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## Multilevel governance framework on grievance redressal for patient rights violations in India

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### Abstract

The notion of patient rights encompasses the obligations of the state and healthcare providers to respect the dignity, autonomy and equality of care-seeking individuals in healthcare processes. Functional patient grievance redressal systems are key to ensuring that the rights of individuals seeking healthcare are protected. We critically examined the published literature from high-income and upper-middle-income countries to establish an analytical framework on grievance redressal for patient rights violations in health facilities. We then used lawsuits on patient rights violations from the Supreme Court of India to analyse the relevance of the developed framework to the Indian context. With market perspectives pervading the health sector, there is an increasing trend of adopting a consumerist approach to protecting patient rights. In this line, avenues for grievance redressal for patient rights violations are gaining traction. Some of the methods and instruments for patient rights implementation include charters, ombudsmen, tribunals, health professional councils, separating rules for redressal and professional liability in patient rights violations, blame-free reporting systems, direct community monitoring and the court system. The grievance redressal mechanisms for patient rights violations in health facilities showcase multilevel governance arrangements with overlapping decision-making units at the national and subnational levels. The privileged position of medical professionals in multilevel governance arrangements for grievance redressal puts care-seeking individuals at a disadvantaged position

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#### Ethical approval

Ethical approval was not required since it is a review paper that uses already published literature and court cases from the Supreme Court of India, which are available in the public domain.

#### Conflict of interest statement

The authors declare that they have no conflict of interest.

during dispute resolution processes. Inclusion of external structures in health services and the healthcare profession and laypersons in the grievance redressal processes is heavily contested. Normatively speaking, a patient grievance redressal system should be accessible, impartial and independent in its function, possess the required competence, have adequate authority, seek continuous quality improvement, offer feedback to the health system and be comprehensive and integrated within the larger healthcare regulatory architecture.

## Keywords

Multilevel governance; patient rights implementation; healthcare facilities; critical interpretive synthesis

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## Background

The United Nations Declaration of Human Rights (1948) proclaimed that it is important to recognize the inherent dignity of all human beings and that inalienable human rights are fundamental for ensuring 'freedom, justice and peace in the world'. Human rights are identified in various forms such as political, civil, social, economic and cultural rights (Hunt, 2017). In the healthcare arena, the human rights principle is reaffirmed as the right of everyone to achieve the highest attainable standard of physical and mental health (United Nations Human Rights Office of the High Commissioner, 1966). The idea of patient rights is deeply engrained in human rights frameworks (Peled-Raz, 2017; Cohen and Ezer, 2013). Patient rights encompass the obligations of the state and healthcare providers to respect the dignity, autonomy and equality of care-seeking individuals in healthcare processes (World Health Organization, 2020). Patient rights could be a powerful tool to address larger health system issues such as access to quality healthcare, health inequities and enhancement of managerial (institutional) and provider accountability (Mold, 2012). Furthermore, the language of patient rights is useful for promoting patient-centred care systems and enabling citizen empowerment in healthcare-related processes (Virone and Tarasenska, 2010). However, many instances of patient rights violations in healthcare institutions are reported across the globe. Abuses range from violation of patient rights to informed consent, privacy, confidentiality and non-discrimination to more serious forms of cruelty, torture and inhumane treatment in healthcare facilities (Cohen and Ezer, 2013; Triantaphyllis *et al.*, 2012). The coronavirus disease (COVID)-19 pandemic has exacerbated the threat to human rights vis-a-vis patient rights in healthcare institutions. In the context of healthcare, issues at the fore include denial of care for non-COVID-related illness, poor quality of care and ignominious treatment in quarantine facilities, fleecing of patients by private hospitals for COVID-19 treatment (e.g. India), issues related to privacy and confidentiality of those affected by COVID-19, and an acute shortage of medical supplies and personal protective equipment for ensuring safe and quality care in health facilities (Hebbar *et al.*, 2020; Human Rights Watch, 2020). The ongoing COVID-19 crisis demands greater attention to patient rights violations.

The United Nations Declaration of Human Rights (1948) reiterates that the states have three obligations with respect to human rights: (1) respect human rights, (2) prevent third parties

from violating human rights and (3) create conditions to realize human rights. Healthcare facilities are more susceptible to human rights violations because of power asymmetry between the care-seeking individuals and healthcare providers. Social inequities further exacerbate this power asymmetry, as in the context of gender, income gap and stigma associated with specific illnesses (Mendez, 2013). Therefore, states are duty bound to enact strong governance systems to protect the rights of care-seeking individuals in healthcare facilities. As one law expert noted, ‘The weakest right is the one for which no legal remedy is available in case of its breach’ (Friedmann, 2005). In that sense, effective and functional grievance redressal systems are crucial for patient rights protection. Coherent frameworks are lacking that can explain the workings of the governance arrangements for grievance redressal in case of patient rights violations in healthcare facilities. Also, scholarly work is scarce in the area of patient rights and grievance redressal in lower- and middle-income country (LMIC) settings. To address this gap, we synthesized the published literature from the high-income and upper-middle-income contexts to establish an analytical framework on grievance redressal for patient rights violation in health facilities. We then used the lawsuits on patient rights violations from the Supreme Court of India (SCI) to analyse the relevance of the developed framework to the Indian context.

### Theoretical lens applied

From the methodological point of view, we applied the critical interpretive synthesis approach. This approach is an amalgamation of systematic review methodology with qualitative research inquiry and enables interrogation of underlying assumptions and critical examination of discourses driving the policy issue under review (Dixon-Woods *et al.*, 2006). From the conceptual standpoint, we used multilevel governance to explore the grievance redressal for patient rights violations in healthcare facilities. Multilevel governance is about intergovernmental relations and the distribution of power, roles and responsibilities between state and non-state actors/institutions at multiple levels of the system (Ongaro *et al.*, 2010). In this way, the multilevel governance analytical lens helps to capture the complex governance architecture for patient rights implementation. We used three broad aspects of multilevel governance proposed by Young (2002): the fit, scale and interplay of both formal ‘thin’ institutions (i.e. rules on paper) and informal ‘thick’ institutions (i.e. rules in practice to implement patient rights). Our initial conceptual framework (Putturaj *et al.*, 2020) is grounded in the literature on patient rights, public policy implementation and multilevel governance to guide the evidence synthesis on grievance redressal. This initial framework was refined based on the review we undertook, as described below.

### Review question

Patient rights are often codified in the form of legally binding or non-binding charters that consolidate the list of rights to which patients are entitled. The patient rights charter usually includes provisions such as the right to informed consent, information, confidentiality, privacy, a second opinion, grievance redressal and compensation. The provision of the right to complain/grievance redressal in the patient rights (charter) is pertinent because it paves the way for making other rights functional and enforceable (Legemaate, 1996; Townend *et al.*, 2016). It can be argued whether ‘patient rights’ is a restricted term applicable only to the curative aspects of healthcare services. Regardless, the ‘right to complain’ provision

within the scope of patient rights captures patient rights violations concerning promotive, preventive, curative and rehabilitative care processes. Hence, the focal question for this review was, ‘In what contexts and how do multilevel actors, institutional structure and processes interact and influence the functioning of grievance redressal systems for patient rights violations in healthcare facilities?’.

## Methods

### Search strategy

**Search of the published literature**—We systematically searched three databases (PubMed, health literature; Web of Science, social sciences; LexisNexis, law) for articles broadly addressing patient rights, their implementation in health facilities and related approaches, strategies, mechanisms and instruments. We determined the search terms based on the feasibility of using them in the respective databases. The systematic search included records published from any date until April 30, 2020, and was not restricted to a specific country. Finally, we hand-searched the reference lists of the specific papers (reference tracking) and the papers that cited the key papers (citation tracking). We have provided the detailed search strategy and results for each of the three databases in Supplementary Tables 1–5 of additional file 1.

**Search of the lawsuits related to patient rights violations from the SCI**—As in many countries, concepts such as the right to life, liberty, equality and dignity are embedded within the Constitution of India. The broader health context in the country is explained in Supplementary Box 1. The SCI at the federal level and the high courts at the state level have a constitutional role and thus act as guardians of human rights. Cases involving the subjugation or exploitation of state, society or the individual are fought in the high courts and the SCI (Jaswal and Singh, 2017). We used the lawsuits from the SCI on patient rights violations to demonstrate the relevance and applicability to the Indian context of the framework that emerged from the published literature. We had many reasons for choosing lawsuits related to patient rights violations from the SCI. Litigation is often considered a vital tool that aids the realization of health (care) rights. It offers powerful narratives and a critical account of human rights violations and implementation, and there is a rising trend of public interest litigations in India on healthcare-related issues (McBroom, 2016).

