**Project Title:** Reducing OOP expenditure on drugs in public facilities of Odisha, through supply and demand side improvements

**Background**

**(Details of the current situation related to the issue based on secondary literature review, the gaps and the research areas this proposal would address)**

Access to medicines has been listed as one of the health systems building blocks and assumes critical in providing universal health coverage to the people. However, many people in India do not have access to essential medicines and a WHO estimate suggested 649 million people in India lacked access to essential medicine[[1]](#endnote-2). Another study showed that in India, median availability of essential medicine was in the range of 0-30% in public sector[[2]](#endnote-3). Further study suggests people incur a huge out of pocket expenditure (OOPE) at the point of care and the recent National health accounts report of India suggests OOPE constituted 63% of current expenditure and of the total current health expenditure, 36.8% is pharmaceutical expenditure which constitutes expenditure on drugs and other pharmaceutical product either prescribed or purchased over the counter[[3]](#endnote-4). Another report showed that 70% of all household spending on healthcare goes towards buying medicines[[4]](#endnote-5), which is catastrophic11 and impoverishing.

There are interstate variations in the availability of medicine and level of OOP due to medicine. For instance, a recent study in Chhattisgarh showed that prescription of generic medicine by the physicians in public health facilities was 68.9% and the availability of prescribed generic medicine was 58%. This study further suggests that 64% of total prescribed medicine in publichealthfacility was available and the rest fraction could lead to increase in OOP[[5]](#endnote-6). Similarly, Bihar and Tamil Nadu, the mean availability of a selected basket of essential medicines was about 43% and h 88% respectively Tamil Nadu[[6]](#endnote-7), while another study[[7]](#endnote-8) noted that the median availability of critical medicines in the public health system was about, 10% in Haryana, 12.5% in Karnataka, 3.3% in Maharashtra.

These evidences show thatthere is huge OOP due to shortage of essential medicines in essential medicines in health facilities. Further there are other compelling evidences which suggest inappropriate prescription practices, limited prescription of generic drugs, over use of use of branded drugs and unnecessary use of vitamins and antibiotics in India. A study in a tertiary care hospital in India [[8]](#endnote-9) suggested, the average number of drugs prescribed per prescription was 2.91, which was higher than the standard value (1.6–1.8). In some Indian studies[[9]](#endnote-10), the average number of drugs per encounter has been reported in the range of 2.8–3.2 giving clear evidence of polypharmacy. Further a study in Southern India showed that 91.4% prescriptions did not contain even a single drug prescribed in its generic name[[10]](#endnote-11).

All these studies in India suggest there are issues in supply of drugs, prescription practices and behaviour of health care providers which pose in major constraints in the availability and use of drugs.

**Specific Issues in Odisha**

Odisha an eastern Indian state with 3.5% of total population of India has made noticeable progress in health indicators in the recent years due to consistent effort by the state government. Infant Mortality Rate (IMR) is 41 per thousand live births against the national average of (33) during 2019. Further, the maternal mortality ratio though was high, has reduced to 150 in 2016-18 from 180 in 2014-16 as compared to 113 at all India during 2016-18[[11]](#endnote-12). Odisha’s health system shows a higher utilization from public sector with a limited role of private sector. As observed, 56.8% of outpatient and 72.2% inpatient visits take place in public facilities. In terms of health financing, according to the state health accounts report[[12]](#endnote-13), total health expenditure constituted 4.58% of GSDP of which the share of public expenditure was 1.12% and rest 3.46% was private in 2013-14. Further, the distribution of health expenditure showed that the risk pooling mechanism was weak as the share of out of pocket expenditure (OOPE) in total health expenditure was 76%, and a further breakdown of household expenditure indicated that a majority around 58% was spent on medicine, followed by diagnostic and patient transport. There has been a minor drop in the share of OOPE to 71.5% of total health expenditure in 2015-16 as indicated in the recent National health accounts report. This suggests that the OOPE is too high in the state even a majority visit public health facility.

