Wipro's Approach to Patient Safety

In this white paper, global IT leader Wipro presents its approach to patient safety in the post-pandemic age. While also diving into highly pertinent topics such as reporting of adverse events (AEs) and verification of medical procedures, Wipro pays particular attention to the roles that new technologies such as artificial intelligence (AI) and radio frequency identification (RFID) can play in promoting patient safety. In our experience, approaches that can be effective range from new technology to improved education, adoption of uniform standards, emphasis on patient monitoring, and building trust to enhance reporting, to highlight just a few of the strategies detailed below.

Patient safety as a framework

We at Wipro see health care as a discipline that is constantly advancing and becoming more sophisticated, while at the same time adding new risks to patient safety. We wholeheartedly concur with the assessment by the World Health Organization (WHO) of patient safety as a framework of organized activities. This framework creates cultures, processes, procedures, behaviors, technologies, and environments in healthcare for lowering risk and reducing occurrence of avoidable harm. We also note that, over the past few years, patient safety has become a more prominent issue in the public eye, since the pandemic exposed the shortcomings of healthcare systems by laying bare their inadequacies. While we do agree that there is some risk involved in all aspects of healthcare, a patient safety framework focuses on keeping it to an acceptable level.

Processes and procedures

Based on our decades of experience, we echo the widely used practice of "systems thinking" for the practices and procedures of patient safety. Here, the focus is on having layered multiple defenses in the system. That way, when one risk appears already, it is likely that the next layer of defense will help prevent a patient safety event from happening.

For instance, in the post-marketing support to our pharma clients, Wipro has multiple layers of quality checks operating before we report any AEs. This practice helps us greatly to identify any near misses before we finally submit a case, and to maintain that gold standard of quality.

Culture, behavior and environment

Another important aspect to enhance patient safety is to build a strong patient safety reporting culture. We suggest this should be based upon a "just culture" — i.e., a culture that successfully focuses

on and learns from larger systemic issues rather than blaming individual staff when things go wrong.

In Wipro's experience in patient safety reporting, the following two key approaches have helped us.

- **Building trust to enhance reporting:** Our leaders work to foster an atmosphere where reporting is psychologically secure and safe so that people feel comfortable speaking up. We advocate programs that reward or praise reporting (such as "Good Catch programs") to strengthen the confidence already being established. Building trust entails demonstrating that reporting will not have any negative repercussions on the physicians reporting, or the clinicians engaged.

- **Reviewing near misses:** This helps to create mature processes to identify helpful information about potential system flaws and react to inadequately discovered risks.

Technology as the cornerstone

We strongly feel that technology is the cornerstone of patient safety with the greatest unrealized potential. This is particularly true of artificial intelligence

(AI)-based technologies that can interact with patients and potentially provide prescriptive analytical solutions as well as fundamental components of clinical judgements, or at the very least, clinical recommendations.

In our view, digital twins is one next generation AI-based breakthrough technology that could increase patient safety immensely. Patient-facing interventions could be evaluated on the patient's digital twin before being used on the patient.

Meanwhile, with respect to current technological interventions with health care personnel (HCPs), we have been observing as well as adopting great advancements in tools for clinicians to drive their best performance, ultimately reducing the occurrence of avoidable harm.

Factors critical to promoting patient safety

The COVID-19 pandemic emphasized the critical role the healthcare system plays in reducing suffering and protecting public safety. Hospitals are expected to provide top-notch healthcare services. However, hospitals can sometimes be rife with hidden risks due to the possibility of medical errors or infections.

In fact, as cited by the WHO in a recent study, "Globally, as many as 4 in 10 patients are harmed in primary and outpatient health care. Up to 80% of harm is preventable. The most detrimental errors are related to diagnosis, prescription and the use of medicines."

The factors listed below are those that we believe are essential for promoting patient safety.

Make use of monitoring technologies: Throughout their shifts, healthcare staff provide care for a number of patients, each with unique needs and prescription regimens. Nurses and doctors can utilize monitoring technologies such as bed alarms that alert staff if a patient falls, or barcode systems that confirm a patient's prescription.

Avoid acronyms: Acronyms can expedite and save time, but they can also lead to a lot of confusion. To help eliminate the lasting effects of this problem, prescriptions can also be monitored and controlled by adoption of automated physician order input systems.

Verify all medical processes: Building regular verification methods into hospital protocols can considerably reduce the risk of medical errors. One example of a verification technique is a universal protocol that helps reduce surgical errors by enabling any member of the surgical team to request a "time out" to confirm specifics of the procedure. Verification also contributes to other facets of healthcare, such as confirming prescription dosage and timing.

