IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

PUBLIC INTEREST LITIGATION ST NO. 9885 OF 2021

MR. NILESH MOHANDAS NAVALAKHA …PETITIONER

V/s.

1. UNION OF INDIA & 5 ANR …RESPONDENTS

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Dated: 23.06.2021

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BRIEF SUGGESTIONS/SUBMISSIONS OF MR. RAJESH INAMDAR, ADVOCATE ON BEHALF OF THE PETITIONER

1. This Hon'ble Court is seized of issues pertaining to Covid Mismanagement in the State of Maharashtra more particularly the Districts falling under the jurisdiction of the Principal Bench. Similarly, the benches at judicature at Nagpur and Aurangabad also have been hearing matters.

2. It is submitted during the second wave of Covid-19 infections, which has devastated patients and families across the State, it is for this Hon'ble Court's timely intervention, monitoring, and a series of orders passed into the realm of Covid management ensured the supply of oxygen to hospitals and availability of antiviral drugs for Covid-19 patients and ease the pain of the Citizens to a larger extent.

3. There is no gainsaying that the global break out of the pandemic of COVID 19, the normalcy in the entire world is affected and several restrictions in form of Lockdown were imposed to contain the spread of the deadly virus as a result of this curtailment, people at large have come to face several inconveniences and grievances several of which are in the nature of emergencies. It may not be incorrect to state that the "Covid Mismanagement" in the State was adapted and transfigured into "*Covid Management*" only by virtue of the intervention of this Hon'ble Court and a series of orders passed therein in the Public Interest Litigations. It is submitted several issues raised by the Petitioner has been graciously addressed and considered by the Hon'ble Court and several directions in this regard have been issued to the Respondents.

4. That, we've already weathered two (2) Covid-19 waves which have hit us like rabid tsunamis, devouring many of our near and dear ones who departed well before time, including countless of our fraternity – both from the Bar and the Bench. That, every moment as the clock ticks, we inch closer to the third Covid wave, which is almost at its horizon and may well be deadlier and more baneful than the past two waves, which passed us by, not without taking away a good slice of our collective lives. It was reported that Japan has currently been hit by a fourth (4th) Covid wave, leading to a spike in the number of infections and deaths.[1] Several countries around the globe, including China, US, etc. have already undergone a fourth Covid wave and have braced themselves for a fifth (5th) Covid wave, which may just be right around the corner.

5. That, our country has already seen two lethal Covid waves and as per top Government scientists and experts, a third wave, even deadlier and more terrifying than the second one[2] , is "inevitable."[3]. All India Institute Of Medical Science (AIIMS) director Randeep Guleria warned against the third wave of coronavirus disease (Covid-19) and said that it can strike the country in the next six to eight weeks [4]

6. The State of Maharashtra has after over two months has eased restrictions by lifting the lockdown which was imposed in April 2021. In the light of the fact that there may be incoming Covid waves, dark and silent like unknown assassins, that may besiege our country, including the State of Maharashtra, any and when they strike, they will fall like thunderbolts. We cannot afford the unsolicited torment of any more causalities or putting our health, safety, and well-being in jeopardy.

7. During the First and Second wave, it is/was noticed that citizens, especially in cases of emergency, have been running from pillar to post for redressal of basic grievances. The situation has arisen as a result of inadequate publicity by the State Government regarding the jurisdictional/ward officers appointed for quick and immediate resolution of the problems of citizens. People are finding it difficult to contact their respective

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[1] https://www.newsbytesapp.com/news/world/japan-s-fourth-covid-19-wave-more-deaths-at-home/story

[2] https://www.thesun.co.uk/news/14870590/india-third-covid-wave-mutant-variants-fuel-crisis/

[3] https://indianexpress.com/article/coronavirus/india-coronavirus-pandemic-third-wave-hospitals-oxygen-shortage-7303234/

[4] https://www.hindustantimes.com/india-news/covid19-third-wave-to-hit-india-in-next-6-8-weeks-aiims-director-randeep-guleria-101624101413209.html

jurisdictional/ward officers such as health officers, Nodal officers, etc. As a consequence, citizens are left in the lurch leading to widespread frustration and helplessness.

8. The undersigned counsels for the Petitioner in the aforementioned Public Interest Litigation enumerate following ***SUGGESTIONS*** to be taken into account and considered by this Hon'ble Court on ancillary issues while adjudicating the larger issues which will help the citizenry to the larger extent during impending "**Third wave**" or otherwise by issuing proper directions to the Respondents:.

I. ORDERS OF THIS HON'BLE COURT TO BE UPLOADED ON THE GOVERNMENTS WEBSITE FOR EASY ACCESS TO PUBLIC.

i. The orders/directions passed by this Hon'ble Court and other co-ordinate benches pertaining to Covid or any other Public Interest causes affecting the populace at large are available on the website of Hon'ble High Court itself, but it is also quite possible that layman may find it difficult to access the website of Hon'ble High Court and the orders passed by this Hon'ble benefitting the public at large may not reach the public due to lack of publicity or otherwise. Hence, the orders passed by Hon'ble Courts pertaining to Covid – 19 or any other Public cause maybe uploaded on the official website of District Collectors, Municipal Corporations, Zilla Parishads etc so that the public at large can have easy access to such orders and implementation of the orders passed by the Courts, by the authorities concerned will be effective. The orders may also be translated in Marathi language so that a larger population (non-English speaking) will be well aware about the judicial orders and directions issued by the Hon'ble High Court in matters pertaining to the larger public interest and the said orders be also given wide publicity

II. MECHANISM TO TAKE BACK UNUSED ESSENTIAL MEDICINES FROM THE PATIENTS.

ii. The State Food and Drug Control Administration (FDCA) and the State may consider issuing directives to the Hospitals, Nodal officers, and the pharmacies to take back the unused essential medicines from such patients or families who were prescribed lifesaving drugs but were unutilized for some or another reason, the said medicines can be of use for other needy patients amid shortage of Covid medicine. There are cases wherein the patient succumbed to Covid or recovered and the family had unused medicine prescribed to the patient with valid bills,

such families could not return the said medicines either to the pharmacy, pharmacy or to the Nodal officers in the absence of any such directives or policies of the FDA. It is submitted that such unused medicines are wasted despite facing a shortage of medicines. Further, the money returned from the unused medicines can be of use for the families since the said medicines are costly. If the batch number or the expiry date is intact from cut strips there must be provision for accepting the unused medicines, so that the scarcity of such medicines can be adverted to up to the certain extent.

iii. It is imperative that considering the hardship faced by several citizens the State and Union may evolve a mechanism for the disposal of expired and unused drugs which does not exist at the moment. It is pertinent to bring to the attention of this Hon'ble Court that the guidelines by the American Society of Anesthesiologists (ASA), recommends not to discard unused and unopened medications, especially those in short supply, without considering options for isolation, disinfection, and segregation of medicines. In this regard Joint Statement by the American Society of Anesthesiologists® and American Society of Health-System Pharmacists is annexed hereto and marked as "**ANNEXURE A**"

III. RESTRICTING PUBLIC EVENTS BY PUBLIC FIGURES/POLITICIANS TO MINIMIZE OVERCROWDING AND ISSUE SEPARATE GUIDELINES.

iv. It is pertinent to bring to attention of this Hon'ble Court the immediate instances of mass crowd gathering during the lockdown and during the current unlock phase. That various political parties started organizing public functions/events/funerals which resulted in congregation of large number of people. In one of the inauguration events held in Pune on 19.06.2021[5] witnessed massive crowd amid Covid-19[6] pandemic, there was no social distancing maintained and a several people were not even wearing masks. Although the organizer of the event has been booked by the police under IPC and Disaster Management Act, however arrest of persons wills not the damage control and

[5] https://indianexpress.com/article/cities/pune/case-against-ncp-leaders-after-massive-crowd-gathers-at-pune-ncp-office-inauguration-attended-by-ajit-pawar-7367555/

