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Review Article

Social Media and Digital Tools in Adverse Drug Reaction

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ABSTRACT

Pharmacovigilance is traditionally based on a voluntary reporting system that suffers from the underlying and delayed, adverse drug reactions (ADRs). The development of social media and digital technology provides new real-time data sources and analytics tools to extend ADR monitoring. This overview examines current drug-specific landscapes and evaluates the role of social media and digital devices as data mining software in artificial intelligence (AI), mobile applications, and ADR detection. We discuss key platforms (e.g., apps, global databases, AI-based text mining workers) and case studies showing successful implementations (e.g., surveillance of vaccine surveillance via the V- SAFE app on the CDC, MED safety reporting app). Describes benefits (Timelier Signal detection, patient-reported knowledge, global reach) and limitations (data quality issues, data protection/ethical concerns), and regulatory considerations (data protection law, reporting obligations). Finally, future instructions are being considered, including advanced AI/ML integration, portable sensors and harmonization of international guidelines. Digital tools may improve the Pharmacovigilance, but require careful evaluation and integration along with traditional methods.

INTRODUCTION

Pharmacovigilance is the science of recognizing, assessing, understanding and preventing adverse drug effects or preventing other drug-related issues. Pre-approval attempts test security in a limited group of people, but using the real world can result in rare or long-term ADRs in a variety

of unrecognized groups before marketing. To protect public health, regulatory authorities (e.g. FDA, EMA) must mandate after security surveillance marketing, including voluntary reporting systems and regular security updates. For example, the Med Watch Programme and the FDA FAERS database are voluntary reports on ADRs and EU's Vigilance systems in the EU,

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collecting ADRs from EU member countries. The WHO Uppsala Monitoring Centre (UMC) coordinates its global network (the program for WHO International Drug Monitoring) to report Vigibase, a repository of approximately 40 million records to ADRs from 150 countries.

Despite these systems, sub reports remain a major challenge. Only a small fraction of ADRs have been reported (some estimates show ~6%). The spontaneous system is also plagued by reporting delays of and limited patient perspectives. These limitations motivate the study of additional data sources. The advent of Web 2.0 and widespread use of mobile internet means that, patients are increasingly sharing their health experiences online. Social media platforms (e.g. Twitter, Facebook, Patient Forum) generate a huge amount of user-generated content, including the medication experience. These rich and actual data can be resolved for ADR signals and patient-reported results. At the same time, advances in digital technology - mobile health apps, AI, machine learning, Big data analysis - have created new tools for supporting Pharmacovigilance. This overview assesses the current status of ADR surveillance for, the role of social media, the study of critical digital devices and platforms, such as Case, and the benefits, limitations, and ethical/regulatory issues with regard to the use of these new sources. We focus on the latest developments (2020 and later) and guidance from the authorities (FDA, EMA, WHO) how digital methods can improve traditional ADR surveillance.

CURRENT STATE OF ADR MONITORING:

Post-advertising pharmacovigilance is based on reporting of suspected ADRs from healthcare professionals, manufacturers, and patients. National and worldwide frameworks govern those activities (e.g. the EU's Good Pharmacovigilance

Practices, ICH E2B trendy for digital case protection reviews). In practice, ADRs are amassed thru more than one channels: the FDA's Adverse Event Reporting System (FAERS) withinside the US, the EU's EudraVigilance, the WHO-UMC's Vigibase, country-precise structures (Yellow Card with inside the UK, VAERS for vaccines with inside the US), and enterprise databases. These structures mixture hundreds of thousands of Individual Case Safety Reports (ICSRs): for example, FAERS consists of destructive occasion and first-class grievance reviews coded through MedDRA terminology, and Vigibase consists of ~40 million reviews contributed through 150+ nations.