The court interprets the laws concerning grievance redressal, and the SCI is at the apex of the grievance redressal for patient rights violations. Thus, the SCI has the most power to review the judgements of other entities such as lower-level courts, consumer protection commissions and human rights commissions. We chose to analyse SCI cases (Appendix 1) as they are also a potential one-stop source for capturing the details of patient rights violations from the time and place where they occurred to their final destination in the grievance redressal system. The selected cases provide a detailed account of the actors and institutional structures from the local to national levels that were involved in resolving grievances concerning patient rights violations in health facilities. Most important, the SCI judgements reference and cite foreign law and jurisprudence to clarify the parameters of the statutes in India (Law Library of Congress, 2010). This feature of the SCI suggests

the potential to use lawsuits regarding patient rights violations to explain in the Indian context the framework that emerged from our review of the literature covering high and upper-middle- income country (HIC) settings. The court judgements of SCI were retrieved from the Indiankanoon website. This website offers free access to more than 1.4 million central laws and judgements from the SCI, 24 high courts, 17 law tribunals, constituent assembly debates, law commission reports and a few law journals. The search for SCI judgements on patient rights violations on the website yielded 293 results.

**Record selection and data extraction**—We considered primary and secondary research papers (both qualitative and quantitative), systematic reviews (all types) and commentaries/perspectives/editorials for this review. MP conducted the title and abstract screening of 3225 records including the lawsuits. We used Rayyan software (Ouzzani *et al.*, 2016) to conduct the title and abstract screening. After removal of all duplicate records and records from LMICs, the title and abstract screening resulted in 370 records. We then performed a full-text screening, which yielded 140 records. SVB independently cross-checked selected and unselected articles in the review. Among the 140 records, an initial set of 25 conceptually rich records on the nature of patient rights, patient rights implementation instruments, or strategies, approaches or mechanisms were chosen for concept mapping. The concept mapping indicated a few other concepts such as informal complaints, barriers to raising grievances concerning healthcare processes and patient support systems in grievance redressal procedures. These had the potential to contribute to the emerging framework, so we gradually added a few more of these records for a final total of 37 records. Supplementary Figure 1 outlines the key steps in the record selection process. Among the lawsuits, after removal of all duplicates and irrelevant cases, 17 of 293 court judgements remained. Supplementary Additional files 2 and 3, respectively, provide details of the selected records from the literature and the 17 lawsuits chosen for this review.

Quality assessment of the selected records was challenging and not meaningful for this review for two reasons: the diverse set of records (empirical and non-empirical) and the theory-building focus of the review. Although many papers were methodologically weak (Donovan and Madden, 2018; Fallberg and Mackenney, 2003; Harris and Wu, 2005; Legemaate, 1996; Segest, 1996), they were found to offer theoretically rich accounts of grievance redressal.

We had to limit the number of records for both practical and theoretical reasons. The purposive selection of 54 records is justified because the synthesis mainly targets the development of a theoretical account rather than a summary of all possible data available for the topic under review.

The basic details of the shortlisted records such as the title, author(s), author(s) affiliation, funding, type of journal, year of publication, record type, study design, study setting (for research papers) and country focus are documented in Supplementary Table 6 of additional file 2. We used NVivo V.12 software for coding the data. To iterate between the previously published theoretical framework (Putturaj *et al.*, 2020) and the data emerging from the review, we adopted both inductive and deductive approaches. The authors discussed and resolved any discordant views on data collection and analysis.

## Results and discussion

We have organized the results into three parts. We first discuss the characteristics of the records from the published literature and the lawsuits on patient rights violations from the SCI included in the review. Then, we present the broad themes identified in the analysis. In parallel, we attempt to show how the broad themes identified speak of the Indian context, in [Supplementary Boxes 2–8](#). Finally, we offer a synthesis of the review in the form of an explanatory framework.

### Characteristics of the records from the published literature included in the review

The time period of the records included in this review cover 1994 to 2018. The records comprise 22 research papers and 15 non-research papers such as commentaries and critical reviews of the grievance redressal systems of selected countries. A majority (18) of the records focused exclusively on European countries and on the USA (6), Australia (4), Canada (Quebec, 1) and Israel (1). Four records from upper-middle-income countries such as Brazil, Iran, China and South Africa were included. One record had a global focus, but the authors acknowledged the scarcity of literature from LMICs on grievance redressal systems. Some records (14) had cross-country comparisons on patient rights implementation and patient grievance redressal systems. Among the research studies selected, seven were quantitative, six were qualitative, three used a mixed-methods design and four were reviews. The study design in one research article was not explicitly mentioned.

Most of the research work (8) on patient rights was funded by either academic or research organizations. In 19 of 37 articles, the financial support for the work was not explicitly mentioned. There are widespread concerns about the implications of industry (e.g. pharmaceutical and medical devices) funding of education, training, advocacy and research activities of academicians and patient groups. Directly or indirectly, consciously or unconsciously, industry-supported groups may advance the profit-oriented interests of the industry, leading to conflicts of interest (Fabbri *et al.*, 2020). These situations could possibly undermine the efforts of the patient advocacy groups to protect their rights. In this light, it is arguably problematic to omit disclosure of financial support received for publications on patient rights. Articles pertaining to patient rights were mainly published in journals focusing on health, healthcare, public health, medicine, (bio)ethics, healthcare quality, health law, health policy and social science. While examining the author affiliations in the articles selected for this review, we found that researchers from various disciplines such as law, sociology, ethics, medicine, nursing and public policy had collaborated in their reports on patient rights. Occasionally, professionals from a patient relations office in a hospital and ombudsman institutions featured as authors as well. Ombudsmen are public officials who investigate complaints against institutions and attempt to resolve conflicts concerning maladministration or violations of rights in institutions. They may also be called by other names such as ombud, ombuds, ombudsperson or public advocate. Depending on the country context, the scope of the ombudsman may cover public and/or private entities, and their decisions may or may not be legally binding (Fallberg and Mackenney, 2003).

## Characteristics of SCI lawsuits related to patient rights violations

The time period of the judgements of the SCI cases used in this review was 1989–2019. Most cases on patient rights (12) were adjudicated through civil lawsuits. The trials were about compensation for medical negligence, violation of the right to confidentiality, poor quality of care in public health facilities and a state-organized eye health screening programme, interpretation of the provisions of a consumer protection act and seeking dignity for leprosy-affected individuals. Most of the cases (13) regarded compensation for medical negligence. Private health facilities were involved in 11 of 13 cases of medical negligence. The nature of the lawsuits included in the review is provided in Supplementary Table 7 of additional file 3.

## Towards the explanatory framework

The major themes discussed below include discourses on patient rights; the fit, scale and interplay of multilevel governance systems for resolving disputes on patient rights violations; contextual factors; key processes and outcomes of the multilevel governance systems for grievance redressal.

## Discourses on patient rights

Broadly, three overlapping discourses on patient rights address them as social rights, individual rights and consumer rights. Of the 40 research and non-research records, 11 articles (Annandale and Hunt, 1998; Bismark *et al.*, 2011; Dew and Roorda, 2001; Donovan and Madden, 2018; Goldstein and Bowers, 2015; Mold, 2015; Nettleton and Harding, 1994; Paterson, 2002; Schlesinger *et al.*, 2002; Slabbert *et al.*, 2011; Sorien and Feder, 1999) explicitly discussed patient rights as consumer rights. In six articles, we found that the idea of consumerism was made implicit by the use of terms such as ‘healthcare system users’ and ‘service users’. Six articles discussed patient rights as individual rights. A combination of social, individual and consumer perspectives to explain patient rights was observed in three articles. Most of the articles (15) (Beaupert *et al.*, 2014; Bismark *et al.*, 2006; Boudioni *et al.*, 2017; Bourne *et al.*, 2017; Cox, 2009; Gal and Doron, 2007; Gogos *et al.*, 2011; Gulland, 2006; Harris and Wu, 2005; Jafarian *et al.*, 2009; Middleton *et al.*, 2007; Mirzoev and Kane, 2018; Persson, 2002; Rabinowitz, 2010; Segest, 1996) merely described the patient grievance redressal systems, and neither of the three discourses were explicit. Broadly framing patient rights as social rights accommodates the ‘right to health (care)’ and obligates the states to take legal measures to improve psychological, physical and financial access to quality healthcare to members of the population, leaving no one behind. Also, it obligates the states to put in place the necessary conditions for realizing other rights pertaining to work, housing, food, education, information and participation (in other words, to address social determinants of health) (Townend *et al.*, 2016). Viewing patient rights as individual rights encompasses the right of the individual to self-determination, informed consent, privacy, confidentiality and access to medical records. These individual rights are founded in human rights and freedom principles (Townend *et al.*, 2016) and form the common basis for classic patient rights.

