

An Enquiry into the Neonatal Deaths in Nashik District

Submitted to

State Human Rights Commission, Maharashtra
& Department of Public Health, Government of Maharashtra

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by

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Executive Summary

An Enquiry into the Neonatal Deaths in Nashik District : A Report Submitted to State Human Rights Commission, April 2, 2018

At the instance of the State Human Rights Commission a three person expert team ¹ did a collaborative enquiry into the issue of neonatal deaths in Nashik district, with the participation of the Department of Public Health, Government of Maharashtra. This is the summary of the findings and recommendations.

Nashik is 3rd largest district of Maharashtra with a population of about 61 lakhs with estimated 64,000 live births per year of about. Infant mortality in the district and state is in the range of 20 per 1,000 live-births (NFHS), and if 75% of these are neo-natal, we anticipate 960 neonatal deaths in a year. The system has been able to capture 427 deaths in the District Hospital's (DH's) Special Newborn Care Unit (SNCU) and about 400 deaths elsewhere within the district in the last one year, and about another 100 deaths unaccounted for. At the Special Newborn care unit (SNCU) itself, there are about 2,800 admissions per year, of which about 13% die- and this case fatality rates are more or less steady over the months. Mortality in the last six months has been significantly higher in out-born babies.

The number of deaths reported are in line with the anticipated deaths according to the known estimates of infant and neonatal mortality. There is little case that can be made out for any sudden increase in any month, much less negligence. It is important to note that Nashik district like much of Maharashtra has seen a considerable reduction on child, infant, and neonatal mortality over the last decade - and the rates of birth and death are consistent with these trends.

However most of the deaths currently happening are also preventable, and there is a government responsibility to ensure this. The challenge is that at this relatively lower baseline for infant and neonatal mortality more-of-the-same would not be a sufficient strategy. A 50% relative reduction in mortality at a neonatal mortality rate of 15 per 1000 live births as compared to the same relative reduction when neonatal mortality is 30 per 1000 live births requires a disproportionately higher public health expenditure and substantially new operational strategies. The low hanging fruits are mostly harvested- these are the high hanging fruits.

District health systems have been designed on the basis of minimum essential services that they are required to provide, leaving the rest to the private sector. But this design is not adequate to meet the current challenges, and private care cannot close the gaps. There needs to be a step-up in the design of public health services at each level- district hospital, rural hospitals, primary health centers and sub-center. We also note that there is continued relevance to action on social determinants- as it is a complex of the tribal context, early age of marriage and pregnancy, frequent pregnancies and malnutrition that underlie the high levels of prematurity recorded. Action of these social determinants will also yield further reductions in mortality, but this needs to be designed to reach the more vulnerable and difficult to reach communities.

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Recommendations:

1. There is a need for the creation of 16 beds of level 3 newborn care unit (NICU- Neonatal Intensive Care Unit), equivalent to what is required in a tertiary care center. The remaining 20 SNCU beds would also need enhanced staff and equipment. The rationale for this, and the human resources and equipment required to achieve these two objectives are detailed in the main report. The central government would have to be approached for the mandate and at least part of the financing and technical support required for this. The government would need to take a call as to which directorate and department has the capacity to undertake this but the need for such upgradation is clearly present- and must be responded to.
2. There is a need for a neonatal advisory committee and a quality assurance system to be put in place- with terms of references as outlined in the main report. The details of this are important- and includes protocols, training, equipment, supplies, infection control and clinical audits.
3. There is a need for a standard protocol for safe neonatal transport and high-risk pregnancies with imminent deliveries from referral centre to the hospital. Such a protocol should include guidelines on when to and how to use the 12 currently available advanced life support ambulances for advanced neonatal transport- which includes ventilation, and avoiding inappropriate referrals. There is also a need for ensuring adequate numbers and efficiency of use of 108 ambulances.
4. There should be creation of 10 -bedded SNCUs for every 5 lakh population which would mean about 10 more SNCU at the intermediate level. This could be achieved by upgradation of all 10 Newborn Stabilization Units and creation of SNCUs in the two corporation hospitals. This can be undertaken in a phased manner, but the aim should be to reach the target in three years.
5. To address the HR requirements of these SNCUs, the Nashik District Hospital SNCU/NICU should act as a training center. Nurses and medical officers and pediatricians willing to work in these proposed SNCU hosting SDH/RH facilities may be prioritised for training and multi-skilled so that they are now enabled to manage the level 2 SNCU. There are a number of other flexible approaches to attracting and retaining skilled professionals in such areas- and these may be adapted for fulfilling this need. The current reliance on doctors serving a one year compulsory rural service bond is a useful stop-gap measure, but a better HR package is needed for the long run.
6. Adequate secondary care at the SDH-Rural Hospital-CHC level is difficult to build and sustain selectively for obstetrics and newborn care. It needs development of a wider range of services and enough volumes of work to sustain a fully functional operation theatre, daily blood transfusions, adequate intensive care and emergency care work- within which systemic context one could also sustain comprehensive emergency obstetrics and newborn care. In the district hospital, we already have a training site for such an expansion.
7. While most PHCs are optimal in identifying and referring high-risk pregnancies and sick newborn in a timely manner, primary care is sub-optimal more distant blocks and urban slums, mapping such vulnerable areas and strengthening services here must be a priority.
8. In urban areas, primary and secondary health care needs to be strengthened. The plight of the urban poor with respect to access to basic primary health services is equal to or worse than the rural poor. It is strongly recommended that there is a directorate or department of health services created within the ministry of urban development at the state level and within each corporation and municipality. Creation of such an institutional structure would allow state and district departments of public health to coordinate much better with the urban health care system, so that universal and comprehensive

urban primary health care can be established sooner. In the absence of such strengthening the secondary and tertiary care centers of the department of public health are getting flooded with primary health care needs of the urban poor.

