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Quality and Safety With Technological Advancements in Radiotherapy: An Overview and Journey Narrative From a Low- and Middle-Income Country Institution

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abstract

PURPOSE To present an overview of quality and safety in radiotherapy from the context of low- and middle-income countries on the basis of a recently conducted annual meeting of our institution and our experience of implementing an error management system at our center.

METHODS The minutes of recently concluded annual Evidence-Based Medicine (EBM-2021) meeting on the basis of technology in radiation oncology were reviewed. The session on quality and safety, which had international experts as speakers, was reviewed. Along with this, we reviewed the literature for preventive and reactive measures proposed to manage errors including error reporting and learning systems (ILSs). Concise summary for the same was prepared for this article.

RESULTS We also reviewed the journey of development of our institutional ILS and present here a summary of achievements, challenges, and future vision.

CONCLUSION Preventive and reactive measures must be followed to achieve high-quality and safe radiotherapy. Despite resource constraints, a successful ILS program can be developed in a low- and middle-income country center by first understanding the patterns of error and developing one that suits the working ecosystem.

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INTRODUCTION

Quality in health care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[1] Although quality and safety are often discussed as distinct topics, safety is one of the dimensions of quality. Ensuring safety always improves the overall quality of care, whereas measures incorporated to improve quality may not necessarily affect safety. The six dimensions of quality in health care are Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equity.[2]

Technology has invariably revolutionized various aspects of radiotherapy (RT) and helped in improving the quality of the same. The road toward modern high-tech radiation oncology has been studded with technological innovations resulting from the collaboration of various science disciplines, namely, mechanical and electronic engineering, computer science, mathematics, imaging physics and technology, statistics, and data sciences. RT has often adopted technology developed in other domains like linear accelerators, proton or heavy ion accelerators replacing telecobalt machines, which came from the nuclear physics domain and better computer hardware/software solutions from the computer science domain.[3]

In this article, we present a brief overview of quality and safety in RT with rapidly evolving technology on the basis of the discussions in our recently concluded annual Evidence-Based Medicine (EBM-2021) meeting. We also present our experience of implementing an error management system developed indigenously in our center.

TECHNOLOGY AND ITS RELATION WITH QUALITY AND SAFETY IN RADIOTHERAPY

Technology has always played an inherent and crucial role in developing RT from its genesis. The translation of new technology from research to clinical practice has been an efficient and quick process in RT.[2] The first of the many steps of the technological evolution in RT was moving from 2-dimensional (2D) simulation and 2D (planar) RT to 3D (computed tomography [CT] and magnetic resonance imaging) simulation and conformal RT, respectively. The introduction of multileaf collimators around the mid-1980s enhanced the concept of field shaping in conformal RT. The introduction of Intensity-Modulated RT (IMRT) by the 1990s expanded the idea of conformal RT by spatially confining

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CONTEXT

Key Objective

To present an overview of quality and safety in radiotherapy from the context of low- and middle-income countries (LMICs) on the basis of a recently conducted annual meeting of our institution and our experience of implementing an error management system at our center.

Knowledge Generated

Summary of error management system in the context of evolving technology in the LMIC setting is presented with a successful example from our center.

Relevance

There are lacunae in knowledge and sensitization regarding approaches toward quality and safety pathways needed with modern technology in LMICs.

the high dose and sparing surrounding normal tissues. IMRT was shouldered by the rapid development of treatment planning systems (TPS), including modulation and rotation (forward planning) into inverse optimization, where plans with the best dose distribution were chosen. Simultaneous developments in improvising daily patient setup verification led to image-guided RT (IGRT). IGRT using portal films or CT has dramatically improved the accuracy of RT delivery and reduced the need for safety margins, thereby enlarging the potential of conformal RT. Subsequently, developments including autosegmentation, 3D robust TPS, stereotactic body RT, particle therapy, adaptive RT, etc have not only improved the quality but also put forth state-of-the-art RT in the current era.[4]

