REVIEW ARTICLE

Pharmacovigilance in the Era of Digital Health Leveraging Big Data and Artificial Intelligence for Enhanced Drug Safety Monitoring

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Abstract

Pharmacovigilance (PV) is the science of drug safety, now established as a separate discipline driven by modern technologies such as digital health tools, big data, artificial intelligence (AI), and machine learning (ML). Legacy PV methods relied on manual reporting and spontaneous submissions of adverse drug reactions (ADRs), but these were hindered by delays in submissions, signal detection, and data quality issues. Emerging technologies such as AI, digital health, and big data play a critical role in drug safety and risk mitigation. Digital health tools, including wearable monitors, patient engagement modules, and electronic health records, generate Real-World Data that help healthcare professionals track patient reactions to drugs over extended periods, providing insights into genomics, vitals, and ADRs. Big data allows PV practitioners to handle complex, heterogeneous datasets, including patient reviews, which are analyzed using natural language processing to extract insights from social media, reports, and clinical data. ML algorithms automate signal detection, predictive modeling, and casualty assessment, significantly improving the speed and accuracy of ADR identification. Technologies such as AI-driven platforms (e.g., World Health Organization VigiBase and Food and Drug Administration Sentinel initiative) demonstrate how large-scale, real-time data can enhance risk signal identification, while digital health devices assist in monitoring patient vitals for early risk detection. Despite these advancements, challenges persist, including ethical concerns, data inoperability, algorithm bias, and regulatory issues. This review underscores the need for global collaboration, standardized reporting methods, and robust regulatory guidelines to address these challenges. Emerging technologies like the internet of medical things pave the way for personalized and ML-driven predictive PV.

Key words: Adverse drug reactions, artificial intelligence, digital health, machine learning, pharmacovigilance

INTRODUCTION

Since the early usage of pharmaceutical drugs, tragic events have been passed due to unknown effects upon the administration of several pharmaceutical products.[1] This led to the understanding and adoption of a widespread drug safety policy known as Pharmacovigilance (PV). It refers to a systematic review of pharmaceutical drugs in their post-marketing phase, where the drug converts into a new molecular entity into its later lifecycle, i.e., after the drug administration.[2] PV originally came from the United States policy-making and drug amendments (commonly

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known as Kefauver–Harris Amendments) in 1962, which came in response to the thalidomide catastrophe that happened in Europe.[3] The drug thalidomide was originally synthesized by a Swiss pharmaceutical company *CIBA* in the year 1953 and was then mass-produced by a German pharmaceutical company *Chemi Grunenthal* in 1956,[4] was sold as an over-the-counter sedative, and became popular among pregnant women due to its anti-emetic properties.[5] However, in 1961, an Australian obstetrician, Dr. William McBride, and, a German pediatrician, Dr. Widukind Lenz independently observed that thalidomide usage in pregnancy links to congenital malformation in newborns[6,7] These malfunctions were mainly caused by thalidomide usage between 34 and 49 days after the last menstrual cycle, with severe risks associated with even a single dose.[3] This incident marked one of the first occurrences of PV reporting by healthcare workers, who analyzed risks and side effects caused by pharmaceutical products.[8]

PV is the study of benefits and risks obtained through the administration of specific drugs and plays an important role in pharmacotherapeutic decision-making. Growing research into pharmaceutical drug synthesis has made PV an aligned scientific discipline that safeguards human health against the adverse effects of many newly developed and post-marketed drugs.[9] PV consists of 3 core functions: Case management, signal management, and signal-risk management.[10] These functions govern the systematic review, which involves input, processes, and output.[11] The central repository of these core functions is added to a database that contains safety-related information on the pharmaceutical drug being manufactured by the company. This database is essential to PV reviews, encompassing data on demographics, conditions, drug administration, dosage, and observed side effects.[12] This database is the main component of the essential to all the core functions in a PV review, as shown in Figure 1.

In the era of digital health, leveraging big data and artificial intelligence (AI) has revolutionized PV by enhancing drug safety monitoring. With the integration of advanced analytical techniques, PV now benefits from real-time data analysis, predictive modeling, and automated adverse event detection. This review paper explores the role of big data and AI in modern PV, highlighting their contributions to improved drug safety and risk assessment.

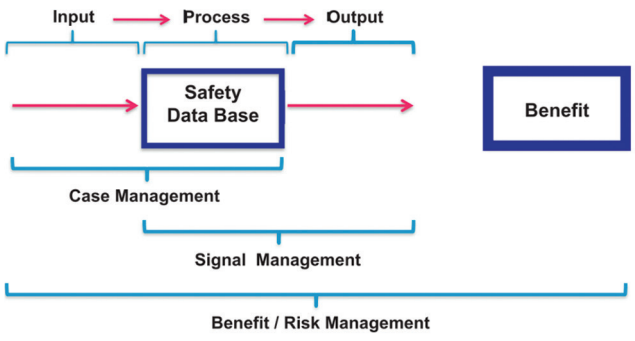

Figure 1: Pharmacovigilance (PV): A systems perspective. Copyright © 2018 PV: An Overview.[13]