9. Protocols relevant to preventing respiratory disease in the premature, and for prevention of birth asphyxia and for post-discharge follow up at the primary care level should be reviewed and improved.
10. An intensive behaviour change communication with a central role for the ASHA and community processes addressing the triad of maternal malnutrition, early age of marriage and first pregnancy, and frequent deliveries in select tribal villages/communities where these problems are high is urgently required. Good epidemiological studies must guide such action.
11. There is a need to include LAMA (left-against-medical-advice) and referral outcomes when measuring neonatal mortality.
12. Nashik NICU must be developed as the last port of call (the apex tertiary care facility) of neonatal intensive care for such a large population. (The population of this district is larger than the population of over 8 states and 6 UTs in India, or on international comparisons, more than the population of Norway). Referrals to KEM and other Mumbai public hospitals, while essential today, should become unnecessary tomorrow.
13. There is a need for the department of medical education to come on board with the need for level 3 SNCUs (or NICUs). All medical colleges must have these level 3 SNCU in place and they should be linked with good referral arrangements to the district health systems. In districts where there are no government medical colleges (and Nashik is an example) they should provide support to DH or themselves establish a level 3 SNCU in these districts. The fact that the medical education and public health come under separate ministries and departments is a barrier to effective coordination- There are many ways in which this can be addressed and they range from unified ministry to establishing task forces that ensure coordination of efforts across department to lower maternal and neonatal mortality.
14. There is a need for much better accountability of departments of women and child, and food and civil supplies and department of education and department of tribal welfare in addressing the issues of early age of marriage and first pregnancy and malnutrition and anemia amongst adolescents. The department of public health may consider setting up a coordination committee in tribal districts to facilitate and provide feedback to these departments, so that their schemes are more effective and better prioritized.

Report
An Enquiry into the Neonatal Deaths in Nashik District:

Submitted to State Human Rights Commission, Maharashtra, April 2nd 2018

I. Background:

The State Human Rights Commission took notice of excessive deaths of newborns in the Nashik district hospital that had come to light through media reports in August- September 2017. The state government submitted a report to the commission. In a subsequent hearing Tata Institute of Social Sciences (TISS) was called as an external expert. The TISS representative submitted that it would be necessary for TISS to constitute a three person team and make a visit and study the issue further before it could give its opinion on this matter. The SHRC asked TISS to coordinate with the state health department for this visit and submit its report and fixed April 2nd, 2018 as the date for the next hearing.

II. Methodology:

A three person team of Dr. T. Sundararaman, Health Systems Expert and Professor and Dean of School of Health Systems Studies(SHSS), TISS; Dr Narendra Kakade, Social Scientist and Assistant Professor in SHSS, TISS and Dr Manish Arya, Consultant Pediatrician and Intensivist, Lilavati Hospital and Research Centre made a visit to Nashik district on March 16th and 17th, 2018.

The visiting team interacted with the health administrators and health professionals in the following chronological order:

- a) District leadership of civil surgeon (Dr. Suresh Jagdale), district health officer (Dr. Sushil S Wakchaure) and supporting officers/administrative team of the district at the civil surgeon's meeting.
- b) Visit to the district hospital: also present: Dr. Gunjal additional CS, Dr. Nikhil- Nodal officer Quality Assurance(QA), VD Patil, (chief accounts officer), Ms. Deshmukh- Matron.
- c) Visit to the Sub-Divisional (SDH) Hospital, Trimbak.
- d) Visit to a Amboli Primary Health Center in Trimbakeshwar tehsil- interaction with medical officers and public health nurse working there and with taluka healthcare officer of that taluka.
- e) Visit to the Talwade health sub-center in Trimbak block and interaction with ANM and ASHAs working there.
- f) Visit to SNCU in district hospital (included visit to kangaroo mother care center)- and interaction with SNCU medical and nursing team. (Dr. Pankaj Gajare- chief pediatrician plus other specialists and nurses working there. Also qualitative interviews with about 5 mothers of babies who had been treated in the SNCU)
- g) Visit to Nutrition Rehabilitation Center in district hospital- interaction with doctors and staff nurses working there.

- h) Visit to District early intervention center (DEIC) in district hospital- interaction with the staff there.
- i) Visit to Corporation Hospital.

The approach followed is drawn from the methods used in the common review mission of the National Health Mission and can be loosely defined as a collaborative inquiry framework. The main features of the methods is to gather the reports that are provided by different facilities regarding the number and type of patients seen and services provided, the complications, the deaths and then have a conversation around this data at the site of service provision with the service providers- so that we understand and appreciate the problems better. Observations of the facility and the ongoing service provision also feed into the discussions. Comparisons with existing norms and guidelines help but taking care to understand why certain guidelines were not implemented and critically examining the adequacy of the guidelines themselves to the particular context and objectives.

III. The Context: District Health and Health Systems context:

Nashik district has a population of 61.07 lakhs of which about 35 lakhs live in rural areas and 26 lakhs in urban areas.

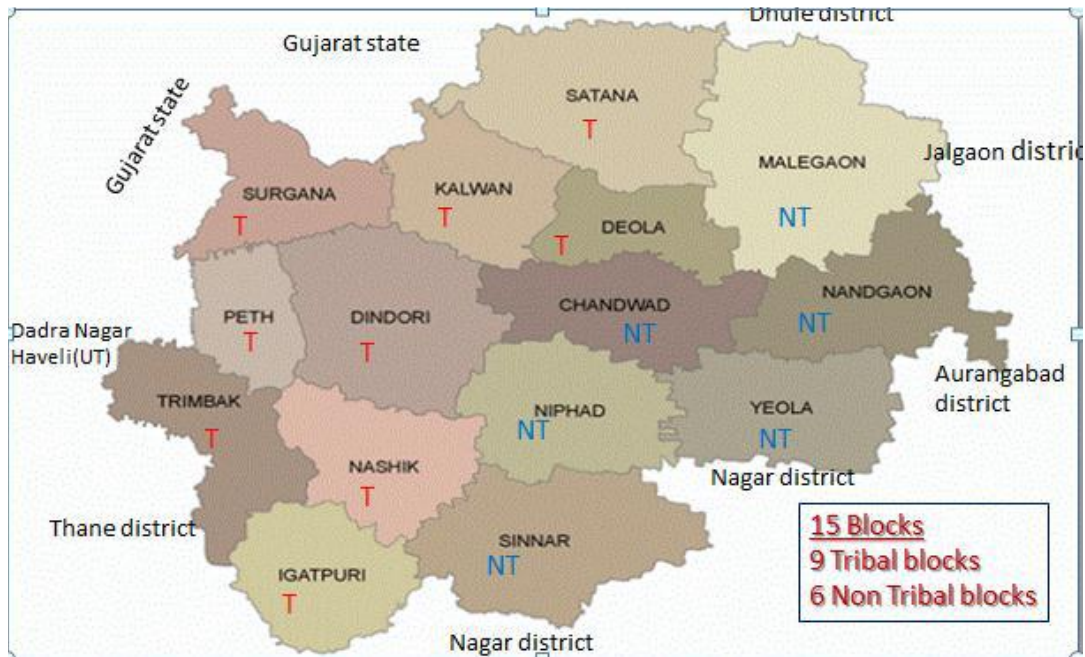
For administrative purposes, the district is divided into four subdivisions.

