







## Hepatitis C Elimination through Access to Diagnostics (HEAD-Start) THE DELHI MODEL







## Foreword

#### Dr. Shiv Kumar Sarin, Director, ILBS

Chronic viral hepatitis is a major global public health problem, an important cause of morbidity and mortality from sequelae which include cirrhosis and primary liver cancer. Viral hepatitis is caused by 5 types (Hepatitis A,B,C,D and E) of viruses. Infection by Hepatitis C virus (HCV) is now a curable disease when treated with short-duration, well-tolerated finite therapy. Despite these advances, however, HCV continues to be a public health threat that requires better identification and linkage to care at the early stage to stay with healthy liver.

The Institute of Liver and Biliary Sciences (ILBS), an autonomous Institute under the Government of National Capital Territory of Delhi (GNCTD), has specialized in liver and biliary disorders for the past 10 years and is dedicated towards the elimination of hepatitis from India. ILBS with this mandate has been instrumental towards the initiation of National Viral Hepatitis Control Program in India. In Delhi ILBS has undertaken a project on "Assessing the implementation of Decentralized HCV diagnostic and treatment services HEAD (Hepatitis C Elimination through Access to Diagnostics)" in collaboration with the Foundation for Innovative New Diagnostics (FIND). This Delhi Model proved that decentralized screening and treatment management at primary health care level is feasible in management of hepatitis C.

I am pleased with an outcome of HCV management of the Delhi Model project which is very effective, sustainable and replicable in entire State. I congratulate entire DHS, Delhi for successfully implementing HCV activities in their 5 Hospitals and 14 Polyclinics in Delhi.

I am confident with the experience of this model project, Health and Family Welfare, Government of Delhi will be able to implement hepatitis C Prevention, Care, Support and Treatment services effectively among general and key population in Delhi. I would like to congratulate Dr. Ekta, Dr. Sanjay Sarin and their teams, to have conceived and organized this pre-World Hepatitis Day summit and to have invited several distinguished experts from Asia. I would like everyone to pledge on this World Hepatitis Day, specially policy makers, health care workers and NGOs to join hands for the elimination of hepatitis C from India.

### Dr. Ashok Kumar, Director DHS, Delhi

डा. अशोक कुमार महानिदेशक स्वाख्स्य सेवाएँ एवं आयुक्त, एस.जे.ऐ.बी DR. ASHOK KUMAR DIRECTOR GENERAL HEALTH SERVICES CUM-COMMISSIONER, SJAB



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The experience of Delhi Model Hepatitis project outcome will help to provide hepatitis C diagnosis and treatment services to the needy on priority basis towards reducing the morbidity and mortality due to HCV.

It is the background of Delhi Model HCV project implemented by DHS, ILBS and FIND, Government of Delhi which will scale up the Hepatitis management activities in entire Delhi. Department of DHS, Delhi will coordinate with all aligned ministries to combat HCV in Delhi region and support National Viral Hepatitis Control Programme (NVHCP) at country level.

I congratulate and complement the efforts taken by ILBS and FIND in strategically positioning the HCV diagnosis and treatment services activities within Hospitals and Polyclinics in Delhi.



Dr. Ekta Gupta, Additional Professor, ILBS

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that causes acute and chronic infection. The introduction of direct-acting antivirals (DAAs) has changed the face of treatment for HCV. Despite such a wonderful treatment, many infected patients are unaware of their diagnosis status due to lack of availability of diagnostic services in the peripheral health settings.

Institute of Liver and Biliary Sciences (ILBS), with its mandate for working towards elimination of Viral hepatitis in India, has undertaken this project on "Assessing the implementation of Decentralized HCV diagnostic and treatment services HEAD (Hepatitis C Elimination through Access to Diagnostics)" in collaboration with Foundation for Innovative New Diagnostics (FIND). This Delhi Model is demonstrating that decentralized screening, testing and treatment at primary health care level is feasible in effective management of hepatitis C. The preliminary observations of this project are showing that the uptake of testing as well as treatment has significantly increased after decentralizing the testing and treatment services.

