

Patient safety and health care regulatory system in Nepal

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The World Health Organisation defines patient safety as the absence of preventable harm to patients and the reduction of unnecessary harm and risks associated with health care to an acceptable minimum level.¹ As patient safety is a fundamental aspect of health care systems, aimed at minimising the risk of adverse events, it is a critical public concern that involves both governmental and public perspectives.² The development of regulations has been driven by the need to address societal challenges, protect public interest, and maintain harmony.³ Consequently, many countries, including Nepal, have been making efforts to formulate and enforce the laws and regulations that serve as the foundation for delivering safe and quality health care for ensuring patient safety. However, fragmented regulatory systems present significant challenges in establishing a strong patient safety culture.⁴ In order to address this challenge, reforming the regulatory framework in alignment with global best practices is necessary.^{5,6}

Globally, countries have adopted different approaches to establish an effective patient safety culture in health care settings. For instance, both Canada and Australia, are concerned about patient safety, which led to the establishment of the Canadian Patient Safety Institute in 2003 and the Australian Council for Safety and Quality in Health Care respectively. These organisations provide national leadership, patient safety, and adverse events reporting system. At the same time, such organisations also promote a co-ordinated approach to enhance the safety and quality of care. The impact of such initiatives contributed in better documentation of adverse drug reactions and medication history, decreasing rate of adverse events, improving performance of health care providers, and public engagement.^{7,8}

Sweden has enforced Patient Safety Act prioritising patient safety and proactive approach to health care. Similarly, countries like Thailand and the Philippines have incorporated multi-stakeholder engagement in shaping policies that address the needs of patients and health care professionals. These initiatives have demonstrated integration, accountability, and national leadership in improving patient safety culture in health care settings.⁶

In context of Nepal, patient safety faces significant challenges. The medical practitioners are overburdened and have limited access to modern equipment, especially in remote areas. Additionally, poor communication among health care providers and with patients, leads to medical errors. Addressing these issues through enforcement of regulatory policies, professional trainings, standardised protocols, and increased awareness of patient safety is essential to improving outcomes.⁵

The major regulatory bodies, including Nepal Medical Council, Nepal Nursing Council, Nepal Health Professional Council, and Nepal Pharmacy Council, oversee their respective professionals with an aim of ensuring patient safety whereas, the Curative Service Division and Quality

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Standard and Regulation Section of Ministry of Health and Population (MOHP) oversee the health care services and Medical Education Commission oversees medical education. The primary functions of all regulators in Nepal share a common aim to deliver quality health care to public but the lack of strong co-ordination, lack of robust monitoring mechanism to oversee the adverse events, and lack of incident reporting system has obstructed to address the existing challenges and establish patient safety culture in health care settings.

The lessons from international experience, such as centralised leadership and incident reporting systems in Australia and Canada, inclusive participation of public in Thailand, and holistic legislation enforced by Sweden, act as valuable guidance for Nepal.⁶ There is a need to develop integrated Patient Safety Framework and one central statutory body responsible for patient safety that efficiently coordinates with all regulatory bodies, health care providers, professionals, and public. This organisation may assist in formulating national safety standards, developing a system of adverse event reporting and improving health care safety protocols.

A study conducted in China, between 2012 to 2017, reflected that nurses were involved in the most incidents (40.7%), followed by physicians (29.5%), medical technologists (13.6%), and pharmacists (5.1%). Incidents involving multiple or other staff

accounted for 11.1%. Additionally, 44.4% of incidents were attributed to medical staff with less than five years of experience, indicating a link between incident severity and work experience.⁹ Therefore, Continuous Professional Development (CPD) should be another priority for fostering patient safety culture among health care professionals. Training health care professionals, strengthening infrastructure, especially in rural regions, and increasing health care funding to at least 5% of gross domestic product (GDP) are critical steps. Additionally, fostering a culture of transparency and accountability through a national level or centralised reporting system would not only enhance monitoring but also encourage continuous improvement in patient safety practices.

In conclusion, Nepal's journey towards improved patient safety demands a unified, well-coordinated approach-based on global best practices. By reforming integrated patient safety regulations, investing on infrastructure, and capacity building of professionals, Nepal can transform its health care system that ensures effective patient safety culture in every level of health care settings. Therefore, strong leadership and stakeholder collaborations are crucial for creating a regulatory system that benefits public well-being.

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