tax Deduction at source as required by the relevant tax provisions

2.4 It is understood that Sponsor enjoys exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by CRO, Investigator and Institution are without levying GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations under Bond or Legal Undertaking without payment of Integrated Tax (LUT)"** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit and ARN no for LUT.

(ii) However, if CRO, Investigator and Institution opt to levy GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations on payment of Integrated Tax. The Integrated Tax paid will have to be claimed as refund and Sponsor will not reimburse GST paid."** Further these invoices should also mention GSTIN No 27AABCS4225M2Z6 of our SEZ unit.

(iii) However, the Sponsor shall reimburse the amount including but not limited to tax liability, interest and penalty thereon imposed on CRO/Investigator/Institution by any competent authorities arising out of breach, action, inaction or failure to comply with provisions of Central Goods and Service Tax Act by Sponsor.

2.5 The payment shall be made in either by electronic transfer to the beneficiary account details given below or cheques should drawn by the CRO and be made payable to **MGM Medical college, Aurangabad** and delivered to the following address

Clinical research unit, Department of pharmacology 4th floor MGM medical college and Hospital N-6 Cidco Aurangabad-431003, MH, India

Beneficiary Name	MGM Medical college ,Aurangabad
Bank Name:	IDBI bank
Bank Address	Adalat Road Branch,Survey No.20292,Ratnaprabha Building Kesarsinghpura Opp.LIC Bld.Aurangabad
Branch	Adalat Road Branch
Beneficiary Account No.	0376104000000107
TAX ID NUMBER (PAN)	AAATM4256E
IFSC Code	IBKL0000376

Article 3 – Institution Staff and Facilities

3.1 The Institution acknowledges that all payments for all necessary laboratory and other facilities, equipment, supplies (other than the Study Vaccine), and physicians and clinical support staff required to discharge its obligations under this Agreement are provided for in the compensation schedule as provided in Schedule B. Institution shall ensure that all such facilities and staff are arranged to support the Study.

3.2 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the Investigator, any Sub-investigators and any support staff used in the Study shall be solely a matter between the Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of the Institution and no amounts payable by CRO under this Agreement shall be considered to be a salary payment by CRO or Sponsor to Investigator, sub-investigator or support staff. All Institution/Investigator staff performing Services under this Agreement shall at all times be employed or engaged by Institution/Investigator and shall not be employees or subcontractors of CRO or Sponsor. Accordingly Institution/Investigator shall deal with all issues relating to the employment or engagement of the Institution/Investigator staff including without limitation: payment of salary and any employment-related benefits; deduction of all Pay As You Earn, National Insurance and any other employee-related taxes and contributions; disciplinary and performance issues; grievances; issues relating to a member of staff's ill health; and issues relating to a member of staff's terms and conditions of employment or engagement

3.3 The Investigator and the Institution will take appropriate steps to inform each physician, Study staff of the terms of this Agreement, obtain their agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement. "**Study Staff**" mean the individuals providing services under the supervision of the Investigator with respect to the conduct of the clinical study, including without limitation sub-investigators, study coordinators, and other trial Site employees, agents, any support staff etc.

Article 4 – Reports

4.1 The Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Investigator will comply with all reporting requirements contained in the Protocol/SOPs/any other Sponsor's specification. The Investigator will provide the CRO/Sponsor with copies of all reports provided to the Investigator's IRB/IEC.

4.2 The Investigator shall keep the CRO advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by both Parties. If required by the Sponsor, there shall also be a final report of the Study presented to the CRO/Sponsor.

4.3 All case report forms and other reports submitted to the CRO and all data including Study Data generated under this Agreement shall be the property and Confidential Information of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Institution and/or the Investigator.

4.4 The Institution and the Investigator shall provide such expense statements/reports to Sponsor as CRO/Sponsor may request, on such forms as Sponsor may supply or as Sponsor may approve. During the time the Study is being conducted and for one year thereafter, Investigator and each sub-investigator shall update such forms promptly and provide the same to the Sponsor/CRO as may be requested by Sponsor and whenever any material changes occur in the information disclosed by the previous forms.

4.5 A Subject's individual medical records shall remain the property of the Investigator / Institution. The Investigator will, where duly authorized or where allowed by law, provide or make such medical records and individual Subject data available to the CRO / Sponsor and governmental agencies.

4.6 Institution shall make and retain records regarding the Study as required by the Protocol, applicable law or regulation, or ICH/GCP Guidelines, and in accordance with Institution's standard archiving procedures. Institution will retain such records for a minimum of fifteen (15) years from conclusion of the Study. Thereafter, Institution will contact Sponsor prior to any destroying such records and will retain the records if requested by Sponsor.

4.7 The Investigator agrees not to provide the Study data to any third party or to use the Study data in any way without the Sponsor's prior written consent. The Investigator also agrees to not identify, Subjects in order to benefit research conducted or sponsored by any third party, without the Sponsor's prior written consent.

4.8 All Study Data and reports and any other information that generated, provided to and created by Investigator or Institution, in the performance of their duties hereunder remain the property and confidential information of Sponsor at all times. The Parties hereby agree that, subject to the applicable laws and requirements and each Party's rights and obligations under this Agreement, Sponsor shall be the sole owner of all the information mentioned above and shall have the unrestricted right during and after the term of this Agreement, to use the same for any purpose; "Study Data" shall mean all records and reports, (other than Study Subject's medical records), generated, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g. CRFs, data summaries, interim reports and the final report) etc.

Article 5 – Inventions

5.1 The Institution and Investigator hereby acknowledge and agree that Sponsor shall own all right, title and interest in and to the Protocol, all intellectual property rights arising from the Study including but not limited to reports, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials, formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, technologies, techniques, systems methods, products, processes, algorithms, concepts, formulas, processes, ideas, writings, trade names, business names, logos, design marks or other proprietary marks, technical research, development and manufacturing data, trade secrets or utility models in any stage of development, whether or not patentable and whether or not reduced to practice, and all improvements, modifications, derivative works from, other rights in and claims related to, any of the foregoing and whether or not made, discovered, conceived, invented, originated, devised or improved by the Institution, Investigator , Sub investigator and Study Staff in the performance of the Study or relating to the Study Vaccine or which incorporate Sponsor's confidential Information (collectively, the "Inventions"), and the Institution and Investigator hereby expressly and irrevocably assign, and will cause Sub-investigators and Study Staff to assign, to the Sponsor, all right, title and interests that they may have in any such Inventions without payment of additional consideration.

5.2 The Investigator shall promptly disclose to the CRO/Sponsor in writing any and all Inventions generated pursuant to this Agreement and undertake not to use such Inventions than for the purposes of this Agreement without the prior written consent of the Sponsor.

5.3 If CRO/Sponsor requests, Institution and Investigator shall execute, and will cause the Sub investigators and Study Staff to execute, any instruments or testify as Sponsor deems necessary for Sponsor and/or Sponsor's Affiliates to draft, file, and prosecute patent applications, defend patents, or to otherwise protect Sponsor 's interest in the Inventions . CRO/Sponsor will reasonably compensate Institution and/or Investigator (as applicable) for the time devoted to such activities and will reimburse Institution and or Investigator (as applicable) for reasonable and necessary expenses incurred. The Institution and the Investigator hereby grant to Sponsor an exclusive, worldwide, irrevocable, non-restrictive and full royalty free license under such Inventions to exploit the same for any purpose whatsoever.