I am truly indebted to the FIND India team who have brought this project to reality. I profusely thank the Directorate of Delhi Health Services for their whole-hearted support to this endeavor. I also take this opportunity to thank all the nodal officers (from Delhi Govt. Hospitals) for successfully implementing the project activities in their Hospitals and Polyclinics in Delhi. Prof. S K Sarin and all of us under his dynamic leadership are trying hard to make the decentralization of the testing and treatment of HCV a reality.

I am confident this small effort of ours will be helpful not only for the people of Delhi but will carve a path for implementation of the National Viral Hepatitis Control Program in the state as well as on a national level. Viral hepatitis in India is a serious public health problem and brings tremendous health, social and economic burdens on the affected individuals, their families, and the country's health system. Recently, the treatment landscape for hepatitis C has undergone rapid transformation with potent, well-tolerated, alloral regimens achieving cure rates of over 90% within 12 weeks. However, rapid, inexpensive and accurate diagnosis remains a crucial bottleneck that must be addressed to eradicate hepatitis C. Currently, nearly 95% of people infected with chronic hepatitis are unaware of their status and are therefore at risk of liver cirrhosis and liver cancer.

Through the current project entitled "Hepatitis C Elimination through Access to Diagnostics" (HEAD-Start), funded by the Unitaid, FIND endeavors to build efficient and sustainable public health responses to HCV across several nations. In India, our operations run in the States of Delhi, Punjab and Manipur piloting different operational models targeting under-served groups in each State. The model in Delhi aims to screen around 50000 patients. HEAD-Start has very successfully demonstrated the strength of decentralized screening and treatment management at a primary level to rapidly and effectively identify and treat hepatitis C cases.

For this success, I would like to express my deep gratitude to our partners DHS, Delhi and ILBS and various sites for their guidance, support and commitment towards achieving the project goals. The team at FIND has worked hard to achieve the project's success and I applaud their tireless efforts.

I am confident that with experience gained from this project, the Ministry of Health and Family Welfare, Government of Delhi will be able to implement Hepatitis C Prevention, Care, Support and Treatment services effectively among general and key population in Delhi.

## Acknowledgments

ILBS and FIND would like to thank all the patients who participated in this project and our supporting partners: Medical Superintendents and Nodal officers of the Hospitals, Medical officers and Lab Technicians of the Polyclinics, Lab Technicians and Data Entry Operators of the HEAD-Start project, Ministry of Health and Family Welfare, Government of Delhi; Directorate of Health Services (DHS), Delhi; National Viral Hepatitis Control Program (NVHCP), Government of India; World Health Organization (WHO) India and the WHO Global Hepatitis Program.



# Acronyms

APRI	AST to Platelet Ratio Index
CBC	Complete Blood Count
DAA	Directly acting anti-viral
DCV	Daclatasvir
FIND	Foundation for Innovative New Diagnostics
GNCTD	Government of National Capital Territory of Delhi
HCV	Hepatitis C Virus
HCVab	Hepatitis C Virus anti-body
HEAD	Hepatitis C Elimination through Access to Diagnostics
HIV	Human Immunodeficiency Virus
ILBS	Institute of Institute of Liver & Biliary Sciences
KFT	Kidney function test
LFT	Liver function tests
NVHCP	National Viral Hepatitis Control Program
OPD	Out Patient Department
PLHIV	People Living with HIV
RDT	Rapid diagnostic test
RNA	Ribo-nucleic acid
SOF	Sofosbuvir
SVR	Sustained Virologic Response
WBFPT	Whole Blood Finger Prick Test
WHO	World Health Organization



## **Organizational Profiles**



Institute of Institute of Liver & Biliary Sciences (ILBS) ILBS is an autonomous super specialty NABH and NABL accredited research and teaching institute under the aegis of the Government of National Capital Territory of Delhi (GNTCD), with the objective to provide a comprehensive set up for state-of-theart patient care services including advanced and dedicated research in the field of Liver and Biliary Diseases.

In addition to providing state of the art treatment, ILBS also runs a liver helpline manned by doctors for patients and families having questions related to their diseases. As a deemed university, the Institute provides accredited fellowships in adult and paediatric hepatology, liver transplant surgery, transplant anaesthesia, Ph.D. courses in basic sciences and other certificate courses, including an accredited National Deceased Organ Donation Certificate Course for Transplant Coordinators. For more information, please visit www.ilbs.in







Foundation for Innovative New Diagnostics (FIND) FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations.

Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; enabling accelerated uptake and and access to diagnostics in low- and middleincome countries (LMICs). Since 2003, we have been instrumental in the delivery of 24 new diagnostic tools. Over 50 million FINDsupported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation, we work with more than 200 academic. industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit www.finddx.org

## Background



**Project HEAD-Start** 

The Hepatitis C Elimination through Access to Diagnostics (HEAD-Start) project is led by FIND and funded by Unitaid. The HEAD-Start project is establishing innovative models for screening and treatment for HCV across 4 countries: Georgia, India, Malaysia and Myanmar.

The HEAD-Start project directly contributes to World Health Organisation (WHO) and the United Nations Sustainable Development Goals targets of achieving 90% reduction in incidence of HCV, 65% reduction in mortality from HCV, and getting 80% of HCV infected individuals on treatment by 2030. HEAD-Start further aims to inform global policy on HCV through introduction of innovative HCV diagnostic tests to low and middle-income markets, establish strategic screening models, contributing to reduction in diagnostics and treatment cost, and provide solid evidence to scale up HCV efforts in innovative ways. For more information, please visit https://www.finddx.org/hcv-hiv/head-start/



**Price barriers** 



The primary objective of this booklet is to share experiences of hepatitis C management through the HEAD-Start project in Delhi, with policy makers and program managers. The Delhi Model will be useful to the persons responsible for planning and implementing hepatitis C diagnosis and treatment services with varied approaches to best reach general populations, especially in resource limited settings.

This booklet is intended to serve as a high level reference document as to how the decentralized approaches used in HEAD- Start Delhi helped in reaching the general population. This was done through using point of care solutions related to hepatitis C diagnosis and management, starting from screening to sustained virologic response (SVR), within public health settings.

Best practices of the HEAD-Start Delhi Model will be handy to healthcare providers to plan and provide access to HCV screening tests, confirmatory tests, treatment and SVR tests within one roof.

## **Project Design**

### Hepatitis C management in Delhi under HEAD-Start

Delhi is one of the Union Territories in India and capital of the country with a population of approximately 18 million people. As per a systematic review and meta-analysis on the burden of hepatitis C virus infection in India: In Delhi, HCV prevalence among blood donors was reported as 0.59%, among pregnant women-0.71%, and among PLHIV-3.51%<sup>1</sup>.

In order to address this significant disease burden, diagnosis of hepatitis C followed by treatment with direct-acting antivirals (DAA) is critical. The HEAD-Start project in Delhi aims to enhance hepatitis C diagnosis and treatment pathways through introducing a simplified and near to patient diagnostic and care pathway.

HEAD-Start has introduced decentralized HCV screening using rapid diagnostic tests (RDTs) through the method of whole blood finger Prick test (WBFPT) in 15 Polyclinics (primary health care centres) and 5 Hospitals (secondary care centres). At the Polyclinics, patients found HCV antibody positive are referred to one of the 5 participating Hospitals. At these 5 hospitals, a blood sample is collected from HCV Ab+ patients and transported to ILBS for HCV RNA test. Results of RNA test are communicated electronically to hospitals. Patients who are HCV RNA+ are initiated on DAAs. Patients who are found to have cirrhosis or other complications are referred to ILBS for further evaluation and management.

<sup>\*</sup>Department of Gastroenterology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, and †World Health Organization India Country Office, New Delhi, India



<sup>1</sup> Journal of Gastroenterology and Hepatology. Meta Analysis and Systematic Review - Burden of hepatitis C virus infection in India: A systematic review and meta-analysis. Amit Goel\*, Nicole Seguy† and Rakesh Aggarwal\*



## **Project HEAD-Start, Delhi coverage:**



### **Inclusion criteria**

- All adult patients attending the general OPD with common ailments
- Medicine
- Dental
- Dermatology (Skin & Venereal Disease
- Obstetrics & Gynecology (Non anti-natal & pre-natal care)
- Orthopedics
- Ophthalmology
- Ear, Nose and Throat
- Surgery

