

Institutionalizing Patient Safety Culture: A Strategic Priority for Healthcare in India

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Abstract: Fledgling steps in the form of policy measures, surveillance mechanisms and safety initiatives have been taken in the Indian healthcare context to address the increasing evidence base of patient safety events. The paper examines whether structural and processual measures alone would contribute to safer care. The article posits that healthcare organisations in India need to look beyond the structural-procedural efforts and evaluate an essential component of healthcare which serves to bind these efforts; that of safety culture. The paper draws on literature from health services and safety culture research as well as news articles in order to examine adverse incidents in care, safety theories and assess whether structural and procedural efforts would alone contribute to safer care. The review examines the current burden of adverse events in care as well as patient safety initiatives in the Indian context. An emergent strategy comprising policy, regulatory and structural measures has evolved over a period of time to address various facets of patient safety. Global research evidence over the years suggests that such structural-processual measures alone have not been able to address the burden of adverse events in care. Safety culture has emerged as an important concept binding quality and performance measures in most high-risk organizations including healthcare. Institutionalizing safety culture has become a strategic priority in most health care organisations globally. Taking a complex adaptive system perspective, the paper argues that synergizing policy, regulatory and structural-processual measures with safety culture engineering at multiple levels would fetch greater dividends in the Indian patient safety landscape.

Keywords: Complex Adaptive System, Developing countries, Patient safety initiatives, Patient safety culture

I. Introduction

The landscape of patient safety in Indian healthcare has been dotted by several incidents large and small, across urban and rural settings; from highly specialized tertiary care to the ubiquitous general practitioner. There are those incidents which have put the national glare on lack of safety foundations in seemingly safe health care environments. Recent in the healthcare horizon has been the horrific death of 93 patients owing to a fire in a super-specialty private health care establishment of a first-tier Indian city [1]. Preliminary reports found several glaring lapses in safety norms. Despite the presence of fire sensors, the smoke alarms did not function the fateful day since it was alleged that doctors and staff habitually deactivated the smoke alarms in order to smoke indoors. As the fire grew, inadequate fire-fighting knowledge of hospital staff worsened the scenario [2]. Multiple interconnected organizational and external factors, such as lack of design redundancies in the ventilation system [2], flouting of safety norms by the hospital authorities [3], lack of egress for the fire-fighting operations [4], served to focus the spotlight squarely on the questionable status of safety norms, culture and ineffective regulation prevalent in healthcare establishments [5,6]. This healthcare establishment was in the national limelight yet again in 2013 for a long-pending case of medical negligence wherein the compensation awarded to the victim's kin was the highest in the history of medical negligence cases in India [7]. While these are recent events, past instances of preventable medical errors in varied clinical settings have also been widely publicized, including the deaths of 18 pregnant women due to contaminated I.V fluids at a specialty government hospital [8], unsafe injection practices leading to Hepatitis-B epidemic and deaths in a north-eastern district of India [9] as well as individual cases indicating gross lapses in medical care [10-13]. A greater concern is that these incidents could very well be the proverbial tip of the iceberg. Increasing emphasis is being placed worldwide on patient safety and measures are being taken towards ameliorating the global burden of harm. Promoting a culture of safety has become one of the pillars of the patient safety movement. In the Indian context few papers have examined the role of patient safety culture and strategies for institutionalizing it. This paper aims to review adverse events in care and the safety initiatives that have taken so far in the Indian context. The paper also makes suggestions, based on a complex adaptive system perspective, for institutionalizing patient safety culture.

II. Safety Events in Healthcare: Hard-Earned Lessons or Lessons Hardly Learnt?

Highly publicized incidents of medical errors as well as safety lapses in several countries have led to pressure for change. In U.K several public enquiries into medical scandals led the editor of the British Medical

Journal to declare that the era of medical self-regulation was over: 'All changed, changed utterly' [14]. The watershed report by the Institute of Medicine (IOM), "To Err is Human: Building a Safer Health System" [15] put patient safety concerns in the media spotlight internationally, galvanizing the momentum for action against the inaction on medical errors in the healthcare industry [16].

