Protocol

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Assessment of relative efficiency of COVID-19 vaccines granted emergency use authorization in India and their respective modes of delivery-an economic evaluation

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ABSTRACT

Background: Effective public health interventions need to be assessed for efficiency in order to optimize results and justify investments especially under conditions of uncertainty and resource constraints. The COVID-19 pandemic has presented unprecedented situations where decisions had to be taken based on limited evidence available in order to save human lives. Vaccines have been identified to be the mainstay of the public health response to the pandemic. In India, nine vaccines have been granted emergency use authorization (EUA) and are being delivered through multiple modes. Efficiency of vaccine delivery needs to be established to maximize results and formulate policy in long run. **Methods:** This study will be conducted in Delhi and Bhubaneshwar. Two systematic reviews, a cross-sectional community survey and a complete economic evaluation using a decision tree model will be carried out to meet the study objectives. Data will be captured through computer assisted personal interviewing (CAPI) using CS pro software. Outcomes will be measured in lives saved and quality adjusted life years (QALYs) gained by vaccination. This will be the first study providing a detailed cost of COVID-19 vaccination and treatment segregated by government or private provider

Conclusions: The study would establish the relative efficiency of each vaccine granted EUA over the other by their individual modes of delivery.

Trial registration: The study does not involve any trial and hence no specific trial registration is not required. However, the protocols for systematic review have been registered in the PROSPERO database (CRD42023432680, CRD42023433006).

Keywords: COVID-19 vaccines, Economic evaluation, Cost of illness, Cost-effectiveness analysis, Cost-utility analysis, Relative efficiency

INTRODUCTION

Public health policy makers have to rely on evidence for sound policy making. However, emergency situations demand immediate action and the priority to save human lives and alleviate suffering, becomes high. Such actions are often based on anecdotal or related evidence, especially when the crisis is unprecedented like the global COVID-19 pandemic. Public health responses have been

based on limited information and research available with the global public health fraternity.

Vaccination has been identified to be the primary ammunition to combat the pandemic. Multiple candidate vaccines are being worked upon and are at different stages of research. The world health organization (WHO) has granted emergency use authorization (EUA) for nine such vaccines as of August 2022. The ministry of health

and family welfare, government of India has granted EUA to nine COVID-19 vaccines as of February 2022.²⁻⁵

Table 1: COVID-19 vaccines approved for restricted use in emergency situation in India.

Vaccine	Manufacturer/ applicant	No. of doses	EUA granted in
Covishield- Produced by AstraZeneca,	Manufactured in India by serum institute India.	Two doses	
Covaxin	Bharat Biotech limited.	Two doses	December 2021
Sputnik-V	Gamaleya Centre, Russia	Two doses	April 2021
Moderna mRNA vaccine Moderna Inc.	M/s Cipla Ltd (Importer)	Two doses	June 2021
Janssen	M/s Johnson and Johnson Pvt. Ltd. (Importer)	Single dose	August 2021
ZyCoV-D vaccine	Cadila Healthcare	Triple dose	August 2021
Corbevax	Biological E Limited	Two doses	December 2021
Covovax	Serum Institute of India	Two Doses	December 2021
Sputnik Light	Dr. Reddy's Lab	Single Dose	February 2022

The COVID-19 vaccination programme in India started from January 2021 and continued in phases. The programme started with vaccinating health and frontline workers in the first phase and gradually expanded to include other population groups based on vulnerability. Currently, the programme aims to vaccinate all individuals above 12 years of age on the day of their vaccination. As a result of rapid vaccine technology advancements, the basket of vaccines approved for administration has increased from two in 2021 to nine vaccines approved for use.

Two modes of vaccine delivery have been adopted in India. Vaccines are provided, free to the user, directly by the government through facilities like hospitals, schools and other sites. Vaccines are also provided through private health care providers at a pre-designated user fee as regulated by the government.³

These modes of delivery are aimed at maximizing vaccine coverage. As per our world in data, until June 2, 2023, 72.5% of the population in India has received at least one dose, while only 67.2% of the population has completed the initial vaccination protocol (2 doses for most vaccines, 1 or 3 for a few manufacturers).

