Promoting patient safety in India: Situational analysis and the way forward

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ABSTRACT
Unsafe healthcare is a well-recognized issue internationally and is attracting attention in India as well. Drawing upon the various efforts that have been made to address this issue in India and abroad, we explore how we can accelerate developments and build a culture of patient safety in the Indian health sector. Using five international case studies, we describe experiences of promoting patient safety in various ways to inform future developments in India. We offer a roadmap for 2020, which contains suggestions on how India could build a culture of patient safety.


INTRODUCTION
Unsafe healthcare is a well-recognized issue internationally. Medical errors are the eighth leading cause of death in the USA, and the levels of disability and stress associated with them are high, as are the financial costs. Thus, most policy-makers and professionals are rightly concerned about and keen to address the problem of patient safety. The issue is attracting attention in India as well. The prevailing situation and some of the actions being taken were described in an editorial in the Natl Med J India, which emphasized the need to speed up efforts to address the problem. We build on this editorial and aim to learn from the various efforts in India and abroad to explore how we can accelerate developments and promote patient safety in the Indian health sector.

This paper consists of four parts. Part one summarizes our assessment of the situation in India. Part two contains five international case studies of different ways of promoting patient safety, to inform future developments in India. In the third part, we briefly describe the global developments in patient safety that may spur on developments in India. The concluding part makes some suggestions on the way forward for building a culture of patient safety in India, and offers a roadmap for 2020. Finally, the appendix lists some useful resources.

PART ONE: EFFORTS IN INDIA AND CHALLENGES
Over the past 5–7 years, a number of initiatives have focused on different aspects of patient safety and have involved various stakeholders. The following account is by no means exhaustive, although between us we know of most of the developments in India; these initiatives are mentioned here largely to illustrate the key learning points.

At the national level, three examples of the initiatives that have been taken are the work being done by the Indian Confederation for Healthcare Accreditation (ICHA); the National Initiative on Patient Safety (NIPS) developed at the All India Institute of Medical Sciences (AIIMS); and the National Health System Resource Centre (NHSRC). ICHA includes almost all national organizations involved in addressing the challenges of patient safety and has been doing pioneering work in this area at the national level for the past 7 years. Apart from holding national and regional workshops to raise awareness, it has worked with the Employees’ State Insurance and Railways Health Systems, for example, to develop and deliver specific and tailored programmes. The NIPS programme has worked on the key challenges to patient safety such as infection control and medication errors. It has held workshops for multidisciplinary teams, including doctors/nurses from institutions across the country, to train them and help them make the necessary improvements in their work settings.

At the institutional level, large corporate hospitals such as the Apollo, Fortis and Max groups have taken an interest in this subject and organized international conferences. They have also instituted internal quality improvement programmes, and ICHA...
has established collaborative centres at the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and the Maulana Azad Institute of Dental Sciences, New Delhi. Although they do not specifically focus on patient safety, India’s world-famous centres for eye care, such as the Aravind Eye Hospitals and Sankara Nethralaya, and the multispecialty Narayan Hrudayalaya health system are now well recognized exemplars of quality care.

The science and evidence base for patient care is being developed in various ways. An example is the efforts of the International Clinical Epidemiology Network (INCLEN), which undertook the largest study on injection practices in India and showed that almost two-thirds of the injections administered were unsafe (personal communication, Professor N.K. Arora). Another example is an international collaboration led by WHO Patient Safety, which worked on checklists, including one for the safety of patients undergoing trauma surgery. This was part of an 11-country pilot study conducted in 2010–11. The early results show a decrease in mortality among patients.5

Recognizing the importance of educating and empowering the public and patients, initiatives such as the Patient Safety Alliance (an India-based non-governmental organization [NGO]) have started holding workshops to raise awareness of the issue and mobilize public support in Mumbai. The Health Education Library for People (the Mumbai-based library of information on consumer health) is promoting the use of ‘information therapy’ to empower patients and is involved in furthering health literacy.6,7

Finally, there have been attempts to leverage international initiatives, such as the courses on patient safety offered by the People’s Open Access Education Initiative (People’s Uni) and the Institute for Healthcare Improvement (IHI) Open School to help build capacity and capability.8,9 ICCHA also facilitates fellowships for Indian professionals to go abroad and learn from other countries.