These worldwide databases allow sign detection thru facts mining (disproportionality analysis) and regulatory review. However, they rely on voluntary reporting, that is fantastically incomplete. Underreporting and reporting biases suggest many ADRs are missed, and identity of latest protection indicators may be slow. For example, conventional structures can also additionally most effectively discover a protection difficulty years after preliminary drug launch. To enhance coverage, a few jurisdictions have carried out energetic surveillance and real-global facts networks: e.g. FDA's Sentinel device makes use of digital fitness data and claims facts to observe protection risks, and numerous nations mandate post-authorization protection studies. Nevertheless, pharmacovigilance stays basically a reactive, facts-restricted process.

Authorities emphasize the want for complementing conventional reasssets. The WHO notes that every drugs have to be constantly monitored after approval, since "medical trials contain most effective a small range of decided on people for a quick period... sure aspect consequences can also additionally most effective emerge in heterogenous populations over a protracted period". As a result, innovators and



regulators are exploring new facts streams. Electronic equipment and real-global facts (social media, virtual devices, wearables) are more and more visible as possibilities to seize a broader spectrum of protection information. For example, the WHO has evolved virtual platforms (e.g. Vigi Flow for AEFI) to ease reporting through healthcare employees and the public. Similarly, reporting cell apps like Med Safety (see below) intention to enhance reporting rates. In summary, whilst spontaneous reporting stays the middle of ADR monitoring, popularity of its gaps has spurred hobby in augmenting PV with digital root and equipment.

ROLE OF SOCIAL MEDIA IN ADR DETECTION:

Social media has emerged as a vast, actual-time repository of affected person studies, along with medicine facet outcomes. This content material gives an affected person-targeted perspective: it regularly consists of free-textual content descriptions of ADRs, perceived severity, effect on first-class of life, and co-medications, which aren't nicely captured in formal reviews. Several research have assessed the application of social media for ADR surveillance. A 2024 scoping overview located that even as frequencies of stated ADRs had been typically decrease in social media than in legitimate databases, the styles regularly reflected set up indicators. Crucially, social media records did display new or surprising unfavourable reactions and tended to floor them extra quickly. For instance, the overview stated that “social media records had been located to be beneficial in figuring out new or surprising AEs and in figuring out AEs in a timelier manner”. Many authors view social media as a supplementary source: it may act as an accessory to conventional surveillance, providing in advance detection for a few indicators. Moreover, due to the fact posts are

regularly unfiltered narratives, they are able to spotlight affected person issues and outcomes (e.g. practical impairment) that could in any other case be under-emphasised in medical reviews. Specific analyses have established those strengths. For example, an AI-pushed have a look at of over 121,000 Twitter and Facebook posts approximately COVID-19 vaccines (Dec 2020–Apr 2021) tracked dialogue developments of unfavourable activities. The most-stated troubles had been urged for food changes (14%), allergies (9%), injection-site pain (10%), and clotting cases (8%), even as uncommon situations like Bell’s palsy regarded handiest 2% of the time. Such analyses illustrate that social media can mirror public issue approximately vaccine protection troubles in (near) actual time. In principle, actual-time tracking of tweets or discussion board posts should alert regulators to rising vaccine AEFIs or drug side effect even earlier than formal reviews accumulate.

Social media’s accessibility to numerous populations is some other advantage. It can seize studies from demographics much less possibly to go to medical doctors or publish reviews, inclusive of more youthful people or sufferers in far flung areas. An international WHO survey of purchaser attitudes cited that many sufferers’ prices virtual reporting; for example, 87% of respondents favoured the use of on-line tools (apps or websites) to record drug reactions in comparison to paper forms. Mobile and social media are therefore promising methods to attain underrepresented companies and boom engagement in pharmacovigilance. However, the unstructured nature of social media enlightened analytics (NLP, ML) is required to sift sign from noise.

Overall, the proof indicates social media can enhance ADR detection, specifically for flagging new or uncommon activities and know-how affected person perspectives. But it isn't always a self-contained solution: analysts have to be



cautious of the smaller sign size (relative to official datasets) and of the superiority of “fake positives” or anecdotes that can’t be simply verified. Current consensus is that social media have to supplement – now no longer replace – conventional PV methods.

