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Childhood Lead Exposure Prevention: Assessment Of Blood Lead Surveillance Capacity

Maharashtra, India

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Abbreviations

ASHA	Accredited Social Health Activist
BLL	Blood Lead Level
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CSIR	Council for Scientific and Industrial Research
DEIC	District Early Intervention Centre
DHS	Directorate of Health Services
DLHS	District-Level Household Survey
DoECC	Department of Environment and Climate Change
ETAAS	Electrothermal Atomic Absorption Spectroscopy
FAAS	Flame Atomic Absorption Spectroscopy
FDA	Food and Drug Administration
HWC	Health and Wellness Centre
ICDS	Integrated Child Development Scheme
ICP-MS	Inductively Coupled Plasma Mass Spectroscopy
ICP-OES	Inductively Coupled Plasma Optical Emission Spectroscopy
InSLAR	Indian Society for Lead Awareness and Research
KEMHRC	KEM Hospital Research Centre
LAMP	Lead and Multi-Element Proficiency
MoHFW	Ministry of Health and Family Welfare
MPCB	Maharashtra Pollution Control Board
NCD	Noncommunicable Disease
NEERI	National Environmental Engineering Research Institute
NGO	Nongovernmental Organization
NHM	National Health Mission
NITI	National Institution for Transforming India
NLEM	National List of Essential Medicines
PHD	Public Health Department
RBSK	Rashtriya Bal Swasthya Karyakaram
UN	United Nations
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
XRF	X-ray Fluorescence

Executive Summary

Preventing exposure to lead (Pb) is particularly important for health, because neurological and behavioral impacts caused by lead exposure among children are generally irreversible. Blood lead surveillance is a critical component of a comprehensive lead poisoning prevention program, as effective and comprehensive prevention begins with information obtained from surveillance. Unfortunately, at present, very few countries in Asia have established blood lead surveillance due to a lack of awareness and resources.

In India, a recent National Institution for Transforming India (NITI) Aayog—Council of Scientific and Industrial Research (CSIR) report has highlighted the importance of establishing blood lead surveillance that can generate high-quality local data to help understand lead exposure and health burden among Indian children. This may be implemented effectively at the state level, starting in states including Maharashtra, where there is demonstrated government commitment to addressing environmental health issues. Statewide childhood blood lead surveillance typically involves monitoring blood lead levels (BLLs) among children and collecting other information that may indicate risks and sources of lead exposure.

As an essential step toward establishing such a system at the state level in Maharashtra, we conducted a capacity assessment to evaluate existing laboratory capacity and health system structure and provide recommendations for capacity strengthening and surveillance options best suited for Maharashtra. This capacity assessment report evaluated the policy landscape, public health infrastructure laboratory capacity to initiate and support a statewide childhood lead surveillance system, which will be fulfilled in close collaboration with the Public Health Department (PHD), Government of Maharashtra.

A blood lead surveillance system can serve many functions and provide information necessary for planning for future interventions and developing policies and programs to protect children's health and the nation's future. The system will serve to:

- Characterize the problem: evaluate the magnitude of lead poisoning by assessing blood lead levels (BLLs) and understanding trends and distribution of lead poisoning in different communities across the state, and, depending on system design, by demographic characteristics, including age, gender, parental occupation, and behavioral and housing characteristics.
- Identify priority areas and groups for effective resource allocation: identify at-risk geographic areas and population sub-groups to help prioritize planning of community-based primary prevention interventions targeted to the highest risk areas (e.g., environmental remediation, health services for early identification and treatment, capacity strengthening).
- Educate for better care: improve knowledge and awareness of lead poisoning prevention and treatment among pediatric health care providers and parents for early detection and timely interventions.

There are two types of surveillance systems: active surveillance and passive surveillance. Active surveillance is when a health worker goes into an area or house to house to collect information about health conditions. In contrast, in passive surveillance, information on health conditions is received from hospitals, clinics, public health units or other sources through periodic reports. In India, malaria surveillance is an example of active surveillance and measles surveillance is an example of passive surveillance. For blood lead surveillance, many resource-constrained countries started with active surveillance to gather high-quality data to understand the severity of the issue to help improve awareness and engage public interest. While passive surveillance can be cheaper, the system often takes a long time to establish as it relies on government mandates and requires prevalent testing of BLL.

Maharashtra benefits from a well-structured health care system providing curative and preventive services. The PHD of Maharashtra consists of various health agencies that implement public health and other disease control programs, including the State Health Society, State Family Welfare Bureau, State Health Systems Resource Centre, State Surveillance Unit and State Public Health Laboratory. Currently, none of the health agencies conduct public health surveillance activities related to lead exposure prevention in populations of any age group. While lead exposure prevention involves multiple stakeholders, the PHD has the technical expertise and functional capacity to design and implement a blood lead surveillance system in the state. The Maharashtra Pollution Control Board (MPCB) can lead overall coordination of lead exposure prevention activities.

One of the essential components of lead exposure prevention is to measure the amount of lead in blood and environment samples using appropriate laboratory standards. The Maharashtra government has no public facility that can measure lead or other heavy metals in biological and environmental samples. A few private laboratories measure lead in blood and two academic institutes have the capacity and expertise to measure lead in blood and environmental samples. The primary objective of the baseline blood lead surveillance is to understand the burden of children with elevated BLL above 5 μg/dL. This can be achieved by using portable analyzers in the field. There is further potential to strengthen the State Public Health Laboratory to provide laboratory analytical services.

The health system assessment shows that multiple health programs can accommodate childhood blood lead surveillance. Rashtriya Bal Swasthya Karyakaram (RBSK), the school health screening program, can identify children at risk of lead exposure and refer them to District Early Intervention Centres for testing and treatment. However, this strategy would require extensive capacity strengthening of current health staff and equipping them with necessary resources. On the other hand, operational guidelines of Health and Wellness Centres mention screening of people occupationally exposed to lead. For Health and Wellness Centres to become the first point of service delivery, laboratory capacity must be strengthened to undertake blood lead surveillance.

In addition to strengthening infrastructure and resources, there is an opportunity to draft and adopt lead-exposure clinical management guidelines, create awareness among the general population, and train health professionals to identify lead-exposed individuals early and treat them.

Below, we discuss in detail the pros and cons of various approaches, providing recommendations that are best suited to the requirements of the state considering its available resources.

Background

Lead is an environmental toxicant, and its exposure can cause anemia, hypertension, renal impairment, immunotoxicity, and toxicity to the reproductive organs. Young children are particularly susceptible to lead poisoning because they absorb far more lead from their environments than adults and because their central nervous systems are still developing (Schwartz, 1994). Lead exposure can affect children's brain development, even at a low level, and can result in behavioral changes, reduced intelligence quotient, and reduced educational attainment and lifetime earnings.

Sources of Lead Exposure

Children are exposed to lead in their daily lives in many preventable ways. Unregulated industrial practices such as mining, smelting, manufacturing, and recycling lead acid batteries can release high lead levels into the air and soil. Lead paint used in households, especially those violating national guidelines, is also an important source of lead exposure for children at home. Children may also be exposed to lead through unsafe consumer products adulterated or contaminated with lead, including spices, cooking or dinnerware, jewelry, toys, packaged food, cosmetics, and traditional medicines. Many of these sources can be reduced and eliminated by enforcing policies and programs that regulate industrial practices and monitoring lead contamination in consumer products. Behavior interventions such as managing household dust, handwashing, post-work clothing changes, and maintaining good nutrition can also reduce lead absorption among children. Studies have shown that reducing lead exposure is very cost-effective. For every dollar spent to reduce lead exposure, there is a 17- to 220-fold return in savings from future societal contribution (Gould, 2009).

Lead Exposure in India

Lead poisoning contributes to significant disease and economic burdens in India. The Institute for Health Metrics and Evaluation estimated that 275 million Indian children have a BLL above 5 μg/dL, which requires action to prevent further exposure (Institute for Health Metrics and Evaluation, 2017). The burden on health care systems and loss of human potential also affects economic development. Lead exposure in India is responsible for a loss of US $236 billion annually, equivalent to 5% of India's gross domestic product (Attina and Trasande, 2013). NITI Aayog and the Council for Scientific and Industrial Research reviewed data from 36 BLL studies carried out in India between 1970 and 2014 and found that in 23 states, the BLL average was above 5 μg/dL, while the country average for children under 2 years was 4.9 μg/dL (Kumar *et al.*, 2022).

Lead Exposure in Maharashtra

In a 2015 study that analyzed blood samples from children and adults across India, over 13% of people living in Maharashtra had high BLLs (>15 μg/dL), ranked highest among all states with data (Iyer, Sengupta and Velumani, 2015). A few studies evaluated BLLs among adult spray painters, jewelry shop workers battery manufacturing workers in western Maharashtra. These workers were reported to have higher BLL (2 to 3 times) than the comparison sample (A. J. Patil *et al.*, 2007; Dongre *et al.*, 2012; Ghanwat *et al.*, 2016; Kshirsagar, Patil and Patil, 2020). A similar study evaluated BLLs among gas station workers, Ganesh idol painters, garage workers people with daily application of lead-containing black pigment to eyes in western Maharashtra. Fuel outlet workers had a mean BLL of 72.77 μg/dL, and Ganesh idol painters had a mean of 12.57 μg/dL (Bawaskar and Bawaskar, 2020). Most studies reported higher BLL resulting from occupational exposure, however, there is limited data on BLL among children in Maharashtra. A recent survey in Mumbai compared the BLL of 15 children having neurological symptoms with 14 matched controls. The mean BLL in cases with neurological symptoms was almost five times higher than the matched control (Goel and Chowgule, 2019). One of the more extensive studies sampled more than 700 children in Mumbai and found an average BLL of 8.36 μg/dL (Nichani *et al.*, 2006).