The overall aim of reduced mortality and morbidity from COVID-19 illness depends on multiple factors like vaccine coverage, vaccine efficacy, treatment efficacy, accessibility and case fatality rates. However, since vaccination has been accepted as the key strategy in the COVID-19 response, the efficiency of the vaccine delivery system must be examined for each vaccine in terms of cost and effectiveness. Moreover, with growing evidence that COVID-19 is going to be a public health priority for a long time in the future, such efficiencies are more important to be achieved to ensure positive outcomes.

Aim

The study aims to assess the relative efficiency of the most used COVID-19 vaccines granted EUA by their modes of delivery through a complete economic evaluation.

Objectives

The following objectives will lead to the achievement of the study aim-To synthesize evidence on cost of COVID-19 vaccination in low and lower middle-income countries, to synthesize evidence on economic evaluation of COVID-19 vaccines in low and lower middle-income countries, to assess the cost of vaccination for the COVID-19 vaccines granted EUA by their modes of delivery, to assess the cost of illness (COI) of COVID-19 illness in Government and Private service providers and to assess the relative efficiency of the most used COVID-19 vaccines granted EUA in India.

METHOD

The study will be conducted from April 2022 to March 2024. This section encloses the specific methods designed to meet the study objectives.

Systematic review

A two-part systematic review will be conducted to meet objectives 1 and 2.

A conceptual framework has been developed to identify the scope of this study that would meet the aims and objectives described above. Relevant databases and journals will be searched with appropriate search terms based on the inclusion and exclusion criteria using Boolean searches. The context of this review will be limited to low and lower-middle income countries as defined by the world bank.⁷

The review will be guided by Cochrane review guidelines for economic evaluation. Meta-analyses for quantitative results will be performed where relevant to inform the study and illustrated using forest plots. Further, a detailed assessment of the quality of selected studies using accepted standards will also be done.

Detailed protocols have been prepared for the two reviews and have been registered on Prospero. (CRD42023432680, CRD42023433006).

Cross sectional community-based survey

A cross-sectional community/ hospital survey will be conducted to meet the objectives 3 and 4. User costs of vaccination and treatment of COVID illness will be collected from the community based cross-sectional study and provider costs will be collected from government and private hospitals.

Cost elements

An ingredient based micro-costing approach will be employed to capture costs. The categories and types of costs to be included is detailed in Table 2.

Table 2: Types of costs to be included.

Direct costs		Indirect costs	
User	Provider	User	Provider
Vaccines	Vaccines	Food	Food (Indoor)
Diagnostics	Diagnostics	Trans- portation	
Drugs	Drugs	Food for care-providers	
Fees/ registration and similar payments	In-patient services	Transporta tion for care providers	
In-patient costs	Out-patient services	Loss of product-ivity	
Other out of pocket expenses	Consumable	Other out of pocket expenses	
	Staff costs		

A detailed care pathway for COVID-19 illness will be created to identify the various modes of uncertainty and cost elements. This pathway will be based on the treatment protocol as provided by the ministry of health, government of India. However, the pathway would be expanded to include local level deviations by service providers. The time-frame for collection of cost and effects will be extended from the initiation of symptoms to completion of treatment which would include the post-discharge period for hospitalised cases.

Study setting and population

The study will be conducted in Delhi and Bhubaneshwar. The cities have been chosen to represent two extreme experiences of the COVID-19 pandemic in the country as

well as two diverse regions. Though both cities have witnessed a huge number of COVID-19 cases, Delhi has experienced an extremely high incidence of the disease as well as morbidity. Bhubaneshwar on the other hand has been less devastated (8). The locations are also convenient as the IIPH-D has its sister organisation at this location (IIPH-B). The study population will be selected from the community. Provider data will be collected from hospitals. The study population will include individuals above eighteen years of age.

Sample size and sampling

Sample size for the cross-sectional study has been estimated by considering the cumulative proportion of COVID-19 infections for each of the states adjusted upwards to factor under-reporting, for which there is evidence. Final sample size for each state was then estimated by using 95% confidence interval and appropriate values of precision depending on the proportion of COVID-19 cases. In order to take care of the cluster sampling design, design effect of 1.5 has been used. Further, the sample size has also been adjusted for the expected non-response of 15%. Hence, a total number of 500 households will be selected for the cross-sectional survey across two cities of India. The details of the sample size estimation are provided in Table 3 below.

