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Human Error Reduction in Pharmaceutical Manufacturing Industry

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ABSTRACT

Human error remains among the major issues encountered in the pharmaceutical sector, which has considerable impact on quality assurance, compliance, and safety. Failure to provide appropriate training, inability to assess the capabilities of staff members, and absence of skills evaluation are some of the factors that increase human errors and inefficiencies in the work environment. Appropriate training – whether SOP, cGMP, or on-the-job training, coupled with performance evaluation, is extremely important for minimizing human errors because such training raises the self-efficacy of employees, leading to better performance. Human errors associated with incorrect execution of tasks need to be analysed in order to understand what triggers human errors – human errors are not the cause of these errors but merely symptoms of deeper issues. Human errors can be classified into active human errors, which are committed by individual persons, and latent human errors, which are committed by organizations, requiring a different strategy. Among other techniques aimed at minimizing human errors are training, error mapping, process automation, assessment of competencies, and creation of an open communication environment.

Keywords: Human Error, Pharmaceutical Manufacturing, Error Reduction, cGMP, SOP Training, On-the-Job Training, Quality Assurance, CAPA, Root Cause Analysis, Self-Efficacy, Process Automation, Competency Evaluation, Error Mapping, Quality Control, Compliance.

1. INTRODUCTION

It is also true that the pharmaceutical industry is a huge, complex industry, covering all stages including research, development, production, packaging, distribution, and sales. The sector is composed of both multinational organizations and locally based organizations. It plays an essential role in the improvement of public health through the provision of safe and efficacious medications for the cure and management of different illnesses. Besides its contribution to the healthcare system, the pharmaceutical sector promotes innovations and economic development while offering jobs for people across the globe [1]. It should be noted that due to strict regulations like GMP, pharma companies have to ensure product quality, safety, and efficacy. However, despite all these improvements, human errors continue to be a common problem in drug manufacture and quality control[2]. Any mistakes that occur during the drug-manufacturing process, such as incorrect dosage, poor documentation, or violations of the Standard Operating Procedure (SOP), can have dire effects, causing not only a drop in the quality of the product but putting patients at risk of harm, breaking the regulations, resulting in losses, and ultimately damaging the organization's reputation. The situation becomes particularly dangerous when human mistakes cause product recall or license suspensions [3]. Human error is typically described as when an intended action fails to accomplish its goal. In the context of pharmacology, human error should be seen as a consequence rather than a root cause, which should trace back to deficiencies in areas such as training, process, document, and organization. Human errors can be categorized into two major classes of errors: active errors that arise out of the actions of the person involved and latent errors that occur due to system weaknesses [4]. Both types of errors must be approached through CAPA. One of the most important techniques that can reduce human error is the creation of comprehensive training programs [5]. Workers in GMP-compliant facilities are required to undergo proper training in technical skills and SOPs [6]. However, most pharmaceutical firms are not aware of the importance of having good training programs and their impact on employee competence and performance. It is noteworthy that regulators focus on proper training and documentation but do not give any specific instructions on how to conduct such training. As a result, training needs to become more systematic and professional [7-8]. In addition to training, there are a number of other human error reduction strategies that are considered best practices [9]. They include the creation of standard processes, development of maps for errors, automation of routine tasks, testing for competence, and creating an atmosphere of openness. The case study from pharmaceutical manufacturing clearly shows how errors associated with aseptic operations or batch documentation can be avoided by designing proper processes [10]. Thus, a combination of human error prevention techniques and quality systems is crucial for excellence in production.