Moreover, a recent survey of NSSO (2017-18) suggest, the average out of pocket expenditure for out-patient episode was about ₹ 547, (₹ 534 -in case of Urban -₹ 550- Rural) while for in-patients it was found to be ₹ 12,295 (₹ 5,283-public to ₹ 30,947-private). A survey conducted recently showed spending on drugs accounted for 69% of outpatient care & 32% of inpatient care expenses.

In Odisha, earlier medicines were procured centrally by the state government through the (State Drug Management Unit within the Department of Health). These were distributed to government health facilities to be made available to all patients free of cost.

Odisha, like many other states, has taken several steps to improve access to medicines. Government centralized procurement of medicines to health facilities has been the mainstay, also encouraged by the National Health Mission. Starting with the establishment of the State Drug Management Unit in the Department of Health and Family Welfare, the Odisha medical services corporation was established of in 2013 as an autonomous body, on the lines of Tamil Nadu and other state experiences. In 2015, Odisha launched the flagship free drugs scheme Niramaya, focusing efforts on ensuring seamless procurement and distribution of medicines and consumables to all government health facilities. Under "Niramaya", 317 essential drugs, 107 numbers of Lifesaving Cancer drugs, 20 types of Non-Essential Drugs List Items & 83 of medical consumables/surgical & sutures have been benchmarked for different institutions. Niramaya covers 527 drug distribution centres (DDC) across the state. The DDCs at all medical colleges, major health institutions, district head quarter hospitals and sub-divisional hospitals function "24 X 7", whereas at CHC the DDC operates as per the OPD timing (Niramaya Website, 2021).

In addition, state also ensures availability of generic medicines at affordable prices, implemented through the Pradhan Mantri Bhartiya Jan-Aushadhi Pariyojana (PMBJP) scheme of the Union Government. These stores are operated by not- for-profit entities with designated minor profit margins for the operators and usually are situated in the premises of health institutions.

Despite gradual increase of the drug budget and policy reforms such as launch of free drugs scheme, Niramaya in 2015 and Biju Swasthya Kalyan Yojana in 2018, there is evidence of lack of drug availability at peripheral health institutions in Odisha mostly due to improper supply chain management[[13]](#endnote-14)[[14]](#endnote-15). Another study conducted in 2018 observed poor availability of drugs in tribal and rural parts of Odisha leading to out-of-pocket expenditure on health. This study reported RNTCP, NVBDCP, family welfare, and essential drugs supply chains were showing higher stock-out, differences in reporting and record maintenance systems which have an adverse effect on the drug supply chain. This affected the national programs in addition to routine health service provision[[15]](#endnote-16).

A recent survey in 2019 found relatively high levels of citizen satisfaction were reported with physical access & availability of drugs & diagnostics at hospitals. However, following challenges do exist more at the peripheral facilities (level of CHC and below):

* Public sector hospitals (not lower-level facilities) had better stocks of drugs (73% of essential medicines in stock) compared to private sector hospitals (59% of essential medicines in stock), 66% in CHCs, 48% in private pharmacies and 38% in PHCs, indicating that supply chains of medicines for tertiary care facilities might be functioning well but stocks at the lower-level facilities are inadequate.
* Even in the state, the dependence on public sector is more, among those seeking outpatient care in the public sector, Share of OOPE contributed by drug expenses from public sector hospitals is 41%, and most of them around 72% reported purchasing drugs from private chemists
* Five commonly self-reported reasons why patients prefer private pharmacies are for the stock of drugs, variety of drugs, convenient hours of operation, preferences, and perception of quality.
* On an average, providers prescribe 2.29 drugs per case and that there is a rampant prescription of antibiotics, even for conditions that do not require their use, such as heart attack & pre-eclampsia.
* Disaggregating by public & private providers, the public providers prescribe more drugs than private providers in most cases. Given that most households in Odisha access care from public providers, the higher number of drugs may lead to higher OOPE on drugs.