5.4 The obligations of this Section shall survive termination of this Agreement.

Article 6 – Publication; Publicity

Except as otherwise expressly agreed between the Parties, Institution and Investigator agree that they will not issue nor allow their employees, sub-investigators or representatives to issue or disseminate any press release or statement, nor any communication of information regarding the Study, written or oral, to the communications media or any third party without the prior written consent of Sponsor. Additionally, all announcements or publicity concerning the Study, or this Agreement by Institution or Investigator may be approved by the Sponsor, at its sole discretion.

The Institution and the Investigator agree not to publish any Study related material, including the Results, other than in accordance with this Section 6.

Article 7 - Confidential Information

7.1 In connection with the performance of Study services, CRO and/or Sponsor may provide, or have provided, certain Confidential Information (hereinafter defined) to Institution and Investigator solely for the purpose of enabling the Institution and Investigator to conduct the Study. Institution and Investigator agree not to use, or permit the use of Confidential Information except for the performance of this Agreement and not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard Sponsor / CRO Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event less than reasonable care.

7.2 In this Agreement "Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans, processes, procedures) of Sponsor / CRO or their Affiliates that are: (1) provided to Institution and Investigator in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, Sub-investigators or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

7.3 The obligations of confidentiality and limited use under this Section shall not extend to:

(i) any information that is or becomes publicly available, except through breach of this Agreement;

(ii) any information that Institution/ Investigator can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

(iii) any information that Institution/ Investigator receives from a third party (other than Sponsor or its Affiliates) which is not legally prohibited from disclosing such information;

(iv) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

7.4 Notwithstanding any termination of this Agreement the provisions of confidentiality will apply for a period of ten (10) years from the date hereof.

7.5 If Institution or Investigator is required by law to disclose certain confidential information to statutory authorities then it shall do so based on legal advice from its legal advisors and only to the extent required. It shall also intimate the CRO and Sponsor immediately on receipt of such disclosure request / notice / order so that CRO / Sponsor can take necessary steps if they wish to in order to limit the dissemination of the Confidential information.

Article 8 – Independent Contractor

The relationship of Sponsor, CRO, Institution and Investigator under the Agreement is that of independent contractors. The Parties do not intend to create a partnership or joint venture employer-employee relationship between themselves. Institution and/or Investigator are not an agent of CRO / Sponsor and have no right or authority to bind CRO and/or Sponsor in any manner to any agreement or obligation whatsoever.

Each Party shall act solely as an independent contractor and shall have no right to act for or to sign the name of or bind the other Party in any way or to make quotations or to write letters under the name of the other Party or to represent that such other Party is in any way responsible for any acts or omissions of such Party. This Agreement does not in any way create a master and servant relationship between Parties. Under no circumstances, the Employees of the Institution and Investigator shall be considered as employees of Sponsor /CRO nor shall such relationship be considered to exist.

Article 9 – Term and Termination; Effect of Termination

9.1 This Agreement shall commence on the Effective Date and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study.

9.2 This Agreement may be terminated by the Sponsor or by the CRO acting solely on the instructions received from the Sponsor in this behalf, at any time, with or without cause, immediately upon notice to Investigator to this effect; a notice by CRO and/or Sponsor that the Study is terminated shall also constitute effective notice of termination of this Agreement.

9.3 Upon termination or expiry of this Agreement:

(a) Institution and Investigator will not enroll additional Study Subjects, and will cooperate with CRO and Sponsor in the orderly discontinuation of the Study;

(b) the Parties will meet and confer promptly to determine an appropriate phase-out for Subjects already enrolled in the Study;

(c) Institution and Investigator shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study;

(d) Investigator and Institution shall be entitled to receive payment by CRO of any amounts accrued as of the date of termination for Study- related work actually performed and expenses actually and reasonably incurred; in the event CRO has pre-paid Investigator and/or Institution for Study services not yet performed as of the date of termination, Investigator shall promptly refund to CRO all such pre-payments;

(e) Investigator and Institution shall deliver to CRO/Sponsor all case report forms and any other reports or documentation prepared during the course of the Study, whether completed or not, in their possession or under their control; and

(f) Investigator and Institution shall either return to CRO / Sponsor or destroy, in accordance with CRO / Sponsor's instructions and / or the terms of the Protocol, all unused or partially used Study Vaccine in their possession or under their control.

(g) All Confidential Information of Sponsor (except for such records that the Institution and Investigator are required by law or regulation to retain) which in the Institution's and/or Investigator's possession shall be promptly delivered to Sponsor, or at Sponsor's discretion destroyed with destruction certified in writing.

(h) Institution represents that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

(i) No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date. Articles 4, 5, 6, 7, 10, and 11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive.

Article 10 – Indemnification

10.1 Sponsor shall defend, indemnify, save and hold harmless the Institution, its directors, officers, employees, agents, assigns and the Investigator (each, an "Institution Indemnitee") from any and all liabilities, claims, actions or suits by third parties for bodily injury or death, that arise out of Institution's administration of the Study Vaccine or procedures provided for by the Protocol ("Institution Claim"), provided that Sponsor shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

(a) failure by Institution Indemnitees to conduct the Study in accordance with (i) this Agreement and the Protocol, (ii) all written instructions delivered by CRO/Sponsor concerning conduct and administration of the Study, (iii) all applicable government laws, rules and regulations and (iv) the manner required of a reasonable and prudent clinical investigator or physician; and

(b) the negligence or willful malfeasance of any Institution Indemnitee, or any other person on the Institution's property or under its control, exclusive of CRO / Sponsor employees.

10.2 Sponsor's obligations under this Section with respect to an Institution Claim are conditioned on:

(a) Prompt written notification to Sponsor of the Institution Claim so that Sponsor's ability to defend or settle the Institution Claim is not prejudiced; and

(b) Institution Indemnitees' agree that CRO/Sponsor has full control over the defense or settlement of the Institution Claim and to fully cooperate with CRO/Sponsor in the defense or settlement of the Institution Claim; provided, that CRO/Sponsor will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee to undertake a future course of action without that Indemnitee's written consent to such components.

10.3 Additionally, Sponsor also agrees to compensate as required by the current compensation guidelines under the new Drugs and Clinical Trials Rules, 2019), and any amendment or new pronouncement notified by the Competent Authority

Notwithstanding clause 10.3, Sponsor shall not stand to pay any medical expenses of any human subject in the Study in the event of any adverse reaction arising out of or resulting from:

(i) A failure to adhere to the terms of this Agreement, Sponsor's written instructions relating to the Study (including the Study Protocol) and/or ICH-GCP guidelines and / or all applicable Standards. All the deviation from the Protocol need to be notified to Sponsor and CRO.

(ii) Institute shall be responsible for all the medical management expenses for the injury caused by negligent acts or omissions or intentional, reckless or willful malfeasance by Investigator, the Institution, or the Study Staff .