Pure Earth and Vital Strategies, both global NGOs, are embarking on a project in Maharashtra, "Realizing Children's Full Potential by Ending Lead Poisoning." Under this project, Pure Earth and Vital Strategies aspire to work in partnership with the state of Maharashtra to conduct public health surveillance to estimate the local burden of childhood lead exposure, evaluate the leading sources of lead exposure, and use these data to inform activities that will reduce exposures to enable children to achieve their full potential.

Objectives of the project

1. **Assess and build capacity to monitor lead exposure among children in Maharashtra**
   - Evaluate the capacity of national/state laboratories and health care systems to identify laboratory and operational needs for conducting statewide monitoring of BLLs.
   - Provide laboratory equipment, training initial support needed to conduct surveillance cost-effectively and sustainably given local infrastructure and capacity

2. **Support the state of Maharashtra in understanding the severity and distribution of childhood lead poisoning through statewide surveillance**
   - Establish statewide representative surveillance to monitor BLLs among young children living in Maharashtra
   - Design a database that incorporates existing environmental, health industry data with information on risk factors for lead and other heavy metal exposure

3. **Increase multi-sectoral knowledge about sources and pathways of exposure of children to lead**
   - Provide training and equipment to establish local capacity to conduct home visits and measure lead in environmental samples
   - Co-design and implement a program in partnership with the local government to identify sources of lead exposure among children with high BLLs through environmental sampling and existing environmental data

4. **Increase knowledge of health professionals, community health workers, teachers, parents, workers with occupational lead exposure**
   - Strengthen the capacity of health professionals to identify, treat and prevent lead poisoning early and educate communities and children about lead poisoning and ways to mitigate and prevent risks
   - Use the information collected in the previous phases of the project to address and evaluate the problem of lead poisoning by working with health professionals and the population

Policy Landscape

Stakeholder Analysis

This section of the report contains a general description of each stakeholder identified and highlights their roles concerning: childhood lead exposure surveillance; identifying pathways of children's exposure to lead; establishing an integrated database; operationalizing poison centres; and training all relevant stakeholders.

Public Health Department

The PHD of Maharashtra, headed by the Principal Secretary, manages the primary and secondary health care facilities such as health sub-centres, health and wellness centres, primary health centres, first referral units, sub-district hospitals, community health centres, district hospitals and dedicated specialty hospitals for specific disease control programs. The Directorate of Medical Education and Research manages tertiary care facilities affiliated with medical colleges. In contrast, most of the city health care facilities are managed by urban local bodies.

Some of the primary functions of the Maharashtra PHD are:

- Providing preventive and curative health care services in the state through primary, secondary and tertiary health care facilities
- Improving services of these health care facilities
- Training of doctors, nurses, and other health care staff
- Implementing national health programs of the National Health Mission (NHM) through the State Health Society set up under the aegis of the State Health Mission
- Imparting health education and creating community awareness

All the executive authorities of the three wings—Directorate of Health Services (DHS) Mumbai, DHS Pune and NHM—are headed by the Commissioner of Health and ex-officio Mission Director-NHM. DHS Mumbai manages the public health care facilities, while DHS Pune manages the implementation of various health and disease control programs.

In this lead poisoning prevention project, the PHD of Maharashtra should manage overall coordination with relevant stakeholders and be the main implementer of the statewide blood lead surveillance and assessment of sources of exposure.

Commissionerate of Health Services and National Health Mission

The National Rural Health Mission was launched in 2003 to strengthen health care services in the rural areas of the country. In 2013, the two sub-missions, National Urban Health Mission and National Rural Health Mission, merged to form National Health Mission. Significant components of NHM are health system strengthening, improving reproductive, maternal, child, neonatal and adolescent health, and implementing national health programs to prevent, control, eliminate or eradicate communicable and noncommunicable diseases (NCDs).

At the state level, the functions of the NHM are carried out through the State Health Society. Some of the essential functions of the State Health Society are:

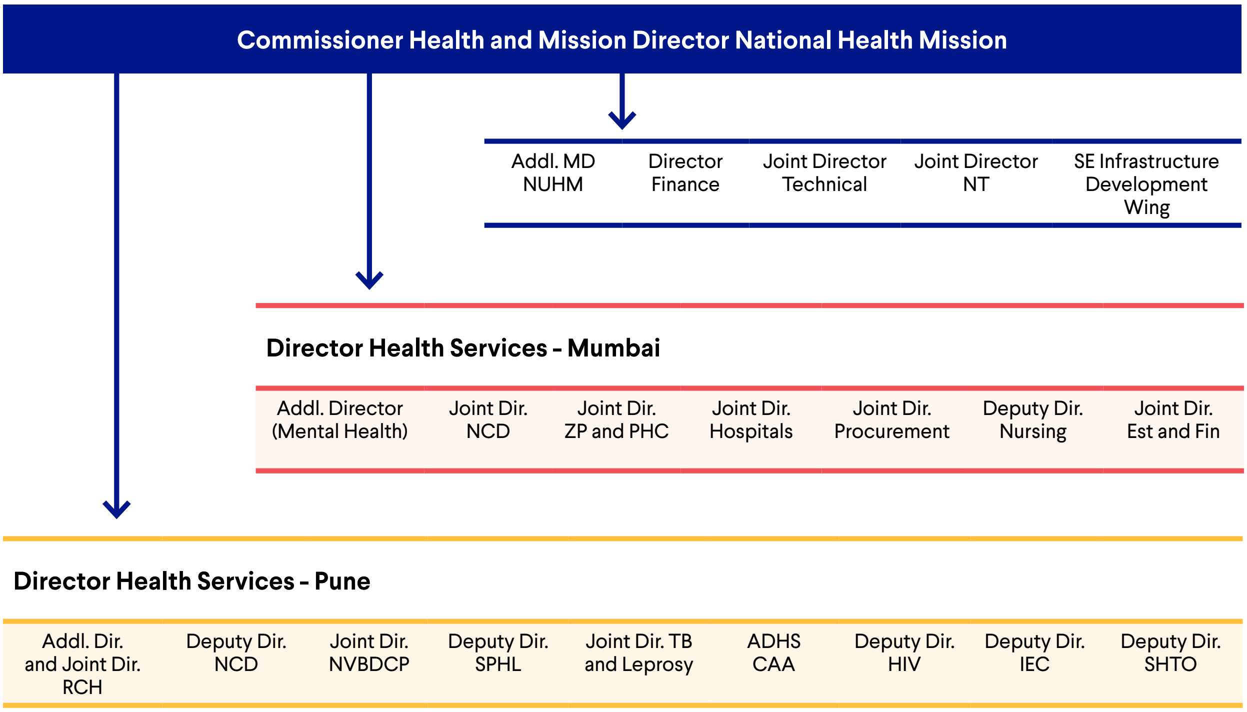
- To manage funds received from the Ministry of Health and Family Welfare (MoHFW) under NHM
- To manage the NGOs/public-private partnership components of the NHM in the state, including execution of contracts, disbursement of funds and monitoring of performance
- To act as a resource centre for the Department of Health and Family Welfare in policy/situational analysis and policy development
- To strengthen the technical and managerial capacity of the State Directorate by recruiting individuals/experts on a contract basis
- To mobilize financial/non-financial resources for complementing/supplementing the NHM components in the state
- To organize training, meetings, conferences, policy review studies/surveys, workshops, inter-state exchange visits, etc., to derive inputs for improving the implementation of NHM in the state
- To undertake other activities for strengthening NHM in the state as may be identified occasionally, including mechanisms for intra- and inter-sectoral convergence of inputs and structures

Most health or disease control programs and surveillance or screening programs like the school health screening program (RBSK) or NCD risk factor surveillance are implemented in the state under the umbrella of NHM activities.

Apart from the NHM-implemented surveillance or screening activities, the State Integrated Disease Surveillance Unit also collects weekly data on epidemic-prone diseases as a part of the Integrated Disease Surveillance Program. Under this program, a central surveillance unit at the National Centre for Disease Control collects weekly data from the State Surveillance Unit, which in turn collects data from district surveillance units. Primary health centres, community health centres, sub-district hospitals share field-level data with district surveillance units in prescribed formats. District laboratories diagnose epidemic-prone diseases, and these laboratories are linked with medical colleges and other state public health laboratories.

Under the purview of the Commissionerate of Health Services, different health agencies, departments or offices—such as DHS-Pune, State Family Welfare Bureau, State Health Systems Resource Centre, State Surveillance Unit-Integrated Disease Surveillance Program and the State Public Health Laboratory—can play a lead role in implementing lead poisoning prevention efforts including blood lead surveillance, blood lead testing training of public health professionals.

Figure 1: Organogram of Commissionerate of Health Services and National Health Mission—Maharashtra



Addl = Additional, Dir = Director, MD = Mission Director SE = Superintending Engineer. ADHS CAA = Assistant Director Health Services and Controller of Audits and Accounts; Est and Fin = Establishment and Finance, IEC: Information, Education, and Communication; NCD = noncommunicable diseases; NT = nontechnical; NUHM = National Urban Health Mission; NVBDCP: National Vector Borne Disease Control Program; RCH = Reproductive and Child Health, SPHL: State Public Health Laboratory; SHTO: State Health Transport Organization, ZP = Zilla Parishad.

Note: The above image was created from a report titled An Assessment of the Maharashtra State Health System (2022) by Prasanta Mahapatra, Sonalini Khetrapal, and Shyama Nagarajan from the Asian Development Bank.

Women and Child Development Department

The Women and Child Development department of the government of Maharashtra, headed by the Principal Secretary, focuses on holistically promoting the survival, protection, development, welfare and participation of women and children. The department has programs for:

- Rehabilitation of women and children who are victims of sexual offenses, acid attacks, and other violence or atrocities
- Promoting the birth of girl children and their education
- Child protection
- Counseling and advisory centres for both women and children
- Foster care

One of the flagship initiatives of the Women and Child Development department is the Integrated Child Development Scheme (ICDS). The ICDS looks after the overall growth and development of preschool children under six years through their ICDS centres or Anganwadi centres. More than 88,000 Anganwadi centres in the state provide early childhood education and nutrition to these children from rural, tribal, and urban slum communities. This program also extends to adolescent girls, pregnant women, and lactating mothers.

