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Research Article

Politics of Evidence and Right to Health Care in India: The Challenges in Fixing Accountability of Medical Doctors in Patient Rights Violations in the Private Health Care Sector in India

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Abstract

Privatization oriented government health care policies have stimulated robust growth of private health care sector in India, without putting in place regulatory architecture that safeguards patients' rights. The lack of adequate regulatory framework to govern them has put patients to undue disadvantage. This paper, based on primary investigation, analyses the 'politics of evidence' that patients are confronted with and are forced to navigate, in redressing ethical and patient rights violations against private medical establishments. The analysis of cases indicates that in the current medico-legal ecosystem is non-conducive to patients and impedes obtaining legally admissible evidence against medical professionals. The prevailing redressal avenues are significantly hostile to patients and unduly favour the private medical establishments who enjoy support and impunity from prosecution under the implicit state patronage. The paper makes a compelling case for a comprehensive regulatory architecture that simultaneously regulates the private medical establishments and safeguards the rights of patients.

Key words: Patient Rights; Politics of Health; Medical Accountability; Private Health Care and Accountability; Medical Negligence and Evidence

Introduction

Evidence forms a critical link between the intersections of public health/health care and the judicial-legal domains. As law of evidence is vital to judicial processes, in public health and health care too, evidence has come to occupy centre stage to deal with the health of the populations as can be seen in the literature on evidence based policy making in public health. [1,2] Besides the importance of substance (material) of evidence, critical public health has drawn our attention to the factors of hegemony, power and politics play in the acceptance and legitimization of certain kinds of evidence in policy making. This is illustrated in the case of the aggrieved patients who face the uphill task of presenting legally admissible and incontrovertible evidence for seeking redressal in legal and judicial domains. This paper draws from the experiences of patients to critically examine the politics behind the construction of the eco-system in which certain kind of evidence is considered superior/legitimate and therefore acceptable, without taking into account patient's own well-being, autonomy and human rights. While dwelling primarily on medico-legal cases, this paper illustrates the diverse facets of 'politics of evidence' through their intersection with legal and judicial domains, with policy process, and engagement with both the civil society as well as the community of suffering and surviving patients. In this paper we explore the following questions:

- How have courts responded to health care litigations on medical malpractice, violations of patient rights emerging from the private sector?
- What is the political-economy of the evidence that is central both to the public health and legal professions? How does the present medico-legal eco-system affect the aggrieved patients and medical professionals and who does it privilege?
- How do patients navigate the medico-legal system and the requirements of evidence and what are the challenges that they face?

The paper in the first part, discusses the context of the medico-legal ecosystem in which the question of evidence is located, the political economy and character of evidence in India are then investigated through the analysis of seven cases. Subsequently, the issue of accountability for the patient rights violations and implications to policy on safeguarding patient rights are discussed.

Medico-legal ecosystem and patient rights in India

Since the opening of Indian economy to a free-market economy in 1990s, the focus on health in India has paradigmatically shifted from health care being a public social good to a private commercial good. [3,4] Such a shift is perceived to be happening in conjunction with and under the influence of the global non-state actors such as World Bank (1993) and International Monetary Fund and other global philanthropic agencies in policy making. [3] This has paved the path for an unprecedented growth of the private medical sector as seen in the private health care that citizens are compelled to seek. National Health Accounts 2016 confirm that the private expenditure in health care is now as high as 75 percent and the share of State in public health spending is only about 25 percent of the total health expenditure. [5]. Such a colossal growth has taken place in concurrence with the fragmentation and further enfeeblement of the already underfunded and under-resourced public health care system as is well-recorded by the reports commissioned by the government of India itself. [6] Consequently, not only the citizens from middle and upper classes with purchasing power, but even the disadvantaged and poorer sections of society are compelled to resort to private health care, both for routine as well as crucial/emergency health care.

In such a scenario, the absence of effective policy measures and the inadequacy of the existing ones for the regulation of private health care sector, has resulted in rampant corruption (as indicated by various scams), irrational and unethical medical malpractices, and the absence of any redressal mechanisms, inaccessible legal mechanisms, among others, have resulted in gross violations of patient's rights. [7,8].

India is a low income country with 1,595.7 USD as per capita GDP ranked in the medium human development category at 135 (of 187 countries) in the Human Development Index (HDI) and the health care system is described as mixed health care system. (The World Bank, n.d.; UNDP, n.d.) India's per capita expenditure by government on health care (i.e.US$33) and percentage of GDP (i.e. 1.2%) are one of the lowest in the world. The citizens cover 75 percent of health care costs out of pocket, which is far higher compared even to other low income countries. The life expectancy in India is now at 66 years, and the maternal mortality ratio and the under-five mortality rate are 190 and 53, respectively. (WHO, n.d.) According to World Health Organisation (WHO), about 45,000 maternal deaths occur in India annually and they 'reflect inequities in access to health services, and highlights the gap between rich and poor' as almost all maternal deaths (99%) occur in developing countries and that 90 percent of these are avoidable.

The underfunded and substantially weakened public health care system with sub-optimal capacity to deliver appropriate services and the profit oriented private health care system with the complete absence of intent to protect patient rights, is a fertile ground for the violations of right to health care. In addition, the absence of a legal and regulatory framework points to an utterly inadequate system for registering and redressing violations of human rights in health care. Accessing courts for redressal is a limited option for ordinary citizens given the challenges in accessing the judicial-legal system, prohibitive costs of litigation and the inordinate delays in the judicial process [9].

Accessing health care is inevitably linked to the medical profession and the rights of patients are embedded in the doctor-patient relationship. Such a relationship is defined in a very limited sense as 'service' by the Consumer Protection Act 1986 (CPA) and hence lacks a comprehensive and inclusive definition, posing severe challenges to the redressal of grievances of patients. Procuring and providing legally admissible evidence to the dereliction of duties tantamounting to medical negligence by medical professionals and to prove the violations of patient rights which are not yet legally defined, is the challenge in bolstering patient rights. Such a process is intricately linked to several interconnected and intersecting social and political arenas where power-inequalities are located.