The dominant discourse on patient rights is consumeristic in nature. There is a growing trend to view people using healthcare services and facilities as ‘consumers’ (Dew and Roorda,

2001; Goldstein and Bowers, 2015; Mold, 2015; Slabbert *et al.*, 2011), which explains the consumeristic approach to patient rights protection (Annadale and Hunt, 1998; Nettleton and Harding, 1994; Schlesinger *et al.*, 2002; Sorian and Feder, 1999). Consumerism in healthcare has drawn more attention to different rights, including rights to information, choice, complaint and compensation, and reiterates the need for rights to quality healthcare within the set of patient rights (Annadale and Hunt, 1998; Goldstein and Bowers, 2015; Townend *et al.*, 2016). The consumerist idea is seen as an antidote to physician paternalism (Goldstein and Bowers, 2015). Several author groups (Dew and Roorda, 2001; Sorian and Feder, 1999; Townend *et al.*, 2016) have argued that patient rights in the consumeristic era represent a way to strengthen the demand for accountability and regain trust in a healthcare market system.

The consumerist ideology has helped patient organizations and consumer groups lobby for a greater role for patients in decision-making in the healthcare processes in the UK (Mold, 2015). But Goldstein and Bowers (2015) posited that viewing care-seeking individuals as consumers might nurture a ‘business-like attitude’ in the interaction between healthcare professionals and those seeking care. Choosing a health facility for treatment would be viewed as similar to a shopping experience looking for the best deals and offers. In a marketized health system, customers may not be always accurate in their assessments because they do not possess all the information, so that power relations are asymmetrical. For example, an individual might demand a computed tomography scan or magnetic resonance imaging for uncomplicated knee pain. Goldstein and Bowers (2015) further argued that a consumeristic healthcare environment in the healthcare setting will lead care-seeking individuals to be sceptical and healthcare providers to behave as profit-making entrepreneurs and leave healthcare institutions to function as enterprises focused on profit at any cost. Most important, healthcare will become inaccessible to those who cannot afford it.

Some counter-narratives on patient rights do exist. In a survey among the members of the British Medical Association, the medical fraternity opined that strict adherence to patient rights will only increase defensive practices by the doctors to avoid litigation (Bourne *et al.*, 2017). Surgical trainees raised similar concerns in a survey conducted in New Zealand (Beaupert *et al.*, 2014). Rabinowitz (2010) analysed the framing in paid media coverage on the patients’ bill of rights debate in 1999 in the USA. The paid political advertisements by the Health Benefits Coalition and Business Roundtable were designed to convince viewers that the legislation would lead to higher health insurance premiums and that workers ultimately would lose employer-sponsored health insurance. One group of politicians argued that patient rights legislation would unnecessarily expand the role of government in medical regulation and that it could be expensive. In contrast, other politicians opined that the patient bill of rights would be pivotal to containing rising healthcare costs in the country. In New Zealand, physicians have argued that external regulation mandated by patient rights legislation will undermine clinical freedom (Dew and Roorda, 2001). The inclusion of non-medical members in the complaint examination processes is also a matter of contention in countries such as the USA and China (Harris and Wu, 2005).

Some framings favour the designing of specific patient rights–related actions, programmes and policies. Given the information asymmetry among patients and healthcare providers,



professionals and cost-conscious healthcare institutions, patient rights provide essential safeguards by enabling a power shift from physicians and healthcare institutions to people seeking care (Annas, 1998; Rabinowitz, 2010; Townend *et al.*, 2016). The frames favouring patient rights are also debated in the context of the ever-increasing complexity of healthcare interventions, increasing ethical concerns in medical practice, demographic challenges with the increase in the ageing population, a trend to increasing incidence of non-communicable diseases, need for continuity in care, emphasis on quality and safety of healthcare and provision of culturally sensitive patient-centred care (Townend *et al.*, 2016). Dew and Roorda (2001) asserted that the growing number of medical scandals highlights lapses in medical ethics and that disciplinary procedures within the self-regulatory frameworks favouring medical professionals over laypersons have necessitated external scrutiny of the medical profession in the UK and New Zealand. Positioning of the patient as an individual, citizen or consumer and the competing frames on the notion of patient rights have implications for the nature of policy debates and political discourse and thus influence the response to patient rights violations.

### Multilevel governance system for resolving disputes on patient rights violations

We place the multilevel governance systems for resolving disputes on patient rights violations under three broad themes: fit, scale and interplay (Young, 2002).

**The fit**—The theme ‘fit’ refers to the appropriateness of the multilevel governance systems to resolve grievances regarding patient rights violations. The enforceability of patient rights arises from several laws such as the constitutional, civil, criminal and administrative laws and laws regulating the various cadres of healthcare professionals. Some of the methods and tools for implementing patient rights have included patient rights charters, ombudsmen, tribunals, health professional councils, separate compensation systems and professional liability systems for patient rights violations, blame-free reporting systems, direct community monitoring and the court systems. We have elaborated each of these methods and tools and their utility in detail in Supplementary Table 8 of additional file 4. Broadly, the existing institutional structures for patient grievance redressal could be classified based on whether those structures are dependent on or function independently of the health sector (European Union Agency for Fundamental Rights, 2013). In general, health professionals are responsible for their own acts in the care delivery processes. But this liability becomes vicarious when the health professionals are employed by the healthcare institutions. Giesen (1993) demonstrated that many countries such as Canada, Australia, the USA and continental European nations impose liability on the healthcare institutions for the torts committed by its employees, which includes healthcare professionals. However, Slabbert *et al.* (2011) highlighted the difficulty in determining liability in medicolegal cases because of the myriad actors involved in organizing and delivering patient care. In the healthcare arena, liability could be imposed on a range of health practitioners who supply, provide access to or provide direct patient care (e.g. implant medical devices). Thus, the care-seeking individual can sue anyone in the supply chain.

Because of sparse data on institutional design, we found it challenging to assess the functional, temporal and spatial fit of various approaches for grievance redressal. We

compiled a list of conditions for which we found consensus in the reviewed articles (Fallberg and Mackenney, 2003; Legemaate, 1996; Mirzoev and Kane, 2018; Nettleton and Harding, 1994).

**Accessible**—In the first place, many patients do not recognize the problem. Even if the problematic issue is identified, several barriers can prevent people seeking care from expressing their dissatisfaction with care processes. Huge costs, time constraints, feeling of powerlessness, sheer lack of awareness of regulatory processes concerning patient rights, difficulty pursuing complaints because of debilitating illness, lack of basic literacy and medical knowledge and inability to express the issue clearly limit an individual's ability to lodge a complaint (Gal and Doron, 2007; Schlesinger *et al.*, 2002; Townend *et al.*, 2016). Social status also determines an individual's ability to complain, and studies show that ethnic minorities, racial minorities, people with poor economic status, rural consumers, patients with low social capital, the elderly and migrants are less likely to complain about care processes (Beupert *et al.*, 2014; Bismark *et al.*, 2006; Donovan and Madden, 2018; European Union Agency for Fundamental Rights, 2013; Harris and Wu, 2005; Schlesinger *et al.*, 2002).

**Impartial**—The complaint procedures and the dispute-resolution processes should establish a trust relationship among the complainant, authorities and staff responsible for handling the complaints. The inquiry and recommendations arising from it should not be influenced by paternalistic approaches and should focus on human dignity and quality improvement of healthcare services (Fallberg and Mackenney, 2003).

**Independent**—In view of the conflicting perspectives of the various stake-holders in patient rights, administrative, financial and statutory autonomy of the complaint examination bodies is crucial to facilitate objective and unbiased evaluation of the complaints. Furthermore, the independent nature reinforces impartiality of the effective grievance redressal system (Fallberg and Mackenney, 2003; Legemaate, 1996).

**Competence**—It would be beneficial if authorities dealing with complaints had the required skills, especially in the clinical and legal domains. Regular training of various cadres of staff at all stages of complaints handling, including the public, is also necessary. Studies reveal how insufficient investment in human resources affects the functioning of complaint management systems (Clement and Gagnon, 2006; Fallberg and Mackenney, 2003; Harris and Wu, 2005; Nordlund and Edgren, 1999).