### **Exclusion criteria**

- Children up to 18 years
- Breastfeeding or Pregnant women
- Patients with Chronic Kidney disease

	Name of the Hospital	Name of the Polyclinic		
1	Maharishi Valmiki Hospital	1a Punjab Colony	1b Rohini Sec 18	1c Rohini Sec 4
2	Sanjay Gandhi Hospital	2a Wazirpur	2b Rohini Sec 2	2c Saraswati Vihar
3	Deen Dayal Upadhaya Hospital	3a Tilak Vihar	3b Pitampura	3c Rani Bagh
4	Pt. Madan Mohan Malviya Hospital	4a Basant Gaon	4b Timarpur	4c Keshavpuram
4	Guru Teg Bahadur Hospital	5a Vivek Vihar	5b Nand Nagri	5c Kanti Nagar

### Project HEAD-Start, Delhi - 3 Arms

#### Arm 1: Hospital Screening 5 HOSPITALS

- HCV Screening at hospitals through WBFPT - result shared within 20 minutes
- Same day sample collection from HCVab+ for HCV RNA confirmation and pre-treatment investigations

### Arm 2: Decentralized screening 15 POLYCLINICS

- HCV Screening at Polyclinics through WBFPT - result shared within 20 minutes
- HCVab+ Patient referred to Hospital for confirmatory tests and further management

### Arm 3: Outreach Screening

- Screening camps at pre-defined locations HCV Screening through WBFPT - result shared within 20 minutes
- HCVab+ Patient referred to Hospital for confirmatory tests and further management

#### Treatment flow; all arms

- HCV RNA confirmatory testing at central lab ILBS
- HCV RNA and pre-treatment results made available within 24 hours
- HCVab+ patients can collect their HCV RNA and pre-treatment results on 2<sup>nd</sup> visit
- HCV RNA detected patients initiated on treatment
- HCV treatment for 12/24 weeks
- · SVR tests after 12 weeks of completion of treatment

## **HCV Diagnosis and Treatment Management**

Visit No	Project Activities	Outcome
Visit 1	HCV screening using RDTs and WBFPT & results shared within 20 mins. Blood collected from HCVab +ve patients for HCV RNA confirmatory test and baseline investigations	<ul> <li>HCV screening result (Ab -ve or +ve) known to patient 20 minutes</li> <li>Blood sample provided for confirmatory and baseline tests</li> </ul>
Visit 2	HCV RNA and baseline investigations reports shared with patient	<ul> <li>HCV RNA: Detected / Not Detected; patient knows if they are viremic and thus needing treatment</li> <li>Non-complicated cases initiated on HCV treatment</li> </ul>
	HCV treatment initiation for non-complicated cases	Complicated cases referred to ILBS for medical advice
Visit 3	Follow up visits of HCV Patients on Treatment	Patient management and HCV DAA refill
	HCV treatment initiation for complicated cases	Complicated cases initiated on HCV treatment
Visit 4, 5	Review on DAA treatment	HCV – DAA Refill
Visit 6	Test for sustained viral response (SVR)	Sample collection for SVR
Visit 7	SVR Report	SVR Test result collection

## Patient Pathway – under HEAD-Start, Delhi

### **Treatment protocol - Management of complicated HCV cases**



\* dose adjustments in PLHIV, renal insufficiency, etc.

## **Findings**

## Arm 1: Hospital – HCV Diagnosis and Treatment services

ILBS and the Government of Delhi selected 5 Hospitals covering various regions of Delhi to implement HEAD-Start activities and serve as hub centers. Project HEAD-Start supports these 5 hospitals with required infrastructure to offer RDTs, further diagnostic testing (samples linked for confirmatory testing), and treatment services.