[6] https://www.punekarnews.in/pune-covid-rules-violated-at-inauguration-of-ncp-office-by-ajit-pawar/

similar other such events were organized in different places by political parties. Similarly, the funeral of a politician was attended by over 20,000/- people including several politicians during the lockdown, a Politian in Pune hosted pre-wedding ceremony of her daughter attended by several people flouting the guidelines are some glaring examples of scant regards shown by the Politicians, public personalities and the State to the Covid-19 guidelines and protocols.

v. There is no gainsaying that Mass gathering (MG) events pose considerable public health challenges to health authorities and governments and a congregation of people in religious, political, and sports events to name a few have been the source of infectious diseases that have spread globally. Considering the present situation as well as the unavoidable "Third Wave" which is expected in coming months, certain restrictions and guidelines are being required with immediate effect to minimize the disaster and irreparable loss which will be caused by "Third Wave" of pandemic.

vi. Though the Central and State governments have clearly stated that not more than 50 people should attend a marriage and not more than 20 people should attend a funeral. It was witnessed that despite the directions the political leaders continued to attend public programs, be it marriages, funerals or inaugural ceremonies that too with scores of their followers, flouting all norms. Even the officials concerned, who were strict with lockdown norms with common men, however, continued to turn a blind eye to political leaders. If the political leaders or public figures attend the public events then party cadre and public would throng the event in large numbers and such events will then become the super spreader events which will not be good for the State since Maharashtra has always been the Centre of Covid-19 with the highest number of cases. **The Aurangabad bench of this Hon'ble Court has taken exception to a minister attending the public event during pandemic more particularly during the lockdown and directed that no leader or minister should conduct physical ceremonies or functions.** The State ought not to become complacent with lockdown restrictions eased and number of Covid cases gone down and it is imperative that all the public events more particularly political rallies, political functions, religious and sports congregation be restricted and **be conducted on virtually as far as possible which will help in avoiding overcrowding and flouting of social distancing norms**. In this

regard, the WHO has issued interim guidelines on 14.02.2020 "Key planning recommendations for Mass Gatherings in the context of the current COVID-19 outbreak" and World Health Assembly's endorsement on Dec 22, 2011, of the 130th Executive Board Decision "Global mass gatherings: implications and opportunities for global health security" which may be referred which is annexed as "**ANNEXURE B**".

vii. It is pertinent to highlight the courage and discipline of Norway wherein the Prime Minister of Norway was fined Rs 1.75 Lakh by police for breaking Covid-19 Rules to celebrate her birthday. **The two-term prime minister had to apologize for organizing an event to celebrate her birthday with 13 family members, despite a government ban on events attended by more than 10 people**.[7] The public cannot be solely held accountable for spread of virus if the State machinery and its prominent leaders or representatives becomes complacent and aids and facilitates larger public events attended by the politicians or public figures. The authorities may also be directed to ensure that the directions of the Centre, State and this Hon'ble Court be implemented uniformly without any discrimination.

viii. Hence it is necessary that this Hon'ble Court may consider deem fit to frame such additional guidelines to regulate holding of rallies, functions, events and funerals of the public figures/politicians/celebrities and fasten serious accountability on the authority who fails to regulate the said guidelines taking into account the pandemic situation which may last for several more months or years.

IV. LOCAL BODY POLLS

ix. The Maharashtra State Election Commission has announced that districts Nagpur, Dhulia, Nandurbar, Washim and Akola will go for local body polls on 19.07.2021 and counting on 20.07.2021.[8] It may be pertinent to quote the German philosopher Georg Hegel famously said, "**The only thing that we learn from history is that we learn nothing from history**". The recently held assembly elections of five states Assam, Kerala, Puducherry, Tamil Nadu and

[7] https://timesofindia.indiatimes.com/world/europe/norwegian-police-fines-pm-for-violating-covid-rules/articleshow/81985775.cms
[8] https://mahasecnews.blogspot.com/2021/06/blog-post.html

West Bengal is considered to be one of the reasons for surge in covid cases contributing to the devastating Second Wave which was also termed as Covid Tsunami. The State of UP which held panchyat elections recently reported over 1621 teachers and support staff to have died from COVID-19 following poll duty and the elections have become super spreader events. The **Hon'ble Allahabad High Court had observed that the Election Commission, the higher courts and the government failed to fathom the disastrous consequences of permitting the elections in few States and the Panchayat elections in Uttar Pradesh**.

x. In view of the above, it is suggested that, priority to public health over elections must be given and it would be against the public interest to hold any kind of elections in the State without ensuring and assessing the ground situation including the minute details of number of Covid cases and preparedness of the State taking into account the warnings issued by the experts about the onset of Third wave.

xi. The State Election Commission ought to take strict steps to develop any mechanism, ban or restrict the traditional way of campaigning to ensure that there is no aggregation of crowd during rallies if any considering the health emergency in the Country and also considering the past record of Covid cases in the State and this Hon'ble Court may call for report in this regard from the State and the State Election Commission to ascertain states preparedness to go for polls to circumvent any possibility of turning the festival of democracy to festival of " fatalities"

V. CONTRACT TRACING AND TESTING.

xii. **As per the latest reports[9] there have been over 21 cases of Delta Plus Variant the mutant version of the Delta variant that unleashed the devastating second wave of the pandemic, have been found in Maharashtra**. It is reported that out of 21 cases, nine were found in Ratnagiri, seven in Jalgaon, two in Mumbai and one each in Palghar, Sindhudurg and Thane. Hence, it may become cause of concern to the State if immediate steps to analyze information

[9] https://indianexpress.com/article/cities/mumbai/21-cases-of-delta-plus-variant-detected-in-state-maharashtra-health-minister-tope-7369637/

like travel history, vaccination status, whether they have been re-infected and if they got infected despite vaccination, to know more about the Delta Plus mutant. It is submitted that **experts have issued warning that Delta Plus can become a variant of concern if anti-Covid rules are ignored**. The WHO has said that this is a variant of interest[10], but it could become a variant of concern[11]. Report of WHO is annexed hereto and marked as "**ANNEXURE C**".

xiii. The number of COVID cases in the State may have been decreased however taking into consideration the probable Third Wave the State ought to trace the contacts, quarantine such contacts and test them and treat them. 'Test, track and treat' has been the mantra of health agencies across the world, including the World Health Organization. The Hon'ble High Court of Gujarat while hearing its *suo moto* **PIL on Covid-19 management in R/WRIT PETITION (PIL) NO. 53 of 2021** has directed the State Government to adopt the **'3T Model'** to curb the outbreak and to devise a preventive action plan. The State has been advised to vigorously follow "Testing", "Tracing" and Treatment' strategy

xiv. It is necessary that the State of Maharashtra also adopts such strategy to curb the onset of Third Wave.

VI. IDENTIFY FAMILIES WHO NEED ASSISTANCE IN FORM OF FOOD GRAINS, OTHER MATERIALS IN SLUM AREAS OR OTHER VULNERABLE SECTIONS DUE TO COVID UNDER FOOD SECURITY ACT

xv. The first wave of pandemic citizens of the country have been suffering through traumas and severe distress, unplanned lockdowns and deaths of their beloved one's have put such an impact to their livelihood is unthinkable, there are uncontainable stories that have come into notice of the undersigned. Since last year's April 2020, till this year June 2021, the lower Strata of the Society have suffered immensely due to job loss, the migrant workers in urban city who used to work as maids, rag pickers, auto-rickshaw pullers, daily wage workers and many others who were on skill based jobs had to see the worst case scenarios of their life. From asking for food from the privileged class to trying to get loans on mortgage people just wanted to ensure the hand to mouth situation gets settled.