**Authority**—Officials in the patient grievance redressal system should possess adequate power and authority to enforce and achieve the objectives of the system, which are to protect individual rights and to enforce quality improvement in health service delivery. If authority is insufficient, the recommendations and instructions from the complaint handling authorities might be disregarded. With too much power, the system could instil unnecessary fear in health professionals and encourage 'defensive' medical practice (Fallberg and Mackenney, 2003). The extent of the authority of the complaint examination bodies should be determined based on the regulatory context of each state. The authorities should be

cognizant of the information asymmetry and unequal power relations between the actors in the grievance redressal system (Mirzoev and Kane, 2018).

**Seeking continuous quality improvement**—The path to an effective grievance redressal system is an ongoing journey of action and reflection. Hence, building a culture of learning will pave the way for improving institutional processes for handling complaints, such as time taken to resolve the complaints and the use of patient support systems (Fallberg and Mackenney, 2003).

**Feedback to health system**—When documented and analysed in a systematic manner, healthcare complaints offer learning opportunities for policymakers and healthcare professionals to improve the quality of care. They have a ‘window of opportunity’ to learn from mistakes and more specifically enhance the quality of therapeutic interaction between the people seeking healthcare and health systems at all levels, including providers, organizations and policies (Fallberg and Mackenney, 2003; Mirzoev and Kane, 2018). Systems should be in place for gathering lessons from both formal and informal complaints lodged by people seeking care. For example, in the UK system, the healthcare commissioner develops anonymized reports on complaints’ investigations for use as learning resource materials for healthcare professionals and policymakers (Dew and Roorda, 2001).

**Comprehensive and integrated**—A sound grievance redressal system is embedded within the larger healthcare regulatory architecture and is responsive to contextual needs. The policies concerning grievance redressal should be compatible and synergistic with each other to increase the efficiency of the grievance redressal systems (Mirzoev and Kane, 2018; Nettleton and Harding, 1994).

**Scale**—Scale refers to the level of and extent to which the specific actor or institution operates in a system for patient grievance redressal. The subnational level institutional structures and processes for patient grievance redressal are nested within national-level frameworks. Local bodies could include an internal complaints committee (England), information complaint offices (Netherlands), consumer tribunals (South Africa), independent patient advocates (Finland and Austria), long-term healthcare facility ombudsmen (USA), offices of citizen support (Greece) and local public health departments (China) (Boudioni *et al.*, 2017; Clément and Gagnon, 2006; Fallberg and Mackenney, 2003; Healy and Walton, 2016; Nordlund and Edgegren, 1999; Slabbert *et al.*, 2011). Such decentralized local arrangements either at the health facility–level or independent of the health facility enable resolution of the problems close to where they actually emerge. Depending on the context, the functions of the local institutional structures and actors differ. In Finland, local institutions offer only information support services (Fallberg and Mackenney, 2003). In Quebec, Canada, the local bodies have more authority to engage in the arbitration process between the aggrieved party and the healthcare professional or facility or to escalate the case to next level if required (Clément and Gagnon, 2006).

Complaint bodies at multiple levels are in place in several HICs. Scotland has a two-tier grievance redressal system, with an internal National Health Service complaints procedure in the first tier and the Scottish Public Services Ombudsman in the second tier. England

and Wales use a three-tier grievance redressal system. The second- and the third-tier bodies provide an independent system of redress for citizens' grievances. These review bodies have the power to investigate second-tier complaints and make recommendations for action (Gulland, 2006). Norway, Hungary and Israel have ombudsman systems at all levels in a series of tiers from national to local. The power of the ombudsmen varies across the settings and usually lies on a spectrum ranging from providing information and advocacy services to offering statutorily independent investigation of the grievances raised by the care-seeking individuals. In several countries, regulatory bodies for healthcare professionals and quality and safety of healthcare also aim to secure the rights of the care-seeking individuals in all aspects of the healthcare system (European Union Agency for Fundamental rights, 2013; Healy and Walton, 2016; Townend *et al.*, 2016). Other complaint bodies complement the judicial system in many countries. The judiciary is organized in a hierarchy and has provisions for appeals in the higher courts (Dew and Roorda, 2001; European Union Agency for Fundamental Rights, 2013; Gogos *et al.*, 2011; Harris and Wu, 2005; Nordlund and Edgegren, 1999; Segest, 1996; Slabbert *et al.*, 2011).

Non-government organizations such as consumer organizations and medical professional associations do play a role in the patient grievance redressal system. The non-state actors and institutions offer a spectrum of services and support: from information services to representation in the disciplinary proceeding committees to strategic litigation and policy planning on patient rights (Beaupert *et al.*, 2014; European Union Agency for Fundamental rights, 2013; Nordlund and Edgegren, 1999; Sienkiewicz and Lingen, 2017). For example, the Italian NGO Tribunal for Patients' Rights (Tribunale per i Diritti del Malato) collaborates with health law experts to support victims of patient rights violations legally, financially and technically (European Union Agency for Fundamental Rights, 2013). In UK, medical professionals' associations offer support when their members face medical lawsuits (Bourne *et al.*, 2017).

### **Interplay among actors in the grievance redressal systems**

Multiple institutions interact in grievance redressal. For example, in Victoria, Australia, the health service commissioner may have to deal with 14 health professional boards, the Australian Health Practitioner Regulatory Agency, parliamentary ombudsman, mental health review board, disability services commissioner, office of the public advocate, coroner, privacy commissioner, the Victorian Equal Opportunity and Human Rights Commission, the Victorian Assisted Reproductive Treatment Authority and the Victorian health department depending on the case involved in the grievance redressal (Healy and Walton, 2016). In South Africa, the National Consumer Commission consults the relevant regulatory authority while dealing with complaints about the health facilities (Slabbert *et al.*, 2011).

Although the rules on paper concerning grievance redressal appear straightforward, putting them into real practice is challenging and fraught with power struggles. An example is illustrated by Dew and Roorda (2001), regarding the challenges associated with health ombudsmen dealing with complaints about health facilities in New Zealand. In that country, with the no-fault insurance for medical mishap victims in place, the complainants can approach only the commissioner to resolve their disputes. The commissioner has

discretionary powers to take up complaints. One such case involved a health commissioner–initiated investigation against Christ Church Hospital, where a number of deaths were reported in the emergency department in 1996. The Ministry of Health started its own investigation independent from the commissioner. The Christ Church Medical Staff Association approached the court seeking an injunction to stop the commissioner’s inquiry because they believed that it did not fall under the commissioner’s jurisdiction. The court ruled that the commissioner could proceed with the investigation; however, at which point, the minister of health stated that the ministry would suspend the investigation from their side. Later, in 1998, the then-minister of health released the investigation report independent of the commissioner’s knowledge. Although the ministry’s report presented a positive image of the functioning of Christ Church Hospital, the commissioner’s report indicated flaws in the hospital’s governance and management. This case illustrates the power struggle among different actors and institutions within and outside the health services in dealing with complaints about health facilities.

In another allegation of professional misconduct against a midwife in New Zealand, the commissioner revealed the name of the midwife to the public, which forced the nursing council to remove the midwife’s name from its registry. In the earlier complaints dealing with medical professionals, the commissioner had published only anonymized reports. The differential approach of the commissioner while dealing with the complaints of different cadres of health workers reflected the power hierarchy in the field of medicine. These incidents best demonstrate ‘the uneasy tensions here between consumer choice and accountability, medical science and lay experience, the will of health advocates and the office of health commissioners’ (Dew and Roorda, 2001).

The underlying power differentials, especially between care-seeking individuals and the medical fraternity, lies at the heart of the interplay between the actors and institutions involved in the grievance redressal of patient rights violations.

Drawing on experiences from the UK and Australia, Nettleton and Harding (1994) and Middleton *et al.* (2007) posited that historically, the bottom line of any patient complaint assessment is that doctors are the ones who look at the appropriateness of a peer’s action to determine if it amounted to substandard medical care. In China, the officials in the medical professional associations are also the authorities in the health department, so Harris and Wu (2005) have expressed apprehension about bias towards the medical fraternity in the course of conducting inquiries into complaints against medical professionals. The fear of bias is further accentuated by the fact that even the institutions that are independent of the health services rely on the opinion of medical experts to determine if patient rights with regard to the quality healthcare and standards of care are violated (Harris and Wu, 2005). Gieson (1993) highlighted the Bolam test that is commonly applied in England and Scotland to assess medical negligence and professional misconduct. This test holds that medical practitioners would be liable only when conduct falls below that of the standards of a reasonably competent practitioner in the field. In a comparative analysis of various court cases on medical negligence in high-income contexts, however, Gieson (1993) showed how the Australian, Canadian, German and US jurisprudence call into question the credibility of the Bolam test in establishing medical negligence. The main critique is that the Bolam

test gives undue privilege to the defendant-doctor in the eyes of the judiciary and prejudices the plaintiff-patient's right to receive compensation for physical and psychological injuries sustained because of the carelessness of the health professionals in genuine cases.