Using newer technologies is effective and time-saving. However, the challenges posed by them are unique—high technical complexity, substandard levels of interoperability and interconnectivity (because of crude integration of new and old technologies and inconsistent interfaces), inadequate testing and commissioning standards, educational shortcomings, lack of standardization, etc.[5,6] If the scope for the above situations is not adequately gauged and safety measures are not integrated, the likelihood of new and sizable errors is very high. An additional surge of such errors is expected when new technology is coupled with pre-existing complex RT workflow consisting of multiple human-human and human-machine interfaces (HMIs). Each process in RT might have multiple points of HMIs, which further multiply the risk of errors. Hence, many technologies adopted in RT are designed with safety and operability in mind to avoid such errors. To truly enhance the quality, we need to focus our attention on key aspects like automation at various levels, establishing a standardized procedure, clinical validation of multimodality image registration, commissioning of calculation algorithms, robust optimization, better respiratory gating, and customized immobilization.

ERROR

Error or accidents refer to any unintended event, including operating errors, equipment failures, or other mishaps leading to consequences with varying severity—nil/minimal, mild, moderate, and severe to fatal.[7] Multiple case reports and reviews have been reported on radiation accidents, highlighting the most common errors as wrong patient/site treatment or the wrong dose delivered, among other errors.[6,8-10] Direct and contributing causes can be categorized into procedural mistakes, professional mistakes, communication mistakes, lack of training, interpretation mistakes, lack of supervision, mistakes in judgment, hardware failure, software, and other mistakes. The possibilities of defining a deviation to be an error can be subjective and are in no way limited to the provided list.

Technological advances in RT delivery can potentially mitigate several errors to an extent via multiple cross-checks, increased automation, and built-in quality assurance (QA) safeguards, yet may also introduce new types of errors.[11] The impact of such errors can not only adversely affect an individual patient but can also falsely prove or disapprove the efficacy of a particular treatment strategy. It must be acknowledged and clearly understood that technology in any field is a double-edged sword. When relied on excessively and handled without adequate clinical and technological expertise, there is a significant chance of inflicting harm than good. A recent meta-analysis on RT protocol deviations and clinical outcomes resulted in a statistically significant decrease in overall survival (hazard ratio, –1.74; 95% CI, –1.28 to 2.35; $P < .001$) and local and locoregional control (hazard ratio –1.79; 95% CI, 1.15 to 2.78; $P = .009$).[12] Similarly, unplanned deviations from standardized operating procedures (SOPs) in clinical practice can lead to errors affecting patient care quality and their outcomes. Hence, ensuring quality and safety forms the cornerstone of effective medical practice, especially in disciplines like RT, which are heavily technology-dependent.

MANAGEMENT OF ERRORS

Traditionally, errors have been considered unacceptable, and when they occur, the natural response is to adopt a

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blame culture. The onus needs to be shifted to the system and not be considered an individual's fault. Despite the remarkable technological advances achieved, the development and implementation of quality control measures have not kept pace.[13-16] Hence, it is quite essential to integrate preventive and reactive measures to decrease the incidence and impact of such events. A summary of various measures is presented in Table 1. While understanding our management systems, performing QA programs, establishing standardization procedures, and participating in voluntary internal/external audits are the preventive measures.[11,13,17-25] The proactive risk assessment, reactive risk analysis, review of reported adverse events, and establishing reporting and learning systems are other important measures adopted in managing errors as described.[14,26-28] Error reporting and learning systems form the backbone of most modern RT centers and associations to constantly learn and improve the safety and quality of patient care and are described further in detail here.

ERROR REPORTING AND LEARNING SYSTEMS

An incident learning system (ILS), as defined by the WHO and many other organizations, is the nonpunitive approach to reporting incidents/near misses. Although ILS can be developed as a standard system for the whole of a hospital/institution, it is better to have an ILS specific to a specific clinical unit—this allows for the inclusion of domain expertise and better follow-up of reports.[29] Voluntary reporting systems focus on safety improvement. They usually focus on errors that do not result in any significant harm (no or mild harm) and near misses. The reports are submitted confidentially, away from the public, and no penalties are issued.[30] On the other hand, mandatory reporting systems are concerned with errors associated with major harm. The primary purpose is to hold the providers accountable. The state regulatory programs that operate above are mandated to investigate such cases and issue penalties. These systems serve three purposes: providing the public minimum safety, incentivizing the organization to improve safety, and forcing every organization to invest in patient safety.