Promote use of checklists: Healthcare facilities should encourage the use of internal checklists created by their own experts on various surgical procedures and related typical complications. Likewise, publicly available resources like the WHO's "surgical safety checklist," the Safe Childbirth Checklist, and Patient Safety Solutions can also prove helpful.

Empower patient involvement: By verifying with patients that they understand their treatment plan, medication and medical procedures, they can be empowered with the tools they need to notice and prevent errors in their own care.

Key sources of AE reporting

Regulatory authorities in each region receive voluntary reports of AEs directly from healthcare professionals, consumers, and others. Still, according to the FDA Adverse Event Reporting System (FAERS), this type of voluntary reporting only accounts to about 4% of all reports received by them as of 2022.

The manufacturers of the products may also receive complaints from consumers, healthcare professionals and others. In fact, this type of report amounts to about 96% of all reports for US FDA as of 2022 as published in the FAERS.

Meanwhile, based on the industry trends we have observed, getting reliable reporting of side effects and other AEs after approval is becoming increasingly necessary. More

and more drugs and vaccines are securing approvals after shorter trials with fewer people. We expect reports from patients outlining their experiences with novel medications, including minor AEs, will become more important in the future when regulators decide whether to approve a product.

Patients might take the lead on this problem with respect to HCPs, as AEs directly affect their quality of life. Clearly demonstrating the trend to more reporting is the massive increase from 1,068,034 reports in 2013 to 2,334,820 in 2021 in the FAERS Dashboard. Of reports submitted in 2021, 1,215,927 were from consumers, 1,102,990 were from health care professionals, and the remainder were unspecified.

Barriers to AE reporting

We consider vaccines very safe and effective. However, they have been linked to several major and minor AEs following immunization (AEFI). If not reported in a timely way and examined properly, these AEFIs can cause severe avoidable patient safety issues, spread misinformation and undermine vaccine confidence.

Studies have shown that many physicians are reluctant to participate in programs to report medical errors, and that in US and UK underreporting of adverse events may be as high as 96%.

In an Australian study published in 2022, 66.4% of pharmacists, nurses, and medical officers responding had encountered adverse drug reactions (ADRs) in their clinical practice, but only 41.8% had ever reported an ADR. A total of 64.9% said they had not received any training on ADR reporting.

Based on our decade long experience in Post Marketing Surveillance processing of vaccine AEs for 30+ countries and industry knowledge, we believe the following stand today as major roadblocks to AE reporting.

Inadequate training on AEFI surveillance and reporting: With the right training, we can enable development of a higher level of knowledge, a more optimistic outlook on AEFI surveillance and reporting, and an enhanced ability to identify and report AEFIs.

At Wipro, we have a 12-week comprehensive AE reporting training program for new HCP hires as well as regular refreshers.

Shortage of time: Several study findings suggest that since they encounter many AEs during their daily practice and lack the time to record all of them, many healthcare workers decide to report only certain AEs.

Assessment variance among reporting HCPs: Despite standard AE definitions from the International Conference on Harmonization (ICH), the assessment of AEs varies significantly among HCPs, causing errors in correct AE reporting.

Misreporting and miscoding of AEs: Our experience also suggests it is difficult to manage and analyze AE data if the fields in reports pertaining to dosage, formulation type, duration, and length of exposure to AEs are not properly stated and classified. This can also raise false alarms.

Lack of enough published case reports: An established method of alerting about drug and vaccine risks is to publish reports in medical journals regarding suspected AEs. These are among the signal-generating reports that clinicians can easily obtain. But these reports are few and often have limitations, such as lack of adequate documentation. Alternative ways for capturing clinical reports of AEs include

regulatory reports, longitudinal patient records, clinical or post-marketing studies, media and other websites, patient support programs, and cohort-event monitoring.

Uniform standards for AEs to build stronger AE data

Global and regional healthcare institutions like the ICH, WHO, FDA, and European Medicines Agency (EMEA), have clearly defined the standards for identifying and reporting Adverse Drug Events (ADEs). These include AE definitions and guidelines for reporting, collection of AE data in registries, standard nomenclature for event coding, and AE management.

However, even after such comprehensive uniform standards, the level of AE reporting does not remain uniform globally. Therefore, the primary objective of the healthcare systems should be to enhance awareness regarding AE reporting not just among HCPs but also among the general public, with a specific focus on developing countries.