Dependency on the medical profession: Patients share an unequal power relationship with doctors and medical establishments, which is inextricably linked to the rise of the medical profession and its exercise of power. Starr (1982)traces the rise of medical profession in USA in the 19th and 20th centuries and qualifies this relationship as that of dependency. Medical profession exercises cultural authority as the key means of establishing their sovereignty and perpetuating this dependency. He alludes the rise of medical profession and establishment of their authority over the society and patients to the economic and political power that medical profession has come to be associated with, and hence not linked merely to the scientific progress. The overpowering agency of a medical practitioner in the health and well-being of an individual is explained by Ivan Illych as 'instrumental consumer', the intermediary holding the power to decide what and how the patient should consume. [10].

Medical professional power and collective resistance: In the Indian Constitution, health care is listed under the state list in the seventh schedule. Whereas,

medical profession (e.g. medical education) is enlisted in the concurrent list of the Constitution, enabling both the central as well as state governments to legislate on medical practice. The Medical Council Act, 1956 regulates modern allopathic system of medicine; the Indian Medicine Central Council Act, 1970 regulates Indian systems of medicine including Ayurveda, Sidha and Unani systems of medicine and the Homoeopathic Central Council Act, 1973 regulates practice of homoeopathic medicine. In respect of each of these branches of medicine most of the State Governments have also enacted provincial laws. All these legislations define qualifications that would entitle practitioners to practice a particular branch of medicine. Thus, Medical Council Act, 1956 regulates the medical education for practicing allopathic medicine and there are other state specific diplomas such as the Maharashtra Medical Practitioners Act prescribes additional list of degrees and diploma which are available in Maharashtra. Medical Councils are set up at both Central and State levels, which apart from other functions also sets the standards for medical ethics and parameters of medical malpractice.

Though there is a lack of critical literature on this issue, there is emerging evidence that the privatization and corporatization of health care in India in the legally unregulated medico-legal ecosystem and unrestrained profiteering motif have stimulated variety of medical malpractices and irrational practices, having serious consequences to patient rights. [11] Medical Council of India (MCI), the ombudsman body purported to regulate the medical profession in India, is embroiled in corruption on matters such as medical education, licensing of medical colleges and conducting admissions to medical schools [8]. Besides, the nexus between the medical profession, health care policy makers and the medico-pharma industrial complex in the context of clinical trials has been severely debated in the parliament. [12] This has led to severe violations of patient rights, standard treatment protocols, guidelines and an increased resistance to limit the autonomy and authority of the medical profession. Number of issues concerning the medical professionals, medical practice and medical negligence have been brought before the higher judiciary through various litigations, most of them referring to the private medical practitioners and private health care establishments [11,13].

Nature and legal dimension of doctor – patient relationship: Mitigation of suffering is the raison d'etre of the medical profession. The Hippocratic Oath and code of medical ethics enunciates this as the noble goal of the profession. (The Hippocratic Oath, n.d; Medical Council of India, 2002)However, in the Anglo-saxon common law, this doctor-patient relationship came to be defined as a private contract and the deficiency of service was adjudicated on the grounds of negligence. Duty of care and negligence was historically defined by 'Bolam Test'. For the medical profession, the scope of negligence is laid down by the Bolam test which is also the accepted test in India. In the case of Bolam vs. Friern Hospital Management Committee the Queen's Bench Division of the British Court held:

Where you get a situation which involves the use of some special skill or competence, then the test whether there has been negligence or not is not the test of the man on the top of a Clapham Omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill …It is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.

The scope of medical negligence is reciprocally linked to the duty of care a medical professional is supposed to exercise, the breach of which is the cause of action for medical negligence. Hence it has three basic ingredients:

- The existence of a duty to take care, which is owed by the doctor to the complainant;
- The failure to attain that standard of care, prescribed by the law, thereby committing the breach of such duty;
- Damage, which is both causally connected with such breach and recognized by the law, has been suffered by the complainant.

Courts and medical profession: Apart from dealing with the issue of medical negligence, the courts had to deal with the issues related to doctor and patient relationships from constitutional, legal, ethical and professional dimensions. It included clarifying the identify of a practitioner in relation to any system of medicine, the power of prescribing drugs and its limitation, grievances of the patient and in some cases the issues of institutional ethics and governance concerning matters such as bribery, sexual harassment, mal-administration in regulatory quasi-judicial institutions or the apex ombudsman bodies such as medical council of India (MCI) itself.

The IMA case historically brought the doctor-patient relationship within the legal framework for the first time in the country, thus empowering the patients with the legal tool of accessing consumer redressal fora. By way of the definition of 'service', the private health and medical care services are covered by the jurisprudence of medical negligence on the basis of deficiency of and negligence in the service rendered in exchange of a consideration (payment).

In Kishore Lal v. ESI Corporation the nature of the doctor-patient relationship was clarified as 'contract for service' and not a 'contract of service. One party undertaking to render service to another such as professional and technical service is covered under contract for service. The latter 'implies relationship of master and servant and involves an obligation to obey order in the work to be performed and as to its mode and manner of performance'. (Para 8) A contract of service is excluded for consideration from the ambit of definition of "service" in the CPA, whereas a contract for service is included. Relating to the medical profession, this judgment further unravelled the nuances of doctor patient relationship.