2. Human Error

Human error is a major consideration in the manufacture of pharmaceutical products as well as the quality systems associated with them. Human errors have a direct bearing on the quality of product and the safety of patients using the product. Human error can be defined as the failure of a planned activity to achieve its desired goal. In regulated sectors, human error is almost impossible to avoid considering the human nature, and yet measures should be put in place to minimize errors. According to good manufacturing practices, errors should not be tolerated within any pharmaceutical firm, and when such occur, an investigation must follow. Human error can be explained in terms of two theories or perspectives: the person approach and the system approach. While the former takes into account individual weaknesses like being inattentive or forgetting something, the latter focuses on the circumstances of the working environment and tries to come up with solutions to make human beings safer. Person approaches attribute failures and defects to individual incompetence. This is based on the traditional view of human being as part of culture and moral considerations. The system approach seeks to identify and implement solutions to minimize human error.[11] There are various ways to classify human errors, including the generally accepted approach that considers human mistakes and human slips as two main types of errors.[12] The former happens when intentions in performing a particular action are wrong, whereas the latter happens when intentions in performing a particular action are correct but something goes wrong during the actual performance of this action. For instance, a person might decide to do something in one way without actually understanding what needs to be done (a mistake). This person could also intend to perform an action in a certain way but would fail to do so because of distraction (slip).[13] Human errors during the manufacture of drugs may cause adverse effects including contamination, erroneous dosing, errors in labelling, and poor batches of products. In fact, about 25% of all quality defects, which include deviations, laboratory errors, complaints, and observations from inspection activities, have been reported to be caused by human error. Also, it has been found that up to 90% of all packaging and labelling recalls are due to human errors. Examples of such errors include failure to adhere to the Standard Operating Procedures (SOPs), line clearance issues, documentation errors, and lack of implementation of approved changes. It is crucial to understand that human error is not usually the main cause of the issue, but rather the effect of deeper problems in terms of poor training, lack of procedures, lack of supervision, or even poor process design. It is mentioned in regulatory guidelines, such as CFR 211.22 and EU GMP, that human errors must be investigated to ensure that other, more serious causes of errors are uncovered. This once again confirms the idea that human errors are symptoms rather than causes. In order to prevent human error, various investigation methods are utilized. For example, root cause analysis or "5 Whys" can be applied to uncover underlying reasons for human error.[14] Such reasons might be related to the lack of necessary tools, poor training, unclear instruction, and others. For example, a mistake committed by the operator could have been caused by poor training and poor process design. Error-risk minimization techniques in the manufacture of drugs involve not only humans but also improvements in systems. Such techniques include adequate training for workers, regular competency testing, well-written documents, and automation whenever possible. Follow-up training sessions, mentoring of employees, and supervision also play vital roles in ensuring proper conduct at all times. Open communication is another important aspect, since it enables employees to communicate errors without being criticized for their mistakes. Human Factors Engineering also serves a crucial purpose in the reduction of errors in designing procedures, machines, and interfaces to complement the strengths and weaknesses of humans. The reduction of complexity and the elimination of distractions may prevent many slips and lapses. Effective change management is essential in the evaluation of all changes to processes and systems and notifying all necessary employees.

2.1 Types of Human Error

A) Stressor Error- Stressor risk influencing factors (pressure causing a feeling of stress) - Errors resulting from stressors are those where the Risks Influencing Factors (RIFs) increase the likelihood of errors by humans. RIFs are generally of a transient character but can be repeated, particularly when connected with such problems as fatigue and very stringent deadlines. Their influence is relative since it depends on the person. Simultaneously, they may reveal some deeper flaws in the system needing investigation.

B) Structural Error - Structural risk influencing factors (inherent weakness in activity) - Structural Risk Influencing Factors (RIFs) are usually long-term in their effects, although they might not always become apparent until acted upon by certain triggers. These RIFs can be present all over the organization and can come from different sources. Examples include those created by difficult processes in which many things vie for one's attention, faulty information systems like ambiguous batch production documents, and resource problems such as noisy surroundings. Other examples of these RIFs can also come from poor organizational planning, such as unproductive shift schedules that dull one's alertness.[15]

C) latent errors - Latent errors are defined as any hidden error present in the system such as poor design of systems, bad decisions, improper policy, and poor quality material, which can go unnoticed until they lead to a mistake or some kind of accident.[16]

D) Active errors - Active failures, on the other hand, involve actions, errors, or events committed by people that lead to harm or adverse consequences, and they generally surface during the time that the mistake is made and affects the system or the individual patient.[17] **E) Cognitive-based Errors -** All people share common cognitive abilities that enable them to interact and perceive their

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surrounding world. Where at the initial stage Dr. Reason identified different categories of mistakes related to actions (i.e., skill-based, rule-based, and knowledge-based), modern classification identifies mistakes depending on types of thoughts.[18] As it was explained by Kahneman, humans think using two systems. System 1 can be characterized as "fast" thinking which is fast, effortless, and automatic. The work of this system is based on recognition of situations where people react using pre-set schemes in an intuitive manner. The second system – System 2 – represents "slow" thinking which is characterized by slow speed and efforts required for its realization. People apply it when they face situations that they cannot recognize; in such cases they analyse the problem, think logically, and create the proper response.[19]