10.4 The Investigator, jointly and severally with Institution, will indemnify and hold the CRO, the Sponsor and their affiliated corporations, successors, directors, trustees, officers, employees

and agents harmless from any and all Liabilities suffered by same as a result of a claim asserted against same, arising, or are alleged to arise, from;

(a) negligence or intentional or gross fault on the part of the Institution, Investigator, or any other Study staff, personnel involved in the performance of the Study;

(b) activities contrary to the provisions of this Agreement, including a failure to use the Study Vaccine in compliance with the Protocol or to adhere to the terms of the Protocol;

(c) the Investigator's failure to obtain IRB review and approval;

(d) the Investigator's failure to obtain proper written informed consent from the Subjects; or

(e) a breach of any applicable laws by the Institution, Investigator, or any other Study personnel involved in the performance of the Study.

In the event a claim or action is or may be asserted, an Institution Indemnitee shall have the right to select and to obtain representation by separate legal counsel. If an Institution Indemnitee exercises such right, all costs and expenses incurred by such Institution Indemnitee for such separate counsel shall be fully borne by the Institution Indemnitee; provided, that without CRO/Sponsor prior written consent, the Institution Indemnitee shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the Liabilities for which indemnification may be sought.

The obligations of this section shall survive termination of this Agreement.

Article 11 – Limitation of Liability

Except for as provided in 10.1 and 10.3, whether attributable to contract, tort, warranty, negligence, strict liability or otherwise, Sponsor/CRO's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the Services performed hereunder shall not exceed the amounts paid by CRO to Investigator and/or Institution for Services under this Agreement.

IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE SUBJECT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK.

Article 12- Insurance

12.1 Sponsor Insurance: Sponsor shall at all times during the term of this Agreement obtain and maintain at its own cost and expense, clinical trial insurance policy, with respect to its activities

hereunder as required by the laws of India or laws as per the country where the clinical trial shall be conducted. Such insurance shall be placed at commercially appropriate levels of insurance.

12.2 Institution Insurance: Institution shall maintain medical professional liability insurance with limits in accordance with the laws of India or laws of the country where the clinical trial shall be conducted, for each medical professional involved in the Study or require that each medical professional maintain such insurance.

12.3 Evidence of Insurance: Upon request, Sponsor and Institution respectively, will provide to each other a certificate of insurance evidencing such coverage.

Article 13 - Human Rights

Institution represents that, with respect to employment and conducting the Study under this Agreement, Institution will comply with all applicable human rights/employment laws /labour laws, including but not limited to compliance with rules and regulations governing child labor, forced labor, safe and healthy work place, minimum wages, employee non-discrimination etc.

Article 14 - Anti-Bribery and Anti-Corruption

The Institution and Investigator represent and warrant that they shall not, directly or indirectly, take any action which would cause them, or their employees and sub-investigators to be in violation of any anticorruption or anti-bribery law or regulations applicable to the Investigator ("Anticorruption Laws").

Article 15 – Equipment

With respect to any equipment ("Loaned Equipment") provided to Institution by CRO or Sponsor exclusively to perform the Services pursuant to this Agreement Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by CRO/Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of CRO/Sponsor, and that, at the completion of the Study or at CRO's/Sponsor's request, Institution will return the Loaned Equipment and all related training materials and documentation to CRO /Sponsor.

(a) Investigator and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required electricity supply, backup power supply, internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. Institution shall also be responsible for maintenance cost and annual calibration cost which is required to keep the loaned equipment in a working condition. If the Institution fails to return the Loaned Equipment within the timeframe specified by CRO/Sponsor, the Institution will be responsible for reimbursing CRO/Sponsor for any penalties, late fees, and/or replacement costs.

(b) Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights,
(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment or
(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

Article 16 – Force Majeure and Delays

In the event either Party shall be delayed or hindered or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, failure of power, restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other similar reason or cause beyond that Party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay; provided the Party provides notice of the existence of and reason for such nonperformance or delay in specific detail. In the event of a delay for a consecutive of 90 days, the non-affected Party will have right to terminate this Agreement by serving written notice to the other Party.

Article 17 – Applicable Law

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of India and dispute under this Agreement and shall be subjected to the exclusive jurisdiction of courts of the City of Pune without regard to its conflict of laws provisions.

Article 18 - Recordkeeping and Regulatory Inspection:

18.1 Throughout the term of this Agreement, Institution/Investigator shall maintain and Investigator shall require Study Staff to maintain the complete and accurate books and records (including scientific, clinical and financial records) pertaining to all work performed and expenses incurred hereunder in connection with the Study and preserve them as per the directions of Sponsor/CRO for a minimum of fifteen (15) years from the date of completion of the Study or termination of this Agreement, whichever is earlier, or such longer period as required by the Protocol and the applicable laws and requirements. Archival of these records will be with Institution. Sponsor and its representatives shall have access to these records during the period of 15 years stated above. If required, Institution shall provide the copies of these records to Sponsor.

18.1.1 Sponsor or its designee shall have the right upon prior written notice to have their representatives review and copy all books and records of Investigator, the trial Site and the Study Staff relating to the Study, including without limitation books and records relating to any funds expended hereunder in connection with the Study. In each case access to such books and records

shall occur during regular business hours (or such other agreed time) following reasonable notice to Institution whose records are sought for review.

18.1.2 Sponsor or its designee upon reasonable advance notice, and during regular business hours (or such other agreed time), shall have the right to access the trial site to carry out Sponsor's rights and obligations hereunder and to inspect such trial site's facilities used in the conduct of the Study. The Parties agree to maintain the confidentiality of any subject-identifiable medical records should such information be made accessible under this Article 18.1.2.

18.2 The Investigator/Institution shall notify the Sponsor/CRO immediately by telephone or facsimile in case they receive any communication from Food and drug Administration or any other governmental or regulatory body with regard to Inspection/Audit of the Institution's facility relating to the Study during the term of this Agreement and shall allow CRO/Sponsor to be present at the inspection or participate in any response to the action, and provide to Sponsor/CRO copies of all materials correspondence, statements forms and records which the site receives, obtains or generate pursuant to any such Inspection. Investigator and Institution agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

Article 19 – Electronic Record and Electronic Signature

Investigator/ Institution acknowledges that Electronic Records (defined hereinafter), Electronic Signatures (defined hereinafter), and handwritten signatures executed to Electronic Records, utilized for capturing study related data and for performing services under this Agreement, will be trustworthy, reliable, and are equivalent to paper records and handwritten signatures executed on paper.

As defined in 21 CFR Part 11 "Electronic record" shall mean any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. "Electronic signature" shall mean a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Investigator/ Institution shall remain accountable and responsible for actions initiated under its Electronic Signature.

Article 20 – Representations and warranties

The Parties each represent and warrant that the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which it is a party and no Party will enter into any, agreements, assignments or encumbrances binding on it or its respective Affiliates inconsistent with the provisions of this Agreement.

