To Appear in IEEE—Engineering Management Review; DOI: 10.1109/EMR.2020.30104382020
Date of Acceptance: Jul 20, 2020

Public Policy in a Pandemic: A Hazard-Control Perspective and a Case Study of the BCG Vaccine for COVID-19

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***Abstract*—The first cases of COVID-19 were reported in China in Dec, 2019, quickly spreading to other parts of the world leading to a global pandemic. A number of potential interventions and treatments are being considered. However, in the midst of a pandemic, much early reporting can contain misleading and contradictory data. Thus, reliable information and reasoned perspectives by decision-makers must be attained to minimize the pandemic's current impact, as well as the impact in the likely second wave in the 'flu season of 2020-2021. One potential treatment is the use of booster doses of the BCG (Bacille Calmette-Guerin) vaccine; this vaccine is mandatory at birth in many lower-income nations. In this paper, using widely available and reliable data, the relationship of per-capita GDP (Gross Domestic Product) and the BCG vaccine's use on the impact of the virus is studied via statistical models. A strong association is seen between lower per-capita GDP and lower impact. Further, a lower impact is witnessed in countries where the BCG vaccine is mandatory at birth, which suggests that clinical trials need to occur to determine the vaccine's efficacy. Perspectives in safety and risk mitigation needed for management of pandemics and similar events are also provided.**

***Index Terms*—Pandemics, healthcare, strategic management, safety, risk management, BCG vaccine, interventions**

I. Introduction

THE COVID-19 pandemic has emerged from a corona virus that has the ability to spread rapidly across the world. The virus was first detected in China in Dec, 2019. Many factors potentially play a significant role in how quickly diseases spread, e.g., the overall health of populations, history of vaccinations, the average age of the population, ventilation of homes, and social and cultural differences, to name a few. Governmental response to the pandemic has varied across countries, especially in its early stages. Unfortunately, there is a great deal of confusing and contradictory information available to strategic decision-makers in this time. Many measures, typically known as "interventions" have been commonly recommended to control the spread and reduce loss of life: testing and tracing, quarantining of sick patients, social distancing, and use of masks [1]. However, there are significant issues related to these measures. First, reliable tests have been difficult to produce for corona viruses in general with high rates of false negatives and positives [2]. Second, data are hard to find for the impact of these interventions.

Different from "interventions," exist potential "treatments," which are being examined in many countries. Some of these include (i) the development of a vaccine for the specific corona virus strains discovered, (ii) plasma therapy, (iii) a link between the BCG (Bacille Calmette-Guerin) vaccine and increased immunity to COVID-19, (iv) the drug Remdesivir, and (v) the drug hydroxy-chloroquine. Determining the efficacy of these treatments will require time-consuming medical studies, but any potential link between the BCG vaccine and reduced fatality rates can be performed from existing data, as the BCG vaccine has been mandatory in many nations and data for spreading and fatality rates are available from those nations as well. The BCG vaccine is for tuberculosis (TB), and since TB has been eradicated from many countries, TB vaccines have been discontinued in many of those countries. However, the TB vaccine is still mandatory in some countries where TB has all but disappeared [3]. The BCG vaccine appears to have produced strikingly different results in the number of casualties between two neighboring countries with vast similarities: Spain and Portugal [4].

The other aspect that governmental agencies take into account is healthcare spending, which is typically higher in more developed nations. Poorer nations often do not have the infrastructure to control a pandemic. In general, decision-makers in more affluent nations tend to have access to a wider variety of resources to tackle public-health issues and control hazards in shorter time intervals. Therefore, intuition suggests that higher per-capita GDP should lead to a stronger ability of

*Communicating Author. The authors would like to acknowledge the information provided about the research of Professor Gobardhan Das on the BCG vaccine in an interview of Professor A. Ranganathan conducted by Kanchan Gupta of the Observer Research Foundation, New Delhi, India.

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a nation to fight an infectious disease. However, it is necessary to conduct a statistical study before a definitive conclusion can be arrived at. Thus, statistically verified information should provide immense value to decision-makers.