Some of the major internationally recognized ILSs that work collaboratively to collate the errors, learn from them, and disseminate the information are given below:

1. Radiation Oncology Safety Information System (ROSIS)—one of the first attempts by the European Society for Radiotherapy and Oncology, which was started in 2001.
2. Safety in Radiation Oncology—established by the International Atomic Energy Agency in 2012 along with the founders of ROSIS. At present, ROSIS has been incorporated into this system.
3. Radiation Oncology-Incident Learning System (RO-ILS)—launched by American Society for Radiation Oncology with the support of Association of Physicists in Medicine (AAPM) in 2014. The framework for the data elements in RO-ILS was provided by the groundwork done by the AAPM on incidental learning database structures.[31]
4. Radiotherapy Incident Reporting and Analysis System—launched by US Veterans Health Administration. It allows for reporting and learning from RT adverse events, good catches, and unsafe conditions that may occur during treatment.
5. Good catches program is an institutional ILS developed at the University of South Carolina, US, where the committee monitors process performance and identifies targets for improvement.

As it should be noted that all major ILS are from HIC and few low- and middle-income countries (LMICs) may be reporting their individual institutional errors to them, identifying them (if any) is beyond the scope of this article. The benefits of participating in an institutional or international ILS are manifold: gaining experiences of uncommon conditions, identifying local hazards, sharing lessons, increasing patient safety measures, etc. While encouraging such systems in a clinical unit, our emphasis should be to make the system more effective by ensuring simplified reporting interfaces, measurable results, transparent information, prioritization of the severity of events and outcomes, and healthy communication within the facility. To the best of our knowledge, there are no known reports on ILS from a LMIC center.

OUR JOURNEY SO FAR

Our institution is one of the largest comprehensive, multidisciplinary cancer care centers in the South East Asian region, performing approximately 7,000 external beam and 2,000 brachytherapy treatments annually. We have a unique scenario where two extremes of technology are practiced simultaneously: telecobalt with conventional treatment using blocks and tissue compensators on the one end and state-of-the-art, rotational IMRT, 3D IGRT with motion management and stereotaxy-based treatment capabilities on the other end. We frequently treat patients with clinical marking in palliative settings and stereotactic RT for oligometastases. For brachytherapy, we practice library plans, 2D x-ray–based and CT-based/magnetic resonance imaging–based image-guided state-of-the-art brachytherapy for the majority. Surface molds and freehand interstitial brachytherapy are also practiced in suitable tumors. Our workforce includes senior tenured clinicians, physicists, and technologists, with residents and trainees constituting more than 70%-80% of the ground workforce. These trainees form the highest score of HHI and HMI in the system.

The existing work environment with complex treatment modalities, nonoverlapping techniques, diverse technologies, and staff of varying levels of training brings additional challenges in an LMIC center where they would be transitioning from older to newer technologies and have an inverse trainer to trainee ratio. This goes beyond the already understated but always desirable ratio of staff to the number of patients cared for.