Donovan and Madden (2018) highlighted the existence of epistemic oppression in the realm of patient grievance redressal. They argued that unequal distribution of regulatory knowledge between the public and the medical profession and processes of epistemic injustice undermine the credibility of public complaints in the eyes of medical regulators. 'Epistemic injustice refers to various systematic ways in which the credibility of some people's testimonies is unfairly deflated and their capacity as knowers is unjustly denied' (Carel and Kidd, 2014, as cited in Donovan and Madden, 2018). As a consequence, their testimonies do not accrue credibility. The 'epistemic injustice' worsens when it intersects with socioeconomic inequalities. Furthermore, the undue 'symbolic power' conferred on the medical profession in the medical field and in the policy arena to decide the institutional definition of professionalism and evidence for medical negligence/professional misconduct might play a role in trivializing complaints lodged by laypersons. These definitions of professional misconduct, i.e. 'a credible complaint' or the norms of the profession, are socially constructed and made to appear socially legitimate by a certain group of power elites (Clément and Gagnon, 2006; Donovan and Madden, 2018). Thus, the knowledge and contributions of the layperson are systematically undervalued in medical regulation (Donovan and Madden, 2018). Also, medical professionals have financial and technical resources to deal with formal grievances raised against them. In the USA, the medical professionals and establishments seek medical malpractice insurance to cover legal costs pertaining to defence against medical litigation (Einy-Rabinovich, 2011). The British Medical Association in the UK stands with its members dealing with court trials (Bourne *et al.*, 2017). Thus, the power and privileges of the medical professionals could be manifested explicitly and implicitly in diverse ways in the governance arrangements meant for patient grievance redressal.

It is contended that the emergence of a new identity of patients as knowledgeable, prudent and rational consumers provides opportunities for greater involvement in the care they receive, to express dissatisfaction in the form of complaints and to seek redressal (Donovan and Madden, 2018; Goldstein and Bowers, 2015). This belief is in accord with neoliberal thinking in which healthcare is marketized and commodified. The responsibility of health and healthcare is shifted to individuals and households. In this context, the clinical encounters of care-seeking individuals are akin to business transactions in healthcare enterprises (Rasooly *et al.*, 2020). In the policy sphere, neoliberalism has favoured the expansion of the private health sector, especially in the LMICs. However, regulation of the private health sector in many LMICs is inadequate (Mills *et al.*, 2002). As a consequence, consumer-patient demands for accountability from healthcare professionals have increased in both the high- and low-income contexts. As an outcome, more stringent regulatory regimes in terms of internal and external control of the medical profession are called for (Beaupert *et al.*, 2014; Dew and Roorda, 2001; Legemaate, 1996). The preference for the term 'consumer' is an attempt to rectify the perceived power imbalances between health professionals and people seeking healthcare (Goldstein and Bowers, 2015).

Considering the multiplicity of fora for grievance redressal, the need for advocacy and support systems for complainants to navigate these systems is apparent (Boudioni *et al.*, 2017; Fallberg and Mackenney, 2003; Schlesinger *et al.*, 2002; Townend *et al.*, 2016). The patient support system can offer a range of assistance, including informing about patient rights, providing clear information about the procedures and processes, and policy advocacy to make the grievance redressal systems more accessible to users both physically and psychologically. In this way, patient support services are fundamental to the processes of empowering care-seeking individuals within the grievance redressal systems. Countries such as the UK, Austria, Finland, New Zealand, Netherlands and Canada (Quebec) have dedicated actors in the roles of patient advocates and hospital ombudsmen and as institutions such as complaint assistance and support centres (Quebec), patient advice and liaison services, independent complaint advocacy services (UK) and the National Information Service (the Netherlands) (Boudioni *et al.*, 2017; Clément and Gagnon, 2006; Fallberg and Mackenney, 2003; Nettleton and Harding, 1994; Nordlund and Edgegren, 1999). One of the foci of these support services is 'low-level resolution and empowerment', which means 'consumers' are encouraged to resolve their issues with health service providers through arbitration and mediation (Dew and Roorda, 2001). The costs of pursuing medical lawsuits in the courts are exorbitant and time-consuming. To address this issue, Denmark offers legal aid to plaintiffs of a vulnerable economic status (Segest, 1996).

Although there are a number of benefits associated with patient advocacy and support services, Segest (1996) has posited criticism. When patient advocates are appointed by the health facilities or when the health professionals act as patient advocates, the extent to which the patient advocates and ombudsmen can support a patient in grievances against the health facilities or professionals is a matter of concern. The other issue is the mismatched professional skill and social status between the physicians and the patient advocates. In that case, the patient advocates may end up orienting patients towards accepting views expressed by the accused physician or the health facility instead of offering the intended services.

In many countries, care-seeking individuals tend to complain more informally than to go through formal channels for grievance redressal (Mirzoev and Kane, 2018). This pattern could be attributable in part to access issues and complex procedures required to engage with a formal grievance redressal system (Schlesinger, 2002). 'Informal complaints' refer to the unwritten complaints made directly to the frontline workers of the healthcare institutions or through other entities and channels that are not meant for formally dealing with the patient complaints (Gal and Doron, 2007). Nettleton and Harding (1994) offered a few examples for which informal complaints are made, such as rude behaviour, lack of cooperation of the health facility staff and a prolonged waiting time, and argued that informal complaints when established with evidence are also an equivalent breach of professional conduct. On the downside, Clément and Gagnon (2006) opined that a requirement to process all kinds of complaints may overburden a grievance redressal system and make it extremely tedious and bureaucratic.

**Context factors**—A number of contextual factors, such as the degree of commitment to protect human rights, administrative and political set-up, and the nature of the health system and policy environment for public engagement shape the implementation of grievance

redressal systems for patient rights violations. This list of contextual factors is only illustrative and not exhaustive. In the Chinese healthcare system, the government owns most of the healthcare facilities, so for aggrieved patients and family members, complaining against the hospital means complaining against the government. There is a trust deficit and lack of confidence in the grievance redressal system, and political and administrative contexts matter. Some settings have a uniform system for handling patient complaints across provinces, e.g. China. The USA, a federal regime, has different liability laws for each state (Harris and Wu, 2005). In most European countries, where the notion of individual rights is strong and human rights institutions are active, patient rights are most often enshrined in law and there is separate legislation for patient rights with detailed arrangements for handling the grievances of the patients at different levels. In fact, the first regional human rights system was established in 1949 in Europe with the establishment of the Council of Europe (Townend *et al.*, 2016; Triantaphyllis *et al.*, 2012). Implementation of patient rights is positively influenced by supportive regulatory acts and policies. In England, the Health and Social Care Acts of 2001, 2003, 2012 and 2013 enable public engagement with health decision-making at various levels of the system (Boudioni *et al.*, 2017). Historical and cultural changes might also influence the people's choice for resolving disputes. Chinese health service users are increasingly turning to legal means to resolve medically related disputes (Harris and Wu, 2015). A plurality of the health systems also enhances the complexity of grievance redressal approaches. China, for example, combines the use of traditional Chinese medicine with modern allopathic medicine, which poses challenges to addressing patient complaints pertaining to the right to quality care (Harris and Wu, 2015).

**Processes**—Litigation is a key process in which either civil or administrative courts are involved in dispute resolution. In settings where ombudsmen structures exist, mediation is a key process. Mediation is considered to be more efficient in terms of cost and time in resolving complaints when compared to lengthy litigation processes (Slabbert *et al.*, 2011; Townend *et al.*, 2016). Out-of-court settlements of patient grievances (e.g. in South Africa) indicate the possibility of arbitration as a process where an impartial adjudicator makes a binding decision on the dispute. An arbitration award is legally enforceable (Harris and Wu, 2005; Slabbert *et al.*, 2011). As noted, more care-seeking individuals complain informally directly to a care provider at the health facility level itself, and the growing trend of informal complaints calls for a critical examination of accessibility to formal grievance redressal fora (Mirzoev and Kane, 2018). On a positive note, such informal complaints might open up avenues for reconciliation and facilitate attempts to restore healthy relationships between care-seeking individuals and healthcare providers (Townend *et al.*, 2016).