The relationship between a medical practitioner and a patient carries within in a certain degree of mutual confidence and trust and, therefore, the service rendered by the medical practitioners can be regarded as a service of a personal nature, but since there is no relationship of master and servant between the doctor and the patient the contract between the medical practitioner and his patient cannot be treated as a contract of personal service and it is a contract for service…(Kishore Lal v. ESI Corporation, Para 8)

For grievances with the services provided by the medical professionals the patient or survivor has been offered three pathways: Criminal prosecution of gross negligence, civil remedy for damages and approaching the Consumer Redressal Fora/Commissions for compensation [14]. However, given the nature of power imbalance between corporate private hospitals, medical profession and patients in general, the relationship between medical practitioners / health care providers and patients is an unequal one. Given that the private doctors and healthcare institutions are not governed by any regular and comprehensive legislation, and that the patient rights too are not defined by any law, any course of action for redressal of patient grievances is heavily tilted against the patient. In addition, compared to the patients, doctors are in an advantageous position aided by their social status, professional and financial influence, to navigate and manoeuvre legal institutions to their advantage. In such circumstances, producing legally admissible evidence is a heavy burden that the patients or their survivors got to bear in addition to the emotional burden that they suffer in cases of deaths and morbidity. The assumption that underlies this paper is that the complex

judicial or legal process, in such hostile contexts, are likely to be skewed in favour of the medical professionals and private health care institutions.

Box (1): Definition of health care as service (IMA v. V. P. Shanta)

i. Services rendered to patient by medical practitioner (except where the doctor renders service free of charge to every patient or under a contract of personal service), by way of consultation, diagnosis and treatment, both medical and surgical, would fall within the ambit of services as defined in Section 2(1)(o) of the Act

ii. The fact that medical practitioners belong to the medical profession and are subject to the disciplinary control of the Medical Council of India and /or State medical Councils would not exclude the services rendered by them from the ambit of the Act.

iii. Services rendered by a medical officer to his employer under the contract of employment is not 'service' under S. 2(1)(o) for purposes of the Act

iv. Services rendered at private or Government hospital, nursing home, health centres and dispensaries for a fee are 'services' under the Act while services rendered free of charge are exempted. Payment of a token amount for purposes of registration will not alter the nature of services provided for free.

v. Services rendered at a Government or a private hospital, nursing home, health centres and dispensaries where services are rendered on payment of charges to those who can afford and free to those who cannot is also 'service' for the purposes of the Act. Hence in such cases the person who are rendered free services are 'beneficiaries' under S. 2(1)(d) thereby 'consumer' under the Act.

vi. Services rendered free of charge by a medical practitioner attached to a hospital/ nursing home or where he is employed in a hospital/nursing home that provides free medical facilities, is not 'services' under the Act.

vii. Where an insurance company pays, under the insurance policy, for consultation, diagnosis and medical treatment of the insurer then such insurer is a consumer under S. 291)(d) and services rendered either by the hospital or the medical practitioner is 'service' under S. 2(1)(o). Similarly where an employer bears the expenses of medical treatment of its employee, the employee is consumer under the Act.

Battling several hostile circumstances and uphill challenges, a few citizens and civil society organisations, however, have ventured into using the existing judicial, quasi-judicial and other legal fora with complaints seeking redressal for grievances with a larger vision of pursuing justice for the violations faced by patients in general. The narrative they represent is not of any freak outlier incident but rampant pervasive violations of the right to health care (RtHC) of vast number of citizens who can neither afford to complain against the private health care personnel and institutions nor can afford the cost of litigation.

Methodology

This paper is a based on the primary research done with a qualitative research design. Seven cases selected on a snow balling method, form the universe of the study. The study began with a purposively selected case, stumbled upon during the campaign for right to health care in Karnataka. Totally three cases were identified as part of the campaign on patient rights by Karnataka Janaarogya Chaluvali

(KJC) - an autonomous health rights campaign in the state of Karnataka - in the process of mobilizing the community on the grave violations of patient rights. The experience of mobilizing judicial and quasi-judicial institutions by KJC forms the empirical data for this paper. Another cohort of four cases were identified by the corresponding author, a lawyer who has been active in the field of patient rights, on a snowballing sampling method during the course of investigating the nature of violations in the private health care sector. It involved documenting the experiences of the aggrieved that had accessed judicial and quasi-judicial fora against the health care institutions and medical professionals. In both the cohorts, data was collected through in-depth interviews with the petitioner-respondents. The case of Dr.Kunal Saha in which SCI laid down landmark and historic judgment in 2013, is considered in this paper as a reference case for a comparative analysis.

The cases were collected during the period July 2015 to June 2016. Written consent was taken from the respondents.

Data Presentation

Profile of Cases

The seven cases analyzed in the paper present interesting variations in terms of background of complainants, the types of facilities they had sought care in, the kind of redressal mechanisms they approached and the kinds of issues emerging relating to evidence.

Of the total seven patient narratives presented here, two involved male patients while the rest were all female patients, and were in the age range of 21 to 77 years. In all but one case, the complainants were close family members. As can be seen in table 1, the complainants in four of the seven cases belonged to upper middle class backgrounds, in occupations of considerable status in society such as lawyers and civil servants. All cases involved seeking care in private hospitals of various categories ranging from a nursing home in small towns of Bagalkote and Gulbarga districts in Karnataka state and Indore in Madhya Pradesh to swanky super specialty hospitals in metro cities of Bangalore, Mumbai and Delhi. The reasons for seeking care ranged from sterilisation, delivery, treatment of gynaecological problems to minor surgery and treatment for cancer. All cases, except one, had resulted in death. Complainants had approached a range of redressal forums ranging from the consumer redressal forum (under CPA) to various statutory Commissions, the medical councils, civil and criminal courts at various levels. Only one case had exhausted all possible legal avenues and had reached SCI. Two other cases had not moved beyond the complaint for want of legal support to families, while the remaining four cases were sub-judice at various levels. The time period of these litigations ranged from as recent as one year upto 28 long years.

Case summaries

In the Indore case (**Case 1**), a private hospital undertook a forced sterilisation on a pregnant woman even when she explicitly refused it. She later suffered several complications and spent an inordinate amount of money which she and her husband could ill afford. They approached the State Human Rights Commission (SHRC) and National Human Rights Commission (NHRC) both of which were unresponsive.