1. Nashik- includes tehsils of Nashik, Igatpuri, Peint (Peth), Dindori and Trimbakeshwar.
2. Kalwan- includes tehsils of Kalwan, Baglan, Surganaand Deola.
3. Niphad- includes tehsils of Niphad, Sinnar and Yevla.
4. Malegaon- includes tehsils of Malegaon, Chandwad and Nandgaon.

There are two Municipal corporations – Nashik Municipal Corporation (NMC) and Malegaon Municipal Corporation (MMC).

In the district, Nashik tehsil is the most populated with 17.6 lakhs persons while Peint tehsil with 1.2 lakhs is the least populated among the fifteen tehsils. Nashik is the most urbanized tehsil with 90.0 percent population being urban while Surgana is the least urbanized with only 3.6 percent population living in urban areas. Nashik district has 82.3 percent literacy rate which is almost equal to state literacy rate.

There are total 15 Blocks (tehsils) in Nashik out of which nine are tribal and six are nontribal. The tribal blocks adjoin tribal areas of Gujarat's tribal district of Dang, the tribal areas of the UT of Dadra and Nagar Haveli and of Thane and Palghar district. For the adjoining blocks of this district, which could be estimated as a population of about 20 lakhs, the de facto referral district hospital would be Nashik District Hospital.



Population characteristics:

The population is predominantly Hindu (about 85%) and then Muslim (11%). The district has a relatively high ST (25.6) and SC population (9.1%). Nashik district has 82.3 percent literacy rate which is almost equal to state literacy rate.

Healthcare Infrastructure:

The public healthcare institutions in the district consist of one 571 bedded district hospital in Nashik town, one 200 bedded additional general hospital in Malegaon town, 6 Sub-divisional Hospitals (one 100 bedded SDH at Kelwan, and five 50 bedded hospitals in other areas of the district); 22 CHCs or rural hospitals, all of which have about 30 beds. Together they account for 1,780 beds- that falls under the purview of the civil surgeon’s office. There is in addition a super-speciality tertiary care hospital with 120 beds.

In addition, there are 106 PHCs and 577 health sub-centers. The PHCs have beds, but most of these are day care beds or utilized for deliveries of pregnant women. There are in all about 3,400 ASHAs who are working in the district. The PHCs, health sub-centers and ASHAs come under the district health officer.

In urban Nashik, under the municipal corporations, there are four hospitals- one of which is 200 bedded and other three are 50 bedded as well as there are 30 urban primary health centers (UPHC). Malegaon municipal corporation has two 50 bedded hospitals under it and nine UPHCs. Each UPHC caters to about 50,000 population (a total of about 450 beds under the two corporations).

There are also nine municipal councils, three of which have urban Primary health centers under the municipal council, whereas in the others it is under the district health officer.

One could easily be impressed by these large numbers. However, the total number of public hospital beds (2,350) which would amount to only one bed per 2,596 population or in other words about 0.38 beds per 1,000 population which is far short of the national average of 0.9 beds per

1000 population or the policy recommendation of 2 beds per 1,000 population. If we take effective population that the District hospital serves as 80 lakh population, since tribal areas of surrounding districts also seek care in this hospital, the public sector bed to population ratio would be even worse.

We would have similar results with human resource deployment in the district. Absolute numbers would look large, but densities would be sub-critical.

There is, however, a substantial private sector in the district. In the area managed by the district health officer- which is all rural and urban areas other than the two corporations there would be 176 private hospitals. In the two corporations, there are over 550 private clinics. Most of these private hospitals are small- with about 10 beds- and more in the nature of small clinics, and a few with about 50 beds. (some sources have since quoted an even higher number of beds in private sector). There are two private medical colleges- one at Igatpuri and the other at Nashik, but there is limited tertiary care capacity even here. Thus even for tertiary care services, it is the government super-specialty hospital that is a major source of care. Though the addition of private sector beds should bring the health infrastructure closer to the normative number of beds required, it is not clear whether this reduces the problems of access, since much of the care provided by the private sector is both unaffordable and supply driven- admissions being restricted to certain conditions and not responding to these needs.

The District Hospital:

Nashik District Hospital has won the Kayakalp award for the cleanest hospital in Maharashtra with an award of Rs 5 lakhs. It is an impressive hospital. It caters to 700 outpatients per day, about 21,000 per month or over 2,50,000 a year. It has 571 beds with a bed occupancy closer to 90%. It manages over 700 deliveries per month or over 8,500 deliveries per year. On an average day, there are over 10 C-sections alone. There are five major operation theatres which are operational.

The most advanced unit is no doubt its Special Newborn care unit- which is described later. But even other aspects of pediatric care are quite advanced. It has a general pediatric ward, a Nutritional Rehabilitation Center and a District Early Intervention Center (DEIC)- both of which are amongst the best in the state. Between these three there are another four pediatricians and seven nurses. The obstetrics department is also very well developed with 6 gynecologists and 12 nurses to staff the labour room. There are 4 anesthetists and 5 operation theatres that can manage major surgeries. There is a blood bank with a functional capacity of 700 bottles of blood per month. The other departments could not be assessed but based on discussions; their development was much more modest. There are in all 30 specialists plus 11 other doctors, an 18 bed intensive care unit.

The Trimbak SDH has 50 beds and sees close to 250 to 300 outpatients per day. It has seven doctors of which six are specialists- one each in pediatrics, general surgery, obstetrics, anesthesia, orthopedics and skin. It performs about 70 deliveries per month of which about 8 are C-sections. There is no functional blood storage- and blood has to be indented from the DH. Most

surgeries are done on spinal anesthesia, and there is a lack of readiness to undertake surgeries requiring general anesthesia though there are both surgeons and anesthetists there. Unlike in the DH, the OBG department does not by itself provide enough work to keep the operation theatres and supportive structure for emergency care active on a round the clock basis. The lack of parallel development of other departments affects the functionality of the mother and child care component also. Moreover, key specialists are available due to compulsory rural service bonds- and there is uncertainty about establishing more sustained structures. The hospital performed 600 deliveries last year of which 45 were C-section surgeries. There is a two-bed NBSU- but clearly most high-risk pregnancies and sick newborns are referred to DH.

The sub-center visited had 69 deliveries in the last year- of which 26 were managed by the ANM, five were referred to PHC, 12 to RH, 22 to district hospital and 7 to private hospitals. There were two newborn deaths- both having been referred to RH and then onwards. The entire set of drugs and skills required were in place- but the newborn deaths are both pre-term and going through two stages of referrals.

The PHC visited was a bigger PHC with 10 beds and a number of deliveries per month. Here again, referral, mostly appropriate was the norm. There were over 100 outpatients per day. This PHC caters to 54,000 population though most of the others cater to 20,000 population.