Evolution of data management in PV

PV knowledge is built upon the accumulation of several case studies and safety reports and their relevant analysis with added epidemiological studies. Increased knowledge about the PV impact creates an increased influx of input of data in the PV process. Hence, an updated and accurate database is needed so the cycle of information upgradation and addition to the knowledge is continuous.[14]

Databases, in the earlier days of PV, were made by entering data into manual databases. Eventually, the widespread adoption of electronic spreadsheets helped researchers collaborate on PV databases. Nowadays, databases have been converted into highly functional and dedicated commercial data sets that can maintain massive data about the adverse effects risen by the usage of a specific drug on a large and differentiated sample.[16]

Historical PV methods used manual data entry for the inputs to the database, which could make the process time-consuming and labor-intensive.[15] Manual data entry caused issues such as underreporting, where healthcare professionals failed to report adverse effects due to a lack of awareness, time constraints, or perceptions that certain reactions were too minor to include in reports.[17] This under-reporting made incomplete data sets creating an incomplete picture of the drug risks involved with a particular drug being administered alone or concurrent with other drugs.

Another major issue with early PV processes was delayed reporting of adverse drug reactions (ADRs). Traditional

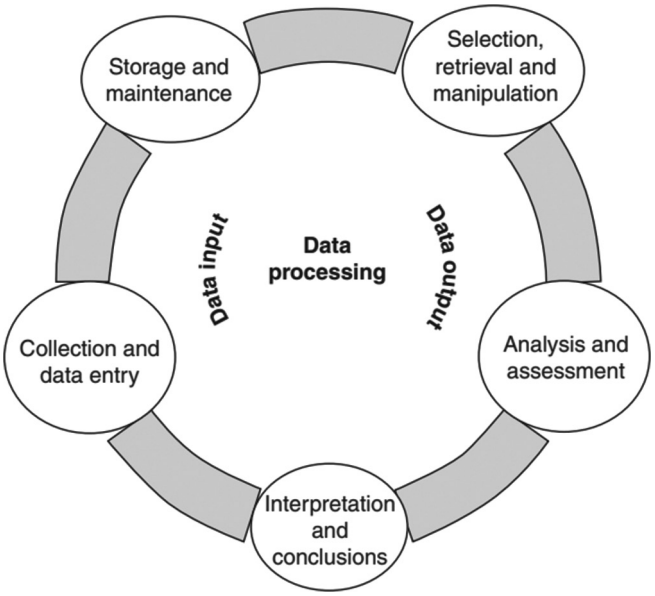

Figure 2: The data processing cycle in the pharmacovigilance (PV) process. Copyright © 2004 Data Quality Management in PV.[18]

PV relied on manual data entry systems and collaboration through electronic spreadsheets, which were slow and prone to errors. These systems only enabled ADR reporting after the incidents occurred, which resulted in significant delays in corrective actions by regulatory authorities [Figure 2]. Figure 2 indicate the data processing cycle of process involve in PV. Delayed ADR reporting further exacerbated the risks posed to patients by unsafe drug usage.[19,20] The lack of standardization in data quality and reporting further hindered effective PV management. Different systems created challenges in data interpretation, collaboration, and coordination across healthcare teams. Legacy PV systems were limited in their ability to provide real-time insights, which made identifying risks and taking timely corrective action more difficult.[19]

Progress in the field of PV has significantly enhanced reporting, storage, and collaborative methods for further analysis and corrective action. From manual data entry to sophisticated big datasets, PV reporting has evolved to reduce inefficiencies and improve the detection of drug risks. Modern technologies such as digital health tools, natural language processing (NLP), AI, and ML have paved the way for further advances in PV reporting. These technologies enable real-time data acquisition, predictive analysis, and automated risk signal detection, revolutionizing PV practices and regulatory actions.

Integration of digital health, big data, and AI in PV

Traditional PV methods had several shortcomings, including underreporting, delayed drug risk detections, and data standardization problems. These challenges warranted the integration of new data strategies into PV processes. By combining digital health, big data analysis, and AI, the PV process has significantly improved in efficiency, accuracy, collaboration, and scalability.[21]

Digital health: Enabling real-time data collection and patient engagement

Modern digital health tools, including wearable health monitoring devices, electronic health records (EHRs), routine clinical data, electronic billing data, and data gathered by marketing companies, can help transform the PV processes and also help with healthcare data collection and patient engagement, addressing gaps that traditional PV methods could not fill.[22]

Tools like blood pressure monitors, glucose monitors, and heart rate trackers now enable real-time data acquisition. This real-time monitoring generates Real-World Data (RWD), allowing for comparative and predictive analysis to identify risks promptly.[23]