**Outcomes**—Although attribution is difficult, the impact of an effective grievance redressal system is presumed to enhance overall health system accountability, improve performance of healthcare professionals and improve healthcare quality (Bismark *et al.*, 2006; Dew and Roorda, 2001; Gogos *et al.*, 2011; Harris and Wu, 2005; Paterson, 2002; Schlesinger *et al.*, 2002; Townend *et al.*, 2016).

Depending on the specificities of cases of patient rights violations and based on the powers held by the grievance redressal fora, outcomes of the grievance redressal systems vary.



Townend *et al.* (2016) mapped patient rights–related policies in 30 European countries and indicated the following possible outcomes of the various grievance redressal systems targeting patient rights violations: seeking apology and/or explanation from the health practitioner/health facility; financial compensation and disciplinary sanctions. Based on an analysis of patient complaint data from the province of Victoria, Australia, Bismark *et al.* (2011) provided a comprehensive list of potential outcomes of the complaints management system, including restoration, communication, correction and sanction. Restoration mainly involves monetary compensation, reimbursement of out-of-pocket expenses or even compensation for lost wages, pain and physical and emotional suffering endured because of the patient rights violation. Communication refers to the wide sharing of the learnings and recommendations obtained from healthcare-related complaints and advocacy with policymakers and other relevant stakeholders. Correction refers to measures taken to improve the quality of healthcare. In the most serious cases, the competence of the healthcare professional could be reviewed as well (Paterson, 2002). Sanctioning is warranted if the healthcare professional or the facility is found guilty of any patient rights violation. Sanctions could include seeking a written apology to the victim, revoking or suspending the practitioner or health facility’s license, imposing a fine or restricting functioning of the healthcare professional or facility (Dew and Roorda, 2001; Nordlund and Edgegren, 1999; Paterson, 2002). A combination of outcomes is possible depending on the severity of the case.

Inadequacy in handling healthcare complaints may cause frustration among people seeking care and lead to violence against healthcare professionals (Harris and Wu, 2005; Mirzoev and Kane, 2018). It also can result in an increase in lawsuits and overall administrative costs if aggrieved users decide to use multiple forums in parallel (Harris and Wu, 2005).

Complaints processes can be mentally and physically exhausting for both the appellant and the respondent parties. In a survey of healthcare professionals, Bourne *et al.* (2017) found that complaints can induce mental health problems such as anxiety, depression, suicidal ideation and fear of lost reputation and social prestige. For patients, it means reliving the painful experience of their rights being violated. Poorly managed healthcare complaints can also be a tool in the hands of healthcare administrators or peers to bully whistle blowers who expose unethical practices in healthcare settings. Jafarian *et al.* (2009) showed that an increased rate of medical complaints may discourage people who aspire to practice medicine because of the perception of high risk in medical practice.

Based on the findings discussed above, we present an explanatory framework in Supplementary Figure 2. We also validated this framework for consistency with four independent public health professionals.

**Description of the framework**—There are three main overlapping discourses on patient rights. Patient rights are viewed as individual rights, as consumer rights and more broadly as social rights. Most nations have adopted a consumerist approach to protecting patient rights. In that vein, grievance redressal structures for patient rights violations are the key institutional response to patient rights protection in health facilities. We use dotted lines to show the possible influence of viewing patient rights as social rights because

the literature was inadequate in this review. The existing grievance redressal systems place special weight on formal complaints. Nonetheless, care-seeking individuals also make informal complaints (unwritten or not recorded) regarding patient rights violations. Institutional structures for patient grievance redressal could be categorized based on whether these structures are embedded within the health service sector. The institutional mechanisms for patient grievance redressal are multilevel, operating at the national, regional and local levels. Furthermore, both state (e.g. tribunals and ombudsmen) and non-state actors (e.g. medical professional associations and consumer groups) interact dynamically in the adjudication of complaints pertaining to patient rights violations in health facilities. Conceptual schemes such as the fit (appropriateness), scale (level and extent) and interplay enable assessment of the dynamic interaction among the actors and institutions for patient grievance redressal. The key dispute resolution processes adopted by the grievance redressal institutional structures involve conciliation, mediation, litigation and arbitration or a combination of these. The power differentials especially between care-seeking individuals or their representatives and healthcare providers shape the interactions among the actors, institutions and levels. The possible outcomes of multilevel governance systems for patient grievance redressal include communication of learnings and recommendations to appropriate stakeholders, compensation for the care-seeking individuals and/or their family members for physical and emotional damage sustained because of the patient rights violation(s), sanctions against the healthcare provider or health facility, initiating course-correction measures to improve quality of care or a combination of these. The consumerist approach favours restoration (compensation) and sanction as key outcomes over the others (communication or correction). However, medicine is not an exact science, establishing patient rights violations can be difficult because of power differentials between laypersons or complainants and the medical fraternity or health facility, burden of proof on the complainants/care-seeking individuals and a disadvantaged position of care-seeking individuals in grievance redressal processes. This imbalance partly explains the difficulty in arriving at restoration or sanction outcomes with existing grievance redressal structures. Specific contextual factors such as a strong normative framework on human rights, the nature of the health system, resource availability for health system functioning and the broader policy environment for public engagement influence the institutional response to patient grievance redressal.

**Generalizability of the framework**—In light of the data sources used in this critical interpretive review, we argue that the current framework is generalizable to democratic regimes with at least some degree of interest and inclination towards the Universal Declaration of Human Rights. It is further applicable to settings where the judicial institutions hold reasonable powers to resolve social, political and economic conflicts within societies. The framework also speaks to contexts with scope for non-governmental organizations to engage in health governance processes, where the trend of healthcare consumerism is evident and in places where healthcare regulatory structures are reasonably available. Finally, the framework can be useful in settings where paternalistic models of healthcare are a point of contention.

**Limitations**—It was difficult to distil the effectiveness and outcomes of each of the approaches, methods and instruments in a multilevel governance system for two reasons:

in most settings, a combination of these strategies are put into practice, and data in the literature are scant regarding contextual conditions and processes, inhibiting assessment of effectiveness. The literature on patient rights is skewed towards HIC contexts. Limited scholarship from LMIC settings motivated us to look into legal data sources, such as the court judgements. We used only court cases from SCI, so for further understanding of the governance of patient rights protection, exploratory research in this domain from other LMICs is required. Other limitations are detailed in the published protocol of this review (Putturaj *et al.*, 2020). The literature also seemed to be increasingly focussed on medical professionals in the grievance redressal systems, thus limiting understanding of the grievance redressal processes adopted for allied health professionals such as nurses, lab technicians and physiotherapists. We do not claim effectiveness of multilevel governance systems for grievance redressal for patient rights violations. The effectiveness of such systems will depend on the social, cultural, political and historical contexts in which these governance systems are embedded. Our focus in this review was to explore the institutional features that are likely to shape the functioning of a multilevel governance system for grievance redressal in cases pertaining to patient rights violations in health facilities. These systems are reactive in nature and offer remedies for individuals when their rights are violated. As a proactive measure to prevent rights violations in healthcare settings, an emphasis on human rights in the health professional curriculum will assist health professionals in internalizing key human rights principles and norms as part of their everyday practice (Erdman, 2017). This preventive aspect of patient rights protection is not covered in this review.

## Conclusions

The current framework on grievance redressal for patient rights violations was established from a critical review of the scholarly work involving high- and upper middle-income countries. However, we demonstrated that elements of the framework are relevant to India, a LMIC setting, allowing us to draw general conclusions. Unlike the many existing theoretical frameworks on public policy implementation, the proposed framework in this paper on the functioning of patient grievance systems takes into account both structure and agency. Furthermore, the model integrates the macro (e.g. discourses on patient rights) and micro policy implementation dynamics resulting from the power differentials between healthcare-seeking individuals and their collectives with the state and socially elite medical profession. The grievance redressal mechanisms for patient rights violations in health facilities showcase multilevel governance arrangements with multiple overlapping decision-making units at the national and subnational levels. With market perspectives pervading the health sector, there is an increasing trend to adopting a consumerist approach to protecting patient rights. In this line, avenues for grievance redressal for patient rights violations are gaining traction. The ‘hegemonic power’ and privileged position of medical professionals because of their financial, technical, political, bureaucratic and social resources in the multilevel governance arrangements for grievance redressal place the care-seeking individuals at a disadvantage during dispute-resolution processes. Inclusion of external structures in health services and the healthcare profession and involvement of laypersons in the grievance redressal processes are heavily contested. Normatively speaking,

a patient grievance redressal system should be accessible, impartial and independent in its function, possess the required competence, have adequate authority, seek continuous quality improvement, offer feedback to the health system and be comprehensive and integrated within the larger healthcare regulatory architecture.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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## Data availability

The articles used in this review are available in the online supplementary material. The lawsuits from the SCI used in this review were retrieved from the source in the public domain.

