Witness Seminar on Regulation of formal private healthcare providers in Maharashtra

Journey of
Bombay Nursing Homes Registration Act and
the Clinical Establishments Act

AND

Journey of
Pre-Conception and Pre-Natal Diagnostics Techniques
(Prohibition of Sex Selection) Act, 1994

Organized by
SATHI, Pune and King's College London

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Indira Chakravarthi, Susan F Murray, Arun Gadre, Abhay Shukla, Benjamin Hunter and Shweta Marathe were involved in conceptualizing this witness seminar as well as themes for discussion among the witnesses; and in identifying the witnesses. We thank Deepali S.Y., and Archana Diwate from SATHI for recording and storing the recordings of the witness seminar proceedings; Jibin George for transcribing the recording; Deepali S.Y. for preparing the initial transcripts, and Shumeela Sabir for copy-editing.

ABOUT WITNESS SEMINARS

The witness seminar is a group oral history method – a way of chronicling important contemporary events. This is done by getting together the people who have been directly involved in these particular events or processes; those who have experienced it first-hand; made it happen, and have in-depth knowledge and observations to share. This group then recollects about those events in a collective and systematic manner, based upon their personal knowledge of the events, places, processes and people involved. The witness seminar is a structured, moderated conversation between these key people in the format of a panel discussion or a seminar, with a small invited audience. The purpose is not to arrive at an agreement or consensus but is rather to produce a collective memoir or account of significant events. The seminars are recorded, transcribed, annotated with key notes, and then published.

Witness seminars have been used to document a wide range of developments in the history of medicine and public health in the UK. Witness seminars have explored topics such as the development of obstetric ultrasound, monoclonal antibodies, human gene mapping, rural medicine, and abortion laws, and also broader changes such as transformations in public health, and the introduction of internal markets in the UK National Health Service. The Wellcome Trust has supported many of these witness seminars and transcripts from the seminars are available from the Wellcome Library: https://wellcomelibrary.org/collections/about-the-collections/archivesand-manuscripts/.

SATHI Pune and the Department of International Development, King's College London, conducted three witness seminars in 2018 in Mumbai and Pune, in the course of a study undertaken on corporatisation, emergent practices and regulation in the private healthcare sector in India, through a case study in Maharashtra (https://unsettlinghealthcare.org/2018/07/04/bearingwitness/). This is the second report of such a witness seminar on regulation of the formal private healthcare sector in Maharashtra, covering respectively the journey of two Acts: Bombay Nursing Homes Registration Act and Clinical Establishments Act; and the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act.

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Journey of
Bombay Nursing Homes Registration Act and the Clinical Establishments Act

Held on 15th September 2018, Mumbai, India

Reference to this witness seminar transcript should take the following form:

Chakravarthi, I. and B. M. Hunter (Eds.) (2019) Regulation of formal private healthcare providers in Maharashtra: Journey of Bombay Nursing Homes Registration Act and the Clinical Establishments Act. Pune: SATHI

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[Witness name], in: Chakravarthi, I. and B. M. Hunter (Eds.) (2019) Regulation of formal private healthcare providers in Maharashtra: Journey of Bombay Nursing Homes Registration Act and the Clinical Establishments Act. Pune: SATHI

ACRONYMS

ACASH	Association for Consumer Action on Safety and Health
AFMC	Armed Forces Medical College Pune
AMC	Association of Medical Consultants Mumbai
BAMS	Bachelor of Ayurvedic Medicine and Surgery
BMC	Brihanmumbai Municipal Corporation
BNHRA	Bombay Nursing Homes Registration Act
CEA	Clinical Establishments Act
CEHAT	Centre for Enquiry into Health and Allied Themes
CII	Confederation of Indian Industry
CPA	Consumer Protection Act
DHS	Directorate of Health Services
FEQH	Forum for Enhancement of Quality in Healthcare
FOGSI	Federation of Obstetrics and Gynaecologists Societies of India
JAA	Jana Aarogya Abhiyan
KEM	King Edward Memorial Hospital Mumbai
MBBS	Bachelor of Medicine and Bachelor of Surgery
MD	Doctor of Medicine
MFC	Medico Friend Circle
MHSDP	Maharashtra State Health Systems Development Programme
MLA	Member of Legislative Assembly
MPJAY	Mahatma Phule Jeevandayee Arogya Yojana
MMC	Maharashtra Medical Council
MS	Master of Surgery
NABH	National Accreditation Board for Hospitals and Healthcare Providers

NHRC	National Human Rights Commission
PIL	Public Interest Litigation
TPA	Third Party Administrators
WHO	World Health Organisation

ABBREVIATIONS

Rs	Indian rupees
Sqft	square feet

Numerical units commonly used in India

1 lakh = 1,00,000 (100,000)

1 crore = 1,00,00,000 (10 million)

INTRODUCTION

Historically, the main approaches for regulating private healthcare providers in India have been based on administrative–legal instruments and on the self-regulation by professional councils. The registration and licensing of healthcare establishments and individual practitioners is the most common form of administrative-legal mechanisms. Several states have legislative requirements for the registration of private facilities (hospitals, clinics and nursing homes), such as the Bombay Nursing Homes Registration Act 1949 (BNHRA) in Maharashtra and the Delhi Nursing Homes Registration Act. The Clinical Establishments (Registration and Regulation) Act 2012 (CEA), introduced by the central (federal) government also mandates registration and some minimum standards or facilities, and services for all clinical establishments, both private and public.

The objective of this witness seminar is to document the contemporary history of regulation of private healthcare in two cities in the Indian state of Maharashtra: Pune and Mumbai. Focusing on two specific legal instruments – BNHRA and CEA – the seminar aims to document the key events and people involved in the design and enactment of these legal instruments for regulating healthcare. It also includes discussion on how attention was drawn to poor quality of care in private hospitals,[1] the emergence of the Consumer Protection Act 1986 (CPA) as an instrument for healthcare regulation after it was made applicable to medical services in 1995, and subsequent concerns with such use of the CPA. Since the mid-1990s, non-governmental organisations, consumer bodies and groups of health professionals have developed and promoted standards and voluntary accreditation for Maharashtra's healthcare sector. These efforts have included: *Lok Vignyana Sanghatana's* [Peoples' Science Organisation Pune] consensus list of minimum investigations for general anaesthesia for certain categories of patients; CEHAT's minimum standards for 30-bedded private hospitals,[2] and collaborative work by CEHAT and the Association of Medical Consultants (AMC) in Mumbai, to implement standards for accreditation of nursing homes through the Forum for Healthcare Standards (FHS) initiative.

Timeline of key events relating to BNHRA and CEA

1949 – BNHRA was introduced in 1949 and was at that time applicable only in Bombay. Rules for implementation of the Act were first drafted as late as in the 1970s and were not comprehensive. The Act was amended in December 2005, and was made applicable across the state.

1 Nandraj, S., Khot, A., and Menon, S. (1999) Accreditation of Hospitals: A new Initiative. CEHAT Mumbai. pp 4-7

2 Nandraj, S and Duggal, R (1997): Physical Standards in Private Hospitals: Case Study of rural Maharashtra, available at: http://www.cehat.org/go/uploads/PhysicalStandards/physicalstandards.pdf (last accessed on 6.4.2019.

1990 –During a campaign on medical malpractice in Mumbai, the Medico Friend Circle (MFC) (Bombay Group) had discovered that this registration law was not properly implemented. A Public Interest Litigation (PIL) was filed in the Bombay High Court by the MFC and the daughter of a patient who had died in a private hospital.

1991 – The Chief Justice of the Bombay High Court directed BMC to set up a permanent committee to oversee and supervise the implementation of the BNHRA and make recommendations on improving its implementation. The committee as one of its tasks examined the functioning of existing hospitals and nursing homes in the city of Bombay, focusing on 24 hospitals and nursing homes in the eastern zone.

Early 2000s – CEHAT Mumbai, was invited by the Government of Maharashtra to facilitate the process of formulating Rules for an amended version of the BNHRA. A working group of representatives from medical associations, consumer groups and health rights organisations was formed to deliberate on the Rules. They participated in three consultations, and additional consultations were held with the Rural Surgeon's Association in Dhule and with consumer groups and health rights groups.

2006 – The BNHRA 2005 working group submitted a set of draft Rules to the state government in June 2006. In October 2006, the Health Minister called a meeting in which the Directorate of Health Services presented its own, different set of draft Rules.

2010 – The CEA was passed by the central government, requiring registration of all healthcare providers. As legislation passed by the central government, the CEA must be ratified and adopted by each state government in its own legislative assembly. It was anticipated that the CEA would replace the BNHRA in Maharashtra.

2012 – A network of civil society organisations in Maharashtra – Jan Aarogya Abhiyan (JAA) – began organising demonstrations during the Maharashtra state assembly sessions, demanding that the CEA be adopted in Maharashtra. JAA proposed that this Act should have provisions for patients' rights and grievance redressal mechanisms, while retaining the positive elements of the central Act and removing certain impractical provisions unfair to the doctors.

2013 – The Health Minister in Maharashtra established a 19-member committee of doctors and non-governmental organisations chaired by the President of Maharashtra Medical Council (MMC), to prepare a consensus draft Clinical Establishments Bill for Maharashtra.

2014 – The committee held eight meetings to finalise the draft Bill and submitted it to the state government in August 2014. The draft was sent to the state government's law and judiciary department in December 2014 to fine-tune legalities.

2015 – After working on legal framework of the draft Bill, the law and judiciary department completed work on the legal framework for the draft Bill and sent it to the state government's finance department in June 2015.

2018 – The state government announced that it would soon adopt the CEA and appointed another committee to look at the consensus draft submitted by the previous committee in 2014. At the time of publishing this report, the Bill had still not been proposed in the Maharashtra state assembly.

WITNESSES

Abhijit More is a medical doctor and a health rights activist associated with Jan Arogya Abhiyan (People's Health Movement), Maharashtra, and a member of Maharashtra state committee for formulation of Rules under the CEA.

Anant Phadke is a medical doctor and co-convenor of Jan Arogya Abhiyan, Maharashtra. He was part of a civil society committee tasked with framing draft Rules under the Bombay Nursing Homes Registration Act (BNHRA) in 2005, and was a member of the committee appointed by the Maharashtra government's Public Health Department to design state-level legislation for a CEA in Maharashtra.

Arun Gadre is a medical practitioner who owned a nursing home in a small town in Maharashtra. He participated in the national level development of standards for the central CEA 2010.

Ketan Parikh is a medical practitioner and past President of the AMC in Mumbai. He worked on developing accreditation for nursing homes and hospitals with CEHAT Mumbai and participated in efforts to create rules under BNHRA.

Mihir Desai is a lawyer and was involved with a PIL in Bombay High Court for implementation of BNHRA and participated in the development of Rules for BNHRA.

Niranjan Agarwal is a medical practitioner and Chair of the Nursing Homes Cell of the AMC.

Prakash Doke is a medical doctor and former Director of the Maharashtra Directorate of Health Services and worked in the Maharashtra State Health Systems Resource Centre.

Sanjay Nagral is a medical practitioner who was part of a Bombay High Court committee set up in 1991 to prepare a report on nursing homes and hospitals in Mumbai. He was also a member of the committee to develop CEA in Maharashtra.

Sujata Rao is a medical practitioner and past President of AMC, Mumbai. She was a member of the committee to develop state-specific CEA in Maharashtra.

Chairperson: Abhay Shukla is a medical graduate and has been working in SATHI, Pune, for two decades on promotion of health rights and regulation of the public and private healthcare sector.

PROCEEDINGS OF THE WITNESS SEMINAR

Session I
BNHRA: Status and impetus for its implementation and amendment

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BNHRA: Status and impetus for its implementation and amendment

Abhay Shukla: We have had a bumpy trajectory of regulation for the private healthcare sector in India, and in Maharashtra. 'Bumpy' because sometimes it goes up and then it goes down, and sometimes it goes forward and then it stops. After almost one-and-a-half decades of various kinds of efforts, this vehicle has still not really moved ahead in the form that was probably expected, but there are certain continuities and evolution that we want to understand. We will begin by talking about the BNHRA and I would like to start with Mihir Desai. In the late 1980s, as we understand, MFC Bombay Group[1] carried out some kind of survey on private hospitals, and certain issues of concern emerged. After that a PIL was launched in the Bombay High Court which had some focus on the need to regulate private hospitals or at least to regulate malpractices in certain private hospitals. Mihir, can you very briefly tell us about why this PIL was filed? What was the core content of the PIL? What was the response to this PIL?

Mihir Desai: Unfortunately, this was 27 years ago, and so some details may have been forgotten. As far as I recall, what happened was that there were five or six deaths of children in the Bombay Hospital, a well-known private hospital as some of us know. A letter was written to the Chief Justice of the Bombay High Court, by some members from the MFC, about the facilities for children, as far as the blood banks were concerned, in that particular hospital. This letter was converted into a writ petition, a *suo motu* writ petition, by the High Court. This conversion happened in 1991 but the event might be of 1990. The members of MFC included Ravi Duggal, Sunil Nandraj, Amar Jesani and a couple of others. Though it was a *suo motu* petition, somebody had to appear for the petitioner, so I appeared for them. That was the first time when I began questioning what minimum facilities are required in a hospital by law. The argument was that this particular hospital did not have these minimum facilities at that point of time, which caused the deaths. That's when we started looking at the law and then came across this Bombay Nursing Home Regulation Act 1949. That was the first time I had heard of it.

We discovered that BNHRA was the only law which regulated nursing homes and hospitals in Maharashtra, and when we went through the law, we realised that the only requirement under the law was an annual registration. So no Rules were framed, effectively nothing was framed. So first of all, we wrote to the BMC and asked the court to give us an idea of how many hospitals and nursing homes are registered annually, because you have to renew it annually. We found some of

1 MedicoFriendCircle (MFC) is a nation-wide platform of secular, pluralist, and pro–people, pro-poor health practitioners, scientists and social activists interested in the health problems of the people of India. Since its inception in 1974, MFC has critically analysed the existing health care system and has tried to evolve an appropriate approach towards health care which is humane and which can meet the needs of the vast majority of the people in our country. For more see www.mfcindia.org.

the big hospitals, the so-called five-star hospitals, were not even registered. Or their registration was not renewed at that time. Once that came to light, the hospitals started registering and renewing with the BMC.

Our second issue was that, even if you registered annually, what were the criteria for registration? The only criterion was that the person who runs the hospital should be a doctor. But what facilities are required? Suppose it is a maternity home, then you would require a midwife and that was mentioned in the Act. But beyond that there was nothing. Do you need a blood-bank? Do you need an operation theatre? If so, what kind? If you want to start a medical college, then everything is laid down. Namely, what should be the size of a classroom, a desk, the toilet? See, if you wanted to open a college, whether, engineering, medical or law, you would need a certain basic infrastructure, which is well defined. To open a hospital nothing was defined. You only needed to register, that's it. And that was also not being done.

This was not a PIL for the implementation of BNHRA. It was a PIL basically arising out of that particular incident in the hospital. Now what happened was that certain complaints were lodged with the police regarding that hospital and the matter took its own course. Somewhere down the line, after we conducted inspections of the hospitals, the whole matter went into cold storage. Possibly because the whole idea was just to get some direction from the court about minimum requirements. Just to inform you - that PIL is still pending! It is still pending. In fact, it came up two weeks ago and none of us had the documents of that PIL. We had taken copies from the court, so we have some hard copies. But we all thought that the PIL was over and done with and we told the judge that this particular incident is over. It was also something to do with availability of drugs, not just a blood-bank. So the court said, 'let's do more, let's see if something can be done'. The basic reason we were keen on this PIL was to get the court to issue some directives or have some kind of a committee set up which would then prescribe some kind of minimum conditions for hospitals and nursing homes. Unfortunately, that did not happen, it lost steam, as happens with many PILs. PILs are judge-driven, so if the judge is not interested then the judge won't do anything because he is not obliged to. If the judge is interested, something will be done . There was a time when the judges were not really keen on this issue. Then the focus shifted from this PIL to another PIL regarding the concessionary beds in charitable hospitals. To my recollection, this was how it all started in the late 1980s and early 1990s.

Abhay Shukla: Okay, thank you Mihir. Anant, would you like to add something to this?

Anant Phadke: I think some slight modification is required. A patient had died because a homeopathic doctor on duty had transfused blood from the wrong blood group. That event triggered a lot of responses from within the MFC, and nationally. The Bombay MFC group decided that this death was unacceptable, and that I think was what triggered that particular PIL.

Secondly, I think as a part of this PIL[2] the High Court appointed a committee.[3] There was no survey before this PIL, to my understanding. It was the High Court which appointed a committee, in which Sunil Nandraj was a member and there were some doctors also, I don't know whether Dr. Parikh was there. They visited many hospitals. What the committee found has been quoted many times in CEHAT documents.[4] That was the first such survey. Apart from the well-known hospitals, the situation in small hospitals was absolutely abysmal. That report is available on the CEHAT website.[5]

There were discussions about having some minimum standards that should be met, which were non-existent in BNHRA. CEHAT had a small project [6] in which, I think, Dr. Veena Muralidharan, then a Medical Officer at New Bombay Municipal Corporation, and two or three doctors in consultation with some of the other medical fraternity, came up with a small document of minimum standards for hospitals with ten or fewer beds. That document is also available in the CEHAT website.[7] It is at that point that we, at CEHAT, got involved. As a follow-up to that PIL, CEHAT decided to have a broader consultation on minimum standards for private hospitals in Mumbai, for which we were invited. Abhay attended that consultation; I was not able to make it. To my memory, that was the first time when systematically, some kind of a discussion took place in Maharashtra about the minimum standards that are needed for any small hospital. Due to the PIL process, there were two positive outcomes: this committee was formed which documented the conditions in small hospitals; and there was debate and a systematic exercise regarding minimum standards for hospitals with fewer than 30 beds.

Sanjay Nagral: I have been involved with these processes in two parts. One was the 1990s MFC Bombay Group and its engagement with the Yasmin Tavaria case in Parsee General Hospital.

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2 Following the death of a patient in Parsee General Hospital, an allopathic hospital, due to transfusion by a homeopathic doctor of a wrong blood type, a Public Interest Litigation was filed by the victim's daughter, Ms. Yasmin Tavaria and the activists of MFC (Bombay Group), on the issue of the implementation of the Bombay Nursing Home Registration Act 1949. The respondents were the B.D. Parsee General Hospital, Bombay Municipal Corporation and the Government of Maharashtra. (Writ Petition No 2269 of 1990). This case raised questions regarding standards of medical practice in private hospitals and nursing homes, quality of staff employed and treatment offered, equipment used, the general administration of these hospitals and their accountability to the people at large. The case also highlighted the role of the implementation agencies. See Nandraj S (1994) Beyond the Law and the Lord: Quality of Private Health Care, Economic & Political Weekly, 29(27), pp 1680-85.

3 In 1991 the Chief Justice of the Bombay High Court, in the case referred to in Note 2 above, directed the BMC, to set up a permanent committee to oversee and supervise the implementation of BNHRA and make recommendations

4 CEHAT (Centre for Enquiry into Health and Allied Themes), Mumbai, is a research centre involved in research, training, service and advocacy on health and allied themes. For more details see: http://www.cehat.org/about

5 The committee, referred to in Note 3, as one of its tasks decided to look at the functioning of existing hospitals and nursing homes in the city of Bombay. As part of the committee, 24 hospitals and nursing homes in the eastern zone of Bombay were studied. See Nandraj, S (1992) Private Hospitals and Nursing Homes: A Social Audit, Report submitted to the Committee appointed to regulate private hospitals and nursing homes in the city of Bombay, Bombay; and Nandraj, 1994, mentioned in Note 2 above.

6 Refers to a CEHAT project on Physical standards in Private Hospitals. See Note 7 for details.

7 As part of its project on Physical standards in private hospitals: A case study of rural Maharashtra, CEHAT evolved a document "Proposed minimum standards for Private Hospital and Nursing Homes" for 30 bedded hospital providing Medical/Surgical/ Maternity care, taking into consideration various aspects of functioning. A one day workshop on "Minimum Physical Standards for Private Hospitals and Nursing Homes" was also held in Bombay on April 23 1995. The participants for the workshop consisted of researchers, government officials, doctors from the public and private hospitals from urban and rural areas. The minimum standards were discussed in the workshop and the suggestions and comments from the participants were incorporated in the final document. This document on standards is incorporated in this study report: Nandraj, S and Duggal, R (1997): *Physical Standards in Private Hospitals: Case Study of rural Maharashtra*, available at: http://www.cehat.org/go/uploads/PhysicalStandards/physicalstandards.pdf (last accessed on 6.4.2019.

I was in King Edward Memorial Hospital (KEM)[8] at that time and in the committee formed to visit nursing homes.[9] Along with Prof. Daniel, from Preventive and Social Medicine, KEM, I visited these places. The mandate for us was to look at and document the existing situation. But everywhere we would go, we would be viewed as inspectors which would worry the employees.

We used to initially tell everyone that we have only come to see the ground reality and are not inspectors. We actually visited quite a few nursing homes in Mumbai which was very good experience for me as I had not been to some of those places. That was a phase where MFC Bombay Group was leading and then somehow CEHAT took the lead. I think there was a flood of cases at that time. Raghunath Raheja was another case. It's a landmark case, which established the fact that the patient has the right to the case papers. This was at Nanavati hospital. Before that, the patient's case paper would not be given to the patient's family members.[10] Amar [Jesani] and others were involved. It was individual patients fighting, with MFC Bombay Group trying to help them. It was realised that BNHRA was a very old Act, very outdated. I was there for a meeting or two about the BNHRA rules, but I don't think I was part of the whole process, so I can't give you more substantive information on that process.

Mihir Desai: Now I remember that, it was Yasmin Tavaria's father who had been given a wrong blood transfusion, which led to this petition. Just to clarify, the other case about the Bombay Hospital was in respect of certain drugs.

Ketan Parikh: Soda bicarb injection. That came later on.

Mihir Desai: That came a little later. This was in the late 1980s, which started this phase. And then we had inspected the nursing homes. What happened afterwards was that Yasmin Tavaria had filed a separate case also for compensation, because at that time there were no consumer courts.

Sanjay Nagral: Mihir, so, the key issue was that, not only was there a wrong blood transfusion, but that the Resident Medical Officer was a homeopathy doctor.

Mihir Desai: He was a homeopathy doctor and whether a homeopathy doctor is entitled to prescribe allopathic treatment. And what is allopathic and what is homeopathic? I mean, I was confused, I am still confused! That was the kind of the situation at that time, which is what led to the whole case. And later on Yasmin withdrew her case, for various other reasons. She has now

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8 King Edward Memorial Hospital (KEM) in Mumbai, established in the 1920s, is a public hospital run the by the BMC. It is attached to Seth Gordhandas Sunderdas Medical College (SGMC)

9 See Notes 2, 3 and 5.

10 In Raghunath Raheja versus Maharashtra Medical Council, Writ Petition No. 3720 of 1991 decided by the Bombay High Court on 11.1.96, the judges upheld the right of patient to medical records, that when a patient or his relative demands case papers from the hospital or the doctor, such case papers had to be supplied to the patient or his relative. The hospitals or the doctors could not claim any confidentiality or secrecy concerning such papers. The judges held that the provisions of the Maharashtra Medical Council Act, 1965 and the rules framed thereunder in 1967, provided for the same. The petitioner Raheja's wife had been admitted in Nanavati Hospital Bombay in 1989 for cardiac surgery, following which she died in early 1990. See https://indiankanoon.org/doc/1068495/ (last viewed 17.4.19)

become a lawyer and is practising in Bombay High Court. But I don't know why that case, the first case which we had filed in which the committee was appointed, didn't come to a logical end, that I don't remember.

Abhay Shukla: Thanks. That was very useful. Now I will turn to Ketan Parikh. I think it was towards the late 1990s that discussions started regarding the need for standards in private hospitals. And as I understand, the AMC actively engaged with this process, and AMC and CEHAT jointly initiated a process of accreditation for private hospitals and nursing homes. Could you briefly tell us about that?

Ketan Parikh: Somewhere around the mid-1990s, there was increasing press coverage and discussion around expectations from the medical community. At that time, I was editor of our journal – GRASP – and prepared an article on the costs incurred in service provision. We did a costing for small nursing homes and it was a big revelation because we realised that the cost per bed was coming to somewhere around 600 rupees (Rs). Most of us were charging some 150 Rs or 100 Rs at that time. That article was even quoted by the Indian Express, because it was the first attempt to undertake a costing of hospital services.

The Veena Muralidharan document on minimum standards for small hospitals mentioned that the minimum space per bed should be 130 square feet (sqft). At that time, most of our nursing homes had 40 sqft per bed. So we said, 'fine, this is our costing today, if now we need to increase it to 130 sqft from 40sqft, what will be the cost?' There was also a demand that certain equipment should be available. We pointed out that for each piece of equipment there will be capital costs and maintenance costs, and that cost will have to be recovered somehow. So we will have to be rational about the demands, because if we keep making demands somebody will have to bear the cost.

Dr. Lalit Kapoor was present at that CEHAT workshop in April 1995 for developing minimum standards, and quoted this article that I had written on costs. I was not at that particular meeting, the one which you are talking about where stakeholders discussed the standards. He quoted this article and said, 'see, this is the issue, that there is a costing involved'. And that is why Sunil Nandraj and others brought this issue to me. I think for the activists, also, this was a bit of an eye-opener, because the costing was all there on paper. At that time, if I remember well, the BMC and the state government had said that their costing per bed was also somewhere around Rs 800 or 900. I said, 'Now, if the BMC and the state government have a cost of Rs 800 and 900 per day, then what do you expect from the private hospitals? The costing for private hospitals has to be higher.'

That is how CEHAT and AMC came together. We said 'our aim as doctors, as the medical community, is very clear, we are also very keen to improve and maintain standards of health care'. For us it is our *karma*[11] . Healthcare is our karma and for the doctors there would be no reason

11 Sanskrit word used in India, meaning work, or actions, or deeds.

not to have good standards. The scenario in India is that a large section of healthcare is in the private sector. Not just private, it is in individually owned or small facilities, at least until 15 years ago. Only now corporate hospitals have emerged . So, there had to be a costing involved and a return of investment, not from a corporate point of view, but there had to be a notion of financial sustainability. We therefore felt we should come together and, see how we could improve health standards without significantly affecting the costing, but still make it rational. The expectations are to be rationalised, because what happens is that the patient will say, 'Why should this facility not be available? Why should this service not be available?' Obviously, the patients, and society in general, are going to expect many facilities. We – the medical community – did not want to be on the defensive.

We were very keen to be a part of this effort to improve standards, but at the same time somebody would have to pay for it. So that was the time when we also discussed if government could subsidise costs. But the government was not ready to subsidise. So, somebody would have to pay, and ultimately it would have to be the patient. Now that was not the way we wanted it - if the costs increased, then patients can't use the hospital. So that is when we started discussing accreditation. At that time CEHAT had a project from WHO to assess the possibility of accreditation of hospitals in India. And they were to write a paper on that, to do a research or survey. CEHAT approached us and asked whether we would be interested in accreditation. We were very keen because many of us were unhappy with the standards which our members were following. It had been left to individuals, so I could improve my standards if I wanted to, but if my neighbour was not ready to do the same and his fees were half of mine then how would I manage? I could not keep telling every patient that my fees are higher because I have these three things and he does not. That is why we thought that there should be some sort of accreditation; it gave us an opportunity to improve standards.

Around 2000, 2001, we started meeting to develop a set of standards and created a body called the Healthcare Accreditation Council. For almost four, five years that body was registered with the company board. We created standards but then there were issues with implementation because the Association of Medical Consultants would not be the correct organisation to implement. Firstly, we would have clashes within ourselves. Secondly, we did not have the infrastructure to implement these standards developed by us. And so, nothing happened for a long time. I think one of these agencies, CRISIL[12] approached us but that was a corporate entity and they said that the cost for accreditation should be fixed at Rs 5 lakhs at least. I said that none of the nursing homes would pay for accreditation at that price. This was in 2003-04, and accreditation was just not moving ahead. Eventually an agency called the Forum for Enhancement of Quality in Healthcare (FEQH)[13] took on the accreditation process and now we have around 350 nursing homes accredited in and around Bombay.

12 CRISIL was formerly Credit Rating Information Services of India Limited, was set up in 1987 as a credit rating company for businesses. See https://www.crisil.com

13 FEQH was set up in 2006 for accreditation of healthcare providers.

There was a lot of discussion about accreditation at that time and I was invited by the central government's Ministry of Health to discuss this. They asked me how do we achieve it? We were very keen to have stratified accreditation, which ran against ideas of a global single standard, but we said, we should have a stratified system because single standards are either too low or too expensive to implement. If you push it to that higher standard, then not everybody can afford the care and so they go to quacks, these unqualified people. If I go to a hospital for a procedure that costs Rs X, which I can't afford, then there is a quack, next to that hospital who says, 'Don't worry, *Mere ghar pe main kar dunga* (I will do it at my house), at one-tenth the price'. And that is something which has to be avoided completely because it reduces the quality of care. We said that we need to stratify the standards: that for simple procedures you really do not require five-star facilities. When we are talking of five-star, we are not talking of the walls or the flooring, but about the equipment. We don't really require five-star equipment for a simple, routine hernia operation. This was something which we discussed at the Government of India level, and right now, our accreditation system has three levels. You can opt for the first level, or the second level. All the accreditation systems across the world, are single level. We insisted on a three level system. At the Armed Forces Medical College (AFMC) and other hospitals, we were invited to explain why we use three levels of standards, and most people were convinced because in India you cannot have a single set of standards. In India, ordinary people use private healthcare and they cannot afford all these high-end facilities, so that's why we introduced the three-level accreditation system.

Abhay Shukla: Thank you Dr. Ketan. This was a very interesting backdrop. And what is emerging from all three of you is that, standards of care emerged as an issue of both, concern and also discourse and initiative. And it initially came from civil society, but then the medical profession actively responded, and the response was in the form of this effort towards accreditation, of course, keeping in view the ground realities. And, so, that is in a sense, I would say a first wave.

Ketan Parikh: Along with working on BNHRA and this accreditation initiative, we also got involved with Sunil Nandraj at CEHAT in creating a Clinical Establishments Act for the Maharashtra State, even before it was discussed at the national level.

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Session II
Amendments to BNHRA and framing of Rules; attempts to incorporate quality and patients' rights in framework of regulation

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Abhay Shukla: Dr. Doke, you were the Director of Health Services and as we understand, from 1998 onwards, there was a Maharashtra Health Systems Development Project (MHSDP), which was an important project for health sector reform in Maharashtra. Most of it was focused on the public health system but there was a small component regarding the private sector also. Within that, as we understand, there was a component to standardise and regulate care in the private medical sector. Can you briefly tell us about this?

Prakash Doke: I was associated at state level from 1998-99 only, before that I was not a state level officer. The argument made by the private sector was that government hospitals were experiencing problems and we should first get our own house in order,before turning attention to others. For this reason we were not really pushing for standards in the private sector. The World Bank project was one of the largest financially supported projects of World Bank, and the largest project for Maharashtra state. The representative of the World Bank said that the World Bank considers government to be a service provider or a funder. He underlined that the government also provides over sight and when we signed the document they said that you have to perform all these three functions: oversight, funder and service provider. We thought about options for the oversight mechanism and came up with strategies like public-private partnerships.

At that time, when we were thinking of issues like quality and accreditation, in the Maharashtra State Assembly questions were raised about how many registered hospitals there are in Maharashtra. To our surprise we found that we had absolutely no idea. At that time the BNHRA was applicable only in Mumbai. It was adopted as such by Pune Municipal Corporation and by Solapur Municipal Corporation. We thought that the first step must be to at least know how many registered maternity homes or hospitals there are. Then as Dr. Ketan Parikh was saying, the other aspect was that if you wanted to improve the quality, then you needed licensing or registration. This would be accompanied by accreditation or quality improvement. There was another project similarly going on; KfW GTZ project.[14] It was decided that in the World Bank project we will focus on nursing home registration and in the GTZ project we will focus on quality. So, among ourselves, this was the accepted convention. Many people were sent abroad for a two-week

14 A Basic Health Programme run by the Maharashtra state health department with support from German aid agency GTZ and KfW, between June 1996 and March 2004. The project involved activities such as: Community Mobilization, Training of the Health Care Delivery Personnel, Operational Research, Management Information System, Construction of health facilities in rural areas, procurement, social marketing and social franchising.

course to understand how to gain accreditation. At that time I was introduced to Dr. Ketan Parikh and we realised that we don't have any such accreditation system in India and whatever there is,it does not have many takers outside of Mumbai. Dr. Vijay Sardesingh was Health Secretary then; and there still is a government resolution stating that the government will take the lead for accreditation of hospitals; and for setting it up there will be a multi-sectoral team, where Health Secretary will be the Chairperson, and Director of Health Services will be Member Secretary. Unfortunately, the government resolution remains in the file; two or three meetings took place and after that nothing happened. This was on the front of quality.

Regarding BNHRA, Sunil Nandraj said that BNHRA did not cover all of Maharashtra and was more or less obsolete because many things have changed, so we must move for Clinical Establishments Act. But as a government officer, I said that enacting a new Act is a very difficult process, because for that voting of each and every Member of Legislative Assembly (MLA) is needed. We felt that it may not be possible at this stage, so we had a discussion and I said we could make amendments to the existing Act, which would not require vote by MLAs. In any Act there are clauses which state that regulations can be made by the concerned department. We resorted to this provision.

At that time, while waiting for an amendment of this BNHRA and the introduction of the Clinical Establishments Act, the health minister,Dr. Vimal Mundada, said we should at least implement BNHRA across the state, so we know how many hospitals are registered. In 2005, the amendment came into place, making BNHRA applicable across Maharashtra State. A very peculiar feature in that amendment was that there was one clause which was unrelated to the registration, but was instead related to the quality of services in the government sector. We know that the majority of government doctors practice outside government hospitals and such practice is officially permitted, but only as a consultancy, not for establishing hospitals. We did not want government doctors to perform private practice. Therefore, in that amendment to BNHRA there was a clause stating that a hospital can be registered only if it is not owned by a government doctor. If a government doctor owns it, then it will not be registered. Once the amendment had been made, we decided that we needed rules for the Act which could specify doctor-patient ratio, doctor-nurse ratio, nurse-bed ratio, space, equipment, and instruments. Unfortunately, in spite of people being nominated to develop these rules, there was not much change. One exception is in Navi Mumbai, which was created in 1991. They slightly modified the BNHRA and even today I feel that it is better implemented in Navi Mumbai.

We also prepared the CEA. The central government said that this Act must go to the Indian Parliament because it will come under the purview the State List and Concurrent List. Before sending it to the Government of India, we took advice from law and judiciary. They said that we have BNHRA, therefore the CEA will be tenable and so Members of Parliament can vote on it and Maharashtra will be first state to ratify and implement the CEA. We said we would be very proud to have the CEA, but unfortunately, nothing changed.

Anant Phadke: Dr Singh took some initiative because of this GTZ project and convened some meetings in Mumbai on the idea of minimum standards and upgradation. The IMA was not involved in this meeting; they were not invited. The AMC was invited. We had a meeting with some of the government officials, the corporation officials were also invited.

Ketan Parikh: But IMA was invited, and at that time IMA was Pune-based.

Anant Phadke: I would like to add to that, firstly, IMA is the largest doctors' organisation, but it was not involved. There are two different camps. Even Dr. Singh did not know that there is a thing like the IMA, which is Pune-based, and the government officials did not have an address. So, I was the one who gave them the address, names of the President of IMA, and therefore they were invited. And when I talked to the IMA people in Pune, they were absolutely not interested in coming to Mumbai for a discussion, because on both sides, based on certain experiences and perceptions, there was some kind of a prejudice.

Ketan Parikh: It was not prejudice; there were a lot of complications.

Anant Phadke: Yes, and these processes tried to bridge the gap. That is the point. When we started, the IMA had a low opinion about the government process. I was not a member of any particular camp, though I didn't have very comfortable relation with the IMA members, but since we kept meeting and had some respect for each other. I was able to convince them to come to Mumbai. I explained that the Act is going to come and if you abstain from the whole process, it will happen in your absence. And therefore they reluctantly came; the IMA President and I travelled in his car. We came together, we had a good discussion on the way and a lot of misunderstandings about each other also were mutated. And then there was a good discussion and therefore, for the first time, the IMA officials got first-hand information and exposure, and understanding of the importance of such meetings. On our journey back from Mumbai to Pune, the President had totally changed his perception about the necessity of things. Earlier, while making the journey from Pune to Mumbai, he had felt that it was just a waste of time - *tumhi mhantay mhanun mi* yetoy [I am coming because you are insisting], pan *hyacha kahi upyog nahi*, [but this is of no use]. *Ya lokana kahi samjat nahi* [these people do not understand anything. However, after this meeting, his perception changed. I just wanted to recall that now probably we have travelled a long distance.

Abhay Shukla: Thank you Dr Doke and Anant, these inputs were very useful. It seems that BNHRA and CEA co-existed for some period of time, in the early 2000s.

Anant Phadke: No, BNHRA was in existence when the CEA was a concept.

Abhay Shukla: Now we will move to the Rules for the amended BNHRA which were formulated in the first half of 2006. There was a kind of a multi-stake holder process, which CEHAT was anchoring, and I would like inputs on how these Rules were formulated and how the discussions took place. Anant, can you start very briefly, by telling us how this CEHAT project came about?

Anant Phadke: When the BNHRA was amended on 15th December 2005, we in CEHAT were quite surprised and not at all happy, because after all the discussion with the Health Secretary about the new Act and accreditation, what was actually there in the Act was only two amendments. First, it was made applicable to all of Maharashtra. Second, this Act empowered the government to decide nurse-patient ratio and floorspace-to-bed ratio. That's all, nothing else. We were very surprised and, in a sense, angry because there had been intense dialogue with the concerned officials and we had put out a press release. Fortunately, Dr Doke who was the Director Health Services then said, 'We can still do it as the rules have to be framed. Acts are always broad but now there is scope for formulating rules and civil society organisations can be involved in formulating these rules through multi-stakeholder consultations'.They said any civil society organisations can come together and initiate this process and amongst the three or four civil society organisations in Mumbai, CEHAT was selected by these organisations themselves. CEHAT had taken a very short project of some six months, from January to June 2006, where we had three consultations in which the IMA, AMC, and probably some other organisations were also present, not just JAA.

Ketan Parikh: ACASH[15] [Association for Consumer Action on Safety and Health] was there.

Anant Phadke: Yes, ACASH was there. And there were two more consultations in Mumbai and one consultation in Nandurbar, with Dr. Tongaonkar, a leading surgeon there, and member of Association of Rural Surgeons of India. We very much felt that the rural hospitals have their own issues and logic, so their views should be taken. We held three consultations, called facilitation meetings, where for the first time we all interacted very intensely on the issue of minimum standards. Sanjay Nagral was probably also there. By June 2006 we submitted a consensus draft, after those multi-stakeholder meetings, on the rules under BNHRA, and Dr. Doke was kind enough to immediately process it. Within a month it was put on the website.

Ketan Parikh: The Directorate had asked three organisations to undertake this study: CEHAT, ACASH and AMC. The three of us met the Directorand discussed the logistics and ACASH said that they will not be able to do this multi-stakeholder study across the state. We at AMC also had the same problem,as we didn't have the resources to go across the state, while CEHAT had the resources. So that is how both ACASH and AMC agreed that it was fine if CEHAT did it, as long as we were involved. I will differ on this issue of consensus statement, because there was a consensus statement that we arrived at, but unfortunately, the statement that was finally given to the government was not that same statement. And that was the breaking point between the medical organisations and the civil society.We were working with civil society because our aims were common, but the document that was finally published and submitted by CEHAT was not the consensus document. That was something which was very unfortunate. I discussed this with Padma Deosthali [then Co-ordinator CEHAT] later on, but, I can't remember the person who was involved in that document.

15 ACASH – Association for Consumer Action on Safety and Health – was founded by a group of doctors, lawyers and other concerned individuals in Mumbai in 1986, as an independent, non-profit, voluntary organisation, to address health- related consumer issues and advocating for the rights of the consumers and the general public.

Anant Phadke: It was AmitaPitre

Ketan Parikh: Amita Pitre, was the one involved in this,and it created a lot of problems. We will have differences but we have to have confidence that if we present something as a consensus document, then that should be the same consensus document - it should not be altered.

Abhay Shukla: What happened in those three consultations? What were the contentious issues? Which were the issues on which there were some debates?

Ketan Parikh: I think there were contentious issues about patients' rights and how prominent this should be. Our point was that, doctor's rights or patient's obligations should be considered alongside patient's rights. As medical practitioners we had problems with patients and non-payments, misbehaviour and not following the prescribed treatments. There was also this issue of not refusing admission; that the doctor does not have the right to refuse admission. We said, 'we cannot have this stipulation, because every nursing home has its own limitations and may not have the necessary facilities. If you go to an ophthalmic nursing home with a cardiac problem, what is the point of insisting on admission there? Another contentious issue was HIV patients – that we should not refuse admission on the basis of HIV. If it comes within the hospital's functioning then yes, but there were other reasons for refusing admission.

Prakash Doke: I remember when this draft was submitted and was being discussed, there was a meeting of association of owners of private hospitals. I think Dr. Bhujang was also involved in that meeting. When we were discussing this, there were very strong allegations from most of the doctors that we were making their lives miserable. They were arguing on points such as: 'my hospital is on the first floor and I cannot do anything to it to meet building rules.'The practitioners said that all these things which are under consideration for rules for BNHRA are so difficult that most of the hospitals may not be able to abide by it.