F) System-based Errors - One problem with safety is that the same errors keep on happening again and again even after they have been detected and measures have been taken to avoid them. The same error committed by one person is replicated by another since some conditions in the environment make errors inevitable. As explained by James Reason, when an identical error is consistently replicated by different persons, it is clear that the problem does not lie with humans but with the environment. Such environmental factors which make human error inevitable are termed as "error-prone conditions" or "error traps." These error traps cannot be easily removed by individual action and instead need systemic changes.[20]

G) Communication-based Errors - Communication errors cannot be classified under either Type 1 or Type 2 reasoning, but they are common sources of errors within hospitals. Such errors can happen when information is conveyed at an inappropriate time (late), conveyed to the wrong individual or wrong individuals, or conveyed in the wrong manner (inaccurately or incorrectly). They can also take place when the desired objective of the message is not accomplished or when critical information is missing from the message. [21-25]

2.2 Defining error, Near miss and violation of health care

An error is described as an unintentional deviation from safe practice.[26] Based on the Swiss Cheese model of system accidents presented by James Reason, several errors can be aligned across multiple defence layers, leading to an adverse event.[27] The term "near-miss" means an error that may have led to patient harm but has not been materialized, either accidentally or due to the identification and correction of the error before harm occurs.[28] In other words, it is a missed opportunity for patient harm that could be prevented either accidentally or intentionally by identifying the error. Tracking near-misses is useful since it helps detect vulnerabilities in the system and implement more safety mechanisms to avoid future accidents. Every error is unintentional. In contrast, the term "violation" describes any deviation from safe practice made intentionally. The violation is deliberate and may stem from poor safety culture and low employee motivation.

3. Approach to error prevention

In the past, many errors were attributed to personal failure, and the prevention strategy involved enhancing the training of the individual in order to ensure that he or she is competent enough to do a particular job. But this is flawed because errors may not be caused by incompetence in most cases. There are other variables that determine whether an error occurs, and even competent people may cause error in some situations. The emphasis has now been put on the system, and this has proven to be more effective because it involves the creation of systems that are less prone to error.[27] Rather than relying on individuals to prevent errors, one can design procedures and machines that will reduce the likelihood of making errors. The use of non-interchangeable filling ports for example reduces the possibility of erroneously filling a vaporizer with the wrong agent. Prevention of error should be directed at addressing the root of the problem. For slips and lapses, appropriate work environment for the anaesthesiologist is recommended. Use of cognitive supports could improve the memory and decision-making process while cognitive forcing will aid in preventing fixations errors. [29-30] However, most of the proposed strategies would address individuals but some recommendations can be instituted as policy for the institution. Communication techniques that would enhance communication among the members of the team, identifying latent errors using reporting techniques, preventing medication errors and training and simulation exercises are some of those methods.