The corporation hospital visited also has a pediatric ward with an intensive care section within it for newborn- but it is clearly under- utilized- with a lot of vacant beds. The attending doctor was of the view that most sick babies need to be referred away. Clearly, this hospital, which provided considerable outpatient care, and has significant infrastructure, did not see itself as having any major accountability with respect to the reduction of neonatal deaths- nor did it relate to larger public health goals. Urban Primary health care was also reported to be very inadequate in coverage, and very selective in what it covered. This aspect could not be assessed in detail.

IV. Newborn Mortality-and its Prevention:

According to the World Health Organization (WHO) Child Health Epidemiology Reference Group, there has been a significant decline in under-5 mortality rate (U5MR) in developing countries. However, whilst the reduction has been mainly concentrated in mortality after the first month, neonatal (babies under 28 days old) mortality and especially mortality in the first week of life remains relatively static. According to available data, the main causes of neonatal deaths are pregnancy-related complications (prematurity and congenital anomalies), delivery-related complications (asphyxia and birth injury) and sepsis. The neonatal mortality rate in India is high and stagnant. Special Newborn Care Units (SNCUs) have been set up to provide quality level II newborn-care services in several district hospitals to meet this challenge. (These are also referred to as Special Care Newborn Units (SCNUs) or as Sick Newborn Care units. We have chosen to go with the usage as SNCUs which is consistent with the guidelines)

It has been estimated that about 70% of neonatal deaths could be prevented if proven interventions are implemented effectively with high coverage. It was further estimated that health facility based interventions could reduce neonatal mortality by 23-50% in different settings. Facility-based newborn care, thus, has a significant potential for improving the survival of newborns in India.

Three levels of neonatal care are envisaged. This is other than the newborn-care corners which are to be established at every level to provide essential care at birth, including resuscitation. Wherever child birth takes place- whether it is primary health center or district hospital and within that the labour room, the ward or the operation theatre, a newborn care corner is to be established.

The three levels of neonatal care are as follows:

- Level I care includes referral of sick newborns from Primary Health Centres (PHCs) to higher centres and includes care at Neonatal Stabilization Units (NSUs) in the first referral units. Care in the NSUs includes stabilization of sick newborns and care of low birth weight (LBW) babies not requiring intensive monitoring.
- Level II care includes functioning of Special Newborn Care Units (SNCUs) which are equipped to handle sick newborns other than those who need ventilatory support and surgical care.
- Level III units are the neonatal intensive care units which are needed to provide continual respiratory support and advanced life support to extremely premature as well as very sick newborn babies.

Neonatal Mortality In Nashik District:

Nashik is 3rd largest district of Maharashtra with a population of about 61 lakhs with estimated live births per year of about 64,000. Infant mortality in the district and state is in the range of 20 per 1000 live-births (NFHS), and if 75% of these are neo-natal, we anticipate 960 neonatal deaths in a year. The system has been able to capture 427 deaths in the DH's SNCU and about 400 deaths elsewhere within the district. (Basis of these estimates: In the year 2017-18 as of February 2018, there have been 391 neonatal deaths reported from the SNCU, which would mean about 427 deaths in the year (an average of about 36 deaths per year). This is not higher than expected if we assume that most high-risk pregnancies and neonates are being effectively transferred to the district hospital. We also have 437 infant deaths reported outside the district hospital till January 2018 which would mean another 524 infant deaths in the year of which we assume 75% to be neonates, i.e., rounded to about 400 infant deaths. The assumption of 75% of infant deaths as neonatal deaths needs to be checked). There are also sick newborn in the district hospital.

Nashik district hospital is the only government health facility which is designed to provide care for all critically sick newborn. These could be both for babies delivered at DH (in-born) or transferred from other health facility in the district and the adjoining areas (out-born).

The overall new-born mortality rates in the District Hospital SNCU are 13.06% of all admissions. There are no major seasonal changes- and the death rates vary from 9.91 percent in November to 16 % in August (when it hit the news) to 16.7 % this February. Before August 2017

both in- births and out-borns contributed equally to neonatal mortality. However, after the enhancement of capacity – especially the doubling of SNCU beds and a more intensive in-born admission policy post-August 2017, the out-borns mortality rate is significantly higher.

SNCU Outcomes are significantly worse for out-born as compared to in-born neonate (figures are from April 2017 to February 2018):

	In-Born Number	Outcome Rates	Out-born Numbers	Outcome rates
Admissions	1,792		1,317	
Discharge	1,222	68%	835	63%
Deaths	189	11%	202	15%
Referred	160	9%	142	11%
LAMA	58	3%	78	6%
Total adverse outcomes	407	23%	422	32%

In-born admissions to SNCU: Out of the total admissions 40% are out-born and 60% are inborn neonates. Nashik DH itself having about 8,000 deliveries in a year or about 700 deliveries per month of which about half are in the high-risk category and about 43 % are delivered through Caesarean section surgery. As many of 25% of the babies delivered in the DH require to be admitted in SNCU. The DH manages with two labour rooms with total 6 beds.

Out-born babies: Out-born babies come in even more sick and compromised conditions. We also observed that transfer of high-risk pregnant mother or critically sick newborn from remote areas sometimes take more than 2 hours and this may also have a role in adverse neonatal outcome. There are 46 ‘Dial 108’ ambulances for a 61 lakh population which is very inadequate. In fact, quite contrary to practices in other states, the majority of ambulance usage is for inter-facility transfer. Transfer from home to facility whether for labour pains or for a sick neonate is usually through self-organized vehicle. The 102 patient transport services is limited to the drop back home. Inter-facility transfers take more time- and the ambulance will not be available for longer periods of time. Sometimes the transfer could even be all the way to KEM hospital. Most of these ambulances are not trained or equipped for sick neonatal care (only 11 ALS) , though they are managing labour and deliveries frequently.

Looking at the pattern of outborns referred in- they tend to be focused in nearer districts, raising the possibility that geographic distance is leading to decreased physical access in more distant tehsils. There are also a substantial number of high-risk pregnancies and sick newborns- almost one in four from the urban area which is roughly proportional to the population. However, given the fact that urban areas do better in most health indicators, there must be a concern as to whether better primary health care would have led to less sick newborns.

During our discussion, we have also noted that many sick newborn are transferred from private hospital to this health facility without proper transport and transfer of care which may also have contributed to the poor outcome. This is mostly in urban areas- since private sector is concentrated

there. There are also transfers from the private medical colleges to the SNCU which could be both due to costs of care as well as the capacity to provide the level and volume of care needed.