Big data: Unlocking insights from diverse and large-scale datasets

Big data has changed the way; healthcare data is collected and analyzed by helping the process of analyzing vast amounts of data collected from various sources and compiling it into a large dataset for analysis. This technology also extracts data from a variety of sources, i.e., EHRs, digital health tools, and other unstructured data sets. With the increase in pharmaceutical data collection through genomics research, online drug reviews, and clinical trials, a huge amount of unstructured data is reported through reports, research articles, and drug performance reports. These descriptive reports are then converted to structured, searchable data through a technique called NLP. It can also use online sources, i.e., social media posts, to detect potential ADRs that might otherwise go unnoticed. NLP also analyzes how a drug review is written and draws meaningful patterns to enhance risk identification. Over the past two decades, PV reporting has had significant leaps in electronic reporting, and a large amount of data is reported. NLP and big data analysis can help analyze this large amount of data to recognize risk patterns, go beyond conventional methods to improve risk assessment, and enable a proactive approach to pharmaceutical drug risk mitigation.[24]

AI: Enhancing automation and predictive capabilities

AI and ML can automate and use data to predict models for PV processes. This challenging task of identifying risk patterns and connections can be done through AI simply and quickly. The irregular data can also be checked for any errors and skewed data points and made dependable through data cleaning tools.[25] ML models can make mathematical models to identify ADRs by comparing available data from patients to historical data, patient demographics, and medical interactions with the prescribed pharmaceutical product.[26] AI also facilitates proactive risk mitigation by predicting and preventing risks before they occur, further addressing inefficiencies in traditional PV systems.[27]

Synergy of digital health, big data, and AI

The integration of digital health, AI, and big data into a single system combines real-time data collection, advanced predictive analytics, and automated insights. This synergy enables corrective action during drug administration, minimizing risks, and ensuring patient safety. Digital health tools provide the raw data, which NLP and big data analysis sort and refine, while AI adds predictive capabilities. Together, these technologies overcome the underreporting and delays of traditional PV methods, shaping a more accurate, patient-focused, and data-driven approach to PV processes.[28,29]

The evolution of PV: From manual reporting to digital transformation

In the mid-20th century, PV emerged as a risk mitigation measure after several drug-related catastrophes. These incidents underscored the need for PV as a discipline to safeguard human health and monitor drug-associated risks. A turning point was the thalidomide tragedy, which

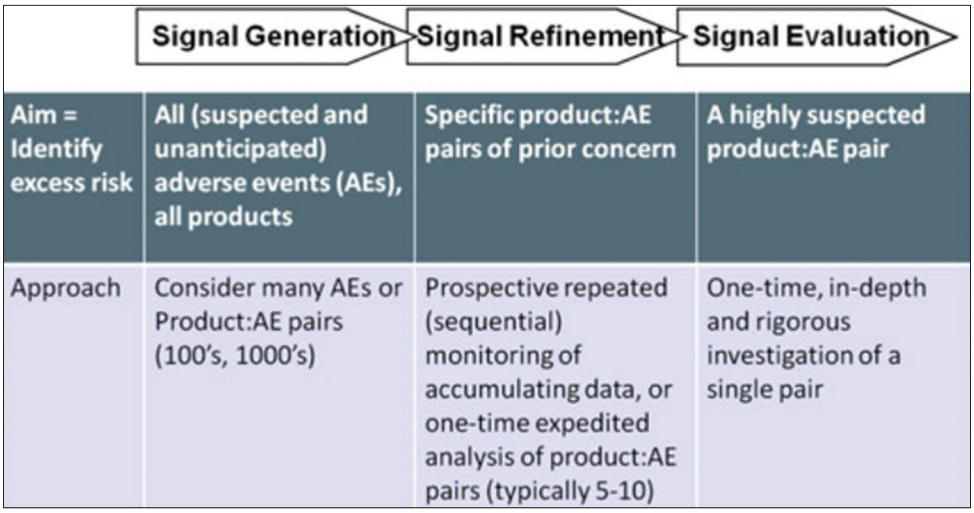

Figure 3: Stages of active medical product safety surveillance. Copyright © 2012 The U.S. Food and Drug Administration's Mini-Sentinel Program.[39]

emphasized the necessity of systematic methods for ADR reporting.[30]

To prevent such tragedies, organizations like the World Health Organization (WHO) established the International Drug Monitoring Program in 1968, encouraging nations to develop their PV centers. These centers enhanced medication safety by exchanging clinical data globally, including patient reports and other health information. This laid the groundwork for coordinated efforts to improve drug safety worldwide.[31]

Initially, ADR data was collected through spontaneous reporting methods, where healthcare professionals voluntarily submitted reports about ADRs without regulatory prompting. Despite its utility in identifying risks, this method was prone to underreporting and delays. An example is the identification of 12,212 SCAR cases associated with 30 different antibiotics through spontaneous reporting. However, the lack of standardized data and slow responses from regulatory agencies made it challenging to draw timely conclusions and implement corrective measures.[32-34]

The introduction of electronic databases transformed PV processes, enabling efficient data storage, retrieval, and analysis. Databases like WHO's VigiBase, managed by the Uppsala Monitoring Center in Sweden, became pivotal. These databases incorporated standardized medical terminologies, such as WHO adverse reaction terminology and the Medical Dictionary for Regulatory Affairs, which facilitated consistent PV reporting and enhanced global collaboration.[35]