A rigorous statistical analysis on the effect of the BCG vaccine and per-capita GDP spending on the impact has *not* been carried out in the literature to the best of the knowledge of these authors. This paper performs a regression-based analysis that seeks to fill this gap in the literature. A significant advantage of developing a model is that it can ascertain in a statistical sense whether a given factor produces an impact. Further, statistical models can also provide a deeper understanding of the underlying critical factors in this pandemic. It needs to be emphasized that statistical models of the kind studied in this paper can only indicate potential relationships; in order to determine the efficacy of the vaccine, clinical (medical) trials need to occur. The paper also provides a so-called hazard-control perspective for pandemic control that can help governments make more informed strategic decisions and thereby reduce loss of life. Mitigation measures need to be implemented without loss of time, as the virus is likely to make a comeback in Fall, 2020, and as such, there is not much time remaining.

II. BACKGROUND

This section develops the background for the statistical models developed in this paper. Section II-A provides a hazard-control perspective with respect to a pandemic in detail. Section II-B discusses the nature of the independent and dependent variables selected in this case study.

A. Perspectives in Safety and Risk Management

In risk analysis for strategic management, one typically considers two scores on behavior [5]: (i) the likelihood (the probability of occurrence) and (ii) the consequence (or the impact) of the event. The consequence is typically measured in terms of loss of life or damage to property. In the case of hazardous events, typically, either the probability or the consequence is high. For instance, high-intensity earthquakes, tsunamis, and 500-year floods occur rarely but have a disastrous impact [6]. River flooding occurs with a higher frequency in many parts of the world, but usually has a lower impact. When it comes to diseases, viruses such as HIV have high consequence, i.e., death rate, but a low probability of spreading from humans to humans. On other hand, in the SARS epidemic of 2003, the viral infection spread with a high probability but the death rate was relatively low with a total number of 773 deaths worldwide [7].

Unfortunately, certain epidemics are either high or moderately high on *both* scores, which separates them into an altogether different category in terms of the devastation caused – rendering them extremely critical for public policy-making for preparedness efforts and planning mitigation. In this critical category, one naturally needs to distinguish the two scores on a finer scale. Thus, one can further categorize these critical pandemics into two sub-categories based on: (a) a moderately high probability of spreading and a high consequence, while some have (b) a high probability of spreading and a moderately high consequence. The NIPA virus is an example of sub-category (a) where the death rate can be 75% [8], while COVID-19 appears to be an example of sub-category (b), because, as of the date of writing this article, worldwide more than four million have been affected and the death toll has already exceeded 270,000.

There are at least three issues that are troubling about this crisis and are counter-intuitive. First, an effective vaccine against corona viruses that caused deaths in the past, e.g., SARS and MERS, has never been discovered, although these viruses have been known and studied for many years now [2]. Secondly, a striking finding loosely reported in media is that countries with higher GDP and healthcare spending appear to be affected more seriously [9]. As a result, it is not clear whether higher investments in resources alone will produce desirable results. Three, testing and tracing are known to keep the spread of infections under check, but while testing may become possible, tracing will be difficult in a country as large as the U.S. Because of these confounding factors and the magnitude of this pandemic, it is essential that statistically reliable studies that help explore its characteristics be carried out.

A long-held perspective in the engineering safety and risk management disciplines is the relationship between the existence of a known *hazard*, a personal or group *exposure* to that hazard, and the ability to *control* either the hazard itself or exposure to it, and ultimately danger and risk [10]. The hazard-exposure-risk relationship can be applied to many areas of personal, occupational, and public safety. Also, from an engineering safety and risk management perspective, control strategies are categorized as controls at the *source* of the hazard, controls of the *path* of transmission, and controls at the *receiver*, i.e., the individual or the population that could be impacted. Knowledge of the mechanism of these three formats of hazard control is helpful in understanding how this pandemic can be controlled. In what follows, these formats are described in some detail along with the nature of interventions needed.