Following the IOM report, a number of empirical studies by different countries over the years [17-21] have revealed high rates of unsafe acts and their consequence. A recent study estimated that 43 million adverse events occur globally of which an alarming two-thirds occur in low-income and middle-income countries [22]. They estimated 5.2 million medical injuries occur in India annually, based on global averages for low and middle income countries [23].

In the Indian context, research on adverse events in care is limited [24] ; with studies carried out mostly in secondary and tertiary care settings. These studies have sought to highlight rates of adverse events including Hospital Acquired Infection (HAI) [25-28], medical errors [24,29] as well as medication errors [30-33]. While the overall HAI rate in acute care settings was found to vary between 33.5 per cent [25] to 4.4 per cent [27]; medical errors varied from 31.5 per cent [24] to 35 per cent [29], and the overall incidence of medication errors varied between 34 per cent [30] to 9.6 per cent [31]. Studies have also attempted to analyse adverse events on a pan-India basis. One such study has been the Indian Intensive Care Case Mix and Practice Patterns (INDICAPS) study; a large scale, multicenter survey launched to gather information about ICUs, patients in ICUs, the type and severity of illness, monitoring and therapeutic abilities as well as types of infections. The study found that 26 per cent of patients in ICUs contracted sepsis; one in four patients admitted in ICUs contracted sepsis in the hospital's emergency departments, with sepsis claiming one out of two patients [34]. A common thread found in most studies however is the lack of active surveillance & paucity of data as limiting the evidence base.

III. Addressing Safety Events in Healthcare: A Call to Arms

The health care industry appeared to be far behind other high risk industries in ensuring basic safety. In 2002, the 55th World Health Assembly adopted a resolution which urged countries to place increased emphasis on the issue of patient safety and strengthen safety and monitoring systems in healthcare. In order to understand the scope of the issues facing policy-makers and researchers involved in improving the safety in health care, the World Health Organization (WHO) created an international alliance; the World Alliance for Patient Safety (WAPS), which was launched in May 2004 [35]. WAPS launched seven major programmes, including the successful *hand hygiene* and *surgical checklist* campaigns which have been adopted globally [36-38].

Ongoing research on patient safety has received a fillip in the form of funding by bodies such as World Health Organization [39], US federal governmental and private agencies such as Agency for Healthcare Research and Quality (AHRQ) and National Patient Safety Foundation (NPSF) respectively [40]. Health system reforms have seen the gradual establishment of standards setting bodies, either private such as Joint Commission in the U.S [41], as well as public bodies such as National Institute for Clinical Excellence (NICE) in United Kingdom [42]. Globally, structural changes have been a large part of health system reforms focusing on safety [43].

Fledgling steps have been taken by Indian health organizations to address the increasing evidence base of patient safety events. Recent efforts at standardization have involved the setting up of a national voluntary accreditation structure, the National Accreditation Board for Hospitals and Healthcare Providers (NABH) in 2006 by the Quality Council of India (QCI) [44]. NABH standards comprise ten chapters with 102 standards and 636 objective elements [45]. NABH currently accredits hospitals, medical laboratories, small healthcare organizations, primary and community healthcare centres, blood banks, dental facilities, as well as imaging facilities [46]. Sustained efforts by patient advocacy groups to address substandard infrastructure and quality in private medical establishments led to the Clinical Establishment Act, a central legislation being passed in 2010 to ensure registration and uniform enforcement of minimum standards across both public and private sectors; from all recognized systems of medicine [47,48]. Normative pressure to change has also come from the global launch of patient safety initiatives. The Indian confederation for Healthcare Accreditation (ICHA) began collaborating with WAPS, the objective being training, identification and setting up of database for adverse incidents in hospitals, nursing homes and clinics [49]. Recognizing the need to address adverse drug events, the government of India initiated the National Pharmacovigilance Programme in early 2005, which was restarted as the Pharmacovigilance programme for India (PvPI) operational from mid-2010 [50]. The All-India Institute of Medical Sciences (AIIMS) in collaboration with WHO has also launched the National Initiative on Patient Safety (NIPS) in 2009, underscoring the increasing priority to patient safety. NIPS aims to train and sensitize clinical professionals across the country on adverse events, reporting systems and patient safety practices[51]. The past few years have also seen international healthcare conferences organized in India by major healthcare providers and academic institutes. These conferences have focused on showcasing best practices in patient safety in India, the role of technology in safety as well disseminating successful patient safety innovations and interventions from other countries[52].