[10] https://www.dailypioneer.com/2021/india/new-delta-plus-variant-could-become-a-variant-of-concern--aiims-chief.html

[11] https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/

xvi. The undersigned is in contact and is closely working with several NGO's and Social workers who have been helping the people from lower strata's with food and other basic groceries and medications. Social workers have observed numerous cases since day 1 of the pandemic people have come forward to help other people, there were several requests by under privileged families for dry ration made by their representative of their area of residence, those volunteers then crowd funded the money on Social media & provided relief to those families, it happened across the country and majorly in cities like Mumbai and Pune where majority of migrant labor class resides.

xvii. The crowded slums of Mumbai were hugely affected, people living in Ghettos had faced the toughest time in this pandemic having job loss and residing in a small 10*10 room with 8 members in a single family, where social distance was a myth, the idea was just to survive as much they could and the inquest to get food for the family member's.

xviii. The chain of volunteers and non-government organizations on ground and the people online who crowd funded all these events have helped such families to survive. The State had also announced several schemes and measures to help the needy however the help does not seem to have either reached or has not reached on time to the needy. The families which didn't had ration card had to run Pillar to Post to procure rations and in such harsh conditions the social workers aided this families, there are numerous SOS requests which were fulfilled by NGO's and volunteers across the cities.

xix. The State had announced that they would provide free rations to under privileged families in the state, but people of Maharashtra majorly from the cities of Mumbai, Pune and Kolhapur were/are striving for dry rations for their families. In some cases when the help was sought from the NGO's, they could not extend the help since they have also exhausted their funds hence this families aren't able to get the dry rations, so many organizations are working on ground and providing free meals through community kitchen and now due to lack of funds NGOs had to stop the relief work.

xx. EXA Education foundation through their online crowd funded campaign started Project Nivala which provided cooked meals and dry rations to the families of beggaries, rag-pickers, auto rickshaw pullers, maids and daily wage workers, however they received a request of 200 families requiring rations from Dharavi and Govandi area couldn't be fulfilled because of their own limitations. The aforesaid NGO also tried to extend help to them through other NGO's however couldn't succeed. The aforesaid NGO has identified about 200 such families in Dharavi and Govandi areas who are in dire and immediate need of food and the undersigned beseeches this Hon'ble Court to direct the State to look into the needs of people and extend support to such families after due verification at their end and provide essential food to this families. The NGO has verified their Aadhar, contact and family income at its level however State may re-verify, scrutinize in a better way and immediately provide such families with food.

xxi. It is hence necessary and imperative to protect the lives and livelihood of people the distribution of food supplies, food security_allowance etc be ensured as mandated under the **National Food Security Act** after identifying such families and State's help reaches every such person and no person is deprived of food.

xxii. This Hon'ble Court may consider directing Secretary, Maharashtra State Legal Services Authority or the authority under the Disaster Management act to deploy its Volunteers to the slum areas and the areas where sections of marginalized families and other such families can be identified with help of the NGO's (**EXA Education Foundation, Mumbai[12], Ummat Un Nisa cares foundation[13], and /or any ther NGO**) who needs assistance in form of food grains and other materials in this period of COVID-19 pandemic.

VII. ORDERS/ DIRECTIONS/ SOP OF THE STATE GOVERNMENT AND ADMINISTRATION /AUTHORITIES BE PUBLISHED IN ENGLISH ALSO.

[12] Exa Education Foundation, Reg no :- U80904MH2020NPL345989 Founder Director – Advocate Saif Alam Contact – 9967862415 Address – Exa education foundation, Shop No 2, Pailipada Trombay Mumbai 400088. Twitter Link: https://twitter.com/exaedufoundatio?s=08,
News article link: https://www.freepressjournal.in/mumbai/angels-of-mumbai-how-a-26-year-old-youngster-is-saving-the-city-from-toxic-waste.

[13] Ummat Un Nisa cares foundation, Founder – Fatima zohra , Contact - 8779445007 Address – Vikhroli Mumbai, Twitter link : https://twitter.com/UmmatunnisaCare?s=08

xxiii. That most of the orders /directions issued by the State / office of Collectors/ District Collectors/ Municipal Corporations are published solely in Marathi language which makes it difficult for other citizens particularly outsiders who are not well versed with Marathi language and the purpose of issuing orders/directions gets defeated as citizens are unable to understand the language, hence they remain unaware about such orders/directions. **That it is highly advisable if all the orders/directions are published in dual language i.e. in English & Marathi** which will effectively assist the citizens to understand and to adhere the same and the purpose for publishing such orders/directions will be benefited at large.

xxiv. Any decision/directions/SOP/Guidelines issued by respective authorities may be published on official website of Municipal Corporation in English as well as Marathi language so that it is swiftly conveyed to its citizens at large.

VIII. **APPOINTMENT OF COUNSELOR'S/PROS AT EVERY HOSPITAL'S.**

xxv. Appoint counselor/PRO/Social Workers at every hospital to help the patients/persons in need by co-coordinating with different departments like PMC, Police, Labs, referring hospitals etc so as to circumvent the notion of uncertainty, chaos, stress and agony.

IX. WIDE PUBLICITY OF NUMBERS/CONTACT DETAILS OF NODAL OFFICERS

xxvi. Giving wide publicity regarding district wise nodal authorities/ward officers including health officials and their contact information. This ought to have been done to ensure that these officers meant for grievance redressal are accessible to each and every citizen in all districts of the State. The numbers of the Nodal officers be published/displayed at prominent places in the hospitals as well as the websites/portals.

xxvii. State Government to give wide publicity to the various methods provided for grievance redressal mechanism. The exercise must be undertaken in the manner and through such medium that would ensure that the information is accessible to every citizen. The object is that large number of citizens can take benefit of this.

xxviii. State is duty bound to cause the least possible inconvenience to the citizens and the publication of basic information such as officers-in-charge of administration

in the district/local area in Marathi and English language will go a long away in achieving the said objective.

xxix. The State create kiosk or help desks at prominent places or near to the police stations/chowkies, chowks ect so that people specially from the rural areas do not find it difficult to get immediate medical help from the State during critical times. The aforesaid information may also be circulated by way of SMS, hoardings, advertisement on cable network as far as Cities are concerned and the in Rural areas the aforesaid information be apart from the above also be circulated through the Zilla panchyat offices and through beat of drums and announcements.

xxx. In urban areas although such information may be available on the website of the respective departments, it may not cater to the public at large since the entire population may not have proper means to access such information and may not be technologically equipped, therefore a person may have to visit multiple websites of different departments to seek necessary information. Moreover, collating all such information and publishing the same on one user friendly separate platform/website will help the citizens and not cause inconvenience and distress to the people to look for the information at different places by visiting the website of different departments along with making such a piece of information available to the citizens by way of publication in newspapers, common directory area-specific, boards/hoardings etc in English, Marathi and Hindi language. This will not cause the Government to incur any huge expenditure.

X. USE OF EMAIL AND SOCIAL MEDIA PLATFORM FOR REDRESSAL OF MINOR GRIEVANCES.

xxxi. The Government authorities/departments may endeavor to use email and social media platforms such as Facebook, WhatsApp and twitter to a larger extent to provide service, resolve minor grievances and/or queries of the citizens which will not only prevent the departments/authorities from overcrowding but will also support the Government in utilizing its manpower in productive work. That every department must develop a proper e-grievance cell/mechanism to resolve at least minor disputes/grievances of people with the help of technology. The fully operational and functional email ids/WhatsApp numbers and social media

handles of each department may be created and published for benefit of public at large.

9. The undersigned would like to appreciate the sacrifice of all the doctors and frontline warriors who have sacrificed their lives and succumbed to COVID 19 in the line of duty. Over 730 doctor's some as young as 27 years, 116 nurses and 199 healthcare workers have died due to COVID-19. As per the list published by the Indian Medical Association the State of **Maharashtra has lost about 23 doctors, similarly over 100 police personnel's have succumbed to Covid-19[14] including several journalists** and other frontline workers and the State may in its own discretion and wisdom consider aptly compensating their sacrifices and recognize their sacrifices.