KEY DIGITAL TOOLS AND PLATFORM:

Advances in technology have created many digital tools for ADR monitoring. These can categorize into; -

1. **AI And Data-Mining System**
2. **Mobile And Web Applications**
3. **Integrated Reporting Platforms and Databases.**

AI and Machine Learning Tools:

Machine Learning (ML) and Natural Language Processing (NLP) is often used to scan large text collection in ADRs (social media posts, patient forums, electronic health records). For example, the system uses a prepared voice model or classification to identify drug names and negative impact terms for tweets or posts. A recent study demonstrated the use of a language model that is excellent for identifying ADR. With the same instructions from human reviewers, serious events of 99.3% and 99.3% ($\kappa=0.96$) of social media contributions were correctly identified. These performance levels suggest that state-of-the-art LLM matches ADR signals from text and human annotations. In a broader sense, ML -Frameworks (e.g. Deep Learning-Classification, Transformer Models) is actively researched to improve signal detection of-digital data. AI can also support autumn triage; For example, you can mark posts with a strong ADR signal or prioritize cases for follow-up tests.

MOBILE APPLICATIONS:

With the increasing number of dedicated apps, users can report ADRs directly through their smartphones. These range from national regulatory apps to international platforms. Notable examples are the Med Safety App (WHO-IMI-WEB-RADR) and various countries-specific coordination. The Med Safety app (formerly the WEB-RADAR app) allows both health-skilled workers to report ADRs to mobile devices, which uses the ICH E2B(R2) SO. This SO flows directly into the national database (e.g., the country's Vigi Flow) and reports that it is continuing with VigiBase. The app is currently used in dozens of countries, particularly countries with low and moderate economic, which is attributed to the amazing reporting (smartphones are easier to access than computers for many users). Another example is the app from EU countries (By work in the Netherlands Bijwerking, Croatia’s HALMED app) that is similar to the UK's yellow card. In the US, the FDA collaborated with Hospitals, from Boston children to Med Watcher and Med Watcher Social, to platforms developed for crowdsourced drug safety reporting and platforms developed for social media flow monitoring. Additionally, the V-Safe App for CDC for Covid-19 vaccine is actively asked in text meetings by symptom testing of vaccinated individuals. The V-SAFE demonstrated high user participation and provided with rapid safety data during the pandemic.

Data Mining Software and Databases:

Established Pharmacovigilance Systems currently offers digital interfaces and mining capabilities. For example, FAERS provides public dashboards and downloadable quarterly data, allowing you to query VigiBase data through WHO UMC's Vigilyze platform. These tools use Med DRA coding to configure reports. AI-based signal detection tool Like the UMCS Vigimine or EMA's



Eudravigilance algorithm, an imbalanced analysis leads to ICSRs to mark unexpected drug pairs. Companies use the database for commercial security (e.g. Oracle Argus, Aris global) for case management and automated signal assessment. Aspiring tools also use big data and APIs. For example, OpenFDA in FDA provides programmatic access to unnecessary event reporting data for rapid analysis.

ONLINE SURVEILLANCE PLATFORMS:

Besides formal databases, social media and web-tracking offerings exist to song drug mentions. Platforms like Twitter's API, Google Alerts/Trends, and fitness discussion board crawlers (e.g. Patients Like Me, fitness forums) had been utilized in studies to quantify ADR dialogue volumes. Recently, researchers have experimented with combining those oblique sources; one look at included alerts from Twitter and FAERS the usage of a Bayesian version to enhance detection. The blended gadget confirmed higher area-under-curve overall performance than Twitter alone (AUC ~0.63 vs 0.53), all even though it nonetheless underperformed FAERS records with the aid of using itself. Such hybrid structures factor to the destiny of included sign detection throughout sources.