### HEAD-Start results from 23 January 2019 to 30 June 2019

Name of the Hospital	Total Screened for HCV	Total anti-HCV Positive	Total Ab+ tested for HCV RNA	HCV RNA Positive	Total Treatment initiated	Total Treatment completed
Pt. Madan Mohan Malviya	3325	39	21	19	14	4
Maharshi Valmiki	3457	27	31	20	11	4
Deen Dayal Upadhya	2680	43	42	31	25	5
Guru Teg Bahadur	3954	181	178	147	97	30
Sanjay Gandhi Memorial	3685	65	56	40	33	8
TOTAL	17101	355	328	257	180	51





## Arm 2: Polyclinics – Decentralized HCV screening

Under HEAD-Start, 15 Polyclinics have been identified as spoke centres to offer decentralized HCV screening services among patients attending for their general ailments at primary health centers in Delhi. Patients identified with HCV ab+ at Polyclinics (spoke centre) are referred to hospitals (hub centre) providing confirmatory tests, pre-treatment investigations and treatment services. Health care providers (Medical officer and Lab Technician) were trained on project protocol and lab consumables including RDT are provided under project resources.

### HEAD-Start results from 1 March 2019 to 30 June 2019

Name of the Polyclinic	Total Screened for HCV	Total anti-HCV Positive
Wazirpur	335	3 (0.89%)
Rohini	410	3 (0.73%)
Vivek Vihar	63	0
Rani Bagh	60	0
Saraswati Vihar	31	0
Sector - 4, Rohini	40	0
Sector - 18, Rohini	87	0
Pitampura	165	0
Tilak Vihar	69	1 (1.45%)
Basant Gaon	130	0
Keshavpuram	300	1 (0.33%)
Punjabi Colony	166	0
Timarpur	126	2 (1.59%)
Nand Nagri	600	3 (0.50%)
TOTAL	2582	13 (0.50%)

## **Arm 3: Outreach Screening**

As part promoting point of care HCV screening, HEAD-Start project team conducted Hepatitis C screening camps in selected public health settings. Those identified HCV ab+were referred to hospitals (hub centre) providing confirmatory tests, pre-treatment investigations and treatment services. Hepatitis C screening camps facilitated general patients to avail entire HCV services at free of cost within public health setting in patient friendly manner (starting from screening to SVR).

#### HEAD-Start results from 26 February 2019 to 30 June 2019

Type of Health Facility	Place of Camp	Number of persons screened	HCV Ab +
Mohalla clinic	Mohalla clinic, Vikas Nagar, New Delhi 110053	66	1 (1.52%)
Dispensary	Dispensary, Near Police Post, Tilak Vihar, New Delhi - 110018	58	1 (1.72%)
Dispensary	Dispensary, B-2/4A Street 4, East Azad Nagar, Delhi-51	53	0
Dispensary	Dispensary, Pancsheel Garden, Near Dilshad Garden	51	2 (3.92%)
Dispensary	Dispensary, Satyam Enclave, Near Karkarduma	58	0
Hospital	Maharishi Valmiki Hospital (MVH)	349	2 (5.73%)
Hospital	Guru Teg Bahadur Hospital (GTB)	253	5 (1.98%)
Hospital	Sanjay Gandhi Hospital (SGH)	166	1 (0.60%)
Hospital	ILBS	302	0
Hospital	Deen Dayal Upadhyay Hospital (DDU)	161	1 (0.63%)
Polyclinic	Punjab Colony Polyclinic	86	0
Dispensary	RHTC Nazafgarh	127	0
Corporate sector	Shree Vishwakarma University, Gurugram	88	0
Corporate sector	JBM Itd, Gurugram	178	0
TOTAL		1996	13 (0.65%)

### Summary of HEAD-Start, Delhi progress till 30 June 2019

Arm wise	Total Screened for HCV	Total anti-HCV Positive	Total Ab+ tested for HCV RNA	HCV RNA Positive	Total Treatment initiated	Total Treatment completed
Arm 1 - Hospital	12523	329	314	246	173	50
Arm 2 - Polyclinics	2582	13	6	6	5	0
Arm 3 - Outreach Camps	1996	13	8	5	2	1
TOTAL	17101	355	328	257	180	51



## **Project HEAD-Start Screening cascade**

20

note: genotyping done for a sub-set of patients only

## Conclusions

Best Practices and learnings from the HEAD-Start Delhi Model

- HCV care cascade of diagnosis and treatment services is free for the patient
- HCV screening done using RDT whole blood finger prick, result shared with patient within 20 minutes
- Sample collected for HCV RNA testing and baseline investigations on the same day from HCV Ab+ patients
- HCV RNA and baseline investigations (pretreatment) reports shared during the 2<sup>nd</sup> visit to the hospital
- Non-Cirrhotic HCV patients initiated on treatment during the 2<sup>nd</sup> visit
- Complicated cases can avail further investigations and specialist opinion at ILBS