The preceding account does not include initiatives such as the National Accreditation Board for Hospitals (NABH) and accreditation through other international agencies, including the Joint Commission International (JCI), since we found that the views regarding their effectiveness are mixed. On the one hand, as the following account will show, the Indian healthcare system is not yet ready for accreditation approaches to patient safety and quality improvement, which are largely seen as paper exercises. On the other hand, individual organizations have made some inroads because of the desire to be ‘at par’ with international organizations for the purpose of health tourism and to obtain additional funding, since reimbursement rates are higher for accredited providers.

So, what have we learnt? Obviously, we recognize that the task of ensuring the safety of the patient will take a long time to achieve, perhaps decades, but are we doing enough to bring about the cultural changes necessary to minimizing harm to patients? We have identified a number of challenges in this regard, on the basis of our collective experience and observations. These are as follows.

The policy framework constitutes the first challenge. There is hardly any national mandate or an overarching comprehensive programme for safer care. Initiatives such as the NABH and other accreditation programmes are in danger of losing their value because of the perception that some accreditations can be easily procured. As for the Clinical Establishment Act, it focuses more on structures and processes than outcomes, and hence, does not offer a way forward at the moment. Independently validated and objective reporting of patients’ concerns does not exist; in the given climate, no organization is prepared to report the data publicly, even if it collects data properly in the first instance. Reporting of incidents related to patient safety is seen as an act of complaining: a report is treated as a complaint, which is used for blaming—fault-finding rather than fact-finding. There follows a vicious cycle that discourages reporting or owning mistakes.

The second challenge is the absence of leadership by the organized professions. There appears to be a limited sense of responsibility or urgency. Although individually, some doctors are championing the cause of patient safety, the quality officers generally find that doctors are the most reluctant participants. The response of the Indian Medical Association to the ‘Satyamev Jayate’ programme, i.e. its demand for an apology from the actor, Aamir Khan, for raising issues pertaining to malpractice, shows how far behind the times the organized profession is.10

The absence of pressure to change, either on organizations or individuals, is the third challenge. Patients are attracted by the perceived quality of service, rather than the actual clinical quality and standards of patient safety. They are strongly influenced by the ‘brand name’ or personal knowledge of the medical staff. As for the ‘sellers’ market, where the demand is higher than the supply in most places, there is no incentive for organizations to change. Even where financial incentives have been introduced, for example, the 20% extra payment for public-sector patients receiving care at NABH-accredited hospitals, the money is either not utilized, or does not suffice for setting up the infrastructure required for quality improvement. Consequently, the staff members concerned with quality feel undervalued, as they do not directly generate any revenue. In fact, it is believed that they cost money. Sadly, the financial impact of inefficiency and complications due to unsafe care do not concern healthcare providers since they pass the cost to the consumers anyway: ‘complications generate revenue!’ The cost–benefit ratio works against investment in patient safety.

The fourth challenge is that the issues of patient safety and quality improvement are barely emphasized in education and training, if at all. Coupled with this is the absence of holistic development and promotion of professionalism in medical education. Much of medical education is based on learning by rote and there is limited development of the faculty of critical thinking. This is reflected in a lack of capability when students attempt to learn about the scientific basis of quality improvement.

The way the care of patients is organized and delivered in India constitutes the fifth hurdle. Given the shortage of trained nurses, the stand-in nurse is usually a family member. The latter is called upon to perform nursing tasks such as monitoring the patient’s temperature as well as the fluid intake–output, and even administer Ambu bag ventilation in some cases. However, even with the best intentions in the world, a patient’s relative cannot be a substitute for a nurse, and the chance of unsafe situations and false alarms increases under such circumstances.