In the Mumbai case (**Case 2**), a well-known surgeon in a private super specialty hospital, with several laurels and national awards to his fame, undertook an unwarranted surgery on a cancer patient against the medical opinion of the previous treating physician in the US. He assigned the surgery to a junior colleague and did not supervise. When the junior doctor found that they had opened up the abdomen in vain, the treating doctor merely instructed him to 'stitch it up'. As a consequence the patient suffered unimaginable pain and suffering and later died. This case traversed the entire hierarchy of civil and criminal

courts and after 28 long years of protracted legal battle, the Supreme Court overturned the compensation awarded by the Mumbai High Court on the grounds that 'there was no doctor-patient relationship because the doctor had not operated on the patient'.

In the Delhi case (**Case 3**), a patient was referred to a private super specialty hospital by his treating cardiologist for 'a minor but an emergency surgery' to remove an anal abscess. The cardiologist even though part of the treating team neither visited the patient nor monitored him. After three weeks of being in hospital the patient died. Medical records accessed by the family later found that the doctors had subjected him to a second surgery without their knowledge and he had suffered three heart attacks while in the hospital because his cardiac medications had not been administered. This case is presently being fought in State consumer redressal forum, the Delhi Medical Council (DMC), Court of the Metropolitan Magistrate and the Delhi High Court.

In the Bangalore case I (**Case 4**), a patient admitted for kidney transplant, the corporate super-specialty hospital also carried out an additional pancreas transplant (for which it did not have license) without patient's express consent. Due to the medical complications that developed post-surgery, the patient died. Criminal and civil complaints were pursued. The hospital manipulated documents and a case of forgery was filed by the police against the hospital. In turn, the hospital filed a defamation suit against the complainant, forcing the latter to spend an inordinate amount of money in his defence. Presently this case is pending before various judicial fora.

In the Bangalore case II (**Case 5**), a private 'boutique' maternity hospital mismanaged labour of a high risk pregnant woman resulting in both maternal as well as neonatal deaths. An FIR was lodged. And post-mortem (PM) was undertaken in a private hospital much against the family's insistence of a government hospital. But the PM report was manipulated by the hospital and the cause of death was said to be Amniotic fluid embolism which conveniently can neither be foreseen nor prevented. The case was investigated by the government maternal death audit committee headed by the deputy commissioner (DC) of the district. The report is pending. The family is planning its next course of action.

In the Bagalkote case (**Case 6**) the private hospital conducted a hysterectomy after delivery without consent and then they left the neonate unattended in the phototherapy unit only to find that the neonate had died. PM was not done and the hospital contended that the neonate had died due to milk aspiration.

The family approached the district administration who conducted an enquiry which found statements of the gynecologist and the pediatrician conflicting and they also found that no records were maintained of the neonate. The hospital did not have any facility for any intensive care of neonatal babies. On behalf of the patient, KJC approached the state directorate of health and family welfare, state human rights commission (SHRC) and Women's Commission. The Directorate passed an order to cancel the license of the hospital but the district health officer (DHO) did not enforce it. The Chief Executive Officer (CEO) of the Zilla Panchayat held a final hearing and fined the hospital a sum of Rs.25000/- (USD 385) under the Karnataka Private Medical Establishments (KPME) Act 2007 for not maintaining records. But the hospital filed a petition in the High Court (Gulbarga bench) and got an injunction on the execution of the said order. The family could not get any legal help to pursue the matter and implead in the case any further. A lawyer who promised to represent them in the court too later refused to appear in the case.

In the Gulbarga case (**Case 7**) a private hospital conducted a hysterectomy on a young woman following which she died on the operation theatre (OT) table.

Sl. No.	Sex	Age of patient	Relationship of complainant to the patient	Occupation of the complainant	Type of institution accessed for health care	Geographical location	Health care intervention	Outcome	Year of the incident	Redressal mechanisms approached	Status of judicial process	Duration of the legal process
1	F	30	Husband	Migrant worker	Private nursing home	Indore	Sterilization	Complication	2012	SHRC	No progress	NA
2	F	55	Husband	retired IAS officer	Private corporate super specialty hospital	Mumbai	Cancer treatment	extreme suffering, pain and death	1988	Lower civil and criminal courts and the MMC	SC judgment passed which exonerated the doctor	28 years
3	M	77	Daughter	lawyer in the Delhi High Court	Private corporate super specialty hospital	Delhi	minor but emergency surgery of anal abcess	Death	2009	State consumer redressal commission, Delhi Medical Council and Court of the Metropolitan Magistrate	underway	NA
4	F	50	Husband	Retired army officer	Private corporate super specialty hospital	Bangalore	kidney transplant	Death		Civil and criminal court, Consumer redressal forum	underway	NA
5	M	Neonate	Parents	petty shop owner	Private Maternity home	Bagalkote	Delivery	death of the neonate and hysterectomy without consent	2012	Maternal death audit, SHRC and Women's Commission	no progress	NA
6	F	28	Husband	works in an IT company	Swanky boutique maternity hospital	Bangalore	Delivery	death of both mother and neonate	2015	Maternal death audit, SHRC and Women's Commission	underway	NA
7	F	21	KJC in public interest	daily wage labourer	Private nursing home	Gulbarga	Hysterectomy	death on the OT table	2015	SHRC, Women's commission, KMC, Directorate of HFW	underway	NA

The family contacted KJC activists while still in hospital and requested them to intervene. In the meanwhile the doctor in collusion with the police and local political middlemen confiscated all the records, intimidated the husband of the deceased woman into signing a statement saying that he voluntarily refuses to conduct post-mortem and absolves the doctor of all responsibility for the death. The doctor paid him Rs. 3 lakh (USD 4615). Even though KJC activists got an order from the IGP for the post-mortem, the body had already been cremated, thus leaving no evidence behind. The doctor also did not undertake any histopathology of the specimen after surgery. Thus valuable medical evidence was destroyed. Directorate of HFW and the Women's Commission each appointed an Enquiry Committee into the larger 'epidemic' of hysterectomies based on KJC's fact finding report in the district and investigated the present case also which provides valuable evidence of the misconduct of the doctor. Presently the case is being heard in the Karnataka Medical Council.