Modern advancements, including EHRs and advanced search engines like PubMed, further streamlined PV processes by organizing long-term data and providing systematic access. Frameworks such as the EMA's EudraVigilance system and the Food and Drug Administration (FDA's) Sentinel Initiative demonstrated the growing regulatory commitment to leveraging technology for drug safety monitoring. EudraVigilance, for example, has become one of Europe's largest web-based drug safety databases, emphasizing the shift from manual to digital PV methods [Figure 3].[36]

AI and longitudinal observational databases now play a crucial role in epidemiological investigations, detecting trends in ADRs, and reducing manual labor. AI-driven tools, such as those sifting through EHRs or social media data, significantly improve signal detection efficiency. These technologies align with principles such as Fairness, Universality, Traceability, Usability, Robustness, and Expandability (FUTURE), as emphasized in the FUTURE-AI framework.[37]

The regulatory environment evolved in collaboration with PV strategies. There are various stages of safety surveillance of product safety [Figure 3]. The development of frameworks such as the EMA's EudraVigilance system and the FDA's Sentinel Initiative demonstrated a growing commitment to utilizing technology for drug safety monitoring.[38] EudraVigilance is a drug safety database developed for the European Economic Area in December 2001 and enhanced in November 2012 to become one of Europe's largest web-based databases.[39]

The digital transformation of PV: From manual reporting to AI-driven approaches

ADR reporting was historically conducted using manual processes, where healthcare practitioners or patients filled forms and submitted them through fax or mail. These forms were then manually entered into databases – a tedious and error-prone process. Issues such as illegible handwriting, incomplete information, and data entry errors limited the speed and efficiency of ADR detection, delaying the identification of safety concerns. However, these early systems highlighted the necessity for PV-type frameworks to systematically monitor drug safety.[40]

The late 20th century marked a turning point with the introduction of computerized reporting systems, revolutionizing PV processes. Electronic data storage and retrieval significantly improved the efficiency of ADR detection and analysis. Standardized computerized forms became the norm for pharmaceutical companies and regulatory bodies, helping to reduce errors and improve speed. Platforms such as WHO's VigiBase and FDA's Sentinel facilitated centralized, global ADR data collection and analysis, allowing researchers and regulators to identify safety signals faster and respond more effectively to protect public health.[41]

The integration of AI and big data analytics into PV systems has transformed ADR detection. Machine learning (ML)-based systems can process vast amounts of structured and unstructured data, learning to identify patterns linked to potential safety concerns. For example, NLP systems can analyze free-text entries in EHRs or scour social media posts for mentions of possible ADRs. This shift has enhanced the speed and accuracy of signal detection, enabling the transition from reactive PV – addressing issues after they arise – to proactive PV, where potential threats are identified and mitigated before significant harm occurs.[8,42]

AI is not limited to detecting current ADRs – it is also being used for predictive modeling to forecast potential adverse events. By analyzing RWD from EHRs, wearable devices, and mobile health applications, AI algorithms can predict risks associated with specific drugs or patient demographics. Predictive modeling allows for early regulatory actions, targeted risk mitigation strategies, and personalized safety monitoring, making PV systems more dynamic and forward-looking.[43,44]

Digital platforms, such as mobile applications and web portals, have empowered patients to play an active role in ADR reporting. Patients can report ADRs in real time, expanding the scope of data available for analysis and enhancing the detection of rare or previously unidentified ADRs. This increased patient engagement not only improves PV reporting but also fosters confidence in the safety monitoring process.[45] Technological advancements, such as wearable devices and mobile health (m-health) applications, provide continuous, real-time data collection from patients. Wearable devices monitor vital signs such as heart rate, blood pressure, and glucose levels, offering early warnings of potential ADRs.[30,47,48] These tools also allow healthcare providers to detect abnormalities and take swift action to prevent adverse outcomes. Unlike traditional spontaneous reporting methods, which rely on delayed and conscious input from patients or healthcare providers, digital health technologies enable automated, real-time data collection, resulting in a more accurate and comprehensive understanding of drug safety.[24,49-52]

The inclusion of data from digital health sources – such as wearables, EHRs, and mobile applications – into PV systems provides a holistic view of drug safety profiles. By merging traditional ADR reports with RWD, researchers can identify risk patterns and chronic ADRs more effectively. This integration enhances the predictive capabilities of PV systems and ensures that monitoring keeps pace with the evolving complexity of modern healthcare.[53,54]

AI and big data in PV

Large and complex datasets that cannot be handled or analyzed with traditional data processing workflows are termed big data. In PV, these data extend to genetic data, social media texts, and EHRs, and RWE-capturing devices such as wearable and mobile health applications. Big data matters because monitoring such data will give a completer and more nuanced picture of a drug's safety profile. Patterns and trends from massive, diverse data sets would go unfound when examined under small or limited data sets.[51]