Problems in communication, both formal and informal, constitute the sixth concern. As a result of these problems, which are often due to the paternalistic system of healthcare, patients and carers are not given adequate information. This is compounded by poor record-keeping and minimal documentation. The absence of teamwork and group practice means that individual physicians practise in isolation, which in itself causes problems. For example, it is stressful for patients when the physician is not available due to holidays/leave. Violence in a hospital, e.g. when there is a sudden or unexpected death, usually that of a child or an infant, can lead to chaos that endangers the lives of other patients. In the
absence of a senior doctor or administrator to soothe the frayed nerves, a junior resident is often responsible for dealing with the crisis. However, the situation sometimes escalates, often leading the junior doctors to go on strike. Eventually, a vicious cycle may set in.11

Finally, patient safety is compromised by downright illegal practices, such as the sale of spurious and low-potency drugs, which are the result of a lack of regulation and quality control;12 unqualified personnel posing as physicians and collecting money from illiterate patients; and non-functional and poorly maintained essential equipment, such as pulse oximeters and air-conditioning ducts, which are a source of fatal infections. Perhaps the problem of antibiotic resistance is the biggest threat to patient safety in India, and increasingly, abroad, too, as the resistant organisms spread. Additional problems are posed by poor physical infrastructure, which leads to further risks, such as fire.

India, therefore, faces a ‘double whammy’ of challenges related to patient safety. The ‘wicked’ (and rather intractable) issues in healthcare mentioned above compound the usual problems of improper labelling, incorrect dispensing and wrong prescription of drugs; the failure to conduct and report tests properly; lack of hand hygiene to reduce infections and performing surgery at the wrong site or on the wrong side, which are similar in nature to those found in other countries. In India, patient safety, as with other aspects of safety, such as road safety, is not a priority. This is partly due to the cultural tendency to believe that if things go wrong, it is because of fate or ‘God’s will’, and partly due to the lack of alternatives. There is also an attitude of ‘why bother when one can get away with it’. Overall, when one assesses the culture of patient safety, it seems that there is no serious commitment at the national/state level. However, a few institutions, supported by a small number of knowledgeable and committed individuals, are taking the necessary steps. While some good work is now being done and world-class standards have been achieved in some cases, given the intractable problems and absence of leadership, we have not yet reached the ‘tipping point’ to ensure safer healthcare in India.

What can we learn from experiences elsewhere and how can we accelerate developments to promote patient safety in India? Five international case studies are presented below to throw some light on this matter.

PART TWO: INTERNATIONAL EFFORTS

1. UK National Health Service

The first case study concerns the National Health Service (NHS) in the UK. A former Chief Medical Officer set the tone for patient safety with the launch of the landmark report, ‘An Organization with a Memory’, which cited the constant failings of the NHS and the failure to learn from these.13 This led to the establishment of the National Patient Safety Agency (NPSA), a special health authority, which launched a range of interventions. The most important of these was the National Reporting and Learning System (NRLS) database of incidents related to patient safety.14 The database was launched in 2003 and is now the largest of its kind in the world; it hosts over seven million reports of episodes of care that could or did result in iatrogenic harm. The NPSA has analysed these incidents and identified possible solutions to safety-related problems. Relevant information and solutions are contained in one-page reports called Rapid Response Reports, quarterly data summaries, and topic-specific information on issues such as preventing inpatient falls in hospitals. The NHS organizations are bound to meet deadlines for the implementation of key findings of the NPSA reports. The NRLS staff members frequently consult subject-matter experts from professional organizations such as the Royal Colleges.

Of course, there are challenges due to the very large number of case reports received, which makes it difficult to undertake a detailed analysis of all incidents. Moreover, such analysis is compromised by the lack of detail in many of the reports and the inability to go back for further information due to anonymized reporting. Notwithstanding this, however, it is clear that reporting is increasing as clinicians become more aware and also, become more confident that there will be no personal repercussions when they do raise concerns.

