

Miracle?

How Ministers, Mycobacteria and Medical Ethics
shaped COVID Response in Mumbai's Slums



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Abstract:

The Dharavi slum of Mumbai represents one of the most population dense and economically blighted polities in the world. With its reputation for crowding (housing 60% of Mumbai's population on 6% of its land), poor hygiene infrastructure, and central role in previous waves of infection notably the 1896 bubonic plague outbreak which took the lives of close to 50% of Mumbai's population, prognostication of devastation in the community when faced with COVID-19 dominated the early days of the pandemic in India[1, 2]. What has emerged instead are reports of a supposed "Dharavi miracle" with even the top levels of the WHO focusing a spotlight on Dharavi's success, stating "Dharavi should be seen as an example across the world." [3] Several papers in the literature recapitulate this assessment portraying Dharavi as a global model for COVID response in low resource settings. The contrast of this glowing global portrayal with first-hand accounts and recent literature regarding COVID in Mumbai motivated a look into the "Dharavi Miracle's" veracity and the rhetoric underpinning it[4]. This paper will explore this so called miracle from the perspectives of governmental and NGO intervention, the interplay of COVID-19 with infections already endemic to Dharavi and in terms of bioethical issues with a primary focus on formal and informal medical trials.

Role of Government and NGO Intervention:

As was the case for much of the globe the Indian government played the central role in defining its nation's response to COVID-19. Article 21 of the Indian Constitution and the Supreme Court of India in line with the belief that "health is the duty of the state and the right of the patient" underscore the right of equitable access to health and healthcare resources as a fundamental one extended to all Indian citizens at least nominally[5]. Additionally, not only is Mumbai, where Dharavi is located, the Indian city hardest hit by COVID-19, it is the gleaming economic and pop cultural heart of the nation. On the basis of both fulfilling constitutional duty

with the eyes of the world watching and safeguarding economic interests to the extent possible, various powerful actors were extremely interested in a robust pandemic response.

The Maharashtra and Indian national governments coordinated to impose exacting measures in their efforts to prevent Dharavi from becoming “Lombardy (Italy) or New York (USA) where COVID-19 spread at a very high rate and resulted in hundreds of casualties”[2, 6]. Taking advantage of Dharavi’s relative geographic compactness, the heart of the response focused on border control and restriction of movement. The state government of Maharashtra closed off the borders of the slum by establishing 24 check-posts at all entry points[2]. In addition to preventing egress from Dharavi, internal movement was impacted as well. To limit internal migration the shops, small factories and markets which constitute the bulk of economic infrastructure were closed; public and private transportation was stopped; stringent restrictions were placed on individuals’ movements and police drone surveillance was operationalized[2]. In addition, prior to implementation of stringent lockdown many economic migrants in Dharavi were strongly encouraged to return to their homes in other parts of India. The suffering and challenges involved in this process of attempting to return home are beyond the scope of this paper but will count among the notable black marks of India’s response to COVID. The Bombay Municipal Corporation (BMC) and NGO's also distributed more than 25,000 grocery kits, food packets for lunch and dinner to minimize the movement of people from their homes[3].

At the same time residents of Dharavi were both kept from moving out of and within the slum their personal boundaries were tightly constricted to facilitate the second major pillar of the governmental response in coordination with supporting NGOs; a proactive approach which they referred to as “chasing the virus”[7]. Leaders of the BMC, with the consent of state and national officials, deviated from the traditional approach of relying on patients to present at health centers towards community outreach. To accomplish this, civic authorities recruited 350 local and private medical practitioners and equipped them with PPE kits and the necessary medical

tools to facilitate door to door screening within Dharavi[2, 7]. Ultimately, approximately 700,000 people were screened in the slum area through assessment of temperatures and oxygen levels. Of those initially screened, 14,000 people were tested following screening and 13,000 placed in quarantine centers[2, 7]. Quarantine centers were necessary as the population density of Dharavi rendered it to utilize social distancing and lockdown as a means of managing patients. Quarantine centers were arranged in nearby schools, sports complexes, marriage palaces, and community halls. The BMC additionally took over five private hospitals in the area to serve as critical care facilities. Individuals found to be symptomatic were immediately shifted to quarantine centers demarcated by symptoms; CCC 1 if asymptomatic, CCC2 with slight symptoms, and severe cases being hospitalized in the 5 government run hospitals[2, 7].