The reference case of Dr. Kunal Saha, a medical professional himself, is a case of the death of his wife Anuradha Saha, allegedly due to negligence of doctors in AMRI super-specialty hospital in Kolkotta (West Bengal). The court processes took 17 year long years. The accused Doctors were prosecuted for criminal negligence, professional negligence and for medical negligence (consumer forum). After 17 long years, it was finally settled by SCI in 2013, awarding 11 crore rupees (USD 1.7 million) as compensation.

Power and politics: Locating the idea of evidence in the broader context of the present medico-legal ecosystem

The analyses of seven cases reveal several issues related to the nature of violations that go beyond the narrow legally defined medical negligence, issues related to accountability that go beyond the doctor-patient relationship, issues related to nature of evidence and judicial process and who it privileges.

Diverse range of violations

The cases present a range of violations from the perspectives of medical ethics, professional conduct, medical /scientific protocol to patient rights. The nature of these violations transcends the scope of justifiability in the present medico-legal ecosystem with its narrow and restricted focus on medical negligence and ignoring all other forms of violations.

Violation of medical ethics and professional conduct: The cases revealed brazen violations of medical ethics and professional conduct by private practitioners. In the Indore case, the doctor conducted sterilization even when she explicitly refused sterilization on knowing that she was pregnant. In the Delhi and Mumbai cases the doctors had violated their primary duty towards their patients. In the Delhi case, the patient was a cardiac patient and was admitted in the private super-specialty hospital for the operation of an anal abscess, where the doctor was practicing as a consultant. In a glaring dereliction of duty, the doctor did not supervise the patient's cardiac condition, was not available while the patient was in the hospital. Making matters worse, the family members were kept completely in the dark about the status of the patient. In the Mumbai case, the doctor was guilty of misconduct when he undertook an unwarranted surgery in the first place, was cavalier and high-handed in the way he casually ordered his junior colleague that the stomach be 'stitched up', communicating his contempt for patients and their suffering. In the Bagalkote case, the doctor undertook hysterectomy without consent of the patient. In the Gulbarga case, the doctor was guilty of criminal misconduct where he used threat and intimidation to get the husband to sign an affidavit absolving the doctor of all responsibility for his wife's death. In the Bangalore case I, the doctors/ hospital were

guilty of a criminal offence of undertaking a pancreas transplant for which they did not have a license, and conducted such a transplant even without the consent of the patient.

Collusion, intimidation, and manipulation/distortion/destruction of evidence: The cases analyzed also revealed blatant collusion between the police, the accused doctors and the local health administration. In the MJ case, the police colluded with the corporate hospital and refused to register an FIR unless the Delhi Medical Council (DMC)'s medical board directed it to do so. The doctors within DMC itself were in collusion with the accused hospital.

In the Gulbarga case, the police, along with the doctor and his political henchmen were active agents in intimidating the husband of the deceased to sign a statement saying that he refused post-mortem on his own volition, that his wife died due to anaphylactic shock and he absolved the doctor of all responsibility for his wife's death. The post-mortem would have provided crucial evidence about the real cause of death. Activists supporting the family even got an order from the Inspector General of Police (IGP) to undertake a post-mortem. But by then the family had been pushed to cremate the body. Similarly the doctor had not undertaken histopathology of the uterus or the purported hydatid cyst which he claimed was the reason why he undertook a lobotomy in the first place. In the absence of a post-mortem or a histopathology test crucial evidence was wilfully destroyed. In fact most cases of negligence involving the most vulnerable sections of society are routinely settled through local political elements with support of the police, all of whom get a part of this 'protection' money. This was found in two other cases of maternal deaths as well, that KJC was following up.

In the Bagalkote case, there was a directive from the State directorate of health and family welfare to cancel the license of the said hospital. However, the DHO did not act on it. It was only after sustained follow-up and letters to the DHO and the State Directorate that the final hearing was arranged with the Zilla Panchayat (ZP) CEO, who is the appropriate authority under the KPME Act to hear such matters.

Breach of medical protocols: In some cases, doctors seemed to be violating whatever little standard protocol of quality of care that has been put in place for clinical practice. In the Indore case, the woman was taken all the way to the OT for sterilization and only then was she screened for pregnancy when in fact screening for pregnancy, anemia and other contraindications for sterilization is the first task to be undertaken as per the guidelines. In the Mumbai case, the doctor willfully dismissed medical opinion of the previous treating doctor in the US who had advised against surgery. He undertook a medically unwarranted surgery on a patient who was not fit for surgery which resulted in extreme pain and suffering and eventually death. In the Delhi case, the cardiologist was a key member of the treating team. One wonders how he even issued a fitness for surgery certificate when he did not provide any directives to the surgeon and his team about continuing cardiac medications. The latter, on their part too did not revert to the cardiologist under whom the patient was admitted. This is a gross violation of surgical protocol. In the Bagalkote case, the doctor did not monitor the neonate during phototherapy. The infant was not breast fed for over three hours and not even the nursing staff attended to the infant during that entire period. Parents' demands to hand over the baby for feeding were not heeded. After death, the doctors did not suggest/ insist on conducting a PM, which would have been an evidence for the cause of death.

Similarly, the Gulbarga case of a death of a woman on the OT table for which post-mortem is mandatory raises more questions than answers. Not only did the doctor not undertake it but he actively thwarted activists' attempts to push for it through threat and intimidation to the

family. He also did not send the specimen for histopathology which would have clearly indicated whether or not the hysterectomy was warranted. He claims he undertook a lobotomy to excise a hydatid cyst. The questions that came up in consultation with some of other medical professionals was – 'wouldn't the doctor have known the location of the cyst through the USG scan? Wouldn't he have known that it was adherent to the uterus even before he undertook the surgery?'