Summarizing, pressure for change in India has come from international bodies advocating safer establishments and patient care. The pressure has been sustained by patient advocacy groups, professional bodies and mounting evidence of harm from deficient quality in care. An emergent strategy comprising policy, structural and processual measures has evolved over a period of time. As a strategy, emergent or otherwise, would policy-structural-procedural measures suffice? Studies in developed and developing countries have shown that despite policies for safety, advancements in safety practice and technology, the burden of adverse events remains a challenge. Are we overlooking something? The following section explores the role of safety culture as the missing link binding the myriad efforts.

IV. Rethinking Patient Safety- Evolving Role of Safety Culture in Healthcare

Advocates of strategic cultural change in healthcare make a number of implicit assumptions, the basic assumption being that organizations possess discernible cultures, which affect quality, safety and performance [43,53,54]. Appeals for culture change draw on a belief that culture is related to organizational performance [43]. The management of organizational culture has been viewed as a necessary part of health systems reform in the US [55] as well as UK [56]. Patient safety culture assessments are required by international accreditation organizations and allow the healthcare organizations to obtain a clear view of the strengths and weaknesses of their safety culture [57]. This is essential since healthcare systems traditionally function as professionalized bureaucracies [58]. Chronic underreporting, “code of silence” among professionals, professional hierarchies, organizational silences akin to the Abilene paradox have created siloed categories of unsafe cultures in themselves [59]. Contributing further is an insular focus on indices such as waiting time, bed occupancy rates, operation theatre utilization rates to name a few, which do not lend themselves to detecting subtler interactions in the system which could potentially lead to adverse events.

Safety culture, a subset of organizational culture, has been embraced by a diverse range of high-risk industries such as aviation, nuclear power, and chemical engineering, wherein safety is a top priority and safety checks have been integrated into all organizational activities [60]. The term ‘safety culture’ first became popular following the Chernobyl nuclear disaster when it was suggested by the International Atomic Energy Agency (IAEA) that operating nuclear power plants can reduce accidents and safety incidents by developing a ‘nuclear safety culture’ [61]. Safety culture has since been formally adopted as a required element of nuclear power safety by the IAEA [62]. Safety culture has been defined as ‘a global phenomenon and encompasses the norms, values and basic assumptions of an entire organization’ [63].

Work on safety culture in high risk industries such as aviation and nuclear industries have informed health care [64]. Initially, healthcare focused on human error [55]; specifically those errors associated with perceptual limitations [65] and employee behavior [66]. This reflected the traditional person-centered philosophy in addressing errors with little focus on system-oriented perspectives [67]. Moving away from the focus on individual attitudes and behavior, two schools of thought based on social science and engineering have addressed the organizational aspects of safety; namely the Normal Accident Theory (NAT) [68] and High Reliability Organizations (HRO) theory [69-72]. While NAT posits that accidents are inevitable or normal in interactively complex and tightly coupled systems, the more optimistic HRO theory asserts that organizations can become highly reliable and avoid system accidents by creating appropriate behaviors and attitudes or ‘collective mindfulness’ [71].

Another approach has been the system-oriented perspective; with examination of organizational structures and system processes [73-74], system reliability [75], and management practices [76], which have all emerged as specific areas of safety culture research. James Reason’s (1995) ‘Swiss cheese’ model comprising ‘active failures’ and ‘latent conditions’ posited that errors occurred from the convergence of multiple and complex contributing factors. The systems approach gained widespread acceptance and has been used to assess safety in healthcare [77]. Another model which expanded on Reason’s model was Vincent et al. (1998) nested hierarchy of factors which included seven categories including patient characteristics. It has been used in assessing safety and safety attitudes in healthcare. [78-80]