ICDS works closely with the health department to provide some of these vital services:

- Supplementary nutrition
- Immunization
- Health care checkup
- Referral health services
- Non-formal pre-school education
- Nutrition and health education

In lead poisoning surveillance, ICDS workers can support the health team in identifying and mobilizing eligible children and pregnant women.

Department of Environment and Climate Change

The Department of Environment and Climate Change (DoECC), headed by the Principal Secretary, manages the implementation of policies and programs related to conserving the state's natural resources and biodiversity and preventing and reducing pollution. It is also responsible for framing climate change-related schemes, plans and programs, and their execution.

Some of the main functions of the DoECC are:

- To assess environmental trends and plan interventions
- To deal with compliance with all environment protection rules/acts, management of bio-medical, solid, plastic, e-waste, hazardous and other wastes (transboundary movement), and construction and demolition waste
- To assess/study implications of environmental impacts brought forward by the Maharashtra Pollution Control Board, biodiversity board, scientific institutions, other government bodies, academia, research and development institutions, and civil society, as well as select technologies/processes relevant to addressing environmental concerns
- To deploy and allocate resources for interventions leading to environmental conservation
- To implement national and state action plans on climate change

DoECC can play a key role in reducing environmental sources of lead or creating legislation to prevent lead exposure.

Maharashtra Pollution Control Board

MPCB is headed by an officer at the rank of secretary who acts as board chairman. The board comprises members from the environment department, urban development department, health department, transport department, Maharashtra Industrial Development Corporation, agriculture and water supply, and sanitation department. The board implements legislation on the prevention and control of air and water pollution and waste management under the administration of the Department of Environment and Climate Change. Some of the significant functions of MPCB include:

- To plan a comprehensive program for the prevention, control, or reduction of pollution
- To collect and disseminate information relating to the prevention, control, or reduction of pollution
- To inspect sewage or trade effluent treatment and disposal facilities and air pollution control systems and to review plans, specifications or any other data relating to the treatment plants, disposal systems and air pollution control systems
- To support and encourage developments in the fields of pollution control, waste recycling, reuse of waste, eco-friendly practices, etc.
- To attend to public complaints about pollution and build understanding among the public about the importance of a clean and healthy environment

MPCB can convene all its member departments and collectively plan to prevent, control and reduce lead exposure.

Directorate of Medical Education And Research

This directorate is responsible for regulating and administering government allopathy and dental medical colleges, and hospitals, along with urban and rural health training centres attached to them. It provides direction and controls all government medical colleges, their standards, and the accreditation of nursing and paramedical institutes. In addition to medical education, it coordinates research activities at these institutions.

The government and private medical colleges (allopathy, dental, and AYUSH) are affiliated to Maharashtra University of Health Sciences. Each medical system and nursing faculty have their respective state-level medical or nursing councils that streamline the registration of medical practitioners and nurses.

The Directorate of Medical Education and Research can help build the capacity of medical professionals and specialists in the early identification, management, and treatment of lead-poisoned individuals.

Public Health Institute, Nagpur

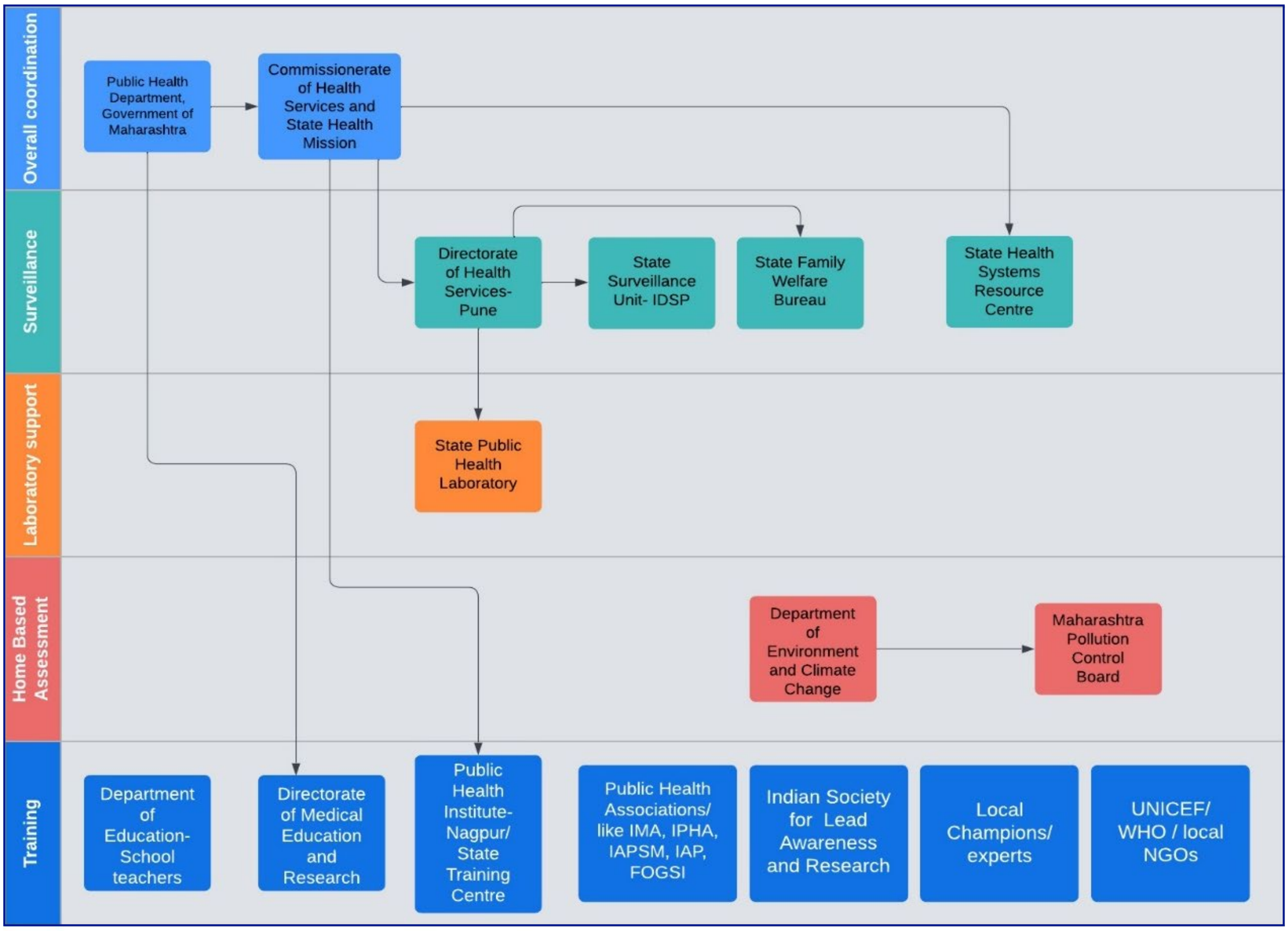
The Public Health Institute, Nagpur, is the apex staff training institute of the health department. This institute has technical and administrative control over the seven regional health and family welfare training centres, 33 district training centres, and 23 hospital training centres in district hospitals to facilitate practical training.

The total number of participants trained by this network was about 13,200 in 2017-18 and 12,500 in 2018-19, increasing to 57,000 in 2019-20.

This apex training institute can strengthen the capacity of public health professionals in the prevention and management of lead poisoning.

Organizational Chart Of Stakeholders

Figure 2: Organizational chart with project roles



Local Champions

People across Indian states are experiencing the side effects of lead exposure, but there remains a need for population-level data on lead exposure to tackle lead toxicity. The Ministry of Health and Family Welfare and its state counterparts have yet to prioritize addressing lead toxicity or other heavy metals toxicity as a matter of public health concern. Individual researchers, public health physicians, local and international NGOs, and UN agencies were instrumental in advocating for phasing out lead from gasoline in the early 2000s. Thus far, the principal emphasis has been preventing occupational exposure to lead rather than understanding community-level exposure, especially among children and pregnant women.

Academic Researchers

In Maharashtra, some researchers and their affiliate organizations have tried to better understand lead exposure by measuring the blood lead levels of occupationally exposed workers. However, limited studies have measured BLLs in children, while none measured lead exposure in pregnant women.

The table below lists academic researchers and the studies they conducted to measure lead exposure. As technical experts, they can provide their input in reviewing reports, attending regional workshops, and formulating state-level action plans to reduce lead exposure in children.