What are newborns dying off?

Distributed by cause- 23.66% are attributed to prematurity. Further 31.6% to respiratory distress and another 29.3% to low birth weight- both of which are also related to prematurity. There were some overlap in giving cause of death as some of the cause may be interrelated. But the majority of neonatal deaths are in some way related to prematurity. In addition, 24.5 % are due to birth asphyxia which usually relate to problems at delivery of the child. Sepsis including pneumonia accounts for 9.2% while congenital malformations accounted for 4.7% of the neonatal deaths (April 1st 2017 to February 2018 data).

Clearly, the single most important factor is prematurity and the more premature the baby, the higher the case fatality rate. The table below shows this (figures are for April 1, 2017, to 31st Dec. 2017):

	Total	< 28 wks	28 to 32 weeks	32 to < 34 weeks	34 to <37 weeks	37 to 42 weeks	>42 weeks
Admissions	2,579	77	219	232	450	1,560	41
Mortality	337	58	95	46	35	99	4
Case fatality rate	13%	75%	43%	20%	8%	6%	10%

In terms of low birth weight, the death analysis in April to December 2017 period shows 99 deaths had a birth weight less than 1 kg, 111 deaths had babies in the 1 to 1.5 kg range, 94 deaths were in babies with birth weight in the 1.5 to 2.5 kg range and 42 has a normal birth weight. Again as with prematurity which overlaps with LBW, the lower the birth weight, the higher the case fatality rate. Thus though there would be fewer admissions with babies below 1 kg and between 1 and 1.5 kg- these, a larger proportion of these neonates would die. These are the babies that require ventilators and hemodynamic support and much higher levels of care. We note that in the last 11 months, 302 neonates or close to 10% were referred out- often to as far as KEM hospital which is over 180 km and four hours away. It is likely that the mortality in these babies was much higher.

Problems that the SNCU faces: At the SNCU facility itself the problems can be categorized into problems of volume and problems related to the complexity of care required.

The SNCU has 36 beds- of which 18 has been added on after the deaths at Nashik district hospital hit the news. But there are now 58 newborns admitted. The DH/SNCU has the rule that no sick baby can be turned away- a principle that is most welcome. But that means that most of the newborn beds which are meant for one child laid longitudinally are now accommodating two

children placed horizontally. Also, the human resources deployed of 5 pediatricians (of which only one is a pediatric specialist on a regular appointment, and other four are contractual under NHM) and 35 nurses including two supervisors which would have been tight but feasible for 36 neonates, is completely overwhelmed.

A large number of newborn deaths are due to respiratory distress syndrome which needs ventilators to address. Or they are listed as premature or very low birth in which case too they are possibly facing respiratory distress. The next common cause of mortality is birth asphyxia which also requires ventilator support to save. To save many of these newborns, one may need invasive and non-invasive mechanical ventilation as well as other advanced life support. About 50-60% of all neonatal deaths could be in this category. Ventilators and such life support are part of level 3 (NICU) care- which is the recommendation for tertiary centers, i.e., medical college hospitals. But Nashik has no government medical college in the vicinity. Some newborns requiring ventilator are referred to the private medical college – but they have only one ventilator that can manage only about one at a time- and that too if the child qualifies for coverage under the publicly funded insurance programmes. More often the private medical colleges and private tertiary care centers are transferring very sick newborns to the district hospital. Many of the babies are potentially covered by the publicly funded insurance programme, and this should have eliminated the financial barriers to accessing private emergency newborn care. But in practice it has not done so. The reasons for this are both limited capacities in private sector for this service and because private sector providers can cherry-pick cases with higher returns and lower risks. (private providers behavior and experiences needs to be studied further)

There is also a problem with adequate number of equipment to support level 2 and level 3 newborn care including neonatal ventilators, CPAP machines, multipara monitors, infusion pumps, syringe pumps, capnography, portable X-RAY machine, portable Sonography, phototherapy units, blood gas analyzer and other necessary equipment based on standard recommendations. Given the fact that there has been a significant infusion of advanced equipment in the last 6 months, and that the center is an impressive intensive care facility in an otherwise modest public health infrastructure- one could miss the point- that given the nature of cases the SNCU is handling it needs much more- in line with the best in tertiary care. Nashik district is bigger in population than say Norway, and to argue that since its administrative status is that of a district. The norms that apply should not be that of an averaged out district, but more as is applicable to a state or national capital hospital.

The district has 10 newborn stabilization units, each located in a RH or SDH. We visited one (SDH Kalwan), and did not get the impression that it is taking up any part of the load of sick newborns. Perhaps some underweight babies with better health are being managed, but nearly all sick newborn babies are being referred, with little in the way of stabilization care. Together they account for some 515 sick newborn admissions of which 358 were discharged, 123 referred and 10 died or ‘went LAMA.’ This can be contrasted to the 3,438 annual admissions and 450 deaths for the SNCU at the district level (note these figures are slightly different since they are extrapolating from a 9 month report).

We note that there is a 12 bed SNCU that is functional in Malegaon additional general hospital and a 10 bed SNCU at the corporation hospital- but these are currently not as functional- and could not be assessed further in the time available.

The Social Determinants of Excessive Neonatal Deaths:

Though in the above discussion the emphasis is on strengthening facility based advanced newborn care, action on social determinants continues to have relevance. The district has 25.6 % tribal and 9.08 % are SC population of which 89.4 % ST and 41.6 % SC population resides in rural or difficult terrain. The number BPL households in SC and ST categories are 29,381 and 145,417 who are primarily residing in rural areas. The tribal communities have their distinct culture or practice of early marriage, early conceptions and delivery. This case study below exemplifies all the social determinants that associate with prematurity- which is the main cause of neonatal deaths currently.

One typical mother with a premature baby whom we interviewed weighed only 39.5 kg and was 20 years old. She had married and had her first child, a girl, at 16- and then become pregnant twice in the intervening years- both of which ended in abortion. Now she had delivered a premature girl baby. When she went into unexpected pre-term labour around mid-night, she was at home and was helped to deliver by the dai from nearby village. She was taken to Mulwad PHC. She too spent about 2 hours at the PHC and was then referred to hospital as a low weight baby with 1,300 grams.

As per NFHS 4, in Nashik district of Maharashtra, about 32 % women of the age of 20-24 years married before the age of 18 years, - almost the same in urban (32.9%) and rural areas (30.0%). This is significant higher than for the state as a whole (26.3%) and the difference is more in urban areas (20.4%) than the rural areas (32.5%). The women in the age of 15-19 years who are either pregnant or have delivered baby in the district is 8.2%, and this is the same levels as for all of Maharashtra.