In summary, digital tools for ADR include enhanced AI analytics, apps for smartphone/tablet-direct reporting, and enhanced data mining software. Continuous innovation includes app functions (multi-language support, offline data entry, user feedback), fall triage of AI control, and API prioritization capabilities, linking digital health files with PV databases. These tools aim to make Pharmacovigilance more aggressive, more efficient and patient-centered.

CASE STUDIES AND EXAMPLES

1.COVID-19 Vaccine Safety Surveillance (V-safe):

In reaction to the COVID-19 vaccine rollout, the United States CDC released V-safe, a smartphone-primarily based totally energetic surveillance system. Vaccinated people acquire ordinary textual content message check-ins to document any facet consequences or fitness worries after vaccination. V-safe's good-sized use (millions of enrolled) furnished near-real-time facts on vaccine reactogenicity and unfavourable events, supplementing the passive VAERS system. For example, CDC analyses used V-secure reviews to reveal anticipated facet consequences (e.g. injection-web website online reactions) and uncommon events. This initiative exemplified how a large-scale virtual device can swiftly seize patient-mentioned ADRs and reassure public fitness decision-making.

2.Med Safety Mobile App:

The IMI WEB-RADR consortium evolved a cellular ADR reporting app to begin with for the UK, Netherlands, and Croatia. This undertaking advanced into the Med Safety App, co-backed through WHO and UMC, that is now used in lots of countries. The app's fulfilment demonstrates virtual impact: past growing document quantity, it advanced statistics first-rate through guiding journalists via established case entry. Notably, Med Safety permits offline document drafting and a couple of languages, catering to consumer wishes in LMICs in which smartphones are prevalent. This cross-country wide platform reduced obstacles for healthcare specialists and sufferers to publish ADRs in actual time.

3.Social Media Monitoring for Signal Detection:



The Academic Project tested social listening as support for signal. For example, a UK study collected over 121,000 Twitter and Facebook contributions related to, Covid-19 vaccines and found significant trends (e.g. loss of appetite, coagulation noise). Similarly, analytics efforts have tested automatic scratching from ADR-based ARC's Twitter. Although the results are mixed, these efforts demonstrate capabilities. FDA's Medwatcher Social (Boston Children's Hospital) processes social media to identify articles that potentially describe ADR. The Medwatcher Social classifier has been updated to adapt to the "concept drift" language. In other words, the algorithm must be developed as a social media change.

4. Combined Data Analysis:

In the research environment, we looked at a combination of social media and classical data. The IBM/IQVIA study (Drug SAF 2020) dismantled Twitter for the expectation of drug ADR and integrated signals with FAERS using Bayesian methods. The combined approach improves performance compared to Twitter, allowing social media to add marginal value to integrated SRS data. The combined model not only surpasses FAERS, but also in advances it uses multiple data flows simultaneously.

5. Country Experiences:

Several national PV centres have reported success in digital reports. UK's Yellow Card App (smartphone) quickly gained downloads and collected thousands of reports from the public. The Netherland's Bijwerking app and half Croatian app (part of WEB-RADR) also made it possible to submit ADRs easily. Seven country-specific ADR apps were identified by 2022 (e.g. MHRA, Lareb, HALMED, Bijwerking, Med Safety). This represents a comprehensive assumption. These

examples show an increase in reporting when regulators actively promote digital channels.

Overall, these case studies demonstrate that the Digital Tools-Von Active Monitoring App provides implemented and implementable safety data, which has been introduced to the AI-controlled social list. They provide the concept of the proof-concept that technology can streamline ADR records and analysis in a variety of healthcare systems.

BENEFITS AND LIMITATIONS

BENEFITS:

Digital tools offer several advantages for ADR monitoring. It can greatly expand your data. Accelerate source and detection. Social media monitoring and reporting uses, patients. This would otherwise be invisible to regulators and would improve early signal production. It also enables triangulation of some source of data. For example, the ADR mentioned on Twitter can be checked against the database report to increase confidence. It is often important that the digital channel allows for real data acquisition. Traditional ICSR can take weeks or months, but social media is instant. Analysis showed that digital reports and mobile check-in significantly improves the locality and reliability of safety data. The mobile app allows unnecessary event reports on points of care or consumption, and AI analysis allows you to process text volumes much faster than manual reviews.