Increasingly however, complexity thinking is being applied in the context of health care systems; with health care organizations being likened to *complex adaptive systems* (CAS). A complex adaptive system is a collection of individual agents who have the freedom to act in ways that are not always totally predictable, and whose actions are interconnected such that one agent’s actions changes the context for other agents [81]. The boundaries of a complex system are arbitrary; for instance, medical professionals as a group are embedded in an organizational group, which is embedded in a regional health care system, which is embedded in a socio-economic-political system and so on. According to the CAS perspective, key to the strategy of designing safer cultures is acceptance of the fact that people populating systems are non-linear and have emergent behavior which could be one of innovation or error [82,83]. More often than not, detailed policies and protocols don’t have the intended effect since local context, political dynamics and resistance or reluctance by people themselves may thwart the process. The basic tenets of CAS include setting a general direction, prohibitions as

well as providing for resources or permission [84]. Efforts could thereby have a broad framework, regulation and boundary setting as well as focus on incentives and resources. The Institute of Medicine (2001) took cognizance of the CAS perspective and consequently their second report *Crossing the Quality Chasm* laid down general aims rather than a detailed blueprint for an ideal health care system in the United States [85].

V. Designing Safer Cultures

While evidence is being accrued and patient safety initiatives are being rolled out in India, a greater challenge will be establishing a cultural transformation of the healthcare system. Taking a cue from CAS perspective, several measures can be taken at multiple levels towards institutionalizing patient safety culture. The measures suggested are based on similar innovations in U.S and U.K healthcare systems which have seen constant evolution, adaptation and innovation in the field of patient safety. The measures suggested are based on policy and regulation, workforce and training, research and development, incentives as well as engagement of key stakeholders including policy makers, patients, healthcare providers and administrators (Fig. 1). Table 1 outlines a few such initiatives which could be taken at National, State and Local levels.

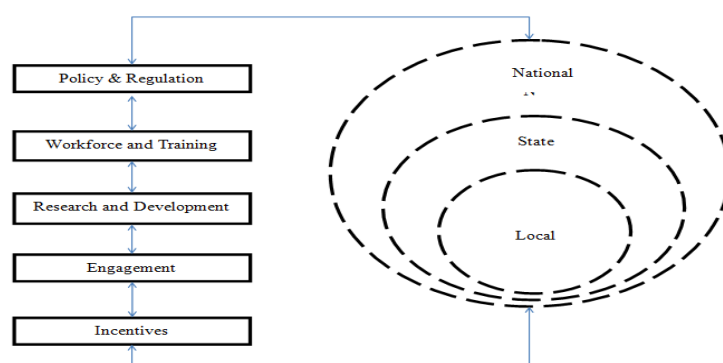


Figure 1: CAS perspective of measures aiding the institutionalization of patient safety culture

Table 1: Engineering the culture of patient safety

	National and State level	Healthcare Organization level
Policy and Regulation	Creation of a single umbrella organization addressing patient safety related concerns would help to centralize patient safety taxonomy, standard setting, surveillance as well as training and development.	At the organizational level, a prerogative should be instituting policies and protocols for patient safety practices, encouragement of error reporting, transparency in communication as well as accountability in care.
	Policies for disclosure of adverse events should be defined. Establishing a system for reporting could include State-wide voluntary reporting systems which could feed into a national registry. Policy would need to be aided by regulation for better results.	
Workforce and Training	A critical need is the dissemination of patient safety practices. While headway has been made by National Initiative on Patient Safety in instituting training for key stakeholders from healthcare institutions across the country, expanding this initiative at State levels with inclusion of smaller healthcare organizations as well as general practitioners would percolate efforts to grass root levels	Directed and consistent training is an important part of organizational efforts to improve skills and sensitize staff on safety issues. Considering the fact that hospitals face high attrition rates especially amongst nursing cadre[86], a robust training programme is essential for consistency in knowledge and performance across all cadres
Incentive	Voluntary efforts such as accreditation lay down policies and protocols in patient safety. However the slow and variable uptake of NABH accreditation has seen only 195 hospitals accredited out of roughly 40,000 hospitals and healthcare establishments; with few States taking the lead [87]. While policy incentives such as CGHS empanelment exist [88] and making accreditation compulsory for empanelment by insurers has been mooted, an added incentive would be increasing consumer awareness on the merits of care provided in accredited hospitals	Incentivizing safety behavior either in the form of recognition as well as celebration of safety efforts and innovations.
Engagement	Engagement of key stakeholders including healthcare providers, administrators and importantly patients including patient advocacy groups at the National and State levels.	The success of patient safety initiatives would hinge on involvement of key stakeholders including clinical, nursing, support and managerial staff. Apart from formal systems, informal systems too should be tapped, for instance clinical professionals