Under-nutrition (measured as BMI below 18.5) in women aged 15 to 49 years in Nashik district is 25.8 percent, which is higher than the all state levels of 23.5 percent. Urban Nashik has higher malnutrition than Urban Maharashtra (20.4%) but rural Nashik has about the same level of malnutrition (32.2%) as compared to rural Maharashtra (30.0%).

Anaemia among women is another major problem of the district which may add complications at the time of delivery. As many as 54.7 % of the all women in the age-group of 15-49 years are anaemic, where the case for pregnant women in this group anaemia rate is 54.7 years. In all Maharashtra 48.4% of all women in age-group of 15- 49 years are anemic.

It is therefore a sub-set of these women who have early marriage, who are anemic and malnourished who are at higher risk for prematurity and low weight babies. A single measure that would be most productive would be to focus on reducing adolescent pregnancies. There is also the need to treat all adolescent pregnancies with low body weight as requiring special attention – which includes nutritional supplementation during pregnancy and delivery where SNCU is available.

Gender issues also come to the fore in relation to health seeking behaviour for sick newborns. Data disaggregated for gender is available for the NBSUs- and shows that whereas in in-borns there is almost an equal number of admissions in both sexes (205 females to 249 males), when it comes to out-borns only 19 female newborns were admitted as compared to 44 male newborns. It is likely that families with a sick girl newborn, born at home or at the peripheral provider are less likely to take the expense and effort of admission in the distant SNCU as compared to those with a male newborn. This gender disaggregated admissions and outcomes needs to be studied further- by district of origin and at the district hospital SNCU also.

The urban areas of Nashik district have almost the same indicator values for these social determinants as the rural areas- and urban Nashik is worse off on these indicators than urban Maharashtra as a whole. Equally worrying is that access to basic primary health care is also much less in urban Nashik as compared to urban Maharashtra. Thus pregnant women who received 4 ANC check-ups is only 52.8 percent for urban Nashik as compared to 65.8 percent in rural Nashik and 75.6% for all of urban Maharashtra- though institutional delivery rates are the same. Which indicates that while curative care access may be the same or better in urban Nashik, access to preventive care which is part of primary health care is less.

The other part of the problems was geographic distances and inappropriate referrals and inadequate referral transport in more remote tribal areas. One mother interviewed during hailed from a remote village 5 km from the Harsul PHC. She started her labor pains at 10.45 pm on 25th Feb and reaches Harsul PHC with her own hired vehicle. At the arrival, she was found with leakage membrane and was suggested for referral. After a travel of 45 minutes to an hour, she reaches to SNCU, Nashik. She had wait Harsul PHC for almost for 3 hours without any testing. Another lady had delivered at SNCU on 11th Feb but had stated her labour pains on Saturday (previous day). She hails from a village near to Bore RH which is about 100 km from the district hospital. The lady took about 2 and half hours to reach SNCU. Of course, without 108 services some of these transfers would not even have been possible.

In summary, action on social determinants is going to require careful analysis of data to understand which blocks and village have higher proportions of pregnancies/newborns at risk and greater problems of access. This would lead to more focused messaging and community action for reducing adolescent pregnancy- and more active health-seeking for the girl newborns. It would also require affirmative action in the form of nutrition supplements, and better emergency and referral transport.

Recommendations:

Underlying the recommendations is the understanding that this district like in much of Maharashtra has seen a considerable reduction on child, infant and neonatal mortality over the last decade and the number of deaths reported are in line with the anticipated deaths according to the known estimates of child mortality. However, most of the deaths currently happening are also

preventable and there is a government responsibility to ensure this. However at such baselines, the operational strategies may need to be modified and the public health expenditure for further equivalent further reductions in child and neonatal mortality may be much higher as compared to earlier- since we are dealing with a more intractable set of problems. The low hanging fruits are mostly in- these are the high hanging fruits. Currently, district health systems are designed on the basis of minimum essential services they should provide- whereas what we need in this context is advanced, comprehensive services. The relevance of action on social determinants and primary health care however remains- and will also yield further reductions in mortality.

I. Improving care at the SNCU at Nashik DH

1. There is a need for the creation of 16 beds of level 3 newborn care unit (NICU- Neonatal Intensive Care Unit). This in contrast to level 2 care-(SNCU) must be fully equipped to provide continual respiratory support and advanced hemodynamic monitoring. Every NICU bed should have adequate equipment based on standard recommendations and this includes neonatal ventilator and CPAP machine, a pulse oximeter and a monitor for each bed. This is on par with what is currently recommended for a tertiary care center. This is based on acknowledging that de facto this hospital is called upon to perform tertiary care services for newborns. In practice, medical colleges are referring cases to it- not the other way around. Accept and embrace this fact- and enhance the facility to meet this requirement with the necessary staff and equipment. Though level 3 care is a tertiary care function and therefore comes under the department of medical education, this DH nevertheless needs this. The options are to ask DME to set this up- or with their assistance set it up under the DPH.
2. Remaining 20 SNCU beds should also have adequate staffs and equipment including CPAP machine, infusion pumps, syringe pumps, multipara monitor, phototherapy units and other instrument based on standard recommendation.
3. Equipment:
 - There should be at least one portable X-RAY, one portable Sonography machine and one blood gas analyzer for the NICU and SNCU. Also required is the provision of one radiographer and one sonologist for emergencies.
 - Provision of adequate number of resuscitation kits.
 - Provision of one transcutaneous bilirubinometer.
 - All emergency drugs and other medication including surfactant should be made available. (this is currently available- but quantities are very insufficient).
4. Human Resource:
 - NICU (level 3 care): should be manned by adequate health professionals based on standard recommendation. These 16 beds alone would require four pediatricians with appropriate neonatal training and 24 nurses.
 - SNCU: This 20 bed unit would also need adequate health professionals with proper rotation of duty is needed to improve the neonatal outcome. This would require

another five pediatricians and 21 nurses. The professionals of the NICU and SNCU could be inter-changeable subject to the clause below. In effect, therefore, we are having recommendation for nine pediatricians and 45 nurses. This is a minimum-standard recommendations would be even higher. Some of the nine could be medical officers with short –course training on neonatal intensive care.