4. Human Error in Industry: Causes and Consequences

Human error in industry is another significant issue and implies unintentional errors committed by employees that lead to accidents, decrease in productivity levels, and harm to resources or environment. In order to prevent such incidents in industry, it is important to understand their causes and develop appropriate measures. Fatigue, distraction, lack of training, and overconfidence can be named among some major causes of human errors in industry [31-32]. Fatigue, which may be attributed to working for too many hours and even working at night, tends to affect attention, judgment, and decisions [33]. For example, studies have been conducted among airline pilots, who suffer from lack of sleep causing problems such as daytime drowsiness and decreased alertness [34]. Lack of sleep also affects physiological factors such as the immune system [35]. High levels of pressure to achieve high productivity tend to encourage workers to violate safety measures, thus creating more opportunities for mistakes [36]. According to Christopher Dejours [37], organization of work plays an important role in determining workers' mental condition. As noted by Jens Rasmussen [38], the majority of accidents in industries are not usually isolated incidents; rather, they tend to be outcomes of slowly changing behaviour in organizations, which could be prompted by factors such as economics and competition. The other critical element in accidents is distraction, either personal or external. Any slight form of distraction may cause serious accidents, particularly in high-risk operations where total concentration is needed [39]. Inadequate training also leads to accidents because poorly trained or inadequately trained individuals tend to make mistakes [40]. Training is therefore important and must be consistent and thorough in order to minimize accidents. As pointed out by Araujo[41], training must involve more than just giving information to employees, but also promoting learning in an organization's culture. Overestimation of one's capabilities and underestimation of risks can be considered another important factor, which results in negligence of safety measures and increases the probability of accidents in different industries like construction, production, and transportation[42]. Safety culture is one of the main factors affecting the number of incidents [43]. The development of a positive safety culture in an organization ensures good safety performance. In an atmosphere of trust, employees feel encouraged to discuss their concerns related to safety issues [44]. Communication failure is another common source of mistakes at work [45]. Here, it becomes crucial to make the difference between information and communication, the former being the message, while the latter refers to the way information is exchanged [46]. Mistakes happen not because there is no information at all, but because there is poor communication, for example, unclear instructions or insufficient updates. Moreover, ergonomics also becomes an integral component of avoiding human errors since it involves creating the environment, tools, and processes that take into account the abilities of people [47]. Worldwide, injuries and illnesses in the workplace lead to millions of deaths annually, making it a very serious problem [48]. Human error is the most common cause of this problem; it can also be attributed to inadequate supervision and poor training, among other factors [49]. Besides resulting in many fatalities, these human errors are very costly and cause problems like pollution [50]. It becomes imperative to have an efficient system in which the human error can be reduced through proper education, standardization, and the use of technology in such a manner that minimal manual involvement is required. It becomes essential for us to build up a strong safety culture and create channels of effective communication. Error reporting should become part of an organization's culture, and the use of FMEA (Failure Modes and Effects Analysis) would also help us in achieving this objective [51].

4.1 Error risk reduction

Even in companies where there is a system of continuous improvement already in place, human error still persists. Even skilled workers operating in a process-oriented manner will inevitably make an error from time to time, which may cause serious problems. Traditional remedies, like re-training, additional verification steps, or warnings, prove to be ineffective since they do not solve the problem at its source [52]. Emphasis on minimizing errors allows for the identification of root causes, aids decision-making by managers, and ensures sustainability in improvement efforts. While the analysis of human errors is usually qualitative, it can be quantified through Human Error Probability (HEP) [53], which is simply the number of errors divided by the number of possible errors. In a structured qualitative approach, first, one identifies the probable human errors and the influencing performance factors for those human errors, and finally, control measures are introduced to eliminate or control those human errors. A system must be such that its operation should involve minimum human interaction, but there must be a provision for recovering from human errors whenever any mistake occurs. One should focus more on PSFs than the procedures and training. In operational analysis, trends like the likelihood of errors during shifts changes and at the end of the period can emerge. It is important to have better communication and staff arrangements when this happens. The procedures must also be reviewed to make sure they match reality, are possible with the current staff, and give directions. Finally, the working conditions must support concentration, avoiding issues like loudness, high temperatures, and stress that could affect performance. The preventive measures must be consistent with the error's nature. Training and simulation are appropriate techniques to prevent knowledge-based and rule-based errors, while they have limited application to prevent skill-based errors such as slips and lapses. Hence, there is a need for structured human factors approach to analyse and manage risks related to human variation. These prevention strategies need to conform with the characteristics of the error. The training and simulating strategies work well in preventing knowledge-based and rule-based errors but are not effective when applied to skill-based errors like slips and lapses. Therefore, a human factors methodology should be developed in order to evaluate and manage any risks that may arise from human variability. Human error leads to a large number of accidents in industries, but human error can be prevented using proper management techniques on the technical system level as well as on the human performance level. Training programs, especially those aimed at building teamwork, are helpful in achieving optimal performance and ensuring safety. However, training alone cannot resolve human errors and other techniques are required. In the field of pharma, adherence to Good Manufacturing Practices guarantees the quality of products and minimizes the risk of any mistakes. Despite the fact that there is no mention of the phrase "human error" in GMP standards, any deviation from the required standards is analysed for its possible cause. The issue of human error should be considered as the last resort after excluding any defects of process or system. The quality management system includes techniques for root cause analysis, CAPA, and continuous monitoring to ensure that any mistakes will not occur again. Usually, human error results from flaws in the system rather than from the negligence of employees, emphasizing the significance of an efficient quality management system. Efficient documentation ensures error prevention through the application of data integrity principles such as (Attributable, Legible, Contemporaneous, Original, Accurate) ALCOA+[54]. Standard operating procedures (SOPs) and document management systems (DMS) are regularly updated to guarantee compliance [55].