Some of the possible explanations for people visiting public facilities purchasing drugs from private chemists could be due to issues with supply of adequate quantity of essential drugs, providers prescription behaviour and demand side issues such as patient preferences. The recent Comptroller Audit General (CAG) Report has highlighted inefficiencies in drug management in Odisha, due to non-utilisation of the e-Niramaya application leading to ineffective indenting, distribution, consumption, unavailability of real time stock position and expiry of drugs[[16]](#endnote-17). In India, inappropriate prescribing practices like polypharmacy, lesser prescription by generic name, and over-prescription were established[[17]](#endnote-18)[[18]](#endnote-19)[[19]](#endnote-20)[[20]](#endnote-21). These prescription practices result in high spending at private chemists. The possible reasons for such prescription behaviour of physicians could be related to provider incentives, lack of knowledge on essential drug list (EDL), perception of poor-quality medicine in government supply chains both among health workers as well as patients. Such perceptions may not only have implications high OOPE on drugs butfor healthcare utilisation, and continuity of care at public facilities. Studies found that actual and perceived patient's expectations for antibiotics also as a major reason that doctors prescribe them inappropriately[[21]](#endnote-22)[[22]](#endnote-23).

**Research Question/ Objectives**

1. What is the structure and functions of OSMCL and what are the processes involved in procurement and supply chain management of drugs in Odisha
2. What is availability of different types of drugs in primary care facility and to what extent generic and other drugs are prescribed by primary care physicians?
3. What are the factors affecting availability of essential drugs particularly at primary care level?
4. What are the factors influencing primary care physicians’ prescription behaviour and how these could be improved?
5. Explore patient preferences and physician perceptions aboutpatient preferences on drugs.

**Scope of work**

* Study the structure, functions and processes of drugs procurement and distribution
* Examine the availability of various categories of drugs and prescription behaviour of primary care physicians
* Assess availability of essential drugs andprescription practices including, prescription from essential drug list, whether prescribing out for medicines to be bought from private pharmacies, branded or generic name prescribed
* Identify reasons behind non-availability of drugs at primary care level by analysing the policy and practices related to drug supply chain management
* [Assessment of facilitatorsand barriers relatedto the acceptance, challenges and perception of patients and providers about medicines](https://www.tandfonline.com/doi/abs/10.1080/16549716.2017.1290315)

**Detailed methodology-quantitative and qualitative and Tools to be developed**

We will use mixed method approach using both quantitative and qualitative study techniques to understand issues with drug availability and distribution.We will undertake this study in two purposively selected districts of Odisha, one from hard-to-reach areas and another from plain areas of the state. It is assumed that the availability of drugs, supply chain management systems, providers’ and patients’ behavior may be influenced by the geographical terrain, hence the selection district from hard to reach areas. In addition to the criterion of hard-to-reach areas, we will also use socioeconomic and health outcome indicators to select the districts, one with poor and the other with better indicators.

We will review policy guidelines related to procurement of medicine, selection of essential drugs, and processes involved in procurement to supply of drugs to heath care institutions. We will also study structure and functions of Odisha state medical corporation and role and responsibility of different units working at the state and two district level. In this exercise, we will also compare and contrast the functioning of Drug corporation of some other state of India for instance Tamil Nadu and Rajasthan and learn key processes from these states for providing inputs to improve the drug availability systems in Odisha.

To find out factors affecting availability of essential drugs at primary care, we will conduct 30 in-depth interviews with staff who work at OSMCL, Central Drug Warehouse (CDW), and staff from District drug warehouses, Sub-stores, Pharmacists at CHC, PHCs and MOICs of the sampled health facilities. During the IDIs, we will explore the bottlenecks at various levels such as procurement, storage and distribution, quality assurance, indenting and reporting.

To understand the factors influencing primary care physicians’ prescription behaviour and ways for improving it, we will conduct 30 in-depth interviews with Primary care physicians (12 from CHCs, 18 at PHC) and key informants (6 experts in the field). In these interviews, we will investigate if any guidelines available for writing prescriptions, do providers aware of available guidelines, systems for ensuring adherence; are there standard treatment guidelines and their adherence; what is the antibiotic policy of the state; awareness and views on generic drugs vs branded drugs; perspectives about quality of medicines at public facilities and reasons backing the views; and suggestions for improving the prescription practices in the state.

