Clinical safety

Clinical safety refers to the measures and processes in place to ensure that medical treatments, interventions, drugs, devices, and procedures are safe for patients and do not pose unnecessary risks or harm. Ensuring clinical safety is a critical aspect of healthcare and medical research to prevent adverse events, side effects, or any negative impact on patients' health.

Key aspects of clinical safety include:

Clinical Trials: Before a new medical treatment, drug, or device is approved for use, it typically undergoes rigorous testing through clinical trials. These trials involve controlled studies with human participants to assess the treatment's safety and effectiveness. Proper trial design, ethical considerations, and informed consent are crucial to maintaining safety during these trials.

Risk Assessment: Health professionals and researchers conduct thorough risk assessments to identify potential hazards or risks associated with a particular medical intervention. This involves considering factors like patient demographics, underlying health conditions, potential interactions with other treatments, and known side effects.

Regulatory Oversight: Regulatory agencies such as the U.S. Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in the European Union play a significant role in evaluating and approving medical interventions. They review clinical trial data and other relevant information to determine if a treatment meets safety and efficacy standards.

Post-Marketing Surveillance: Even after a medical intervention is approved and in use, ongoing monitoring and surveillance are crucial to identify any unexpected or rare adverse events that may not have been detected during clinical trials. This includes reporting and investigating adverse events reported by healthcare providers, patients, and other sources.

Medical Device Safety: Ensuring the safety of medical devices involves proper design, manufacturing, and monitoring. Devices must meet specific safety standards, undergo testing, and adhere to regulations to ensure that they function as intended and do not pose risks to patients.

Pharmacovigilance: This refers to the process of monitoring the safety of pharmaceutical products once they are on the market. Healthcare professionals and regulatory agencies collect and analyze data on adverse drug reactions to identify any emerging safety concerns.

Continuous Improvement: Healthcare organizations and providers work to continually improve patient safety by identifying and addressing potential risks, learning from past incidents, and implementing best practices.

Ultimately, clinical safety aims to protect the well-being of patients and ensure that medical interventions provide more benefits than risks. It involves collaboration between researchers, healthcare professionals, regulatory bodies, and patients to uphold high standards of patient care and ethical practice.

Healthcare discipline that emphasizes the reporting, analysis, and prevention of medical error that often leads to adverse healthcare events. The frequency and magnitude of avoidable adverse patient events was not well known until the 1990s, when multiple countries reported staggering numbers of

patients harmed and killed by medical errors. Recognizing that healthcare errors impact 1 in every 10 patients around the world, the World Health Organization calls patient safety an endemic concern.

Indeed, patient safety has emerged as a distinct healthcare discipline supported by an immature yet developing scientific framework. There is a significant transdisciplinary body of theoretical and research literature that informs the science of patient safety.

The resulting patient safety knowledge continually informs improvement efforts such as: applying lessons learned from business and industry, adopting innovative technologies, educating providers and consumers, enhancing error reporting systems, and developing new economic incentives.

"Changing our culture to advance patient safety" served as the theme of the 81st Annual Meeting of the American Association of Neurological Surgeons and is an issue of personal importance to the author. To improve outcomes for patients and prevent avoidable surgical errors, neurosurgeons must change the culture that currently exists in the operating room so that safety concerns are of the utmost importance and that each member of the care team has a personal sense of accountability. Doing this will involve implementing and consistently applying systems-based strategies to ensure an adequate level of safeguards; improving communication with all members of the care team and dismantling authority gradients; and maintaining a well-trained and well-rested workforce [1].

Patient safety-related adverse events were strongly associated with in-hospital mortality. Moderate to strong correlations were found between PSIs, HACs, and hospital procedural volume. Patients treated at the highest-volume hospitals had consistently lower rates of mortality, PSIs, and HACs compared with those treated at the lowest-volume facilities [2]

Indicators

see Patient Safety Indicators

[1]

Berger MS, Wachter RM, Greysen SR, Lau CY. Changing our culture to advance patient safety: the 2013 AANS Presidential Address. J Neurosurg. 2013 Dec;119(6):1359-69. doi: 10.3171/2013.10.JNS132034. PubMed PMID: 24289847.

[2]

Nuño M, Carico C, Mukherjee D, Ly D, Ortega A, Black KL, Patil CG. Association between in-hospital adverse events and mortality for patients with brain tumors. J Neurosurg. 2015 May 22:1-9. [Epub ahead of print] PubMed PMID: 26053457.

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