- The hospital must ensure that there is at least two resident doctors at all times on the premises and immediately available to deal with all emergencies in the NICU. There should also be a pediatricians on call at all times should be there is an accredited paediatrician, adequately trained and competent in neonatal intensive care (i.e., neonatologist). Which means at least four of the nine recommended pediatricians.
 - Every high-risk delivery should be attended by a qualified doctor trained in neonatal resuscitation program and should be competent in neonatal intubation. Given the high volume of sick deliveries per day- it may mean at least two pediatricians posted in the labour room/operational theatre for this purpose alone.
 - Labour room and operation theatres should be designed and equipped for the neonatal resuscitation.
 - Neonatal Advisory committee : The hospital may appoint a neonatal advisory committee (which shall include senior accredited paediatrician/neonatologist) to establish, maintain and enforce standards for professional work in the NICU and standards of competency for doctors, nurses and all staff involved in neonatal care. Their terms of reference would include adaptation of standards to suit local needs, annual review recommendations on equipment needed, review of quality assurance programme and periodic training of health professional in basic and advanced neonatal resuscitation program along with basic newborn care is needed.
5. Quality assurance program: There must be a formal written quality assurance program. This would include in the least: regular clinical audits and review; properly documented infection control policies and its periodic review; written NICU protocols along with antibiotic policy based on hospital culture sensitivity pattern; regular reports of such QA activities. The QA Programme shall include documented regular audit on the indications for admission of all neonates to the NICU.
6. Infrastructure Support : All life support and monitoring equipment shall be connected to an uninterruptable electrical supply source

II. High-Risk Pregnancy and Sick Neonatal Transport

1. There is a need for standard protocol for safe neonatal transport and high-risk pregnancies with imminent deliveries from referral centre to the hospital.
2. Twelve advanced life support ambulances must be equipped and placed to provide advanced neonatal transport- which includes ventilation. Currently, the paradox is that though ambulances have ventilators none of the facilities to which they transfer the case have them. These ventilators in the ambulances are seldom if ever, deployed.

3. There is a need to save time by avoiding inappropriate referrals to centers not equipped to manage that level of complexity. These intermediate hospitals should clearly indicate their availability or on pass status to the 108 system, as also the level of care they can provide- so that transfer can avoid intermediate stages.
4. The number of 108 ambulances is insufficient for such a population. It seems that the system is coping by limiting most trips to inter-facility transfer- for which other means should be available. The pick-up from home/village needs much more emphasis. There also seem a number of areas where due to lack of mobiles, roads, and even operational efficiency, the systems is not optimally functional. This needs to be mapped and studied further along with the increase of ambulances.

III. Expanding facility based newborn care: More SNCUs

1. There should be creation of 10 bedded SNCUs for every 5 lakh population which would mean about 10 more SNCU. The Newborn stabilization units are neither here nor there and serve little purpose. They should all be upgraded to SNCUs. Instead of a norm of one SNCU per district, given the large size of the districts, one SNCU per five lakh population is a more appropriate norm.
2. Adequate secondary care at the SDH-Rural Hospital-CHC level is difficult to build and sustain selectively for obstetrics and newborn care. Blood banks, diagnostics, imaging, and other support services, and even retention of professionals would take place only if other services- general surgery, orthopedic, general medicine, ophthalmology, etc. developed in parallel. This would ensure enough volumes of work to sustain a fully functional operation theatre, daily blood transfusions, adequate intensive care and emergency care work- within which systemic context one could also sustain comprehensive emergency obstetrics and newborn care.
3. HR – skilled nurses and doctors with neonatology skills for managing these SNCUs are a major challenge. The following measures may be considered to address this
 - i. Development of Nashik district hospital NICU and SNCU into training centres for neonatal care is an urgent priority. Already some specialist training is happening here- but it is for producing specialists under the college of physicians programme- not for providing services in the SNCUs (currently NBSUs) in the district.
 - ii. Identifying nurses and medical officers who are part of permanent staff and who are willing to be resident and work in these SDH/RH where the SNCUs are proposed. Prioritise such staff for short-term courses conducted in the Nashik NICU/SNCU so that they develop the necessary skills and deploy them back.
 - iii. Consider a package of incentives – monetary and non-monetary to attrac/retain skilled professionals-(nurses and doctors) in this area. There are many examples nation-wide to choose from.

4. The private medical colleges and the corporation 200 bedded hospitals should also develop a NICU with adequate capacity. Long term goal to establish more NICU beds at other health facilities to meet the requirements.

IV. Improving Primary Health Care:

1. The primary health care centers visited seemed optimal in their functioning- especially as regards identifying and referring high-risk pregnancies and sick newborn in a timely manner. However, discussion shows that there are areas- mostly nearer the district borders and select villages where the care is sub-optimal. Mapping such vulnerable areas- is possible based on the lack of referrals from such areas- and these must be attended to. It must be noted that over 50% of neonatal deaths in the district are still happening outside the SNCUs and perhaps even outside the primary care facilities.
2. Urban poor is also a major area where primary healthcare requires to be strengthened. A disproportionately larger part of the patients – both high-risk pregnancies and sick newborns are from urban areas. Also (as per NFHS-4) access to key preventive and promotive care like ante-natal check up is poorer in urban areas than in rural areas.
3. Given that prematurity is the most important medical reason, use of antenatal steroid based on standard recommendation needs to be strengthened to reduce prematurity related complications. Greater emphasis on availability and appropriate use of betamethasone (even as contrasted to dexamethasone) in the periphery would be of considerable help.
4. Reduce the incidence of birth asphyxia, and related complications can be assisted by introducing ANMs and ASHAs and primary health centers to neonatal resuscitation.

V. Social Determinants of Pre-term deliveries and Birth Asphyxia

1. Large epidemiological studies are needed to find the suggestion to reduce preterm deliveries, birth asphyxia and improve the overall health of mother and child. Now that almost every newborn death is identified - whether it is at home or at the house the social determinants of this can be better studied.
2. Three factors are likely to be related a) early age of marriage and first pregnancy b) frequent pregnancies, not necessarily proceeding to term, with lack of proper gap between them and c) under-nutrition of the mother. This is more in certain communities and areas- and careful data analysis and consultations with community can help identify these villages and urban wards which are most at risk. In these areas, an intensive behaviour change communication addressing the issue of adolescent pregnancy with a central role for the ASHA and community processes is urgently required. Strengthening nutrition supplementation programmes for such mothers may also be considered.