The approach utilized in Dharavi has been defined as the 4-Ts model i.e. Tracing, Tracking, Testing, and treating patients proactively[7]. This strategy has come to be viewed in much of the literature as a role model to combat the virus across the globe. Some literature even goes as far as to say that the Dharavi model will come to be held as the template for future pandemic response in contexts where social distancing is impossible or difficult to follow for instance) and consequently social distancing or lockdown is not a viable option such as Makoko in Lagos (Nigeria), Mbare in Harare (Zimbabwe) and Kibera in Nairobi (Kenya) [3].

Impacts of Co-infection:

A rarely mentioned aspect of why Dharavi's COVID 19 death rate was so relatively low may ironically be due to the areas vulnerability to infectious disease particularly tuberculosis (TB). Mumbai, is a densely populated metropolis with a population of approximately 12 million, 4.8 million (40%) of whom reside in overcrowded slums. Since 1990, a resurgence of TB has occurred, characterized by a 70% to 140% increase in the rate of TB-related deaths among adults aged 25–44 years particularly in crowded and resource limited settings like Dharavi[8].

While normally this would be considered tragic, with COVID it may carry an unexpected silver lining as in the past year numerous papers have established a potential protective effect of both the BCG tuberculosis vaccine and latent TB itself in the face of COVID infection[9].

Recent work by Sharma et. Al suggests that BCG vaccination induces long-term changes in blood immune cell transcriptome that partly mimic and partly oppose transcriptomic changes induced by viral respiratory illnesses including COVID-19. The first mechanism responsible for upregulation of defense response to virus is molecular mimicry based on the fact that BCG vaccine generates cross-reactive T cells against SARS-CoV-2 due to containing a similar 9-amino acid sequences with SARS-CoV-2 with high binding affinity to common HLA class I molecules[10]. The second is downregulation of myeloid cell activity[11]. Literature suggests that BCG vaccination can modulate anti-inflammatory cytokine and chemokine responses, preventing hospitalization and resulting in less severe cases of COVID-19. In conjunction these responses to the BCG vaccine appear to reduce susceptibility to respiratory viruses including COVID 19 while also mitigating the overactive immune response that demarcates the most severe cases of SARS COV-2.

Koneru et. Al recapitulate Sharma's findings that some vaccines (such as BCG, adult pneumococcal and adult seasonal influenza) has been studied in relation with COVID-19 mortality and produced suggesting that BCG-vaccinated individuals have reduced mortality rates[10]. Based on data from these studies, countries with BCG in their national vaccination programs (BCG countries) show lower numbers of confirmed COVID-19 cases/million inhabitants than countries with no BCG vaccination policy (non-BCG countries) along with findings of a reduced mortality rate from COVID in BCG countries. Escobar et al. quantifying this data further showed that each 10% increase in BCG index was associated with a decrease in COVID-19 mortality by 10.4%[12]. Moreover, a negative correlation was observed between cases and deaths of COVID-19 and the years following BCG administration[10]. These studies

also reiterate that the pathophysiology of this responses lies in trained immunity involving reprogramming of myeloid cells, and enhanced capacity for cytokine production and antimicrobial function. A retrospective cohort has also recently reported that BCG vaccination is not associated with systemic inflammation, alleviating the concern that the vaccine may produce deleterious effects in severe COVID-19 by adding to hyper-inflammation[13].

BCG vaccination has also demonstrated benefit in terms of symptomatic control[13]. Notably, a recent clinical trial has found that moderate adult COVID-19 patients administered a single dose of intradermal BCG achieve faster resolution of hypoxia, and significant radiological improvement and viral load reduction, without showing evidence of BCG induced cytokine storm[14]. The present observation of persistently upregulated antiviral defense response and downregulated myeloid cell activation in BCG vaccinated subjects in blood cells is in line with this new finding. In conclusion, the present evidence suggesting high durability of BCG induced trained immunity provides a measure of protection from COVID infection and symptomatology.