To explore patients’ preferences and physicians’ perceptions of patient preferences, we will conduct in-depth interviews/focus groups with 24 patients from the sampled CHC and PHC coverage areas. In this, we will explore demand-side barriers influencing prescription practices, such as, patients’ preferences regarding drugs, awareness and views on generic drugs vs branded drugs, views about drugs provided at public facilities and private pharmacy, reasons behind their perceptions; Further, we will explore what providers think of patient expectations, as these often influence the prescriptions.

For studying the availability of essential drugs, shortage duration of drugs,their categories, prescriptionbehavior of primary care physicians, we will select districts and health care institutions as given below.

**Sampling plan**

In the recently concluded first phase of the study, we had selected 6 districts based upon socio-economic, demographics and geographical characteristics and these six districts also represents the three administrative divisions of Odisha- central, southern,and Northern. The districts from each division were

Noth RDC- Jharsuguda, Keonjhar

South RDC- Rayagada and Kalahandi

Central RDC– Khurda and Balasore

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Region** | **Sampled dist** | **Sampled CHCs** | **Sampled PHCs** | **Sample  patients** |
| Districts | North | Jharsuguda | 2 | 2 | 40 |
| Central | Khurda | 5 | 5 | 100 |
| South | Rayagada | 5 | 5 | 100 |
|  |  | 12 | 12 | 240 |

From these 3 divisions, we will select three districts each from each region namely Jharsuguda, Rayagada, and Khurda. From each district, we will select 50 percent of CHCs and from each CHC, we will select 1 PHC to study the availability, categories and shortage of different categories of drugs.

From the sampled health care institutions, we will collect information about various drugs available and categorize or classify them essential, non-essential, generic, branded and what percentage of time those drugs were not available in those institutions. Further, for prescription behavior, the OP visits of the patients in the last one week will be collected from the health care institutions and around 10 patients from each CHC and PHC will be contacted to study the prescription practices including prescribing drugs from EDL, generic drug name, antibiotics, injections, and vitamins. Further, we will look at the readability, prescribing in short form, abbreviations or other forms of coded prescriptions that only concerned pharmacists can understand. These patients will be selected from the villages located nearby the health care institutions.

For Qualitative data collection, the study participants will be selected from the sampled districts and health care facilities. The study participants will be selected using maximum variation sampling, a purposive sampling technique used to capture wide range of perspectives relating to the topic studied.

Semi-structured interview schedules will be developed for conducting in-depth interviews with health staff involved in drug supply chain management at various levels, primary care physicians at CHCs and PHCs, and beneficiaries from CHC and PHC coverage areas.The objective wise methodology is summarized in the table below -