Digital approaches can also improve commitment and integrity. For example, the survey found that 87% of consumers preferred the digital (mobile/web) ADR reporting tool compared to paper formats. The digital form can include free text fields, dropdowns, and immediate feedback that helps users provide more extensive information. The results provided an extensive



case data. Additionally, mobile platforms can deliver a wider demographic. Users - Friendly app lowers barriers to busy healthcare providers and enables patients/carer directly.

LIMITATIONS:

Despite the promise, virtual ADR tracking has high-quality drawbacks. Social media content material regularly consists of noise, misinformation, and inappropriate chatter. Users may also misattribute aspect consequences to drugs, or talk media reviews in place of non-public experience. Biases are inherent: social media customers skew younger, greater tech-savvy, and positive demographic groups (e.g. older sufferers with persistent diseases) can be underrepresented. Misinformation can unfold rapidly, developing fake alarms or undermining actual alerts.

Data validity is any other concern. ADR reviews commonly require positive information elements (affected person age, drug publicity date, outcome, etc.) to evaluate causality. Informal posts regularly lack this detail, making it tough to verify a reaction. AI classifiers may also misread slang or scientific terms. Indeed, one take a look at discovered that even as AI may want to fit human annotation in identifying “presence of an ADR mention,” nuances like severity grading have been more difficult to capture. The Drug Safety take a look at with the aid of using Li et al. concluded that Twitter information by myself had restrained predictive cost for sign detection as compared to FAERS. This shows social media alerts have to be interpreted carefully and now no longer utilized in isolation.

Ethical and solitude demanding situations additionally restrict use of virtual sources (mentioned below). Furthermore, the sheer extent of information calls for strong infrastructure and expertise. Not all pharmacovigilance facilities have the sources to install superior analytics or

hold social listening programs. Digital surveillance needs to consequently be focused and validated, now no longer a blanket substitute for verified methods. In summary, virtual equipment can beautify pharmacovigilance with the aid of using presenting extra eyes and ears on drug safety, however their outputs need to be weighed seriously towards conventional information.

ETHICAL AND REGULATORY CONSIDERATIONS:

Using digital data for social media and pharmacovigilance creates ethical and legal issues. Even, social media posts are often publicly available, meaning the use of this information in the privacy and approval of Health Research. Commentators say that social media is "publicly deemed publicly and there is no user consent when collecting social media data." However, users do not voluntarily explicitly have health data for research, and contributions may contain sensitive information. Even "de-identified" content can contain sufficient details to identify an individual or its provider. The Members of, health professionals are concerned about HIPAA compliance and data protection if online texts are reduced. In the jurisdiction, the GDPR has set strict requirements for the processing of personal data to limit the records of identifiable patient information. Businesses and researchers should anonymize data and use it responsibly to avoid data protection violations.

Regulatory frameworks must also adapt to these new sources. Currently, most regulations have voluntarily treated patient reports (emails, hotline calls, etc.) as case security reports. For example, if a pharmaceutical company discovers, patients about side effects, is it an obligation to report this to the supervisory authority? In 2019, EMA's WEB-RADAR Project demonstrated the need for clear instructions. The conclusion was that



"screening and reporting suspected adverse reactions of remained an important pillar," and sought principles regarding the use of social media in PV. Without such instructions, businesses can ignore all consequences regarding conformance (message) or social media to avoid stress.

Furthermore, regulators and businesses must protect against misinformation and inappropriate impact. Social media could become a channel for rumours and anti-science messaging. An ethical concern is the possibility of a "crowdsourced" ADR signal that causes panic or stigma if interpreted incorrectly. Data quality and guarantees to avoid misunderstanding from the public are extremely important. The supervisory authority may need to issue a disclaimer or "Digital Advisories" to explain how such data is being used.