Sources of big data in PV

There are numerous big data sources in PV. Each offers a different viewpoint on drug safety. Some of the most important sources include EHRs. These provide great detail about a person's medical history, diagnoses, treatments, and outcomes.[25] EHRs are especially useful in PV because they record RWD regarding drug use across a series of patient groups and settings. By analyzing such data for patterns and trends in ADRs, it is possible to spot safety signals not apparent in clinical trials. EHRs can be connected to other data, such as imaging studies and laboratory results, to provide a fuller picture of a patient's health.[55]

Another very important source of big data for PV includes social media. Social media sites such as Facebook, Twitter, and patient forums provide an inconceivable amount of information, such as ADRs and side effects experienced by people about pharmaceuticals. Social media data are unique in that they document the results; patients became aware of PRO in real-time, making it particularly useful for understanding how drugs affect the day-to-day lives of patients.[56] Social media posts could be analyzed using NLP techniques to find all mentions of possible ADRs and extract relevant information. Studies provide a perspective of drug safety different from that of traditional data sources and contribute to filling in the gaps raised by those sources, whereas the social media data force itself within them to come across as messy and disorganized at times.[57]

Big data faces several challenges in PV, particularly regarding data consistency and quality. Big data is often described as Volume, Variety, and Velocity, which typically makes it hard to maintain data quality and integrity. For instance, social media data can be very noisy and unstructured; EHRs, on the other hand, can have inconsistent or missing data. If these problems are neglected properly, they can cause a lot of friction in the analysis of big data and result in erroneous

conclusions. Preprocessing and cleaning processes are some of the key challenges facing big data management; the actual work involved is time-consuming and can consume significant resources, especially when dealing with large and heterogeneous datasets.[58]

Challenges of managing and analyzing big data

There are several challenges in the use of big data for PV, primarily concerning data consistency and quality. Big data is often defined as having volume, great velocity, and increasing variety, which complicates the task of assuring the quality and reliability of the data. For instance, while social media data can often be noisy and unstructured, EHR data may suffer from inconsistency and missing values. Such issues, if unresolved properly, can make big data analysis more challenging and can give rise to erroneous findings. Preprocessing and cleansing of data are an integral part of big data management. However, they could be time-consuming and resource-intensive.[25]

Confidentiality and privacy of patient data have been a great hurdle in the way of implementing big data for PV. The input and analysis of big data often involve private patient data, such as social media interactions, demographics, genetic information, and patients' medical histories. Protecting this data is crucial to maintaining patients' and stakeholders' confidence in the advanced data technologies for healthcare monitoring. To ensure compliance with data protection laws, several acts have been passed in the US and EI, i.e., the Health Insurance Portability and Accountability Act (HIPAA) in the US and the general data protection regulation (GDPR) in the EU.[46,59] Where encryption and anonymization could be helpful for patient privacy, at some point, they would fail in some respects as the sanctity of the data could then be lost. Furthermore, the[54] availability of big data gives rise to ethical issues regarding who owns and gives consent to such collection of information, especially in situations where the data is collected from social media and other data repositories.

Furthermore, the difficulty associated with integrating and analyzing big data arises from its complex nature. Big data often derives from a wide variety of sources that use different languages, peculiar morphologies, and formats. Complex methods of data harmonization and standardization are required for the amalgamation of these heterogeneous streams of data and yet can be very tedious to implement and manage. Moreover, massive data analysis requires advanced computational tools and knowledge, such as ML and AI techniques. These techniques can allow huge amounts of big data to yield actionable insights, while their reliability and credibility need to be carefully verified and interpreted.[37]

Despite its promise, the use of AI in PV has raised concerns regarding biases in algorithms. For example, biases in ML models can arise from the underrepresentation of certain demographic groups in training datasets. This lack of diversity can result in AI systems failing to accurately detect ADRs in minority populations, potentially leading to inequitable healthcare outcomes. A study highlighted that certain populations, such as those with rare diseases or underrepresented ethnic groups, are more likely to be overlooked in AI-driven safety monitoring tools due to imbalanced datasets. Similarly, NLP algorithms used to analyze social media posts or EHRs may reflect biases present in the input data, resulting in skewed ADR detection or reporting.

Mitigation strategies are essential to address these biases. One effective approach is to curate diverse, representative training datasets to ensure that all population segments are adequately captured. Regulatory bodies can set guidelines for bias testing and validation of AI models before implementation. Another strategy includes using explainable AI to make decision-making processes transparent, enabling stakeholders to identify and rectify biases more effectively. In addition, collaboration between AI developers, healthcare professionals, and policymakers can help create frameworks to audit and mitigate biases at every stage of AI development and deployment in PV.