Ketan Parikh: There was one simple example -it insisted on a 12-foot ceiling. I said, 'how do I create a 12-foot ceiling in Mumbai unless I make a new structure?'Because none of the existing flats in Mumbai have a 12-foot ceiling! I can't go into the house of the person above my hospital and create a 12-foot ceiling over there.

Abhay Shukla: Mihir, would you like to add, because you were the main legal expert in that consultative process?

Mihir Desai: I was there in one meeting, where the legality of the rules was discussed. The patient's charter was discussed too. But the main issues were about the balance between rights, facilities and expenses, to what extent they can be brought in for controlling private sector hospitals. That seemed to be one of the main discussion points.

Anant Phadke: There were minutes from the working group meetings for drafting Rules for BNHRA. Whatever happened in the earlier meetings was all documented properly, it was

sent to everybody, including the 19group members. Generally whatever was decided, agreed upon broadly, was always shared with whoever was participating. Of course, there were certain issues and disagreements that were not included in the minutes or in the recommendations. For example, the point about HIV patients was not included in the recommendations because there was a difference of opinion on that. Patients' rights were not specifically followed in terms of responsibilities. In principle, we had always agreed that patients' rights and responsibilities have to be included. For example, JAA, Federation of Obstetric and Gynaecological Societies of India (FOGSI) and the IMA jointly drafted a charter of patient's rights and responsibilities as the title, and together released a press note on patient's rights and responsibilities. The then-President of Bombay IMA, Dr. Mehta, came all the way from Mumbai to Pune for this event.

It is one thing to say that patients have responsibilities, but in an Act which is meant to regulate the private sector establishments, the authority like the Director of Health Services has no power over the patient. The authority does have power over the person in charge of private establishments, and so if that person doesn't abide by the rules they can issue a warning. But there is no legal implication for patients for not abiding by their responsibilities, such as sharing all your history properly or cooperating with doctor. There are half-a-dozen responsibilities that every patient has to abide by, but is there any point in formulating something in a legal document which has actually no practical value? The patient is a peripheral stakeholder in that sense and the health authority has no control over them. As a matter of principle, patients must be responsible for their own good and for the good of the society, but in the rules there are no punitive actions on the patients which can be implemented.

What Ketan is saying may be correct. The document that came to you Ketan may have been one that was not decided upon. But, then an attempt was made to come to consensus: the whole half-a-dozen points on which after a lot of discussion we had consensus argument.

Ketan Parikh: Yes, we had a consensus on lot of things, there is no question.

Abhay Shukla: Although there may be some grey zone whether patients' responsibilities can come under regulatory acts, the rights of healthcare providers certainly can be included. And the rights of healthcare providers are symmetrical to the patient's responsibilities. So there is a way of legally dealing with that point. The point is that there was an attempt to reach a consensus and in principle, there was no objection from the health movement to the issue of patient's responsibilities. I think that is an important point.

Abhay Shukla: Dr. Sujata and Dr. Niranjan, were there any discussions within the AMC, on the issue of patient's rights, which you were part of?

Sujata Rao: We may not have mentioned the term 'patient's rights', which has got a lot of prominence in the last few years - the charter of patient's rights - but we have acknowledged the existence of these rights. We have acknowledged that it is a much needed perspective of any healthcare decision, or much, much needed perspective to develop any behaviour changes in our practice.

Niranjan Agarwal: As Dr. Ketan Parikh has already pointed out: a healthy patient-doctor relationship is always good for us. And AMC has never ever promoted unethical practices. We have always promoted ethical practices. And we conduct seminars to educate doctors about medico legal problems; medical errors, not negligence, even the errors. Now, when you tackle all those things, ultimately it is the patient who benefits. And indirectly, we also benefit, because there is less trouble for us. So, it is not that we have not discussed it, as she rightly said that, we may not have given it a name, but the welfare of the patient is actually our priority. Much before the government even asked for accreditation, before the TPA (third party administrator in insurance) came in, we have voluntarily taken up accreditation process: the very idea of it being to improve health services, which ultimately helps the patient. So, that is where, again, AMC has given thought to the patient.

Abhay Shukla: Coming to the fate of the draft rules that were submitted to the Directorate of Health Services (DHS),the DHS put it up on the website, sometime probably in July 2006. But, subsequently, a completely different set of rules were adopted. So, Dr. Doke, could you tell us what happened to that draft? A lot of effort had gone into it. Whatever it was, some kind of consensus was there, at least on some of the points. So, how did it get replaced?

Prakash Doke: At that time, the concept of developing a website and taking comments from general public was new. We started our website and on insistence from civil society and particularly from Sunil Nandraj, we said let's take the general public's opinion. That was the sole reason why this was put on the website. The Rules for BNHRA were referred also to the Law and Judiciary Department, who said that they were tenable and as a procedure let comments come from all bodies including the IMA and the general public, and then we'll make the Rules and send them to the state legislature. The Rules disappeared from the website after some time, maybe after five-ten years. The other reason to remove the Rules was the new CEA of the Government of India which meant there was no point in continuing with the amended Rules. But I think there were almost no comments from the general public or IMA to the draft Rules on the website.

Abhay Shukla: Yes, but a different set of Rules were adopted,is it not so?

Prakash Doke: Yes

Abhay Shukla: So, how did that change take place? That was the question. There was this whole consensus or semi-consensus document, which emerged through some discussion, and then a completely different set of rules were adopted. At which level was that decision taken?

Prakash Doke: Probably, by one section in Directorate. Dr. Phadke was referring to one person who was instrumental, Dr. Bahubali Nagaokar. He also consulted with some other people and then within the department the rules were changed, by persons working in the quality and hospital section. I do not know the details because I had retired. But there were some discussions with other stakeholders and these new amendments were uploaded.

Abhay Shukla: And that was sometime in 2008?

Prakash Doke: 2008-09, after my retirement I think so.

Anant Phadke: August 2008.

Abhay Shukla: So, Anant and Mihir, could you comment on, what the later Rules were adopted and the earlier, sort of consensus document which was submitted - what were the difference between these two?

Anant Phadke: Yes, we prepared a table comparing the June 2006 document and the one adopted by government, clause by clause.[16] We found that many of things that were said in the June 2006 document were deleted, like points about multi-stakeholder participation and issues related to protection of doctors. For example, the June 2006 rules stipulated that: no inspection can take place without sending a notice, unless some exceptional situation develops; the findings of the inspection have to be given in writing; there will be an explanation from the clinical establishment in response to the written notice, and then there should be a period of six months for the clinical establishment to make adjustments. Many of these things simply disappeared from the later version and it looked more like a bureaucratic process and lost the multi-stakeholder aspect. I think the charter of patient's rights which we had incorporated in the rules we submitted was also not in the one adopted by the government. We were really angry. We had spent a lot of time and energy, our Sundays, working in meetings, and with no result. We also protested about this.

This is an important matter, because a similar process has taken place two months before. We'll come to that later. We submitted a document on CEA in June 2014, when Sujata Rao was also involved, Dr. Sanjay Gupte from Pune was involved. And suddenly, we come to know that the whole thing is changing, and more or less changed before we intervened, before we protested. After a lot of detailed, engaging discussion we try and agree to come to consensus on certain things, we go whole-heartedly with it for a broader cause, and then suddenly, things take a different turn. Some kind of, behind the door consultations take place and things are changed. So, this is a pattern probably,and it's little painful.

Mihir Desai: I have come to the conclusion that, most of the times we are bouncing our heads against the walls. So, I really don't pay much attention now, to these committees.

Prakash Doke: It could have been a consequence of these efforts that rights of persons who sought care in government health institutions got framed between 2002 and 2004.We prepared a citizen's charter to be observed in the government health institutions, almost 50,000 copies were printed and were circulated to the government facilities in the state. Each PHC, each hospital, each sub-centre was given this charter. But that was a really big effort then, laying down the rights of the persons who come to the public health institutions. After introducing Community Based

16 This comparative table is provided in Annexure 1.

Monitoring of public health services (CBM) in 2006, it was fully adopted.

Abhay Shukla: So, from 2006 to 2008, there is a kind of period of waiting, as I understand. The draft Rules had been put on the website, there was an expectation that the modified, amended BNHRA Rules would actually be passed. It did not happen in that form and then, ultimately, as Dr. Doke mentioned, it was completely changed. So what was the response from civil society in this period? Dr. Abhijeet More is one of the conveners of JAA. Can Anant and Abhijeet fill us in about this part of the story?

Anant Phadke: I think three things happened. First, when these new Rules were put on the website, we tried, of course,to follow up. We repeatedly tried to meet the health minister, Vimal Mundada, because after all, the minister has to take the next step. We also went to her town to meet her and apprise her that, after a lot of processes, these consensus Rules have been made, please sign it and take it further, but without any success, we just couldn't meet her. She probably was not interested. After her, Rajendra Shingne was the health minister, whom we approached with the same request. Vimal Mundada didn't have time for two and-a-half years to meet us, but Shingne met us in May 2009 and we had an extensive discussion on this and other issues also. It was a very good meeting, but despite promises, nothing happened. We thought therefore that we will do parallel activities with civil society. So, we campaigned a lot. For example in Pune we went around the streets and distributed the pamphlets. There was a signature campaign. We prepared a pictorial exhibition on patients' rights, which was shown all over Maharashtra by different branches of JAA. Unfortunately, we were not successful in changing the government's attitude, in instilling political will. We tried to re-petition, where people would circulate widely the June 2006 draft Rules that were put up on the website. A lot of people sent the petition to Dr. Rajendra Shinghne in May 2009. At the third level, we had a direct discussion with the Indian Medical Association, leading elements of which were in the Pune branch. After a long intense discussion, in which Dr. Sanjay Gupte played a very good catalytic role, we came to a consensus. He was the President of FOGSI then, or immediate ex-President, and we had meetings in his hospital premises, rather than in IMA, because there were some other issues. And we came out with the charter of patients' rights and responsibilities. That is still available, it was a joint declaration. In February 2010 we came out with a joint statement. As I said, Dr. Mehta was the President of IMA, who came all the way from Mumbai, and we were in continuous touch with Dr. Suhas Pingle then. He was one of those enlightened representatives from IMA, who was able to sort of dialogue with us. So, this is what happened up to 2010, without much success. And then we had a campaign; we met P.C. Sharma, who was the member of the National Human Rights Commission (NHRC). We had a state level consultation on patient's rights when he came to Mumbai. We also met Jogendra Kawade, who was one of the leading leaders in social sphere. The central CEA was expected soon, therefore the state government was not interested. But we were not clearly told, that 'look, forget about BNHRA, a much better Act is coming'. But we didn't know what the central Act would look like, and health is a state-level subject, so the Maharashtra government could take the lead, but there was a silence on that. Sunil Nandraj went to Delhi as a WHO consultant and he was able to draft the CEA and push it too. And I would say that, because of people like him, some of the points we had proposed for the BNHRA rules were incorporated in the CEA, such as multi-stakeholder consultations and due process for hospital

inspections. Sunil Nandraj was very keen on avoiding an inspector raj approach to regulation, so these provisions for due process were included.

Abhay Shukla: Abhijeet, do you see any evolution in the IMA's response to this whole issue of patient's rights?

Abhijeet More: Initially we held a meeting on patients' rights at Pune and tried to have one-to-one dialogue in that meeting with IMA. But we did not meet with any success. Then we organised a Patients' Rights consultation in Pune on 19 July 2009, chaired by Dr. Narendra Dabolkar[17] and Dr Anil Achawat. Representatives of several social organisations of Pune, media persons, IMA representatives and representatives of Hospitals Owners Association were there and several cases were discussed. At that meeting IMA and Hospital Owners Association decided to extend support to patients' rights. Patients' Rights Committee of JAA, IMA and FOGSI together prepared a joint Charter of Patients' Rights and Responsibilities, and the understanding was that this charter will be jointly published. It was decided that IMA would disseminate it among its representatives, its members and they would display it in their hospitals. And Jan Arogya Abhiyan would disseminate it among the general public as much as possible. As Anant mentioned, Dr Bakulesh Mehta, the state IMA President, came to Pune and in a joint press conference IMA declared that they support patient's rights and responsibilities charter, and then the Charter got wide publicity. Unfortunately, after that there wasn't much progress in the part where IMA was to publicise it among doctors to display it. However since 2010 there has been a change and there is no official opposition from IMA to the issue of patients' rights; there may be negotiations on some aspects, but there is no opposition.

Anant Phadke: Just one line about the consultation –Dr. Jaya Saagde, who was the Vice Principal of ILS Law College Pune had also come. Dr. Amar Jesani had come from all the way Mumbai, because he is the one who knew everything right from the beginning.

Abhay Shukla: We see an evolving response from the private medical profession, from an initial reaction where there was a kind of scepticism to a reasonable degree of acceptance of the idea of Patients' Rights with patients' responsibilities.

Sanjay Nagral: So, if the sweep is over ten, fifteen years, as opposed to those four to five years, I would say that, now there is a reluctant acceptance, not happily, that there is this concept called patients' rights. I think the problem is that it is not about something good, but it is as an outcome of conflict. It's in more conflict terms: that there is an inherent conflict of interest, and that we will have to reluctantly accept that there is something called patients' rights, as opposed to actual genuine acceptance. For that matter, I think, it has got worse in some ways. And I think, a part of it is related to the violence. I am bringing in another issue, but a part of it is related to the violence issue. Because that is in everybody's mind. And it's a key issue.

17 Dr Narendra Dabholkar was a Pune-based medical doctor and social activist, well-known as founder of the Maharashtra Andhashraddha Nirmoolan Samiti (MANS - Committee for Eradication of Superstition in Maharashtra). He was murdered on 20th August 2013 in Pune while out on a morning walk. For more on Dr Dabholkar see: Phadke, A (2013) The murder of Dr Narendra Daholkar: a fascist attack on rationalism. Indian Journal of Medical Ethics, 10(4), pp 217-19.

Abhay Shukla: we have not talked at all about the CPA, which was also evolving somewhere during this period. We have not talked about the Maharashtra Medical Council (MMC) and its role or non-role, depending on our viewpoints. And whether the medical profession was successful in self-regulation or that self-regulation did not really work very well, at least through the official bodies. In fact, one can see a kind of a contrast, that on one hand, MMC went through a very bumpy trajectory, to put it briefly, and through periods of almost, non-functionality or whatever. On the other hand, a body like AMC was trying to do some sort of self-regulation, through the accreditation process, at least on one front. So, the official self-regulatory bodies, did they really achieve their objectives or not. So, these were some side-stories, they are not central to our story, so, any quick comments about these?

Sanjay Nagral: One quick comment is that, whether it is the IMA or whether it is the AMC, it is not a monolith. There are varying interests in the medical profession, and sometimes the interests in the medical profession also are in contradiction to each other. We experience that very often. So, the interest of a small nursing home owner versus interest of doctors working in government hospitals versus interest of doctors working in private hospital. So, it is not always a monolith and you get varying responses to regulation.

Abhay Shukla: Are there any comments about the Maharashtra Medical Council and self-regulation by the medical profession, to the extent that it reflects some new story of regulation of the private medical sector.

Ketan Parikh: Unfortunately, what has happened was the politicisation of the Maharashtra Medical Council over a period of time. A group of people were capturing an organisation and they would run it in their manner. In fact, the medical profession was at loggerheads with MMC. There was a time when the medical profession used to say that it is only of nuisance value. It was AMC along with ACASH, which took a very large initiative at the grassroots level to change the attitude of the medical profession towards the Maharashtra Medical Council. So, it was in 1997-98-99 that we said that we need to have reforms. We said, 'this is our regulatory body and if we don't improve that body, then it is a reflection on us'. So, AMC took it up and that is how the 1998 elections of MMC got countermanded by the court, because we could produce all evidence that the elections had been rigged. At that time, our proposal was given to the government which required physical voting, because this whole ballot voting or postal voting was actually leading to rigging. We had given a document to the state government through the courts and state government agreed on that. At that time MMC was charging Rs 15 for registration for a five-year period. With that Rs 15 I said, 'you cannot register, you cannot function with Rs 15'. We as doctors said that it is ridiculous, with this Rs 15 MMC cannot sustain itself. So, we said that, you must charge minimum Rs 500, and be functional. So what has happened is that, this is an evolution that has happened as far as MMC is concerned, that now the MMC has got some funds of its own and is able to function. And the IMA also has been supportive,agreeing that there needs to be an improvement in standards.

Sujata Rao: The period from 2000 to 2010, that entire decade saw a lot of turbulence you can say, or activity from all quarters, whether it was a patient burden or it was regulation inefficiency, or whether it was a patchy implementation of existing rules. So what happens is that, there are number of offsets to each arm of this, that inefficiencies create more problems, Acts are trying to be inclusive, at the same time, not being implemented correctly. And so, we had number of issues of separate access to the nursing homes or we had problems about the registration of nursing home, like change of user and all that. And it was patchily coming, not from the idea of governance per se, but it was coming from the idea of implementation at the time where there was pressure on the BMC. It was not that it was a coordinated effort to govern in a methodical manner.

Niranjan Agarwal: We are talking today about regulation of private hospitals. In many of the seminars it is said that the medical profession in the country is not regulated at all, it is unregulated. Especially, the insurance companies keep on shouting on top of their voice. Right? Whereas, what does the medical field feel about it? If you have to start a small nursing home or a big hospital, there are at least, more than seventy licenses you need. And then you say that we are not regulated. And all these seventy licenses are on paper, not implemented, or there is a leeway. It is our strong suspicion, with the corporatisation, all these rules which we were just mentioning, they keep creeping up slowly. You know, there is an attempt, subtle attempt to try and see that these small healthcare providers shut down. So above all this when there comes more of patient's rights or such things, anybody would get sceptical, and feels one more new issue has come up. Regarding what Dr. Parikh was saying about costing and quality: with cashless insurance coming in, the insurance company and TPA are hell bent upon giving you about 40 to 50% less than what the normal charges are, and you cannot provide quality with that kind of money. Quality doesn't come cheap. These regulations which are there for a tertiary care hospital or a secondary care hospital are applied to the nursing homes. Now, a small setup of five beds or fifteen beds cannot comply with all the regulations that a bigger hospital can comply with. There is always a sword hanging on their neck, of closure in the next registration. And now the biggest hurdle for all of us, is the fire-regulations. If you ask the people of Nashik, they are running their hospitals without registrations because the fire-officer is just hell bent upon not agreeing to anything; they are getting illegal structures in a way. So, there are many problems which even the medical fraternity is facing vis-à-vis regulations.

Abhay Shukla: It has been a very interesting discussion and at least, four or five stands have been reflected since morning. Two of these relate to, I would say the tensions between patients and healthcare providers, including doctors. One has been around standards versus rates. There are concerns from the doctor's community. But the standards came on to the agenda first, historically. The second are Patients' Rights, versus responsibilities, and patient's rights viewed in the larger context of existing regulations. So, probably, the resistance is not so much to patient's rights per se, but there is a larger reluctance regarding multiplicity of regulations, within which it becomes a kind of an area of some scepticism, probably, though not exactly opposition. The third is a kind of tension between having a multi-stakeholder process versus a bureaucratic decision-making. And that we see in the BNHRA rules process, that there is initially a multi-stakeholder process

that went on up to a certain stage, and then, it was effectively cut short and a bureaucratic kind of decision was taken. So, both medical profession and civil society were sort of side-lined when the final rules were adopted, which was a different kind of dynamics. So, this is a triangular sort of process that we are seeing. So, the medical profession, civil society and government, each of them, having their own stakes, having their own view points and these playing out. And another is basically the spectrum of positions within the medical profession which is not a monolith, there is a spectrum. Then also, certain sections of the medical profession who have also been standing up, ACASH for example, or individuals like Sanjay Nagral would probably represent another end. So, this is a kind of spectrum within the medical profession and those tensions and those sorts of issues have also been playing out.

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Session III
Central CEA 2010 and state CEA -
No to Central CEA Yes to Maharashtra CEA

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Abhay Shukla: Once the CEA was adopted at the national level, there were different responses within Maharashtra. Anant, once the central CEA was adopted, what was JAA's response? JAA was demanding a state-level modified Act rather than straight adoption of the central CEA. What was the reason for this? And did JAA try to address any of the concerns of the medical profession in this process?

Anant Phadke: We welcomed the CEA because it's a central Act and there are certain positive features to it: it incorporates multi-stakeholder processes and public health services were brought under the Act. So, there are some very good, positive features about the central Act. But there were certain important points which we felt were in adequately addressed in the central Act. We formulated a letter to the Chief Minister of Maharashtra, saying, 'no to central CEA, yes to Maharashtra CEA'. That was the title. The fundamental point was that the central CEA was very likely to just remain on paper and nothing would happen in practice. There was no mechanism in the Act to implement the CEA, only one Secretary at the central level. At the state level there was no additional officer to implement the CEA. So the same government machinery which has been inadequate, not very tuned to private sector and therefore, not in a position to really play any role, the same district health officer who is currently not able to manage their own affairs, would be incharge of regulating a large number of doctors, which is something like five times or even seven times the number of doctors in public sector.

Since the public health services, with the exception of the military, are also brought under this Act, there is a conflict of interest. The District Health Officer, or even the Health Secretary at the state level, would be incharge of all the grievances mechanisms against erring establishments. These officers manage the public health system but would also become regulator. In no other sector do we see a service provider also being the regulator; there is always an autonomous regulatory body. There is no district-level mechanism for grievance redressal, so if any doctor in Gadchiroli has a problem with their local supervisor, then the case has to go to the state capital Mumbai. But the state-level body has hardly any functional full-time persons, so meetings will take place once in a while and hundreds of cases will accumulate and the whole thing will become dysfunctional. There was also a very valid point made by doctors who were concerned by having police officers in the local supervising authority. We fully supported that concern - there should beno place for a police officer to be in the local supervisory authority, involved in giving certificates and permissions. We had suggested that there be a multi-stakeholder grievance redressal system at the district level. The chairperson of that multi-stakeholder system should be a retired judge

and independent of the health department. A government bureaucrat from the health department should not be part of it because there is a conflict of interest. It is something which is a full-time job. We had taken legal opinion on this matter. Dr. Jaya Sagade, a constitutional expert said district level retired judge is an adequate level of expertise and power.

Then there was no mention of patients' rights in the CEA and no scope for patients' grievance redressal. The National Human Rights Commission (NHRC) has come out in support of patients' rights and patients' rights are broadly being accepted by the medical profession, but the Act doesn't say anything about patients' rights. Then there was a problem which doctors' bodies had pointed out: the emergency stabilisation clause in the CEA. Every clinical establishment is supposed to take on any emergency that comes to it. If a cardiac case is brought to an ophthalmic surgeon who has a small hospital, the case has to be looked after. The minimum care requirements for the patient is not mentioned in the CEA, only that the patient must be stabilised. As patients' representatives, we have argued for very basic elementary life-saving measures be provided to a certain extent, for example putting the head in a low position, providing nasal oxygen, achieving haemostasis, and administering simple medications like pain-killer, or intravenous saline. To stabilise a patient of any serious disorder is impossible, and it is hazardous to the patients also. You cannot expect an ophthalmic surgeon or a gynaecologist surgeon to look after cardiac cases. And who pays for the cost of emergency care when the patient is very poor and simply cannot afford it? There is no mention of that. We said the government should bear the cost; you cannot expect the private practitioner to bear the cost.

There were other points we thought were problematic, for example about the size of penalty charges for providers, but these ones I have mentioned were the key points for JAA. We felt the central CEA was not properly formulated and needed substantial changes, without which it will be basically bureaucratic regulation.

Abhay Shukla: So, Dr. Sujata, what was the response from the medical profession to the central CEA?

Sujata Rao: We thought, when we read through the central Act, that a number of points which were governing the nursing homes or clinical establishments, will not be similarly governed in Maharashtra because we have a number of quacks, which is unique to Maharashtra and it is not so in the central. You may have a proper nursing home, but it may be governed by a quack, an unqualified person. The police licensing has been a bad experience in the past and the policy of stabilisation, that you must admit, and stabilise anyone is not possible in a city or in a small pocket establishment. And the regulating authority didn't have proper representation from all the sectors. So, these were the issues which I remember we had with the CEA.

Niranjan Agarwal: The central CEA was a consequence of some states not having any regulatory Act. So the central government formulated one and then left it to the states to follow or not. They formed a committee under Amar Singh, friend of Amitabh Bachchan [Indian actor], who was a Member of Parliament that time. This man was supposed to tour the country and gather

responses. I remember he was staying in the Oberoi Hotel and it was advertised in the newspapers that he was coming and anybody who had objections could make a representation. Ketan, Anant and I got hold of that advertisement and went to make a representation. There were only seven or eight people in all –three of us and four others. When we started talking this man said, '*aap representation de do, hum dekh lenge baad mein*' [you give the representation and we will look into it later]. So, we gave the representation we had prepared to the person who was with him. They had made arrangements for 150 lunches at the Oberoi for people making representations; this is how government's money is wasted. We had some objections. In the central CEA there was minimum area requirement, 400 square feet for clinics or something like that, which was not possible in Bombay. Minimum requirements for GP clinics were also very exaggerated.

Abhay Shukla: Was that there in the CEA?

Sujata Rao: It was never there. The bit about area was not there. It got circulated, it was a perception. The IMA had circulated this information. I think the idea came because the rules were drafted pre-maturely or whatever - Sunil Nandraj was the person who was drafting the rules also while the Act was being declared. Somewhere in 2000s IMA had a national shutdown, to object to the central CEA.

Niranjan Agarwal: We also objected to this stabilisation. It was said that the doctor should arrange the ambulance, accompany the patient, and ensure that there is a ventilator in the hospital we are transferring the patient to. Everything had to be done by the doctor.

Ketan Parikh: If the doctor leaves the facility and goes along with the patient, then who is going to manage the hospital?

Sujata Rao: A single person cannot perform the role of regulator, executor, and provider. But this is what society expects from doctors. We felt that there was too much expectation placed on the medical professional without having a fair representation of our concerns.

Ketan Parikh: See, it does not make sense: those Rules do not make sense, essentially. It is not that we want to oppose Rules made. So, what we have been talking about all this while is that the Rules have to be rational, whatever rules you make. And I am not aware of who has made these rules, but I have not seen them on the official site. From whatever I understood, there was some misunderstanding by IMA, as regards the area requirement and certain rules about the central CEA; that there is a minimum area requirement for a clinic, for a consulting room. I have not read any of these things in the central CEA Act, but IMA has circulated its document, I don't know from where this document has come.

Abhay Shukla: Actually, to make the facts clear, both the Act and the Rules which were passed in 2012 are there on the website. Neither of them mentions anything about square area or any standards. After that, much later, draft standards have been developed, for hospital level one, two and three, separately, which are different sizes of hospitals. At the time,when all this opposition

took place there were no standards, there was only the bare Act. It is basically focused on registration and it mentioned that, for registration, the due standards need to be fulfilled. Sanjay, would you like to comment at this stage on whatever the initial response, let us say, of IMA, especially to the central CEA?

Sanjay Nagral: I would rather talk about what happened in Maharashtra because I was in that committee. I mean, my direct sort of engagement came, when I was appointed on that committee. Before that, I know the background, but I am not going to add anything much. But the response of the profession, I think is a continuum. It took some different forms in the Maharashtra CEA.

Arun Gadre: I was a representative of Jan Swasthya Abhiyan[18] on two sub-committees of the central CEA, on rate regulation and standards. Most of the points on which IMA was protesting had been addressed by even civil society. At the first sub-committee meeting in Delhi,on rate regulation in December 2014, the IMA said that they were not accepting CEA and were against it. The Chairman was asking them to contribute, if at all, or otherwise go to the Parliament and have the Act undone. I have personally looked into all the Rules, and we need those Rules. We need an operation theatre of 140 sqft., nobody has to tell us. The problem was that of 400 sqft carpet area per bed. But I was so startled that IMA was not opposing that. But then the Chairperson, who was an ENT surgeon from Delhi said, 'We will scrap the necessity of carpet area'. In the sub-committee meetings for setting standards and for rate regulation too, the standards and rates were simply read out, there was not much discussion. The rates for some procedures in some hospitals in Delhi were read out and the average was suggested as the rate. When I objected and said 'Delhi is not India', I was given the task of coming out with the methodology of calculating the rate per square feet, which I did with help from Anant and Abhay. I and many other friends of mine in private hospitals prepared the rates. But then they just dissolved the committee. So, this is the central CEA and my interaction with them.

Sujata Rao: I think, all these facts, we should have the minutes and record them, because personal implications on an organisation, when the organisation representative is not there, is not fair, in a recorded witness program. Unless you have the minutes, I don't think you can discredit an organisation. I think the facts should be gathered from the required official. I am not comfortable here, maligning an organisation in the absence of a representative. We have met here to see the evolution of a particular Act and go ahead.

Ketan Parikh: See, we don't know what exactly IMA said; we cannot discuss IMA because there is nobody from IMA. In all fairness, we are talking about a specific issue regarding IMA. So, there has to be a person from IMA to say what has happened. We can say there was an opposition. What I am trying to say is, mentioning that there was an opposition is one thing, to judge that opposition is not fair.

Abhay Shukla: We actually wanted Dr. Suhas Pingle to represent the IMA, but he couldn't come.

18 Jan Swasthya Abhiyan is the Indian chapter of Peoples' Health Movement.

Anant Phadke: I wish to say something in response which needs to be recorded. I wish Dr. Suhas Pingle was here, but some of these things are documented. What I am saying is based on documentation, not hearsay. This is a documentation of history and I want SATHI to document this history of my side. The response of IMA was unfortunate based on prejudice and ignorance. Firstly, 80% of the objections taken by IMA were factually incorrect. The first claim was that the representation of medical profession is inadequate, or that the doctors are inadequate. This is factually incorrect.[19] We have a representative of Maharashtra Medical Council, statutorily. We have a representative of Indian Medical Association, in a sense, statutorily, which normally doesn't happen as part of any other law. Then we also had a representative of post-graduate doctors. AMC specifically was named, now in Maharashtra, but at the national level too. So, there are more than adequate representations. The point is, there are other medical professions, like Ayurvedic doctors whom we don't consider as medical professionals, but there was more representation of doctors there too. So, factually it is incorrect to say that medical profession has not been consulted, that all the babus [bureaucrats] are going to regulate this Act. On 3rd March 2012, I was part of the IMA programme on CEA in Pune. I listened to the programme, I went home and I sent them a written letter stating most of the points that were made were factually incorrect. Rules were not framed at all, when the CEA came in 2001. Rules came much later. So, let us not create confusion between an Act and Rules. Rules are different, an Act is different. Even in those Rules no requirements have been specified, such as how many square feet of space is required, nothing of that sort. All it says is that committees will be set up, and in every committee, an IMA member will be there. And adequate space and opportunity were given to IMA to make representations to the committee and argue the kind of things that Dr Gadre argued. Later, we went to the IMA office and were able to convince the leading executive members of Pune IMA that most of these objections were factually incorrect. But these three or four problems with the CEA that I mentioned, we said, let us change this - let us say no to central CEA and say yes to Maharashtra CEA. Most ordinary IMA members do not go to the website and see the draft. It's a complicated draft. So it takes a lot of effort. Then it was the duty of the leading IMA members to put a factual document in front of the IMA members, which they did not do.

Abhay Shukla: Let us now come to the Maharashtra CEA. Within Maharashtra there was a certain level of consensus between both the medical profession and the JAA in that the central CEA in its existing form was not an appropriate Act for the state of Maharashtra. And therefore, as Anant has mentioned, no to central CEA, yes to Maharashtra CEA, this was the kind of position that was taken by the health movement. There were some meetings between JAA and medical professionals from Mumbai and Pune, for example one in mid-2013.

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19 For more on this issue of the activities and position of IMA then on the CEA see the following:
(i) Express News Service, Indian Express, February 8 2010, IMA doctors against Clinical Establishment Bill, available at: http://archive.indianexpress.com/news/ima-doctors-against-clinical-establishment-b/576939;
(ii) PTI NDTV June 25 2012, https://www.ndtv.com/india-news/nationwide-strike-of-doctors-called-by-indian-medical-association-today-489665 (both links last viewed on 17.4.2019)
(iii) Ekbal, B (2012) IMA Strike: Need for public debate. Indian Journal of Medical Ethics, 9(4), 226-8.
(iv) Phadke, A. (2010) The Indian Medical Association and the Clinical Establishment Act 2010: Irrational Opposition to Regulation. Indian Journal of Medical Ethics, 7(4), 229-232

Arun Gadre: Just to give you details of that meeting held on 15th July 2013. We collected the common objections, and formulated a response that these problems needed to be corrected in a Maharashtra CEA. That letter was endorsed by 55 doctors, including Dr. Sanjay Gupte, Dr. Vijay Ajgaonkar, Dr. H.V Sardesai, Dr. Arun Bal and Dr. Santosh Karmarkar. We tried to collect the support of rational doctors for these modifications.

Abhay Shukla: On 3rd December 2013, the Health Minister of Maharashtra, convened a meeting in Mumbai, where representatives from IMA, AMC, JAA, MMC,and also some other individuals participated. In that meeting a decision was taken to formulate an Act, a draft Act for Maharashtra, through a multi-stakeholder process, and a committee was formed. If I am not mistaken, a 19-member committee was formed, in which, health officials were centrally involved; Dr. Satish Pawar, Dr. Nagaonkar were the key officials. Sanjay, what was your experience of the functioning of this committee,especially the contentious issues in that committee? Was some kind of a consensus finally evolved? Or were there differences of opinions which could not be resolved?

Sanjay Nagral: I remember that meeting by the way. It was in Raj Bhavan, in Varsha or some of those strange names that government offices have.

Sujata Rao: It was in Sahyadri Guest House, and we waited for a long time.

Sanjay Nagral: Yes, we waited for a long time for that meeting. One of the things about the Maharashtra CEA, which was different from the central CEA, was in the objectives to the committee. Three objectives were given to the committee, one of which was to formulate a CEA, but also to look at rate regulation.

Abhay Shukla: There were four objectives, this was one.

Sanjay Nagral: I think that was partly due to the fact that there was a health secretary at that time who was very keen that rates are standardised, that's my belief. I don't think there was something acute about rates, but there was some interest from some people in government. That was one area where there was huge disagreement. It was a very contentious issue, to the extent that I think we even discussed the constitutional rights of doctors.

Sujata Rao: Yes, we submitted a legal opinion on it, through Advocate Rui Rodrigues.

Sanjay Nagral: There was a Supreme Court judgement regarding professional charges. But to me it is a marker of a bigger process, that if you want to achieve consensus with stakeholders, those stakeholders whose income will directly be impacted are never going to support you, or at least the majority will not be supportive. It either needs a very strong state which is willing to sacrifice its popularity or there is huge political will needed. I think that was one big thing which I saw in those meetings. I am a practising doctor and would worry about my income, but I think there was huge opposition even to the idea of standardisation. The reason why I am saying this is

that Anant, Raju Jotkar and I, we looked at various hospitals in Maharashtra and in one meeting we were told to complete a data gathering exercise, which we did, and submitted a report on it. I am not saying it was an academically rigorous exercise, we looked at four tiers of hospitals and their prices, but to me it was very clear that rate standardisation was going to hurt a lot of economic interests. Therefore, there was huge opposition and I think it would be very foolish to think that large sections of the medical profession will support the idea of rate regulation, because it is too complex an issue. [20]

There was also the issue of standard guidelines. If I remember right, we discussed standard treatment guidelines and there was some interesting opposition to whether we can have a standard guideline, for example for snake bites. Whilst you have various clinical scenarios where things can be different and there is variation in treatment, across the world there is something called standard treatment guidelines. This is not something peculiar or unique to India that we were proposing, but there was opposition. To me, that whole process was very depressing and scary. Forget about economics and even rate regulation, if a medical profession is not willing to acknowledge the fact that there needs to be standard treatment guidelines, then I think we have a huge problem on our hands.. We are talking of science now, we are not talking economics. Some of us submitted an alternative, dissenting report from that committee: Anant, Raju Jotkar and I.

The lesson that I learned from that whole exercise was that there is opposition to many aspects of regulation. When I used to go to meetings for my speciality I would be labelled as 'the fellow who is supporting CEA.'I realised that there is a lot of misinformation. I once went to give a talk on liver-transplantation in Dhule IMA and people came up to me and said, '*kyun support kar rahe hai usko*? [why are you supporting it?]. At one point there was very much an impression that that the CEA is going to finish off their practices and my batch-mates who graduated with me would say: *'hamare pet pe laath kyun maar raheho?*' [why are you destroying our livelihoods?] There was this sense of panic being created, there was a siege mentality.

The big take-away for me was that these processes are difficult and that the state was not very serious about it. I think at one stage they thought that this is a good thing to talk about in public, but when the elections were announced and the same government, Mr. Shetty was the Health Minister I think, became less serious about it. Across parties there is not much support for the CEA because I think there is also entanglement between political parties and doctors. A lot of senior people in medical associations are close to ruling parties, all sorts of ruling parties,so they are, I think, deciding state policy. It is not so much the doctors;individuals who are powerful are deciding policies. I suspect that for any regulation, it is the health minister and their connections in the profession and other stakeholders who unfortunately derail these processes.

Sujata Rao: AMC comes from a perspective where we had particular objections and recommendations based on our analyses of CEA. We had not opposed standard treatment guidelines completely, but rather we said they should evolve through a consultative process.

20 This dissenting note is provided in Annexure 2

There was an expectation that every nursing home would display a rate chart in the waiting room, and we objected on the grounds that you can't have a standard rate chart like a restaurant because there are 'n' number of procedures and 'n' number of surgeries or medical reasons for admission; the entire wall would be filled up. So instead we recommended that there is a rate booklet for particular services at the counter.

Regarding the standardisation of rates - that was also not agreed on because there is a Supreme Court judgement which says that a professional's charges cannot be standardised, and we consider ourselves to be professionals because we are postgraduates or graduates with an MBBS degree and an MS or MD. We submitted a legal opinion pertaining to that case and a competitive regulation authority opinion was also submitted because, after all, this is a profession. Even if you do not consider the individual right for a professional to have his own consultation charges, you have to think about the competitive regulations also, where every individual has to have some way of earning in a society. It should not be deferred just because we are educated in a medical field.

We are the only persons who are delivering the medical services and catering to the demands of the clientele, and who are expected to have a good grievance redressal system. We have to coordinate with multiple regulations and multiple parties, whether it is the insurance, pharmacy provider, medical equipment provider, the government or the regulating authority. If there is central co-ordination by a single person who is also delivering medical services, that needs some consideration and that was the angle from which we have given our recommendation. It was very well analysed and it was a representation of 10,000 members, not an individual, because I was the person who was representing the AMC. Recommendations were made according to the general perspective of the consultants who are with us.

Ketan Parikh: There was a meeting in AMC also.

Sujata Rao: Yes, every singular point was discussed in person or by e-mail, because these things are important to us. We have dealt with the problems when there was inadequacy of the regulations. We have dealt with the problems when patients were creating violence in the hospital. We have dealt with the situation where people walk into one clinic or a nursing home and demand for some fine on pretext of no calibration of our weighing machine or having no fire NOC. When we said no to the display of rates, we gave them a solution. For every objection, we have given a solution,so we do not believe in only creating hurdles.

Niranjan Agarwal: Dr. Rao was the voice of the AMC. Before the committee meeting, we would meet in the AMC office, where all the points that could be raised were thought of and responses discussed.

Abhay Shukla: Were there any areas of consensus which also emerged and found a place in the final draft, which was formulated in June 2014?

Sujata Rao: There was no consensus between JAA and AMC over rights of clinical establishment. As mentioned earlier, the patient's responsibilities can't be included in an Act, because you cannot fine a patient. It is a lopsided Act where you are expecting the world out of the medical service provider, because he is a service provider according to the Consumer Protection Act. You are making an additional regulation to make the doctor even more answerable, to punish him with the removal of his registration and 'n' number of things. We proposed to include the rights of clinical establishments as we also have our concerns. After all, when you create an Act, it has to be an all-inclusive perspective where the views of both the doctor and the patient have to be considered. So as per the doctor's point of view, let the rights of clinical establishment be included in this. But I think there was opposition to that.

Second, there was an issue with the recovery of payments from the patients. A number of times we have no access to recover the payments. There are a number of patients who go away without paying and there are a number of patients who occupy our beds in spite of being discharged, or who have no relatives to pay. The hospital suffers in these cases. The patients get their politician relatives involved and then there is violence. We have studied that. We suggested that the patient has to pay the bill; he can then make a complaint against the clinical establishment provided s/he has given the payment. Because we are witnessing day-in-day-out that patients have a grievance only when it comes to billing; there is no grievance when the billing is low. That is where we said there should be some bar to that - the patient can make a complaint against the clinical establishment if he has paid the mutually agreed fees.

Anant Phadke: I will start with a positive note, which was that representatives of the medical profession and civil society had three, four meetings. Good substantive discussion took place and ultimately we came up with a consensus draft Act, despite all the differences. That was the condition that the health minister Suresh Shetty had laid down; as representatives of the medical profession and from civil society were meeting him separately, he said, 'you people have to come together and give me a common draft'. And we achieved that. Several important objections that both medical professionals and JAA had were all addressed in the state Act. The requirement of a police officer in the local supervisory authority was struck off; provisions for district level mechanisms, for appointing an additional full-time medical officer, regarding patients' rights and responsibilities, all of which were non-existent in the central CEA, were incorporated. Our central criticism, that the Act will remain only on paper and will not be implemented, was also taken on board. Lastly, the emergency stabilisation clause, which was wrongly formulated, was removed. These are five major points I can remember, about which, after lot of debate, there was consensus. Regarding transparency in the rates, in the meeting we never said all the rates should be displayed all over the wall. Some people may have said so outside the meeting. But we came to the consensus that there will be a booklet available at the counter.