Table 1: Researchers and their studies since the year 2000

Target Population	First author	Affiliation	Published Year/Study Title
Children	Archana Patel	Lata Medical Research Foundation/ Department of Pediatrics, Indira Gandhi Government Medical College, and Hospital	2001/Blood Lead in Children and its Determinants in Nagpur, India 2006/Association of Umbilical Cord Blood Lead with Neonatal Behaviour at Varying Levels of Exposure 2008/Association of the Pattern of Transition Between Arousal States in Neonates with the Cord BLL 2009/BLLs in Children with Encephalopathy 2009/Determinants of Lead Level in Umbilical Cord Blood 2011/Feeding Practices and BLLs in Infants in Nagpur, India
	Vikram Nichani	Department of Environmental Health Sciences, College of Public Health, The University of Georgia	2006/BLLs in Children after Phase-Out of Leaded Gasoline in Bombay, India
	Shilpa Pratinidhi	Bharat Ratna Atal Bihari Vajpayee Medical College, Pune, Maharashtra	2014/Effects of BLL on Biochemical and Hematological Parameters in Children with Neurological Diseases of Western Maharashtra, India
	Rohini Chowgule	Indian Institute of Environmental Medicine, Kasturba Hospital	2019/Outbreak investigation of lead neurotoxicity in children from artificial jewelry cottage industry
Occupational workers	Arun J. Patil	BLDEU's Shri B.M. Patil Medical College, Bijapur, Karnataka & Department of Biochemistry, Krishna Institute of Medical Sciences University, Karad, Maharashtra	2006/Biochemical Aspects of Lead Exposure in Silver Jewelry Workers in Western Maharashtra (India) 2006/Effect of Lead (Pb) Exposure on the Activity of Superoxide Dismutase and Catalase in Battery Manufacturing Workers (BMW) of Western Maharashtra (India) with Reference to Heme biosynthesis 2007/Occupational Lead Exposure in Battery Manufacturing Workers, Silver Jewelry Workers, and Spray Painters in Western Maharashtra (India): Effect on Liver and Kidney Function

Occupational workers	Vinod Bhagwat	SBH Govt Medical College, Dhule, Maharashtra	2008/Occupational Lead Exposure and Liver Functions in Battery Manufacture Workers around Kolhapur (Maharashtra)
	Ganesh Ghanwat	Department of Biochemistry, Krishna Institute of Medical Sciences University, Karad, Maharashtra	2015/Biochemical Effects of Lead Exposure on Oxidative Stress and Antioxidant Status of Battery Manufacturing Workers of Western Maharashtra, India 2016/Effect of Vitamin C Supplementation on BLL, Oxidative Stress and Antioxidant Status of Battery Manufacturing Workers of Western Maharashtra, India
	Jyotsna A. Patil	Department of Biochemistry, Krishna Institute of Medical Sciences University, Karad, Maharashtra	2017/Benefits of Vitamin C Supplementation on BLLs, Oxidative Stress, Antioxidant Status 2019/Activated Carbon Fabric Mask Reduces Lead Absorption and Improves the Heme Biosynthesis and Hematological Parameters of Battery Manufacturing Workers 2020/Activated Carbon Fabric Respiratory Mask reduces Blood Lead, Oxidative Stress and Improves the Antioxidant Status and Liver Functions in Unorganized Battery Workers
	Mandakini Kshirsagar	Krishna Institute of Medical Sciences University, Karad, Maharashtra	2019/Increased BLL Induces Oxidative Stress and Alters the Antioxidant Status of Spray Painters 2020/Elevated Blood Lead Results in Oxidative Stress and Alters the Antioxidants of Silver Jewelry Labors 2021/Elevated blood Lead impairs the Hematological and Heme Biosynthesis related parameters of Silver Jewelry Workers
	Himmatrao Bawaskar	Bawaskar Hospital and Clinical Research Centre, Mahad, Raigad, Maharashtra	2020/BLL among Fuel Station Workers, Ganesh Idol Painters, Persons with Routine Daily Application of Lead-containing Black Pigment to Eyes, and Garage Workers

Public Health Associations

Multiple public health associations with their state chapters in Maharashtra promote and advocate for improving public health and health education.

Some of the critical public health associations are listed below.

- Indian Medical Association
- Indian Public Health Association
- Indian Association of Preventive and Social Medicine
- Indian Association of Pediatrics (focused on pediatric health)
- The Federation of Obstetric and Gynecological Societies of India (focused on women and newborn health)

These associations can play an instrumental role in disseminating and extending the reach of health education activities as part of the lead poisoning prevention project.

Indian Society For Lead Awareness And Research

In 2013, the Indian Society for Lead Awareness and Research (InSLAR) was formed to disseminate evidence-based information to the government, NGOs, and clinicians and to create community awareness.

InSLAR has established about 48 lead centres across India dedicated to screening for lead exposure by measuring BLLs. Out of the 48 centres, five are in Maharashtra:

1. Krishna Institute of Medical Sciences and Research Centre (now known as "Krishna Vishwa Vidyapeeth"), Karad, Satara
2. Golwilkar Metropolis (now known as "A.G. Diagnostics"), Pune
3. Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Mumbai
4. Mahatma Gandhi Institute of Medical Sciences, Wardha
5. Tata Green Battery, Pune

These five centres are equipped with portable analyzers for one of these purposes:

- To measure BLL to screening people with suspected lead exposure
- To measure BLL for commercial diagnostic purposes
- To periodically measure occupational lead exposure
- To conduct lead exposure-related research activities

InSLAR is pivotal in advocating for community-based lead poisoning surveillance and generating awareness among all stakeholders, including government, academia, and clinicians.

Academic Institutes & Nongovernmental Organizations

In addition to government departments and public health associations, numerous public health institutes and NGOs work simultaneously or support the government to provide and strengthen health care services in the state. We have listed institutes and NGOs that could potentially support or help supplement lead poisoning prevention activities in Maharashtra. The list includes academic institutes and NGOs with well-established relationships within the state.

Table 2: Academic institutes and NGOs in Maharashtra

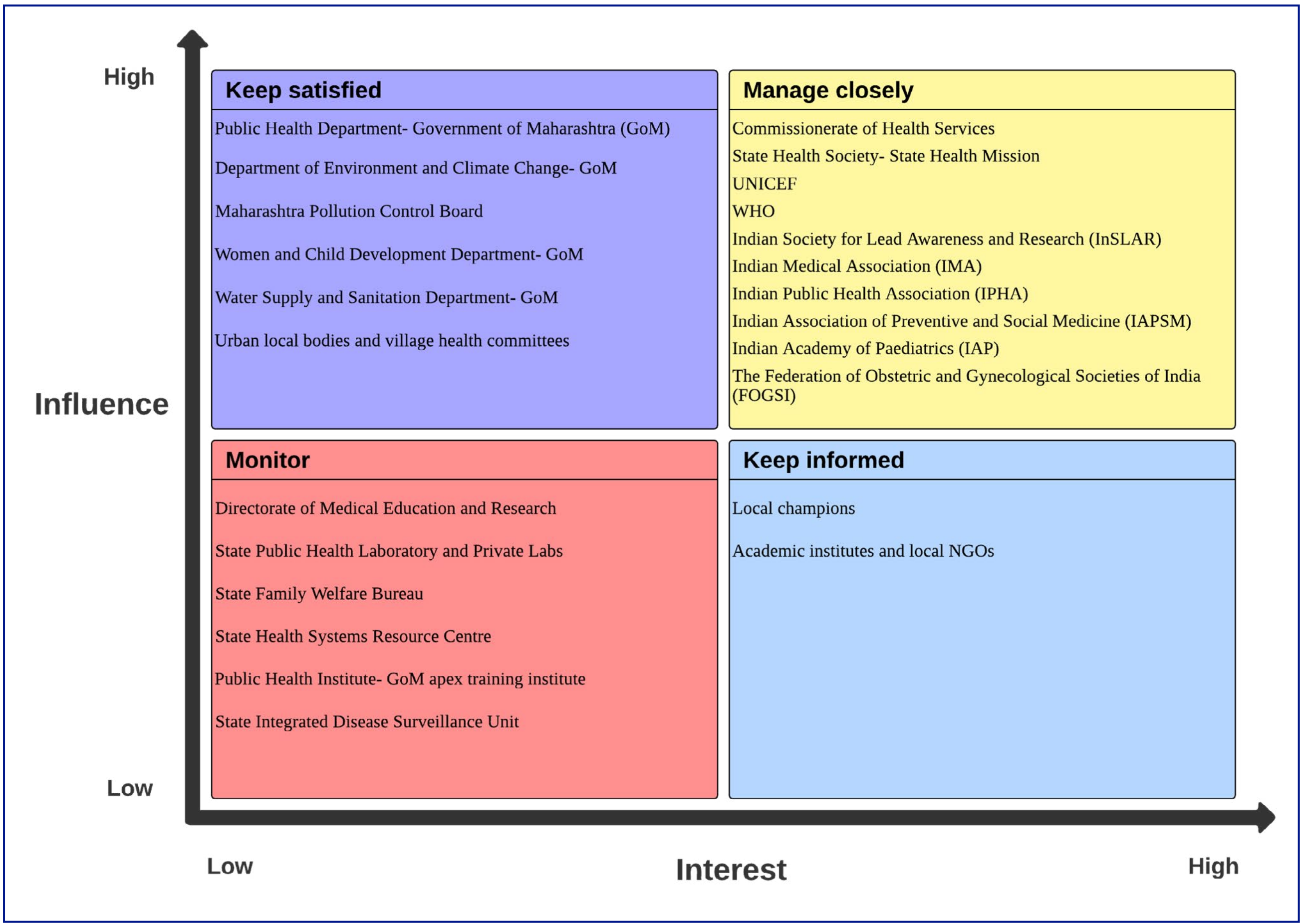
	Name of the NGO	Description and expertise
1	International Institute for Population Sciences (IIPS)	IIPS is an academic institute conducting population health-related teaching and research. It has a reputation for conducting large-scale surveys like the National Family Health Survey, District Level Household Survey (DLHS), and nutrition surveys. IIPS can support the Maharashtra health department in conducting statewide representative BLL surveys and managing BLL data.
2	National Environmental Engineering Research Institute (NEERI)	NEERI is a Council of Scientific and Industrial Research (CSIR) institute pioneered for conducting research and developmental studies in environmental science and engineering. It has initiated research and development initiatives for ecological monitoring in the country. It has participated in previous lead exposure studies by using its laboratory capacity to measure BLL. NEERI can support the government in identifying potential lead sources and strengthening laboratory capacity.
3	KEM Hospital Research Centre (KEMHRC)	KEMHRC is a not-for-profit organization that has been conducting translation research for decades. Some prominent research areas include endocrine disorders, reproductive and child health, and improving the quality of health services. It has undertaken large-scale cohort studies, interventional, biomedical, and operational research studies, and clinical/vaccine trials. KEMHRC also has a rural health program and a health and demographic surveillance system. KEMHRC can support the Maharashtra health department in conducting statewide representative BLL surveys and managing BLL data.
4	Lata Medical Research Foundation (LMRF)	LMRF is a not-for-profit organization and has contributed extensively to the field of medical research in diverse areas such as maternal and child health, environmental health, thalassemia, sickle cell anemia, tuberculosis, HIV, cardiology, oncology, bioinformatics, genetics, pathology, diabetes, neurophysiology, and behavioral health. Dr. Archana Patel, Program Director at LMRF, has done some notable research on childhood, newborn and maternal lead exposure. She has also contributed to WHO Gguidelines for the clinical management of exposure to lead. LMRF can support the health department in surveillance design, drafting clinical management guidelines, and training clinicians/specialists.