Article 21 - Assignment:

No Party may assign this Agreement or any interest hereunder without the prior written consent of other Party; provided, however, that Sponsor may assign this Agreement to any corporation with which it may merge or consolidate or to which it may sell all or substantially all of its assets, without obtaining the prior written consent of Institution. In the event of any assignment by any Party permitted under this Agreement, such assignment will be effective only if (i) the assignee has the requisite power, authority and capability to fulfill all obligations of the assignor Party under this Agreement and (ii) such assignee agrees in writing to other Party, in a form reasonably acceptable to the other Party, to fulfill all obligations and liabilities of the assignor Party under this Agreement. Each Party will promptly notify other Party of any such assignment. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

Article 22 – Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected. In the event that the terms and conditions of this Agreement are materially altered as a result of this Article 20, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities, adhering as closely as possible to the original intent of the Parties.

Article 23 – Waiver / Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by a Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by a Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

Article 24 – Miscellaneous

24.1 Institution will obtain written consent from staff involved in the Study that allows Sponsor, Sponsor affiliates, and third party suppliers working for Sponsor or its affiliates to hold and process personal data provided with respect to Study Staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the SPONSOR group of companies, and for compliance with applicable procedures, laws, and regulations. Investigator consents to the use, storage and processing of his/her personal data as set out above.

24.2 This Agreement, including the annexed Schedules and Appendices , sets forth the entire understanding between the Parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof and supersedes all other prior agreements, discussions whether oral or in writing. This Agreement may not be changed or supplemented, except by a writing executed by all Parties.

24.3 All legal notices to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at their respective addresses first set forth above to the attention of:

If to the Institution, to:

MGM Medical college and hospital N-6 Cidco Aurangabad-431003,MH,India
Name: Dr. Rajendra Bohra
Designation: Dean
Address: MGM Medical College and hospital N-6 Cidco Aurangabad-431003, MH, India
Phone No.: 9225304660
Email: rajbohra@msn.com

If to the Investigator, to:

Dr. Tayade Deepak Narayan

MGM Medical College and Hospital N-6 Cidco Aurangabad431003, MH, India
Name: Dr. Tayade Deepak Narayan
Designation: Assistant Professor of Community Medicine
Address: MGM Medical College and Hospital N-6 Cidco Aurangabad431003, MH, India
Phone No.: 7776900089 / 8788416747
Email: drtayadepsm@gmail.com

If to the CRO, to:

Name: Mr. Mandar Vaidya, Director - Operations
DiagnoSearch Life Sciences Pvt. Ltd
702, Dosti Pinnacle, Plot No. E-7, Road No. 22,
Wagle Industrial Estate, Thane- 400604,
Maharashtra, India
Name: Mr. Mandar Vaidya
Phone No.: 022 6777 6314
Email: mandar.vaidya@diagnosearch.com

If to the Sponsor, to:

Dr. Hitt Sharma
Additional Medical Director
Serum Institute of India Private Limited 212/2 Hadapsar, Pune 411 028, India
Phone: 91-20-26602451
Facsimile: 91-20-26993921
Email: drhjs@seruminstitute.com

With a copy to:
Name: Makarand Karkare, General Counsel
Serum Institute of India Private Limited,
Sarosh Bhavan, 16/B-1, Dr. Ambedkar Road
Pune 411001
Phone: 91-20-26100341
Email: mac@seruminstitute.com

Or to such other address and any Party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

24.4 The Parties hereby agree that, considering the current scenario of Novel COIVD 19 pandemic and non availability of stamp papers, the Agreement shall be executed on the plain paper and subsequently upon availability the stamp paper signed / initialed by all the Parties shall be appended to the Agreement which shall form an integral part of the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

FOR Principal Investigator:

By: Tayade Date 11 May 2020
Name: Dr. Tayade Deepak Narayan
Title: Principal Investigator

FOR AND ON BEHALF OF:
MGM Medical College and Hospital
N-6 Cidco Aurangabad-431003, MH, India

By: Date 11 May 2020
Name: Dr. Rajendra Bohra
Title: Dean

FOR AND ON BEHALF OF:
DiagnoSearch Life Sciences Pvt. Ltd.

By: Date May 08, 2020
Name: Gajendra Sharma
Title: Controller Finance & Accounts

FOR AND ON BEHALF OF:
Serum Institute of India Pvt. Ltd.

By: Date 8th May, 2020
Name: Dr. Hitt Sharma
Title: Additional Medical Director

SCHEDULE A
PROTOCOL NUMBER: SII-rBCG/COVID-19/IN-01
CLINICAL TRIAL PROTOCOL SYNOPSIS

STUDY TITLE	A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects
SPONSOR	Serum Institute of India Pvt. Ltd.
CLINICAL RESEARCH ORGANIZATION (CRO)	DiagnoSearch Life Sciences Pvt. Ltd.
PROTOCOL ID	SII-rBCG/COVID-19/IN-01
CLINICAL DEVELOPMENT PHASE	Phase III
INDICATION	Protection of high-risk population from SARS-CoV-2/COVID-19 through immune boost/activation by rBCG (VPM1002) vaccination
NUMBER OF SITES	Approximately 40 sites will be initiated to enroll the required population
STUDY POPULATION	A total of 5946 male and female adults ≥18 years of age who are at a high risk of SARS-CoV-2/COVID-19 infection
DURATION OF PARTICIPATION	The maximum duration of study participation for a subject will be 194 days

STUDY RATIONALE

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is accelerating globally leading to an increase in morbidity and mortality. Although individuals of any age can acquire SARS-CoV-2/COVID-19, certain individuals are at a higher risk of infection with SARS-CoV-2/ COVID-19. The high-risk group includes the health care workers (HCW) (physicians and paramedical staff) working amid SARS-CoV-2/COVID-19 infected patients and all other people including household contacts of SARS-CoV-2/ COVID-19 confirmed patients or people currently residing or working in SARS-CoV-2/ COVID-19 hotspots/outbreak areas where there is a high risk of transmission of COVID-19 infection. Though SARS-CoV-2/ COVID-19 infection may cause mild symptoms in many, nearly 14% develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit (ICU). In severe cases, COVID-19 can be complicated by the acute respiratory distress syndrome, sepsis, septic shock and multiorgan failure with an estimated case fatality of 3.5% in China.

The COVID-19 pandemic is rapidly worsening in all parts of the world, overwhelming health systems. There is a serious threat to HCW capacity in a thickly populated country like India. Also, reports from all