In a context like Dharavi the impact of TB infection must be considered in addition to vaccination. It should be noted that TB infection leads to latent infection in 90%–95% of cases, while only 5%–10% of individuals develop active TB[15]. Work by Takahashi et. Al lends statistical support to the hypothesis that latent tuberculosis infection (LTBI) rates offers a measure of protection against COVID-19 mortality. Their models indicate that for “every 10% increase in LTBI prevalence would be expected to reduce the CFR of COVID-19 by about a 0.2 percentage point”[16]. South-East Asia with an estimated LTBI incidence of 587 cases per million inhabitants represents the highest rates of latent TB, while Europe, with an estimated LTBI incidence of 124 cases per million people represents the lowest[16]. Based on these findings and their modeling results Takahashi’s group offers this as a potential explanation for why the COVID fatality rate is so low in Southeast Asian countries compared with European countries.

On the basis of studies on BCG and latent TB the literature has attempted to assert that citizens of countries with high prevalence of TB infection have enhanced innate immunity compared with the citizens of lower TB burden countries and that it is his high level of natural immunity which can be held responsible for the lower COVID-19 mortality rate.

While considerations of TB play the dominant role in discussions of COVID co-infection, a final aspect of the issue in the context of the “Dharavi miracle” is that COVID infections are perhaps being ascribed to other “acceptable” conditions, namely diarrheal disease. SARS-CoV-2 RNA was detected in wastewater of communities within Dharavi which reported no Covid-19 disease. In addition, studies elucidate the frequency of diarrhea seen in young children diagnosed with Covid-19 disease. Taken together these two findings raise the possibility that gastrointestinal Covid-19 may insidiously be present in individuals and communities reportedly free from COVID [17]. Within bats, the commonly held animal origin of SARS COV-2, .the fecal oral route is the standard mode of transmission of betacoronaviruses and can occur in the absence of clinical disease[18]. Underscoring the possible role of gastrointestinal COVID in the narrative of Dharavi’s success, in a study of hospitalized COVID patients in New York, gastrointestinal involvement was shown to attenuate severity of Covid-19 disease[19].In essence, the type of disease and severity of disease of SARS-CoV-2 infections may be profoundly shaped by the nature of the transmission event.

Overall it seems highly probably that co-infection either through the interaction between pathogens or simply by masking COVID infections played a role in the “Dharavi Miracle”.

Bioethics:

The use of vulnerable segments of Indian society in clinical research has long been a topic of academic interest and the response to COVID in Dharavi forces us to examine it once

more. One significant step taken in Dharavi was the deployment of prophylactic hydroxychloroquine as mechanism to control corona virus. The Municipal Corporation of Greater Mumbai (BMC) which as already considered played the lead role in shaping Dharavi's COVID response made the decision to implement a 7 week course of chloroquine (CQ) and hydroxychloroquine (HCQ) mass community prophylaxis for the people living in slums [7]. The decision was primarily based on the decision by the Indian Council of Medical Research (ICMR) to advocate for prophylaxis of asymptomatic healthcare workers involved in the care of suspected or confirmed cases of covid-19 and asymptomatic household contacts of confirmed cases [8]. While numerous smaller and strongly partisan periodicals have lionized the move, more credible journals such as Nature, the British Medical Journal and the Telegraph along with Indian citizens have expressed concern, explicitly stating that "inhabitants of two of India's largest slums" Worli and Dharavi "will be used as 'guinea pigs' in a controversial trial of an unproven malaria drug"[20, 21]. The BMJ additionally described the move as "baffling" and further notes that muddled and contradictory messages about the benefits and risk of using anti-malarials for mass prophylaxis to the marginalized communities in the slums are fueling confusion and mistrust[20, 22]. Public pressure forced the Indian Council of Medical Research to launch a study into the side-effects of the drug but activists countered that should be completed before the Mumbai slum trials begin. This is all the truer given that health professionals have largely discounted the investigation which initially indicated possible utility form Hydroxychloroquine as it only involved a small sample size of 36 patients and was contrasted with a follow-up study on 150 people in China which found hydroxychloroquine did not have a significant impact on fighting coronavirus[23]. The drug was however noted to be a "game changer" by former president Donald Trump, someone the Indian prime minister Narendra Modi and his party frequently seek to strengthen and flaunt their ties to indicating potential political reasoning behind the decision.