In addition to the above-mentioned academic institutes and NGOs, there are other notable organizations that can assist the health department in designing, planning and strengthening systems to implement childhood lead exposure prevention and management activities. These include: All India Institute of Medical Sciences-Nagpur, Interactive Research School of Health Affairs, School of Health Systems Studies-Tata Institute of Social Sciences, and Centre for Environment Education

U.N. agencies including WHO and UNICEF are present in Maharashtra and support the health department. WHO provides technical assistance to strengthen health systems, carrying out routine immunization and vaccine-preventable disease surveillance activities under their flagship project, the National Public Health Surveillance Project. UNICEF closely works with the Public Health Department, Women and Child Development department, and urban local bodies to sustain and expand the state's health, nutrition, water and sanitation, education, and child protection programs.

Stakeholder Mapping

Figure 3: Stakeholder mapping



Laboratory Investigation

This section on laboratory investigation summarizes the strengths and limitations of biomarkers of lead exposure and the analytical methods for measuring blood lead concentrations. We evaluated the existing laboratory capacity in Maharashtra and how it can be strengthened to support statewide blood lead surveillance.

Biomarkers of Lead Exposure

Blood lead testing is recommended over other human tissue sampling since blood is the best biomarker for lead. Hair, nails, and other tissues have been used in studies to evaluate lead exposure. Still, they are subject to contamination, uncertain exposure timeframes, and lack standardized levels linked to outcomes (Brief guide to analytical methods for measuring lead in blood, second edition. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO).

We list the strengths and limitations of capillary and venous blood sample types below, summarizing observations from previous studies and WHO's guidelines on analytical methods for measuring lead in blood.

Table 3: Blood sample types

Method	Strengths	Potential challenges
Capillary	Easier to obtain consent, less invasive and painful for children, the procedure is shorter, and trained nurses and phlebotomists are not required. Immediate results can be shared with caregivers, reducing the burden on the study team for follow-up.	Vulnerable to environmental contamination; only collects small blood samples. Low levels are unreliable or below the limit of detection. Capillary samples are most often paired with LeadCare II, but occasionally tested with advanced laboratory-based analytical methods.
Venous	Obtaining a more significant amount of blood samples is easier, and samples are less likely to be contaminated.	Requires a trained medical professional, is more invasive, makes it harder to obtain consent, and can fail if the child has a small or deep vein or dehydration. Time lag in reporting of findings—uncertain state laboratory capacity for timely analysis. Venous blood samples can be paired with different laboratory-based analytical methods. Based on the U.S. Food and Drug Administration warning, venous blood should not be paired with LeadCare II due to the risk of underestimation.
Dried blood spot	Minimal pain, stable and easy to store and transport, no local laboratory needed.	Both filter and sampling processes are vulnerable to contamination. No immediate result. Heterogeneous distribution may bias results. Dried blood spot samples are generally analyzed by ICP-MS.

In the eight BLL studies conducted among children in Maharashtra, two studies used capillary blood, and the other six used venous blood to measure blood lead concentrations. We did not identify any study conducted in Maharashtra measuring BLL among children using dried blood spots or any laboratory equipped to analyze lead levels in dried blood spot samples in Maharashtra. Therefore, we made recommendations mainly for capillary and venous blood samples. Several factors are involved when choosing the most suitable blood sample type between capillary and venous blood for statewide blood lead surveillance.

- **Purpose:** Overall, capillary blood is recommended for screening purposes. If a concerning BLL is reported, a venous blood sample is recommended for confirmatory testing.
- **Analytical method:** Capillary blood samples are generally paired with a portable analyzer due to the small sample volume (200-500 μL). While capillary blood samples can be analyzed using a laboratory-based approach with more advanced equipment and a highly controlled laboratory environment, all laboratories we identified in Maharashtra only accept venous blood samples. Also, venous blood should not be analyzed by a portable analyzer (i.e., LeadCare), as warned by the U.S. FDA after an investigation in 2017. This investigation found that LeadCare tends to underestimate BLLs in venous blood samples due to a substance released from the rubber cap of tubes used to collect venous blood samples.
- **Participation:** There is evidence suggesting that participation rates will be greater and less biased when parents are offered less invasive testing. This may be particularly important when conducting surveillance in the general population as parents may be less willing to test their children than parents living in high-risk areas. More invasive testing likely requires more time and effort from the local field team to mobilize participants.
- **Environmental contamination:** Capillary blood is more vulnerable to environmental contamination overall, so venous blood should be prioritized if environmental contamination is a particular concern (e.g., when a low BLL is expected).
- **Sample collection, storage, and transportation:** Collecting venous blood from young children often requires more experienced personnel (e.g., certified nurse, phlebotomist). Collection may fail if a child has a small or deep vein, dehydration, or a specific health condition (e.g., anemia) or is hard to keep calm. It is essential to ensure the availability of experienced personnel for surveillance conducted in low-resource or remote areas. As venous blood samples are generally analyzed in a designated laboratory, it is essential to evaluate if the local team can provide suitable storage conditions and if a system allows the timely transport of samples. Capillary blood samples are generally analyzed on-site with a portable analyzer, so no storage and transportation are required.
- **Additional testing:** Because of the larger sample volume, a venous blood sample should also be considered if there are other blood tests required (e.g., additional hematology tests, storage for future use, coupling lead analysis with that of other heavy metals).

Based on existing resources and experiences, we recommend both venous and capillary blood as suitable options for future blood lead surveillance in Maharashtra. We do not recommend using dried blood spots at this time due to a lack of local laboratory capacity to analyze this type of sample.

Analytical Methods

The choice of analytic method for BLLs should consider the surveillance purpose, existing laboratory capacity, local testing ability and costs. In the table below, we have provided strengths and limitations of common methods to analyze BLLs (cost considerations are in USD and may vary across locations).

Table 4: Blood testing and analysis options

Option	Strength	Limitation	Cost consideration (INR)
Portable analyzer (LeadCare II)	• Portable, battery-operated • Small blood volume (50 µL) • Can be used at non-laboratory sites • Uses capillary sample • Simple to use, does not require skilled laboratory personnel • Low purchase and running costs • Report results on-site within 3 minutes • Has comparable accuracy with laboratory-based methods (U.S. FDA validated and approved)	• Limited analytical working range (3.3–65 µg/dL) • Higher risk of sample contamination • Risk of low-biased results on venous blood collected with specific evacuated blood tubes • Will not work at high altitudes (above 2,400 meters) and high ambient temperature	Equipment cost: ~ INR 2,28,920/unit (US $2,800) Cost per test: ~ INR 700 per test (US $9)
FAAS	• Short analysis time (seconds) • Relatively easy to use • Relatively few interferences • Relatively low capital and running costs	A large sample volume is usually needed (typically in mL), but the cup method can allow the use of 50-100 µL samples. • Relatively high detection limit (5 µg/dL) • Cannot be left unattended (flammable gas) • Results cannot be obtained on-site (only available after sending samples back to the laboratory for analysis)	Equipment cost: 48,00,000 INR to 65,00,000 INR (US $57,831-$78,314) + Operating cost INR 500 per test (US $6) + Personnel cost 30,000 INR per month (US $362)
ETAAS	• Low detection limit (< 1 µg/dL) • Can analyze small volume samples (50–100 µL) • Can be fitted with autosampler so multiple samples can be processed • Well-documented applications • May be left unattended • No need for sample preparation	• Limited analytical working range • Requires some laboratory expertise • Longer analysis time • Results cannot be obtained on-site (only available after sending samples back to the laboratory for analysis)	Equipment cost + Operating cost + Personnel cost Information not available at this moment

Option	Strength	Limitation	Cost consideration (INR)
ICP-MS	• Very low limit of detection (0.02 µg/dL) • Can analyze small volume samples (50–100 µL) • Very fast analysis time (‹ 1 minute) • Wide analytical working range • Multi-element capabilities and can be economical if used for large sample runs • Potential to perform isotopic ratio analyses with some forms of ICP-MS, which may help to identify the source of the lead	• High purchase and running costs • Requires highly skilled and certified laboratory staff • Analysis of a large number of samples is cheaper than ETAAS • Results cannot be obtained on-site (only available after sending samples back to the laboratory for analysis)	Equipment cost + Operating cost + Personnel cost Information not available at this moment

In the eight BLL studies conducted among children in Maharashtra, four studies used portable analyzers, three studies used FAAS, and one study used anodic stripping voltammetry. The largest study in Mumbai used a portable analyzer (ESA LeadCare) to measure BLLs in 754 children.

If the Public Health Department partners with a high-quality private laboratory or upgrades its State Public Health Laboratory for blood lead testing, we recommend laboratory-based methods for blood lead surveillance in the general child population in Maharashtra. Laboratory-based methods will only involve collecting blood samples in the field and transporting them to designated laboratories. The health teams have been trained to collect blood samples from the field for various routine health programs, so no additional training on testing instruments is needed. However, LeadCare can still be considered an option for screening BLLs, especially in remote areas and areas with a higher risk of lead exposure.

Below is a summary of important factors to consider when determining the analytical approach.