5. Human factors approach

The strategy employed in integrating human factors into risk analysis must correlate with the number of hazards an organization may encounter. In the majority of cases, a qualitative method would suffice in conducting risk analysis for such risks [56]. The idea behind human factors emerged in World War II as a result of difficulties encountered in designing equipment that can be handled by humans. Human weaknesses that cause mistakes emanate from numerous shortcomings in terms of cognition, physical strength, and behaviour. These weaknesses are brought about by issues such as impatience, poor memory and concentration skills, moods, low morale, prejudice, fear, poor judgment, poor sight, and susceptibility to distractions. Humans cannot multitask easily, have a strong dependence on short-term memory, and vary widely in their abilities and perceptions. Other factors that play a role in influencing mistakes are tiredness, resistance to change, shortage of time, high levels of pressure, and neglecting small issues because a task is repetitive. Humans acquire knowledge more effectively by gaining practical experience rather than theoretical learning, and complicated facts should be presented in an organized manner. To cope with these elements, there must be considerations on the system, processes, procedures, training, and the environment, because all of these affect the probability of making mistakes. While system improvement is essential, there is still some level of personal accountability that must be involved. Once the risks have been controlled, the system must be improved further until acceptable levels are attained. Error made by humans is due to various reasons, and hence any observed error must be investigated in order to establish its true source. Human errors are especially prevalent within certain industries such as the manufacture of medicines. These types of errors can occur due to reasons such as being distracted, stressful conditions, and exhaustion from lack of sleep. Distraction results in a decrease in focus and makes one more prone to making errors, while stress impacts negatively on work performance and teamwork. Human errors can be attributed to bad human-machine interface, unfavourable working conditions, and situational factors. Many times, the cause of the error may be due to faulty design of the system or equipment. Rather than blaming the user, we need to understand that faulty design is one of the major contributors to human error. Likewise, bad procedural design can also lead to errors. However, the common knowledge is that total elimination of human error is impossible, which underlines the necessity of knowing the human factors. Some other workplace factors causing error include low-quality lighting, high noise levels, lack of adequate training, insufficiency of skills, inappropriate tools, and bad workspace design. Moreover, errors during the planning process and making decisions can be a factor of mistakes. From the standpoint of human resources, improper recruitment and lack of training may cause errors. Nevertheless, some companies continue to stick to the blame culture, which means that an individual takes full responsibility for their mistakes. However, it makes no sense because such an attitude only hides the problem from the managers. Placing blame on individuals will not stop the occurrence of a similar mistake in the future, since the same mistake is bound to happen again with other people working in the same setting. The solution to mistakes lies in balancing individual accountability with an environment conductive to safety.

6. Building focused workplace culture

The working environment culture and impact of that culture will decide the level of success that the organization will be able to achieve, as well as about how the way the worker feels. The inclusion of beliefs, values, and informal norms will shape the actions of the worker. In cases where there are no clear relationships between such elements, the situation may arise where there will be errors. A good culture calls for effective communication. At times, messages must be relayed using different means and times. It would even help if instructions were properly given.

7. Using human factors for preventative actions

Following the analysis, the next step includes recognizing different types of mistakes and considering the necessary steps to avoid or limit their occurrence. The typical example of such a classification and the subsequent actions is illustrated through a table 1 [57].

Table 1: Classification of errors Type of error / Action Eliminate Prevent

Type of error / Action	Eliminate	Prevent	Reduce	Mitigate
Mistake	Competency assurance	Communication conventions	Software interface logic and layout	Automate the process
Slip	Design for tactile differentiation	Confirm prompt	Error management training	Automate the process
Memory lapse	Checklist	Independent check	Alert/Alarm system	Automate the process