Table 3: Details of the sample size estimation for two cities.

Parameters	Bhubaneswar	Delhi	Total
COVID-19 cumulative proportion (%)*	6.8	7.1	
COVID-19 cumulative proportion (%)**	10	10	
Absolute precision (%)	5.0	5.0	
Confidence interval (%)	95	95	
Sample size	138	138	276
Sample size with design effect	207	207	414
Sample size with 15% non-response	244	244	488
Total sample size	250	250	500

^{*} From https://www.covid19india.org/. (Aug 10, 2021), **Increased proportion based on the evidence that the actual figures might be under-reported.

For selecting the required number of households in each of the two cities, multistage sampling technique will be done. The schematic diagram showing the method of selection of households is given in Figure 1. From each of the selected city, wards will be selected randomly covering all the geographical directions of the city, i.e. North, South, East and West. Adequate number of localities from each of the selected ward will then be

randomly selected. Finally, about 30-40 households from each of the selected locality will be selected using systematic sampling. This will ensure adequate representation of the entire city.

Similarly, provider data will be collected from the hospitals in each city. A complete list of government and private hospitals located in the North, South, East and West of the cities will be prepared. Same wards selected for community survey will be used for hospital selection as well. Two Government and two private hospitals will be randomly selected from the list. This is subject to requisite approvals and cooperation from hospitals. Hospitals will be conveniently selected if the sample hospitals are not available for data collection.

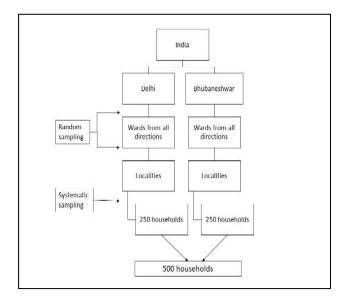


Figure 1: The proposed sampling strategy for selection of households for the cross-sectional study.

Data collection

A structured interview tool has been prepared for the study and has been presented in annexure-1. In-person interviews will be conducted and the data will be collected electronically using computer assisted personal interviewing (CAPI). A tablet computer will be used with pre-loaded tools developed in CS-Pro. Electronic format of EQ-5D-5l will be used to collect quality of life information, which will be transformed into Quality Adjusted Life Years (QALY) using the appropriate value set provided by EuroQol. Technology assisted data collection will seek to minimize errors, reduce time and improve continuous quality monitoring. Moreover, using CAPI will also reduce risk of COVID infections due to multiple handling of paper-based tools. All data will be collected by trained enumerators.

Quality control

The enumerators will be trained by the PI. The substantive data collection phase will be preceded by a mock drill to provide on-site training to enumerators. The

initiation of data collection at each site will be supervised by the senior project team. Completed tools will be checked at the site to provide feedback and continuous training to the enumerators to ensure high quality data. Data will be collected over a period of four months.

Pretesting and piloting

The tool will be pretested and piloted in a similar population and necessary changes to the tool will be made based on the results of the pretest.

Data analysis plan

Data from the CAPI will be uploaded directly onto the central database. The EQ-5D-5L data will be converted to QALYs using a Stata interface provided by EuroQol. Data analysis will be done using Stata 15.1. Descriptive statistics will be used to express costs and presented in mean, median and standard deviation. Probability data will be expressed in ratios with standard errors and 95% confidence interval.

Economic evaluation

A complete economic evaluation will be done to meet objective 5.

Study population

The study population will include individuals who are susceptible or were infected with COVID-19 and treated either at home or at an in-patient facility in the last 3 years in Delhi.

Perspective

The study will follow a limited societal perspective and will include costs and effects irrespective of who spends or experiences them. User costs will be limited to direct and indirect costs with financial implications. Direct cost will include cost of vaccination, drugs, diagnostics or any other cost directly attributable to the treatment. Indirect costs will include cost of transportation, food or any other costs related to access to services but not to the treatment. This will include the patient/vaccine recipient and the accompanying person. Cost of wages lost will be limited to the patient and the immediate care provider. Wages lost will be valued in monetary terms as well as qualitatively (days lost) to enable comparison across settings with variability in wage rates.