- **Purpose of the surveillance:** Since the health department aims to screen and identify the proportion of children at risk of lead poisoning (i.e., % of children with BLL above 5 µg/dL), we can choose a testing method with higher detection limits such as the portable analyzer.
- **Expected BLL levels among children**: It is important to note that the FDA-certified portable analyzer LeadCare II (3.3 µg/dL) has a higher detection limit than laboratory-based methods (often below two µg/dL). This can be a problem in areas where the BLLs of most children are expected to be lower than 3.3 µg/dL. Of the two studies that used the FAAS method for blood analysis, one reported BLL below 1 µg/dL. Hence, it is valuable to use lab-based methods due to their low detection limits. However, the health department's goal is to determine the proportion of children above and below the 5 µg/dL threshold. Hence, a portable analyzer is acceptable, given the limited laboratory capacity.
- **Environmental contamination and quality control:** Because portable analyzers are often used in the field rather than in a controlled laboratory environment, they are more vulnerable to environmental contamination. In addition, the quality control procedure is more comprehensive for a laboratory-based approach involving blank and repeated tests. When testing with a portable analyzer, repeated tests may not always be available

due to the small sample volume from capillary blood. Also, the LeadCare test kits have a short expiry period of six months, which might make it difficult for the health staff to replenish them. This also adds to the health staff's inventory management and procurement burden.

- **On-site or local testing ability:** Results of BLLs are available in minutes using a portable analyzer, while results from laboratories will take weeks or months. Getting testing results on-site can be a high priority if the government plans to provide education or recommendations for the participants based on their BLLs. Sharing results with participants turns out to be difficult when there is a time lag between collection and analysis, as it can be challenging to reconnect with participants once months have passed while awaiting laboratory results to report back findings. A portable analyzer can also be distributed to allow testing locally in remote areas since it is simple to use, and a community health worker can be trained to use it properly. For example, if the local government is interested in maintaining a local testing capacity for community screening rather than sending samples to be tested in a centralized laboratory location, a portable analyzer would be a good option.
- **Cost considerations:** The cost of different analytical methods can vary based on the sample size and existing setup of laboratories. For the portable analyzer, the cost is generally the sum of the initial purchase of equipment (~ INR 2,28,920) and the cost of testing kits (~INR 700 per test). To establish or expand the capacity of a testing laboratory, the total cost will be a combination of the purchase of equipment, operating and maintenance costs (e.g., reagents, gases, electricity), and personnel costs. Generally, these costs are the highest for an ICP-MS laboratory because it requires more expensive instruments, a stable operating environment, and highly skilled technicians. Often, the cost of a portable analyzer per sample will be lower if there is no established laboratory and with a moderate sample size. However, when there are established laboratories (especially government ones), the cost can be low when processing a large number of samples.

Table 5: Estimated cost of tests based on different testing options

	LeadCare II	Using an established laboratory
Cost of instrument	INR 2,28,920 (US $2,800)	None
Cost of testing kits	33,512 (US $405)	None
Cost of operation and maintenance	N/A	N/A
Cost per sample for 2,500 samples	INR 700 (US $9)	INR 1600 – 2150 (US$ 20-$26 USD)
Total cost for 2,500 samples	INR 17,50,000 (US $21,100)	INR 40,00,000 – 53,75,000 (US $48,192 – $64,760)

Existing Laboratory Capacity in Maharashtra

If the laboratory-based approach is selected for blood lead surveillance in the future, it will be essential to evaluate if existing laboratories can handle the number of samples required, reach a reasonable turnaround time, and have a satisfactory quality management system. In this section, we summarize the information collected through an online search of laboratories or institutes performing blood lead testing and discussion with State Public Health Laboratory authorities.

We have identified eight laboratories or institutes in the state that test BLLs or have previously supported blood lead testing. These include five private laboratories, two institutional laboratories and one government laboratory. These laboratories reported using analytical methods including ICP-MS, ICP-OES, FAAS and ASV requiring venous blood samples. These laboratories conduct BLL testing for a wide range of purposes, including clinical diagnosis, public health surveillance, and research. We didn't identify any laboratories that currently accept capillary blood or dried blood spots for the BLL test.

We recommend first considering Agilus Diagnostics Limited, National Environmental Engineering Research Institute (NEERI), and All India Institute of Medical Sciences (AIIMS)-Nagpur to support blood lead surveillance among the identified laboratories. Agilus Diagnostics Limited laboratory is preferred because of its high-quality testing standards and previous experience in supporting venous blood lead testing in Bihar. If the Public Health Department is willing to consider using a private laboratory, we recommend establishing a public-private agreement with Agilus Diagnostics Limited. NEERI and AIIMS are preferred because of their experience supporting blood lead testing among children and pregnant women. They are affiliated with the Council of Scientific and Industrial Research and Ministry of Health and Family Welfare, respectively; hence, they can help the state strengthen its laboratory capacity.

Table 6: Identified laboratories in the state and their characteristics

Lab name/ Location	Affiliation	Sample type	Analytical method	Detection limit	Maximum testing ability	Cost/ Turnaround time	Accreditation/ Purpose of Testing
NEERI-Nagpur	Council of Scientific and Industrial Research	Venous blood	FAAS/ ICP-MS	0.07 µg/dL		-	Ministry of Science and Technology, India/ Research
AIIMS-Nagpur	MoHFW	Venous blood	ICP-MS	Not available	100 in a day	350 INR	Christian Medical College-Vellore/ Research and Diagnostics
Agilus Diagnostics Limited-Mumbai	Private	Venous blood	ICP-MS	Not available		2150 INR/24 hours	NABL & CAP/ Clinical Diagnostics
A.G. Diagnostics Private Limited-Pune	Private	Venous blood	DP-ASV/ ICP-MS	Not available		1900 INR	NABL/ Clinical Diagnostics
Metropolis Healthcare Limited-Mumbai	Private	Venous blood	ICP-MS	Not available		-	NABL & CAP/ Clinical Diagnostics
Thyrocare Technologies Limited- Navi Mumbai	Private	Venous blood	ICP-MS	Not available		-	NABL & CAP/ Clinical Diagnostics
General Diagnostics International Private Limited-Navi Mumbai	Private	Venous blood	ICP-MS	Not available		-	NABL/ Clinical Diagnostics

*National Accreditation Board for Testing & Calibration (NABL) and College of American Pathologists (CAP)

Opportunity to Expand In-State Laboratory Capacity

There are a handful of certified laboratories with moderate testing capacity in Maharashtra, and it is not necessary to establish a new BLL testing laboratory. Existing laboratories are adequate to support active surveillance using a representative sample of the population (e.g., analyzing a subset sample of participants in state or national surveys, surveillance, or screening programs) over multiple cycles. After reviewing these laboratories, we recommend focusing resources on advancing capacity with existing laboratories at NEERI-CSIR and AIIMS-Nagpur or partnering with a private lab that can provide diagnostic services at a discounted rate.

Our first recommendation is the NEERI, which is a CSIR institute. NEERI has supportedearch studies on lead exposure by extending its laboratory capacity to monitor BLLs. Based on the literature, the lead levels were analyzed within 48 hours of sample collection by FAAS (Hitachi Z-8000) using the method described by Lagesson *et al*. We also recommend AIIMS-Nagpur since their biochemistry laboratory is well equipped with ICP-MS. Both institutes have expressed their interest in supporting the statewide blood lead surveillance and testing home-based samples for lead. NEERI and AIIMS can be a potential technical partner of the Public Health Department to strengthen the testing capacity of the state. Further assessment is needed to understand the need, costs involved, analytical method preferred, sample acceptance, and equipment present at NEERI and AIIMS. The Public Health Department may not express interest in working with NEERI since they are not affiliated with the PHD. However, AIIMS–Nagpur being affiliated with MoHFW could be of interest to the PHD.

The state also has a Public Health Laboratory, a government laboratory affiliated with the Maharashtra PHD. This laboratory is headed by a deputy director for day-to-day management and reports to the Director of Health Services-Pune. The State Public Health Laboratory analyzes food, water and wastewater samples submitted by different government agencies under the provisions of the Food Safety and Standards Act, 2006, and as per standards of the Bureau of Indian Standards, etc. The laboratory has ICP-OES equipment, which has been used to test heavy metals in food items. The Deputy Director also mentioned that they have tested the blood lead of government printing press workers using ICP-OES. Currently, the equipment is not operational and needs repair. Their technician has the expertise to test heavy metals in food items and could be further trained to test blood lead concentrations. They are also easy to work with as they can accept samples through mail or in-person drop-off and have experience analyzing large samples. However, they would need extensive support in certification or setting up high laboratory standards since they are not certified to test heavy metals in blood. This may take a substantial amount of time, delaying further project activities.

NEERI-CSIR, AIIM-Nagpur and the State Public Health Laboratory also expressed interest in participating in the U.S. CDC Lead and Multi-element Proficiency (LAMP) program. To maintain the high analytical quality of existing laboratories, we recommend promoting participation in the free U.S. CDC LAMP program, which can provide consultation for international laboratories.

Use of Portable Analyzer For Blood Lead Testing

Although we recommend a laboratory-based approach for ongoing surveillance, for the baseline blood lead surveillance proposed in 2024, we recommend that LeadCare II be used for the screening of children, with on-site testing and immediate sharing of results with participants. LeadCare has been used in four BLL studies in India. One of these studies used LeadCare to analyze venous blood samples. This practice should be avoided in future studies since the U.S. FDA and the manufacturer strongly suggested not analyzing venous blood with LeadCare due to potential underestimation of lead levels. A common practice that helps validate LeadCare testing results is collecting venous blood from a subset of participants (5-10%) to be analyzed in a laboratory. Comparison of results from the laboratory and LeadCare can help understand whether environmental contamination is occurring in capillary draws.