With respect to the NHS in Wales, the Welsh government adapted the landmark 100 000 Lives Campaign from the United States, and set out its vision that ‘by 2015, Wales will have minimized avoidable death, pain, delays, helplessness and waste’.15 The Welsh 1000 Lives Campaign aimed to improve patient safety and the quality of healthcare services across Wales, with the goal of preventing 1000 unnecessary deaths and 50 000 cases of harm in 2 years. All six of the hospital organizations in the country signed up voluntarily and were responsible for recruiting their frontline staff to introduce a series of interventions. These focused on reliability of the system and consistency of delivery, grouped into six major content areas. Table I lists example interventions for each content area. Hospital organizations set up teams that were enrolled in a series of learning events for each content area. The teams attended learning sessions to discuss and plan activities (and later report back on the progress), and undergo ‘action periods’, during which the plans were enacted and tested. The 1000 Lives Campaign organizers claimed 1119 additional lives were saved and 65 869 episodes of harm avoided in 2 years.16

2. Institute for Healthcare Improvement (IHI) Open School

Our second case study concerns the efforts made by healthcare students and junior professionals who have perhaps been an unexpected agent of reform of healthcare, as well as catalysts for the improvement of patient care. Via the IHI Open School, over 135 000 students, junior professionals and faculty members are making use of a catalogue of online courses and a growing network of chapters to gain the knowledge and skills required to ensure patient safety, improve the quality of care and provide

| TABLE I. 1000 Lives Campaign—content areas and examples of interventions |
|-----------------------------|---------------------------------------------------------------|
| Content area | Example of interventions |
| Improving leadership for quality | Patient safety leadership walkrounds* |
| Reducing healthcare-associated infections | Patient stories at executive meetings |
| Improving critical care | Hand hygiene |
| Improving management of medicines | Ventilator-associated pneumonia bundle† |
| Reducing surgical complications | Severe sepsis pathway |
| Improving general medical and surgical care | Medicines reconciliation |
| WHO Surgical Safety Checklist | High-risk medication protocols |
| Deep vein thrombosis prophylaxis | |

* Walk rounds are an informal method used by leaders to talk to the frontline staff about safety issues in the organization and show their support for staff-reported errors.† A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices.
leadership, so as to improve the systems within which they train and work. The IHI Open School has three guiding principles: provide educational content to equip members with the knowledge and skills required to lead change; establish community networks, called chapters, at hospitals and universities where like-minded students and practise professionals can jointly learn from and about each other’s experiences of improvement; and support experiential learning by encouraging members to bring about improvements in practice. The IHI has 700 chapters in 70 countries, and 13 of these are in India.

In 2009, students and junior professionals explored the IHI Open School community’s potential to collaborate through a campaign called ‘Check a Box. Save a Life.’ It was a global movement for patient safety, organized by students and junior professionals to encourage their peers to raise awareness and implement the WHO surgical safety checklist in operating rooms in developed and developing countries worldwide. After one week of planning, the campaign had succeeded in mobilizing participants at 182 hosting sites from 121 distinct institutions. An estimated 1400 participants from six continents were mobilized for the launch event. As a result of the junior-driven efforts, thousands more patients were potentially reached by the life-saving checklist. The ‘Check a Box. Save a Life.’ campaign leveraged an untapped audience by using the shared experiences of students and their inner desire to practise safer healthcare. It disrupted the leadership paradigm with respect to patient safety.

3. United States Agency for International Development

One of the larger efforts focusing on the improvement of the quality of healthcare in low- and middle-income countries has been led by the United States Agency for International Development (USAID). The organization has been funding a series of multi-country projects since the 1980s to bring about improvements in the quality and safety of healthcare. It has carried out its work under various names over time—Primary Health Care Operations Research Project (PRICOR) I and II, Quality Assurance Project (QAP) I, II and III, and USAID Health Care Improvement Project (HCI). In its most recent form, the project has been re-christened USAID ‘Applying Science to Strengthen and Improve Systems’ (ASSIST), in recognition of the fact that there are scientific methods of quality improvement and patient safety that can be applied to strengthen and improve health systems. These projects have covered all areas of care, including maternal and child health, HIV, tuberculosis, malaria and infection control, and have been implemented in more than 40 countries.