Hazard Control at Source: Typically, this is interpreted as elimination of a hazard *altogether* and thus eliminating exposure and consequently danger and risk. In a wide variety of safety applications, elimination of the hazard is always the highest design objective. In many situations, however, elimination of a hazard may be technically or economically infeasible. In these situations, attention can be focused on minimizing exposure and transmission of hazards.

In the case of this virus, controlling the hazard at its source could include a vaccine for human hosts, thus, eliminating the hazard and its transmission to potentially new and susceptible hosts. At this date, as discussed above, a proven vaccine has not been developed. Complete isolation of a source, in theory, could also be an effective source control mechanism. However, there are logistical and economic limitations to complete and secure isolation of an individual, and certainly entire populations, that render this method a theoretical construct.

Hazard Control in the Path: Preventing transmission of any hazard is the next priority for system designers when the hazard cannot be eliminated at the source. If effectively implemented, danger and risk can be greatly reduced through this strategy. But a key perspective is that under this condition, the hazard is still present (i.e., it has not been fully eliminated) and risk can only be mitigated to the extent of the effectiveness and reliability of the pathway control. Some common examples of this strategy in the current pandemic are quarantining, hand washing, or use of various personal protection equipment (PPE), such as gloves and facial masks. However, as these technologies and procedures can only *partially* mitigate the transmission of a hazard, the hazard can still be present and, therefore, these techniques are not fail-safe, regardless of the degree of designed safety. Thus, quarantining and full hazmat suit are examples of extreme controls, while social distancing and face masks are examples of less severe controls that are easier to implement or produce. But both are subject to failure from technology or human factors such as errors of usage [11].

Hazard Control at Receiver: This control strategy typically seeks a direct mode of protection for the receiver, independent of pathway. Some PPE can be classified as controlling at the receiver, but superior examples of this form of control would be for the receiver to possess a validated antibody for the virus. The control is systemic to the receiver in this case. Further, the receiver is thought to be protected against infection by this same virus again, and under normal circumstances cannot pass on the virus to others. Another example could include segregating and applying more advanced path controls to a subpopulation known to be more vulnerable to the virus, such as the elderly or those with known pre-conditions [12].

As discussed above in the context of different hazard control mechanisms, social distancing, lockdowns, use of masks, handwashing, and testing and tracing are some of the many interventions suggested to reduce the spread of a pathogen during an epidemic. It is unfortunately difficult to find data on all of these variables for the different countries affected by COVID-19 for many reasons discussed next. Data on the scale of social distancing and the severity of the lockdown are difficult to quantify and are not available at this time, since no systematic processes have been established to gather such data. Tests were not available in most countries for a long time, while many countries that used tests discovered later that they were unreliable with alarmingly high rates of false negatives and positives. One of the exceptions to this is Germany, which produced its own tests and their manufacturing started in January, 2020 [13]. S. Korea also performed extensive testing, but there is no data available on how reliable their tests were. Small countries like New Zealand have performed tracing after testing, but again data on the exact magnitude of testing and tracing are not available. Lockdown started in different countries at different points in time, and the severity of lockdown has also varied significantly across countries. Only in Sweden, the lockdown was less severe in comparison to that of other European nations [14]. Data are also hard to find for variables stemming from cultural and climate-related differences, e.g., ventilation of homes, use of public transport etc.

B. Variables Considered in this Study

Because of the difficulties in obtaining data on the interventions discussed above, despite their direct impact on hazard control, and since the focus here is on strategic management for governments, this study chose to look at a different angle, as discussed above: The impact of GDP and the BCG vaccine. Thus, two independent variables for which reliable data are available were considered: (i) per-capita GDP of a nation and (ii) the prior history of the BCG vaccine in a nation.

Before a statistical study is conducted, it is necessary to determine which societal metrics are to be measured and improved. These metrics generally form the dependent variables in this study. Two metrics were selected: (i) spread index (*SI*) and (ii) the fatality index (*FI*). The Spread Index (*SI*) for a country was defined as:

$$SI = \frac{Number\ of\ incidents}{Population}.$$

The Fatality Index (*FI*) for a country was defined as:

$$FI = \frac{Number\ of\ deaths}{Population}.$$

These two metrics were chosen as they capture the health impact of the pandemic in quantitative terms; furthermore, accurate data are also available to compute these metrics for different countries. Data from 36 nations were used in this study.