Vital Strategies and Pure Earth recently collaborated with Mahavir Cancer Sansthan and Research Centre in Bihar to conduct a BLL survey in eight districts. We tested BLLs in almost 700 children and more than 50 pregnant women by collecting capillary blood samples analyzed by LeadCare. To validate the LeadCare measurements, we also drew venous blood samples from around 5% of our study participants and analyzed them in a certified laboratory using ICP-MS. The correlation between LeadCare and laboratory measurements was strong (r=0.70), and the difference in medians was relatively small (difference=2.18 µg/dL). The majority of samples had a difference smaller than 5 µg/dL, and LeadCare generally reported a slightly higher value than the ICP-MS. The findings were shared and well-received by the Bihar State Health Department. We note that we could not do independent quality control on the ICP-MS laboratory, and it is difficult to conclude which set of results more accurately reflects true exposure.one accredited supplier of LeadCare devices and testing kits in India called SPARK Services. Vital Strategies has purchased LeadCare devices and testing kits from this vendor in the past. The current cost of purchasing LeadCare through this supplier is 228,920 INR (US $2,800), and the cost of each box of testing kit is 33,512 INR (US $405) for 48 tests. Pure Earth continues to seek a donation of LeadCare devices from the manufacturer.

Under the school health screening program (RBSK) children from birth till school age are screened for defects at birth, diseases, deficiencies, and developmental delays. Children at risk are referred to District Early Intervention Centre. These centres can also be equipped with portable analyzers to test BLL and act as poison prevention centres specific to heavy metal poisoning.

Out-of-Country Laboratory Capacity

We do not recommend shipping samples to be tested outside the country as there are many satisfactory laboratories within the state and nation. There are legal hurdles to shipping biological samples outside of India, and the cost may be prohibitive. Most lead studies in India have used local laboratories or LeadCare devices.

Public Health Surveillance

The Public Health Department and the National Health Mission of Maharashtra carry out a handful of state disease surveillance and screening programs. To sustain the efforts of generating primary surveillance data on childhood lead poisoning, it is advantageous to integrate representative surveillance activities into the current surveillance programs. Blood lead surveillance in other countries often resides in the public health sector. One of the reasons is that blood lead surveillance often adopts the model of biomonitoring, that is, blood lead concentration measurement. This section examines previous/existing public health and blood lead surveillance activities, analyzes their capacity to collect, manage and communicate data, and finally recommends potential mechanisms to set up blood lead surveillance.

Previous Studies That Tested BLL Among Children in Maharashtra

Only eight studies have measured BLLs among children in Maharashtra since 2000 (the year in which lead gasoline was banned in India). Of these eight studies, three were hospital-based and five were community-based. Hospital-based studies reported a higher mean BLL compared to most community-based studies. However, the three hospital-based studies were not designed to be representative of the population of children, as they often studied hospitalized children.

Only five studies (highlighted below) measured BLLs among children living in a general community (i.e., without known/high risk of lead exposure). Two more extensive studies were conducted two decades ago. Nichani et al. sampled more than 700 children in Mumbai and found an average BLL of 8.36 µg/dL, a good proxy of BLL among urban children then. By incorporating the BLL testing into the National Family Health Survey, Jain et al. had a representative sample of the urban population in Mumbai and Delhi. They failed to report the overall or city specific average BLLs. However, 47% of children combined in both cities had BLLs above 10 µg/dL.

Table 7: Summary of previous studies that tested BLL among children in Maharashtra

Authors	Year	Location	Study population	Mean BLL (µg/dL)
Tripathi et al.	2001	Mumbai and Hyderabad	576 urban children between 3 and 6 years	8
Patel et al.	2001	Nagpur	297 community-based, urban children between 6 months and 6 years	18.4
Jain et al.	2005	Mumbai and Delhi	1082 urban children below 3 years of age	Female: 10.8 Male: 10.8
Nichani et al.	2006	Mumbai	754 children below 12 years of age (435 from low socioeconomic areas and 319 recruited from hospital)	8.36 (geometric mean)
Patel and Athawale	2009	Nagpur	49 with encephalopathy and 51 consecutive hospital controls	12.18 among children with encephalopathy 4.19 among hospital controls

Patel et al.	2011	Nagpur	200 infants from hospital	10.14
Pratinidhi et al.	2014	Pune	60 children between 3 to 12 years (30 with neurological disorders and 30 healthy children)	8.6 among children with neurological disorders 5.2 among healthy children
Goel and Chowgule	2019	Mumbai	15 cases from the primary childcare clinic with neurological complaints and 14 controls from the neighborhood of cases without neurological complaints (aged between 6 months and 13 years)	42.6 among clinic cases 8.7 among controls

Existing Public Health Surveillance Programs in The State

Table 8 compares the strengths and limitations of various national and state health programs on public health surveillance or screening that can accommodate childhood lead poisoning surveillance. These programs currently do not collect data on BLLs or risk factors of lead exposure.

Table 8: Ongoing disease surveillance/screening health programs

Health Program	Organization	Type of Activity	Target population	Components
Rashtriya Bal Swasthya Karyakaram (RBSK), the school health screening program	National Health Mission-Child Health Department	Screening	Birth to 18 years	• Child health screening and early intervention services • Screening for 4 Ds: defects at birth, diseases, deficiencies, and developmental delays
Integrated Disease Surveillance Program	National Health Mission–State Surveillance Unit	Surveillance	All age groups	• Disease surveillance system for epidemic-prone diseases, to monitor disease trends and to detect and respond to outbreaks • Surveillance units at the country, state, and district levels • Dedicated staff at state and district: state surveillance officer, state, and district epidemiologists • Periodic data management and analysis • Affiliated public health laboratories
National Program for Prevention and Control of Non-Communicable Diseases (NP-NCD)	National Health Mission-NCD Wing	Screening	30 years and above	• Since 2016, implemented in all states under the National Program for Prevention and Control of Cancer, Diabetes Cardiovascular Diseases and Stroke • NCD cells and NCD clinics at health facilities for screening, early detection, and management

Potential Mechanisms to Monitor Blood Lead Levels

Additional Testing of Existing Blood Samples For Blood Lead Concentrations

Health facilities collect blood samples for routine health conditions related to vector-borne diseases, vaccine-preventable diseases or infectious diseases, routine laboratory diagnostics, and during antenatal care for blood group, HIV testing, blood sugar testing, and hemoglobin estimation. The health department may consider testing for lead toxicity in the blood samples collected or stored during the above-mentioned conditions. This will only involve additional sample collection and testing at certified labs.

Incorporating Childhood Blood Lead Surveillance Into Existing Surveys

One of the potential mechanisms is to incorporate the BLL survey into an existing national health survey. It requires relatively low public interest and testing capacities. The human resources and operational costs and management required are fairly low as the existing survey partially covers them. It will be essential to understand the design of the national survey and its implementation plan when selecting a survey. Ideally, the survey should reach a nationally representative sample of children under age 5, to capture the most vulnerable population of lead poisoning. Other factors to consider include:

- **Sample collection:** Does the survey collect blood samples or do some health outcome assessment (e.g., BMI, weight) in person in addition to the questionnaire?
- **Relevant health information:** Does the survey collect information on the children's nutrition or health status (e.g., anemia) that can be linked with lead exposure?
- **Agency in charge:** Does a government agency organize the survey with an excellent connection to the state public health department (or by the state public health department themselves)?

Table 9: Strengths and limitations of ongoing disease surveillance/screening health programs

Health Program	Strengths	Limitations
Rashtriya Bal Swasthya Karyakaram (RBSK), the school health screening program	• The target population for proposed blood lead surveillance overlaps with the target population of RBSK • Conducts an age-specific physical examination • Collects information on the anemia status of children • Strong convergence with the Women and Child Development and Education departments • Dedicated staff of medical officers, nurses, paramedics • Screening for developmental delays in children aligns with health outcomes of maternal lead exposure in newborns • Referral facilities (District Early Intervention Centres) are available. These centres can also act as poison prevention centres specific to heavy metal poisoning.	• Current screening focuses on physical examination of the children • Does not involve biological measurements • No affiliated laboratories

Integrated Disease Surveillance Program	• Ongoing since 2004 • Well-established reporting protocols: Integrated Disease Surveillance Program online portal and Integrated Health Information Platform • Periodic data collection on epidemic-prone diseases • Network of public health laboratories	• Highly dependent on frontline health workers (nurses and ASHAs) for field visits and reporting • Diseases with standard case definitions are reported (not applicable for lead poisoning since poisoned individuals often are asymptomatic or report non-specific symptoms) • Understaffed below district level • District-level staff dependent on state counterparts for technical expertise • Public health laboratories may not be well equipped, trained or certified to test lead in blood
National Programme for Prevention and Control of Non-Communicable Diseases	• Relatively new program with a scope to incorporate or integrate new activities • Can screen the adult population on lead exposure • Health and Wellness Centres have been mandated to screen and follow up on care for occupational diseases, including lead poisoning	• Since NCD screening normally involves adults or aging populations, it cannot screen children and pregnant women for lead exposure • The population screened may not be representative since only sick people attend these NCD clinics, and people with lead poisoning may remain asymptomatic or with no specific symptoms or signs of poisoning

The Integrated Disease Surveillance Program requires routine reporting of notifiable diseases, syndromes events. If enough awareness and public interest consider elevated BLL a high-priority condition, identification and reporting of lead poisoning cases can be added to the list and reported through this program. In this case, the challenge will be case identification. Unlike many infectious diseases monitored in this system (e.g., measles, malaria, etc.), people with elevated BLLs can be asymptomatic or with non-specific symptoms. This will require assessment of lead exposure history and testing BLLs as a regular medical practice. To our knowledge, no current guideline from MoHFW or medical society recommends BLL testing for young children in India, and BLL testing during routine pediatrician visits is rare. Another challenge for this approach is the current in-state laboratory capacity. We have elaborated more about this in the in-state laboratory capacity section.