There were four major limitations. JAA had always argued that the executive authority and the regulating authority have to be separate physically,and that was not accepted by the government bureaucracy. Secondly, we had said that there should be a full-time, autonomous, district-level committee chaired by a retired judge, and that was also not accepted by the bureaucracy.

Lastly, rate regulation was not accepted. We could not come to a consensus. We agreed on transparency in rates, but there was no agreement on rate regulation. Therefore, a dissenting note was submitted by Dr. Nagral, me and Dr. Jotkar, a government officer who took some risk in signing that dissenting note,[21] as he thought it was a very reasonable proposal about rate regulation.

Sujata Rao: One more point of consensus - was regarding an ombudsman. Both of us had agreed that the government should pay when there is emergency management because there was a law commission statement. But it was not accepted by the bureaucrats.

Sanjay Nagral: We need to look at the bigger process. As I have said the medical profession is not a monolith. In that CEA committee there were all sorts of representatives: AMC, IMA, MMC. Despite the differences we had with AMC, we were able to have some common ground. And the fact that they are sitting here today for four hours also sort of demonstrates that. So, what I am pointing out is this, that varying sections of the professions respond partly based on what their strong interests are, what is their base. I think that is what we saw in that committee. And I agree with Anant, that there was a move forward. But the point is that there are huge political processes behind the scenes. Committees in India, I think, are ways to dissipate or diffuse a situation, rather than actually, serious efforts to address the problem. I used to think it is a very serious effort, having ten meetings, for six to eight hours. But committees can be ways to defuse the situation, sort of postpone matters.

Sujata Rao: There was a very important point which was raised by Dr. Nagral about emergency management in the city, a very valid recommendation which was not taken for ward. One more thing that was not taken into account was about the poor quality of public health infrastructure. All of us had mentioned that. Everybody was arguing that the problem of private practitioners and out-of-pocket expenses is because there is a poor public infrastructure. If you improve that, then automatically, everything will come on par. So, these two things were not accepted in the final draft.

Abhay Shukla: After so much energy, a semi-consensus draft was prepared in June 2014. Why did it not go ahead? The Maharashtra state assembly elections were to be held later that year, around October 2014. So, it could have been a good opportunity for the state government to say, look, we brought together doctors and civil society, and we have developed a law that will help patients but will also be fair to doctors. They could have projected it as an achievement of the government and brought it in the monsoon session or before the elections. But what happened?

Sujata Rao: It came as a surprise to us that it was revived in 2018 and we were not involved in it. Even AMC was not called. We came to know from some others. We went and met the Chairman and said, 'please include us for sake of continuity of the number of hours we have put in'.

21 See Note 22

Abhay Shukla: JAA was also not invited in the new committee round. So, what is your reading of this situation? Abhijit, would you also like to comment about what happened?

Sanjay Nagral: It's not a very nice explanation but I think somebody, somewhere, went to a connected person within the political arena and said, *'ye sab abhi mat karo'* [Don't do all of this now]. I think the tide may be turning now, because the political class is beginning to slowly realise that there is some purchase in the electoral processes on health regulation. Public discontent is there now, very much, on the issues of health access and quality and safety. So, they are now making those noises and that may be the explanation for the revival. In 2014 they may have thought that it is not something worth getting into, because it is double-edged and connected people in the medical profession were probably talking to the right people and saying,'don't do it now'. It may be something as frivolous as that. Perhaps Dr. Doke can tell us how these processes take place?

Prakash Doke: The basic feeler was that the IMA is not happy. That was the main reason not to push forward. Indirectly, or directly, this feeling was that medical fraternity –the IMA –is not happy with this.

Abhijit More: I think for the sake of documentation, I would like to briefly summarise what kinds of efforts were taken by the JAA even for this draft. The central CEA was enacted in 2010, and in the first year there was some confusion, as to what kind of position is to be taken on it. There were a series of discussions and then JAA came up with the position, 'no to the central CEA, yes to Maharashtra CEA'. In 2012, we marched to the state assembly session in Nagpur and in March 2013 we held a protest meeting at Azad Maidan in Mumbai. In June 2013 we submitted a memorandum with signatures of 50-60 doctors, demonstrating that there is a group of doctors who are in favour of this Act, and that the state government should come up with this Bill. Then, we had a discussion with the state health secretary, who asked JAA to develop its own Bill. In September 2013 JAA submitted its own version of Maharashtra Clinical Establishment Bill and subsequently, a meeting was organised by Observer Research Foundation. In December, the Health Minister announced the formation of the committee, but the composition of the committee was very uneven. There was only one civil society representative and that too was a doctor. It was a committee comprised entirely of doctors. We insisted on taking some public feedback, which the government and that committee accepted. The state government arranged public feedback at five to six regional places. JAA tried its best to mobilise public opinion around this Bill, and a lot of suggestions were given in writing by many civil society organisations. At the table there was only one representative for the JAA, but through the public feedback mechanism we were able to provide a voice to alarge number of civil society organisations. Afterwards, the draft bill was submitted to the government and elections took place and then it was put in cold storage. In 2015 and 2016, we tried to meet repeatedly with the Maharashtra health minister. In December 2014, at the first session of the health minister, we met him with the memorandum and asked him to take forward this consensus draft. But nothing happened.

In 2015 and 2016, we kept meeting the health minister, and in 2017 we organised a people's ballot in Pune on this issue and got the feeling that people were overwhelmingly in support of this Bill, and also for improvement in the public health system. A ballot was organised at 80 places in Pune and around 22,000 people voted in this exercise. We submitted that exercise to the MLAs. In December 2017, JAA again marched in front of the state assembly in Nagpur, and gave a memorandum to the health minister. We had discussions with the health minister and liaised with many MLAs, some of whom raised questions in the legislative assembly session in December 2017. In response to those questions and the memorandum of JAA, the very next day the minister announced that Maharashtra government will come up with CEA, and he also tweeted that. In January 2018 there was an announcement that a committee was being set up, to give feedback on the consensus draft that had been submitted to the government in 2014. Surprisingly, the stakeholders who had been involved in the initial drafting of the Bill, like the AMC and JAA were not included in the new committee. So JAA mobilised civil society organisations, again gave a memorandum to the health ministry, and went to the press. Subsequently, the AMC, Anant Phadke and I were invited to that meeting. The AMC also approached the health ministry and were subsequently invited. I think afterwards they included two or three other stakeholders too. From February to April 2018two or three meetings took place, but they were not very well-organised meetings; in two of the meetings the chairperson of the committee was not present.

Sujata Rao: And no minutes were given.

Abhijit More: In each and every meeting we were giving our versions of the draft bill, but in every meeting new issues were coming up. It was not very well organised. The composition of the drafting committee, I think, is very, very crucial: who sits at the table while drafting the provisions. I think, that is very important and that shapes the entire structure of the bill and that needs to be taken into account. In 2013-14, the only civil society organisation represented in that committee was JAA. We had demanded that there are many organisations working on health issues, and they should be also given representation, but that didn't happen. The role of state officials is also very important. In these committee meetings there were only two health officials –the Chairperson and one other official. The Chairperson was leaving the meeting and going away *saying,'aap aapas mein baatcheet kar lo, phir dekh lenge'* [discuss matters among yourselves, we will see later]. I think that is not the way to conduct the discussion around the Bill. We don't know what the final draft is like. I came to know that the Chairperson Dr. Mohan Jadhav submitted the draft Bill to the government, but we don't know what is included in it.

Sujata Rao: If, according to what Dr. Doke has said, the IMA was the one that didn't want the 2014 draft to be submitted, then who was in a hurry to submit it this time?

Prakash Doke: Any document that is provided to the government by civil society goes through to legal professionals who prepare the bill, which then goes to the law and judiciary department. They add only the technical words and see whether this Act is contradictory to an existing Act. After that it will be displayed in the public domain, for example on the internet, for the public to comment upon. This indicates that this particular draft Bill is ready and will be submitted to the state assembly. But as of today no such billfor CEA has been uploaded.

Abhijit More: I think Dr. Jadhav was about to retire in June 2018. So, he must have finished his job, submitted it to his boss and said goodbye.

Abhay Shukla: One point which has not come out so strongly in the discussion, is whether there is any perception that large corporate hospitals were influencing the regulatory framework in some form, directly or indirectly. Because one change between the 2014 committee and the 2018 committee, in my understanding is, that this time large or corporate hospitals were involved.

Sujata Rao: In the last committee in 2014 there was no corporate hospital representation. This time Joy Chakraborty [Confederation of Indian Industry (CII), Western region representative] was there.

Prakash Doke: Most of them have plenty of space and the certifications so it does not matter to them.

Sujata Rao: Yes, it doesn't concern them, according to what he told me.

Abhay Shukla: Okay. The larger corporate hospitals, whether they directly sit in the committee or not, in some form they would benefit from very stringent regulations of a certain kind, about infrastructure, which may adversely affect smaller hospitals or hospitals in rural areas, or smaller towns which may not be able to fulfil the same infrastructural standards. This has been an issue which has been in a general kind of anecdotal discussion. Is there any evidence for this?

Sujata Rao: I think if there are very stringent restrictions on smaller healthcare providers, then it is not of any consequence to the larger ones - the corporate hospitals will benefit.

Abhay Shukla: Is there any evidence in form of any submission or inputs by them in any committee or is this operating behind the scenes, something which we cannot document but we can only suspect?

Niranjan Agarwal: See, there cannot be direct evidence. But we have been to these business meetings as representatives of small-scale providers, to CII, and NABH, even NATHEALTH[22]. They are all businesspeople, from big companies like instrument manufacturing companies. And all the talk there is about looking at the potential of the healthcare, like any business - *Ye sector ko aisa karo, itna aajaega, ye aajaega,* [Do this in this sector, this much can be made]. When we listen to such conversations it makes sense that – okay, these people are trying to get all the business for themselves.

Sujata Rao: Their yardsticks are different from our yardsticks.

22 NATHEALTH set up in 2012 is a federation of private healthcare providers comprising large corporate and trust hospitals, nursing homes, small to mid-size hospitals, pathological labs, imaging companies, medical technology and devices, healthcare consultancy firms and educational institutions. See www.nathealthindia.org.

Ketan Parikh: Personally, I feel that there is an evolution of the society. People are demanding more and more, the average person is exposed to more information, and that's why they make certain demands. When they see a corporate hospital and the facilities available there, they demand those facilities elsewhere too. The number of people who have visited healthcare organisations abroad has increased dramatically, leading people to ask 'why can't we have that system here?' These expectations then actually have an influence.

Personally, I am not sure whether the corporate hospitals are united enough to influence the government. Because influencing the government is not a one-man job. Whatever meetings that I have seen of theirs, you can see that they are definitely not united. They are worse than even doctors. But this is my personal impression, that this is more an evolution. Whether we influence or the industry influences, it will have to finally be the responsibility of the government to see to it that healthcare is not hijacked by any one particular group, which is extremely important. People in the government have to understand, that if it is hijacked by one group, it's going to go haywire, and it the responsibility of the society also that it is not hijacked by one group. What I have definitely seen, what the industry has tried to do is to hijack NABH, because the trustees of NABH are the people from the representatives from the industry. Whether they have been able to hijack government, I am not so sure, but NABH is a very important thing.

We are completely forgetting this big player that is insurance. They have hijacked NABH and insurance. And that is going to be a major driver, because insurance is going to control the charges and NABH is going to control the standards. NABH and insurance have been hijacked by industry, it is very obvious.

Abhay Shukla: Any other comments on this corporate influence on the healthcare sector which may have influenced the regulatory process in any way? Dr. Ketan Parikh talked about influencing NABH. This is a new angle which I had not thought of.

Ketan Parikh: You see the NABH trustees – I think it's Siemens and all these industry people – are the ones controlling NABH. Even pharmaceuticals are controlling NABH. Johnson and Johnson has a stake in NABH. What Niranjan said about the corporate thinking is very true.

Niranjan Agarwal: See, there is a new culture in the corporate hospital of a salaried doctor. In a small setup, the doctor owns the hospital, runs the hospital, and manages everything. So he decides his fees accordingly, to what suits him well. In the corporate hospital people know that I am employed for Rs 3 lakh per month, and whether I operate on 10 cases or 100 cases, it is immaterial. In fact, they will force me to operate on 100 cases. And that is where they influence the government health insurance schemes also. All the government schemes are particularly taken up by these people, more than anything else, because they can afford it. Otherwise, their beds would be vacant.

Ketan Parikh: Who are the two principal advisors of Ayushman Bharat?

Abhay Shukla: Dr. Naresh Trehan and Dr. Devi Shetty.[23]

Niranjan Agarwal: There is your evidence.

Prakash Doke: But I slightly differ. These are two sectors in insurance: one is where you pay the premium and the other is where government pays the premium. Whenever government is paying the premium most of the corporates run away from the schemes. Their clientele is absolutely different.

Niranjan Agarwal: The scene is different between Mumbai and Delhi. In Mumbai, the corporate hospitals are actually the trust hospitals, most of them. Like Bombay Hospital, Hinduja, Jaslok, these are trust hospitals, whereas the Delhi hospitals which I just spoke about, are actual corporates. They have employed doctors. So, it makes sense for them to make them work more. At the same cost, they can achieve more by feeding in these patients. They don't have to spend extra, other than probably the medical/consumable part of it. Their beds are otherwise vacant, and their staff are sitting idle. In the beginning they will work at very low costs. When the nursing homes or the small-scale providers cannot afford it they will walk-out, and slowly the only the big corporates will be left. That is the time they can still influence the government and get their charges hiked. This is their business strategy.

Prakash Doke: One point I will like to share about the positive outcome from the government side, is that after this Clinical Establishment Act, it was expected that there will be some standard treatment protocols. Until then, we did not have any standard protocols, but now we can proudly say that there are standard treatment protocols for government hospitals, for 50 diseases each in surgery and in medicine, and 30 diseases in paediatrics. There is a website and it is mandatory for all government institutions to abide by them. If any case goes to court of law, the judge will ask, 'did you follow the standard protocol?'If it emerges that the standard protocol has not been followed, a certain fine will be imposed. That is one positive fall-out of this CEA at least, which has occurred in government sector.

Abhijit More: Recently there was a news report that they are trying to extend this protocol to the hospitals empanelled under Mahatma Phule Jan Arogya Yojana[24] . There is some discussion going on about that.

Abhay Shukla: Okay. I think we can wind up now. On behalf of SATHI and our collaborators King's College London, I thank each one of you for your contributions.

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23 Dr Naresh Trehan and Dr Devi Shetty are cardiac surgeons who established respectively two popular corporate hospital chains in India: Escorts Hospitals Delhi and Medanta Medicity Gurugram, and Narayana Health in Bengaluru.

24 MPJAY is the government health insurance scheme in Maharashtra launched in 2012. See https://jeevandayee.gov.in/MJPJAY/RGJAY.jsp

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ANNEXURES

ANNEXURE 1
Document comparing two drafts of BNHRA Rules

ANNEXURE 1
Document comparing two drafts of BNHRA Rules

Comparison of draft Rules put on the web site in July 2006 and revised draft Rules of September 2008

(In the column 'Draft Rules 2006, the additions suggested by JAA in Dec. 06 are in blue font, comments are in bracket in blue font and suggested deletions in red font.)

Short title, extent and commencement

	'Draft Rules 2006' -section 1	**Revised draft rules Sept. 08 - Rule 1**
1	These rules may be called the Bombay Nursing Home Registration Rules 2006	These rules may be called the Maharashtra Nursing Home Registration Rules 2008.
2	They shall come into force from the date of their publication in the Official Gazette	They shall come into force from the date of their publication in the Official Gazette.
3	These rules shall apply to the whole of Maharashtra	These rules shall apply to the whole of Maharashtra state.

Definitions

	'Draft Rules 2006' -section 1	**Revised draft rules Sept. 08 - Rule 2**
1	In these rules, unless there is any thing repugnant in the subject or context,- "The Act" means the Amended Bombay Nursing Home Registration Act 2005	In these Rules, unless the context requires otherwise – (a) ''Act" means the Bombay Nursing Home Registration Act 1949 (b) "Amended Act" means the Bombay Nursing Home Registration (Amendment) Act 2005. (c) ''Form " means form appended to the Rules and (d) ''Section" means a section of the Act.

2	Appendix means appendix to these rules;	No Provision
3	Local supervisory authority" means,- in the areas falling within the jurisdiction of the municipal corporation – the h Health Officer of the concerned municipal corporation; in the areas falling within the jurisdiction of the municipal council –the Civil Surgeon of the District in which such council is situated in the areas falling within the jurisdiction of the Cantonment – the Health Officer of the Cantonment; in the areas not falling in sub-clauses (i), (ii) and (iii) above, the District Health Officer of the concerned Zilla Parishad"	No Provision
4	State competent authority – A multi stakeholder body at state level to guide District competent authority in discharging the functions under chairmanship of Director of Health services. This is appellate body at state level.	No Provision
5	'Maternity Homes "any premise used or intended to be used for the reception of pregnant women for normal delivery; this would exclude those not having OT. They should have gynecologist / surgeon, anesthetist, pediatrician on panel.	No Provision
6	Qualified medical practitioner "a medical practitioner registered under the relevant Medical Act in force" It would mean "a person who possesses any of the recognized medical qualifications and who has been enrolled in the register of the respective Medical Council. Viz., Allopathy, Dental, Homeopathic and Board of Indian Medicine or any such council, Board or any other statutory body recognized by the government". Allopathy – Maharashtra Medical council act 1965 & Indian Medical council act 1956 ;Aurved, Unani and sidhha – Maharashtra Medical Practitioners act 1961 & Indian Medicine Central council act 1970; Homeopathy - Maharashtra Medical Practitioners act 1961 & Homeopathy central council act 1973	No Provision

7	Nursing Home also means "a place where patients are treated as inpatients with facilities for admission as inpatients for treatment of illness without or with surgery or conduct of delivery and also includes other gynecological operations where women are received or accommodated for the purpose of sterlisation, hysterectomy, or medical termination of pregnancy etc. with or without overnight inpatient facilities". Nursing Home would also include "any inpatient medical clinic, nursing home, maternity home, hospital, old age homes, day care centers (any intervention which would require observation and on-going care/ monitoring for more than an hour).	No Provision
8	Medical Laboratory means "an establishment where bio-Medical tests such as hematology, biochemistry, serological tests, bacteriological, cytology, histology, genetic investigations or any other diagnostic tests are carried out.	No Provision
9	Imaging centre is an establishment where Radiological, sonography, colour Doppler, Echocardiography, CT Scan, MRI tests or such tests are carried out.	No Provision
10	DMO (Duty medical officer) is a residential Doctor working in Nursing home engaged for particular discipline like Allopathic, Homeopathic, Aurvedic, Unani system of medicine with requisite qualifications and registration under Government recognized council, for the particular discipline for which nursing home is set up.	No Provision
11	Disease means "a notifiable disease which a Registered Medical Practitioner is required to notify to the Medical and Health Officer of his area under the law for the time being in force"	No Provision
12	Appellate authority – State competent authority at state level	No Provision
13	Company – Corporate body, trust or society running the hospital.	No Provision
14	Qualified Nurse – Nurse registered under Bombay Nurses, midwives, and Health visitors act 1954 trained in a institute recognized by Maharashtra Nursing Council.	No Provision

Local Supervisory Authority and State Competent Authority

	‘Draft Rules 2006’ -section 1	Revised draft rules Sept. 08 - Rule 2
	Local Supervisory Authority for different areas would mean as follows- 1) Corporation -------- MOH 2) Municipal Council ---------Civil Surgeon 3) Cantonment----------Health Officer, Cantonment Area not falling in (1),(2),(3) - DHO ZP	No Provision
	Functions of Local supervisory authority a) To grant, suspend or cancel registration of Nursing home b) To enforce standards prescribed for nursing home c) To investigate breech of provisions of the act d) To supervise implementation of the provisions of the act and rules e) Keeping record of registration, renewals, inspections, cancellations, any other matters pertaining to act, record of meeting of District competent authority.	No Provision
	Powers of Local supervisory authority a) Inspection of Nursing Homes b) Summon individual or organization who is in possession of information relating to violation of the act c) Verification of hospital records d) Issue search warrant for any nursing home on receipt of complaints. e) LSA can take Suo Moto legal action against a nursing home.	No Provision

	Composition of the State competent authority 1) Director of Health Services (Ex-officio)-- Chairperson 2) Representative from the State Indian Medical Association ---Member 3) One representative from the Hospital Owners Association. ---Member 4) Representative from State level consumer organization ---- Member 5) Representative from state level NGO working in the area of health--- Member 6) Representative from a state level women's group -- Member 7) Representative from Law & Judiciary Dept Mantralaya -----Member 8) Representative from DMER------ Member 9) Representative from DDHS Nursing --- Member 10) Representative from LSA as nominated by chairman --- Member 11) Joint Director of Health services, (Medical) --Member Secretary 12) A representative of Nurses' Association -----member	No Provision
	Functioning of the State Competent authority i) The meeting of the SCA will be called by the Chairperson with a minimum notice of 15 days with period between two meetings not exceeding more than 90 days. ii) Emergency meetings could be called by the Chairman with a three days notice on receipt of serious complaints made to the SCA. iii) The constitution of the State competent authority should be valid for the period of five years. iv) The government and non- government members appointed to the state Competent authority will be entitled to traveling allowance and daily allowance according to the traveling allowance rules of the state government, for attending the meeting.	

Short title, extent and commencement

	‘Draft Rules 2006’ -section 3	Rule Revised draft rules Sept. 08
1	Prohibition to carry on nursing home without registration No person should run a nursing home unless it has been duly registered and registration in respect thereof has not been cancelled under section – 7. Provided that nothing in this section shall apply in case of nursing home which is in existence at the date of commencement of this act, for a period of three months from such date or if application for registration is made within that period in accordance with provisions of section 4 until such application is finally disposed off.	No Provision

Maintenance of Register

	‘Draft Rules 2006’------ SECTION – 5 Rule 3	Revised draft rules Sept. 08----Rule 3
1	On receipt of fees for registration and after grant of registration name is registered in office of LSA in a register in form A	The Local Supervisory Authority should maintain Register in form A showing names of persons registered under section 5 of the Bombay Nursing Home Registration (Amendment) Act 2005.

Application for registration

Application of Registration/Renewal of Registration of a Nursing home

	'Draft Rules 2006'------ section 4	Revised draft rules Sept. 08 -Rules 4 & 6
	i. An application for registration, renewal or for duplication of the registration shall be made to the Local supervisory Authority (LSA), in duplicate, on Form A ii. An application for the registration / renewal of registration shall be made in advance in the prescribed form at least three months before the date on which the registration and the registration are to expire and shall be accompanied by the fee prescribed.	**Rule 4 -** Any person intending to carry out Nursing Home shall make an application to concerned Local Supervisory Authority in Form B, and shall be accompanied by fees at least one month before expiry of previous registration. Such application should be accompanied by fee prescribed. **Rule 6-** (1) a) Renewal shall be made once in three years. b) An application for renewal of registration shall be made at least one month before expiry of previous registration and shall be accompanied by fees prescribed under rule 7. (2) On receipt of application made in Form B, the Local Supervisory Authority shall if satisfied that the application is in order, issue renewal of registration in Form C.
	iii. If an applicant submits an application for renewal of registration after one month from the expiry of the date of registration, such application shall not be treated as a case of renewal of registration and shall be accompanied by up to date fee for original registration.	No Provision

	iv. If the applicant is aggrieved in anyway regarding registration or renewal thereof he/ she may appeal to the State Competent authority within one month of expiry of registration. Once an appeal is filed the cancellation or refusal order will be deemed stayed till the appeal is disposed of. The appeal may be disposed of within three months.	No Provision
	v. The intervening period, that is, from the date of expiry of the previous registration up to the date before issue of the new registration, unless the case is under appeal, shall be treated as irregular period of running the establishment by the applicant. Without providing any information the licensing authority can then proceed to seal the establishment during that period. The registration can subsequently be obtained only after making a fresh application to the LSA after receiving the full payment toward the fee for original registration.	No Provision
	vi. If the nursing home is unable to employ qualified nurses, registration can be granted if owner of nursing submits undertaking/ affidavit regarding recruitment of qualified nurses within three months of submitting the affidavit. Before submitting the affidavit owner of nursing home should present sufficient documents of efforts taken to recruit qualified nurses. The clause of employment of qualified nurses should be implemented in phased manner. **Municipal corporations –** Within one year of rules coming in to force. **Municipal councils -** Within two years of rules coming in to force. **Gram Panchayat -** Within three years of rules coming in to force. With regard to criteria of nurses' employment, two categories of nurses should be decided. **Qualified nurses –** Nurses registered with Nursing council. **Trained Nurses –** Nurses who have taken training of six months duration at Govt recognized institutions. There should be at least one qualified nurse for three trained nurses.	No Provision

Registration

	‘Draft Rules 2006’ -section 5	Revised draft rules Sept. 08 - Rule 5
	Section 5 (1) (b) Provided that LSA may refuse to register the applicant if it is satisfied: (b) That the nursing home is not under the management of a person who is holding a any of the recognized medical qualifications and who has been enrolled in the register of the respective Medical Council. Viz., Allopathy, Dental, Homeopathic and Board of Indian Medicine or any such council, Board or any other statutory body recognized by the government and who is resident in the home or that there is not a prescribed proportion of qualified nurses employed in the nursing home to the number of patients in it; or “	No Provision
	Section 5 (1) (c) (c) That in the case of a maternity home it has not got on its staff a qualified midwife; (give definition) or (c-1) That the area of the premises of the nursing home is less than the prescribed area; (c-2) That the number of beds available in the nursing home exceeds than those prescribed (c-3) That the nursing home is owned or is under the management of a Government Medical Officer;”	No Provision

	Section 5 (3) The registration certificate should be displayed at a conspicuous place in the nursing home. No registration for nursing home shall be granted unless the LSA is satisfied that the applicant and the Nursing home fulfill the following conditions; i. The person supervising the Nursing Home is a qualified and registered medical practitioner. ii. Application (Form ---) shall be filled in with the particular name of the applicant and not with the name of Registered Firm, Company or Partnership Organization so that responsibility of the nursing home shall be fixed upon a particular person .So in case of a Firm, Company or a Partnership Organization, the name of a person from amongst the Directors, Partners or Owners, that may be the Applicant, shall be specified through a resolution of the personnel in the management of such Firm, Company or Partnership Organization. iii. The premises and equipments are reasonably suitable and adequate with a stock of emergency and lifesaving drugs. iv. The nursing home adheres to all the minimum standards as prescribed in annexure… v. Proportion of qualified nurses to the beds in nursing home. vii) Change of user certificate from housing society if nursing home is in premises of housing society.	No Provision

	Procedure for granting registration or renewal of registration Rule 6 i. The Local Supervisory Authority or authorized representative on receiving the application form and various forms and details must check the application for compliance with all requirements provided. ii. After the Local Supervisory Authority is satisfied that the applicant has complied with all the requirements as mentioned in the Act and the Rules, the Local Supervisory Authority should ensure inspection of the nursing home by any person or persons appointed by Local Supervisory Authority to verify the adherence to standards prescribed. iii. The Local Supervisory Authority shall dispose of every application received within three months from the date of receipt of application. The Nursing home would be deemed to have been registered in case there is no response from the local supervisory authority in three months from the date of application. iv. A certificate of registration issued under this section shall, subject to the provisions of section …., be in force and shall be valid until the 31st day of March of the third year next following the date on which such certificate is issued or renewed, as the case may be. v. In case of non-compliance to standards found on inspection, the registration fees will not be refunded. vi. The fees shall be paid by DD to LSA vii. Occupancy certificate & Permission from town planning Dept viii. Approved plan ix. Receipt of property tax x. List of Doctors with their qualifications on panel and names of specialties available in nursing home.	**Rule 5; Grant of Certificate of Registration** The Local Supervisory Authority shall if satisfied that there is no objection to registration, register the applicant in respect of Nursing Home and issue him certificate of registration in Form c.

Penalty for non-registration

	'Draft Rules 2006' -section 6	**Revised draft rules Sept. 08**
	Whoever contravenes the provisions of section 3, shall, on conviction, be punished with imprisonment, which may extend to six months or with the fine, which may extend to ten thousand rupees or with both. a) On finding contravention of provision of section 3 from the Act, a show cause notice may first be served to the owner and asked to register within a month after paying a fine amounting to 50% of registration fee. b) On further contravention will be liable for punishment as per the act. Contravention of renewal after three years, will also invite a show cause notice, along with a fine as per section 12 of Act. Failure to renew registration three months after show cause notice will amount to non-registration.	No Provision

Cancellation of Registration to run the establishment

	‘Draft Rules 2006’ -section 7	Revised draft rules Sept. 08
	The LSA may refuse to register the applicant or renew the registration or cancel the registration if it is not satisfied that a. The nursing home is not under the supervisory management of a person who is qualified and registered in the council recognized by the government, b. The rules and by-laws under the act are not followed, c. Used for purposes, which are in violation of any other law, which the Nursing Home is expected to comply with or it is found that the Nursing Home is carrying out activities for which it is not registered. d. Subject to provisions of the act LSA can cancel the registration at any time of a person in respect of nursing home on the ground person has been convicted of an offence under the act. e. The owner of the nursing home could be a non-medical person but it should be under the supervisory management of a person who is a qualified and registered medical practitioner. e. The owner of the nursing home could be a non-medical person but it should be under the supervisory management of a person who is a qualified and registered medical practitioner. f. If at any time after the nursing home has been registered and granted a registration therefore, the LSA is satisfied that the terms of registration are not being complied with, may cancel such registration and registration. g. 31st day of March of the third year next following the date on which such certificate is issued or renewed, as the case may be.” (This would mean that the LSA would be totally overburdened with work from January to March and would find it impossible to complete its work of granting / rejecting registration, renewal and would have very little work in other months. Hence substitute above provision by following one.) Section 5, subsection 2 - A certificate of registration issued under this section shall, subject to the provisions of section 7, be in force and shall be valid until the completion of three years from the date of approval of the registration application.	No Provision

Notice of refusal or of cancellation of registration

	'Draft Rules 2006' -section 8	Revised draft rules Sept. 08
1	The LSA should make a detailed note of observations made and its comments on inspection of the premises of the applicant. It should indicate in writing the applicant about the deficiencies and submit a report to the board	No Provision
2	LSA would reject or cancel the registration only after enquiry and giving opportunity of being heard to the applicant and is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall for the reasons to be recorded in writing, reject the application for registration and communicate such rejection and the reason thereof to the applicant within three months of the date of the application as specified in particular form.	No Provision
3	A reasonable rectification period of a month three months is given to the nursing home to make-up for the deficiencies pointed out in the LSA's report. This would be followed by reapplication by the owner and re -inspection by the LSA before a final decision is taken by the LSA.	No Provision
4	Redressal for refusal to register or renew or cancellation of registration i. If the applicant is not satisfied with the decision of the LSA and wants to seek redressal, the applicant should appeal to the State competent authority with the reasons given by the LSA for refusal of registration within a period of 30 days from the date of order of the LSA. ii. The State competent authority should render its decision within 90days of receipt of the appeal, after hearing all the parties as well as getting the nursing home inspected afresh if it is so found necessary.	No Provision

Inspection of Nursing home

	‘Draft Rules 2006’ -section 8	Revised draft rules Sept. 08
	i. Every nursing home shall offer reasonable facilities for inspection of the place, equipment and records to the local supervisory authority or any other officer duly authorized by the local supervising authority. LSA can inspect any relevant records, register, document, and equipment and article necessary for the purpose of the provision of the act.	No Provision
	ii. The routine inspection will be done at the time of original registration and/or at time of renewal/and if the nature of the work is being changed, after prior intimation. Such routine inspection will be done at a time, which is unlikely to disturb /interfere with the treatment of the patient and/or doctor’s work.	No Provision
	iii. Surprise inspection would be done only when there is a written complaint from a patient or a representative body of patients/ citizens alleging non-compliance of the provision of the act. Suo moto inspection can be initiated by the LSA.	No Provision
	iv. In case of specific complaint, the Local Supervisory authority ordering inspection must record in writing the reasons for inspection. The procedure of inspection would be laid down in annexure. The LSA will designate the relevant govt. medical officer to be in charge of a team of three persons.	No Provision
	v. Person in charge of inspection should be a Medical Doctor, who may be assisted by others.	No Provision
	vi. The decision to do unscheduled inspection should be taken by the supervisory authority in cases of emergency or a serious complaint.	No Provision
	vii. Frivolous /vexatious complaint would be punishable with a fine of Rs.5000/-	No Provision
	viii. Nothing in this Act shall be deemed to deter any such officer to inspect any clinical/ medical record relating to any patient in a Nursing home by maintaining confidentiality and taking care that it doesn’t come into public domain.	No Provision
	ix. If any person refuses to allow any such officer to enter or inspect any such premises as aforesaid, or to inspect any such records as aforesaid or obstructs any such officer in the execution of his powers under this section, he shall be guilty of an offence under this Act and the registration will be liable to be cancelled or suspended.	No Provision
	x. Every nursing home shall maintain an inspection book for LSA & complaint book for patients.	No Provision

Income of Local Supervising Authority

	‘Draft Rules 2006’ -section 10	Revised draft rules Sept. 08
	i. Any fees or service charges received under this Act shall be paid into the fund of the local supervising authority, in a personal ledger account and used only for the implementation of the act and logistics for the same. ii. Part of the revenue collection, as decided by the State competent authority, will be deposited in personal ledger account of Director of Health Services for carrying out functions and responsibilities under BNHRA (expenses for inspection, TA/DA of members attending meeting etc.).	No Provision

Income of Local Supervising Authority

	‘Draft Rules 2006’ -section 10	Revised draft rules Sept. 08 -
	i. Any fees or service charges received under this Act shall be paid into the fund of the local supervising authority, in a personal ledger account and used only for the implementation of the act and logistics for the same.	No Provision
	ii. Part of the revenue collection, as decided by the State competent authority, will be deposited in personal ledger account of Director of Health Services for carrying out functions and responsibilities under BNHRA (expenses for inspection, TA/DA of members attending meeting etc.).	No Provision

Expenses of Local Supervising Authority

	‘Draft Rules 2006’ -section 11	Revised draft rules Sept. 08
	The LSA should be allocated suitable resources, which would include an office, clerk and data entry operator, clerk peon, computer and logistic expenses to conduct meetings and carry out it’s responsibilities including inspection of Nursing Homes, secretarial work, maintain records etc. If there are any legal formalities, fees of lawyer should paid from revenue generated. All the expenses incurred should be debited from amount of registration fees deposited in PLA.	No Provision

Penalty for offences under Act

	‘Draft Rules 2006’ -section 12	Revised draft rules Sept. 08
	Whoever contravenes any of the provision of this Act or of any rule shall, if no other Penalty is elsewhere provided in this Act or the rules for such contravention, on conviction, be punished with fine which may extend to five thousand rupees and in the case of a continuing offence to a further fine of fifty rupees in respect of each day on which the offence continues after such conviction up to six months following which the registration of the nursing home would be cancelled.	No Provision

Offences by Corporations

	‘Draft Rules 2006’ -section 13	Revised draft rules Sept. 08
	Where a person committing an offence under this act is a company or other body corporate, trust or society every person who at the time of the commission of the offence was a director, manager, secretary, agent or other officer or person specified in the registration form and concerned with the management thereof shall, unless the person proves that the offence was committed without his/her knowledge or consent be deemed to be guilty of such offence.	No Provision

Court competent to try offences under Act

	‘Draft Rules 2006’ -section 14	Revised draft rules Sept. 08
	No court other than that of Magistrate of first class shall take cognizance of any offence under this act.	No Provision

Indemnity to persons acting under this Act

	‘Draft Rules 2006’ -section 15	Revised draft rules Sept. 08
	No suit, prosecution or other legal proceeding shall be instituted against LSA or any person, which is done in good faith provided no laws are violated	No Provision

Indemnity to persons acting under this Act

<table>
<tr><th></th><th>‘Draft Rules 2006’ -section 16</th><th>Revised draft rules Sept. 08</th></tr>
<tr><td></td><td>Section 16 Subsection 2 Clause b
The date on which an application for registration or renewal of registration to be made and the fees to be paid for such registration or renewal of registration, “provided that State Government may prescribe different rates of fees for registration of nursing homes, having regard to the area in which such nursing home is situated, the number of beds therein, the number of specializations offered in such nursing home.</td><td>No Provision</td></tr>
<tr><td></td><td>RULE – 7 SUB – RULE (1) and (2)
The application Form…… should be accompanied with the registration fees.</td><td>Rule 4:..... Such application should be accompanied by fee prescribed.</td></tr>
<tr><td></td><td>Fees structure
<table><tr><th></th><th colspan="2">Rural</th><th colspan="2">Municipal</th><th colspan="2">Corporation</th></tr><tr><th></th><th>Reg</th><th>Renewal</th><th>Reg</th><th>Renewal</th><th>Reg</th><th>Renewal</th></tr><tr><td>Hospitals, Nursing Homes, Maternity home, any Health Centers upto 10 beds</td><td>2000</td><td>1000</td><td>3000</td><td>2000</td><td>4000</td><td>3000</td></tr><tr><td>Hospitals, Dental Hospitals, Nursing Homes, Health Centres with 11 to 30 beds</td><td>3000</td><td>2000</td><td>4000</td><td>3000</td><td>5000</td><td>4000</td></tr><tr><td>Hospitals, Dental Hospitals, Nursing Homes, Health</td><td>5000</td><td>4000</td><td>8000</td><td>5000</td><td>10000</td><td>8000</td></tr><tr><td>Centers with 31 to 100 beds</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>For each additional bed above 100 beds</td><td>20</td><td>10</td><td>30</td><td>20</td><td>40</td><td>30</td></tr></table></td><td>Rule 7: Fees for registration and renewal of registration
The fees to be paid for registration and renewal of registration shall be charged as under.
Rural Urban
Reg Renewal Reg Renewal

Per 10 Beds
1000 500 2000 1000</td></tr>
</table>

(We had suggested the registration fee as given in the table below. The rationale for this fee structure was also shared. The rationale is as follows –

Triannual Regulatory Expenses per 10 bedded hospital-

A team of three to four persons (Office Assistant, Clerk, Driver, Inspector/Medical Officer) would be required. Out of this only the inspector/Medical Officer would visit the hospital for physical inspection once in three years. This officer would spend in total half a day for one hospital – for examining the application form, visiting the hospital and making a report in a prescribed format. The support staff would also spend about half a day in the correspondence, and other deskwork. This team's monthly salary would be about Rs. 40,000/- (MBBS doctor gets a starting salary of Rs. 18,000/- per month). With average of 20 days' of working per month, the per day salary cost would be Rs. 2,000/-. Hence for covering one hospital, the salary cost would be Rs. 1,000/-. Add Rs. 250/- for an average petrol and DA expenses per hospital and Rs. 250/- (25% of salary) for other non-salary cost for office expenses. Total – Rs. 1,500/- per hospital. The triannual service charge for 10-bedded hospital can be Rs. 1,000/- R. 1,500/-, Rs. 2,500/- for rural, urban, metropolitan hospital respectively. Larger hospitals with multispeciality facilities would mean more complex work to inspect, approve and hence would pay more.)

	Rural	Urban	Metropolitan
Hospitals, Nursing Homes, Maternity home, any Health Centers upto 10 beds	1000	1500	2000
Hospitals, Dental Hospitals, Nursing Homes, Health Centres with 11 to 30 beds	1500	2750	3000
Hospitals, Dental Hospitals, Nursing Homes, Health Centers with 31 to 100 beds	2000	3000	4000
For each additional bed above 100 beds	20	30	40

EMERGENCY MEDICAL SERVICES

	'Draft Rules 2006' -section 16 RULE 13	**Revised draft rules Sept. 08 - RULE 17**
	1) All emergency patients attending a nursing home, wherever registered medical practitioner/s are engaged, must be attended primarily to provide basic life support without considering the financial capability of the patient, and then, may be referred with	All emergency patients attending a nursing home, wherever registered medical practitioners are engaged, must be attended primarily to provide basic life support without considering the financial capability of the patient, and then may be referred to suitable nearest referral hospital with medical report about the ailments, as early as possible if necessary. Golden Hour Treatment protocols should be followed.
	2) Each NH should have all logistics for emergency basic life support with trained medical and paramedical personnel	Each NH should have all logistics for emergency basic life support with trained medical and paramedical personnel.
	3) LSA will be District EMS authority and in cases of disaster or emergency patients will have access to nearest NH as far as basic life support is concerned.	No Provision
	4) Every Nursing Home has the professional obligation to extend services with due expertise basic life support measures for protecting life in emergency or disaster.	Every Nursing Home has obligation to extend its services with due expertise for protecting life in emergency or disaster

Rules regarding Registration

	‘Draft Rules 2006’ -section 16 RULE 8,9,10 & 11	Revised draft rules Sept. 08 - RULE 8,9,10,11,12
	Rule 8 :- Transfer of ownership of nursing home – Transfer of ownership or management of nursing home should be informed to LSA within 72 hours jointly by transferor and transferee. The transferee shall make an application	**Rule 8 :- Transfer of ownership of nursing home-** Immediately after transfer of the ownership or management of a nursing home, the transferor and transferee shall jointly communicate the transfer affected to the Local Supervisory Authority and the transferee shall make an application for registration in accordance with Rule 4. In case the Nursing home ceases to function, the certificate of registration shall be surrendered to Local Supervisory Authority.
	Rule 9: - Change in address – Any change in address shall be communicated to LSA not later than 15 days of such change.	**Rule 9: - Change in address:** A person registered under the act in respect of nursing or maternity home shall communicate to the Local Supervisory Authority any change in his address or situation of Nursing Home in respect of which he is registered not later than seven days after such changes.