AI in PV

AI is defined as an emulation of human intelligence through software and hardware capabilities of computers to do activities such as learning, reasoning, comparing, reciting trends, and problem-solving. AI in PV refers to the use of AI in creating methods and tools to examine sizeable data sets to predict trends, provide forecasts, and aid decision-making for any ADR signals associated with pharmaceutical products. ML is one of the important branches of AI, and it is defined as the creation of algorithms to learn data and gradually get better at their performance. To detect ADR from large datasets and identify risk groups, ML systems can be trained on historical data to find patterns and connections between data points.[60]

NLP is the process by which AI applications examine how computers interact with human language and derive structured data from different data sources. EHRs, social media posts, and medical documentation are such emplaces of unstructured data where NLP may be used to derive meaningful information and spot any safety signals that m might arise.[61] NLP can be used to search large data sets for ADRs when these datasets are unstructured. It can also keep an eye on social media for reports on specific pharmaceutical products that are creating ADRs. NLP creates structured data from large unstructured data sets, which are not easily searchable for risks through manual search methods. NLP improves the efficiency and precision of drug safety monitoring procedures and automates the process of data extraction and analysis for text data.[54] In PV reporting, AI has become an essential tool that provides creative and efficient ways to improve drug safety

monitoring; AI can effectively and accurately predict signals and evaluate causalities among large datasets.[62] Manually reviewing ADRS is a common but difficult part of the traditional PV monitoring framework, as it can be laborious and prone to human errors. AI, and particularly ML, can help healthcare professionals to effectively identify possible drug safety risks through the analysis of massive datasets created from data from social media, demographics, genomics, and EHRs. For example, AI can help identify trends in EHRs and can help regulators and drug manufacturers reduce drug risks before further damage. AI can also help determine the caution of risks by checking the probability that an adverse event was caused by a particular product, depending on the patient's demographics, genomics, medical history, physical conditions, and drug interactions.[62]

Signal detection and causality assessment

Signal detection, which refers to the function of finding out possible drug safety issues, stands as the most important application of AI in PV. Conventional signal detection techniques rely largely on spontaneous reporting systems, which are often confined by delays, lack of reporting, and excessively large amounts of data to analyze.[54] To handle the above-stated problems, AI and ML algorithms automate the analysis processes of complex databases to include a wide range of data from sources such as social media, clinical trials, and EHRs. NLP techniques assist in extracting relevant information from unstructured text, greatly improving the capacity to notice signals that may otherwise go overlooked, such as in physician notes or patient discussion forums.[25] With the introduction of AI, the more accurate detection of dangers affords prompt regulatory action by the PV team for the protection of patient safety. In addition to industrial and regulatory settings, AI-driven PV systems find use across academic-based research. For instance, a prediction model created by researchers at Stanford University was recently blessed with a machine-learning algorithm that predicts the risk of ADRs in hospitalized patients using EHRs. By identifying patterns in patient data which includes drug history, laboratory values, and comorbidities, the algorithm estimates the likelihood that acute kidney injury and gastrointestinal bleeding might arise.[63] The predictive power of this might ensure a decrease in the risk of serious ADRs through appropriate actions by health practitioners about changes in prescriptions or close surveillance of patients showing signs early in treatment. These case studies indicate the applicability and potential of AI-powered PV systems to advanced starts toward improving the safety of drugs across regulatory bodies, pharmaceutical corporations, and healthcare institutions.

Integration of big data and AI in PV

Pharmaceutical product safety monitoring can become greatly efficient using advanced datasets and data analysis using AI, big data, and ML technologies. These separate advanced techniques complement each other when dealing with large data sets coming from several input sources, i.e., genomics data, patient demographic data, social media trends, and EHRs.[64] This data cannot be analyzed with the help of traditional data manipulation and analysis techniques due to their immense value and complications. AI, ML, and NLP intervene to effectively handle and deduct actionable results from these large sets of data. To detect ADRs, AI systems help find and identify trends in data that can provide us with signals without delay.[65] Large data and AI also make a synergetic partnership in which data is transformed by AI to display only important information and remove noise and skewed data.[66] AI and big data integration is one of the most effective methods of surveillance in PV methods. One excellent example of this synergy is the FDA's Sentinal initiative, where data from more than 30 organizations was pooled into a singular data set to get real and actionable results.[67] A comparison of these case studies highlights their strengths and limitations. The FDA's Sentinel initiative demonstrates the advantage of integrating diverse healthcare data sources to generate real-time insights. However, a limitation lies in its reliance on U.S.-centric data, which may not fully account for global ADR trends. In contrast, WHO's VigiBase provides an international perspective, pooling data from diverse regions worldwide. This global approach ensures wider applicability but introduces challenges related to data harmonization, as countries have differing data standards and reporting mechanisms. Pharmaceutical companies such as Novartis, Pfizer, and Roche benefit from proprietary NLP-powered databases, allowing for rapid ADR detection tailored to specific drugs. Yet, these private databases may lack transparency, limiting broader regulatory oversight and collaboration. These comparisons illustrate the trade-offs between accessibility, data inclusivity, and global harmonization in leveraging big data for PV. Also, WHO created VigiBase, which is an international PV database that takes and analyzes PV data from all around the world and timely releases notices to the public to caution against specific drugs having a high-risk profile. This pooling and synergizing of data helps casualty evaluation and early signal detection.[68] Several pharmaceutical companies have also created their databases, i.e., Novartis, Pfizer, and Roche, which are NLP-powered and can combine large unstructured data inputs to form singular data sets to anticipate and stop ADRs.[69] These technologies help us realize that big data and AI can help produce reliable and actionable data for drug safety monitoring. AI and big data have several advantages when used for medication safety monitoring. One of the main advantages of using AI and big data is faster ADR detection. AI can evaluate big data sets in real time, so possible safety concerns are far easier to identify than conventional manual or electronic data management techniques. Because of this swift result complication and data monitoring, large pharmaceutical companies and regulators can promptly react to reduce hazards.[70] Furthermore, by introducing AI, human error and human bias can be removed from the