Patient rights violations: All cases illustrate the blatant and often wilful disregard and violation of patient's autonomy, self-determination and their right to participate in decision-making, concerning patient's own body and health. Nearly all cases had issues related to explicit violation of consent. In the Delhi case, during the entire 26 day duration of the patient's stay in the hospital, the doctors did not communicate to the family at all, even as they undertook a second surgery without their consent. They did not indicate that the patient had suffered three heart attacks while being admitted. Suppressing such vital information, prevented the patient and his family from seeking care in a different facility which might have saved the life of the patient. Rural illiterate patients and not knowing the English language at all, were required to sign blanket consent forms that had serious repercussions on how it would be used as evidence against patients. In the Bagalkote case, for example, the consent form was drafted in English and was worded in such a way that the patient rescinded all his/her rights. (See box 2)

Box (2): Draft of a consent form

I_____in full knowledge and understanding give my consent to undergo diagnostic tests and treatment for my health condition which may involve anaesthesia, blood transfusion, immunisation, surgical intervention or any other medication. I do not hold the treating doctor, surgeon, anaesthetist or the hospital responsible for anything. I agree to clear all my dues before discharge. I have been given clear information about the risks and dangers related to the treatment and diagnostic procedures and I am satisfied with the same. I agree to abide by all the conditions laid out in this agreement.

(Source: Consent form obtained as part of the patients' medical records)

In Gulbarga case, where the patient was a daily wage laborers, the consent form was used as evidence to justify the hysterectomy conducted, as the patient did not know what it was. In the Mumbai case, the treating doctor overrode the second opinion of a surgeon from USA without any scientific rationale. In the interview with the petitioner/complainant, the husband of the deceased who was a retired civil servant (Government of Rajasthan of IAS rank), attributed it to the arrogance of the surgeon who was a celebrity and the contempt he showed for other doctor's opinions.

The rights of patients get derailed in the roadblocks that they encounter in redressing their grievances. In two of the seven cases, the suffering patient or a surviving relative had no information on or access to redressal. The Indore case was brought to the notice of SHRC. The complainant was a daily wage laborer and was incapable of pursuing any litigation, The SHRC not only did not take up the case suo moto and pursue it, it only gave oral assurances of recommending compensation and free care for the patient who was now suffering after the hysterectomy, but also did not summon the accused doctor, nor did it call for the medical records.

Some aggrieved patients were able to access legal redressal, only because of the support they got from the civil society activist groups. What also emerges in these cases is the fact that due to the civil nature of these cases (as they are considered private litigations) as compared to the criminal cases, the state or para-legalbodies

are not bound to pursue the cases on behalf of the complainants. As the mandate of the statutory commissions is to protect the rights of the vulnerable, and even though they could play a proactive role by taking suo moto cognisance of the issue, they did not do so. As illustrated in the Indore case, the SHRC did not hold a hearing, did not call for records from the hospital and did not continue the proceedings against the hospital. This poignantly points out that though such bodies are vested with the power of the civil court, they do not act in matters of the vulnerable patients, in the absence of any pressure from the complainants or civil society groups.

Toxic mix of hostility and intimidation: The Gulbarga and the Delhi cases illustrate how the private hospitals blatantly use a toxic mix of hostility and intimidation to push patients/ caregivers to their limits, manipulate evidence, distort medical records and derail investigation. In the Gulbarga case, for example, the family initially contacted the activists of KJC for help. But intimidation and threats by the doctor-proprietor of the hospital and pressing for monetary settlement prevented them from pursuing the case. The fact that the case reached the KMC is only because the activist group pursued it actively and relentlessly.

The toughest battle families and patients face is the hostility from the medical councils. In the Delhi case, the Delhi Medical Council (DMC) was outright hostile and broke every rule in the procedure book. DMC insisted that the complainant has to be represented by herself and disallowed representation by an advocate, did not conduct hearings with due respect for natural justice, changed guidelines half way through the process, changed the disciplinary committee, conducted hearings without adequate notice to the petitioner, and did not serve the copies of material presented by the respondent doctor and so on. Even though a medical board formed by the State Consumer Redressal Commission involving the Maulana Azad Medical College (MAMC) testified for negligence and the State Consumer Redressal Commission accepted it, the DMC refused and insisted on referring the issue to its own Board. Similarly in the Bangalore case II, during the maternal death audit review meeting the father in law of the deceased confronted the gynaecologist and in the process had an emotional breakdown. The hospital alleged that this was an 'intimidating tactic' by the complainant and sought the intervention of the chair at the next meeting.

Issues of accountability and culpability

Private health sector provides various kinds of services through complex arrangements with the resident or consultant doctors as well as the diagnostic centers in the area. The analysis of the cases in this paper points to the important of defining the role and functions of the health care providers at the individual and institutional levels and the services expected to be provided as part of that role. This would help in delineating between the expected and actual executions of those functions and availability of these services, which will help in identifying violations and fixing accountability for any violations. Lack of standardization of these functions has made fixing accountability for lapses in duty a great challenge for patients.

Absence of standards and multiplicity of undefined categories of providers: Among the six cases reviewed we find a range of medical care providers involved the entire continuum of private sector providers, from small nursing homes in peri-urban towns, and general hospitals in medium size cities to swanky 'boutique' maternity hospitals and 'five-star' super speciality hospitals in metropolitan cities.

Multiplicity and wide variety of these hospitals make regulation and monitoring very complex and fixing accountability even more challenging. For instance, what is a 'boutique' hospital? Do such commercial terms even be allowed in the nomenclature of health care providers? What is the fundamental difference between the maternity home in Bagalkote and the 'boutique' hospital in Bangalore?