III. Regression Model and Analysis

Liner regression models were used to determine if per-capita GDP and the use of BCG vaccine affected the two societal metrics discussed above. The regression models used the following format:

$$Y = \beta_0 + \beta_1 X + \epsilon$$

where Y denotes the dependent variable, X the independent variable, and ϵ the error in the model. Four regressions were run:

(i) Model 1: *SI* as *Y* and per-capita GDP as *X*,
(ii) Model 2: *FI* as *Y* and per-capita GDP as X,
(iii) Model 3: *SI* as *Y* and BCG as *X*, and
(iv) Model 4: *FI* as *Y* and BCG as *X*.

For the independent variable, the following coding of data was performed: For per-capita GDP, the natural log of the per-capita GDP was used as the value of X. For the BCG vaccine, X was set to 0 in countries where the vaccine is *not* mandatory and set to 1 where it is mandatory.

For the spread and fatality indexes, data are being made available by Google [15]. For GDP, the data were sourced from the World Bank's website and the BCG data were retrieved from [16]. Data for 36 nations from different regions of the world were used. The regions include North America, Europe, and Asia. The data used for the analysis for the GDP, the BCG vaccine, and the two societal metrics are provided in Table I. The output from the regression models, i.e., results for Models 1 through 4, are presented in Table II.

PLACE TABLE I ABOUT HERE

PLACE TABLE II ABOUT HERE

Models 1 and 2 study the association between per-capita GDP and the incidence and fatality rates respectively, while Models 3 and 4 study the same between the use of the BCG vaccine and the incidence and fatality rates respectively. Model 1 establishes the relationship between the Spread Index and GDP per capita. The β_1 value from the regression result for this model indicates that the higher the GDP per capita of a country, the greater the expected spread of the virus. For this model, the β_1 value has a 99% level of significance (p-value) and the absolute value of the t-statistic, i.e., $|t\text{-stat}|$, is more than double the accepted value of 2.0. Model 2 studies the relationship between the Fatality Index and GDP per capita. Although the value of β_1 in this model is not as high as in Model 1, the level of significance is 95% and the $|t\text{-stat}|$ value exceeds 2.0, indicating that the countries with higher GDP per capita are *more likely* to have a higher fatality rate because of the virus than other countries.

A part of the reason for the concerning results of Models 1 and 2 can be found within the results of Models 3 and 4, which investigate the relationship between the BCG vaccine and two indexes—Spread and Fatality. The β_1 values for both the regressions in Models 3 and 4 are negative which suggests that the countries that have been administering the BCG vaccine are experiencing *fewer* cases of the spread and fatalities respectively resulting from the virus than other countries. Results from Models 3 and 4 have a 99% level of significance (p-values), and their $|t\text{-stat}|$ values have more than double the accepted threshold of 2 (4.11 and 4.95 respectively for Models 3 and 4).

PLACE TABLE III ABOUT HERE

In the immediate term, these results seem to indicate that booster doses of the BCG vaccine could potentially save lives in countries where the vaccine is not mandatory. TB has virtually disappeared in countries with higher living standards, leading to the discontinuation of the BCG vaccine, but there is also biological evidence supporting the claim that the BCG vaccine makes the body resistant to other pathogens [17]. This suggests that the option of phased clinical trials should be considered by the medical community to determine whether the vaccine does indeed improve resistance to this virus. One other conclusion that can be drawn is that countries with higher per-capita GDP cannot remain complacent in light of this finding and every avenue that potentially reduces the probability of the infection needs to be pursued. A glossary of terms used in this paper is provided in Table III.