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### Key messages

- Given the fragmentation of grievance redressal functions across multiple platforms, the need for patient support and advocacy services at different levels to navigate the patient grievance redressal system is apparent.
- Normatively speaking, a patient grievance redressal system should be accessible, impartial and independent in its function, possess the required competence, have adequate authority, seek continuous quality improvement, offer feedback to the health system and be comprehensive and integrated within the larger healthcare regulatory architecture.
- A complex dynamic interplay of power and privilege characterizes the interaction between care-seeking individuals, their family members and other actors/institutions dealing with complaints on patient rights violations. Underlying this is the disproportionate symbolic power conferred to the health profession in the society, especially to the medical fraternity. This undermines the role of actors/institutions who are external to the health services within the multilevel governance systems for grievance redressal.



**Box 1****The health care context of India**

India has a pluralistic mixed health system with a predominance of the private health sector in health service delivery. Three fourths of the inpatient care and a quarter of the outpatient care is by the private health sector (Hooda, 2015). Problems such as insufficient public health spending (<1.3% of the GDP) (World Health Organization, 2014), human resource shortages in public health facilities (Rao *et al.*, 2011), provision of substandard care, use of less-qualified staff in service delivery in private hospitals (Bhate *et al.*, 2011; Das *et al.*, 2012), commission practices (paying a fee for referral), cross-practice behaviours (a non-allopathic practitioner practicing an allopathic system of medicine and vice versa) (Gautham *et al.*, 2014) and high out-of-pocket expenditure for health care (World Health Organization, 2014) reflect the current ineffective state of the health governance in India.

The “social gradient” in access and use of health services by marginalized communities (e.g., Dalits, Adivasis) in India is well documented (Acharya and Sanghmitra, 2007; George, 2015; Irudayam *et al.*, 2006; Navaneetham and Dharmalingam, 2002; Shivkumar *et al.*, 2010). Some of these studies (Acharya and Sanghmitra, 2007; Goerge, 2015) give a fair account of the wide range of discriminatory practices of health care providers towards socially disadvantaged populations, such as avoidance of physical touch during examination, separate waiting lines in the health facilities for lower caste people, indifferent verbal responses, refusal of medical treatment, substandard medical treatment and unwillingness of community workers to visit Dalit households. These inequities illustrate the violations of the patient’s right to dignity, the right to respectful care and the right to quality care. Captions like “Cure the doctor”, “Indian women pushed into (unwarranted) hysterectomies”, “Human chain formed against violation of patient rights in private hospitals”, and “Tribal man walks with wife’s (dead) body (on his shoulders) for 10 kms (since the public hospital denied transport services)” in some media capture public concerns about patient rights violations in public and private health care facilities in India (McGivering, 2013; Patel, 2015; Press Trust of India, 2019).

**Box 2****Discourses on patient rights in India**

In the Constitution of India, Articles 32 and 226 enable the citizens to approach the higher courts in the form of writ petitions when their fundamental individual rights are breached. Writ petitions made on patient rights violations in the SCI invoke patient rights as individual rights in the judicial realm. In almost all cases, the court has discussed patient rights from a consumer point of view or at least touched on the contractual nature of the relationship between the health care provider and care-seeking individuals. The influence of consumerist ideology on the patient grievance redressal mechanisms was articulated as follows in the legal case, “Indian Medical Association vs VP Shantha” (1995). “The new talk is of ‘producers and consumers’ and the concept that ‘he who pays the piper calls the tune’ is established both within the profession and in its relationships with patients. The competent patient’s inalienable rights to understand his treatment and to accept or refuse it are now well established”. Further, “Consumerism is now firmly established in medical practice ... Complaint is central to this ethos — and the notion that blame must be attributed, and compensated, has a high priority”.

In one legal case (“Paschim Banga Khet Mazdoor Samity vs State of West Bengal”, 1996) involving a care-seeking individual who was denied emergency medical services in government hospitals because of a lack of facilities and shortage of health care staff, the overlapping nature of the social rights and individual rights discourses on patient rights was evident. The court observed that failure of the welfare state to provide quality health care in public health facilities violates the individual’s fundamental constitutional right to life in India. This implies that access to quality health care is a social right emerging from the social contract between the state and the citizens. When the right to quality health care (a social right) is not realized, the individual’s right to life is at stake. Furthermore, the court reiterated the embeddedness of patient rights in human rights in the legal case of “Balram Prasad vs Kunal Saha” (2013), quoting, “The patients irrespective of their social, cultural and economic background are entitled to be treated with dignity which not only forms their fundamental right but also their human right”. The social contract of the medical profession to the society to provide good, competent and accountable service to the public was highlighted in “State of Punjab vs Shiv Ram and Ors” (2005). The restrictions of individual rights were discussed at length in a right-to-privacy and confidentiality case initiated by an individual affected with HIV. The court observed that the right to privacy of an individual is not treated as absolute and is subject to such action as may be lawfully taken for the prevention of crime or disorder or protection of health or morals or protection of rights and freedoms of others.

The SCI, while interpreting the Consumer Protection Act in a case filed by a medical professional association, observed that the lay representation in dispute resolution will enhance public confidence in the fairness of the grievance redressal processes. In this way, laypersons are not “mute spectators” in the procedures and processes designed to resolve their disputes (Indian Medical Association vs VP Shantha, 1995).

**Box 3****Fit**

In India, the source for patient rights protection also emerged from civil, criminal and administrative laws and legal rules pertaining to health professionals' conduct (e.g., Indian Medical Council Act of 1956, a law that was repealed and replaced by the National Medical Commission Act of 2019). In a few cases (Martin F Dsouza vs Mohd Isfaq, 2009; Mr X vs Hospital X, 1995; State of Punjab vs Shiv Ram and Ors, 2005), the court invoked a non-legally binding Hippocratic oath to emphasize the importance of ethics in medical practice. Structures internal to the health sector (e.g., inquiry by the committees formulated by the health sector and state medical councils) and external to health sector (e.g., the consumer dispute redressal commissions/forums and judiciary) deal with the complaints pertaining to patient rights violations (Indian Medical Association vs VP Shantha, 1995). The court cases increasingly point to the presence of a fault-based complaint management system in India. Liability for patient rights violations is determined on a case-by-case basis. It could be the professionals or the state (in case of public health facilities) or the private hospitals who are held vicariously liable for the professional misconduct of employees (A.S. Mittal & Om Prakash Tapas vs State of Uttar Pradesh, 1989; Kusum Sharma vs Batra Hospital and Medical Research, 2010; Maharaja Agrasen Hospital vs Master Rishabh Sharma, 2009; State of Haryana and Others vs Smt. Santra, 2010; State of Punjab vs Shivram and Others, 2005). In some cases, both the health professionals and the hospital management were held liable (Balram Prasad vs Kunal Saha & Others, 2013; Maharaja Agrasen Hospital vs Master Rishabh Sharma, 2019; Martin F. D' Souza vs Mohd. Ishfaq, 2009; State of Punjab vs Shiv Ram & Others, 2005).

**Box 4****Scale**

Various fora are available for grievance redressal at the national and subnational levels in India. However, the list is not exhaustive. The formal structures for grievance redressal include structures and actors that are internal and external to the health sector. It is also possible for care-seeking individuals to activate more than one forum at the same time. An aggrieved care-seeking individual could lodge a police complaint against a medical practitioner and at the same time approach the medical professional council to raise a grievance (State of Maharashtra vs Dr. Praful. B. Desai, 2003) or approach the court (A.S. Mittal & Om Prakash vs State of India). The patient grievance redressal fora frequently mentioned in the legal cases include the National Consumer Dispute Resolution Commission, state medical professional councils and national and subnational courts. It was noted that petitioners approached the national level consumer dispute redressal fora directly despite the availability of the local and state options. The reason is that as per the consumer protection legislation in India, the choice of forum for grievance redressal depends on the value of compensation claimed, and the plaintiff should turn to options at the state and national levels if a higher compensation is claimed (Indian Medical Association vs VP Shantha, 1995). One case indicated the attempt of grievance redressal at the health facility level where the complaint actually originated (PB Desai vs State of Maharashtra, 2013).