In case of vaccination/treatment by private providers, the user costs will be used as the complete estimate of cost as they are not expected to subsidise costs for the user. In case of Government providers, unit costs will be derived from personal interviews, secondary literature and hospital records.

Intervention

The efficiency of COVID-19 vaccination among adults with the vaccines authorized for emergency use in India will be assessed.

Comparator

The vaccines will be compared to each other.

Analytic horizon

Analytic horizon represents the period over which the costs and effects will be accounted for. The model will be analyzed over one-year analytic horizon.

Time frame

Time frame represents the period over which the intervention/treatment is administered. An incidence approach will be followed and individuals who have been infected with COVID-19 within the last three years will be included for data collection and subsequently for modelling. This would ensure inclusion of patients who were infected without any vaccine doses as well as with one or two doses of the vaccine.

Model

A decision tree model will be used for this analysis. An indicative model is included in Figure 2.

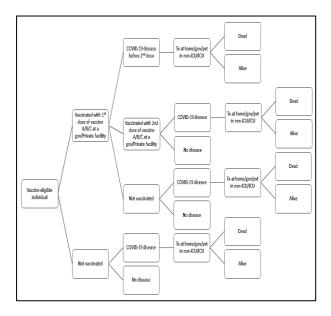


Figure 2: Indicative model for economic evaluation.

Cost and effectiveness data for economic evaluation

The study will involve data from primary as well as secondary sources. Primary data from objective 2 and 3 will be used to the extent possible for base case analysis. Secondary sources would include data from published

literature, Government databases and policy documents etc. Data from secondary sources will be used for sensitivity analysis. Both cost and probability data will be collected. The type of cost and probability data with their respective sources have been listed in Table 4.

Effectiveness in this study will be expressed in terms of final outcomes of lives saved. Intermediate outcomes will be modelled to the final outcome based on primary data, where available. Vaccine effectiveness depends on a number of factors including vaccine coverage, efficacy, disease incidence rates and case fatality rates. The variability in the parameters lead to uncertainty in outcomes and the need for decision modelling. The probability parameters and the source of data collection are listed in Table 4.

Table 4: Outline of cost and probability data with their sources.

then sources.			
Parameters	Source of data		
Cost parameters			
Cost of vaccination per dose for each vaccine type in a government/private setting	Primary data collection, secondary literature, policy documents		
Cost of treating COVID-19 illness in a government setting/private setting differentiated by non-ICU/ICU treatment	Primary data collection		
Cost of treating COVID-19 illness at home	Primary data collection		
Probability parameters	Source of data		
Probability of vaccination with each vaccine type with the first dose at a government/private facility	Secondary sources, primary data collection		
Vaccine efficacy after 1 dose and 2 doses	Secondary literature, policy documents		
Probability of vaccination with each vaccine type with the second dose at a government/private facility	Secondary sources, primary data collection		
Probability of treatment of COVID-19 disease in a government facility/private facility with non-ICU/ICU treatment	Secondary sources, primary data collection		
Probability of treatment of COVID-19 diseases at home	Secondary sources, primary data collection		
Case fatality rate in a government/private facility differentiated by non-ICU/ICU treatment	Secondary sources, primary data collection		
Case fatality rate at home	Secondary sources, primary data collection		

Study outcomes

The results of the economic evaluation will be expressed in terms of incremental cost effectiveness ratios (ICER) and presented as incremental cost/live saved.

Statistical analysis

Data will be analysed using Treeage Pro Healthcare. Base case analysis will provide the primary incremental cost effectiveness ratio (ICER). Univariate sensitivity analysis will provide information on key parameters influencing the ICER. An appropriate cost-effectiveness threshold will be used to interpret cost-effectiveness. Probabilistic sensitivity analysis using 10,000 montecarlo simulations will be done to ensure robustness of results under conditions of uncertainty. Future research areas will be identified by calculating expected value of perfect information (EVPI). This is done by systematically removing uncertainty in parameters and quantifying the value of removing uncertainty in the remaining ones.