For state-level surveillance, we recommend incorporating lead testing into RBSK since it ideally screens children up to 18 years of age for health outcomes that can be linked to lead exposure, has dedicated staff up to the block/primary health centre level, and collaborates with the Women and Child Development department, which can also provide support in assessing pregnant women for lead exposure at Anganwadi centres. Also, RBSK teams conduct in-person physical examinations, which provide an opportunity to collect biological samples.

At national level, there is a potential to incorporate blood lead testing with National Family Health Survey. In 1998-99, National Family Health Survey, with support from USAID and UNICEF, measured the blood lead concentration of 1082 children (below 3 years of age) from Mumbai and Delhi using a portable analyzer. We are not considering integrating BLL into this survey as this may need commitment from the Ministry of Health and Family Welfare and other implementing agencies.

Home-Based Assessment For Lead Source Identification

Home-based assessments play a crucial role in identifying lead sources and pathways of exposure, particularly for young children. Once a child's blood lead level is determined, the next essential step is to pinpoint the factors contributing to elevated lead levels in their blood (typically exceeding 5 µg/dL), and the entire process of sample collection and analysis is called home-based assessment. This not only aids in developing effective interventions for the child and their family but also contributes to understanding broader trends that can guide interventions at local, state, or regional levels. Home-based assessment is typically conducted after testing a child's BLL. Investigators collect and test samples from the home environment, including soil, paint, indoor dust, water, foods, toys, and other consumer products.

In the field, the investigators use a portable X-ray fluorescence analyzer (XRF) to quickly read lead content in various media. Also, a subset of samples are sent to a laboratory for re-examination to confirm XRF readings and trends. In cases where media cannot be evaluated with an XRF, like water and liquid food products, samples are sent to a certified laboratory for analysis.

XRF is a non-destructive analytical technique to determine the elemental composition of materials. The method is non-destructive, meaning it doesn't alter the sample, making it valuable as a subset of unaltered samples are sent to labs for further analysis.

The device works on the principle that when a material is exposed to X-rays, the material emits fluorescent X-rays. The emitted X-rays exhibit characteristics of the elements present in the material, and the analyzer analyses these characteristic X-rays to identify and quantify the elements such as lead and other heavy metals within the sample. Here's a breakdown of the process:

- **Excitation**: The sample is irradiated with high-energy X-rays, typically from an X-ray tube. This high-energy radiation causes inner-shell electrons of the atoms in the sample to be ejected.
- **Fluorescence**: The ejected inner-shell electrons leave vacancies in the electron shells. Outer-shell electrons then fall into these vacancies, and as they do, they emit X-rays. The energy of these emitted X-rays is characteristic of the specific elements in the sample.
- **Detection and Analysis**: A detector measures the energy and intensity of the emitted X-rays. The resulting spectrum provides information about the elements present and their concentrations in the sample.

Clinical Management

There are no national guidelines for lead exposure prevention, treatment management for any age group in India.

As per WHO guidelines for clinical management of exposure to lead, Dimercaprol, Penicillamine, Sodium calcium edetate Succimer are the four chelating agents that are commonly used to treat extreme cases of lead poisoning. Out of these four chelating agents, MOHFW-India has listed D-penicillamine and Dimercaprol under the National List of Essential Medicine (NLEM), 2022.

As per NLEM-2022, D-Penicillamine should be available at primary, secondary tertiary health care facilities in the dosages of 150 mg and 250 mg capsules. Dimercaprol should be available at secondary and tertiary health care facilities in 50 mg/ml injection dosage. However, their availability at the health care facilities of Maharashtra will be explored later.

The standard treatment protocol of the Maharashtra Public Health Department highlights that children with PICA are at increased risk of lead poisoning, and they should be investigated and treated suitably. However, this protocol has no information on the treatment or management of lead poisoning in children or people of any age group.

Maharashtra state hasn't established a poison control centre that could impart information related to heavy metal toxicity to the general public, providing preventive and curative services. According to WHO, there are six poison centres in India, none in Maharashtra.

Also, a regional newspaper in 2021 highlighted the need to set up poison control centres in the state of Maharashtra to address poisoning cases. A reputed private hospital and medical research institute functions as a Poison and Drug Information Centre in Mumbai. However, limited information is available on the services available, how to access them, and their capacity to address poisoning cases. It is noteworthy that in addition to providing expert guidance for clinicians and the public on intoxications, poison control centres serve an important cost-saving function by preventing the unnecessary use of emergency rooms and hospitals for minor or insignificant exposures that may be managed at home.

Apart from the availability of medicines and poison control centres in Maharashtra, there is no evidence of training or capacity strengthening of medical and other health care professionals in identifying, treating and managing cases of lead poisoning.

Risk Communication

The Ministry of Health and Family Welfare has not developed any program for the prevention, care or treatment of heavy metal toxicity, including lead poisoning. There seems to be some interest in addressing occupational exposure to lead as the operational guidelines of Ayushman Bharat mention early identification, screening, referral follow-up care for occupational diseases, namely lead poisoning at Health and Wellness Centres.

We have not identified any major government-led communication campaign to raise awareness of lead poisoning in the country or Maharashtra. However, UN agencies or NGOs often publish posts or statements about managing toxic elements and reducing heavy meal exposure during International Lead Poisoning Prevention Week.

Conclusion

Activity	Conclusion and recommendation
Project implementation and stakeholder coordination	• The health department is best suited to lead the design, implementation coordination of blood lead surveillance. They routinely conduct public health surveillance and are well-equipped with technical expertise, overseeing health centres that may serve as bases for surveillance networks. • While DHS-Pune is well-suited to lead the design and implementation of blood lead surveillance, it may encounter difficulty coordinating interventions or policy actions when other departments (e.g., environment, education, pollution control board) are needed. • Meanwhile, Maharashtra Pollution Control Board can be a good coordinator when cross-sectoral actions are needed as they convene regular meetings with governmental stakeholders across different departments. • DHS-Pune can coordinate internally with health agencies such as the State Health Systems Resource Centre, State Public Health Laboratory, State Family Welfare Bureau—Child Health Department, and State Surveillance Unit for health-specific activities of the project, like blood lead surveillance, lab capacity strengthening, and training health staff. • Health departments and medical associations are essential allies in doing health education and communication on the threats of elevated BLLs and advocating for adding blood lead surveillance as one of the passive disease surveillance systems. • It can be helpful to involve medical associations, local champions, NGOs UN agencies to get their support and input in various project-related activities like developing clinical guidelines, increasing the training reach, and formulation of state-level action plans.

Public Health Surveillance	• There are several well-established routine health surveillance/screening activities established in Maharashtra. Integrating lead exposure assessment into surveillance into these activities can be a sustainable and efficient option for the health department. • For childhood blood lead surveillance, RBSK can incorporate lead exposure assessment for children ranging from newborns to school-age children. Local RBSK teams can refer children at risk to District Early Intervention Centres for further testing and management. • For blood lead surveillance among pregnant women, we suggest incorporating testing for important heavy metals (e.g., lead, arsenic, mercury) into routine antenatal care. • For blood lead surveillance among adults, Health and Wellness Centres can screen members of households where a child/pregnant woman with elevated BLLs has been detected or those with occupational exposure under the National Programme for Prevention and Control of Non-Communicable Diseases. For people with occupational exposure, employers can monitor BLLs periodically. • Integration of blood lead surveillance integration into ongoing activities will need fewer resources but additional training on assessing lead exposure. • There may also be an opportunity to pilot a local passive surveillance system by recommending screening of BLL and lead exposure to children during medical visits at Health and Wellness Centres and mandating this reporting from community health officers. This will require strong support and commitment from leadership, making BLL testing available and affordable and guiding changes in local medical practices. This type of surveillance is particularly effective in improving early detection and treatment of lead poisoning cases, raising public awareness, and informing local policy decisions. • If there is not enough incentive to incorporate lead exposure assessment into existing surveillance systems, we recommend starting with a round of active surveillance using a state-representative sample based on Health and Wellness Centres to characterize the problem and demonstrate feasibility.
Laboratory capacity	• There is adequate laboratory capacity in Maharashtra to support an active surveillance system using a statewide representative sample. However, most high-quality laboratories are either private or academic. A strong partnership needs to be forged between the health department and any of these laboratories to support the statewide representative surveillance. • However, for a statewide passive surveillance system that requires wide testing of children, installing BLL testing ability at the State Public Health Laboratory and setting up regional testing facilities is needed. • Venous blood is the only sample type accepted by all known BLL testing laboratories in Maharashtra. We summarized several main challenges the team will face when using venous blood for a wider surveillance effort. • Based on the interaction with the health department, using portable analyzers as the testing tool seems feasible when the goal is to screen children with elevated BLLs.

Data management	• Focused public health data management assessment is highly recommended to locate the crux for data sharing and communication. • This could be achieved through close observation and study of existing databases and how they operate and interviews with personnel at each data processing level.
Clinical Management	• Out of the four chelating agents, two of them have been listed in the National List of Essential Medicines. This is an opportunity to develop and institutionalize the lead exposure management clinical guidelines. • No national or state-level clinical guidance is available. We recommend adopting the WHO guidelines for lead exposure management in close collaboration with governmental agencies and regional subject matter experts, so exposed children identified in surveillance can receive proper management. It can be critical in raising awareness among health professionals and building the base for passive surveillance. • We recommend that the Directorate of Medical Education and Research, which has a broad reach to medical professionals, include training on sources and health impacts of lead exposure and WHO clinical guidelines in the curriculum of medical graduates since no local clinical guidelines are available yet.
Risk Communication	• Overall, the awareness of lead poisoning among public and governmental agencies is still fairly low, and there were no campaigns to raise awareness of lead poisoning identified in Maharashtra before. • Delivering health education to participants during surveillance and training for health professionals and community health workers may be effective ways to improve knowledge and awareness of lead poisoning in Maharashtra.

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