Synthesis:

In this paper so far we have examined three key aspects which lay at the heart of the “Dharavi Miracle”. Now we will seek to establish that while these topics may seem disparate, attempts to find common threads are hardly desperate. At the core of each of these approaches to the unprecedented challenge of COVID in Mumbai’s slums is an unfortunately persistent apathy to the consequences of blunt approaches on vulnerable populations.

Let us first return to our discussion of the governmental strategy utilized in Dharavi to control COVID. While barricades, drone surveillance and movement restrictions are common fare in portrayals of fictional epidemics, Dharavi was the first time I encountered this type of measure being utilized in reality and receiving praise rather than censure. It is difficult to imagine any context outside the politically and economically impotent residents of Mumbai’s slums where this could occur with so little domestic and foreign introspection. Equally overlooked is the economic impact of the government’s policies. As we noted earlier government intervention in Dharavi saw the closure of the shops, small factories and markets which constitute the informal economy of the polity and account of close to 1 billion dollars in revenue per annum[24]. Admittedly, the government did attempt to mitigate impacts of closures through the Mumbai government distributing 10,000’s of meals, however laudable as this is in principle, the Dharavi slums have a population of over 1 million people so exactly how helpful these efforts were remains questionable.

The psychological morbidity and mortality induced by economic lockdown must also be considered. It has been documented that in India the poorest wealth tercile had significantly higher rates of anxiety in response to COVID[25]. Losing a job increased the risk of anxiety by 2.50 times[25]. Even compared to those who occupy similarly low socioeconomic strata in other low and middle income nations India’s poor seem to be uniquely psychologically injured[25].

While some authors do acknowledge that in areas like Dharavi where most people depend upon daily wages and have to step out to earn their livelihood a strict lockdown is impossible without proper planning they fail to explain how this was accounted for in Dharavi while extolling its brilliance[2]. What is perhaps more notable than the failure to consider the impact on the lives of the citizens of Dharavi is the reification of these policies as acceptable. By upholding the 4T strategy as a future model around which to shape future interventions to pandemics in densely populated slums globally, the literature justifies and in fact praises ignoring the impact of draconian policies on vulnerable populations.

The consideration that reduced mortality from COVID does not necessarily mean reduced mortality overall motivates a return to our discussion of TB. While numerous papers point to the fact that latent tuberculosis reduces COVID viruses' fitness they are less clear on the mechanism. Work from India however offer evidence that TB's anti-COVID effects are achieved by increasing the fitness of mycobacteria and consequently the conversion of latent to active TB infection. Underlying this remarkable and timely finding is the fact that *Mtb* reactivation is associated with significant boosting of ASC mediated anti-viral activity, a phenomena explored within our own institution[26, 27]. When confronted with the challenge of the immune system mycobacteria can through the ASC pathway sacrifice a measure of individual fitness to benefit the population as a whole by adopting a more stem cell like morphology, a unique defense mechanism which can be explained as a charitable deed that help the neighbors to survive unfavorable conditions[26]. In a preliminary study researchers demonstrated that an ASC based innate defense response against infection with the mouse coronavirus; MHV-1. Assessment of the lung tissue of MHV-1 infected mice exhibited the ASC phenotype, expression of genes associated with the HIF-2alpha stem cell morphology promoting pathway, and subsequently "activation of p53 and its downstream genes including p21 and p53 up-regulated modulator of apoptosis"[26]. Further evidence of ASC

reprogramming *in vitro* emerged from an analysis of the cytoprotective activity of these ASCs in MHV-1 mediated toxicity of lung alveolar epithelial cells. The consequence of these findings at least in murine models is that *Mtb* infection may boost defense against MHV-1 which while potentially protective against Covid-19 could also be instrumental in TB reactivation.