over the world demonstrate that the disease takes a severe course in the elderly people and people with co-morbid conditions leading to higher mortality rates. Thus, there is an urgent need to ensure the safety and health of existing HCWs and all other people living in SARS-CoV-2/COVID-19 infected areas where there is a high risk of disease transmission and find strategies to reduce the incidence, duration and intensity of SARS-CoV-2/COVID-19 infection among such population. Evidence from experimental studies suggest that Bacille Calmette Guérin (BCG) vaccine has beneficial heterologous effects and proven antiviral and immune modulatory properties that protect against infectious diseases other than tuberculosis. BCG vaccine can potentiate immune responses to other vaccines through induction of trained innate immunity and heterologous adaptive immunity. Based on this evidence it is hypothesized that BCG vaccination may induce protection against susceptibility to SARS-CoV-2/COVID-19 infection. VPM1002, a genetically modified BCG vaccine, is being developed with an aim to replace BCG by a vaccine that has a better safety profile and superior efficacy. Evidence from pre-clinical and clinical studies demonstrate that VPM1002 is safer and more immunogenic. It is therefore anticipated that VPM1002 will perform well and may improve the clinical course of SARS CoV-2/COVID-19 infection. Even though vaccine manufacturers across the globe have embarked on rapid development, SARS-CoV-2 vaccines are many months away from widespread availability to the masses. VPM1002 rBCG may act to ameliorate disease severity and mitigate transmission. Even moderate individual efficacy can have dramatic impact at population level directly by reducing severe disease burden on health systems and possibly indirectly by reducing the disease transmission and spread thereby sustaining health systems through this crisis, using a safe, affordable and available vaccine. The manufacture of VPM1002 using state-of-the-art production methods will help hasten the production of millions of doses in a very short time and thus would be beneficial in the current situation. Investment in large scale manufacturing will depend on strong evidence of efficacy from randomized evaluation. Thus, the current study will evaluate the efficacy of VPM1002 in reducing infection incidence and disease severity of SARS-CoV-2/COVID-19 infection including hospital admissions and clinical consequences of SARS-CoV-2 infection in the high-risk subjects.	
INVESTIGATIONAL VACCINE	**VPM1002** The active ingredient of the recombinant BCG vaccine, VPM1002 is Mycobacterium bovis rBCG ΔureC::hly, freeze-dried and standardized to number of viable colony forming units (CFU) of mycobacteria per application available as lyophilized cake. After reconstitution with water for injection, 1 dose (0.1 ml) contains VPM1002, live, 2-8 x 10e5 CFU. A single dose of 0.1 ml of the reconstituted vaccine is to be administered as an intradermal injection in the arm, over the distal insertion of the deltoid muscle onto the humerus (approximately one

	third down the upper arm) OR lateral to posterior aspect of forearm.
COMPARATOR	**Placebo,** 0.1ml 0.9% sodium chloride, will be used as the comparator
PRIMARY OBJECTIVE	1. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among health care workers (HCW) 2. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among other high-risk subjects
PRIMARY ENDPOINT	1. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among HCWs 2. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among other high-risk subjects 3. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among HCWs 4. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among other high-risk subjects
SECONDARY OBJECTIVE	1. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in other high-risk subjects 3. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in HCWs 4. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in other high-risk subjects 5. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in elderly subjects (≥ 60 years of age) 6. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in subjects with co-morbidities 7. To assess the safety of VPM1002 when administered as a single dose in subjects at a high-risk of disease exposure during the SARS-CoV-2 outbreak
SECONDARY ENDPOINT	1. Duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. Duration of SARS-CoV-2/COVID-19 symptoms in other high-

	risk subjects 3. Severe Disease Outcomes in HCWs: ● Cumulative incidence of hospital admission among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among HCWs due to documented SARS-CoV-2 infection 4. Severe Disease Outcomes in other high-risk subjects ● Cumulative incidence of hospital admission among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among other high-risk subjects due to documented SARS-CoV-2 infection 5. Severe Disease Outcomes among in elderly subjects (≥ 60 years) ● Cumulative incidence of hospital admission among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative ICU admission among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among elderly subjects due to documented SARS-CoV-2 infection 6. Severe Disease Outcomes among subjects with Co-morbidities (including hypertension, diabetes mellitus, COPD, asthma, any other cardiac conditions) ● Cumulative incidence of hospital admission among subjects with co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among subjects with

	co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among subjects with co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among subjects with co-morbidities due to documented SARS-CoV-2 infection 7. Incidence of Adverse Events (AE) and Serious Adverse Events (SAE)
EXPLORATORY OBJECTIVE	Immunogenicity analysis will be performed in a subset of approximately 500 subjects who provide consent for the same. Blood samples will be collected at baseline prior to vaccine administration and at 3 months post vaccine administration

STUDY DESIGN

This is a placebo controlled, randomized, double blind, adaptive study to evaluate the reduction in infection incidence and severity of SARS-CoV-2/ COVID-19 infection among high-risk subjects by enhanced trained immune response through VPM1002 vaccine.

A total of 5946 subjects who fulfil the criteria for high-risk will be enrolled across various hospitals treating COVID-19 patients in India. The Investigator/site staff at each site will inform the Health care workers (HCWs) about the clinical trial while other high-risk subjects (household contacts or people living or working in SARS-CoV-2/ COVID-19 infected areas) will be recruited through contact tracing of confirmed SARS-CoV-2/ COVID-19 cases and through posters/advertisements.

All interested subjects will be requested to download a mobile application/portal designed for the study on their smart phone/tablet/laptops and to register themselves. The study has a screening period of up to 14 days during which subjects who provide informed consent will be assessed for eligibility criteria which includes RT-PCR testing to rule out SARS-CoV-2/ COVID-19 infection. Among the household contacts, the laboratory sampling to rule out SARS-CoV-2/ COVID-19 infection will be done 14 days after the last contact with the confirmed SARS-CoV-2/ COVID-19 patient while in other high risk subjects, the laboratory sampling will be performed on the day of screening. The subjects who fulfill all the eligibility criteria will be randomized in a 2:1 ratio to receive a single dose (0.1 ml) of either VPM1002 or placebo, administered as an intradermal injection. The preparation and administration of the study vaccine will be done by designated unblinded personnel who will not participate in any of the clinical study evaluations. Considering that India is currently in a lockdown situation, the vaccine administration may happen at the study clinic or at the place of isolation of the subject. All the study personnel working with the subjects will wear personal protective equipment with adequate gloves as recommended by Indian Council of Medical Research (ICMR) and Ministry of Health and Family Welfare (MoHFW). The study vaccine should be administered within 48 hours of randomization.

Post vaccination the subjects will be observed for 20 minutes for any hypersensitivity/anaphylactic

reactions.

While the monthly follow-up visits are telephonic for all subjects, in case of HCWs, these may be clinic visits depending on the circumstances (e.g., if they are reporting for their routine duty at the study site). Subjects can consult/visit the study site or request for home visit anytime during the study for emergencies or any safety concerns.

Follow-up information must be entered by the subjects regularly. In case the follow-up information is not completed within 7 days, subjects will receive reminders via the mobile application/portal and further telephonic reminders, if required. In case the subjects do not answer the telephone, information on subject's well-being and symptoms may be obtained from alternate contacts. Additionally, follow-up information regarding hospital admission, ICU admission or death will also be retrieved from the hospital.

The duration of follow-up will be based on the results of interim analysis however the maximum follow-up period will be up to 180 days.

Immunogenicity analysis is planned in a subset of approximately 500 subjects. Immunogenicity samples will be collected, from approximately 500 subjects who provide consent for the same, at two time-points, at baseline prior to vaccine administration and at the end of at 3 months (± 14 days) post vaccination. Based on the circumstances, if necessary, the immunogenicity sampling may be done at subject's place of isolation.

During the follow-up, if any subject experiences fever AND cough and/or shortness of breath, all attempts should be made to obtain a throat (nasopharyngeal and/or oropharyngeal) swab or any appropriate sample as directed by the treating physician. Subjects can consult/visit the study site anytime during the study for emergencies or any safety concerns. The sample will be collected by trained health care professionals who shall wear appropriate PPE with adequate gloves (as recommended by ICMR) while collecting the sample from the subject and maintain proper infection control when collecting specimens.