Recently, a rigorous evaluation of 135 time-series charts from 1338 health facility teams was carried out at USAID HCI project sites in 12 countries. The evaluation showed that 87% of the sites had achieved performance levels of 80% or higher, and 76% had reached performance levels of at least 90%, even though two-thirds had a baseline performance of below 50%. On an average, the time taken to reach a performance level of 80% was 9.2 months, and to reach the level of 90%, 14.4 months. The evaluation showed that large-scale, sustainable improvements in patient safety and the quality of care can be made even in low-resource settings. Major gains have been made across various areas of healthcare in countries such as Niger, Afghanistan, Nicaragua and Kenya, all of which face challenges similar to those faced by India, such as overburdened staff, poor working conditions, and issues related to governance and accountability.

4. Institute for Clinical Effectiveness and Health Policy, Argentina

The fourth example, which we shall deal with briefly, is that of the Institute for Clinical Effectiveness and Health Policy (IECS) in Buenos Aires, Argentina. The IECS was founded in the 1990s by a group of professionals who realized that compared to developed countries, few research studies are led by developing countries. They also realized that decision-makers in the health sector must have local scientific evidence because in many instances, interventions designed in developed countries are not applicable or they need to be adapted to take account of the local cultural and social context. The IECS has a Department on Patient Safety and Health Care Quality, which focuses on research, education and technical cooperation to advance patient safety in the region. Over the past decade, the IECS has conducted several projects on patient safety and quality improvement in the region, and has become a resource centre for patient safety in Latin America. It is also conducting several courses on patient safety and the quality of care, both through classroom training and distance education.

5. African Partnerships for Patient Safety

Our final case study focuses on the work being done in Africa. Since 2008, when ministers of health across the WHO Region of Africa committed to take action on the issue of patient safety, steady progress has been made to transform this commitment into tangible action at the national regional and facility levels. One channel for translating commitment into action is African Partnerships for Patient Safety (APPS), a WHO programme with three simple objectives. First, it facilitates the establishment of hospital-to-hospital partnerships between Europe and Africa; second, it catalyses improvements in patient safety in hospitals by encouraging the application of existing methods and tools, with an emphasis on co-development and bi-directional learning; and finally, it encourages the spread of improvement in patient safety both within and beyond countries.

The programme has been rolled out in waves. The APPS partnerships have empowered healthcare workers to improve care and communities to engage themselves in actions to improve the safety of hospitals. They have also made it possible for the ministries of health to take system-wide action to improve safety. The challenge is to achieve a balance between applying the technical interventions for improvement and understanding the cultural and contextual factors which will form the backdrop for the introduction of these interventions. In this manner, effective partnerships are nurtured on the basis of respect.

Gaps in the capacity and infrastructure necessary to ensure patient safety are identified through an in-depth needs assessment, using a situational analysis template. The situational analysis comprises 12 sections or action areas. The areas in which gaps exist can be prioritized, allowing for the development of targeted action plans to help build stronger health systems. The situational analysis assists in addressing cultural and contextual factors that might have an impact on the improvement of patient safety, and is not focused solely on the implementation of technical interventions. For example, action area four, i.e. Patient Safety Awareness Raising, encourages partners in African hospitals to consider the role of those who can champion the cause of patient safety within hospitals as well as patient- and community-based organizations. Leadership development is a common thread throughout the situational analysis. The steps emphasize the importance of establishing teams and leaders, and raising awareness of the situation and the context.
One of the areas in which action is taking place across all partnerships is the strengthening of knowledge and skills for effective prevention and control of infection. As a direct result of participating in APPS, African partner hospitals which were working in this field and had no staff previously have now secured named leads to drive activity in patient safety. The sharing of information, as well as the provision of support to the training and development activities of their colleagues in the African partnership hospitals, has also strengthened the role of infection prevention and control in hospitals in the UK.