Both provider care obstetric / delivery care. Is the difference merely cosmetic? Or is there a fundamental difference in the qualification of the persons providing services in these two hospitals, the standard treatment protocol followed, in the quality standards adhered to? Given that the categories are themselves undefined and there is no common set of standards that these wide varieties of private providers agree to, there will be no prescribed standards to compare against and there will always be huge gaps in the system which make pinning down responsibility and accountability for violations virtually impossible.

Locating doctor-patient relationship in the complex web of arrangements: Hospitals have various forms of arrangements for procuring services from the doctors. Several specialist doctors are not fulltime employees in the hospital, but function as 'consultants'. In terms of patient care and accountability, a consultant doctor - patient relationship opens up a vast grey area, legally and institutionally. Patient care is done by a treating team of medical and para –medical professionals under the instructions of the doctor, while doctors themselves responsible for the decisions function as consultants.

In such a scenario, the ultimate responsibility of the doctor towards the patient needs to be clarified, explicated and defined. For example, in the Mumbai case, the doctor was a senior consultant at the hospital, under whom the patient was admitted. He assigned the patient to a junior doctor for surgery. The case of negligence was dismissed by SCI (after traversing through various courts for over 28 years) on the ground that there was no doctor-patient relationship between the two. The Apex Court's verdict that that "there was no doctor-patient relationship" because the surgeon had not personally operated on the patient is simplistic, reductionist, removed from reality and sets a dangerous precedent against patients and their well-being. The analysis of the cases points to the need to standardise the hospital procedure and protocols. When and under what conditions can a consultant assign a patient to a junior colleague and when s/he cannot? What are the considerations for assigning /not assigning? Did the consultant assign it in writing and also indicate the reason for the same? What are his/her supervisory responsibilities in such a situation? What measures did s/he take to ensure his patient's well-being and safety? Who is ultimately responsible for such a decision? Such protocols will create an ecosystem where the medical records and other circumstantial evidence will facilitate the protection of rights of patients within the complex terrain of doctor-patient relationship.

Similarly in Delhi case, it was the cardiologist who referred the patient to the said hospital for treatment and who was a crucial part of the treating team. Yet he had clearly failed in his duty by not visiting the patient, by not monitoring the patient's recovery or the lack thereof. This was a gross violation of his professional duties towards patient care and safety.

While these hospitals claim to have various forms of accreditation and certification of standards such as National Accreditation Board for Hospitals and Healthcare Providers (NABH), they seem to have done little to enhance accountability, transparency or protection of patient rights. NABH certified hospitals are required to undertake audits of deaths and other sentinel events. Therefore in the Delhi case, the pertinent question is whether the said hospital undertook a death and complication audit, what did the audit indicate was the cause of multiple surgeries and death, why weren't these audit reports called for as evidence? Such audit reports are not accessible to the public or patients because it could potentially damage the 'image' of the hospital and thereby its 'profits'.

Paradox and dilemmas concerning the evidence in the present medico-legal ecosystem

Though the violations of patients' rights are wide ranging, medical negligence is the only thing that has been legally articulated so far, that too in its narrowest sense, viz. 'deficiency' of service under the CPA (Box 1). Such a definition does not consider or cover the violation of patient rights, as patients are not legally defined so far. The process through consumer courts heavily relies on medical experts who not only maintain medical data but also interpret it and provide expert evidence.

'Admissible' evidence and the power of the alleged 'violators' over medical records: The doctors /hospital staff that document and maintain all data (evidence) on all procedures and services administered to the patient. Such evidence is in the custody of the medical establishment, and quite often, is susceptible to be manipulated, distorted, as has been pointed to in our analyses of cases. In the Bangalore II case of maternal and neonatal death in the corporate boutique hospital, on the day of the death, the DHO did not seize the records even after receiving the complaint. He only made observations that the labour room and OT register did not contain entries of the patient and of the subsequent death. Subsequently, after a few days, during the maternal death audit chaired by the Assistant Commissioner, the hospital submitted all completed records covering up for all the gaps pointed out by the DHO. These records were reviewed by two gynecologist's, who independently concurred in their opinion that the manner the notes were written and details were explained, was indicative clearly not how one would write under 'normal' hospital circumstances, and that too when it involved an emergency. Yet the experts had no way to prove that the records were doctored.

Patients/ care givers and the double burden of suffering and gathering evidence: While the evidence is documented and maintained by the potential violators the onus of gathering and presenting evidence is on the complainants. Given the technical nature of evidence and complexity of medical technology involved the task of gathering evidence is practically beyond the capacity of ordinary citizens and even more so in case of those from non-literate and marginalized backgrounds.

Families are faced with the double burden of grief over the loss of a loved one and of gathering evidence. Unless there is someone advising at the time of death/ complication, the crucial evidence is lost. For instance in the Bangalore case II of maternal and neonatal death, friends of the deceased contacted a proactive pro-people doctor who immediately advised them to seek PM which the family agreed to and got it done. Very often, caretakers refuse PM due to emotional and religious reasons, as was seen in the Bagalkote case. In the critical conditions the couple were in, there was no one to advise or persuade them and they acquiesced to pressure from extended family members not to undertake a PM. During the hearing in this case, the appropriate authority designate under the KPME Act 2007 (ZP CEO) expressed his helplessness in the absence of a PM report, that could have provided the much-needed evidence to pursue criminal charges against the doctors.

The decision to pursue a legal path for redressal has to be taken by the patient or the grieving family even as they deal with anger, frustration and grief over the loss of the loved ones, which requires a tremendous determination and will. For the patients coming from poorer households, the dilemma is even acute. They have to make a choice between a meek surrender in their struggle for survival or pursuing the case which would be expensive with uncertain results in an unknown future time, being economically poor and having already spent considerable amount of

money on patient care, monetary settlement rather than litigation appears as a great relief. Therefore it is no surprise that several cases involving vulnerable groups are settled through a combination of intimidation, coercion and offer of money for out of court settlement. In the Gulbarga case, the husband of the deceased had the immediate impending responsibility to take care of his three young children. He was angry at the way he was bullied and intimidated by the hospital and the fear of retaliation if he pursued the case. However, the struggle for survival and responsibilities of his children prevailed over him for not pursuing any legal course of action.