	Rule 10: - Change in staff – Any change in medical or nursing staff together with dates on which changes have taken place shall be communicated to LSA not later than 15 days of such change.	**Rule 10: - Change in staff –** Any change in medical, nursing, midwifery or other staff together with dates on which such change has taken place shall be communicated to the Local Supervisory Authority and in any case not later than seven days of such change.
	. No Provision	**Rule 11. Change in facilities/construction/up-gradation:** Any change in construction, facility and up-gradation of services provided to the patients should be communicated to the Local Supervisory Authority together with dates on which such change has taken place and in any case not later than one month of such change. * No fees shall be payable for changes informed under rule 8, 9, 10 and 11.
	Rule 11: - Lost Certificate: If a certificate of registration is lost or destroyed the holder may apply for fresh certificate. A Certificate marked as "duplicate" will be issued on payment of Rs. 500	**Rule 12. Lost Certificates-** In the event of certificate of registration being lost or destroyed, the holder may apply to the Local Supervisory Authority for fresh certificate, and the Local Supervisory Authority, may if think fit, issue such certificate upon payment of fees of Rs 1000. A certificate issued under this rule shall be marked '' Duplicate ''

Standard charter of patients' rights

	'Draft Rules 2006' -section 16 RULE 14	**Revised draft rules Sept. 08 - RULE 18**
1	No person suffering from HIV may be denied care only on the basis of the HIV status, provided the curative or diagnostic care is available at the NH. Not having a Voluntary Testing and Counseling Center cannot become grounds to refuse care. For management of patients who is HIV positive, the nursing home would follow guidelines circulated from time to time by NACO (National AIDS Control Organization)	Person suffering from HIV/ AIDS must not be denied care.
2	Every nursing home shall maintain an inspection book and a complaint register (for the patients party), which shall be produced before the LSA as and when required.	Complaint register should be kept in Nursing Home at reception counter.
3	. No Provision Every nursing home shall make available as a routine, to any patient a rate card mentioning all charges of the Nursing Home. Basic charges like bed charges, daily consultation charges for outpatients and inpatients, visit fee charges for ICU and non-ICU patients should be displayed on a board at a suitable place for the patients.	(Rule 19). Display of standard rates of treatment: Nursing homes shall have printed brochures of standard rates charged for various treatments and services provided e. g. Consulting fees, normal and caesarian deliveries, minor and major surgeries, various diagnostic tests, overnight stay charges, OT charges etc.
	All nursing homes must adopt a Standard Charter of Patient's Rights, observe it and orient their staff for the same. This Standard Charter of Patient's Rights would include that – A) The patients and / or Person authorized by patient should receive The relevant information about the nature, cause, likely outcome of the present illness. The relevant information about the proposed care, the expected results, possible and the expected costs and likely complications.	No such explicit provisions made. Standard Charter of Patient's Rights would include that- The patients and / or Person authorized by patient or his or her next kin must receive the relevant information about the nature, cause of illness, proposed care, the expected results of treatment, possible complications and the expected costs.

	B)	Patient and/ or person authorized by patient has a right to have - An access to his / her clinical records at all times during admission to NH - Photocopy should be available within 24 hrs when admitted to NH or within 72 hrs of making an application after discharge or death after paying fees for photocopy. - A discharge summary at the time of discharge, which should contain: The reasons for admission, significant clinical findings and results of investigations, diagnosis, treatment and the patient's condition at the time of discharge. In a language and manner any lay person can understand, follow-up advice, medication and other instructions and when and how to obtain urgent care when needed in an easily understandable manner. In case of death, the summary of the case should also include the cause of death.	No Provision
	C)	Treating patient information as confidential.	No Provision
	D)	Patient has a right to personal dignity and privacy during examination, procedures and treatment.	Privacy During Examination
	E)	Patient and family rights include informed consent before anesthesia, blood and blood product transfusions and any invasive / high-risk procedures / treatment. Informed consent includes information in a language and manner that the patient can understand, on risks, benefits, and alternatives if any and as to who will perform the requisite procedure. nformation and consent before any research protocol is initiated (see below)	No Provision
	F)	Patient and family rights include information on how to voice a complaint. Appropriate procedure for grievance redressal must be put in place by the hospital.	Complaint register should be kept in Nursing Home at reception counter.

	G)	Rights of women as patients - Privacy during examination. In case of examination by male doctor, a female attendant must be present. - Right to confidentiality of reports and information not to be disclosed to any person other than one who is authorized by the patient - Confidentiality of HIV positive patients	No Separate Provisions For Women
	H)	Patient has the right to seek second opinion. All medical and diagnostic reports must be made available to the patient or authorized person to facilitate second opinion. The expert giving second opinion should give it in writing and after talking the current doctor in charge to know the rationale of the current management.	No Provision
	I)	Non-discrimination on the basis of HIV status - Patients and families should be informed about the above rights in a format and language, that they can understand - Patients and family are informed about the financial implications when there is a change in the patient condition or treatment setting.	Person suffering from HIV/ AIDS must not be denied care.
	J)	In case of Nursing Homes undertaking clinical research- Documented policies and procedures should guide all research activities in compliance with national (ICMR) guidelines.	No Provision
	K)	Right to buy prescribed drugs from any medical store/ and of any standard brand of the same medicine, from any pharmaceutical shop.	No Provision

Medical Records

	'Draft Rules 2006' -section 16 RULE 15	**Revised draft rules Sept. 08**
	MEDICAL RECORDS: Maintenance of medical records of all patients attending the nursing home is of utmost importance. The "OPD paper" of a patient attending the OPD should contain the doctor's name and detailed clinical notes including patient's name, age, occupation, chief complaints, onset/ duration/progress of illness, past history, personal history, family history, detailed examination findings, provisional diagnosis and treatment advised. A separate prescription should be written out for the medication that has been advised. The OPD paper should be given to the patient along with X-rays and all investigation reports. Nursing homes should maintain a copy of the OPD paper. All indoor papers should be complete, i.e. clinical notes (as detailed above) should be written along with whatever treatment has been given during the admission and reports of investigation carried out.	No Provision
	INDOOR RECORDS The nursing home shall keep the following registers of the patients received or accommodated or both at the nursing home as an out-door or in-door patient namely: - a) Register of admission /discharge /death of the patient; c) Records of treatment, both outpatient and inpatient. These registers shall be entered fully, chronologically and legibly. Copies of which shall be kept in the record room of the nursing home concerned for at least 5 years. The information in this regard shall be supplied to the LSA, as and when required.	No Provision

Functional Programme of Nursing Home

	‘Draft Rules 2006’ -section 16 RULE 16	Revised draft rules Sept. 08
	THE SPECIALITIES PROVIDED AND LIST OF DMOs AND SPECIALIST DOCTORS ALONG WITH THEIR QUALIFICATIONS SHOULD BE DISPLAYED AT PROMINENT PLACE IN NURSING HOME.	No Provision
	The basic minimum functions provided by a nursing home should include the following: **1. EMERGENCY FIRST AID:** In case a patient had been admitted in such a facility for more than 24 - 48 hours, and in case the patient is in a critical condition, it is expected that the patient will be transferred with a medical attendant *accompanying the patient and all medical records (including X-rays, investigation reports, clinical notes) will be made available to the next doctor who will be treating the patient. It is also expected that the doctor who had treated the patient initially will keep in touch with the institution to which the patient has been transferred in order to remain aware of the patient’s condition. This may not be applicable for patients leaving the premises Against Medical Advice (AMA). * As far as possible, the Medial Attendant or the DMO should accompany the patient at the time of transfer if patient’s condition requires so	No provision for medical attendant accompanying the patients in critical condition, while transferring.
	2. Maternity Facilities: All nursing homes providing maternity facilities should provide basic obstetric facilities and neonatal facilities. All maternity homes should be able to carry out procedures like suction and evacuation, dilatation and curettage, Lower Segment Cesarean Section and Hysterectomy on an emergency basis. Blood transfusion facilities should be available with nearest blood bank. Maternity home should have gynaecologist /surgeon, anaesthetist and paediatrician on panel. In villages with less than 10,000 population deliveries without high-risk pregnancy can be handled when above-mentioned facilities are not available. These should be labeled as Maternity homes with facilities of basic obstetric care, which should have minimum facility of delivery table, emergency tray, oxygen cylinder, suction machine (electric and foot operated), basic instruments required for normal delivery & episiotomy.	No Provision

	3. Co-operation in the National Health Programmes – Nursing homes should maintain records of all cases of notifiable diseases and this record must be available to the regulating bodies for checking on a periodic basis. LIST OF DISEASES TO BE REPORTED TO LOCAL SUPERVISORY AUTHORITY (LSA) Cholera Plague Diphtheria Neonatal Tetanus Acute Flaccid Paralysis Japanese Encephalitis Dengue Infective Hepatitis Gastroenteritis AIDS Leptospirosis SARS Avian Influenza Malaria Chikungunya	**Rule 21- Diseases to be reported to Local Supervisory Authority:** Reporting of diseases to the Local Supervisory Authority after confirmation of diagnosis. List of diseases enclosed (Annexure 2). LIST OF DISEASES TO BE REPORTED TO LOCAL SUPERVISORY AUTHORITY (LSA) Cholera Plague Diphtheria Neonatal Tetanus Acute Flaccid Paralysis Japanese Encephalitis Dengue Infective Hepatitis Gastroenteritis AIDS Leptospirosis SARS Avian Influenza Malaria Chikungunya

Minimum equipments required for Nursing Home

	'Draft Rules 2006' -section 16	**Revised draft rules Sept. 08 - Rule 15**
1	All instruments equipments required for emergency & Basic life support.	All instruments equipments required for emergency & Basic life support.
2	Emergency Tray	Emergency Medicine Tray
3	One suction machine & one standby foot suction machine	One suction machine & one standby foot suction machine
4	Minimum one oxygen cylinder for 8 beds with one standby cylinder	Minimum one oxygen cylinder for 8 beds with one standby cylinder
5	All basic instruments & equipments of speciality of nursing home	All necessary instruments & equipments required for concerned specialty
6	Fire fighting equipment	Fire fighting equipment.
7	Dressing trolly	Dressing trolley
8	ECG Machine	No Provision

Minimum equipments required for Maternity Home

	'Draft Rules 2006'	**Revised draft rules Sept. 08**
	1) Foetal monitor	No Separate Provisions For Maternity Homes
	2) Labour table	
	3) Neonatal Rescutitation Resuscitation kit	
	4) One suction machine with generator connection & one standby foot suction machine	
	5) Minimum one oxygen cylinder for 8 beds with one standby cylinder.	
	6) Minimum one infant warmer.	
	7) All instruments equipments required for emergency & Basic iife support (CPR)	
	8) Emergency Tray	
	9) Fire fighting equipment.	
	10) Dressing trolly.	
	11) Instruments & equipments required for Emergency obstetric care. (LSCS, Obstetric hysterotomy, Forceps, Ventouse)	
	12) ECG Machine	

Minimum requirements of O.T.

	'Draft Rules 2006'-------section 16	**Revised draft rules Sept. 08------ Rule 16**
1	Operation Table	Operation Table
2	Boyles Machine with four stand by cylinders	Anesthesia Machine with four stand by cylinders & accessories for anesthesia.
3	Laryngoscope with 5 blades	No Provision
4	Endotracheal Tubes of various all sizes with connections.	No Provision
5	Pulse oxymeter (Is this needed in every small nursing home ???????- it should not be included.)	Pulse oxymeter
6	Electric suction machine with generator connection	Electric suction machine with generator connection
7	Foot suction machine	Foot suction machine
8	Emergency tray	Emergency tray
9	Electric autoclave with additional stand by.	All necessary facilities for proper sterilization of O.T. suit
10	Fixed or mobile shadow less lamp.	Fixed or mobile shadow less lamp
11	Minimum required instruments & equipments for particular speciality.	Minimum required instruments & equipments for particular specialty
12	Cautry if major surgeries carried out.	No Provision
13	O.T. Care machine	No Provision

MINIMUM REQUIREMENTS FOR ICU

	'Draft Rules 2006'-------section 16	**Revised draft rules Sept. 08------ Rule 20**
	MINIMUM REQUIREMENTS FOR 8 BEDED BEDDED ICU:	**MINIMUM REQUIREMENTS FOR ICU:**
1	Floor space 120 sq ft per bed	Floor space 75 sq ft per bed
2	Central oxygen system or one oxygen cylinder per bed with two standby cylinders	Central oxygen system or one oxygen cylinder per bed with two standby cylinders
3	Two suction machines and one foot suction Machine	Two suction machines and one foot suction Machine
4	Each bed separated by curtain	Each bed separated by curtain
5	Bedside monitoring of ECG, SPO2, NIBP with central monitor	Bedside monitoring of ECG, SPO2, NIBP with central monitor
6	Ventilator (minimum pressure generator) with defibrillator	Ventilator (minimum pressure generator) with defibrillator
7	Attached toilet	No Provision
8	One MBBS Doctor on duty with Physician (Medical ICU)/ Surgeon (Surgical ICU) on call.	One MBBS Doctor on duty with Physician (If Medical ICU) / Surgeon (If Surgical ICU) on call.

REQUIREMENT OF HUMAN RESOURCE

<table>
<tr><td></td><td>‘Draft Rules 2006’-------section 16, Rule 17</td><td>Revised draft rules Sept. 08-----Rule 13</td></tr>
<tr><td></td><td>REQUIREMENT OF HUMAN RESOURSE RESOURCE
Duty Medical Officer: MBBS, BAMS, or BHMS should have completed one year of internship. Responsibility regarding clinical decisions, procedures etc. is that of the consultant and not the DMO. He should be available round the clock. If in charge of nursing home resides adjacent to nursing home, DMO is not necessary.</td><td>Staffing norm
Resident Medical Officer shall not be less than MBBS medical graduate rendering services round the clock.</td></tr>
<tr><td></td><td>No Provision</td><td>Resident or visiting Doctors should have successfully completed mandatory service either in Government or Corporation as laid down in Government Resolution wherever applicable and same should be substantiated by producing certification from competent authority.</td></tr>
<tr><td></td><td>Nursing staff:
One nurse for every 10 beds on shift duty (total 4 nurses per 10 beds.)</td><td>Nursing staff:
One nurse for every 10 beds in each shift (total 4 nurses per 10 beds.)</td></tr>
<tr><td></td><td>Three qualified nurses for labour room. One in each eight-hour shift</td><td>No Provision</td></tr>
<tr><td>.</td><td>STAFFING NORM
<table>
<tr><th>No</th><th>Category of staff</th><th>No of beds</th><th>Number to be provided</th></tr>
<tr><td>1.</td><td>Resident medical officer</td><td>10 patients or its part</td><td>1 round the clock</td></tr>
<tr><td>2</td><td>Registered nurse or midwife</td><td>5 patients or its part</td><td>1 round the clock</td></tr>
<tr><td>3</td><td>General duty assistant</td><td>3 patients or its part</td><td>1 round the clock</td></tr>
<tr><td>4</td><td>Sweeper</td><td>5 patients or its part</td><td>1 round the clock</td></tr>
</table></td><td>STAFFING NORM:
The minimum staff for 10 bedded Nursing Home :

Sr No Category of staff No of beds
----
1. Resident medical officer ------- 1 in each shift
2. Registered nurse or midwife
----1 per 10 beds in each shift
(Total 4 nurses per 10 beds)
----------</td></tr>
</table>

PHYSICAL STANDARDS FOR NURSING HOME

	'Draft Rules 2006'-------section 16,Rule 18	**Revised draft rules Sept. 08------ Rule 14**
	It is recommended that for existing registered nursing homes for renewal of registration, there may be a relaxation of 25% as regards space requirements like OT, toilets etc. except the per bed floor space. (The provision of exemption would defeat the very purpose of the standard setting and. would foster corruption.)	Norms of physical structure for Nursing Home: These criteria may not be applicable to existing registered Nursing or Maternity Homes, however the newly coming up Nursing Homes shall adhere to the minimum standard norms laid down Annexure 1.
1	**PHYSICAL STANDARDS:** **Entrance zone:** Reception and Registration: sufficient space for receptionist, furniture and waiting area for patients including drinking water facility and toilets should also be provided.	Nursing Home with more than 30 beds should have independent entrance zone (Reception).
2	**Ambulatory zone** a. Nursing station / may overlap with reception/ registration area.	Nursing Home with more than 30 beds should have independent ambulatory zone (OPD).
3	**Diagnostic zone:** Laboratory	Nursing Home with more than 30 beds should have independent Diagnostic zone.

4	**Intermediate zone** **Wards :-** 1) Fire fighting equipment 2) Emergency Tray 3) Oxygen cylinder with ventimask 4) Suction machine 5) Dressing trolly a) Wards should be relegated at the back to ensure quietness and freedom from unwanted visitors. b) Beds would conveniently correspond to the ratio for provision of W.C. facilities. c) Separate ward units shall be provided for male and female patients. (Is this really necessary. Many small good hospitals do not have such a separation) d) Every patient shall have access to a toilet area without having to enter the general corridor area. **Operation Theatre** Demarkated by a redline and separated by compartment and door. It Should have 1) Clean zone 2) Neutral zone – Changing and scrubbing room with O.T. stretcher 3) Sterile zone – Must have mobile/ shadow less lamp, Boyle's Machine, Operation Table with head low, uptown, Suction machine.	Nursing Home with more than 30 beds should have independent intermediate zone (ward).
5	Ambulatory Zone-Clinic with consultation & examination room	Nursing Home with more than 30 beds should have independent ambulatory zone (OPD).

6	**Critical Zone** **Delivery room.** 1) All maternity homes and all nursing homes offering maternity services shall make provisions for a delivery room 2) In maternity homes an arrangement must be possible to isolate a patient of ecclampsia. A specific ecclampsia room/ward may be provided for every twenty post natal beds. 3) A neonatal unit should be provided in nursing homes providing obstetric facilities or should be accessible in near vicinity or services of pediatrician on call basis should be available.	Nursing Home with more than 30 beds should have independent critical zone (operation theatre labor room).
7	**Service zone** Space for storage of oxygen & nitrous oxide cylinders: Enough reserve cylinders should be kept. Generator / Inverter: In case of a power failure, all Essential equipments, instruments and electrical points of the nursing home should be able to work as normal.	No Provision

PHYSICAL CRITERIA FOR DIFFERENT UNITS

	'Draft Rules 2006'-------section 16,Rule 18	**Revised draft rules Sept. 08-----Annexure 1**
Items	**Area Provisions**	**Area Provisions**
Minimum floor space per bed in ward	65 sq.ft in a ward accommodating not less than 4 patients	65 sq. ft in a ward
Minimum distance between centers of two beds	6 ft	6 ft
Minimum clearance between bed and wall	60 mm	No Provision
Minimum width of doors in the wall	3 ft	3 ft
Minimum height of dado in all wards	3.94 m	3 feet
Minimum area to be provided for the bath & toilet	36 sq. ft	36 sq. ft
Number of urinals	1 per 16 beds	No Provision
Number of toilets and baths	1 per 8 beds	1 per 8 beds
Number of Wash basins	1 per 10 beds	1 per 10 beds
Clean zone, Neutral zone of OT	100, 120 sq feet respectively	100, 120 sq feet respectively (if operation theatre is available)
Minimum area for operation theater (sterile zone) and minor OT, if operation theatre	Up to 10 beds and minor OT---140 sq. ft >10<30---200 sq. ft >30----300 sq. ft	140 sq. ft (No differentiation, of required area, according to number of beds)
Minimum area for instrument sterilization	50 sq. ft	No Provision
Minimum area for scrub up	25 sq. ft	No Provision
Minimum area for pantry (NH more than 20 beds)	80 sq. ft	80 sq. ft
Labour room	With 2 delivery tables per 5 maternity beds + Toilet-------- 140 sq feet + 20sq feet	With delivery table + Toilet if available------140 sq feet + 20sq feet

Minimum area for nursing station	100 sq. ft (with toilet)	No Provision
Minimum area for RMO' s room	100 sq. ft (with toilet)	No Provision
Dental/Eye/ENT clinic with equipments	140 sq. ft	No Provision
Delivery room	120 sq. ft	No Provision
Minimum area for USG or TMT	As PNDT Guidelines	No Provision
Minimum area for laboratory:	Small -120 sq. ft+ 40 sq. ft Medium-160 sq. ft + 60 sq. ft Large-210 sq. ft + 72 sq. ft	No Provision
Minimum area for Physiotherapy unit with Equipments	160 sq. ft	No Provision
Ward store	100 sq feet	No Provision
Trolley bay	30 sq feet	No Provision
Doctor room + Toilet	50 sq ft + 20 sq ft	No Provision
Consulting room & Examination room with toilet	140 sq feet	140 sq feet
Room for infant warmers for Maternity homes	100 sq feet for two infant warmers	If available-100 sq feet for two infant warmers
Nurses room + toilet	50 sq.ft + 20 sq.ft	No Provision

Building Engineering Environmental Standards

	'Draft Rules 2006'-------section 16,Rule 19	**Revised draft rules Sept. 08-----Rule 15**
1	**Location** The site should be compatible with other considerations such as accessibility and availability of services and should be approved by the town planning department or the appropriate authority.	No Provision
2	If the nursing home is situated in premises of housing society – Change of user certificate from society (from residential to commercial) is essential.	No Provision
3	Ceilings – R.C.C./ False ceiling	No Provision
4	Floor Height The height of all the rooms in the hospital should not be less than 3.00m and not more than 3.65m, measured at any point from the surface of the floor to the lowest point of the ceiling.	No Provision
5	Floors and Walls The architectural finishes in hospitals shall be of high quality in view of maintenance of good hygienic conditions. The walls should be impervious with oil paint. Floors should be covered with good quality tiles with non slip surface. The aim being that floor materials shall be readily cleanable and appropriately wear-resistant. Floors should be smooth so as to allow smooth passage of wheelchairs and trolleys. Wall finishes shall be washable and shall be smooth Wall bases in areas that are frequently subject to wet cleaning shall be covered with the tiles. Floor and wall areas penetrated by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed. Operating room / Labour room/Delivery room should be made dust-proof and moisture proof. Walls of operation theatre, delivery room, recovery room, and scrub room should be partly covered with dado tiles In other areas of critical zone, tiling should be provided uptil a height of 1.2m.	No Provision
6	**Doors:** The minimum door width for patient use shall be (2 feet 10 inches) 86cms	No Provision

<table>
<tr><td>7</td><td>Water Supply, Plumbing And Other Piping Systems
Supply 350 liters of potable water per day per bed to meet all requirements (including laundry) Systems should be designed to supply water at sufficient pressure. Within the operation theatre there should not be any drains. The material used for plumbing fixtures shall be non-absorptive and acid-resistant.</td><td>No Provision</td></tr>
<tr><td></td><td>For more than 20 beds (if central oxygen system is available)
<table>
<tr><th></th><th>Oxygen</th><th>Vaccum</th><th>Nitrous oxide</th></tr>
<tr><td>Operation</td><td>Two outlets</td><td>Three outlets</td><td>Two outlets</td></tr>
<tr><td>Delivery room, LDR room,</td><td>Two outlets</td><td>Three outlets</td><td>One outlet</td></tr>
<tr><td>Obstetric recovery room</td><td>per room</td><td>per room</td><td>per room</td></tr>
<tr><td>Labour room</td><td>Separate outlet for each bed</td><td>One outlet accessible to each bed</td><td>One outlet accessible to each bed</td></tr>
<tr><td>Recovery</td><td>Separate outlet for each bed</td><td>Separate outlet for each bed</td><td>One outlet accessible to each bed</td></tr>
<tr><td>Nursing</td><td>One outlet accessible to each bed</td><td>One outlet accessible to each bed</td><td>One outlet accessible to each bed</td></tr>
<tr><td>First aid and emergency treatment</td><td>Separate outlet for each bed</td><td>Separate outlet for each bed</td><td>Separate outlet for each bed</td></tr>
</table></td><td>No Provision</td></tr>
<tr><td></td><td>Oxygen cylinders
Operating theatre - Three cylinders
Wards - Two cylinders/8 beds
Delivery room - Two cylinders</td><td>Minimum one oxygen cylinder for 8 beds with one standby cylinder</td></tr>
<tr><td>9</td><td>For less than 20 beds
One suction apparatus for every eight beds.
One suction apparatus for operating theatre.
One suction apparatus for delivery room</td><td>One suction machine & one standby foot suction machine</td></tr>
</table>

10	Electrically operated automatic control lifts or Ramp shall be provided in all categories of hospitals having more than one story. The lift should be easily accessible from all entrances of the hospital. Lifts should be conveniently situated near ward and operation theatres departments. There should be approval from inspector of Lifts and escalators for the lifts. There shall be sufficient space near the landing door for easy movement of stretcher/trolley. Lift should be large enough to accommodate a trolley, a wheel chair and 3-4 persons at a time.	No Provision
11	Ramp should provided for movement of patients from ground to upper floors required in case lift is not available or in situation of power failure when lift is available	No Provision
12	Fire-fighting system Efficient fire fighting systems should be installed in every nursing home.	Fire fighting equipment

By-laws

	'Draft Rules 2006'-------section 17	**Revised draft rules Sept. 08------Rule 20**
1	The local supervisory authority can make By-laws not inconsistent with this act or rule Prescribing the records to be kept of the patients received in nursing home and in case of maternity home, of miscarriages, abortion or still births occurring in the nursing home and of children born therein and of the children so born who are removed from the home otherwise than to the custody of care of any parent, guardian or relative.	No Provision
2	No by-law made by local supervisory authority shall come into force until it has been confirmed by the state Govt with or without modification.	No Provision
3	All bylaws made under this section shall be published in official gazette.	No Provision
4	Whoever contravenes any of the provision of this Act or of any rule shall, if no other penalty is elsewhere provided in this Act or the rules for such contravention, on conviction, be punished with fine which may extend to five thousand rupees and in the case of a continuing offence to a further fine of fifty rupees in respect of each day on which the offence continues after such conviction up to six months following which the registration of the nursing home would be cancelled.	No Provision

Exclusion from the Act

	'Draft Rules 2006'-------section 18	**Revised draft rules Sept. 08**
	Nothing in this act shall apply to a) Any nursing home carried on by Government, Corporation, Municipality Mental Hospitals who are governed by Mental Health Act 1987.	No Provision

Repeal

	'Draft Rules 2006'	**Revised draft rules Sept. 08------Rule 22**
	No Provision	The Maharashtra Nursing Home Registration Rules 1973 are hereby repealed, except as respects things done or omitted to be done there under.

Special provision in Form B

	'Draft Rules 2006'	**Revised draft rules Sept. 08----Form B, entry n.25**
	No Provision	Whether Nursing Home has obtained authorization from Maharashtra Pollution Control Board for disposal of Biomedical Waste and functional Infection control committee.

Mention of other Laws Related with Nursing Home

	'Draft Rules 2006' ---Annexure - I	**Revised draft rules Sept. 08**
	Laws in relation to Nursing homes, which are to be followed. So not mentioned in rules. 1) Indian Penal Code sections – 52, 80, 87, 88, 90, 92, 270, 304 A , 320. 2) Indian Medical Council Act 1956 with amendment 1964 section 20 A & 33(m) 3) Indian Medical Council (professional conduct, etiquette and ethics) Regulations 2002 4) Consumer protection act 5) MTP Act 1971 6) The Transplantation of Human Organs Act 1994 7) PNDT Act 1994 8) BMW Act 1998 9) The Epidemic Diseases Act 1897 10) The Drugs and Cosmetics Act 1940 11) The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 12) Atomic Energy Act 1962 13) Minimum Wages Act 14) Different legal provisions governing service conditions of employees in private sector. 15) FDA Guidelines regarding functioning of Blood Bank and preparation of Blood components 16) Bombay Public Trust act section 41 AA for charitable hospitals 17) Mental Health act 1987 18) Birth and Death registration act (Amendment 2006) dated 08.02.06 Note: The nursing homes will abide by the rules and procedures under above-mentioned acts.	No such mention

Forms under BNHRA Proposed Rules 2006 and 2008
Proposed Rules 2006-SECTION – 5 Rules 3

FORM 'A'

Register showing names of persons registered under section 5 of the (Bombay) Nursing Homes Registration Act, 1949.

Name (in full) of the applicant	Full address of the applicant	Nationality of the applicant	Name & other particulars of the nursing home in respect of which the applicant is registered	Places where the Nursing home is situated	Total number of patients for whom the nursing home		Number & date of registration	Date of renewal of registration
					Maternity patients	Other patients		
1	2	3	4	5	6	7	8	9

Proposed Rules 2008- Rules 3

FORM 'A'

Name (in full) of the applicant	Full address of the applicant	Nationality of the applicant	Name & other particulars of the nursing home in respect of which the applicant is registered	Places where the Nursing home is situated	Total number of patients for whom the nursing home		Number & date of registration	Date of renewal of registration
					Maternity patients	Other patients		
1	2	3	4	5	6	7	8	9

Proposed Rules 2006-Annexure -2

FORM 'B'

(See rules 4 & 6)

Application for Registration / Renewal of registration under section 5 of the Bombay Nursing Homes Registration Act, 1949.

The replies to be written in this column

1	Full name of the applicant	
2	Full residential address of the applicant	
3	Technical qualification if any, of the applicant	
4	Nationality of the applicant	
5	Situation of the registered or principal office of the Company, Society, Association trust or other body corporate.	
6	Nature of firm - ownership, partnership, trust, society	
7	Name & other particulars of the nursing home in respect which the registration is applied for	
8	Type of Nursing home 1) Maternity home with O.T. 2) Maternity home without O.T. 3) General Nursing home 4) Others (please specify)	
9	Place where nursing home is situated with phone no	

In case the application is made on behalf of a Company, Society, trust, Association or other body corporate the name & residential address of the person in charge of the management of such Company, Society, Association or body corporate should be given. This item is applicable only when the application is made on behalf of a Company, Society, association or other body corporate.

10	Brief description of the construction, size & equipment of the nursing home or any premises used in connection therewith as detailed below :-
(i)	Plan of construction approved by local authority(Gram panchayat, Municipality, Corporation) –For New
(i)	Floor space of beds provided – Per square foot
(ii)	Arrangements made for medical check – up & immunization of the employees.
(vi)	Generator available (with connection to suction machine)

11	(a) Number of beds for maternity patients
	(b) Number of beds for other patients
12	Names, ages & qualifications of the members of the nursing staff in the nursing home.
13	Place where the nursing staff is accommodated.
14	Names, ages & qualification of the resident or visiting physicians or surgeons in the nursing home.
15	Names with qualifications of medical and paramedical staff in case of Lab, X-ray, C.T., USG, MRI, other diagnostic facilities
16	(a) Whether the nursing home is under the supervision of qualified nurse & if so, his & her name, age & qualifications.
17	Whether any person of alien nationality is employed in the nursing home & if so, his name & other particulars.
18	Names of specialities, Concerned Doctors, DMO displayed.
19	No & date of expiry of the certificate of registration.(in case of renewal)

I solemnly declare that the above statements are true to the best of my knowledge and belief.

Date Signature of the Applicant.

Proposed Rules 2008-

FORM 'B'

(See rules 4 & 6)

Application for Registration / Renewal of Registration under section 5 of the Bombay Nursing Homes Registration (Amendment) 2005 Act

The replies to be written in this column

1	Full name of the applicant	
2	Full residential address of the applicant	
3	Technical qualification if any, of the applicant	
4	Nationality of the applicant	
5	Situation of the registered or principal office of the Company, Society, Association trust or other body corporate.	
6	Nature of Nursing home - owned by individual, partnership, trust.	
7	Name & other particulars of the nursing home in respect which the registration is applied for	
8	Type of Nursing home Maternity home. 2) Nursing home with specialties	
9	Place where nursing home is situated with phone no.	
10	Brief description of the construction, size & equipment of the nursing home or any premises used in connection therewith as detailed below :-	
(i)	Plan of construction approved by local authority (Gram panchayat, Municipality, Corporation) -For New	
(ii)	Floor space of ward – with number of beds and total area for beds in ward in respect to floor space per bed.	
(iii)	Arrangements made for medical check – up & OPD injections.	
(iv)	Generator available (with connection to suction machine)	
v)	Floor space of Other rooms with details of user and area.	
vi)	Details of arrangements made for sanitary convenience for patients, employees and visitors giving their numbers.	

vii)	Details of arrangement made for storage and service of food in case hospitals giving diet to patients, Nursing home with more than 50 beds should provide diet to patients.	
11	Information of cleaning arrangement.	
12	**(i) Staffing Norms :** Whether the nursing home has (a) One nurse for every 10 beds on shift duty (total 4 nurses per 10 beds). - (Yes/No) (b) Availability of staff in any shift (Duty allotted in 3 shifts) - (Yes/No) --- Sr no Category of staff No of beds --- 1. Resident medical officer 1 in each shift 2. Registered nurse or midwife in each shift 1 per 10 beds --- Whether Resident Medical Officer shall be qualified MBBS medical practitioner available round the clock - (Yes/No) Whether Resident or visiting Doctors have successfully completed mandatory service either in Government or Corporation as laid down in Government Resolution wherever applicable and whether same is substantiated by certification from competent authority **(ii) Minimum Requirement for Nursing Home :** • Whether the following instruments equipments required for emergency & Basic life support. available - (Yes/No) • Emergency Medicine Tray • One suction machine & one standby foot suction machine • Minimum one oxygen cylinder for 8 beds with one standby cylinder • All basic instruments & equipments of specialty of nursing home. • Fire fighting equipment. • Dressing trolley.	

	(iii) Whether following equipments available for Operation Theatre: - (Yes/No) • Operation Table • Anesthesia Machine with four stand by cylinders • Pulse oxymeter • Electric suction machine with generator connection • Foot suction machine • Emergency tray • Electric autoclave with additional stand by. • Fixed or mobile shadowless lamp. • Minimum required instruments & equipments for particular specialty. • All necessary facilities for proper sterilization of O.T. suit **(iv) Whether following requirements are fulfilled for ICU : - (Yes/No)** (a) Floor space 75 sq ft per bed (b) Central oxygen system or one oxygen cylinder per bed with two standby cylinders (c) Two suction machines and one foot suction Machine (d) Each bed separated by curtain • Bedside monitoring of ECG, SPO2, NIBP with central monitor • Ventilator (minimum pressure generator) with defibrillator • One MBBS Doctor on duty with Physician (If Medical ICU) / Surgeon (If Surgical ICU) on call.	
13	Number of beds for maternity patients	
	Number of beds for other patients	
14	Names, ages & qualifications of the members of the nursing staff in the nursing home.	
15	Dedicated changing room with toilet facilities for female staff.	

16	Names, ages & qualification of the resident or visiting physicians or surgeons in the nursing home. All Resident and visiting Doctors should have successfully completed mandatory Government service as required by Government wherever applicable and accordingly should produce certification from competent authority	
17	Names with qualifications of medical and paramedical staff in case of Lab, X-ray, C.T., USG, MRI, other diagnostic facilities if available.	
18	Name and qualifications of administrative and clinical head of hospital. Nursing home with more than 50 beds shall have separate administrative and clinical heads.	
19	Whether the nursing home has qualified nurse, midwife as per norms, give details	
20	Whether any person of alien nationality is employed in the nursing home & if so, his name & other particulars.	
21	List of Fees charged to patients available.	
22	Names of specialties, Concerned Doctors, DMO displayed.	
23	Whether the applicant is interested in any other nursing home or business and if so the place where such nursing home is situated or whether such business is conducted.	
24	Date of expiry of the certificate of registration.(in case of renewal)	
25	Whether Nursing Home has obtained authorization from Maharashtra Pollution Control Board for disposal of Biomedical Waste and functional Infection control committee.	

I solemnly declare that the above statements are true to the best of my knowledge and belief.

Date Signature of the Applicant.

* In case the application is made on behalf of a Company, Society, Trust, Association or other body corporate the name & residential address of the person in charge of the management of such Company, Society, Association or body corporate should be given. This item is applicable only when the application is made on behalf of a Company, Society, association or other body corporate.

Proposed Rules 2006

FORM 'C'

Certificate of Registration under Section 5 of the Bombay Nursing Homes Registration Act, Amendment 2006

(Under Rule 5)

No. : .....

This is to certify that Shri. / Shrimati .....

..... has been registered under the Bombay Nursing Homes Registration Act Amendment 2006 in respect of .....

..... Situated at ..... and has been authorized to carry on the said Nursing Home.

Registration No. … … … … …	Maternity … … … … … … … … …	Cots … … …
Date of Registration … … … …	Other Nursing Patients … … … …	Cots … … …

Place :

Date of issue of Certificate :

This Certificate shall be valid up to 31st March .....

Executive Health officer / Civil Surgeon /

District Health Officer

Proposed Rules 2008

FORM 'C'

Certificate of Registration under Section 5 of the Bombay Nursing Homes Registration Act (Amendment) 2005 (Under Rule 5)

No. : .....

This is to certify that Shri. / Shrimati .....

.....has been registered under the

Bombay Nursing Homes Registration Act (Amendment) 2005 in respect of .....

..... Situated at .....

and has been authorized to carry on the said Nursing Home.

Registration No. ... ... Maternity ... ... Cots ... ...

Date of Registration ... ... Other Nursing Patients ... ... Cots ... ...

Place :

Date of issue of Certificate :

This Certificate shall be valid up to 31st March .....

Health officer Municipal Corporation / Civil Surgeon / District Health Officer

ANNEXURE 2
Dissenting note

ANNEXURE 2

Dissenting note

Non-Inclusion of the Provision For

Regulation of Charges of Clinical Establishments in the Draft Maharashtra CEA Bill 2014

It is our contention that the Draft Maharashtra CEA Bill 2014 should have a provision for regulation of charges of Clinical Establishments. Our rationale for this above suggestion has been as follows-

1) As we had pointed out during the deliberations of the Expert Committee, the terms of reference of the Committee clearly make a mention of making health care easily available at affordable rate (माफक दरात) for the ordinary people (सामान्य जनतेला). By not including a provision for regulation of charges of Clinical Establishments, Expert Committee has violated, contradicted one of the important terms of reference of the appointment of this Committee.

2) Mr. Sunil Nandraj had reported that when the CEA -2010 was debated in the Parliament, it was criticized for not including this provision. The Health Minister then promised its inclusion in the Rules and hence in the Rules of CEA-2010 published in May 2012, the following provision has been included under para 9 ii of the Rules –

"The clinical establishment shall charge rates for each type of procedure and services within the range of rates determined by and issued by the Central government from time to time, in consultation with the State Governments".

We, therefore, argued that in the Maharashtra legislation also a provision for regulation of rates of clinical establishments should be included. This is particularly relevant given also the background that Civil Society organizations have also this point on their agenda as a priority item, more than 400 letters have been sent by various civil society organizations to the Expert Committee during recent Public Consultation, in which one of the main demands has been regulation of rates of Clinical Establishments. Secondly this inclusion would surely be demanded in the legislative assembly by the elected representatives. It would be better that the Expert Committee deliberates on this point and formulates a provision by taking into account the nuances involved.

Thus we suggested the following provision in para 14 (2) of the draft of the Maharashtra CEA Bill 2014, for regulation of rates of clinical establishments –

"For patients in general wards and semi-private rooms, Hospitals and Nursing Homes shall charge, within the range of rates for fees and services as may be prescribed by the state council.

The range of any ***professional fee*** may be decided on the basis of qualification, experience of the health care provider, the nature of intervention, and -level of institution (primary, secondary etc) at which professional service is being provided as well as the geographical location of the clinical establishment.

The rates for ***services*** in different geographical locations (like village, town, metro) may be decided on the basis of the cost of infrastructure, of equipment, consumables and of skilled human resources.

These rates may be revised as per annual market inflation."

Further there should be the provision that "Key indicative rates as may be prescribed of facilities and services of the clinical establishment should be displayed prominently on the notice board and all rates should be available for patients at the reception counter."

It may be noted that the above formulation excludes outpatient consultations and investigations and even for hospitals and nursing homes, it includes general ward patients. In case of patients from private rooms, deluxe rooms and above, there will be no cap on charges. For regulating the charges we have mentioned only 'general wards' even if the risk is – if this provision is included in the Maharashtra CEA Bill in some hospitals the category of general wards may disappear!

The rationale for different rates and fees based on the type of ward or room is as follows – even though diagnosis, treatment, clinical service or the skill/approach of the provider (including nursing care) etc. should not change with the type of ward or room, ***in case of semi-private rooms and general wards the profit/net income earned by the clinical establishment should be limited to 'reasonable' level of range, whereas there will be no such cap on the 'profit/net income' to be earned from patients in deluxe rooms and above.*** It may be noted that for none of categories of patients, there will be any subsidy/charity.