8. Regulations and Impacts

Errors committed during production by humans have the potential to lead to critical errors that affect the integrity of drugs and endanger patient lives. These errors make up one of the greatest sources of accidents and quality problems in the pharmaceutical industry [20]. The implementation of process automation is an important tool in mitigating the possibility of such accidents occurring due to less dependence on human labour [58]. On the other hand, constant training will help workers stay updated with all safety precautions and procedures [59]. Some of the effects of human errors could be quite severe, which may include threats to the safety of the patients, which may include ineffectiveness of treatment or even some sort of allergic reaction to the treatment. The organizations might have to face legal action, product recall, and may end up losing consumer confidence [2]. Such an outcome could result in huge monetary damages for the organization [36]. In Brazil, the safety, quality, and efficacy of the pharmaceuticals are controlled by the National Agency of Sanitary Vigilance, and there are very high-quality standards set by it for the industry [60]. The implementation of the standards is necessary to ensure the safety and efficacy of medicines for consumers. This regulatory body acts as an important part of ensuring the safety of consumers through the prevention of poor-quality products [61]. An effective framework for protecting the public health is the presence of a regulatory system such as Good Manufacturing Practices (GMP) and Good Distribution and Storage Practices (GDP). Following these standards would not only ensure consumer safety but also increase their confidence in these products [62]. Regulatory practices are applied at every step of the production cycle, ranging from the procurement of raw materials to the packing and shipment of the finished product. Strict adherence to GMP standards helps ensure uniformity, dependability, and quality throughout the production lot while avoiding contamination, variability, and mistakes. There is ample evidence to show how crucial the use of GMP is in terms of ensuring that products remain intact while keeping the consumers safe [63]. Companies that comply strictly with these rules are less likely to experience recalls and other problems which affect their reputation and bottom line. It also helps make companies more efficient and competitive in the pharmaceutical sector [64].

9. Interventions and safeguards

A) Local Incident Reporting Systems and Safety Culture

It is important to understand that because everyone thinks alike, everyone's mistakes are alike as well as these mistakes are the "errors traps", and cannot be explained with such simple reasons as the mistake being "caused by careless behaviour" [27]. These errors are traps into which everyone could easily fall, and thus system change would be the best approach to getting rid of vulnerability. Hazards and vulnerabilities vary significantly among hospitals due to differences in hospital culture (that is, how things are done here), equipment (presence or absence of pulse oximeters), personnel and staff training, etc. Failure to detect hypoxia is much more likely to occur at a recovery room that lacks pulse oximeters than at one where there are pulse oximeters. Because vulnerabilities usually occur locally, the most efficient method of detecting and dealing with vulnerabilities is through an incident reporting process that is specific to the area involved. This incident reporting process needs to foster a culture in which people feel comfortable sharing information about errors or potential errors without fear of being blamed, shamed, or punished [65-66]. The goal of this process must be understanding and empathy towards system flaws. These interventions should be rigorously tested in order to measure their efficacy. Such actions as education or training are typically quite ineffective and rarely bring positive results [67]. On the other hand, the interventions that are relatively powerful include changing the process design by adding certain controls (such as an independent double check of vital medication such as insulin and heparin). The interventions with even greater power include structured communication techniques. Forcing functions are the best intervention techniques since they are designed to make it impossible to errors. The use of the pin-index safety system for connecting gas cylinders is a case in point. Computer-driven safeguards like hard stops that do not allow for the entry of medications based on patients' allergies and erroneous dosing in smart infusion pumps are very efficient at minimizing errors. Nevertheless, although simpler strategies are cost-effective and easy to implement, more robust ones involve substantial costs and system alterations. For instance, incorporating specific small-bore connectors to avert wrong route delivery entails major modifications in production procedures. Although resource-constrained healthcare facilities might not be in a position to employ sophisticated interventions, they should use simpler ones, albeit appreciating their efficacy. The development of good safety practices in the organization on the local level is necessary in order to prevent mistakes, and it has to be actively supported by senior leaders. Even inexpensive improvements in safety standards demand certain investments on the part of managers and workers in terms of spending time on them, as well as making changes in operations, such as taking extra time to verify certain actions or information. In addition, it is hard to persuade employees to change their established ways, especially when something simple has to be done. Leadership needs to develop an environment whereby incidents are not only reported but dealt with constructively. In the event of accidental occurrences, lessons need to be learned so that systems may be improved, but when there is a clear case of wrongdoing, people responsible need to be punished appropriately. With time, the development of good leadership will ensure the establishment of a safety culture, just like in high reliability organizations such as the aviation and nuclear industries [68]. Table 2 explains to effectiveness of interventions to improve workplace safety.