The other learning areas include the crucial importance of the sustained engagement of executive decision-makers focused on accrued benefits for participating institutions; agreement on core partnership principles at the start of activities so as to form a group for partnership working; regular communication between the partners to maintain the momentum of improvement; and a keen awareness of divergent cultural contexts.

PART THREE: GLOBAL DEVELOPMENTS IN PATIENT SAFETY

Around 10% of hospital admissions are associated with healthcare errors, of which 0.5%–2% may result in death. We know that these estimates are conservative, since recent Indian studies have shown that almost one-third of critically ill surgical patients and children suffer an adverse event. Medical errors, which have serious economic and social consequences, span the entire disease spectrum, from maternal deaths to surgical errors, hospital infection control and inadequate care for chronic diseases. Nearly 80% of these errors are preventable, and there is a moral and ethical obligation to ensure that every person who accesses healthcare receives care of the safest and highest quality possible. No effort should be spared in keeping patients safe from preventable harm—and if harm does take place, we should have the courage to learn from it, talk about it and become even more determined to make healthcare safer and better.

At the global level, multiple events have taken place to increase the momentum and share learning to ensure safer and better healthcare. In 2002, the World Health Assembly (WHA) Resolution 55.18 recognized ‘the need to promote patient safety as a fundamental principle of all health systems’. This was instrumental in the formation of the WHO World Alliance on Patient Safety (WHO WAPS) programme, which has actively advocated for patient safety with Member States and led several successful global campaigns on various themes, such as surgical safety and hand hygiene. The work of the programme continues to be innovative. It also supports research on patient safety and the development of partnerships between institutions to build capacity for patient safety. In October 2008, 30 healthcare leaders and improvement experts from 15 countries met at the Rockefeller Foundation Bellagio Centre in Bellagio, Italy, to share lessons and find more effective ways of improving patient safety.

In 2012, two major global events signalled a growing momentum in the areas of patient safety and quality improvement in low- and middle-income countries. In April 2012, the Salzburg Global Seminar (SGS) brought together 58 health leaders from 33 countries to review experiences in improving the quality and safety of healthcare services in low- and middle-income countries; synthesize the lessons learned from those experiences; and discuss the challenges and opportunities. It recommended steps that could be taken to stimulate improvement in these countries. In May 2012, the 65th WHA held a technical session on the issue of patient safety, hosted by the Ministry of Health, Qatar, to share the achievements made in patient safety since the 2002 WHA Resolution 55.18. A renewed call to action was made to promote patient safety and to highlight how this issue is fundamental to the achievement of the Millennium Development Goals and strengthening of health systems.

Although India is a signatory to the WHO WAPS, and some influential individuals from India have participated in some of the developments aimed at enhancing the quality and safety of care, there is no one accountable person or body responsible for patient safety in India.

PART FOUR: PROMOTING PATIENT SAFETY IN INDIA

Quality improvement and patient safety efforts in developing countries face several major challenges. These include the lack of good-quality data, or the inability to generate such data, which makes any improvement or safety efforts particularly difficult. Moreover, most of the larger quality improvement work is currently supported by donors, or is voluntary. Thus, there is limited ownership and sustainability after the funding is over. Another major need is to foster a culture that holds people accountable without apportioning blame or using punishment.

It is essential, therefore, that we reflect on the challenges and build on the work already being done; learn from experiences elsewhere; take advantage of the gathering global momentum; and develop a roadmap for the next decade. As our analysis shows, progress can be made through top-down and bottom-up initiatives, as well as partnerships. We could, therefore, launch a programme, 2020 Safer Care in India, which could start by addressing seven specific areas, as follows.