Three objections are raised about regulating rates in private establishments and these need to be answered.

Objection 1: Given the very wide range of situations, clinical conditions, nature of interventions, knowledge and skill required, it is impossible to devise any rational system of rate structure for clinical establishments.

The answer is – In different parts of the world and in India also various 'third party payment systems' are all based on rate-structures. Though a very complex issue, rate-structures for clinical establishments is already a reality. The challenge is to make it as rational as possible.

Objection 2: To cap professional fees is to encroach upon a fundamental right of the medical professionals and violates the principle of the market economy

The answer is – The unique nature of medical profession is widely recognized. Though every profession has its professional ethics, medical ethics is a unique entity. It is widely recognized that in the doctor-patient relations, the patient is inherently vulnerable and this is the basis of

Hippocrates's oath and code of medical ethics which mandates a doctor to use the inevitable power s/he has over the patient for the best interests of the patient and to put the interests of the patient ahead of the interests of the doctor. This is the basis of calling medical profession a noble one and the basis of so much respect and gratitude the society still has despite a great deal of degeneration in doctor-patient relationship. This is the basis of the 'Standard Charter of Patient's Rights', something which has no parallel in any other profession.

It is widely recognized that in health care in all countries there has invariably been 'market failure' because of the very nature of doctor-patient relationship. Hence in all developed countries, health care market is regulated through different mechanisms. In India the Supreme Court has asked the government to control prices of medicines on these same grounds of vulnerability of patients. It may be noted that more than half the Indian population finds it difficult to pay for bills of private hospitals.

Objection 3: Insurance and other third party payments are increasing rapidly and this will make legal regulation unnecessary.

The answer is – All such third party payment mechanisms cover very small proportion of patients, far far less than universal coverage. There is no possibility in the foreseeable future that majority of patients will come under its ambit.

We conclude that there is no rationale for excluding a provision for regulating rate-structure in the Maharashtra draft CEA bill, especially in view of the substantial information and power asymmetry between the health care provider and the patient.

We have attached as an annexure, some correspondence among the Expert Committee members on this issue of regulation of rates of clinical establishments.

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On 26-Mar-2014, at 10:42 pm, Anant Phadke <anant.phadke@gmail.com> wrote ::

Dear all,

It may be noted that Meeta Rajivlochan madam, in her letter of 24th March has said " I agree that a provision for regulating general ward rates is needed. As Dr Phadke suggests, the area demarcated for general ward should also be given a minimum value." She then moves to the issue of transparency in rate structure of 'private wards'. Let us not focus only on the transparency part. Mere transparency is not adequate for majority of patients.

It may also be noted that during the third meeting of the Expert Committee, which was held in Pune we did discuss the issue of inclusion of a provision for regulating the rates of private clinical establishment. During this discussion it was pointed out that given the terms of reference of the Committee, it will be necessary to include this provision. It was quite clear then that there is no escape from including this provision. Meeta Rajivlochan madam's letter of 24th March also underscores this point. So let there be no deviation from this now. As I wrote earlier, let us not go into details of how the rates will be decided. But to be sure we have to formulate a provision in the Draft Maharashtra CE Bill (MCEB) in such manner that this rate structure would be mandatory. I would formulate this provision as follows –

"For certain category of patients as may be prescribed, every nursing home, hospital, maternity home, would levy fees for services within the range prescribed by the State government; provided this range takes into account the qualification, experience, location and level of services being provided."

The above formulation includes only certain kinds of clinical establishments and hence takes care of one of Sunil Nandraj's concerns. Secondly it offers scope for including only certain category of patients like the ones semi-private, private and general wards and to exclude patients from deluxe rooms and above.

Sunil has a query regarding the rationale for the rates and fees charged based on the type of ward or room. The rationale is as follows - Diagnosis, treatment, clinical service or the skill/ approach of the provider (including nursing care) etc. should not change with the type of ward or room. But in case of semi-private, private and general wards the profit/net income earned by the clinical establishment would be limited to 'reasonable' level of range, whereas there will be no 'reasonable' limit to the 'profit/net income' to be earned for patients in deluxe rooms and above. It may be noted that for none of categories of patients, there will be any subsidy/charity.

As regards display of fees for services, Sunil has suggested the same formulation as in the CEA- 2010. –

"Every Clinical Establishment shall display the rates & fees charged for the services provided & facilities available for the information of the patients in the local as well as in English language in a manner as prescribed."

But it is quite clear that it is impossible to display all rates and fees given the number of items in this. Hence in the Draft we have prepared during the meeting on 30th January, we had formulated this provision in section 12 as follows -

“Display of key indicative rates of facilities and services available as may be prescribed.” We can add the clause – “ in a prominent manner, in the local as well as in English language in a manner as prescribed.” We also need to add that a comprehensive list of charges for all interventions should be available at the reception counter. “

Let us move ahead and not go back on issues which have been already discussed in previous meetings.

With Regards,
Sincerely Yours,

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On 24-Mar-2014, at 8:51 PM, Meeta lochan <meetarajivlochan@gmail.com> wrote

Dear All,

I have been following the discussion on provisions for regulation of rates. I agree that a provision for regulating general ward rates is needed. As Dr Phadke suggests, the area demarcated for general ward should also be given a minimum value.

However regarding private wards, may I suggest that instead of focusing so much on what the hospital should charge, what is needed is that hospitals should be transparent in making information available to consumers about what those rates are, whether it be 5000 or 5 lakh. Otherwise we leave the door open for the hospital to negotiate with each individual patient depending on his or her bank balance. I am sure all would agree that such behaviour is unacceptable. So please do provide for transparency and full disclosure about the rates charged, irrespective of general or private ward.

Regards
Meeta Rajivlochan


WITNESS SEMINAR
on
Journey of PCPNDT Act, Maharashtra
GIRISH LAD

Journey of
Pre-Conception and Pre-Natal Diagnostics Techniques (Prohibition of Sex Selection) Act, 1994

Held on 16th September 2018, Pune, India

Reference to this witness seminar transcript should take the following form:

Chakravarthi I. and B. M. Hunter (Eds.) (2019) Regulation of formal private healthcare providers in Maharashtra: Journey of Pre-Conception and Pre-Natal Diagnostics Techniques (Prohibition of Sex Selection) Act, 1994. Pune: SATHI

Direct quotations from this witness seminar transcript should take the following form:

[Witness name], in: Chakravarthi I. and B. M. Hunter (Eds.) (2019) Regulation of formal private healthcare providers in Maharashtra: Journey of Pre-Conception and Pre-Natal Diagnostics Techniques (Prohibition of Sex Selection) Act, 1994. Pune: SATHI

ACRONYMS

AIDWA	All Indian Democratic Women's Association
AIIMS	All India Institute of Medical Sciences Delhi
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
CEHAT	Centre for Enquiry into Health and Allied Themes Mumbai
CITU	Centre of Indian Trade Unions
CMHO	Chief Medical and Health Officer
CPA	Consumer Protection Act
CSB	Central Supervisory Board
CWDS	Centre for Women's Development Studies Delhi
DASDSP	Doctors Against Sex Determination and Sex Pre-selection
FAOW	Forum Against Oppression of Women Mumbai
FASDSP	Forum against Sex Determination and Sex Pre-selection
FIGO	International Federation of Gynaecology and Obstetrics
FOGSI	Federation of Obstetricians and Gynaecologists Societies of India
FRCH	Forum for Research in Community Health Mumbai
IMA	Indian Medical Association
IRIA	Indian Radiology and Imaging Association
IT	Information Technology
JJ Hospital	Jamsetjee Jeejebhoy Hospital Mumbai
KEM	King Edward Memorial Hospital Mumbai
MFC	Medico Friend Circle
MGM	Mahatma Gandhi Memorial Hospital, Parel Mumbai

MLA	Member of Legislative Assembly
MMC	Maharashtra Medical Council
MP	Member of Parliament
MTP	Medical Termination of Pregnancy
NGOs	Non-Governmental Organisations
PCPNDT	Pre-Conception Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act 1994
PIL	Public Interest Litigation
TIFR	Tata Institute of Fundamental Research Mumbai
UNFPA	United Nations Population Fund, formerly United National Fund for Population Activities
UNICEF	United Nations Children's Fund
WHO	World Health Organisation
YWCA	Young Women's Christian Association

Numerical units commonly used in India

1 lakh = 1,00,000 (100,000)

1 crore = 1,00,00,000 (10 million)

INTRODUCTION

Historically, the main approaches for regulating private healthcare providers in India have been based on administrative–legal instruments and on self-regulation by professional councils. The registration and licensing of healthcare establishments and individual practitioners is the commonest form of legal–administrative mechanisms. Often this legislation focuses on the registration of medical establishments (see accompanying witness seminar on the Bombay Nursing Home Registration Act and Clinical Establishments Act). Other legislation governs particular healthcare practices. For example,the Pre-Conception and Pre-Natal Diagnostics Technologies Act (PCPNDT) 1994 and the Medical Termination of Pregnancy (MTP) Act 1971 govern the conditions under which pregnancies can be terminated.

The objective of this witness seminar is to document the contemporary history of regulation of private healthcare in two cities in the Indian state of Maharashtra: Pune and Mumbai. Focusing on PCPNDT, the seminar aims to document the key events and people involved in the design and enactment of this legal instrument for regulating use of a technology by healthcare providers.

Timeline of key events relating to BNHRA and CEA

1978 - The central (federal) government issued a directive banning the misuse of amniocentesis in government hospitals/laboratories, following the alarming findings of an All India Institute of Medical Sciences (AIIMS) survey (1974) on the demand for sex selective abortions.

1986 - In April 1986 the Forum against Sex Determination and Sex Preselection (FASDSP) began its campaign in Mumbai against discriminatory abortions of female foetuses. Through the 1980s and 1990s non-governmental organisations (NGOs) and social activists engaged in intensive campaigning on the issue. Another group, Doctors against Sex Determination and Sex Pre-selection (DASDSP) was formed in Mumbai as an initiative amongst FASDSP, Medico Friends Circle (MFC) and Indian Medical Association (IMA) members. The DASDSP focused on medical malpractices and the ethical dimensions of sex determination and sex pre-selection.

In the same year, a committee to examine the issues of sex determination tests and female foeticide, formed at the initiative of the Maharashtra government, appointed Dr. Sanjeev Kulkarni to conduct a study. The study was to be done under the Foundation of Research in Community Health (FRCH) and was to investigate the prevalence of this test in Mumbai.

1987 - The Maharashtra government appointed an expert committee in March to propose comprehensive legal provisions regarding sex determination, in response to a private bill introduced in the assembly by a member of the legislative assembly (MLA).

1988 - the Maharashtra government introduced a bill in April to permit prenatal diagnosis only for the purpose of detecting genetic abnormalities and congenital anomalies. The aim was to prevent the misuse of prenatal sex determination leading to female foeticide. The bill was approved by the state assembly in June 1988 and became the Maharashtra Regulation of Pre-Natal Diagnostic Techniques Act, making Maharashtra the first Indian state to ban pre-natal sex determination. The purview of the Act was however limited only to sex determination tests and made no reference to sex pre-selection techniques. The Act noted that medical technology could be misused by doctors and it forbade the advertising of these tests.

1991 - By this time FASDSP had become active at a national level and the central government formed a committee to formulate a national law on this issue.

1994–The central government passes the Pre-Natal Diagnostic Techniques (PNDT) (Regulation and Prevention of Misuse) Act, prohibiting sex selection across the country, however the PNDT Act did not come into force until in January 1996.

1997–Two NGOs, Centre for Enquiry into Health and Allied Themes (CEHAT), Mumbai, and Mahila Sarvangeen Utkarsh Mandal (MASUM), Pune,and Sabu George filed a public interest litigation (PIL) to strengthen the enforcement of the1994 Act. The case was fought on their behalf by the Lawyers Collective, based in Delhi.

2001 - Following a series of campaigns by activist organisations to publicise the PIL, the Supreme Court directed all state governments on 4 May 2001 to promptly and effectively implement the PNDT Act. The Supreme Court issued detailed guidelines to the central and state governments to strengthen enforcement of the Act.

2003- the PNDT Act was amended to both emphasise the "prohibition" of sex selection and to widen its scope to include pre-conception techniques. It was renamed the Pre-Conception and Pre-natal Diagnostic Techniques (PCPNDT) (Prohibition of Sex Selection) Act.

2009- In Kolhapur district, Maharashtra,a machine named the 'Silent Observer' (SIOB) was installed in ultrasound clinics on an experimental basis with the aim of monitoring use of ultrasound equipment to deter sex-determination.

2015- Jail terms were handed to two doctors from Pune in September 2015, leading to widespread protests by radiologists in Pune and Mumbai, who claimed innocent doctors were being framed by government authorities under the PCPNDT Act and the MTP Act.

WITNESSES

Amar Jesani is a medical graduate and was associated with the campaign for prevention of sex determination and sex selective abortions; while Co-ordinator of CEHAT, he was associated with the filing of a PIL in the Supreme Court in 1999 on non-implementation of the central PNDT Act

Arun Gadre is a gynaecologist-obstetrician who practiced for more than two decades in the rural and small towns of Maharashtra.

Girish Lad is the Chief Executive Officer of Magnum Opus, a Pune-based company associated with the invention, promotion and installation of the SIOB and Active Tracker, a tracking device attached to sonography machines to record the sonography images.

Kiran Moghe is a women's rights activist and member of the All India Democratic Women's Association (AIDWA); she is a member of the Advisory Committee, Pune Municipal Corporation on PCPNDT.

Sanjay Gupte is a Pune-based gynaecologist-obstetrician; a past President of Federation of Obstetricians and Gynaecologists' Society of India (FOGSI); past Chairman, Ethics Committee Maharashtra Medical Council (MMC); member of Advisory Committee Pune Municipal Corporation on PCPNDT; Medico-Legal Consultant and member of the medico-legal cell for IMA Pune.

Shailesh Sangani is a radiologist from Navi Mumbai, and office bearer of Indian Radiology and Imaging Association (IRIA), Maharashtra Chapter.

Ravindra Rukmani Pandarinath was actively involved in campaigning in Mumbai through the 1980s and 1990s against use of amniocentesis for sex determination; and in enactment of the state and subsequently the central legislations prohibiting sex determination.

Vibhuti Patel is currently Professor of Women's Studies at Tata Institute of Social Sciences, Mumbai. She was active in the campaign against sex determination by amniocentesis in the 1980s in Mumbai, and in the introduction of the PNDT Act in Maharashtra and its implementation.

Chairperson

Indira Chakravarthi is a public health researcher and currently a Senior Consultant at SATHI, Pune, where she is leading the project on *Practices, Regulation and Accountability in the evolving private healthcare sector: Lessons from Maharashtra state, India.*

PROCEEDINGS OF THE WITNESS SEMINAR

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Indira Chakravarthi: The origins of the PCPNDT Act lie in the state of Maharashtra, from the state Act to the central Act, so a lot has taken place in Maharashtra. When it started, it was unique in many ways, arising out of the campaigns that went on around it. I could be corrected on this, but whatever little I understood, it is one act which offers no role to the police in its entire implementation and which involves civil society in implementation. Yet, today we see that there is a lot of consternation, especially within the medical profession, from 2015 onwards. A profession that does not readily come out onto the streets has threatened to strike, and doctors are refusing to do obstetric ultra sonography. That is the situation we are in. So, the point is to understand how we have reached this point, the entire 35-year journey since the 1970s and 1980s.

We will begin with the campaigns and how the law itself came about. We have the state Act, as well as the central PNDT/PCPNDT Act. We will look at the state Act first, how that came about, its implementation, and the issues that it raised. We will then move on to the central Act and its implementation– to explore the entire journey from introduction to implementation as the implementation is what is quite critical here.

Session I
1970s – Practice of sex-determination and sex-selective abortions in Maharashtra and framing as a problem

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1970s – Practice of sex-determination and sex-selective abortions in Maharashtra and framing as a problem

Indira Chakravarthi: We will begin by asking Vibhuti Patel to tell us how the problem was recognised: the fact that this kind of sex determination and sex related abortions were happening in Mumbai as you have written about this. Then Dr. Sanjay Gupte can tell us about how it was recognised in the medical community.

Vibhuti Patel: My awareness of this issue arose in 1972 because many of my relatives staying in Anand and Kheda districts in Gujarat started talking about chorion villi biopsy. Amul Dairy[1] had introduced this chorion villi biopsy for cows and buffaloes, to know the sex of the foetus. If it was a male foetus, they would abort; a female foetus was allowed to be born because the enhancement of milk production was a priority. Because of the Green Revolution and tractorization[2], farmers in Gujarat did not want oxen. The patidars[3] of my community brought this test into the state. Many of our *fufis and chachis* [aunties], and those who came from Kheda district, would tell the stories of who did what when they became pregnant. In my family, I have the only female child in the whole clan; none of my relatives have daughters. They will have one or two sons, none of them have a daughter. When *Aalya tai* [elder sister], *Mrinal tai, Manju* tai from Mumbai came to Baroda to form an anti-price rise women's organization, I was the student volunteer to receive them and I told them the story. I was so overwhelmed by the testimonies I was receiving from my relatives in Kheda district. They told me, 'you are reading too much science fiction, people don't have money to even have safe drinking water and you are talking of amniotic fluid being tested and all'. Back then our priorities were different. When I came to Bombay in 1977, I got to meet our feminist friends from other parts of the country, like Delhi - people like Sathyamala and Amrita Chachi, who were in the research team of All India Institute of Medical Sciences Delhi (AIIMS), where 12,000 couples were volunteers for the test on pregnant women. The test was mainly to find 84 types of medical conditions in the foetus. But the main interest of these couples was to know the sex of foetus. The gynaecologist who was working in this team in AIIMS raised

1 Amul Dairy is a dairy company, in Anand district, Gujarat, of a co-operative of milk producers, Kaira District Co-operative Milk Producers' Union Limited, Anand, formed in the 1940s, to undertake procurement, processing and marketing facilities for the milk producers/farmers of the district. These producers owned the dairies, their elected representatives managed the societies and the union, and they employed professionals to run the dairies and manage the business. The producers were given support for dairy farming by the co-operatives by providing veterinary services.

2 Green Revolution and tractorization refers to the changes in agricultural practices introduced in India in the 1960s, to overcome food shortages then by increasing agricultural yields, with better irrigation systems, high yielding varieties, agricultural machinery (such as tractors), fertilizers, and pesticides.

3 Patidars are a caste group in Gujarat associated with land-ownership and agriculture.

this issue that if this test becomes popular and is commercially used, then it is going to create lots of problem in the society, because among these couples also, the moment the sex of the foetus was revealed, if it turned out to be female, they would resort to abortion. So when they came back to the research team they would say 'still birth'. Amrita Chachi and Sathyamala wrote about the findings of this AIIMS experience in MFC[4] Bulletin. In Chandigarh in Haryana too, newspaper advertisements were appearing in Punjabi and Gurumukhi saying, 'Do you want a son? Solution to dowry problem, better 5,000 now, then 5 lakhs later'. Even Times of India used to publish these advertisements. In Gujarati, we had such advertisements in small towns like Surat,Anand, and Valsad and Baroda. Advertisements in Gujarati said: *'Dahejni Samasya nu nikal*' [Remove the problem of dowry]. In 1977 a friend in Mumbai - a pathologist and feminist - Swati Paranjape, who was working in JJ Hospital said, 'Yes, these tests were routinely done.' In 1975 Vina Mazumdar, Director of Centre for Women's Development Studies (CWDS), Delhi, and others had given a memorandum to the government on the basis of AIIMS study that we must ban this test. The response of the government was that, 'we have a 5-point program, population control is a major goal of the 5-point programme and this is going to be handy. Fewer women means less reproduction -Indian women produce several girls in anticipation of a boy. So these are the two ways in which we can use this test for population stabilization'. That was the argument given and they did not do anything.

In the widely used public transport system in Mumbai, in its local trains, there were advertisements such as, 'Rs 70 for *garba olakh* [know about your foetus] and Rs 80 for abortion. So in Rs 150 you can solve your problem of dowry'. Such advertisements were in Gujarati, Hindi, Urdu and Marathi. We thought *garba olakh* means pregnancy test. But, when our *bais* [female domestic worker] started telling us, *'Tumhi hi test karun ghyana Lata behen*' [You get this test done sister Lata], we feminists felt - people know more about this than we do. Meera Savara, a columnist in Eve's Weekly, wrote, 'it's a question of choice. You know what the fate of Indian girls is any way and this is more humane. Instead of ill-treating a girl all her life, it is more humane, not to allow her to be born.' And that created a major controversy. We had many meetings on this issue and said, 'this is a very, very anti-women argument. If there is poverty in India, you don't say throw a bomb in Dharavi [slum in Mumbai], you have to fight against poverty. So, you have to eliminate inequality, not women'. That was the stand which feminists had taken. We had several meetings. Then we ourselves decided to go, six of us, to various hospitals as pregnant women. We had no difficulty in getting any information. In Harkisandas Hospital we were told that from 1977-82 about 8,000 pregnant women had approached them. Only one Jewish lady who had three sons, wanted a daughter, all the rest wanted a son. They said, 'We are Jains, we don't even eat boiled eggs or boiled potatoes and onions, and these are not even given to our patients. Even TB patients are not given eggs. We are anti-abortion, we only conduct the test and give the results we then tell rich women to go to Bhatia hospital, and poor women can go to JJ hospital.They have to bring back the foetus in a plastic bag because Harkisandas Hospital had a research lab.'

4 Chachi, A. and Sathyamala, C. (1983) "Sex determination Tests: A Technology, which will eliminate women. Medico Friend Circle Bulletin, November No.95, p 3-5. MFCis a nation-wide platform of secular, pluralist, and pro-poor health practitioners, scientists and social activists interested in the health problems of the people of India. Since its inception in 1974, MFC has critically analysed the existing healthcare system and has tried to develop an appropriate approach towards healthcare which is humane and which can meet the needs of the vast majority of the people in India.

JJ, KEM[5] and MGM hospitals were noticing that only the women who had female foetuses were the ones coming for abortion, for a free abortion. There were two private clinics in Andheri East JB Nagar area that also said that they were doing social work. They said that 'this is social work - we are helping women, because women come crying, they say if they don't have a son, if they produce daughter, they will be deserted and divorced.'And the most interesting findings we had, were in Pearl Centre, by Dr. Pai; he said that he had got Padmashri[6].

Ravindra RP: He got the Padmashri and was a MLA[7], and a spokesperson for the doctor's lobby.

Vibhuti Patel: He also received many awards for conducting the highest number of sterilisation operations and so on. He said, 'Madam, you are talking about commercial interests. I don't have any commercial interests; I am doing my patriotic duty. Which hospital would provide both an abortion and sex selection service within Rs 150?' 'Nowhere', he said, 'this is the lowest rate, and it doesn't even cover my costs but just because I am concerned about population explosion, I am doing this.' Finally, we published our report of four pages, a cyclostyled report. We cut the stencil ourselves. In those days there was no xeroxing facility. We had a meeting and got an excellent response because that Meera Savara's article in Eve's Weekly had really created tremendous turmoil in the women's movement. Then we were asked by all the elderly feminists, except for Mrinal tai, who had a medical background, to 'explain the technical aspects to us, the historical aspects, legal aspects and what can be done - the strategies'. So we had a one-day workshop to discuss these four different dimensions: we called lawyers Indira Jaising and Anand Grover to cover the legal aspects, and many sociologists, anthropologists and ethnographers came to cover the culture of son preference and such issues. We invited our doctor friends to cover the medical aspects, to demystify the technology because all the words which were thrown at us – chorion villi bioscopy, fetoscopy, needling, amniocentesis – we could not even pronounce amniocentesis, let alone remember its spelling and all. After this workshop, the participants took on the responsibility of writing scholarly papers. The papers which Harkisandas Hospital doctors were churning out were published by FOGSI. An international gynaecologist's associate argued that we needed to have this technique and every time we talked about this we were told 'this is anecdotal information, what we need is scientific study with primary data - hard-core data'. We met our central government health minister in 1978, Mr. Raj Narain, who got the sense of the problem and he said, 'yes, at least in government sector, I will ban it'. So, he sent out a Government Resolution stopping the test in government hospitals. And that was the time when commercial use of this test became very aggressive in Chandigarh, Jalandar, Faridkot, Delhi, Mathura.

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5 Harkisandas Hospital, a reputed private hospital in Bombay, conducted antenatal sex determination tests until the official ban on the test in 1988 by the state government. The handout of the hospital declared the test to be 'humane and beneficial'.The out patient facilities in the hospital were so overcrowded during 1978-1994 that couples desirous of the sex-determination test had to book for the test one month in advance. As its Jain management did not support abortion, the hospital recommended women to various other hospitals and clinics for abortion and asked them to bring back the aborted female foetuses for further 'research'.

6 Padmashri Award is the fourth highest civilian award given by the Government of India annually to an Indian citizen in recognition of their work.

7 e Maharashtra legislature comprises the Vidhan Sabha [Legislative Assembly] and Vidhan Parishad[Legislative Council]. Members of the Vidhan Sabha are known as MLAs and members of the Vidhan Parishad as known as MLCs.

Indira Chakravarthi: Clearly from what Vibhuti has just shared it was already happening on a large scale in the hospitals, the government hospitals and private hospitals, before the activists or the feminists or civil society got wind of it. Dr Gupte can you tell us about when did it become a concern or when it was noticed in the medical profession, what was their response to all of this?

Sanjay Gupte: As Vibhuti rightly pointed out, the whole thing initially started with medical termination of pregnancies (MTP), when the MTP Act had been introduced and I had just recently joined Sassoon Hospital. This is about 1975, 1977, because the first MTP outpatient clinic in the government sector was opened at Sassoon hospital at that time. That was the first MTP outpatient clinic in the government sector and Dr. Anjeneyelu had gone to Japan at that time and had brought in the new method of Second Trimester Safe Abortion, with extra amniotic ethacridine lactate injection. Before that only that intra-amniotic hypotonic saline was used, which was quite problematic as patients used to die as a result of it. So, this was a safe method that was brought in, with all good intentions at that time. We used to carry out something like 35, 40 second trimester MTPs at Sassoon hospital on a daily basis. To that extent, the whole antenatal ward was completely full of these cases. And they were actually problematic cases, all sorts of problematic cases. As an MD student my dissertation was on extra-amniotic instillation of prostaglandin. That was first time prostaglandin was brought to India. And so, I had to work on it. As soon as I finished my MD, in my first year I was put in charge of this MTP clinic, so I was looking after all these cases. We conducted a good study of almost 550 cases of unmarried, second trimester MTPs which was handed over to the World Health Organisation. And that was the original purpose of MTP law - to bring in the safe abortion practices[8] .

Then the reports from Mumbai started coming in, about Harkisandas Hospital doing the study on amniocentesis and sex determination. I think it must have been the work done by the women activists. In between all this, in 1977, we were all going around doing vaginal sterilisations in the Konkan region. Every morning we used to start and used to do nearly 300, 400 vaginal sterilisations; the District Collectors had targets. We were kept at really nice *dak bungalows* [government guest houses], well catered for, because, the Collectors knew they were at risk - that if we didn't do the sterilisation they would get into trouble. In 1979, I happened to go to AIIMS, where this discussion was taking place - another method of population control. Then I returned to Pune,and I remember Dr Arun Kendre and I had some long discussions with Dr. Banoo Coyaji[9], and that was an important thing. Though she was all for sterilisations, she was the one who pointed out to us that this is wrong - what is happening is female foeticide. At the same time, I don't remember the exact date, Sabu George had come. He was associated with that Salem issue, where infanticide was practiced[10]. We had a meeting in my hospital and

8 Abortion was legalized in India in 1971 through the introduction of the MTP Act. In 1975 the Act was revised and abortion allowed on several grounds, mostly medical, but also on the grounds of contraceptive failure or pregnancy resulting from rape.

9 Dr Banoo Jehangir Coyaji was a physician and activist in family planning and population control; she was based at the King Edward Memorial hospital in Pune.

10 This refers to the practice of female infanticide in several parts of Tamil Nadu, including Salem district. Sabu George wrote about the history and prevalence of this practice, and later was active in the campaign for implementation of the PCPNDT Act. For more on this see: George, S. (1997): Female Infanticide in Tamil Nadu, India: From Recognition Back to Denial? *Reproductive Health Matters*, 5(10), (November), pp. 124-132.
Chunkath, S.R. and Athreya, V.B. (1997) Female Infanticide in Tamil Nadu: Some Evidence.*Economic and Political Weekly,* 32(17) (Apr. 26 - May 2), pp. WS21- WS25+WS27-WS28.

Dr Banoo and Sabu George said 'let's do something about it'. Then Dr. Banoo spoke to the government people,and Dr. Arun Kendre and I did a video campaign with the Media Research Centre at Pune University at the time. We prepared videos explaining sex selective abortion is wrong and so on, and we showed them around.

However, after that I had a very peculiar experience. While this was happening I started receiving some phone calls at night, around 1.30, 2.00am, threatening phone calls - nothing to do with this issue. At that time there were a lot practices such as *khandani* [extortion] and similar underworld activities. Somebody on the phone would say, 'we know you have small daughters, they go to this school and we'll kidnap them'. So, I was tremendously scared and then my wife felt that we were getting into trouble. We did not know who was doing it, and for what purpose, so we approached Pune police. There were good people there, like Commissioner Devre and Commissioner Shinde, and they tapped my phone to find out who was calling, those days there were landline phones so it was easy to do so. They discovered somebody was calling from couple of public phone booths, so they put plain clothes officers on watch and they found that a gynaecologist, a colleague of ours, was doing it. At 2.00am, he used to have couple of pegs [drinks] and then he used to call. He was subsequently caught and arrested. At that time, it was a non-cognizable [relatively minor] offence. His wife was my wife's student and she requested us not to take action. But it went to the MMC and he took a stay from the High Court, saying that this was not done in a professional capacity, this was done in non-professional capacity. It was that same person that Madam Kiran finally managed to catch in her sting operation years later. And those phone calls did work, because I was scared and my wife said, 'our children are small', so I kept away from the issue for quite some time.

Indira Chakravarthi: Just to clarify. So, it was to do with the campaign against the sex selection followed by the abortions, which had already started in Pune, at that time?

Sanjay Gupte: You are right.

Ravindra RP: It was in 1975, I think, when the technology became available in AIIMS and it started the amniocentesis programme[11]. In 1978, Raj Narain, as the Health Minister in the Janata Dal government banned it. He said that it should not be allowed in government hospitals and 1978 onwards, the ban was implemented in government institutions. That was the trigger for the private practitioners to take over. Then we had a section of intellectuals who supported it, as Vibhuti has mentioned. Meera Savara's article was very important as it gave a pseudo-feminist justification for sex-selective abortions. Another respected name was that of Dharma Kumar, a very respected scholar. She wrote an article in Economic & Political Weekly, giving similar arguments[12] . So, on the one hand is the section of government and doctors who feel it's a

11 See Mazumdar V (1994) Amniocentesis and Sex Selection. Occasional Paper Series No. 21, 1994, of Centre for Women's Development Studies (CWDS), Delhi. Reproduced in: Sex Selection: Issues and Concerns, Compiled by Qudsia Contractor, Sumita Menon and Ravi Duggal, 2003, CEHAT Mumbai, available at: http://www.cehat.org/uploads/files/37Sex-Selection-IssuesConcerns%281%29.pdf#page=37

12 Dharma Kumar opined that sex selection may improve the position of girls, by raising their value as they become scarce. She wondered whether selective abortions were worse than the neglect and infanticide of girl children. See Kumar, Dharma (1983) "Male Utopias or Nightmares?" Economic and Political Weekly, 18(3), 61-64.

technique for population control, on the other side, there are academics who are trying to give their support. This is the background of amniocentesis, around 1982-84: where they are trying to justify the practice with the arguments that it is a population control tool, that it is much more humane to kill female foetuses because otherwise they are going to be killed anyway, and third is the human rights issue: that it is the women's right to choose. So, these arguments were there, right from the beginning. The story is quite long, I'll just come to 1982 part. 1982 is a period when major things are happening.

Indira Chakravarthi: Just one-minute Ravindra.So, you are jumping to 1982, was there anything in between?

Vibhuti Patel: The CWDS report to the government also highlighted the declining sex ratio. Vina Mazumdar was member secretary of the *Towards Equality* report[13], which for the first time highlighted continuous declining sex ratio in India, and they said there are serious reasons for women in all age groups being fewer in number. So, they had linked up this issue with that of sex selective abortions. My experience between 1978-82 in Gujarat was very different. In Gujarat, all the doctors said, 'negative publicity is the best publicity - each time you write in Gujarati, I get more queries about sex selection'. Here in Maharashtra they were getting threatening calls, and Gujaratis said that commercial interests were strengthened, because of our campaign and writing on the issue.

Indira Chakravarthi: Since we have moved on to the campaign already, first, if Amar can tell us what was happening in Mumbai, and then Kiran can tell us about the campaign in Pune?

Amar Jesani: I think it was in the early 1980s, I would say 1983, 1984, that was the time when the campaign starts crystallising. Earlier there was criticism and discussions about it, but the campaign had not crystallised: up to that point separate groups had been campaigning on this subject. I think there were quite a few, what I would call, historical reasons why the campaign happened. One was that Bombay was a seat of massive women's movement. In late 1970s, early 1980s, the forums against rape came up, which evolved into the Forum Against Oppression of Women [FAOW], which was extremely active. I mean, it almost affected the entire city life. And they took up campaigns on one issue after another, starting with sexual assault and rape, but also dowry and issues of women's safety, like reclaiming the streets. I remember participating in a series of actions of that time. The second area of turbulence was a textile workers' strike in 1981-82, which went on for over a year and ultimately collapsed. It shook up Bombay at that time. A large number of NGOs were coming up. There were a few of us who were involved in health research. I come from a medical background however, I didn't practice medicine. But that was the time when I started working in health research, earlier with health policies in 1979, in Foundation for Research in Community Health. Dr. Antia was a very dynamic, mercurial person who had many contacts. And from 1983-85, Manisha Gupte, Ravi Duggal and I were involved in doing a lot of research on health systems. I think health systems research was initiated in

13 Vina Mazumdar was secretary of the Committee on Status of Women in India that brought out in 1975 *Towards Equality*, the first report on the conditions of women in India.

a big way by the FRCH in 1970s and 1980s. And we were travelling; I come from Gujarat and had never seen Maharashtra. But those were projects, 1983-87/88, where we saw almost every district of Maharashtra, we went around studying NGOs. And staying in the villages we came to know about what was happening in Bombay and how it was getting replicated at the district and sub-district level, because we were seeing all the advertisements of both abortions, as well as sex selection. I think in 1983 things started happening and there was a meeting at the end of 1983, or early 1980s, in the Young Women's Christian Association (YWCA). In 1984 the Forum against Sex Determination and Sex Pre-selection (FASDSP) was formed which was an initiative of the women's movement with others, with health activists from MFC. One thing which I want to point out is that, at that time we did not use the term 'sex selection' very much - it was 'sex determination'. The MFC group was very active at that time. There was another factor - MFC had taken up campaign on irrational use of drugs and technology. In 1982 we had a meeting in Pune city, where the All India Drug Action Network was established. MFC and other organisations were coming together at that time and we were looking at false positive and false negative results during screening and the excess use of technology. So, this was another reason why we were more sensitive to how it was being used. When FASDSP was formed the one person who was actually practising and who had connection to the profession was Mohan Deshpande. We thought that we should raise awareness among doctors. Since I was not practising, and being from Gujarat, I didn't have any contact with the doctors in Bombay City. So, it was he who provided us the direct connection to the doctors. He was in Bangur Nagar, Goregaon where Ravindra also lived, and Goregaon had a very good, active doctor's group. I think it was called Goregaon Medical Association, and Mohan was part of it. That's how, when Mohan became part of the FASDSP, he thought that we should take some initiatives within the medical profession. He went back to Goregaon, and there, I think, primarily gynaecologists and some others like Dr. Bal Inamdar, who was the leader of the entire pack, got together and said, 'let us have a separate organisation called 'Doctors against Sex Determination and Sex Pre-selection'. This is how it was formed - in 1984-85. In 1984, we had a journal special issue on women and health.

Vibhuti Patel: He also brought out the Special Number of the Radical Journal of Health - that special number on medical technology.

Ravindra RP: The Doctor's Forum was launched in 1987.

Amar Jesani: I remember we had a demonstration in Azad Maidan, where D T Joseph, who was the Health Secretary, had joined. So, doctors were part of this process. The other thing that happened was related to FRCH, Foundation for Research in Community Health, where Dr. Antia was located. We had a very strong connection with the Health Department in Maharashtra at that time. From 1986 onwards I was working on a project supported by the Government of Maharashtra. The previous Health Secretary, Dr. Srinivasan, used to come to FRCH regularly, and when Srinivasan retires, and D T Joseph takes over he also continues with the same tradition. Almost every couple of months, the Health Secretary would be visiting Dr. Antia or we would be going to them. That's when we conceived the idea of doing a study of primary health centres and sub-centres. And so, I spent almost a year in different parts of Maharashtra, staying at the

primary health centres, through 1986-87. That was the time when the FASDSP was taking shape. Dr. Sanjeev Kulkarni, a gynaecologist, who would come to Bombay to visit his brother and sister-in-law, used to come to the meetings of the FASDSP. He was inspired by the meetings and said that he will do a study on this issue. As FRCH and FASDSP were already in contact with D T Joseph, through Dr. Antia's help a project was given to FRCH, to do a study of sex selection or sex determination practices going on in city of Mumbai. It was not a population-based study; rather it was based on his interviews with gynaecologists and obstetricians describing their practices. Sanjeev interviewed a cross-section of obstetric gynaecologists and based upon that he tried to estimate the number of sex selective abortions that had taken place. It was a rather crude way of making the estimates, but it was the one which caught the public imagination,[14] because the Times of India wrote an editorial on it.

Kiran Moghe: That was the '40,000 effect', was it not - 40,000 foetuses and all being aborted in Mumbai in one year?

Vibhuti Patel: And the Lancet also published it.

Amar Jesani: While methodologically it was weak, the obstetricians and gynaecologists were speaking very frankly as a gynaecologist was interviewing them. And they provided data which helped us in generalising to a certain extent. I think Praful Bidwai was in Times of India and he wrote an editorial that triggered a lot of debate.

Ravindra RP: Achin Vinaik was there.

Vibhuti Patel: Achin also wrote. And then, Dharma Kumar gave a rebuttal.[15]

Amar Jesani: There were two other reasons why health activists got involved in this issue. One was there was lot of churning in Bombay because of the litigations that were being filed under the Consumer Protection Act (CPA) against doctors and there were protests against it. The first major case of negligence was against Dr. Desai, filed by Singhi.[16] I remember organising his press conference, which was well attended by the press and reported widely. Another reason was the JJ hospital tri-glycerol tragedy.[17] The tragedy took place in early 1986 but over the next two years

14 A committee to examine the issues of sex determination tests and female foeticide, formed at the initiative of the Maharashtra government in 1986, appointed Dr. Sanjeev Kulkarni to investigate the prevalence of this test in Mumbai. This was done with the Foundation of Research in Community Health (FRCH). Forty-two gynaecologists were interviewed by Dr. Kulkarni. His findings disclosed that about 84% of the gynaecologists interviewed were performing amniocentesis for sex determination. For more information on the study see: Kulkarni, S. (1986) Sex Determination Tests and Female Feticide in the city of Bombay, Foundation for Research in Community Health – FRCH, Reproduced in: Sex Selection: Issues and Concerns, as in Note 11.

15 See Note 12

16 P.C. Singhi, a bureaucrat, filed a complaint of negligence against Dr. P.B. Desai a reputed oncologist at Bombay Hospital, following the death of his wife in 1989. The complaint was filed with the Medical Council of India which took disciplinary action against Dr Desai and found him guilty of professional misconduct and issued warning to him under the Maharashtra Medical Council Act, 1965. Singhi also lodged a criminal complaint against Dr Desai and the trial court convicted him. The doctor appealed in the higher courts and finally in 2016, in a legal battle spanning three decades, the Supreme Court upheld orders of the High Court in favour of Dr Desai, and ruled that he was not criminally liable under section 338 of the Indian Penal Code.

17 In early 1986 14 patients aged between 10-76 years, in different departments at the government JJ hospital, who were recovering from their problems, died unnatural and untimely deaths. They had all been administered glycerine, a harmless drug in therapeutic doses. Following the furore over these deaths the Maharashtra state government appointed a one-man enquiry commission under Justice B Lentin, who submitted his report in 1988.

the Lentin Commission open inquiry took place. And the Lentin Commission report led to a better awareness among the general population about the malpractices by the medical community. So, this was another trigger and for the first time, as far as I know, doctors started getting attracted to the idea of ethics in medicine. This was the time, 1984-85, when we had started a journal of our own – Radical Journal of Health. We started using increasingly the terminology of 'human rights' and 'ethics', and then organised meetings on that subject. And Dr. Arun Bal was involved in some of the agitations that were taking place in the health arena. I remember his case in 1986 in a big way, because he wrote couple of articles in Economic & Political Weekly, and he used to write regularly in the Times of India. He was a big critic of the pharmaceutical industry. He was practising in Sushrusha Hospital, which is run by Brahmin Sabha.[18] Suddenly in 1986-87, I don't remember the exact date, but somewhere in that year, he was thrown out by Sushrusha hospital. There was a complaint submitted to the MMC about sex determination and ethics, but there is also background to this. And it opened up another area – namely, what to do with the MMC. That is when we thought that we should be interacting with the MMC, otherwise, we never discussed or wrote about it. I remember that, except for taking registration, I had never thought of the MMC at all. The President of the Brahmin Sabha, Dr Sane, was the Vice-President of the MMC. When Arun Bal was suspended, a large number of doctors held a protest at that hospital, at Dadar. Dr. Sane came out with a threat in the press conference that all those doctors who participated in that protest would be identified, notice served to them and they would be de-registered from the MMC. We woke up to the presence of the MMC and the realisation that we need to talk about it and try to unite it. But it was so difficult to get copy of the MMC Act, the bare Act - the rules were not available. One had to bribe somebody in the MMC office to get a photocopy, which was also very difficult at that time. So, we got that copy and found that there is some possibility that MMC can take *suo moto* action, or a complaint can be made by a third party to MMC, on this issue of sex determination. I found one women's group, was it Nari Vimukti Sanghatan?