TABLE 1. Errors Management Summary

Category	Measures	Description
Preventive measures	Risk management	Defined as the identification, evaluation, and prioritization of risks followed by coordinated application of resources to minimize, monitor, and control the probability or impact of unfortunate event. Multiple models have been used for the same, such as Swiss Cheese Model NAT Human factor engineering
	QA programs	QA in RT includes all procedures that ensure consistency and safe fulfilment of the medical prescription, regarding dose to target volume, normal tissue sparing, and minimal personnel exposure to determine the result of treatment
	Standardization	Standardization of the entire flow and various individual procedures is the key to preventing events in any system. Consistent protocols and SOPs will avoid confusion among members (requiring instructions on a patient basis) and earn the patient's confidence. Also, such standardizing procedures will reduce the additional mental effort and workload warranted in the absence of the same. There are various standardization procedures that have been developed: ASTRO White paper developed by ASTRO IHE-RO is an American AAPM-/ASTRO-sponsored initiative under Target Safely plan
	Audits and peer-review process	Includes reviewing contours, plan evaluation, and clinical decision with the feedback mechanism by a multidisciplinary team. Such processes bring uniformity in treatment strategies and assure the quality of potentially controversial patient-specific decisions: IROCA has several important aims that include selecting key quality indicators, the design and implementation of an international audit, and harmonization of key aspects of RT processes among participating institutions QUATRO was developed by the IAEA for comprehensive quality audits. The audits are performed in response to a voluntary response
Management measures	Proactive risk assessment	Enables health care organizations to identify specific points of placing safeguards to protect against a bad outcome even when an error does occur. It considers the way in which the quality of treatments can fail to achieve the desired goals. There are various methods for assessing the same: Process map FTA ETA FMEA and FMECA Risk matrix
	Reactive analysis of events	It is the response to an error. There are several methods used for reactive analysis: RCA—systematic questioning to identify the primary cause. However, this method does not maintain chronology Causal tree analysis—A schematic representation of the whole event performed with reconstruction of chronology ORION method—This is a systematic analysis method with the recreation of context surrounding the event and factual analysis of chronology of events. It tries to identify contributing factors—system errors and failure of barriers
	RLS	ILS, as defined by the WHO and many other organizations as the nonpunitive approach to reporting incidents/near misses Voluntary reporting systems focus on safety improvement. They usually focus on errors that do not result in any significant harm (no or mild harm) and near misses. The reports are submitted confidentially, away from the public, and no penalties are issued: ROSIS SAFRON RO-ILS RIRAS Good catches program TRIP Mandatory reporting systems are concerned with errors associated with major harm. The primary purpose is to hold the providers accountable. The state regulatory programs, which operate above, are mandated to investigate such cases and issue penalties
	QII	Aims to make a difference to patients by improving safety, effectiveness, and patient experience. QI is always an ongoing process that needs designing, testing, and implementing changes using real-time measurement for improvement

Abbreviations: AAPM, Association of Physicists in Medicine; ASTRO, American Society for Radiation Oncology; ETA, Effect Tree Analysis; FMEA, Failure Mode and Effect Analysis; FMECA, Failure Mode, Effect, and Criticality Analysis; FTA, fault tree analysis; IAEA, International Atomic Energy Agency; IHE-RO, Integrating the Healthcare Enterprise-Radiation Oncology; ILS, incident learning systems; IROCA, Improving Quality in Radiation Oncology using Clinical Audits; NAT, Normal Accident Theory; QA, quality assurance; QI, Quality Improvement; QII, Quality Improvement Indices; QUATRO, Quality Assurance Team for Radiation Oncology; RCA, root cause analysis; RIRAS, Radiotherapy Incident Reporting and Analysis System; RLS, Reporting and Learning Systems; RO-ILS, Radiation Oncology—Incident Learning System; ROSIS, Radiation Oncology Safety Information System; RT, radiotherapy; SAFRON, Safety in Radiation Oncology; SOP, Standardized Operating Procedures; TRIP, TMH Radiation Incident Program.

As a first step in starting the program, we had to fully understand the need and ensure acceptance. As a pilot study, cross-sectional audit of all external beam radiotherapy charts (1,005) of radical treatments was performed from May to August 2015. It identified a significant proportion of charts with errors (6.5%). All identified errors were brought to the attention of the treating units so that corrections could be made. A thorough root cause analysis with individual error detail presentations and discussions was held with all members of the department. A review of the workflow and process map was carried out, and the study team proposed several actions, published previously.[32] What was similar to the western literature was that transcriptional errors and HMI were the most common types and steps involved, respectively; but this could have been biased by the scope of the audit conducted.

This report refuted all arguments against developing a systemic approach to the ILS program, which can be a major challenge in any institution not sensitized to the relevance of such systems as it requires acceptance from all team members and associated cultural, emotional, and psychological challenges. Postaudit, the development of ILS was commissioned with clinicians, physicists, and therapists as team members led by the respective heads of departments to enable implementation of corrective administrative actions when needed. Although the fundamentals were inspired by other western ILS, the mandate was to be cost-effective and ensure effective implementation of indigenous corrective actions applicable to our needs and ecosphere.

The ILS was officially named TMH Radiation Incident Program or TRIP and rolled out in late 2016. The year 2017 began with the introduction of voluntary online reporting, made available on every workstation for all employees in the department. Three monthly sensitization and awareness meetings were conducted for the first 1 year. A detailed report of all errors submitted was presented to the department, and several measures were implemented over the next few years with continuous awareness, education, and training sessions. Some of the unique and relevant excerpts with learnings are presented here.