Table 2 – Effectiveness of Interventions to Improve Safety [67]

Weaker Actions	Warnings and labels New procedures, memoranda, policies Training, re-education Additional study or analysis
Intermediate Actions	Checklists or cognitive aids Redundancy Enhanced communication techniques such as speak-back, three-way communication Decision support embedded in computer order entry systems (can over-ride) Improved labelling of medications Elimination of look-alike, sound-alike medications Separation of dangerous medications from routine medications (hypertonic saline) Elimination of concentration medications from anaesthesia carts
Strong Actions	Forcing functions (pin-indexing of gas tanks, unique small-bore connectors for neuraxial route, anaesthesia machines with anti hypoxic gas mixture function) Standardization of equipment New device usability testing prior to purchase

B) Policies, Procedures, Standardised Order-Sets

Policies and procedures can generally be regarded as less robust tools for error prevention, but they have their importance in creating standards and accepted best practices in terms of process uniformity. Process standardization will enable early identification of deviation from the norm or possible errors. Automated order sets have inbuilt mechanisms that prevent error occurrence, such as the addition of a blood glucose level measurement after an hour of insulin dosage administration. This is possible in resource-rich environments. In poor-resource environments, the automated system is not available, and the reminder will be manual at the bedside. Care pathways, also known as care maps, can also be created to delineate evidenced-based practices for certain illnesses. For example, in high resource countries, anaesthesia during cesarean delivery will entail the spinal injection of bupivacaine. In low resource nations, where there might be a lack of qualified anaesthetists, guidelines that detail such things as ketamine dosages and needed monitoring are essential [69].

C) Technology

There are a number of technologically advanced precautions that high-resource health care facilities have at their disposal in order to reduce the incidence of drug errors. For example, there are bar code medication systems which scan barcodes on the vials, create labels on syringes, and then verify the medications upon administration. Both visual and sound notifications can be made by such systems. Additionally, they could generate an alert regarding proper dosing based on weight or renal functions [70]. Barcode Medication Administration (BCMA) is commonly used in hospitals, especially in anaesthetics, although not all departments utilize it yet [71-72]. Moreover, there are fewer chances of mistakes arising out of preparation of medicines in pharmacies or their pre-filled vials. In case of pre-filled syringes, these help in avoiding errors resulting from changes in medicine labels due to shortage of stock. Infusion pumps are another technological innovation that makes things even safer as they use pre-filled drug libraries and limit dosing within safety parameters. However, in case of poor resource settings, one cannot always rely on advanced technology, but there are other methods too that can help. Some of these include filling of medicine in a distraction-free zone, double checking of high-risk medicines, and verification of drug names verbally before its administration.

D) Cognitive Safeguards

However, unconscious biases play a considerable role in causing cognitive failures, like diagnosing and picking treatment options. Even though the decision-making process can occur quickly through intuitive reasoning [19], it is still possible for one to use his/her consciousness to review and reflect on the conclusions made, so as to check for any form of bias. This entails evaluating three possible conclusions and ruling out the worst scenario. As for picking treatment options, it is crucial for one to consciously make sure that the selected treatment is the best choice. Collaborative decision-making makes the process more accurate by virtue of having several perspectives that come from people with varied experiences and reasoning capacities. Effective communication among members of the team will ensure that all essential aspects and facts come to light. For example, voicing fears during a procedure can help one to hear others' opinions too.

E) Communication Safeguard

Unconscious bias plays a major role in causing errors of cognition during diagnosis and treatment choices. While decisions are generally rapid and intuitive, it is possible for an individual to develop his or her conscious awareness to reflect on these judgments, making a bias detection or evaluation of any flaws in judgment. For instance, a healthcare practitioner can make sure that he or she considers at least three other possibilities while making a diagnosis, especially the one most likely condition that needs to be ruled out. Decisions made collectively are accurate due to the diversity of thought involved since different people have different experience levels and ways of thinking. The process of open communication among group members may unearth vital information that would otherwise have been ignored. For example, highlighting issues about a process may encourage other people to provide pertinent information.

F) Simulation – High- and Low-Fidelity

In well-provisioned facilities such as academic institutions, simulation is done using a very sophisticated laboratory equipped with realistic mannequins and monitoring devices to enable preparation for handling emergencies [73]. Such training improves response time and facilitates adherence to protocols when an emergency arises. But, such facilities require high costs and are not accessible even in resource-abundant facilities. This means low-fidelity simulation provides a cheap substitute in most healthcare facilities. In this regard, low workload times could be used by the labour and delivery departments to run drills on selected emergency cases.