Vibhuti Patel: Nari Samata Manch.

Kiran Moghe: Must have been Nari Kendra.

Amar Jesani: Some organisation ultimately filed a complaint that sex determination is unethical and we provided support to it. They said that we should pressure the MMC. That's how, I think, quite a few doctors got drawn into the campaign. Many of them were giving passive resistance, but those who came out openly, they came out at all these levels. They made statements on the MMC, about their own colleagues and their practices. Some of them directly identified with the FASDSP and became very articulate. And in 1987-88, when a committee was formed to develop a law to prohibit sex selection in Maharashtra, Dr. Bal Inamdar was on that committee. Otherwise, doctors were very reluctant to stick their necks out at that time. But we didn't have any gynaecologist in the campaign. Inamdar was our icon – to show to everybody that we had a gynaecologist on our side. He participated and did lot of work.

18 Forum of Brahmins, the upper-most caste in the caste hierarchy among Hindus in India

Kiran Moghe: I started working with AIDWA, around 1984-85, in Pune. The FASDSP had already started its activities in Mumbai. But we came at the whole issue in a rather different way. At that time, we were working as an organisation in some of the poorer areas, in Navi Peth and that area. We were talking about the functioning of ration shops[19] and issues that affected the daily existence of poorer communities. There we met a large number of nurses who were working in private hospitals. In fact, we even started a union of nurses in private hospitals in 1985, called Hospital Karmachari Sanghatna and it was affiliated to the Centre of Indian Trade Unions (CITU). While we were talking about the issues of low pay and long working hours, and all the exploitation that went on because there was no regulation, at that time some of them started talking about the other problems that they had. One of the things that the nurses described, in one particular hospital, was that they used to induce labour at seven to eight months and the nurses then had to dump the foetus in buckets to kill them. This was in Ahuja Nursing Home, run by two sisters - I don't know whether it still exists. The whole trauma of having to do this was something that the nurses started describing to us. That's how we came to the issue in a different manner. Of course, nurses also mentioned other hospitals where such sex selective abortions were done. There was no Act, there was no regulation; we didn't even know what to do at that time so we started having demonstrations and submitting complaints to the police. That was the only thing we could do; we did not know what else we could have done at that time. And that's how the whole issue came about ; it was reported in the press at that time. In fact, I think, some police action was taken and then things quietened down. But we then got connected to the FASDSP in Mumbai and started our own campaign here in Pune. We had an exhibition, a poster exhibition. I think we still have photographs of that. I don't think we would ever use some of those posters today; it had those horrible images of a foetus and a syringe going through it.

Amar Jesani: Mohan Deshpande made those.

Kiran Moghe: Those kinds of images which we would never, now subscribe to in today's day and age. But at that time that news item about 40,000 foetuses being aborted in Mumbai in one year - these were making headlines, so for us it was a very big thing. And AIDWA took up this issue nationally from the very beginning. This is how we came to the campaign during the 1980s and connected with the Mumbai campaign.

Arun Gadre: When the campaign was happening in Mumbai, I was busy setting up my small hospital in Kimvat and then relocating into Lasalgaon, in Nashik district by 1988-89. All around me there was demand for amniocentesis. At that time Nashik was the hub. It is near Gujarat. And, Lasalgaon is a rich area in that part. So, as a newcomer who is barely surviving, struggling to afford food, it was a great temptation then. I was in the medical care market and the demand for second trimester abortions was very high, for various reasons including unmarried pregnancy. But this demand for sex determination was growing. It was a daily temptation throughout the next 20 years; I had to turn people away saying that I don't do it and refuse the money. After a few years I was in a position to refuse, but for four, five years, from 1987, I was not aware of this

19 Sale of subsidised food grains, pulses, oil and other items through shops known as ration shops or the public distribution system (PDS).

campaign going on. I was shut off there, though I was from MFC and all that, but I was isolated. I was facing a daily struggle and there was a huge demand. And then I started receiving requests from a Nashik gynaecologist, I will not name them. They sent me feelers – 'you can send the patients to us.' Two or three gynaecologists in Nashik were arranging monthly bus services to Surat for amniocentesis. I mean, Nashik must not have had the facilities to do it. But they were taking the patients

Sanjay Gupte: That was after the Maharashtra Law came in, in June 1988, when women were taken to Vapi and Surat in Gujarat.

Arun Gadre: Radiologists were yet to start using ultrasonography for this purpose, so gynaecologists had the bigger say and there was a huge demand for sex determination. There was a very big tussle to do away with that, with so much money involved. That is also one of the pressures on newcomers who are coming as entrepreneurs in medical practices. I remember those days, when I used to think, 'Shall I bend, should I give in?' It was tough.

Amar Jesani: One more point I just wanted to say about how the campaign crystallised. I think there was another reason which also influenced us health activists, who were doing research and writing. Most of us were part of MFC. We were very sensitive about the issue of population control, we had been critiquing what happened during the Emergency period,[20] were debating why doctors succumbed to state pressure, how they violated ethics. But here we suddenly realised that the technology could be bad, research could be bad. In Hyderabad Depo-provera was being tested out, and the women's organisations found out that the women who were part of the trial were being deceived saying that this was a contraceptive. They wanted to file a PIL. In that period, around 1986, some of us would meet in JJ Hospital, where one of our doctor friends Kamakshi worked - Anil Pilgaonkar, myself and a few others. The MFC members from Delhi would send us various queries and we would discuss them, and this is how the petition against injectable contraceptives like Depo-Provera was formulated and filed in the Supreme Court. So, the doctors in MFC Bombay group were continuously working at that time on reproductive health issues - on population control and the drive for net fertility rate having to be one. Our feminist friends like Malini Karkal encouraged doctors to enter the campaign. There were multiple events which played a role in driving the campaign against sex selection.

Vibhuti Patel: Madam Rehamattulah who was in the personnel section of Larsen and Toubro in 1984, which had 12,000 workers then, said that all the young workers in their late 20s and early 30s were submitting medical bills of Rs 1,600, Rs 1,800, Rs 2,200, for gynaecological problems. She wondered how come suddenly, all these workers' wives had gynaecological problems. She asked me to counsel them. During the counselling it came out that these workers wanted either one or two child families; they said daughters are a burden and would ruin the family. These were educated workers, 12th pass, so had completed higher secondary education, and had

20 Emergency in India refers to a 21-month period from June 1975 to March 1977, when a state of national emergency was declared due to internal disturbance. Among other things, this period became notorious for forced mass sterilizations in many parts of the country, especially vasectomies. See: Gupte P R (2017) *India: "The Emergency" and the politics of mass sterilizations*. Demographics, Social Policy and Asia (Part I), 22(3), pp 40-44

undergone industrial training; many of them spoke English. Those who lived in slums wanted to move to *chawls*.[21] Those who were in *chawls* wanted to go to one room flats. So, these were upwardly mobile workers and they said, 'we don't want a daughter because daughters mean dowries and we will be ruined'. Some believed in one-child families and others believed in two-child families, but both the children should be sons. Then we suggested that she should organise a seminar on this subject. At this Larsen and Toubro seminar, key groups in the state were invited: Family Planning Association of India, FOGSI, IMA, women's organisations and government officials. The consensus was that this issue was not a problem. In fact, we were hounded by people, because we feminists were the only ones who were against it. But the kind of statements which were made by the responsible people and the office bearers was revealing and shocking – that from Kashmir to Cape Comorin,[22] they were getting calls continuously. Like one Dr. Sharad Gokate said that people phoned him at all hours of the day to find out about the test. Even his six-year-old son had learnt how to ask relevant questions on the phone such as, "Is the pregnancy past 16 weeks?" They said, 'we are performing a social service,' and, 'if you really want to do philanthropy, why don't you do the sex determination test?' They said, 'what will be the fate of these women without this? They will be *takleli baia, parityakta* [abandoned, deserted].' We highlighted what happened during the Bhopal Gas tragedy,[23] and how doctors refused to go to Bhopal in the aftermath of the disaster even though amniocentesis was needed to check foetal condition amongst pregnant women, many of whom were having stillborn babies. The only clinic that was run there was by Dr. Mira Sadgopal and MFC. So, that was one very important experience.

In Pune, Sadhana Dadhich and Nari Samata Manch had been very active in the early 1980s. They had also got information from nurses and had met with the MMC. In 1986 they picketed in front of Harkishandas Hospital. Around 15, 20 people were there, including Dr. Jayant Naralikar, well-known scientist from Tata Institute of Fundamental Research, Mumbai. He also organised study circles at the Institute and invited us to speak on the subject.

Kiran Moghe: Nari Samata Manch told me later, after we had done the sting on Makarand Ranade, that during the 1980s they had picketed his hospital. We didn't remember at that time. But it was much later that we came to know that Makarand had been on the radar for many years.

Ravindra RP: The 1981 census gave some sense that the sex ratio was going down. Then Barbara Miller's book 'The Endangered Sex' comes. But then all the scholars were saying, 'there is no direct evidence, there are no macro studies, so this is not acceptable to us'. But we had several micro studies, some were done by activists, but a number of them were published in journals

21 Chawl is residential tenements in Mumbai, usually populated by low-income workers

22 This phrase Kashmir to Cape Comorin or Kanyakumari is used in India to refer to the length and breadth of the country.

23 The Bhopal Gas tragedy remains one of the world's worst industrial disasters. On the night of 2nd December 1984, tonnes of methyl isocyanate gas leaked out of the Union Carbide pesticide plant in Bhopal. The gas spread over large parts of the city, killing thousands of residents and causing long-term health effects for hundreds of thousands.

and had references that gave us very clear idea that the sex ratio would indeed deteriorate with sex-selective abortions. I can think of Bambawale's study and by Roger Jeffrey, and others.[24]

From different parts of Punjab and Maharashtra, we had enough evidence to show that people were using abortion as a tool for sex selection. That was very clear. Now, I'll come to a very important thing - something for which I have not found a reference. It has been reported that in 1982 it became, for the first time, a national issue. As it happens, a question on the issue of sex selection was raised in the Indian Parliament. The opposition staged a walk-out and then the Prime Minister had to intervene and gave an assurance that 'we shall not allow these things to happen. We will take all possible measures to ban these tests and stop this social evil'. The centre of the controversy was Dr. Prithipal Singh Bhandari and his wife, who ran a clinic in Amritsar, and they had this advertisement 'Spend Rs 5,000 now and save 500,000 later' all over North India, and they used to give direct commission to doctors who used to send patients to them. The interesting part is why it came out in the open. One of the senior bureaucrats from Delhi had sent his wife to this clinic in Amritsar for foetal sex determination, and it was a case of wrong diagnosis. A male child was diagnosed as female and after abortion, this bureaucrat found out that it was a male. So, he said, *'mein abhi badla loonga'* [I will take revenge]. That is how it got attention.

A second very interesting thing was that all newspapers wrote editorials against this practice of sex determination, including Times of India and Indian Express. But many of them including Times of India continued to carry advertisements of sex determination clinics in the same issue. Then the entire debate was centred on the accuracy of tests to predict foetal sex. As Vibhuti said earlier, there were pressures personally to undergo this test. My personal story is also of 1982 - there was a lot of pressure on us too. We could find many middle-class people going for this test. When my wife Lata and I went to Delhi, we could see all the advertisements in a very open form. This was the context in which the controversy broke out. After six months, it subsided, and absolutely nothing happened. Everything – protest, ban, promises - stopped completely. The geneticist who was practising with Dr. Prithpal Singh Bhandari in Amritsar shifted to Delhi for better prospects, as the issue had received a lot of publicity there. And after 1982, there was a huge surge in the sex determination business. In fact, you can see, if you look at the graph, there was tremendous surge in the sex determination business in Delhi itself.

So, what had happened? We saw that we, the progressive people, had done all that was possible, but nothing happened to the doctor, in fact, his business was doing better. Both, Prithipal Singh Bhandari and his wife's business was doing better in Amritsar, and the geneticist also had a business in Delhi. After that, it started in a big way in Maharashtra too. It was in 1984 we realised what was going wrong. In the meantime, all of us friends – health groups, women's groups, human rights groups – all came together. First, we talked to different people and groups and then formed the FASDSP in 1986. For two years we worked very hard just to understand the

24 Jeffery R, Jeffery P and Lyon P (1984), "Female Infanticide and Amniocentesis", Social Science and Medicine (UK) 19(11), 1207-12. For several such articles/authors referred to by the participants see: Patel, V (1989) Sex-determination and sex pre-selection tests in India: Modern techniques for femicide. Bulletin of Concerned Asian Scholars, 21(1), pp 2-11.

problem. We used to meet once every week, conduct study circles and study everything related to the issue - right from what is demography - we had no idea. Malini Karkal told us what NRR1 [net reproductive rate 1] was all about. I told her, I thought it's like *'urea jaisa kuch toh bhi hoga'* [must be something like urea][25]. So, she told us about demography, and we tried to understand it, and we agreed to look at it from feminist viewpoint. And interestingly, a lot of men were part of this process. This was happening for the first time. We all received training in demography, in technical aspects, in legal aspects also, and in a very systematic way we started the campaign in 1986. I think this is the first example of a campaign which was done so methodically. We said that we will learn from all that had happened from 1978-82 on this issue and from things that were happening sporadically after 1982. And, of course, we saw that the same Times of India used to publish the advertisement too. So, our starting point was, first, it's going to be a question of medical ethics, equality of men and women and human rights. Thus, this issue is a common focal point for many, a starting point for various debates. Second, we are not going to talk about the accuracy - what is false-positive, negative and all those things, because that is how media will side-track the real issue. So, we said, we are going to have a systematic campaign in the media. But we will not give media the chance to side-track it. Third, women's issues are discussed but are rarely acted upon, because men feel that they have no obligation to them. So, we shall raise this issue as concerning both women and men, as a social issue, rather than only as a women's issue. With such background we launched the campaign on 8th April 1986 at the YWCA, Byculla. Around 50 journalists participated in the day-long seminar. Only at the end of the day did we give them the papers, where all the four aspects – technical, legal, social and campaign – were covered in detail, so that there was no room for error or ambiguity. Then of course, the response was much more than what we had expected. We wanted to do some small protest, but it developed into something larger.

Indira Chakravarthi: Dr. Gupte, was there any discussion in the mainstream medical organisations, whether it be MMC or FOGSI? Was it raised?

Sanjay Gupte: No, unfortunately the voices were all for population control. At that time, the major issue was population control, discussed all the time. The committees which were given importance were all those based around controlling the population, MTPs and how they would be done, and what would be done for sterilisations. I don't remember discussing this sex determination at all in our meetings. This issue did not come up, until almost when the Maharashtra Regulation of Pre-natal Diagnostic Techniques Act came.

Amar Jesani: If you look at the scenario in 1980, you will find a very prominent gynaecologist, who made a determined effort to make abortion accessible - Dr. Dutta Pai of Pearl Centre. If you see his advertisement, you find that it was a pioneering effort by them that impressed upon people that abortion is legal. That was one of the major efforts. I remember after 1971, one of the major problems of Indian scenario was that people still believed, including women, that abortion is bad and illegal. There was still a moral stigma against it, but legally they did not know that they

25 Refers to nomenclature used for pesticides and fertilisers – such as urea etc.

could go and have one. The second thing was the economic angle. These doctors made it so cheap because they created sort of a conveyor belt of abortion. Now you can look back and say that the quality was not good enough, but it always happens like that because you want to do as many as possible. You are advertising it as an outpatient procedure and keep saying that this is the cheapest and easiest solution. It is like what you see today around caesarean-sections and hysterectomy; that there is no side-effect, there is no problem, you can get it done. This is how it was then around abortion. But this is why they were pioneers and were highly committed to population control - they were completely ideologically minded and committed. I had differences with them, I fought with them, but I can see that people like Avabai Wadia,[26] even Banu Coyaji were sincere supporters of population control. They did not like what we were doing – it was an irritation. I remember shouting against each other in seminars in the 1980s, on population issues, as well as on sex determination. Today you will find the tension remains: the gynaecologist will keep arguing that because we have brought in the law, we want to restrict abortion. Those who are campaigning within women's movements, for safe abortion, they would say that PCPNDT Act is a threat to the safe abortion movement. So, there is a huge tension within the women's movement about what to do with the PCPNDT Act. These are all connected. At that time, the tension was because of the population control ideology. Today, nobody will say that the sex selection is good and yet, anything that you try to do against sex selection will be looked at as a way of undermining abortion in general. There is an interesting dilemma around how to approach the problem.

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26 Avabai Wadia was the founder of the Family Planning Association of India and International Planned Parenthood Foundation, which promote family planning.

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Indira Chakravarthi: To move on now to the Maharashtra Regulation of Pre-natal Diagnostic Techniques Act and how it came about. Ravindra, could you tell us about that? And Vibhuti can join, and Dr. Sanjay Gupte also has something to add.

Ravindra RP: When we were working for the campaign and drafting the law, there was the fear the women's groups strongly felt that we should not be branded 'anti-abortion'. We have always said that we are for women's right to choose, but it is not at the cost of women's lives. So, we are for the right to abortion, but we are against discrimination, we are not against abortion per se. In 1986 we started with the campaign, we had very innovative methods and we caught the attention of the media and people. It started in Mumbai, in Pune, in other parts of Maharashtra and it was very well-reported. We had very innovative methods of campaigns like parent-daughter *yatra* [marches] on Children's Day[27] where we had proud parents saying that they were proud of their daughters and hence were marching with them. I remember Vijay Tendulkar[28] and his daughter Priya Tendulkar participating in it. The following year we had children from Dharavi slum, from South Bombay [an affluent area of Mumbai] and from tribal areas playing together, singing songs, presenting skits on *Ladka Ladki Ek Samaan* [boys and girls are equal]. Amar had mentioned about the advertisements of Pearl Centre in the local trains of Mumbai, informing people about sex-determination tests and abortions at very cheap rates. We prepared counter-posters, saying 'girls are being killed after sex determination tests in every nook and corner. Is that fair?' Through these posters we reached out to millions of Mumbaikars [Mumbai residents] in a few days. We had extremely good ideas that ensured that the sex determination test was an important part, but only a part of the entire debate. We conducted *Stree Jeevan Sangharsh Yatra* [Journey of Women's Struggles through Life] in which we focused on gender-based discrimination from womb to tomb, covering aspects like discrimination in care and nurture of girl child, murders of women for dowry, riots, rapes, *sati*,[29] and other forms of violence and oppression faced by women. We addressed extremely aggressive gatherings of doctors, and talked to women and men too. We had open debates with the proponents of sex-determination tests and put forth our position uncompromisingly on all possible fora. And, as Amar said, a person like D.T. Joseph, who was the Secretary in Maharashtra Public Health Department, was almost an activist himself. He participated fully in our activities.

27 In India 14th November is celebrated as Children's Day, in memory of Jawaharlal Nehru, one of the Prime Ministers of India

28 Well known writer and playwright from Maharashtra and his daughter Priya Tendulkar was an actress

29 Sati is an outlawed practice where a widow would be burnt on her dead husband's funeral pyre

So, what happens against this background? Frankly, we had no idea what was to be done. The only option which we had in mind was to draft a PIL. That was the standard practice in those days. Advocate Gayatri Singh and I sat in my place one night and drafted a petition to be filed as litigation in the High Court or Supreme Court. Suddenly one person comes to me and shows me a draft private member's bill to be introduced in the Maharashtra assembly. He was a retired bureaucrat who drafted such bills as a kind of hobby, and he used to do it every year. Nobody was bothered because he used to do it regularly; somebody would either just look at the bill or throw it away without much discussion. At that time, we had not heard of private member's bills. This draft was a small one and a half page petition or appeal, a very brief one. He said that, based on our campaign, he got some materials and used them to write this bill, asking the government to ban amniocentesis or its misuse. It so happened that we had earlier talked to Mrinal Gore [a Member of the Legislative Assembly], who was very active on women's issues. But she had not been very interested initially. As the campaign grew, she realised that this was a very important issue and at the last minute she got her name added to this private member's bill[30]. Her name being added at the last moment was very interesting. Mrinal Gore was a very strong person, and the speech which she made while presenting this bill is considered one of the most memorable speeches in the history of Maharashtra legislature. It is there in the history of the Maharashtra Vidhan Sabha [legislative assembly] - they have documented it as one of the most memorable speeches. And she was such a good human being, even though she had some medical background she used to sit like a student when we used to talk to her and take down notes.

Vibhuti Patel: As she did not have time, she would call both of us at 7.00 in the morning. She said, *'mi pawa dael'* [I will serve breakfast]; she would give us breakfast, and we would go with our babies sleeping - my baby and his baby in our laps and sit with her.

Ravindra RP: But she learnt very fast. That was the trigger - Mrinal Gore giving that speech. The campaign was taking place outside, and inside the legislative assembly she gave her speech. So, the government had to bow down; they asked her to withdraw the private members' bill and said, 'We assure the house that we will come up with our own bill'. Based on that assurance, she withdrew the bill. Then, as government does, it appointed an expert committee.[31] But of course there were counter-pressures from the medical lobby. Hence, in the expert committee Manisha Gupte and I were representatives of campaigners, Dr. Pai himself was there, and a very strong doctors' lobby was there to curtail the idea of any ban on sex determination tests. In the initial meetings they tried their level best to prevent any business being done seriously. But then very systematically, we gave pointed answers to each and every query put up by the opponents and put them before the government. Then they realised that they had no points on which they could defeat us academically or stop us in our efforts. There was a lot of pressure growing outside

30 This private members' bill was presented in the Assembly by Mrinal Gore of Janata Party and Shyam Wankhede and Sharayu Thakkar of the Indian National Congress (Indira faction) party.

31 Following the introduction of the private members' Bill in the Assembly, the state government constituted an Expert Committee on Sex Determination and Female Foeticide which included some members of the FASDSP. The report was submitted in May 1987 but was never published by the government.

the committee, so at that time they decided to keep mum and after some time they gave up. And they said, 'okay whatever decision is taken by the committee, it will be acceptable to us'. So, the report of the committee was unanimous. They had signed it, but they had not genuinely accepted it at all. That was a part of their strategy, they had to do it, they had no option.

A second parallel thing that was happening was that D T Joseph had commissioned this study of attitudes of gynaecologists about sex-determination tests and appointed Dr. Sanjeev Kulkarni to conduct it. Sanjeev Kulkarni told the gynaecologists that he was coming here officially as a part of Government of Maharashtra study, to ask questions. Still, 85% of gynaecologists surveyed in Mumbai said that they were doing the test only for sex determination, and not for detecting genetic abnormalities. So, this study and the report of the committee were very powerful tools for us. After that D.T Joseph approached the cabinet twice to get its consent for an Act banning misuse of amniocentesis for sex determination, but the cabinet turned down his request on both the occasions because the doctors' lobby had already started its campaign. These decisions are not officially made known, they may not be written down. The pro-sex-determination lobby said that no MLA was going to support us, but ultimately, at the third attempt, the cabinet accepted it, when I think Sharad Pawar was the Chief Minister. And on 31st December 1987, Chavan, who was Chief Minister by then, announced that they will bring the Bill into the assembly. In the April session of 1988, the Bill was brought into the assembly. There are things that happened for which we will not be able to produce evidence, so I cannot say clearly, but which were important lessons. For example, even when the Bill was being printed, on three occasions I saw major changes had been made to the Bill itself, by vested interests. I could see small changes were included, which would make major changes in the very nature of Act.

The lobbying did not stop at that level. Ultimately when the bill came, on that day, all the MLAs and MLCs received letters and some materials from the doctor's lobby, saying, 'Please stand up, *asa konta manus ahe* [is there such a person?] who will say that I don't want a son. *Agar tumme himmat hai to haath khada karke khade raho* [If you have the courage to say so put up your hand and stand up]. *Nahi toh* [Or else] oppose the bill!' Another development was that in the aftermath of the Lentin Commission, the state health minister Bhai Jagtap who was very supportive to this cause had to resign. So, the junior minister had to present it and then she sent a message to us saying, 'I am not able to put the bill in the assembly or council, because I am not prepared. No MLA or MLC is ready, they might oppose the bill and are ready to vote according to their conscience'. So again, we had to give point by point rejoinder to each and every question. She read it and said, 'yes, as a woman I am convinced. This is my duty to do it, I am going to do it'. And then we sent all those rejoinders to all the MLAs. And the government felt that our answers were quite satisfactory. And the Bill was introduced, first in the council, and then in the assembly.

There were certain provisions in the Bill which were not acceptable to us, two or three provisions. One thing on which there was consensus in the campaign – because this is very interesting and relevant to our implementation part – was that the women undergoing the test should not be considered as the perpetrator of the crime, because she does not have the choice. If she doesn't undergo the test she will be thrown out of the family or divorced or deserted. So, she should be

always considered to be innocent under all circumstances. That was something which was very much clear to us.

Secondly, we as a matter of principle said that its implementation is going to be very tough. Something else was very interesting – there was provision for a Vigilance Committee in the Maharashtra Regulation of Pre-natal Diagnostic Techniques Act, which is not there anywhere. There are three stakeholders: the society, the government and the medical community. So, in all the bodies, whether it is a body like the Central Supervisory Board (CSB) or the advisory committee, there should be equal representation of all the three stakeholders, so that it is balanced; nobody will be able to dominate it and the purpose will be served. Otherwise it is going to be like it is always. We fought for it, and in the Maharashtra Regulation of Pre-natal Diagnostic Techniques Act, we got it. But somehow, after that, I think as with all the laws in the centre, power remains with the bureaucracy.

The third thing, we had also asked was that if you are punishing family members who pressurise the woman and the doctors, then also put a clause that any government official, who by acts of omission or commission, does anything which is against the principle of the Act, should also be allowed to be prosecuted. You can have some process for that but in principle even that part should be there. There was strong opposition to that and it was not considered acceptable at any stage. They said, 'you already have a mechanism - you can approach the government and there will be departmental inquiry'. So, this is the background to the law [32].

The law came into force, I think, on 18th April 1988. Immediately following that, as soon as the law comes into picture, D.T Joseph was pushed out and removed from his job. He was sent somewhere else to another department; shipping or something like that. The new person who joined as Public Health Secretary did not meet us anytime. Over the next three years there was not a single meeting between the activists and the Government of Maharashtra. A Vigilance Committee was to be set up under the law. Names had been given for all the bodies; and we had given names of medical experts from each field, with the gynaecologists and others, like Dr. Inamdar, who was also the part of the committee in some capacity. Those names were not accepted. None of the people who had taken a stand were made member in the committee.

A famous geneticist who had published a report internationally, saying she had done some 1,000 cases for non-genetic reasons emerged . Interestingly, immediately after the law came into existence, 90% of the doctors stopped the sex determination business in Maharashtra. One of our journalist friends went to this famous geneticist, as a decoy and said, 'I am pregnant, and I would like to do the test'. The geneticist said, 'now, *government ne itna mushkil kar diya* [the government has made it very difficult]. It is very difficult, but I am a very pro-women person, I understand your problems. The rates will be a little higher, but I will do it for you'. And this appeared as a front-page news in Midday. The government did not take any action. But the government appointed that same geneticist on the Vigilance Committee. There was so much pressure from outside that,

32 The Bill that was presented by the state government in April 1988 had provisions that contravened certain recommendations from the Expert Committee. See p 20 of Sex Selection: Issues and Concerns, cited in Note 11 above.

ultimately, she had to resign. The government did not remove her, she had to resign. That made their intentions very clear. In the first six months everybody found that the patients were sent from Maharashtra to Gujarat, because business really decreased, by almost 90 to 95%.

Vibhuti Patel: They were sent to Gujarat, Karnataka, Goa.

Sanjay Gupte: To Vapi, Valsad and Surat in Gujarat.

Ravindra RP: This happened in April 1988. In December 1987, Government of India convened a conference on this issue. Manisha, Vibhuti and I, as well as some others, were invited. They appointed a committee in April 1988 and said that the time has come for us to enact the law at the central level. The report of the committee was submitted around 1992. The Maharashtra Act had influenced this. Because after that there were three states, in which similar legislations were enacted - Gujarat, Goa and Karnataka.

Vibhuti Patel: All three had strong women's movements.

Ravindra RP: In Maharashtra, what happened after the law was enacted was that the bureaucracy said they will not support the activists. They appointed people like those geneticists on the Vigilance Committee. The signal was that, *'cheh mahine jane do* [let six months pass], then we will take care of it', and then we'd see that after six months nothing had been done, no implementation, and after a year or so, business resumes in Maharashtra. But then, at the same time, they are sceptical because the central Act is going to come anyway. So, the Maharashtra Act is being discussed as a model because good provisions are there, but at the implementation level nothing is being done.

Indira Chakravarthi: Dr. Gupte, can you tell us about the implementation part or even the reactions of the medical community?

Sanjay Gupte: This was very big news, Dr Hema Purandare being appointed on the same Vigilance Committee. All doctors at that time felt that the government must not be sincere about this ban, so that means we continue sex determination. As Ravindra very rightly pointed out, people would stop doing it themselves, but were sending women to Gujarat, mainly Vapi was a big centre, in Surat. They said, 'if the government was serious then how can you have this person on the committee?' That was the first time the discussion started in FOGSI also, and some of us became agitated as a result. Dr Subhash Salunke was the Director-General of Health Services in the government. He happened to be my immediate senior colleague, and we were quite close. So, I approached him and said, 'what are you doing?' He convened a meeting and many stakeholders were there, it was then decided again that we needed to do something about it. By then this pre-implantation genetic diagnosis (PGD) had emerged, so it was suggested in that meeting that now it is time to add pre-conception to this pre-natal – up until then it had been the PNDT (Pre-natal Diagnostic Techniques) Act. Then I remember a discussion in that committee on 'What is pre-conception? What is PGD? And that's why PC (pre-conception) was made part of that Act, at that particular meeting. Subhash Salunke was instrumental in that change.

Vibhuti Patel: There were private courier services to take amniotic fluid samples of pregnant women for the amniocentesis test. All the drivers and conductors in the state transport buses were also involved in taking it to the small centres. When we asked whether they would do this for the pulse polio programme they said, 'no, that is the government's job'; while here they would take it to the diagnostic centres, in Gujarat and Maharashtra also.

Kiran Moghe: To centres in the border areas of the states.

Ravindra RP: To Akola. And there was a lab in Mumbai.

Shailesh Sangani: I am from Akola, and Akola was quite famous for this. There was one Dr. Bagadi, who was well-known for this purpose. All hotels in Akola were full in those times. People used to come from many areas because Akola is a railway junction and trains coming from several parts would pass through Akola, such as trains from Mumbai to Calcutta, from Rajasthan to Hyderabad, and so on. So people would come from the south from Hyderabad, from the eastern parts like Gondia and Raipur, from Ajmer in Rajasthan in the west. I was a student at that time, so we never knew all these things until we came to Bombay. Even during our education in government colleges, nobody knew about all these things. We never knew until we became MD radiologists and people would ask us. So, these things came out later on and Dr Bagadi was arrested and jailed for three months [under the Act]. But Akola was a big hub because of her. There was also a centre in Madhya Pradesh.

Vibhuti Patel: Doctors would tell us that 'amniocentesis and appendicitis are our bread and butter'. They would share experiences and jokes such as 'you make just one slit, for anybody with stomach-ache and take Rs 10,000'. There was lot of controversy within FASDSP about punishment: 'Who should be punished – should it be doctors? What should be the punishment for doctors? Can it be only monetary?' Earlier the government had said only fines would be imposed. But it would be very easy for these people who are making money to pay the fines. So, it was said, 'even imprisonment should also be an option'. Doctors said, 'no, they are doctors, they are not bootleggers'. That is the argument politicians used against us. And about the women, and even family members of women accused of this sex selection abortion, what should be their punishment? Dr. Shirish Seth in Mumbai had organised a workshop for gynaecologists on sex selection. So that's why we said that there should be punishment for doctors. This same doctor was invited to China too; sex selection had already entered Bombay's medical market, and the same thing was happening in China. And the Japanese Centrifuge method was also introduced. The cost too increased after the law was enacted, by Rs 12,000 to 30,000.

Amar Jesani: As soon as the law was passed I wrote an article in the Radical Journal of Health criticising the law[33]. We ourselves were involved in pushing it, but at the same time we were not very happy with the law. I was not directly involved in lobbying for the law itself, because that was the time when I spent lot of time in the rural areas of Maharashtra for the study that I was

33 Jesani, A. (1988), *Banning Pre-natal Sex Determination II: Scope and Limits of Maharashtra Legislation, Radical Journal of Health, 2(2).*

doing. I think Vibhuti, Ravi and Inamdar were directly involved and they were fighting the battle there. There were three things that made me uneasy when I saw the Act. The first was the issue of women's agency and that was debated quite a lot. I remember when the complaint was filed with the MMC, the complainants declared it unethical but the MMC refused to do so. My interaction with them at that time was based on their argument – it was a very simple and very powerful argument saying that, 'we are taking full consent, we are telling women what the pros and cons are of doing it, and they are coming willingly. And so, as a gynaecologist, what is my fault? They are asking for a service, negotiating the service, sex determination is a service and I am providing the service. I do amniocentesis and I provide the information they require. And that is with full consent'. Now, if you connect it to the law, it says that if sex determination is done, the women are also guilty and will be punished too. What is happening here is that the law contains a provision which is self-defeating in the sense that the one who undergoes sex determination just cannot report the sex determination, because if you do it you are also guilty, and will be imprisoned. So, the person who is getting sex determination done, that is the woman, is just out of the picture; there is no complainant. She is not the complainant at all. And that makes this law and the implementation problematic.

The second issue that was raised was how do you regulate the medical technology? I had a lot of reservations about having separate laws for separate technologies. That is how Indian regulatory system has emerged. And that is what I wrote in Radical Journal of Health, saying that, 'you want to have a safe abortion, so you came up with MTP'. If you just go ahead and say, 'right to abortion', then it could have been sufficient. But no, you wanted safe abortion, so the MTP Act also lays down the provision for what should be the standards under which you can have an abortion. That's how you can have the registration of the doctor, registration of the institution, the standards required for institution, you know, for the first trimester, second trimester, everything is mentioned. However, what you are actually talking about is what comes under purview of say Clinical Establishment Act and standards, but standards in relation to abortion are laid down in the MTP Act. Now, what you are doing is putting together another standard for another technology regarding sex determination for the foetus. And tomorrow you will have standards for some other procedure or technology. It's like how they did it for the transplantation technology, separately. How can we have so many separate laws and implement them?

Another problem is that you don't control the institution itself, but are just controlling the processes within the institution. Bombay Nursing Home Registration Act is not being implemented. There is nothing about standards in it. It has only been implemented in Bombay City and Solapur, nowhere else. That is the third point. You will look at sex determination, but if you are doing caesarean section, or hysterectomy – even within reproductive health – nobody's there to ask you to have any standards. So, this was the other issue - that this law becomes very difficult to implement. And that's why I believe that, every law that India has passed, it is only for a specific technology, and is struggling to be implemented in a proper manner. And this includes the transplantation law. Every two years or three years we have a big scandal, simply because institutions are not controlled properly. We are just looking at what the doctor is doing in that institution. That is not going to work. So, these are some of the major issues that were raised. Having said that, this

Act is good, it delegitimises sex selection which is a very, very important area. The last thing is agency related to women's right to abortion.

And I can say personally, in my case, as we fought for PCPNDT Act, I became more interested in abortion. And that's how over the next ten years I got involved in doing lot of projects on social aspects of abortion in CEHAT and ultimately the national level 'Abortion Assessment project', that came from the sensitisation that started here,[34] that we need to preserve abortion. We just spoke about technology and did not talk about discrimination. But it is a very important issue. Well, what if you are saying that sex determination is bad then it is related to the discriminatory knowledge of the sex of the foetus - that is the problem. And that's, I think, the challenge we faced. When we were in U.K. – Vibhuti was in London School of Economics, and I had gone to a British Medical Association meeting – I found that the bioethics debate as well as regulation is very different from what we are doing here. In South Asia we have a different kind of problem. Abortion is campaigned as a women's right to choose; and right to life is a foetus's right to life and that has more of a religious origin. When you are making a choice you are making a selection, but how do you decide whether that selection is discriminatory or not, because you are going to oppose only discriminatory choice and not the choice made by the person? So, it's not that you cannot find out anything about the foetus. Can you find out something that can lead to discrimination? So, that created another area of debate around the law – is it going to really help you by just looking at the discrimination or it will affect the entire abortion processes?

Sanjay Gupte: Last year FIGO [International Federation of Gynaecology and Obstetrics] ethics committee and World Midwives Association had come out with a statement to allow sex determination. I had to fight tooth and nail to say no, not in our country. If FIGO and World Midwives Association come out with this statement, ethical statement, then it will be terrible. Then FOGSI will say, 'See, this is permitted'. I had to fight out, absolutely tooth and nail and finally we managed to put it on hold [35].

Arun Gadre: Amar has perfectly nailed it. We are regulating the processes but not the institutions. And I will go beyond that - they are still keeping everything in the market. Now, if they are not controlling the market of healthcare, and not regulating the institution, these piecemeal regulations fail. I will share my experience. The MTP Act was there when I started practising in Lasalgaon. That Inspector came to my nursing home and demanded a Rs 5,000 bribe to certify that I could conduct MTP, which I didn't give. So, he wrote that operation theatre is not fit for doing MTP. I was doing caesarean sections, I was doing hysterectomies, but it was not fit for MTP. I said, 'okay, I won't bother'. I just waited for three more years and then one good person came. But this is the experience of every doctor, those who are well meaning and ethical. And that is also the root cause of a reflex reaction against regulation. But then the solution is you regulate the market and you regulate the institutions.

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34 See Johnston, H.B. (2002) Abortion practice in India: Review of Literature. Abortion Assessment Project - India. CEHAT Mumbai. See http://www.cehat.org/researchareas/project/1489666089 and http://www.cehat.org/researchareas/project/1489666089/publications for details.

35 See https://www.figo.org/news/non-medical-gender-biased-sex-selection-joint-icm-figo-statement-0015659 (last viewed 22.4.19)

Amar Jesani: But, Arun, the problem is the profession does not want regulations for themselves, as well as for the institutions.

Sanjay Gupte: This is where I must put forward the doctor's point of view too. That is why, when any Act comes in, doctors are worried that tomorrow somebody will say 'you were not paying the bribe, you can't do a caesarean or hysterectomy or anything, Clinical Establishments Act bans you or your hospital'. So, that's why there is a problem. Regulations should be there, but the implementation should be proper. That's the concern.

Kiran Moghe: I think, what you are saying Amar, is very correct. Look at the incident in Mhaisal.[36] I think Mhaisal is an example of where there was no regulation. It's completely unregulated, I mean, one cannot even call it a hospital. How can you call it a hospital, it wasn't even regulated by those rules and regulations? Today there is a news headline, have you seen? Some illegal abortions have been reported from Sangli. Now, what is illegal in it is not clear, whether it is the hospital that doesn't have an MTP registration or whether the abortion itself was beyond its term. Nothing is clarified.

Girish Lad: One patient asked me a question – and these are often intelligent questions by people who are internet savvy – a woman who is herself a lawyer, asked me why the Indian Constitution does not allow them to select the sex of the foetus. Does it not qualify as a fundamental right for a woman? She was pregnant for the second time. She had a boy and she wanted a girl, so she said 'I want to know'. I said that it was not possible. 'Why was it not possible?' was her question, 'How can it be banned?' The fundamental problem is socio-economic. We are not solving the socio-economic problem, even by PCPNDT law. And it will go on. We have reduced it, you can say from, when 100 or maybe 50 doctors were doing it, now one or two doctors may be doing it. But they are still doing it. And affluent people are going to Singapore, Dubai, have the test done and return and say, 'you are fools, you are not minting the money'. So that is the way they circumvent. The problem is socio-economic, that will not be solved in an easy way.

Amar Jesani: A clarification, otherwise what I am saying is misinterpreted. What I am arguing is that sex selection is opposed on the issue of discriminatory selection. And discriminatory selection the Constitution will not allow, because it violates human rights. I acknowledge that this is based on systematic discrimination against women in the society. That is a patriarchal system. As long as the patriarchal system is there and it continues, the selection of the foetus becomes discriminatory. And that was our argument, on the basis of which we fought for the law. We also fought for the law on sociological arguments on the issue of consent, because this is what the proponents of sex selection argued. We said that, well there is a systemic coercion of the women. And when system coerces you, you may have to see whether there is a real moral force which is forcing the women to go and have a selection done. If she, on her own, without any prejudice against women is doing it, it is fine. But, there are pressures from the family and other social institutions.