decision-making and increase the integration accuracy. AI systems are also able to identify possible problems in the data and can compare multiple data sets to get a unified agreed-upon result that is backed up by more data sets than usual. AI also has better resource efficiency, which means that more data can be processed and routine work can be automated, so human capital is reserved for the implementation of the results rather than clerical work.[71] AI has far better predictive skills than humans, and it can identify potential risk groups that can then be removed from pharmaceutical products altogether.

Challenges and limitations

One of the most highlighted challenges when using AI and big data to identify trends in PV is the inoperability of data. Healthcare data is usually scattered into diverse systems that are often not interconnected or integrated to form a single data set. The data usually have different formatting styles, standards, and terminologies. For instance, hospitals mostly create different coding schemes for their internal ADR reports in their EHRs.[72] These data sets are difficult to format and segregate for effective data analysis. Algorithm bias is also present, which can only be mitigated if the AI is trained on multiple data sets and not many data inputs are present in the real world to be used as inputs for a data set due to ethical concerns.[73] Algorithm bias yields skewed results, which can also result in unfair evaluations of the available data. To overcome this challenge, an AI-driven PV system is used with multiple data inputs and consistency in data to get actual results.

Ethical and legal issues with respect to applications of AI and big data in PV are now under scrutiny, especially in terms of data privacy. Highly sensitive patient data is often used to get genetic and medical histories. To ensure a more comprehensive approach, global regulatory perspectives must be considered. For instance, while the U.S. relies on HIPAA to protect patient data, the European Union enforces GDPR, which provides stricter guidelines on data privacy and consent, particularly in cross-border data transfers. In addition, Japan has implemented the Act on the Protection of Personal Information, ensuring similar protections while balancing innovation in healthcare technologies. In India, the Personal Data Protection Bill highlights the need for localized regulatory frameworks for healthcare data. These regional differences emphasize the need for international collaboration and the establishment of harmonized global standards to promote safe and ethical AI applications in PV. Such collaboration could be facilitated through organizations like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, fostering convergence in regulatory practices for AI and big data. These data sets need to be regulated concerning GDPR and HIPAA guidelines. Although much of the data that is stored through these PV data sets ensures anonymity, doing that might reduce the data effectiveness and can also reduce the change of backtracking data in case of large errors. ML also incorporates the important algorithm function commonly known as the "black box," which makes it challenging to know where the different findings have arrived from.[74] Another issue is the openness of AI models derived from these data sets, which makes it particularly difficult for regulators to approve AI-driven models for PV practices.[61] The lack of transparency that is inherited from the predictive nature of AI models might erode the confidence that is much needed to adopt new technologies in sensitive areas, i.e., healthcare.[58,75] Strong ethical guidelines and precise rules are needed to appropriately use AI in PV practices to mitigate these worries.

Healthcare systems are typically slower to adopt newer technologies due to the high cost of implementation, which includes hiring staff, maintaining infrastructure, purchasing cutting-edge technology, and creating financial means to run this new infrastructure. Healthcare workers often resist changes to their working methods and are hesitant to abandon their traditional methods of work.[76] Furthermore, ambiguity brought about by the absence of uniform rules governing the use of AI in healthcare and PV creates a hindrance to adopting these newer technologies. Stakeholder education, targeted resource allocation, and the creation of a transparent AI regulatory framework can help increase the adoption of this new technology into healthcare systems and help remove obstacles from the path of AI in PV.[77]

Future directions

In recent years, the fields of AI and digital health have made headway and are shaping the future of PV. Wearable technology and the internet of medical things (Yom) devices have enabled continuous, real-time monitoring of the patient, which causes the availability of huge amounts of data for monitoring medication safety.[78] Advanced data management and enterprise analytics technologies, such as NLP and predictive analytics, facilitate more precise risk assessments and prompter detection of ADRs. In addition, novel pathways for patient-specific drug safety monitoring – potentially tailoring therapies to parallel patient genetic profiles – are now being enabled by the incorporation of genomics and precision medicine into PV. These changes are leading to an evolution in PV, making it more proactive, data-driven, and patient-centered.[79] The future of PV practices depends on international cooperation and the exchange of data between organizations. Different stakeholders are often involved in each step of medical safety profiling, and collaboration between them can democratize data for the benefit of society. Data from several sources, i.e., clinical trials, social media, and EHRs from around the world, can improve the PV process, with a range of examples being the FDA Sentinal Initiative and the WHO VigiBase.[80] Overcoming obstacles such as data privacy, regulatory harmonization hurdles, and inoperability can help healthcare professionals gain global PV competency.