All treatment protocols for HCW and household contacts as recommended by ICMR and MoHFW will be permitted throughout the duration of the study.

Subjects will receive a notification on the mobile application/portal whenever the study ends and will be requested to fill in an end-of- study questionnaire. A subject is considered to have completed the study if he/she completes the end-of-study questionnaire. The end of the study is defined as the last subject's completion of end of study questionnaire in the mobile application/portal.

Interim analyses are planned at 2-monthly intervals during the study to assess the efficacy and futility based on which the study will be stopped.

An independent Data and Safety Monitoring Board (DSMB) will be appointed to review the safety and primary endpoint data for efficacy/futility. Safety data pertaining to incidences of SARS-CoV-2/COVID-19 infections, hospitalizations, ICU admissions and deaths and interim analysis data will be provided to the DSMB, at 2-monthly intervals. The DSMB will provide their observations to the sponsor with recommendations as to whether there are safety concerns and whether the study should continue without change, be modified, or terminated. The DSMB recommendations will be carefully considered by the

sponsor. The final decision rests with the sponsor.	
STUDY ELIGIBILITY CRITERIA	
INCLUSION CRITERIA	Subjects are eligible to be included in the study only if all of the following criteria apply 1. Male or Female subjects ≥ 18 years of age at high-risk of SARS-CoV-2/COVID-19 infection Subjects with high-risk of infection to COVID-19 cases defined as: ● Health care workers (physicians, nurses, ward boys, paramedical staff) working in direct contact with COVID-19 patients ● Other high-risk subjects: o House-hold contacts* defined as a resident in the same dwelling as a confirmed case of COVID-19 o People currently residing or working in COVID-19 hotspots/outbreak areas with a history of contact* with suspected or confirmed case of SARS-CoV-2/COVID-19 infection * Definition of contact ● Face-to-face contact with a suspected/confirmed case (as applicable) within 1 meter and for more than 15 minutes ● Direct physical contact with a suspected/confirmed case (as applicable) ● Direct care for a patient with a confirmed COVID-19 disease without using proper personal protective equipment, OR, ● Other situations as indicated by local risk assessments Adapted from WHO Definition [**Error! Reference source not found.**] 2. Test negative for SARS-CoV-2 infection (RT-PCR test) at screening ● For House-hold contacts, the sampling should be performed 14 days after the last contact with the confirmed SARS-CoV-2 patient and the result should be negative. ● For HCWs and other high- risk subjects, the sampling can be done on the day of screening 3. Capable of giving informed consent
EXCLUSION CRITERIA	Subjects are excluded from the study if any of the following criteria apply 1. Previous history of Tuberculosis or known active Mycobacterium tuberculosis infection 2. Received BCG vaccine within one year prior to screening

	3. Fever (≥ 38 ºC/100.4°F) or any other respiratory symptoms/illnesses within the past 14 days 4. Pregnant or lactating women 5. Women of child-bearing potential not agreeing to use adequate contraception 6. Current active viral or bacterial infection 7. Expected vaccination during the study period, independently of the type of vaccination 8. Severely immunocompromised subjects. This exclusion category comprises a) subjects with known infection by the HIV; b) subjects with solid organ transplantation; c) subjects with bone marrow transplantation; d) subjects under chemotherapy/radiotherapy; e) subjects with primary immunodeficiency; g) treatment with any anticytokine therapies. h) treatment with oral or intravenous steroids defined as daily doses of 10mg prednisolone or equivalent for longer than 3 months from the time of screening, or probable use of oral or intravenous steroids in the following four weeks 9. Active solid or non-solid malignancy or lymphoma within the prior two years 10. Individuals known to be hypersensitive to any component of the vaccine 11. Eczema or other significant skin lesion or infection at the site/s of injection. 12. Any other medical condition which in the opinion of the investigator may affect the subject's safety or study participation and conduct
SAFETY ASSESSMENTS	Subjects will be observed for 20-minutes post vaccination for any hypersensitivity/ anaphylactic reactions. After this, data regarding documented SARS-CoV-2/COVID-19 infections, hospitalizations, any other AEs will be obtained via various short questionnaires configured in the mobile application/portal. The investigators will review the safety data and if required, may call the subject to obtain more details or may ask the subject to visit the site for further evaluation. All AEs and SAEs will be collected from the time of informed consent

	until the end of study. The investigator/designee will report all SAEs, irrespective of causality or expectedness to the sponsor, DCG(I) and ethics committee (IEC) within 24 hours of occurrence of the SAE.
SAMPLE SIZE	This is adaptive design based on Bayesian approach. Since sufficient data is not available for COVID-19 disease if assumptions change then sample size re-estimation can be done. For initial sample size calculation, we used Fisher's exact test for testing two independent proportion in terms of Relative Risk (RR) [Hazard ratio (HR) for cox proportional hazard model], considering following assumptions: RR under H_1 = 0.7 (30% reduction in incidence of laboratory confirmed SARS-CoV-2/COVID-19 infection observed in Other High-Risk Subjects / HCWs. Same assumption is used for two primary endpoints defined for each strata), Power = ~ 90% α = 0.0125 (one-sided, adjusted for two primary endpoints analyzed for strata: Other High-Risk Subjects) Allocation Ratio: VPM1002 group: Placebo group = 2:1 The study is separately powered in "Other High-Risk Subjects" and "HCWs" treating them as strata. ● Other High-Risk Subjects: Assumption - Percentage of "Other High Risk" Subjects in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 20% (same assumption is used for two primary endpoints) Thus, for stratum "Other High-Risk Subjects", the total sample size calculated is 2228 evaluable subjects, 1485 in VPM1002 group and 743 in Placebo group. Considering approximately 10% drop out rate we need to randomize 2478 subjects, 1652 in VPM1002 group and 826 in Placebo group. ● HCWs Assumption - Percentage of HCWs in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 15% (same assumption is used for two primary endpoints) Similarly, for stratum "HCWs" for the total sample size calculated is 3119 evaluable subjects, 2079 in VPM1002 group and 1040 in Placebo group. Considering approximately 10% drop out rate we need to randomize 3468 subjects, 2312 in VPM1002 group and 1156 in