The petitioners and respondents in the legal cases mainly included individuals who sought care from the health facilities and their family members (4), medical professionals and health facility managements (6), state governments (3), a medical professional association (1), non-governmental organizations (NGOs) and social activists (3). Thus, a number of lawsuits (15 of 18) were initiated by non-state actors. Health activists and NGOs used strategic litigation to bring about system-level changes to protect, promote and ensure patient rights (A.S. Mittal and Om Prakash Tapas vs State of UP, 1989; Pankaj Sinha vs Union of India, 2008; Paschim Banga Khet Mazdoorsamity vs State of West Bengal, 1996). The litigation analysis demonstrated a crucial role for the judiciary in the interpretation of laws pertaining to patient rights protection and patient grievance redressal. For example, the court critically examined the conditions for the health care services to come under the purview of the consumer protection act (Indian Medical Association vs VP Shantha, 1995). In another legal case (Balram Prasad vs Kunal Saha & Ors, 2013), the court scrutinized the criteria for apportioning compensation in a contributory negligence scenario where a team of health care professionals and hospitals was involved in the treatment of a patient. In some instances, the court also took measures to ensure that its decisions emerging out of the cases on patient rights violations are enforced. See, for example, the case of “Maharaja Agrasen Hospital vs Master Rishabh Sharma” (2009), in which the court directly monitored the payment of compensation to the care-seeking individual by the hospital.

**Box 5****Interplay**

Serious cases of patient rights violations that reach the court system usually take a long time to get resolved. Some of the reasons identified in the litigation analysis were the complex nature of the legal proceedings in question, a long journey of the cases from the lower to the higher courts and the use of multiple fora for grievance redressal at the same time. In one gross medical negligence case, the respondent (a mother whose baby suffered permanent blindness because of improper care at a private hospital) had to run from pillar to post and wait for 2 years to access the medical records from the private hospital. It took almost 12 years to resolve this case (Maharaja Agrasen Hospital vs Master Rishab Sharma, 2013). In another gross medical negligence case, the respondent was himself a doctor practicing in the United States, and the legal proceedings went on for more than 15 years in the National Consumer Redressal Commission and the court (Balram Prasad vs Kunal Saha, 2013).

The traditional legal system and the various fora set under the ambit of Consumer Protection Act seek medical experts' opinions to adjudicate medical malpractice cases (Jacob Mathew vs State of Punjab, 2005; Maharaja Agrasen Hospital vs Master Rishabh Sharma, 2009; Malay Kumar Ganguly vs Sukumar Mukherjee & Others, 2009; Martin F D Souza vs Mohd. Ishfaq, 2009; P.B. Desai vs State of Maharashtra, 2019; the State of Maharashtra vs Dr. Praful B Desai, 2003). The judiciary in India commonly applies parameters set down in the Bolam test to establish medical negligence or professional misconduct (Maharaja Agrasen Hospital vs Master Rishabh Sharma, 2009; Malay Kumar Ganguly vs Sukumar Mukherjee & Others, 2009; Martin F D Souza vs Mohd. Ishfaq, 2009; P.B. Desai vs State of Maharashtra, 2019; the State of Maharashtra vs Dr. Praful B Desai, 2003). In some cases, the Bolam test was put into doubt. It was laid down that the definition of an ordinary competent person and ordinary skill is arbitrary and is left to the discretion of individual judges, and that too after consulting the body of medical professionals. A criticism was that the test does not take into account the complex array of nonmedical factors that influence clinical judgement in the treatment of a patient. Thus, the outcome of litigation related to medical malpractice is unpredictable (Samira Kohli vs Dr. Prabha Manchanda & Others, 2008). In another case, the judge argued that the Bolam test is inconsistent with the right to life in India unless the courts construe that the requirement to take reasonable care is equivalent with the requirement of making adequate provision for medical care (Pankaj Sinha vs Union of India & Others, 2008).

The idea of a health ombudsman to manage complaints in the health sector is not so common in India. In southern India, an experimental health ombudsman project between 2001–2005 in the state of Karnataka was successful in terms of raising public awareness and increasing public willingness to raise complaints. However, it suffered from legal and political constraints to follow through on the complaints and take action. Investigations required collaboration with the police department, which was suboptimal because of capacity issues and complex administrative procedures. This complexity led to inadvertent delays in the judicial proceedings. The inconsistencies between the federal

and state laws revealed tensions over authority and jurisdictions to govern the public complaints in the health sector in Karnataka (Vian, 2013).

**Box 6****Context factors**

As mentioned in box 2, the SCI extensively made references to the rights of individuals, consumers and citizens of a welfare state while adjudicating cases of medical negligence and professional misconduct. The court dealt with cases emerging from both public and private health care facilities. Because health care is a state subject in India, the state governments were the respondents in several cases involving public health facilities. In addition to the contextual factors identified in the published literature, the court recognized the importance of resource availability for health systems to prevent patient rights violations. In a legal case involving the failure of a private medical practitioner to obtain informed consent before surgery (Samira Kohli vs Dr. Prabha Machanda, 2008), the SCI observed the challenges for respecting patient rights in resource-constrained health institutions. The court said:

The position of doctors in Government and charitable hospitals, who treat them, is also unenviable. They are overworked, understaffed, with little or no diagnostic or surgical facilities and limited choice of medicines and treatment procedures. They have to improvise with virtually non-existent facilities and limited dubious medicines. They are required to be committed, service oriented and non-commercial in outlook. What choice of treatment can these doctors give to the poor patients? What informed consent they can take from them?

In another case (Paschim Banga Khet Mazdoor Samity vs State of West Bengal & Anr, 1996) against the state that failed to provide adequate public health facilities, the court reiterated the obligation of the state to provide adequate and good-quality health care services to preserve the right to life guaranteed by Article 21 of the Indian constitution. Furthermore, the court emphasized that the government hospitals run by the State and the medical officers employed in these institutions are duty bound to extend medical assistance for preserving human life. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in violation of the individual's right to life.

**Box 7****Processes**

The legal cases clearly indicate that litigation is the key process in the dispute resolution concerning patient rights violations in health facilities in India. However, the existence of alternative dispute resolution processes such as mediation, reconciliation or arbitration could not be ascertained using the legal cases chosen for this review. Nevertheless, we note that after the successful evaluation by the SCI of the Mediation and Conciliation Project, court-integrated mediation and conciliation centres have been established in different courts since 2006 for the amicable and informal resolution of disputes between the parties. The processes are governed by the Arbitration and Conciliation Act of 1996 (Supreme Court of India, undated). Therefore, out-of-court settlements through processes such as arbitration, mediation and conciliation are still possible in cases pertaining to patient rights violations in health facilities in India.



**Box 8****Outcomes**

The most common outcome in legal cases involving patient rights violations in health facilities was monetary compensation. In one case, a warning notice was sent to the medical practitioner against whom a medical negligence case was established. If negligence of gross nature against the medical professional is established, revocation of their licensure by the state medical council, suspension from the medical register for a specific period and rigorous imprisonment with or without a fine are possible (Martin F. D' Souza vs Mohd. Ishfaq, 2009). The court gave a number of recommendations for course correction of policies concerning the protection of dignity of care-seeking individuals. For instance, the court instructed the state government to repeal laws that are discriminatory against persons affected by leprosy and reaffirmed that all persons affected by leprosy and members of their families shall be entitled to the recognition, enjoyment and exercise, on an equal basis, of all human rights including freedoms guaranteed by the Constitution of India (Pankaj Sinha vs Union of India, 2018). In a handful of cases, the court gave recommendations to the federal and the state governments regarding standards to be followed during the conduct of eye health screening programme, to strengthen infrastructure, ensure other resources for effective functioning of public health facilities and enact laws to regulate the functioning of private health facilities (Balram Prasad vs Kunal Saha, 2013; Maharaja Agrasen Hospital vs Master Rishabh Sharma, 2009; Martin F Dsouza vs Mohd Ishfaq, 2009; Pankaj Sinha vs Union of India, 2008; Paschim Banga Khet Mazdoor Samity vs State of West Bengal, 1996). Because of a landmark judgement in the case "Indian Medical Association vs VP Shantha" (1995), the federal government brought the health care services under the ambit of the Consumer Protection Act. Since 1995, consumer redressal commissions are the most popular grievance redressal forum for aggrieved care-seeking individuals and their family members, as is evident from a number of cases in which the court reviewed the judgements passed by the National Consumer Dispute Redressal Commission of India.