Another key element that this paper points to is that by the time families recover from their initial shock and grief, crucial evidence is lost, distorted or manipulated. In the Bangalore maternal/neonatal death case, the DHO did not seize the records immediately even as the hospital refused to give records to the deceased's family immediately. In the time gap, records were manipulated with no way to prove they did so.

Complexity of interpretation of evidence: Patients and their families feel severely constrained by the complexity of the medical procedures, the associated technicalities and jargons. Comparatively, complainants with the medical background, technical knowledge and expertise have an edge over others. The (Dr.) Kunal Saha case, which is one of the successful litigations against a corporate hospital, clearly demonstrates that it is not class alone, but also his medical profession that enabled him to challenge the powerful corporate hospital successfully. However, even for him such a process of pursuing criminal and civil litigations and appeals in the higher judicial domains, took about 17 years.

The support of a practising doctor with a reasonable level of skill and expertise helps lay persons immensely in providing better evidence. A gynaecologist going through the reports of the pregnant woman, who died in labour in a corporate hospital in Bangalore (case II), made several crucial observations which only a practising gynaecologist can. She pointed out, for example, that there was no need to induce labour because the woman already had reasonable contractions as per the readings at 6 pm. and that the dosage of mesoprestol used to induce labour was very high. She also questioned the decision to induce labour in the evening which could have been avoided. Yet none of these issues were raised by the doctor or experts in the audit committee during its meeting. Activists and the deceased woman's husband raised these issues as 'non-medical' persons with the inputs given by the supportive gynecologist.

Lack of concurrence among doctors on interpretation of evidence: Expert reviewers not concurring on an issue is a great challenge for interpretation of evidence. Reviewing records of the maternal death in the Bangalore hospital the gynaecologist whom the family of deceased and activists approached had averred to several lapses. However, this was contested by another practising gynaecologist who reported that she had not encountered such problems with mesoprestol dosage. The contestation of the same material evidence, interpreted differently by two 'reasonably skilled' medical professionals, calls for putting in place stringent standard treatment protocols (STP). The absence of such STPs further ads to the complexities. For instance activists tracking the rash of hysterectomies in Karnataka tried in vain to obtain a set of protocols that laid down guidelines when to undertake and when not to undertake a hysterectomy. In the absence of such a single guideline, a panel of three experts was constituted to independently review records. The expert panel members showed a high level of concurrence on the issue.

Summary and Conclusion

Justice has consistently eluded victims of medical malpractice, gross criminal negligence and grave health care violations. In illness, a patient or their families/ caregivers are in distress, emotional turmoil and hence are extremely

vulnerable. Patients go to health care providers with a trust and expectation of being provided care. Hence, the orientation of patients and families is of seeking healing and not a combative one with preparedness and alertness to gather evidence systematically in the process. However, such expectations are increasingly shattered in recent years with commercial exploitation of patients especially by corporate hospitals. Their distress due to an ailment is compounded by anxiety about costs, mistrust and suspicion about being exploited and cheated. Nonetheless, they are utterly dependent on the private hospitals for being treated in the context of increasing failing public health care. It is this deadly mix of fear, anxiety, suspicion and helplessness that characterises patients seeking medical care in the private health sector in India.

The fact that there is no adequate and effective regulatory or patient rights protection architecture, renders complainants even more vulnerable, isolated and target of hostility and intimidation. The CPA is the only available law for addressing medical negligence currently. This law considers patients as consumers and health care as service, thus departing drastically from the understanding of health care as a human right, casting the duty on the state to protect patient rights. The medico-legal ecosystem, the judicial process and the idea of evidence is dominated and shaped by a deadly combination of unregulated, unaccountable medical profession propelled by commercial interests while the discourse around citizens' health /patient rights in a democratic context is conspicuous by its absence.

The paper while dealing with the politics of evidence provides insights into the power inequity that exists between patients and private medical establishments, in an environment where the state almost abets with the private providers rather than protecting the patient rights. [15]. Private medical establishments are not regulated and they enjoy state supported impunity in several ways which makes accessing information and documents practically an impossible task. For instance, they are excluded from the purview of even the Right to Information Act and this makes accessing information on procedures and protocols difficult. The private establishments make use of this legal gap for manipulating patient records. The recent events in India, in which the super-specialty Fortis and Apollo hospitals were involved in overcharging, medical malpractice and medical negligence, has only confirmed the exploitation of patients. [17].

The patients are not adequately supported legally or medically in the process of seeking care or in seeking redressal. Hence, while a majority of the aggrieved patients give up, only a few who are determined to fight the injustice, face severe challenges with a clear possibility of the case either being dismissed or being decided not in their favour. The medical profession is well organised and enjoys significant clout with the government bureaucracy. On the other hand, patients are scattered, are not organised and hence are weak in their representation and articulation on patient rights.

The evidence that needs to be produced and placed in the legal domain is to be seen in this perspective of the imbalance of power. It is this imbalance of power which is skewed heavily against the patients that increases their vulnerability and susceptibility to be exploited by the private health care establishments. The medical profession which is central to the profiteering of the private health care establishments operates like a shield to protect the latter. In the corporate health care industry, doctors are employees compelled to increase the business and profit of the establishment rather than safeguard the rights of patients. Patients hardly have any wherewithal to confront the medical profession on the one hand and the private medical establishment on the other. Some cases of upper middle class litigants in the paper has shown that even

when they have the knowledge and sufficient evidence, they lacked the financial resources and wherewithal to navigate the legal system to its logical end with appeals and reviews. Hence, this paper makes a compelling case to enact a comprehensive regulatory law to deal with the private medical establishments and legally institutionalize patient rights.

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