	Placebo group. Thus, we require 5946 randomized subjects in two strata distributed in 2:1 ratio in two groups VPM1002 and Placebo.
STATISTICAL ANALYSIS	Data will be reported quantitatively. Efficacy analyses will be performed on FAS population using the intention-to-treat principle. Two primary endpoints for each strata are "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection" and "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator". These endpoints are treated as Time-to-event data. The endpoints represent incidence of first laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator. The events will be considered till time point when study is stopped due to decision rule of interim analysis or patient is discontinued due to any reason or followed up to maximum follow-up of 180 days (6 months follow-up). To analyze this endpoint hazard ratio (HR) is calculated and compared between VPM1002 vaccine group and Placebo group. Cox proportional hazards model will be used treating treatment groups as fixed effects and hospital, age, comorbidities, severity, time to recovery will be evaluated as covariates for including them in the model. Secondary endpoints related to severe disease outcomes in HCWs, Other high risk subjects, Elderly subjects (≥ 60 years) and subjects with co-morbidities measured in terms of incidence such as cumulative incidence of hospital admission due to documented SARS-CoV-2 infection, Cumulative incidence of ICU Admission due to documented SARS-CoV-2 infection, Cumulative incidence of death due to documented SARS-CoV-2 infection, Cumulative incidence of requirement of mechanical ventilation due to documented SARS-CoV-2 infection will be analyzed using cox proportional Hazard model. Secondary endpoints related to duration such as Duration of SARS-CoV-2/COVID-19 symptoms in HCWs and Other high-risk subjects will be analyzed by analysis of covariance using mixed model analysis. Continuous baseline characteristics will be reported as mean and

	standard deviation or median and inter-quartile range, as appropriate. Categorical baseline characteristics will be reported as count and percentage. No statistical testing for baseline characteristics will be performed. Safety data related to AE, SAE will be analyzed as frequency and % by System organ Class (SOC) and Preferred term (PT) Coded using MedDRA. The frequency and % will be provided for overall AEs, AEs by severity and relatedness.
INTERIM ANALYSIS	An interim analysis will be performed by the study statistician of the trial, once every 2 months. The results if available for futility or efficacy (with group level unblinding) will also be provided to the DSMB, once every 2 months along with safety data. In case of suggested futility or efficacy, the DSMB statistician may independently replicate the full data analysis before drawing conclusions. The Bayesian model used for primary endpoint yields a posterior distribution of the relative risk RR (hazard ratio (HR) of incidence rates). The posterior probability of the superiority hypothesis (RR < 1) will be calculated as well as the posterior probability of futility hypothesis (RR > 0.7). If during any of the interim analyses, the posterior probability of superiority is > 0.995 or the posterior probability of futility is > 0.99, a conclusion is reached, and the trial will be stopped. These posterior probability breakpoints have been chosen such that the type-1 error rate is <0.025 (similar to a two-sided alpha of 0.05) and the power of detecting superiority is > 90% if the true RR is 0.7.

SCHEDULE B
STUDY BUDGET AND PAYMENT SCHEDULE

No.	Budget Head	Unit	No. of Subjects	Unit Fees / Cost	Total
1	Investigator & Site Team Fees (Screening visit + vaccination)	Screening visit + vaccination	175	INR 6,500.00	INR 11,37,500.00
2	Investigator & Site Team Fees (Post screening visit data completion)	Post screening visit data completion	175	INR 4,700.00	INR 8,22,500.00
3	Investigator & Site Team Fees (End of study visit data completion)	End of study visit data completion	175	INR 2,000.00	INR 3,50,000.00
4	Transportation expenses for home visits (assumed average one per subject for High Risk Subject) *	Subject	100	INR 1,000.00	INR 1,00,000.00
5	Subject compensation (transportation expenses for site visits, if required) **	Subject			
	For Health care workers	04 visits (Per visit Rs. 500)	75	INR 2,000.00	INR 1,50,000.00
	For High Risk subjects	02 visits (per visit Rs. 500)	100	INR 1,000.00	INR 1,00,000.00
6	Advertisements, recruitment Related, Referrals expenses CRC marketing strategies, miscellaneous charges	Site	1	INR 10,000.00	INR 10000.00
7	Payment for screen failures ***	Screen failed subject**	18	INR 4,000.00	INR 72,000.00
8	Institutional overheads (applicable on Investigator & Site Team Fees and Payment for screen failures)	Percentage	25% on Sr. No.1,2,3		INR 5,77,500.00
9	Archival expenses	Site	1	INR 50,000.00	INR 50,000.00
	Total				**INR 33,69,500.00**

*	Transportation cost will be applicable for visits outside site i.e. for home visit of high risk subjects or in rare case Health Care workers as well
**	Average number of subjects estimated per site. Since recruitment will be competitive, the actual number per site may vary and even the proportion of Health Care worker and other High risk subjects may also vary accordingly subject compensation visits will also vary
***	Payment for screen failures refers to payment for the Investigator's and site team members' time towards activities conducted for screen-failed subjects. For each 10 eligible subjects, payment will be made for one screen failed-subject.
****	Cost of RT-PCR COVID test will be reimbursed.
*****	Expenses for medical care for related AEs and expenses related to treatment or compensation in case of related SAEs has not been included herein. These will be paid at actuals.
******	Personal Protective Equipment cost will be provided to the site.

In connection with the Study, Sponsor will pay in accordance with the terms set forth in the Budget (schedule B):

1. Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the Inclusion / Exclusion criteria. CRO/Sponsor retain the right, to be exercised at CRO's/Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. The Investigator /Institution shall complete and deliver the work to CRO/Sponsor (including any technical report and financial statement that may be required) by the date fixed in this Agreement or any additional period that may be granted by CRO/Sponsor. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

3. In full and complete consideration of Investigator's and Institution's participation in the Study and of their covenants and obligations hereunder, within the date agreed in the Agreement or any alternative that may be granted by the CRO/Sponsor (including submissions of technical report and financial statements that may be required under the Agreement), and to cover their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B. Said amount is based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Investigator to CRO/Sponsor or CRO's/Sponsor's designee and all queries have been resolved. The Parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

4. Institution agrees to apply all funds received from CRO, including all interest accrued on such funds, if any, toward the performance of the Study. Within the Study Budget as provided in Schedule B, Institution may adjust budget line item amounts as reasonably necessary for performance of this Agreement; provided, however, that such adjustments shall not exceed ten percent (10%) of any line item without the prior written approval of Sponsor. Without the prior written approval of Sponsor/CRO, the total payments to Institution shall not exceed the amounts set forth in the Study Budget.

5. If a subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by CRO completed case report forms for such Subjects have been accepted by CRO/Sponsor.

6. There is no payment for Subjects who are chart screened, but who do not have a informed consent as required by the regulation for the research project and do not complete any of the Screening Visit procedures.

7. All payment obligations are conditioned upon Institution's and Investigator's compliance with the standards identified in this Agreement. CRO will not make payments for or, if payment has been made, Institution/Investigator will repay to CRO any payments for Study visits, procedures, or other work associated with a Study subject if CRO/Sponsor determine that the Study visits, procedures or other work associated with the subject was not conducted by Investigator, sub investigator or Study Staff in compliance with the Protocol, applicable law or regulation, or ICH/ GCP Guidelines.

8. Investigator and Institution are responsible for all applicable direct taxes including but not limited to State, Central and municipal taxes presently or hereafter imposed upon any and all such amounts, including but not limited to professional and incomes taxes, Wealth Tax, Transaction tax. However CRO agrees to pay any indirect tax that may be introduced by any local, state, Central Government / authority including but not limited to service tax, excise, Goods and service tax (GST) based on the revenue and /or out of pocket expenses that are paid/payable by CRO to the Investigator/Institution under this agreement.