Limitations

The study is planned with data from two metro cities. Hence, the results may not be generalizable to the entire country where the majority of the population is rural. Retrospective cost of illness studies are subject to recall bias. Respondents also tend to over report indirect expenses like transportation, loss of wages etc. with an expectation of future relief. This study will also be prone to such biases. A higher sample size leads to a more realistic distribution of values.

DISCUSSION

Cost of illness (COI) data is rare for most disease conditions in India. This study will generate primary data on cost of treating COVID-19 illness from two cities in India. The data will be segregated by various modes of treatment and by types of service providers including government and private. Apart from this, the study will also generate the cost of COVID -19 vaccination segregated by government and private providers. The study finally aims to assess the relative efficiency of the most used COVID-19 vaccines granted EUA by their modes of delivery through a complete economic evaluation (cost-effectiveness and cost-utility analysis). Economic evaluations of COVID vaccines have been conducted in other countries like China, Kenya, Pakistan, Iran and Canada with varying results. 12-17 While some found the vaccine to be efficient for elderly populations, some other found it to be efficient only at low vaccine prices. The study scenarios have also been varied. While one compared a booster dose with two previous doses of the vaccine while another looked at the various speeds of roll out of vaccine aiming to identify the optimal vaccine strategy. While, epidemiological studies estimating mortality and morbidity has however, been conducted no assessment of efficiency incorporating both costs and effects of the vaccination strategy has been conducted in India.⁸⁻¹¹ While India has responded relatively fast to the pandemic the assessment of the response will be valuable to prepare for future pandemics and will constitute an important part of public health learning.

CONCLUSION

Economic evaluations are crucial in assessing effectiveness of health technologies, especially in resource constrained settings. The results of this study will provide important information for outbreak management in pandemic situations. Apart from this, the incremental cost effectiveness ratios generated in this study will add to the country league table enabling comparison with other public health programmes including emergency management and pandemic preparedness.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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ANNEXURE 1

Variables		Cadalist	Cl-:
Variables		Code list	Skip pattern/comments
Date Did you suffer from COVID in last	Yes	1	Auto
Did you suffer from COVID in last	No No	0	Do not march
3 years	Yes		Do not proceed
Consent provided	No	0	Do not proceed
Enumerator ID	NO	U	*
Respondent ID			To be entered manually Auto
Respondent ID	Karolbagh	1	Auto
	Rohini	2	
Zone	West	3	
	South	4	
	East Patel Nagar	1	
	Guru Harkishan Nagar	2	
Ward	Rajouri garden	3	
	Chittaranjan park	4	
Are you resident of slum/ JJ colony	Cilitaranjan park	-	
Age (in years)			Continuous
	Male	0	Continuous
Sex	Female	1	
	Hindu	1	<u> </u>
	Muslim	2	
	Christian	3	ı
Religion	Sikh	4	
Kengion	Buddhist/Neo-Buddhist	5	
	Jain State Buddinst	6	
	Others	7	
	No schooling	1	
	<5 years complete	2	
Educational status	5-7 years complete	3	
Lucusiui status	8-9 years complete	4	
	10-11 years complete	5	
	12 or more years complete	6	
	Professional Professional	1	
	Clerical	2	
	Sales worker	3	
Occupation	Agricultural worker	4	
occupation .	Service worker	5	
	Production worker	6	
	Other	7	
	Don't know	8	
	Own	0	
Accommodation	Rented	1	
Average household income			Continuous
<u> </u>	Never married	1	
Marital status	Currently married	2	
	Divorced/widowed/ separated/ deserted	3	•
Staying with	Alone	1	
	Family	2	
	Friends/colleagues	3	
	Supplied tap	1	
Do you have access to clean water	Community tanker	2	
	Treated	3	
	Within the household	1	
Do you have a toilet facility	Community	2	
	Open	3	

Continued.