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36 This refers to the retrieval in March 2017 of 19 aborted female foetuses near a clinic in the village of Mhaisal, in Sangli district near Pune on the Maharashtra-Karnataka border. This happened in the course of a police investigation into the death of a woman during abortion in the clinic, where she had gone after knowing that she was carrying a girl child.

Sanjay Gupte: What you are saying is absolutely right Amar. Finally, in our FIGO committee I said, 'Terminating a male child, because you don't want a male child is also discrimination'. That's how they were finally convinced. I In India we are talking about female, then what about other countries? Secondly, this issue was discussed. Maneka Gandhi[37] mentioned it even before we had discussed that, in India, if we allow sex determination women will be killed. That's the main thing. Pregnant woman will be so maltreated knowing she has a female child inside -this cannot be allowed in India.

Ravindra RP: I had this problem because of my role as an activist, and in drafting and then even in the interpretation, somewhere I was involved. Firstly, we always said that law cannot solve all the problems. PCPNDT Act or any Act is not going to solve the problem within the health system nor of discrimination. We were very much convinced when we said that more importance should be given to social awareness and institutional reforms which will try to at least lessen the discrimination, if not achieve equality. So, we had all, for years together, discussed these issues. In the report of the central committee it has also been mentioned, whatever the other laws related to dowry and inheritance and others, they need to be strengthened. But, all said and done, this is going to take some time before things take some shape. Until then we cannot simply sit idle, we need to intervene; this is the intervention only for that period.

Secondly, it is always going to be a heterogeneous society. We have a few privileged class women who would say that wanting a male child is their conscious choice and this law would mean negating their choice. But the law became a necessity because millions of women have no choice but to undergo the test. This law is not in contradiction with the MTP Act. But someone might be refused an MTP if the gynaecologist suspects that it is sex-selective abortion. The law cannot provide all of the answers to all issues. See the Malpani case that we took to the Supreme Court.[38] We have seen people who, very independently say that 'this is my choice'. But there are always going to be exceptional people. We cannot have a law which will take into account each and every individual in the society. But, to look at most Indian women, majority of them, what is their status?

Thirdly, the one part which has not been taken care of is a bigger awareness of genetic abnormalities. We thought that after this Act comes into force there will be more awareness among the people about the genetic abnormalities, and the detection of those would get some sort of encouragement. We had also mentioned this during the debate demanding regulation. But hardly anything has been done on this front. People only know about amniocentesis as a sex determination tool, and we have told the government that they should always advertise that these

37 Maneka Gandhi is a politician.

38 This is a reference to the intervention of Dr Aniruddha Malpani, Medical Director of Malpani Infertility Clinic, Mumbai, in the PIL in the Supreme Court of India (see Note 46 later). Dr Malpani argued for permitting pre-implantation sex selection, on grounds of personal choice of couples and also as a way of ensuring family planning. See:

Malpani, A. (2002) Why shouldn't couples be free to choose the sex of their baby? and

George, S.M. (2002) Sex Selection/Sex Determination in India: Contemporary Developments, both articles in *Reproductive Health Matters* 10(19), 192-3 and 190-2 respectively.

tests are done for detecting abnormalities. Sonography is a different story altogether. What I am trying to say that this being the only tool available for detecting abnormalities is something which is not being discussed at all and certain issues will not be resolved. For example, the debate on what we call an abnormality and whether you should abort when an abnormality is detected, we won't go into that. You cannot answer all the questions through one Act. These are, I think, some interventions in the given socio-economic condition, at the given time that we had done. In both, the Maharashtra and the central Act, we always maintained – before sonography, which has changed things later on – that the facility of detecting genetic abnormality should be done only in government hospitals, because, it is possible to monitor them and checks and balances are available. So even in this report of the Central Committee on Sex Determination,[39] I had given a note of dissent on this matter.[40] In 1978, after the ban by central government, government hospitals had stopped doing it, most of them. Private treatments are not very easy to monitor and so we said we should restrict only to the government hospitals. Of course, that was not accepted by the government and now it becomes a market force, it is not possible to control it. We cannot have one act to take care of all the things because in drafting law it becomes such a specialised thing, you need to define each and every term, and it applies only for a particular time, which is very difficult to even control everything within that area. So, if you have to have one sex determination, sex pre-selection, together, it is quite difficult. But if you want to have a surrogate pregnancy, or you want to have institutional care, you want everything in one Act, it becomes so amorphous, it cannot be implemented at all. But there needs to be some sort of stock taking, review, and linking of definitions. That should be done, but is not being done. Every issue is being looked at in isolation, and that's why some discrepancies will emerge. We need to have some regular review of all these Acts; how the lacunae will be filled up and how those could be co-related.

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39 Report of the Central Committee on Sex Determination. June 1989 Bombay. In 1987 the Government of India appointed a small committee under the chairmanship of D.T. Joseph, Health Secretary, Government of Maharashtra with seven other members, to: (i) go into details of comprehensive legislation (ii) to suggest in-built mechanism for an infrastructure for ensuring proper implementation of proposed legislation and (iii) to propose measures for generating public opinion against these tests either as a part of legislation itself or otherwise.

40 This dissenting note is provided in Annexure I.

Session III
Introduction of the national Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994 and the subsequent PIL

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Introduction of the national Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994 and the subsequent PIL

Indira Chakravarthi: To sum up briefly, we have covered the background and the Maharashtra Regulation of Pre-Natal Diagnostic Techniques Act 1988. There has been so much opposition to the law from various quarters, and there are many nuances in the law. We have heard of the acknowledgement that the law, by itself, is not enough, and that it was brought in with limited expectations as to what it can do and what else needs to be done. We move on now to discuss the central PNDT Act, the influence of the Maharashtra Regulation of Pre-natal Diagnostic Techniques Act on the design of the central PNDT Act, and the differences between the two. We will then cover the implementation of the Act, which is a particularly contentious issue. Ravindra, can you start things off by telling us about the central Act?

Ravindra RP: A committee was appointed on 20th February 1987 for the drafting of a central Act on sex selection, along with the measures for creating awareness. That was within the mandate of the committee – that it should suggest measures for creating awareness, institutional reforms as well as legal and non-legal measures. In June 1989, this committee submitted its report.[41] The interesting part of this committee was that a lot of people from the medical community were involved. We could get people specially for certain meetings – for example we could involve gynaecologists from AIIMS. Radiologists were not involved at that time, because sonography was not in the picture; it came later with the PCPNDT Act. Sex pre-selection had just begun but there wasn't much sex detection at that time. In a way, actually, it was a good model of working together with all of the stakeholders, and the report is very interesting. The most important part of this is that it is, in a way, quite close to the Maharashtra Regulation of Pre-natal Diagnostic Techniques Act, except that the provision of Vigilance Committee is not in the Maharashtra Act. And, of course, like the Maharashtra Act, it doesn't restrict services to government, it also allows private sector to provide them. But, at the same time, it states very clearly that unless and until it is established otherwise, a woman will be presumed to be innocent under the law. Even the definitions have been more specific. The interesting part here is the unique feature of this Act; that we considered the experience of what happened in Maharashtra. Taking that into consideration, we gave thought to how this law could be sabotaged. We did not use the word 'sabotage' in the report but we considered how the entire purpose of the law could be defeated by vested interests, by bureaucracy, and what measures should be done to counteract that. For example,

41 The Government of India, Ministry of Health and Family Welfare, in response to the mounting public pressure, convened a conference of medical experts, administrators, voluntary organisations and legal experts on 19.12.1986, in Delhi. Miss Mira Seth, Additional Secretary and Commissioner (Family Welfare), presided over this conference, wherein the almost unanimous view was that, the pre-natal diagnostic tests should be used only for detection of genetic and other abnormalities and such use should be regulated in Government and other institutions, the advertisement of such tests should be banned and public awareness generated against the misuse of these tests for prediction of sex of the foetus. The Government of India accepted these recommendations in principle and constituted a committee in 1987. For details of this committee see Note 39 above. A copy of this report is available in SATHI- Pune library.

it seemed that certain Acts were not implemented because there were no official government directions at all, so we said, this law will come into force the moment the President gives assent. We found what the loopholes in Maharashtra Act were and addressed them in the report. There was only one point of difference, where I only wanted it to be done in government hospitals, but that was not acceptable to the committee, so I gave a note of dissent on that.[42]

This report was totally buried and no action was taken until 1994. Before that there had been some attempts to draft some hotchpotch Act. I had seen that some draft was prepared but we had to tell the government not to introduce that law because it was going to be counterproductive. I think we got help from some MPs, like Brinda Karat from CPI-M [Communist Party of India – Marxist]. Lotika Sarkar[43] and other people were also helpful.

After that, in 1994, the law was enacted because of pressure from UNICEF and other international agencies. There was a conference organised by UNICEF in Delhi,[44] where Vibhuti and I attended. Unanimously, a resolution was passed that-, as the government has drafted bill, they should come up with an Act. They came up with the Act but it was not implemented for the next six years. In that process I think we interacted with three or four prime ministers, something like six or seven health ministers, n number of bureaucrats, and every time we had to start afresh. That was our problem. At that time the problem used to be that there was less stability among activists compared to the medical community, or say FOGSI. There is no committed organisation among activists like that. At that time people would blame us, *'aap log usi issue pe itne saal se kaise kaam kar rahe hain?'* [How are you people still working on that issue after so many years?]. It is difficult to get people to work on the same issue and have a national level campaign, and to sustain it. We knew all this but then there was a problem because people in Delhi could not follow it up for a long time. So, there are 'n' number of issues which happened to the advocacy. After 1994 onwards, I think, we could not sustain enough pressure on the central government; locally and state level, it was possible, but centrally to go and do something in Delhi was not possible at all. Law-making is ultimately a very political process, and it's a question of all the checks and balances and the interests that play the role. The doctor's lobby had introduced very strong people there and we could find them in the bureaucracy also, so those bureaucrats were not ready to listen to us. In 2002 or so, after the petition was ultimately filed, the Supreme Court gave a directive, and again after so many years, a good Public Health Secretary came to Delhi and he somehow contacted me. I told him, 'what happened to the report we submitted?' He said, 'I have not seen this report, not a single copy is there with the government. I am not aware that such a report exists.' They had not seen the report at all, they are so smart.

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42 See Note 40.

43 Lotika Sarkar was a noted Indian feminist and lawyer, and a pioneer in the field of women's studies and women's rights in India. She was a founding member of Centre for Women's Development Studies (CWDS), Delhi, established in 1980, and also Indian Association for Women Studies, established in 1982. She taught law at Faculty of Law, University of Delhi. Lotika Sarkar was the co-author of the seminal report in 1975, T*owards Equality: The Report of the Committee on the Status of Women in India,* along with Vina Mazumdar, another scholar of woman's studies and founding member of CWDS. See Note 17 above.

44 International Conference on Child Rights, Health and Environment, organised by UNICEF at Delhi.

Sanjay Gupte: There was the PIL in 2000 and the Supreme Court acted on it.[45] There was no meeting of the Central Supervisory Board for a long time. Then, we pointed out to Ghulam Nabi Azad, then Health Minister who had come for our FOGSI meeting inauguration, that if you do not hold the committee meeting, then it is going to be contempt of court and so, at least for your sake, you must start having these meetings. So that meeting was held. In the first meeting it was realised was that nobody had clarification, right from issues such as who should be doing ultrasonography. The first two meetings we spent discussing this and unfortunately radiologists were also against this at that time, saying that gynaecologists cannot do ultrasonography. Brinda Karat was the one who said that gynaecologists are allowed to do it. So, that was a big issue that we had to sort out in first two meetings, which meant one year had passed only on that discussion. Then we pointed out that definitions in this Act are terrible, because for example there is no category of sonologist in India.

Shailesh Sangani: By definition there is no sonologist, there is no degree for sonology.

Sanjay Gupte: By definition, it never existed, it is radiologist. Even right now, the way the Act is written, the definitions are extremely unclear. And though so many rules have been brought in, still, peculiar issues are there. In genetic labs, genetic counsellors need to have done twenty cases of this type, only then they will be recognised. How do you do 20 cases if you are not recognised? You are doing it illegally. So, how do you get the experience of doing those 20 cases? Nobody explains it in the law. All those peculiar issues are there, so the law is still terribly faulty and needs a lot of clarification on many issues.

Indira Chakravarthi: Amar, in 1994 the central Act is passed, in 1996 the rules were made and then in 2000 or 1999 comes the PIL by CEHAT, Masum and Sabu George.[46] Could you give the background to that PIL, the Supreme Court orders that came out and how the government and medical profession responded?

Amar Jesani: Well, the 1990s was a very bad decade in a way, because I think the focus for which law was required and what the people were seeking from the law that changed in my understanding. When the campaign started in 1980s it was primarily in defence of women's rights. It was a very, very principled issue, saying that patriarchy violates women's rights and it is violence. During the 1990s much of the discussion came to focus on sex ratio. Once the 1991 census data started coming in it intensified. So, by the time the law is passed in 1994, that focus was entrenched. It changed from what I would call a very principled position to a very

45 Refers to the Public Interest Litigation filed in February 2000 in the Supreme Court of India, (Writ Petition (Civil) 301 of 2000), under Article 32 of the Constitution of India, by Centre for Enquiry into Health and Allied Themes (CEHAT), a research organization; Mahila Sarvangin Utkarsh Mandal (MASUM), a non-governmental organization and Dr. Sabu M. George, a civil society member, bringing to the notice of the Court that although the Act prohibiting sex determination had been passed by the central government in 1994 and rules were also framed in 1996, no steps for its implementation were taken either by the central government or by the state governments. This case was argued on their behalf by the Lawyers Collective (Delhi). The Supreme Court took note of the fact that the law was not being implemented. After calling for data and compliance reports from the central and state governments regarding the implementation, the Supreme Court passed four different Orders in 2001, and finally disposed of the Petition in March 2003, giving various directions to the central and state governments, and implementing bodies under the Act.

46 See Note 45 above.

consequentialist position. It was being said that because it is causing imbalance in sex ratio, this law is required and should be implemented. The emphasis from the sex determination started to change to sex selection. Because sex selection ultimately leads to imbalance in sex ratio, sex determination may or may not. It depends on how things get worked out. If you stop it, the couple will not come to know the sex of the foetus, and the issue of selection will not arise. That was the basis. We had a debate I remember in 1988 in Lawyers Collective journal, brought out by The Lawyers Collective. One of their senior staff members wrote an article saying that, 'Maharashtra law is not going to be effective because it is looking at the determination part and is not doing anything to the selection part. In order to do something on the selection part, you need to amend the abortion law, and explicitly do not allow women to choose to do the sex selection. Then you will be able to see that the sex ratio is not affected.' I responded to that saying, 'hands off the MTP Act'.[47] My point was don't touch MTP law. This became a very big issue in 1990. Even in the 1980s, during the campaign, a lot of pro-life people, anti-abortion people, would come to the meetings, particularly the Christian missionaries and others, and they would say 'we oppose sex selection because abortion is wrong'.

Sabu George was extremely committed to this issue. He was kind of the One Agenda activist - he would not get involved in any of our work except on sex selection. He had done pioneering work on infanticide and it was very good work that he carried out. His devotion to fight against sex determination just cannot be disputed. He used to come to Bombay and stay in our house, and in CEHAT and MFC meetings he would pester us, saying that 'you must do something!' One of his concerns was that the Act was not being implemented, the sex ratio was falling, and something needed to be done. We were also worried because we were involved in bringing about the law and nothing was happening. After 1989 nothing much happened in Maharashtra, except that sex determination went underground. Something that was costing Rs 100 started costing Rs 1,000. That is what everybody in the medical sector was telling us, that this has not stopped, it is there, but price has gone up because you have made it illegal. In 1994 the central law was passed and nothing was happening on that front. All the committees were formed; initially they took good people from the NGOs in their committees and in the Appropriate Authorities. [48] But once their term was over, they had their people from their own political NGOs sitting there and nobody was interested in doing anything. So, we thought that something should be done. I was not involved fully in the petition but I was there in 1999, in 2000, for two years when Sabu was coming very regularly and we decided to go for the petition. We were worried about the impact on the abortion law quite a lot. That's how we kept consulting Manisha Gupte, of MASUM Pune, while thinking of petitioning. We thought that if a women's organisation joins that will ensure that things don't get out of the hand. I had already relinquished my position in CEHAT and I was on

47 Jesani, A. (1988), "Hands Off the MTP Act!" A Response to Nilima Dutta's Comment on the Law Relating to Prenatal Diagnosis. The Lawyers, October, 3(9), pp 22-3, (Response)

48 The Appropriate Authority (AA) is a three-member committee mandated by the Act to be constituted by the central or state government. The AA has several functions, all relating to the implementation of the Act, such as enforcement of standards of the testing centres registered under the Act, looking into complaints of breach of provisions of the Act, creating public awareness. The three members would be: an official each from the Health Department and Law Department and an eminent woman representing women's organisations. See: Government of India (2006) Handbook on Pre-conception and Pre-natal Diagnostic Techniques Act and Rules with Amendments. Ministry of Health and Family Welfare.

the way to Kerala. In 2001 I went away to Kerala, so when all the hearings took place I was not present. There was hearing after hearing because the state governments were not releasing reports on implementation of the Act, despite directives from the Supreme Court to do so. The other thing that was done strategically was that we got Indira Jaising as a lawyer. As she was part of the women's movement in Bombay, we all knew her very well and we thought that she will ensure that the MTP Act was not tampered with.

It took a long time – the petition was filed in 2001, but it went on for three years or four years, when I was not in Bombay. I was working full-time in Kerala, Trivandrum, at that time. But I used to go to Delhi regularly. And I remember a few things because Mr. Nanda was the Health Secretary around that time, and he was a big supporter of this petition. Not only that, Nanda was influenced a lot by Sabu George and I think the 'right to life' people. He commissioned films, documentary films, which are anti-abortion while arguing against sex determination and sex selection. We were very upset with him, and we had a big fight with him at that time. Because the Ministry of Health was being very soft on this kind of thing, the international organisations jumped into the frame, particularly UN organisations - UNFPA and UNICEF. I remember going all the way from Kerala for a meeting in India Habitat Centre, where they called people from various religious organisations, Hindus, Christians, Muslims, Sikhs - all of them were represented there. It was in an auditorium and the tenor of that talk was very simple, *'na rahega baas, na baje baasuri* [there will be no bamboo, there will be no flute to play] - abolish abortion and everything will be fine'. They all would say that this discrimination against women is bad so you should not have sex selection, but then why are you having abortion, because it is abortion that is allowing sex selection to take place. The growing role of these faith-based organisations happened during the period when the petition was being heard. That was the major problem - faith-based organisations saying that 'sex selection' is an issue so we have to take it up and ban abortion altogether. My position has remained consistent: if you have a law to curb sex determination, don't go into the whole issue of the sex selection at all. It is up to the women - we should leave it to them. But you ensure that the woman does not come to know the sex of the foetus, except under certain conditions that are laid down under the law. If you are able to do that then it will be effective. because that places the responsibility on the doctor, on the provider. Don't ask the woman whether she has got sex determination done, don't amend the MTP Act; the issue is whether the doctor is communicating the sex of the foetus or not.

Other changes came about during the 1990s. – When we had campaigned in the 1980s it was all about amniocentesis, but ultrasonography became important in the 1990s. A technological change had come about which created a problem because you are no longer talking about controlling genetic laboratories. With an ultrasound one can see the sex of the foetus, so how can we implement the law? I am not going into the nitty-gritty of rules, whether you have to fill up the forms, but if you keep our discussion on the heart of the implementation, it is how to ensure that a woman does not come to know the sex of the foetus unless certain other conditions are met. The only way to do that is to ensure that the doctor does not convey, or anybody in the hospital does not convey, the sex of the foetus. That's how during this period and afterwards the sting operations started. They found that was the only way to find out if sex determination

was taking place. The woman could say, 'yes, I was told by the doctor, because my husband prompted the doctor to do it, or my family members prompted the doctor to do it', but she won't do that because she will herself go to the prison. So instead somebody can track the doctor doing it. That's how the sting operations started and were then taken over by people who were, I would say, fanatically involved, very committed. I had gone to Rajasthan, I spent a lot of time in six districts and I saw this group, a community level group of women and other activists who would come to know that a particular doctor was doing sex determination and then trap them. In Maharashtra lawyers were also involved, quite a few very strong lawyers. But these are the things that happened because of this petition and the outcome of that.

Sanjay Gupte: One important point is that the law was developed when technology was different. Amniocentesis was the main technology then, and the attempt has been to apply the same law in a similar way to new technologies, and because of that, this law has remained faulty. There is not even a word about ultrasound clinics in the original law, because ultrasound was not thought of at that time. That is why there are no proper specifications as to who should do it and so on. That has to be addressed at some point. Now, since new technology has come in, of pre-fitted DNA. I think we should also be aware of this new technology, that if you are going to make some amendments of this, we have to take into consideration this entirely new technology. Ultrasound will not be needed and sex will be decided much earlier.

Arun Gadre: There are two points relating to implementation. That PIL was required because around me, up to 2006 when I left Lasalgaon, there was no implementation of PCPNDT. Secondly, we are doing something on a philosophical basis, moral basis, legal basis, and we came up with the Act. But we have misplaced our impulses, because the Act did not consider the market in the picture. I have observed that overall, if the sex ratio has gone down the fulcrum of it was a few hospitals, a few centres. In Yevla there were two centres in operation for 20 years. They had political connections. Those centres were responsible for 80% of sex determination and sex selective abortion. It was the same in Mhaisal. I don't know whether we are looking into this aspect, because that is the most workable administrative aspect. If I am in a market and I want to earn money out of sex determination and sex selective abortion, then people should come to know that I am in the market. In 1994 I attended a program in Pravaranagar to receive an award for one of my novels. Nearly 10,000 people were there and I asked this dumb question, related to a sub-plot in that novel, that 'everyone knows where sex determination takes place, so why we don't boycott that place?' There was unrest after I raised this question, and actually there was a fear that people may thrash me. Even today everybody knows where to go. And only the police and administration seem not to know.

Sanjay Gupte: They claim to not know.

Arun Gadre: As Amar has raised the philosophical aspect, I will share my journey briefly. My perspective entirely changed when I bought a sonography machine. Until then I was supporting the MTP Act, supporting the PCPNDT. I am not against any choice, that is very fundamental, and it should be. But the moment I first saw the heart beating inside foetuses on my ultrasonography

machine, that was my first time, I was visualising the early life. I felt that we are tampering with the right to life of a foetus. That is my biological, philosophical take. I always was thrilled to have a look at all this life under the machine and I changed. And when I changed, even I tried to convince people that if you actually do not need to go for MTP please don't do it - not only second trimester, not only sex determination, so that is a change. Many doctors feel guilty even while conducting first trimester abortion. Of course there are issues of conditioning and all that, I am not denying it. But that point onwards I have been carrying that guilt, and then when it came to implementation, I had some practical dilemmas.

Ravindra RP: One thing is that, whatever be the discussion outside, within the committee it was always very clear that we are not going to tamper with the MTP law at all, whether it was in 1994 or in 2003 – that was very, very clear. We maintained the position we had started with: 'we are not against abortion; we are not against the technology being used - whether it is amniocentesis, any other genetic technology or sonography. The only thing is that we are going to regulate it - it should be used for the right purpose, and we should encourage the right purpose. The only problem is if it is used for discrimination and sex selection. Secondly, the question of woman being afraid of reporting is not there because all the laws very clearly say that women will not be punished. That was very clear. Of course we know that women will not be powerful enough to come out and talk about her husband, but whenever such a thing happens, as it happened in a recent case, where the woman could muster up the courage to go against her husband, then of course such a provision is there to protect them. So, there is no question of not protecting the woman or of having the law going against the woman.

The 1990s was the most important decade. There are two things which you should remember; a process of globalisation was unfolding, leading to changes in technology and the attitude and role of the state also changed. At that time, we could not really point it out - the effects of globalisation were seen after a decade or so. Today we can talk about its impact. The government was in the process of withdrawing from all these responsibilities. The welfare state was in decline and the commitments shown by the government earlier in 1980s, was not shown in 1990s and 2000 onwards; any government or any bureaucrat will not show that much political will to implement or enact the law, because they just wanted to withdraw.

I want to counter something that others have said - there was in fact some consideration of sonography. I think the earlier law says genetic counselling centre, imaging centres and sonography centres, because the role of sonography became clearer later on. Sonography was defined, and then the identification of the gender was possible at an earlier stage of pregnancy, which was not possible with amniocentesis. All through the drafting the top organisations from the medical field were represented, for example IMA and FOGSI were represented. The problem for radiologists was that they didn't have an organisation which could take a stand at that time. Experts were called, such as from AIIMS and were asked to give expert opinion.

Shailesh Sangani: Our organisation was there, but the Ministry never called us. That was the problem - radiologists were not called.

Ravindra RP: They were called, and when we discussed how to describe a radiologist in the definition it was kept ambiguous: anybody having a post-graduate qualification in radiology, or anybody who has got a degree of medicine, or a sonologist.

Shailesh Sangani: Actually, such a degree doesn't exist so that was an erroneous inclusion.

Ravindra RP: Yes, at that time we didn't have postgraduate qualifications in sonography. So, it was in a transition phase where clear-cut qualifications for radiologist were not there. Secondly, we also had to keep a balance - because we wanted gynaecologists to also have sonography cover, if they could get it, if they needed that. We did not want to deprive them of having a sonography centre. That's why we kept it ambiguous; even a paediatrician or a gynaecologist with some training could be given the license.

I remember the first case which was filed in Maharashtra under this Act. We got a call from the Magistrate saying that, 'I do not have the copy of the PCPNDT Act, can you give us the copy of the Act?', so we had to start with that. We had mentioned that there should be adequate training sessions for the public prosecutor, as well as the magistrates, which was not done. It may have been done later on, but for the first two-three years, the magistrates had absolutely no idea about the law. And one very interesting part is that, in the law, we had drafted a preamble based on feedback of the campaign. We said the problem is always in interpretation and the magistrate will not have the historical references in their mind and will not be aware of that, so we should give the entire logic in the preamble. We had drafted the entire preamble - why we want the law, why it is for women and what the related points are regarding medical ethics and discrimination. All those things were done. The government, state and central removed this preamble saying, 'we don't need a preamble for the Act'. So the question of how to interpret the law becomes so difficult, because the magistrate will go only as per the definitions and technical aspects.

Sanjay Gupte: One thing from the IMA's point of view - I would definitely say they have completely failed in understanding the situation. They said 'we don't want any regulation, we don't want this law', whereas, a few of us had discussions with Bindu Madhav Joshi [49] – who was from Pune. If the doctors had said 'this is how we want the law to be changed, in this particular manner', then it would have been good for implementation and for the doctors as well. We as doctors are completely in denial in saying that we don't want any regulation – we did so at the time of PCPNDT and now we are doing it in the case of Clinical Establishments Act. Somewhere I hope that some sense will prevail, otherwise whatever comes has to be accepted and then there is no point in fighting it.

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49 Bindu Madhav Joshi set up in 1974 the Akhil Bharatiya Grahak Panchayat [All India Consumer Forum] and is considered to be a pioneer in the consumer rights movement in India, and was active in the enactment of the Consumer Protection Act 1986, to protect consumers from poor commercial services. It was made applicable to medical services in 1995 and was seen as an important step towards improving quality of care.

Session IV
Experiences of Implementation of the central Act in Maharashtra and of the Silent Observer/Active Tracker

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Indira Chakravarthi: There are these problems with the state and central laws, and the question of whether they can address many problems. I think we can move on to implementation now. We don't have any government representatives, but Kiran and Dr. Sanjay Gupte, you have been part of the advisory committee and the Vigilance Committee. How was the Act implemented in Maharashtra? And what was the impact on the medical practitioner? We also have Girish Lad here with us, who can talk about a technology used to address this implementation issue.

Kiran Moghe: I think the law originates, as we all understand, from the movement, and I think there has been a weakness of the movement also, that very often we have pushed for laws and once they have been put in place we have not monitored its implementation. I think it happened with several of us and we are learning in that process. I think even with the PCPNDT Act that was a weakness and the petition brought it out; because for so many years those structures that were intended to implement the Act were actually not in place, which is what then came out with the Supreme Court's orders.

The experiences of the movement in getting the Act implemented, in that sense, are still limited. Maharashtra is one of the states where it has happened and so we can draw on that experience. Also, numerically, the number of cases – now we do not go into the merit of whether those cases are right or wrong – but the point is that even the number of cases is the highest in Maharashtra. And I think that is important because actually a law is drafted at a particular point in time, but I think it's in the course of its implementation that you understand its strengths and weaknesses. It's from case law actually that we learn.[50] So I think the experience of Maharashtra and its case law needs to be taken into consideration when we look into the implementation of the PCPNDT Act now, and I think we have a rich experience there. The other state is Haryana, to some extent. They did it in a different way and we did it differently. But these are two states where we can even have some more studies to compare how the implementation has taken place. I think there have always been problems and as I was saying to Dr. Sanjay Gupte earlier, there is always a systemic problem of any law being implemented because of the way we have a bureaucratic culture and a culture of corruption. We need to not focus too much on those points otherwise we will end up only talking about them. You know every implementation authority is corrupt. It's the same with every Act. So let's keep that aside and then look at the implementation aspects.

50 Joshi, S. P. (2013) Compilation and Analysis of Case Law on Pre-Conception and Pre-Natal Diagnostics Techniques (Prohibition of sex selection) Act, 1994. Maharashtra Judicial Academy and UNFPA.

My point is that we have to look at the implementation and see whether the law has been successful or not in an overall sense. To me, from the movement perspective, it's been successful in the sense that it definitely brought the whole question of sex determination and selection, and discrimination to the forefront. It brought in the whole angle of anti-abortion views and the fact that the women's movement needed to be very careful about how it positioned itself on that debate. So it was successful in that and at the practical level it was definitely successful in, what shall I say, curtailing to a large extent the practice of sex determination. Those doctors who thought that it was easy money and were doing it very easily definitely stopped doing it, and it is perhaps now the really hard-core ones who do it as a matter of making money, taking advantage of the whole son preference in our country. So now the question we also have to look at is what has happened to sex ratios? I mean unfortunately, despite all this, sex ratios continue to fall, at least as per the census figures. Now has the implementation been successful or not from that point of view? I feel that the states - and I am now talking about Maharashtra government - never really sincerely, in the spirit of the Act implemented it. When did they implement it? They implemented it every time the census data showed falling sex ratio, especially 2001, 2011, when they realised 'oh now we have got to do something about it'. Because the sex ratios are falling, the districts where it is falling are increasing; earlier it used to be Western Maharashtra, but now it includes Marathwada and has even spread to the tribal districts. At a national level, even the north east is showing red. So now they have to do something. You have to show that you are implementing the Act and then you go into 'drive mode'. We always have drives to implement the Act, but we never had a systematic implementation taking into consideration the opinions and understanding of involved stakeholders.

What has happened is, unfortunately, it has gone into this mode where it is the implementing authority versus the doctors. And especially in the last four or five years where ratio is falling, we've had statistics, we've had memorandums, we've had all this. But I think it is really because the state itself has not been serious about implementation. And there are all these other problems about the bureaucracy. Has there actually been any analysis for instance of the 'F' forms? Why were all these forms created to start with? I'm sure that, when the law was drafted, the people who were drafting it were looking at a mechanism, therefore all these came into existence. Regarding the 'F' form,[51] there was a committee to even look into its revision. Nobody actually said that the 'F' form should be scrapped, it was revised. What has happened with all the forms? The government has actually never used that data. One Collector in Hyderabad, I think, did some work,[52] and that could have become a model. But there are no operating procedures which have

51 The 'F' form is one of the records mandated under the PCPNDT Act 1994 that has to be maintained by the owner of an ultrasound machine, specifically for pregnant women. Among other details, the name of the referring doctor and the indications and results of the ultrasound examination must be mentioned in the form. For more details see: Mani S. (2012) Guidelines for ultrasound owners and owners of clinics, diagnostic centres, nursing homes and hospitals. Indian J Radiol Imaging, 22:125-8.

52 This is a reference to the proper implementation of the Act in Hyderabad city by the erstwhile Collector in the early 2000s, which led to a significant drop in the cases of sex-selective abortions in 2005. According to the Act, diagnostic centres which do not keep the mandated records of patients as laid down will have their licences cancelled. Of the 381 scan centres in Hyderabad at that time, such action was taken against 81 and their machines confiscated. Action was also initiated against the producers of the scan machines – GE, Wipro and Philips – for selling their products to unregistered clinics. These actions were accompanied by an increase in the sex ratio at birth in Hyderabad city, from 942 in 2004 to 1,014 in 2005. The sex ratio subsequently fell again, coinciding with the transfer of the Collector. See: Editorial (2012) Life Giving Leadership, Economic and Political Weekly, 47(25), p 8.

been put in place to get the Act implemented and collected data are not used to check whether sex selection is going on or not, or determination is going on or not. All we are focused on is the sex ratio. Other parts of the implementation were never looked at, that's one thing.

Secondly, if you look at the mechanisms, there's been a debate about whether it should be the health authorities who should implement. But definitely when it is the health authorities you think that they have an understanding of the issue, so they should be in charge. I have never been in favour of giving it to the district collector. It would have been just one of his several committees. But at the same time, one must not forget that there are nexuses that operate, and there is a network of doctors, so there is scope for collusion, and you need to have mechanisms which will ensure that kind of collusion doesn't take place. But really how can you do that? Ravindra, you said that the law happened because D T Joseph was there. Similarly, in all these mechanisms, if you have genuine people who are in place they will use the mechanism properly. But if you don't, then it can be a very loose thing. Even if you look at the definitions, it says in the advisory committee, 'three social workers, of which one should be member of a women's organisation'. Now, how do you define a social worker? It is difficult. Without taking names, even in our committee one of the social workers is actually a doctor, a gynaecologist, who represents a charitable trust. Now I am not saying anything personal here. What I am trying to say is that all these things can be worked around, so you can ensure even in the mechanisms, a situation where there is collusion. The first sting operation that we did in Pune, 2005, Dr Nagne, was a member of the district advisory committee. Now, he is also a radiologist, and interestingly, if you look at the provisions for the constitution of the advisory committee, there is no radiologist. In fact, as far as the social worker, or rather the NGO, as it has shifted from 'social worker' to 'NGO' – in the minds of every government officer today anybody who is not a government representative comes from an NGO – they do not differentiate between health NGOs and between women's NGOs. So, the IMA was also an NGO in our advisory committee and they were represented. The stakes can always be tilted in favour of the medical profession if you do not want to implement the Act. I feel that all these mechanisms themselves are not just inadequate, they are malleable, they can be moulded. And I do not know how we can actually suggest a mechanism whereby this can be implemented sincerely.

Vibhuti Patel: That's why a person like Dr. Munde[53] could thrive.

Kiran Moghe: Yes. Much depends on whether those mechanisms operate 'honestly' – I want to use that word – whether they operate honestly and whether the people who were deputed are actually looking at the implementation of the Act in its spirit or not. And I think those are important points which somehow we never discuss. Today, unfortunately, the whole implementation debate has become one of authorities versus doctors.

53 This refers to the arrest in June 2012 of a doctor couple, Dr. Sudam and Dr. Saraswati Munde, in Beed for conducting abortions on women following sex determination. The couple surrendered following the death of a pregnant woman in their hospital while undergoing an abortion. In 2015 the couple was sentenced to imprisonment under various sections of the PCPNDT Act. That the couple was conducting sex determination and selective abortions was exposed by a sting operation by an NGO in 2010. Following this sting operation the authorities had sealed their sonography machines under the PCPNDT Act and cancelled their licence under the MTP Act, but the couple had continued to perform abortions illegally until 2012.

The second point I think we need to discuss is whether those clerical mistakes, which are called clerical mistakes, are really mistakes or not, whether they are minor, whether they are major, and what can be done about that. Because I do believe that the forms and the entire structure of the Act was put in place with some consideration. I do believe that some of the things are important, like whether you have a referral slip or not is an important point. Maybe a signature missing is not so important, but a referral slip is definitely more important than a missing signature. So, we also have to have some kind of a check list whereby those so-called minor or clerical points that we keep having debates about are actually laid down. And I feel that there is a process by which some of the issues that are coming up in the discussion need to actually be discussed , and whether you need to amend the rules, you need to amend the Act, all these things are actually not being discussed in a very, what shall I say, conducive manner. What has happened is that it has become a debate as if on one side is the activist, and on the other side are the doctors.

And I do believe, lastly, that there is some opposition to regulation. I mean for instance even in our advisory committee we find that doctors who have been told that you are making these mistakes, keep making the mistakes and pay no heed. I think that in the beginning the doctors also took the PCPNDT Act rather casually. I mean, ultimately, we mustn't forget that the doctor considers himself as a prestigious member of the community, and the person who is coming to inspect is seen as a minion of the government. So, this tension is also there. You know, like, 'who is he to ask me? Who is he to check my records? Who are they to ask me?'

But there is scope, which is not being explored enough, for activists, for people who are implementing the Act – the government agencies as well as the medical fraternity – to sit down and actually discuss some of these points without getting into adversarial positions. And if that is done then this Act has a future. Otherwise it seems to me that there is a strong lobby today which is in favour of amending it. If they can't amend the Act, they will amend the rules. These kinds of things are not good, because ultimately it is the doctor who will tell the patients whether it is a boy or a girl. So the onus, I feel, in implementation is ultimately on the medical community. It is because they did not self-regulate that the Act had to come. So now something has to be done by the community itself to create that sense of trust, so that people feel, yes, it is from the medical professionals' side that it will happen, and it will be properly implemented.

I have heard very often this point about socio-economic situation and son-preference, which is why I am reacting to it. We are always told that unless you do something about son-preference we can't do anything about sex selection. It's not either/or, it's never like that. The whole process of instilling values of equality in society is a much longer process. We all know that. *'Marathi madhe apan chivat ha shabd vaparto na?'* [in Marathi we use the word *chivat,* don't we?] Son-preference is a very, very *chivat* [deep-rooted] value. It is not going to go away so easily. So, of course women's movements are trying to change attitudes, but the situation in society is so regressive today; I mean all the values that are coming to us from the wider situation, are so regressive. We are actually under great threat and it's a big challenge for us. In that situation, implementation of this Act is becoming even more difficult and these are some of the issues that we have to think of.

Vibhuti Patel: It's wiping out what we achieved in the 19th century social reform movements – it is so regressive.

Indira Chakravarthi: Dr. Shailesh Sangani, did you wish to add something to what Kiran has just said, from the perspective of radiologists?

Shailesh Sangani: Yes, from the radiologist's point of view, I will say that the clerical work has increased, which has bogged down the radiologist. They took it casually initially, and now they have realised that it has become a big problem. For minor errors we are being targeted, the machines are sealed, and our careers are destroyed by our own colleagues. The reference slips that Kiran mentioned are a problem because many patients come without referral slips as they are quite educated and they don't go to the gynaecologist at all, nowadays they just come directly to us. They say, 'we have done a pregnancy test this morning and it is positive, we want to do the confirmation by sonography'. They are all Google-savvy people, so they come directly. What should we do in those cases? There is a provision for self-referral, but when we do self-referrals the Appropriate Authority says *'Tere idhar toh bahut self-referral aarahe hai, kya baat hai?'* [There are too many self-referrals at your place, what is going on?] We are in urban areas, people are quite educated and they come in by themselves. They come from a doctor, referring doctor, gynaecologist or a general practitioner, for confirmation of pregnancy. Then they come for even third month sonography saying, 'Sir, we want to do NT [nuchal translucency] scan', because Google has taught them that this scan is important, the third month scan is important to rule out the earliest anomalies of Down's syndrome, trisomy and all that. So again we have to only turn back that patient saying 'please come with a gynaecologist's letter' and they say 'we work in an IT company, we don't have time, we have finish late at 8pm, we can't go to gynaecologist, please do it'. So again, it becomes a contentious issue. We have to tell them, 'please go back'. Particularly, in Navi [New] Mumbai, we get many patients who come because they stay in Navi Mumbai, but their doctors are in Mumbai. Their doctors are in Hinduja Hospital at Pedder Road, or even at Bandra Kurla Complex. Because they are in IT sector, they are working there, and they come to Nerul Centre, to our Navi Mumbai centres, where they are living. And they say, 'we cannot go back to the doctor just for a referral slip'. Now the other new thing that has started is that they phone their doctor, who writes a referral slip and sends it to them by WhatsApp, which the patient again sends to us by WhatsApp. We take a print-out and attach it to the patient's record. This is just nonsense. Basically, it is just unnecessary clerical work which the doctor has to do. Instead of checking the patients we have to do all those things. So, this has become a big problem.

Another issue is about the bribes. We have people telling, off the cuff, not officially - they don't tell this to the association officially, but when we meet, they say that although Rs 25,000 is the official government fees for renewal of license, another Rs 25,000 is needed under the table. If you are a new applicant, namely for recent graduates, Rs 1 lakh has to be paid under the table to get the registration under the Act, otherwise the authorities will not clear the papers for several months; the applicants realise that the officials are not passing it, so they will approach somebody and then that approach shows them the way. When the officials come for inspections, with a few

Appropriate Authority and NGO people accompanying them, they ask for money just to avoid shutting down the centre, to avoid a complaint being filed. Radiologists avoid telling us because they settle it then and there. See, they have learned from the bitter experiences of other senior colleagues: 'That radiologist's machine has been laying sealed for seven years; it would have been wiser had he given the bribe earlier. It is better that we settle the matter now itself by paying Rs 4 or 5 lakh'. These things are happening and it is wrong. If the radiologist is really culpable, the machine should be sealed. But if the paperwork is good, if everything is fine, then the machine should not be sealed. Of course, there is always some minor issue like the board has not put up in a proper place or something, so they try to extract the money out of us. As everything happens in India, laws generate new modus operandi and new ways of earning money for the officials. This is one side-effect of the law.