10. The undersigned also seeks liberty to appreciate efforts of such group of volunteers, NGO's and public spirited persons who formed their own task force and worked tirelessly with all dedication and sincerity in order to safeguard the precious life of its citizen during pandemic, these NGO's and Social workers ensured that the help reached such patients wherein States arms failed to reach them. The State may consider identifying such volunteers and individuals who have selflessly come forward to help the community and assist the State and performed their fundamental duties embedded under Article 51 of the Constitution, such certification if any will not only act as reward but will also encourage many such individuals to come forward to help the citizens during such distressing times.

AND FOR THIS ACT OF KINDNESS THE UNDERSIGNED SHALL BE DUTY BOUND EVER PRAY.

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[14] https://timesofindia.indiatimes.com/city/aurangabad/over-100-cops-succumbed-to-covid-in-two-months/articleshow/83286424.cms

April 22, 2020

Minimizing Medication Waste during the Coronavirus-19 Global Pandemic

Joint Statement by the American Society of Anesthesiologists® and American Society of Health-System Pharmacists

The surge in COVID-19 patients requiring acute medical care has resulted in shortages of some medications critical to their care. Institutions must balance the preservation of scarce resources with the risk of exposure from possible sources of contamination. In some cases, this may include deciding whether to discard unused and unopened medications that might be contaminated with the SARS-CoV-2 virus to prevent spread of the infection to patients and healthcare workers. These decisions are even more critical given the nationwide shortage of medications needed for intubation and mechanical ventilation of COVID-19 patients. Wasting medications in critically short supply should be avoided unless absolutely necessary. Without preferred agents, practitioners may be required to use medications with which they are unfamiliar, that are less effective, or that have more side effects, thereby introducing patient safety risks. The following statements summarize our joint recommendations for minimizing medication waste during COVID-19:

- **Infection Prevention and Control -** Do not discard unused and unopened medications, especially those in short supply, without considering options for isolation, disinfection, and segregation. Protect medications from contamination by keeping them out of patient rooms unless necessary. When possible, place medications in zip-lip baggies to protect them from contamination until the point of use. Unused medications that have been exposed to SARS-CoV-2 may be decontaminated with an EPA-registered disinfectant that is qualified under the viral pathogens program using appropriate dwell times, or they may be segregated from unaffected inventory until sufficient time has passed to deem them decontaminated.[1,2]
- **Medication storage policies** - Our organizations also support other means of waste prevention for medications critical to the treatment of COVID-19 patients. We advocate for the use of primary literature to support extended dating beyond the list in FDA-approved manufacturer labeling. Regulators should adopt policies that allow the use of evidence-based stability data to prevent waste of medications.
- **Beyond-use dating and compounding medications –** The United States Pharmacopeia Compounding Expert Committee developed a resource with considerations for sterile compounding and beyond-use dates to prevent the waste of drugs in short supply.[3] These considerations include longer storage times at room temperature than the currently official version of Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Hospitals should review these considerations and consider how they may be applied to prevent waste of compounded preparations of drugs in shortage during the COVID-19 pandemic. In addition, the FDA has issued guidance that during the COVID-19 public health emergency, outsourcing facilities and pharmacy compounders not registered as outsourcing facilities have flexibilities to compound several needed drugs if the drugs are in shortage and will be used to treat hospitalized patients with COVID-19.[4,5]

Wasting of medications during this time of increased demand and supply chain disruption due to COVID-19 must be minimized. These recommendations outline strategies for stewarding critically important medications.

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5. Food and Drug Administration. Temporary policy for compounding certain drugs for hospitalized patients by pharmacy compounders not registered as outsourcing facilities during the COVID-19 public health emergency. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-compounding-certain-drugs-hospitalized-patients-pharmacy-compounders-not-registered. Accessed April 21, 2020.

Additional Resources:

ASHP Drug Shortages Database

ASHP Guidelines on Managing Drug Product Shortages

FDA Drug Shortages Database

About ASA: Founded in 1905, the American Society of Anesthesiologists (ASA) is an educational, research and scientific society with more than 54,000 members organized to raise and maintain the standards of the medical practice of anesthesiology. ASA is committed to ensuring physician anesthesiologists evaluate and supervise the medical care of patients before, during and after surgery to provide the highest quality and safest care every patient deserves. For more information on the field of anesthesiology, visit the American Society of Anesthesiologists online at asahq.org.

About ASHP (American Society of Health-System Pharmacists): ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's over 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. Visit ASHP online at ashp.org. Access our COVID-19 Resource Center at https://www.ashp.org/COVID-19.

 Annexure B

Key planning recommendations for Mass Gatherings in the context of the current COVID-19 outbreak

Interim Guidance

14 February 2020

World Health Organization

1 Introduction

Mass gatherings are highly visible events with the potential for serious public health consequences if they are not planned and managed carefully. There is ample evidence that mass gatherings can amplify the spread of infectious diseases. The transmission of respiratory infections, including influenza, has been frequently associated with mass gatherings.[1] Such infections can be transmitted during a mass gathering, during transit to and from the event, and in participants' home communities upon their return.

The purpose of this document is to outline key planning considerations for the organizers of mass gatherings in the context of the novel coronavirus (COVID-19) outbreak. It should be read in conjunction with WHO's *Public health for mass gatherings: key considerations*,[2] which provides general advice on the public health aspects of mass events. It is also adapted from the interim planning considerations that were previously released by WHO addressing mass gatherings in the context of pandemic (H1N1) 2009 influenza and guidance for international meetings attended by individuals from countries affected by Ebola virus.[3,4] Updated technical guidance on the COVID-19 disease outbreak should also be consulted (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance).

2 General information about the COVID-19 virus

Coronaviruses are a large family of viruses found both in animals and humans. Some infect people and are known to cause illness ranging from the common cold to more severe diseases, such as Middle East respiratory syndrome (known as MERS) and severe acute respiratory syndrome (known as SARS).

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[1] Rashid H, Haworth E, Shafi S, Memish ZA, Boov R. Pandemic influenza: mass gatherings and mass infections. *Lancet* 2008;8:526–7. doi: 10.1016/S1473-3099(08)70186-5.

[2] Public health for mass gatherings: key considerations. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/handle/10665/162109, accessed 19 February 2020).

[3] Interim planning considerations for mass gatherings in the context of pandemic (H1N1) 2009 influenza. Geneva: World Health Organization; 2009 (https://www.who.int/csr/resources/publications/swineflu/h1n1_mass_gatherings/en/, accessed 19 February 2020).

[4] WHO interim guidance for international meetings attended by individuals for Ebola virus disease–affected countries. Geneva: World Health Organization; 2014 (https://apps.who.int/iris/handle/10665/135751, accessed 19 February 2020).

A novel coronavirus is a new strain of coronavirus that has not been previously identified in humans. The new, or novel, coronavirus, now called the COVID-19 virus, had not been detected before the outbreak that was reported in Wuhan, China, in December 2019.

So far, the main clinical signs and symptoms reported in people during this outbreak include fever, coughing, difficulty in breathing and chest radiographs showing bilateral lung infiltrates. As of 27 January 2020, human-to-human transmission was confirmed largely in Wuhan, but also in some other places in China and internationally. Not enough is known about the epidemiology of COVID-19 disease to draw definitive conclusions about the full clinical features, the intensity of human-to-human transmission, and the original source of the outbreak.

In planning appropriate preparedness measures, meeting organizers may want to consider the following three phases:

- **planning phase** – the period (weeks or months) before the event begins, when operational plans for health and security services during the event are developed, tested and revised;
- **operational phase** – the period after plans are finalized and the delivery of the event services begins; this may be several weeks before the event commences if teams arrive in advance to complete their training or preparations;
- **post-event phase** – the period after the event finishes when participants are returning to their home countries and organizers are reviewing the event delivery and any follow-up actions that are necessary, as well as reviewing any lessons learned and the event's legacy.