Variables		Code list	Skip pattern/comments
	Electricity	1	, î
Do you have access to clean	LPG/ Natural gas	2	
cooking fuel	Kerosene	3	-
cooking fuer	Solid (wood, charcoal, cow-dung cakes)	4	
Would you consider yourself a	Permanent resident	0	
permanent resident of Delhi or just staying for work	Staying for work	1	
Vaccinated with 1st dose	Yes	1	
vaccinated with 1 dose	No	0	
Vaccinated with 2 nd dose	Yes	1	-
vaccinated with 2 dose	No	0	
Vaccinated with 3 rd dose	Yes	1	
, meening with a most	No	0	
	Covaxin	1	
	Covishield	2	
	Sputnik V	3	
Which vaccine did you take	Moderna mRNA	4	
(separately for each dose)	Janssen	5	
	ZyCov-D	6	
	Corbevax	7	
	Covovax	9	
Whose did you get vessionted	Sputnik light	0	
Where did you get vaccinated (separately for each dose)	Govt. facility Private facility	1	
Approximately how far was	r iivate raciiity	1	
vaccination facility from your			Continuous
residence (separately for each dose)			Continuous
Cost of vaccination (separately for ea	nch dose)		
Vaccine cost	,		Continuous
Transportation cost			Continuous
Food/snacks			Continuous
Other related cost (parking etc.)			Continuous
Total direct cost of vaccination			28 + 29
Total indirect cost of the			30 + 31
vaccination			
Total vaccination cost			32 + 33
	At home treated by government providers	1	
	At home treated by private provider	2	
	At home treated by a mix of	3	
	government and private provider		
Where did you get treated for COVID	Admitted in a government facility	4	
, , , , , , , , , , , , , , , , , , , ,	Admitted in a private facility	5	
	First at home and then admitted to a	6	
	government facility		
	First at home then in private facility	7	
	Did not take any treatment/self-medicated	8	
	Allopathic	1	
What sort of a treatment did you take	AYUSH	2	
for your COVID illness	Both	3	
Duration of illness	Dour	3	
How long were you ill at the home			Continuous
How long were you hospitalised			Continuous
Total duration of illness			37 + 38
			31 T 30

Continued.

Variables		Code list	Skip pattern/comments	
Cost of treatment	<u> </u>			
Hama Anadam and	Yes	1	Continue to 40	
Home treatment	No	0	Skip to G, Mark 44 as 0	
Diagnostics			Continuous	
Drugs			Continuous	
Doctor's fees			Continuous	
Care provider at home			Continuous	
Total treatment at home			40 + 41 + 42 + 43	
Tuestment equipment	Yes	1	Continue to 45	
Treatment equipment	No	0	Skip to F, Mark 51 as 0	
Pulse oximeter			Continuous	
Thermometer			Continuous	
Vaporiser			Continuous	
Nebuliser			Continuous	
Oxygen concentrator			Continuous	
Oxygen cylinder			Continuous	
			44 + 45 + 46 + 47 + 48 +	
Total equipment			49	
C	Yes	1	Continue to 52	
Consumables	No	0	Skip to G, Mark 54 as 0	
Canula/oxygen mask sets			Continuous	
Oxygen refills			Continuous	
Total consumables			52 + 53	
Total home treatment			44 + 51 + 54	
	Yes	1	Continue to 56	
Hospital treatment	No	0	End interview, mark 68	
A 1			as 0	
Admission charges			Continuous	
Bed charges			Continuous	
Drugs			Continuous	
Diagnostics			Continuous	
Food for patient			Continuous	
Other charges in hospital			Continuous	
Total hospital charges			56 + 57 + 58 + 59 + 60 +	
			61	
Ambulance charges			Continuous	
Total direct cost hospital treatment			62 + 63	
Transport for care provider			Continuous	
Food for care provider			Continuous	
Total indirect cost at hospital			65 + 66	
Total treatment cost at hospital			64 + 67	
Total treatment cost all providers	X 7	1	55 + 68	
Did you have access to insurance to	Yes	1	Continue to 71	
cover your expenses	No D. L.U.	0	Skip to 73	
Type of insurance	Public,			
	Pvt			
How much was	Amount of coverage			
F 4 2	Self-paid		0.4.	
Enumerator's comments			Option to write text	