G) Barriers to Implementation of Safeguards

The cost is a significant barrier to adopting patient safety interventions because the most effective interventions are costly. But even the cheapest solutions, like speak-back, are not adopted because of the human factor. Many people have an issue recognizing their vulnerability, are reluctant to admit their mistakes, and have a problem being led by someone else. Individual habits and personal preferences make people resistant to changes even when there are safer options available. While doctors cherish their independence, their autonomy must not come before the patient's right to receive safe and science-based treatment.

10. Case Study

The pharmaceutical batch record case study addresses batch records that are vital for capturing all actions performed during the manufacturing of the drug. It is important to document every activity of the batch process using writing or computer systems in order to facilitate the actions of the person who needs to release the batch according to the regulatory standards. The batch records help to verify that the processes involved in production are in agreement with the Good Manufacturing Practices (GMP), procedures, specifications and licensing criteria. This needs to be done at particular milestones and could involve application of the Quality by Design (QbD) philosophy aimed at making equipment and processes as efficient as possible and decreasing the chances for making mistakes[74]. The batch record may also contain designated spaces for comments, wherein the operator or reviewer can mark down any matters that need to be attended to by management. The comment needs to detail the nature of the matter, provide reasons why it is important, point out any deviations, if there are any, with details on the remedial action taken, and any preventive measures put into place. Every time the batch record is reviewed, the person doing the reviewing needs to sign off and indicate the date when this was done. Once the final processing stage/test is done, an evaluation needs to take place. It includes checking whether all necessary inputs have been entered and that there is no mistake in their recording. In addition, GMP principles have to be adhered to. All the important figures need to be verified by an independent third party. The reasons for unusual results, deviations from established standards, or rejection of materials need to be recorded and further investigated. Other information, such as expiry dates, also needs to be reviewed [75]. Each entry should have the signature and date of review. All recurring issues found should be analysed, paying special attention to human mistakes, as they should be corrected using focused training programs. Attention needs to be paid to shifting focus from the “training for compliance” approach to the “training for competence,” which is much better at ensuring consistent GMPs. Finally, better structure and layout of the documents used will prevent a lot of mistakes. Emphasis on proper and appropriate batch documentation, periodic inspections, and investigations into deviations and out-of-scope findings could improve the effectiveness of the batch review process and minimize chances of product recalls. Though shifting from paper documentation to electronic data collection may facilitate better access to information, provide greater data integrity, and improve confidentiality, such practices come with associated risks, which include those relating to system controls and data management.

11. Conclusion

The main objective of this study is to find out the ways to reduce human errors in the pharmaceutical industry. Exploratory research design was used, consisting of semi-structured interviews conducted with seven experts from the industry. Such design helped participants discuss the topic freely and share their experience. Data gathered from the interviewees were sorted through the development of a mind map, which assisted in understanding interconnection of the concepts. Six best practices were revealed: training, error mapping, documenting, competency assessment, openness, and automation. Application of the techniques depends on the organization's size and situation, but training was the central one connected to processes and documentation updates. Active training techniques such as those involving competitions and rewards were recommended to enhance participation and productivity. Another critical requirement that should be met is competency assessment, which ensures that employees have all the technical and behavioural skills they need as well as helps companies allocate their functions appropriately. Automation was found to be a good approach, but certainly not an infallible one as even automated process can be compromised by human error. Intriguingly enough, fatigue did not appear among the causes of errors in the study, as opposed to results obtained in other sectors. It is most likely explained by high levels of attention paid to ergonomics, safety and controlled environments in the pharma industry. There are many directions in which future studies could focus – communication skills training, effective communications practices, and competencies. Human errors are inevitable, but can be reduced through detailed process analysis, either preventive or post-error analysis. Human factor techniques in conjunction with strict procedures and briefings greatly mitigate the risk of error. Investigations in the case of error become part and parcel of regulations; batch failure is directly linked with competitive success. Hence training and awareness are crucial. In conclusion, the quality of pharmaceutical products is based on SISPQ concepts, which include safety, identity, strength, purity, and quality, with a focus on minimizing human error. Leadership, safety culture, technology, and communication are some of the factors that facilitate optimal patient safety, while underinvestment, poor leadership, and change management are among the challenges faced.

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