1. Policy mandate. Gaining a meaningful (in terms of well-resourced and accountable) commitment from policy-makers has to be a top priority. To our knowledge, it is difficult to promote this agenda unless there is political commitment. The experience of Ernest A. Codman, who started the End Results Hospital in Boston, USA in 1911, after leaving the Massachusetts General Hospital, shows how long it can take for a new idea to become widely accepted if one relies on individual efforts. Codman’s idea was nothing short of revolutionary in his day: to follow every patient until the success or otherwise of his or her treatment was clear, and then to examine any treatment failures to learn from them and prevent similar failures in the future. Though his idea is no longer disputed today, Codman’s approach is still not fully implemented. Much of what has been achieved in the UK has been thanks to strong political backing. In the Indian context today, there is an opportunity to bring about large-scale, meaningful change to promote patient safety because of the considerable interest in providing universal healthcare coverage. Without ensuring patient safety, universal healthcare coverage is a recipe for disaster. The costs and suffering associated with unsafe care, without proper safeguards, may outweigh the benefits arising from the well-intentioned efforts towards universal coverage to alleviate healthcare-related poverty, unless we get it right.

2. Professional leadership. The policy mandate should be visibly supported, and the sentiment reciprocated, by professionals, who must provide the necessary leadership. Recognizing the difficulty of engineering this cultural shift, we suggest a two-pronged approach: (i) incorporating quality improvement (QI) science in the medical and nursing curricula to ensure that the
next generation is well equipped, and (ii) providing for targeted and well-structured continuing medical education (and similarly for nursing) for established professionals. In addition to making provisions for technical assistance for education on QI science, we should create a critical mass of professionals who can serve as leaders and champion the cause of patient safety. Bespoke leadership development programmes, recognizing the Indian context, are a must for the necessary cultural shift. Using social media and junior professionals is also a good way forward.

3. **Data and research.** Establishing a clear programme of research to document the extent of the problem and creating, either at the state level (more feasible) or national level, a system for reporting and learning will help to establish the baseline and document progress. The data could be grouped into the usual categories of medication safety, diagnostic safety, information safety, communication safety, environmental safety systems, inter alia. This would help determine who could help develop and deliver the measures necessary for better outcomes in the area of patient safety. We do not underestimate the difficulties associated with this, but unless we start somewhere and establish a baseline, it will be impossible to know what to do and how to proceed. Another useful adjunct to this would be the establishment of a limited number of ‘confidential enquiries’, such as for to determine causes of maternal and child deaths linked to the Millennium Development Goals, possibly using the ‘verbal autopsy method’. We could also collect data on a set of ‘Never events’ in India and prioritize their reduction and ultimate elimination.

4. **Independent scrutiny.** A quality and safety commission should be set up to ensure that the outcomes of state-funded schemes, including universal healthcare coverage, are subject to appropriate scrutiny through the collection of data, inspections and training support. This body should have a strong patient/public representation, and all its work should be publicly reported. One of the biggest drivers of change in the USA, for example, has been public reporting of the performance data of hospitals. The Leapfrog group approach is another model that can be emulated in India.

5. **Medical regulation.** There is an urgent need to set up a system of medical regulation to deal with doctors whose performance is poor. This is mandatory for restoring public confidence and encouraging the silent, interested and seemingly powerless good doctors who want to provide high-quality and safer care.

6. **Consumer empowerment.** There are many mutually reinforcing trends which are opening a window of opportunity for consumers to ‘demand’ quality healthcare rather than accept the status quo, educate them on correct/ideal practices, and monitor and measure changes. These include the awareness of consumer courts, the Right to Information Act (applicable to public sector institutions), lawyers specializing in assisting with litigation (this can have a positive or negative effect), and the ability to disseminate information rapidly through the social media.

7. **Regulation of drugs and devices.** India is now producing medical equipment, devices, drugs and vaccines, and some of these (especially equipment and devices) are poorly regulated from the perspective of patient safety. Some of these goods are destined for other countries and the absence of demonstrable quality control is a big business risk. Manufacturers can play a big role in driving improvements by manufacturing better and safer devices.

We acknowledge the defeatism and deep sense of cynicism among professionals and the public in India, and the feeling that nothing can be done. There is little faith in the regulatory and legal approaches to improving the quality and safety of healthcare, since these approaches themselves are in danger of becoming sources of corruption. Nonetheless, doing nothing is not an option. Patient safety is not an issue that affects others; it is deeply personal since all of us need healthcare for ourselves and those close to us. Unsafe care affects everyone equally. It does not distinguish between the rich and the poor, or people with different religious affiliations, for example.