3 Planning phase

Good planning should ensure that robust systems and processes are in place to manage public health issues during mass gatherings. Organizers should review their plans to ensure they are fit for purpose. Additional advice could be sought through consultation with global experts.

General advice on planning for the public health aspects of an event is set out in WHO's key considerations document (mentioned in Section 1). Specific actions to be taken in relation to the COVID-19 outbreak are discussed in this section.

3.1 Liaison with local and national public health authorities

- Event organizers should establish direct links with local and national public health authorities. This should include the local provider of health services for the event.
- There should be a nominated liaison person in the organizing team and also one in the designated public health agency. Contact information should be shared, and contacts should be available 24 hours.
- Regular contact should be maintained throughout the planning period to share information, risk assessments and plans.
- Channels of communication between agencies and organizers, and with the public, should be agreed in advance.

3.2 Risk assessment

The decision to proceed with a mass gathering or to restrict, modify, postpone or cancel the event should be based on a thorough risk assessment. Event planners should undertake such an assessment in partnership with local and national public health authorities.

For highly visible or particularly large events, WHO may provide advice and technical support to the host country to help with assessing the public health risks associated with the event.

3.2.1 General considerations

General considerations include the following.

- A comprehensive risk assessment should be undertaken at the beginning of the planning phase, reviewed regularly during planning and updated immediately prior to the handover to the operational phase.
- The risk assessment should include input from the public health authority and should take into account the security assessment for the event.
- In relation to COVID-19 disease, the risk assessment should include consulting WHO's updated technical guidance and ensuring that there is an up-to-date evaluation of the epidemiological situation.
- The risk assessment for the event must be coordinated and integrated with the host country's national risk assessment.

3.2.2 Specific considerations in relation to COVID-19 disease

Specific information that is necessary for the risk assessment includes:

- the global COVID-19 situation report as provided by WHO;
- the national COVID-19 situation report.

The risk assessment for COVID-19 disease should consider both general features and specific features.

- General features of COVID-19 disease include
    - transmission dynamics
    - future likely spread of the epidemic
    - clinical severity
    - treatment options
    - potential for prevention, including available pharmaceuticals and vaccine.

- Specific features of the event that should be considered include
    - crowd density;
    - the nature of contact between participants (for example, a concert or religious event, indoors or outdoors, the layout of the venue);
    - whether the event will be attended by registered and non-registered participants;
    - the profession of the participants and their possible previous exposure;

- the number of participants coming from countries or areas affected by the COVID-19 outbreak within 14 days prior to the event;
- the age of participants; because elderly people who have co-morbid conditions appear to be more seriously affected, mass gatherings composed principally of this cohort may be associated with increased transmission;
- the type or purpose of event (for example, sporting, festival, religious, political, cultural);
- the duration and mode of travel of participants; if the duration of the mass gathering is longer than the incubation period for COVID-19 infection (14 days), then most event-associated cases would be expected to occur while the event is under way. In contrast, if the duration is shorter, most cases would likely occur after the event as people travel and return to their home communities.

WHO's *Public health for mass gatherings: key considerations* can be consulted for a detailed discussion of the general principles and elements of risk assessment and management. Additionally, online training is available about public health preparedness for mass gatherings.

3.3 Specific action plan for COVID-19 disease

Action plans should be developed to mitigate all risks identified in the assessment. Some actions will be the responsibility of the public health authority to deliver, some will be the responsibility of the local health service provider, and the event organizer will be responsible for others; each action plan should specify who is responsible for delivering each action, the timescale for delivery, and how and by whom delivery will be ensured. Action plans should include:

- integration with national emergency planning and response plans for infectious diseases;
- command and control arrangements to facilitate the rapid communication of information and efficient situation analyses and decision-making;
- any appropriate screening requirements for event participants – for example, will participants be screened for COVID-19 symptoms on arrival?
- disease surveillance and detection – for example, how will the disease be recognized and diagnosed in participants?
- treatment – for example, how and where will ill participants be isolated and treated?
- decision trigger points – for example, who will decide whether affected participants can continue or resume their role in the event? What trigger points will indicate the need to reconsider or revise the plans? What would trigger postponement or cancellation of the event?

If the decision is made to proceed with a mass gathering, planning should consider measures to:

- detect and monitor event-related COVID-19 disease;
- reduce the spread of the virus;
- manage and treat ill persons;
- disseminate public health messages specific to COVID-19 disease.

3.4 Capacity and resource assessment

Some of the capabilities and resources to be considered when planning for an event include the following.

- National health authorities should assess whether additional resources and capacity are needed to deliver appropriate risk-mitigation actions to the local community during and after the event, for example, by adding diagnostic testing capacity, isolation and treatment facilities, and resources for contact tracing.
- Event organizers should asses the capacity needed and the resources available to deliver all specific COVID-19 risk-mitigation actions that arise from the risk assessment.
- Capacity and resources should be coordinated with the public health authority and health service provider to avoid duplication or gaps.

3.5 Risk communication and community engagement plan

Event organizers should agree with the public health authority how participants and the local population will be kept informed about the health situation, key developments and any relevant advice and recommended actions.

4 Operational phase

There is no published experiential data specific to planning and implementing a mass gathering during the current COVID-19 outbreak. However, arrangements must be in place to ensure regular communication between event organizers and the public health authority.

These arrangements should include:

- regular and full sharing of information by organizers and public health authorities;
- arrangements to provide participants with information about how to access health advice;
- arrangements for ongoing, dynamic risk assessments to be conducted by the public health authority and organizers as the event progresses;
- arrangements for communicating with participants and the local population to ensure messaging is consistent.

To date, there is no scientific evidence that supports the screening of participants as a cost-effective measure.

4.1 Risk communication

Risk communication is an integral part of mass gatherings. The following measures should be considered.

- Key messages for the local population and event participants must be coordinated and consistent.

- Consideration should be given to how messages about risk can be delivered to the population and to participants quickly if an unusual event occurs.
- Messaging should include:
    - an overall assessment of the local risk;
    - advice on preventive measures, especially respiratory etiquette and hand hygiene practices;
    - advice about how to access local health care if necessary, including how to do so without creating a risk to healthcare workers;
    - advice on self-isolation and not attending the event if symptoms develop;
    - information about disease signs and symptoms, including warning signs of severe disease that require immediate medical attention;
    - advice on self-monitoring for symptoms and signs for participants travelling from affected countries, including checking their temperature;
    - information that WHO does not currently recommend quarantine for healthy travellers or other travel restrictions;
    - information that wearing a face mask is recommended for participants who have respiratory symptoms (for example, cough); it is not recommended for healthy participants.

Event organizers in collaboration with public health authorities may wish to consider whether specific information or advice is needed about the potential risks that persons already at increased risk of severe disease might face in the setting of a mass gathering, especially if the COVID-19 virus is circulating in the community.

More information on COVID-19 risk communication and community engagement can be found in *Risk communication and community engagement (RCCE) readiness and response to the 2019 novel coronavirus (2019-nCoV).*[5] WHO's advice for the public about COVID-19 disease can be found here and information about myths can be found here.[6,7]

4.2 Surveillance of participants

Some of the key features to consider for surveillance include the following.

- Detection and monitoring of event-related COVID-19 disease should be considered in the context of surveillance schemes that are already in place and if new or enhanced surveillance is deemed necessary.

[5] Risk communication and community engagement (RCCE) readiness and response to the 2019 novel coronavirus (2019-nCoV): interim guidance v2, 26 January 2020. Geneva: World Health Organization; 2020 (WHO/2019-nCoV/RCCE/v2020.2; https://www.who.int/publications-detail/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses-(-ncov), accessed 19 February 2020).
[6] Coronavirus disease (COVID-19) advice for the public. In: WHO/coronavirus disease 2019 [website]. Geneva: World Health Organization; 2019 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public, accessed 19 February 2020).
[7] Coronavirus disease (COVID-19) advice for the public: myth busters. In: WHO/coronavirus disease 2019 [website]. Geneva: World Health Organization; 2019 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters, accessed 19 February 2020).