IV. Conclusions

The overarching goal of this work was to provide a fundamental hazard-control risk perspective to decision-makers and those advising decision-makers in pandemic management. In light of the often-contradictory information available to decision-makers, this paper conducted a statistical analysis on reliable data to develop insights that should help in making informed decisions. A significant effort is being devoted in the literature to developing simulation models that can help predict the spread index in case lockdown and other measures currently adopted are eliminated. In this paper, a different aspect of this pandemic was studied. The analysis showed that the fatality rates seem to be higher in nations with higher income (per-capita GDP) levels, which indicates that there is no room for complacency in dealing with this virus. The research further showed a statistical link between the BCG vaccine, mandatory in lower-income nations, and a lower spread and fatality indexes; this does *not* prove that the vaccine may be effective but it indicates that phased clinical (medical) trials may help determine its efficacy. A general conclusion from this work is that outside-the-box thinking and engaging with protocols of hazard control at the source, e.g., existing vaccines discontinued in some parts of the world, may also be necessary to control the pandemic.

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Table 1: Data for per-capita-GDP, Spread and Death Indexes, and BCG.

Country	Spread Index (*SI*)	Fatality Index (*FI*)	BCG	Log of Per-capita GDP
U.S.	0.003668	0.000211	0	10.92808
Austria	0.001765	6.84E-05	0	10.74204
Belarus	0.001938	1.13E-05	1	9.783682
Bulgaria	0.000242	1.12E-05	1	9.868935
Canada	0.001637	0.000105	0	10.69372
Croatia	0.000516	1.97E-05	1	10.07172
Denmark	0.001688	8.65E-05	0	10.78766
Estonia	0.001299	4.18E-05	1	10.34288
Finland	0.000978	4.45E-05	0	10.64687
France	0.002521	0.000375	0	10.58546
Germany	0.002011	8.45E-05	0	10.73501
Greece	0.000246	1.36E-05	1	10.13224
Ireland	0.004493	0.000274	1	11.1684
Italy	0.00353	0.000469	0	10.4865
Latvia	0.000468	8.87E-06	1	10.17425
Lithuania	0.000512	9E-06	1	10.34745
Netherlands	0.002391	0.000301	0	10.81551
Norway	0.001472	3.99E-05	0	11.08811
Poland	0.000381	1.89E-05	1	10.26763
Portugal	0.002511	0.000105	1	10.27503
Romania	0.000715	4.34E-05	1	10.10798
Spain	0.005363	0.000548	0	10.45825
Sweden	0.002265	0.000278	0	10.77306
Switzerland	0.003498	0.000173	0	10.99066
UK	0.002917	0.00044	0	10.60961
Ukraine	0.000286	7.12E-06	1	9.012775
India	3.4E-05	1.15E-06	1	8.837563
Indonesia	4.46E-05	3.22E-06	1	9.359265
Japan	0.00012	4.25E-06	1	10.57882
Malaysia	0.0002	3.32E-06	1	10.24711
Philippines	8.96E-05	5.89E-06	1	8.979985
Singapore	0.003399	3.15E-06	1	11.40858
S. Korea	0.000211	4.91E-06	1	10.51261
Sri Lanka	3.54E-05	4.14E-07	1	9.388947
Thailand	4.29E-05	7.76E-07	1	9.735347

Table II: The results of the regression models: *L* and *U* denote the lower and upper limits of the 95% confidence interval of β_1

	Model 1	Model 2	Model 3	Model 4
β_0	-0.01369	-0.00089	0.00255	0.00023
β_1	0.001476	9.7E-05	-0.0017	-0.0002
L	0.000842	1.72E-05	-0.00255	-0.00029
U	0.002109	0.000177	-0.00086	-0.00012
p-value	3.94E-05	0.018793	0.000243	2.16E-05
t-stat	4.741931	2.471355	-4.11385	-4.94661
R^2	0.405254	0.156174	0.338992	0.425776

Table III: A glossary of terms used in this paper

Term	*Definition*
Intervention	A procedure such as use of masks, quarantining, or handwashing to mitigate the risk of a pandemic
Treatment	A medical treatment such as a vaccine or an anti-viral drug given after or before the infection
Likelihood	Probability of the occurrence of a hazardous event
Consequence	Magnitude of the impact of the event, e.g., in terms of loss of life or property
Spread Index	$\frac{Number\ of\ incidents}{Population}$
Fatality Index	$\frac{Number\ of\ deaths}{Population}$