VI. Governance

1. There is an important role in providing support to the staff who are working.

2. There has to be a feedback and presentation of data on referral outcomes. Failure to include this may lead to under-estimation of mortality.
3. While monitoring is important to ensure that opportunities for further reduction of mortality are not lost- any top-down directive of reducing mortality below 10% will lead to pressures against truthful reporting and encourage misdiagnosis and increase LAMA and referral rates. Other process indicators would have to be developed- and the outcomes would follow.
4. Nashik NICU must be developed as the last port of call, the last tertiary care resort of neonatal intensive care for such a large population (which is larger than Norway, or the population of over 10 states and UTs in India). Referrals to KEM, while essential today should become unnecessary tomorrow.
5. Such an advanced tertiary care at the district hospital and adequate secondary care at the SDH-Rural Hospital-CHC level requires a more comprehensive development of the facilities- where other services- not only obstetrics and newborn care- develop in parallel (If the private medical college or larger private providers is seen as a higher service provider it is not due to what it can do for advanced newborn care- but what is able to provide overall).
6. There is an urgent need to create a directorate/ department of health under the Urban Development Ministry with its counterpart in each urban area under its jurisdiction. They should be accountable for establishing adequate primary health care services. Creating such an institutional set up would allow for better coordination with state department of health.
7. There is a need for the department of medical education to come on board with the need for level 3 SNCUs (or NICUs). All medical colleges must have these in place and they should be linked with good referral arrangements to the district health systems. In districts where there are no government medical colleges (and Nashik is an example) they should provide support to DH or themselves establish a level 3 SNCU in these districts.
8. There is a need for much better accountability of departments of women and child, and food and civil supplies and department of education and department of tribal welfare in addressing the issues of early age of marriage and first pregnancy and malnutrition and anemia amongst adolescents. The department of public health may consider setting up a coordination committee in tribal districts to facilitate and provide feedback to these departments, so that their schemes are more effective and better prioritized.

Appendix A

Enquiry into the deaths of Newborns at Nashik District in 2017-18 Presentation of the Report and Discussions with Hon' Minister and senior officials of Department of Health and Family Welfare, Maharashtra:

Record of Proceedings

Meeting was held on 6th April 2018, began at 11.30 am and proceeded for about two hours.

The Meeting was chaired by the Dr Deepk Savant, Hon. Minister, Public Health and Family Planning and convened by Dr Pradeep Vyas, Principal Secretary, Public Health Dept.

Others present were

1. Dr Sanjeev Kumar, Commissioner (Health Services) & Director (NHM)
2. Dr A.Patil, Addil Director, DHS (SFWB)
3. Dr Satish Pawar, Addil Mission Director, NHM
4. Dr. ..Special Secretary to Minister
5. Dr Geeta Kakade, Assit. Director, DHS
6. Dr. Suresh Jagdale Civil Surgeon, Nashik District Hospital
7. Dr. Sushil S Wakchoure, District Health Officer, Nashik.
8. Dr Sundararaman, Dean, SHSS, TISS, Mumbai, Convenor of TISS enquiry team
9. Dr Narendra Kakade, Assistant Prof. SHSS, TISS, Mumbai- Member of Enquiry team
10. Dr. Manish Arya, Lilavathi Hospital- also Member of enquiry team,
11. Dr Bal Rakshase, Associate Prof. SHSS, TISS, Mumbai
12. Mr Sagar Sinha, Research Assistant/Student TISS.

The meeting was convened for a consultation over the findings and recommendations of the enquiry report submitted to SHRC on the Deaths of Newborns at SNCU, Nashik in year 2017 at the instance of the Maharashtra State Human Rights commission.

The enquiry team set up by TISS, made a presented their report on Newborn Deaths at Nashik SNCU. Each of the points of findings and recommendations was deliberated and discussed during the meeting. The officials also pointed out several steps that have already been taken in this direction. (The details of the presentation are not repeated here. The power-point slides used for the presentation are attached and it is self-explanatory).

We record the inputs received from Minister and officers with respect to the recommendations of the inquiry team.

1. There was much discussion on the problems of introducing neonatal ventilators and the recommendation to upgrade 16 beds in the 36 bed units into level 3 care. The concerns in implementing such a recommendation- a) there is no clear guideline for this from the NHM/Central Ministry which recommends only level 2 SNCU care b) Level 3 care is tertiary care and therefore better undertaken by the department of medical education and not the department of public health. It could be located in the tertiary care hospital under them in Nashik. c) Introduction of ventilators would further increase work-load and public expectations. There was no disagreement with the contention that a considerable number of babies would be saved with ventilator support and level 3 care and not much increment would happen at the hospital without it- but the question was really of who should

undertake this. Also if it is done here there is a case to do the same across most districts- at least all those districts where there are no medical college hospitals. The enquiry team appreciated these issues, but pointed out that nevertheless for bringing down intra-SNCU mortality, these measures are going to be required. As regards the rising public expectations, civil society and political society would have to understand that well functional SNCUs will make deaths more visible, but this should not be confused with increasing deaths. The staff working in such centers must feel supported against misplaced public ire.

2. With regard to the suggestion to the number of level 2 SNCUs to one for every 5 lakh population (which means about 10 to 12 in all), the department reported that it had sanctioned one more and was planning to sanction some more. There are problems of finding pediatricians and neonatologists for further expansion. A suggestion was mooted that the Nashik SNCU could also act as training center and be used to train medical officers who are willing to work in these SDH/RH where SNCUs will be proposed. But officers were unsure of how this HR challenge could be met.
3. Most deaths are due to prematurity and low birth weight and this in turn was related to social determinants like early marriages, early pregnancies, and multiple pregnancies with no spacing. There is a need to strengthen the mother's health at each stage of her life cycle and not only at the point of pregnancy or delivery. To address these social determinants the main accountability should be of other departments such as Women and Child Welfare, Rural Development Department, Tribal Development Department, Food and Civil Supplies etc.
4. One area of concern was the very weak primary and secondary care in the urban areas- which come under the urban municipality. Many of the sick newborns and complications coming in from urban areas could have been prevented. It was pointed out that it is very difficult to coordinate with the urban governance structures for health areas. This could be vastly strengthened if there is a directorate and/or department of health services created at state and city level within the urban local bodies- who are then accountable for showing better outcomes and with whom the state departments could then coordinate.
5. There was also discussion on the high quality of data that is available in SNCUs and which can be analyzed further to identify hot spots from which more cases are coming and to identify more social determinants and use such analysis to direct preventive public health action. Timely referrals and transport delays also tend to be concentrated in some PHC areas- where primary care and referral transport systems could be strengthened.
6. On most other recommendations there was agreement, and many of these could be considered. On some of the recommendations the government has, even prior to this report, initiated a number of measures- and these include setting up neonatal care expert advisors, additional equipment, upgrading newborn stabilization units to SNCU etc.

The enquiry team agreed to include all these concerns into the report- and modify the report accordingly and submit. The Minister and the secretary thanked the team for the presentation and informed us that they are already seized of these issues and would be

addressing them and the findings and recommendations of the report would help in this process.