*Table1. Objective wise methodology*

|  |  |  |  |
| --- | --- | --- | --- |
| Research Objective | What we intend to explore | Methods | Study participants |
| 1. Structure and functions of OSMCL and processes involved in PCM of drugs in Odisha |  |  |  |
| 1. Availability of essential drugs and prescription behaviour at primary care | Assess availability of essential drugs, whether drugs prescribed from EDL or prescribed out, whether branded or generic drugs prescribed | Review of Drug stock register and prescriptions at primary care | Secondary data analysis of drugs andpercentage of time non-availability of essential medicines facilities  Prescription analysis  Prescription analysis |
| 1. Factors affecting availability of essential drugs at primary care | Understand policy and practice - Processes involved and bottlenecks in ensuring drug availability at primary care   * Procurement * Storage and distribution * Quality Assurance * Indenting and Reporting | Review of documents/Guidelines related to procurement, selection of essential drugs.  Structure and function of Odisha State medical corporation(OSMCL)  Interviews using semi-structured interview schedule | Staff at OSMCL, Central Drug Warehouse (CDW), District drug warehouses, Sub-stores, Pharmacists at various levels, MOICs |
| 1. What are the factors influencing primary care physicians’ prescription behaviour and how can we improve | * Whether guidelines available for prescription practices, if available – do the providers aware of, systems for ensuring adherence * Standard treatment guidelines and adherence; Antibiotic policy * Awareness and Views on Generic drugs vs branded drugs * Perspectives about quality of medicines at public facilities and reasons backing the views * Suggestions for improvement | In-depth interviews using semi-structured interview schedule | Service providers – primary care physicians and other involved in prescribing, if any  KII’s – experts in the field from GO/ Pvt/ Academicians/ NGOs |
| 1. Patient preferences and Physician Perceptions of Patient Preferences | * Explore demand-side barriers influencing prescription practices, under and over usage * Awareness and Views on Generic drugs vs branded drugs * View about drugs provided at public facilities – acceptance; Vs private pharmacy * Reasons behind their perceptions | Patient exit interviews with semi-structured interview schedule  IDIs using semi-structured interview schedule  Focus group discussion using a topic guide | Beneficiaries after a hospital visit  Service providers  Community members – men and women |

**Data collection & Quality monitoring of data collection**

Data will be collected by Research Associates and a team of field investigators. All the staff involved will be trained and tested for their concordance in the data collection prior to start data field work. The IIPHB faculty will accompany the initial interviews to ensure quality in data collection and conduct field visits during data collection for monitoring purposes. The IIPH B will develop a detailed field movement plan for the data collection across the study sites to help in ensuring timely data collection, monitoring and quality check.

**Data analytics plan**

We will present the shortage of drugs and duration, availability of generic and branded drugs in percentage terms and simple averages, and sums. Further, descriptive statistics will be used to present the prescription behaviours of providers in public health facilities. The qualitative data collected through in-depth interviews and field notes will be analysed using inductive analysis technique with frame work approach [Ritchie, J. and Lewis, J. 2003]. The steps involved in framework approach are – familiarization with the data, identifying emerging themes, coding and data interpretation. Qualitative data analysis software - Atlas Ti / NVivo will be used to manage and analyse qualitative data. In house capacity including licenced software and skill for the same exists at IIPH Bhubaneswar.

**Ethical approval**

Institutional Ethical clearance will be obtained from the Indian Institute of Public Health, Bhubaneswar IEC committee. Informed consent will be obtained from all the study participants. Necessary permission from Department of Health and Family Welfare, Government of Odisha will be sought prior to data collection data.

**Research Team**

The proposal has been co-developed by IIPH Bhubaneswar and HSTP Delhi. The broad responsibilities for both the team members are mentioned below -

From IIPHB, the team will comprise of two faculty members Dr Sarit Kumar Rout and Mr Srinivas Nallala and a full team research Associate who will be hired for this project. Dr Rout with expertise in health economics and financing will work as the Principal investigator and will be responsible for overall coordination with the donor and state government, desk review, finalisation of research tools, data analysis and report writing. Mr Nallala, with experience in qualitative research and project management will provide support for qualitative study design, data collection and management, data analysis and report writing. The RA will work in close coordination with the PI and Co-PI and support in desk review of the supply chain management system, developing study tools, monitor data collection process, analysis and writing draft report.

From HSTP, Dr Sudha will co-lead the project. The HSTP team will be involved in the entire process of research starting from providing inputs to conceptualisation, development of study tools, analytical frameworks, and bringing external experts as per the requirement of the project.