The number of errors reported increased from 209 in 2017 to 309 in 2018. As an impact of continuous education and awareness campaign, the trend of reporting saw a significant change; the number of incidents, which formed a majority of errors reported in the first year, reversed to the majority of near misses in the second year. The steps and types of errors remained similar, and hence, certain interventions were planned during these 2 years.

Less is Better

As we introduced several direct and indirect changes in the workflow on the basis of the incident learning process, we saw a decline in the reported errors. From 309, it dropped to 75 in 2019, 70 in 2020, and 56 in 2021, with a consistently maintained proportion of incidents to the total number of errors (10%-20%) for the past 3 years. The numbers of patients treated during this period were similar despite the COVID-19 pandemic. Other than the decline in the number of errors reported over the years, refinement in the working culture and system was also noted and is worth mentioning here. To differentiate between the genuine decline in errors from reluctance to report, we periodically conduct audits and they have been assuring time and again regarding the reporting consistency and numbers.

Transcriptional Error

It was identified that a major proportion of errors (near misses) were in the transcription of treatment plan details such as field collimation from clinical plan, simulator console, and TPS to telecobalt electronic RT charts. On root cause analysis, the availability of transitional technology with varying levels of automation and technical mismatch of various field parameters in between them (conventional simulator to TPS to and in between various telecobalt machines procured over various times) was identified as the primary cause. The cross-checks required with newer technology are usually minimized by better automation, which lacked with older technologies. Keeping mixes of technologies from various generations introduces new transcription errors to either match automation or more cautiously continue checking for older versions. Early interventions with training sessions to appropriately convert these mismatches were held as corrective actions in our case, and mechanical matching of telecobalt units with simulator and TPS by the company's technical support teams was performed as a long-term strategy.

SOPs

The development of SOPs is essential for each treatment unit for QA and safety. One of the areas of major concern in this regard was the department's bladder protocols. It was noted that the protocols for filling the bladder followed at different disease sites varied and would change and evolve. This would quite often lead to a lot of confusion and errors, which, in turn, could lead to inconveniences for the patient and the machine (eg, intermittent urine overflow on the treatment table). On detailed analysis, it was determined that the main reason for this was rotation of residents through different disease groups and unavailability of written SOPs, leading to reinvention/modification of protocols. Similarly, several other bugs with a similar root cause were identified, which could be successfully addressed through the introduction of SOPs. Establishing SOPs also aided in the successful execution of the ILS, as it clearly defined an error that needed to be reported or corrected, from an acceptable deviation in the process.

Creating SOPs was a long and never-ending process. The initial design was completed by clinic groups from each disease site over a period of 3-6 months. Thereafter, these were reviewed twice at a gap of three months each to