- Organizers will need to work with local public health authorities to ensure that systems are in place to identify indicators of illness arising in the local population or in event participants, such as increases in the number of people experiencing symptoms or a rise in the use of proprietary medicines.
- Surveillance systems will need to operate in real time or near−real time to support rapid response actions.
- Surveillance systems should be linked to risk assessments, so that any abnormal signal in the surveillance systems triggers an immediate revision of the risk assessment

4.3 Testing and diagnostic arrangements

Organizers need to consider with the local health authority how and where participants presenting with COVID-19-like symptoms will be tested. In the current absence of commercial testing kits for the COVID-19 virus, organizers will need to ensure that their health provider has access to appropriate testing tools, probably from the national public health agency. This will also require prior agreement about how to transport specimens or participants to a testing facility.

4.4 Treatment facilities

Some considerations for treatment facilities include the following.

- Event organizers should consider the need to provide isolation facilities at the event site for participants who develop symptoms and need to wait for a health assessment. Whether this is necessary depends on the nature of the event and the extent to which the event will provide its own medical services rather than depend on the local health service to do so. Preparing for an isolation facility includes training healthcare workers, implementing infection control and prevention measures in any healthcare setting, and preparing personal protective equipment to be used by staff.
- Organizers need to consider where any participant who becomes unwell with COVID-19-like symptoms will be treated and how they will be transported to a treatment facility. This is likely to be in a national health facility where there is appropriate containment capacity and expertise, so participants will not be able to remain in the event's medical facility. Agreements about any consequent funding issues should be confirmed in advance.
- Participants at events sometimes expect that they will be returned to their home country for medical treatment rather than be treated in the host country; this will not be possible for anyone diagnosed with COVID-19 illness except through the use of specific medical evacuation flights that have appropriate isolation and containment facilities: such facilities are scarce and expensive and not readily available for illnesses such as COVID-19 infection.
- Organizers need to consider how any affected participants will be transferred home if their illness extends beyond the end of the event and pre-arranged travel is no longer available.
- Event organizers working with public health and healthcare officials need to assess national healthcare capacity to deliver supportive treatment, including admitting participants to an intensive care unit and providing ventilator support. Such care should be provided near to the mass gathering.
- National plans for deploying and providing access to medical supplies, such as antibiotics, ventilators, and personal protective equipment (known as PPE), should be reviewed.

4.5 Decision-making

In collaboration with local health authorities, organizers should also agree in advance the circumstances in which risk-mitigation measures would need to be enhanced or the event postponed or cancelled. Prior agreement on potential trigger points will facilitate these discussions if they become necessary.

4.6 Operational practices for reducing event-related transmission of the COVID-19 virus

The basic general principles for reducing transmission of the COVID-19 virus are applicable to a mass gathering.

- People should be advised to stay away from the event if they feel ill.
- Persons who feel unwell (that is, have fever and cough) should stay at home and not attend work or school and avoid crowds until their symptoms resolve. This applies to participants as well as staff.
- Promoting appropriate hand hygiene and respiratory etiquette in mass gathering venues requires providing informational materials that reach a range of age groups and varying reading and educational levels. In addition, soap and water or alcohol-based hand sanitizers and tissues should be easily accessible in all common areas, and especially at medical treatment sites at the event.
- People who become ill while at the event should be isolated.
- Organizers should plan for the likelihood of persons becoming ill with fever and other typical symptoms of COVID-19 infection during the event. Organizers should consider establishing isolation areas in on-site medical treatment clinics or facilities where such persons can be initially assessed and triaged. Persons who are ill can be provided with a mask to help contain respiratory droplets generated from coughing and sneezing. The isolation area should be equipped with the necessary supplies to facilitate hand hygiene and respiratory etiquette. In addition, medical staff attending persons who are ill should wear a mask, dispose of it immediately after contact with someone who is ill, and cleanse their hands thoroughly afterwards.
- The usual precautions should be practiced with travellers arriving from international destinations.
    - If travellers have symptoms suggestive of acute respiratory illness before, during or after travel, they should be encouraged to seek medical attention and share their travel history with the healthcare provider.
    - Public health authorities should provide to travellers information about reducing their general risk of acute respiratory infections through health practitioners, travel health clinics, travel agencies, transportation operators and at points of entry.
- Crowding should be minimized where possible, and event organizers should consider using distancing measures to reduce close contact among people during the gathering (for example, by increasing the frequency of transport, staggering arrivals, diverting departures and minimizing congregation at sanitary stations and food and water distribution areas).

5 Post-event review

After the conclusion of the mass gathering, the following should be considered.

5.1 After the event

After the gathering, if public health authorities suspect that transmission of the COVID-19 virus has occurred, organizers and participants should support the response of authorities.

- Meeting organizers must liaise with public health authorities and facilitate the sharing of information about all symptomatic participants (such as their itineraries, contact information, visa procedures, hotel bookings).

- Individuals who develop symptoms during the mass gathering and their stay in the country should isolate themselves, seek medical attention and inform the appropriate public health authorities about their potential exposure, both in the country where the event was held and upon returning to their country of residence.

5.2 Risk communication for departing participants

- It may be necessary both for clinical reasons and under International Health Regulations to notify the home countries of returning participants of any people who developed COVID-19 infection while attending the event.
- Organizers also need to ensure that test results reported after the event are notified to the participant and, possibly, to the home country's public health system.

5.3 Lessons identified

As always, it will be important for lessons from any event to be identified through review after the event so that they can be passed on to future event organizers.

5.4 Legacy

Organizing mass gatherings during a global health emergency is unusual, but it can be done depending on the risk assessment. Organizers should see any such event as an opportunity to enhance their ways of working and to pass this learning on to both future events and the host country.

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Global mass gatherings: implications and opportunities for global health security

Report by the Secretariat

1. Mass gatherings have significant implications for public health beyond the acute public health events which may occur and require rapid detection and effective management. These implications extend to the benefits of cross-sectoral preparedness planning and increased capacity in the health infrastructure; the international spread of epidemic or pandemic disease; or the powerful leverage that public awareness and interest in such events present for communication of information. Mass gatherings represent risks to health security, with the potential to directly endanger the health of populations, to raise levels of social anxiety, political urgency and to cause economic disruption on a local, regional or global scale. The many challenges posed by mass gatherings have stimulated research and debate.[1]

2. This report outlines the implications of such gatherings for public health security, the resources available, and the potential opportunities for strengthening health systems. WHO's existing and potential contribution to the planning and preparedness for such events is described, including pre-emptive and preventive measures, as well as the global response mechanisms for disease outbreaks in place. This report also suggests improvements for public health systems, including the coordination and interdisciplinary approaches required to address the range of public health risks posed by international mass gatherings.[2]

THE CURRENT SITUATION

3. The public health implications of mass gatherings are becoming more pronounced, as such events draw ever-larger international crowds. Data collected during the hajj show that the proportion of international pilgrims increased by almost 30% between 1996 and 2006.[3] Attendance at the London

[1] A number of academic and research institutions have produced material recently on mass gatherings, such as Flinders University in Australia, the University of Washington and the Centers for Disease Control and Prevention in the United States of America, and Umm Al-Qura University in Saudi Arabia. In addition, important academic conferences, such as The Lancet Conference on Mass Gatherings Medicine, hosted by the Kingdom of Saudi Arabia, have led to policy guidance such as the Jeddah Declaration on Mass Gatherings Health.

[2] See also *Weekly Epidemiological Record*, 2011, **86**(39):425–428.