9. The payments represent all Study costs, and no other money will be payable by CRO.

10. Payments (Investigator Grant, Institutional overheads and Patient Compensation) will be made on monthly basis for the amount proportional to the no. of subject visits completed in the preceding month. Site should submit the invoice for the completed subject visit at the end of each month. Sponsor/ designee will arrange to remit the funds to site within 45 days of receipt of correct invoice from the site. If for any reason, site is unable to randomize even one patient in the study, the advance payment(if applicable) will be returned to the Sponsor/ designee within a reasonable period (not exceeding 30 calendar days) on receipt of written communication from Sponsor/ designee to refund this amount.

11. Monthly invoices will be cleared by the Sponsor/ designee within 45 days of submission irrespective of the data being source verified by the monitors. However, site needs to ensure that source data is updated real time and electronic Case Report Form is filled within 05 working days of subject visit. While clearing the invoices at Sponsor/ designee end, in-house monitors will remotely review the compliance to the data entered vs. actual patient visit in the period of invoicing

12. Payment will be pro-rata based on the actual no. of visits completed by the subject.

13. Screen failures would be paid at 4000 INR per subject. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 10% of randomized subjects at site.

14. Reimbursement for any investigation performed for safety evaluation will be on actuals on submission of bills.

<u>Other Terms and conditions:</u>

1. Investigator acknowledges that the Study is a multicenter study and the recruitment for this Study will be through competitive enrolment, and investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study

will be restricted pursuant to the Protocol based on the inclusion / exclusion criteria. CRO / Sponsor retain the right, to be exercised at Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. Payment for drop outs or early terminated subjects would be pro-rated depending on the number of completed study visits. Invoice for completed visit will be raised at the end of each month.

3. If the payment towards the Institutional grant and subject compensation is paid to the investigator/institute directly by DiagnoSearch then it will be sole responsibility of the investigator/institute to pay the same to the concerned parties / individual (as applicable)

PAYMENT INSTRUCTIONS

1. All payments except subject compensation will be released after deduction of applicable taxes.

2. Payments will be made through cheque / bank transfer as per the payee details provided below.

Beneficiary Name	MGM Medical college ,Aurangabad
Bank Name:	IDBI bank
Bank Address	Adalat Road Branch, Survey No.20292,Ratnaprabha Building Kesarsinghpura Opp.LIC Bld.Aurangabad
Branch	Adalat Road Branch
Beneficiary Account No.	0376104000000107
TAX ID NUMBER (PAN)	AAATM4256E
IFSC Code	IBKL0000376

Annexure 9

औरंगाबाद महानगरपालिका औरंगाबाद

दुरध्वनी क्र.२३३३५३६-४०, २३४८००१-०५ फॅक्स क्र. (०२४०) २३३१२१३

जा.क्र.मनपा/आस्था-१/२०२०/४३०. दिनांक :- ०८/०५/२०२०.

आदेश:-

औरंगाबाद शहरात कोव्हीड-१९ या विषाणुचा प्रार्दुभाव मोठया प्रमाणावर होत आहे. तसेच दिनांक १७ मे, २०२० नंतर लॉकडाऊन उठविल्यानंतर मोठया प्रमाणात लागण होण्याची शक्यता आहे. ही शक्यता विचारात घेऊन, महानगरपालिकेमार्फत ३००० रुग्णांकरीता कोव्हीड केअर सेंटर(CCC) तयार करण्यात आले आहे. त्यापैकी सध्या ०७ केंद्र Active झालेले आहेत व उर्वरीत कोव्हीड केअर सेंटर आवश्यकतेनुसार Active होतील. तथापि कोव्हीड केअर सेंटर येथे प्रशासकीय मनुष्यबळ,तांत्रिक मनुष्यबळ,तज्ञ मनुष्यबळ तसेच या कोव्हीड केअर सेंटर येथे लागणारे मुळ इन्फ्रास्ट्रक्चर व वैद्यकीय सुविधा या बाबी प्रोटोकॉल नुसार होणे आवश्यक आहे. याबाबत सविस्तर अहवाल व सूचना होणे आवश्यक आहे. याकरीता खालीलप्रमाणे टास्क फोर्सची स्थापना करण्यात येत आहे.

अ.क्र.	समिती सदस्यांचे नांव व पदनाम	
१)	डॉ.कानन येळीकर, अधिष्ठाता, शासकीय वैद्यकीय महाविद्यालय, औरंगाबाद	अध्यक्ष
२)	डॉ.सुंदर कुलकर्णी, जिल्हा शल्य चिकित्सक, सामान्य रुग्णालय, चिकलठाणा, औरंगाबाद	सदस्य
३)	डॉ.प्रविण सुर्यवंशी,एम.जी.एम.हॉस्पीटल	सदस्य
४)	डॉ.हिमांशु गुप्ता,धुत हॉस्पीटल	सदस्य
५)	डॉ.तुपकरी, हेडगेवार हॉस्पीटल	सदस्य
६)	डॉ.आलोक श्रीवास्तव,कमलनयन बजाज हॉस्पीटल	सदस्य
७)	डॉ.संतोष रंजलकर, अध्यक्ष,आय.एम.ए.	सदस्य
८)	डॉ.संजय पटणे,अध्यक्ष,फिजीशिअन असोसिएशन	सदस्य
९)	डॉ.अभिजित चपळगांवकर,अध्यक्ष,डेंटल असोसिएशन	सदस्य
१०)	डॉ.निता पाडळकर, आरोग्य वैद्यकीय अधिकारी, महानगरपालिका औरंगाबाद	सदस्य सचिव

वरील टास्क फोर्सने अभ्यास करुन महानगरपालिकेचे कोव्हीड केअर सेंटरवर प्रोटोकॉलप्रमाणे आवश्यक मनुष्यबळ, फिजिशिअन, एम.बी.बी.एस., बी.ए.एम.एस./ बी.एच.एम.एस., नर्सेस, टेक्निशिअन्स, वॉर्ड बॉय इ. आवश्यक इन्फ्रास्ट्रक्चर(पीपीई किट, ऑक्सीजन सिलींडर, व्हेंटीलेटर, other related infrastructure) मेडीसिन्स रिक्वायरमेंट तसेच प्रत्येक मनुष्यबळाची कामाची जबाबदारी, रुग्ण दाखल झाल्यापासून ते गरज भासल्यास रुग्ण स्थलांतर करण्याची जबाबदारी यासह या कोव्हीड केअर सेंटरमध्ये नियुक्त प्रत्येक व्यक्तीची कामाची जबाबदारी, कामाच्या वेळा यासह सविस्तर अहवाल तयार करुन तीन दिवसांत सादर करावा. त्यानुसार महानगरपालिकेचे हे कोव्हीड केअर सेंटर लवकर कार्यान्वित करणेबाबतचे काम सुरु करता येईल.

(आस्तिक कुमार पाण्डेय)
भा.प्र.से.
प्रशासक
महानगरपालिका,औरंगाबाद.

प्रत :-

१) मा.विभागीय आयुक्त,औरंगाबाद यांना माहितीस्तव सादर.
२) जिल्हाधिकारी,औरंगाबाद.
३) सर्व समिती सदस्य
४) शहर अभियंता,महानगरपालिका औरंगाबाद
५) आरोग्य वैद्यकीय अधिकारी,महानगरपालिका औरंगाबाद
६) आदेश संचिका