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· External quality assurance ensured at all levels

#### Conclusion

This hub and spoke model of decentralized HCV care provision using point of care screening proved to be effective in establishing an evidence base for HCV care in public health settings in Delhi. The results are very helpful in guiding policies for increasing the uptake of testing in resource limited countries at a larger scale. It paves the way to eliminate HCV through increasing access to care at primary healthcare level using existing resources in public health settings in India.

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## **Project Team**

## ILBS Team – HEAD-Start, Delhi

	Name and designation of Investigators
Principal Investigator	<b>Dr. Ekta Gupta</b> Additional Professor, Department of Clinical Virology, ILBS, New Delhi
Co-Principal Investigator	<b>Dr. Manoj Sharma</b> Professor, Department of Hepatology, ILBS, New Delhi
Co-Principal Investigator	<b>Dr. Archana Ramalingam</b> Assistant Professor, Department of Epidemiology, ILBS, New Delhi
Co-Principal Investigator	<b>Dr. Reshu Agarwal</b> Assistant Professor, Department of Clinical Virology, ILBS, New Delhi
Project Manager	Dr. Kavita Aggarwal ILBS, New Delhi

Name of the Nodal Officers at 5 Hospitals			
Deen Dayal Upadhyay Hospital			
Dr Shalini Kakar	Dr Depak Upadhya		
Guru Teg Bahadur Hospital			
Dr. Kuldeep Kumar	Dr. N.P. Singh		
Maharshi Valmiki Hospital			
Dr Vivek Mohan Arora	Dr Rajiv Singhal		
Pt. Madan Mohan Malviya Hospital			
Dr Mala Vinayak	Dr Akansha		
Sanjay Gandhi Memorial Hospital			
Dr Trishla	Dr Suphala Bodo		



## FIND Team – HEAD-Start, Delhi

### ER BABU, Country Project Manager

Over the years, treating HCV has been the challenge. Given the increase in diagnostic and therapeutic options, there is a possibility of reaching the needy with required HCV services. The HEAD-Start project including the Delhi model proved to be efficient and sustainable in offering HCV diagnostic and treatment services at primary health care centers. I hope the outcome of the Delhi model will be useful in supporting the NVHCP in India to achieve its objectives and targets. I am proud to be part of HEAD-Start and lead implementation of HCV Projects in India. I would like to thank all my colleagues at FIND, the project team at ILBS, officials of DHS, Delhi, Medical Officers and Lab Technicians at Hospitals and Polyclinics and most importantly Project Lab Technicians and Data Entry Operators who made this project a successful one.

#### NAVNEET TEWATIA, Advocacy Officer

Today, we have unprecedented opportunity to reap the full-benefit of low cost and highly effective antiviral drugs to eliminate hepatitis C. It will take innovative diagnostic tools and new service delivery models, along with mass awareness, enabling policies, finances and public health infrastructure. The Delhi Model, demonstrated under HEAD-Start project, is paving way for the capital city, and beyond, towards elimination of hepatitis C.

#### PREETISHIRIN KATAPUR, Lab Specialist

HCV-A Silent Epidemic: Eradication of HCV is possible through increasing awareness about HCV infection through screening, improving treatment uptake by providing linkage to care and effective treatment, and ultimately combining education efforts to prevent transmission and reinfection which in due course will stop the "silent epidemic.

#### PRAKASH BASNET, Project Assistant

Hepatitis C is preventable and those infected can easily be treated by newer inexpensive medicines. However, diagnosis remains the major bottleneck along with regular supply of lab consumables and drugs to prevent potential stockout situations. Thus, a well-integrated supply chain management and efficient administrative operations play a significant role in ensuring timely and effective services to patients. As part of the HEAD-Start team, I feel privileged to have the opportunity to contribute and learn about operations and logistics aspects.



## **FIND India**

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