For service providers like Wipro, there is also a major need to adhere to the established uniform standards. Our case processors must have competence to assure correctness and consistency because they are in charge of processing AE data and coding AEs into a standard nomenclature. By using coding conventions such as MedDRA to code the exact terms, we can capture the core data accurately,

For a leading multinational pharmaceutical and biotechnology corporation producing the Coronavirus vaccine globally for ages 12+, Wipro ensured the required regulatory compliance and patient safety process for the vaccine.

The client's challenge involved the backlog of Adverse Events and volume spikes that kept growing as more and more countries began approving their vaccine in a very short period. If unaddressed, this could have resulted in regulatory non-compliance. To tackle this situation, they needed expert healthcare professionals to manage their adverse event reporting. However, a distributed workforce during the pandemic posed a significant roadblock to sourcing and training resources quickly. In addition, the regulatory authorities were constantly releasing updates on conventions for performing case processing. Cases from different countries required in-depth understanding of different country level conventions, adding to the complexity of the process Keeping up with such a high frequency of updates and tracking digital acknowledgments and signoffs required immediate attention as the pandemic continued to ravage the world.

Fortunately, Wipro was ready with our decade plus years of experience for both swift sourcing and training of the right talent. Wipro ramped up hundreds of Health Care Professionals in just few months by deploying an extended panel of interviewers on a rotation basis to fulfill the huge sourcing ask. Wipro alone has processed over 0.7 M reports from 35 countries since December 2020.

thoroughly, and in a manner that is as close to “natural” clinical language as feasible. This increases the possibility that safety signals will be picked up.

How we see technology evolving over the next five years to strengthen patient safety

The life sciences sector is currently undergoing a transformation, with patient safety at the forefront. Automation, innovation, and advancements in digital health, AI, medical devices, and information technology (IT) are boosting collaboration and overall patient safety in both available treatments and those still in research and development (R&D).

Automation in data processing and drug development

Patient safety is impacted by using technology to accelerate innovation. Teams may unearth important data results faster than ever before by eliminating repetitive, manual activities of the past. According to ArisGlobal’s 2021 State of the Industry Report, 83% of the life sciences sector is using automation in some capacity throughout their R&D processes to bolster productivity and shorten time to market.

Digital health opportunities and decentralized settings

The intelligent decentralized model for virtual care or treatment development lessens the burden on patients and increases retention and safety when patients enrolled in clinical trials are at higher risk. Also, Decentralized Clinical Trials execute telemedicine through mobile or intelligent monitoring devices, radically uprooting the traditional analysis of the data gathered in inpatient treatment settings.

IT in healthcare

IT will also play a key role in the transformation of patient safety. Using radio frequency identification (RFID), patients will be tracked inside hospitals from the moment they arrive until they depart. IT will come into play for smart medication ordering through computerized systems, drug administration via “smart” pumps, dissemination of information about laboratory anomalies, use of handheld devices to monitor patients’ responses to drugs, and medication tracking through barcoding and electronic medication administration records. All of these technologies will be connected electronically, significantly reducing the likelihood of error and enhancing patient safety.

Wipro has also partnered with Transcell Oncologics to transform vaccine safety assessment using AI through development of “NeuroSAFE,” a next-gen neurovirulence solution for life sciences clients. Through NeuroSAFE, organizations involved in vaccine research and production can utilize intelligent automation technologies to generate highly accurate readings of (a) potential adverse effects and risks in an immunized population, and (b) adventitious contaminants in the produced batches that may even be fatal.

Medical device safety

With the use of RFID in medical devices, two of the three most infamous surgical errors—wrong site/wrong side/wrong patient surgery and retained surgical instruments and sponges—have been eliminated. The electronic medical record (EMR), as well as therapeutic and life-support devices, are linked to the patient's identification and health information contained in the hospital wristband RFID tag. RFID tags are also helping to prevent the administration of unnecessary procedures, medications, and therapies.

The Right Balance – High Quality Patient Care and Technology

Clearly, advancements in health care are a double-edged sword. The potential for life-enhancing and life-saving medical procedures is balanced by an acceptable level of patient risk. Based on our experiences at Wipro, the best way to mitigate the risk is to adopt a holistic approach combining promising new technologies such as AI, telemedicine, and RFID with multi-faceted strategies in safety promotion and awareness for patients, health practitioners, and the public.

Wipro responded to this market opportunity for automation in data processing by launching its Pharmacovigilance automation service platform 'TaloSafe. An AI-based, intelligent digital case processor trained with domain and process knowledge, TaloSafe employs the latest technologies, including machine learning (ML) and clinical natural language processing (NLP), to enable comprehensive capabilities for processing data from multiple sources in quick intervals.

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IND/iCORE/FEB2022-JAN2024