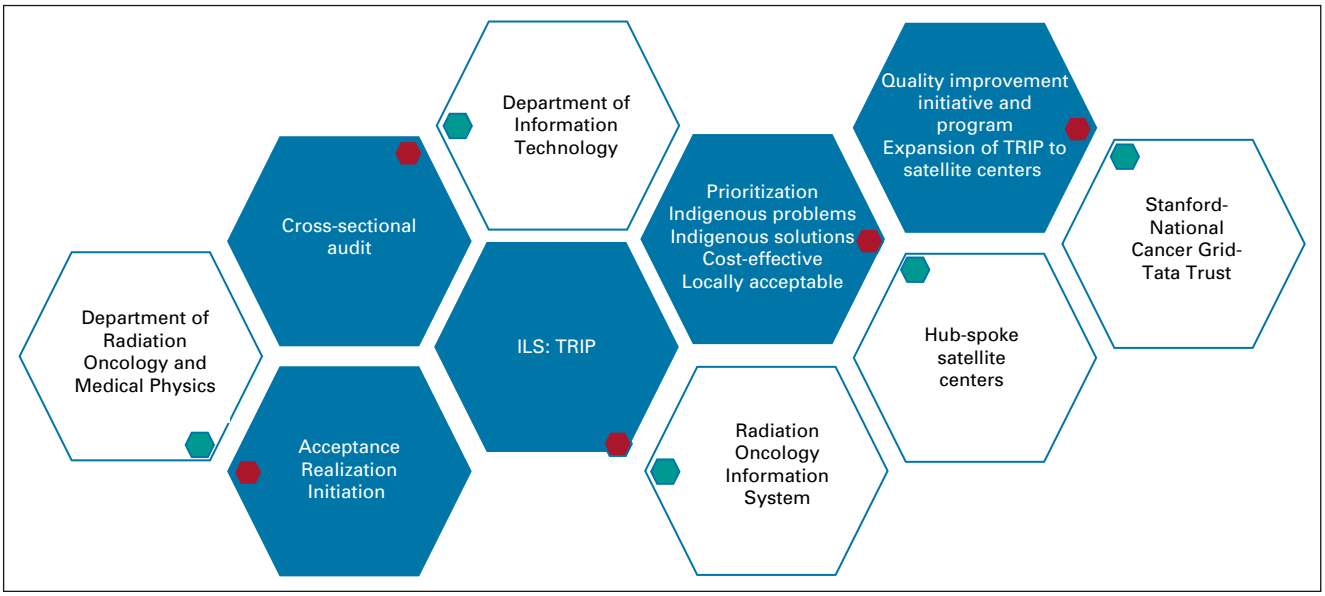

FIG 1. Footprints of our error learning system and quality improvement program. The figure shows the main steps taken during the journey—cross-sectional audit (resulting in acceptance of errors and realization that an ILS is needed), development of TRIP, addressal of the errors, integration of TRIP into our indigenous oncology information system (ROIS), incorporation of QI programs (in collaboration with Stanford and Tata Trust), and dissemination of this system to other spokes of Tata Memorial Hospital. ILS, incident learning system; QI, Quality Improvement; TRIP, TMH Radiation Incident Program.

incorporate feedback based on errors reported during that period. At the end of 2 years, the annual review was found to be sufficient. Later, we also involved medical physicists and radiotherapists in the formulation of their SOPs, and in 2020, common SOPs were introduced. In 2021, we initiated awareness raising at our other spokes/satellite centers across the country. As a first step, we adapted the SOPs on the basis of practices and recommendations from different centers to create a compiled SOP document after consultations over a year. In the next few years, we plan to roll out and integrate the incident learning system across all satellite hubs.

Preventive and QI Initiatives

Being an LMIC center, cervical cancer is still common cancer in women here and brachytherapy remains an integral part of their treatment. Our center completes 5-10 applications with treatment executions in a usual day, which can be a very mixed bag of treatment types of varying complexities. This requires direct coordinated attention of all team members on-site at all the time. Multitasking at multiple stations is quite common in LIMIC centers to balance patient care. This would delay the processes while waiting for missing team members at various stations. Continuous delays would end in chaos at the end of the day increasing the probability of errors to a great extent. This issue was brought to the TRIP team, and an amicable solution from the team was provided with a revised individual member schedule to ensure that smooth running of the system was performed.

As part of quality improvement, TRIP team members participated in the joint Stanford-National Cancer Grid (India) and Tata Trust collaborative Quality Improvement (QI) course (2019-2020). As a project, we reviewed our workflow on the first day of radiation treatment to successfully reduce in-hospital waiting times by 25%. As LMIC, we have indigenously developed our own radiation oncology information system (ROIS) using collaboration with our information technology department. It functions to schedule patient appointments and maintain patient treatment records and billing information avoiding costs associated with similar software packages from various vendors. Our TRIP reporting system and SOPs are also provided through intranet over the ROIS system on all work stations in the hospital and at all satellite hubs in the country. Figure 1 highlights the footsteps that we followed to develop our quality and safety program to date and future direction. If we review Table 1, which summarizes various steps to error management and quality improvement, we have been consistently on that path using several measures such as development of ILS, SOPs, charting work flows, strengthening of pre-existing audits and peer reviews,[32] and QI exercises.

In conclusion, high-quality and safe RT must be the goal of every clinical unit, despite limited resources. Efforts including formation of a QI team with regular meetings, standardization procedures, and formal training will help achieve the same. Advanced technological advancements should be accompanied by appropriate safety measures to keep the new types of errors in check. As we adopt programs to improve quality, we must also cultivate a culture that discourages blaming and shaming but constantly works toward a better, error-free system.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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