Beyond the direct immunological interaction is the impact the pandemic has had on routine TB care particularly in settings like Dharavi. In one public Indian hospital it was noted that in the first three months of lockdown there was a 98% decrease in the number of tuberculosis patients (both pulmonary and extra-pulmonary tuberculosis) coming for their scheduled post-anti-tuberculosis treatment CT in the first two months of lockdown and a 90% decrease in the third month of lockdown compared to the prelockdown month. The number of active tuberculosis cases detected on CT also decreased by 62%–72%[28]. Rather than an overall positive what we may be seeing is a shift from COVID deaths to Tuberculosis ones due to patients being lost in our hyper focus on the pandemic.

We now come to the experimental nature of the Indian government's therapeutic interventions. While only briefly discussed in our initial considerations, it forms an invaluable aspect of this paper's synthesis as it reveals the key issues in play in establishing the "Dharavi Miracle". Before refocusing on Dharavi and COVID a brief overview of India's medical trial industry is essential. India is the only country in which the violation of good clinical practice represents a criminal not civil offence[29, 30]. In addition, Indian research organizations place extreme emphasis on informed consent. Take for example Vimta Laboratories, a major player in the Indian COVID testing marketplace. Beyond its diagnostic testing branch, Vimta represents the gold-standard of Indian clinical research organizations, is the only one traded on the Bombay Stock Exchange, and has been audited twice by the FDA—passing both times with flying colors. Integral to the organizations success is the great pains it takes to adhere to ethical guidelines. In the waiting room a white board outlines all the risks that could accrue to participants

in a clinical trial. In addition, all subjects who wish to participate have to be literate and male (Vimta only enrolls females if the trial sponsor specifies a need for female subjects). The company itself introduces its own specific guidelines such as the fact that subjects weighing less than 55 kg's are immediately rejected due to the unacceptable risk of complication[31]. As the sincere concern with informed consent and good clinical practice, reflected both in national laws and in the practices of companies such as Vimta demonstrate, the issues so often observed in foreign medical trials are not exclusively or even primarily a matter of ethical guidelines.

As Vimta and broader Indian policies demonstrate the lettering of research protocols can be transplanted and well established in developing countries; what is often ignored in the rush for universal standards however is the need for societal values and structural frameworks that give these guidelines value[32]. In the Indian context, there is no guarantee that an experimental drug tested on a local population will necessarily be marketed there after approval—let alone be made available at an affordable cost[31]. Consequently, Indian populations are left without the implicit social contract of eventual therapeutic access and research participants are reduced to purely experimental subjects. Ethics in the Indian context and more generally developing world are in absence of appropriate social frameworks provisional, partial, and focused on legal concerns such as acquiring informed consent rather than any truly meaningful patient protections. As a consequence, research participation in the global south represents a form of high risk labor not an investment in the social good.

The discrepancies between trials conducted in developed and developing nations are also inextricably tied with the principle of bio capital, both facilitating and being facilitated by it. Bio-capital closely mirrors Marx's views of capital with the exception that in Foucauldian terms, "it is not labor but life itself which becomes the locus of value, with health becoming the index of life, rather than the facilitator of labor." [33] Research participation plays a central role in the generation of surplus health and the perpetuation of systems of bio capital. As we have seen,

biomedical markets in advanced liberal societies—especially the United States—depend on the generation of surplus health, which in turn relies on the setting of risk thresholds. The knowledge of disease risk provided by diagnostic-testing capabilities, and calibrated through these thresholds, enables the marketing of drugs for diseases that are increasingly reframed as ‘chronic’. Much of the Phase 1 experimentation necessary to establish these baseline values initially performed on marginal populations in the US; is now being increasingly exported to Third World sites such as India[32]. This move stems as we have demonstrated not from a desire to escape research protocols but knowledge that experimental subjects outside the circuits of pastoral care and incapable of therapeutic consumption, can be merely risked[32]. This further underscores the close relationship between surplus value and surplus health as much like machinery increases surplus-value through an increase in efficiency, clinical trials serve to bolster surplus health by demonstrating therapeutic efficacy; vital to both these endeavors is the availability of populations to conduct high risk labor[32].