**List of Activities/ Tasks to be performed by IIPH B and HSTP**

|  |  |  |
| --- | --- | --- |
| Activities | IIPHB | HSTP |
| Develop technical and financial proposal |  |  |
| MoU/Contract signing with the funder |  |  |
| Review of literature |  |  |
| Development data collection tools |  |  |
| Pilot test and revised the tools |  |  |
| Obtain institutional ethics approval |  |  |
| Data collection both qualitative and quantitative data |  |  |
| Analysis of quantitative data |  |  |
| Translation of qualitative data |  |  |
| Familiarisation and developing coding framework |  |  |
| Data organisation and Coding |  |  |
| Data analysis using qualitative data analysis software |  |  |
| Report writing |  |  |
| Submission of draft report |  |  |

**Outputs/ Milestones**

* Submission of project inception report
* Finalisation ofstudy tools
* IEC application and approval
* Draft report submission
* Final report submission
* Develop dissemination materials including publications

**Timelines -Gantt Chart**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Activities | M1 | M2 | M3 | M4 | M5 | M6 | M7 | M8 | M9 | M10 | M11 | M12 |
| 1 | Agreement on the project with ACCESS-HSTP |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Recruitment of project staff and Induction |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Desk review |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Understanding SCM process and developing report |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 | Review of other state drug corporations |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 | Development of study tools |  |  |  |  |  |  |  |  |  |  |  |  |
| 7 | IEC approval and state government approvals |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 | Data collection (at state, district, block and patients |  |  |  |  |  |  |  |  |  |  |  |  |
| 9 | Data entry and cleaning |  |  |  |  |  |  |  |  |  |  |  |  |
| 10 | Data analysis –Quantitative |  |  |  |  |  |  |  |  |  |  |  |  |
| 11 | Translation of qualitative data |  |  |  |  |  |  |  |  |  |  |  |  |
| 12 | Familiarisation and coding |  |  |  |  |  |  |  |  |  |  |  |  |
| 13 | Data analysis – Qualitative |  |  |  |  |  |  |  |  |  |  |  |  |
| 14 | Report preparation |  |  |  |  |  |  |  |  |  |  |  |  |
| 15 | Development of dissemination/ advocacy materials |  |  |  |  |  |  |  |  |  |  |  |  |
| 16 | Engagement with the state |  |  |  |  |  |  |  |  |  |  |  |  |
| 17 | Dissemination of study findings |  |  |  |  |  |  |  |  |  |  |  |  |

**Dissemination plan**

The dissemination of the findings from the research study will be done through communication to the state government and publications in peer reviewed journals. At the end of the study, a formal written report of the findings and recommendations will be submitted to both the state governments. The project findings will be submitted for presentation in national and international conferences and published in relevant journals.

**Budget**

The total budget for proposed engagement will be INR 4,103,200 inclusive of all applicable taxes.

**Bank Account Details**

|  |  |  |
| --- | --- | --- |
| Name of the Beneficiary | : | Public Health foundation of India |
| Bank Name | : | HDFC Bank Ltd. |
| Bank Address | : | H-7 Green park extension, New Delhi, New Delhi - 110016 |
| Account Number | : | 05861110000013 |
| Swift Code | : | HDFCINBBDEL |

**Remuneration**

The entire fee/compensation, not exceeding INR 4,103,200 inclusive of all applicable taxes would be paid in below tranches to the account mentioned above held by the Indian Institute of Public Health, Bhubaneswar (PHFI/IIPHB).

**Deliverables and Payment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Instalment** | **Month** | **Contribution** | **Deliverables** |
| 1. | December 2021 | 25% of Total Grant Value (INR10,25,800) | ·       Finalised Project Proposal |
| 2. | March 2022 | 50% of Total Grant Value  (INR 20,51,600) | ·       Project Inception Report  ·       Research synopsis with finalised methodology & tools  ·       Approved IEC application |
| 3. | August 2022 | 15% of Total Grant Value (INR 6,15,480) | ·       Draft Report |
| 4. | November 2022 | 10% of Total Grant Value (INR 4,10,320) | ·       Final Report  ·       Publication |

**Term of Contract**

This contract period is from **December 01, 2021** to **November 30, 2022.** Indian Institute of Public Health, Bhubaneswar (PHFI/IIPHB) will be engaged under the agreement from the date of signing the contract till the date of closure as mentioned above**. The contract will be considered closed when the deliverable is received, and final report is submitted.**

1. [↑](#endnote-ref-2)
2. [↑](#endnote-ref-3)
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