[3] Official data from the Ministry of Hajj, Kingdom of Saudi Arabia, http://www.hajinformation.com/main/l.htm (accessed 28 November 2011).

Olympic Games in 2012 is expected to be some seven million. These events offer valuable opportunities for public health actions, as unprecedented attention and resources are focused for a brief, but intense, period of time on health systems in host communities and nations. However, alongside their potential positive impact, mass gathering events also have the potential to strain the health resources of host communities, and to import and export infectious diseases as international participants arrive and depart.

4. Urgent, complex health and social situations can result from mass gatherings, influenced by the purpose of the mass gathering, the demographics and external factors. Public health risks can increase from close contact in crowded venues and accommodation, and extreme climatic conditions. Temperature-related illness and dehydration are common causes of illness during mass gathering events (cases of heatstroke, for example). Familiar disease problems may be amplified and increase the demands placed on local health services during an event: researchers undertaking a prospective study in two hospitals during the hajj identified respiratory disease as the most common cause (57%) of admission to hospital, with pneumonia being the leading reason for admission in 39% of all patients. Outbreaks of respiratory disease were also reported at the 2002 Winter Olympics in Salt Lake City, and cases of pandemic (H1N1) 2009 influenza were reported in music festivals across Europe in that year. Unexpected disease transmission may occur and may cause outbreaks beyond the immediate venue; in 2000 and 2001, in association with the hajj, there was an international outbreak of disease caused by a previously rare strain of *Neisseria meningitidi*s, serogroup W135.

5. Few studies are available on how to prepare for and manage public health risks at such gatherings; resource materials available for planning purposes are limited. However, the transfer of expertise between organizers and hosts of mass gatherings across the globe is increasing. In October 2010, The Lancet Conference on Mass Gatherings Medicine was hosted by the Kingdom of Saudi Arabia. This was an important step and led to the Jeddah Declaration on Mass Gatherings Health. The Declaration stresses the importance of providing comprehensive and safe health care at mass gatherings. In 2011, WHO designated the United Kingdom Health Protection Agency as a Collaborating Centre on Mass Gatherings and High Visibility/High Consequence Events.

6. Bodies such as the International Olympic Committee or the Fédération Internationale de Football Association have a key role in facilitating public health preparedness and response, health promotion and health legacy, by imposing public health planning requirements for host nations. WHO has signed a Memorandum of Understanding with the International Olympic Committee and the Bureau International des Expositions. WHO has also worked closely with several national governments in preparing health authorities for international mass gatherings, such as the Olympic Games (e.g. Athens 2004, Beijing 2008, Vancouver 2010 and London 2012), 2010 FIFA World Cup (South Africa), 2010 Shanghai World EXPO, and many other events.

PLANNING AND PREPAREDNESS

7. Preparedness for mass gatherings includes specific public health measures developed in advance of the event, training for their implementation, as well as planning for improvements in the hosting nation's health systems.[1] Because of its size and features, the Glastonbury Festival of Contemporary Performing Arts in the United Kingdom, for example, recently served as a model and exercise ground

[1] Report on WHO support to the 2010 FIFA World Cup South Africa™. January 2011, http://www.afro.who.int/en/south-africa/south-africa-publications.html (accessed 28 November 2011).

for field-testing epidemiological assessments in highly crowded environments. Such planning includes:

- *Emergency medical services and hospitals.* Plans for the management of mass casualties or mass fatalities and preparedness for emergencies[1] at the community level, as well as at event venues and related locations (e.g. "fan zones").

- *Infection control.* Best practice and correct standards for infection control should be ensured, including outbreak management, vaccinations, isolation and other measures that may be required.

- *Laboratory capacity*. Preparedness for surge capacity includes ensuring adequate diagnostic capacities (human resources and reagents, transport procedures from unusual sites).

- *Travel medicine.* Procedures to provide updated health advice and vaccination guidance for visitors. WHO's publication on mass gatherings, International travel and health, will be expanded in forthcoming editions. The Organization may also increase awareness-raising for specific events.

- *Points of entry strengthening.* The ability of port health services to detect disease among attendees.

- *Health promotion*. Promotion of healthy behaviours in relation to the event, such as increased physical activity, cessation of tobacco use and avoidance of excess alcohol.

8. Mass gatherings often generate political momentum and resources, and present an important opportunity to improve health systems, minimize health risks and promote healthy behaviours. Mass gatherings may be discrete or recurrent, but the impact of public health measures can be sustainable. Careful planning and preparation is needed to increase the long-term positive impact.

9. Ideally, any enhancements to a health system should be sustainable. Through strengthening the core functional capacities of Member States, planning for mass gatherings may also facilitate the implementation of the International Health Regulations (2005).

Risk assessment and reduction

10. The International Health Regulations (2005) can also be used as a framework on which to build further capacity. Reducing public health risks associated with mass gatherings requires a planning and management approach that coordinates across sectors and strengthens partnerships. Preparing public health systems and medical services is a complex process that should begin well in advance to identify potential risks and ensure capacities to prevent, minimize and respond to public health emergencies. An all-hazard approach to public health risks is generally recommended by WHO.

11. **Types of risk assessment.** Risk assessment processes for mass gatherings include a *strategic* risk assessment, and an *event-based* risk assessment.

[1] A hospital emergency response checklist for hospital administrators and emergency managers has been prepared by the WHO Regional Office for Europe, see http://www.euro.who.int/en/what-we-do/health-topics/emergencies/disaster-preparedness-and-response/publications/2011/hospital-emergency-response-checklist (accessed 28 November 2011).

12. Strategic risk assessment is conducted by the organizing country throughout the cycle of event planning and operations and includes the identification of hazards that could pose a risk to the mass gathering, assessment of their likelihood of occurring, and assessment of their potential impact.

13. Event-based risk assessment is a process that should include an enhanced surveillance and outbreak alert and response mechanism:

(a) *Enhanced surveillance*: Disease surveillance systems should be enhanced to quickly detect and communicate information related to diseases and health events among participants.

(b) *Outbreak alert and response*: An adequate existing local infrastructure enhanced to address the pressures introduced by the mass gathering is crucial to the ability to respond and implement timely infection-control activities.

14. **Command, control and communication**. The heightened visibility and involvement of many sectors in mass gatherings require a robust and flexible command and control structure with the clear allocation of roles and responsibilities, decision-making protocols and predefined communication strategies. Public health and emergency services are essential players within this system; both need to work together to respond to the ad hoc requirements of mass gatherings.

DISEASE TRANSMISSION

15. Introduction, amplification and transmission of diseases during an event, as well as the importation/exportation of diseases more widely after an event, represent serious risks to public health. An example of this arose at the 2010 FIFA World Cup in South Africa. A mass vaccination campaign for measles had taken place in the host country, in preparation for the sporting event; however, measles cases occurred as a result of imported cases of a European strain.

16. Two of the most important factors at mass gatherings that contribute to the enhanced transmission of communicable disease are high crowd density and increased population mobility. Other factors include poorly handled mass catering and inadequate sanitation. The detection of disease outbreaks, as well as public health measures to manage them, are further complicated by the increased demand on medical services and by the short duration of stay of many participants.

17. A significant strain on host communities is often the need to handle diseases and injuries related to the event while maintaining normal services for local communities. In addition, there is a danger that local health needs may displace the longer-term international consequences for public health security of infections arising through close crowd contact.

18. A number of scientific studies conducted around World Youth Day 2008 in Sydney, Australia, found that overseas attendees to Australia introduced influenza during a non-seasonal period. The influenza outbreak, with over 100 laboratory-confirmed cases, was exacerbated by accommodation conditions (i.e. crowding) and may have affected seasonal influenza patterns in Australia and in several countries of origin of the participants.