With this understanding we can now return to our considerations of Dharavi. When considering the steps taken in Dharavi with respect to Hydroxychloroquine we see the expansion of biocapital from the confines of formalized research into vulnerable segments of the Indian public more generally. It is for example well known that monitoring of patients on antimalarial medications like hydroxychloroquine is important even for those deemed at low risk.as electrocardiographic abnormalities may be serious, particularly in people who have serum electrolyte abnormalities, or are on other medications, including diuretics, macrolides, other QT-prolonging drugs and those who have chronic renal insufficiency and heart diseases[34]. In Dharavi where nutritional and infectious co-morbidities are often the rule not the exception monitoring is all the more important[35]. With the weakening of routine health infrastructure due to COVID this type of surveillance already challenging in the Indian context becomes all the more so. Challenging does not mean impossible however. While ideally the

deployment of hydroxychloroquine should only occur after assessment including ECGs, baseline QT interval measurements and serum electrolyte levels, low cost, handheld, portable, pocket sized ECG devices offer an alternative and allow for pre-administration assessment at far lower cost[20]. While we can be charitable and accept the intention of the Indian Council of Medical Research and the BMC to protect the people from the pandemic through empiric and pre-emptive mass administration of CQ and HCQ, a police-led forceful implementation of any public-health measures in the present situation to the urban slum communities appears unwise to say the least[20]. That some of the calls against the measure are from inside the house so to speak should give us further pause: Varsha Eknath Gaikwad, Maharashtra's minister of education, was an author of a critical BMJ piece. As the situation stands at present unless convincing evidence is available, an ethically approved randomized controlled trial for studying the role of prophylactic hydroxychloroquine in preventing secondary SARS-CoV-2 infections, based on the ring vaccination design for smallpox and Ebola should be implemented [18]. While Indian regulatory bodies most notably the Indian Research Council cite troubled times as requiring a tradeoff in stringency for timeliness, the same excuse was used elsewhere in India when the People's Hospital in Bhopal enrolled multiple poor, illiterate people – many of them survivors of the 1984 gas tragedy – for Covaxin's phase 3 trials while denying them the appropriate compensation and care, a frank breach of ethics in any circumstance undercutting the argument to an extent[36].

What emerges from our assessment of the "Dharavi Miracle" is an increasingly apparent distinction between the kind of life encompassed by the American, European and higher income Indian beneficiary of government interventions and more vulnerable citizens who simply have to accept and endure their consequences. The ultimate consequence of the factors we have contemplated is that India is rendered a pool of cheap, bioavailable bodies. What began with research has now unfortunately expanded to encompass broad swathes of society. It is now

increasingly politically acceptable to sacrifice the economic wellbeing and privacy rights of the poor in addition to risking their health in the name of securing the health needs of the more affluent. At the same time allowing and in certain circumstances covertly celebrating the historic diseases of crowding and poverty like Tuberculosis and Diarrheal disease by painting them in the veneer of scientific language and studies as tools against novel pathogens serves only to further obscure the plight of those society largely already overlooks. As should now be perceivable the answer to global inequalities in power and treatment rests not with a standardization of ethics or globalization of markets but with a standardization of human lives. Perhaps authors of both scientific and journalistic literature are to some small extent aware of this uncomfortable truth as no follow up studies have emerged as India drowns in new waves of COVID and the results for Dharavi have been anything but miraculous. In conclusion, so long as systems of bio-capital view and subsequently render some mere subjects and others consumers, life itself becomes a commodity and all are vulnerable to exploitation. In the absence of meaningful interventions to increase accessibility to medication and health services along with addressing still extant neocolonial chains, those more powerful people and institutions whether domestically or globally will continue to utilize “vulnerable people in vulnerable countries as drug laboratories” as they have for centuries[31].

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