Unlocking full PV potential through global collaboration would need the establishment of standardized data input and storage frameworks and the development of a collaborative environment between global pharmaceutical firms, research intuitions, and regulatory authorities.[42] Regulatory bodies are in place to secure the lives of many people from any catastrophize arising from ADRs caused by drugs. Regulatory policies should focus on establishing clear and harmonized global guidelines for integrating AI, digital health, and big data technologies into PV systems. These policies must prioritize data privacy, algorithm transparency, and ethical considerations to build trust and confidence among stakeholders. Regulatory agencies, such as the FDA and EMA, can play a crucial role by developing frameworks that encourage the ethical use of AI, promote data-sharing agreements, and establish interoperability standards across borders. Industry best practices should include continuous investments in research and development to enhance AI capabilities, foster global collaboration for sharing RWD, and create standardized data formats to facilitate seamless integration. Organizations must also focus on training healthcare professionals to use these technologies and ensure that infrastructure investments are aligned with future needs for data management and analysis. Public-private partnerships can act as catalysts by pooling resources and expertise, thus accelerating the implementation of innovative solutions for global PV monitoring. However, regulations also need to strike a balance between the safety and innovation of different healthcare practices. Regulatory bodies are essential in forming the way for PV practices in the future. AI and digital health are embraced by organizations such as the FDA and EMA due to the efficiency of newer technologies. Innovations like EMA's Data Analysis and Real-World Interrogation Network (EU) and FDA's Digital Health Center for Excellence are excellent examples of regulatory bodies embracing the scientific innovations of recent times.[55,81] Regulatory bodies must also keep practicing precise rules to regulate the application of AI to keep ethical concerns mitigated. Data privacy and algorithm transparency must be considered for any AI model that is put in place. Agencies can also promote innovation by establishing a favorable and workable regulatory environment. AI and digital health are the need of time in the field of PV monitoring. The main objectives of the research should be to increase the efficacy and precision of the PV systems to incorporate RWD into PV.[46,82] Investment in research to train healthcare workers is needed to use these instruments effectively. Investments in this sector will also provide the adequate infrastructure needed for healthcare workers to properly handle issues in the future.[83] Public-private collaboration and financing efforts are needed so stakeholders can enhance medical safety for patients globally by sharing research with different organizations.

CONCLUSION

This review summarized many important aspects of big data, digital health, and AI contributing to the advancements in PV. The PV process has been substantially revolutionized using modern reporting and database creation methods. Previously, the data capturing methods were manual, and regulatory corrective action was reactive. Now, with the advent of real-time data, AI and ML predictive models for different PV processes have been developed, hence creating a proactive approach to the PV processes. Digital tools, i.e., mobile health apps, wearable devices, and EHRs, are transforming the way for monitoring and reporting ADRs. By solving the most important problem of PV reporting, i.e., underreporting and delayed signal detection through real-time data and AI predictive analysis, there has been a significant increase in patient participation and monitoring.

An important aspect of medication safety through modern techniques is the advent of big data, which is accumulated from a wide range of sources, including clinical trials, social media data scraping, patient demographics, and genomics. When this data is paired with AI and ML predictive modeling, the precision and efficiency of PV reporting and corrective action are significantly enhanced. By working in conjunction with each other, these technologies help create a more dynamic and patient-focused approach that can reduce health hazards and also mitigate risks associated with pharmaceutical products.

There are still many hindrances to using advanced technologies for PV systems. For AI-driven solutions to be effective and reliable, technical problems with AI and ML need to be mitigated first. This includes bias and data inoperability in existing databases. To enhance stakeholders' confidence in these advanced technologies and guarantee the effectiveness of these advanced technologies, international standards must be set to incorporate AI, ML, big data, and digital health tools in the PV process. Mitigating these issues can also help create openness in AI models and emphasize data protection measures in the advanced echelon of these processes.

To enhance the efficiency of PV processes, it is crucial to establish global standards for the integration of AI, ML, and big data into PV systems. Policymakers must ensure robust data security measures, transparency in AI model functionality, and ethical use of advanced technologies. Increased funding and investments should be directed toward the development and implementation of advanced PV systems. Training programs for healthcare professionals and stakeholders are essential to build competence and confidence in using these modern tools effectively. In addition, fostering international collaboration is imperative for seamless data sharing, innovation, and the development of standardized frameworks to address global drug safety challenges.

Adoption hurdles for the advanced PV processes need to be removed by reducing implementation costs, increasing investments in healthcare systems, and preparing people for the change through training. Regulatory environments should also encourage healthcare providers, pharmaceutical

companies, and technology developers to work together and create innovative AI and big data solutions to these complex technical problems mentioned before.

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