19. Disease outbreaks have also been associated with contaminated water and food at mass gatherings; for example in 1997, *Escherichia coli* O157 was transmitted through cattle faeces in contaminated mud at the Glastonbury arts festival. An outbreak of leptospirosis was reported among triathlon athletes in 1998 in Springfield, Illinois, where 11% of tested participants had laboratory

results which were positive for leptospirosis. It is likely that this large outbreak arose from ingestion of contaminated lake water. The safe preparation of food and drink, appropriate storage and distribution, and tracking of food origin in an acceptable time frame require expertise, planning, oversight, enforcement, infrastructure and resources, as does monitoring of water safety. For example, the organizers of the Athens Olympic Games in 2004 developed a scoring system for inspecting water systems to prevent outbreaks of legionellosis.

PUBLIC AWARENESS

20. Not only do mass gatherings draw together unusually large concentrations of people, presenting local opportunities for dissemination of information, they also offer potential extended access to more distant populations through the involvement of mass media and social networking. The televised 2008 Beijing Olympic Games and the 2010 FIFA World Cup in South Africa were the most watched events of their sort ever. An estimated 4700 million viewers followed the 2008 Olympic Games.[1] This has obvious implications for the dissemination of promotional messages or information with either positive or negative health impacts.

21. The hosting of the Olympic Games raises the profile of the positive medium- and longer-term effects of public health initiatives. Health promotion and awareness campaigns can be galvanized by the high-profile nature of mass gatherings but they can also, along with other health interventions, be formalized through the requirements for potential host bidding documents. For example, the International Olympic Committee has recently included a section on health legacy in its technical manual on medical services.

22. Health promotion campaigns can be used to reinforce healthy behaviours during and after the event. Examples include food safety initiatives and tobacco control measures, including cessation services. Interventions to prevent interpersonal violence and campaigns against alcohol abuse can also benefit from heightened visibility and media attention. The 2003 WHO Framework Convention on Tobacco Control also provides a legal platform for tobacco control.[2]

EXISTING WHO RESOURCES TO SUPPORT PLANNING AND CONDUCT OF MASS GATHERINGS

23. In addition to the provision of specific risk-based support to those involved in the planning of mass gatherings, WHO has a number of initiatives and tools in place for developing and propagating knowledge based on experience of mass gatherings, including the following:

- The Virtual Interdisciplinary Advisory Group on mass gatherings is maintained by WHO to generate evidence-based knowledge of mass gatherings and can be deployed in response to the needs of hosts and organizing bodies.

[1] *The health legacy of the 2008 Beijing Olympic games: successes and recommendations.* World Health Organization, Manila, 2010.

[2] Technical guidance is available on tobacco control measures at mass gatherings, see *A Guide to Tobacco-Free Mega Events*, WHO Regional Office for the Western Pacific, Manila, 2010.

- WHO's training programme on mass gatherings ensures that ad hoc support is provided on demand to Member States and organizing bodies, thereby raising awareness and building global capacity to respond effectively to public health emergencies during mass gatherings.

- WHO's Observer Programme facilitates the training and placement of international observers at current events by organizations that will be hosting events in the future. This programme was created explicitly to start a culture of event-to-event transfer of expertise.

- WHO is collaborating with the United Kingdom Health Protection Agency on a web-based mass gatherings planning and assessment tool to make it easier for hosts to assess their readiness for mass gatherings.

- The WHO Interdepartmental Mass Gatherings Group is a source for countries of WHO expertise and provision of guidance on elements of health-system preparedness, health promotion and capacity-building to implement the International Health Regulations (2005).

ACTION BY THE EXECUTIVE BOARD

24. The Board is invited to note the report.

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Annexure C

World Health Organization

Tracking SARS-CoV-2 variants

All viruses, including SARS-CoV-2, the virus that causes COVID-19, change over time. Most changes have little to no impact on the virus' properties. However, some changes may affect the virus's properties, such as how easily it spreads, the associated disease severity, or the performance of vaccines, therapeutic medicines, diagnostic tools, or other public health and social

measures.

WHO, in collaboration with partners, expert networks, national authorities, institutions and researchers have been monitoring and assessing the evolution of SARS-CoV-2 since January 2020. During late 2020, the emergence of variants that posed an increased risk to global public health prompted the characterisation of specific Variants of Interest (VOIs) and Variants of Concern (VOCs), in order to prioritise global monitoring and research, and ultimately to inform the ongoing response to the COVID-19 pandemic.

WHO and its international networks of experts are monitoring changes to the virus so that if significant mutations are identified, we can inform countries and the public about any changes needed to react to the variant, and prevent its spread. Globally, systems have been established and are being strengthened to detect “signals” of potential VOIs or VOCs and assess these based on the risk posed to global public health. National authorities may choose to designate other variants of local interest/concern.

Current strategies and measures recommended by WHO continue to work against virus variants identified since the start of the pandemic.

Naming SARS-CoV-2 variants

The established nomenclature systems for naming and tracking SARS-CoV-2 genetic lineages by GISAID, Nextstrain and Pango are currently and will remain in use by scientists and in scientific research. To assist with public discussions of variants, WHO convened a group of scientists from the WHO Virus Evolution Working Group, the WHO COVID-19 reference laboratory network, representatives from GISAID, Nextstrain, Pango and additional experts in virological, microbial nomenclature and communication from several countries and agencies to consider easy-to-pronounce and non-stigmatising labels for VOI and VOC. At the present time, this expert group convened by WHO has recommended using labeled using letters of the Greek Alphabet, i.e., Alpha, Beta, Gamma, which will be easier and more practical to discussed by non-scientific audiences.

31 May 2021 | Departmental news

WHO announces simple, easy-to-say labels for SARS-CoV-2 Variants of Interest and Concern

SARS-CoV-2 Variants of Concern and Variants of Interest, updated 15 June 2021

Variants of Concern

A SARS-CoV-2 variant that meets the definition of a VOI (see below) and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

- Increase in transmissibility or detrimental change in COVID-19 epidemiology; or
- Increase in virulence or change in clinical disease presentation; or
- Decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics.

WHO label	Pango lineage	GISAID clade/lineage	Nextstrain clade	Earliest documented samples	Date of designation
Alpha	B.1.1.7	GRY (formerly GR/501Y.V1)	20I (V1)	United Kingdom, Sep-2020	18-Dec-2020
Beta	B.1.351	GH/501Y.V2	20H (V2)	South Africa, May-2020	18-Dec-2020
Gamma	P.1	GR/501Y.V3	20J (V3)	Brazil, Nov-2020	11-Jan-2021
Delta	B.1.617.2	G/478K.V1	21A	India, Oct-2020	VOI: 4-Apr-2021 VOC: 11-May-2021

Variants of Interest

A SARS-CoV-2 isolate is a Variant of Interest (VOI) if, compared to a reference isolate, its genome has mutations with established or suspected phenotypic implications, and either:

- **has been identified to cause community transmission/multiple COVID-19 cases/clusters, or has been detected in multiple countries; OR**
- **is otherwise assessed to be a VOI by WHO in consultation with the WHO SARS-CoV-2 Virus Evolution Working Group.**

WHO label	Pango lineage	GISAID clade/lineage	Nextstrain clade	Earliest documented samples	Date of designation
Epsilon	B.1.427/B.1.429	GH/452R.V1	21C	United States of America, Mar-2020	5-Mar-2021
Zeta	P.2	GR/484K.V2	20B/S.484K	Brazil, Apr-2020	17-Mar-2021
Eta	B.1.525	G/484K.V3	21D	Multiple countries, Dec-2020	17-Mar-2021
Theta	P.3	GR/1092K.V1	21E	Philippines, Jan-2021	24-Mar-2021
Iota	B.1.526	GH/253G.V1	21F	United States of America, Nov-2020	24-Mar-2021
Kappa	B.1.617.1	G/452R.V3	21B	India, Oct-2020	4-Apr-2021
Lambda	C.37	GR/452Q.V1	20D	Peru, Aug-2020	14-Jun-2021