Indira Chakravarthi: One thing you have written about is that the law is better implemented in Navi Mumbai.[54] How is that so?

Shailesh Sangani: First of all, I would say however good or bad the law may be, the doctors have to accept it. As Dr. Sanjay Gupte told me, 'I have to accept it in principle, whatever it may be, first by heart then by mind'. You have to accept it because it is a moral thing. I was one of the first radiologists to register in Navi Mumbai and hence my PCPNDT registration number was 001 when I started my clinic in 1997, and registration under the law started in 1998. During that time a lot of general practitioners and gynaecologists tried to force me to do sex determination, which I would refuse. They would ask, 'why? What is the moral reason?' I used to say, 'Sir, I am a Vaishnav, a Krishna bhakt [devotee of Lord Vishnu, of Krishna]. I don't like this thing'. This was my reason. I don't even eat eggs. I don't like female foeticide. So, *'woh paap mujko lagta hai'* [that sin will be on me]. This was my thinking. I am a religious person, so they stopped sending patients to me. I was at a loss. I had financial commitments and I had to take loans from my father to repay them. Then I joined various other hospitals, including MGM Hospital and then Terna Medical College. This was my personal experience to sustain my financial position because I had a son and a family to take care of. But this is not possible with each and every person, and a few radiologists succumb to the pressures and the lures. There is lot of money in that. We have seen that.

Now, since the year 2000, when the local Appropriate Authorities started implementing the Act strictly, the vulnerable radiologist started abiding by the law. This is true. However, later on as and when the drives came in, so the skeletons started tumbling out. In 2011 when more than 250 machines were seized and cases were filed against the centre owners, radiologists, gynaecologists, it was found that many of these cases were because of the errors in the records, or incomplete forms and not wearing the name plates or the aprons by the doctors or the staff. This was nothing but an overzealous drive by the government officials because people said that they were doing nothing, so they had to do something. When we had an official conversation with

54 Sangani, S. G., Grover, S., Suprabhat, B., Beri, S. and Chotai, H. (2014) Analysis of the understanding of the radiologists regarding PCPNDT Act and their perspective about its effects on society. IOSR Journal of Dental and Medical Sciences, 13(9), 42-48.

them, they said, 'there is pressure on us from above, we have to do something; so what if we shut down 15 centres out of 150?'. But, the officials themselves did not realise the repercussions of these closures, because the doctors had to face the court cases, even until now. They didn't realise this at that time, but they destroyed the careers of all those doctors. I have a few examples here which I will tell you later, and after almost ten years, many cases are still going on and the machines are still sealed, and they have lost their careers. These have made a permanent scar on the collective psyche of the radiologists from India, [55] across the state, which was one of the reasons for the state-wide strike.[56]

I will only quote a few of the cases which were very illogical. Regarding seizure of the machine, the lower courts dismissed them but the government is still pursuing them in high courts, and the radiologist community feel this is harassment; so do the centre owners and even the gynaecologist running the hospitals with the sonography machines. One radiologist visiting a gynaecology hospital had stopped visiting in 2007 and informed the authority. This was recorded and the paper was kept on record. The gynaecologist's machine was sealed in 2012 because of some errors in the form keeping or whatever. But the radiologist who had stopped visiting in 2007 is also now included in the FIR, and because of that his license to practice has been cancelled and a notice has been served by the MMC. There is another example – intimation of changes of machine from one centre to another, done in Gondia, and the fees were paid and the Appropriate Authority has the receipt. The Appropriate Authority did not verify the records and sealed the machines next month- this case has been with the court for seven years. The machine was sealed for seven years, so it accumulated lot of dust and humidity and when they opened it up the machine does not work. Now the parts are not available - the machine cost Rs. 12 lakhs and it is totally dysfunctional. There was a big financial loss and the doctor then shifted from Gondia to Nagpur. In another example, machines were bought by one owner for two of his radiology centres: two centres, same owner, two machines with two serial numbers from the same company. The company placed one machine in this centre, another in that centre, but the numbers did not match the certificates issued by the Appropriate Authority. Both the machines are of the same owner, same centre, same name, in Mumbai. And the machines are now sealed for almost six years now.

These are the minor things which do not prove sex determination. Now next type of case is that two forms being incomplete; the patient's signature is there but the forms are incomplete, so the machine was sealed. The High Court has dismissed the case and said that the immediate completion of the Form 'F' record is not required and have ordered the de-sealing of the machine after three years. Such incidents have happened in Gujarat also. This proves that the Appropriate Authority of the various districts have their own ways of interpreting the law. This was evident

55 See for example: Bano, S, Chaudhary V, Narula M, and Venkatesan B (2012) The PC-PNDT Act: An attempt to gender equality: Radiologists' Perspective. Indian Journal of Radiology and Imaging, 22(2), 144-45.

56 During mid-late 2016, radiologists and gynaecologists in Mumbai went on a strike and stopped performing ultrasonography on pregnant women and held protests, as they felt they were being unduly harassed in the name of implementation of the PCPNDT Act. See: Kashyap A (2016) https://indianexpress.com/article/cities/mumbai/maharashtra-radiologists-call-off-strike-after-cm-fadnavis-gives-assurance-2870047/ ; and Express News Service (2016) https://indianexpress.com/article/cities/mumbai/pcpndt-act-doctors-to-join-protest-from-sep-1-radiology-sonography-services-to-be-shut-down-2999761/

when we ourselves conducted a seminar in Navi Mumbai through the Maharashtra state branch of the IRIA, in which we called the Appropriate Authority of both nearby districts. And on the dais, both had their own way of interpreting the rules and then there was contradiction, in front of the audience, when one Appropriate Authority said, 'no, it cannot be like this', other said, 'it cannot be like this'. This, we recorded and posted to our head office and then from there the PCPNDT coordinators gave it to the State Appropriate Authority, Dr. Khade, and told them to at least educate their Appropriate Authorities properly. Now, the state government took this effort and the Additional Director, Dr. Khade, took this seriously and he tried his level best to educate all the Appropriate Authorities by conducting seminars in various districts [57]. But as the radiologist could not understand the law, initially, because it was too complicated, similarly, the Appropriate Authority also didn't understand the law. It is very simple because they are also human and to err is very human. After all, they are also doctors and they are also humans. So it is difficult for them also to understand and they also make mistakes while sealing the machines. Now, the IRIA in Maharashtra discussed with the government, had multiple meetings, to at least make a standard operating procedure. After the strike, and because of the change of the government, there was some change, they took up the matter and now, ultimately, now this standard operating procedure was published in 2016.

I conducted research with 100 doctors – government and a range of private – in Navi Mumbai, and we found out that the implementation of the Act was good. The reason was that we in Navi Mumbai had been active with continuing medical education and running workshops ourselves, and we co-ordinated this with the Appropriate Authority and the local Urban Health Centre Medical Officer. What happens is, they say something on the stage, but when we go back, after another month or two, the local Urban Health Centre fellow who comes for the checking says 'no, no, this is not how it is' - the Appropriate Authority has given the instruction to the radiologist or to the centre owners, but local fellow doesn't obey you. So we called the local Urban Health Centre people along with the Appropriate Authority and along with all the centre owners – there are 124 centres in Navi Mumbai, all radiologists, gynaecologists and centre owners – to sit and understand the matter and follow the rules, like putting up a board. The rules say that the board should be put up at a visible site, at an appropriate site. It doesn't say that it should be put inside the sonography room, but during a quarterly inspection the local authority of that particular area will say, 'you have not put it inside the room, I will put this as a point against you in the quarterly reports'. It becomes a negative thing and then the Appropriate Authority of the district gives us show-cause notice, that you have not put the notice board at a proper site. But what do you mean by proper site? So these things are there to harass us. These things have been happening, so we took this initiative, radiologists as well as the Appropriate Authorities, and from all this there was an increase in the sex ratio in 2013. Navi Mumbai Appropriate Authority Dr. Deepak Paraokar got an award, from the Chief Minister for improving the sex ratio in that district. That was a good sign.

We also found out in our study that 46% of the patients' relatives still ask for sex determination. That was in 2015, and it has dropped now. Out of that, 18% were ignorant of the rules, and others

57 See: Government of India (2006) Handbook on Pre-conception and Pre-natal Diagnostic Techniques Act and Rules with Amendments. Ministry of Health and Family Welfare.

said they were asking out of curiosity. They might say out of curiosity, but they may actually want to know and are afraid to say so; doctors cannot confirm this. Still, roughly 50% people don't know about or they still ask, so we really need socio-economic upgradation. And 75% of the doctors felt that the relation between the incomplete 'F' form and the sex determination does not really exist. Because those who want to practice sex determination will not fill the form at all, or they will fill the form so perfectly that you will not realise it. So that 'F' form is not the way to track sex selection.[58] It is a way to collect data, to track the identity of the woman, and to track the whole scene of whether she gave birth or not, but it is not the way to understand whether the doctor did it or not. For that there are only two ways according to us. One is that you do the sting operations, which, as madam said, initially it was done with lot of zeal and then they become complacent and just forgot about it. And that is really the thing that has to be done. Or second option, as Maneka Gandhi had said, but of course Dr. Sanjay Gupte warned us against: is to make it compulsory to officially declare the sex of the foetus, so no doctor, no patient, no relative, no gynaecologist, no radiologist will dare to touch that female for another four, five months and they will see that it is safely delivered because now it is officially known that this foetus is a female foetus. So that pregnancy becomes a precious pregnancy.

Sanjay Gupte: Just one more point about the law I would like to make is that there are so many laws in the Indian Penal Code in our country that if you are charged with murder, you don't face any consequences because the justice process is so slow. This is the only law when you are charged and you immediately face the consequences: your machine is sealed, your livelihood is stopped and your license is removed. And this happens whether you are proved innocent or guilty in the court of law. This is the biggest problem with the law.

Shailesh Sangani: Yes, the decision of the court might take 10, 20 years. That's why we had this representation repeatedly with the Health Ministry at the central level, and they even had the advisory committee meeting. Every time the meeting takes place, they don't go up to the level of making amendments. We wanted a distinction to be made between minor errors – the form filling errors – and the actual sex determination co-related with the form filling, then also sting operation.

Kiran Moghe: I just want to respond to the point about sting operations because very often in meetings we are told that, 'well, these are clerical errors, these are minor errors, this is not the way to find out whether sex determination is going on, so the best thing to do is a sting operation'. But having been involved in two sting operations I just want to say that sting operations should not be done, frankly, because they put the pregnant woman at extreme risk. You see you are enacting a scenario where you do not know what is going to happen. Everything depends on the situation and it is extremely stressful and difficult for her and I really think they should not be done. I am

58 In 2017 FOGSI, aggrieved with Section 23 of the PCPNDT Act and the placing of what they termed as 'clerical errors' on the same footing with the actual offence of sex determination, approached the Supreme Court seeking decriminalisation of anomalies in paperwork/record keeping/clerical errors in Form F. In May 2019 the Court gave its decision upholding the constitutional validity of Section 23, saying that Form F was not a clerical requirement but a condition precedent for the test, hence mandatory and the responsibility of the person conducting the test. For details see: https://www.livelaw.in/top-stories/-sc-upholds-constitutionality-of-section-23-of-pcpndt-act-144751

saying so having done two. What happens in sting operations, particularly the ones that are supposed to be conducted by government authorities, is that the decoy invariably turns out to be a poor woman. I think that is very unfair. You use poor women from deprived communities to become your decoys, because obviously middle-class or upper-class women are not going to make themselves available. In fact, I have said this to the association doctors who keep saying, 'do a sting operation'. I said, 'then why don't you send your family members to do the sting operation?' This is a rather unfortunate way of reacting. But that is what happens. Normally sting operations end up being done by poor women. Today, because of the Act, sex determination has gone down and it is really the very hard-core people who are doing it - it has gone underground, totally underground. We did a sting in 2005 and it was so simple. We did one in 2011 and it wasn't so easy. Two doctors were involved and there was a chain. Now, it is virtually impossible to find out, at least for us. Maybe, within the community of doctors, you may have some inkling of who is doing it and why.

Shailesh Sangani: Even we don't know nowadays.

Kiran Moghe: But, now it has become underground and it is not local. This is what we feel. It has just moved out. So, people in Pune will go to Solapur, maybe they will go to the other districts. So that mobility makes it even more difficult. For instance, we did get a tip off about three months ago, and somebody said, 'can you find out?' But when we found out that it actually involved either taking a train or taking a bus, going somewhere else in the night, how would I even suggest to any patient, will you do it? So it is ruled out now. I think we should now forget about sting operations for sex determination.

Indira Chakravarthi: The silent observer is an important issue, as a technology being brought in to try to solve the issue of implementation. Girish, what can you tell us about the reception to the Silent Observer?

Girish Lad: I started my journey with PCPNDT in 2009, so I am completing almost nine years of work on PCPNDT across various states, in around more than 100 districts, and the results of the effectiveness of the technology can be expected now. It started in Kolhapur. I was told that Kolhapur has the worst sex ratio, which was shocking as there is a positive image about Kolhapur. So I started meeting people, I started reading the PCPNDT Act, about the rules and regulations. I met the Appropriate Authorities and doctors, and tried to understand the subject. I then went through the census figures, did some data analysis and then I imagined myself as an Appropriate Authority, because I am not a doctor, I am not a lawyer, I am not an official, I am not a social activist. So I had that advantage of looking at the things from a third perspective. I tried to imagine myself as an Appropriate Authority in charge of Pune district and with responsibility for PCPNDT implementation, and tried to visualize, 'If I am supposed to implement this Act, then what are the challenges in front of me?' I realised I had four challenges. First thing I would want to know is, how many women are pregnant in Pune district. Sitting in my office, how would I come to know this? In our culture we don't tell family members and relatives about the pregnancy until the fifth month. The second challenge that I needed to address was: which lady went to which

sonography centre on which date? How would I come to know that sitting in my office? The third challenge was that, given sex determination is done using sonography machines between 12-20 weeks, how many women who have done sonography are within the range of 12-20 weeks. And the last question was, during the sonography what exactly do doctors see on the screen? Has he checked the femoral length, has he done complete anomaly test or whether he just checked for 2 minutes? The doctor does the sonography and switches off the sonography machine; nothing is recorded, so there is no evidence of what the doctor has seen - whether he has seen the gender or whether he has seen something else. So these were the four challenges that I had to address, and I started thinking of the solutions for these four challenging parts.

Simultaneously, I realised that as this is done in consent with the pregnant female and doctor, there is no complainant. As the Act says, in every pregnancy filling up the 'F' form is mandatory with the standard formalities and on the 5th of every month the report is to be submitted to the Appropriate Authority. In 2009 Kolhapur district had 251 registered sonography centres, and on an average, monthly, 8,000-9,000 'F' forms, in hard copies, would be submitted. If you go to any PCPNDT office in any district, you will see the bunch of F forms tied up in cloth bundles. Nobody has even opened them to date, because they don't have the man power. The Chief Medical and Health Officer or Civil Surgeon is the Appropriate Authority, and for them, because they are fighting several epidemics all year around, PCPNDT is the least and the last priority for them. So they don't have time. Recently we have seen that some states have appointed district PCPNDT coordinators. But, until 2009, they were not there, or were there in very few places. So there was no dedicated staff at the district level to take care of the PCPNDT. And in places where PCPNDT coordinators are appointed they are employed on fixed-term contract basis; they are not permanent employees. We still have a TB officer, but we don't have a PCPNDT officer. So who is going to look at that forms? And there is no complainant. As Dr. Shailesh Sangani correctly said, if I have to do sex determination then why will I fill the form? I will not keep any documentation; I will just do sonography and ask when do we abort. That's it, so simple! So, those people who are following the Act, they will fill the form. Or I will fill the form in only those cases where there is no sex determination. So all the records of 'F' form generated are of no use. It is a waste of time and effort, and still that is happening.

Now, since the Appropriate Authority is not getting the related information of the pregnancy and of the sonography centres, we came up with the first solution - to make the records of sonography centres online, and have the filling of 'F' form also to be completed online. That was well accepted by Kolhapur doctors, because more than 90% cases filed across India are those of incomplete documentation. After the Munde case in Beed,[59] in an area called Kaij, six of the seven sonography centres were sealed. I was witness to a video conference, conducted by Chief Secretary, and every Collector was there. The Chief Secretary asked, 'How many sonography centres are there in your district?', '220', so 'seal 20 centres'. Because they had to show that after the Munde case 'we have taken action, we were so prompt'. So targets were given to the district authority: 'There are 50 centres in your area, I want five centres sealed'; those were the

59 See Note 53

orders given by the Chief Secretary and I was the witness. In Kaij, six sonography centres were sealed and only one centre was working, and that belonged to a political family. The charge for sonography, which was at that time Rs 600, shot up to Rs 1,000. The opposition party went and destroyed that last sonography centre too. So in Kaij there were no sonography centres. Then Beed section court issued an order to release those sonography machines on the condition that they should install the device that we have invented. So I went there and met the doctor. His centre was sealed just because in a few columns where he had to write 'not applicable' he had instead written 'NA'; the form was complete in all other respects. In Rajasthan I have seen that centres were sealed because an apron was not there. A few days later, some more centres were sealed - an apron was there, but there was no name plate. And on the following day, one more centre was sealed - he had an apron and name plate, but no degree was mentioned on the name plate. This is how the Act is being implemented. I have so many cases, I have 100 plus cases, and I have met those people personally.

Coming back to when I started this online filling of forms. The first advantage that it created for the doctors was that it will not allow you to submit an incomplete form. If you took a printout, that meant your 'F form, printed 'F' form, was 100% compliant with the guidelines and it needed only the signature of the doctor and the patient. Incomplete documentation rate was relieved by this online application and that was well accepted by Kolhapur doctors and so the first phase was implemented.

But online form alone was not sufficient because the person who does not want to create a form will not create an online record either. So we wanted to have a mechanism to ensure that everybody would have to fill in the form. There are few doctors who are not filing the 'F' form and are doing the illegal work but are not being troubled, and there are genuine doctors who are following the law and are being troubled. We wanted everybody to be on one platform. So we came up with a technology called the Silent Observer. Now we have a more advanced version and we are calling it an Active Tracker. What does it do? It is connected to the sonography machine. The power supply goes to the sonography machine through the Active Tracker and it is like a projector. When I connect the projector to my laptop, whatever I am seeing on the laptop screen is replicated on the larger screen. What we did, rather than replicating on a larger screen, we converted it into a video and stored in the local hard disk of that Active Tracker devices. So whenever I start Active Tracker, immediately the sonography machine starts and whatever is happening on the sonography machine monitor, is converted into a video, stored and encrypted. We added a sim card dongle so whenever the machine starts it will send a message to the mobile phone of the centre owner, that the sonography machine has started at so and so time, this much of the hard disc is full and this much is free, and other operating issues. The same message will go to the Appropriate Authority's online software. So the Appropriate Authorities sitting at one place can see what is happening on the machine at this point of time. For instance, I can tell you right now, how many sonography machines are turned on in Rajasthan, at what time they were switched on, and what time they were switched off. This can show who started the sonography machine at 12 AM.

When this was implemented there was resistance, initially, in Kolhapur. But, like there are good people, there are bad people. Good people support it and they initiated and asked us to install it first in their place, and slowly then we implemented it in all the 251 centres. The first result was that, In Kolhapur, where every month 8,000 to 9,000 'F' forms were being submitted, suddenly 17,000 forms started coming in. We did it in Indore, where there were 350 sonography centres. Prior to this technology, there used to be 10,000, 11,000 forms, now it has reached 20,000 'F' forms. So, we have seen an increase of 100% in reporting by this technology. Now because that form is online, doctors and Appropriate Authorities don't need to wait until 5th of every month to get the physical records. They are getting it 24/7. Right now, an Appropriate Authority can log into that software and check how many pregnant women are those who already have two daughters, who are pregnant for the third time and so who are probable suspects, and can see where they are going. Similarly, you can monitor the sonography centres, if you click on a particular sonography centre, you can see the number of patients' portfolios, why pregnant woman who have only daughters are going to just these three centres, and then what is happening to them. We have the Accredited Social Health Activist worker network, Anganwadi worker network, and Auxiliary Nurse Midwives[60] in the rural areas. There are various government schemes for which these health workers have to visit pregnant women, to give nutrition and medical support. Whatever probable suspicious data of pregnant woman we get from the online system, we share it first with the concerned Medical Superintendent who then, under his observation, shares this data with ASHA workers and Anganwadi workers, so that they simply go and physically check whether the pregnancy has been continued or aborted or delivered, whether it is a fake address or whether she has gone to her mother's home. There are five possibilities and an ASHA worker simply types one option from A-B-C-D-E-F, and sends an SMS to the concerned health officials. 'A' means aborted, and so on. That is how the pregnancy status is tracked, rather than the pregnant woman. The system generates information on entire sonography centres. Right now, wherever this technology is not there, the district Appropriate Authority does not even know how many sonography centres there are, how many doctors there are, and who is attached to which sonography centre; they don't have that data.

Sanjay Gupte: I think it was in 2010, when I was President of FOGSI that Girish and Laxmikant Deshmukh[61] had come to my place. I felt this technology was very good and I whole heartedly supported it. We inaugurated it in Kolhapur at that time. Doctors accepted it, but there were some issues. The main problem – to which no answer was given at that time – was that doctors asked the Collector, 'okay we are accepting this, but we know of a clinic in Kolhapur that we have pointed out is doing rampant sex determinations, why don't you act on him first before you take up the other issue?' The problem was that person was also politically strong and that Collector also wouldn't take any action on it, and that's how all the other people got annoyed, 'if you are putting this Active Tracker on us, then do something about somebody who we are telling you

60 ASHA worker, Anganwadi worker and ANMs are the three categories of frontline workers in the district level health network, the ones who interact with the village population, maintain records of pregnant women and children, among other tasks.

61 Laxmikant Deshmukh was the District Collector, Kolhapur, who in March 2010 issued a Circular whereby all doctors, sonologists and radiologists practicing in Kolhapur District are called upon to install the `Silent Observer' in their sonography/ ultra-sound machines.

does it'. There has to be political will also to stop it. But I think that the technology has improved so much. We have to sit together with Girish Lad as medical associations and then work out a solution where this technology becomes acceptable, and I am sure it will become acceptable to all of us. But we have to at least give a hearing to Girish's explanation about this technology. The minute we even said something to this effect in our meeting, the next day I got phone calls inquiring, 'we heard that you are going to again support this Silent Observer, we already warned you once'. Such conflicts keep arising, so who is going to act on them?

Indira Chakravarthi: Dr Sangani, the IRIA, I think, filed a petition on the Silent Observer, and the High Court dismissed that petition.[62] What was the complaint being made by the radiologists?

Shailesh Sangani: IRIA filed a writ petition and raising three or four issues.

Girish Lad: They had placed three or four points. The first point was that this is not in the Act so this is illegal - there is no rule in the Act that 'F' forms should be filled online. We say that the form is to be completed within 24 hours and output from the Active Tracker or Silent Observer, it is to be attached, but this is not stated in the Act, so they say it is illegal. The second point raised was that the Collector, as the Appropriate Authority, does not have the power in the Act to enforce such kind of initiatives which are not in the Act. The third point that they raised was that it was a breach of patient privacy. They had an impression that whatever recording was going on, there is a district server and all the videos were uploaded to that district server, and that the Collector sitting in his cabin could see what the practitioner was seeing on the monitor. These were their assumptions and the basis for filing the writ petition.

Shailesh Sangani: From the radiology point of view our concern was that whenever we do sonography we can always see the sex of the foetus while measuring the femoral length, even if we don't intend to see it. It is a moral duty of the radiologist not to show the sex on the image, as well as not to record it, but while calculating the femoral length, while looking at these parameters, it is invariably seen there on the screen. Now suppose he has put a Silent Tracker on my machine and a Collector wants to take revenge on me – because as we have heard government officials can do anything. I have not done sex determination but the Collector might say, 'this fellow is seeing sexual organs while calculating the femoral size, seize the machine'. Who is going to take responsibility for that? How do we rule out that a particular Appropriate Authority will not try to take advantage of this technology – that is a big, big issue. That's why the doctors felt rather we should stop doing the sonography of pregnant women, let the government handle it, it is not our responsibility at all. This is a real threat because we saw the demonstration in Navi Mumbai, some years back, when your people had come. Some other representative had come from your company Magnum. That's why our organisation is not ready, because people are afraid of this misuse.

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62 This refers to the writ petition filed in January 2011 by the Maharashtra state chapter of the IRIA in the High Court at Mumbai, against the state and central governments and the District Collector of Kolhapur, challenging two circulars issued by the Collector and District Magistrate, Kolhapur: 1) dated 10th March 2010 calling upon all doctors, sonologists and radiologists practicing in Kolhapur District to install the `Silent Observer' in their sonography/ultra-sound machines; and 2) dated 14th January 2011 requiring doctors, sonologists and radiologists to perform online submission of the 'F' form.

Girish Lad: There are so many myths regarding this technology. First, regarding this issue of accidently seeing the sex while doing a sonography - that was not part of the writ petition. I was briefing about the writ petition, about the points that have been raised there. The High Court has dismissed the first three points in their petition, stating that the Appropriate Authority has the necessary powers and it is clearly mentioned in the Act that any effective measure taken in good faith by the Appropriate Authority cannot be appealed. As far as the major issue of patient privacy is concerned, there is no system for uploading videos; videos are recorded are stored in the local hard disk of that device that is connected to that sonography machine and that is in the custody of the centre owner. Whenever an Appropriate Authority wants to see some video, they have to go physically to that centre and copy the data in the presence of the centre owner, so that there was no question of patient privacy violation. There is no real-time monitoring. And related to patient's privacy, the High Court judgement clearly stated that right to life prevails over right to privacy, considering the declining sex ratio, so that petition was dismissed. They again appealed, 'why is a private company doing this? If it has to be done, then it should be done by the government'. The High Court said that who performs this task is at the discretion of the state. After that, in 2012, Rajasthan High Court made this tracking technology compulsory in the entire state of Rajasthan; since 2012 every sonography machine in the Rajasthan state is connected to the Active Tracker. In Madhya Pradesh there are 29 districts where this was implemented.

The last point which he has raised, the most important - that sex is seen. Yes, sex is seen, you do complete anomaly examination and the gender is seen. The Act does not restrict you from seeing the gender; the Act very clearly says that you must not disclose. As of now, in the last nine years, in 100 districts, there is not a single case filed by any Appropriate Authority – on grounds that there is a video of the gender of gender of the foetus. This invention was not introduced with the objective that it will be misused to catch doctors practising properly. We had a very clear objective that these are the rules and regulations, these are the lacunae and these can be overcome by this fashion; and later on this worked out to be a continuous deterrence. Sting operations are not a continuous deterrence, but this technology is a continuous deterrence because something is being monitoring. And the primary objective of the Act, that the 'F' forms are to be filled, that is 100% successful.

Arun Gadre: I will first respond to this Silent Observer. Basically, there are two points. As Kiran has said, the government doesn't want to implement this Act. So number one is the effect of this lack of motivation. The Silent Observer is a modified version of the 'F' Form, with a video record, as I understand. But what will happen if we use this data? The government is not using it. I too am a critic of the 'F' Form and linking the 'F' Form to sex determination. I have accepted that the 'F' form is important in a sense that, if the government knows that in this particular 'X' sonography clinic or gynaecology hospital, sex determination is more common, then the government can definitely take action. So in that way it is useful. Similarly, even Girish Lad's machine could be, provided that the data is used properly by the government. And the government should use the data only if it is actually going to implement the law with sincerity.

Secondly, a few of the points have not come about the impact of this PCPNDT Act on the medical group.[63] I will just enumerate three things. Actually, many gynaecologists have returned their sonography machine. As a gynaecologist, I was not charging for sonography; I was using it as a stethoscope. I never charged. I never gave a report also. I never claimed that I was a sonographer. But for me it was like a stethoscope and my accuracy level in obstetric examinations had gone to nearly 100%. That luxury is no longer possible for me. Up to 2006 fortunately there was no implementation of the law, so I could do it. But with very strict implementation of the law, I would have to give the machine away. Similarly, other gynaecologists would have done and the loss is to the patient, because at 2 AM, if you can use a probe on the abdomen, it's a huge gain for diagnosis. We have collectively lost, as a gynaecologist and as a patient. Secondly: we cannot move the machine from one floor to another floor and that has cost some lives. Sonography is used not just in obstetrics it is now used extensively to give the anaesthetic block. Now mostly they are using it illegally. They are not supposed to shift the machine. If they are following the law, anaesthetists cannot use it. And third, most importantly, a few of my friends have stopped doing obstetric sonography. And if we continue in that direction it will be very difficult for society. We are targeting the machines and we have to know what the consequences are. Lastly, the Silent Observer will be of fantastic use if the implementing authority analyses the data, as they will have something more than 'F' Form in their hands. My impression is, during routine sonography, about 50% of the time inadvertently we see the gender. Suppose in case of a centre it is 80%, then your data could be of very much use to pin down the responsibility and then go further for the investigation.

Girish Lad: Since the last nine years, no medical association has wanted our technology - there is a lobby against it. You face the pressure of the doctors' lobby while implementing the Act; I have been facing that pressure for the last nine years. Even the authorities don't want this technology, because after this technology is introduced, their means of taking bribes and making money goes down. I was expecting initially that the social activists will support this initiative, or at least we will have some dialogue and discussion. But the maximum opposition I have received is from the social activists. Even though a writ petition was filed by IRIA, until today they have not seen what this device is. Those who have gone to the court are those doctors who have never seen our technology. They have not seen this machine, whether it is black or white. Just merely out of that fear that this might be another way of troubling them they have gone to the courts. Not a single doctor in Rajasthan, or Indore, of Kolhapur has challenged that judgement of High Court.

Ravindra RP: When we started, at that time the entire medical lobby felt that, 'this is something against us - any method, any attempt to regulate our practice is against us'. There was strong opposition from all the doctors, especially gynaecologists. I can see the change in their position very clearly now. Especially in 2001, 2002, 2003, the members were totally supportive. The first

63 For impact of PCPNDT on medical use of ultrasonography, and access to it as a diagnostic tool in rural India, see respectively: Tabaie, S. (2017) Stopping female feticide in India: the failure and unintended consequence of ultrasound Restriction. Journal of Global Health, 17(1), pp 25-27; Phutke, G. Laux, T. S., Jain, P, and Jain, Y. (2018) Ultrasound in rural India: failure of best intentions. Indian Journal of Medical Ethics Published online on May 18, 2018. DOI: 10.20529/IJME.2018.041.

woman secretary of IMA, and FOGSI all took a stand, a large number of medical people are now aware of the problem. What I want to say is, we can't see this issue as: they versus us. I don't think it's that. This is the first law where all the stakeholders have tried to come together. Problems have come because the technology has changed, the perceptions have changed and whatever the initial idea of the 'F' Form was, has also undergone so many changes. I would think now it is possible, for example that all the cases related to PCPNDT in a particular state should be given to a Fast-Track Court, only to one or two judges and they could be disposed of within a short period of time. All the problems would be solved. Second, there could be a gradation of offences – minor and major – that can be taken care of. And I think the Silent Observer could be a good beginning.[64] We can come up with some facts. There could be contradictions but supporting that we need to do some detailed work, looking at the data which is available by an independent body; it could be a government body, could be a non-governmental body. They can undertake this serious study and come out with the report, it can be discussed. All stakeholders can sit together, because now our intentions are very similar. You have to accommodate the interests of your profession but we all are on the same page, that we want to stop this problem. Many of these problems have come up in implementation stage, and they could be thrashed out if there is a dialogue.[65]

Kiran Moghe: I have heard about Mr. Lad's technology for many years. And we have actually taken no stand about it for the simple reason that I think, as activists, we do not have any hard data in front of us to show us whether the technology works or not. To me, it's just having an 'F' Form in a digital form, right? So my concerns today are really with the attitudes of implementing authority, and of the medical profession, and getting them to see that there is still a problem of sex selection and that we need to work together. Whether we have a digital form or we don't is actually for me, at the moment, not such a great concern. But I remember some UNFPA report which said that it wasn't good or whatever. We need to refute this because even our law was based on study. So if Rajasthan has adopted it, if Madhya Pradesh has adopted it, then actually it would be better if we had studies which showed us what it has it done for better implementation, that's my point.

Girish Lad: Latest study is done by UNICEF. But the good things don't get propagated.

Amar Jesani: There is some large study was going on in Rajasthan and other places, where the technology has been adopted, right? So we'll know whether it has really you know, shown the efficacy that it was supposed to.[66] My points are slightly more general than this, because actually his talking about technology brought home the realisation that the extent to which we have shifted from where we were in 1984 to what we are in 2018. To my understanding, what we started with, as I was describing earlier also, was an idea of fighting against gender discrimination. From there the petition was filed in Supreme Court and the law was revised, and particularly the new rules

64 See article by medical practitioners from rural India, cited in Note 63 for how silent observer could be better used.

65 See: Public Health Foundation of India (2010) Implementation of the PCPNDT Act in India: Perspectives and Challenges.

66 See DNA Correspondent (2017) 186 ultrasound machines tampered with: Report, October 4. Available at: https://www.dnaindia.com/jaipur/report-186-ultrasound-machines-tampered-with-report-2550246 (last viewed 24.4.19)

were brought, and all these forms and reporting and such procedures were instituted. These were not there in 1989, or in the 1984 law. So these have all happened, which shows that we shifted from fighting against gender discrimination, to having a law which is going to do something to rectify the sex imbalance in the population. Now suddenly you find the whole issue of gender and equality is reduced to demography. As a consequence everything that we are trying to do is to achieve the demographic change rather than achieving equality for the women. And this is where the problem lies. The implementation is not being done with an objective of protecting women, of working for gender equality, but in order to see that the demographic balance is achieved. As he said, he looked at the law and he said, 'I have to implement this law'. Passionate to find out whether a woman has aborted a foetus because of the gender discrimination, you just monitor her from the conception to the end, right? But in a way it violates the human rights of women. You are monitoring her throughout. How many of us will be ready to be monitored for something in our lives, where some state authority, through a tracker is continuously tracking me? It is like trying to find out how HIV gets transmitted: let us find out what happens in everybody's bedroom, or where everybody goes. This is where the problem lies. Ultimately our objective was not the sex ratio; objective was having gender equality. I think that is where we went wrong.

The second thing is the whole area of how the reports are created and maintained - I think there is one problem. And I have earlier mentioned this, that if you create a law and implement laws for specific technologies separately, this is what happens. Why only look at radiological records for pregnant women and not other records, like sonography? Every instrument that you are using, the utilisation records should be available in the institution, irrespective of whether there is a law or not. Because this is what an ideal medical record system is - it is a part of the quality of the care. Once you have that you do not require separate people for ensuring justice, it becomes part of the entire system. And for that you can always investigate what is happening in the institutions, whether it is wrongly using the instrument or not. But we don't want the institution to have a very good medical record system. What you want is that only for certain things we keep records. The state is not interested in the medical records in order to provide justification for caesarean-sections. We are interested in only some aspects.

My last point is: suppose we want to look at it as a gender non-discrimination law. How do we assess it? Because you raised it, saying, 'it has not impacted the sex ratio'. So then how do we monitor the implementation of law? It has to be based on certain criteria because you cannot have the kind of tangible thing that we are talking about here. As I was saying, the key is: are doctors, or the institutions or anybody in the hospital, communicating the sex of the foetus to the woman or the family? That is the key, that is where the entire issue of law is related. Now how do you find it out? There are ways. Three ways are very important. One is that those who are involved, particularly the woman who was there, should be able to speak out and report it, that 'yes, this was what was communicated'. Another is that there may be other people who are there in these institutions, they should be able to report, that is file a complaint. And the third is you have more whistle-blowers coming forward. That is the only way you can do it. Or you have a sting operation, which is a whistle-blowing operation. However, with sting operations the problem is of using a subject. And here, as Kiran says, when you are using a pregnant woman for a sting

operation there is a lot of protection that the pregnant woman requires. And if that is not part of the sting operation then it is a major problem. So that has to be taken care of. But these are the only ways you can find out whether the practice of communicating sex of the foetus has come down or not. This law cannot be judged on the basis of whether the sex ratio has gone down or not. There is enough scientific evidence to show that the sex ratio is dependent upon many, many factors related to the gender discrimination, not just one. Medicine is an important, significant contributor, but that is not the only one. To make this law bear the burden of correcting the sex imbalance is too much to expect. You can have a broad law to fight against gender discrimination in medicine and also gender discrimination in society, but this law has to have a very modest objective. That is one of the major distortions that has taken place in the implementation. The bureaucrats think only in terms of numbers, and the numbers are how many sex determinations have been prevented and how the sex imbalance has been taken care of. And every census becomes a judgement on this law, which I don't think should be done.

Arun Gadre: As a society we are hypocritical in a way, we want to have some spectacular action, like lightning, and not a holistic approach to the problem. That is what is happening here in PCPNDT also. Inadvertently we are looking at a machine as the enemy rather than seeing that the enemy is actually outside the machine. My second observation is that this is a very significant Act and from this we have to learn that in future Acts we should select the marker cleverly. I mean here we selected the marker – the F form – and even in those early days I never thought that this could be a problem. It is very important to select a good marker, and if there is no marker there should be another mechanism rather than putting a false marker in the place, which will actually hamper the implementation. The third thing: as we at SATHI are running a community-based monitoring project, we are always talking about accountability. And as Ravindra said, that bureaucracy is always resistant to accountability. So now one aspect of future regulation should be multi-stakeholder accountability of even bureaucrats and government officials, because corruption is the key; it that particular virus which erodes all the Acts from within. So that needs to be countered. And lastly, as Kiran suggested, and many have suggested, we need to keep this Act, but as Kiran was telling, we should distinguish between the major issues and the minor ones. There is need to educate even the implementing authority.

Indira Chakravarthi: We have to stop because of practical reasons but thank you all very much for participating today.

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ANNEXURE

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Note of Dissent by Ravindra RP

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1. Punishment to the women undergoing SD test

I believe that a woman's choice to undergo a SD test is a result of subtle or not-so-subtle pressures exerted on her by her family, community and Society. It is not a conscious choice by an account. So it is unjust to pronounce her guilty under this Act. Punishing her for her 'crime' would mean further victimising the victim of oppression and equating her with the oppressors. So, such a woman should not be punished at all.

The provisions of the Maharashtra Act and the Draft Central Bill are highly ambiguous in this context. According to one interpretation, a woman convicted for undergoing SD test on her own would be subjected to imprisonment upto 3 months and a fine upto Rs 1000/-. Under the existing social conditions even a woman burnt to death by her husband's family chooses to defend it by calling the act a suicide. One can imagine the pressures on the mind of a woman throughout her life and even on her death-bed. Hence it is inconceivable that a woman undergoing SD test would ever accuse her family members of pressurising her into the act. Thus, in practice, a woman who refuses to undergo SD test has to face harassment or desertion. If she undergoes SD test and is caught, she faces imprisonment and fine. This reality is a very cruel choice. The only way out is to pronounce the woman not guilty under all circumstances.

2. Restricting the use of pre-natal diagnostic techniques to Government/Public Institutions:

The expert Committee on Sex Determination appointed by the Government of Maharashtra recommended that the use of pre-natal diagnostic techniques should be restricted to Government/Public Institutions. The initial declaration by the Chief Minister of Maharashtra was also in conformity with this stand. This view was upheld at the National Conference on Amniocentesis and Female Foeticide convened by the Govt. of India, Ministry of Health and Family Welfare in December 1986. It needs to be noted that the Public Hospitals in India have not carried out SD tests since 1982 after receiving instructions to that effect.

On the other hand, the mushrooming of SD clinics in different parts of India since 1982 has been restricted to the private sector. In fact, the 'incentive for unlimited profit' has triggered the growth of SD business on an unprecedented scale. In Maharashtra even after the enactment of the law, Private Centres and Laboratories continue to violate it.

The Public Sector in India possesses the necessary infrastructure for ensuring the proper use of pre-natal diagnostic techniques, especially the pre-natal diagnostic tests. In view of the above facts, I am certain that pre-natal diagnostic techniques should be restricted to the Public Sector, to prevent its probably misuse for SD in private sector.

Chairman's Observations

I agree with the broad observations made by Mr. Ravindra that the woman who is already harassed by others to undergo pre-natal sex determination test should not further be harassed by law or authorities. At the same time, at the present stage of social conditions in our country, if a woman is allowed to go scot-free under all circumstances, there is always a possibility that in every case the entire responsibility will be placed only on the woman, with the result that no person will get conviction for possible violation of the Act, thereby rendering the entire legislation ineffective. Hence the Committee decided to retain the penal provisions for the women at this stage.

As regards private institutions to be held eligible for a grant of permission for carrying out pre-natal diagnostic tests, the Committee felt that since permission is to be given only for legitimate purposes, it was not necessary to make any distinction between the public and private sectors, considering that some of the private institutions have already made large investments on the equipment etc., necessary for advanced medical technology in respect of the pre-natal diagnostic procedure. It is also felt that scope may be given to them in the initial stages. If the institutions in private sector do not fall in line with Government policy, or do not behave properly the Committee has suggested a review in this regard.

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