After all, there are broader considerations about justice and accessibility. Digital tools should not broaden the differences; the PV should include populations with limited internet access. All deployments of digital surveillance should involve efforts to continue these offline traditional public relations (such as personal reporting). In short, using social media and digital tools in PV requires attention to ethical norms (privacy, consent, fairness).

FUTURE DIRECTIONS:

The future of ADR monitoring is likely very digital and data-controlled. AI plays a crucial role: advances in understanding natural language (e.g., transformation models, multimodal AI) improve the extraction of security information from text, speech (telehealth transcripts), and even images (e.g. rash photographs). As seen in the recent design of the CIOMS Working Group, "technology advances have changed PV, with artificial intelligence playing a developing role." Future Guidelines (CIOMS) should provide a

principle of reliable and transparent AI use in drug safety. We hope to use more large, pre-formed models (GPT, BERT) tailored to medical texts to honour notes on News, blogs, forums and ADR patterns.

Wearable devices and digital therapeutics open new signal channels. Through continuous monitoring devices (smart watches, portable sensors), physiological changes (heart rate, glucose) can record the drug effect of signals, particularly for cardio-toxicity or metabolic effects. Patient integration with patients via smartphone diary enriches data on the side effects of chronic drugs. Electronic Health databases and damage databases are increasingly linked to PV systems (through popular data models, such as (OMOP/FHIR) for real-time security analysis.

Regulatory science is developed to take these tools into consideration. Official instructions for using social media and apps are expected. The CDC's COVID experience already suggests that the supervisory authority officially supports digital surveillance of the (e.g. V-Safe). International Cooperation (WHO ICDRA, CIOMS) could provide, harmonized standards for the use of digital PV data. Comments on applied clinical research highlight the requirements for a unified digital source aggregation system. In other words, future platform is aggregated from any source (app, social media, direct entries). You'll probably see a multi-language interoperable database.

On the horizon is a predictive PV model; an AI system that can predict security issues. Block chain or secure data exchange can be used to protect patient privacy, allowing cross-system analysis at the same time. Patient commitments must also grow. Dynamic involvement reports, Community Control monitoring, and real-time feedback loops (such as the public dashboard of ADR statistics) can increase vigilance.

A low resource setting further expands the mobile solution. Tools like Med Safety and Vigi-Mobile



accept and improve global signal detection. Furthermore, the synergy between technology and politics (e.g., PVs for digital health apps) is a key future trend. In summary, Future Pharmacy is probably a mixture of traditional expertise and modern technology, aiming for faster, more accurate ADR detection, while simultaneously adjusting the ethical use of individual data.

CONCLUSION:

Monitoring adverse drug reactions is at the top of the digital conversion. Social media and digital tools provide an unprecedented opportunity to record safety data beyond traditional channels. It can increase patient voice, accelerate signal detection, and include various population groups in the drug presence. Research shows that social media surveillance reveals new or rare ADRs and capture patient-oriented results and enrich security assessments. In the meantime, the mobile app and AI-powered analytics will allow ARDs to be easily accessible and efficiently reported.

However, these innovations do not replace the need for rigorous evaluation. The limitations of data quality, ethical limitations on, and the current widespread lack of regulations reveal that social media and digital signals must be used with caution. Experts now agree that these should not be as separate systems but as additions to enhance the traditional PV. Policymaker, Manufacturers and industries must work together to develop framework conditions that responsibly integrate digital safety data

Look forward to it and make drug students more proactive and patient-centered with continuous innovation-led regulatory oversight and ethical principles. Pharmaceutical Landscape will develop (with new therapies and interventions for digital health), but the merger of social media intelligence, big data, and AI is extremely important to ensure the safety of drug reliability.

By thinking about these tools, we hope that EDRS has previously recognized, better characterize them, and ultimately protects patients more effectively within the digital age.

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