In conclusion, this paper is an attempt to learn from the recent Indian and global experiences of promoting patient safety with the aim of exploring how we can build a culture of patient safety in the Indian health sector. Our analysis shows that while some progress is being made to address various challenges in reducing healthcare-related harm, the conditions for creating an effective and sustainable system for promoting patient safety do not yet exist in India. Different parts of the Indian health system are in different stages of the journey. Although the larger corporate hospitals have made a start and there are some world-class health systems, the smaller private providers (a substantial proportion of inpatient care is provided by units with 30 or fewer beds) and the totally unorganized primary care sector need support and encouragement. The problem with the public sector is the overwhelming demand and patient workload, which make it almost impossible to put proper systems in place, although the new AIIMS institutes being set up, as Greenfield sites, offer the potential to become the game-changer.

Despite the hurdles, with the measures described above, we have the opportunity to create a safer healthcare system in this decade. We also need to note that even with all the efforts made over the years in the West, things can and still do go wrong, for example, in the NHS, as recent incidents have shown (the report on the inquiry at Mid Staffordshire Hospital—www.midstaffspublicinquiry.com/report). However, the developed countries at least have systems and procedures to continually review the situation, and hence, there is scope for improvement. This would not have been possible without firm commitment from the government, followed by reciprocation by the professionals, as well as open discussion and debate involving the public and media.

We need to do the same in India and recognize that progress will be slow, but, with a systematic and focused approach, a beginning can be made. India needs to take patient safety seriously if it is to be recognized as a world leader, not just in healthcare but generally.

**ACKNOWLEDGEMENTS**

We are grateful to many colleagues, both in India and overseas, who have helped us and continue to do so. The views expressed here are personal, and not of any of the organizations with whom we are associated.

**REFERENCES**

APPENDIX

1000 Lives Plus

The website of the national healthcare improvement programme in Wales has resources that include ‘improvement guides’ to improve the quality and safety of clinical care, e.g. reducing surgical complications.

http://www.1000livesplus.wales.nhs.uk/home

African Partnerships for Patient Safety (APPS)

The APPS has co-developed a series of tools to support the planning, implementation and review of improvement in patient safety across Africa. Although primarily developed by and focused on the APPS partnership hospitals, the APPS tools series is available for any hospital attempting to bring about improvements in patient safety.


Health Education Library for People

A free library of consumer health information for patients

http://www.healthlibrary.com

Indian Confederation for Healthcare Accreditation

A confederation of national professional organizations engaged in promoting patient safety in India

http://www.icha.in/

Institute for Healthcare Improvement (IHI)

The IHI, an independent not-for-profit organization based in Cambridge, Massachusetts, is a leading innovator in health and improvement of healthcare worldwide. The ‘Knowledge Center’ section of its website offers tools, ideas for change, measures to guide improvement, IHI white papers, audio and video material, and stories about improvement.

http://www.ihi.org/knowledge/Pages/default.aspx

IHI Open School

The IHI Open School provides healthcare students with the opportunity to learn about quality improvement and patient safety at no charge. The online, educational community has a growing catalogue of online courses, extensive content and resources, and a network of local chapters that organize events and activities on campuses around the world.

http://www.ihi.org/offers/IHIOpenSchool/

People’s Open Access Education Initiative (People’s Uni)

The People’s Uni provides public health education to those working in low- to middle-income countries who would otherwise not have been able to access such education, via the Internet.

http://www.peoples-uni.org

USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project

The USAID ASSIST knowledge portal aims to promote an open exchange of ideas and lessons among healthcare providers and improvement practitioners all around the world. It contains a database of short reports on improving healthcare, and guidelines on designing your own improvement activity and research studies on improvement methods. Readers can also submit their own stories related to improvement and join communities of practice with others interested in improving specific areas of care.

http://www.usaidassist.org/