		would be more likely to own a process if influenced by opinion makers from their field.
		An invested leadership – ‘WalkRounds’ by senior leaders and executives to patient care areas to gain a first-hand assessment of safety concerns[89].
Research and Development	A central body with research capacities and resources should be designated to direct research patient safety events, efficacy and outcomes of safety interventions in care.	Research in healthcare organizations could focus on assessing safety interventions and their outcomes. Further, reliable and validated surveys could be conducted to understand the safety culture in the organisation [90, 91].

Safety efforts would need to begin with establishing a dedicated infrastructure and capacity-building to address the creation of a patient safety framework. Similar to the ambit of patient safety bodies such as AHRQ and NPSF in U.S, parameters such as quality indicators, evidence based guidelines; training and dissemination of best practices as well as patient safety culture surveys could be initiated centrally. Patient safety culture assessments, required by international accreditation organizations, have allowed healthcare organizations to obtain a clear view of the strengths and weaknesses of their safety culture[57]. Such surveys could be conducted confidentially and would help to establish benchmarks. Apart from identifying problem areas it would also allow participating establishments to assess themselves against national or State benchmarks.

A greater challenge would be instituting disclosure of adverse events. Disclosure is a complex notion and has been heavily debated by healthcare professionals. Of prime concern is shielding the patient safety data from legal proceedings as well as protection of whistle blowers [92]. In the Indian context, policy for disclosure would need to be aided by regulation. For instance Patient Safety Organizations (PSO), came into being in U.S with passage of The Patient Safety and Quality Improvement Act of 2005, which allowed for voluntary and confidential reporting of patient safety events by hospitals, doctors and other healthcare providers [93].

Research on adverse events and systemic issues in care in the Indian context has lagged behind. A greater thrust is needed for evidence based action. Policy incentives, infrastructure and funding would be drivers for research. Research capabilities would help in building the evidence base of adverse events as well as evaluation of safety interventions. Research outcomes would drive implementation of evidence based interventions as well as direct strategic allocation of resources.

At the national and State level, engaging with key stakeholders including healthcare professional bodies, patient advocacy groups, healthcare industry and administrator groups, would be necessary for the success of any initiative as well as addressing conflicting concerns.

Additional measures have been proposed at the organizational level based on successful safety innovations in the healthcare field in several countries and which could be easily adopted in the Indian context. For instance, simple concepts such as ‘WalkRounds’ by senior leaders and executives to patient care areas in order to discuss patient safety issues have paid dividends. Discussions at the front-lines of care indicate an invested senior leadership and a well-organized support structure [89,94].

To summarize, taking a cue from available evidence of best practices and innovations, policy incentives and regulatory aids, a framework for safety cultural transformation is being espoused. The framework could be expanded to include several more facets of patient safety. Factors such as lack of infrastructure and trained manpower, workload and attrition are ubiquitous realities in the Indian healthcare system. In the light of these realities, the paper has limited itself to those measures which could be adopted despite resource constraints.

VI. Conclusion

‘One’s destination is never a place, but rather a new way of looking at things’ [95]

Safety interventions in healthcare are manifold in the form of improved technology, processes and medical advances, enabling greater and safer therapeutic care. Safety science and the presence of underlying safety theories have not necessarily translated into an error-free healthcare sector. Murphy’s Law thrives in high risk organizations such as healthcare.

Policy makers and healthcare administrators in the Indian context need to consider the concept of safety culture as the critical link binding myriad safety efforts in the organization. Dismissing the concept as an abstract trait far removed from ‘machine-like’ ethos of healthcare organizations would only limit the understanding of safety in complex systems such as healthcare.

Based on studies and experiences of several countries, what seems certain is that safety systems are impacted by culture which also set limits to structural and procedural changes. Taking a cue, an amalgamation of structural-procedural-cultural efforts at the national, State and local levels would foster greater gains in the safety outlook of Indian healthcare organizations.

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